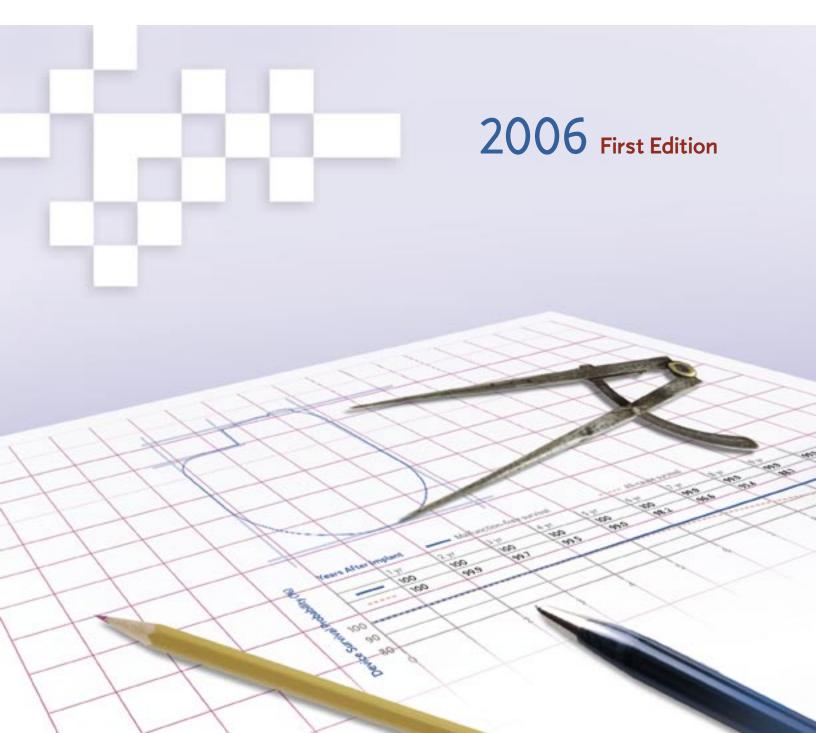


CRM PRODUCT PERFORMANCE REPORT

Important Patient Management Information for Physicians



This report is available online at www.CRMPPR.medtronic.com

Medtronic Commitment to Quality

For each patient, with each device, quality means everything. Quality is at the core of our Medtronic Mission which has driven our actions since 1960...

"To strive without reserve for the greatest possible reliability and quality in our products, to be the unsurpassed standard of comparison, and to be recognized as a company of dedication, honesty, integrity, and service."

Medtronic instituted the industry's first product performance reports in 1983 by publishing data on our chronic lead studies. Pacemakers and other devices followed as our performance reporting has constantly evolved based on customer need and feedback. One thing has been a constant. It is our sincere commitment to communicate clearly, offering timely and appropriate product performance data and reliability information. This has always been and will continue to be our goal.

In keeping with our commitment, this edition of our product performance report includes a number of updates and additions:

- New, easy-to-use format organized by product family and model number. Data on each model is presented in one place with links provided when additional details are available.
- Extended malfunction listings to include the number of malfunctions that have affected the generator's ability to deliver therapy. This provides a perspective on how often a malfunction may have the potential for more serious clinical impact.
- Addition of a malfunction-free survival curve for all generator models. This allows comparison of overall device survival with and without normal battery depletion data.
- Expanded discussion of the methods and assumptions used to determine survival estimates. This enables comparison of our performance results with those published by others in the industry.

Through the AdvaMed Pacemaker/ICD Working Group, Medtronic is helping lead an effort to standardize the reporting of product performance data across the industry. We feel strongly that uniform standards will further help physicians and patients gain greater understanding that will allow them to weigh the risks and benefits related to individual products or overall device-based therapies. Physician and patient confidence is critical to fully realizing the life saving and quality of life benefits medical device technologies can offer.

Your feedback is of the utmost importance. As in all quality efforts, we must continue to listen and learn while effectively and efficiently providing the information you need.

Please contact CRM Returned Product Quality at 1 (800) 328-2518, extension 48644 or our Technical Services Department at 1 (800) 723-4636 with any comments or questions. Your input will help us continue to advance and improve our communication of vital product performance information.

Thank you for your support and dedication.

Michay O Baca

Michael D. Baca Vice President of Quality Cardiac Rhythm Management Medtronic, Inc.

Contact Information

We invite our customers to use these telephone numbers to call with suggestions, inquiries, or specific problems related to our products.

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CapSureFix®	InSync III Marquis™	Maximo®	Quick Look™	Synergyst™
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EnRhythm®	Intrinsic®	Minuet®	Spectrax™	Thera [®] -i
EnTrust™	Isoglide™	Onyx [®] VR	Sprint™	Transvene™
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2006 First Edition

Date cutoff for this edition is July 11, 2005 for leads and October 31, 2005 for devices

This report is available online at www.CRMPPR.medtronic.com

New with This Edition

Survival data for: 7297 InSync Sentry 7299 InSync Sentry 7304 InSync Maximo 7288 Intrinsic 7290 Onyx VR 2187 Attain 4076 CapSureFix Novus E2DR31 EnPulse 2 DR E2VDD01 EnPulse 2 VDD P1501DR EnRhythm DR

Product Advisory Update Product Performance Report

Sigma Implantable Pulse Generators

Original Date of Advisory: November 2005

Potential Separation of Interconnect Wires

Product

A specific subset of Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. Approximately 28,000 devices, with approximately 6,650 in the United States, out of an initial implant population of 40,000 worldwide, remain implanted and in service. Specific model and serial numbers of affected devices are available online at http://SigmaSNList.medtronic.com.

Advisory

This subset of Sigma series pacemakers that may fail due to separation of interconnect wires from the hybrid circuit may present clinically as loss of rate response, premature battery depletion, intermittent or total loss of telemetry, or no output. There have been no reported patient injuries or deaths due to this issue.

Separation of redundant interconnect wires has been observed on hybrid terminal blocks. Device failure occurs only where both interconnect wires separate from a hybrid terminal block. In October 2005, testing and analysis identified the root cause of these failures and the affected population. Hybrid circuits used in this subset of devices were cleaned during manufacturing with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time.

Our modeling predicts a failure rate from 0.17% to 0.30% over the remaining lifetime of these pacemakers. No provocative testing can predict which devices may fail.

Patient Management Recommendations

To assist physicians in their patient care and after discussion with physician consultants, Medtronic offers the following recommendations:

- Medtronic does not recommend replacement of these devices prior to normal elective replacement (ERI), based on the low probability of occurrence of a serious event in this population.
- Continue routine follow-up in accordance with standard practice.
- Advise patients to seek attention immediately if they experience return of symptoms (e.g., syncope or light headedness).
- Determine whether device replacement is warranted on a case-by-case basis based upon consultation with patients, review of the individual patient's medical history and consideration of the relative risks of an invasive procedure.

Status Update (December 2005)

The Sigma Family device performance related to the interconnect wires separation mechanism continues to be within Medtronic's engineering projections and expectations. As of December 31, 2005, 25 devices out of approximately 40,000 devices worldwide (0.063% incidence) have been confirmed as having interconnect wire separation. Sixteen (16) of these devices were returned from the United States. There have been no reported serious injuries or deaths due to this issue.

Seventeen (17) of the 25 returns were identified via either a regularly scheduled follow-up or during a non-device related hospital visit. Two (2) devices were identified due to the patient experiencing syncope. The other 6 devices were replaced with no clinical symptoms associated with the interconnect wire separation. Among the 6 devices, 4 were returned due to a device/system upgrade, and 2 were returned due to infection.

Consistent with previous Medtronic projections, the probability of occurrence remains low and is within failure rate predictions. Implant duration for the 25 failures has ranged from 17-44 months.

7274 Marquis [®] DR	7277 InSync Marquis [™]
7230 Marquis [®] VR	7289 InSync II Marquis [™]
7278 Maximo [®] DR	7279 InSync III Marquis [™]
7232 Maximo [®] VR	7285 InSync III Protect™
Original Date of Advisory: Februar	y 2005

Potential Premature Battery Depletion Due to Battery Short

Product

The specific subset of Marquis family ICD and CRT-D devices having batteries manufactured prior to December 2003 is affected. Devices manufactured with batteries produced after December 2003 are not affected. Specific model and serial numbers of affected devices are available online at <u>http://MarquisSNList.</u> medtronic.com.

Advisory

Medtronic Marquis family of ICD and CRT-D devices having batteries manufactured prior to December 2003 may experience rapid battery depletion due to a specific internal battery short mechanism. Battery design changes were implemented in December 2003 that eliminate the possibility of this internal shorting mechanism.

Highly accelerated bench testing indicated the rate of this shorting mechanism may increase as the battery is depleted. As of February 2005, the rate of shorting was approximately 1 in 10,000 (0.01%); bench test data indicated the rate may increase to between 0.2% and 1.5% over the second half of device life.

No provocative testing can predict which of these devices will experience this issue. Once a short occurs, battery depletion can take place within a few hours to a few days. After depletion the device ceases to function. It is also possible that as the battery depletes quickly, patients may experience temporary warmth in the area surrounding the ICD.

Patient Management Recommendations

The following recommendations apply to the affected population:

- Continue to conduct routine (e.g., quarterly) followup procedures.
- Turn on low battery voltage PatientAlert indicator.
- Inform patients that should they experience warmth in the area surrounding the ICD to seek follow-up care.
- Consider providing patients with a hand-held magnet to check device status. Device operation may be monitored periodically (e.g., daily) by patients using the magnet, which will result in a device tone indicating device function (provided PatientAlert is turned on). If no tone is heard, follow-up care should be sought.

Status Update (December 2005)

The Marquis Family device performance related to the battery shorting mechanism continues to be within Medtronic's engineering projections and expectations. As of December 31, 2005, 30 Marquis Family devices have been confirmed as having the internal battery shorting mechanism. Eighteen (18) of these devices were returned from the United States. There have been no reported serious injuries or deaths due to this issue.

Fourteen (14) of the 30 returns have been identified via either a regularly scheduled follow-up or during a nondevice related hospital visit, 13 by patients reporting warmth in the ICD pocket, 1 for return of bradycardia symptoms, and 2 due to the PatientAlert sounding.

Consistent with previous Medtronic projections, the observed rate of shorting in the second half of device life is higher than that observed in the first half of device life. Of the devices that have exhibited shorting in the last half of device life, 67% occurred in the last quarter of device life, and 53% in the last 10% of device life.

Discussion of Changes to Report Layout and Format

Medtronic first published a product performance report in 1983. Since that time, the report has evolved to include more information on an ever increasing number of products.

With this issue of the report, we have incorporated a new layout and format for the report with the goal of making the report more valuable and useful.

For the past several months, Medtronic CRM has been helping lead an effort by an industry working group to develop requirements for uniform product performance reporting. The goal of this effort is to have product performance reports provide the most objective, feasible representation of device performance and to make comparison across different manufacturers practical. This report conforms to the latest working draft of those requirements.

In addition, this version of the product performance report has been prepared in accordance to International Standard ISO 5841-2:2000(E).

Highlights of Changes

- Since its inception, Medtronic has used the standard actuarial method to determine survival probabilities and Greenwood's formula for calculating confidence intervals. Medtronic has also routinely adjusted its results to address underreporting of events. While these techniques have not changed, new in this issue is an expanded discussion of how these techniques are applied.
- As long ago as 1987, Medtronic included in its product performance report a table that separately identifies the number of malfunctions as well as the number of normal battery depletions for its implantable pulse generators, and more recently, implantable cardioverter defibrillators. With this issue, malfunctions for many models are further separated into malfunctions with compromised therapy function and malfunctions without compromised therapy function.
- Since 1998 for ICD leads and since 2002 for pacing leads, Medtronic has included tables showing the nature and frequency of lead complications observed via our multicenter prospective clinical studies. With this issue, the complication tables are positioned adjacent to the survival curves for easier reference.
- For over 10 years, safety advisory information has been summarized in the product performance report. With this issue, the advisory summaries have been reformatted and more clearly linked to the affected products.

The intent of these changes, and other changes not highlighted above, is to make this report more useful for anyone seeking to understand the performance of these products. If you have comments or additional suggestions on the content and format of this report, please contact us. Contact information can be found on page 2.

Introduction

All product performance reports are not created equal. For over 20 years, Medtronic CRM has monitored performance with both returned product analysis and multicenter clinical studies.

This Product Performance Report (PPR) presents device survival estimates, advisory summaries, technical articles, and other information pertinent to assessing the performance of Medtronic IPG, ICD, and CRT devices, and implantable pacing and defibrillation leads.

This product performance report has been prepared in accordance with International Standard ISO 5841-2:2000(E).

The survival estimates provided in this report are considered to be generally representative of worldwide performance.

Survival Estimates

All product performance reports are not created equal. Medtronic CRM uses both returned product analysis and multicenter clinical studies to monitor performance.

Medtronic, like other companies, monitors device performance using returned product analysis. We also monitor device performance using an active multicenter clinical study. Medtronic CRM is unique in the industry in that we track device survival using both methods.

Returned product analysis is a passive approach to assessing product performance. This approach provides a suitable measure of product performance only when a significant number of explanted products are returned to the manufacturer. Returned product analysis provides a measure of hardware performance, but not necessarily the total clinical performance (e.g., the incidence of complications such as infection, erosion, muscle stimulation, etc. are not estimated).

The survival estimates provided in this report for IPG, ICD, and CRT generators are based on returned product analysis. This approach is suitable because a significant number of explanted generators are returned for analysis.

In contrast, a very small percentage of leads are returned to the manufacturer due to the difficulty of explanting them. For leads, an active clinical study will provide much more accurate survival estimates compared to estimates based solely on returned product analysis. Survival estimates for implantable pacing and defibrillation leads are based on clinical observations recorded via Medtronic CRM's chronic leads studies. These multicenter clinical studies are designed to record clinical observations representative of the total clinical experience. Therefore, the lead survival estimates include both lead hardware failure *and* lead related medical complications, and do not differentiate a lead hardware failure from other clinical events such as exit block, perforation, dislodgement, or concurrent pulse generator failure.

ICD Charge Times

For several years, Medtronic has provided important information on charge time performance of ICDs. The information provided in this report shows how ICD charge time can vary during the time a device is implanted. The information is presented in graphical format showing charge time as a function of implant time. The data for charge times are collected from devices enrolled in the multicenter clinical studies.

Advisory Summaries and Technical Articles

This product performance report includes advisory summaries applicable to the performance of the devices included in the report. Each summary includes a description of the devices affected by the advisory, a description of the reason for the advisory, and patient management recommendations.

In addition to advisories, this report includes a number of Technical Articles selected to provide additional performance information relevant to follow-up practice and patient management.

How You Can Help

We continually strive to improve this CRM Product Performance Report. In keeping with this philosophy, we ask for your suggestions on the content and format of this report, as well as any information you have regarding the performance of Medtronic products.

Chronic Lead Data Resolution

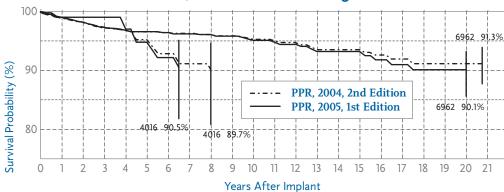
Medtronic is the only company that uses active post-market studies to monitor lead performance, conducting chronic lead studies for over 20 years.

For more than 20 years, Medtronic has remained committed to reporting the performance of chronically implanted devices via multicenter prospective clinical studies. The Chronic Lead Study for pacing leads and the Tachyarrhythmia Chronic Systems Study for ICD leads have been ongoing in several geographies since 1983 and 1991, respectively. Currently these two studies are undergoing unification into one study named the System Longevity Study.

Since the inception of these studies, the mechanism of patient follow-up has changed due to evolution in hospital follow-up practices and extrinsic issues such as the impact of the Health Insurance Portability and Accountability Act for US centers. As a result, some patients who were thought to be active participants in the study are no longer available for study followup. Therefore, Medtronic has initiated an additional process to verify lead status for all active study patients. This process is ongoing and is expected to conclude in the year 2007. Combined with our prospective study monitoring practices, this process aligns with our continuous efforts to improve product performance reporting. The survival curves in this edition of the Product Performance Report (PPR) reflect this additional process.

Under the study protocol, each lead is assumed to be event-free unless a failure event is confirmed, it is electively abandoned or explanted, or the patient is no longer available for follow-up. Changes in the survival curves can occur when patients in whom leads were thought to be active at the time of the previous analysis have since been determined to no longer be available for follow-up. This has the effect of shortening the curve if leads that were previously presumed to be among those with the longest survival are no longer active at that time. Such a determination also decreases the number of leads remaining in the analysis cohort, which generally lowers the estimated probability of survival.

As the data resolution process proceeds, survival curves can change from one issue of the PPR to the next. For example, as noted in the figure below, the curve for the ventricular lead model 4016 extends to 8 years with an estimated survival probability of 89.7% in the 2004 2nd Edition PPR, but extends to 6.5 years with an estimated survival probability of 90.5% in the 2005 1st Edition. In contrast, the curve for the ventricular lead model 6962 extends to 20.75 years with an estimated survival probability of 91.3% in the 2004 2nd Edition, but extends to 20 years with an estimated survival probability of 90.1% in the 2005 1st Edition. The confidence intervals at the ends of the curves are included here for consistency with those in the rest of the report. In general, these confidence intervals are not statistically comparable for assessing whether survival probability has changed between different editions of the PPR.





Method for Estimating ICD and Pulse Generator Performance

Medtronic urges all physicians to return explanted product and to notify Medtronic when a product is no longer in use, regardless of reason for explant.

The next sections of the Product Performance Report present the performance of Medtronic IPG, ICD, and CRT devices. The performance of these devices is expressed in terms of device survival estimates, where "survival" refers to the proper function of the device, not the survival of the patient. These survival estimates are intended to illustrate the probability that a device will survive for a given number of years without malfunction or normal battery depletion.

The survival estimates are determined from the analysis of Medtronic CRM's device registration data and returned product analysis data. These data are presented graphically and numerically.

Because this analysis is based on returned product analysis, IPG and ICD performance data does not reflect any IPG or ICD related medical complications, such as erosion, infection, muscle stimulation, or muscle inhibition.

Categorization of Depleted and Malfunction Devices for Survival Analysis

For survival estimation, every device returned to Medtronic CRM and analyzed in the CRM Returned Product Analysis laboratory is assigned to one of three categories. The device 1) has functioned normally, 2) has reached normal battery depletion, or 3) has malfunctioned. This categorization is combined with data from our device registry for the total number of implants and the implant durations to create the survival curves presented on the following pages.

Medtronic CRM considers a device as having malfunctioned whenever the analysis shows that any parameter was outside the performance limits established by Medtronic while implanted and in service.

Devices damaged after explant, damaged due to failure to heed warnings or contraindications in the labeling, or damaged due to interaction with other implanted devices (including leads) are not considered device malfunctions. A device subject to a safety advisory is not considered to have malfunctioned unless it has been returned to Medtronic CRM and found, through analysis, to actually be outside the performance limits established by Medtronic.

Not all malfunctions expose the patient to a loss of pacing or defibrillation therapy. Some malfunctions included in the following survival estimates may not have been detected at all by the physician or the patient. These malfunctions, however, are included in the survival estimates and provide important feedback to our product development organization. For this reason, **Medtronic urges all physicians to return explanted product and to notify Medtronic when a product is no longer in use, regardless of reason for explant.**

To provide insight into the nature of malfunctions, each malfunction is categorized as Therapy Function Compromised or Therapy Function Not Compromised. A summary of these malfunctions is presented for the most recently market released models.

For this report, Normal Battery Depletion, Malfunction with Compromised Therapy Function and Malfunction without Compromised Therapy Function are defined as follows:

Normal Battery Depletion - The condition when

- (a) A device is returned with no associated complaint and the device has reached its elective replacement indicator(s) with implant time that meets or exceeds the nominal (50 percentile) predicted longevity at default (labeled) settings, or
- (b) A device is returned and the device has reached its elective replacement indicator(s) with implant time exceeding 80% of the expected longevity calculated using the available device setting information.

Medtronic CRM establishes expected longevity by statistically characterizing the power consumed by the device and the power available from the device battery. This characterization is applied to a number of parameter configurations to derive a statistical mean longevity value and standard deviation for each parameter configuration. The statistical mean value minus three standard deviations is used as the expected longevity for determining if a battery depleted normally.

Method for Estimating ICD and Pulse Generator Performance, continued

The Standard Actuarial Method is used to estimate IPG and ICD survival. This product performance report has been prepared in accordance with International Standard ISO 5841-2:2000(E).

For reference purposes, the following pages include an estimated longevity for each model. The actual longevity achieved for any device while implanted will depend on the actual programmed parameters and patient factors, and may differ significantly from this estimate.

Malfunction with Compromised Therapy Function

The condition when a device is found to have malfunctioned in a manner that compromised pacing or defibrillation therapy (including complete loss or partial degradation), while implanted and in service, as confirmed by laboratory analysis.

Examples: Sudden loss of battery voltage; accelerated current drain such that low battery was not detected before loss of therapy; sudden malfunction during defibrillation therapy resulting in aborted delivery of therapy, intermittent malfunction where therapy is compromised while in the malfunction state.

Malfunction without Compromised Therapy Function

The condition when a device is found to have malfunctioned in a manner that *did not* compromise pacing or defibrillation therapy, while implanted and in service, as confirmed by laboratory analysis.

Examples: Error affecting diagnostic functions, telemetry function, data storage; malfunction of a component that causes battery to lose power quickly enough to cause premature battery depletion, but slowly enough that the condition is detected through normal follow-up before therapy is lost; mechanical problems with connector header that do not affect therapy.

Laboratory Analysis Process

Analysis of returned product is performed according to written procedures. These procedures determine the minimum analysis required. The analysis required varies depending on the type of device, age of the device, the associated information received with the device, actual field experience with models of similar design, and other factors. Additional analysis is performed as necessary to investigate performance concern from a customer, or to collect specific reliability data.

When a device is returned with a performance concern from a customer, the general analysis process includes a preliminary analysis of the device in its as-received condition, followed by an automated functional test using test equipment equivalent to the equipment used in manufacturing.

When a malfunction is identified, failure analysis is performed to provide the detailed information necessary to investigate possible causes and actions. Medtronic CRM maintains in-house expertise and performs its failure analysis using facilities it owns and supports. This capability permits detailed failure analysis.

Statistical Methods for Survival Analysis

Of the several different statistical methods available for survival analysis, the Standard Actuarial Method, with suspensions distributed across the intervals, is used to determine estimates of IPG and ICD survival. This method is chosen because the calculations are relatively straight forward and many medical researchers and clinicians are accustomed to this approach.

For the IPGs and ICDs that remain implanted and in service, we determine the number of months each has been in service. For devices no longer in service and returned for analysis, we determine the number of months they were in service and the reason for removal from service. From this data an estimate of the probability of device survival is calculated at each month interval.

Method for Estimating ICD and Pulse Generator Performance, continued

Medtronic CRM adjusts all-cause survival estimates to account for underreporting. While this lowers our all-cause survival estimates, we feel it gives a more accurate perspective on real performance.

On the following pages, each graph includes an all-cause survival curve, where all-cause includes malfunctions and normal battery depletions. The all-cause survival is a good representation of the probability for a device to survive a period of time without malfunction and without normal battery depletion. For example, if a device survival probability is 95% after 5 years of service, then the device has a 5% chance of being removed due to normal battery depletion or malfunction.

In addition to the all-cause survival curve, a second curve is included to show malfunction-free survival. Malfunction-free survival is a good representation of the probability for a device to survive without malfunction. This curve excludes normal battery depletion.

Because these survival curves are based on returned product analysis, IPG and ICD survival curves do not reflect any IPG or ICD related medical complications, such as erosion, infection, muscle stimulation, or muscle inhibition.

For some models, the length of the survival curve is less than the period of time since the model was market released. This is because a minimum sample size is required before a survival estimate is calculated. For IPG and ICD curves, data is presented for each month where at least 100 devices have been exposed.

The plotted data is also presented, in yearly intervals, in table form above each graph. The data in the tables is rounded to the nearest tenth of one percent. Occasionally, a graph may show 100% survival, but have 1 or more malfunctions or battery depletions. This occurs because even with the malfunctions or battery depletions, the data rounds to 100%. The survival curves are statistical estimates. As field performance experience accumulates, the estimation improves. Confidence intervals are provided as a way to indicate the degree of certainty of the estimates. Greenwood's formula is used to calculate corresponding 95% confidence intervals for the standard errors and the complementary log-log method is used to produce the confidence bounds.

Sample Size and How the Population and Population Samples Are Defined

The population sample from which the survival estimates are derived is comprised of the devices registered as implanted in the United States as of the report cutoff date. The number of registered implants, as well as an estimate of the number that remain in active service, is listed for each model. To be included in the population, the device must have been registered with Medtronic's registration system and implanted for at least one day.

This sample based on United States implants is considered to be representative of the worldwide population, and therefore the survival estimates shown in this report should be representative of the performance worldwide of these models.

To be considered a malfunction or normal battery depletion the device must have been returned to Medtronic and analyzed. The analysis findings are used to classify a device as malfunction, normal battery depletion, or OK (within performance limits established by Medtronic). The tables on the following pages list the number of normal battery depletions and malfunctions recorded for each model.

In general, a model or model family will be included in this report when it has accumulated at least 10,000 implant months, and will remain in the report as long as at least 500 devices remain active.

Methods Used to Adjust for Underreporting of Malfunction and Normal Battery Depletion

The tables on the following pages show the actual number of malfunctions and normal battery depletions recorded by our analysis lab. Since not all devices are returned to Medtronic CRM for analysis, these numbers underestimate the true number of malfunction and normal battery depletions. To more accurately estimate the all-cause device survival probabilities, the number of malfunction and normal battery depletions used to plot the all-cause survival curves is adjusted (increased) by an amount that is based on our estimates of the magnitude of underreporting. The magnitude of underreporting is estimated by analyzing our experience in clinical studies (including our System Longevity Study) and our device registration system.

However, at this time, no adjustment for underreporting is applied to the malfunction-free survival curve because a method for estimating malfunction-only underreporting has not been developed.

Adjustments to Registered Implants to Compensate for Unreported Devices Removed from Service

Devices are at times removed from service for reasons other than device malfunction or normal battery depletion. Examples are devices removed from service due to non-device related patient mortality and devices removed due to changes in the patient's medical condition. Because an accurate estimate of device survival depends on an accurate estimate of the number of devices in service, it is important not to overstate the number of devices in service.

To ensure the number of devices in service is not overstated, the patient mortality rate derived from our device registration system is monitored and compared to published mortality rates for comparable patient populations. If, during calculation of the survival curves, the patient mortality indicated by the data in our device registration is significantly different from published rates, an adjustment is applied to correct the difference.

7272 InSync ICD

*			
US Market Release	Jul-02		NBD Code
Registered US Implants	13,000		Serial Num
Estimated Active US Implants	7,000		Max Delive
Normal Battery Depletions	107		Longevity
Malfunctions	63		
Therapy Function Not Compromised Therapy Function Compromised	50 13		
Advisories	None		

Product Characteristics

NBD Code	VVED
Serial Number Prefix/Xray ID	PJP
Max Delivered Energy	34 J
Longevity	See page 32

``	Years After	r Implant		Malfunction	-free survival		A	ll-cause si	urvival	
		1 yr	2 yr	3 yr	4 yr					
		99.9	99.8	99.2	98.3	97.9 at 54 mo				
		99.8	99.3	95.8	91.5	79.0 at 54 mo				
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	Sync Ma		N4 02			VVED	
JS Market	Release		Mar-03		NBD Code		
Registered	US Implants	5	7,000		Serial Number Prefix/Xra	ay ID PLT	
Estimated	Active US Im	nplants	3,000		Max Delivered Energy	30 J	
Normal Bar	ttery Deplet	ions	142		Longevity	See page 32	
Malfunctio	ns		35	(5 related to advisory)			
The		on Not Compromi nction Compromi		(0 related to advisory) (5 related to advisory)			
Advisories			1	<u>see page 142</u> – 2005 P	otential Premature Battery De	epletion Due to Battery Short	
	r Implant		۱ function-fre		otential Premature Battery De		
	r Implant 1 yr 100	Mal 2 yr 99.2			,		
	1 yr	2 yr 99.2	function-fre		,		
ears Afte	1 yr 100 99.9	2 yr 99.2 92.6	function-fre 99.1 at 29 mo		,		
ears Afte	1 yr 100	2 yr 99.2 92.6	function-fre 99.1 at 29 mo		,		
ears Afte	1 yr 100 99.9	2 yr 99.2 92.6	function-fre 99.1 at 29 mo		,		

Device Survival Probability (%)

US Market	Delesse		Jul-03		NBD Code		VVE	D	
US Market	Release		,		NBD Code		V V L		
Registered US Implants Estimated Active US Implants		27,000		Serial Numb	er Prefix/Xra	y ID PRJ			
		19,000		Max Delivered Energy		30 J	30 J		
Normal Bat	ttery Deplet	tions	56		Longevity		See	page 33	
Malfunctio	ns		32 (2 r	elated to advisory)					
The		on Not Compromised Inction Compromised		elated to advisory) elated to advisory)					
Therapy Function Compromised								attery Short	
				<mark>page 142</mark> – 2005 Pot				<mark>o Battery Sho</mark>	ort
	r Implant	– Malfund	<mark>عود ا</mark> ction-free su	<u> </u>		r <mark>e Battery De</mark> p cause surviva		o Battery Sho	ort
Advisories ⁄ears Afte	r Implant	1		<u> </u>				o Battery Sho	ort
	r Implant 1 yr	2 yr		<u> </u>				Battery Sho	ort
'ears Afte	r Implant 1 yr 99.9	2 yr 99.6		<u> </u>				Battery Sho	ort
rears Afte	r Implant 1 yr 99.9	2 yr 99.6		<u> </u>				D Battery Sho	prt
'ears Afte	r Implant 1 yr 99.9	2 yr 99.6		<u> </u>				b Battery Sho	Drt
/ears Afte	r Implant 1 yr 99.9	2 yr 99.6		<u> </u>				Battery Sho	prt

7297 InSync Sentry

JS Market Re	lease	Nov-04	NBD Code		VVED	
Registered US Implants		8,000	Serial Number Pre	Serial Number Prefix/Xray ID		
stimated Active US Implants		8,000	Max Delivered Ene	Max Delivered Energy		
Normal Batter	ry Depletions	1	Longevity		See page 33	
Malfunctions		0				
	y Function Not Comp lerapy Function Comp					
Therapy Function Compromised						
		None				
		None Malfunction-free survival	All-cause s	survival		
ears After Ir	nplant		All-cause s	survival		
ears After Ir			All-cause s	survival		
ears After Ir	100 at 8 mo		All-cause s	survival		
ears After Ir	100 at 8 mo		All-cause :	survival		
ears After Ir	100 at 8 mo		All-cause s	survival		

Device Survival Probability (%)

Device Survival Probability (%)

7299 InSync Sentry **Product Characteristics** VVED NBD Code US Market Release Apr-05 Serial Number Prefix/Xray ID **Registered US Implants** 4,000 PRK Estimated Active US Implants 4,000 Max Delivered Energy 35 J Normal Battery Depletions 0 Longevity See page 33 Malfunctions 0 Therapy Function Not Compromised 0 Therapy Function Compromised 0 Advisories None Malfunction-free survival ---- All-cause survival Years After Implant 100 at 3 mo 100 at 3 mo 100 90 80 2 3 5 6 7 8 9 10 0 4 1

US Market Release		Jun-04		NBD Code		٧١	/ED		
Registered	egistered US Implants		16,000	16,000		Serial Number Prefix/Xray ID		L	
Estimated /	stimated Active US Implants		15,000		Max Deliver	Max Delivered Energy		35 J	
Normal Bat	tery Deplet	ions	2		Longevity		Se	See page 33	
Malfunction	15		5						-
	Therapy Function Not Compromised								
Therapy Function Compromised									
Advisories	merapyru		None						
	r Implant 1 yr	Ma	None	ival	All-	cause survival			
Advisories	1 yr 100	—— Ma 100 at 14 mo	Ilfunction-free surv	ival	All-	cause survival			
Advisories	r Implant 1 yr	Ma	Ilfunction-free surv	ival	All-	cause survival			
Advisories Tears After	1 yr 100	—— Ma 100 at 14 mo	Ilfunction-free surv	ival	All-	cause survival			
Advisories Tears After	1 yr 100	—— Ma 100 at 14 mo	Ilfunction-free surv	ival	All-	cause survival			
Advisories Tears After	1 yr 100	—— Ma 100 at 14 mo	Ilfunction-free surv	ival	All-	cause survival			

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7304 InSync Maximo

US Market Release	А	pr-05	
Registered US Implants		3,000	
Estimated Active US Implants		3,000	
Normal Battery Depletions		0	
Malfunctions		0	
Therapy Function Not C Therapy Function C		0 0	
Advisories		None	

Product Characteristics

NBD Code	VVED
Serial Number Prefix/Xray ID	PRL
Max Delivered Energy	35 J
Longevity	See page 33

Device Survival Probability (%)

	Years After	r Implant	Malfunction-free survival				All-c				
		100 at 4 mo									
		100 at 4 mo									
100		1				I	ſ	I	1	1	
90											
80											
00		1	2 5	 3 4		 5 f	5 7	 7 {	2 0	 9 1(0
	-		۲ - ۲	· · ·	-						

US Market	Release		Aug	-01		NBG Code		DDDR	
Registered	US Implant	s	15,0	000		Serial Number Pre	fix/Xray ID	PIN	
Estimated /	Active US Ir	nplants	7,0	7,000		Longevity		6.8 yrs @ 2.5 V(A), 5.0 V(
Normal Bat	lormal Battery Depletions			79					
Malfunction	ns			10					
The	rapy Function Therapy Fu	on Not Comp Inction Comp	romised romised	4 6					
	incrup) i u								
Advisories				one					
			Nalfunction-		al 5 yr	All-causes	survival		
Advisories	r Implant		Malfunction-	-free surviva		All-cause : 99.7 at 61 mo	survival		
Advisories	r Implant	2 yr	Malfunction-	-free surviva	5 yr		survival		
Advisories 'ears After	r Implant 1 yr 100	2 yr 100	Malfunction- 3 yr 99.9	-free surviva 4 yr 99.7	5 yr 99.7	99.7 at 61 mo	survival		
Advisories 'ears After	r Implant 1 yr 100	2 yr 100	Malfunction- 3 yr 99.9	-free surviva 4 yr 99.7	5 yr 99.7 94.7	99.7 at 61 mo	survival		
Advisories 'ears After	r Implant 1 yr 100	2 yr 100	Malfunction- 3 yr 99.9	-free surviva 4 yr 99.7 95.8	5 yr 99.7 94.7	99.7 at 61 mo	survival		

1

8042 InSync III

Device Survival Probability (%)

	Sync III					Product Chara	acteristics		
US Market R	Release		Feb	-03		NBG Code		DDDR	
Registered l	US Implant	s	17,0	000		Serial Number Prefix/Xray ID		PKF	
Estimated A	Active US Ir	nplants	12,0	000		Longevity		6.8 yrs @ 2.5	ν
Normal Batt	ormal Battery Depletions			6					
Malfunction				2					
		on Not Comp Inction Comp		1 1					
Advisories			N	one					
/									
Years After	l yr	2 yr	3 yr	-free surviva		All-cau	se survival		
rears After		1		1	100 at 50 mo	All-cau	se survival		
rears After	l yr	2 yr	3 yr	4 yr		All-cau:	se survival		
	1 yr 100 100	2 yr 100	3 yr 100	4 yr 100	100 at 50 mo	All-cau:	se survival		
	1 yr 100 100	2 yr 100	3 yr 100	4 yr 100	100 at 50 mo	All-cau:	se survival		
	1 yr 100 100	2 yr 100	3 yr 100	4 yr 100	100 at 50 mo	All-cau:	se survival		

Device Survival Summary (95% Confidence Interval)

The following table shows CRT device survival estimates with 95% confidence intervals. Estimates are shown for both malfunction-free survival (which excludes normal battery depletion) and all-cause survival (which includes both malfunctions and normal battery depletion).

Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device	Surviva	I Probabi 3 yr	lity (%) 4 yr	5 yr	6 yr
7272	InSync ICD	Jul-02	13,000	7,000	107	63	50	13	Malfunction- free	99.9 +.0/1	99.8 +.1/1	99.2 +.2/3	98.3 +.7/-1.1	97.9 +.9/-1.5 (54 mo)	
									All-cause	99.8 +.1/1	99.3 +.1/2	95.8 +.5/6	91.5 +1.8/-2.2	79.0 +4.6/-5.6 (54 mo)	
7277	InSync Marquis	Mar-03	7,000	3,000	142	35 (——	29 - total —	6)	Malfunction- free	100.0 +.0/1	99.2 +.2/3	99.1 +.3/4 (29 mo)			
	Advisory: se Premature E Battery Sho	Battery De				(5) (advisoi	(0) ry-related	(5) I subset)	All-cause	99.9 +.1/1	92.6 +.8/9	89.5 +1.5/-1.7 (29 mo)			
7289	InSync II Marquis	Jul-03	27,000	19,000	56	32	15 - total —	17)	Malfunction- free	99.9 +.0/0	99.6 +.2/3				
	Advisory: se Premature E Battery Sho	Battery De				(2) (advisor	(0) ry-related	(2) I subset)	All-cause	99.8 +.0/1	96.2 +.9/-1.2				
7297	InSync Sentry	Nov- 04	8,000	8,000	1	0	0	0	Malfunction- free	100.0 +.0/0 (8 mo)					
									All-cause	100.0 +.0/1 (8 mo)					
7299	InSync Sentry	Apr-05	4,000	4,000	0	0	0	0	Malfunction- free	100.0 +.0/0 (3 mo)					
									All-cause	100.0 +.0/0 (3 mo)					
7303	InSync Maximo	Jun-04	16,000	15,000	2	5	3	2	Malfunction- free	100.0 +.0/1	100.0 +.0/1 (14 mo)				
									All-cause	99.9 +.0/1	99.9 +.0/1 (14 mo)				
7304	InSync Maximo	Apr-05	3,000	3,000	0	0	0	0	Malfunction- free	100.0 +.0/0 (4 mo)					
									All-cause	100.0 +.0/0 (4 mo)					
8040	InSync	Aug-01	15,000	7,000	79	10	4	6	Malfunction- free	100.0 +.0/0	100.0 +.0/1	99.9 +.0/1	99.7 +.2/4	99.7 +.2/4	99.7 +.2/4 (61 mo)
									All-cause	99.9 +.0/1	99.8 +.1/1	98.5 +.2/3	95.8 +1.1/-1.5	94.7 +1.7/-2.4	93.0 +2.5/-3.8 (61 mo)
8042	InSync III	Feb-03	17,000	12,000	6	2	1	1	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0	100.0 +.0/0 (50 mo)	
									All-cause	100.0 +.0/1	99.9 +.0/1	99.7 +.2/3	99.7 +.2/3	97.9 +1.5/-4.8 (50 mo)	

7223 Micro Jewel II	Non-Advisory Population	Advisory Population	Product Characteristics	
US Market Release	Nov-96	Nov-96	NBD Code	VVEV
Registered US Implants	10,000	11,000	Serial Number Prefix/Xray ID	PFR
Estimated Active US Implants	2,000	0	Max Delivered Energy	30 J
Normal Battery Depletions	386	453	Longevity	See page 32
Malfunctions	62	1,291		
Advisories			2000 Potential Long Charge Times Due to Ca 2004 Potential Long Charge Times Due to Cap	

Years After	Implant		Malfunction	-free survival		A			
Non-Adv	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr		
	99.9	99.8	99.7	99.6	99.6	99.4	99.3	96.5 at 92 mo	
	99.8	99.6	99.3	98.5	96.7	91.6	84.1	61.3 at 92 mo	
Adv Pop	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr			
	99.9	99.3	94.7	86.3	84.1	83.7	80.9 at 80 mo		
	99.7	98.4	89.0	70.8	62.1	51.8	20.3 at 80 mo		



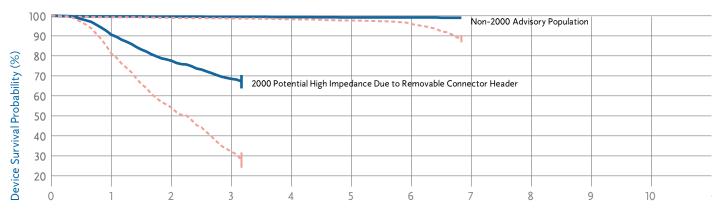
			 		No	n-Advisory Po	pulation	
0					-			
80 -				2000, 200	Detential Lo	ng Charge Tim		
70 				Due to Cap	acitor	ig charge fin		
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ICD Implantable Cardioverter Defibrillators, continued

7227 GEM	Non-2000 Advisory Population	2000 Advisory Population	Product Characteristics
US Market Release	Oct-98	Oct-98	NBD Code VVEV
Registered US Implants	22,000	1,000	Serial Number Prefix/Xray ID PIP, PLN, PLP, PLR
Estimated Active US Implants	11,000	0	Max Delivered Energy 35 J
Normal Battery Depletions	137	0	Longevity See page 32
Malfunctions	129	297	
Advisories		see page 153 –	1999 Potential Circuit Overload 1999 Potential High Current Drain 2000 Potential High Impedance Due to Removable Connector Header
Years After Implant	 Malfunction-free 	survival	All-cause survival

Non-2000	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr		
	99.7	99.6	99.5	99.4	99.2	99.2	99.0 at 82 mo	
	99.3	99.0	98.7	98.3	97.7	95.9	88.7 at 82 mo	

2000 Adv	l yr	2 yr	3 yr				
	90.6	77.5	68.5	67.2 at 38 mo			
	81.2	54.1	32.0	27.8 at 38 mo			



7229 GEM II VR		Product Characteristics	
US Market Release	Jul-99	NBD Code	VVEV
Registered US Implants	11,000	Serial Number Prefix/Xray ID	PJJ
Estimated Active US Implants	5,000	Max Delivered Energy	30 J
Normal Battery Depletions	136	Longevity	See page 32
Malfunctions	24		
Advisories	see page 151 – 199	000 Potential Weak Solder Connection 99 Potential Circuit Overload - Technical article on ICD battery discharge	behavior
Years After Implant	 Malfunction-free survival 	All-cause survival	

I Cal 3 Alter	Implant					All C	1	
	l yr	2 yr	3 yr	4 yr	5 yr			ĺ
	99.9	99.8	99.8	99.7	99.7	99.7 at 70 mo		
	99.8	99.4	99.3	98.4	95.9	90.0 at 70 mo		

100

90											
50											
80											
								I			
0)	1 2	2 3	3 4	5	6	5 7	8	9) 10)

egistered U			Dec	-02		NBD Code	VVEV
	IS Implant	s	19,	000		Serial Number Prefix/Xray ID	PKD, PLW, PLY
stimated Ac	ctive US Ir	nplants	13,	000		Max Delivered Energy	30 J
Normal Batte	ery Deplet	ions		6		Longevity	See page 32
Malfunctions	5			13 (0 related to	advisory)		
		on Not Compror nction Compror		8 (0 related to 5 (0 related to			
Advisories				1 see page 142	– 2005 Pote	ential Premature Battery Depletion	on Due to Battery Short
ears After I	Implant 1 yr	2 yr	alfunction 3 yr	-free survival		All-cause survival	
	100	99.9	99.9				
	99.9	99.7	99.6				

US Market	Release		Dec-	-00		NBD Code		VVEV	,
Registered	US Implant	s	17,C	000		Serial Number Pre	fix/Xray ID	PJL	
Estimated	Active US Ir	nplants	11,C	000		Max Delivered Ene	rgy	30 J	
Normal Ba	ttery Deplet	tions		40		Longevity		See p	age 32
Malfunctio	ons			20					
The		on Not Compi Inction Compi		15 5					
	тпегару ги	inction comp	onniseu	5					
Advisories		inction compi			<u>e 164</u> – Technical	article on ICD batte	ry discharge be	ehavior	
				one <u>see page</u>		article on ICD batter		ehavior	
	er Implant		No Malfunction-	one <u>see page</u> -free surviva		All-cause s		ehavior	
	er Implant	2 yr	Nalfunction-	one <u>see page</u> -free surviva 4 yr	al	All-cause s		ehavior	
'ears Afte	er Implant 1 yr 99.9	2 yr 99.9	Malfunction- 3 yr 99.8	one <u>see page</u> -free surviva 4 yr 99.8	al 99.8 at 54 mo	All-cause s		ehavior	
'ears Afte	er Implant 1 yr 99.9	2 yr 99.9	Malfunction- 3 yr 99.8	one <u>see page</u> -free surviva 4 yr 99.8	al 99.8 at 54 mo	All-cause s		ehavior	
'ears Afte	er Implant 1 yr 99.9	2 yr 99.9	Malfunction- 3 yr 99.8	one <u>see page</u> -free surviva 4 yr 99.8	al 99.8 at 54 mo	All-cause s		ehavior	

JS Market	Release		Oct-03		NBD Code		VVED	
Registered	US Implant	s	21,000		Serial Number Prefix/Xray	ID	PRN	
stimated /	Active US In	nplants	19,000		Max Delivered Energy		35 J	
Normal Bat	ttery Deplet	ions	1		Longevity		See page	e 32
Malfunction	ns		4	(0 related to advisory)				
		on Not Compromis nction Compromis		(0 related to advisory) (0 related to advisory)				
Advisories					otential Premature Battery Dep	<mark>letion Due to</mark>	Battery S	hort
	r Implant		ا unction-fre		otential Premature Battery Dep All-cause survival	letion Due to	Battery S	hort
		Malfi 99.9 at 22 mo				letion Due to	Battery S	hort
	1 yr					letion Due to	Battery S	hort
ears After	1 yr 100 99.9	99.9 at 22 mo				letion Due to	Battery S	hort
ears After	1 yr 100 99.9	99.9 at 22 mo				letion Due to	Battery S	hort
ears After	1 yr 100 99.9	99.9 at 22 mo				letion Due to	Battery S	ihort

7250 Jewel AF **Product Characteristics** VVED NBD Code US Market Release Jun-00 1,000 Serial Number Prefix/Xray ID **Registered US Implants** PID Estimated Active US Implants 400 Max Delivered Energy 27 J Normal Battery Depletions 40 Longevity See page 32 Malfunctions 11 Advisories None Years After Implant Malfunction-free survival ---- All-cause survival 2 yr 3 yr 5 yr 6 yr 1 yr 4 yr 98.9 99.6 99.4 99.3 99.3 98.9 98.9 at 73 mo 79.7 99.1 98.7 98.5 96.9 90.7 **79.7** at 73 mo 100 ----90 <u>-</u>., 80 0 2 3 4 5 6 7 8 9 10

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Implantable Cardioverter Defibrillators, continued

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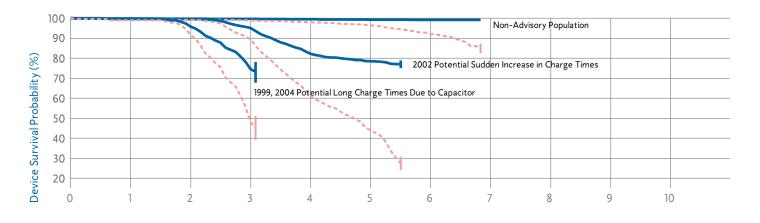
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7271 GEM DR	Non-Advisory Population	2002 Advisory Population	1999, 2004 Advisory Population	Product Characteristics
US Market Release	Oct-98	Oct-98	Oct-98	NBD Code VVED
Registered US Implants	15,000	4,000	400	Serial Number Prefix/Xray ID PIM
Estimated Active US Implants	7,000	40	0	Max Delivered Energy 35 J
Normal Battery Depletions	163	145	17	Longevity See page 32
Malfunctions	67	499	112	
Advisories		see page 150	– 1999 Poten	ntial Sudden Increase in Charge Times Itial Long Charge Times Due to Capacitor Itial Long Charge Times Due to Capacitor – Supplement

ars After	ппріані	I.		-free survival	I	All-	cause survival	1	
Non-Adv	1 yr	2 yr	3 yr	4 yr	5 yr	бyr	at 82 mo		
	99.9	99.8	99.7	99.5	99.3	99.2	99.2		
	99.7	99.5	98.9	98.0	96.5	92.2	85.1		
2002 Adv	1 yr	2 yr	3 yr	4 yr	5 yr	at 66 mo			
	99.9	99.6	95.1	82.2	78.5	77.1			
	99.7	99.2	89.4	61.1	44.0	27.5			
1999,		1	1	1				1	
004 Adv	1 yr	2 yr	3 yr	at 37 mo					
	99.5	95.7	74.4	73.2					



Normal Battery Depletions 1,628 Longevity See page 32 Maifunctions 52 Advisories 1 see page 164 - Technical article on ICD battery discharge behavior ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 99.8 99.7 99.6 99.6 99.6 at 55 mo 99.5 98.7 95.6 82.6 48.1 25.3 at 65 mo 1 yr 2 yr 3 yr 4 yr 5 yr 99.6 at 55 mo 99.5 98.7 95.6 82.6 48.1 25.3 at 65 mo 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur 1 ur <td< th=""><th></th><th>Release</th><th></th><th>Feb</th><th>-99</th><th></th><th>NBD Code</th><th></th><th>VVED</th><th></th></td<>		Release		Feb	-99		NBD Code		VVED		
Estimated Active US Implants 1.000 Max Delivered Energy 30 Normal Battery Depletions 1.628 Longevity See page 32 Malfunctions 52	Registered	US Implant	S	15,C	000		Serial Number Pre	efix/Xray ID	РЈК		
Normal Battery Depletions 1.628 Longevity See page 32 Maifunctions 52 Advisories 1 see page 169 - 2000 Potential Weak Solder Connection also see page 164 - Technical article on ICD battery discharge behavior Image 32 ears After Implant Maifunction-Free survival All-cause survival 1/yr 2 yr 3 yr 4 yr 5 yr 99.8 99.7 99.6 99.6 99.6 99.6 99.5 98.7 95.6 82.6 48.1 25.3 at 50 mo 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 1 2 3 4 5 6 7 8 9 10 2 3 4 5 6 7 8 9 10 <t< td=""><td></td><td></td><td></td><td>1,0</td><td>000</td><td></td><td></td><td></td><td></td><td></td></t<>				1,0	000						
Malfunctions 52 Advisories 1 see page 149 – 2000 Potential Weak Solder Connection also see page 164 – Technical article on ICD battery discharge behavior ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 99.8 99.7 99.6 99.6 99.6 so 99.6 so mo 99.5 98.7 95.6 82.6 48.1 25.3 at 65 mo 100 100 100 99.6 99.6 99.6 99.6 100 100 10 10 10 10 10 10 10 10 11 10 10 10 10 10 10 10 10 10 10 11 10				1,6	528			0.			
aiso see page 164 – Technical article on ICD battery discharge behavior ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr All-cause survival 99.8 99.7 99.6 99.6 99.6 99.6 at 65 mo	Malfunction	ns			52						
Image: New York Image: York Image: York Image: York Image: York Image: York Image: York York Image: York York Image: York York <td>Advisories</td> <td></td> <td></td> <td></td> <td>1 <u>see page 14</u> also see pag</td> <td>9 – 2000 Po <u>e 164 –</u> Te</td> <td>otential Weak Solder C chnical article on ICD</td> <td>Connection battery discharg</td> <td>e behavior</td> <td></td>	Advisories				1 <u>see page 14</u> also see pag	9 – 2000 Po <u>e 164 –</u> Te	otential Weak Solder C chnical article on ICD	Connection battery discharg	e behavior		
99.8 99.7 99.6 99.6 99.6 99.6 at 65 mo Image: Control of the cont	ears After	r Implant		Malfunction-	-free survival		All-cause	survival			
99.5 98.7 95.6 82.6 48.1 25.3 at 65 mo 99.5 98.7 95.6 82.6 48.1 25.3 at 65 mo 99.5 98.7 95.6 82.6 48.1 25.3 at 65 mo 99.5 98.7 95.6 82.6 48.1 25.3 at 65 mo 99.5 98.7 95.6 82.6 48.1 25.3 at 65 mo 99.5 98.7 95.6 82.6 48.1 25.3 at 65 mo 90.7 90.7 90.7 90.7 90.7 90.7 7274 Marquis DR 9 10 1 1 1 1 2 3 4 5 6 7 8 9 10 Product Characteristics NBD Code VVED Serial Number Prefix/Xray ID PKC MasDelivered Energy 30.1 Longevity See page 32 Mar-02 Max Delivered Energy 30.1 NBD Code VVED Serial Number Prefix/Xray ID PKC <td cols<="" td=""><td></td><td>1 yr</td><td>2 yr</td><td>3 yr</td><td>4 yr</td><td>5 yr</td><td></td><td></td><td></td><td></td></td>	<td></td> <td>1 yr</td> <td>2 yr</td> <td>3 yr</td> <td>4 yr</td> <td>5 yr</td> <td></td> <td></td> <td></td> <td></td>		1 yr	2 yr	3 yr	4 yr	5 yr				
7274 Marquis DR Product Characteristics VS Market Release Mar-02 Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC MarDelivered Energy 30 J Normal Battery Depletions 11 Longevity See page 32 Malfunctions 64 (9 related to advisory) Therapy Function Not Compromised 32 (1 related to advisory) Therapy Function Compromised 32 (1 related to advisory) Therapy Function Compromised 32 (1 related to advisory) Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short ease After Implant Malfunction-free survival All-cause survival 1 1 yr 3 yr 100 99.9 99.7 99.5 at 42mo u		99.8	99.7	99.6	99.6	99.6	99.6 at 65 mo				
7274 Marquis DR Product Characteristics US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) 32 (1 related to advisory) See page 122 - 2005 Potential Premature Battery Depletion Due to Battery Short Advisories 1 see page 142 - 2005 Potential Premature Battery Depletion Due to Battery Short Sears After Implant All-cause survival 1 yr 2 yr 3 yr All-cause survival All-cause survival 1 yr 2 yr 3 yr All-cause survival All-cause survival		99.5	98.7	95.6	82.6	48.1	25.3 at 65 mo				
7274 Marquis DR Product Characteristics US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) Therapy Function Not Compromised 32 (1 related to advisory) Therapy Function Compromised 32 (1 related to advisory) 32 (8 related to advisory) Therapy Function Compromised 32 (1 related to advisory) Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Sears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr All-cause survival 100 99.9 99.7 99.5 at 42 mo											
7274 Marquis DR Product Characteristics US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) Therapy Function Not Compromised 32 (1 related to advisory) Therapy Function Compromised 32 (1 related to advisory) 32 (8 related to advisory) Therapy Function Compromised 32 (1 related to advisory) Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Series After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr All-cause survival 100 99.9 99.7 99.5 at 42 mo					· • •						
7274 Marquis DR Product Characteristics US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) Therapy Function Not Compromised 32 (1 related to advisory) Therapy Function Compromised 32 (1 related to advisory) 32 (8 related to advisory) Therapy Function Compromised 32 (1 related to advisory) Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Series After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr All-cause survival 100 99.9 99.7 99.5 at 42 mo											
7274 Marquis DR Product Characteristics US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) Therapy Function Not Compromised 32 (1 related to advisory) Therapy Function Compromised 32 (1 related to advisory) See page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr All-cause survival 100 99.9 99.7 99.5 at 42 mo u u u											
7274 Marquis DR Product Characteristics US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) Therapy Function Not Compromised 32 (1 related to advisory) Therapy Function Compromised 32 (1 related to advisory) See page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr All-cause survival 100 99.9 99.7 99.5 at 42 mo u u u											
7274 Marquis DR Product Characteristics US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) Therapy Function Not Compromised 32 (1 related to advisory) Therapy Function Compromised 32 (1 related to advisory) 32 (8 related to advisory) Therapy Function Compromised 32 (1 related to advisory) Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Series After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr All-cause survival 100 99.9 99.7 99.5 at 42 mo					•	•					
7274 Marquis DR Product Characteristics US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) 32 (1 related to advisory) See page 32 (8 related to advisory) Therapy Function Not Compromised 32 (1 related to advisory) 32 (8 related to advisory) See page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Series After Implant Malfunction-free survival 1 yr 2 yr 3 yr All-cause survival - 1 yr 2 yr 3 yr All-cause survival - 1 00 99.9 99.7 99.5 at 42 mo - - -											
7274 Marquis DR Product Characteristics US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) Therapy Function Not Compromised 32 (1 related to advisory) Therapy Function Compromised 32 (1 related to advisory) See page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr All-cause survival 100 99.9 99.7 99.5 at 42 mo u u u											
7274 Marquis DR Product Characteristics US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) Therapy Function Not Compromised 32 (1 related to advisory) Therapy Function Compromised 32 (1 related to advisory) See page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr All-cause survival 100 99.9 99.7 99.5 at 42 mo u u u											
US Market Release Mar-02 NBD Code VVED Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) See page 12 Serial Number Prefix/Xray ID NBD Code Therapy Function Not Compromised 32 (1 related to advisory) See page 12 See page 142 - 2005 Potential Premature Battery Depletion Due to Battery Short Advisories 1 see page 142 - 2005 Potential Premature Battery Depletion Due to Firee survival All-cause survival 1 yr 2 yr 3 yr All-cause survival 1 yr 2 yr 3 yr											
Registered US Implants 48,000 Serial Number Prefix/Xray ID PKC Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) 32 (1 related to advisory) See page 122 (1 related to advisory) See page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Gears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 99.5 at 42 mo All-cause survival		1	2	3	4	5	6 7	8	9 10)	
Estimated Active US Implants 29,000 Max Delivered Energy 30 J Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) 32 (1 related to advisory) 32 (1 related to advisory) Therapy Function Not Compromised Therapy Function Compromised 32 (1 related to advisory) 32 (8 related to advisory) Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short rears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr Image: Sard Sard Sard Sard Sard Sard Sard Sard	7274 M	I	_	3	4	5	-	-	9 10)	
Normal Battery Depletions 111 Longevity See page 32 Malfunctions 64 (9 related to advisory) 32 (1 related to advisory) 32 (8 related to advisory) Therapy Function Not Compromised Therapy Function Compromised 32 (1 related to advisory) 32 (8 related to advisory) Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr All-cause survival 1 100 99.9 99.7 99.5 at 42 mo Intervitian		arquis D	_			5	Product Charac	-)	
Malfunctions 64 (9 related to advisory) Therapy Function Not Compromised Therapy Function Compromised 32 (1 related to advisory) 32 (8 related to advisory) 32 (8 related to advisory) Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short rears After Implant Malfunction-free survival 1 yr 2 yr 3 yr 100 99.9 99.7 99.5 at 42 mo	US Market	arquis D Release	DR	Mar	-02	5	Product Charac	teristics	VVED)	
Therapy Function Not Compromised Therapy Function Compromised 32 (1 related to advisory) 32 (8 related to advisory) Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short rears After Implant Malfunction-free survival 1 yr 2 yr 3 yr Image: Strate Survival 1 00 99.9 99.5 at 42 mo	US Market Registered	arquis D Release US Implant:	PR	Mar- 48,0	-02 000	5	Product Charac NBD Code Serial Number Pre	teristics efix/Xray ID	VVED PKC)	
Therapy Function Compromised 32 (8 related to advisory) Advisories 1 see page 142 – 2005 Potential Premature Battery Depletion Due to Battery Short Gears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 100 99.9 99.7 99.5 at 42 mo	US Market Registered Estimated /	arquis D Release US Implant: Active US In	s nplants	Mar- 48,0	-02 000 000	5	Product Charac NBD Code Serial Number Pre Max Delivered En	teristics efix/Xray ID	VVED PKC 30 J)	
ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 100 99.9 99.7 99.5 at 42 mo 100	US Market Registered Estimated <i> </i> Normal Bat	arquis D Release US Implant Active US In tery Deplet	s nplants	Mar- 48,0	-02 000 000 111		Product Charac NBD Code Serial Number Pre Max Delivered En	teristics efix/Xray ID	VVED PKC 30 J)	
1 yr 2 yr 3 yr 100 99.9 99.7 99.5 at 42 mo 100	US Market Registered Estimated / Normal Bat Malfunctior Thei	arquis D Release US Implant Active US In tery Deplet ns rapy Functio	S nplants tions	Mar- 48,0 29,0 romised	-02 000 000 111 64 (9 related to 32 (1 related to	o advisory) advisory)	Product Charac NBD Code Serial Number Pre Max Delivered En	teristics efix/Xray ID	VVED PKC 30 J)	
100 99.9 99.7 99.5 at 42 mo <	US Market I Registered Estimated <i>I</i> Normal Bat Malfunctior The	arquis D Release US Implant Active US In tery Deplet ns rapy Functio	S nplants tions	Mar- 48,0 29,0 romised	-02 000 000 111 64 (9 related to 32 (1 related to 32 (8 related to	o advisory) advisory) o advisory)	Product Charace NBD Code Serial Number Pre Max Delivered En Longevity	efix/Xray ID ergy	VVED PKC 30 J See page 32		
	US Market I Registered Estimated A Normal Bat Malfunction Then Advisories	arquis D Release US Implant: Active US In tery Deplet ns rapy Function Therapy Fu	s nplants cions on Not Compr nction Compr	Mar- 48,0 29,0 romised romised	-02 000 000 111 64 (9 related to 32 (1 related to 32 (8 related to 1 see page 14:	o advisory) advisory) o advisory)	Product Charace NBD Code Serial Number Pre Max Delivered En Longevity	teristics efix/Xray ID ergy tery Depletion D	VVED PKC 30 J See page 32		
99.8 99.6 97.5 95.1 at 42 mo Image: Control of the second	US Market I Registered Estimated A Normal Bat Malfunction Then Advisories	arquis D Release US Implant: Active US In tery Deplet ns rapy Function Therapy Function Therapy Function Therapy Function	s nplants cions on Not Compr nction Compr	Mar 48,0 29,0 romised romised Malfunction-	-02 000 000 111 64 (9 related to 32 (1 related to 32 (8 related to 1 see page 14:	o advisory) advisory) o advisory)	Product Charace NBD Code Serial Number Pre Max Delivered En Longevity	teristics efix/Xray ID ergy tery Depletion D	VVED PKC 30 J See page 32		
	US Market I Registered Estimated A Normal Bat Malfunction Then Advisories	arquis D Release US Implant: Active US In tery Deplet ns rapy Function Therapy Function Therapy Function r Implant	s nplants cions on Not Compr nction Compr	Mar- 48,0 29,0 romised romised Malfunction- 3 yr	-02 000 111 64 (9 related to 32 (1 related to 32 (8 related to 1 see page 142 -free survival	o advisory) advisory) o advisory)	Product Charace NBD Code Serial Number Pre Max Delivered En Longevity	teristics efix/Xray ID ergy tery Depletion D	VVED PKC 30 J See page 32		

Device Survival Probability (%)

Device Survival Probability (%)

Registered US Implants 20,000 Serial Number Prefix/Xray ID PJM Estimated Active US Implants 11,000 Max Delivered Energy 30 J Normal Battery Depletions 404 Longevity See page 32 Malfunctions 28 Therapy Function Not Compromised 10 10 Advisories None see page 164 – Technical article on ICD battery discharge behavior Years After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr All-cause survival 1 yr 2 yr 3 yr 4 yr All-cause survival 99.9 99.9 99.8 99.8 at 55 mo	US Market	Release		Nov	-00		NBD Code			VVED	
Normal Battery Depletions 404 Longevity See page 32 Malfunctions 28 Therapy Function Not Compromised Therapy Function Compromised 18 10 Advisories None see page 164 – Technical article on ICD battery discharge behavior ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 99.9 99.9 99.8 99.8 at 55 mo Image: Compression of the set of the	Registered	US Implant	S	20,0	000		Serial Numb	er Prefix/Xra	ay ID	PJM	
Malfunctions 28 Therapy Function Not Compromised 18 Therapy Function Compromised 10 Advisories None see page 164 – Technical article on ICD battery discharge behavior ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 99.9 99.9 99.8 99.8 at 55 mo	Estimated	Active US Ir	nplants	11,0	000		Max Deliver	ed Energy		30 J	
Therapy Function Not Compromised 18 Therapy Function Compromised 10 Advisories None see page 164 – Technical article on ICD battery discharge behavior ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 99.9 99.8 99.8 at 55 mo Image: See page 164 at 55 mo	Normal Bat	ttery Deplet	tions	4	404		Longevity			See page 32	
Therapy Function Compromised 10 Advisories None see page 164 – Technical article on ICD battery discharge behavior ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 99.9 99.9 99.8 99.8 at 55 mo	Malfunctio	ons			28						
ears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 99.9 99.8 99.8 99.8 at 55 mo	The										
1 yr 2 yr 3 yr 4 yr 99.9 99.9 99.8 99.8 at 55 mo											
									0	lavior	
99.7 99.1 96.8 91.3 82.8 at 55 mg		er Implant 1 yr	2 yr	Malfunction 3 yr	-free survival 4 yr				0	navior	
		er Implant 1 yr	2 yr	Malfunction 3 yr	-free survival 4 yr				0	navior	
	ears Afte	er Implant 1 yr	2 yr	Malfunction- 3 yr 99.8 96.8	-free survival 4 yr 99.8 91.3				0		
	ears Afte	er Implant 1 yr 99.9	2 yr 99.9	Malfunction- 3 yr 99.8 96.8	-free survival 4 yr 99.8 91.3	99.8 at 55 mo			0	navior	
	ears Afte	er Implant 1 yr 99.9	2 yr 99.9	Malfunction- 3 yr 99.8 96.8	-free survival 4 yr 99.8 91.3	99.8 at 55 mo			0		

JS Market F	Release		Feb	-01		NBD Code		DDED
Registered	US Implants	S	14,C	000		Serial Number Prefix/	Xray ID	PKE
Estimated A	Active US In	nplants	8,0	000		Max Delivered Energy		30 J
Normal Batt	tery Deplet	ions	:	274		Longevity		See page 32
Malfunction	ıs			14				
		on Not Compi nction Compi		8 6				
			No	one <u>see page</u>	164 – Technical	article on ICD battery c	lischarge beł	navior
Advisories	Implant		Malfunction-	-free surviva		article on ICD battery c	0	navior
Advisories	Implant	2 yr	Malfunction-	-free surviva		·	0	navior
Advisories	Implant		Malfunction-	-free surviva		·	0	
Advisories ears After	Implant	2 yr	Malfunction-	-free surviva		All-cause sur	0	navior
Advisories	Implant 1 yr 100	2 yr 99.9	Malfunction- 3 yr 99.9	-free surviva 4 yr 99.8	99.8 at 54 mo	All-cause sur	0	navior
Advisories	Implant 1 yr 100	2 yr 99.9	Malfunction- 3 yr 99.9	-free survival 4 yr 99.8 89.3	99.8 at 54 mo	All-cause sur	0	

Device Survival Probability (%)

US Market	Release		Oct-03	NBD	Code	VVED
Registered	US Implants	5	24,000	Serial	Number Prefix/Xray ID	PRM
Estimated	Active US In	nplants	21,000	Max D	elivered Energy	35 J
Normal Bat	tery Deplet	ions	2	Longe	evity	See page 32
Malfunctio	ns		4 (0 related to ad	dvisory)		
The		on Not Compromised nction Compromised				
Advisories	rimplant	Malfun			emature Battery Depletio	on Due to Battery Short
Advisories (ears Afte	1 yr		1 <u>see page 142</u> – ction-free survival		All-cause survival	on Due to Battery Short
		Malfun 100 at 22 mo 99.9 at 22 mo				on Due to Battery Short
/ears Afte	1 yr 100	100 at 22 mo				on Due to Battery Short
′ears Afte	1 yr 100	100 at 22 mo				on Due to Battery Short
/ears Afte	1 yr 100	100 at 22 mo				on Due to Battery Short

7288 Intrinsic			Proc	luct Characteristics		
US Market Release		Aug-04	NBD	Code	VVED	
Registered US Implants		18,000	Seria	l Number Prefix/Xray ID	PUB	
Estimated Active US Im	plants	17,000	Max	Delivered Energy	35 J	
Normal Battery Depletion	ons	1	Long	evity	See page 33	
Malfunctions		2				
	n Not Compromised Iction Compromised					
Advisories		None				
1 yr	- Malfun	ction-free surviva		- All-cause survival		
	Malfun	ction-free surviva	ı	All-cause survival		
100	Malfun	ction-free surviva		All-cause survival		
1 yr 100 100	Malfun	ction-free surviva		All-cause survival		
1 yr 100 100	Malfun	ction-free surviva		All-cause survival		
1 yr 100 100	Malfun	ction-free surviva		- All-cause survival	9 10	

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7290 Onyx VR

US Market Release	Mar-04
Registered US Implants	1,000
Estimated Active US Implants	1,000
Normal Battery Depletions	0
Malfunctions	0
Therapy Function Not Comp Therapy Function Comp	
Advisories	None

Product Characteristics

NBD Code	VVEV
Serial Number Prefix/Xray ID	PRP
Max Delivered Energy	30 J
Longevity	See page 33

(0/)	Years After	Implant	— Ma	lfunction-fre	ee survival		All-c	ause surviva			
		1 yr									
001 001 000 000 000 000 000 000 000 000		100									
		100									
100		_									
90											
80											
5 ()	1	2	3	4	5	6	7	3	9 1	0

Device Survival Probability (%)

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Device Survival Summary (95% Confidence Interval)

The following table shows ICD device survival estimates with 95% confidence intervals. Estimates are shown for both malfunction-free survival (which excludes normal battery depletion) and all-cause survival (which includes both malfunctions and normal battery depletion).

<u>0</u>

Implantable Cardioverter Defibrillators, continued

													<i>,</i> ,				
Model Number	Family	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival Probabilities	Device	Survival F	Probabilit	: y (%) │4 yr	5 yr	6 yr	7 yr	8 yr
7223 Non- Advisory	Micro Jewel II	Nov-96	10,000	2,000	386	62	-	-	Malfunction- free	99.9 +.0/1	99.8 +.1/1	99.7 +.1/1	99.6 +.1/2	99.6 +.1/2	99.4 +.2/2	99.3 +.2/3	96.5 +1.3/-2.1 (92 mo)
Population									All-cause	99.8 +.1/1	99.6 +.1/1	99.3 +.2/2	98.5 +.3/3	96.7 +.4/5	91.6 +.7/8	84.1 +1.1/-1.2	61.3 +4.1/-4.5 (92 mo)
7223 2000, 2004	Micro Jewel II	Nov-96	11,000	0	453	1,291	_	-	Malfunction- free	99.9 +.1/1	99.3 +.2/2	94.7 +.5/5	86.3 +.8/8	84.1 +.8/9	83.7 +.9/9	80.9 +1.1/-1.1 (80 mo)	
Advisory Population	Advisories: <u>see</u> Times Due to C Long Charge Ti	apacitor; an	d page 143 -	- 2004 Poten	tial	-	-	_	All-cause	99.7 +.1/1	98.4 +.2/3	89.0 +.6/7	70.8 +1.0/-1.1	62.1 +1.2/-1.2	51.8 +1.5/-1.5	20.3 +3.1/-3.0 (80 mo)	
7227 Non-2000 Advisory	GEM	Oct-98	22,000	11,000	137	129	-	_	Malfunction- free	99.7 +.1/1	99.6 +.1/1	99.5 +.1/1	99.4 +.1/1	99.2 +.1/2	99.2 +.1/2	99.0 +.2/3 (82 mo)	
Population	Advisories: see and page 153 -				erload;	—	_	_	All-cause	99.3 +.1/1	99.0 +.1/1	98.7 +.2/2	98.3 +.2/2	97.7 +.2/3	95.9 +.4/5	88.7 +1.7/-1.9 (82 mo)	
7227 B, D, E 2000	GEM	Oct-98	1,000	0	0	297	-	-	Malfunction- free	90.6 +1.7/-2.0	77.5 +2.6/-2.9	68.5 +3.2/-3.4	67.2 +3.2/-3.5 (38 mo)				
Advisory Population	Advisory: <u>see</u> Due to Remova			al High Impec	lance	_	-	_	All-cause	81.2 +2.3/-2.6	54.1 +3.3/-3.4	32.0 +3.8/-3.8	27.8 +3.9/-3.8 (38 mo)				
7229	GEM II VR	Jul-99	11,000	5,000	136	24	-	-	Malfunction- free	99.9 +.0/1	99.8 +.1/1	99.8 +.1/1	99.7 +.1/1	99.7 +.1/1	99.7 +.1/1 (70 mo)		
	Advisories: see Connection; an also see page 10 discharge beha	d page 151 – 64 – Techni	1999 Potent	tial Circuit Ov	verload;	_	_	_	All-cause	99.8 +.1/1	99.4 +.1/2	99.3 +.2/2	98.4 +.3/3	95.9 +.5/6	90.0 +1.8/-2.1 (70 mo)		
7230	Marquis VR	Dec-02	19,000	13,000	6	13 (8 total ——	5 —)	Malfunction- free	100.0 +.0/0	99.9 +.1/1	99.9 +.1/1					
	Advisories: see Battery Depleti				2	(0) (adviso	(0) ry-related s	(0) subset)	All-cause	99.9 +.0/1	99.7 +.1/1	99.6 +.1/2					
7231	GEM III VR	Dec-00	17,000	11,000	40	20	15	5	Malfunction- free	99.9 +.0/1	99.9 +.0/1	99.8 +.1/1	99.8 +.1/1	99.8 +.1/1 (54 mo)			
	<u>see page 164</u> – discharge beha		rticle on ICD) battery					All-cause	99.8 +.1/1	99.5 +.1/1	99.1 +.2/2	98.8 +.3/3	98.5 +.3/5 (54 mo)			
7232	Maximo VR	Oct-03	21,000	19,000	1	4 (2 - total ——	2 —)	Malfunction- free	100.0 +.0/1	99.9 +.1/3 (22 mo)						
	Advisory: seep Depletion Due			al Premature	Battery	(0) (adviso	(0) ry-related s	(0) subset)	All-cause	99.9 +.0/1	99.7 +.1/4 (22 mo)						

Device Survival Summary continued

Model Number	vlir	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival	Device	Survival	Probabili	ty (%)				
Nur	Family	USI	Reg USI	Esti Act Imp	Dep	Mal	Cor Fun	Cor The	Probabilities	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
7250	Jewel AF	Jun-00	1,000	400	40	11	-	-	Malfunction- free	99.6 +.3/6	99.4 +.3/7	99.3 +.4/7	99.3 +.4/7	98.9 +.5/-1.0	98.9 +.5/-1.0	98.9 +.5/-1.0 (73 mo)	
									All-cause	99.1 +.4/7	98.7 +.5/9	98.5 +.6/9	96.9 +1.0/-1.4	90.7 +2.2/-2.8	79.7 +4.6/-5.7	79.7 +4.6/-5.7 (73 mo)	
7271 Non- Advisory	GEM DR	Oct-98	15,000	7,000	163	67	_	_	Malfunction- free	99.9 +.0/1	99.8 +.1/1	99.7 +.1/1	99.5 +.1/2	99.3 +.2/2	99.2 +.2/2	99.2 +.2/2 (82 mo)	
Population									All-cause	99.7 +.1/1	99.5 +.1/1	98.9 +.2/2	98.0 +.3/3	96.5 +.4/5	92.2 +.8/9	85.1 +2.2/-2.5 (82 mo)	
7271 2002 Advisory	GEM DR	Oct-98	4,000	40	145	499	_	_	Malfunction- free	99.9 +.1/2	99.6 +.2/3	95.1 +.7/9	82.2 +1.5/-1.6	78.5 +1.7/-1.8	77.1 +1.8/-2.0 (66 mo)		
Population	Advisory: <u>see p</u> in Charge Time		002 Potentia	al Sudden Inc	rease	—	-	-	All-cause	99.7 +.1/2	99.2 +.3/4	89.4 +1.1/-1.2	61.1 +2.0/-2.1	44.0 +2.5/-2.5	27.5 +3.4/-3.3 (66 mo)		
7271 1999, 2004	GEM DR	Oct-98	400	0	17	112	_	_	Malfunction- free	99.5 +.4/-1.6	95.7 +1.7/-2.9	74.4 +4.7/-5.5	73.2 +4.8/-5.6 (37 mo)				
Advisory Population	Advisories: see Times Due to C Long Charge Ti	apacitor; an	d page 143 -	2004 Poten	tial	_	-	-	All-cause	98.9 +.7/-1.8	91.4 +2.6/-3.6	47.9 +5.9/-6.1	45.2 +5.9/-6.1 (37 mo)				
7273	GEM II DR	Feb-99	15,000	1,000	1,628	52	-	_	Malfunction- free	99.8 +.1/1	99.7 +.1/1	99.6 +.1/1	99.6 +.1/1	99.6 +.1/2	99.6 +.1/2 (65 mo)		
	Advisory: see p Connection; als battery dischar	o see page 1	64 – Techn			_	—	-	All-cause	99.5 +.1/1	98.7 +.2/2	95.6 +.4/4	82.6 +.8/8	48.1 +1.5/-1.6	25.3 +2.9/-2.8 (65 mo)		
7274	Marquis DR	Mar-02	48,000	29,000	111	64 (——	32 - total —	32)	Malfunction- free	100.0	99.9 +.0/0	99.7 +.1/1	99.5 +.1/2 (42 mo)				
	Advisory: <u>see p</u> Depletion Due			al Premature	Battery	(9) (adviso	(1) ory-related	(8) subset)	All-cause	99.8 +.0/0	99.6 +.1/1	97.5 +.3/4	95.1 +1.4/-2.0 (42 mo)				
7275	GEM III DR	Nov-00	20,000	11,000	404	28	18	10	Malfunction- free	99.9 +.0/0	99.9 +.0/1	99.8 +.1/1	99.8 +.1/1	99.8 +.1/1 (55 mo)			
	<u>see page 164</u> – discharge beha		rticle on ICD	battery					All-cause	99.7 +.1/1	99.1 +.1/2	96.8 +.3/3	91.3 +.6/7	82.8 +1.8/-2.0 (55 mo)			
7276	GEM III AT	Feb-01	14,000	8,000	274	14	8	6	Malfunction- free	100.0 +.0/1	99.9 +.0/1	99.9 +.1/1	99.8 +.1/1	99.8 +.1/1 (54 mo)			
	104	Technical a	rticle on ICD	battery					All-cause	99.7 +.1/1	98.9 +.2/2	97.0 +.3/4	89.3 +1.0/-1.1	80.2 +3.3/-3.9			

G

Device Survival Summary continued

-		ket	lants	ts ts	Normal Battery Depletions	ctions	y on Not omised	Therapy Function Compromised		Device	Survival F	Probabilit	y (%)				
Model Number	Family	US Market Release	Registered US Implant:	Estimated Active US Implants	Normal Depleti	Malfunctio	Therapy Function Comprom	Therap Functio Compre	Survival Probabilities	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr
7278	Maximo DR	Oct-03	24,000	21,000	2	4 (0 — total —	4)	Malfunction- free	100.0 +.0/0	100.0 +.0/1 (22 mo)						
	Advisory: see p Depletion Due			al Premature	Battery	(0) (adviso	(0) ory-related	(0) subset)	All-cause	99.9 +.0/1	99.9 +.1/1 (22 mo)						
7288	Intrinsic	Aug-04	18,000	17,000	1	2	2	0	Malfunction- free	100.0 +.0/0							
									All-cause	100.0 +.0/1							
7290	Onyx VR	Mar-04	1,000	1,000	0	0	0	0	Malfunction- free	100.0 +.0/0							
									All-cause	100.0 +.0/0							

Implantable Cardioverter Defibrillators, continued

ICD Reference Chart

ICD

				Delivered Energy		Estimat	ed Longe	vity				End of Life
					y**						Replacement RI)***	
Model Number	Family	Connector Style	Volume/ Mass*		Charging Frequency ^{**}	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	Charge Time	End of Life (EOL) Battery Voltage
7202	Jewel CD	C, D, E	80-83 cc* 129-139 g	34 J	Monthly Quarterly Biannual	3.6 4.5 4.8	4.1 5.3 5.7	4.5 6.0 6.6	4.7 6.4 7.1	≤ 4.91 V	Two≥14.5 sec	≤ 4.57 V
7219	Jewel	B, C, D, E	80-83 cc* 129-139 g	34 J	Monthly Quarterly Biannual	3.6 4.5 4.8	4.1 5.3 5.7	4.5 6.0 6.6	4.7 6.4 7.1	≤ 4.91 V	Two≥14.5 sec	≤ 4.57 V
7220	Jewel Plus	B, C, D, E	80-83 cc* 135-143 g	34 J	Monthly Quarterly Biannual	3.7 4.4 4.7	4.2 5.2 5.5	4.6 5.9 6.4	4.8 6.3 6.8	≤ 4.91 V	Two≥14.5 sec	≤ 4.57 V
7221	Micro Jewel	B, Cx, D, E	69-72 cc* 118-125 g	34 J	Monthly Quarterly Biannual	4.4 5.7 6.2	4.8 6.4 7.0	5.2 7.0 7.7	5.3 7.2 8.0	≤ 4.91 V	_	≤ 4.57 V ^{‡‡}
7223	Micro Jewel II	Cx	54 cc 97 g	30 J	Monthly Quarterly Biannual	4.9 6.3 6.8	5.4 7.1 7.7	5.8 7.8 8.5	6.0 8.1 9.0	≤ 4.91 V	-	≤ 4.57 V ^{‡‡}
7227	GEM	B, Cx, D, E	49 cc* 90 g	35 J	Monthly Quarterly Biannual	5.3 7.7 8.8	5.7 8.5 10.0	6.0 9.3 11.0	6.1 9.6 11.5	≤ 2.55 V	_	≤ 2.40 V [§]
7229	GEM II VR	Cx	39 cc 77 g	30 J	Monthly Quarterly Biannual	3.6 5.0 5.6	3.9 5.5 6.3	4.1 6.0 6.9	4.2 6.2 7.1	≤ 2.55 V	-	≤ 2.40 V
7230	Marquis VR	B, Cx, E	36 cc 75 g	30 J	Monthly Quarterly Biannual	4.9 7.3 8.5	5.2 8.0 9.3	5.4 8.5 10.0	5.5 8.7 10.4	≤ 2.62 V	_	3 months after ERI
7231	GEM III VR	Cx	39 cc 77 g	30 J	Monthly Quarterly Biannual	4.3 6.0 6.6	4.7 6.8 7.5	5.0 7.4 8.5	5.2 7.8 8.9	≤ 2.55 V	-	≤ 2.40 V
7232	Maximo VR	B, Cx, E	39 cc 76 g	35 J	Monthly Quarterly Biannual	4.4 7.0 8.2	4.7 7.5 9.0	4.8 8.0 9.7	4.9 8.3 10.0	≤ 2.62 V	-	3 months after ERI
7250	Jewel AF	G, H	56 cc* 96 g	27 J	Monthly Quarterly Biannual	5.3 6.5 7.0	6.1 7.6 8.2	6.7 8.7 9.4	7.0 9.2 10.0	≤ 4.94 V	-	≤ 4.50 V
7271	GEM DR	DR	62 cc 115 g	35 J	Monthly Quarterly Biannual	6.0 7.4 7.9	6.9 8.4 9.0	7.5 9.3 10.0	7.8 9.8 10.6	≤ 4.91 V	_	≤ 4.57 V ^{\$}
7272	InSync ICD	DR+LV	66 cc 117 g	34 J	Monthly Quarterly Biannual	5.4 6.5 6.9	6.3 8.0 8.5	7.3 9.4 10.3	7.8 10.3 11.2	≤ 4.91 V	-	≤ 4.57 V
7273	GEM II DR	DR	39.5 cc 77 g	30 J	Monthly Quarterly Biannual	2.8 3.7 4.0	3.2 4.3 4.7	3.5 4.8 5.4	3.7 5.1 5.8	≤ 2.55 V	_	≤ 2.40 V
7274	Marquis DR	DR+LV	36 cc 75 g	30 J	Monthly Quarterly Biannual	4.0 5.6 6.2	4.4 6.4 7.2	4.8 7.1 8.1	4.9 7.5 8.6	≤ 2.62 V	-	3 months after ERI
7275	GEM III DR	DR	39.5 cc 78 g	30 J	Monthly Quarterly Biannual	3.3 4.2 4.5	3.8 5.0 5.5	4.3 5.8 6.5	4.4 6.3 7.0	≤ 2.55 V	_	≤ 2.40 V
7276	GEM III AT	DR	39 cc 77 g	30 J	Monthly Quarterly Biannual	3.3 4.3 4.5	3.8 5.1 5.5	4.3 5.9 6.5	4.5 6.3 7.0	≤ 2.55 V	-	≤ 2.40 V
7277	InSync Marquis	DR+LV split	38 cc 77 g	30 J	Monthly Quarterly Biannual	3.7 5.0 5.5	4.3 6.0 6.7	4.7 7.0 8.0	4.9 7.5 8.6	≤ 2.62 V	_	3 months after ERI
7278	Maximo DR	DR	39 cc 77 g	35 J	Monthly Quarterly Biannual	3.7 5.3 6.0	4.1 6.1 7.0	4.3 6.8 8.0	4.5 7.1 8.5	≤ 2.62 V	-	3 months after ERI
7287	Intrinsic 30	DR	36 cc 75 g	30 J	Monthly Quarterly Biannual	4.0 5.5 6.2	4.3 6.3 7.2	4.7 7.0 8.2	4.8 7.4 8.6	≤ 2.62 V	-	3 months after ERI

ICD Reference Chart continued

				Delivered Energy		Estimat	ed Longe	evity		Elective		
Model Number	Family	Connector Style	Volume/ Mass*		Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	Charge Time Time	End of Life (EOL) Battery Voltage
7288	Intrinsic	DR	38 cc 76 g	35 J	Monthly Quarterly Biannual	3.7 5.4 6.1	4.1 6.1 7.0	4.3 6.8 8.0	4.5 7.1 8.5	≤ 2.62 V	-	3 months after ERI
7289	InSync II Marquis	DR+LV true	38 cc 76 g	30 J	Monthly Quarterly Biannual	3.3 4.2 4.5	3.6 4.9 5.4	4.0 5.5 6.1	4.2 5.8 6.6	≤ 2.62 V	_	3 months after ERI
7290	Onyx VR	Сх	39 cc 77 g	30 J	Monthly Quarterly Biannual	3.8 5.0 5.4	4.1 5.6 6.1	4.3 6.2 6.7	4.5 6.4 7.0	≤ 2.55 V	-	≤ 2.40 V
7295	InSync II Protect	DR+LV true	38 cc 77 g	30 J	Monthly Quarterly Biannual	3.3 4.2 4.5	3.7 4.9 5.4	4.0 5.5 6.2	4.2 5.9 6.6	≤ 2.62 V	_	3 months after ERI
7297	InSync Sentry	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Biannual	3.3 4.5 5.0	3.7 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	-	3 months after ERI
7299	InSync Sentry	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Biannual	3.3 4.5 5.0	3.7 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	_	3 months after ERI
7303	InSync Maximo	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Biannual	3.3 4.5 5.0	3.7 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	-	3 months after ERI
7304	InSync Maximo	DR+LV true	40 cc 78 g	35 J	Monthly Quarterly Biannual	3.3 4.5 5.0	3.7 5.3 6.0	4.1 6.2 7.1	4.3 6.6 7.7	≤ 2.62 V	_	3 months after ERI
D153ATG, D153DRG	EnTrust	DR	33 cc 63 g	30 J	Monthly Quarterly Biannual	3.5 4.8 5.3	3.8 5.4 6.1	4.1 6.0 6.9	4.2 6.3 7.2	≤ 2.61 V	-	3 months after ERI
D153VRC	EnTrust	Cx	32 cc 63 g	30 J	Monthly Quarterly Biannual	4.4 6.8 7.9	4.7 7.4 8.7	4.9 7.9 9.5	5.0 8.1 9.8	≤ 2.61 V	_	3 months after ERI
D154ATG, D154DRG	EnTrust	DR	35 cc 68 g	35 J	Monthly Quarterly Biannual	3.8 5.5 6.1	4.2 6.1 7.0	4.4 6.8 7.9	4.6 7.0 8.3	≤ 2.61 V	-	3 months after ERI
D154VRC	EnTrust	Cx	35 cc 68 g	35 J	Monthly Quarterly Biannual	4.8 7.5 9.0	5.0 8.3 10.0	5.2 8.8 10.7	5.3 9.0 11.0	≤ 2.61 V	_	3 months after ERI

* Volume and mass differ by connector style.

** A full charge is a full energy therapeutic shock or capacitor reformation.

*** The minimum time between ERI and EOL is 3 months (100% pacing, two charges per month).

‡ Pacing mode is DDD for dual chamber devices and VVI for others:

60 ppm, 3.0 V, 0.4 ms, 510 ohms for Intrinsic 30 7287, Intrinsic 7288, EnTrust D153ATG / D153DRG / D153VRC, EnTrust D154ATG / D154DRG / D154VRC, Onyx VR 7290, InSync Sentry 7299 (LV:3.0 V, 0.4 ms, 510 ohms), InSync II Protect 7295 (LV:3.0 V, 0.4 ms, 510 ohms), Maximo DR 7278, Maximo VR 7230, InSync II Marquis 7289 (LV:3.0 V, 0.4 ms, 510 ohms), InSync Marquis 7277 (LV:510 ohms), Marquis DR 7274, Marquis VR 7230, GEM III AT 7276, GEM III DR 7275, GEM III VR 7231, GEM II DR 7273, GEM II VR 7229, GEM DR 7271, GEM 7227, and Jewel AF 7250.

 $60\ \text{ppm}$ biventricular pacing, 4.0 V, 0.4 ms, and 510 ohms for InSync ICD 7272;

65 ppm, 4.0 V, 0.4 ms, and 500 ohms for Micro Jewel II 7223 and Micro Jewel 7221;

65 ppm, 5.6 V, 0.5 ms, and 500 ohms for Jewel 7219, Jewel Plus 7220, and Jewel CD 7202.

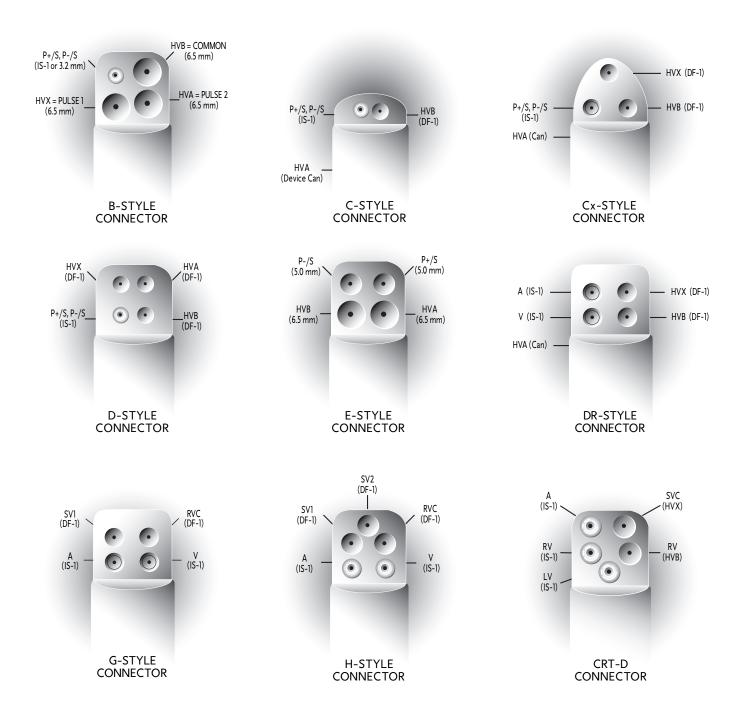
For all cases, sensing rate was assumed at 70 bpm.

For Model 7221 and 7223 devices, if charge time exceeds 60 seconds, the devices are at EOL. If 2 consecutive charge cycles exceed 60 seconds, the "charge circuit inactive" indicator is tripped and all therapies except emergency output VVI pacing are disabled.

§ For Model 7271 and 7227 devices, if charge time exceeds 30 seconds, the device is at EOL. Immediate replacement is recommended. If 3 consecutive charge cycles exceed 30 seconds, the "charge circuit inactive" indicator is tripped and all therapies except emergency VVI pacing are disabled.



ICD Connector Styles



JS Market Re	elease		Mar	-03		NBG (Code		DD	DRP
Registered U	S Implants		11,C	000		Serial	Number Pref	ix/Xray ID	IJF	
Estimated Ac	tive US Imp	olants	9,0	000		Estima	ated Longevi	:y		yrs @ 2.5 V
Normal Batte	ery Depletio	ons		75						$\Omega \Omega$ impedance 0% pacing
Malfunctions				5 (2 related	d to advisory)				1
		Not Compr			l to advisory) l to advisory)					
Advisories								ory Circuit Se Pacing Syste		p Protocol
								0,		
ears After I	mplant	(Malfunction-	-free surviva			All-cause s			
1	mplant 1 yr	 2 yr	Malfunction-							
		1	1	-free surviva						
	lyr	2 yr	3 yr	-free surviva 4 yr	l 5 yr					
	1 yr 100	2 yr 100	3 yr 99.8	-free surviva 4 yr 99.1	l 5 yr 99.1					
	1 yr 100	2 yr 100	3 yr 99.8	-free surviva 4 yr 99.1	l 5 yr 99.1					
	1 yr 100	2 yr 100	3 yr 99.8	-free surviva 4 yr 99.1	l 5 yr 99.1					
	1 yr 100	2 yr 100	3 yr 99.8	-free surviva 4 yr 99.1	l 5 yr 99.1					

Elite 7074, 7075, 7076, 7077		Product Characteristics	
US Market Release	Apr-91	NBG Code	DDD/RO
Registered US Implants	48,000	Serial Number Prefix/Xray ID	YE, YF, 2E, 1X
Estimated Active US Implants	2,000	Estimated Longevity	11.4 yrs @ 2.5 V
Normal Battery Depletions	2,993		500 Ω impedance 100% pacing
Malfunctions	85		1 0
Advisories	None		

Years After Implant

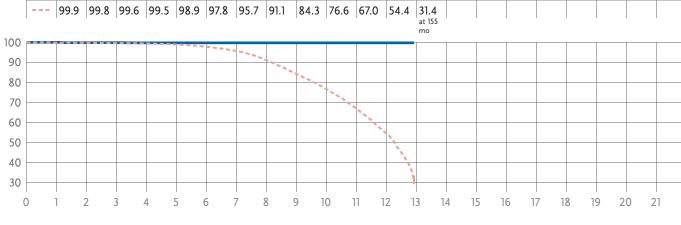
Malfunction-free survival



1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr					
 100	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8	99.8				
 99.9	99.8	99.6	99.5	98.9	97.8	95.7	91.1	84.3	76.6	67.0	54.4	31.4				
												at 155				



Device Survival Probability (%)



JS Market	Release		Dec-	92		NBG Code			DDD/RO	
Registered	US Implants	5	57,00	00		Serial Numb	oer Prefix/Xra	y ID	3U, 3V, 3Y	
Estimated	Active US In	nplants		4		Estimated L	ongevity		7.0 yrs @ 2.5 \	/
Normal Ba	ttery Deplet	ions	7,1	08					500 Ω impeda 100% pacing	ince
Malfunctio	ns			45					ieero paenig	
Advisories			No	ne						
ears Afte	r Implant		Malfunction-	free survival		All-0	cause surviva	al		
	1 yr	2 yr	3 yr	4 yr	5 yr	бyr	7 yr	8 yr		
	100	100	99.9	99.9	99.9	99.9	99.9	99.9	99.9 at 103 mo	
	99.9	99.8	99.1	96.1	90.5	82.5	69.9	47.1	15.3 at 103 mo	
	I	I	I	1	1	I	I	1	1 1	
							1.			
					1					
								1		

EnPulse DR EIDROI

US Market R	lelease		Dec-03		NBG C	ode		DDDR	
Registered L	JS Implants		7,000		Serial	Number Prefix/Xray	y ID	PRA	
Estimated A	ctive US Impla	ants	6,000		Estima	ted Longevity		7.5 yrs @ 2.5	
Normal Batt	ery Depletion:	s	0					500 Ω impeo 100% pacing	
Malfunction	s		0					iee, o pacing	2
		Not Compromise							
Advisories			None						
lears After	Implant	- Malfu	nction-free su	rvival		All-cause surviva			
	Implant	Malfu		rvival		All-cause surviva			
				rvival		All-cause surviva			
	1 yr			rvival		All-cause surviva			
/ears After	1 yr 100 100	100 at 20 mo		rvival		All-cause surviva			
/ears After	1 yr 100 100	100 at 20 mo		rvival		All-cause surviva			
/ears After	1 yr 100 100	100 at 20 mo		rvival		All-cause surviva			
/ears After	1 yr 100 100	100 at 20 mo		rvival		All-cause surviva			

Product Characteristics

Device Survival Probability (%)

Device Survival Probability (%)

US Market Release		Dec-03	NBG Code	DDDR
Registered US Implan	ts	2,000	Serial Number Prefix/Xray ID	PPT
Estimated Active US I	mplants	2,000	Estimated Longevity	5.4 yrs @ 2.5 V
Normal Battery Deple	tions	0		500 Ω impedance 100% pacing
Malfunctions		0		10070 pacing
Thorapy Funct	ion Not Compromis			
	unction Compromise	ed 0		
Therapy F		ed 0 None		
Therapy F Advisories Years After Implant	unction Compromise		All-cause survival	
Therapy F Advisories Years After Implant 1 yr 100	Malfu	None	All-cause survival	
Therapy F Advisories Years After Implant	unction Compromise	None	All-cause survival	
Therapy F Advisories 'ears After Implant 1 yr 100	Malfu	None	All-cause survival	
Therapy F Advisories Years After Implant 1 yr 100 100	Malfu	None	All-cause survival	

US Market Release		Feb-04	NBG (Code	DDDR
Registered US Implants	5	53,000	Serial	Number Prefix/Xray ID	PNB, PNC, PNH
Estimated Active US Im	nplants	50,000	Estima	ated Longevity	7.5 yrs @ 2.5 V
Normal Battery Deplet	ions	0			500 Ω impedance 100% pacing
Malfunctions		1			loovo pacing
TI 5	on Not Compromised	0			
	nction Compromised	1			
Therapy Fui Advisories	nction Compromised	1 None			
Therapy Fun Advisories Years After Implant	nction Compromised	1 None tion-free survival		All-cause survival	
Therapy Fur Advisories ears After Implant	nction Compromised			All-cause survival	
Therapy Fun Advisories ears After Implant	nction Compromised			All-cause survival	
Therapy Fun Advisories ears After Implant 1 yr 100 100	Malfunc			All-cause survival	
Therapy Fun Advisories Tears After Implant 1 yr 100	Malfunc			All-cause survival	

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US Market F	Release		Feb-04		NBG C	ode		DDDR	
Registered	US Implants	5	6,000		Serial	Number Prefix/Xray	/ ID	PMU	
Estimated A	Active US Im	nplants	5,000		Estima	ted Longevity		5.4 yrs @ 2.5	
Normal Bat	tery Depleti	ions	0					500 Ω impeo 100% pacing	
Malfunction	IS		0					ioo puella	2
		on Not Compromise nction Compromise							
Advisories			None						
	1 yr		None Inction-free	survival		All-cause survival			
Advisories		Malfu 100 at 15 mo 100 at 15 mo		e survival		All-cause survival			
Advisories Years After	1 yr 100 100	100 at 15 mo		e survival		All-cause survival			
Advisories Years After	1 yr 100 100	100 at 15 mo		e survival		All-cause survival			
Advisories Years After	1 yr 100 100	100 at 15 mo		e survival		All-cause survival			

EnPulse 2 DR	E2DR31

EnPulse 2 DR E2DR31							
JS Market Release	Fe	eb-04		NBG Code		DDDR	ł
Registered US Implants		200		Serial Number P	refix/Xray ID	PNL	
Estimated Active US Implants		200		Estimated Long	evity		s @ 2.5 V
Normal Battery Depletions		0				500 Ω 100%	impedance pacing
Malfunctions		0					p
Therapy Function Not Co Therapy Function Co		0 0					
Advisories Years After Implant		None on-free surviv	val	All-caus	e survival		
			ral	All-caus	e survival		
rears After Implant			ral	All-caus	e survival		
Years After Implant			ral	All-caus	e survival		
Years After Implant			val	All-caus	e survival		
Years After Implant			val	All-caus	e survival		
Years After Implant			ral	All-caus	e survival	9	

EnPulse	2 SR E2	SR01, E2SR03, E2S	SR06		Product	Characteristics	
US Market F	Release		Dec-03		NBG Cod	le	SSIR
Registered	US Implants		11,000		Serial Nu	mber Prefix/Xray ID	PMW, PMY, PNA
Estimated A	Active US Im	plants	10,000		Estimate	d Longevity	7.2 yrs @ 2.5 V
Normal Bat	tery Depleti	ons	0			ũ ,	500 Ω impedance 100% pacing
Malfunction	IS		0				100% pacing
		n Not Compromised					
Advisories			None				
Advisories Years After	Implant	Malfun	None	al	A	ll-cause survival	
		Malfun 100 at 19 mo		al	A	ll-cause survival	
	1 yr			al 	A	II-cause survival	
Years After	1 yr 100 100	100 at 19 mo		al 	A	Il-cause survival	
Years After	1 yr 100 100	100 at 19 mo		al	A	II-cause survival	
Years After	1 yr 100 100	100 at 19 mo		al 	A	II-cause survival	
Years After	1 yr 100 100	100 at 19 mo		al	A	Il-cause survival	9 10

US Market Release		Dec-03	NBG Code		VDD
Registered US Implants		300	Serial Number Pre	fix/Xray ID	PMV
Estimated Active US Impla	ants	200	Estimated Longev	ity	6.1 yrs @ 2.5 V
Normal Battery Depletion	s	0			500 Ω impedance 100% pacing
Malfunctions		0			
Therapy Function N		0			
Therapy Funct	ion Compromised	0			
Advisories		None			
		-	All-cause	survival	
Advisories ears After Implant		None	All-cause	survival	
Advisories ears After Implant 100 at 9 mo 100 at 9 mo		None	All-cause	survival	
Advisories ears After Implant 100 at 9 mo		None	All-cause	survival	

Device Survival Probability (%)

US Market Release	M	ay-05	NBG Code		DDDRP
Registered US Implants		5,000	Serial Number Pr	efix/Xray ID	PNP
Estimated Active US Implan	nts	5,000	Estimated Longe	vity	10.5 yrs @ 2.5 V
Normal Battery Depletions		0			500 Ω impedanc 100% pacing
Malfunctions		1			100% pacing
The second Free stices N	ot Compromised	1			
	on Compromised	0			
Therapy Function Advisories	on Compromised	None			
Therapy Function	on Compromised	-	All-cause	e survival	
Therapy Function Advisories Years After Implant	on Compromised	None	All-cause	e survival	
Therapy Function Advisories Years After Implant	on Compromised	None	All-cause	e survival	
Therapy Function Advisories Years After Implant	on Compromised	None	All-cause	e survival	

US Market	Release		Jan	-98		NBG Cod	de		DDD/RO	
Registered	US Implant	s	46,0	000		Serial Nu	umber Prefix/X	Xray ID	PER, PET	
Estimated /	Active US Ir	nplants	21,0	000			d Longevity	,	7.8 yrs @ 2.5 V	/
Normal Bat	tery Deplet	tions		547			0 ,		500 Ω impeda	
Malfunction	ns			19					100% pacing	
		on Not Compr Inction Compr		10 9						
Advisories			N	one						
	r Implant	2 yr		one -free surviva 4 yr	al 5 yr	A	ll-cause surv	vival		
Advisories Years After		1	Malfunction	-free surviva	1	1	1	vival 99.9 at 91 mo		
	1 yr	2 yr	Malfunction 3 yr	-free surviva	5 yr	6 yr	7 yr			
	1 yr 100	2 yr 100	Malfunction 3 yr 100	-free surviva 4 yr 100	5 yr 99.9	6 yr 99.9	7 yr 99.9	99.9 at 91 mo		
	1 yr 100	2 yr 100	Malfunction 3 yr 100	-free surviva 4 yr 100	5 yr 99.9	6 yr 99.9	7 yr 99.9 92.3	99.9 at 91 mo		
	1 yr 100	2 yr 100	Malfunction 3 yr 100	-free surviva 4 yr 100	5 yr 99.9	6 yr 99.9 97.8	7 yr 99.9 92.3	99.9 at 91 mo		

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US Market	Release		Feb	-98		NBG Cod	de		SSI/R	
Registered	US Implants	S	15,0	000		Serial Nu	umber Prefix/	Xray ID	PEU, PGD	
Estimated /	Active US In	nplants	7,0	000		Estimate	ed Longevity		7.9 yrs @ 2.5 V	
Normal Bat	tery Deplet	ions		48					500 Ω impedan 100% pacing	nce
Malfunction	15			4					ioo yo pacing	
The	rapy Functio	on Not Compre		3						
	Therapy Fu	nction Compre	omised	1						
	Therapy Fu	nction Compro		1 one						
Advisories	Implant	r	No Malfunction-	-free surviva	1	I	\ll-cause sur\	vival		
Advisories 'ears After		·	No		I 5 yr 100	А 6 yr 100	II-cause surv			
Advisories	r Implant	2 yr	No Malfunction- 3 yr	-free surviva	5 yr	6 yr	7 yr	Vival 100 at 89 mo 94.9 at 89 mo		
Advisories Tears After	1 yr 100	2 yr	No Malfunction- 3 yr 100	-free surviva 4 yr 100	5 yr 100	6 yr 100 98.8	7 yr 100 97.4	100 at 89 mo		
Advisories ′ears After	1 yr 100	2 yr	No Malfunction- 3 yr 100	-free surviva 4 yr 100	5 yr 100	6 yr 100 98.8	7 yr 100	100 at 89 mo		

JS Market	Release		Jan	-99		NBG Cod	le		DDD/RO
Registered	US Implant	s	23,0	000		Serial Nu	mber Prefix/Xray ID		PHF, PHH, PHG
Estimated	Active US Ir	nplants	13,0	000		Estimate	d Longevity		7.7 yrs @ 2.5 V
Normal Bat	ttery Deple	tions		76					500 Ω impedance 100% pacing
Malfunctio	ons			13 (8 related	l to advisory)				
The		on Not Comp Inction Comp			to advisory) I to advisory)				
Advisories				1 <u>see page</u>	<u>146 – 2002 Pot</u>	tential Fractu	ured Power Supply W	ires	
	er Implant	1	1	-free survival		A	ured Power Supply W II-cause survival	<mark>ires</mark>	
		2 yr 100	Malfunction 3 yr 100					ires	
	er Implant	2 yr	3 yr	-free survival	l 5 yr	A 6 yr	II-cause survival	ires	
ears Afte	er Implant 1 yr 100	2 yr 100	3 yr 100	-free survival 4 yr 99.9	5 yr 99.9	A 6 yr 99.9	Il-cause survival	ires	
ears Afte	er Implant 1 yr 100	2 yr 100	3 yr 100	-free survival 4 yr 99.9	5 yr 99.9	A 6 yr 99.9	Il-cause survival	ires	
ears Afte	er Implant 1 yr 100	2 yr 100	3 yr 100	-free survival 4 yr 99.9	5 yr 99.9	6 yr 99.9 98.0	Il-cause survival	ires	

S Market	Release		Ma	ır-01		NBG Code		DDD/	RO
egistered	US Implant	s	14,	000		Serial Number Prefix/X	Kray ID	PLJ, PI	_K
stimated	Active US Ir	nplants	9,	000		Estimated Longevity			@ 2.5 V
Iormal Bat	tery Deplet	tions		11					impedance pacing
lalfunctio	ns			3 (0 relate	d to advisory)				P
		on Not Comp Inction Comp			d to advisory) d to advisory)				
duite aut				1 see page	146 - 2002 Poter	ntial Fractured Power Su	pply Wires		
	r Implant		Malfunction			All-cause surv			
advisories ears After	r Implant	2 yr	3 yr	-free surviva					
		1	1	-free surviva					
ears After	1 yr 100	2 yr 100	3 yr 100	4 yr 100	100 at 52 mo				
ears After	1 yr 100	2 yr 100	3 yr 100	4 yr 100	100 at 52 mo				
ears After	1 yr 100	2 yr 100	3 yr 100	4 yr 100	100 at 52 mo				

Карра		-					naracteristic			
US Market	Release		Jan-99	Ð		NBG Code			DDD	
Registered	US Implant	S	300)		Serial Numb	er Prefix/Xra	ay ID	РНК	
Estimated	Active US In	mplants	200)		Estimated L	ongevity		7.7 yrs @ 2.	
Normal Bat	tery Deple	tions	2	2					500 Ω impe 100% pacir	
Malfunctio	15		(0 (0 related	d to advisory)				loo yo puch	'5
The		on Not Compromi Inction Compromi			d to advisory) d to advisory)					
	inci apy i t	anetion compronin								
Advisories -	.,				<u>146 – 2002 Pote</u>					
<mark>Advisories</mark> ′ears Afte	.,	- Mal					<mark>d Power Supp</mark> cause surviva			
	Implant	Mal	lfunction-fr	ee survival						
	Implant	Mal 2 yr 100	lfunction-fr 3 yr	ee surviva 4 yr						
′ears Afte	Implant 1 yr 100	Mal 2 yr 100	lfunction-fr 3 yr 100	ee surviva 4 yr 100	100 at 58 mo					
′ears Afte	Implant 1 yr 100	Mal 2 yr 100	lfunction-fr 3 yr 100	ee surviva 4 yr 100	100 at 58 mo					
′ears Afte	Implant 1 yr 100	Mal 2 yr 100	lfunction-fr 3 yr 100	ee surviva 4 yr 100	100 at 58 mo					

US Market	Release		Feb	-99		NBG Cod	e	DDD/RO
Registered	US Implant	s	182,	000		Serial Nu	mber Prefix/Xray ID	PGU, PGY, PGW
Estimated	Active US Ir	nplants	116,	000		Estimate	d Longevity	7.7 yrs @ 2.5 V
Normal Ba	ttery Deplet	tions		599				500 Ω impedance 100% pacing
Malfunctio	ns			123 (91 relate	ed to advisory)			10070 pading
The	rapy Function	on Not Compr			d to advisory)			
	Therapy Fu	Inction Compr	romised	106 (91 relate	ed to advisory)			
Advisories	.,	Inction Compr	romised		· ·	<mark>tential Fractu</mark>	red Power Supply Wire	s
	r Implant		Malfunction	1 <u>see page</u> -free surviva	<u>146 – 2002 Po</u>	A	<mark>ired Power Supply Wire</mark> Il-cause survival	s
<mark>Advisories</mark>	r Implant	2 yr	Malfunction	1 <u>see page</u> -free surviva 4 yr	146 – 2002 Po Il 5 yr	A 6 yr	II-cause survival	s
<mark>Advisories</mark>	r Implant		Malfunction	1 <u>see page</u> -free surviva	<u>146 – 2002 Po</u>	A		S
Advisories 'ears Afte	r Implant	2 yr 99.9	Malfunction 3 yr 99.9	1 <u>see page</u> -free surviva 4 yr 99.9	146 – 2002 Po Il 5 yr 99.9 98.5	A 6 yr 99.9 96.8	II-cause survival	S
Advisories 'ears Afte	r Implant	2 yr 99.9	Malfunction 3 yr 99.9	1 <u>see page</u> -free surviva 4 yr 99.9	146 – 2002 Po Il 5 yr 99.9 98.5	A 6 yr 99.9	II-cause survival	S

		Feb	o-99		NBG Cod	de	DDD/RO
JS Implant	S	10,	000		Serial Nu	umber Prefix/Xray ID	PGR
ctive US In	nplants	4,	000		Estimate	ed Longevity	5.5 yrs @ 2.5 V
ery Deplet	ions		224				500 Ω impedanc 100% pacing
S			5 (4 related	d to advisory)			
			1 see page	146 – 2002 Pot	ential Fract	ured Power Supply Wire	s
Implant 1 yr	2 yr	Malfunction 3 yr	-free surviva 4 yr	l 5 yr	A	All-cause survival	
100	100	100	100	99.9	99.9	99.9 at 73 mo	
99.9	99.7	99.0	96.8	91.4	74.9	71.8 at 73 mo	
				1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			
	ctive US Ir ery Deplet s apy Function Therapy Function Implant 1 yr 100	ctive US Implants ery Depletions s apy Function Not Comp Therapy Function Comp Implant 1 yr 2 yr 100 100	ctive US Implants 4, ery Depletions s apy Function Not Compromised Therapy Function Compromised Implant Malfunction 1 yr 2 yr 3 yr 100 100 100	ctive US Implants4,000ery Depletions224s5 (4 relatedapy Function Not Compromised Therapy Function Compromised1 (0 related1 see page1 see pageImplantMalfunction-free surviva1 yr2 yr3 yr10010010099.999.799.096.8	ctive US Implants4,000ery Depletions224s5 (4 related to advisory)apy Function Not Compromised Therapy Function Compromised1 (0 related to advisory)4 (4 related to advisory)1 see page 146 - 2002 PotImplantMalfunction-free survival1 yr2 yr3 yr4 yr10010010010099.999.799.096.891.4	ctive US Implants4,000Estimateery Depletions224s5 (4 related to advisory)apy Function Not Compromised1 (0 related to advisory)4 (4 related to advisory)4 (4 related to advisory)1 see page 146 - 2002 Potential FractImplantMalfunction-free survival1 yr2 yr3 yr4 yr10010010010099.999.799.096.891.474.9	ctive US Implants 4,000 Estimated Longevity ery Depletions 224 s 5 (4 related to advisory) apy Function Not Compromised 1 (0 related to advisory) 1 (0 related to advisory) 1 see page 146 - 2002 Potential Fractured Power Supply Wire Implant Malfunction-free survival 1 yr 2 yr 100 100 100 100 99.9 99.7 99.0 96.8

JS Market	Release		Feb	-99		NBG Cod	le	SSI/R
Registered	US Implant	S	50,0	000		Serial Nu	mber Prefix/Xray ID	PHT, PHW, PHU
Stimated	Active US Ir	mplants	26,0	000		Estimate	d Longevity	7.4 yrs @ 2.5 V
Normal Bat	tery Deple	tions		201				500 Ω impedance 100% pacing
Malfunctio	ns			5				ie e vo pacing
		on Not Comp Inction Comp		1 4				
Advisories			N	one				
	r Implant	2 yr	Malfunction		al 5 yr	A	ll-cause survival	
		I	Malfunction	-free surviva	- I	1	II-cause survival	
	1 yr	2 yr	Malfunction 3 yr	-free surviva 4 yr	5 yr	6 yr		
ears After	1 yr 100	2 yr 100	Malfunction 3 yr 100	-free surviva 4 yr 100	5 yr 100 98.0	6 yr 100 96.3	100 at 78 mo	
ears After	1 yr 100	2 yr 100	Malfunction 3 yr 100	-free surviva 4 yr 100	5 yr 100	6 yr 100 96.3	100 at 78 mo	
ears After	1 yr 100	2 yr 100	Malfunction 3 yr 100	-free surviva 4 yr 100	5 yr 100 98.0	6 yr 100 96.3	100 at 78 mo	

JS Market Rel	ease		Ja	n-99		NBG Code		VDD/	′RO
Registered US	Implants		2	,000		Serial Number Pre	fix/Xray ID	PHP	
Estimated Act	ive US Imp	olants	1	,000		Estimated Longev	ity		s @ 2.5 V
Normal Batter	y Depletio	ons		7					2 impedance pacing
Malfunctions				2 (2 related	d to advisory)				1 0
		Not Comp ction Comp			d to advisory) d to advisory)				
					146 0000 0		C 1 187		
Advisories						ential Fractured Powe	er Supply Wire	S	
ears After In	nplant yr	2 yr	Malfunction	n-free surviva		All-cause		s	
ears After In			1	n-free surviva	.1			s	
ears After In 1 9	yr	2 yr	3 yr	n-free surviva	ll 5 yr	All-cause		S	
ears After In 1 9	yr 99.9	2 yr 99.9	3 yr 99.9	n-free surviva 4 yr 99.8	l 5 yr 99.8	All-cause		S	
ears After In 1 9	yr 99.9	2 yr 99.9	3 yr 99.9	n-free surviva 4 yr 99.8	l 5 yr 99.8	All-cause		S	
ears After In 1 9	yr 99.9	2 yr 99.9	3 yr 99.9	n-free surviva 4 yr 99.8	l 5 yr 99.8	All-cause		S	

Jormal Battery Depletions2500 Ω impedance 100% pacingMalfunctions0Therapy Function Not Compromised Therapy Function Compromised 00AdvisoriesNone	JS Market Release		Jan	-02	NBG Code	DDD/RO
Normal Battery Depletions 2 Malfunctions 0 Therapy Function Not Compromised 0 Therapy Function Compromised 0 Advisories None ears After Implant Malfunction-free survival 1 yr 2 yr 100 100 100 100	Registered US Implar	ts	4,0	000	Serial Number Prefix/Xray	ID PKW, PKY
Normal Battery Depictions 2 Malfunctions 0 Therapy Function Not Compromised 0 Therapy Function Compromised 0 Advisories None Pears After Implant Malfunction-free survival 1 yr 2 yr 3 yr Image: Comparison of the survival 100 100 100 100 at 37 mo	Estimated Active US	mplants	3,0	000	Estimated Longevity	
Malfunctions 0 Therapy Function Not Compromised 0 Therapy Function Compromised 0 Advisories None Pears After Implant Malfunction-free survival 1 yr 2 yr 3 yr All-cause survival 1 00 100 100 at 37 mo	Normal Battery Deple	etions		2		
Therapy Function Compromised 0 Advisories None ears After Implant Malfunction-free survival 1 yr 2 yr 3 yr 100 100 100 at 37 mo	Malfunctions			0		
Pears After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 100 100 100 at 37 mo						
1 yr 2 yr 3 yr 100 100 100 at 37 mo						
100 99.9 99.8 99.8 at 37 mo		2 yr	Malfunction 3 yr	-free survival	All-cause survival	
	ears After Implant	2 yr 100	Malfunction 3 yr 100	-free survival	All-cause survival	
	ears After Implant	2 yr 100	Malfunction 3 yr 100	-free survival	All-cause survival	
	ears After Implant	2 yr 100	Malfunction 3 yr 100	-free survival	All-cause survival	
	ears After Implant	2 yr 100	Malfunction 3 yr 100	-free survival	All-cause survival	

JS Market	Release		Jan	-02	NBG Cod	e	DDD/RO
Registered	US Implant	s	108,C	000	Serial Nu	mber Prefix/Xray ID	PKM, PKN, PKP
Estimated	Active US Ir	mplants	87,0	000	Estimate	d Longevity	7.7 yrs @ 2.5 V
Normal Bat	tery Deple	tions		17			500 Ω impedance 100% pacing
Malfunctio	ns			6			
The		on Not Compr Inction Compr		4 2			
				one	A		
		2 yr		one -free survival	A	ll-cause survival	
Advisories ears Afte	r Implant	1	Malfunction-		A	II-cause survival	
	r Implant	2 yr	Malfunction-	-free survival	A	II-cause survival	
ears Afte	r Implant 1 yr 100	2 yr 100	Malfunction- 3 yr 100	-free survival	A	II-cause survival	
ears Afte	r Implant 1 yr 100	2 yr 100	Malfunction- 3 yr 100	-free survival	A	II-cause survival	
ears After	r Implant 1 yr 100	2 yr 100	Malfunction- 3 yr 100	-free survival	A	II-cause survival	

S Market	Release		Jan	-02	NBG Co	ode	SSI/R
egistered	US Implant	S	29,0	000	Serial N	lumber Prefix/Xray ID	PLF, PLG, PLH
stimated	Active US Ir	nplants	20,0	000	Estimat	ed Longevity	7.3 yrs @ 2.5 V
lormal Bat	ttery Deple	tions		6			500 Ω impedance 100% pacing
lalfunctio	ns			3			10070 pacing
The		on Not Comp Inction Comp		3 0			
	r Implant			one -free survival	,	All-cause survival	
Advisories ears Afte	r Implant	2 yr	Malfunction 3 yr	-free survival	,	All-cause survival	
		I.	Malfunction		,	All-cause survival	
ears Afte	1 yr 100	2 yr 100	Malfunction- 3 yr 100	-free survival	, 	All-cause survival	
ars Afte	1 yr 100	2 yr 100	Malfunction- 3 yr 100	-free survival	,	All-cause survival	
ears Afte	1 yr 100	2 yr 100	Malfunction- 3 yr 100	-free survival		All-cause survival	

Kappa 900 VE			Product Chara			
US Market Release		Jan-02	NBG Code		VDD	
Registered US Impla	nts	1,000	Serial Number F	Prefix/Xray ID	PLE	
Estimated Active US	Implants	500	Estimated Long	evity	6.3 yrs @ 2.5	
Normal Battery Dep	etions	0			500 Ω impeda 100% pacing	
Malfunctions		0			ieevo pacing	
	tion Not Compro Function Compro					
Advisories (ears After Implan	N	None Malfunction-free survival	All-caus	e survival		
Advisories Years After Implan	2 yr	None Malfunction-free survival 100 at 35 mo	All-caus	e survival		
Years After Implan	2 yr	Malfunction-free survival	All-caus	se survival		
/ears After Implan 1 yr 100	2 yr 100	Malfunction-free survival	All-caus	se survival		
/ears After Implan 1 yr 100 100	2 yr 100	Malfunction-free survival	All-caus	e survival		
/ears After Implan 1 yr 100 100	2 yr 100	Malfunction-free survival	All-caus	se survival		
/ears After Implan 1 yr 100 100	2 yr 100	Malfunction-free survival	All-caus	e survival		

JS Market I	Release		Jan	-02	NBG Code		DDD/	/RO
Registered	US Implant	s	15,0	000	Serial Number	Prefix/Xray ID	PKR	
Estimated A	Active US Ir	nplants	11,0	000	Estimated Lor	gevity		s @ 2.5 V
Normal Bat	tery Deplet	ions		8				2 impedance pacing
Malfunctior	ns			1				P
		on Not Comp nction Comp		0 1				
Advisories ears After	r Implant			one -free survival	All-ca	use survival		
	1 yr	2 yr	Malfunction 3 yr	-free survival	All-ca	use survival		
	1 yr 100	2 yr 100	Malfunction 3 yr 100	-free survival	All-ca	use survival		
Advisories ears After	1 yr	2 yr	Malfunction 3 yr	-free survival	All-ca	use survival		
ears After	1 yr 100	2 yr 100	Malfunction 3 yr 100	-free survival	All-ca	use survival		
ears After	1 yr 100	2 yr 100	Malfunction 3 yr 100	-free survival	All-ca	use survival		
ears After	1 yr 100	2 yr 100	Malfunction 3 yr 100	-free survival	All-ca	use survival		

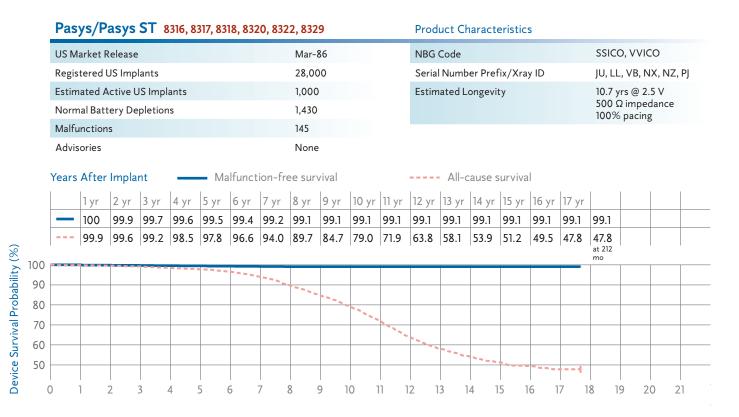
03 1018	arket R	elease				Aug-89					NBG	Code				SSIR	С	
Regis	tered l	JS Impl	ants			57,000					Serial	Numb	er Pref	ix/Xra	/ ID	ХΤ, ν	vj, wn	, ZT
Estim	ated A	ctive U	IS Impl	ants		4,000					Estim	ated Lo	ongevit	y			rs @ 2.	
Norm	al Batt	ery De	pletion	IS		2,441											Ω impe 5 pacin	
Malfu	nction	s				145										10070	puem	5
Advis	ories					None												
	1 yr	Impla 2 yr	3 yr	4 yr	6 yr				10 yr	11 yr 99.6								
	99.9 99.9	99.9 99.7	99.8 99.4		 99.7 97.2		99.6 90.7						64.3		99.6 58.8			
					 				81.4						99.6 58.8 at 187 mo			
					 97.2	94.7	90.7	86.0							58.8 at 187			
					 97.2		90.7	86.0							58.8 at 187			
					 97.2	94.7	90.7	86.0	81.4	76.9	73.1	69.1		60.8	58.8 at 187			

US Market	Release					Nov-91					NBG	Code				SSI	20		
Registered	l US Impl	ants				58,000					Serial	Numb	er Pref	ix/Xra	y ID	2P, 3	2T, 2L	J	
Estimated	Active U	S Impla	ants			8,000					Estim	ated Lo	ongevi	ty				2.5 V	
Normal Ba	ttery De	oletion	s			1,424											Ωim % pao	pedar cing	ice
Malfunctio	ons					37													
Advisories						None													
Years Afte	2 yr	nt 3 yr 100		1	1	7 yr	e surv 8 yr 99.9	9 yr	10 yr 99.9	11 yr 99.9	12 yr 99.9	1	ause s	urviva					
1 yr 100 99.9	2 yr 100 99.8	3 yr 100	99.9	5 yr	6 yr 99.9	7 yr 99.9	8 yr	9 yr 99.9	99.9	11 yr	12 yr	13 yr 99.9		urviva					
1 yr	2 yr 100 99.8	3 yr 100	99.9	5 yr 99.9	6 yr 99.9	7 yr 99.9 97.3	8 yr 99.9 94.9	9 yr 99.9 92.0	99.9 89.4	11 yr 99.9 86.1	12 yr 99.9 83.8	13 yr 99.9 81.0	99.9 78.3 at 163	urviva					
1 yr 100 99.9	2 yr 100 99.8	3 yr 100	99.9	5 yr 99.9	6 yr 99.9	7 yr 99.9 97.3	8 yr 99.9	9 yr 99.9 92.0	99.9 89.4	11 yr 99.9	12 yr 99.9 83.8	13 yr 99.9 81.0	99.9 78.3 at 163	urviva					

J2 M	arket R	elease					Oct-90)				NBG	Code					SSI	со	
Regis	tered L	JS Impl	ants				7,000)				Serial	Numb	er Pref	ix/Xra	y ID		ZU		
Estim	ated A	ctive U	S Impl	ants			400)				Estim	ated L	ongevit	y				yrs @	
Norm	al Batt	ery De	pletion	IS			255	5) Ω im % pac	ce
Malfu	nctions	5					2	2												
Advis	ories						١	l see p	age 159	9 – 1991	Poten	tial Del	ayed R	estorat	ion of	Perma	nent S	etting	s	
	After	2 yr	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100	8 yr 100	9 yr 100	10 yr 100	11 yr 100	12 yr 100	13 yr 100	100					_	
_	100 99.9	100 99.8			98.0	94.5	86.7	80.1	75.5	72.6	70.2	70.2	69.0	67.7						
		99.8			98.0	94.5	86.7	80.1	75.5	72.6	70.2	70.2	69.0	67.7 at 167 mo						
					98.0	1	86.7	80.1	75.5	72.6	70.2	70.2	69.0	at 167						
					'						70.2	70.2	69.0	at 167						
					'					72.6	70.2	70.2	69.0	at 167						

03 101	arket R	elease					Dec-89)				NBG	Code					SSIR	0		
Regis	tered l	JS Impl	ants				58,000)				Seria	l Numb	er Pref	ix/Xra	y ID		2P, 2	T, 2U		
Estim	ated A	ctive U	S Impl	ants			6,000)				Estim	ated L	ongevit	y				rs @ 2		
Norm	nal Batt	ery De	pletion	s			1,37	I											2 impe 5 pacir	edance Ig	
Malfu	inction	s					49)												0	
Advis	ories						1	l <u>see p</u>	age 159	9 - 1991	Poten	tial Del	ayed R	estorat	ion of I	Permar	ient Se	ttings			
ears	After	Impla	nt		Ma	lfunct	ion-fre	ee sur	vival				All-c	ause s	urviva						
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr					
	1 yr 100	2 yr 99.9	3 yr 99.9	4 yr 99.9	-	6 yr 99.9	7 yr 99.9		9 yr 99.9		11 yr 99.9	12 yr 99.9	/	14 yr 99.9	15 yr 99.9	16 yr 99.9	99.9				
	/	99.9	99.9		99.9	99.9		99.9		99.9		99.9	/	99.9	99.9						
	100	99.9	99.9	99.9	99.9	99.9 97.7	99.9 95.2	99.9 91.9	99.9 89.2	99.9 87.1	99.9 85.4	99.9 83.7	99.9 82.0	99.9	99.9	99.9	78.2 at 196				
	100	99.9	99.9	99.9	99.9	99.9 97.7	99.9	99.9 91.9	99.9 89.2	99.9	99.9 85.4	99.9 83.7	99.9 82.0	99.9	99.9	99.9	78.2 at 196				

Min	uet	7107, 7	'108									Prod	uct Ch	aracte	eristic	5				
US M	larket R	lelease				J	Mar-92					NBG	Code				DD	DCO		
Regis	stered l	JS Imp	ants				17,000)				Serial	Numb	er Pref	ix/Xra	/ ID	1Z1	, 2G1		
Estim	nated A	ctive U	IS Impl	ants			3,000)				Estim	ated Lo	ongevit	y				9 2.5 V	
Norm	nal Batt	ery De:	pletion	IS			470)) Ω in)% pa	ipedar cing	ice
Malfu	unction	s					4	,									100	//o pu	cing	
Advis	sories						None	2												
	After	2 yr	3 yr	4 yr	1	бyr		8 yr	9 yr		-	12 yr	1	ause s						
	100	100	100	100	100	100	100	100	100	100	100	100	100	100						
	100 100	100 100	100 99.8	100 99.5	100 98.9	100 98.2	100 96.9	100 94.7	100 92.1	100 89.3	100 85.5	100 82.8	100 78.7	78.0						
						98.2	96.9	94.7	92.1											
						98.2	96.9	94.7	92.1	89.3	85.5	82.8		78.0 at 159						
						98.2		94.7	92.1	89.3	85.5	82.8		78.0 at 159						
						98.2	96.9	94.7	92.1		85.5	82.8		78.0 at 159						



	7068					Product	Characteris	tics		
US Market	Release		Nov	-96		NBG Cod	le		DDDCO	
Registered	d US Implant	s	1,0	000		Serial Nu	mber Prefix/2	Xray ID	PIE	
Estimated	Active US In	nplants	:	300		Estimate	d Longevity		9.8 yrs @ 2.	
Normal Bar	ttery Deplet	tions		9					500 Ω impe 100% pacin	
Malfunctio	ons			1						5
Advisories			N	one						
	er Implant		Malfunction	nee surviva		A	ll-cause surv	11001		
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr			
		1	1	1	I	1	1	99.9 at 91 mo 94.4 at 91 mo		
	1 yr	2 yr 99.9	3 yr 99.9	4 yr 99.9	5 yr 99.9 98.7	6 yr 99.9 97.7	7 yr 99.9 95.5	99.9 at 91 mo		
	1 yr	2 yr 99.9	3 yr 99.9	4 yr 99.9	5 yr 99.9 98.7	6 yr 99.9	7 yr 99.9 95.5	99.9 at 91 mo		
	1 yr	2 yr 99.9	3 yr 99.9	4 yr 99.9	5 yr 99.9 98.7	6 yr 99.9 97.7	7 yr 99.9 95.5	99.9 at 91 mo		

US Market ReleaseJul-96NBG CodeDDD/RORegistered US Implants25,000Serial Number Prefix/Xray IDPGJ, PGKEstimated Active US Implants10,000Estimated Longevity9.7 yrs @ 2.5 V 500 Ω impedar 100% pacingNormal Battery Depletions2863Malfunctions3 All-cause survival	Serial Number Prefix/Xray ID PGJ, PGK Estimated Longevity 9.7 yrs @ 2.5 V 500 Ω impedance 100% pacing All-cause survival 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 at 109 mo	gistered US Implants 25,000 imated Active US Implants 10,000 rmal Battery Depletions 286 Iffunctions 3 visories None rs After Implant — Malfunction-free survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 100 100 100 100		1									`
Estimated Active US Implants10,000Estimated Longevity9.7 yrs @ 2.5 VNormal Battery Depletions286500 Ω impedarMalfunctions3AdvisoriesNone	Estimated Longevity 9.7 yrs @ 2.5 V 500 Ω impedance 100% pacing All-cause survival 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 at 109 mo	imated Active US Implants 10,000 rmal Battery Depletions 286 Ifunctions 3 visories None rs After Implant Malfunction-free survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 100 100 100 100	US Market Re	elease		Ju	1-96		NBG Cod	le		DDD/RO)
Normal Battery Depletions286500 Ω impedarMalfunctions3AdvisoriesNone	500 Ω impedance 100% pacing 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 at 109 mo	strmal Battery Depletions 286 Ifunctions 3 visories None rs After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 100 at 109 mo 100 99.9 99.8 99.6 99.1 98.3 97.0 94.2 89.7 88.0 at 109 mo	Registered US	S Implants		25,	000		Serial Nu	mber Prefix/	Xray ID	PGJ, PGK	C
Normal Battery Depletions 286 100% pacing Malfunctions 3 Advisories None	100% pacing All-cause survival 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 at 109 mo	Ifunctions 286 100% pacing Ifunctions 3 visories None rs After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 100 at 109 mo 100 99.9 99.8 99.6 99.1 98.3 97.0 94.2 89.7 88.0 at 109 mo	Estimated Ac	tive US Im	plants	10,	000		Estimate	d Longevity			
Malfunctions 3 Advisories None	All-cause survival 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 100 at 109 mo	Ifunctions 3 visories None rs After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 100 100 at 109 mo 100 99.9 99.8 99.6 99.1 98.3 97.0 94.2 89.7 88.0 at 109 mo	Normal Batte	ery Depletio	ons		286						
	5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 100 at 109 mo	rs After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 100 100 at 109 mo 100 99.9 99.8 99.6 99.1 98.3 97.0 94.2 89.7 88.0 at 109 mo	Malfunctions				3					10070 pu	
Gears After Implant — Malfunction-free survival All-cause survival	5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 at 109 mo	1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 100 100 100 100 100 100 100 100 at 109 mo 100 99.9 99.8 99.6 99.1 98.3 97.0 94.2 89.7 88.0 at 109 mo	Advisories			N	one						
	39.1 98.3 97.0 94.2 89.7 88.0 at 109 m			1 C C C C C C C C C C C C C C C C C C C									
	51.0 51.0 51.0 51.0 51.0			l yr									100
				1 yr 100	100	100	100	100	100	100	100 94.2	100 89.7	
				1 yr 100	100	100	100	100	100	100	100 94.2	100 89.7	

JS Market	Release		Jul	I-96		NBG Cod	le		SSI/R	
Registered	US Implant	s	18,0	000		Serial Nu	mber Prefix/	Xray ID	PGL, PGN	Λ
Estimated	Active US Ir	nplants	5,0	000		Estimate	d Longevity		9.6 yrs @	
Normal Bat	ttery Deplet	tions		157					500 Ω im 100% pao	
Malfunctio	ns			1					10070 put	
Advisories			N	one						
ears Afte	r Implant		Malfunction	-free surviva	al	A	ll-cause surv	vival		
ears Afte	r Implant 1 yr 100	2 yr 100	Malfunction 3 yr 100	-free surviva 4 yr 100	al 5 yr 100	A 6 yr 100	Il-cause surv 7 yr 100	vival 8 yr 100	9 yr 100	
ears Afte	l yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr		
	1 yr 100	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100	8 yr 100	100	
	1 yr 100	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100	8 yr 100 94.5	100 90.6	
	1 yr 100	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100 95.9	8 yr 100 94.5	100 90.6	

US Market	Release		Nov	-96		NBG Cod	le		DDD/RO
Registered	US Implant	s	1,0	000		Serial Nu	mber Prefix/2	Xray ID	PIF
Estimated	Active US Ir	nplants	3	300		Estimate	d Longevity		9.7 yrs @ 2.5 V
Normal Bat	tery Deplet	tions		9					500 Ω impedance 100% pacing
Malfunctio	ns			0					loovo pacing
Advisories Years Afte	r Implant			one -free surviva	ıl	A	I-cause surv	vival	
Advisories Years Afte	r Implant	2 yr	Nalfunction 3 yr		ıl 5 yr	A	ll-cause surv	vival	
		1	Malfunction	-free surviva	I.	1	1	/ival	
	1 yr	2 yr	Malfunction 3 yr	-free surviva	5 yr	6 yr	7 yr		
Years Afte	1 yr 100	2 yr 100	Malfunction- 3 yr 100	-free surviva 4 yr 100	5 yr 100 99.0	6 yr 100 98.1	7 yr 100 96.4	100 at 93 mo 95.4 at 93 mo	
Years Afte	1 yr 100	2 yr 100	Malfunction- 3 yr 100	-free surviva 4 yr 100	5 yr 100 99.0	6 yr 100 98.1	7 yr 100	100 at 93 mo 95.4 at 93 mo	

US Market	Release		Oct	t-95		NBG Cod	de		SSI	
Registered	l US Implant	:s	4,0	000		Serial Nu	umber Prefix/	Xray ID	PGL, PGM	
Estimated	Active US Ir	mplants	1,0	000		Estimate	ed Longevity		9.6 yrs @ 2.5 \	
Normal Ba	ttery Deple	tions		10					500 Ω impeda 100% pacing	ince
Malfunctio	ons			1					10070 Pacing	
Advisories	visories			one			. 11	· 1		
		2 yr	Nalfunction 3 yr		al 5 yr	A	All-cause surv	vival 8 yr		
	r Implant	2 yr 100	Malfunction	-free surviva	1	1	1		99.9 at 105 mo	
	r Implant		Malfunction 3 yr	-free surviva	5 yr	6 yr	7 yr	8 yr	99.9 at 105 mo 97.4 at 105 mo	
ears Afte	r Implant 1 yr 100	100	Malfunction 3 yr 100	-free surviva 4 yr 100	5 yr 99.9	6 yr 99.9	7 yr 99.9	8 yr 99.9		
ears Afte	r Implant 1 yr 100	100	Malfunction 3 yr 100	-free surviva 4 yr 100	5 yr 99.9	6 yr 99.9	7 yr 99.9	8 yr 99.9		

	US Market	Release		Oct	-95		NBG Cod	de		DDDCO	
Normal Battery Depletions 33 Malfunctions 0 Advisories None Years After Implant Malfunction-free survival	Registered	US Implants	5	3,(000		Serial Nu	mber Prefix/	Xray ID	PDL, PDM, PDN	
Malfunctions 0 Advisories None Years After Implant Malfunction-free survival	Estimated	Active US In	iplants				Estimate	ed Longevity		9.7 yrs @ 2.5 V	
Malfunctions 0 Advisories None Years After Implant Malfunction-free survival	Normal Bat	tery Deplet:	ions		33						
Years After Implant — Malfunction-free survival All-cause survival	Malfunctio	ns			0					leeve pacing	>
	Advisories			N	one						
			1	1	1		I		1	9 yr	
<u> </u>											
99.9 99.7 99.5 98.9 98.7 97.8 97.3 96.0 92.9		100	100	100	100	100	100	100	100	100	
											-
									96.0	92.9	

	Release		Oct	-95		NBG Cod	le		DDD/RO	
Registered	US Implants	i		000			mber Prefix/	Xray ID	PDH, PDJ	, PDK
-	Active US Im		14,0	000		Estimate	d Longevity	,	9.7 yrs @	
Normal Bat	tery Depleti	ions		403					500 Ω im 100% pa	
Malfunction	ıs			10					10070 pa	ung
Advisories			N	one						
Years After	1 yr	2 yr	Malfunction 3 yr	4 yr	5 yr	6 yr	II-cause surv	8 yr	9 yr	
	100	100	100	100	100	100	100	100	100	100 at 112 r
	99.9	99.9	99.8	99.6	99.1	98.4	97.0	94.1	90.8	89.7 at 112

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US Marke	t Release		Oct	-95		NBG Cod	le		SSIC	
Registere	d US Implants	S	2,0	000		Serial Nu	mber Prefix/2	Xray ID	PEG, PEH, PEJ	J
Estimate	d Active US In	nplants	1,0	000		Estimate	d Longevity		9.8 yrs @ 2.5	
Normal E	attery Deplet	ions		11				500 Ω impeda 100% pacing	anc	
Malfunct	ons			0						
Advisorie	s		N	one						
Voors Af	or Implant		None Malfunction-free survival							
Years Af	er Implant 1 yr 100	2 yr	3 yr	4 yr	5 yr	6 yr	II-cause surv 7 yr 100	8 yr	100 at 106 mo	
Years Af			1	1	l.	1	1	1	100 at 106 mo 96.1 at 106 mo	
	1 yr	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100	8 yr 100 97.1	96.1 at 106 mo	
)	1 yr	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100	8 yr 100 97.1	96.1 at 106 mo	
	1 yr	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100 98.8	8 yr 100 97.1	96.1 at 106 mo	

Estimated Active US Implants7,000Estimated Longevity9.6 yrs (500 Q in 100% prNormal Battery Depletions189500 Q in 100% prMalfunctions5AdvisoriesNone	Estimated Longevity 9.6 yrs @ 2.5 V 500 Ω impedance 100% pacing All-cause survival 6 yr 7 yr 8 yr 9 yr 100 100 100 100 at 110 me	US Market	Release	IS Implants 22,000 ctive US Implants 7,000 ery Depletions 189 s 5 None Implant Malfunction-free survival 1 yr 2 yr 3 yr 4 yr 100 100 100 100		NBG Cod	de		SSI/R			
Normal Battery Depletions189Malfunctions5AdvisoriesNone	500 Ω impedance 100% pacing All-cause survival 6 yr 7 yr 8 yr 9 yr 100 100 100 100 at 110 mm	Registered	US Implant	S	22,0	000		Serial Nu	mber Prefix/	Xray ID	PEM, PEI	D, PEE, PEF
Normal Battery Depletions 189 100% p. Malfunctions 5 Advisories None	IO0% pacing All-cause survival 6 yr 7 yr 8 yr 9 yr IO0 IO0 IO0 IO0 at 110 m	Estimated	Active US Ir	nplants	7,0	000		Estimate	d Longevity			
Malfunctions5AdvisoriesNone	All-cause survival 6 yr 7 yr 8 yr 9 yr 100 100 100 100 at 110 m	Normal Bat	· · · · · · · · · · · · · · · · · · ·		189							
	6 yr 7 yr 8 yr 9 yr 100 100 100 100 at 110 m	Malfunctio	ns			5					10070 pu	
Years After Implant — Malfunction-free survival All-cause survival	6 yr 7 yr 8 yr 9 yr 100 100 100 100 at 110 m	Advisories			N	one						
lyr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr		Years Afte	isories		Malfunction	-free surviva		A		vival		
		Years Afte	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr		
99.9 99.7 99.5 99.1 98.6 97.8 96.7 95.0 92.5	97.8 96.7 95.0 92.5 91.2 at 110 r	Years Afte	1 yr	2 yr	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr	8 yr	100	100 at 110 n
			1 yr 100	2 yr 100	3 yr	4 yr	5 yr	6 yr	7 yr 100	8 yr 100 95.0		100 at 110 mc 91.2 at 110 mc
			1 yr 100	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100	8 yr 100 95.0	100	
			1 yr 100	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100	8 yr 100 95.0	100	

G, PJH 9 yrs @ 2.5 V 10 Ω impedance 0% pacing
$0^{\circ} \Omega$ impedance
I

IS Market	Release		Aug	<u>;</u> -99		NBG Code		DDD/RO
egistered	US Implant	s	15,0	000		Serial Number Pref	ix/Xray ID	PJD
stimated A	Active US Ir	nplants	10,0	000		Estimated Longevi	y	9.9 yrs @ 2.5 V
Iormal Bat	tery Deplet	tions		10				500 Ω impedance 100% pacing
Alfunction	ıs			3 (0 relate	d to advisory)			
					d to advisory) d to advisory)			
dvisories	Therapy Function Not Compromise Therapy Function Compromise cories			2 see page	141 – 2005 Po	otential Separation of In	terconnect W	ires
avisories				and page	<mark>e 152</mark> – 1999 Ma	anufacturing Issue		
	r Implant	_	Malfunction	<mark>and page</mark> -free surviva		anufacturing Issue	urvival	
	r Implant	2 yr	Malfunction 3 yr			U	urvival	
		1	1	-free surviva	1	U	urvival	
	l yr	2 yr	3 yr	-free surviva	ll 5 yr	All-cause s	urvival	
ars After	1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	11 5 yr 100	All-cause s	urvival	
ars After	1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	11 5 yr 100	All-cause s	urvival	
ars After	1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	11 5 yr 100	All-cause s	urvival	

JS Market	Release		Sep	-99		NBG Code		SSI/	R
Registered	US Implant	s		000		Serial Number Pre	fix/Xray ID	PJG	
Estimated	Active US Ir	nplants	6,0	000		Estimated Longev	ity		rs @ 2.5 V
Normal Bat	tery Deplet	tions		8					Ω impedance % pacing
Malfunctio	ns			0 (0 related	d to advisory)				8
	herapy Function Not Compromised Therapy Function Compromised			d to advisory) d to advisory)					
Advisories						ential Separation of Ir	<mark>iterconn</mark> ect W	'ires	
				and page	<u> 152</u> – 1999 Mar	nufacturing Issue			
ears Afte		1	1	-free surviva	.1	All-cause	survival	I	1
	1 yr	2 yr	3 yr	-free surviva	ll 5 yr	All-cause	survival		
		1	1	-free surviva	.1	-	survival		
ears Afte	1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	l 5 yr 100	All-cause	survival		
ears Afte	1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	l 5 yr 100	All-cause	survival		
ears Afte	1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	l 5 yr 100	All-cause	survival		

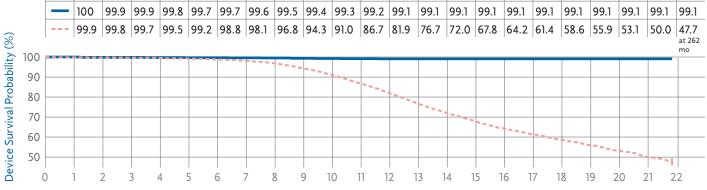
JS Market	Release		Aug	g-99		NBG Code		DDD/	RO
Registered	US Implant	s	91,	,000		Serial Number Pref	ix/Xray ID	PJD, PJ	E
Estimated	Active US Ir	nplants	62,	,000		Estimated Longevi	y		s@ 2.5 V
Normal Bat	tery Deplet	tions		42					impedance pacing
Malfunction	ns			28 (10 relate	ed to advisory)				F 0
		on Not Compr Inction Compr			d to advisory) ed to advisory)				
				•	141 2005 0 1			inee	
Advisories						tential Separation of In nufacturing Issue	terconnect w	ires	
Advisories ears Aftei	r Implant		Malfunctior		<mark>e 152</mark> – 1999 Ma			ires	
	r Implant	2 yr	Malfunctior 3 yr	and page	<mark>e 152</mark> – 1999 Ma	nufacturing Issue			
		1	1	and page	<mark>: 152 – 1999 Ma</mark>	nufacturing Issue			
	1 yr	2 yr	3 yr	and page n-free surviva 4 yr	<mark>: 152 – 1999 Ma</mark> Il 5 yr	nufacturing Issue All-cause s			
ears After	1 yr 100	2 yr 100	3 yr 100	and page n-free surviva 4 yr 99.9	152 – 1999 Ma Il 5 yr 99.9	nufacturing Issue All-cause s 99.9 at 71 mo			
ears After	1 yr 100	2 yr 100	3 yr 100	and page n-free surviva 4 yr 99.9	152 – 1999 Ma Il 5 yr 99.9	nufacturing Issue All-cause s 99.9 at 71 mo			
ears After	1 yr 100	2 yr 100	3 yr 100	and page n-free surviva 4 yr 99.9	152 – 1999 Ma Il 5 yr 99.9	nufacturing Issue All-cause s 99.9 at 71 mo			

Therapy Function Not Compromised Therapy Function Compromised 1 (0 related to advisory) sories 2 see page 141 – 2005 Potential Separation of Interconnect Wires and page 152 – 1999 Manufacturing Issue s After Implant Malfunction-free survival 1 yr 2 yr 3 yr 4 yr 5 yr 100 100 100 100 100 100	US Market	red US Implants ed Active US Implants Battery Depletions tions Therapy Function Not Comprom Therapy Function Comprom tes	Sep	-99		NBG Code			SSI/R		
nal Battery Depletions 22 500 Ω impedance 100% pacing unctions 4 (1 related to advisory) Therapy Function Not Compromised Therapy Function Compromised 1 (0 related to advisory) sories 2 see page 141 - 2005 Potential Separation of Interconnect Wires and page 152 - 1999 Manufacturing Issue s After Implant Malfunction-free survival 1 yr 2 yr 3 yr 4 yr 100 100 100 100	Registered	US Implant	:s	45,0	000		Serial Numb	er Prefix/Xra	y ID	PJG, P	ŊН
Indigenerations 22 Inctions 4 (1 related to advisory) Therapy Function Not Compromised 1 (0 related to advisory) Sories 2 see page 141 – 2005 Potential Separation of Interconnect Wires and page 152 – 1999 Manufacturing Issue Softer Implant Malfunction-free survival 1 yr 2 yr 3 yr 4 yr 100 100 100 100	Estimated /	Active US Ir	mplants	26,0	000		Estimated L	ongevity			
unctions 4 (1 related to advisory) Therapy Function Not Compromised Therapy Function Compromised 1 (0 related to advisory) sories 2 see page 141 - 2005 Potential Separation of Interconnect Wires and page 152 - 1999 Manufacturing Issue s After Implant Malfunction-free survival 1 yr 2 yr 3 yr 4 yr 5 yr 100 100 100	Normal Bat	tery Deple	tions		22						
Therapy Function Compromised 3 (1 related to advisory) sories 2 see page 141 - 2005 Potential Separation of Interconnect Wires and page 152 - 1999 Manufacturing Issue s After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 100 100 100 100 100 at 69 mo	Malfunction	nctions Therapy Function Not Compror		4 (1 related	to advisory)					P	
After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 100 100 100 100 100 at 69 mo		unctions Therapy Function Not Compro									
After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 100 100 100 100 100 at 69 mo	Advisories	Therapy Function Compromised 3 (1 related to advisor ies 2 see page 141 – 2005							ect Wire	S	
100 100 100 100 100 100 at 69 mo	Auvisories	Therapy Function Not Compro Therapy Function Compro pries			and page	<u>e 152</u> – 1999 Mar	nufacturing Issu	le			
		r Implant		Malfunction			-		I		
100 99.9 99.9 99.8 99.6 99.5 at 69 mo Image: Control of the second sec			1	1	-free surviva	.1	-		1		
		l yr	2 yr	3 yr	-free surviva	ll 5 yr	All-c				
Image: Second		1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	1 5 yr 100	All-c				
	ears After	1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	1 5 yr 100	All-c				
	ears After	1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	1 5 yr 100	All-c				
	ears After	1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	1 5 yr 100	All-c				

IS Market	Release		9	Sep-99		NBG Code		VDD	D
egistered	US Implant	S		1,000		Serial Number P	refix/Xray ID	PJD	
stimated	Active US Ir	mplants		400		Estimated Long	evity		rs @ 2.5 V
Iormal Bat	tery Deple	tions		0					Ω impedance % pacing
Alfunction	ns			0 (0 related	d to advisory)				
The	tions herapy Function Not Compromised Therapy Function Compromised								
	., .			0 (0 related to advisory) 0 (0 related to advisory) 2 see page 141 – 2005 Pote		tial Separation of	Interconnect V	Vires	
dvisories	ed US Implants d Active US Implants attery Depletions ions herapy Function Not Compromised Therapy Function Compromised es ter Implant — Malfun 1 yr 2 yr 3 yr 100 100 100 100			141 – 2005 Poter 152 – 1999 Manu					
			1	and page on-free surviva	<u>152 – 1999 Manu</u>	facturing Issue	e survival		
		-	Valfuncti 3 yr	and page	<u>152 – 1999 Manu</u>	facturing Issue			
	l yr	2 yr	1	and page on-free surviva	<u>152 – 1999 Manu</u>	facturing Issue			
	1 yr 100	2 yr 100	3 yr	and page on-free surviva 4 yr	<mark>152 – 1999 Manu</mark> I	facturing Issue			
ears Afte	1 yr 100	2 yr 100	3 yr 100	on-free surviva 4 yr 100	152 - 1999 Manu	facturing Issue			
ears Afte	1 yr 100	2 yr 100	3 yr 100	on-free surviva 4 yr 100	152 - 1999 Manu	facturing Issue			
ears Afte	1 yr 100	2 yr 100	3 yr 100	on-free surviva 4 yr 100	152 - 1999 Manu	facturing Issue			

Spe	ctra	x S :	5940,	5940L	.P, 594	1						Р	roduc	t Chai	racter	istics					
US Ma	arket F	Release	2				Jul-	-83				N	BG Co	de					VVIPO	С	
Regist	tered	US Imp	lants				25,0	00				S	erial N	umber	Prefix	/Xray	ID		NF, PE	D, LP	
Estim	ated A	Active	US Imp	olants			1,0	00				E	stimate	ed Lon	gevity					s @ 2.5	
Norm	al Bat	tery D	epletio	ns			8	02												impeo pacing	
Malfu	nction	IS						76												pacing	2
Adviso	ories						No	ne													
—	1 yr 99.9	2 yr 99.8	3 yr 99.8	99.8	5 yr 99.7	6 yr 99.7	7 yr 99.7	8 yr 99.6	99.6	10 yr 99.6	99.5	12 yr 99.5	13 yr 99.5	14 yr 99.5	15 yr 99.5 70.5	16 yr 99.5	99.5	99.5	99.5	99.5	21 yr 99.5 64.5
1		I		1.2.2.1	199.2	1.0	120.0	127.5	199.0	121.2	00.0	100.0	10.5	1, 2.2	1,0.0	00.7	107.0	00.7	00.0	05.1	0 1.5
																[·					

JS Market Release	Oct-81	NBG Code	SSIMO
Registered US Implants	111,000	Serial Number Prefix/Xray ID	GL, HJ, HN, 3E
Estimated Active US Implants	3,000	Estimated Longevity	13.7 yrs @ 2.5 V
Normal Battery Depletions	4,391		500 Ω impedance 100% pacing
Malfunctions	466		
Advisories	None		



US M	arket R	elease		Jan	-95		NBG Code			DDDCO	
Regis	tered U	S Implants		2,0	000		Serial Numb	oer Prefix/Xra	ay ID	PBD, PBE	PBF
Estim	ated A	ctive US Im	plants		30		Estimated L	ongevity		7.4 yrs @	
Norm	nal Batte	ery Depleti	ons		168					500 Ω im 100% pac	
Malfu	inctions	;			2						Ū
Advis	ories			No	one						
Years	After	Implant		Malfunction	-free survival		All-	cause surviva	al		
		l yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
		99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.9	99.7	99.7 at 110
		99.9	99.8	98.9	97.3	93.6	90.2	83.0	66.8	53.8	48.4 at 110
)											
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										<u> </u>	
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0			2	3	4	5	6	 7	8	9	10

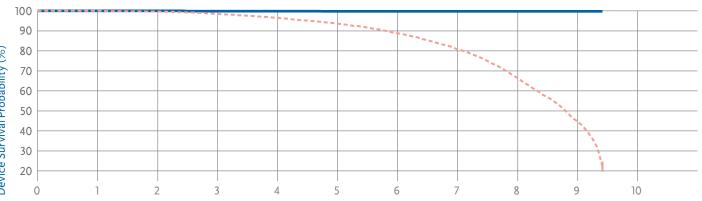
Thera DR-40 7940, 7941, 7942	2		Product Characteristics	
US Market Release	Jan-95		NBG Code	DDD/RO
Registered US Implants	30,000		Serial Number Prefix/Xray ID	PAF, PAP, PAT
Estimated Active US Implants	20		Estimated Longevity	7.4 yrs @ 2.5 V
Normal Battery Depletions	2,828			500 Ω impedance 100% pacing
Malfunctions	37			1 0
Advisories	1 see p	<mark>age 154</mark> – 1997 Pot	ential Integrated Circuit Failure	

Years After Implant

Malfunction-free survival

---- All-cause survival

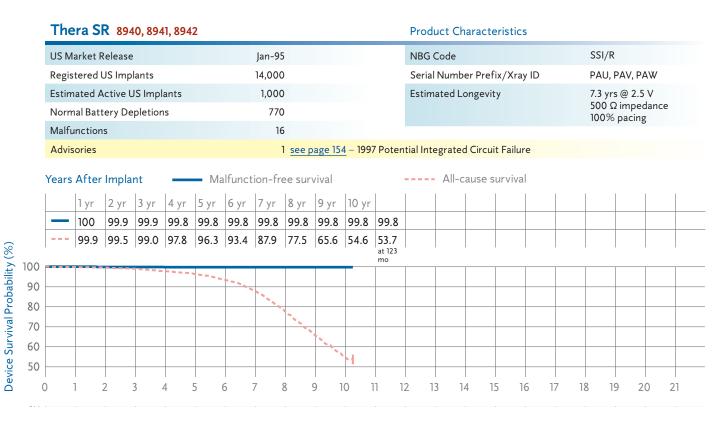
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
	100	100	99.9	99.9	99.8	99.8	99.8	99.8	99.8	99.8 at 113 mo
	100	99.7	98.5	96.5	93.6	88.8	80.8	66.4	48.9	22.1 at 113 mo



Source: Medtronic Device Registration and Returned Product Analysis Data as of October 31, 2005

US Marke	et Release					Jan-95					NBG	Code				DD	D/RO		
	ed US Imp					5,000						Numb	er Pref	⁻ ix/Xra	y ID			, PBW	
Ū	d Active L		ants			1,000					Estim	ated L	ongevi	ty				2.5 V	
Normal B	Battery De	pletion	s			111) Ω im % pa	ipedan cing	ce
Malfuncti	ions					1													
Advisorie	es					1	see p	age 154	4 – 1997	7 Poten	tial Inte	egrate	d Circu	it Failu	re				
Years Aft	ter Impla ^{vr} 2 yr	I.	4 yr	Ma 5 yr	lfuncti 6 yr			1	10 yr			All-c	ause s	surviva 	1				
L.	vr 2 yr	nt 3 yr 100	4 yr 100	1	1	1		vival 9 yr 100	10 yr 100	100		All-c	ause s	surviva	1 				
1 yr 100	r 2 yr 0 100 0 100	3 yr	-	5 yr 100	6 yr	7 yr 100	8 yr	9 yr 100	/	100 83.6 at 125 mo		All-c	ause s	surviva					
1 yı	r 2 yr 0 100 0 100	3 yr 100	100	5 yr 100	6 yr 100	7 yr 100	8 yr 100	9 yr 100	100	83.6 at 125		All-c	ause s	surviva					
1 yr 100	r 2 yr 0 100 0 100	3 yr 100	100	5 yr 100	6 yr 100	7 yr 100	8 yr 100 96.0	9 yr 100	100	83.6 at 125		All-c	ause s	surviva					
1 yr 100	r 2 yr 0 100 0 100	3 yr 100	100	5 yr 100	6 yr 100	7 yr 100	8 yr 100 96.0	9 yr 100	100	83.6 at 125		All-c	ause s	surviva					

1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 99.9 99.8 99.8 99.8 99.8 99.8 99.8 99.8 99.8 99.8 99.8 at 118										0.01/5	
Estimated Active US Implants 200 Estimated Longevity 7.4 yrs @ 2.5 V 500 Ω impedance 100% pacing Malfunctions 3 Advisories None Years After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 99.9 99.8 <	US Market	Release		Jan	-95		NBG Cod	le		SSI/R	
Normal Battery Depletions 76 500 Ω impedance 100% pacing Malfunctions 3 Advisories None Years After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 99.9 99.8 99.8 99.8 99.8 99.8 99.8 99.8 99.8 99.8 at 118	Registered	US Implant	S	3,0	000		Serial Nu	mber Prefix/2	Xray ID	PBG, PBI	H, PBJ
Malfunctions 3 Malfunctions 3 Advisories None Years After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 1000 100 99.9 99.8 100	Estimated	Active US Ir	mplants	:	200		Estimate	d Longevity			
Malfunctions 3 Advisories None Years After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 99.9 99.8 100	Normal Ba	ttery Deple	tions		76						
Years After Implant Malfunction-free survival All-cause survival 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 99.9 99.8	Malfunctio	ns			3					10070 pu	5
1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr 9 yr 100 100 99.9 99.8	Advisories			N	one						
100 99 9 99 5 98 4 96 7 95 9 93 2 88 5 79 8 70 4 et us	Years Afte			1	1		I.	1	1		
100 99 9 99 5 98 4 96 7 95 9 93 2 88 5 79 8 70 4 et us	lears Afte			1	1		I.	1	1	9 yr	
	Years Afte	l yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr		99.8 at 118 m
		l yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr 99.8 93.2	8 yr 99.8 88.5	99.8 79.8	
		1 yr 100	2 yr 100	3 yr 99.9	4 yr 99.8	5 yr 99.8	6 yr 99.8 95.9	7 yr 99.8 93.2	8 yr 99.8 88.5	99.8 79.8	
		1 yr 100	2 yr 100	3 yr 99.9	4 yr 99.8	5 yr 99.8	6 yr 99.8 95.9	7 yr 99.8 93.2	8 yr 99.8 88.5	99.8 79.8	70.4 at 118 m
		1 yr 100	2 yr 100	3 yr 99.9	4 yr 99.8	5 yr 99.8	6 yr 99.8 95.9	7 yr 99.8 93.2	8 yr 99.8 88.5	99.8 79.8	70.4 at 118 m



Registered US Implants Estimated Active US Impla	nts	3,0	00		Serial Nu	mber Prefix/2	Krav ID	PDE, PDF	DDC
Estimated Active US Impla	nte					,		102,101	, PDG
	1115	1,0	00		Estimate	d Longevity		9.7 yrs @	
Normal Battery Depletions			57					500 Ω im 100% pa	
Malfunctions			1					10070 pu	
Advisories		No	ne						
Years After Implant	2 yr	alfunction- 3 yr	4 yr	5 yr	6 yr	ll-cause surv 7 yr	8 yr	9 yr	
100	100	100	100	100	100	100	100	100	100 at 113 mo
100	99.9	99.6	99.5	99.1	97.5	96.2	93.3	90.3	88.2 at 113 n

US Market R		0i, 7961i, 796	2i			Product	Characteris	tics		
	elease		Oct	t-95		NBG Cod	le		DDD/RO	•
Registered L	JS Implant	s	122,0	000		Serial Nu	mber Prefix/2	Xray ID	PDB,PDC	, PDD
Estimated A	ctive US Ir	nplants	42,0	000		Estimate	d Longevity		9.7 yrs @	
Normal Batt	ery Deplet	tions	2	,176					500 Ω im 100% pa	ipedance cing
Malfunctions	s			49						8
Advisories			N	one						
Years After	1 yr 100	2 yr 100	3 yr 100	-free surviva 4 yr 100	5 yr 100	6 yr 100	III-cause surv 7 yr 99.9	8 yr 99.9	9 yr 99.9	99.9 at 117 m
	100	99.9	99.7	99.5	99.0	98.2	96.6	93.4	88.1	

JS Market	Release		Ju	I-96		NBG Cod	le		DDD/RO
legistered	US Implant	ts	4,0	000		Serial Nu	mber Prefix/	Xray ID	PGH
stimated	Active US Ir	mplants	1,0	000		Estimate	d Longevity		7.0 yrs @ 2.5 V
Vormal Bat	tery Deple	tions		112					500 Ω impedance 100% pacing
Malfunction	ns			3					i e e / e pucing
Advisories			N	one					
ears Aftei	r Implant		Malfunction	-free surviva	1	A	ll-cause surv	vival	
ears After	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	99.9 at 100 mg
ears After			1	I			1	1	99.9 at 100 mo 75.9 at 100 mo
	1 yr 100	2 yr 100	3 yr 99.9	4 yr 99.9	5 yr 99.9 97.0	6 yr 99.9 94.2	7 yr 99.9 90.1	8 yr 99.9	
	1 yr 100	2 yr 100	3 yr 99.9	4 yr 99.9	5 yr 99.9	6 yr 99.9 94.2	7 yr 99.9 90.1	8 yr 99.9 80.7	
	1 yr 100	2 yr 100	3 yr 99.9	4 yr 99.9	5 yr 99.9 97.0	6 yr 99.9 94.2	7 yr 99.9 90.1	8 yr 99.9 80.7	

Thera-It	5 8964i, 8	8965i, 8966i	i			Product	Characteris	tics		
US Market R	elease		Oct	t-95		NBG Cod	e		SSIR	
Registered U	JS Implants	;	4,	000		Serial Nu	mber Prefix/2	Xray ID	PDY, PEA	, PEB
Estimated A	ctive US Im	plants	1,0	000		Estimate	d Longevity		9.8 yrs @	
Normal Batte	ery Depleti	ions		27					500 Ω im 100% pa	
Malfunctions	5			1						5
Advisories			Ν	one						
Years After	Implant		Malfunction	-free surviva	.1	A	ll-cause surv	vival		
	l yr	2 yr	3 yr	4 yr	5 yr	б yr	7 yr	8 yr	9 yr	
	100	100	100	100	100	100	100	100	100	100 at 113 mo

Thera-I	SR 8960) <mark>i, 8961i, 896</mark>	2i			Product	Characteris	tics		
US Market R	Release			Oct-95		NBG Cod	le		SSIR	
Registered l	US Implant	s		50,000		Serial Nu	mber Prefix/	Xray ID	PDU, PD	V, PDW
Estimated A	Active US Ir	nplants		13,000		Estimate	d Longevity		9.6 yrs @	
Normal Batt	tery Deplet	tions		522					500 Ω in 100% pa	ipedance cing
Malfunction	ıs			7					10070 pu	
Advisories				None						
Years After	1 yr	2 yr	3 yr	-free surviva 4 yr 100	5 yr	6 yr	II-cause surv 7 yr 100	8 yr	9 yr	100 at 117 mg
		99.9	99.7	99.4	99.0	98.3	97.1	95.2	91.9	
	100	55.5	55.1		22.0	20.5	27.1	JJ.2	21.2	89.2 at 117 m
	100	99.9	55.7	1	199.0	08.5			0	89.2 at 117 m
	100	99.9			55.0					89.2 at 117 m
		99.9				70.5				89.2 at 117 m

US Market	t Release		Mar	-96		NBG Cod	le		VDD	
Registered	d US Implant	s	5,0	000		Serial Nu	mber Prefix/	Xray ID	PEC	
Estimated	Active US Ir	nplants	2,0	000		Estimate	d Longevity		11.5 yrs @	
Normal Ba	attery Deple	tions		20					500 Ω in 100% pa	ipedance cing
Malfunctio	ons			0						
Advisories	5		N	one						
Years Afte	er Implant		Malfunction	-free surviva	al	A	ll-cause surv	vival		
Years Afte	er Implant	2 yr	3 yr	4 yr	5 yr	6 yr	II-cause surv 7 yr 100	8 yr	9 yr	100 at 111 n
Years Afte		1	1	1	1	1	I	1	9 yr 100 97.3	100 at 111 m 97.3 at 111 r
	1 yr 100	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100	8 yr 100	100 97.3	
	1 yr 100	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100	8 yr 100 98.4	100 97.3	
	1 yr 100	2 yr 100	3 yr 100	4 yr 100	5 yr 100	6 yr 100	7 yr 100	8 yr 100 98.4	100 97.3	

Device Survival Summary (95% Confidence Interval)

The following table shows IPG device survival estimates with 95% confidence intervals. Estimates are shown both with and without normal battery depletions included.

yir	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival	Device	e Surviv	val Prob	ability (%)							
Family	Nur	US Rel	Reg US	Est Act Imp	Noi Dej	Ma	The Not	Cor	Probabilities	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
AT500	AT501, 7253	Mar-03	11,000	9,000	75	5 (———	2 - total —	3)	Malfunction- free	100.0 +.0/1	100.0 +.0/1	99.8 +.2/-1.0	99.1 +.6/-1.5	99.1 +.6/-1.5							
	Memory C	Circuit Setti	ng; also see	otential Inco <u>page 160</u> – Follow-Up Pi	Technical	(2) (advisc	(1) ory-relate	(1) d subset)	All-cause	100.0 +.0/1	99.9 +.1/1	98.3 +.8/-1.5	88.7 +2.7/-3.4	53.9 +5.9/-6.4							
Elite	7074, 7075, 7076, 7077	Apr-91	48,000	2,000	2,993	85	_	_	Malfunction- free	100.0 +.0/0	99.9 +.0/0	99.9 +.0/0	99.8 +.0/0	99.8 +.0/1	99.8 +.0/1	99.8 +.0/1	99.8 +.0/1	99.8 +.0/1	99.8 +.0/1	99.8 +.0/1 (155 mo)	
									All-cause	99.9 +.0/0	99.8 +.0/0	99.6 +.1/1	99.5 +.1/1	98.9 +.1/1	97.8 +.2/2	95.7 +.2/3	91.1 +.4/4	76.6 +.7/7	54.4 +1.1/-1.1	31.4 +2.2/-2.2 (155 mo)	
Elite II	7084, 7085, 7086	Dec-92	57,000	4	7,108	45	-	_	Malfunction- free	100.0 +.0/0	100.0 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0 (103 mo)			
									All-cause	99.9 +.0/0	99.8 +.0/0	99.1 +.1/1	96.1 +.2/2	90.5 +.3/3	82.5 +.4/4	69.9 +.6/6	47.1	15.3 +1.4/-1.4 (103 mo)			
EnPulse DR	EIDR01	Dec-03	7,000	6,000	0	0	0	0	Malfunction- free	100.0 +.0/0	100.0 +.0/0 (20 mo)										
									All-cause	100.0 +.0/0	100.0 +.0/0 (20 mo)										
EnPulse DR	EIDR21	Dec-03	2,000	2,000	0	0	0	0	Malfunction- free	100.0 +.0/0	100.0 +.0/0 (19 mo)										
									All-cause	100.0 +.0/0	100.0 +.0/0 (19 mo)										
EnPulse 2 DR	E2DR01, E2DR03, E2DR06	Feb-04	53,000	50,000	0	1	0	1	Malfunction- free	100.0 +.0/0	100.0 +.0/0 (18 mo)										
									All-cause	100.0 +.0/0	100.0 +.0/0 (18 mo)										
EnPulse 2 DR	E2DR21	Feb-04	6,000	5,000	0	0	0	0	Malfunction- free	100.0 +.0/0	100.0 +.0/0 (15 mo)										
									All-cause	100.0 +.0/0	100.0 +.0/0 (15 mo)										
EnPulse 2 DR	E2DR31	Feb-04	200	200	0	0	0	0	Malfunction- free	100.0 +.0/0 (5 mo)											
continued									All-cause	100.0 +.0/0 (5 mo)											

Source: Medtronic Device Registration and Returned Product Analysis Data as of October 31, 2005

y!	el ber	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised		Devic	e Surviv	val Prob	ability (%)							
Family	Model Number	US N Rele:	Regi US Ir	Estin Activ Impli	Norr Depl	Malf	Ther Not (Ther Com	Survival Probabilities	1 yr	2 yr	3 yr			6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 y
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	Dec-03	11,000	10,000	0	0	0	0	Malfunction- free	100.0 +.0/0	100.0 +.0/0 (19 mo)										
									All-cause	100.0 +.0/0	100.0 +.0/0 (19 mo)										
EnPulse 2 VDD	E2VDD01	Dec-03	300	200	0	0	0	0	Malfunction- free	100.0 +.0/0 (9 mo)											
									All-cause	100.0 +.0/0 (9 mo)											
EnRhythm DR	P1501DR	May-05	5,000	5,000	0	1	1	0	Malfunction- free	100.0 +.0/2 (4 mo)											
									All-cause	99.9 +.0/2 (4 mo)											
Kappa 400 DR	KDR401, KDR403	Jan-98	46,000	21,000	547	19	10	9	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0 (91 mo)				
									All-cause	99.9 +.0/0	99.9 +.0/0	99.8 +.0/1	99.6 +.1/1	99.2 +.1/1	97.8 +.2/2	92.3 +.5/5	82.7 +3.0/-3.6 (91 mo)				
Kappa 400 SR	KSR401, KSR403	Feb-98	15,000	7,000	48	4	3	1	Malfunction- free	100.0 +.0/0	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1 (89 mo)				
									All-cause	99.9 +.0/1	99.9 +.0/1	99.8 +.1/1	99.5 +.1/2	99.5 +.1/2	98.8 +.3/3	97.4 +.6/7	94.9 +1.4/-1.9 (89 mo)				
Kappa 600 DR	KDR601, KDR603, KDR606	Jan-99	23,000	13,000	76	13 (4 - total —	9 —)	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	99.9 +.0/0	99.9 +.0/1	99.9 +.0/1	99.9 +.0/1 (77 mo)					
	Advisory: Power Sup	see page 1 ply Wires	<u>46</u> – 2002 F	Potential Frac	tured	(8) (adviso	(1) ory-related	(7) d subset)	All-cause	100.0 +.0/0	99.9 +.0/0	99.9 +.0/1	99.6 +.1/1	99.1 +.1/2	98.0 +.4/4	96.7 +1.0/-1.4 (77 mo)					
Kappa 600 DR	KDR651, KDR653	Mar-01	14,000	9,000	11	3 (2 - total —	1 —)	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/1	100.0 +.0/1 (52 mo)							
	Advisory: Power Sup		<u>46</u> – 2002 F	Potential Frac	tured	(0) (adviso	(0) ory-related	(0) d subset)	All-cause	100.0 +.0/0	100.0 +.0/1	99.9 +.0/1	99.7 +.1/2	99.3 +.4/8 (52 mo)							
Kappa 700 D	KD701	Jan-99	300	200	2	0 (0 - total ——	0)	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (58 mo)							
	Advisory: Power Sup	see page 1 ply Wires	<u>46</u> – 2002 F	Potential Frac	tured	(0) (adviso	(0) ory-relate	(0) d subset)	All-cause	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	98.7 +1.0/-3.8	98.7 +1.0/-3.8 (58 mo)							

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liy	Model Number	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised	Survival	Device	e Surviv	val Prob	ability (%)							
Family	Nun	US I Rele	Reg US I	Esti Act Imp	Dep	Mal	The Not	The Con	Probabilities	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Kappa 700 DR	KDR701, KDR703, KDR706	Feb-99	182,000	116,000	599	123 (17 — total —	106	Malfunction- free	100.0 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0 (79 mo)					
	Advisory: Power Sup		<u>46</u> – 2002 P	Potential Fra	ctured	(91) (advis	(0) ory-relate	(91) ed subset)	All-cause	99.9 +.0/0	99.9 +.0/0	99.7 +.0/0	99.3 +.1/1	98.5 +.1/1	96.8 +.2/2	93.5 +1.3/-1.6 (79 mo)					
Kappa 700 DR	KDR721	Feb-99	10,000	4,000	224	5 (——	1 – total —	4)	Malfunction- free	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	99.9 +.1/3	99.9 +.1/3	99.9 +.1/3 (73 mo)					
	Advisory: Power Sup		<u>46</u> – 2002 P	Potential Fra	ctured	(4) (advis	(0) ory-relate	(4) ed subset)	All-cause	99.9 +.0/1	99.7 +.1/2	99.0 +.2/3	96.8 +.4/5	91.4 +1.0/-1.1	74.9 +3.2/-3.5	71.8 +3.8/-4.3 (73 mo)					
Kappa 700 SR	KSR701, KSR703, KSR706	Feb-99	50,000	26,000	201	5	1	4	Malfunction- free	100.0	100.0	100.0	100.0 +.0/0	100.0 +.0/0	100.0	100.0 +.0/0 (78 mo)					
									All-cause	100.0 +.0/0	99.9 +.0/0	99.6 +.1/1	99.1 +.1/1	98.0 +.2/3	96.3 +.5/5	95.9 +.6/7 (78 mo)					
Kappa 700 VDD	KVDD701	Jan-99	2,000	1,000	7	2 (0 – total —	2)	Malfunction- free	99.9 +.1/4	99.9 +.1/4	99.9 +.1/4	99.8 +.1/5	99.8 +.1/5	99.8 +.1/5 (71mo)						
	Advisory: Power Sup		<u>46</u> – 2002 P	Potential Fra	ctured	(2) (advis	(0) ory-relate	(2) ed subset)	All-cause	99.9 +.1/4	99.9 +.1/4	99.7 +.2/5	99.1 +.4/7	98.8 +.5/9	95.9 +2.1/-4.2 (71mo)						
Kappa 800 DR	KDR801, KDR803	Jan-02	4,000	3,000	2	0	0	0	Malfunction- free	100.0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (37 mo)								
									All-cause	100.0 +.0/0	99.9 +.1/2	99.8 +.2/4	99.8 +.2/4 (37 mo)								
Kappa 900 DR	KDR901, KDR903, KDR906	Jan-02	108,000	87,000	17	6	4	2	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (44 mo)								
									All-cause	100.0 +.0/0	100.0 +.0/0	99.9 +.0/0	99.9 +.0/0 (44 mo)								
Kappa 900 SR	KSR901, KSR903, KSR906	Jan-02	29,000	20,000	6	3	3	0	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/1	100.0 +.0/1 (43 mo)								
									All-cause	100.0 +.0/0	99.9 +.0/1	99.9 +.1/1	99.7 +.2/3 (43 mo)								
Kappa 900 VDD	KVDD901	Jan-02	1,000	500	0	0	0	0	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (35 mo)									
continued									All-cause	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (35 mo)									

	a	rket e	Registered US Implants	us US its	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised						o.()							
Family	Model Number	US Market Release	ls Imp	Estimated Active US Implants	Vorma Deplet	Malfur	Therap Not Co	Cherag	Survival Probabilities	Device 1 yr	2 yr	al Prob	ability (4 yr	%) 5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yı
Kappa 920 DR	KDR921	Jan-02	15,000	11,000	8	1	0	1	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/2	100.0 +.0/2 (41 mo)			7 91			12 y1		
									All-cause	100.0 +.0/0	99.9 +.1/1	99.7 +.1/2	99.6 +.2/3 (41 mo)								
Legend	8416, 8417, 8417M, 8418, 8418, 8419	Aug-89	57,000	4,000	2,441	145	-	-	Malfunction- free	99.9 +.0/0	99.9 +.0/0	99.8 +.0/0	99.8 +.0/0	99.7 +.0/1	99.7 +.1/1	99.6 +.1/1	99.6 +.1/1	99.6 +.1/1	99.6 +.1/1	99.6 +.1/1	99.6 +.1/ (187 r
									All-cause	99.9 +.0/0	99.7 +.0/1	99.4 +.1/1	98.9 +.1/1	98.3 +.1/1	97.2 +.2/2	94.7 +.3/3	90.7 +.4/4	81.4 +.6/6	73.1 +.7/8	64.3 +1.0/-1.0	58.8 +1.8/ (187)
Legend II	8424, 8426, 8427	Nov-91	58,000	8,000	1,424	37	—	_	Malfunction- free	100.0 +.0/0	100.0	100.0 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0 (163 mo)	
									All-cause	99.9 +.0/0	99.8 +.0/0	99.6 +.1/1	99.2 +.1/1	98.9 +.1/1	98.2 +.1/1	97.3 +.2/2	94.9 +.3/3	89.4 +.4/4	83.8 +.6/6	78.3 +1.8/-1.9 (163 mo)	
Micro Minix	8360	Oct-90	7,000	400	255	2	_	_	Malfunction- free	100.0 +.0/1	100.0	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1 (167 mo)	
		see page 1 on of Perma		ntential Delay ngs	red	_	—	-	All-cause	99.9 +.1/1	99.8 +.1/1	99.6 +.1/2	99.4 +.2/3	98.0 +.4/5	94.5 +.8/9	86.7 +1.4/-1.5	80.1 +1.7/-1.9	72.6 +2.2/-2.4	70.2 +2.4/-2.6	67.7 +3.1/-3.3 (167 mo)	
Minix/ Minix ST	8330, 8331, 8331M, 8340, 8341, 8341M, 8342	Dec-89	58,000	6,000	1,371	49	-	_	Malfunction- free	100.0 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0	99 . +.0/ (196
		see page 1 on of Perma		otential Delay ngs	red	—	-	-	All-cause	99.9 +.0/0	99.7 +.0/0	99.5 +.1/1	99.2 +.1/1	98.7 +.1/1	97.7 +.2/2	95.2 +.3/3	91.9 +.4/4	87.1 +.5/5	83.7 +.6/6	80.8 +.8/8	78 . +1.4 (196
Minuet	7107, 7108	Mar-92	17,000	3,000	470	4	—	_	Malfunction- free	100.0 +.0/0	100.0	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1 (159 mo)	
									All-cause	100.0 +.0/0	100.0 +.0/0	99.8 +.1/1	99.5 +.1/1	98.9 +.2/2	98.2 +.2/3	96.9 +.3/4	94.7 +.5/5	89.3 +.7/8	82.8 +1.2/-1.2	78.0 +2.0/-2.2 (159 mo)	

		US Market Release	Registered US Implants	ated e US nts	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised		Davis	e Surviv	al Drob	ability (961							
Family	Model Number	JS Ma Relea:	Regist JS Im	Estimated Active US Implants	Norm Deple	Malfu	Thera Not C	Thera Comp	Survival Probabilities	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 y
Pasys/ Pasys ST	8316, 8317, 8318, 8320, 8322, 8329	 Mar-86	28,000	1,000	1,430	145	-	-	Malfunction- free	100.0 +.0/0	99.9 +.0/1	99.7 +.1/1	99.6 +.1/1	99.5 +.1/1	99.4 +.1/1	99.2 +.1/1	99.1 +.1/2	99.1 +.1/2	99.1 +.1/2	99.1 +.1/2	99.1 +.1/2 (212 m
									All-cause	99.9 +.0/0	99.6 +.1/1	99.2 +.1/1	98.5 +.2/2	97.8 +.2/2	96.6 +.3/3	94.0 +.4/4	89.7 +.5/6	79.0 +.9/9	63.8 +1.2/-1.3	53.9 +1.5/-1.5	47.8 +1.8/-1 (212 m
Preva D	7068	Nov-96	1,000	300	9	1	-	_	Malfunction- free	100.0 +.0/0	99.9 +.1/9	99.9 +.1/9	99.9 +.1/9	99.9 +.1/9	99.9 +.1/9	99.9 +.1/9	99.9 +.1/9 (91 mo)				
									All-cause	100.0 +.0/0	99.7 +.2/8	99.4 +.4/-1.0	98.7 +.7/-1.3	98.7 +.7/-1.3	97.7 +1.0/-1.8	95.5 +1.7/-2.8	94.4 +2.1/-3.3 (91 mo)				
Preva DR	7088, 7089	Jul-96	25,000	10,000	286	3	_	_	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (109 mo)			
									All-cause	100.0 +.0/0	99.9 +.0/1	99.8 +.1/1	99.6 +.1/1	99.1 +.1/2	98.3 +.2/2	97.0 +.3/3	94.2 +.5/6	88.0 +2.5/-3.1 (109 mo)			
Preva SR	8088, 8089	Jul-96	18,000	5,000	157	1	_	_	Malfunction- free	100.0 +.0/0	100.0	100.0 +.0/0	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1 (108 mo)			
									All-cause	100.0 +.0/0	99.9 +.0/1	99.7 +.1/1	99.4 +.1/2	98.8 +.2/2	98.0 +.3/3	95.9 +.5/6	94.5 +.7/7	90.6 +1.9/-2.3 (108 mo)			
Preva ST DR	7078	Nov-96	1,000	300	9	0	-	_	Malfunction- free	100.0 +.0/0	100.0	100.0 +.0/0	100.0	100.0	100.0 +.0/0	100.0	100.0 +.0/0 (93 mo)				
									All-cause	99.7 +.2/8	99.7 +.2/8	99.4 +.4/9	99.4 +.4/9	99.0 +.5/-1.2	98.1 +.9/-1.6	96.4 +1.4/-2.3	95.4 +1.8/-2.9 (93 mo)				
Prevail S	8085, 8086	Oct-95	4,000	1,000	10	1	-	-	Malfunction- free	100.0 +.0/0	100.0	100.0 +.0/0	100.0	99.9 +.1/4	99.9 +.1/4	99.9 +.1/4	99.9 +.1/4	99.9 +.1/4 (105 mo)			
									All-cause	100.0 +.0/1	100.0 +.0/1	99.9 +.1/2	99.9 +.1/2	99.3 +.3/6	99.1 +.4/6	98.6 +.5/9	98.3 +.6/-1.0	97.4 +1.1/-1.9 (105 mo)			
Prodigy D	7864, 7865, 7866	Oct-95	3,000	1,000	33	0	_	-	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (108 mo)			
									All-cause	99.9 +.1/2	99.7 +.1/3	99.5 +.2/4	98.9 +.4/6	98.7 +.4/6	97.8 +.6/8	97.3 +.7/9	96.0 +1.0/-1.3	92.9 +1.9/-2.6 (108 mo)			

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		ırket se	Registered US Implants	ated e US mts	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised		Dovice	e Surviv	al Prob	ability (941							
Family	Model Number	US Market Release	Regist US Im	Estimated Active US Implants	Norm Deple	Malfu	Thera Not C	Thera Comp	Survival Probabilities	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 y
Prodigy DR	7860, 7861, 7862	Oct-95	37,000	14,000	403	10	-	-	Malfunction- free	100.0 +.0/0	100.0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0	100.0	100.0 +.0/0 (112 mo)			
									All-cause	99.9 +.0/0	99.9 +.0/0	99.8 +.0/1	99.6 +.1/1	99.1 +.1/1	98.4 +.2/2	97.0 +.2/3	94.1 +.5/5	89.7 +1.4/-1.6 (112 mo)			
Prodigy S	8164, 8165, 8166	Oct-95	2,000	1,000	11	0	—	_	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (106 mo)			
									All-cause	99.9 +.1/3	99.9 +.1/3	99.8 +.2/4	99.2 +.4/7	99.2 +.4/7	99.2 +.4/7	98.8 +.5/-1.0	97.1 +1.1/-1.8	96.1 +1.6/-2.6 (106 mo)			
Prodigy SR	8158, 8160, 8161, 8162	Oct-95	22,000	7,000	189	5	-	-	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (110 mo)			
									All-cause	99.9 +.0/1	99.7 +.1/1	99.5 +.1/1	99.1 +.1/2	98.6 +.2/2	97.8 +.3/3	96.7 +.4/4	95.0 +.6/6	91.2 +2.0/-2.5 (110 mo)			
Sigma 100 S	SS103, SS106	Aug-99	1,000	300	1	0 (0 total —	0)	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (56 mo)							
		nnect Wire	<u>141</u> – 2005 s; <u>and page</u>	Potential Se _l <u>152</u> – 1999	paration	(0) (adviso	(0) ry-relate	(0) d subset)	All-cause	100.0 +.0/0	100.0 +.0/0	99.5 +.4/-1.5	99.5 +.4/-1.5	99.5 +.4/-1.5 (56 mo)							
Sigma 200 DR	SDR203	Aug-99	15,000	10,000	10	3 (1 total —	2)	Malfunction- free	100.0 +.0/0	100.0	100.0 +.0/0	100.0	100.0	100.0 +.0/0 (68 mo)						
		nnect Wire		Potential Sej <u>152</u> – 1999	paration	(0) (adviso	(0) ry-relate	(0) d subset)	All-cause	100.0 +.0/0	100.0 +.0/1	99.9 +.0/1	99.8 +.1/1	99.5 +.2/3	99.5 +.2/3 (68 mo)						
Sigma 200 SR	SSR203	Sep-99	12,000	6,000	8	0 (0 - total —	0)	Malfunction- free	100.0 +.0/0	100.0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (68 mo)						
		nnect Wire		Potential Se <u>152</u> – 1999	paration	(0) (adviso	(0) ry-relate	(0) d subset)	All-cause	100.0 +.0/1	99.9 +.0/1	99.8 +.1/1	99.8 +.1/1	99.7 +.1/2	99.7 +.1/2 (68 mo)						
Sigma 300 DR	SDR303, SDR306	Aug-99	91,000	62,000	42	28 (———	2 - total —	26)	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0 (71mo)						
		nnect Wire		Potential Sej <u>152</u> – 1999	paration	(10) (adviso	(0) ry-relate	(10) d subset)	All-cause	100.0 +.0/0	99.9 +.0/0	99.8 +.0/0	99.7 +.1/1	99.5 +.1/1	99.5 +.1/1 (71mo)						

Device Survival Summary continued

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~	el ber	US Market Release	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	apy Function promised		Device	e Surviv	al Prob	ability (%)							
Family	Model Number	US M Rele	Regis US In	Estin Activ Impla	Norn Depl	Malfu	Ther Not 0	Therapy l Compron	Survival Probabilities	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yı
Sigma 300 SR	SSR303, SSR306	Sep-99	45,000	26,000	22	4 (1 - total —	3)	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (69 mo)						
	Advisories: of Intercon Manufactu	nect Wires		Potential Sep <u>152</u> – 1999	paration	(1) (adviso	(0) ory-relate	(1) d subset)	All-cause	100.0 +.0/0	99.9 +.0/0	99.9 +.0/1	99.8 +.1/1	99.6 +.1/2	99.5 +.2/3 (69 mo)						
Sigma 300 VDD	SVDD303	Sep-99	1,000	400	0	0 (0 - total ——	0)	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (56 mo)							
	Advisories of Intercon Manufactu	nect Wires		Potential Sep <u>152</u> – 1999	paration	(0) (adviso	(0) ory-relate	(0) d subset)	All-cause	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0 (56 mo)							
Spectrax S	5940, 5940LP, 5941	Jul-83	25,000	1,000	802	76	—	_	Malfunction- free	99.9 +.0/1	99.8 +.0/1	99.8 +.1/1	99.8 +.1/1	99.7 +.1/1	99.7 +.1/1	99.7 +.1/1	99.6 +.1/1	99.6 +.1/1	99.5 +.1/1	99.5 +.1/1	99.5 +.1/2 (252 mo
									All-cause	99.7 +.1/1	99.6 +.1/1	99.5 +.1/1	99.4 +.1/1	99.2 +.1/1	99.0 +.1/2	98.6 +.2/2	97.5 +.3/3	91.2 +.6/6	80.6 +1.0/-1.0	73.3 +1.2/-1.3	64.5 +1.8/-1.9 (252 mo
Spectrax SXT	8420, 8422, 8423, 8423M	Oct-81	111,000	3,000	4,391	466	_	_	Malfunction- free	100.0 +.0/0	99.9 +.0/0	99.9 +.0/0	99.8 +.0/0	99.7 +.0/0	99.7 +.0/0	99.6 +.0/1	99.5 +.1/1	99.3 +.1/1	99.1 +.1/1	99.1 +.1/1	99.1 +.1/1 (262 mo
									All-cause	99.9 +.0/0	99.8 +.0/0	99.7 +.0/0	99.5 +.0/0	99.2 +.1/1	98.8 +.1/1	98.1 +.1/1	96.8 +.1/2	91.0 +.3/3	81.9 +.4/4	72.0 +.6/6	47.7 +1.7/-1.8 (262 mg
Thera D	7944, 7945, 7946	Jan-95	2,000	30	168	2	—	_	Malfunction- free	99.9 +.0/3	99.9 +.0/3	99.9 +.0/3	99.9 +.0/3	99.9 +.0/3	99.9 +.0/3	99.9 +.0/3	99.9 +.0/3	99.7 +.3/-1.3 (110 mo)			
									All-cause	99.9 +.1/3	99.8 +.2/4	98.9 +.4/7	97.3 +.8/-1.0	93.6 +1.3/-1.6	90.2 +1.6/-1.9	83.0 +2.3/-2.6	66.8 +3.5/-3.8	48.4 +4.8/-5.0 (110 mo)			
Thera DR-40	7940, 7941, 7942	Jan-95	30,000	20	2,828	37	—	_	Malfunction- free	100.0 +.0/0	100.0	99.9 +.0/0	99.9 +.0/1	99.8 +.0/1	99.8 +.0/1	99.8 +.0/1	99.8 +.0/1	99.8 +.0/1 (113 mo)			
	Advisory: Circuit Fail		<u>54</u> – 1997 P	otential Integ	grated	_	_	-	All-cause	100.0 +.0/0	99.7 +.1/1	98.5 +.1/2	96.5 +.2/3	93.6 +.3/4	88.8 +.5/5	80.8 +.6/6	66.4 +.9/9	22.1 +2.6/-2.5 (113 mo)			
Thera DR-50	7950, 7951, 7952	Jan-95	5,000	1,000	111	1	-	-	Malfunction- free	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1	100.0 +.0/1 (125 mo)		
	Advisory: s Circuit Fail		5 <u>4</u> – 1997 Po	otential Integ	rated	-	_	-	All-cause	100.0 +.0/1	100.0 +.0/1	99.7 +.1/2	99.5 +.2/3	99.2 +.3/4	98.5 +.4/5	97.3 +.6/7	96.0 +.7/9	87.2 +1.7/-1.9	83.6 +2.4/-2.8 (125 mo)		

Device Survival Summary continued



<u>م</u>	el ber	Market ease	Registered US Implants	Estimated Active US Implants	Normal Battery Depletions	Malfunctions	Therapy Function Not Compromised	Therapy Function Compromised		Devic	e Surviv	val Prob	ability (%)							
Family	Model Number	US Mark Release	Regi US In	Estin Activ Implå	Norn Depl	Malfi	Ther Not (Ther Com	Survival Probabilities	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr
Thera S	8944, 8945, 8946	Jan-95	3,000	200	76	3	_	_	Malfunction- free	100.0	100.0	99.9 +.1/4	99.8 +.2/5	99.8 +.2/5	99.8 +.2/5	99.8 +.2/5	99.8 +.2/5	99.8 +.2/5 (118 mo)			
									All-cause	100.0 +.0/0	99.9 +.1/3	99.5 +.2/5	98.4 +.5/8	96.7 +.9/-1.2	95.9 +1.0/-1.3	93.2 +1.5/-1.8	88.5 +2.1/-2.6	70.4 +4.3/-4.9 (118 mo)			
Thera SR	8940, 8941, 8942	Jan-95	14,000	1,000	770	16	-	-	Malfunction- free	100.0 +.0/0	99.9 +.0/1	99.9 +.0/1	99.8 +.1/1	99.8 +.1/1	99.8 +.1/1	99.8 +.1/1	99.8 +.1/1	99.8 +.1/1	99.8 +.1/1 (123 mo)		
	Advisory Circuit Fa	: <u>see page 1</u> ailure	<u>54</u> – 1997 Po	otential Integ	grated	—	—	—	All-cause	99.9 +.1/1	99.5 +.1/1	99.0 +.2/2	97.8 +.3/3	96.3 +.4/4	93.4 +.5/6	87.9 +.8/9	77.5 +1.2/-1.3	54.6 +2.3/-2.4	53.7 +2.4/-2.5 (123 mo)		
Thera-i D	7964i, 7965i, 7966i	Oct-95	3,000	1,000	57	1	-	-	Malfunction- free	100.0 +.0/0	100.0 +.0/2	100.0 +.0/2	100.0 +.0/2	100.0 +.0/2	100.0 +.0/2	100.0 +.0/2	100.0 +.0/2	100.0 +.0/2 (113 mo)			
									All-cause	100.0 +.0/0	99.9 +.1/2	99.6 +.2/3	99.5 +.2/4	99.1 +.3/5	97.5 +.6/8	96.2 +.8/-1.1	93.3 +1.3/-1.6	88.2 +2.5/-3.2 (113 mo)			
Thera-i DR	7960i, 7961i, 7962i	Oct-95	122,000	42,000	2,176	49	-	-	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	99.9 +.0/0	99.9 +.0/0	99.9 +.0/0 (117 mo)			
									All-cause	100.0 +.0/0	99.9 +.0/0	99.7 +.0/0	99.5 +.0/0	99.0 +.1/1	98.2 +.1/1	96.6 +.1/1	93.4 +.2/2	81.3 +1.5/-1.6 (117 mo)			
Thera-i DR	7968i	Jul-96	4,000	1,000	112	3	_	_	Malfunction- free	100.0 +.0/0	100.0 +.0/0	99.9 +.1/2	99.9 +.1/2	99.9 +.1/2	99.9 +.1/2	99.9 +.1/2	99.9 +.1/2	99.9 +.1/2 (100 mo)			
									All-cause	100.0 +.0/0	99.8 +.1/2	99.5 +.2/3	98.6 +.4/6	97.0 +.6/8	94.2 +1.0/-1.1	90.1 +1.4/-1.6	80.7 +2.8/-3.2	75.9 +3.8/-4.3 (100 mo)			
Thera-i S	8964i, 8965i, 8966i	Oct-95	4,000	1,000	27	1	-	-	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0	100.0 +.0/3	100.0 +.0/3	100.0 +.0/3	100.0	100.0	100.0 +.0/3 (113 mo)			
									All-cause	99.9 +.0/2	99.9 +.1/2	99.8 +.1/3	99.3 +.3/5	98.9 +.4/6	98.2 +.5/8	97.4 +.7/-1.0	97.0 +.8/-1.1	94.4 +1.5/-2.0 (113 mo)			
Thera-i SR	8960i, 8961i, 8962i	Oct-95	50,000	13,000	522	7	-	-	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0	100.0 +.0/0 (117 mo)			
									All-cause	100.0 +.0/0	99.9 +.0/0	99.7 +.1/1	99.4 +.1/1	99.0 +.1/1	98.3 +.2/2	97.1 +.2/2	95.2 +.3/4	89.2 +2.0/-2.4 (117 mo)			
Thera-i VDD	8968i	Mar-96	5,000	2,000	20	0	_	_	Malfunction- free	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0 +.0/0	100.0	100.0 +.0/0 (111 mo)			
									All-cause	100.0 +.0/1	99.8 +.1/2	99.6 +.1/3	99.6 +.2/3	99.3 +.2/4	99.2 +.3/4	99.2 +.3/4	98.4 +.5/7	97.3 +1.0/-1.7 (111 mo)			

IPG Elective Replacement Time Indicators

Family	Model Number	Indicators*
Activitrax	8400, 8402, 8403, 8403M	Rate and mode change to 65 ppm and VVI (non-rate responsive). Telemetry indication.
Activitrax II	8412, 8413, 8413M, 8414	If programmed to non-rate responsive mode (e.g. VVI), rate
Legend	8416, 8417, 8417M, 8418, 8419	decrease of 10% from programmed rate. Telemetry indication. If programmed to rate responsive mode (e.g. VVIR), rate change to 65 ppm
Legend II	8424, 8426, 8427	and mode change to VVI. Telemetry indication.
AT500	AT501, 7253, 7253B	 Telemetry indication. Pacing mode and rate (magnet and non-magnet) as programmed
Classix	8436, 8437, 8438	30% increase in pulse width (measured with the Model 9431 transmitter). Rate decrease of 10% from programmed rate. Telemetry indication.
Micro Minix	8360	Rate decrease of 10% from programmed rate. Telemetry indication. In a 1993 Product Education Brief, Medtronic provided an update to the longevity of the Micro Minix Model 8360 pacemaker. Analysis indicates that the Micro Minix battery delivers approximately 0.1 amp-hour less capacity than originally projected during the period from ERI. This represents an average longevity from BOL to ERI of 6.7 years (≥ 90 days from ERI to EOL) under nominal parameters, 500 ohms and 100% pacing. The original projection was 7.8 and 1.5 years respectively under the same conditions.
Minix/ Minix ST	8330, 8331, 8331M, 8340, 8341, 8341M, 8342	Rate decrease of 10% from programmed rate. Telemetry indication.
Pasys/ Pasys ST	8316, 8317, 8318, 8320, 8322, 8329	Rate decrease of 10% from programmed rate. Telemetry
Prevail S	8084, 8085, 8086	indication.
Spectrax S	5940, 5940LP, 5941, 5984, 5984LP, 5985	Rate decrease of 10% from preset
Spectrax SXT	5976, 5977 (SX-HT), 8420, 8422, 8423, 8423M,	or programmed rate. Telemetry indication in SXT family devices.
Synergyst II	7070, 7071, 7071A, 7071M	 Telemetry indication. Magnet rate of 75 ppm, or Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

* Unless otherwise specified, "rate" refers to pacing rate without magnet applied

Note: Testing of explanted units at room temperature may introduce an error due to the change in temperature in certain models. For details, call Medtronic Technical Services at 1 (800) 505-4636.

	Model	
Family	Number	Indicators*
Elite	7074, 7075, 7076, 7077	
Elite II	7084, 7085, 7086	
EnPulse DR	EIDR01, EIDR06, EIDR21	
EnPulse 2 DR	E2DR01, E2DR03, E2DR06, E2DR21, E2DR31	
EnPulse 2 SR	E2SR01, E2SR03, E2SR06	
EnPulse 2 VDD	E2VDD01	
EnRhythm DR	P1501DR	
InSync	8040	
InSync III	8042	
Kappa 400 DR	KDR401, KDR403	
Kappa 400 SR	KSR401, KSR403	
Kappa 600 DR	KDR601, KDR603, KDR606, KDR651, KDR653	
Kappa 700 D	KD701	
Kappa 700 DR	KDR701, KDR703, KDR706, KDR721	
Kappa 700 SR	KSR701, KSR703, KSR706	
Kappa 700 VDD	KVDD701	
Kappa 800 DR	KDR801, KDR803	
Kappa 900 DR	KDR901, KDR903, KDR906	
Kappa 900 SR	KSR901, KSR903, KSR906	
Kappa 900 VDD	KVDD901	
Kappa 920 DR	KDR921	
Minuet	7107, 7108	
Preva D	7068	 Telemetry indication.
Preva DR	7088, 7089	 Rate and mode change to 65 ppm and V/V/I
Preva SR	8088, 8089	to 65 ppm and VVI respectively (VOO/65
Preva ST DR	7078	with magnet).
Prodigy D	7864, 7865, 7866	
Prodigy DR	7860, 7861, 7862	
Prodigy S	8164, 8165, 8166	
Prodigy SR	8158, 8160, 8161, 8162	
Sigma 100 S	SS103, SS106	
Sigma 200 D	SD203	
Sigma 200 DR	SDR203	
Sigma 200 SR	SSR203	
Sigma 300 DR	SDR303, SDR306	
Sigma 300 S	SS303	
Sigma 300 SR	SSR303, SSR306	
Sigma 300 VDD	SVDD303	
Symbios	7005, 7005L, 7006, 7008	
Thera D	7944, 7945, 7946	
Thera DR-40	7940, 7941, 7942	
Thera DR-50	7950, 7951, 7952	
Thera S	8944, 8945, 8946	
Thera SR	8940, 8941, 8942	
Thera-i D	7964i, 7965i, 7966i	
Thera-i DR	7960i, 7961i, 7962i, 7968i	
Thera-i S	8964i, 8965i, 8966i	
Thera-i SR	8960i, 8961i, 8962i	
Thera-i VDD	8968i)

Method for Estimating Lead Performance

Medtronic CRM has tracked lead survival for over 20 years with its multicenter chronic lead studies.

Leads Performance Analysis

The human body is a hostile environment for an implantable device. Typically, the human body will attack and attempt to isolate or destroy any foreign object, including leads. Additionally, implanted leads are subjected to bending and twisting associated with heart motion, body motion, and patient anatomy, which can cause a lead to wear out.

In this environment, pacemaker and defibrillation leads cannot be expected to last forever. While implantable pulse generators (IPGs) and implantable cardioverter defibrillators (ICDs) have a battery that will deplete after a predictable length of time, a lead's longevity cannot be predicted nor are there simple indicators that a lead is approaching the end of its service life. Therefore, to determine that a lead may be approaching the end of its service life requires regular monitoring while implanted and evaluation of lead integrity upon IPG or ICD replacement.

Returned Product Analysis Shortfalls

All leads and lead segments returned to Medtronic are analyzed to determine whether or not they meet performance limits established by Medtronic. Although returned product analyses are valuable for gaining insight into lead failure mechanisms, this data cannot be used by itself for determining the survival probability of leads because only a small fraction of leads are explanted and returned for analysis. Additionally, those leads which are returned cannot be assumed to be statistically representative of the performance of the total population for a given lead model. Partial or total lead extraction can result in significant damage to a lead, making a definitive analysis of a suspected failure and its cause impossible. Thus, lead survival probabilities are more appropriately determined through a clinical surveillance study. Medtronic's study for tracking lead survival is its System Longevity Study.

System Longevity Study (SLS)

The SLS is a prospective, multicenter study designed to monitor the performance of market released cardiac therapy products. The SLS is the unification of the Chronic Lead Study (CLS) for pacing leads and the Tachyarrhythmia Chronic Systems Study (TCSS) for ICD leads, which have been ongoing in several geographies since 1983 and 1991, respectively. More than 35 centers participating as CLS study sites or TCSS study sites, or both, are expected to complete the unification to become SLS study sites throughout the next year. Through these studies, Medtronic has over 20 years of lead data from over 65,000 leads studied.

Patients are eligible for enrollment in the study if

- 1) They are within 6 months post-implant of a Medtronic market-released lead connected to a market-released IPG, ICD, or CRT device and the lead is used for a pacing, sensing, or defibrillation application, or
- 2) They participated in a qualifying study of a Medtronic cardiac therapy product and for whom the product is market-released, complete implant and follow-up data are available, and the data is appropriately and legally released for use in the study.

Methods

The SLS protocol requires regular follow-up reporting on all leads actively followed in the study. Each study center must inform Medtronic whenever a lead complication has occurred or when a patient is no longer participating in the study. The data analyses assume that the patient is still part of the study and there are no lead complications at the time of data update unless specifically reported by the center or by correlation with returned product analysis. Follow-up times are calculated from the implant date to the earlier of the complication date, out-of-service date (for example, patient leaves the study or the lead is no longer being used), or the cutoff date of the report. If a lead experiences more than one complication, the first is used to calculate survival time; although all complications associated with a lead are reported in PPR tables.

continued

Method for Estimating Lead Performance continued

The Standard Actuarial Method is used to determine estimates of lead survival.

The actuarial method is used to determine estimates of lead-related adverse event-free survival. Greenwood's formula is used to calculate corresponding 95% confidence intervals for the standard errors and the complementary log-log method is used to produce the confidence bounds. Survival curves are presented for leads, grouped according to similarity in design and function. New leads are added when there are more than 100 implanted and no fewer than 50 leads followed for at least 6 months. Data for individual models are plotted against grouped results for comparative purposes; however, the minimum 50 lead criterion is not applied to these curves.

Lead Complications

The SLS complication criteria are defined below. These criteria do not, however, enable a lead integrity or "hardware" failure to be conclusively differentiated from other clinical events such as an undetected lead dislodgement, exit block, or concurrent pulse generator failure manifested as a sensing or capture problem.

A lead-related complication is considered to have occurred if at least one of the following clinical observations is reported and at least one of the following clinical actions is made 30 days or more after the implant.

Clinical Observations

- Failure to capture
- Failure to sense/Undersensing
- Oversensing
- Abnormal pacing impedance (based on lead model, but normal range is typically 200-3000 ohms)
- Abnormal defibrillation impedance (based on lead model, but normal range is typically 20-200 ohms)
- Insulation breach, observed visually, that has degraded system performance
- Conductor fracture, observed visually or radiographically
- Extracardiac stimulation
- Cardiac perforation
- Lead dislodgement

Clinical Actions

- Lead surgically abandoned/capped
- Lead electrically abandoned/capped
- Lead explanted
- Lead replaced
- Polarity reprogrammed (i.e., bipolar to unipolar; unipolar to bipolar)
- Lead use continued based on medical judgment despite a known clinical performance issue
- Other lead-related surgery performed (e.g., lead mechanical alteration or unsuccessful repositioning)

Note: Successful lead repositioning is not a qualifying action.

Left-Heart Leads

2187 Attain

2187 Attain		Product Charact	eristics
US Market Release	Aug-01	Serial Number Pre	fix LEY
Number of Leads Enrolled in Study	125	Type and/or Fixati	ion Tranvenous, Left Ventricular Cardia Vein, Distal Continuous Curve
Complications in Study	0	Polarity	Unipolar
Cumulative Months of Follow-Up in Study Advisories	3,779 None	Steroid	No
Auvisories	ivone		

Years After Implant

1 yr

2 yr

at 33 mo

(%)
robability
Survival Pi
Lead

Lead Survival Probability (%)

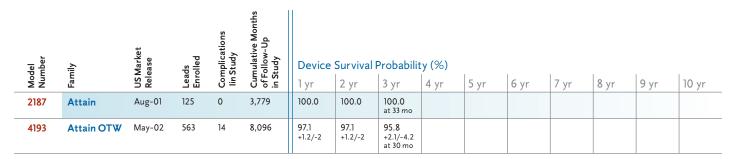
4193 Attain OTW

	VI VV			Product Cri	aracteristic.	,		
US Market Release		May-02	2	Serial Numb	er Prefix	BAA		
Number of Leads En	rolled in Study	563	3	Type and/or	Fixation		, Left Ventricu Double Curve	lar Cardia
Complications in Stu	dy]4	ļ.				Double Curve	
Ex	tra Cardiac Stim Failure to C Dislodg Misc:	apture 6	ļ.	Polarity Steroid		Unipolar Yes		
Cumulative Months of	of Follow-Up in S	tudy 8,096	5					
Advisories		None	2					
ears After Implant	÷							
1 yr	2 yr							
		95.8 at 30 mo						
1 yr	2 yr							
1 yr	2 yr							
1 yr	2 yr							
1 yr	2 yr							

Product Characteristics

Left-Heart Leads continued

Lead Survival Summary (95% Confidence Interval)



Source: System Longevity Study Data as of July 11, 2005

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
2187	Attain	Aug-01	16,800	12,400	7	0	16
2188	Attain	Aug-05	2,800	1,800	1	1	0
4193	Attain OTW	May-02	81,500	68,400	51	8	56
4194	Attain	Aug-04	18,200	17,300	16	1	3

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes, and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

Left-Heart Leads continued

Reference Chart

Model Number	Family	Туре	Insulation	Conductor Material	Tip Electrode	Connector Type
2187	Attain	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 UNI
2188	Attain	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 BI
4193	Attain OTW	Transvenous Cardiac Vein Preformed Body	Polyurethane (55D)	MP35N	Platinized Platinum	IS-1 UNI
4194	Attain	Transvenous Cardiac Vein Preformed Body	Polyurethane/ Silicone (55D)	MP35N	Platinum Alloy	IS-1BI

Defibrillation Leads

US Marke	et Release		Feb-	93		Serial Nur	nber Prefix	TBH, TBG, TBB	, TAD, TAC, or T
	of Leads Enro	,		98			or Fixation		b Patch, Suture
Complica	ations in Study	y		26		Polarity		Defib Electrode	e only
		Conductor F edance Out c ardiovert/Det Insulatior	of Range fibrillate	20 3 2 1		Steroid		No	
Cumulati	ive Months of	Follow-Up in	Study 17,4	32					
Advisorie	25		No	ne					
	ter Implant	2 yr	3 yr	_ead group o	overall 5 yr	б yr	ndividual lead r	nodels	
		2 yr 98.6	1		1		1	nodels 82.3 at 90 mo	
Years Aft	1 yr 100	98.6	3 yr	4 yr 94.7	5 yr	6 yr	7 yr 82.3	82.3	
Years Aft	1 yr 100	98.6	3 yr 95.8	4 yr 94.7	5 yr	6 yr 84.8	7 yr 82.3 6721	82.3 at 90 mo	
Years Aft	1 yr 100	98.6	3 yr 95.8	4 yr 94.7	5 yr	6 yr 84.8	7 yr 82.3 6721	82.3 at 90 mo	

6932 Sprint

Lead Survival Probability (%)

US Market	t Release		Aug-	96		Serial Nu	mber Prefix	TCA			
		olled in Study	4	09		Type and	/or Fixation	Transvenous, Vent, Defib and P Sense, Tines			
Complicat	ions in Study	ý		7			D L V		True bipolar with one coil		
	Fail to C		Capture	1 1 2 1 2		Polarity Steroid		Yes	ipolar with o	ne coli	
Cumulativ	e Months of	Follow-Up in	Study 15,7	44							
Advisories	5		No	ne							
ears Afte	er Implant										
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr					
	99.4	98.3	98.3	98.3	97.6	97.6	96.1 at 78 mo				

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05 Market r	Release		Dec-	93		Serial Nu	mber Prefix	ΤΑΤ, ΤΒΙ	J, or TAF	
Number of	Leads Enro	lled in Study	9	64		Type and	/or Fixation	Tranven	eous CS or SV	C Defib
Complicatio	ons in Study	/		23		Polarity		One Def	ib Coil	
		ardiovert/Def Insulation	f Range gement ibrillate	14 2 1 2 3		Steroid		No		
Cumulative	Months of	Follow-Up in S	Study 42,9	35						
Advisories			No	ne						
Years After	Implant			_ead group o	overall		ndividual lea	ad models		
	1 yr	2 yr	3 yr	4 yr	5 yr	б yr	7 yr	8 yr	9 yr	
	99.6	99.2	99.2	98.5	96.8	96.1	94.7	94.1	93.3	93.3 at 114 m
	000000000000000000000000000000000000000	**********		**************************************	*****					933 93.8% 963 93.5%
									5937 87.4%	1

6936, 6966 Transvene

6936, 6966 Transver				Product	Characteris	TICS				
US Market Release	D	ec-93		Serial Nu	mber Prefix	TAV or T	AL			
Number of Leads Enrolled in S	tudy	1,351		Type and	/or Fixation		ious, Vent, De	fib and Pac		
Complications in Study		135				,	Sense, Screw-in			
Condu	ctor Fracture	16		Polarity	Polarity		olar/ One Coil			
Fa Inaj Inaj Insj	t/Defibrillate re to Capture ilure to Sense opropriate VF opropriate VT alation Breach Misc: Other le Stimulation Oversensing	2 5 1 3 13 1 12 5 1 73 3		Steroid		No				
Cumulative Months of Follow-	Up in Study 🛛 🤅	51,100								
Advisories		None								
ears After Implant		Lead group c	overall	••••••	ndividual lea	id models				
1 yr 2 y	r 3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr			
99.1 98.	5 97.1	96	92.7	86.9	78.6	73.9	66.3	63.7 at 114 mg		

÷= -	100											
Р	100			THE REPORT OF TAXABLE PARTY OF TAXABLE P	000000000000000000000000000000000000000							
ba	90											
Pro	80								••••	6966 65.2%		
vival	00 70											
Sur	70								6936 63.7%	*******		
ad	60											
Le	() .	1 2	2 3	3	4	5 6	5 7	7 8	3 9)	10

Lead Survival Probability (%)

Lead Survival Probability (%)

Source: System Longevity Study Data as of July 11, 2005

6939, 6999 Sub-Q Patch

US Mar	ket Release		Dec-	-93		Serial Numb	er Prefix	TBA or T	ΓΑΡ	
Numbe	r of Leads Enro	lled in Study	3	389		Type and/or	Fixation	Subcuta	neous Defit	o Patch, Suture
Complie	cations in Study	,		20		Polarity		Defib Ele	ectrode only	у
	Fail to C	Conductor F ardiovert/Def Insulation Misc	fibrillate	10 2 6 2		Steroid		No		
Cumula	ative Months of	Follow-Up in	Study 16,8	373						
Advisor	ries		No	ne						
Years A	fter Implant			Lead group o	overall	······ Ind	ividual lead	l models		
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr			
	99.1	98.7	98.2	98.2	94.0	90.6	87.0			
	22.1	20.7	20.2		24.0	90.0	07.0			
		120.7	190.2		I	90.0	87.0			
-					I	6939 90.2%	87.0			
					I	6939 90.2%	87.0			
					I	6939 90.2%	87.0			

Product Characteristics

6942 Sprint

Lead Survival Probability (%)

US Mar	rket Release		Jul-9	97		Serial Num	per Prefix	ТСВ			
Numbe	er of Leads Enro	lled in Study	35	50		Type and/o	r Fixation	Transvenous, Vent, Defib and Pa Sense, Tines			
Compli	ications in Study	1		6		Polarity					
				1 1 1 3		Steroid		Integrated Bipolar/Two Coils Yes			
Cumula	ative Months of	Follow-Up in	Study 12,44	44							
	ries		Nor	ne							
Advisor	ries After Implant	2 yr	Nor 3 yr	4 yr	5 yr						
Advisor	After Implant	2 yr 99.3	I		5 yr 96.5	96.5 at 66 mo					
Advisor	After Implant		3 yr	4 yr							
Advisor	After Implant		3 yr	4 yr							
Advisor	After Implant		3 yr	4 yr			7	8	9	10	

6943 Sprint

US Market Release	Oct-97	
Number of Leads Enrolled in Study	1,302	
Complications in Study	38	
Conductor Fracture Dislodgement Fail to Cardiovert/Defibrillate Failure to Capture Failure to Sense Inappropriate VF Insulation Breach Misc: Other Oversensing Pacing Impedance Out of Range	1 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	
Cumulative Months of Follow-Up in Study	41,763	
Advisories	None	

Product Characteristics

Serial Number Prefix	TCE
Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Polarity	True Bipolar/One Coil
Steroid	Yes

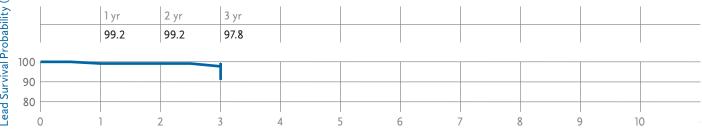
Years After Implant

	1 yr	2 yr	3 yr	4 yr	5 yr	б yr					
	98.8	97.9	96.9	95.9	94.2	93.6					
100											
100											
90											
80											
1											
0	1	2	3	4	5	6	7	8	9	10	

6944 Sprint Ouattro

6944 Sprint Quattro		Product Characteristics
US Market Release	Dec-00	Serial Number Prefix TDC
Number of Leads Enrolled in Study	162	Type and/or Fixation Transvenous, Vent, Defib and Pace/ Sense, Tines
Complications in Study	3	Polarity True Bipolar/Two Coils
Inappropriate Misc: Oth		Steroid Yes
Cumulative Months of Follow-Up in Study	4,284	
Advisories	None	

Years After Implant



6945 Sprint

US Market Release		Sep-97	
Number of Leads Enrolle	ed in Study	1,150	
Complications in Study		18	
	Conductor Fracture Failure to Sense Inappropriate VF Misc: Other Muscle Stimulation Oversensing dance Out of Range	2 3 2 1 7 2	
Cumulative Months of Fo	ollow-Up in Study	39,033	
Advisories		None	

Product Characteristics

Serial Number Prefix	TDA
Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Polarity	Integrated Bipolar/Two Coils
Steroid	Yes

Years After Implant

(%)		Years After	Implant									
bability			1 yr	2 yr	3 yr	4 yr	5 yr					
bab			99.6	99.1	98.9	98.1	96.3	95.6				
Pro			1					at 66 mo	1			,
ead Survival	100											
nrvi	90						-					
d Si	80											
Lea	(C	1	2	3	4	5	6	7 8	8	9 1	0

6947 Sprint Quattro Secure

US Market Release	Nov-01
Number of Leads Enrolled in Study	1,317
Complications in Study	9
Conductor Fracture Defib Impedance Out of Range Dislodgement Failure to Sense Insulation Breach Misc: Other Oversensing	1 2 1 1 2 1
Cumulative Months of Follow-Up in Study	21,747
Advisories	None

Product Characteristics

Serial Number Prefix	TDG
Type and/or Fixation	Transvenous, Vent, Defib and Pace/ Sense, Screw-in
Polarity	True Bipolar/Two Coils
Steroid	Yes

Years After Implant

(%)		Years After	Implant									
bility			l yr	2 yr	3 yr							
bab			99.3	99.3	98.4							
l Pro	100											
vival					1							
Surv	90											
ad	80											
Ľ		0	1	2	3 4	4 .	5	6	7 8	3	9 10	0

Lead Survival Summary (95% Confidence Interval)

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow–Up in Study	Device	Survival I	Probabilit 3 yr	:y (%) 4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
6721, 6921	Epicardial Patch	Feb-93	398	26	17,432	100.0	98.6 +0.9/-2.4	95.8 +2/-3.4	94.7 +2.3/-3.9	92.7 +2.9/-4.7	84.8 +5/-7.2	82.3 +5.7/-7.9	82.3 +5.7/-7.9 at 90 mo		
6932	Sprint	Aug-96	409	7	15,744	99.4 +0.4/-1.9	98.3 +1/-2.4	98.3 +1/-2.4	98.3 +1/-2.4	97.6 +1.4/-3	97.6 +1.4/-3	96.1 +2.3/-5.7 at 78 mo			
6933, 6937, 6963	SVC/CS	Dec-93	964	23	42,935	99.6 +0.3/-0.8	99.2 +0.4/-1.1	99.2 +0.4/-1.1	98.5 +0.7/-1.4	96.8 +1.3/-2.2	96.1 +1.5/-2.4	94.7 +2/-3	94.1 +2.2/-3.4	93.3 +2.5/-3.9	93.3 +2.5/-3.9 at 114 mo
6936, 6966	Transvene	Dec-93	1,351	135	61,100	99.2 +0.4/-0.7	98.5 +0.6/-1	97.1 +0.9/-1.4	96.0 +1.2/-1.6	92.7 +1.7/-2.3	86.9 +2.6/-3.1	78.6 +3.6/-4.3	73.9 +4.2/-4.9	66.3 +5.3/-6.1	63.7 +5.8/-6.5 at 114 mo
6939, 6999	Sub-Q Patch	Dec-93	389	20	16,873	99.1 +0.6/-2	98.7 +0.8/-2.3	98.2 +1/-2.6	98.2 +1/-2.6	94.0 +2.7/-4.9	90.6 +3.8/-6.2	87.0 +4.9/-7.5			
6942	Sprint	Jul-97	350	6	12,444	99.3 +0.5/-2.2	99.3 +0.5/-2.2	98.2 +1.1/-3.1	97.5 +1.5/-3.5	96.5 +2/-4.7	96.5 +2/-4.7 at 66 mo				
6943	Sprint	Oct-97	1,302	38	41,763	98.8 +0.5/-0.8	97.9 +0.7/-1.1	96.9 +0.9/-1.4	95.9 +1.3/-1.7	94.2 +1.9/-2.7	93.6 +2.1/-3.1				
6944	Sprint Quattro	Dec-00	162	3	4,284	99.2 +0.7/-4.7	99.2 +0.7/-4.7	97.8 +1.7/-6.8							
6945	Sprint	Sep-97	1,150	18	39,033	99.6 +0.3/-0.7	99.1 +0.4/-1	98.9 +0.6/-1	98.1 +0.8/-1.5	96.3 +1.6/-2.6	95.6 +1.9/-3.4 at 66 mo				
6947	Sprint Quattro Secure	Nov-01	1,317	9	21,747	99.3 +0.3/-0.8	99.3 +0.3/-0.8	98.4 +1.1/-3.1							

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
6721	Epicardial Patch	Mar-94	1,700	800	0	12	0
6921	Epicardial Patch	Feb-93	7,000	1,400	5	65	0
6930	Sprint Fidelis	Jun-04	100	100	0	0	0
6931	Sprint Fidelis	Sep-04	1,400	1,300	2	1	0
6932	Sprint	Aug-96	15,200	7,700	16	36	7
6933	SVC/CS	Apr-94	8,500	3,000	17	118	5
6934S	Transvene	Mar-96	400	200	0	4	0
6936	Transvene	Apr-94	19,400	5,900	57	364	16
6937	SVC/CS	Mar-96	2,500	1,300	0	12	0
6937A	SVC/CS	Apr-01	600	500	0	0	0
6939	Sub-Q Patch	Apr-94	1,200	300	2	6	0
6942	Sprint	Jul-97	18,100	9,800	31	32	5
6943	Sprint	Oct-97	21,300	11,800	50	56	8
6944	Sprint Quattro	Dec-00	27,400	20,900	22	21	8
6945	Sprint	Sep-97	44,000	25,900	195	74	11
6947	Sprint Quattro Secure	Nov-01	118,500	96,300	204	60	12
6948	Sprint Fidelis	Sep-04	1,600	1,600	1	0	0
6949	Sprint Fidelis	Sep-04	57,700	54,900	176	17	19
6963	SVC/CS	Dec-93	5,400	1,600	14	59	8
6966	Transvene	Dec-93	5,200	1,100	33	81	3
6996	Sub-Q Lead	Jun-01	1,000	800	0	0	0
6999	Sub-Q Patch	Dec-93	3,100	800	2	26	1

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes, and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

Reference Chart

Model			Pin Cor	figuration	Lead Body	Insulation,	
Number	Family	Туре	Pace/ Sense	High Voltage	Diameter	Lead Body	Fixation, Steroid
6721	Epicardial Patch	Epi Patch	_	DF-1	S, M, L	Silicone, Single Lumen	Suture
6921	Epicardial Patch	Epi Patch	_	6.5 mm	S, M, L	Silicone, Single Lumen	Suture
6930	Sprint Fidelis	Endo RV True Bipolar Sensing	IS-1	DF-1	6.6 Fr	Silicone with polyurethane overlay, Multilumen	Passive, Steroid
6931	Sprint Fidelis	Endo RV True Bipolar Sensing	IS-1	DF-1	6.6 Fr	Silicone with polyurethane overlay, Multilumen	Active, Steroid
6932	Sprint	Endo RV True Bipolar Sensing	IS-1	DF-1	7.8 Fr	Silicone, Multilumen	Passive, Steroid
6933	SVC/CS	Endo SVC/CS Coil	_	DF-1	7 Fr	Silicone, Single Lumen	Passive
6934S	Transvene	Endo RV True Bipolar Sensing	IS-1	DF-1	12 Fr	Silicone, Coaxial	Passive, Steroid
6936	Transvene	Endo RV True Bipolar Sensing	IS-1	DF-1	10 Fr	Polyurethane, Coaxial	Active
6937	SVC/CS	Endo SVC Coil	_	DF-1	5.5 Fr	Silicone, Single Lumen	Passive
6937A	SVC/CS	Endo SVC Coil	_	DF-1	7.5 Fr	Silicone with polyurethane overlay, Single Lumen	Passive
6939	Sub-Q Patch	SQ Patch	_	DF-1	One Size	Silicone, Single Lumen	Suture
6942	Sprint	Endo RV/SVC Integrated Bipolar Sensing	IS-1	2 DF-1	7.8 Fr	Silicone, Multilumen	Passive, Steroid
6943	Sprint	Endo RV True Bipolar Sensing	IS-1	DF-1	7.8 Fr	Silicone, Multilumen	Active, Steroid
6944	Sprint Quattro	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	8.2 Fr	Silicone with polyurethane overlay, Multilumen	Passive, Steroid
6945	Sprint	Endo RV/SVC Integrated Bipolar Sensing	IS-1	2 DF-1	7.8 Fr	Silicone, Multilumen	Active, Steroid
6947	Sprint Quattro Secure	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	8.2 Fr	Silicone with polyurethane overlay, Multilumen	Active, Steroid
6948	Sprint Fidelis	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	6.6 Fr	Silicone with polyurethane overlay, Multilumen	Passive, Steroid
6949	Sprint Fidelis	Endo RV/SVC True Bipolar Sensing	IS-1	2 DF-1	6.6 Fr	Silicone with polyurethane overlay, Multilumen	Active, Steroid
6963	SVC/CS	Endo SVC/CS Coil	-	6.5 mm	7 Fr	Silicone, Single Lumen	Passive
6966	Transvene	Endo RV True Bipolar Sensing	3.2 mm L.P.	6.5 mm	10 Fr	Polyurethane, Coaxial	Active
6996	Sub-Q Lead	SQ Coil	-	DF-1	7.5 Fr	Silicone, Single Lumen	Passive
6999	Sub-Q Patch	SQ Patch	_	6.5 mm	One Size	Silicone, Single Lumen	Suture

Ventricular Pacing Leads

4003, 4003M CapSure

US Market Release Jul-86 Number of Leads Enrolled in Study 684 Complications in Study 7 Extra Cardiac Stimulation 2 Failure to Capture 4 Oversensing 1 Cumulative Months of Follow-Up in Study 41,175 Advisories None Years After Implant

Product Characteristics

Product Characteristics

Serial Number Prefix	IH or LAX
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	Yes

		1 yr	2 yr	3 yr	4 yr	5 yr	б yr	7 yr	8 yr	9 yr	
		99.3	99.3	99.3	99.1	99.1	98.8	98.5	98.5	98.5	98.5 at 111 mo
100									1		
90											
80											
0		 1 ·	 2 :	2	4 5	 5 6	-	 7 {	2 0) 10	0
0	1	1 .	۷ ۲	5	4	o () /	ζ	5	9 [(J

4004, 4004M CapSure

US Market Release Feb-89 Serial Number Prefix PS or LAV 1,462 Number of Leads Enrolled in Study Type and/or Fixation Transvenous, Vent., Tines **Complications in Study** 276 Polarity Bipolar **Conductor Fracture** 7 Steroid Yes **Electrical Abandonment** 1 Extra Cardiac Stimulation 2 Failure to Capture 131 Failure to Sense 62 Impedance Out of Range 32 Insulation (ESC) 4 Insulation (MIO) 4 Insulation (not further defined) 6 Medical Judgment 1 Oversensing 25 Unspecified Clinical Failure 1 Cumulative Months of Follow-Up in Study 71,546 Advisories 1 see page 157 – 1993 Lead Survival Below Expectations Years After Implant 4 yr 1 yr 2 yr 3 yr 5 yr 6 yr 7 yr 8 yr 9 yr 10 yr 99.7 99.2 95.6 85.4 73.6 59.3 52.9 47.7 65.1 46.1 46.1 at 126 mo 100 90 80 70 60 50 40 0 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21

Lead Survival Probability (%)

Lead Survival Probability (%)

Source: System Longevity Study Data as of July 11, 2005

4011 Target Tip

US Market Release	Nov-82	
Number of Leads Enrolled in Study	821	
Complications in Study	23	
Extra Cardiac Stimulatior Failure to Capture Insulation (not further defined Oversensing	9) 9	
Cumulative Months of Follow-Up in Study	54,262	
Advisories	None	

Product Characteristics

Serial Number Prefix	IB
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	No

Years After Implant

Lead Survival Probability (%)

lyr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr						
99.4	99.2	99.0	98.8	97.5	96.3	95.9	95.9	95.9	94.8	93.4	92.5	91.6	91.6	91.6	91.6					
															at 183 mo					
														_						
																				_
-				-		-														21
-					99.4 99.2 99.0 98.8 97.5		99.4 99.2 99.0 98.8 97.5 96.3 95.9	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 95.9	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 94.8	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 94.8 93.4	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 94.8 93.4 92.5	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 94.8 93.4 92.5 91.6	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 94.8 93.4 92.5 91.6 91.6	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 95.9 94.8 93.4 92.5 91.6 91.6 91.6	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 95.9 94.8 93.4 92.5 91.6 91.6 91.6 at 183 mo	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 95.9 94.8 93.4 92.5 91.6 91.6 91.6 91.6 at 183 mo	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 95.9 94.8 93.4 92.5 91.6 91.6 91.6 at 183 mo	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 95.9 94.8 93.4 92.5 91.6 91.6 91.6 91.6 at 183 mo	99.4 99.2 99.0 98.8 97.5 96.3 95.9 95.9 95.9 94.8 93.4 92.5 91.6 91.6 91.6 at 183 mo

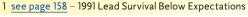
4012 Target Tip

Product Characteristics

US Market Release	Jul-83	Serial Number Prefix	HQ
Number of Leads Enrolled in Study	2,349	Type and/or Fixation	Transvenous, Vent., Tines
Complications in Study	315	Polarity	Bipolar
Conductor Fractur Extra Cardiac Stimulatio Failure to Captur Failure to Sens Impedance Out of Rang Insulation (BSC Insulation (MIC Insulation (not further defined Medical Judgmer Oversensin	n 3 e 126 e 76 e 26 C) 9 0) 4 d) 16 ht 1	Steroid	No
Cumulative Months of Follow-Up in Study	151,033		

Advisories

Years After Implant





Lead Survival Probability (%)

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rce: System Longevity Study Data as of July 11, 2005

US Market	Release		Aug	-85		Serial Nu	mber Prefix	KY		
Number of	Leads Enro	lled in Study	-	215		Type and	/or Fixation	Transver	10us, V or A, S	crew-in
	ions in Study			14		Polarity		Bipolar		
	Insulation	pedance Out n (not further Ove	Capture to Sense of Range defined) ersensing	2 4 2 1 2 3		Steroid		No		
Cumulative	e Months of	Follow-Up in	Study 12,	880						
Advisories			N	one						
Years Afte	r Implant									
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
	99.0	99.0	99.0	97.0	94.8	92.2	90.5 at 78 mo			

4016A	Screw-	In
TUIUA	JUICW-	

Lead Survival Probability (%)

40104	Screw-In	1				Product	Characterist	ics		
US Mark	ket Release		Feb	-88		Serial Nur	nber Prefix	ХВ		
Number	r of Leads Enroll	ed in Study		68		Type and	or Fixation	Transven	ous, V or A, S	Screw-in
Complic	ations in Study			1		Polarity		Bipolar		
		Failure to	Capture	1		Steroid		No		
Cumulat	tive Months of F	ollow-Up in	Study 3,	354						
Advisori	ies		N	one						
	fter Implant	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
	100									
	I					1	I	1		

US Market Release		Aug	g-91		Serial Nu	mber Prefix	LAK		
Number of Leads En	olled in Study	1,	140		Type and	d/or Fixation	Transvei	nous, Vent., T	ines
Complications in Stu	dy		12		Polarity		Unipolar		
Failure to C Insulation (not further d Lead Dislodg Cumulative Months of Follow-Up in St		r defined) 1 odgement 2			Steroid		Yes		
· · ·		· · ·							
			one						
Advisories				5 yr	6 yr	7 yr	8 yr	9 yr	
Advisories 'ears After Implant		N	one	5 yr 98.7	6 yr 98.7	7 yr 97.3	8 yr 97.3	9 yr 97.3	97.3 at 111 mc
Advisories Tears After Implant 1 yr	2 yr	3 yr	one 4 yr						
Advisories Tears After Implant	2 yr	3 yr	one 4 yr						

US Mar	ket Release		Oc	t-91		Serial Nu	mber Prefix	LAJ	
Number of Leads Enrolled in Study		1,1	202		Type and	/or Fixation	Transvend	ous, Vent., Tines	
Compli	cations in Study			3		Polarity		Bipolar	
		Failure to	Capture	3		Steroid		Yes	
Cumula	ative Months of	Follow-Up in	Study 49	.361					
Adviso	ries		N	one					
'ears A	After Implant	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
ears A	1	2 yr 99.8	3 yr 99.8	4 yr 99.8	5 yr 99.8	6 yr 99.8	7 yr 99.8	8 yr 99.8	99.8 at 105 mo
'ears A	1 yr					/			
'ears A	1 yr					/			

Lead Survival Probability (%)

	033 CapSure Z					Product	Characterist	ics		
US Market I	Release		Mar	-94		Serial Nu	mber Prefix	LCA		
Number of	Leads Enrolle	ed in Study		536		Type and	l/or Fixation	Transver	ious, Vent., Tines	
Complicatio	ons in Study			9		Polarity		Unipolar		
		Conductor Failure to		1 8		Steroid		Yes		
Cumulative	Months of Fo	ollow-Up in S	Study 26,	989						
Advisories			N	one						
leave After										
Years After	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr		
		2 yr 99.3	3 yr 99.1	4 yr 98.7	5 yr 98.3	6 yr 97.7	7 yr 97.7	8 yr 96.8	95.4 at 99 mo	
rears Artei	1 yr									
	1 yr									
rears Artel	1 yr									

4057 4057M Screw-In

Lead Survival Probability (%)

US Market I	Release		Aug	-88		Serial Nu	mber Prefix	XQ or LA	AN	
Number of	Leads Enrol	lled in Study		250		Type and	Type and/or Fixation		Transvenous, V or A, So	
Complicatio	ons in Study	/		7		Polarity		Unipolar		
	Ext	Conductor tra Cardiac Sti Failure to Failure	mulation	2 2 2 1		Steroid		No		
Cumulative	Months of	Follow-Up in	Study 14,	957						
Advisories			N	one						
ears After	r Implant	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	
lears After	1	2 yr 99.4	3 yr 99.4	4 yr 98.6	5 yr 97.6	6 yr 96.6	7 yr 95.5	8 yr 95.5	9 yr 94.1	94.1 at 114 m
(ears After	1 yr									
(ears After	1 yr									94.1 at 114 m
/ears After	1 yr									

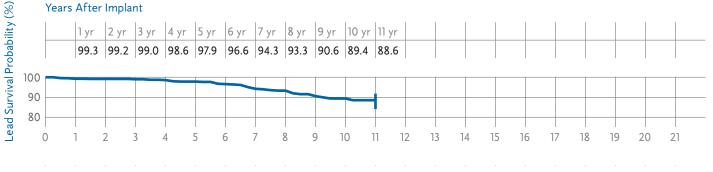
4058, 4058M Screw-In

US Market Release		Jan-89	
Number of Leads Enrolle	d in Study	1,634	
Complications in Study		46	
Impe	Conductor Frac Cardiac Stimula Failure to Cap Failure to S dance Out of R not further defi Lead Dislodger Overser	ation 3 oture 21 ense 11 ange 4 ned) 3 nent 1	
Cumulative Months of Fo	llow-Up in Stud	y 75,270	
Advisories		None	

Product Characteristics

Serial Number Prefix	ZY or LAW
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	No

Years After Implant



4068 CapSureFix

Lead Survival Probability (%)

00 market	Release		Mar	-96		Serial Nu	mber Prefix	LCE		
Number of	Leads Enro	lled in Study	1,	726		Type and	/or Fixation	Transver	ious, V or A, S	crew-in
Complicati	ions in Study	1		24		Polarity		Bipolar		
	Im	pedance Out	mulation Capture to Sense of Range	1 1 18 3 1		Steroid		Yes		
Cumulative	e Months of	Follow-Up in	Study 67,	434						
Advisories			N	one						
ears Afte	r Implant									
ears Afte	r Implant	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yı
ears Afte		2 yr 98.8	3 yr 98.8	4 yr 98.5	5 yr 98.0	6 yr 97.7	7 yr 96.9	8 yr 95.6	9 yr	10 yı
′ears Afte	l yr								9 yr	10 yr
ears Afte	l yr								9 yr	10 yı
ears Afte	l yr								9 yr	10 yr

92 Medtronic CRM Product Performance Report

4074 CapSure Ser	nse			Product Characteris	stics	
US Market Release		Jun-02		Serial Number Prefix	BBD	
Number of Leads Enrolled	in Study	362		Type and/or Fixation	Transveno	ous, Vent., Tines
Complications in Study		0		Polarity	Bipolar	
umulative Months of Follow-Up in Study		4,557		Steroid	Yes	
Advisories		None				
	2 yr					
			-			
1 2	3	4	5	6 7	8	9 10

4076 CanSureFix Novus

4076 CapSureFix Novus		Product Characterist	ics	
US Market Release	Feb-04	Serial Number Prefix	BBL	
Number of Leads Enrolled in Study	143	Type and/or Fixation	Transvenous, V	/ or A, Screw-in
Complications in Study	0	Polarity	Bipolar	
Cumulative Months of Follow-Up in Study	1,217	Steroid	Yes	
Advisories	None			
Years After Implant				

Lead Survival Probability (%)

Lead Survival Probability (%)

Complications in Study3PolarityUnipolarConductor Fracture Failure to Sense1 2SteroidNoCumulative Months of Follow-Up in Study9,447SteroidSteroid	ansvenous, Vent., Tines iipolar
Complications in Study3PolarityUnipolarConductor Fracture Failure to Sense1 2SteroidNoCumulative Months of Follow-Up in Study9,447SteroidSteroid	ipolar
Conductor Fracture Failure to Sense1SteroidNoCumulative Months of Follow-Up in Study9,447	
Failure to Sense2Cumulative Months of Follow-Up in Study9,447	
Advisories None	
Years After Implant	
100 100 100 100 100 100	

4092 CapSure SP Novus

Lead Survival Probability (%)

4092	CapSure	SP Novus				Product C	haracteristic	s		
US Mar	ket Release		Sep	-98		Serial Num	per Prefix	LEP		
Numbe	r of Leads Enro	lled in Study	1,	,124		Type and/o	r Fixation	Transvenou	is, Vent., Tir	ies
Compli	cations in Study	,		11		Polarity		Bipolar		
	Ext	Conductor ra Cardiac Sti Failure to Lead Dislo	mulation Capture	2 1 5 3		Steroid		Yes		
Cumula	ative Months of	Follow-Up in	Study 30,	268						
Advisor	ries		N	one						
Years A	fter Implant									
	1 yr	2 yr	3 yr	4 yr						
	99.0	98.8	98.8	98.8	98.8 at 51 mo					
				-						

5023,	,5023M C	apSure SI	0			Product	Characterist	ics		
US Mark	ket Release		Nov	/-88		Serial Nu	mber Prefix	SX or L	AS	
Number	r of Leads Enro	lled in Study	1,	,343		Type and	/or Fixation	Transv	enous, Vent	., Tines
Complic	cations in Stud	/		4		Polarity		Unipol	ar	
		tra Cardiac Sti Failure to pedance Out	Capture	1 2 1		Steroid		Yes		
Cumulat	tive Months of	Follow-Up in	Study 49,	609						
Advisor	ies		Ν	one						
Years Af	fter Implant									
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr			
	99.7	99.7	99.7	99.5	99.5	99.5	99.5			
)			3	1	5	6	1	8	9	10

5024, 5024M CapSure SP

5024, 5	024M	Cap	Sure	e SP							Prod	uct Ch	aracte	eristic	S				
US Market	Release					Mar-90)				Serial	Numb	er Pref	īx	SY or	LAT			
Number of	Leads E	nrolled	d in Stu	dy		7,964	Ļ				Туре	and/or	Fixatio	on	Trans	venou	s, Vent	., Tines	
Complicati	ons in S [.]	tudy				39	9				Polari	ty			Bipola	ar			
Cumulative		Extra ation (r	Cardiao Failur Fail Ins Ins Inot furt Lead D	ctor Fra c Stimu re to Ca lure to ulation ther de vislodge Overse o in Stu	llation apture Sense (ESC) fined) ement ensing	3 23 2 4 4 4 401,73	1 3 2 1 4 4 1				Stero	id			Yes				
Advisories						None	2												
Years Afte	r Impla	nt																	
1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr							
99.7	99.6	99.5	99.5	99.5	99.4	99.4	99.2	99.0	99.0	99.0	99.0	99.0							

Lead Survival Probability (%)

5026	CapSure					Product	Characterist	ics		
US Marl	ket Release		Feb	-88		Serial Nu	mber Prefix	RZ		
Numbe	r of Leads Enro	olled in Study		165		Type and	/or Fixation	Transv	enous, Vent	., Tines
Complie	cations in Stud	у		4		Polarity		Bipolar		
	E	lectrical Aban Failure to	donment Capture	1 3		Steroid		Yes		
Cumula	tive Months of	Follow-Up in	Study 9,	398						
Advisor	ries		N	one						
Years A	fter Implant	2 yr	3 yr	4 yr	5 yr	6 yr				
	100	99.2	98.2	97.0	97.0	95.6	95.6 at 75 mo			
							at 75 mo			
)		2	3	4	5	6	7	8	9	10

5033 CapSure 7

Lead Survival Probability (%)

Lead Survival Probability (%)

JS Market F	Release		Feb	-96		Serial Nu	mber Prefix	LDK	
		lled in Study	1,	885		Type and	/or Fixation	Transver	10us, Vent., Tines
Complicatio	ns in Study	1		18		Polarity		Unipolar	
Cumulative	Insulatio	Cardiac Pe Conductor Failure to pedance Out n (not further Lead Dislo Follow-Up in	Fracture Capture of Range defined) dgement	1 4 8 2 1 2 324		Steroid		Yes	
Advisories				one					
ears After	Implant								
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
	99.7	99.6	99.2	99.0	98.9	98.5	98.3	97.1	97.1 at 105 mo
									1

5034	CapSure	Z				Product	Characterist	ics		
US Mar	ket Release		Feb	-96		Serial Nu	mber Prefix	LDF		
Numbe	er of Leads Enro	olled in Study	1,	577		Type and	/or Fixation	Transven	ous, Vent., Tines	
Compli	cations in Study	Y		12		Polarity		Bipolar		
		Conductor Failure to Failure Lead Disloo	Capture to Sense	1 8 1 2		Steroid		Yes		
Cumula	ative Months of	Follow-Up in S	Study 72,	028						
Advisor	ries		N	one						
Years A	fter Implant									
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr		
	99.8	99.6	99.3	99.1	99.1	99.1	98.8	98.2	98.2 at 99 mo	

5054 CapSure 7 Novus

US Marl	ket Release		Jun	-98		Serial Number	Prefix	LEH		
Numbe	r of Leads Enro	lled in Study	,	.378		Type and/or F	ixation	Transvenou	ıs, Vent., Tir	ies
Complia	cations in Study	/		9		Polarity		Bipolar		
	Im	Failure to Failure pedance Out Lead Dislo	to Sense of Range	5 1 1 2		Steroid		Yes		
Cumula	tive Months of	Follow-Up in	Study 39,	024						
Advisor	ies		N	one						
	fter Implant									
Years A										
Years A	1 yr	2 yr	3 yr	4 yr	5 yr					
Years A		2 yr 99.5	3 yr 99.5	4 yr 99.3	5 yr 99.3					
Years A	1 yr									
Years A	1 yr									
Years A	1 yr									

1000	Target Tip)			Produ	uct Characterist	ics		
US Mar	ket Release		Mar-85		Serial	Number Prefix	GX		
Numbe	er of Leads Enro	lled in Study	118		Туре	and/or Fixation	Transvenou	us, Vent., Tine	es
Compli	cations in Study	1	1		Polari	ty	Unipolar		
		Failure to	Capture 1		Stero	id	No		
Cumula	ative Months of	Follow-Up in	Study 4,868						
Advisor	ries		None						
	fter Implant	2 yr	3 yr						
		2 yr 98.7	3 yr 98.7						
	1 yr								
	1 yr								
	1 yr								
	1 yr	98.7	98.7			7			
	1 yr			5	6	7	8	9	10

US Mar	ket Release		lun	-85		Serial Nu	mber Prefix	IZ		
	er of Leads Enrol	led in Study		176			/or Fixation	Transvo	nous, Vent., Ti	ines
									nous, vent., n	ines
Compli	cations in Study			4		Polarity		Bipolar		
			Capture to Sense ersensing	2 1 1		Steroid		No		
Cumula	ative Months of I	Follow-Up in	Study 11,	547						
A 1 ·	rios		N	one						
Advisor	iles			one						
	fter Implant	2	I	1	E.ur	6 vir	7	9	0.54	10.00
	fter Implant	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
	fter Implant	2 yr 99.3	I	1	5 yr 96.8	6 yr 96.8	7 yr 96.8	8 yr	9 yr	10 yr
	fter Implant		3 yr	4 yr				8 yr	9 yr	10 yr
	fter Implant		3 yr	4 yr				8 yr	9 yr	10 yr
	fter Implant		3 yr	4 yr				8 yr	9 yr	10 yr

US Mark	et Release		Jan	-97		Serial Number Pref	ix LDJ		
Number	r of Leads Enro	lled in Study	1,	336		Type and/or Fixatio	n Trans	svenous, V or	A, Screw-in
	ations in Study			5		Polarity	Bipol		
		Conductor Failure to Lead Dislo	Capture	1 3 1		Steroid	Yes		
Cumulat	tive Months of	Follow-Up in	Study 30,	450					
Advisori	ies		N	one					
'ears Af	fter Implant	2 yr	3 yr	4 yr	5 yr				
ears Af	fter Implant 1 yr 99.8	2 yr 99.6	3 yr 99.4	4 yr 99.0	5 yr 99.0	99.0 at 69 mo			
'ears Af	1 yr								
ears Af	1 yr								

5076 CapSureFix Novus

JS Market Release		Aug	-00	Serial Nur	nber Prefix	PJN		
Number of Leads Er	rolled in Study	-	294	Type and	or Fixation	Transvenou	us, V or A, Scre	ew-in
Complications in St		,	4	Polarity		Bipolar		
	Cardiac Per Failure to		1 2 1	Steroid		Yes		
Cumulative Months	of Follow-Up in S	Study 26,	,518					
Advisories		N	one					
Advisories ears After Implar	t	N	one					
	t 2 yr	No 3 yr	one 4 yr					
ears After Implar	1		1					
ears After Implar	2 yr	3 yr	4 yr					
ears After Implar	2 yr	3 yr	4 yr					
ears After Implar	2 yr	3 yr	4 yr					

	CapSure	SP INOVUS	;			Product Chara	cteristic	S			
US Mark	ket Release		Jun	-98		Serial Number P	refix	LET			
Number	r of Leads Enro	lled in Study		1,131		Type and/or Fixa	ition	Transvenous, Vent., Tin			
Complic	cations in Study	1		6		Polarity		Bipolar			
		Failure to Lead Dislo		1 5		Steroid		Yes			
Cumula	tive Months of	Follow-Up in	Study 29,	399							
Advisori	ies		N	one							
lears Af	fter Implant	2 yr	3 yr	4 yr	5 yr						
	99.6	99.4	99.2	99.2	99.2	99.2					
	99.0	99.4	JJ.Z	99.Z	JJ.Z	at 66 mo				I	

6957 Spectraflex

6957 Spectraflex		Product Characteristi	ics
US Market Release	Jul-79	Serial Number Prefix	VC
Number of Leads Enrolled in Study	1,780	Type and/or Fixation	Transvenous, V or A, Screw-in
Complications in Study	42	Polarity	Unipolar
Conductor Fract Extra Cardiac Stimulat Failure to Capt Failure to Sen Impedance Out of Rar Insulation (not further define Oversens	ion 2 ure 19 nse 2 uge 1 ed) 1	Steroid	No
Cumulative Months of Follow-Up in Study	95,710		
Advisories	None		

Years After Implant

(%)		Years	After	Implai	nt																		
bability			1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr					
bab			99.5	99.2	98.7	98.2	97.6	96.9	96.7	96.0	96.0	95.1	94.7	94.1	94.1	93.4	93.4	92.2	90.7				
val Prc	100													1					at 201 mo				
.>	90																	\neg					
ead Sur	80																					+	
L	(0	1 2	2 3	3 4	4	5	6 7	7 8	8 9	9 1	0 1	1 1	2 1	3 1	4 1	5 1	6 1	7 1	8 1	9	20	21

6961 Tenax

US Market Release		Jan-78	
Number of Leads Enrolled in Stu	dy	608	
Complications in Study		21	
Fail Insulation (not furt Lead D	e to Capture ure to Sense	4 7 6 2 1 1	
Cumulative Months of Follow-Up	o in Study	43,052	
Advisories		None	

Product Characteristics

Serial Number Prefix	ТВ
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Unipolar
Steroid	No

Years After Implant



6962 Tenax

US Market Release	Jan-78	
Number of Leads Enrolled in Study	1,435	
Complications in Study	51	
Conductor Fracture Extra Cardiac Stimulation Failure to Capture Failure to Sense Impedance Out of Range Insulation (not further defined) Lead Dislodgement Oversensing	5 1 27 10 2 2 1 3	
Cumulative Months of Follow-Up in Study	110,834	
Advisories	None	

Product Characteristics

Serial Number Prefix	UB
Type and/or Fixation	Transvenous, Vent., Tines
Polarity	Bipolar
Steroid	No

Years After Implant

	1	l yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	18 yr	19 yr	20 yr	
	9	99.0	98.2	97.3	96.8	96.6	96.4	96.2	96.1	95.8	95.1	94.8	94.4	93.2	93.2	93.2	91.8	91.0	90.1	90.1	90.1	
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Lead Survival Summary (95% Confidence Interval)

Model Number	, ii	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device S	Survival P	robability	r (%)										
Nun	Family	US I Rele	Enre	in S	of F in S	l yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 yr
4003, 4003M	CapSure	Jul-86	684	7	41,175	99.3 +0.5/-1	99.3 +0.5/-1	99.3 +0.5/-1	99.1 +0.5/-1.2	99.1 +0.5/-1.2	98.8 +0.7/-1.5	98.5 +0.8/-1.8	98.5 +0.8/-1.8	98.5 +0.8/-1.8 at 111 mo					
4004,	CapSure	Feb-89	1,462	276	71,546	99.7	99.2	95.6	85.4	73.6	65.1	59.3	52.9	46.1	46.1				
4004M	Advisory: <u>see</u> Expectations	page 157 -	1993 Lea	d Surviva	al Below	+0.2/-0.5	+0.4/-0.8	+1.2/-1.6	+2.4/-2.8	+3.2/-3.6	+3.7/-4.1	+4.1/-4.4	+4.5/-4.7	+5/-5.2	+5/-5.2 at 126 mo				
4011	Target Tip	Nov-82	821	23	54,262	99.4 +0.4/-1	99.2 +0.5/-1.1	99.0 +0.6/-1.2	98.8 +0.6/-1.3	97.5 +1.1/-1.9	96.3 +1.4/-2.4	95.9 +1.6/-2.6	95.9 +1.6/-2.6	94.8 +2/-3.2	92.5 +2.8/-4.4	91.6 +3.1/-4.9	91.6 +3.1/-4.9 at 183 mo		
4012	Target Tip	Jul-83	2,349	315	151,033	99.6	99.1	98.3	95.4	91.7	86.8	82.1	75.4	66.9	62.8	60.0	59.3		
	Advisory: <u>see</u> Expectations	page 15 <mark>8</mark> -	1991 Lea	d Surviva	al Below	+0.2/-0.4	+0.3/-0.6	+0.5/-0.8	+0.9/-1.3	+1.4/-1.6	+1.8/-2.1	+2.2/-2.5	+2.7/-3	+3.3/-3.6	+3.6/-3.9	+4.1/-4.3	+4.2/-4.5 at 189 mo		
4016	Screw-In	Aug-85	215	14	12,880	99.0 +0.7/-3.1	99.0 +0.7/-3.1	99.0 +0.7/-3.1	97.0 +1.9/-5.2	94.8 +2.9/-6.4	92.2 +4/-7.6	90.5 +4.6/-8.7 at 78 mo							
4016A	Screw-In	Feb-88	68	1	3,354	100.0													
4023	CapSure SP	Aug-91	1,140	12	50,766	99.9 +0.1/-0.7	99.4 +0.4/-0.8	98.9 +0.5/-1	98.7 +0.6/-1.2	98.7 +0.6/-1.2	98.7 +0.6/-1.2	97.3 +1.5/-3	97.3 +1.5/-3	97.3 +1.5/-3 at 111 mo					
4024	CapSure SP	Oct-91	1,202	3	49,361	99.9 +0.1/-0.5	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7	99.8 +0.1/-0.7 at 105 mo					
4033	CapSure Z	Mar-94	536	9	26,989	99.3 +0.5/-1.3	99.3 +0.5/-1.3	99.1 +0.5/-1.6	98.7 +0.8/-1.8	98.3 +1/-2.1	97.7 +1.3/-2.6	97.7 +1.3/-2.6	96.8 +1.8/-3.7	95.4 +2.6/-5.7 at 99 mo					
4057, 4057M	Screw-In	Aug-88	250	7	14,957	99.4 +0.5/-3.7	99.4 +0.5/-3.7	99.4 +0.5/-3.7	98.6 +1/-4.3	97.6 +1.6/-4.9	96.6 +2.1/-5.4	95.5 +2.6/-6.1	95.5 +2.6/-6.1	94.1 +3.3/-7 at 114 mo					
4058, 4058M	Screw-In	Jan-89	1,634	46	75,270	99.3 +0.4/-0.6	99.2 +0.3/-0.8	99.0 +0.5/-0.7	98.6 +0.6/-1	97.9 +0.7/-1.3	96.6 +1.2/-1.7	94.3 +1.7/-2.5	93.3 +1.9/-2.8	89.4 +3/-4	88.6 +3.2/-4.5 at 132 mo				
4068	CapSureFix	Mar-96	1,726	24	67,434	99.3 +0.3/-0.6	98.8 +0.5/-0.7	98.8 +0.5/-0.7	98.5 +0.6/-0.9	98.0 +0.8/-1.2	97.7 +0.9/-1.6	96.9 +1.4/-2.8	95.6 +2.3/-4.3						
4074	CapSure Sense	Jun-02	362	0	4,557	100.0	100.0												
4076	CapSureFix Novus	Feb-04	143	0	1,217	100.0 at 9 mo													
4081	Target Tip	Jul-89	255	3	9,447	100.0	100.0	100.0	100.0	100.0									
4092	CapSure SP Novus	Sep-98	1,124	11	30,268	99.0 +0.5/-0.9	98.8 +0.6/-0.9	98.8 +0.6/-0.9	98.8 +0.6/-0.9	98.8 +0.6/-0.9 at 51 mo									
5023, 5023M	CapSure SP	Nov-88	1,343	4	49,609	99.7 +0.2/-0.5	99.7 +0.2/-0.5	99.7 +0.2/-0.5	99.5 +0.3/-0.9	99.5 +0.3/-0.9	99.5 +0.3/-0.9	99.5 +0.3/-0.9							

Ventricular Pacing Leads continued

continued

Lead Survival Summary continued

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device S	Survival P	robability 3 yr	(%) 4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 yr
5024, 5024M	CapSure SP	Mar-90	7,964	39	401,731	99.7 +0.1/-0.2	99.6 +0.1/-0.2	99.5 +0.2/-0.2	99.5 +0.1/-0.2	99.5 +0.1/-0.3	99.4 +0.2/-0.2	99.4 +0.2/-0.3	99.2 +0.3/-0.4	99.0 +0.3/-0.6	99.0 +0.3/-0.6	99.0 +0.3/-0.6 at 156 mo			
5026	CapSure	Feb-88	165	4	9,398	100.0	99.2 +0.7/-4.9	98.2 +1.3/-5.4	97.0 +2/-6	97.0 +2/-6	95.6 +2.8/-7.2	95.6 +2.8/-7.2 at 75 mo							
5033	CapSure Z	Feb-96	1,885	18	81,324	99.7 +0.2/-0.4	99.6 +0.2/-0.4	99.2 +0.3/-0.8	99.0 +0.5/-0.7	98.9 +0.5/-0.9	98.5 +0.6/-1.1	98.3 +0.7/-1.3	97.1 +1.4/-2.5	97.1 +1.4/-2.5 at 105 mo					
5034	CapSure Z	Feb-96	1,577	12	72,028	99.8 +0.1/-0.4	99.6 +0.2/-0.6	99.3 +0.3/-0.7	99.1 +0.4/-0.7	99.1 +0.4/-0.7	99.1 +0.4/-0.7	98.8 +0.6/-1.1	98.2 +1/-2.5	98.2 +1/-2.5 at 99 mo					
5054	CapSure Z Novus	Jun-98	1,378	9	39,024	99.6 +0.2/-0.6	99.5 +0.3/-0.6	99.5 +0.3/-0.6	99.3 +0.4/-0.9	99.3 +0.4/-0.9									
5 06 1	Target Tip	Mar-85	118	1	4,868	100.0	98.7 +1.1/-7.7	98.7 +1.1/-7.7											
5064	Target Tip	Jun-85	176	4	11,547	99.3 +0.6/-3.9	99.3 +0.6/-3.9	96.8 +2/-5.2	96.8 +2/-5.2	96.8 +2/-5.2	96.8 +2/-5.2	96.8 +2/-5.2							
5068	CapSureFix	Jan-97	1,336	5	30,450	99.8 +0.1/-0.6	99.6 +0.3/-0.8	99.4 +0.4/-1.1	99.0 +0.6/-1.6	99.0 +0.6/-1.6	99.0 +0.6/-1.6 at 69 mo								
5076	CapSureFix Novus	Aug-00	1,294	4	26,518	99.8 +0.1/-0.6	99.6 +0.3/-0.8	99.6 +0.3/-0.8	99.6 +0.3/-0.8										
5092	CapSure SP Novus	Jun-98	1,131	6	29,399	99.6 +0.2/-0.7	99.4 +0.4/-0.7	99.2 +0.5/-1.1	99.2 +0.5/-1.1	99.2 +0.5/-1.1	99.2 +0.5/-1.1 at 66 mo								
6957	Spectraflex	Jul-79	1,780	42	95,710	99.5 +0.3/-0.4	99.2 +0.3/-0.7	98.7 +0.5/-0.9	98.2 +0.7/-1.1	97.6 +0.8/-1.3	96.9 +1/-1.5	96.7 +1.1/-1.6	96.0 +1.2/-1.9	95.1 +1.6/-2.2	94.1 +2/-2.8	93.4 +2.2/-3.4	92.2 +2.9/-4.3	90.7 +3.6/-5.7 at 201 mo	
6961	Tenax	Jan-78	608	21	43,052	99.4 +0.4/-1.2	99.2 +0.5/-1.4	99.2 +0.5/-1.4	97.7 +1.1/-2.1	97.1 +1.3/-2.4	96.3 +1.5/-2.8	96.3 +1.5/-2.8	95.3 +1.9/-3.2	93.5 +2.5/-4	92.7 +2.8/-4.4	90.0 +4/-6.4	90.0 +4/-6.4 at 171 mo		
6962	Tenax	Jan-78	1,435	51	110,834	99.0 +0.4/-0.8	98.2 +0.6/-1	97.3 +0.8/-1.2	96.8 +0.9/-1.3	96.6 +0.9/-1.4	96.4 +1/-1.4	96.2 +1.1/-1.4	96.1 +1/-1.6	95.1 +1.3/-1.9	94.4 +1.6/-2.1	93.2 +1.9/-2.7	91.8 +2.5/-3.5	90.1 +3.1/-4.6	90.1 +3.1/-4.6

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
4003, 4003M	CapSure	Jul-86	40,000	8,500	24	54	2
4004, 4004M	CapSure	Feb-89	74,500	4,100	55	679	19
4011	Target Tip	Nov-82	64,000	8,600	29	138	5
4012	Target Tip	Jul-83	96,800	7,100	50	814	34
4016	Screw-In	Aug-85	8,100	1,100	57	59	3
4016A	Screw-In	Feb-88	3,800	700	19	20	0
4023	CapSure SP	Aug-91	43,700	17,800	48	18	6
4024	CapSure SP	Oct-91	229,200	99,900	264	82	34
4057, 4057M	Screw-In	Aug-88	12,100	3,300	39	6	4
4058, 4058M	Screw-In	Jan-89	111,100	31,200	388	220	23
4067	CapSureFix	Jan-97	1,300	600	3	1	1
4068	CapSureFix	Mar-96	131,700	68,600	406	66	11
4074	CapSure Sense	Jun-02	29,400	25,500	7	1	1
4076	CapSureFix Novus	Feb-04	38,900	36,300	16	2	1
4081	Target Tip	Jul-89	4,100	1,100	4	5	0
4092	CapSure SP Novus	Sep-98	120,400	86,900	30	5	5
5023, 5023M	CapSure SP	Nov-88	10,600	3,500	15	7	0
5024, 5024M	CapSure SP	Mar-90	211,400	86,700	723	99	29
5025	CapSure	Jul-86	1,600	300	1	3	0
5026	CapSure	Feb-88	7,800	1,600	60	7	1
5033	CapSure Z	Feb-96	2,500	1,200	6	1	3
5034	CapSure Z	Feb-96	58,700	27,300	85	29	11
5054	CapSure Z Novus	Jun-98	74,100	50,200	39	11	6
5061	Target Tip	Mar-85	5,500	1,000	5	1	0
5062	Target Tip	Dec-85	2,800	500	10	1	1
5064	Target Tip	Jun-85	8,500	1,500	11	15	0
5067	CapSureFix	Jan-97	200	120	0	0	0
5068	CapSureFix	Jan-97	108,000	62,000	455	46	15
5072	SureFix	Jun-98	8,200	5,300	21	2	1
5076	CapSureFix Novus	Aug-00	580,200	465,800	531	80	42
5092	CapSure SP Novus	Jun-98	90,600	64,600	37	12	10
6957	Spectraflex	Jul-79	29,100	3,400	85	39	25
6961	Tenax	Jan-78	44,700	2,500	103	27	0
6962	Tenax	Jan-78	70,600	4,400	170	84	0

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes, and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and

continued

Laboratory Analysis continued

metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

Reference Chart

Model Number	Family	Туре	Insulation	Conductor Material	Tip Electrode	Connector Type
4003, 4003M	CapSure	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 4 Filars	Porous/Steroid	5 mm (4003) IS-1 UNI (4003M)
4004, 4004M	CapSure	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 6/4 Filars	Porous/Steroid	3.2 mm Low Profile (4004) IS-1 BI (4004M)
4011	Target Tip	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 4 Filars	Target Tip Concentric Grooves	5 mm
4012	Target Tip	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 6/4 Filars	Target Tip Concentric Grooves	3.2 mm Low Profile
4016	Screw-In	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/2 Filars	1.5 mm Helix	3.2 mm Low Profile
4016A	Screw-In	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/2 Filars	2.0 mm Helix	3.2 mm Low Profile
4023	CapSure SP	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 4 Filars	Porous Platinized/ Steroid	IS-1 UNI
4024	CapSure SP	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
4033	CapSure Z	Transvenous Ventricular Tines	Polyurethane (55D)	MP35N 2 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
4057, 4057M	Screw-In	Transvenous V or A Screw-In	Polyurethane (80A)	MP35N 1 Filar	2.0 mm Helix	5 mm (4057) IS-1 UNI (4057M)
4058, 4058M	Screw-In	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/1 Filars	2.0 mm Helix	3.2 mm Low Profile (4058) IS-1 BI (4058M)
4067	CapSureFix	Transvenous V or A Screw-In	Polyurethane (80A)	MP35N 3 Filars	1.8 mm Helix/Steroid	IS-1 UNI
4068	CapSureFix	Transvenous V or A Screw-In	Polyurethane (80A/55D)	MP35N 4/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4074	CapSure Sense	Transvenous Ventricular Tines	Polyurethane/ Silicone (55D, 4719)	MP35N 5/5 Filars	TiN Coated Platinum Iridium	IS-1 BI
4076	CapSureFix Novus	Transvenous V or A Screw-In	Polyurethane/ Silicone (55D, 4719)	MP35N 4/6 Filars	TiN Coated Platinum Alloy	IS-1 BI
4081	Target Tip	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 4 Filars	Target Tip Concentric Grooves	IS-1 UNI w/Removable 5 mm Sleeve
4082	Target Tip	Transvenous Ventricular Tines	Polyurethane (80A)	MP35N 6/4 Filars	Target Tip Concentric Grooves	IS-1 BI

Reference Chart continued

Model Number	Family	Туре	Insulation	Conductor Material	Tip Electrode	Connector Type
4092	CapSure SP Novus	Transvenous Ventricular Tines	Polyurethane/ Silicone (55D/4719)	MP35N 6/4 Filars	Porous Platinized/ Steroid	IS-1 BI
5023, 5023M	CapSure SP	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Porous Platinized/ Steroid	5 mm (5023) IS-1 UNI (5023M)
5024, 5024M	CapSure SP	Transvenous Ventricular Tines	Silicone	MP35N 4/5 Filars	Porous Platinized/ Steroid	3.2 mm Low Profile (5024) IS-1 BI (5024M)
5025	CapSure	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Porous Platinized/ Steroid	5 mm Unipolar
5026	CapSure	Transvenous Ventricular Tines	Silicone	MP35N 6/4 Filars	Porous Platinized/ Steroid	3.2 mm Low Profile
5033	CapSure Z	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
5034	CapSure Z	Transvenous Ventricular Tines	Silicone	MP35N 4/5 Filars	CapSure Z Platinized/Steroid	IS-1 BI
5054	CapSure Z Novus	Transvenous Ventricular Tines	Silicone (4719)	MP35N 5/5 Filars	CapSure Z Porous/Platinized/ Steroid	IS-1 BI
5061	Target Tip	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Target Tip Concentric Grooves	5 mm
5062	Target Tip	Transvenous Ventricular Tines	Silicone	MP35N 6/4 Filars	Target Tip Concentric Grooves	3.2 mm Low Profile
5064	Target Tip	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Target Tip Concentric Grooves	5 mm Bifurcated
5067	CapSureFix	Transvenous V or A Screw-In	Silicone	MP35N 3 Filars	1.8 mm Helix/Steroid	IS-1 UNI
5068	CapSureFix	Transvenous V or A Screw-In	Silicone	MP35N 4/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
5072	SureFix	Transvenous V or A Screw-In	Silicone	MP35N 4/5 Filars	1.8 mm Helix/Steroid	IS-1 BI
5076	CapSureFix Novus	Transvenous V or A Screw-In	Silicone (4719)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
5092	CapSure SP Novus	Transvenous Ventricular Tines	Silicone (4719)	MP35N 5/5 Filars	Porous Platinized/ Steroid	IS-1 BI
6907	(no brand name)	Transvenous Ventricular Flange	Silicone	MP35N 2 Filars	Cylinder Tip	5 mm
6907R	(no brand name)	Transvenous Ventricular Flange	Silicone	MP35N 2 Filars	Ring Tip	5 mm
6957	Spectraflex	Transvenous V or A Screw-In	Polyurethane (80A)	MP35N 1 Filar	2.0 mm Helix	5 mm
6961	Tenax	Transvenous Ventricular Tines	Silicone	MP35N 3 Filars	Ring Tip	5 mm
6962	Tenax	Transvenous Ventricular Tines	Silicone	MP35N 4 Filars	Ring Tip	5 mm Bifurcated

Atrial Pacing Leads

JS Marl	ket Release		Aug-	85		Serial Nu	mber Prefix	KY		
lumbe	r of Leads Enro	lled in Study	۱	72		Type and	d/or Fixation	Transver	10us, V or A	, Screw-in
omplic	cations in Study	/		5		Polarity		Bipolar		
	Insulation	Failure to Failure t Insulatic (not further c	o Sense on (ESC)	2 1 1		Steroid		No		
umula	tive Months of	Follow-Up in	Study 11,4	42						
dvisories										
dvisor	ies		No	ne						
	fter Implant	1		1	I	I	I		I	I
		2 yr	No 3 yr	ne 4 yr	5 yr	6 yr	7 yr			
	fter Implant	2 yr 99.4		1	5 yr 97.4	6 yr 96.1	7 yr 96.1	96.1 at 90 mo		
	fter Implant		3 yr	4 yr						
	fter Implant		3 yr	4 yr						
	fter Implant		3 yr	4 yr						

4016A Screw-In

Lead Survival Probability (%)

Lead Survival Probability (%)

US Mai	rket Release		Feb-88		Serial Numb	er Prefix	XB		
Numbe	er of Leads Enro	olled in Study	67		Type and/or	Fixation	Transvenou	ıs, V or A, Scr	ew-in
Compli	ications in Stud	у	3		Polarity		Bipolar		
		Failure to Capture Failure to Sense Oversensing	e 1		Steroid		No		
Cumula	ative Months of	Follow-Up in Study	5,285						
A 1 ·	rioc		None						
Adviso	nes		None						
Adviso 'ears A	After Implant	2 vr							
		2 yr							
	After Implant								
	After Implant								
	After Implant								

Source: System Longevity Study Data as of July 11, 2005

4058, 4058M Screw-In

US Market Release	Jan-89
Number of Leads Enrolled in Study	2,204
Complications in Study	30
Extra Cardiac Stimulation Failure to Capture Failure to Sense Impedance Out of Range Insulation (not further defined) Lead Dislodgement Oversensing	15 6 3 1 3
Cumulative Months of Follow-Up in Study	129,085
Advisories	None

Product Characteristics

Serial Number Prefix	ZY or LAW
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	No

Years After Implant

99.6 99.4 99.	9.0 98.6 98.2	98.1 9	7.3 97.3	96.2	96.2	96.2	96.2							
													1	
							1							
3 /	5 6	7 8	9	10 1	1 1:	2 13	3 14	15	16	17	/ 13	8 1	92	20 2
	3 4	3 4 5 6	3 4 5 6 7 8	3 4 5 6 7 8 9	3 4 5 6 7 8 9 10 1	3 4 5 6 7 8 9 10 11 1	3 4 5 6 7 8 9 10 11 12 12	3 4 5 6 7 8 9 10 11 12 13 14	3 4 5 6 7 8 9 10 11 12 13 14 15	3 4 5 6 7 8 9 10 11 12 13 14 15 16	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 13	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 1	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 2

4067 CanSureFix

4067 CapSureFix		Product Characteristics			
US Market Release	Jan-97	Serial Number Prefix	LCV		
Number of Leads Enrolled in Study	97	Type and/or Fixation	Transvenous, V or A, Screw-in		
Complications in Study	3	Polarity	Unipolar		
Failure to Capture	3	Steroid	Yes		
Cumulative Months of Follow-Up in Study	4,985				
Advisories	None				

Years After Implant

Uaumuy		1 yr	2 yr								
המר		96.7	96.7	96.7 at 27 mo							
2				at 27 mo		'					
100 90 90											
90											
80											
										T	
í í	0	1	2	3	4	5	6	7	8	9 1	0

4068 CapSureFix

US Market Release	Mar-96
Number of Leads Enrolled in Study	2,223
Complications in Study	39
Extra Cardiac Stim Failure to C Failure to Impedance Out of Insulatior Lead Dislodg Overs	apture 16 Sense 8 Range 1 n (ESC) 2
Unspecified Clinical	Failure 1
Cumulative Months of Follow-Up in S	tudy 98,939
Advisories	None

Product Characteristics

Serial Number Prefix	LCE
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes

Years After Implant

`		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr		
		99.0	98.7	98.2	97.9	97.5	97.5	97.5	97.1	97.1 at 102 mo	
100					1	1	I				1
90											
80											
()	1	2	3	4	5 (5 7	7 8	3) 1	0

4076 CapSureFix Novus

4076 CapSureFix Novus		Product Characteristi	cteristics		
US Market Release	Feb-04	Serial Number Prefix	BBL		
Number of Leads Enrolled in Study	121	Type and/or Fixation	Transvenous, V or A, Screw-in		
Complications in Study	0	Polarity	Bipolar		
Cumulative Months of Follow-Up in Study	1,031	Steroid	Yes		
Advisories	None				

Years After Implant

100								
at 9 mo								
	2	2	A 1	5 6		7 5	2 0	2
	100 at 9 mo	at 9 mo						

Advisories 1 <u>see page 155</u> – 1996 Lead Survival Below Expectations	JS Ma	arket Release		Mar	-90		Serial Nu	umber Prefix	QM or LBA	
Complications in Study48PolarityBipolarElectrical Abandonment3SteroidYesExtra Cardiac Stimulation1Failure to Capture14Failure to Capture14Failure to Capture14Failure to Sense16Impedance Out of Range9Insulation (MIO)1Lead Dislodgement1Oversensing331see page 155 – 1996 Lead Survival Below Expectationsears After Implant1 yr2 yr3 yr4 yr5 yr6 yr7 yr8 yr	lumb	er of Leads Enro	olled in Study		323		Type and	d/or Fixation	Transvenou	us, Atrial-I, Tines
Electrical Abandonment 3 Steroid Yes Extra Cardiac Stimulation 1 Failure to Capture 14 Failure to Sense 16 Impedance Out of Range 9 Insulation (MIO) 1 Lead Dislodgement 1 Oversensing 3 Cumulative Months of Follow-Up in Study 19,824 Advisories 1 see page 155 – 1996 Lead Survival Below Expectations Fears After Implant 1 yr 2 yr A yr 6 yr 7 yr 8 yr 1 yr 9 yr 1 yr 9 yr 1 yr 9 yr					48					,
Advisories 1 see page 155 – 1996 Lead Survival Below Expectations ears After Implant 1 yr 2 yr 3 yr 4 yr 5 yr 6 yr 7 yr 8 yr		E Ex	lectrical Aban tra Cardiac St Failure to Failure npedance Out Insulati Lead Dislo	imulation Capture to Sense of Range on (MIO) dgement	1 14 16 9 1 1		Steroid			
ears After Implant	Cumul	lative Months of	Follow-Up in	Study 19,	324					
	Adviso	ories			1 see page	<mark>e 155</mark> – 1996 Le	ad Survival Be	elow Expectatio	ons	
		A.C								
	ears I	After Implant								
	ears /		2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	
	ears /	1 yr								
	ears /	1 yr								
	ears /	1 yr								
	ears /	1 yr								
	ears /	1 yr								
	ears	1 yr								
	ears /	1 yr								

4511 Target Tip

US Market Release		Nov-82	Serial Number Prefix	MB
Number of Leads Enrolled	d in Study	144	Type and/or Fixation	Transvenous, Atrial-J, Tines
Complications in Study		3	Polarity	Unipolar
	Failure to Capture Oversensing	2 1	Steroid	No
Cumulative Months of Fo	llow-Up in Study	9,096		
Advisories		None		

Product Characteristics



4512 Target Tip

US Market Release	Jul-83	
Number of Leads Enrolled in Study	556	
Complications in Study	35	
Electrical Abando Failure to (Failure to Impedance Out o Insulatio Insulation Insulation (not further d Lead Dislod Over	Capture 6 o Sense 14 of Range 3 on (ESC) 2 n (MIO) 4 defined) 2	
Cumulative Months of Follow-Up in S	Study 40,010	
Advisories	None	

Product Characteristics

Serial Number Prefix	PF
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	No

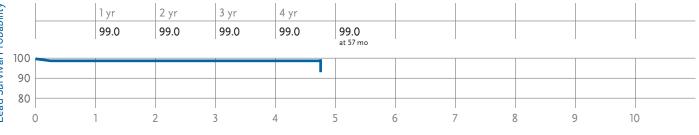
Years After Implant



4523 CapSure SP

4523 CapSure SP		Product Characterist	ics
US Market Release	Aug-91	Serial Number Prefix	ZE
Number of Leads Enrolled in Study	110	Type and/or Fixation	Transvenous, Atrial-J, Tines
Complications in Study	1	Polarity	Unipolar
Lead Dislodgem	ent l	Steroid	Yes
Cumulative Months of Follow-Up in Stud	y 6,567		
Advisories	None		

Years After Implant



4524 CapSure SP

	99.6	99.3	99.3		99.0	99
	1 yr	2 yr	3 yr		4 yr	5
Years Afte	er Implant					
Advisories				None		
Cumulative	e Months of	Follow-Up in	Study 3	36,369		
		Failure to Failure t Lead Dislod	o Sense	3 2 1		
Complicat	ions in Study	/		6		
Number of	f Leads Enro	lled in Study		879		
US Market	Release		(Oct-91		

Product Characteristics

Serial Number Prefix	LAR
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	Yes

6 yr 7 yr i yr 9.0 99.0 99.0 99.0 at 93 mo 100 90 80 2 0 1 3 4 5 6 7 8 9 10

4533 CapSure Z

4533 CapSure Z	-				Product	Characterist	ics		
US Market Release		Mar-	94		Serial Nun	nber Prefix	LCB		
Number of Leads Enrol	led in Study	1	98		Type and/	or Fixation	Transveno	us, Atrial-J,	Tines
Complications in Study			4		Polarity		Unipolar		
	Failure to C Failure to Lead Dislodg Overs	Sense	1 1 1		Steroid		Yes		
Cumulative Months of F	ollow-Up in S	Study 10,7	'18						
Advisories		No	ne						
Years After Implant									
1 yr	2 yr	3 yr	4 yr	5 yr	6 yr				
100	99.4	98.7	97.8	97.8	97.8	97.8 at 78 mo			
					-				
0 1	2	3	4	5	6	7	8	9	10

4557, 4557M Screw-In

US Market Release	Aug-88
Number of Leads Enrolled in Stud	y 272
Complications in Study	6
Failure	timulation 1 o Capture 3 e to Sense 1 ersensing 1
Cumulative Months of Follow-Up	in Study 18,076
Advisories	None

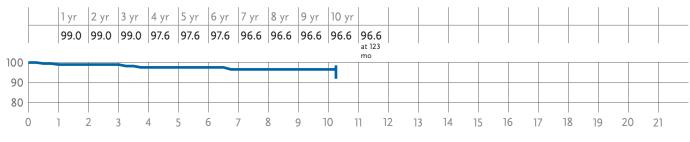
Product Characteristics

Serial Number Prefix	VQ or LAM
Type and/or Fixation	Transvenous, Atrial, Screw-in
Polarity	Unipolar
Steroid	No

Years After Implant

Lead Survival Probability (%)

Lead Survival Probability (%)



4558M Screw-In

JS Market	Release		Nov-	94		Serial Nu	mber Prefix	LDC		
Number of	Leads Enro	olled in Study	5	06		Type and	d/or Fixation	Transver	10us, Atrial-J, Sc	rew-in
Complicatio	ons in Study	Ý		9		Polarity		Bipolar		
	Imp	ctrical Aband Failure to Failure t edance Out o (not further o	Capture o Sense of Range	1 3 2 2 1		Steroid		No		
Cumulative	Months of	Follow-Up in	Study 21,5	56						
Advisories			No	ne						
ears After	r Implant									
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr		
	99.3	99.3	99.3	99.3	99.3	97.6	96.5	96.5	94.8 at 99 mo	

4568 CapSureFix

US Mar	rket Release		Jai	1-97		Serial Number P	refix L	.DD		
Numbe	er of Leads Enrol	lled in Study		534		Type and/or Fixe	ation T	ransvenous	, Atrial-J, Scr	ew-in
Compli	ications in Study	,		19		Polarity	В	Bipolar		
		Failure to C Lead Dislodg Medical Juc	gement	11 7 1		Steroid	Y	′es		
Cumula	ative Months of	Follow-Up in S	Study 14	,295						
Advisor	ries		N	one						
	Constant for the st									
'ears A	After Implant	2 yr	3 yr	4 yr						
'ears A		2 yr 96.1	3 yr 96.1	4 yr 96.1	96.1 at 57 mo					
ears A	1 yr									
ears A	1 yr									
ears A	1 yr									

Product Characteristics

4592 CapSure SP Novus

1332	2 CapSure	JP NUVUS				Product Characteri	SUCS		
US Ma	rket Release		Oct-	98		Serial Number Prefix	LER		
Numbe	er of Leads Enro	olled in Study	2	24		Type and/or Fixation	Transv	venous, Atria	l-J, Tines
Compl	lications in Stud	у		4		Polarity	Bipola	r	
		Failure to Lead Dislod		2 2		Steroid	Yes		
Cumul	ative Months of	Follow-Up in	Study 6,9	79					
			Nie	ne					
Advisc	bries		NO	iie					
	After Implant	2	1	I	I		I	I	
		2 yr 97.7	3 yr 97.7	4 yr 97.7					
	After Implant		3 yr	4 yr					
	After Implant		3 yr	4 yr					
	After Implant		3 yr	4 yr					
Adviso (ears A	After Implant		3 yr	4 yr					

5068 CapSureFix

US Market Release		Jan-97	
Number of Leads Enrolle	d in Study	935	
Complications in Study		3	
Impec	Failure to Capture lance Out of Range	2 1	
Cumulative Months of Fo	ollow-Up in Study	29,605	
Advisories		None	

Product Characteristics

Serial Number Prefix	LDJ
Type and/or Fixation	Transvenous, V or A, Screw-in
Polarity	Bipolar
Steroid	Yes

Years After Implant

Lead Survival Probability (%)

	l yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr			
	99.7	99.7	99.7	99.3	99.3	99.3	99.3	99.3		
								at 90 m	10	
100										
100										
90										

5072 SureEix

5072 SureFix					Product Charac	cteristics		
US Market Release		Jun-98	3		Serial Number Pr	refix LEM		
Number of Leads En	rolled in Study	449	9		Type and/or Fixa	tion Tran	svenous, V or A,	Screw-in
Complications in Stu	ldy	2	2		Polarity	Bipol	ar	
	Cardiac Perf Failure to C		1		Steroid	Yes		
Cumulative Months	of Follow-Up in	Study 17,684	1					
Advisories		None	5					
Years After Implan	t							
1 yr	2 yr	3 yr	4 yr	5 yr	6 yr			
99.7	99.7	99.4	99.4	99.4	99.4			

5

4

6

7

8

9

0

1

2

3

10

5076	CapSureF	ix Novus				Produc	t Characterist	ics		
US Marke	et Release		Aug-0	00		Serial N	umber Prefix	PJN		
Number	of Leads Enro	olled in Study	1,6	68		Type an	d/or Fixation	Transve	nous, V or A,	Screw-in
Complica	ations in Study	y		7		Polarity		Bipolar		
	Extr	Cardiac Per Conductor F ra Cardiac Stir Failure to Lead Dislod	Fracture nulation Capture	1 1 2 1 2		Steroid		Yes		
Cumulati	ive Months of	Follow-Up in	Study 35,6	79						
Advisorie	25		No	ne						
ears Aft	ter Implant									
	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr
	99.5	99.5	99.4	99.4						
	·									

5524, 5524M CapSure SP

5524, 5524M CapSure SP		Product Characteristi	CS
US Market Release	Mar-90	Serial Number Prefix	XV or LAV
Number of Leads Enrolled in Study	4,231	Type and/or Fixation	Transvenous, Atrial-J, Tines
Complications in Study	30	Polarity	Bipolar
Conductor Fractu Failure to Captu Failure to Sen Insulation (not further define Lead Dislodgeme Oversensir	re 18 se 3 d) 1 nt 4	Steroid	Yes
Cumulative Months of Follow-Up in Study	217,340		
Advisories	None		

		1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr										
Daull		99.8	99.7	99.5	99.3	99.2	99.2	99.1	98.7	98.0	97.5	97.5	97.5									
2													at 138									
10	0												mo									
9	×											-										
2 9	0																					
8	0	 																				
			1	1	1	1	1	1	-	1			1	1	1			1	I		1	1
Ľ	0		2	3 4	4.	5 (6	7	8	91	0 1	1 1	2 1	3 1	4 1	5 1	61	7 1	8 1	92	0 2	21

Lead Survival Probability (%)

5534 CapSure Z

US Market Release	Feb-96	
Number of Leads Enrolled in Study	252	
Complications in Study	6	
Failure to Capture Impedance Out of Range	5 1	
Cumulative Months of Follow-Up in Study	11,756	
Advisories	None	

Product Characteristics

Serial Number Prefix	LDG
Type and/or Fixation	Transvenous, Atrial-J, Tines
Polarity	Bipolar
Steroid	Yes

Years After Implant

Lead Survival Probability (%)

Lead Survival Probability (%)

	l yr	2 yr	3 yr	4 yr	5 yr					
	98.2	97.7	97.7	97.0	97.0	97.0 at 69 mo				
100 -		1		1		at 69 mo	1	1	1	
90 -										
80 -	 									
0	1	 ว ·	2	4	5	6	 7 (3 9	ן ר ג	0

5554 CapSure Z Novus

JS Marke ⁴	t Release		Jun-	98		Serial Number	Prefix	LEJ		
Number o	of Leads Enro	olled in Study	3	08		Type and/or Fix	ation	Transvend	ous, Atrial-J,	Tines
Complicat	tions in Study	ý		4		Polarity		Bipolar		
	Imp	Failure to edance Out c Lead Dislod Over	of Range	1 1 1 1		Steroid		Yes		
Sumulativ	ve Months of	Follow-Up in	Study 11,8	61						
Advisories	s		No	ne						
auvisorie:										
	er Implant	2 yr	3 vr	4 yr	5 vr					
		2 yr 99.1	3 yr 98.6	4 yr 97.9	5 yr 97.9	97.9 at 69 mo				
	er Implant									
	er Implant									
	er Implant									

5568 CapSureFix

US Market Release		Jan-97	
		juli 27	
Number of Leads Enrolle	811		
Complications in Study		3	
	Failure to Capture	2	
l	ead Dislodgement	1	
Cumulative Months of Fo	llow-Up in Study	20,708	
Advisories		None	

Product Characteristics

Serial Number Prefix	LDN
Type and/or Fixation	Transvenous, A or V, Screw-in
Polarity	Bipolar
Steroid	Yes

Years After Implant

Lead Survival Probability (%)

	l yr	2 yr	3 yr	4 yr	5 yr			
	99.8	99.6	99.6	99.6	98.4	98.4 at 63 mo		
100						at 63 mo		 1
90							 	
90 80								

5592 CapSure SP Novus

	CapSure S	SP Novus				Product Cha	racteristic	S		
US Mark	et Release		Jul-	-98		Serial Number	Prefix	LEU		
Number	of Leads Enro	lled in Study	6	00		Type and/or F	ixation	Transvenous	s, Atrial-J, ⁻	Tines
Complica	ations in Study	/		4		Polarity		Bipolar		
		Failure to C Lead Dislod		2 2		Steroid		Yes		
Cumulati	ive Months of	Follow-Up in S	Study 16,	147						
Advisorie	es		No	ne						
Years Af	ter Implant									
Years Af	ter Implant	2 yr	3 yr	4 yr						
Years Af		2 yr 99.1	3 yr 99.1	4 yr 99.1	99.1 at 54 mo					
Years Af	1 yr									
Years Af	1 yr									
Years Af	1 yr									

6940 CapSureFix

S Market Release		Oct-98
Number of Leads Enroll	ed in Study	615
Complications in Study		6
	Conductor Fracture Dislodgement Failure to Sense Oversensing	1 1 2 2
Cumulative Months of F	ollow-Up in Study	21,567
Advisories		None

Product Characteristics

Serial Number Prefix	ТСР
Type and/or Fixation	Transvenous, A or V, Screw-in
Polarity	Bipolar
Steroid	Yes

Years After Implant

Lead Survival Probability (%)

Lead Survival Probability (%)

	1 yr	2 yr	3 yr	4 yr	5 yr					
	99.8	99.8	98.6	98.3	98.3	98.3 at 66 mo				
•						at 66 mo				
C C					1					
)										
1	1	2	2	1	5	6	7	• •	0	10
0	1	2	3	4	5	6	7	8	9	10

6957 Spectraflex

JS Mar	rket Release		Jul-	79		Serial Nu	ımber Prefix	VC		
lumbe	er of Leads Enro	olled in Study	6	651			d/or Fixation	Transvenous, V or A, Screw-ir		
Complie	cations in Study	у		10				Unipolar		
	Extr			1 3 5 1		Steroid		No		
Lumula	ative Months of	Follow-Up in	Study 24,6	07						
Advisor	ries		No	ne						
	ries After Implant	2 yr	No 3 yr	e 4 yr	5 yr	6 yr	7 yr	8 yr		
Advisor ears A	fter Implant	2 yr 99.7	1	1	5 yr 97.9	6 yr 97.9	7 yr 95.5	8 yr 93.4	93.4 at 99 mo	
	Ster Implant		3 yr	4 yr			-			
	Ster Implant		3 yr	4 yr			-			
	Ster Implant		3 yr	4 yr			-			

6957J Spectraflex

US Market Release	Sep-80	
Number of Leads Enrolled in Study	2,180	
Complications in Study	82	
Conductor Fra Extra Cardiac Stimul Failure to Ca Failure to S Insulation (Insulation (not further def Lead Dislodger Overse	lation 3 pture 48 Gense 13 (ESC) 1 ined) 3 ment 2	
Cumulative Months of Follow-Up in Stu	udy 160,202	
Advisories	None	

Product Characteristics

Serial Number Prefix	GG
Type and/or Fixation	Transvenous, Atrial-J, Screw-in
Polarity	Unipolar
Steroid	No

Years After Implant

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	9 yr	10 yr	11 yr	12 yr	13 yr	14 yr	15 yr	16 yr	17 yr	18 yr			
	99.4	98.9	98.5	97.6	97.3	96.5	95.9	95.3	93.5	92.7	92.0	91.5	91.5	90.7	90.7	90.1	88.3	87.2	87.2 at 219		
100																			mo		
90 80																		-1			
00				4	-							 2 1	 2 1	 4 1	 	 < 1	 	 8 1) 2	1

Lead Survival Summary (95% Confidence Interval)

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Model Number	ylir	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device	Survival F	Probabilit	y (%)										
Mo	Family	Rel	Lea Enr	in S	of F in S	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 y
4016	Screw-In	Aug-85	172	5	11,442	99.4 +0.5/-3.6	99.4 +0.5/-3.6	98.6 +1.1/-4.2	98.6 +1.1/-4.2	97.4 +1.8/-5.7	96.1 +2.5/-6.5	96.1 +2.5/-6.5	96.1 +2.5/-6.5 at 90 mo						
4016A	Screw-In	Feb-88	67	3	5,285	100.0	98.1 +1.6/-11												
4058, 4058M	Screw-In	Jan-89	2,204	30	129,085	99.8 +0.1/-0.3	99.6 +0.2/-0.5	99.4 +0.3/-0.5	99.0 +0.4/-0.6	98.6 +0.5/-0.8	98.2 +0.6/-1	98.1 +0.6/-1.1	97.3 +0.9/-1.3	96.2 +1.3/-2	96.2 +1.3/-2	96.2 +1.3/-2 at 156 mo			
4067	CapSureFix	Jan-97	97	3	4,985	96.7 +2.2/-6.5	96.7 +2.2/-6.5	96.7 +2.2/-6.5 at 27 mo											
4068	CapSureFix	Mar-96	2,223	39	98,939	99.0 +0.4/-0.5	98.7 +0.4/-0.6	98.2 +0.6/-0.7	97.9 +0.6/-0.8	97.5 +0.7/-1	97.5 +0.7/-1	97.5 +0.7/-1	97.1 +1/-1.5	97.1 +1/-1.5 at 102 mo					
4076	CapSureFix Novus	Feb-04	121	0	1,031	100.0 at 9 mo													
4504,	CapSure	Mar-90	323	48	19,824	100.0	100.0	99.0 +0.7/-2.9	97.9 +1.3/-3.5	88.7 +4/-6.1	79.6 +5.7/-7.6	69.6 +7.2/-8.8	66.2 +7.7/-9.2						
4504M	Advisory: see Expectations	page 155 - 19	96 Lead S	urvival B	elow			+0.7/-2.9	+1.3/-3.3	+4/-0.1	+3.//-7.0	+7.2/-0.0	+7.7/-9.2						
4511	Target Tip	Nov-82	144	3	9,096	100.0	100.0	100.0	98.5 +1.3/-8.6	95.3 +3.1/-9.3	95.3 +3.1/-9.3 at 63 mo								
4512	Target Tip	Jul-83	556	35	40,010	99.6 +0.3/-1.3	99.6 +0.3/-1.3	99.0 +0.6/-1.6	97.8 +1.1/-2.2	96.4 +1.6/-2.6	95.2 +1.9/-3.1	94.3 +2.1/-3.5	90.3 +3.2/-4.7	86.1 +4.2/-5.9	83.4 +4.9/-6.6	82.2 +5.2/-7 at 159 mo			
4523	CapSure SP	Aug-91	110	1	6,567	99.0 +0.9/-5.7	99.0 +0.9/-5.7	99.0 +0.9/-5.7	99.0 +0.9/-5.7	99.0 +0.9/-5.7 at 57 mo									
4524	CapSure SP	Oct-91	879	6	36,369	99.6 +0.3/-0.8	99.3 +0.4/-1	99.3 +0.4/-1	99.0 +0.6/-1.3	99.0 +0.6/-1.3	99.0 +0.6/-1.3	99.0 +0.6/-1.3	99.0 +0.6/-1.3 at 93 mo						
4533	CapSure Z	Mar-94	198	4	10,718	100.0	99.4 +0.5/-3.7	98.7 +1/-3.7	97.8 +1.5/-4.4	97.8 +1.5/-4.4	97.8 +1.5/-4.4	97.8 +1.5/-4.4 at 78 mo							
4557, 4557M	Screw-In	Aug-88	272	6	18,076	99.0 +0.7/-3	99.0 +0.7/-3	99.0 +0.7/-3	97.6 +1.5/-3.9	97.6 +1.5/-3.9	97.6 +1.5/-3.9	96.6 +2/-4.7	96.6 +2/-4.7	96.6 +2/-4.7	96.6 +2/-4.7 at 123 mo				
4558M	Screw-In	Nov-94	506	9	21,556	99.3 +0.5/-1.5	99.3 +0.5/-1.5	99.3 +0.5/-1.5	99.3 +0.5/-1.5	99.3 +0.5/-1.5	97.6 +1.5/-4.2	96.5 +2.1/-5.3	96.5 +2.1/-5.3	94.8 +3.1/-7.3 at 99 mo					
4568	CapSureFix	Jan-97	534	19	14,295	96.1 +1.4/-2.3	96.1 +1.4/-2.3	96.1 +1.4/-2.3	96.1 +1.4/-2.3	96.1 +1.4/-2.3 at 57 mo									

Lead Survival Summary continued

Model Number	Family	US Market Release	Leads Enrolled	Complications in Study	Cumulative Months of Follow-Up in Study	Device S	Survival F	1	y (%)	1			1				1		
	Fai		ЦС	ů.≘	in of Cu	lyr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr	8 yr	10 yr	12 yr	14 yr	16 yr	18 yr	20 yr
4592	CapSure SP Novus	Oct-98	224	4	6,979	97.7 +1.4/-3.8	97.7 +1.4/-3.8	97.7 +1.4/-3.8	97.7 +1.4/-3.8										
5068	CapSureFix	Jan-97	935	3	29,605	99.7 +0.2/-0.9	99.7 +0.2/-0.9	99.7 +0.2/-0.9	99.3 +0.5/-1.6	99.3 +0.5/-1.6	99.3 +0.5/-1.6	99.3 +0.5/-1.6	99.3 +0.5/-1.6 at 90 mo						
5072	SureFix	Jun-98	449	2	17,684	99.7 +0.3/-1.5	99.7 +0.3/-1.5	99.4 +0.4/-1.9	99.4 +0.4/-1.9	99.4 +0.4/-1.9	99.4 +0.4/-1.9								
5076	CapSureFix Novus	Aug-00	1,668	7	35,679	99.5 +0.3/-0.5	99.5 +0.3/-0.5	99.4 +0.3/-0.7	99.4 +0.3/-0.7										
5524, 5524M	CapSure SP	Mar-90	4,231	30	217,340	99.8 +0.1/-0.3	99.7 +0.1/-0.2	99.5 +0.2/-0.3	99.3 +0.3/-0.4	99.2 +0.3/-0.4	99.2 +0.3/-0.4	99.1 +0.3/-0.5	98.7 +0.5/-0.8	97.5 +1.1/-1.9	97.5 +1.1/-1.9 at 138 mo				
5534	CapSure Z	Feb-96	252	6	11,756	98.2 +1.1/-2.8	97.7 +1.3/-3.2	97.7 +1.3/-3.2	97.0 +1.7/-3.7	97.0 +1.7/-3.7	97.0 +1.7/-3.7 at 69 mo								
5554	CapSure Z Novus	Jun-98	308	4	11,861	100.0	99.1 +0.7/-2.6	98.6 +0.9/-2.9	97.9 +1.3/-3.6	97.9 +1.3/-3.6	97.9 +1.3/-3.6 at 69 mo								
5568	CapSureFix	Jan-97	811	3	20,708	99.8 +0.2/-0.9	99.6 +0.3/-1.3	99.6 +0.3/-1.3	99.6 +0.3/-1.3	98.4 +1.2/-5.2	98.4 +1.2/-5.2 at 63 mo								
5592	CapSure SP Novus	Jun-98	600	4	16,147	99.6 +0.3/-1.2	99.1 +0.6/-1.5	99.1 +0.6/-1.5	99.1 +0.6/-1.5	99.1 +0.6/-1.5 at 54 mo									
6940	CapSureFix	Oct-98	615	6	21,567	99.8 +0.2/-1	99.8 +0.2/-1	98.6 +0.8/-2	98.3 +0.9/-2.2	98.3 +0.9/-2.2	98.3 +0.9/-2.2 at 66 mo								
6957	Spectraflex	Jul-79	651	10	24,607	100.0	99.7 +0.3/-1.7	99.3 +0.5/-2	98.4 +1/-2.6	97.9 +1.2/-3	97.9 +1.2/-3	95.5 +2.3/-4.7	93.4 +3.2/-6	93.4 +3.2/-6 at 99 mo					
6957j	Spectraflex	Sep-80	2,180	82	160,202	99.4 +0.3/-0.5	98.9 +0.4/-0.6	98.5 +0.5/-0.8	97.6 +0.7/-0.9	97.3 +0.7/-1.1	96.5 +0.9/-1.1	95.9 +1/-1.3	95.3 +1.1/-1.4	92.7 +1.6/-2	91.5 +1.8/-2.4	90.7 +2.1/-2.6	90.1 +2.3/-3	87.2 +3.5/-4.7	87.2 +3.5/-4.7 at 219 mo

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
4016	Screw-In	Aug-85	8,100	1,100	57	59	3
4016A	Screw-In	Feb-88	3,800	700	19	20	0
4058, 4058M	Screw-In	Jan-89	111,100	31,200	388	220	23
4067	CapSureFix	Jan-97	1,300	600	3	1	1
4068	CapSureFix	Mar-96	131,700	68,600	406	66	11
4076	CapSureFix Novus	Feb-04	38,900	36,300	16	2	1
4503, 4503M	CapSure	Jul-86	8,900	1,800	2	9	0
4504, 4504M	CapSure	Mar-90	16,600	2,000	5	169	4
4511	Target Tip	Nov-82	10,300	1,000	5	22	3
4512	Target Tip	Jul-83	11,600	1,300	4	82	8
4523	CapSure SP	Aug-91	12,000	4,300	5	2	1
4524	CapSure SP	Oct-91	106,900	45,400	47	15	8
4557, 4557M	Screw-In	Aug-88	22,500	6,400	53	14	4
4558M	Screw-In	Nov-94	21,000	7,500	111	10	1
4568	CapSureFix	Jan-97	72,500	45,900	195	3	4
4592	CapSure SP Novus	Oct-98	62,100	43,800	10	1	0
5068	CapSureFix	Jan-97	108,000	62,000	455	46	15
5072	SureFix	Jun-98	8,200	5,300	21	2	1
5076	CapSureFix Novus	Aug-00	580,200	465,800	531	80	42
5524, 5524M	CapSure SP	Mar-90	63,700	27,700	65	17	7
5534	CapSure Z	Feb-96	27,700	11,300	29	6	5
5554	CapSure Z Novus	Jun-98	47,200	32,000	7	6	4
5568	CapSureFix	Jan-97	45,000	32,000	189	7	7
5592	CapSure SP Novus	Jun-98	20,400	15,700	4	2	0
6940	CapSureFix	Oct-98	26,600	15,300	114	16	3
6957	Spectraflex	Jul-79	29,100	3,400	85	39	25
6957J	Spectraflex	Sep-80	30,000	2,800	74	28	30

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes, and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

continued

Laboratory Analysis continued

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These

lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

Reference Chart

Model Number	Family	Туре	Insulation	Conductor Material	Tip Electrode	Connector Type
4503, 4503M	CapSure	Transvenous Atrial-J Tines	Polyurethane (80A)	MP35N 4 Filars	Porous/Steroid	5 mm (4503) IS-1 UNI (4503M)
4504, 4504M	CapSure	Transvenous Atrial-J Tines	Polyurethane (80A)	MP35N 3/4 Filars	Porous/Steroid	3.2 mm Low Profile (4504) IS-1 BI (4504M)
4511	Target Tip	Transvenous Atrial-J Tines	Polyurethane (80A)	MP35N 4/3 Filars	Target Tip Concentric Grooves	5 mm
4512	Target Tip	Transvenous Atrial-J Tines	Polyurethane (80A)	MP35N 2/4 Filars	Target Tip Concentric Grooves	3.2 mm Low Profile
4523	CapSure SP	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 2 Filars	Porous Platinized/ Steroid	IS-1 UNI
4524	CapSure SP	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 4/5 Filars	Porous Platinized/ Steroid	IS-1 BI
4533	CapSure Z	Transvenous Atrial-J Tines	Polyurethane (55D)	MP35N 2 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
4557, 4557M	Screw-In	Transvenous Atrial-J Screw-In	Polyurethane (80A)	MP35N 1 Filar	1.5 mm Helix	5 mm (4557) IS-1 UNI (4557M)
4558M	Screw-In	Transvenous Atrial-J Screw-In	Polyurethane (80A/55D)	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4568	CapSureFix	Transvenous Atrial-J Screw-In	Polyurethane (80A/55D)	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4574	CapSure Sense	Transvenous Atrial -J Tines	Polyurethane/ Silicone (55D,4719)	MP35N 5/5 Filars	TiN Coated Platinum Iridium	IS-1 BI
4592	CapSure SP Novus	Transvenous Atrial-J Tines	Polyurethane/ Silicone (55D/4719)	MP35N 6/3 Filars	Porous Platinized/ Steroid	IS-1 BI
5032	CapSure VDD	Transvenous V or A Tines	Silicone	MP35N 5/6/1 Filars	Porous Platinized/ Steroid	IS-1 BI
5524, 5524M	CapSure SP	Transvenous Atrial-J Tines	Silicone	MP35N 6/5 Filars	Porous Platinized/Steroid	3.2 mm Low Profile (5524) IS-1 BI (5524M)
5534	CapSure Z	Transvenous Atrial Tines	Silicone	MP35N 4/5 Filars	CapSure Z Platinized/Steroid	IS-1 BI
5554	CapSure Z Novus	Transvenous Atrial-J Screw-In	Silicone (4719)	MP35N 6/5 Filars	CapSure Z Porous Platinized/ Steroid	IS-1 BI
5568	CapSureFix	Transvenous Atrial-J Screw-In	Silicone	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
5592	CapSure SP Novus	Transvenous Atrial-J Tines	Silicone (4719)	MP35N 6/5 Filars	Porous Platinized/ Steroid	IS-1 BI
5594	CapSure SP Novus	Transvenous Atrial-J Tines	Silicone (4719)	MP35N 6/5 Filars	Platinized Platinum	IS-1 BI
6940	CapSureFix	Transvenous A or V Screw-in	Silicone	MP35N 3/6 Filars	Platinum Alloy	IS-1 BI
6957J	Spectraflex	Transvenous Atrial-J Screw-In	Polyurethane (80A)	MP35N 1 Filar	1.5 mm Helix	5 mm

Epi/Myocardial Pacing Leads

		ectraflex									
US Market	Release			Oct-81			Serial Nun	nber Prefix	TF or LBJ		
Number of	^F Leads Enro	lled in Study		133			Type and/	or Fixation	Myocardia	l Stab-in, V or	A, Peds
Complicat	ions in Study			10			Polarity		Unipolar		
		Failure to C Failure to edance Out of Insulation (not further d	Sense Range n (ESC)	4 3 1 1 1			Steroid		No		
Cumulative	e Months of	Follow-Up in S	Study	5,811							
Advisories				None							
Years Afte	r Implant	1	I	1			1	1	1	1	1
	1 yr	2 yr	3 yr								
	97.1	95.7	95.7								
			-								
0	1	2	3	4	5	5	6	7	8	9	10

4965 CapSure Epi

S Market Release			Sep-96	Serial N	umber Prefix	LBT	
Number of Leads Enro	olled in Study		141		d/or Fixation		Suture-On V or A
Complications in Stud			6	Polarity	a, er i maneri	Unipolar	
	Conductor Fr Failure to C Failure to	Capture	2 1 1 2	Steroid		Yes	
Cumulative Months o	Follow-Up in S	Study	4,032				
Advisories			None				
′ears After Implant │1 yr	2 yr	3 yr					

Epi/Myocardial Pacing Leads continued

	8 CapSure					Product Ch				
US Ma	irket Release		Se	p-99		Serial Numb	er Prefix	LEN		
Numbe	er of Leads Enr	olled in Study		211		Type and/or	Fixation	Epicardial S	uture-On V or A	4
Compl	lications in Stud	ly		9		Polarity		Bipolar		
		Conductor F Failure to (Failure to Over	Capture	4 3 1 1		Steroid		Yes		
Cumul	lative Months o	f Follow-Up in a	Study 10),206						
Advisc	ories		I	None						
ears A	After Implant									
	1 yr	2 yr	3 yr	4 yr	5 yr					
	99.5	97.1	96.3	95.1	93.7	93.7 at 66 mo				

E	Δ	7	1
5	U	1	1

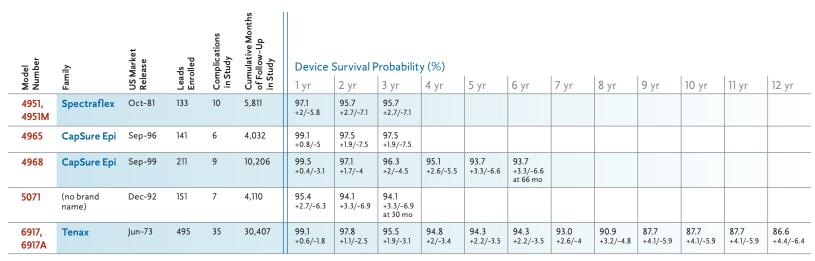
5071				Product Charac	teristics		
US Market Release		Dec-92	2	Serial Number Pro	efix LAQ		
Number of Leads Enro	lled in Study	15	1	Type and/or Fixat	ion Myocardi	al Screw-in V	'ent.
Complications in Study	1	7	7	Polarity	Unipolar		
	Failure to C	apture 7	7	Steroid	No		
Cumulative Months of	Follow-Up in S	Study 4,110)				
Advisories		None	2				
Coars After Implant							
Years After Implant	2 yr						
1	2 yr 94.1	94.1 at 30 mo					
1 yr							
1 yr							

Lead Survival Probability (%)

Epi/Myocardial Pacing Leads continued

US Market Release		Jun-	73				Serial Nu	umber P	refix	WV	or WO	2			
Number of Leads Enr	olled in Study	,	95				Type and			My	ocardia	l Scre	w-in Ve	ent.	
Complications in Stud			35				Polarity	,			polar				
·	Failure to Ca Failure to S Insulation (Overse	ense MIO)	26 6 1 2				Steroid			No					
Cumulative Months o	f Follow-Up in Stu	idy 30,4	07												
Advisories		No	ne												
Years After Implant															
Tears After Implant															
lyr 2yr 3	yr 4yr 5yr	6 yr 7 y	vr 8 yr	9 yr	10 yr	11 yr	12 yr								
99.1 97.8 9	5.5 94.8 94.3	94.3 93	.0 90.9	87.7	87.7	87.7	86.6								
											_				

Lead Survival Summary (95% Confidence Interval)



Epi/Myocardial Pacing Leads continued

Epi/Myocardial Pacing Leads continued

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
4951, 4951M	Spectraflex	Oct-81	25,000	4,400	15	93	28
4965	CapSure Epi	Sep-96	15,400	9,600	7	70	2
4968	CapSure Epi	Sep-99	8,900	6,900	1	3	0
5071	(no brand name)	Dec-92	25,100	16,700	20	3	1
6917, 6917A	Tenax	Jun-73	180,200	7,700	115	42	1

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes, and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

> Source: US Returned Product Analysis Data as of October 31, 2005

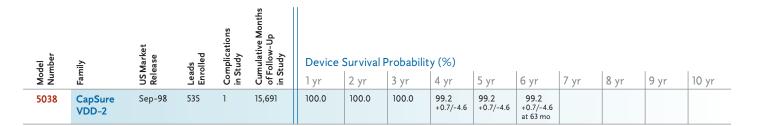
Model Number	Family	Туре	Insulation	Conductor Material	Tip Electrode	Connector Type
4951, 4951M	Spectraflex	Myocardial Stab-In V or A/Peds	Polyurethane (80A)	MP35N 4 Filars	Barb	5 mm (4951) IS-1 UNI (4951M)
4965	CapSure Epi	Epicardial Suture-On V or A	Silicone	MP35N 5 Filars	Porous Platinized/ Steroid	IS-1 UNI
4968	CapSure Epi	Epicardial Suture V or A	Silicone	MP35N 5 Filars	Porous Platinized/ Steroid	IS-1 B1
5069	(no brand name)	Myocardial Screw-In	Silicone	MP35N Multifilars	3-Turn Helix	IS-1 UNI
5071	(no brand name)	Myocardial Screw-In Ventricular	Silicone	MP35N Multifilars	2-Turn Helix	IS-1 UNI
6917	Tenax	Myocardial Screw-In Ventricular	Silicone	Pt Ir Tinsel Wire	3-Turn Helix	5 mm
6917A	Tenax	Myocardial Screw-In Ventricular	Silicone	Pt Ir Tinsel Wire	2-Turn Helix	5 mm

Reference Chart

VDD Single Pass Pacing Leads

5038 Ca	pSure V	DD-2				Product	Characterist	ics		
US Market Re	US Market Release Number of Leads Enrolled in Study		Sep-98 535			Serial Number Prefix		LEE, LEG, or LEF		
Number of L						Type and	Type and/or Fixation		Transvenous, Atr-Vent., Tines	
Complication	ns in Study			1		Polarity		Quad	ripolar	
		Failure to	Sense	1		Steroid		Yes		
Cumulative N	Nonths of Fo	ollow-Up in S	tudy 15,69	91						
Advisories			Non	e						
Years After I	I mplant 1 yr	2 yr	3 yr	4 yr	5 yr					
	100	100	100	99.2	99.2	99.2 at 63 mo				
00										
0										
0 1		2	3	4	5	6	7	8	9	10
0										

Lead Survival Summary (95% Confidence Interval)



VDD Single Pass Pacing Leads continued

Laboratory Analysis

Model Number	Family	US Market Release	Estimated US Implants	Estimated Active US Implants	Implant Damage	Electrical Failure	Other
5032	CapSure VDD	Mar-96	5,500	2,500	21	10	0
5038	CapSure VDD-2	Sep-98	5,900	3,800	6	2	1

Every lead or lead portion returned to Medtronic receives an analysis. The table on this page summarizes the analysis results.

Lead failures are divided into three categories: Implant Damage, Electrical, and Other. Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes and conductor fracture due to overtorquing. An electrical failure is defined as a hardware failure resulting in a break in the insulation or a break in the conductor that could affect the electrical performance of the lead. A break in the insulation is defined as a breach allowing entry of body fluids, or inappropriate current flow between the conductors, or between the conductor and the body. Examples include cuts, tears, depressions, environmental stress cracking (ESC), and metal ion oxidation (MIO). A break in the conductor of a lead is defined as the loss of continuity in the metallic components that could interrupt the current flow or voltage. Examples include fractured conductors and defective crimps.

The number of US implants is estimated based on the total number of leads sold in the United States. The number of active implants is estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure. While the number of implanted leads and active leads is adjusted for underreporting of patient mortality, elective replacement, and lead failure, the number of failures listed is the actual number confirmed in the laboratory.

For leads designed for either ventricular or atrial use, the numbers listed include both.

Some lead models included in this table do not have a survival curve presented earlier in this report. These lead models do not have a survival curve because they have insufficient sample size in the System Longevity Study. Laboratory results for these models are included here for reference and comparison.

> Source: US Returned Product Analysis Data as of October 31, 2005

Reference Chart

Model Number	Family	Туре	Insulation	Conductor Material	Tip Electrode	Connector Type
5032	CapSure VDD	Transvenous V and A Tines	Silicone	MP35N 5/6/1 Filars	Porous Platinized/ Steroid	Atr. IS-1 BI, Vent. IS-1 BI
5038	CapSure VDD-2	Transvenous Ventricular Tines	Silicone	MP35N	Porous Platinized/ Steroid	Atr. IS-1 BI, Vent. IS-1 BI

ICD Charge Time Data

Medtronic continues its commitment to providing updated information on charge time performance of Medtronic ICDs.

Introduction

Information on charge time performance of Medtronic ICDs is presented in this section of the CRM Product Performance Report. The collection of Save-to-Disk files for all Medtronic ICD models, from 7221 Micro Jewel onwards, was implemented on July 1, 1999. The files are collected via our ongoing active clinical study of long-term system performance called the System Longevity Study.

Charge times are normally affected by several factors:

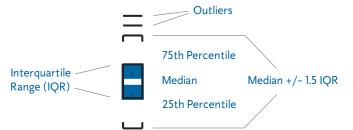
- (a) the gradual decline in battery voltage and increase in battery resistance that occurs over the life of the device,
- (b) the deformation of capacitors that occurs normally between capacitor formations, and
- (c) the different rates of capacitor deformation due to component variability.

Certain early Model 7223Cx and Model 7271 devices demonstrated longer than typical charge times due to greater component variability in the capacitors used in these devices. This information has been communicated directly to physicians via Safety Advisories. At this time, we estimate very few, if any, of the affected advisory populations of 7223Cx and 7271 ICDs remain implanted and in-service. Charge time data for these advisory populations are no longer included in this issue of the Performance Report.

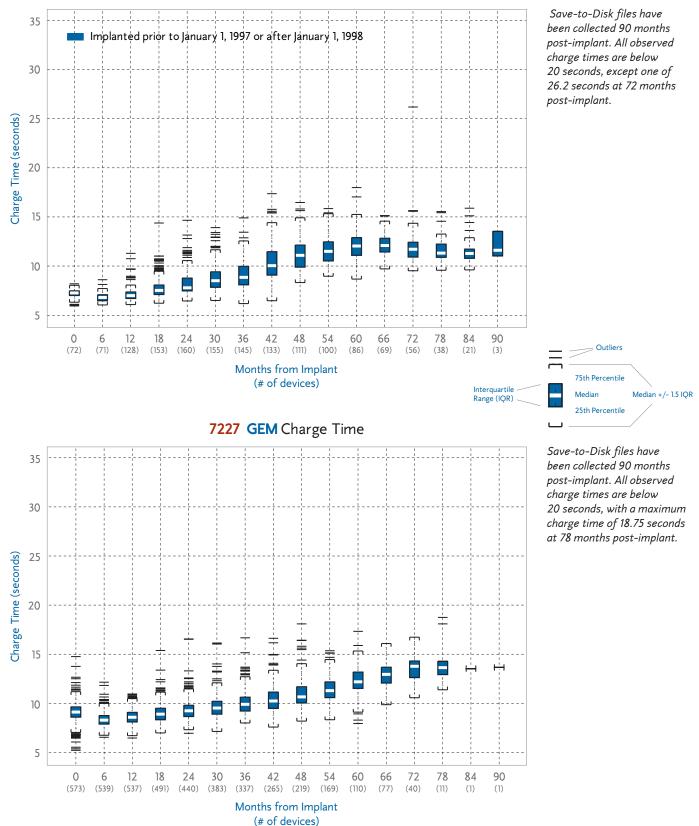
Data Presentation

Charge time data for ICD models are presented via boxplots at 6-month intervals. The shaded box on the plots represents the middle half of the data – the Interquartile Range (IQR). The white line in the middle of each box is the median charge time. The top of the box representing the IQR is the 75th percentile (i.e., 75% of all charge times fall below this line), whereas the bottom of the box represents the 25th percentile. The brackets around the box represent the variance in charge times (analogous to a confidence interval), and are calculated as a function of the median and IQR. Individual values falling outside the brackets are labeled as outliers.

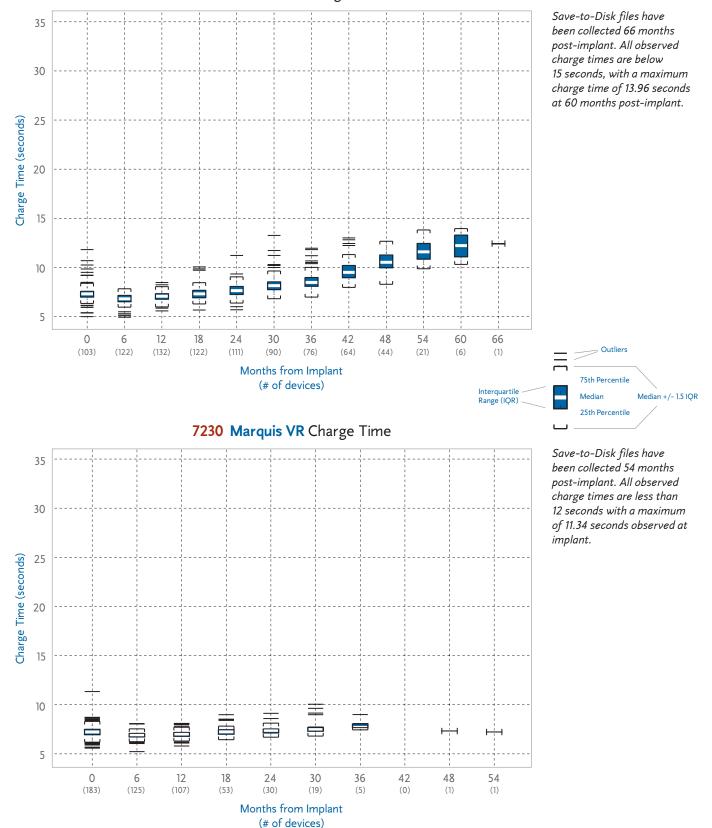
Only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. A conservative approach has been adopted whereby only the maximum charge in each 6-month interval is reported. As charge time is a direct product of time since last capacitor reformation, charges occurring within 15 days of a previous charge are excluded. This precludes the reporting of overly optimistic results.



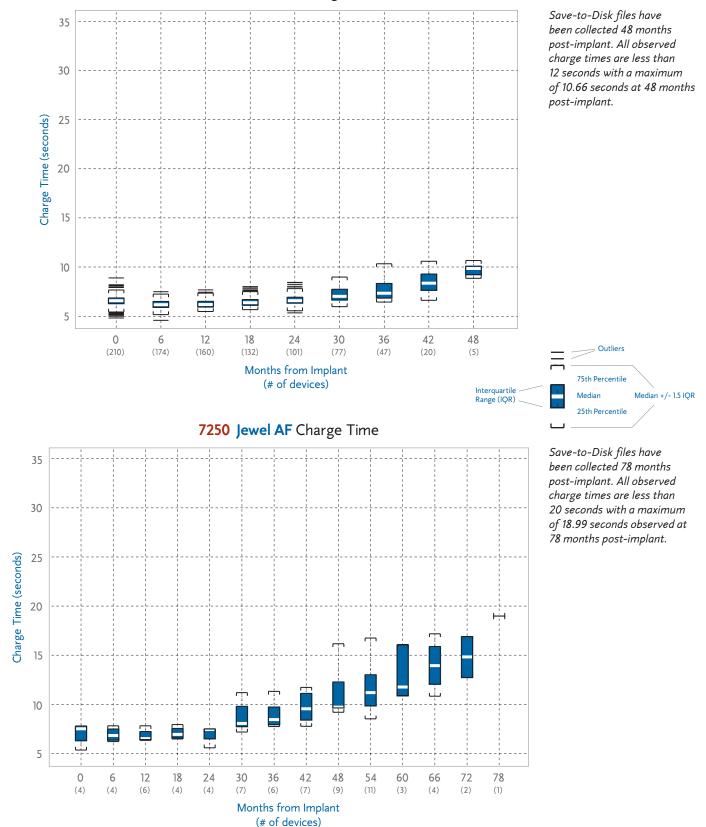




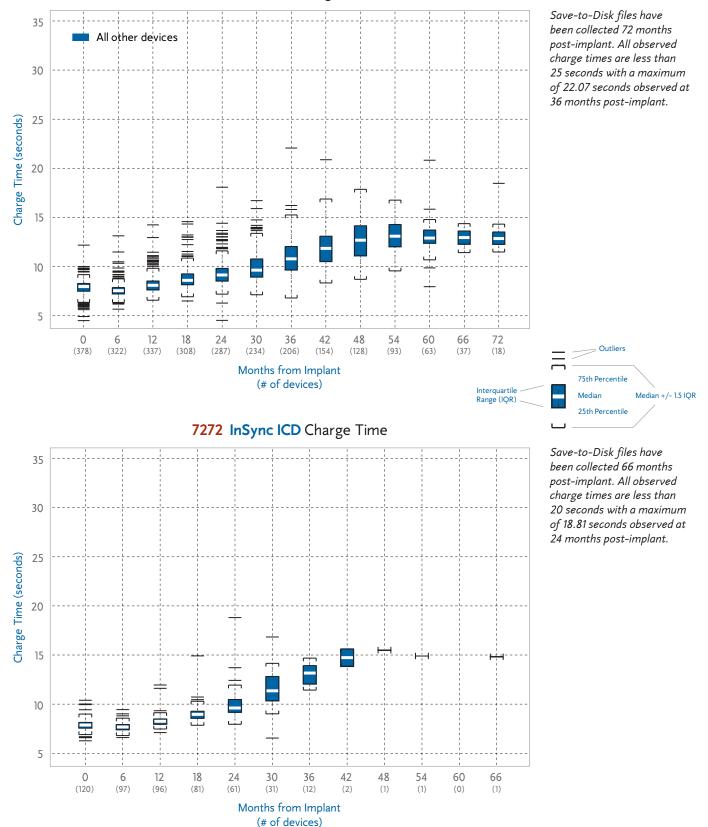
7229 GEM II VR Charge Time



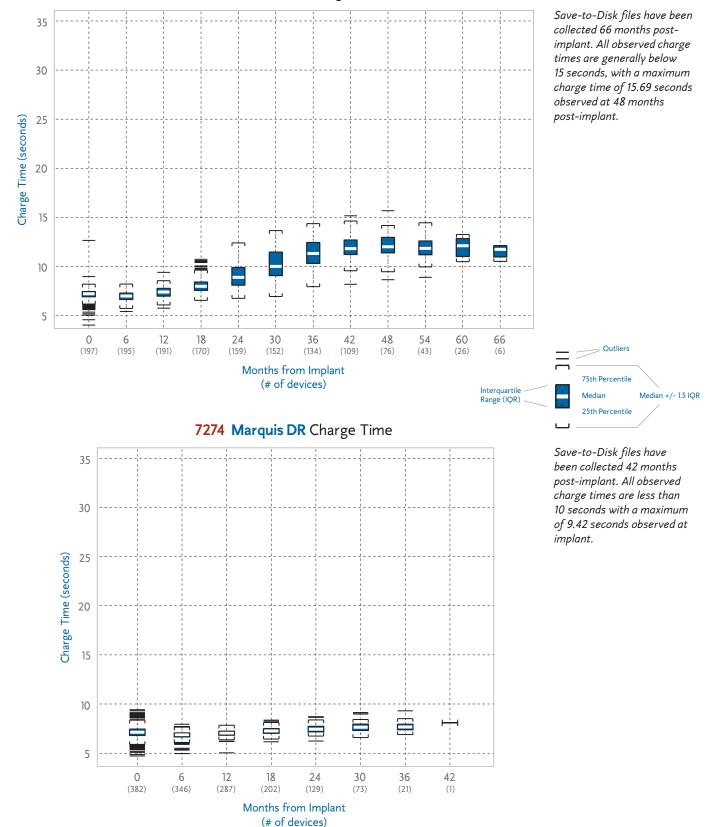
7231 GEM III VR Charge Time



7271 GEM DR Charge Time

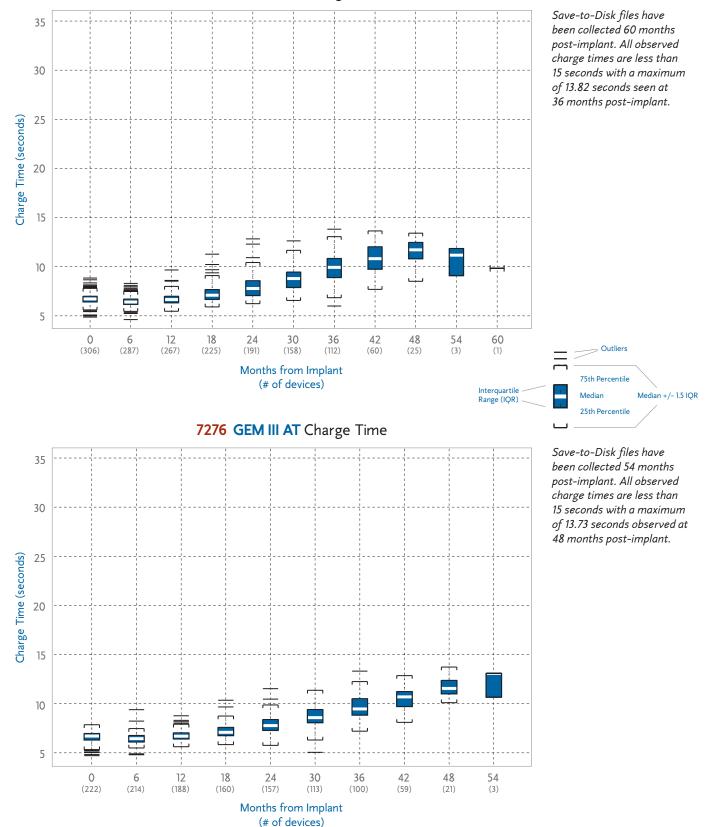


7273 GEM II DR Charge Time

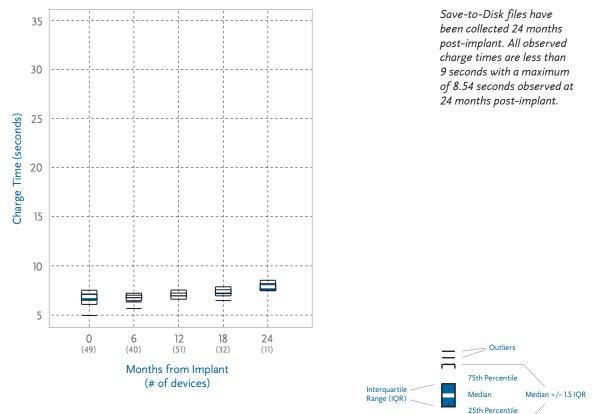


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7275 GEM III DR Charge Time



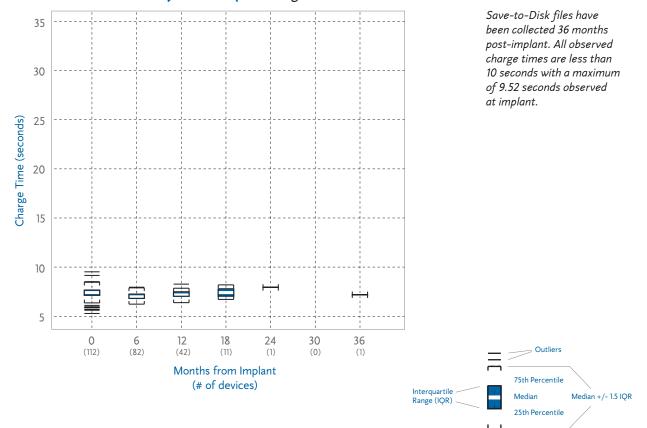
7277 InSync Marquis Charge Time



continued

ı.

7289 InSync II Marquis Charge Time



Advisories

Sigma Implantable Pulse Generators

Original Date of Advisory: November 2005

Potential Separation of Interconnect Wires

Product

A specific subset of Sigma series pacemakers may fail due to separation of interconnect wires from the hybrid circuit. Approximately 28,000 devices, with approximately 6,650 in the United States, out of an initial implant population of 40,000 worldwide, remain implanted and in service. Specific model and serial numbers of affected devices are available online at http://SigmaSNList.medtronic.com.

Advisory

This subset of Sigma series pacemakers that may fail due to separation of interconnect wires from the hybrid circuit may present clinically as loss of rate response, premature battery depletion, intermittent or total loss of telemetry, or no output. There have been no reported patient injuries or deaths due to this issue.

Separation of redundant interconnect wires has been observed on hybrid terminal blocks. Device failure occurs only where both interconnect wires separate from a hybrid terminal block. In October 2005, testing and analysis identified the root cause of these failures and the affected population. Hybrid circuits used in this subset of devices were cleaned during manufacturing with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time.

Our modeling predicts a failure rate from 0.17% to 0.30% over the remaining lifetime of these pacemakers. No provocative testing can predict which devices may fail.

Patient Management Recommendations

To assist physicians in their patient care and after discussion with physician consultants, Medtronic offers the following recommendations:

- Medtronic does not recommend replacement of these devices prior to normal elective replacement (ERI), based on the low probability of occurrence of a serious event in this population.
- Continue routine follow-up in accordance with standard practice.
- Advise patients to seek attention immediately if they experience return of symptoms (e.g., syncope or light-headedness).
- Determine whether device replacement is warranted on a case-by-case basis based upon consultation with patients, review of the individual patient's medical history, and consideration of the relative risks of an invasive procedure.

Status Update (December 2005)

The Sigma Family device performance related to the interconnect wires separation mechanism continues to be within Medtronic's engineering projections and expectations. As of December 31, 2005, 25 devices out of approximately 40,000 devices worldwide (0.063% incidence), have been confirmed as having interconnect wire separation. Sixteen (16) of these devices were returned from the United States. There have been no reported serious injuries or deaths due to this issue.

Seventeen (17) of the 25 returns were identified via either a regularly scheduled follow-up or during a non-device related hospital visit. Two (2) devices were identified due to the patient experiencing syncope. The other 6 devices were replaced with no clinical symptoms associated with the interconnect wire separation. Among the 6 devices, 4 were returned due to a device/system upgrade, and 2 were returned due to infection.

Consistent with previous Medtronic projections, the probability of occurrence remains low and is within failure rate predictions. Implant duration for the 25 failures has ranged from 17-44 months.

Advisories continued

7274 Marquis DR	7277 In	Sync Marquis				
7230 Marquis VR	7289 In	Sync II Marquis				
7278 Maximo DR	7279 In	Sync III Marquis				
7232 Maximo VR		Sync III Protect				
Original Date of Advisory: February 2005						

Potential Premature Battery Depletion Due to Battery Short

Product

The specific subset of Marquis family ICD and CRT-D devices having batteries manufactured prior to December 2003 is affected. Devices manufactured with batteries produced after December 2003 are not affected. Specific model and serial numbers of affected devices are available online at http://MarquisSNList.medtronic.com.

Advisory

Medtronic Marquis family of ICD and CRT-D devices having batteries manufactured prior to December 2003 may experience rapid battery depletion due to a specific internal battery short mechanism. Battery design changes were implemented in December 2003 that eliminate the possibility of this internal shorting mechanism.

Highly accelerated bench testing indicated the rate of this shorting mechanism may increase as the battery is depleted. As of February 2005, the rate of shorting was approximately 1 in 10,000 (0.01%); bench test data indicated the rate may increase to between 0.2% and 1.5% over the second half of device life.

No provocative testing can predict which of these devices will experience this issue. Once a short occurs, battery depletion can take place within a few hours to a few days. After depletion the device ceases to function. It is also possible that as the battery depletes quickly, patients may experience temporary warmth in the area surrounding the ICD.

Patient Management Recommendations

The following recommendations apply to the affected population:

- Continue to conduct routine (e.g., quarterly) followup procedures.
- Turn on low battery voltage PatientAlert indicator.
- Inform patients that should they experience warmth in the area surrounding the ICD to seek follow-up care.
- Consider providing patients with a hand-held magnet to check device status. Device operation may be monitored periodically (e.g., daily) by patients using the magnet, which will result in a device tone indicating device function (provided PatientAlert is turned on). If no tone is heard, follow-up care should be sought.

Status Update (December 2005)

The Marquis Family device performance related to the battery shorting mechanism continues to be within Medtronic's engineering projections and expectations. As of December 31, 2005, 30 Marquis Family devices have been confirmed as having the internal battery shorting mechanism. Eighteen (18) of these devices were returned from the United States. There have been no reported serious injuries or deaths due to this issue.

Fourteen (14) of the 30 returns have been identified via either a regularly scheduled follow-up or during a nondevice related hospital visit, 13 by patients reporting warmth in the ICD pocket, 1 for return of bradycardia symptoms, and 2 due to the PatientAlert sounding.

Consistent with previous Medtronic projections, the observed rate of shorting in the second half of device life is higher than that observed in the first half of device life. Of the devices that have exhibited shorting in the last half of device life, 67% occurred in the last quarter of device life, and 53% in the last 10% of device life.

7223 Micro Jewel II

7271 GEM DR

Original Date of Advisory: April 5, 2004

Potential Long Charge Times Due to Capacitor - Supplement

Product

Micro Jewel II Model 7223Cx ICDs with capacitor lots received from a supplier that were implanted in 1997 and GEM DR Model 7271 ICDs with capacitor lots received from a supplier that were implanted between November 1997 and December 1998. It is estimated that less than 0.5% of currently implanted Micro Jewel II and GEM DR devices built with these specific capacitors may exhibit performance concerns with typical battery depletion.

Affected devices that were subjects of previous physician letters in 1999 and 2000, defined as an isolated group of suspect capacitors, may not be consistently capable of providing high voltage energy delivery near or at ERI (4.91 volts) and continuing through EOL (4.57 volts).

Advisory

Several Micro Jewel II devices have been reported or returned which exhibited the inability to provide a full energy shock when the battery voltage was below 5.13 volts.

Because the same capacitor component lots were also used in a small subset of GEM DR Model 7271 ICDs (implanted from late 1997 through 1998) the company is providing these recommendations for both devices.

Patient Management Recommendations

April 5, 2004 letter supplements earlier Micro Jewel II letters (August 1999 and November 2000) and a GEM DR letter (December 1999) regarding this same previously identified population of devices with capacitors from specific component lots.

The following recommendations apply to Micro Jewel II 7223 and GEM DR Model 7271 devices for advisory population.

- As soon as possible, verify the charge time and battery voltage of each affected device by scheduling a follow-up with the patient, or, if the patient's last follow-up was within the previous 3 months, through review of the patient's medical records.
- Schedule replacement for any device with:
 - Battery voltage of 5.16 volts or less (NEW RECOMMENDATION)
 - OR charge time of 18 seconds or greater.
- If the verified charge time is less than 18 seconds but greater than 14 seconds, program the Automatic Capacitor Formation Interval to 1 month. If verified charge time is less than 14 seconds, no additional reprogramming is required.
- Follow these patients every 3 months, at a minimum.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

AT500 Pacing System Original Date of Advisory: September 15, 2003

Potential Incorrect Memory Circuit Setting

Product

The affected devices are limited to AT500 implantable pulse generators manufactured prior to November 2001 and it is predicted that less than 1% of these devices will experience this high current drain. A list of affected serial numbers is attached to the September 15, 2003 physician communication letter, or is available from your Medtronic representative, or by calling US Technical Services at 1 (800) 723-4636.

AT500 devices manufactured after October 2001 are not affected.

Advisory

At the time of the advisory, Medtronic had received 14 AT500 Pacing System devices Model AT501 returned for premature battery depletion due to high current drain from a subpopulation of approximately 4,500 devices. Our investigation isolated the root cause to a unique condition that involves the use of the AT/AF EGM "All Episodes" (Episode Full Disclosure mode) feature. The affected device's memory circuit contains 4 bytes of information that can cause the high current drain when specific memory locations store patient intrinsic activity. This results in sooner than anticipated battery depletion; generally within a 2-month period from the time the error occurs. While implanted, each of the returned devices initially appeared to be operating normally and in many cases had been through multiple follow-ups in which the battery level was monitored and at predicted levels.

Patient Management Recommendations

A simple non-invasive procedure will permanently correct the memory circuit and prevent this cause of premature depletion from occurring in the affected AT500 devices. It involves programming the diagnostic setup for Summary Data and EGM strips to "Treated Episodes" followed by a reprogramming to "All Episodes." Note that diagnostic data will be cleared with this programming; therefore, we recommend that a full summary printout or a save-to-disk be done. This will correctly reset the device's software and prevent the identified premature depletion. Programming will only need to be done once over the life of the device. Step-by-step reprogramming instructions are available from your Medtronic representative.

For patients who are pacemaker dependent with no underlying rhythm, it is recommended the reprogramming be done as soon as possible. For non-pacemaker dependent patients the reprogramming could be done at the next regularly scheduled follow-up.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remain unchanged. The devices affected by this advisory are generally at or beyond the mid point of their expected battery longevity.

7271 GEM DR ICDs

Original Date of Advisory: November 14, 2002

Potential Sudden Increase in Charge Times

Product

A specific subset of devices consisting of less than 20% of the GEM DR ICD manufactured between 1998 to 1999 have suspect batteries that could exhibit sudden increased charge times. Suspect devices are GEM DR Model 7271 ICDs with the engineering series number "4" in the fourth position of the serial number. For example, PIM4xxxxx.

Advisory

Suspect GEM DR devices can exhibit sudden increase in charge times (charge time greater than 18 seconds) at approximately 32 months post-implant.

Patient Management Recommendations

Verify the charge time of each affected suspect device either by scheduling a follow-up with the patient, or through review of the patient's medical records, if the patient's last follow-up was within the previous 3 months.

- Automatic capacitor formation should be programmed to monthly on all suspect devices. This will provide additional warning should an extended charge time unexpectedly occur.
- PatientAlert for Excessive Charge Time should be programmed ON. 18 seconds is the default setting for PatientAlert – Excessive Charge Time.
- Replacement of the device should be considered for any GEM DR device with an unformed charge time of 18 seconds or greater.

At the time of the advisory, a written communication was provided to physicians who have patients implanted with the affected devices, along with serial numbers of those devices.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remain unchanged. The devices affected by this advisory are nearing the end of their expected battery longevity. Kappa 600, 700 Dual Chamber (D, DR, and VDD) IPGs

Original Date of Advisory: March 15, 2002

Potential Fractured Power Supply Wires

Product

A specific subset of Kappa 700/600 Dual Chamber (D, DR, and VDD) Implantable Pulse Generators have been identified by serial numbers. Hospitals and Physicians were notified. Specific model and serial numbers of affected devices are available by calling US Technical Services at 1 (800) 723-4636.

Advisory

As of March 15, 2002, Medtronic observed 53 related failures (0.02%) in over 255,000 Kappa 700/600 Dual Chamber (D, DR, and VDD) Series devices sold worldwide. Medtronic voluntarily communicated this information to physicians because these failures had been observed in patients having submuscular implants. There have been no reports of serious injury or death related to this issue.

These devices have presented with an electrical reset, intermittent output, or no output. Our investigation identified the root cause as fractured wires supplying power to the pacemaker. This has been directly correlated to submuscular placement of these devices. Submuscular implant locations (e.g., subpectoral, abdominal, etc.) can result in additional stress and repetitive flexing on the implanted device causing excessive fatigue on these wires. Of the estimated 4,000 devices implanted submuscular, approximately 200 (5%) may experience this failure. These stresses on the implanted device are unique to submuscular implant sites and do not exist with subcutaneous implants.

Patient Management Recommendations

While there is no provocative testing or time dependency that will predict which submuscular placed device will fail, certain electrical resets may be an indicator that a wire fracture has occurred. Normal electrical resets can occur as a result of electrosurgical procedures such as cautery and ablation or from defibrillation therapy. If none of the normal causes of electrical reset can be confirmed, or if a device serial number presents as "000000" following an electrical reset, this may be an indicator of a wire fracture.

For patients who have submuscular implants of devices within the designated serial number range and who are pacemaker dependent with no underlying rhythm, replacement of the device should be considered. Medtronic will provide the replacement device free-of-charge under the terms of its warranty program if a device is replaced in these patients.

For patients having subcutaneous implants, no change to your current patient care and follow-up is advised.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remain unchanged.

7227 with Interchangeable Connector System

Original Date of Advisory: December 20, 2000

Potential High Impedance Due to Removable Connector Header

Product

All Model 7227 devices with the interchangeable connector system may be affected.

Advisory

Affected devices may exhibit high impedance warnings due to the connection between the removable header piece and its receptacle on the device. These high impedance measurements may trigger the PatientAlert feature.

Testing and analysis indicate that despite the high connector impedance, after further evaluation and confirmation of lead integrity, these devices should continue to provide therapy over their service life.

As of December 20, 2000, 45 instances of this out of 1,200 implants worldwide have been identified where connector-related high impedance warnings have occurred. While the warning messages displayed at device interrogation appear to indicate a potential lead problem, it is possible for the source of the high impedance measurement to be located in the connection between the removable header piece and its receptacle on the device.

If device interrogation displays a high impedance warning message, further investigation is recommended prior to taking corrective action. In cases where a high impedance warning is displayed and follow-up has determined that the lead is functioning normally, analysis indicates that:

- High voltage therapy delivery is not affected.
- Sensing of VT and VF will not be affected.
- Oversensing may occur which could potentially result in unwarranted delivery of therapy.
- Pacing threshold increases may be observed.

Patient Management Recommendations

- The PatientAlert option for "Lead Impedance Outof-Range" should be enabled at the next scheduled follow-up for both the pacing and defibrillation lead. This will support identification of patients with outof-range lead impedances.
- When a patient presents with a high impedance warning, a "Save To Disk" file should be created and forwarded to Medtronic Technical Services. Your Medtronic representative can coordinate and support evaluation of the implanted system. Analysis of this data can identify if the impedance increase is a result of connector issues, lead failure, or a combination of both. The save-to-disk file can be sent as an email attachment to <u>crmtechnicalservices</u> @medtronic.com. Medtronic Technical Services can also be contacted at 1(800) 723-4636.
- After a high impedance trigger of the PatientAlert has occurred as a result of this issue, we would recommend disabling the feature for that lead to avoid recurrent triggering of the alert tone. In cases where the interchangeable connector is the source of the impedance increase, routine follow-up of the patient to assess pacing, sensing, and defibrillation performance is warranted.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

7223Cx Micro Jewel II ICDs

Original Date of Advisory: November 20, 2000

Potential Long Charge Times Due to Capacitor

Product

Affected devices within an isolated group of suspect capacitors could exhibit a sudden increase in charge times > 18 seconds.

Several Micro Jewel II devices have been returned which exhibited charge times in excess of 60 seconds.

November 20, 2000 letter updating previous recommendations communicated August 5, 1999. A separate written communication has been provided to physicians who have patients implanted with the affected devices, along with serial numbers of those devices.

Advisory

May 2000 Product Performance Report combines the Micro Jewel II Model 7223Cx and GEM DR Model 7271 advisory. Based on performance differences these model advisories have been separated.

Micro Jewel II devices implanted throughout 1997 can exhibit formed and/or unformed charge times greater than 18 seconds at approximately 18 months post-implant. Devices displaying this behavior contain capacitors from specific component lots.

Patient Management Recommendations

The following recommendations apply to Micro Jewel II 7223 devices.

- As soon as possible, verify the charge time of each affected device either by scheduling a follow-up with the patient, or through review of the patient's medical records, if the patient's last follow-up was within the previous 3 months.
- If you identify any affected devices that have a charge time of 18 seconds or greater, replacement of the device is recommended. If the verified charge time is less than 18 seconds, at a minimum, quarterly follow-ups are recommended for those patients.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

7273 GEM II DR 7229Cx GEM II VR

Original Date of Advisory: February 11, 2000

Potential Weak Solder Connection

Product

Sixteen hundred (1,600) devices with potential for a weakened solder connection have been implanted worldwide. Medtronic estimates that this failure mode will affect less than 50 devices worldwide. Specific model and serial numbers of affected devices are available by calling US Technical Services at 1 (800) 723-4636.

IMPORTANT REMINDER:

Medtronic strongly advises physicians who have patients under their care affected by this issue to reprogram the PatientAlert feature "ON" without delay.

Advisory

Solder connections on a specific component may exhibit loss of integrity.

Affected devices have solder connection that may weaken over time and can result in loss of telemetry and device therapy output.

Patient Management Recommendations

- Program "Lead Impedance Out-of-Range" to ON within the PatientAlert feature. *Both pacing and defibrillation lead alerts must be enabled.*
- In the event of a device malfunction, the pacing or defibrillation lead impedance will be reported as outof-range – this will cause an activated PatientAlert tone to sound. The PatientAlert feature will check the lead impedances once each day.
- If the PatientAlert tone sounds, evaluate the device to determine the cause of the alert. If the device cannot be interrogated (no telemetry), then device replacement is recommended. If the device can be interrogated, it is unlikely the alert tone is due to this issue, and other potential causes for the PatientAlert tone should be investigated.

The PatientAlert parameter must be programmed ON for the remainder of the device life in order to detect any future occurrences of this failure mode.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remained unchanged. The devices affected by this advisory are nearing the end of their expected battery longevity.

7271 GEM DR ICDs

Original Date of Advisory: December 16, 1999

Potential Long Charge Times Due to Capacitor

Product

GEM DR devices implanted November 1997 -December 1998 (during the PMA clinical trial and early commercial release) can exhibit unformed charge times greater than 18 seconds, and formed charge times greater than 10 seconds, at approximately 18 months post-implant.

Advisory

Affected devices can exhibit unformed charge times > 18 seconds 12-24 months post-implant.

Devices displaying this behavior contain capacitors from specific component lots.

Patient Management Recommendations

The following recommendations apply to the GEM DR 7271 device.

- At normal scheduled follow-up, check the stored automatic capacitor formation time to ensure the charge time is in a range acceptable for each individual patient.
- If the charge time is greater than 14 seconds prior to battery elective replacement indicator (ERI), program the Automatic Capacitor Formation Interval to 1 month.

Note: Stabilization and/or reduction in charge times may take 3-6 months to become apparent after programming the formation to 1 month.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

7227Cx GEM 7229Cx GEM II VR Original Date of Advisory: October 15, 1999

Potential Circuit Overload

Product

Model 7227Cx Implantable Cardioverter Defibrillators supplied before October 15, 1999, with serial numbers ending in an "H." For example, PIPxxxxxH or PJJxxxxxH, where x is a variable numeric, may be affected. Specific model and serial numbers of affected devices are available by calling US Technical Services at 1 (800) 723-4636.

IMPORTANT REMINDER:

Medtronic strongly advises physicians who have patients under their care affected by this issue to reprogram the PatientAlert feature "ON" without delay.

Advisory

Manufacturing error in a small percentage of devices may cause circuit overload when AX ≥ B High Voltage energy is delivered via an integrated bipolar lead. GEM Model 7227Cx and GEM II VR Model 7229Cx devices with dedicated bipolar sensing leads are not affected by this issue. Devices affected may not be able to subsequently charge to full energy and experience "charge circuit timeout."

Patient Management Recommendations

- Assessment of all patients with the potentially affected devices implanted AND an integrated bipolar ICD lead such as the 6942 and 6945 should take place without delay.
- Reprogram polarity pathway to B ≥ AX for all cardioversion and defibrillation therapies.
- Confirm correct device function:
 - Perform a full energy charging sequence.
 - If "charge circuit timeout" is observed, contact your Medtronic representative.
 - If device charges normally, it has not been damaged and will function appropriately with polarity programmed B ≥ AX.

Recent studies have demonstrated that DFTs are similar or lower in a $B \ge AX$ polarity pathway when compared to $AX \ge B$.

Devices implanted with functional dedicated bipolar leads such as the 6932, 6934S, 6936, 6943, and 6966 are not affected.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remained unchanged. The devices affected by this advisory are nearing the end of their expected battery longevity.

Sigma Implantable Pulse Generators

Original Date of Advisory: September 27, 1999

Manufacturing Issue

Product

The affected devices are limited to subset of Sigma pulse generators manufactured between July 5, 1999 and August 31, 1999. All affected devices were distributed outside the United States. Medtronic representatives provided a list of affected device serial numbers of this Implantable Pulse Generator.

Advisory

A manufacturing issue was identified which could result in a sudden loss of sensing or pacing output, under worst case conditions. The cause was isolated to a defined manufacturing time period, a specific manufacturing process, and a limited number of units distributed in various countries outside the United States.

Patient Management Recommendations

There is no patient monitoring or provocative testing that will predict the occurrence of this potential failure. If any of these devices have been implanted, you may wish to consider whether prophylactic replacement would be appropriate, especially in patients at high risk such as pacemaker dependent patients. However, individual patient circumstances and medical judgment should, as always, dictate patient care. If you choose to replace the device, Medtronic will provide a new device under the applicable warranty program.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendations remained unchanged.

7227Cx GEM ICDs

Original Date of Advisory: April 2, 1999

Potential High Current Drain

Product

Affected devices can be identified by reviewing battery voltage: If the battery voltage is > 3.03 volts and it is at least 3 months post-implant, then the ICD is not affected. Model 7227Cx devices delivered after April 2, 1999 are not affected.

Advisory

High current drain in the electronic hybrid circuit causes premature battery depletion in affected devices. The high current drain occurred during manufacturing and has been traced to a specific component.

Patient Management Recommendations

Review battery voltage records for each 7227Cx patient. 1) If the battery voltage at implant was

- ≤ 3.07 volts or unknown, then bring the patient in for evaluation as soon as possible.
- > 3.07 volts, then review the battery voltage at 3 months post-implant.

2) If the battery voltage at the 3 month follow-up is

- < 3.03 volts, then contact your Medtronic representative for further evaluation.
- > 3.03 volts, then no further action is required.

Status

All potentially affected implanted devices have been implanted for at least 3 months. No further action is required.

Thera Implantable Pulse Generators

Original Date of Advisory: February 18, 1997

Potential Integrated Circuit Failure

Product

One hundred seventy-seven (177) Thera Implantable Pulse Generators are affected. These have been identified by serial number and each respective physician has been notified. The models of the affected generators include 7940, 7941, 7942, 7950, 8940, 8941, 8942, and 8948. Specific model and serial numbers of affected devices are available by calling US Technical Services at 1 (800) 723-4636.

Advisory

These devices are susceptible to a sudden loss of telemetry, sensing, or pacing output functions.

The cause of the anomaly is a potential failure in one integrated circuit.

Patient Management Recommendations

There is no patient monitoring or provocative testing that will predict the occurrence of this anomaly. You may wish to consider prophylactic replacement of the device if your patient is at high risk, e.g., pacemaker dependent.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged.

4504, 4504M CapSure Atrial Lead

4582 Target Tip Atrial Lead

Original Date of Advisory: October 4, 1996

Lead Survival Below Expectations

Product

All Models 4504, 4504M, and 4582 Implantable Pacing Leads

Advisory

Lead survival probability is below expectations and is primarily associated with insulation degradation due to Metal Ion Oxidation (MIO).

Patient Management Recommendations

- Follow patients in accordance with Medicare Guidelines.
- Avoid the use of the AAI or AOO mode.
- During patient evaluation, give careful attention to lead performance such as:
 - Review patient ECG for indications of transient sensing and/or capture abnormalities.
 - Monitor in clinic for impedance less than 250 ohms or a decrease of more than 30% from implant values (or an established baseline using telemetry) which would suggest lead failure.
- Consider the use of unipolar if the pulse generator has this capability.
- At the time of pacemaker system revision (e.g., normal pulse generator or ventricular lead revision), carefully evaluate lead integrity and patient status before choosing to reuse.

Status

Patient management recommendations remained unchanged. Laboratory analysis trends and engineering conclusions remained unchanged. According to System Longevity Study results, lead survival is estimated to be 66.2% at 8 years.

8446, 8448 Legend Plus IPGs

Original Date of Advisory: June 14, 1996

Potential for Improper Programming

Product

All Models 8446 and 8448 Implantable Pulse Generators

Advisory

Potential for improper acceptance of the programming of a rate responsive mode resulting in irregular rate intervals.

Patient Management Recommendations

The anomaly can be initiated only during the programming (or reprogramming) of the pacing system to a rate responsive mode. In the unlikely event that the anomaly occurs, reprogramming the pacing system to the desired mode should restore normal operation.

- New software has been developed that provides clinicians the ability to verify the proper programming of the rate responsive modes.
- As always, individual circumstances and medical judgment dictate patient care.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

4004, 4004M CapSure Ventricular Lead

4082 Target Tip Ventricular Lead

Original Date of Advisory: October 8, 1993

Lead Survival Below Expectations

Product

All Models 4004/4004M and 4082 Implantable Pacing Leads

Advisory

Lead survival probability is below expectations due primarily to polyurethane insulation failure (MIO) and conductor fracture (associated with "subclavian crush").

Patient Management Recommendations

- Increase, as appropriate, the frequency of patient evaluation through in-clinic visits supplemented with transtelephonic and/or ambulatory monitoring; for example, consistent with Guideline I under Medicare Pacemaker Monitoring Guidelines (50-1 Cardiac Pacemaker Evaluation Services).
- During patient evaluations, give careful attention to lead performance such as:
 - Reviewing patient ECGs carefully for indications of transient sensing and/or capture abnormalities.
 - Monitoring in-clinic for impedances less than 300 ohms or a decrease of more than 30% from implant values (or an established baseline using telemetry) which would suggest lead failure.
 - Eliciting and thoroughly investigating any patient complaints suggestive of lead failure.

- Consider whether prophylactic replacement would be appropriate, especially in patients at high risk, such as pacemaker dependent patients.
- Carefully evaluate lead integrity when performing routine pulse generator replacements. Replace lead if:
 - Insulation breaches are observed.
 - Lead impedance is less than 300 ohms or has decreased by more than 30% from implant values.
 - Impedance or voltage threshold measurements vary significantly when multiple readings are taken.
 - If the risk of continued use outweighs the risk associated with implanting a new lead.
- As always, individual circumstances and medical judgment dictate patient care and frequency of follow-up.
- Consider lead replacement during normal pulse generator change-out. Carefully evaluate lead integrity and patient status before choosing to reuse.

Status

Patient management recommendations remained unchanged. Laboratory analysis trends and engineering conclusions remained unchanged. According to System Longevity Study results, lead survival is 46.1% at 10 years.

4012 Target Tip Ventricular Lead

Original Date of Advisory: September 26, 1991

Lead Survival Below Expectations

Product

All Model 4012 Implantable Pacing Leads

Advisory

Lead survival probability beyond 5 years is below expectations due primarily to polyurethane insulation failure (due to ESC and/or MIO) and conductor fracture (associated with "subclavian crush").

Patient Management Recommendations

Consider increasing frequency of monitoring (e.g., from quarterly to bimonthly or monthly). Consider the following activities as part of normal follow-up procedures:

- Monitor for significant changes in impedance which could be an indication of impending failure (pulse generator must have impedance telemetry capabilities).
- Review patient ECGs carefully for indications of transient sensing and/or capture abnormalities.
 This can be done using transtelephonic or in-clinic monitoring and/or using ambulatory monitoring.
- Elicit any patient complaints suggestive of lead failure and investigate thoroughly lead integrity/ performance characteristics following reports of patient complaints or symptoms using the above techniques.

- Consider whether prophylactic replacement would be appropriate in patients at high risk, such as pacemaker dependent patients.
- Evaluate carefully the integrity of the lead during routine pulse generator replacement before choosing to reuse. Specifically, Medtronic recommends placement of a new lead if:
 - Insulation breaches are observed.
 - Lead impedance is less than 300 ohms or has decreased by more than 30% from implant values.
 - Electrical properties such as impedance and threshold vary significantly when multiple readings are taken.

As always, medical judgment must be used to establish the appropriate schedule and course of care for every individual, particularly pacemaker dependent or other patients at higher risk.

Status

Patient management recommendations remained unchanged. Laboratory analysis trends and engineering conclusions remained unchanged. The System Longevity Study results show 59.3% lead survival at 15 years.

Minix, Minix ST, Micro Minix IPGs

Original Date of Advisory: May 6, 1991

Potential Delayed Restoration of Permanent Settings

Product

All Models of the Minix, Minix ST, and Micro Minix families of Implantable Pulse Generators

Advisory

Possibility of delayed restoration of permanent pacing mode and parameters, after the magnet or programming head is removed under certain conditions.

Patient Management Recommendations

To eliminate any potential risk associated with temporary programming, depress the INTERROGATE KEY and verify successful interrogation before moving the programming head away from the pulse generator. The delay condition can also be terminated by repositioning the programming head and depressing the EMERGENCY VVI key.

Status

Device performance related to this advisory continues to be within Medtronic's engineering projections and expectations. Patient management recommendation remained unchanged. The devices affected by this advisory are nearing the end of their expected longevity.

Technical Articles

AT500 Pacing System Follow-Up Protocol

Purpose of This Information

This article is intended to provide clinical guidance regarding follow-up practice and patient management when the AT500 battery voltage approaches the Elective Replacement Indicator (ERI) level of 2.6 volts.

Background

Many AT500 pacing systems are now reaching their Elective Replacement Indicator voltage level (2.6 volts). This is expected since the battery used has an approximate longevity of 5-6 years under normal conditions (100% DDD pacing, 3 volts, 0.4 ms).

Technical Services has received reports of battery voltage levels below End-of-Life (EOL of 2.20 volts) where EGM pre-storage is programmed ON, or higher outputs and/or pacing rates are necessary. It is important for Physicians and Allied Professionals to understand battery depletion characteristics between ERI and EOL so that they, in turn, can understand how this affects management of follow-up visits for the AT500 as this device nears the end of its expected longevity.

AT500 Battery and Longevity Information

In contrast to other IPGs, the AT500 does not change its mode, stimulation rate, or any other parameter when the battery voltage drops below the ERI level of 2.60 volts (with or without magnet applied). The Threshold Margin Test (TMT) is also not available.

Therefore, it is not possible to perform transtelephonic assessment of AT500 battery status. This must be done during an in-clinic follow-up session. A warning will be displayed on the Quick Look screen at the beginning of a programmer (follow-up) session when the ERI battery level occurs. The measured battery voltage will also appear on the programmer display and on printouts.

Battery depletion curves at **common parameter settings** are shown in Figure 1, with special focus on device longevity when programming EGM pre-storage ON or OFF.

continued

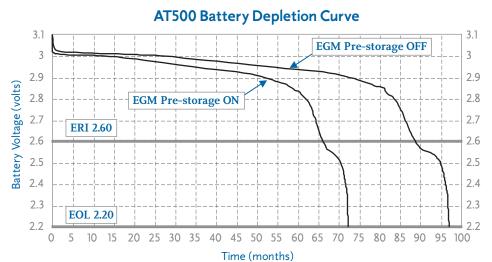


Figure 1

AT500 battery depletion curve for common parameter settings of DDDR, LR 70 ppm, UR 120 ppm, 100% pacing, Atrial – 2 V, 0.4 ms, 600 ohms, Ventricle – 2 V, 0.6 ms, 900 ohms, and EGM Pre-storage ON versus OFF.

AT500 Pacing System Follow-Up Protocol continued

Medtronic's review of ongoing AT500 battery life test data matches our original longevity modeling and so meets our expectations. However, when using longer durations between follow-up periods (> 3 months), clinicians should consider the following in setting their remaining longevity expectations:

- Enabling the "EGM Pre-storage On" capability will increase current and reduce device longevity by approximately 9 days for each month pre-storage is ON.
- Longevity decreases with an increase in pacing rate, an increase in pacing amplitude or pulse width, a decrease in pacing impedance, a higher ratio of paced to sensed events, or extended use of the Atrial Preference Pacing, EGM pre-storage, or Holter Telemetry features.

Recommendations

Follow-up frequency should always be accelerated as devices reach ERI voltage levels to ensure device explant/replacement occurs prior to End of Life voltage levels. With the wide variety of follow-up schedules being used, Medtronic recommends a 3-month follow-up frequency for the AT500 pacing systems. This is particularly important for patients in whom EGM pre-storage is programmed ON, or higher outputs and/or pacing rates are necessary.

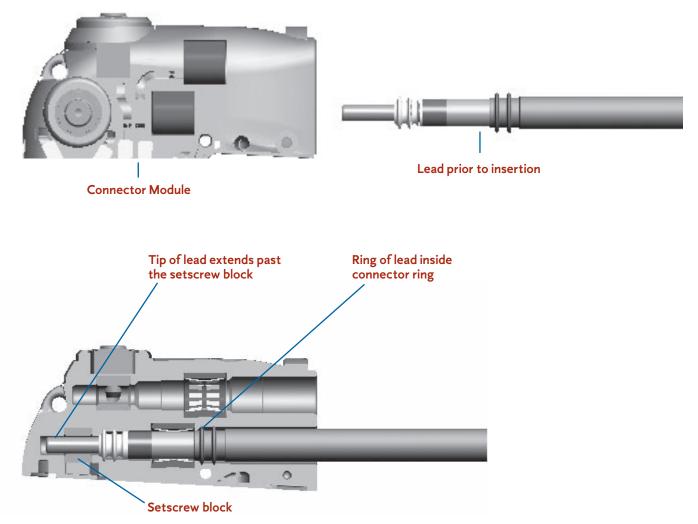
Insertion of the Lead into the Device

The implantable system consists of a pulse generator and at least 1 lead. The system operation depends on proper electrical and mechanical operation. With the advent of internationally recognized connector standards the challenge of ensuring proper mechanical fit between the lead and device connectors has been simplified, although the international connector standard does not address all aspects of the procedure for connecting a lead to the device.

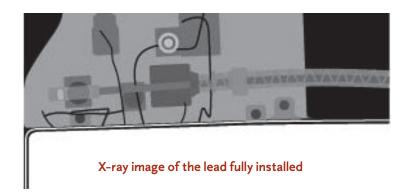
If the lead connector is not fully installed, oversensing may result as described in the connector problems section of the technical article, "Clinical Management of High Voltage Lead System Oversensing." Performing the following steps can be used for each lead connection during the implant procedure:

- 1 Insert the torque wrench into the appropriate setscrew. For easier lead insertion, insert the lead closest to the device first.
- **2** Look down the connector port to verify that the port is not obstructed. If the port is obstructed retract the setscrew to clear the bore. Take care not to disengage the setscrew from the connector block.
- **3** Push the lead into the connector port until the lead pin is clearly visible beyond the setscrew block.
- **4** Hold the lead in position while tightening the setscrew until the torque wrench clicks.
- **5** Tug gently on the lead to confirm a secure fit.

continued



Insertion of the Lead into the Device continued



Current publications may provide additional information on implant procedures used by others, e.g., radiographic evaluation of the terminal pin beyond the terminal post.¹ ¹ Pickett RA III, Saavedra P, Ali MF, Darbar D, Rottman JN. Implantable cardioverter-defibrillator malfunction due to mechanical failure of the header connection. *J Cardiovasc Electrophysiol.* September 2004;15(9):1095-1099.

GEM II DR/VR and GEM III DR/VR/AT ICD Battery Discharge Behavior

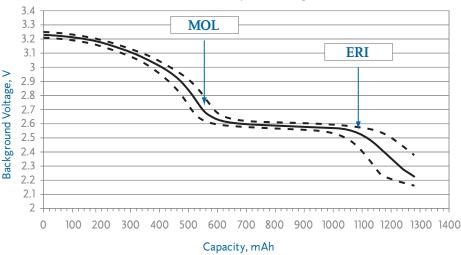
Medtronic manufactures and utilizes a unique Lithium/Silver Vanadium Oxide battery in the GEM II/III family of ICDs. This battery has a distinctive voltage discharge with two regions of constant voltage at 3.2 volts and 2.6 volts.

The battery discharge curve (see curve below) is characterized by a significant decrease in the battery voltage approaching middle-of-life (MOL), followed by a plateau (MOL to Elective Replacement Indicator) where the battery voltage remains around 2.6 volts. The transition to the plateau could be easily misinterpreted as the battery rapidly approaches ERI, when the battery in fact may have several years remaining until ERI; which occurs at 2.55 volts.

It is important to understand that this battery voltage decrease in the GEM II/III family of ICDs is a normal characteristic of the battery function in these devices and should not create a need for additional follow-up or monitoring. As a general rule of thumb, the longevity from implant to MOL = MOL to ERI.

The design of the recently released Marquis battery has been modified to present a more linear battery discharge curve.

If you are concerned about early ERI in your patient's device, you can utilize the battery trend measurements stored in the save-to-disk file, which can be accessed and interpreted through the Medtronic Technical Services at 1 (800) 723-4636.



GEM II/III Battery Discharge Curve

General Follow-Up and Replacement of ICD Leads

The human body is a hostile environment for an implantable device. Typically, the human body will attack and attempt to isolate or destroy any foreign object. Additionally, implanted leads are subjected to continuous flexural and torsional stresses associated with cardiac activity, body motion, and patient anatomy, which can adversely impact lead integrity.

In this environment, pacemaker and defibrillation leads cannot be expected to last forever. Unlike implantable cardioverter defibrillators (ICDs), a lead's longevity cannot be predicted nor are there simple indicators that a lead is approaching the end of its service life. The determination that a lead may be approaching end of service life requires followup of the chronically implanted lead and thorough evaluation of lead integrity at ICD replacement.

Follow-Up of Chronically Implanted Leads

The frequency of follow-up for ICD patients will depend on a number of factors including the patient's medical condition, ICD system implant time, hospital/ clinic follow-up practice, and Medicare guidelines. In all cases, it is important to assess the functionality of the ICD system and the integrity. For newly implanted leads, it is beneficial to establish a baseline of chronic performance parameters once the lead has stabilized, generally within 6 to 12 months after implant. These performance parameters should include pacing and sensing thresholds and impedance. During routine patient follow-up, these procedures can be used to evaluate lead integrity:

- Measure pacing and sensing threshold and compare to the chronic baseline. Significant increases or decreases may be indicative of lead failure, dislodgement, perforation, exit block, etc.
- Measure pacing impedance where possible and compare to the chronic baseline. Decreases of 30% or more or pacing impedances below 200-250 ohms may be indicative of insulation failure. Sudden and significant increases in pacing impedance may be indicative of conductor fracture.
- High voltage lead circuit impedance should be between 10-75 ohms at system implant. Chronic measurements below 10 and above 200 ohms may be indicative of high voltage lead circuit failure.
- Carefully review ECGs or the non-sustained detection log on Medtronic ICDs for indications of pacing and/or sensing abnormalities such as oversensing, undersensing, and loss of capture.
- Elicit and investigate any patient complaints/ symptoms which may be suggestive of potential lead failure.

Where routine follow-up indicates, additional tools should be used to further evaluate performance. Tools include radiographic data, ICD electrograms, ICD PatientAlert and performance information from the Tachyarrhythmia Chronic Systems Study (TCSS).

continued

General Follow-Up and Replacement of ICD Leads continued

The final decision on the functional integrity and continued use of an implanted lead must be a matter of medical judgment based on these factors as well as specific patient conditions.

General Criteria for Lead Replacement

The evaluation of a chronically implanted lead is an important part of the decision to continue to use the lead with a new ICD. However, these results alone do not necessarily predict the future integrity of that lead. With the expected longevity of today's ICDs varying between approximately 5 and 10 years, a physician replacing a device should consider a number of factors, including those listed below.

Factors which should be considered in a decision to replace or continue to use include:

- Pacing and sensing thresholds should be evaluated for the potential to maintain acceptable levels.
- Pacing impedance should be measured. Bear in mind that pacing impedance below 250 ohms results in excessive battery current drain, which may seriously compromise ICD longevity, regardless of lead integrity.

- The physical appearance of the lead should be examined for insulation cracks, breaches, or other indications of lead wear or degradation.
- Medtronic Chronic Systems data should be referenced. Actuarial survival of the lead and the observed lead failure mechanisms are specific factors to consider. Use of a new lead should be considered if failure mechanisms suggest an increased time dependency as suggested in the shape of performance curve for the specific lead model.
- Current publications may provide additional information on the clinical management of leads.^{1,2} Ultimately, the decision to replace an implanted lead involves medical judgment.
- ¹ Hauser RG, Cannom D, Hayes DL, et al. Long-term structural failure of coaxial polyurethane implantable cardioverter defibrillator leads. *PACE*. June 2002;25(6):879-882.
- ² Ellenbogen KA, Wood MA, Shepard RK, et al. Detection and management of an implantable cardioverter defibrillator lead failure: incidence and clinical implications. *J Am Coll Cardiol.* January 1, 2003;41(1):73-80.

Clinical Management of High Voltage Lead System Oversensing

Appropriate sensing by an ICD system refers to the sensing of cardiac events that may or may not require therapy delivery. ICD systems must sense relatively large QRS complexes while avoiding sensing of smaller T-waves, yet continue to sense often small variable amplitude ventricular fibrillation. Thus ICD systems attempt to dynamically adjust sensing of electrical events, and discriminate between them based on detection algorithms and programmed settings.

Inappropriate sensing can occur when an ICD system classifies events of non-cardiac origin as QRS/VF events, or senses and counts T- and far field P-waves as ventricular depolarizations. This is often referred to as "oversensing," and may result in delivery of inappropriate high voltage therapies. This is due, in part, to the desire to err on the side of delivering lifesaving high voltage therapy rather than withholding it. Thus, an ICD system which is experiencing oversensing issues will continue to deliver therapeutic shocks as required, but may also subject the patient to unnecessary shocks.

Oversensing can be difficult to manage, in that the precipitating cause of the oversensing can be problematic to isolate. Oversensing can be caused by many factors, including myopotentials/far field sensing, electromagnetic interference, T-wave sensing, connector issues, incomplete conductor fractures, and insulation breaches. While the individual physician must exercise medical judgment in determination of appropriate clinical management of ICD systems, the chart below may assist in the process of causal factor differentiation and possible intervention.

Phenomenon	Causal Factors	Characteristics	Management/Comments
Myopotentials/ Far Field Sensing	Diaphragmatic muscle potentials in breathing, wide tip-ring (coil on integrated bipolar leads) spacing.	Nonphysiological sensed event on EGM, which may confuse detection potentially resulting in false positive shocks.	Check R-waves for deterioration. Reprogram sensitivity. Try repositioning lead. Consider change- out to true bipolar lead, or if true bipolar lead in use – one with closer tip-ring spacing than current lead.
EMI (Electro-Magnetic Interference)	Arc welders, electrical generators, store walk-through security scanners, poorly insulated electrical equipment.	Multiple and consecutive short intervals (< 140 ms) independent of underlying sinus beats. Associated with proximity to the EMI source.	Avoid EMI areas. True bipolar leads less susceptible.
T-wave Sensing	Drugs, ischemic tissue, exercise, long QT syndrome, electrolyte imbalance.	Sense markers seen on EGM related to T-wave. False positive detection.	Check for R-wave deterioration and characteristics. If R-wave > 3.0 mV reprogram sensitivity. If R-wave < 3.0 mV – reposition/replace lead. Address causal factor (e.g., drugs [if appropriate/medically viable]).
Connector Problems	Loose set screw, cross-threaded set screw, incomplete lead insertion into header.	This is an acute phenomenon seen within 6 months of implant (usually sooner).	Requires invasive check of connections. May be reproducible with pocket manipulation.
Incomplete Conductor Fracture	One or more filars of a multifilar conductor fracturing while leaving enough filars intact to provide a conduction circuit.	Characterized by chaotic oversensing related to motion of the fracture site.	Check EGMs and x-rays. Manipulate lead at suspected fracture site if possible as a provocative test. If confirmed – replace lead.
Lead Insulation Breach	Cuts, tears, metal ion oxidization, abrasion, cold flow, environmental stress cracking.	Characterized by cyclical and/or erratic, intermittent, spontaneous oversensing, often post-pace or post-shock can cause false positives.	Replace lead. If acute, usually secondary to implant damage/ replacement damage. If late – material characteristic.

Technical Services is available at all times to advise clinicians in the troubleshooting and management of Medtronic products. For assistance in the United States, please call 1 (800) 723-4636. In other countries, please contact your local Medtronic representative.

Tests and Observations for Clinical Assessment of Chronic Pacing Leads

Test/Observation	Possible Insulation Failure	Possible Conductor Failure	Possible Other System Failure	Affect on Test/ Observation
Pacing Impedance (Telemetered or Measured Invasively)	Sudden and Significant Decrease	Sudden and Significant Increase	Dislodgement. Perforation. Electrolyte Imbalance. Improper IPG/Lead Connection.	. Increase or Decrease . Increase or Decrease
Pacing Thresholds (Telemetered/Programmed or Measured Invasively)	Sudden and Significant Increase Especially in Bipolar System	Sudden and Significant Increase	Dislodgement. Exit Block. Infarct at Electrode Site. Perforation. Improper IPG/Lead Connection.	.Increase .Increase .Increase
Electrograms (Telemetered or Measured Invasively)	Sudden and Significant Decrease in Amplitudes and/or Slew Rates for P- and/or R-Waves	Sudden and Significant Decrease or Disappearance of Amplitudes and/or Slew Rates for P- and/or R- Waves	Dislodgement. Perforation . Infarct at Electrode Site. Electrolyte Imbalance. Improper IPG/Lead Connection.	Decrease Decrease .Decrease
Waveform Analysis (Oscillographs of Pacer Artifact from ECG Electrodes)	Sudden Increase in Ratios of Leading-Edge Voltages to Trailing-Edge Voltages (i.e., over 25% increase)	Intermittent or No Pacer Artifacts (even in asynchronous mode)	Improper IPG/Lead Connection	Intermittent or No Pacer Artifact (even in asynchronous mode)
Radiographs (Post-Implant, Recent, Current)	Not Discernible	Visual Observation of Conductor/Connector/ Electrode Fracture (sometimes discernible)	Dislodgement or Perforation Improper IPG/Lead Connection	. Sometimes Discernible
Visual Inspection (Invasive)	Insulation Breach and/or Degradation, or Ligature Cut-Through	Not Easily Discernible	Connector Defect or Connector Pulled Apart Improper IPG/Lead Connection	Sometimes Discernible
Pectoral Muscle Stimulation	Sudden Onset Especially in Bipolar System		Connector Defect in Bipolar or Unipolar. Hypersensitivity to Unipolar Pulse Generator Can. Anti-Stim Coating or Protection Deficient	
Phrenic Nerve/ Diaphragmatic Stimulation	Sudden Onset in Bipolar or Unipolar Systems		Perforation or Displacement of Atrial Lead (phrenic nerve)	
Pacemaker ECG Stimulus Artifact Size and Morphology Change (May Not Be Possible with Digital ECG)	Sudden Onset and Significant Change, Especially in Bipolar System (Increase in Size)	Sudden Changes, Usually a Decrease in Size	Perforation or Dislodgement Connector Defect Improper IPG/Lead Connection	Sometimes Discernible
Oversensing (Intermittent or Continuous)	Sudden Onset, Especially in Bipolar Systems		Physical Contact between the Electrode(s) on the Lead and That of Another Lead. Inappropriate IPG parameter setting. Improper IPG/Lead Connection	
Undersensing (Intermittent or Continuous)	Sudden Onset in Either Unipolar or Bipolar Systems	Sudden Onset in Either Unipolar or Bipolar Systems	Dislodgement or Perforation Infarct at Electrode Site Electrolyte Imbalance. Inappropriate IPG Parameter Setting. Improper IPG/Lead Connection	. Sometimes Discernible
Loss of Capture	See "Pacing Thresholds" Above	See "Pacing Thresholds" Above	See "Pacing Thresholds" Above	

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