Medtronic

CRM PRODUCT PERFORMANCE REPORT

Important Patient Management Information for Physicians

2004 2nd EDITION

CRM Product Performance Report
is now available on

www.MedtronicConnect.com

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Medtronic Quality Policy:

"CRM will satisfy customer expectations by striving without reserve for product quality and patient safety through effective, agile, and compliant processes."

The Product Performance Report (PPR) presents device survival estimates for Medtronic implantable cardioverter defibrillators (ICDs), implantable pulse generators (IPGs), and leads approved for market release in the United States. In this report, "survival" refers to the proper function of the device, not the survival of the respective patient.

Medtronic tracks device survival through three sources: the Tachyarrhythmia Chronic Systems Study (TCSS), Chronic Leads Study, and Returned Product Analysis (RPA). Returned Product Analysis provides a suitable measure of hardware performance because a significant number of ICDs are explanted and returned to the manufacturer.

Pulse generator survival probabilities are based on the analysis of devices returned to Medtronic, and thereby provide 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). Lead survival probabilities, in contrast, are based on clinical observations involving sensing, capture, and various other complications, rather than strictly returned product analysis. Therefore, the lead survival probabilities include both 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.

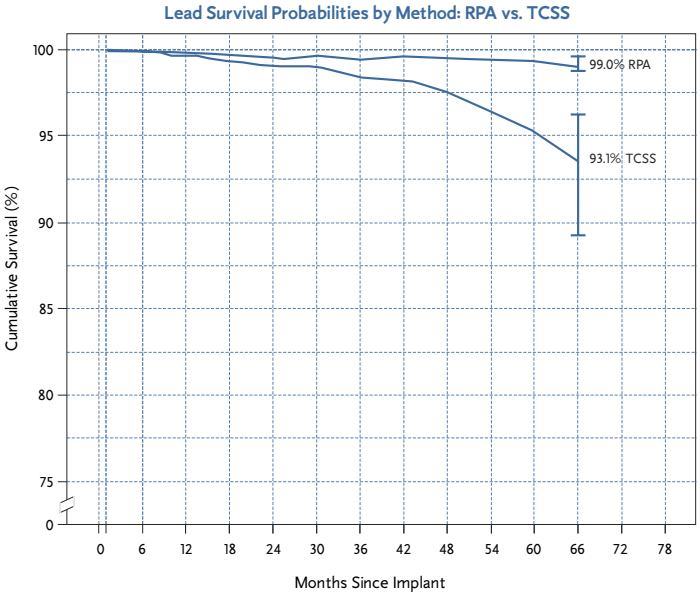
In contrast, because a small percentage of leads are returned to the manufacturer (due to the difficulty of extracting them), a much less accurate estimate of lead survival is generated when the results are based solely on Returned Product Analysis.

Current TCSS experience shows that of the lead-related adverse events reported, 73% were not explanted. The graph below is an example of the difference in lead survival probabilities when they are determined by chronic lead study versus Returned Product Analysis.

We strive to continually improve the 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 significant information you have regarding the performance of Medtronic products.

Please call Dale Staffanson at 1-800-328-2518, extension 46135 or call our Technical Services Department at 1-800-723-4636 should you have any comments or questions. We look forward to hearing from you.

Brian Urke
Vice President
Cardiac Rhythm Management, Quality



Contact Information

U.S. TECHNICAL SERVICES DEPARTMENT

PHONE: 1-800-723-4636

FAX: 1-800-824-2362

We invite our customers to use this telephone number to call with suggestions, inquiries, or specific problems related to our products or the CRM Product Performance Report.

Or write to:
Dale Staffanson
Medtronic, Inc.
7000 Central Avenue NE MS T135
Minneapolis, MN 55432-3576 USA

e-mail: dale.staffanson@medtronic.com

Or

Or write to:
Susan Gorecki
Medtronic, Inc.
7000 Central Avenue NE MS T306
Minneapolis, MN 55432-3576 USA

e-mail: susan.gorecki@medtronic.com

International Technical Centers:
Europe (Kerkrade NL) 011/31-45-566-8000
Canada (Toronto) 905-816-5353
Japan (Hokkaido) 011-81-44-540-6124

EDITORIAL STAFF

Authors

Dale Staffanson, *Principal Product Performance Engineer, Cardiac Rhythm Management, Trending and Data Analysis*
Susan Gorecki, *Project Coordinator II Cardiac Rhythm Management, Released Product Quality*
Michael Hull, *Pr. Statistician Clinical Statistics Projects*
Brian Johnson, *Statistician, Clinical Statistics Projects*

2nd EDITION

2004

Date cutoff for this edition is August 1, 2004.

New for this issue

- Charts relating to the graphs are now placed below the graphs.
- Graphs are in the order of US Market Release date so that the newest product is in the front of each section.
- Maximo DR Model 7228 has been added to the "ICD Survival: Returned Product Analysis Results" Table on page 17.
- Maximo VR Model 7232Cx has been added to the "ICD Survival: Returned Product Analysis Results" Table on page 17.
- New Sections added:
  - CRT – page 5
  - Left-Heart Leads – page 31
  - ICD Charge Times – page 61

Cardiac Resynchronization Therapy

Returned Product Analysis

Introduction

Cardiac resynchronization therapy (CRT) is a new, proven treatment for selected patients with heart failure-induced conduction disturbances and ventricular dyssynchrony. When used in combination with stable, optimal medical therapy, CRT is designed to reduce symptoms by restoring the mechanical sequence of ventricular activation.

Medtronic monitors the performance of its CRTs through Returned Product Analysis. Because a significant number of explanted ICDs are returned to the manufacturer, this analysis provides a measure of hardware performance. For this reason, the reliability of Medtronic CRTs are monitored using Returned Product Analysis and reported here as event-free survival estimates.

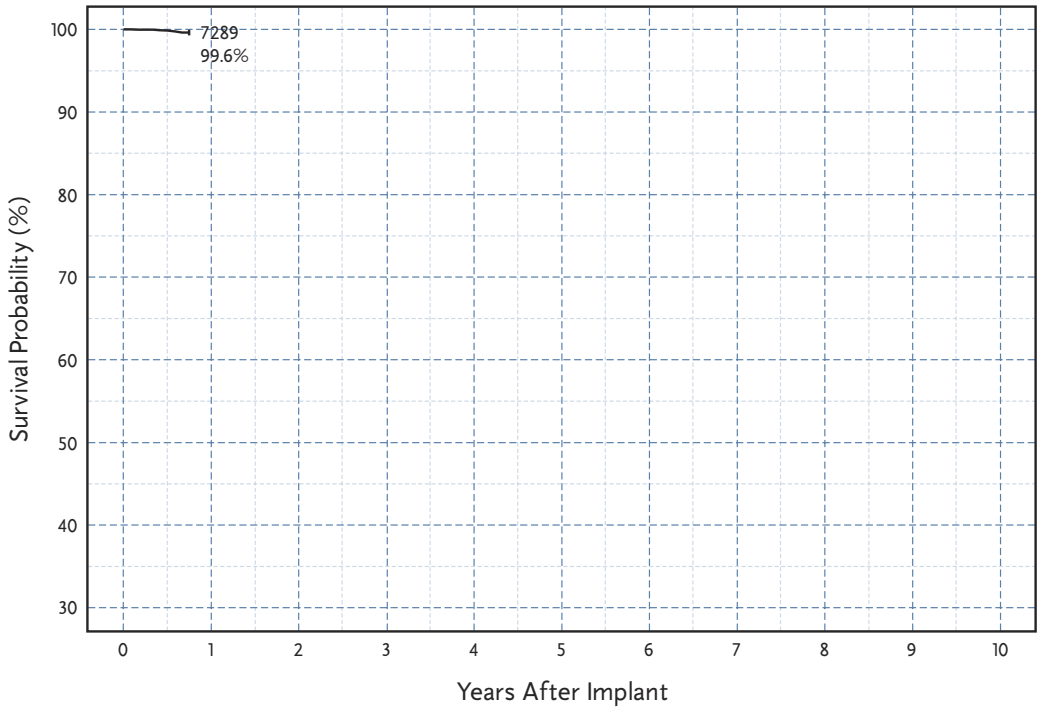
Methods

The analysis of returned CRTs includes the following Medtronic CRTs approved for market release in the United States. Results are reported for all the CRT models listed below:

- **InSync II Marquis** Model 7289
- **InSync Marquis** Model 7277
- **InSync III** Model 8042
- **InSync ICD** Model 7272
- **InSync** Model 8040

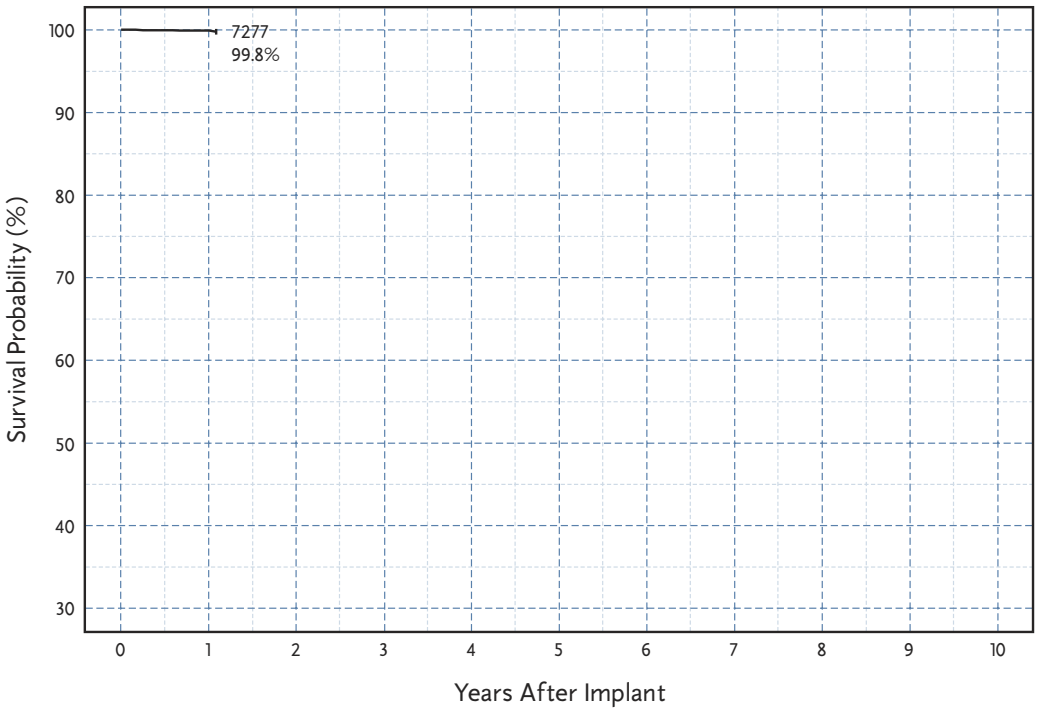
The actuarial method and Greenwood's formula are used to determine estimates of CRT event-free survival and corresponding confidence intervals, respectively. These estimates are based on survival from electrical failures (out of specification) or normal battery depletion. Using one-month intervals, event-free survival is determined to the point where at least 100 CRTs remain. These data do not reflect CRT-related medical events, such as erosion, infection, muscle stimulation or muscle inhibition.

Survival Estimate of InSync II Marquis 7289



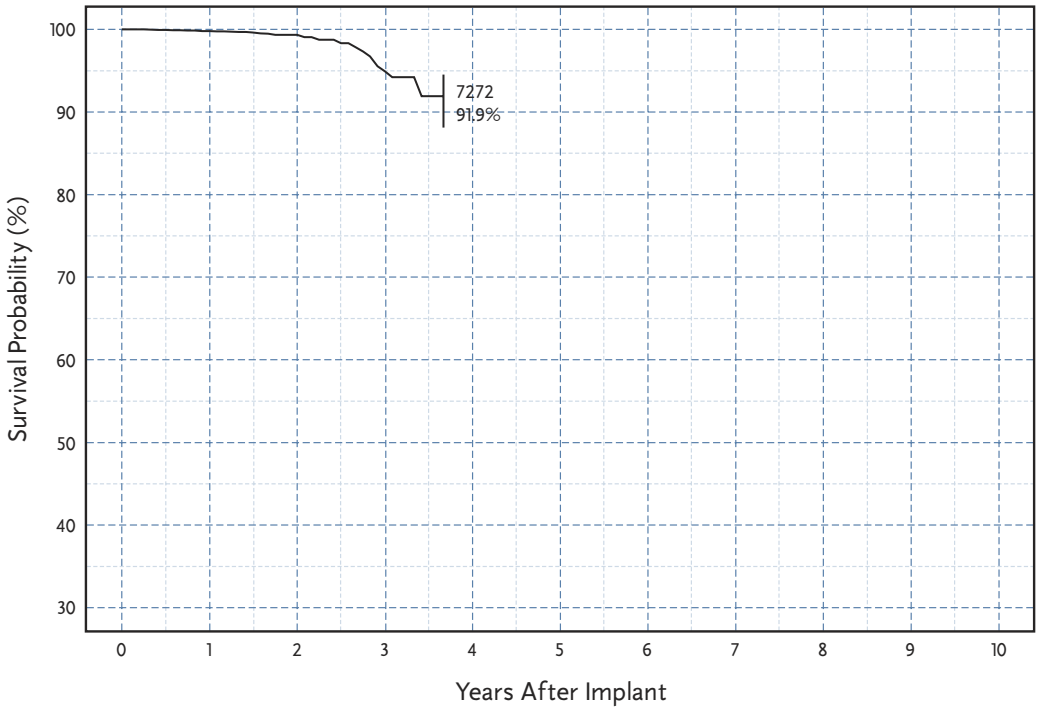
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
InSync II Marquis 7289	Jul-03	14,000	13,000	0	8	99.6 +0.2/-0.2 at 8 mo.							

Survival Estimate of InSync Marquis 7277



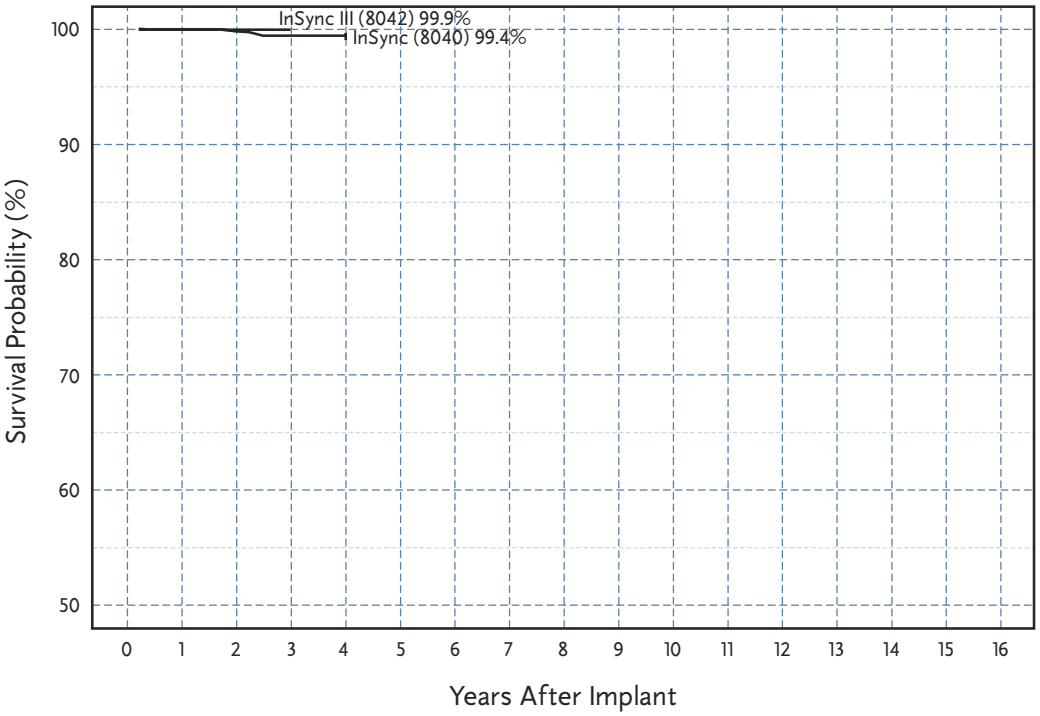
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
InSync Marquis 7277	Mar-03	6,000	5,000	3	1	99.9 +0.1/-0.1	99.8 +0.1/-0.4 at 13 mo.						

Survival Estimate of InSync 7272



ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
InSync ICD 7272	Jun-02	13,000	9,000	8	27	99.8 +0.1/-0.1	99.3 +0.2/-0.2	94.9 +1.7/-2.5	91.9 +2.6/-3.8 at 44 mo.				

InSync III 8042 & InSync 8040 Pulse Generators



ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
InSync III 8042	Feb-03	10,000	9,000	0	1	99.9	99.9	99.9					
InSync 8040	Aug-01	15,000	10,000	11	5	99.9	99.8 +0.1/-0.1	99.4 +0.2/-0.4	99.4 +2.8/-4.0				

CRT Survival: Returned Product Analysis Results*

						CRT Device Survival (95% Confidence Interval)							
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions†	Electrical Failures‡	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
InSync II Marquis 7289	Jul-03	14,000	13,000	0	8	99.6 +0.2/-0.2 at 8 mo.							
InSync Marquis 7277	Mar-03	6,000	5,000	3	1	99.9 +0.1/-0.1	99.8 +0.1/-0.4 at 13 mo.						
InSync III 8042	Feb-03	10,000	9,000	0	1	99.9	99.9	99.9					
InSync ICD 7272	Jun-02	13,000	9,000	8	27	99.8 +0.1/-0.1	99.3 +0.2/-0.2	94.9 +1.7/-2.5	91.9 +2.6/-3.8 at 44 mo.				
InSync 8040	Aug-01	15,000	10,000	11	5	99.9	99.8 +0.1/-0.1	99.4 +0.2/-0.4	99.4 +2.8/-4.0				

† ICD battery depletion includes devices that have reached elective replacement time as indicated in the technical manual or by telemetry.

‡ Electrical failures include CRT devices that have tested out of electrical specification.

* This table represents data for registered U.S. implants with returned and confirmed battery depletions or electrical failures as of August 1, 2004.

Implantable Cardioverter Defibrillators

Returned Product Analysis

Introduction

An ICD is an Implantable Cardioverter Defibrillator. It is used to treat heart rhythm disorders in which the heart beats too fast (ventricular tachyarrhythmias – VT). The heart rhythm may also be unstable and irregular (ventricular fibrillation – VF).

When the ICD detects VT or VF, it sends electric impulses to the heart. These impulses can return the heart to a normal rhythm and can reduce the chance of cardiac arrest.

Medtronic monitors the performance of its ICDs through Returned Product Analysis. Because a significant number of explanted ICDs are returned to the manufacturer, this analysis provides a measure of hardware performance. For this reason, the reliability of Medtronic ICDs are monitored using Returned Product Analysis and reported here as event-free survival estimates.

Methods

The analysis of returned ICDs includes the following Medtronic ICDs approved for market release in the United States. Results are reported for all the ICD models listed below:

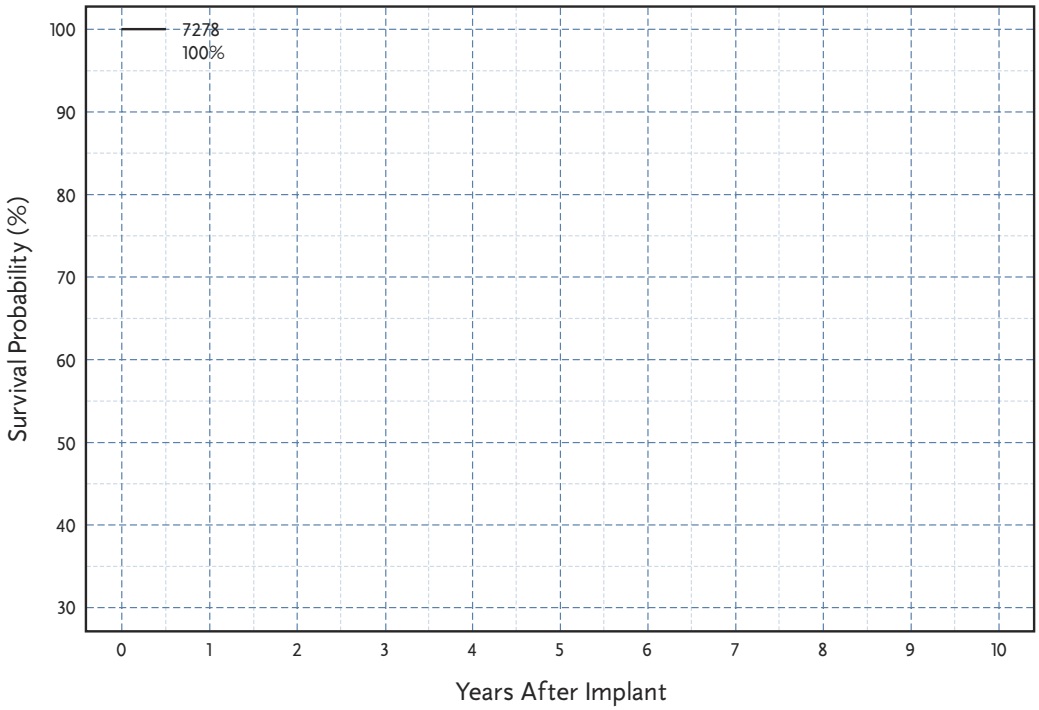
- **Maximo DR** Model 7278
- **Maximo VR** Model 7232Cx
- **Marquis VR ICD** Model 7230Cx, B, E
- **Marquis DR ICD** Model 7274
- **GEM III AT ICD** Model 7276
- **GEM III VR ICD** Model 7231Cx
- **GEM III DR ICD** Model 7275
- **Jewel AF ICD** Model 7250
- **GEM II VR ICD** Model 7229Cx
- **GEM II DR ICD** Model 7273
- **GEM ICD** Model 7227Cx, B, D, E
- **GEM DR ICD** Model 7271
- **Micro Jewel II ICD** Model 7223Cx
- **Micro Jewel ICD** Model 7221

The actuarial method and Greenwood's formula are used to determine estimates of ICD event-free survival and corresponding confidence intervals, respectively. These estimates are based on survival from electrical failures (out of specification) or normal battery depletion. Using one-month intervals, event-free survival is determined to the point where at least 100 ICDs remain. These data do not reflect ICD-related medical events, such as erosion, infection, muscle stimulation or muscle inhibition.

Results

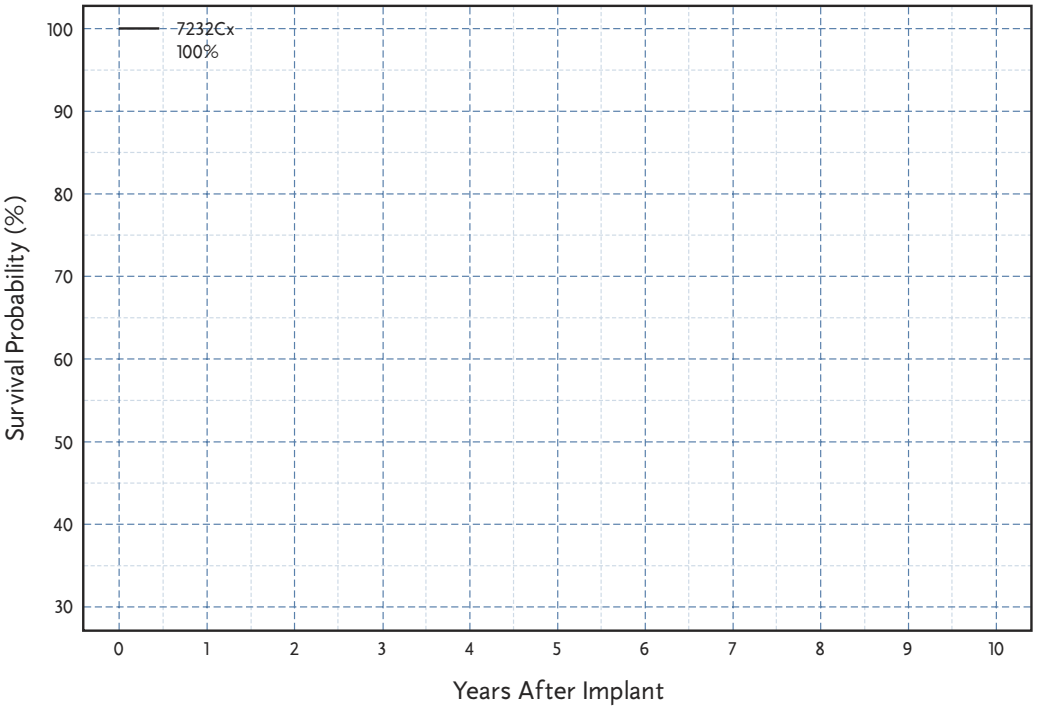
The following results are generated based on returned product data through a database cutoff of August 1, 2004.

Survival Estimate of Maximo DR 7278



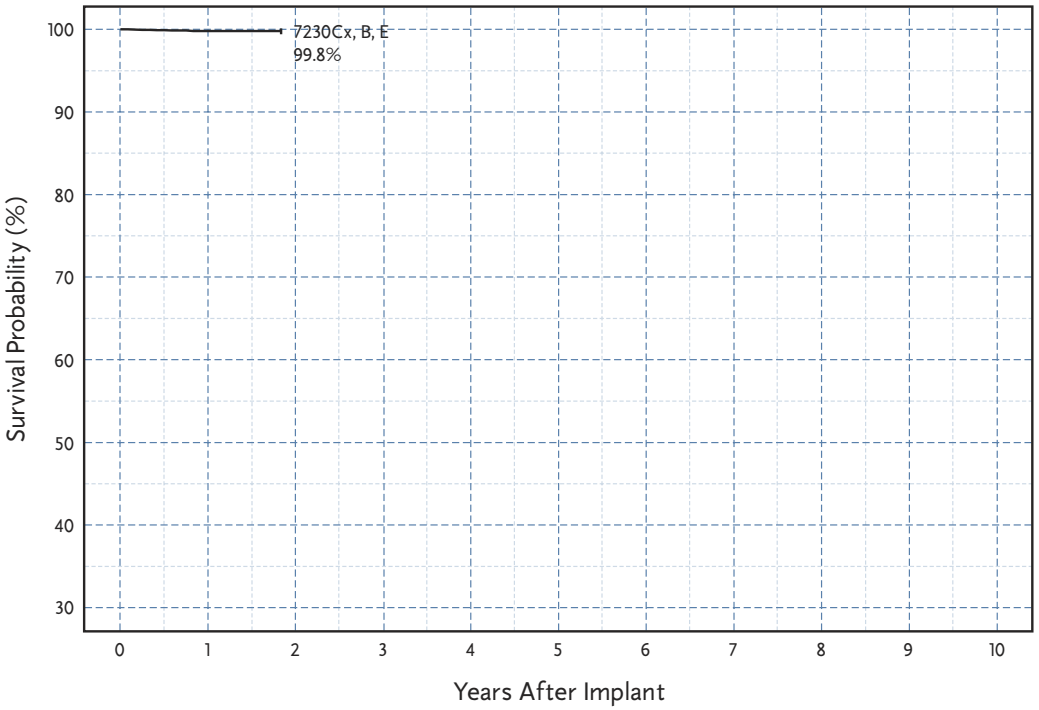
ICD Survival (95% Confidence Interval)													
Model Familly	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
Maximo DR 7278	Oct-03	3,000	3,000	0	0	100 +0/ -0 at 6 mo.							

Survival Estimate of Maximo VR 7232Cx



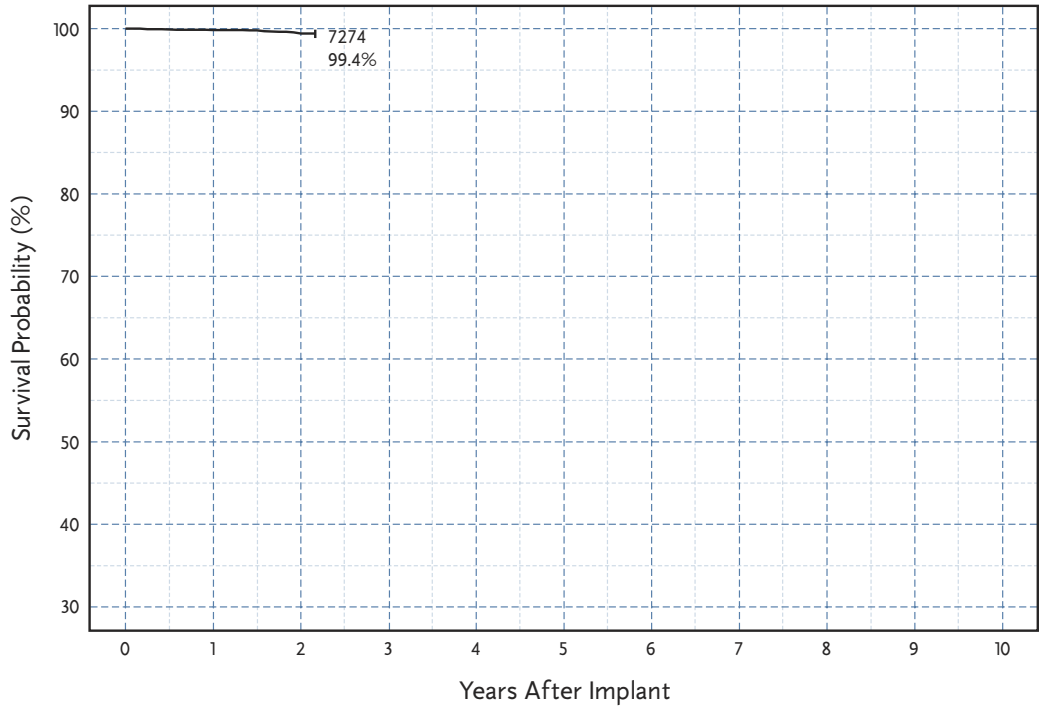
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 year	6 Year	7 Year	8 Year
Maximo VR 7232Cx	Oct-03	2,000	2,000	0	0	100 +0/ -0 at 6 mo.							

Survival Estimate of Marquis VR 7230Cx, B, E



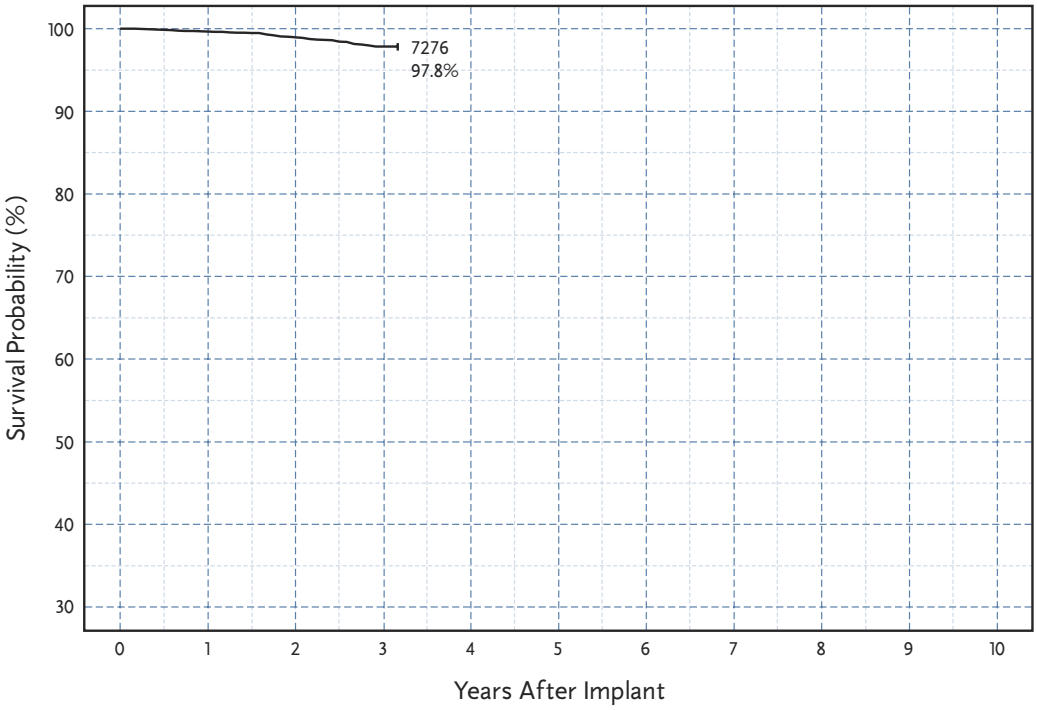
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
Marquis VR 7230Cx, B, E	Dec-02	13,000	11,000	3	5	99.8 +0.1/-0.1	99.8 +0.1/ -0.1 at 22 mo.						

Survival Estimate of Marquis DR ICD Model 7274



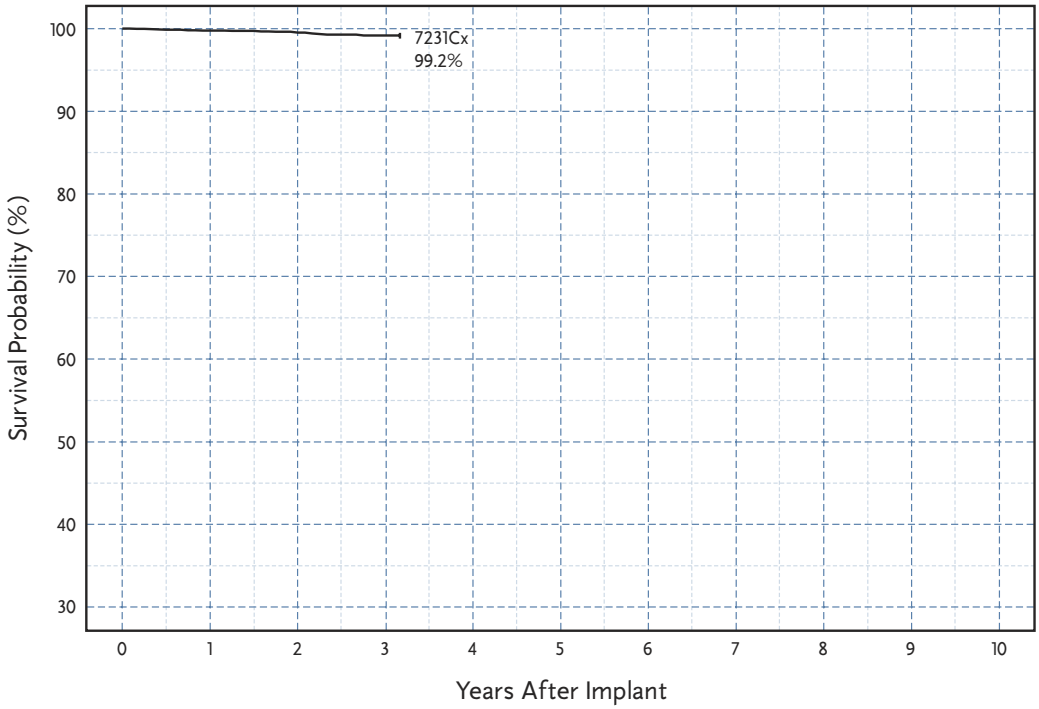
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
Marquis DR 7274	Mar-02	39,000	34,000	15	24	99.8 +0.1/-0	99.4 +0.2/-0.2	99.4 +0.2/-0.2 at 26 mo.					

Survival Estimate of GEM III AT 7276



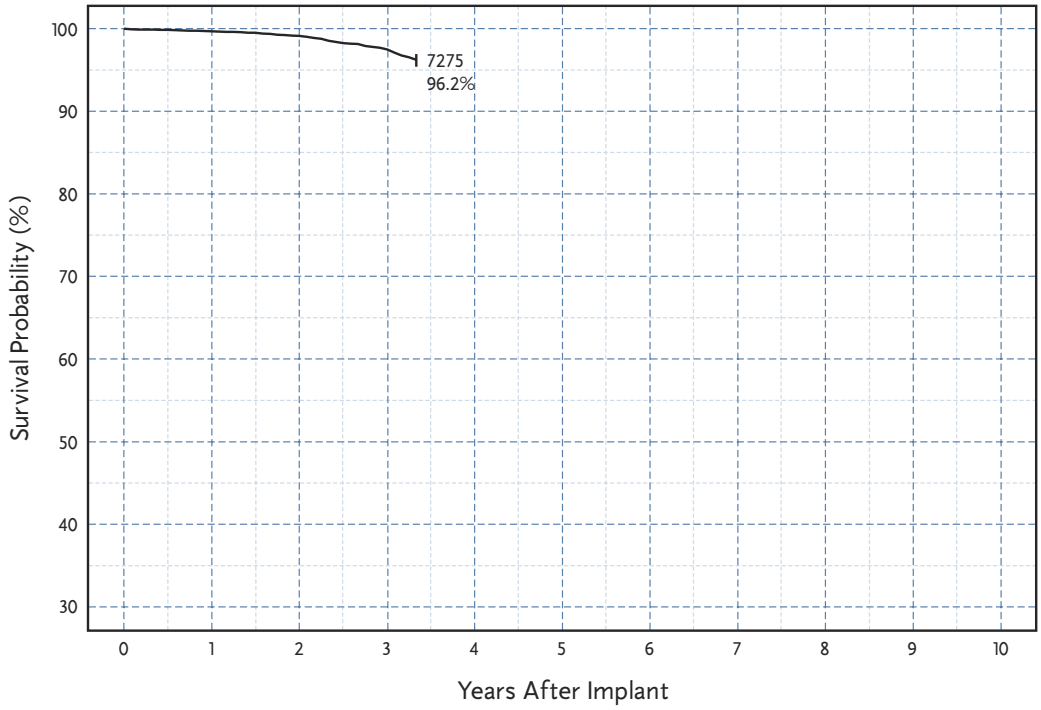
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 year	6 Year	7 Year	8 Year
GEM III AT 7276	Feb-01	13,000	9,000	39	27	99.7 +0.1/-0.2	99 +0.2/-0.3	97.8 +0.4/-0.4	97.8 +0.4/-0.4 at 38 mo.				

Survival Estimate of GEM III VR 7231Cx



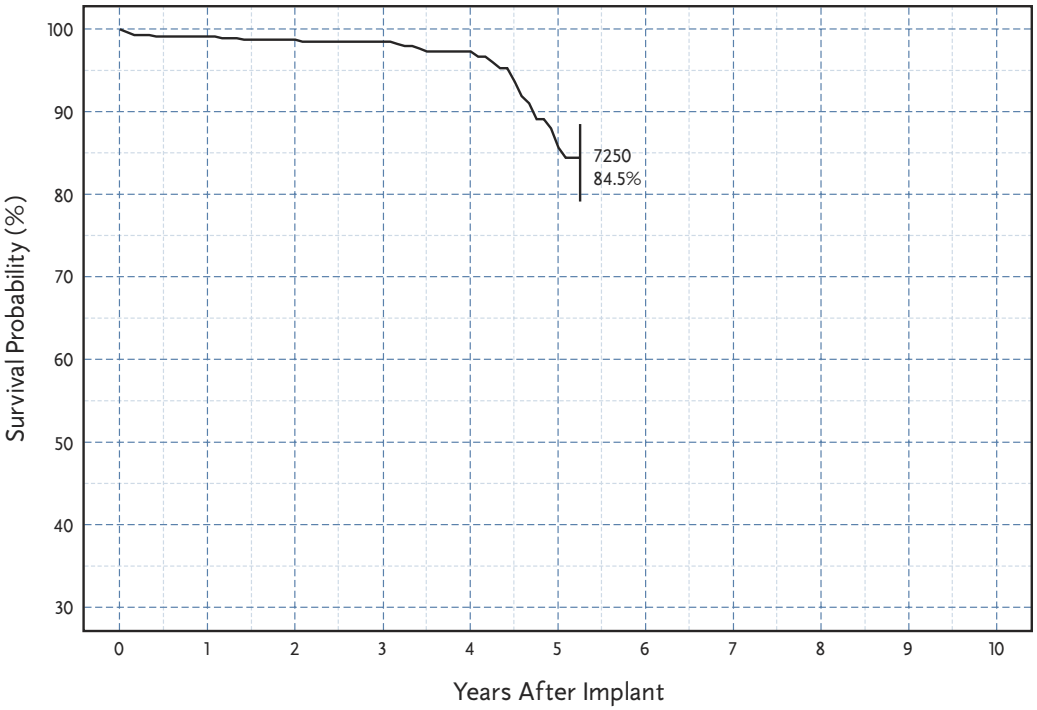
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
GEM III VR 7231Cx	Dec-00	15,000	12,000	16	18	99.8 +0/-0.1	99.5 +0.1/-0.1	99.2 +0.2/-0.3	99.2 +0.2/-0.3 at 38 mo.				

Survival Estimate of GEM III DR 7275



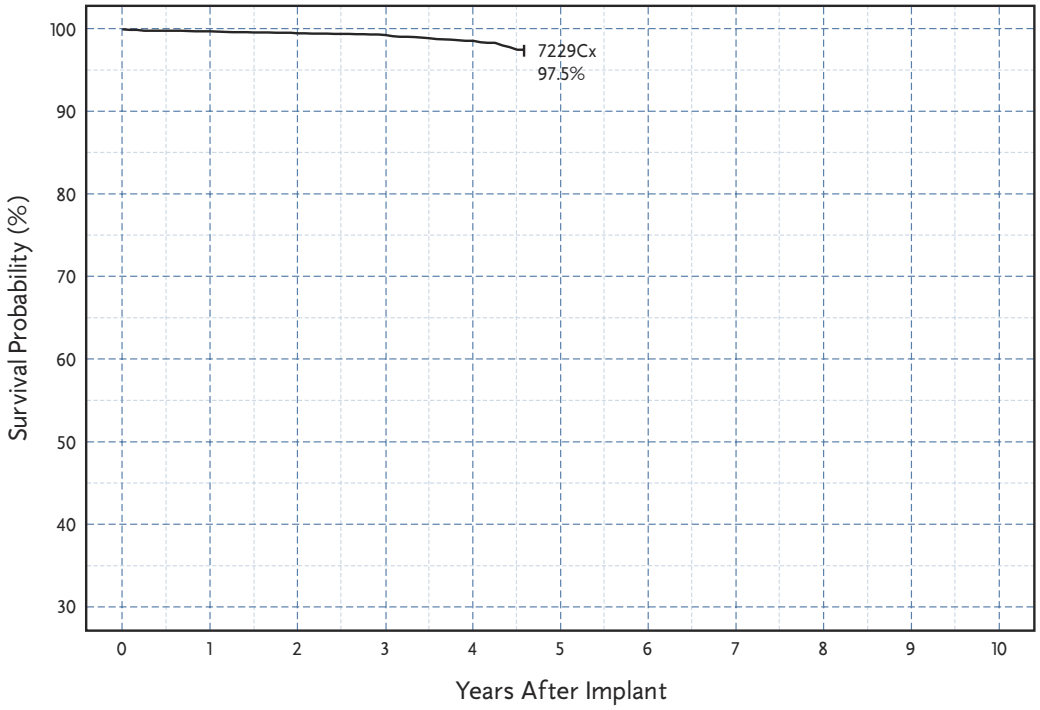
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
GEM III DR 7275	Nov-00	18,000	13,000	75	46	99.7 +0.1/-0.1	99.1 +0.2/-0.1	97.5 +0.3/-0.4	96.2 +0.7/-0.8 at 40 mo.				

Survival Estimate of Jewel AF 7250



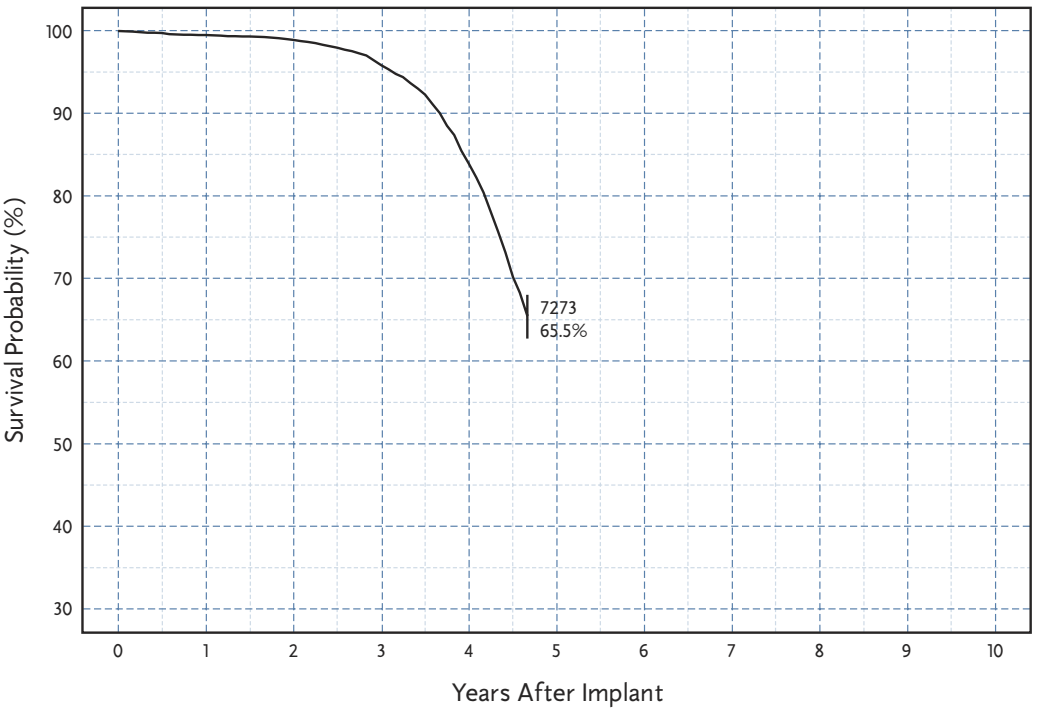
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
Jewel AF 7250	Jun-00	1,000	1,000	13	16	99.1 +0.4/ -0.7	98.7 +0.5/-0.9	98.5 +0.6/-0.9	97.3 +0.9/-1.3	85.7 +3.8/-5.1	84.5 +4/ -5.4 at 63 mo.		

Survival Estimate of GEM II VR 7229Cx



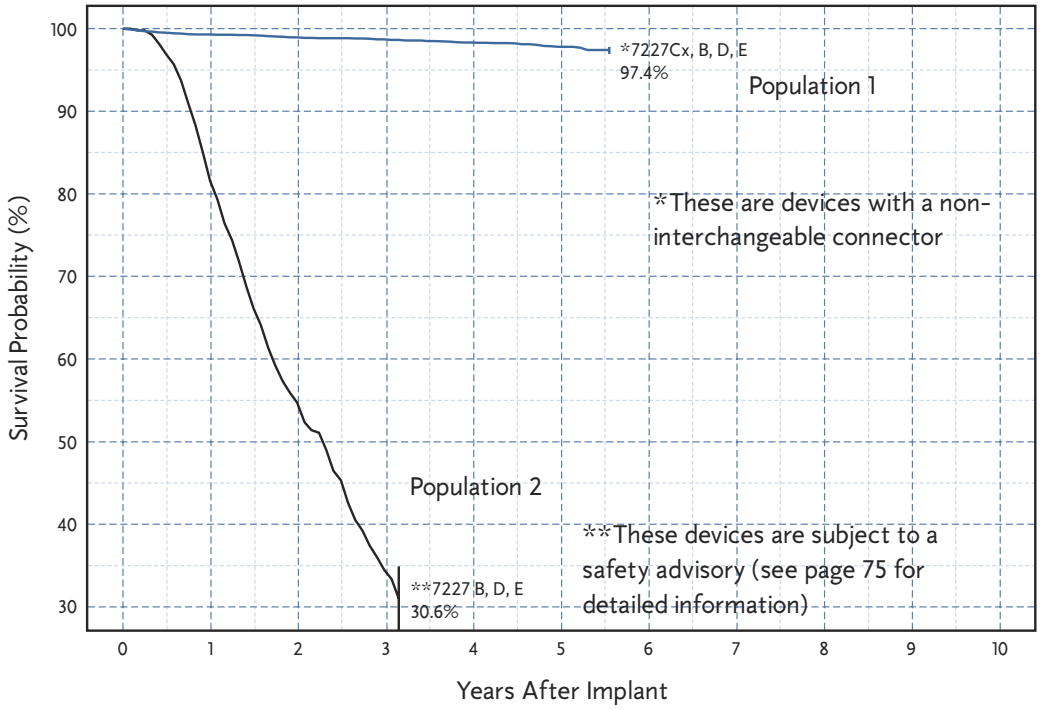
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
GEM II VR 7229Cx	Jul-99	10,000	6,000	25	31	99.8 +0/-0.2	99.5 +0.1/-0.2	99.3 +0.2/ -0.2	98.6 +0.3/ -0.3	97.5 +0.6/-0.8 at 55 mo.			

Survival Estimate of GEM II DR 7273



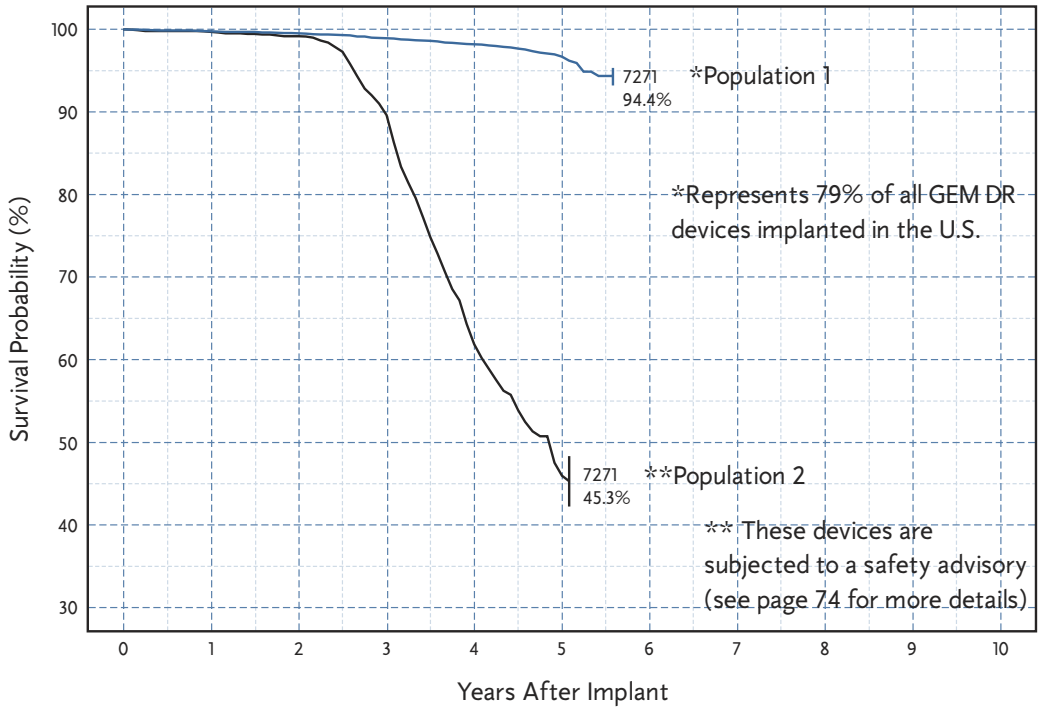
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
GEM II DR 7273	Feb-99	15,000	6,000	631	90	99.5 +0.1/-0.1	98.9 +0.2/ -0.2	95.9 +0.3/ -0.4	83.9 +0.9/ -0.9	65.5 +2.6/ -2.7 at 56 mo.			

Survival Estimate of GEM 7227Cx, B, D, E



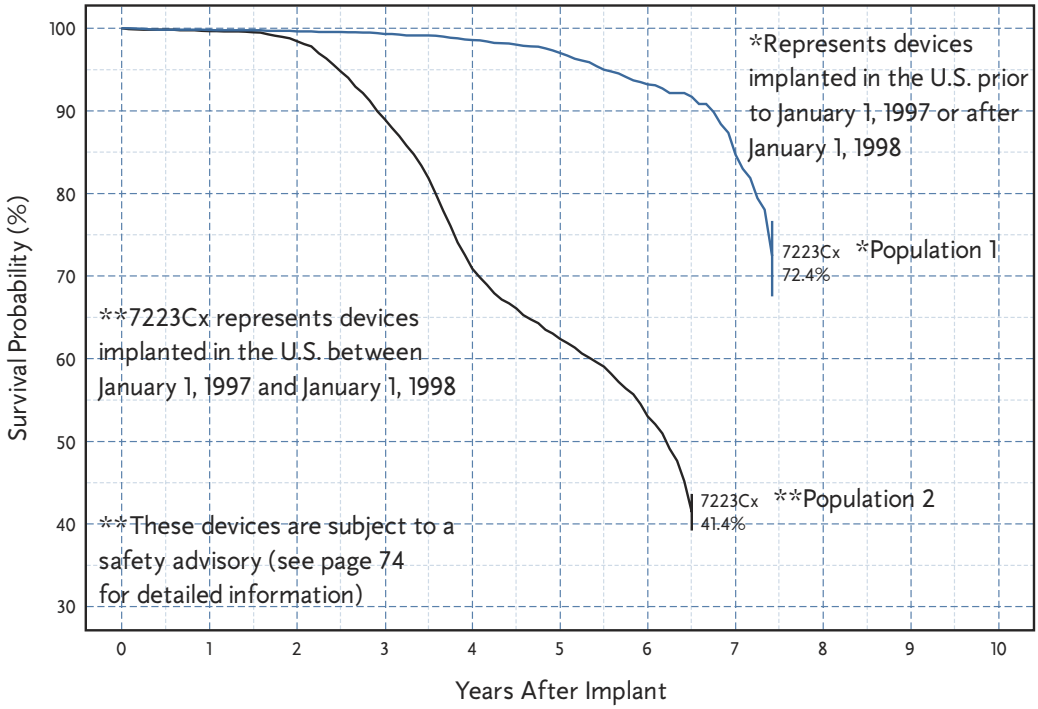
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
GEM 7227 Cx, B, D, E (pop 1)*	Oct-98	22,000	13,000	33	117	99.3 +0.1/-0.1	99 +0.1/-0.2	98.7 +0.2/-0.2	98.3 +0.2/-0.2	97.8 +0.3/-0.3	97.4 +0.4/ -0.5 at 67 mo.		
GEM 7227 B, D, E (pop 2)**	Oct-98	1,000	30	0	276	81.5 +2.2/-2.6	54.5 +3.3/-3.4	34.1 +3.8/-3.8	30.6 +3.9/-3.9 at 38 mo.				

Survival Estimate of GEM DR 7271



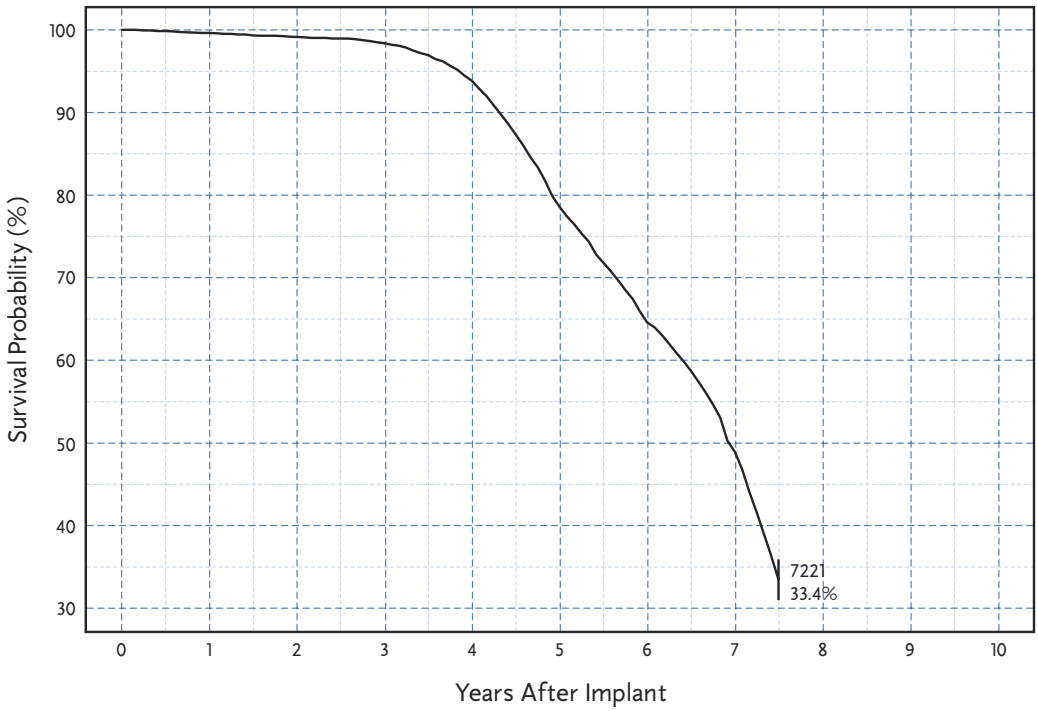
ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
GEM DR 7271 (pop 1)*	Oct-98	15,000	9,000	48	67	99.7 +0.1/-0.1	99.5 +0.1/-0.1	98.9 +0.2/-0.2	98.2 +0.3/-0.3	96.7 +0.5/-0.6	94.4 +0.9/ -1.2 at 67 mo.		
GEM DR 7271 (pop 2)**	Oct-98	4,000	400	40	501	99.7 +0.1/-0.3	99.2 +0.2/-0.4	89.6 +1.1/-1.2	61.9 +2/-2.1	45.9 +3/-3	45.3 +3/-3.1 at 61 mo.		

Survival Estimate of Micro Jewel II 7223Cx



ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
Micro Jewel II 7223Cx (pop 1) *	Nov-96	10,000	4,000	138	73	99.8 +0.1/-0.1	99.6 +0.2/-0.1	99.3 +0.2/ -0.2	98.6 +0.2/-0.3	97 +0.4/-0.5	93.2 +0.7/-0.8	84.7 +2.5/-3	72.4 +4.3/-4.9 at 89 mo.
Micro Jewel II 7223Cx (pop 2)**	Nov-96	11,000	400	328	1,237	99.7 +0.1/-0.2	98.4 +0.3/-0.2	89 +0.7/-0.7	70.9 +1/-1.1	62.4 +1.2/-1.2	53 +1.5/-1.5	41.4 +2.2/-2.2 at 78 mo.	

Survival Estimate of Micro Jewel 7221



ICD Survival (95% Confidence Interval)													
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
Micro Jewel 7221	Jul-96	13,000	1,000	708	454	99.6 +0.1/-0.1	99.1 +0.2/-0.2	98.4 +0.2/-0.3	93.8 +0.5/-0.5	78.6 +1/-1.1	64.6 +1.4/-1.5	48.9 +1.9/-1.9	33.4 +2.5/ -2.5 at 89 mo.

ICD Survival: Returned Product Analysis Results*

						ICD Survival (95% Confidence Interval)							
Model Family	U.S. Market Release	Registered U.S. Implants	Estimated Active U.S. Implants	Battery Depletions†	Electrical Failures‡	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
Maximo DR 7278	Oct-03	3,000	3,000	0	0	100 +0/-0 at 6 mo.							
Maximo VR 7232Cx	Oct-03	2,000	2,000	0	0	100 +0/-0 at 6 mo.							
Marquis VR 7230Cx, B, E	Dec-02	13,000	11,000	3	5	99.8 +0.1/-0.1	99.8 +0.1/-0.1 at 22 mo.						
Marquis DR 7274	Mar-02	39,000	34,000	15	24	99.8 +0.1/-0	99.4 +0.2/-0.2	99.4 +0.2/ -0.2 at 26 mo.					
GEM III AT 7276	Feb-01	13,000	9,000	39	27	99.7 +0.1/-0.2	99 +0.2/-0.3	97.8 +0.4/-0.4	97.8 +0.4/ -0.4 at 38 mo.				
GEM III VR 7231Cx	Dec-00	15,000	12,000	16	18	99.8 +0/-0.1	99.5 +0.1/-0.1	99.2 +0.2/-0.3	99.2 +0.2/ -0.3 at 38 mo.				
GEM III DR 7275	Nov-00	18,000	13,000	75	46	99.7 +0.1/-0.1	99.1 +0.2/-0.1	97.5 +0.3/-0.4	96.2 +0.7/ -0.8 at 40 mo.				
Jewel AF 7250	Jun-00	1,000	1,000	13	16	99.1 +0.4/-0.7	98.7 +0.5/-0.9	98.5 +0.6/-0.9	97.3 +0.9/-1.3	85.7 +3.8/-5.1	84.5 +4/-5.4 at 63 mo.		
GEM II VR 7229Cx	Jul-99	10,000	6,000	25	31	99.8 +0/-0.2	99.5 +0.1/-0.2	99.3 +0.2/-0.2	98.6 +0.3/-0.3	97.5 +0.6/-0.8 at 55 mo.			
GEM II DR 7273	Feb-99	15,000	6,000	631	90	99.5 +0.1/-0.1	98.9 +0.2/-0.2	95.9 +0.3/-0.4	83.9 +0.9/-0.9	65.5 +2.6/-2.7 at 56 mo.			
GEM 7227 Cx, B, D, E (pop 1)	Oct-98	22,000	13,000	33	117	99.3 +0.1/-0.1	99 +0.1/-0.2	98.7 +0.2/-0.2	98.3 +0.2/-0.2	97.8 +0.3/-0.3	97.4 +0.4/ -0.5 at 67 mo.		
GEM 7227 B, D, E (pop 2)	Oct-98	1,000	30	0	276	81.5 +2.2/-2.6	54.5 +3.3/-3.4	34.1 +3.8/-3.8	30.6 +3.9/-3.9 at 38 mo.				
GEM DR 7271 (pop 1)	Oct-98	15,000	9,000	48	67	99.7 +0.1/-0.1	99.5 +0.1/-0.1	98.9 +0.2/-0.2	98.2 +0.3/-0.3	96.7 +0.5/-0.6	94.4 +0.9/-1.2 at 67 mo.		
GEM DR 7271 (pop 2)	Oct-98	4,000	400	40	501	99.7 +0.1/-0.3	99.2 +0.2/-0.4	89.6 +1.1/-1.2	61.9 +2/-2.1	45.9 +3/-3	45.3 +3/-3.1 at 61 mo.		
Micro Jewel II 7223Cx (pop 1)	Nov-96	10,000	4,000	138	73	99.8 +0.1/-0.1	99.6 +0.2/-0.1	99.3 +0.2/-0.2	98.6 +0.2/-0.3	97 +0.4/-0.5	93.2 +0.7/-0.8	84.7 +2.5/-3	72.4 +4.3/-4.9 at 89 mo.
Micro Jewel II 7223Cx (pop 2)	Nov-96	11,000	400	328	1,237	99.7 +0.1/-0.2	98.4 +0.3/-0.2	89 +0.7/-0.7	70.9 +1/-1.1	62.4 +1.2/-1.2	53 +1.5/-1.5	41.4 +2.2/-2.2 at 78 mo.	
Micro Jewel 7221	Jul-96	13,000	1,000	708	454	99.6 +0.1/-0.1	99.1 +0.2/-0.2	98.4 +0.2/-0.3	93.8 +0.5/-0.5	78.6 +1/-1.1	64.6 +1.4/-1.5	48.9 +1.9/-1.9	33.4 +2.5/-2.5 at 89 mo.

† ICD battery depletion includes devices that have reached elective replacement time as indicated in the technical manual or by telemetry.

‡ Electrical failures include ICDs that have tested out of electrical specification.

* This table represents data for registered U.S. implants with returned and confirmed battery depletions or electrical failures as of August 1, 2004.

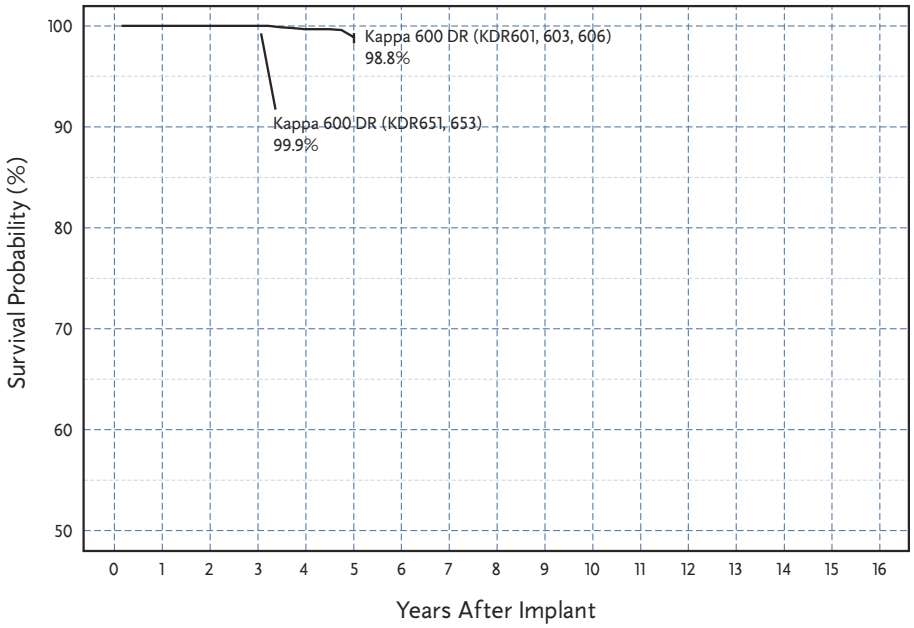
Pulse Generator Performance

The performance of Medtronic pulse generators is expressed in terms of pulse generator survival probability. This is determined from the analysis of returned product data and Medtronic's device registration data in the U.S. These data, current as of August 1, 2004, are presented graphically and numerically in the referenced figures and tables. Because it is based on returned product analysis, pulse generator performance data (i.e., survival probability) does not reflect any pulse generator related medical complications, such as erosion, infection, muscle stimulation, or muscle inhibition. The returned product data considers a device as having failed whenever the analysis shows that any parameter is out of specification, or that the device has reached Elective Replacement Time.

Survival Probability (%) based on Returned Product Analysis. Error bars represent two Standard Errors at the leading 3-month interval. "Survival Probability" refers to proper functioning of the device, not the survival of the patient. (For example: A survival probability of 98% is a statistical assessment that, by the point in time indicated, each patient has had a 2% risk of incurring a device malfunction or normal battery depletion.)

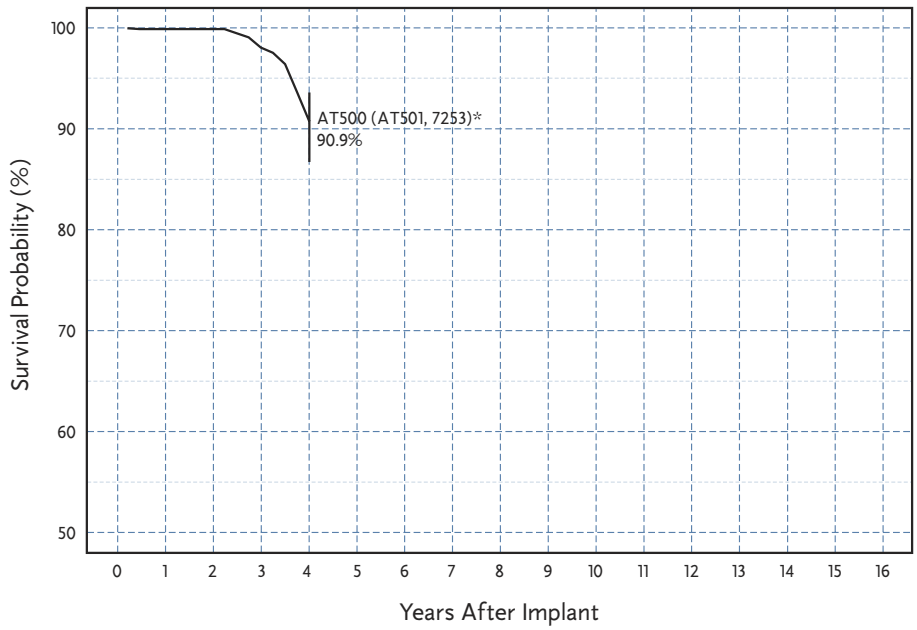
Medtronic urges all physicians to return explanted products and to notify Medtronic when a product is no longer in use.

Kappa 600 Dual Chamber Pulse Generators



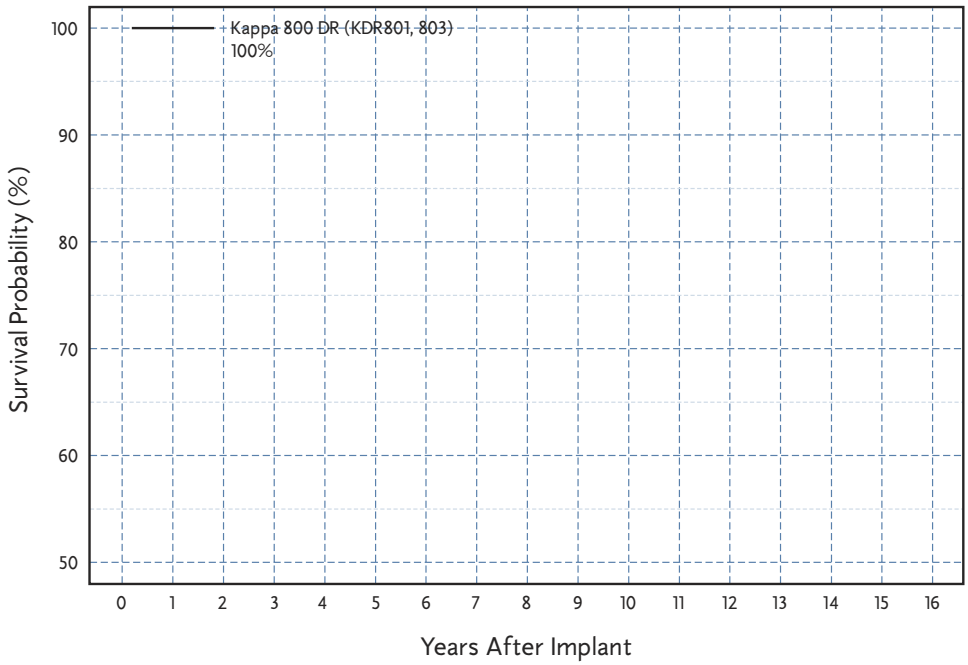
						IPG Survival (95% Confidence Interval)										
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Kappa 600 DR KDR651, KDR653	Mar-04	14,000	11,000	2	3	99.9	99.9	99.9									
Kappa 600 DR KDR601, KDR603, KDR606	Jan-99	23,000	15,000	22	14	99.9	99.9	99.9	99.6 +0.1/ -0.1	98.8 +0.4/-0.6							

AT500 Pulse Generators



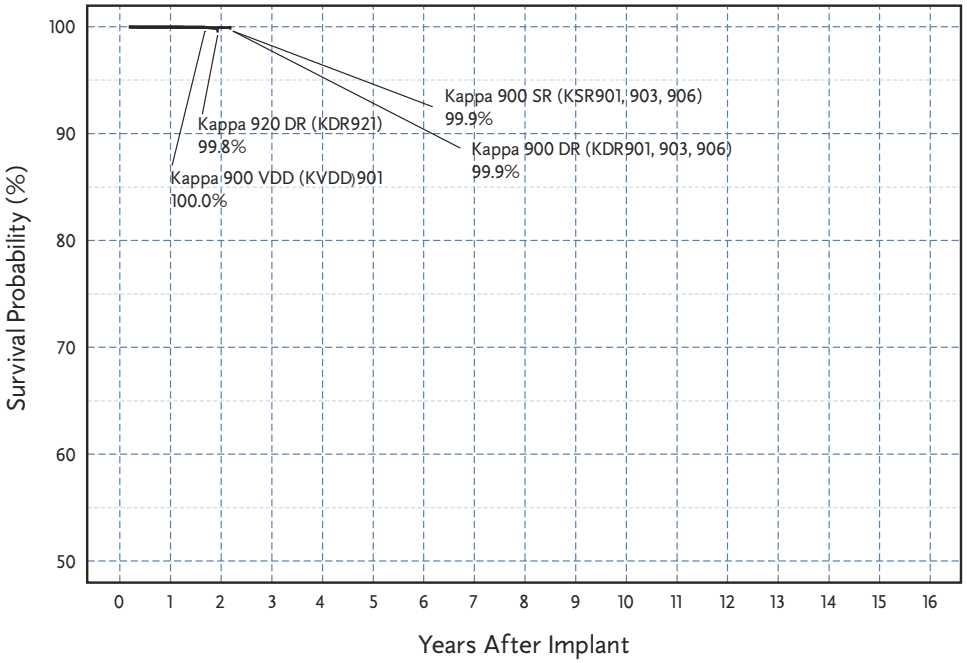
						IPG Survival (95% Confidence Interval)										
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
AT500 AT501, 7253	Mar-03	7,000	6,000	18	3	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	98.1 +0.9/ -1.8	90.9 +2.8/-4.0								

Kappa 800 Pulse Generators



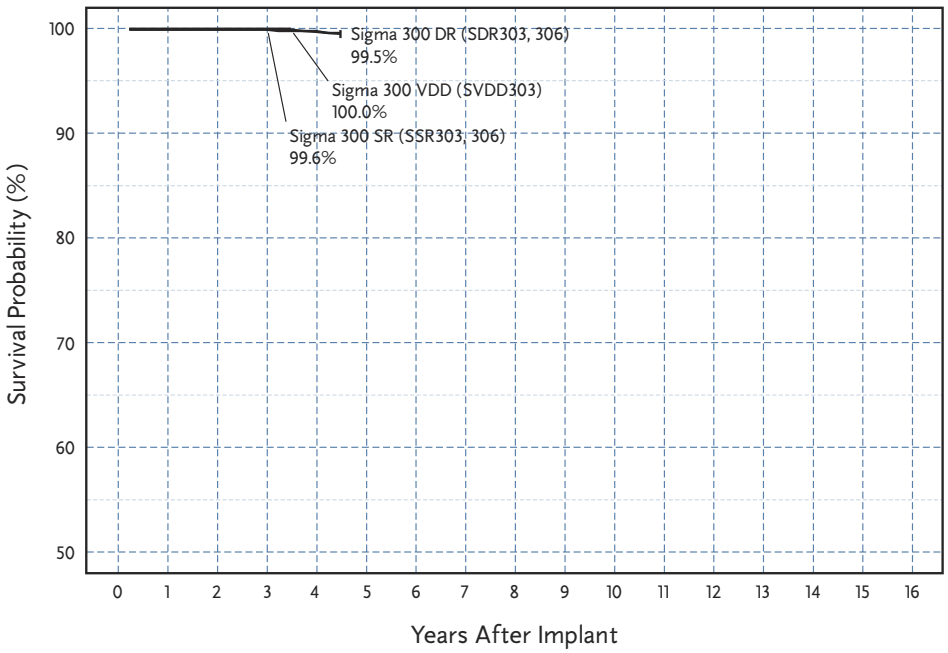
	IPG Survival (95% Confidence Interval)																
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Kappa 800 DR KDR801, KDR803	Jan-02	4,000	4,000	0	0	100	100 (21 mo.)										

Kappa 900 Pulse Generators



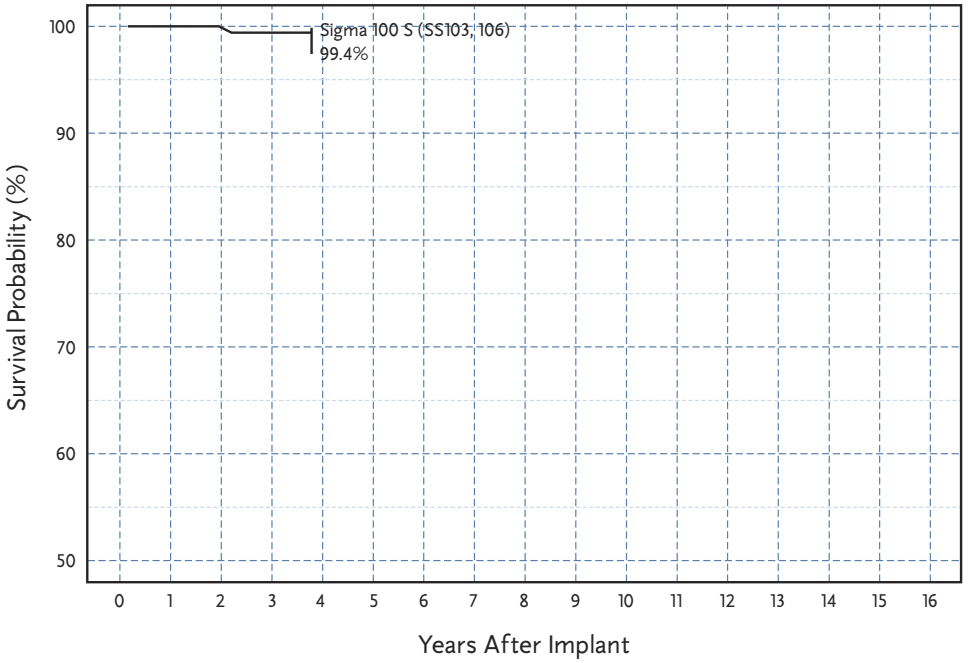
	IPG Survival (95% Confidence Interval)																
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Kappa 900 DR KDR901, KDR903, KDR906	Jan-02	85,000	75,000	1	12	99.9	99.9	99.9 (27 mo.)									
Kappa 900 SR KSR901, KSR903, KSR906	Jan-02	21,000	17,000	2	2	100	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2 (27 mo.)									
Kappa 900 VDD KVDD901	Jan-02	1,000	1,000	0	0	100	100 (21 mo.)										
Kappa 920 DR KDR921	Jan-02	12,000	11,000	2	2	99.9	99.8 +0.1/ -0.3										

Sigma 300 Pulse Generators



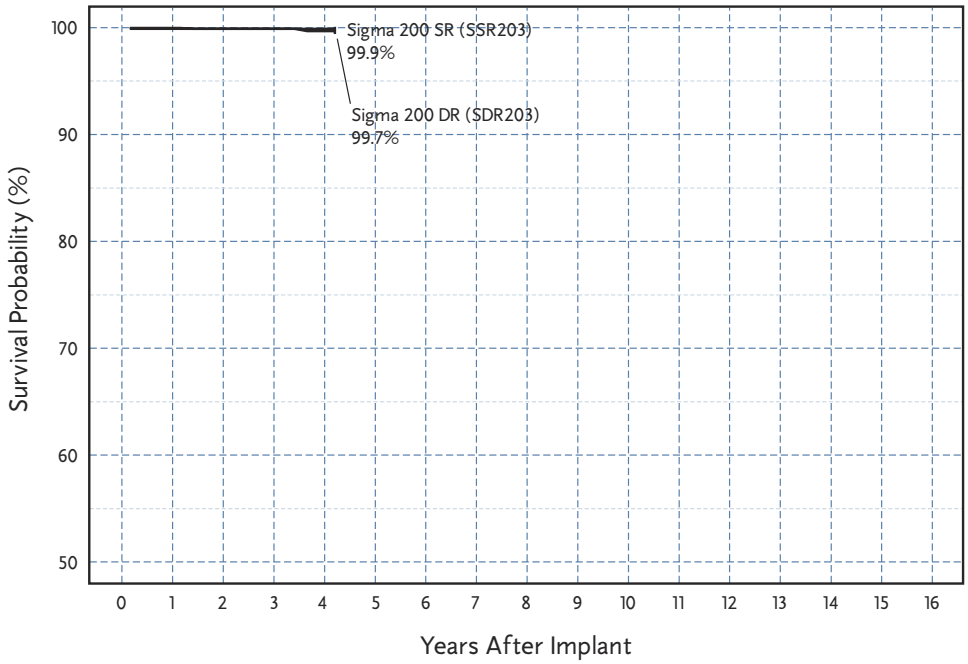
						IPG Survival (95% Confidence Interval)										
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Sigma 300 SR SSR303, SSR306	Sep-99	38,000	24,000	10	6	99.9	99.9	99.9	99.8 +0.1/ -0.1	99.6 +0.2/-0.4 (54 mo.)							
Sigma 300 VDD SVDD303	Sep-99	1,000	400	0	0	100	100	100	100 (42 mo.)								
Sigma 300 DR SDR303, SDR306	Aug-99	76,000	57,000	22	14	99.9	99.9	99.9	99.7 +0.1/ -0.1	99.5 +0.2/-0.4 (54 mo.)							

Sigma 100 Pulse Generators



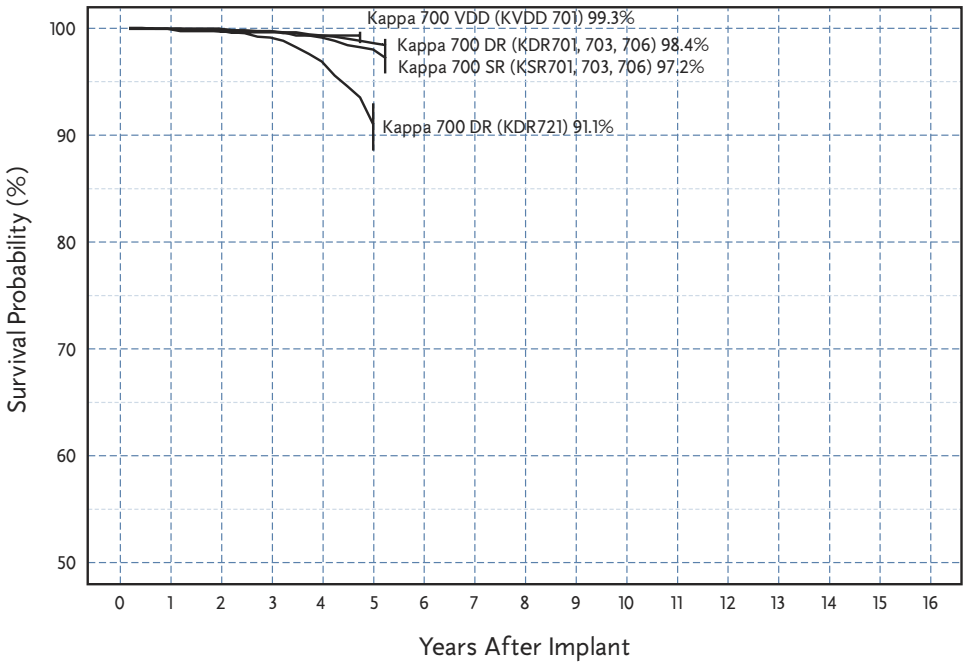
						IPG Survival (95% Confidence Interval)										
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Sigma 100 S SS103, SS106	Aug-99	1,000	400	1	0	100	100	99.4 +0.5/-2.0	99.4 +0.5/-2.0 (45 mo.)								

Sigma 200 Pulse Generators



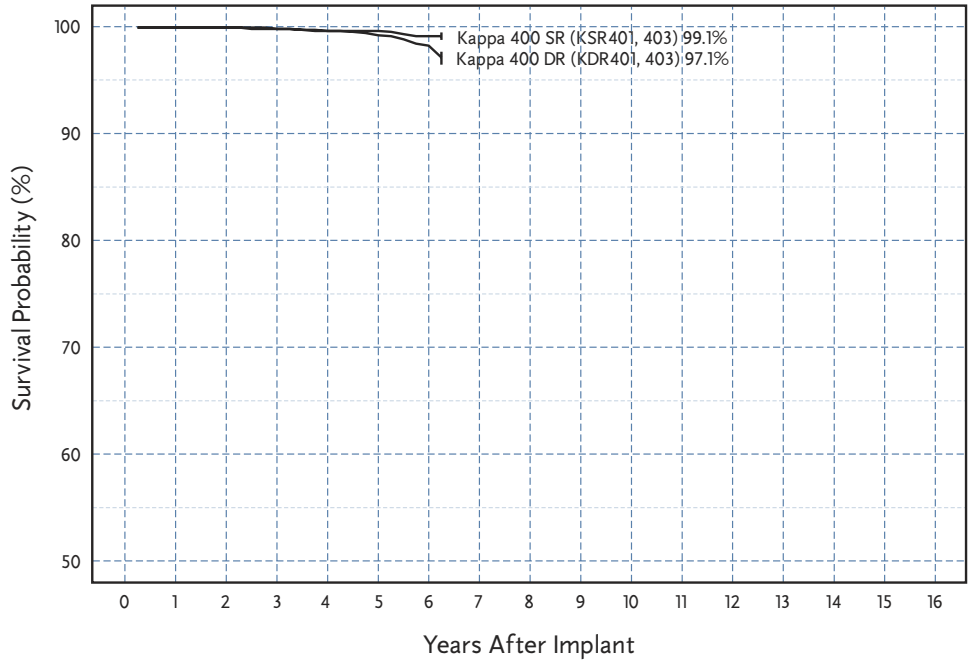
IPG Survival (95% Confidence Interval)																	
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Sigma 200 SR SSR203	Sep-99	11,000	7,000	3	0	100	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2 (51 mo.)							
Sigma 200 DR SDR203	Aug-99	14,000	10,000	4	5	99.9	99.9	99.9 +0.1/ -0.2	99.7 +0.1/ -0.3	99.7 +0.1/ -0.3 (51 mo.)							

Kappa 700 Pulse Generators



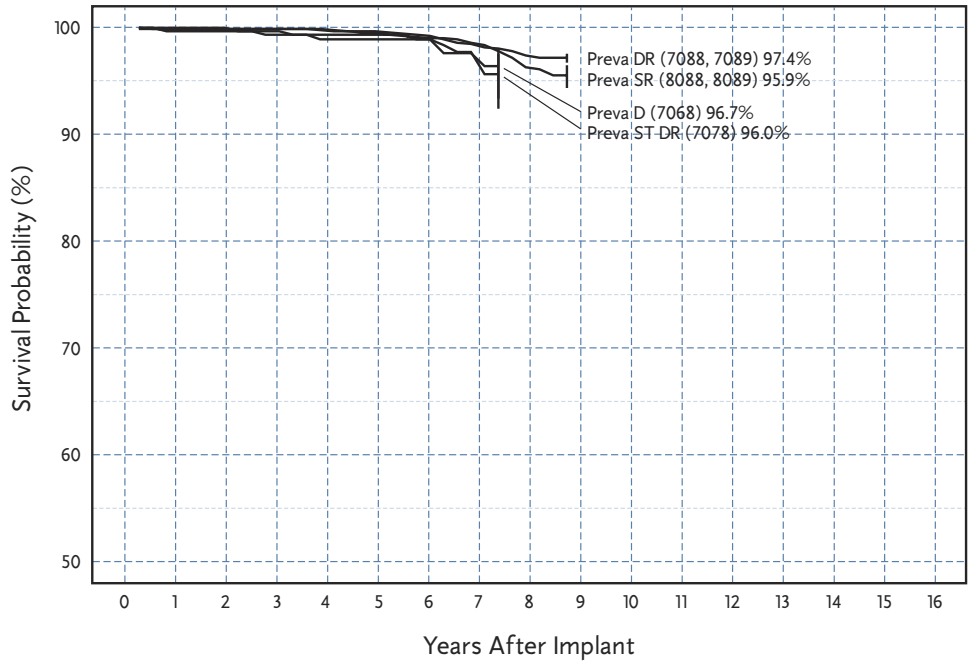
IPG Survival (95% Confidence Interval)																	
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Kappa 700 DR KDR701, KDR703, KDR706	Feb-99	166,000	119,000	202	116	99.9	99.9	99.7	99.3 +0.1/ -0.1	98.6 +0.2/-0.2	98.4 +0.2/-0.2 (63 mo.)						
Kappa 700 DR KDR721	Feb-99	10,000	6,000	78	6	99.9 +0.1/ -0.2	99.7 +0.1/ -0.1	99.1 +0.2/ -0.2	96.9 +0.6/-0.8	91.1 +1.9/ -2.4							
Kappa 700 SR KSR701, KSR703, KSR706	Feb-99	46,000	28,000	87	9	99.9	99.9	99.7 +0.1/ -0.1	99.1 +0.2/ -0.2	98.0 +0.4/-0.4	97.2 +1.0/ -1.5 (63 mo.)						
Kappa 700 VDD KVDD701	Jan-99	2,000	1,000	3	4	99.9 +0.1/ -0.6	99.7 +0.2/ -0.5	99.6 +0.2/-0.4	99.3 +0.4/ -0.7	99.3 +0.4/-0.7 (57 mo.)							

Kappa 400 Pulse Generators



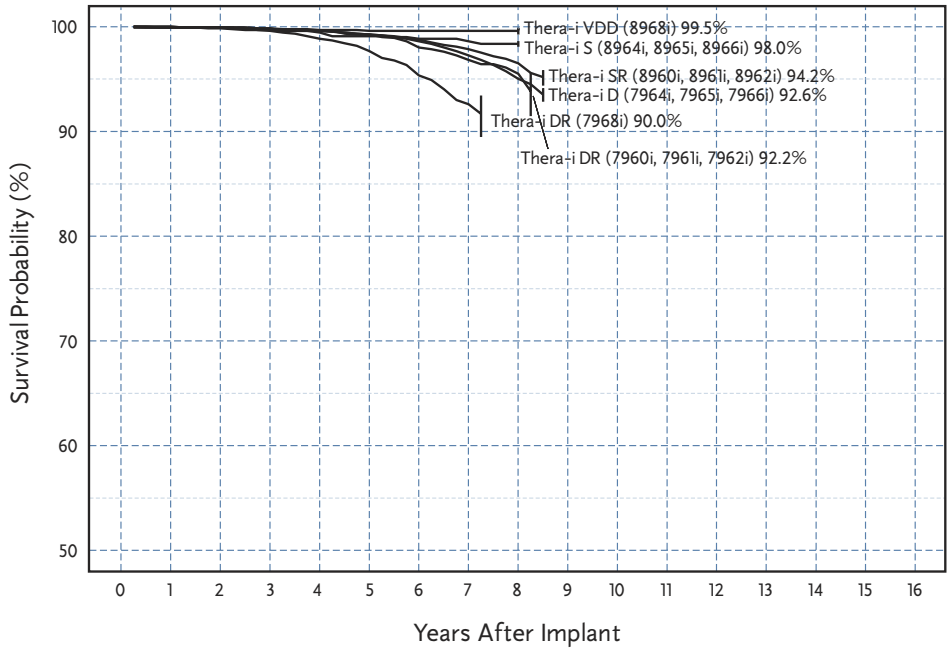
IPG Survival (95% Confidence Interval)																	
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Kappa 400 SR KSR401, KSR403	Feb-98	14,000	8,000	20	3	99.9	99.9 +0.1/ -0.2	99.8 +0.1/ -0.1	99.6 +0.2/-0.3	99.6 +0.2/-0.3	99.1 +0.3/ -0.3	99.1 +0.3/ -0.3 (75 mo.)					
Kappa 400 DR KDR401, KDR403	Jan-98	44,000	26,000	141	25	99.9	99.9	99.8	99.6 +0.1/ -0.1	99.2 +0.1/ -0.1	98.2 +0.3/ -0.3	97.1 +0.5/ -0.7 (75 mo.)					

Preva Pulse Generator



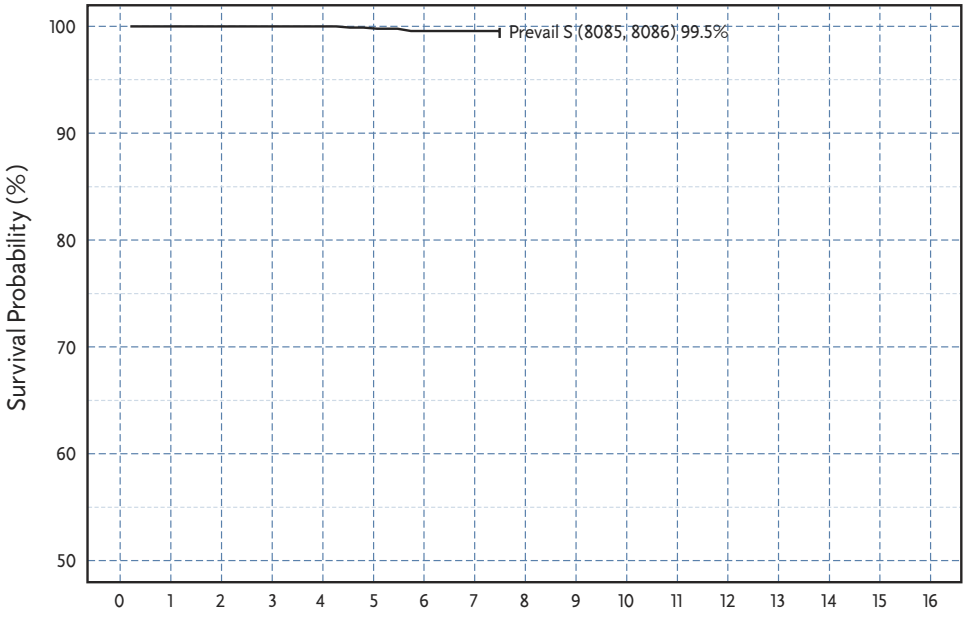
IPG Survival (95% Confidence Interval)																	
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Preva D 7068	Nov-96	1,000	400	5	1	100	99.7 +0.2/ -0.8	99.4 +0.4/-1.0	99.0 +0.5/-1.2	99.0 +0.5/-1.2	97.8 +1.1/ -2.1	96.7 +1.5/ -2.8 (78 mo.)					
Preva ST DR 7078	Nov-96	1,000	400	7	0	99.7 +0.2/ -0.8	99.7 +0.2/ -0.8	99.4 +0.4/-1.0	99.4 +0.4/-1.0	99.0 +0.5/-1.2	97.9 +1.0/ -1.7	96.0 +1.7/ -3.0 (78 mo.)					
Preva DR 7088, 7089	Jul-96	25,000	12,000	118	4	99.9	99.9	99.9	99.7 +0.1/ -0.1	99.4 +0.1/ -0.1	98.6 +0.2/-0.2	97.6 +0.4/-0.4	97.4 +0.4/-0.4 (93 mo.)				
Preva SR 8088, 8089	Jul-96	18,000	6,000	73	3	99.9	99.9	99.9 +0.1/ -0.2	99.6 +0.1/ -0.1	99.2 +0.2/-0.2	98.7 +0.3/ -0.3	96.6 +0.6/-0.8	95.9 +0.9/-1.1 (93 mo.)				

Thera-i Pulse Generators



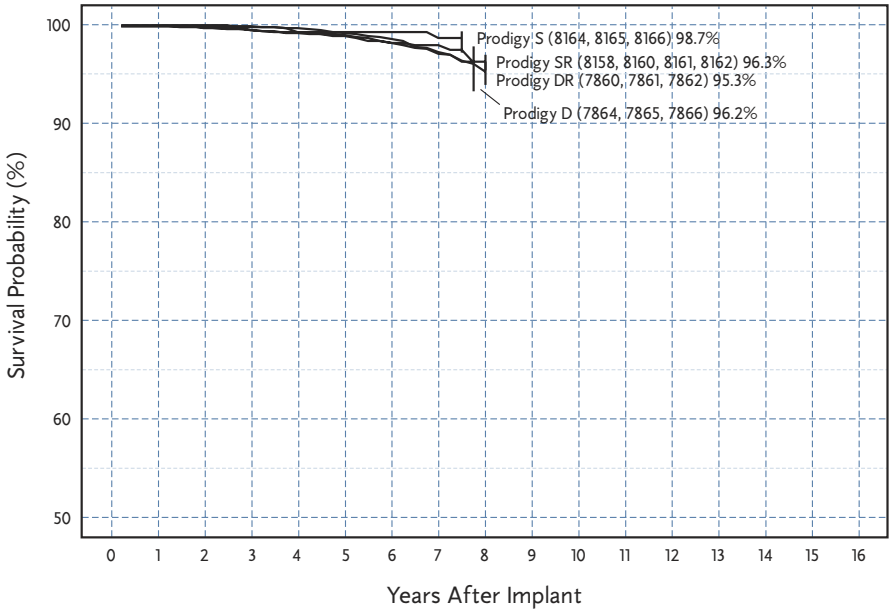
IPG Survival (95% Confidence Interval)																	
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Thera-i DR 7968i	Jul-96	4,000	1,000	56	5	100	99.8 +0.1/ -0.3	99.5 +0.2/-0.4	98.6 +0.4/-0.6	97.2 +0.6/-0.8	94.4 +1.1/ -1.3	91.1 +1.7/ -2.1	90.0 +2.1/ -2.6 (87 mo.)				
Thera-i VDD 8968i	Mar-96	5,000	2,000	10	0	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.7 +0.1/ -0.3	99.6 +0.2/-0.3	99.5 +0.2/-0.2	99.5 +0.2/-0.4	99.5 +0.2/-0.4	99.5 +0.2/-0.4				
Thera-i D 7964i, 7965i, 7966i	Oct-95	3,000	1,000	33	2	100	99.9 +0.1/ -0.2	99.6 +0.2/-0.4	99.5 +0.2/-0.4	99.1 +0.3/ -0.5	97.6 +0.7/ -0.9	96.2 +0.9/-1.1	94.6 +1.4/ -1.8	92.6 +2.1/ -2.9 (99 mo.)			
Thera-i DR 7960i, 7961i, 7962i	Oct-95	122,000	54,000	1,102	58	99.9	99.9	99.8	99.5	99.1 +0.1/ -0.1	98.3 +0.1/ -0.1	96.7 +0.2/-0.2	94.0 +0.3/-0.3	92.2 +0.7/-0.8 (102 mo.)			
Thera-i S 8964i, 8965i, 8966i	Oct-95	4,000	1,000	17	1	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.8 +0.1/ -0.3	99.3 +0.3/ -0.5	98.9 +0.4/-0.6	98.6 +0.5/-0.7	98.3 +0.6/ -0.8	98.0 +0.6/-1.0				
Thera-i SR 8960i, 8961i, 8962i	Oct-95	50,000	17,000	305	14	99.9	99.9	99.7 +0.1/ -0.1	99.5 +0.1/ -0.1	99.1 +0.1/ -0.1	98.5 +0.2/-0.2	97.4 +0.3/ -0.3	95.8 +0.5/ -0.5	94.2 +0.8/-1.0 (102 mo.)			

Prevail Pulse Generator



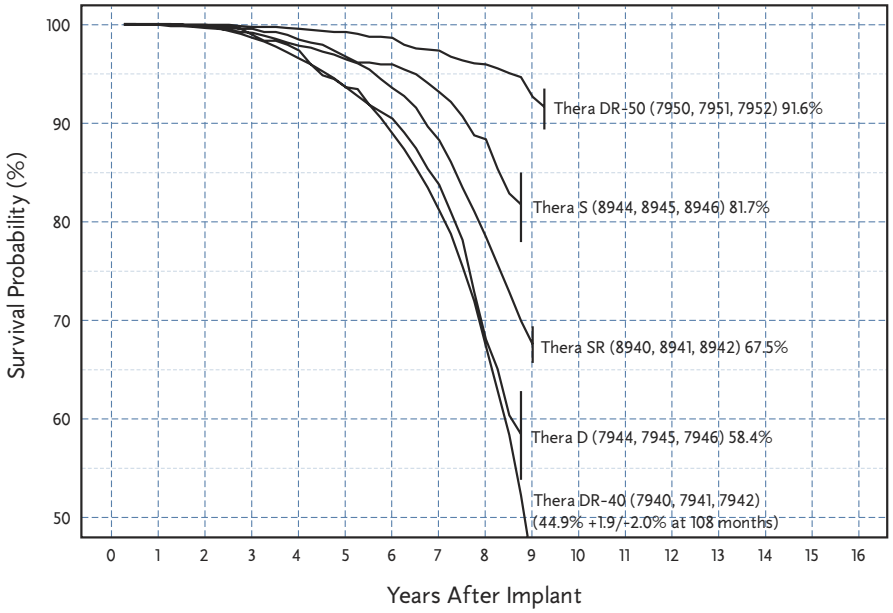
IPG Survival (95% Confidence Interval)																	
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Prevail S 8085, 8086	Oct-95	4,000	1,000	5	1	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.7 +0.2/-0.5	99.5 +0.3/ -0.6	99.5 +0.3/ -0.6	99.5 +0.3/ -0.6 (90 mo.)				

Prodigy Pulse Generators



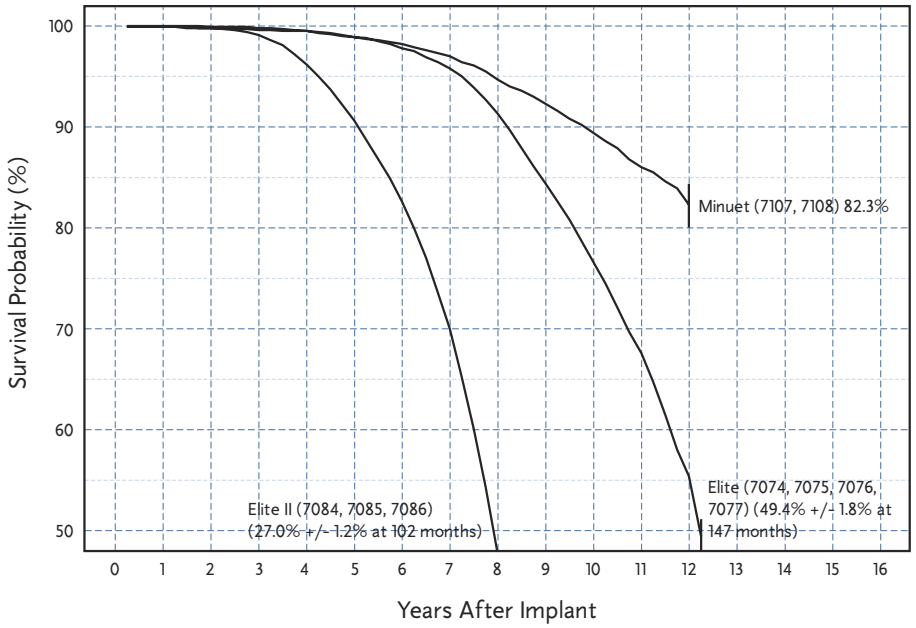
IPG Survival (95% Confidence Interval)																	
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Prodigy D 7864, 7865, 7866	Oct-95	3,000	1,000	18	0	99.9 +0.1/ -0.2	99.7 +0.1/ -0.3	99.5 +0.2/-0.4	99.2 +0.3/-0.5	99.0 +0.4/-0.6	98.2 +0.6/-0.8	98.0 +0.6/-0.8	96.2 +1.7/ -2.9 (93 mo.)				
Prodigy DR 7860, 7861, 7862	Oct-95	37,000	18,000	191	13	99.9	99.9	99.9	99.7 +0.1/ -0.1	99.2 +0.1/ -0.1	98.6 +0.2/-0.2	97.3 +0.3/ -0.3	95.3 +1.0/ -1.3				
Prodigy S 8164, 8165, 8166	Oct-95	2,000	1,000	7	0	100	100	99.8 +0.1/ -0.3	99.3 +0.4/-0.7	99.3 +0.4/-0.7	99.3 +0.4/-0.7	98.7 +0.7/ -1.5	98.7 +0.7/ -1.5 (90 mo.)				
Prodigy SR 8158, 8160, 8161, 8162	Oct-95	22,000	8,000	108	11	99.9	99.8 +0.1/ -0.1	99.5 +0.1/ -0.1	99.3 +0.1/ -0.1	98.9 +0.2/-0.2	98.2 +0.3/-0.3	97.1 +0.5/ -0.5	96.3 +0.7/ -0.9				

Thera Pulse Generators



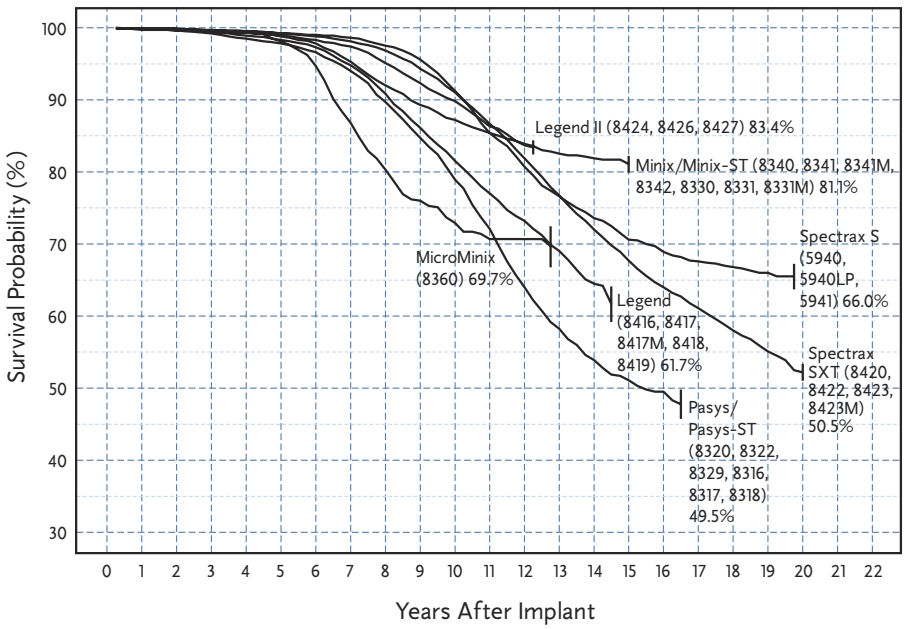
IPG Survival (95% Confidence Interval)																	
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Thera D 7944, 7945, 7946	Jan-95	2,000	200	143	2	99.9 +0.1/ -0.6	99.8 +0.1/ -0.3	98.9 +0.5/-0.8	97.3 +0.8/ -1.0	93.6 +1.2/ -1.5	90.4 +1.6/ -1.9	83.7 +2.3/ -2.6	68.0 +3.5/ -3.8	58.4 +4.4/-4.7 (105 mo.)			
Thera DR-40 7940, 7941, 7942	Jan-95	30,000	2,000	2,483	42	99.9	99.7 +0.1/ -0.1	98.6 +0.2/-0.2	96.5 +0.2/-0.2	93.6 +0.3/ -0.3	88.9 +0.5/-0.5	81.1 +0.6/ -0.6	67.3 +0.9/ -0.9	44.9 +1.9/ -2.0			
Thera DR-50 7950, 7951, 7952	Jan-95	5,000	2,000	64	2	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.7 +0.1/ -0.3	99.5 +0.2/-0.4	99.2 +0.2/-0.4	98.6 +0.3/ -0.5	97.3 +0.5/ -0.7	95.9 +0.7/ -0.9	91.6 +1.8/ -2.3 (111 mo.)			
Thera S 8944, 8945, 8946	Jan-95	3,000	300	61	3	100	99.9 +0.1/ -0.6	99.5 +0.2/-0.4	98.4 +0.6/-0.9	96.7 +0.8/-1.1	95.9 +1.0/ -1.4	93.1 +1.5/ -1.9	88.3 +2.1/ -2.6	81.7 +3.2/ -3.8 (105 mo.)			
Thera SR 8940, 8941, 8942	Jan-95	14,000	1,000	671	18	99.9 +0.1/ -0.2	99.6 +0.1/ -0.1	99.1 +0.2/ -0.2	97.8 +0.3/ -0.3	96.4 +0.4/-0.4	93.5 +0.6/ -0.6	88.2 +0.8/-0.8	78.4 +1.1/ -1.2	67.5 +1.8/ -1.9			

Dual Chamber Pulse Generators



						IPG Survival (95% Confidence Interval)											
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Elite II 7084, 7085, 7086	Dec-92	57,000	200	6,916	115	99.9	99.8	99.1 +0.1/ -0.1	96.2 +0.2/ -0.2	90.6 +0.3/ -0.3	82.6 +0.4/ -0.4	70.0 +0.6/ -0.6	47.6 +0.8/ -0.8	27.0 +1.2/ -1.2 (102 mo.)			
Minuet 7107, 7108	Mar-92	17,000	4,000	382	9	100	99.9	99.8 +0.1/ -0.1	99.5 +0.1/ -0.1	98.9 +0.2/ -0.2	98.2 +0.3/ -0.3	97.0 +0.4/ -0.4	94.7 +0.5/ -0.5	89.4 +0.8/ -0.8	82.3 +2.0/ -2.3		
Elite 7074, 7075, 7076, 7077	Apr-91	48,000	4,000	2,532	109	99.9	99.8	99.6 +0.1/ -0.1	99.5 +0.1/ -0.1	98.9 +0.1/ -0.1	97.8 +0.2/ -0.2	95.8 +0.3/ -0.3	91.3 +0.4/ -0.4	76.6 +0.7/ -0.7	55.4 +1.3/ -1.3	49.4 +1.8/ -1.8 (147 mo.)	

Single Chamber Pulse Generators



						IPG Survival (95% Confidence Interval)											
Model Family	U. S. Market Release	Registered Implants	Active Implants	Battery EOL Indicators	Electrical Failures	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Legend II 8424, 8426, 8427	Nov-91	58,000	11,000	1,202	55	99.9	99.8	99.6 +0.1/ -0.1	99.3 +0.1/ -0.1	98.9 +0.1/ -0.1	98.3 +0.1/ -0.1	97.4 +0.2/ -0.2	95.1 +0.3/ -0.3	89.8 +0.4/ -0.4	83.7 +0.9/ -0.9	83.4 +1.0/ -1.0 (147 mo.)	
MicroMinix 8360	Oct-90	7,000	1,000	244	13	99.9 +0.1/ -0.2	99.9 +0.1/-0.2	99.6 +0.2/ -0.3	99.4 +0.2/ -0.2	98.1 +0.4/ -0.6	94.7 +0.8/ -1.0	86.8 +1.3/ -1.4	80.3 +1.8/ -1.9	72.9 +2.3/ -2.4	70.7 +2.5/ -2.6	69.7 +2.7/ -2.9 (153 mo.)	
Minix/Minix ST 8340, 8341, 8341M, 8342, 8330, 8331, 8331M	Dec-89	58,000	8,000	1,301	85	99.9	99.8	99.5 +0.1/ -0.1	99.3 +0.1/ -0.1	98.8 +0.1/ -0.1	97.8 +0.2/ -0.2	95.3 +0.3/ -0.3	92.0 +0.4/ -0.4	87.2 +0.5/ -0.5	83.9 +0.7/ -0.7	81.9 +0.8/ -0.8	81.1 +1.1/ -1.2 (180 mo.)
Legend 8416, 8417, 8417M, 8418, 8419	Aug-89	57,000	6,000	2,209	219	99.9	99.7	99.4 +0.1/ -0.1	98.9 +0.1/ -0.1	98.3 +0.1/ -0.1	97.3 +0.2/ -0.2	94.8 +0.3/ -0.3	90.8 +0.4/ -0.4	81.5 +0.6/ -0.6	73.2 +0.8/ -0.8	64.5 +1.3/ -1.3	61.7 +2.4/ -2.5 (174 mo.)
Pasys/Pasys ST 8320, 8322, 8329, 8316, 8317, 8318	Mar-86	28,000	1,000	1,415	173	99.9	99.6 +0.1/ -0.1	99.2 +0.1/ -0.1	98.5 +0.2/ -0.2	97.8 +0.2/ -0.2	96.6 +0.3/ -0.3	94.0 +0.4/ -0.4	89.7 +0.6/ -0.6	78.9 +0.9/ -0.9	64.0 +1.3/-1.3	53.9 +1.5/ -1.5	47.8 +/ -2.1 (198 mo.)
Spectrax S 5940, 5940LP, 5941	Jul-83	25,000	1,000	805	97	99.7 +0.1/ -0.1	99.6 +0.1/ -0.1	99.5 +0.1/ -0.1	99.4 +0.1/ -0.1	99.2 +0.1/ -0.1	99.0 +0.2/ -0.2	98.6 +0.2/ -0.2	97.5 +0.3/ -0.3	91.2 +0.6/ -0.6	80.7 +1.0/ -1.0	73.6 +1.2/ -1.3	66.0 +1.8/ -1.9 (228 mo)
Spectrax SXT 8420, 8422, 8423, 8423M	Oct-81	111,000	3,000	4,338	566	99.9	99.8	99.7	99.5	99.2 +0.1/ -0.1	98.8 +0.1/ -0.1	98.1 +0.1/ -0.1	96.8 +0.1/ -0.1	91.0 +0.3/ -0.3	81.9 +0.4/ -0.4	72.0 +0.6/ -0.6	50.5 +1.6/ -1.6 (240 mo)

Implantable Pulse Generators

Laboratory Analysis and Actuarial Survival Probability (%)[1] (95% Confidence Interval)[2]

Source: U.S. Returned Product Analysis
(Data as of August 1, 2004)

						1 Year Intervals								2 Year Intervals			
Model Family	U. S. Market Release	Registered Implants	Active Implants[3]	Battery EOL Indicators[4]	Electrical Failures[4]	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Kappa 600 DR KDR651, KDR653	Mar-04	14,000	11,000	2	3	99.9	99.9	99.9									
Kappa 600 DR KDR601, KDR603, KDR606	Jan-99	23,000	15,000	22	14	99.9	99.9	99.9	99.6 +0.1/ -0.1	98.8 +0.4/-0.6							
AT500 AT501, 7253	Mar-03	7,000	6,000	18	3	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	98.1 +0.9/ -1.8	90.9 +2.8/-4.0								
Kappa 800 DR KDR801, KDR803	Jan-02	4,000	4,000	0	0	100	100 (21 mo.)										
Kappa 900 DR KDR901, KDR903, KDR906	Jan-02	85,000	75,000	1	12	99.9	99.9	99.9 (27 mo.)									
Kappa 900 SR KSR901, KSR903, KSR906	Jan-02	21,000	17,000	2	2	100	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2 (27 mo.)									
Kappa 900 VDD KVDD901	Jan-02	1,000	1,000	0	0	100	100 (21 mo.)										
Kappa 920 DR KDR921	Jan-02	12,000	11,000	2	2	99.9	99.8 +0.1/ -0.3										
Sigma 200 SR SSR203	Sep-99	11,000	7,000	3	0	100	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2 (51 mo.)							
Sigma 300 SR SSR303, SSR306	Sep-99	38,000	24,000	10	6	99.9	99.9	99.9	99.8 +0.1/ -0.1	99.6 +0.2/-0.4 (54 mo.)							
Sigma 300 VDD SVDD303	Sep-99	1,000	400	0	0	100	100	100	100 (42 mo.)								
Sigma 300 DR SDR303, SDR306	Aug-99	76,000	57,000	22	14	99.9	99.9	99.9	99.7 +0.1/ -0.1	99.5 +0.2/-0.4 (54 mo.)							
Sigma 100 S SS103, SS106	Aug-99	1,000	400	1	0	100	100	99.4 +0.5/-2.0	99.4 +0.5/-2.0 (45 mo.)								
Sigma 200 DR SDR203	Aug-99	14,000	10,000	4	5	99.9	99.9	99.9 +0.1/ -0.2	99.7 +0.1/ -0.3	99.7 +0.1/ -0.3 (51 mo.)							
Kappa 700 DR KDR701, KDR703, KDR706	Feb-99	166,000	119,000	202	116	99.9	99.9	99.7	99.3 +0.1/ -0.1	98.6 +0.2/-0.2	98.4 +0.2/-0.2 (63 mo.)						
Kappa 700 DR KDR721	Feb-99	10,000	6,000	78	6	99.9 +0.1/ -0.2	99.7 +0.1/ -0.1	99.1 +0.2/ -0.2	96.9 +0.6/-0.8	91.1 +1.9/ -2.4							
Kappa 700 SR KSR701, KSR703, KSR706	Feb-99	46,000	28,000	87	9	99.9	99.9	99.7 +0.1/ -0.1	99.1 +0.2/ -0.2	98.0 +0.4/-0.4	97.2 +1.0/ -1.5 (63 mo.)						
Kappa 700 D KD701	Jan-99	300	200	1	0	100	100	100	100 (45 mo.)								
Kappa 700 VDD KVDD701	Jan-99	2,000	1,000	3	4	99.9 +0.1/ -0.6	99.7 +0.2/ -0.5	99.6 +0.2/-0.4	99.3 +0.4/ -0.7	99.3 +0.4/-0.7 (57 mo.)							
Kappa 400 SR KSR401, KSR403	Feb-98	14,000	8,000	20	3	99.9	99.9 +0.1/ -0.2	99.8 +0.1/ -0.1	99.6 +0.2/-0.3	99.6 +0.2/-0.3	99.1 +0.3/ -0.3	99.1 +0.3/ -0.3 (75 mo.)					
Kappa 400 DR KDR401, KDR403	Jan-98	44,000	26,000	141	25	99.9	99.9	99.8	99.6 +0.1/ -0.1	99.2 +0.1/ -0.1	98.2 +0.3/ -0.3	97.1 +0.5/ -0.7 (75 mo.)					
Preva D 7068	Nov-96	1,000	400	5	1	100	99.7 +0.2/-0.8	99.4 +0.4/-1.0	99.0 +0.5/-1.2	99.0 +0.5/-1.2	97.8 +1.1/ -2.1	96.7 +1.5/ -2.8 (78 mo.)					
Preva ST DR 7078	Nov-96	1,000	400	7	0	99.7 +0.2/ -0.8	99.7 +0.2/ -0.8	99.4 +0.4/-1.0	99.4 +0.4/-1.0	99.0 +0.5/-1.2	97.9 +1.0/ -1.7	96.0 +1.7/ -3.0 (78 mo.)					
Preva DR 7088, 7089	Jul-96	25,000	12,000	118	4	99.9	99.9	99.9	99.7 +0.1/ -0.1	99.4 +0.1/ -0.1	98.6 +0.2/-0.2	97.6 +0.4/-0.4	97.4 +0.4/-0.4 (93 mo.)				
Preva SR 8088, 8089	Jul-96	18,000	6,000	73	3	99.9	99.9	99.9 +0.1/ -0.2	99.6 +0.1/ -0.1	99.2 +0.2/-0.2	98.7 +0.3/ -0.3	96.6 +0.6/-0.8	95.9 +0.9/-1.1 (93 mo.)				

[1] "Actuarial survival probability" refers to the proper functioning of the device, not the survival of the patient. For example, a survival probability of 98% is a statistical assessment that, by the point in time indicated, each patient has had a 2% risk of incurring a pulse generator malfunction or normal battery depletion.

[2] Rounded to closest 0.1%.

[3] The number of active implants was estimated using the total number of implantable pulse generator registered implants, returns and normal patient mortality projections.

[4] Registered and non-registered devices are included in the number of devices exhibiting battery elective replacement time indicators and the number of devices exhibiting electrical failures.

NOTE: For information on unlisted models contact Medtronic Technical Services (see page 2).

Implantable Pulse Generators (cont.)

Laboratory Analysis and Actuarial Survival Probability (%)[1] (95% Confidence Interval)[2]

Source: U.S. Returned Product Analysis
(Data as of August 1, 2004)

						1 Year Intervals								2 Year Intervals			
Model Family	U. S. Market Release	Registered Implants	Active Implants[3]	Battery EOL Indicators[4]	Electrical Failures[4]	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Thera-i DR 7968i	Jul-96	4,000	1,000	56	5	100	99.8 +0.1/ -0.3	99.5 +0.2/-0.4	98.6 +0.4/-0.6	97.2 +0.6/-0.8	94.4 +1.1/ -1.3	91.1 +1.7/ -2.1	90.0 +2.1/ -2.6 (87 mo.)				
Thera-i VDD 8968i	Mar-96	5,000	2,000	10	0	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.7 +0.1/ -0.3	99.6 +0.2/-0.3	99.5 +0.2/-0.2	99.5 +0.2/-0.4	99.5 +0.2/-0.4	99.5 +0.2/-0.4				
Thera-i D 7964i, 7965i, 7966i	Oct-95	3,000	1,000	33	2	100	99.9 +0.1/ -0.2	99.6 +0.2/-0.4	99.5 +0.2/-0.4	99.1 +0.3/ -0.5	97.6 +0.7/ -0.9	96.2 +0.9/-1.1	94.6 +1.4/ -1.8	92.6 +2.1/ -2.9 (99 mo.)			
Thera-i DR 7960i, 7961i, 7962i	Oct-95	122,000	54,000	1,102	58	99.9	99.9	99.8	99.5	99.1 +0.1/ -0.1	98.3 +0.1/ -0.1	96.7 +0.2/-0.2	94.0 +0.3/-0.3	92.2 +0.7/-0.8 (102 mo.)			
Thera-i S 8964i, 8965i, 8966i	Oct-95	4,000	1,000	17	1	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.8 +0.1/ -0.3	99.3 +0.3/ -0.5	98.9 +0.4/-0.6	98.6 +0.5/-0.7	98.3 +0.6/ -0.8	98.0 +0.6/-1.0				
Thera-i SR 8960i, 8961i, 8962i	Oct-95	50,000	17,000	305	14	99.9	99.9	99.7 +0.1/ -0.1	99.5 +0.1/ -0.1	99.1 +0.1/ -0.1	98.5 +0.2/-0.2	97.4 +0.3/ -0.3	95.8 +0.5/ -0.5	94.2 +0.8/-1.0 (102 mo.)			
Prevail S 8085, 8086	Oct-95	4,000	1,000	5	1	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.7 +0.2/-0.5	99.5 +0.3/ -0.6	99.5 +0.3/ -0.6	99.5 +0.3/ -0.6 (90 mo.)				
Prodigy D 7864, 7865, 7866	Oct-95	3,000	1,000	18	0	99.9 +0.1/ -0.2	99.7 +0.1/ -0.3	99.5 +0.2/-0.4	99.2 +0.3/-0.5	99.0 +0.4/-0.6	98.2 +0.6/-0.8	98.0 +0.6/-0.8	96.2 +1.7/ -2.9 (93 mo.)				
Prodigy DR 7860, 7861, 7862	Oct-95	37,000	18,000	191	13	99.9	99.9	99.9	99.7 +0.1/ -0.1	99.2 +0.1/ -0.1	98.6 +0.2/-0.2	97.3 +0.3/ -0.3	95.3 +1.0/ -1.3				
Prodigy S 8164, 8165, 8166	Oct-95	2,000	1,000	7	0	100	100	99.8 +0.1/ -0.3	99.3 +0.4/-0.7	99.3 +0.4/-0.7	99.3 +0.4/-0.7	98.7 +0.7/ -1.5	98.7 +0.7/ -1.5 (90 mo.)				
Prodigy SR 8158, 8160, 8161, 8162	Oct-95	22,000	8,000	108	11	99.9	99.8 +0.1/ -0.1	99.5 +0.1/ -0.1	99.3 +0.1/ -0.1	98.9 +0.2/-0.2	98.2 +0.3/-0.3	97.1 +0.5/ -0.5	96.3 +0.7/ -0.9				
Thera D 7944, 7945, 7946	Jan-95	2,000	200	143	2	99.9 +0.1/ -0.6	99.8 +0.1/ -0.3	98.9 +0.5/-0.8	97.3 +0.8/ -1.0	93.6 +1.2/ -1.5	90.4 +1.6/ -1.9	83.7 +2.3/ -2.6	68.0 +3.5/ -3.8	58.4 +4.4/-4.7 (105 mo.)			
Thera DR-40 7940, 7941, 7942	Jan-95	30,000	2,000	2,483	42	99.9	99.7 +0.1/ -0.1	98.6 +0.2/-0.2	96.5 +0.2/-0.2	93.6 +0.3/ -0.3	88.9 +0.5/-0.5	81.1 +0.6/ -0.6	67.3 +0.9/ -0.9	44.9 +1.9/ -2.0			
Thera DR-50 7950, 7951, 7952	Jan-95	5,000	2,000	64	2	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.7 +0.1/ -0.3	99.5 +0.2/-0.4	99.2 +0.2/-0.4	98.6 +0.3/ -0.5	97.3 +0.5/ -0.7	95.9 +0.7/ -0.9	91.6 +1.8/ -2.3 (111 mo.)			
Thera S 8944, 8945, 8946	Jan-95	3,000	300	61	3	100	99.9 +0.1/ -0.6	99.5 +0.2/-0.4	98.4 +0.6/-0.9	96.7 +0.8/-1.1	95.9 +1.0/ -1.4	93.1 +1.5/ -1.9	88.3 +2.1/ -2.6	81.7 +3.2/ -3.8 (105 mo.)			
Thera SR 8940, 8941, 8942	Jan-95	14,000	1,000	671	18	99.9 +0.1/ -0.2	99.6 +0.1/ -0.1	99.1 +0.2/ -0.2	97.8 +0.3/ -0.3	96.4 +0.4/-0.4	93.5 +0.6/ -0.6	88.2 +0.8/-0.8	78.4 +1.1/ -1.2	67.5 +1.8/ -1.9			
Elite II 7084, 7085, 7086	Dec-92	57,000	200	6,916	115	99.9	99.8	99.1 +0.1/ -0.1	96.2 +0.2/-0.2	90.6 +0.3/-0.3	82.6 +0.4/-0.4	70.0 +0.6/-0.6	47.6 +0.8/-0.8	27.0 +1.2/ -1.2 (102 mo.)			
Minuet 7107, 7108	Mar-92	17,000	4,000	382	9	100	99.9	99.8 +0.1/ -0.1	99.5 +0.1/ -0.1	98.9 +0.2/-0.2	98.2 +0.3/-0.3	97.0 +0.4/-0.4	94.7 +0.5/-0.5	89.4 +0.8/-0.8	82.3 +2.0/-2.3		
Elite 7074, 7075, 7076, 7077	Apr-91	48,000	4,000	2,532	109	99.9	99.8	99.6 +0.1/ -0.1	99.5 +0.1/ -0.1	98.9 +0.1/ -0.1	97.8 +0.2/-0.2	95.8 +0.3/ -0.3	91.3 +0.4/ -0.4	76.6 +0.7/ -0.7	55.4 +1.3/ -1.3	49.4 +1.8/ -1.8 (147 mo.)	
Legend II 8424, 8426, 8427	Nov-91	58,000	11,000	1,202	55	99.9	99.8	99.6 +0.1/ -0.1	99.3 +0.1/ -0.1	98.9 +0.1/ -0.1	98.3 +0.1/ -0.1	97.4 +0.2/-0.2	95.1 +0.3/ -0.3	89.8 +0.4/-0.4	83.7 +0.9/ -0.9	83.4 +1.0/ -1.0 (147 mo.)	
MicroMinix 8360	Oct-90	7,000	1,000	244	13	99.9 +0.1/ -0.2	99.9 +0.1/ -0.2	99.6 +0.2/-0.3	99.4 +0.2/-0.2	98.1 +0.4/ -0.6	94.7 +0.8/-1.0	86.8 +1.3/ -1.4	80.3 +1.8/ -1.9	72.9 +2.3/ -2.4	70.7 +2.5/ -2.6	69.7 +2.7/ -2.9 (153 mo.)	
Minix/Minix ST 8340, 8341, 8341M, 8342, 8330, 8331, 8331M	Dec-89	58,000	8,000	1,301	85	99.9	99.8	99.5 +0.1/ -0.1	99.3 +0.1/ -0.1	98.8 +0.1/ -0.1	97.8 +0.2/-0.2	95.3 +0.3/ -0.3	92.0 +0.4/-0.4	87.2 +0.5/-0.5	83.9 +0.7/ -0.7	81.9 +0.8/ -0.8	81.1 +1.1/ -1.2 (180 mo.)
Legend 8416, 8417, 8417M, 8418, 8419	Aug-89	57,000	6,000	2,209	219	99.9	99.7	99.4 +0.1/ -0.1	98.9 +0.1/ -0.1	98.3 +0.1/ -0.1	97.3 +0.2/ -0.2	94.8 +0.3/-0.3	90.8 +0.4/-0.4	81.5 +0.6/ -0.6	73.2 +0.8/ -0.8	64.5 +1.3/ -1.3	61.7 +2.4/ -2.5 (174 mo.)
Pasys/Pasys ST 8320, 8322, 8329, 8316, 8317, 8318	Mar-86	28,000	1,000	1,415	173	99.9	99.6 +0.1/ -0.1	99.2 +0.1/ -0.1	98.5 +0.2/-0.2	97.8 +0.2/-0.2	96.6 +0.3/ -0.3	94.0 +0.4/-0.4	89.7 +0.6/-0.6	78.9 +0.9/-0.9	64.0 +1.3/ -1.3	53.9 +1.5/ -1.5	47.8 +/ -2.1 (198 mo.)
Spectrax S 5940, 5940LP, 5941	Jul-83	25,000	1,000	805	97	99.7 +0.1/ -0.1	99.6 +0.1/ -0.1	99.5 +0.1/ -0.1	99.4 +0.1/ -0.1	99.2 +0.1/ -0.1	99.0 +0.2/-0.2	98.6 +0.2/-0.2	97.5 +0.3/ -0.3	91.2 +0.6/ -0.6	80.7 +1.0/ -1.0	73.6 +1.2/ -1.3	66.0 +1.8/ -1.9 (228 mo.)
Spectrax SXT 8420, 8422, 8423, 8423M	Oct-81	111,000	3,000	4,338	566	99.9	99.8	99.7	99.5	99.2 +0.1/ -0.1	98.8 +0.1/ -0.1	98.1 +0.1/ -0.1	96.8 +0.1/ -0.1	91.0 +0.3/ -0.3	81.9 +0.4/ -0.4	72.0 +0.6/-0.6	50.5 +1.6/ -1.6 (240 mo.)

[1] "Actuarial survival probability" refers to the proper functioning of the device, not the survival of the patient. For example, a survival probability of 98% is a statistical assessment that, by the point in time indicated, each patient has had a 2% risk of incurring a pulse generator malfunction or normal battery depletion.

[2] Rounded to closest 0.1%.

[3] The number of active implants was estimated using the total number of implantable pulse generator registered implants, returns and normal patient mortality projections.

[4] Registered and non-registered devices are included in the number of devices exhibiting battery elective replacement time indicators and the number of devices exhibiting electrical failures.

NOTE: For information on unlisted models contact Medtronic Technical Services (see page 2).

Lead Performance

Introduction

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 follow-up of the chronically implanted lead and thorough evaluation of lead integrity at ICD replacement.

To provide clinicians with reliable survivability data, Medtronic monitors the performance of its ICD leads through two sources: the Tachyarrhythmia Chronic Systems Study (TCSS) and Returned Product Analysis (RPA). The data from these sources are critically evaluated by a review board. The graphs in this section are derived from TCSS data, and are designed to report those data as lead-related adverse event-free survival. In addition, TCSS data is presented in tabular form.

Tachyarrhythmia Chronic Systems Study Analysis

Methods

This prospective study is designed to monitor the chronic clinical performance of ICD leads approved for market release in the United States. Centers currently participating in this study on an ongoing basis are located in the United States and Canada.

Patients are eligible for enrollment in the study if they either (1) participate in a Medtronic ICD or lead clinical study and the device is later approved for market release, or (2) receive a Medtronic market-released ICD or lead. Implant date eligibility varies from center to center but no data is included for leads implanted prior to January 1, 1991.

The TCSS requires that the center inform Medtronic each time an enrolled patient is seen, as well as whenever a lead-related adverse event, patient death, or loss to follow-up occurs. The TCSS protocol requires patient follow-up visits take place at least every six months. The active prospective nature of this study minimizes potential under-reporting, and analyses are performed only on data obtained through to each patient's last documented follow-up visit.

Overall survival curves are presented for leads grouped according to similarity in design and function with a leading edge corresponding to no less than 50 leads followed for at least six months. Data for individual models are plotted against grouped results for comparative purposes, however, the 50 lead minimum criterion is not applied to these plots.

The actuarial method is used to determine estimates of lead-related adverse event-free survival, and Greenwood's formula is used to calculate corresponding 95% confidence intervals. These estimates are based on reports of chronic lead-related adverse events. Six-month intervals were used and event-free survival was determined to the point where at least 50 leads remain free from such adverse events.

A chronic lead-related adverse event is considered to have occurred if one of the following clinical observations is reported and one of the following clinical responses is made 30 days or more after the implant.

Observations:

- Failure to capture
- Failure to sense
- Oversensing
- Muscle stimulation
- Conductor fracture, observed visually or radiographically
- Insulation breach, observed visually, that has degraded system performance
- Abnormal pacing and/or defibrillation impedance (as determined by testing method used and physician discretion)
- Dislodgement

Clinical Responses:

- Lead abandoned
- Lead explanted
- Lead replaced
- ICD mode or polarity reprogrammed to circumvent problem
- Other lead-related surgery performed
- Lead use continued based on medical judgment despite a known clinical performance issue. This applies only to nonsurgical observations above

Note: Successful lead repositioning is not a qualifying response.

Lead Performance (Continued)

Returned Product Analysis

All leads and lead segments returned to Medtronic are analyzed to determine whether or not they meet the required electrical, mechanical, and materials specifications. This analysis has always provided the most accurate information on specific hardware performance and failure modes. The information included in this report is determined from Returned Product Data in the U.S. because of the accuracy of U.S. device registration. The presentation of this information in the Product Performance Report distinguishes between implant damage and electrical failures. Although Returned Product Analyses are valuable for gaining insight into lead failure mechanisms, this data cannot be meaningfully used by itself for determining the survival probabilities of leads. Only a small fraction of leads are explanted and returned for analysis. Those failed leads which are returned cannot be assumed to be statistically representative of the performance of the total population for a given lead model. In addition, partial or total lead extraction can result in significant damage to a lead, precluding a definitive analysis of a suspected failure and its cause. Thus, lead survival probabilities are more appropriately determined through a clinical surveillance study, specifically, Medtronic's Chronic Lead Study.

Chronic Lead Study (CLS)

Since 1983, the clinical performance of Medtronic market released pacing leads has been continuously monitored in a multicenter study which currently involves 27 representative clinical centers in North America, Europe, and Japan and over 62,000 leads. An analysis of actuarial survival results, comparing North American and European centers reported experience with the same lead models, shows no statistical significant difference. The sample size from Japanese centers is insufficient to make a comparison at this time. Medtronic's Chronic Lead Study has been the source of data used by Medtronic to determine actuarial lead survival probabilities, regularly reported to the pacing medical community in updates of the Product Performance Report.

The Chronic Lead Study protocol continues to require that each center inform Medtronic whenever a lead complication, patient death, or lost to follow up occurs. The data analyses assume that there are no such events at the time of data update unless specifically reported by the center or determined by correlation with Returned Product Analysis. Medtronic annually conducts an onsite monitoring visit of each Chronic Lead Study center to assure overall study compliance.

The Chronic Lead Study 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 sensing or capture problems.

In the Chronic Lead Study, a lead complication is considered to have occurred if BOTH of the following conditions are met:

Condition 1.

One or more of the following clinical observations beyond 30 days post-implant is reported:

- Failure to Capture
- Failure to Sense
- Oversensing
- Extra Cardiac Stimulation
- Conductor Fracture (observed visually or radiographically)
- Insulation Breach exposing conductor (observed visually)
- Pacing Impedance of 200 ohms or less, or 3,000 ohms or greater
- Dislodgement
- Cardiac Perforation

Condition 2.

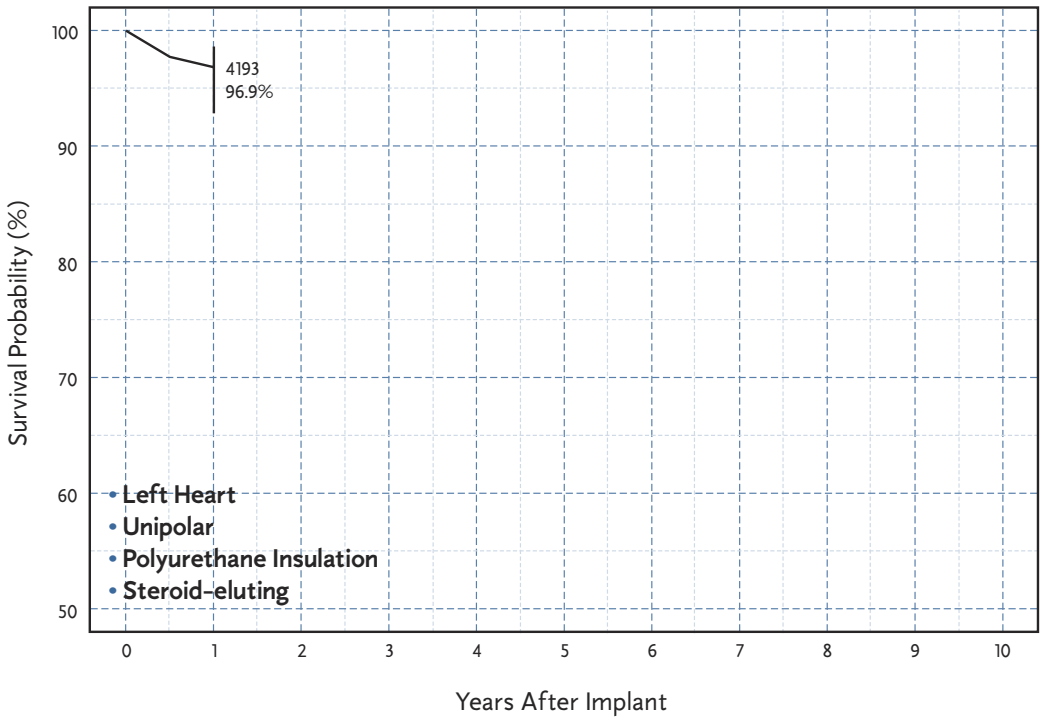
One or more of the following clinical actions directly results and is reported:

- Lead Abandoned
- Lead Explanted
- Lead Replaced
- New Lead Implanted
- Other Lead Related Surgery Performed (e.g., lead mechanical alteration or unsuccessful repositioning)
- Pacemaker Mode or Polarity Reprogrammed to circumvent problem (i.e., "electrical abandonment")
- Lead Use Continued, based on medical judgement

[Note: Successful lead repositioning is not a qualifying action.]

Survival Probability based on Lead Complications in the Chronic Lead Study. "Survival probability" refers to proper functioning of the lead, not the survival of the patient. (For example: A survival probability of 98% is a statistical assessment that, by the point in time indicated, each patient has had a 2% risk of incurring a lead hardware failure and/or lead-related complication.)

LV Lead 4193



ICD Lead Survival: TCSS Results

Lead Survival (95% Confidence Interval)												
Model Family	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
4193	May-02	294	2,309	96.9 +1.7/-4								

Leads Lab Analysis with Dates

Model Family	Model	Market Release	Initial Implants	Active Implants	Implant Damage	Electrical	Other
Attain	4193	May-02	55,000	49,000	46	1	54

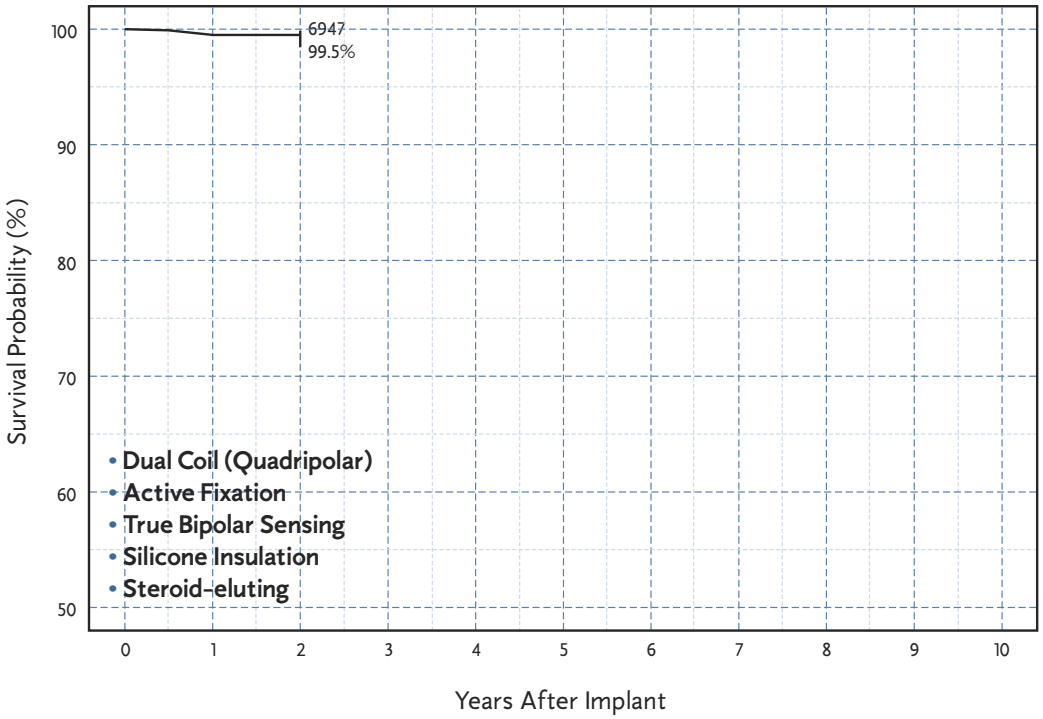
Lead Related Adverse Events

Type of Failure	4193
Muscle Stimulation	0
Failure to Capture	4
Failure to Sense	0
Oversensing	0
Conductor Fracture	0
Insulation Breach	0
Failure to Cardiovert/Defibrillation	0
Pacing Impedance Out of Range	0
Defib Impedance Out of Range	0
Dislodgement	2
Inappropriate VT	0
Inappropriate VF	0
Misc: Other	0
Total	**6**

Results

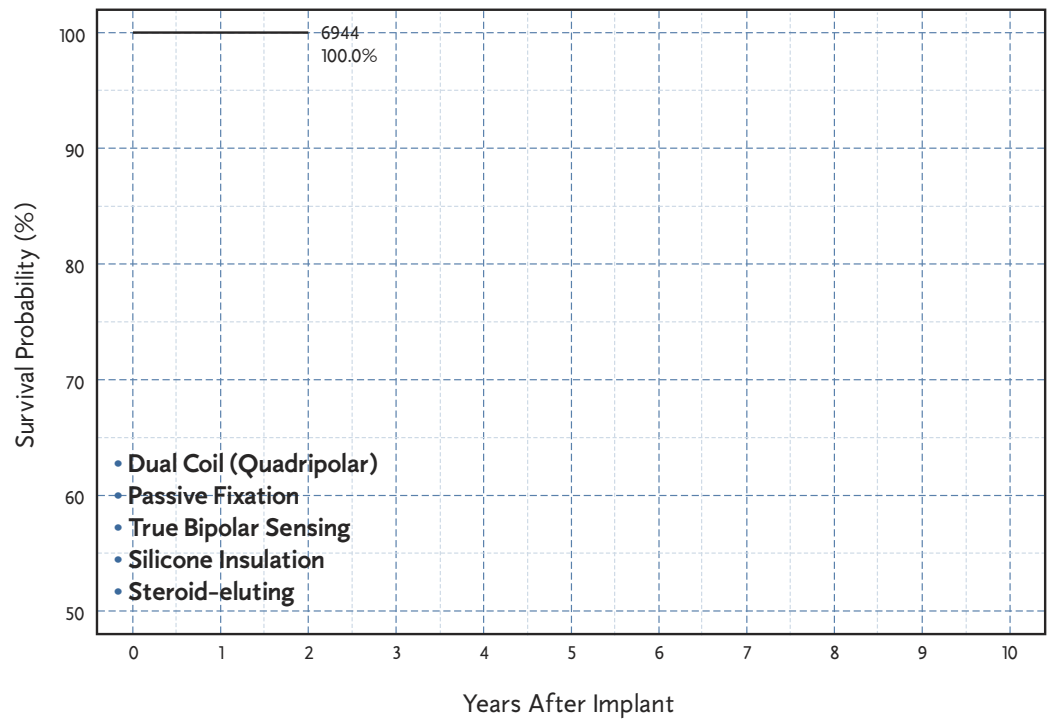
These results are generated based on TCSS data through a database cutoff of August 1, 2004.

Sprint Quattro Lead Model 6947



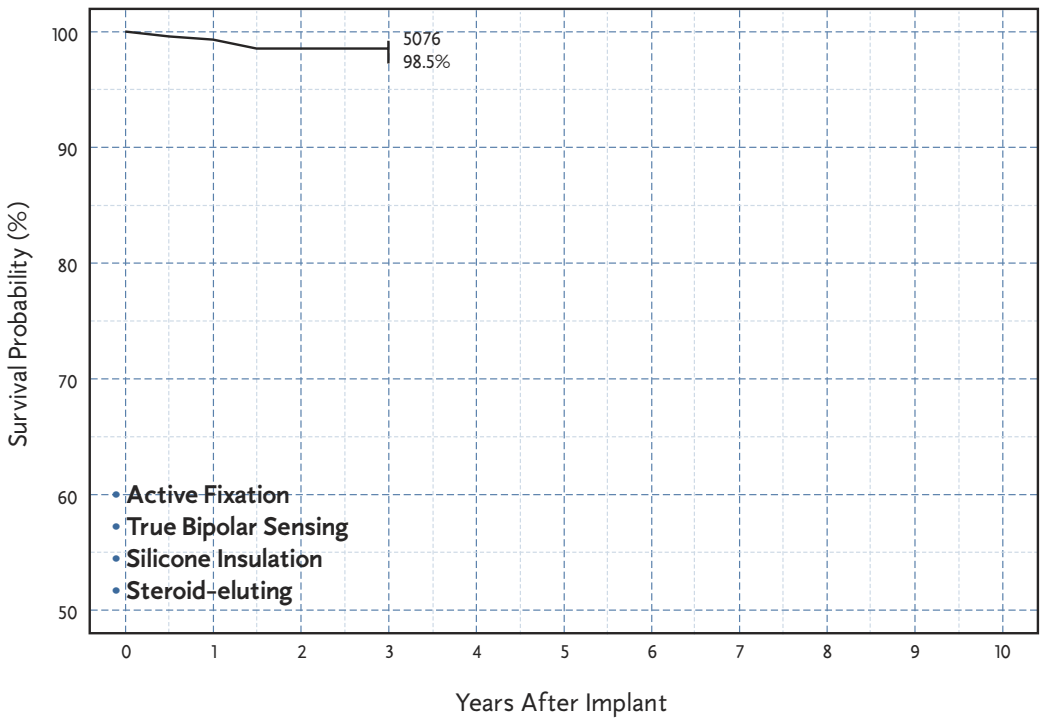
				Lead Survival (95% Confidence Interval)								
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6947	Nov-01	1,051	10,933	99.5 +0.4/-1.1	99.5 +0.4/-1.1							

Sprint RV Lead Model 6944



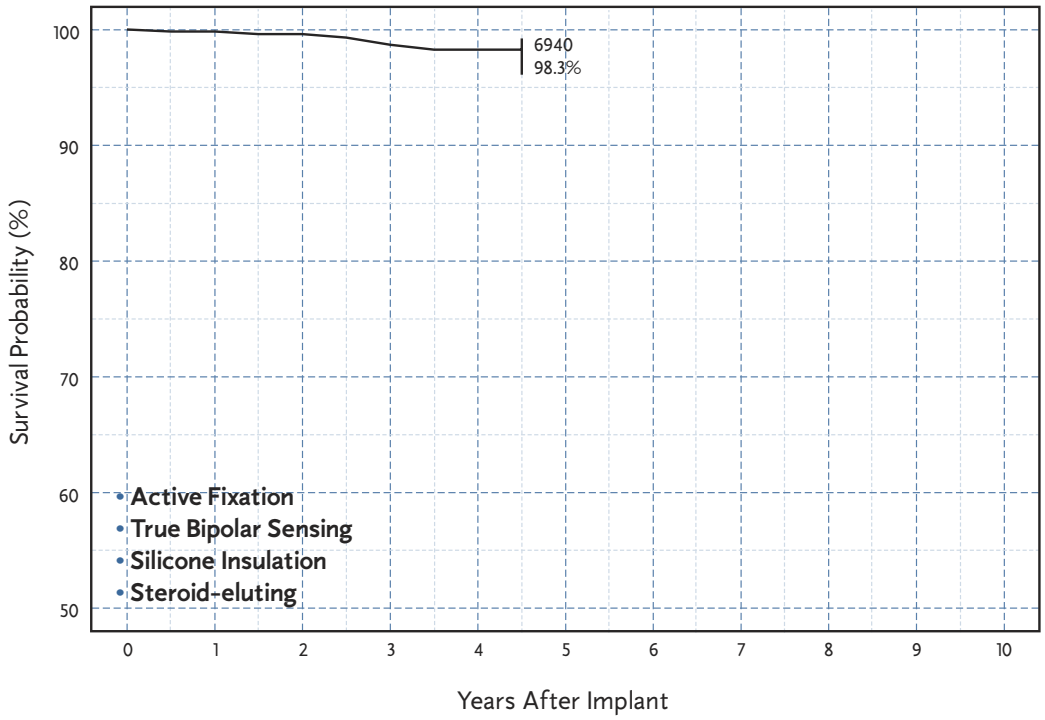
				Lead Survival (95% Confidence Interval)								
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6944	Dec-00	153	3,089	100	100							

CapSureFix Novus Lead Model 5076



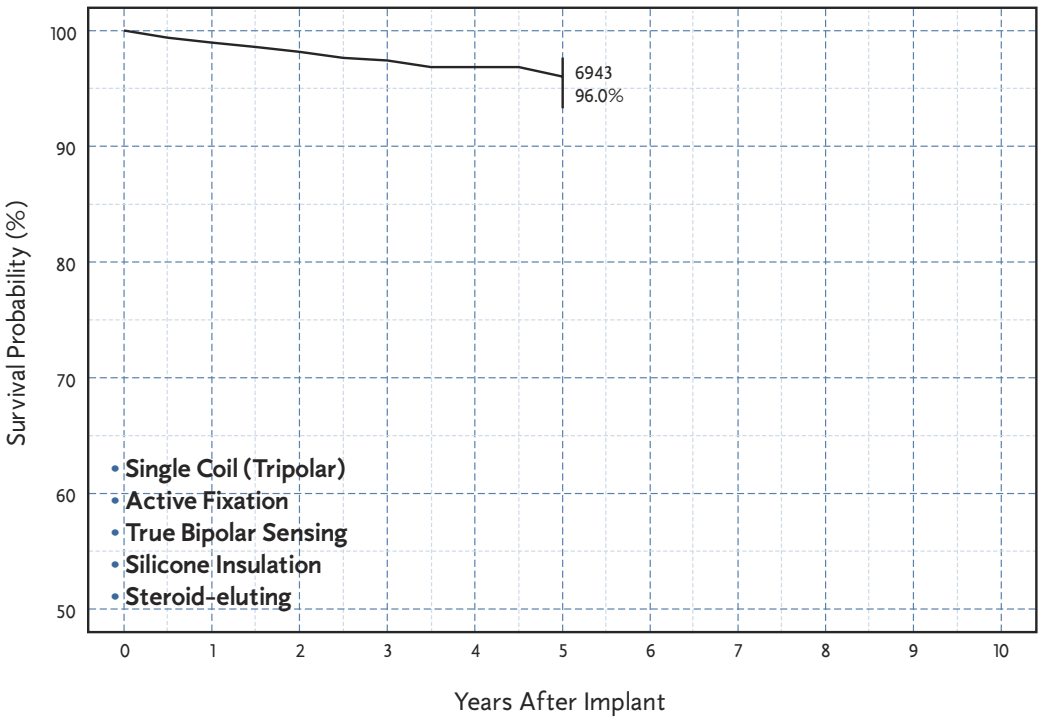
Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
5076	Aug-00	1,076	16,966	99.3 +0.4/ -0.9	98.5 +0.7/ -1.3	98.5 +0.7/ -1.3						

CapSureFix Lead Model 6940



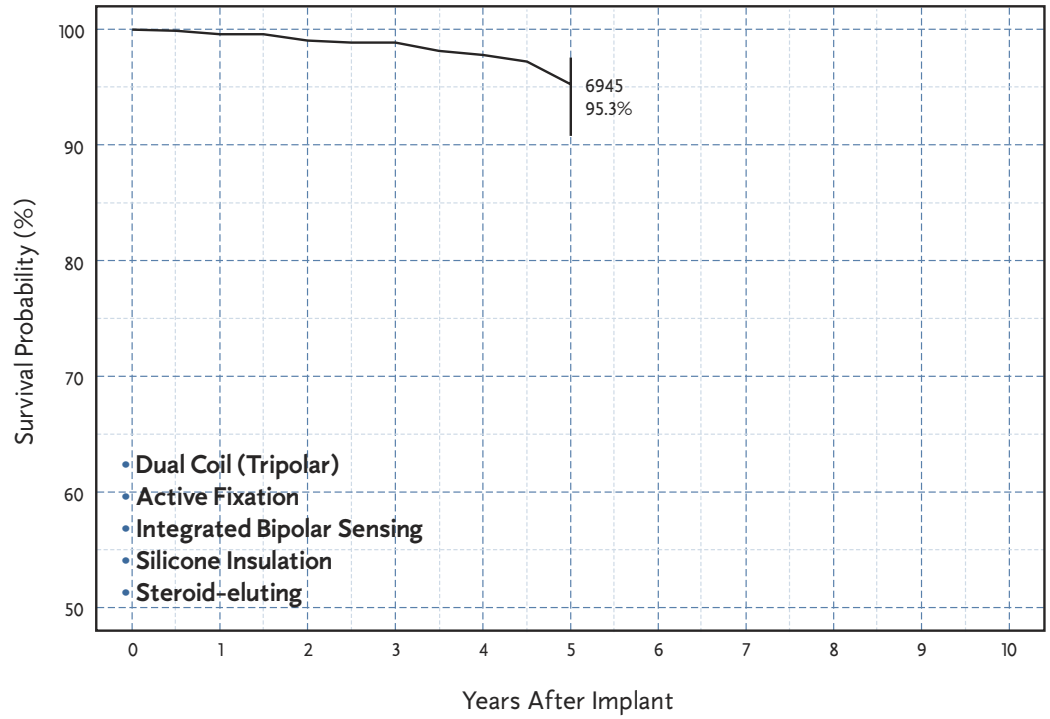
Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6940	Oct-98	612	18,789	99.8 +0.2/-1	99.6 +0.3/ -1.2	98.7 +0.8/-2	98.3 +0.9/ -2.2	98.3 +0.9/ -2.2 at 4.5 yrs.				

Sprint RV Lead Model 6943



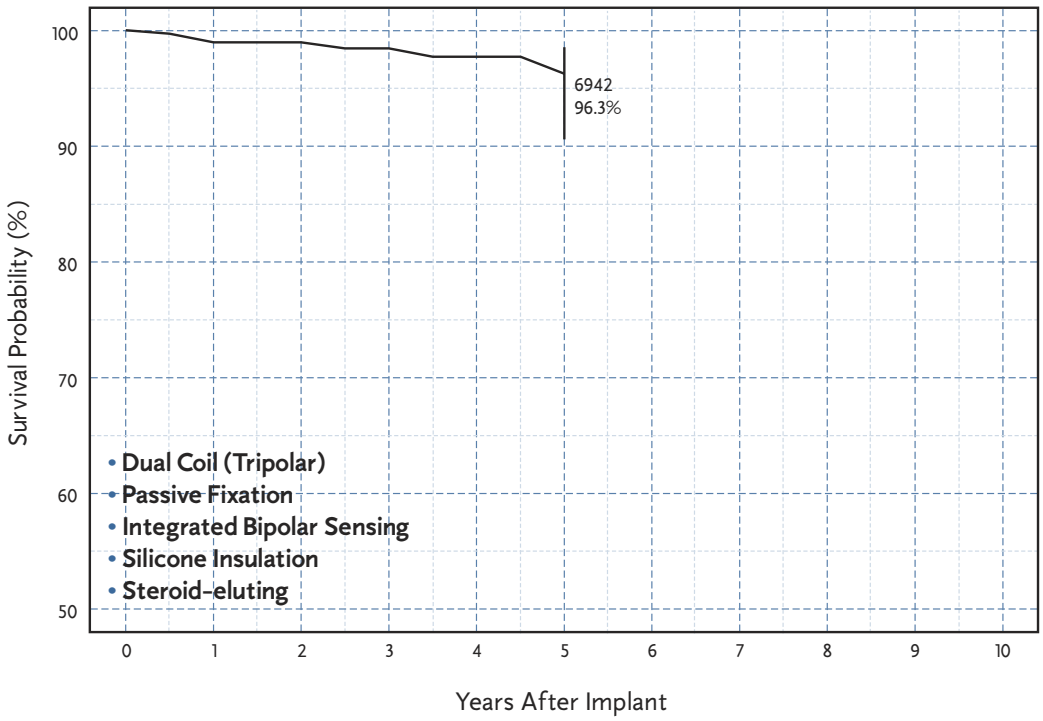
Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6943	Oct-97	1,204	32,921	98.9 +0.5/ -0.8	98.2 +0.7/ -1.2	97.4 +0.9/ -1.4	96.8 +1.2/-1.7	96 +1.7/-2.7				

Sprint RV Lead Model 6945



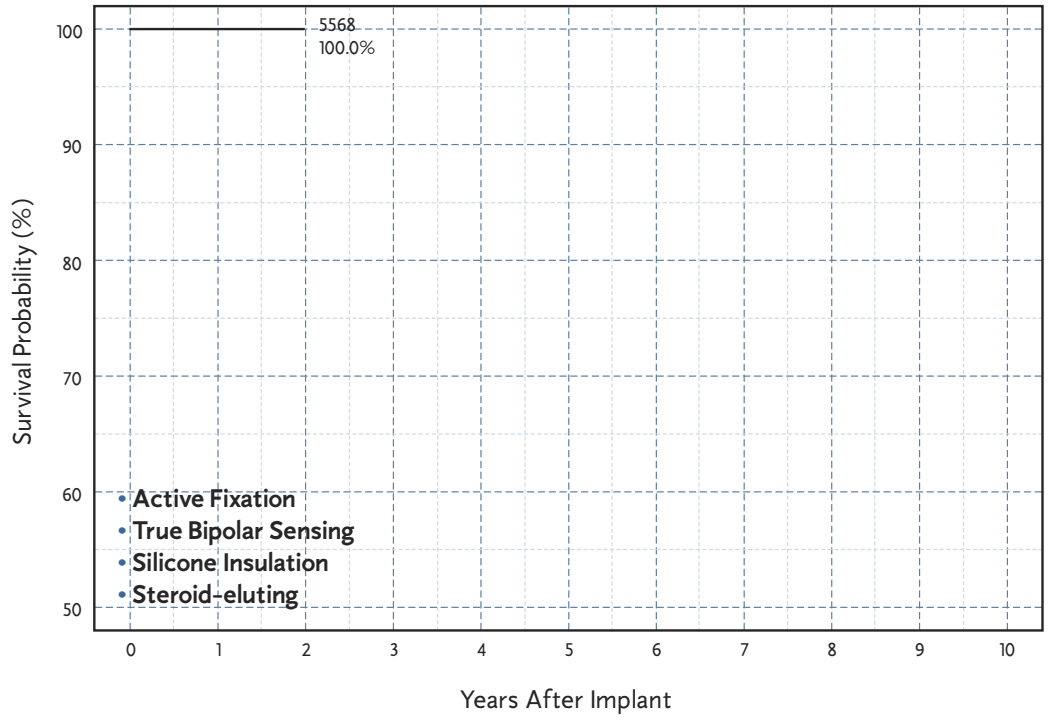
Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6945	Sep-97	1,154	34,330	99.6 +0.3/ -0.7	99.1 +0.4/-1	98.9 +0.5/-1	97.8 +1/-1.8	95.3 +2.3/ -4.5				

Sprint RV Lead Model 6942



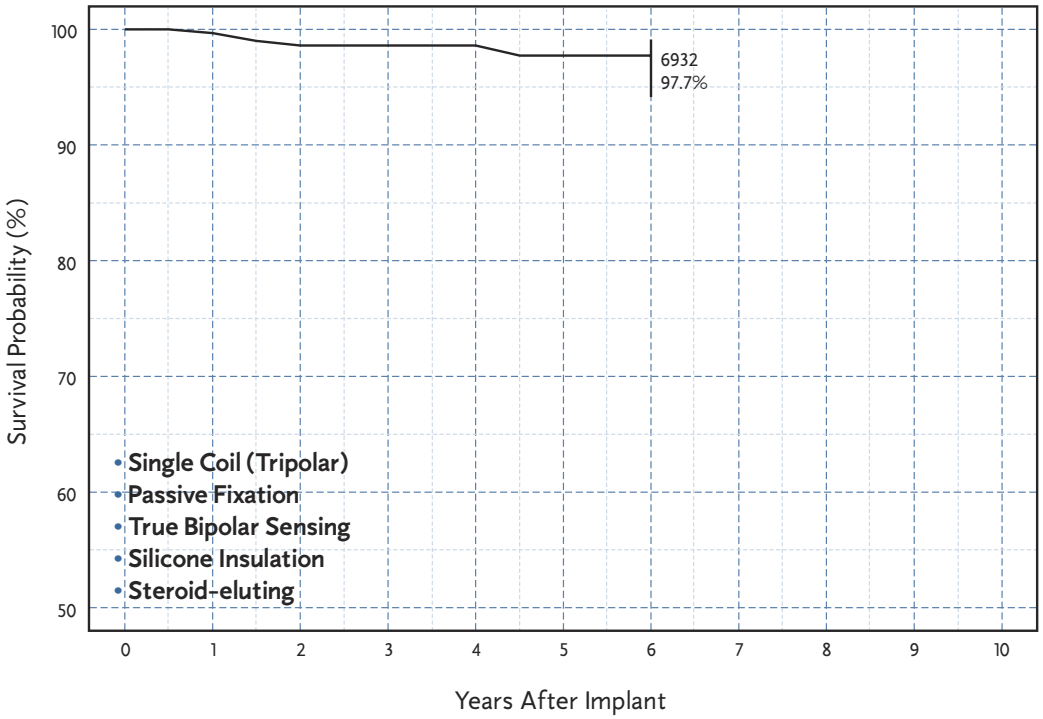
Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6942	Jul-97	349	11,182	98.9 +0.8/ -2.1	98.9 +0.8/ -2.1	98.4 +1/-2.6	97.7 +1.4/ -3.4	96.3 +2.2/ -5.7				

CapSureFix Novus Lead Model 5568



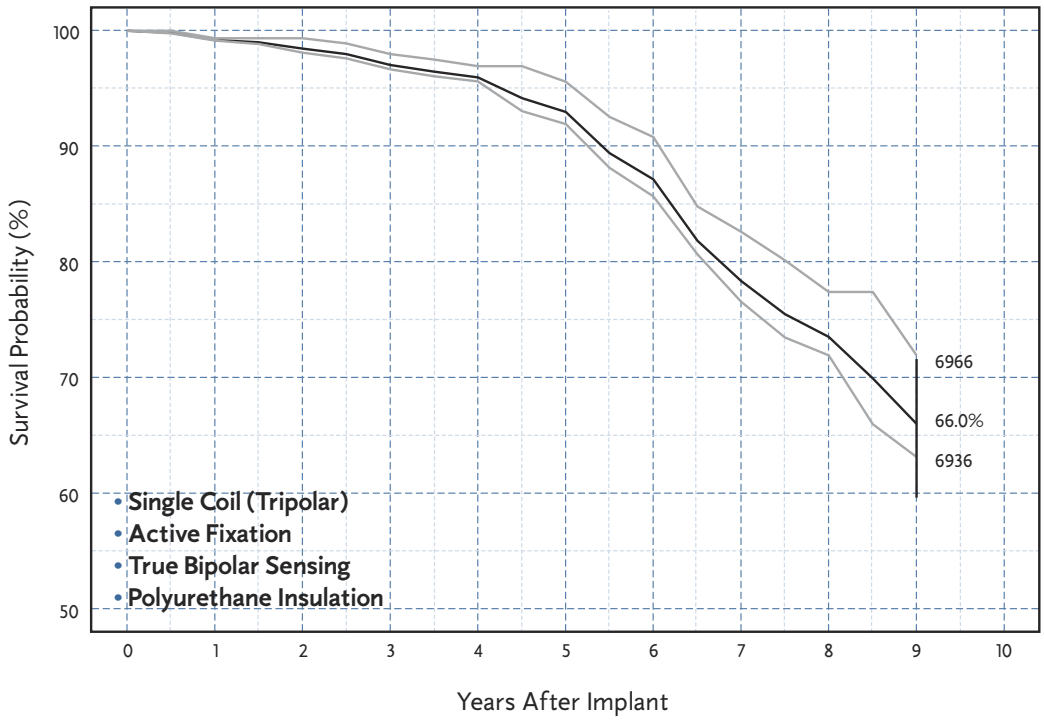
Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
5568	Jan-97	156	3,310	100	100							

Sprint RV Lead Model 6932



Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6932	Aug-96	408	14,211	99.7 +0.3/ -1.9	98.6 +0.9/ -2.3	98.6 +0.9/ -2.3	98.6 +0.9/ -2.3	97.7 +1.4/ -3.6	97.7 +1.4/ -3.6			

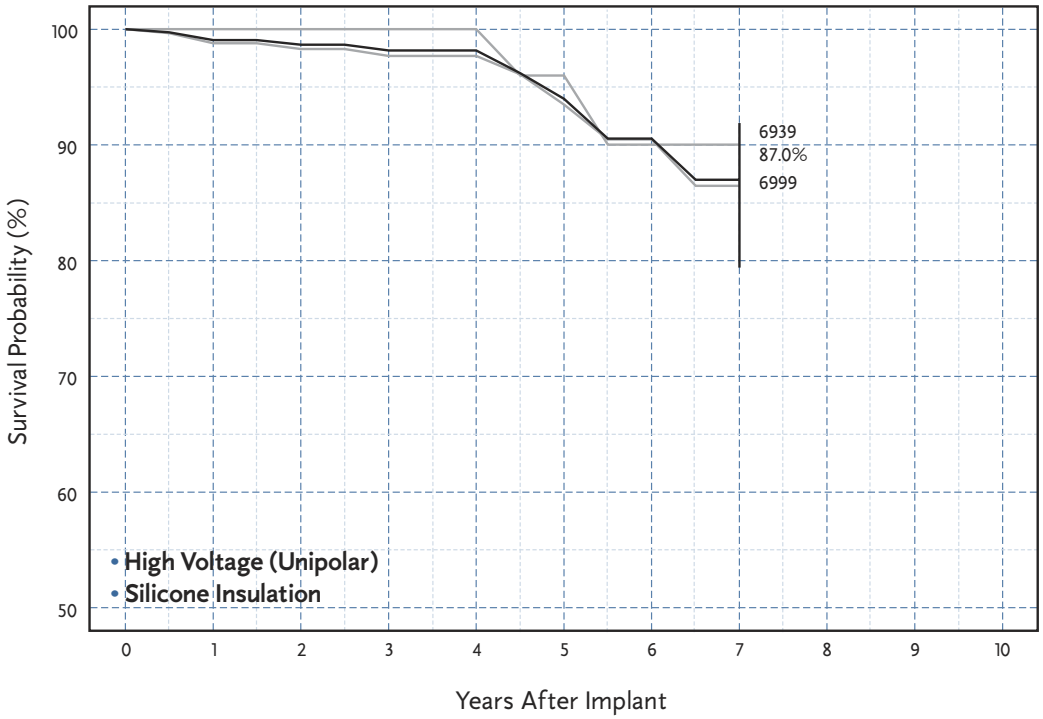
Transvene RV Models 6936, 6966



Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6936, 6966	Apr-94	1,350	59,659	99.2 +0.4/ -0.7	98.5 +0.6/-1	97 +1/-1.3	96 +1.1/-1.6	93 +1.7/-2.3	87.1 +2.6/ -3.2	78.4 +3.7/ -4.4	73.5 +4.4/-5	66 +5.6/-6.4

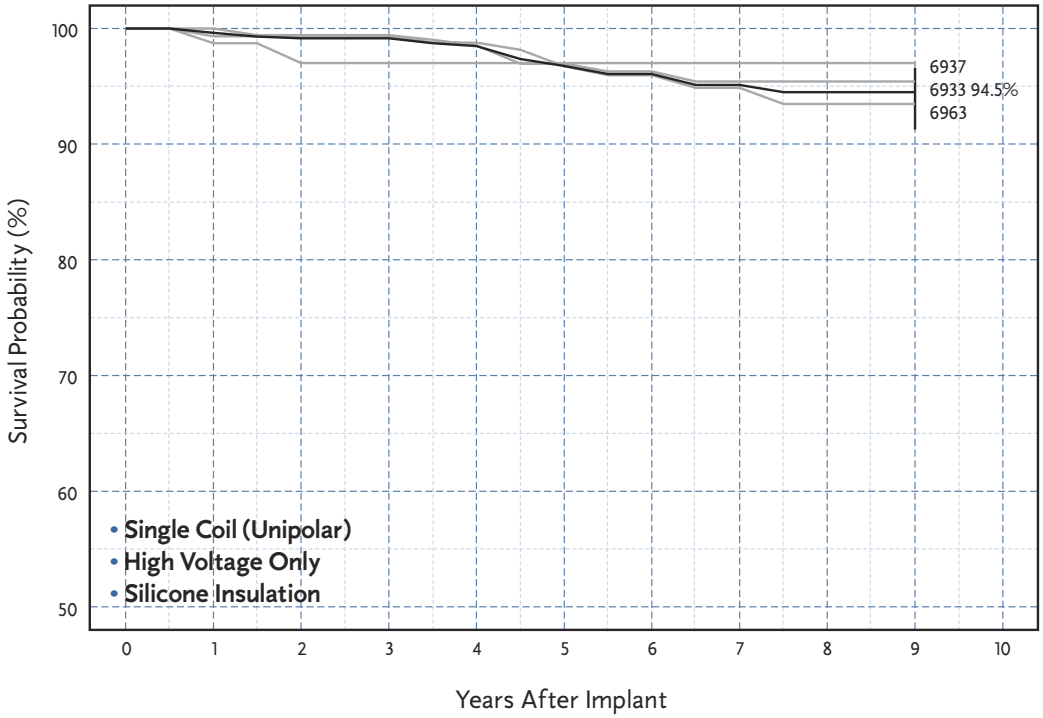
Note: The blue lines represent individual lead models, as labeled. The black lines represent the overall survival experience for the lead group.

Transvene Sub-Q Patch Models 6939, 6999



Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6939, 6999	Dec-93	389	16,695	99.1 +0.6/-2	98.7 +0.8/ -2.3	98.2 +1.1/ -2.6	98.2 +1.1/ -2.6	94 +2.7/-5	90.5 +3.8/ -6.1	87 +4.9/-7.6		

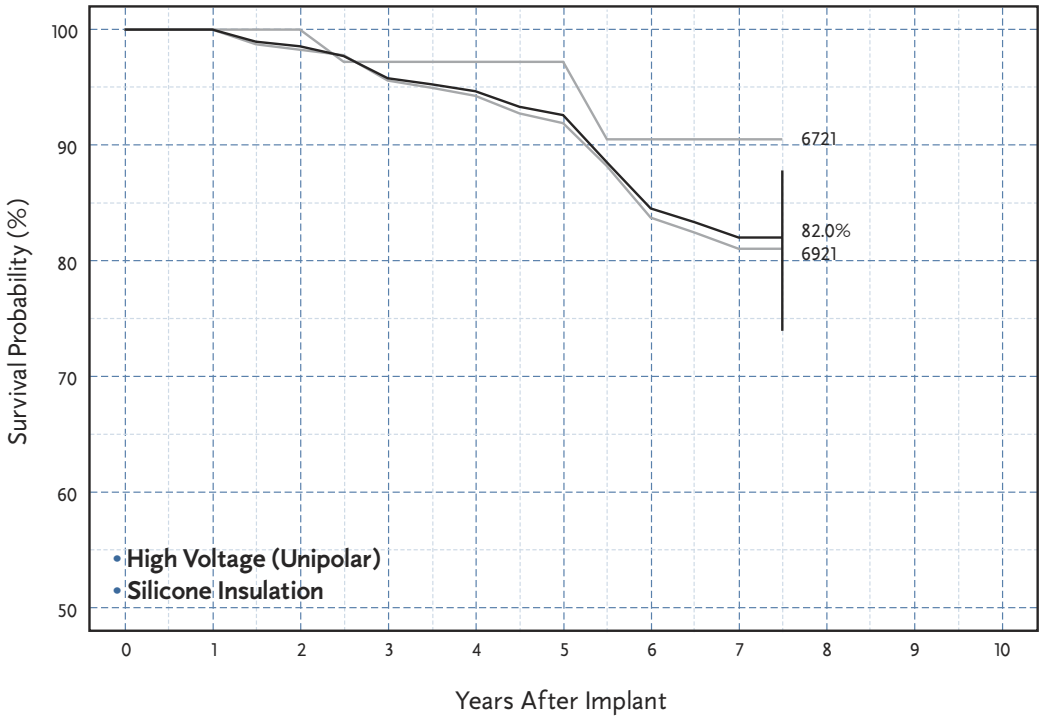
Transvene SVC/CS Models 6933, 6937, 6963



Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6933, 6937, 6963	Dec-93	964	42,046	99.6 +0.3/ -0.8	99.2 +0.4/ -1.1	99.2 +0.4/ -1.1	98.5 +0.7/ -1.5	96.8 +1.3/ -2.2	96.1 +1.5/ -2.5	95.1 +1.9/ -2.9	94.5 +2.1/ -3.3	94.5 +2.1/ -3.3

Note: The blue lines represent individual lead models, as labeled. The black lines represent the overall survival experience for the lead group.

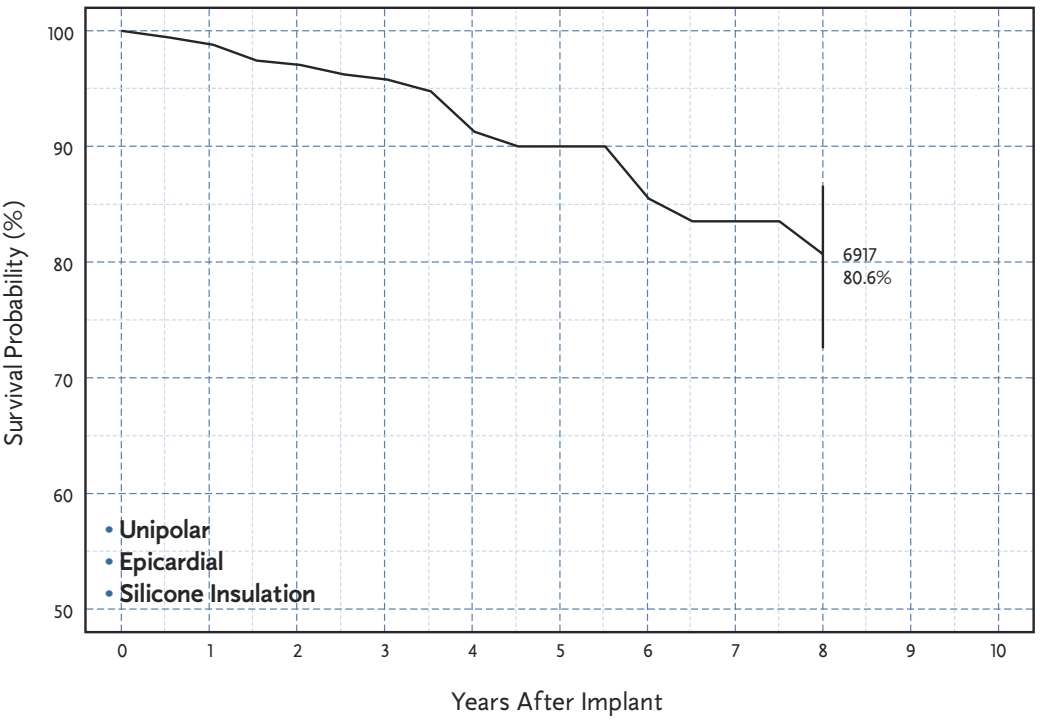
Epicardial Patch Models 6721, 6921



Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6721, 6921	Feb-93	397	17,097	100	98.6 +0.9/ -2.4	95.8 +1.9/ -3.5	94.7 +2.3/-4	92.6 +3/-4.8	84.5 +5.2/ -7.3	82 +5.8/-8	82 +5.8/-8 at 7.5 yrs.	

Note: The blue lines represent individual lead models, as labeled. The black lines represent the overall survival experience for the lead group.

Tenax Lead Model 6917



Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6917	Jun-73	383	17,561	98.8 +0.8/-2	97.1 +1.4/-2.7	95.8 +1.8/ -3.2	91.3 +3.1/-4.7	90 +3.4/-5.1	85.4 +4.7/ -6.6	83.5 +5.1/-7.1	80.6 +6/-8.2	

ICD Lead Survival: TCSS Results

Lead Survival (95% Confidence Interval)												
Model	Market Release	Number of Implanted Leads	Cumulative Months of Follow-up	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
6947	Nov-01	1,051	10,933	99.5 +0.4/-1.1	99.5 +0.4/-1.1							
6944	Dec-00	153	3,089	100	100							
5076	Aug-00	1,076	16,966	99.3 +0.4/ -0.9	98.5 +0.7/ -1.3	98.5 +0.7/ -1.3						
6940	Oct-98	612	18,789	99.8 +0.2/-1	99.6 +0.3/ -1.2	98.7 +0.8/-2	98.3 +0.9/ -2.2	98.3 +0.9/ -2.2 at 4.5 yrs.				
6943	Oct-97	1,204	32,921	98.9 +0.5/ -0.8	98.2 +0.7/ -1.2	97.4 +0.9/ -1.4	96.8 +1.2/-1.7	96 +1.7/-2.7				
6945	Sep-97	1,154	34,330	99.6 +0.3/ -0.7	99.1 +0.4/-1	98.9 +0.5/-1	97.8 +1/-1.8	95.3 +2.3/ -4.5				
6942	Jul-97	349	11,182	98.9 +0.8/ -2.1	98.9 +0.8/ -2.1	98.4 +1/-2.6	97.7 +1.4/ -3.4	96.3 +2.2/ -5.7				
5568	Jan-97	156	3,310	100	100							
6932	Aug-96	408	14,211	99.7 +0.3/ -1.9	98.6 +0.9/ -2.3	98.6 +0.9/ -2.3	98.6 +0.9/ -2.3	97.7 +1.4/ -3.6	97.7 +1.4/ -3.6			
6936, 6966	Apr-94	1,350	59,659	99.2 +0.4/ -0.7	98.5 +0.6/-1	97 +1/-1.3	96 +1.1/-1.6	93 +1.7/-2.3	87.1 +2.6/ -3.2	78.4 +3.7/ -4.4	73.5 +4.4/-5	66 +5.6/-6.4
6939, 6999	Dec-93	389	16,695	99.1 +0.6/-2	98.7 +0.8/ -2.3	98.2 +1.1/-2.6	98.2 +1.1/-2.6	94 +2.7/-5	90.5 +3.8/ -6.1	87 +4.9/-7.6		
6933, 6937, 6963	Dec-93	964	42,046	99.6 +0.3/ -0.8	99.2 +0.4/ -1.1	99.2 +0.4/ -1.1	98.5 +0.7/ -1.5	96.8 +1.3/ -2.2	96.1 +1.5/-2.5	95.1 +1.9/-2.9	94.5 +2.1/ -3.3	94.5 +2.1/ -3.3
6721, 6921	Feb-93	397	17,097	100	98.6 +0.9/ -2.4	95.8 +1.9/ -3.5	94.7 +2.3/-4	92.6 +3/-4.8	84.5 +5.2/ -7.3	82 +5.8/-8	82 +5.8/-8 at 7.5 yrs.	
6917	Jun-73	383	17,561	98.8 +0.8/-2	97.1 +1.4/-2.7	95.8 +1.8/ -3.2	91.3 +3.1/-4.7	90 +3.4/-5.1	85.4 +4.7/ -6.6	83.5 +5.1/-7.1	80.6 +6/-8.2	

ICD Lead-Related Adverse Events: TCSS Results*

Type of Failure	6947	6945	6943	6942	6932	6934	Transvene RV	SVC/CS	SQ Patch	Epi Patch	Tenax 6917	CapSureFix 6940	CapSureFix Novus 5076	CapSureFix 5568	Total
Muscle Stimulation	0	1	0	0	0	0	1	0	0	0	0	0	0	0	2
Failure to Capture	0	0	2	0	1	0	0	0	0	0	4	0	5	1	13
Failure to Sense	1	3	3	1	2	0	4	0	0	0	5	2	0	0	21
Oversensing	0	6	11	3	1	0	69	0	0	0	8	1	3	0	102
Conductor Fracture	0	2	2	1	0	1	16	13	10	20	7	1	0	0	73
Insulation Breach	1	0	0	0	0	0	12	2	6	1	0	0	0	0	22
Failure to Cardiovert/Defibrillation	0	0	0	0	1	0	5	1	2	2	0	0	0	0	11
Pacing Impedance Out of Range	0	2	2	0	0	0	3	0	0	0	2	0	0	0	9
Defib Impedance Out of Range	0	0	0	0	0	0	2	2	0	3	0	0	0	0	7
Dislodgement	1	0	1	1	0	0	0	1	0	0	0	1	2	0	7
Inappropriate VT	0	0	0	0	0	0	1	0	0	0	2	0	0	0	3
Inappropriate VF	0	2	2	0	0	0	11	0	0	0	7	0	0	0	22
Misc: Other	0	1	1	0	0	0	4	1	2	0	0	1	0	0	10
Total	**3**	**17**	**24**	**6**	**5**	**1**	**128**	**20**	**20**	**26**	**35**	**6**	**10**	**1**	**302**

* This table represents all qualifying lead-related adverse events reported in the TCSS.

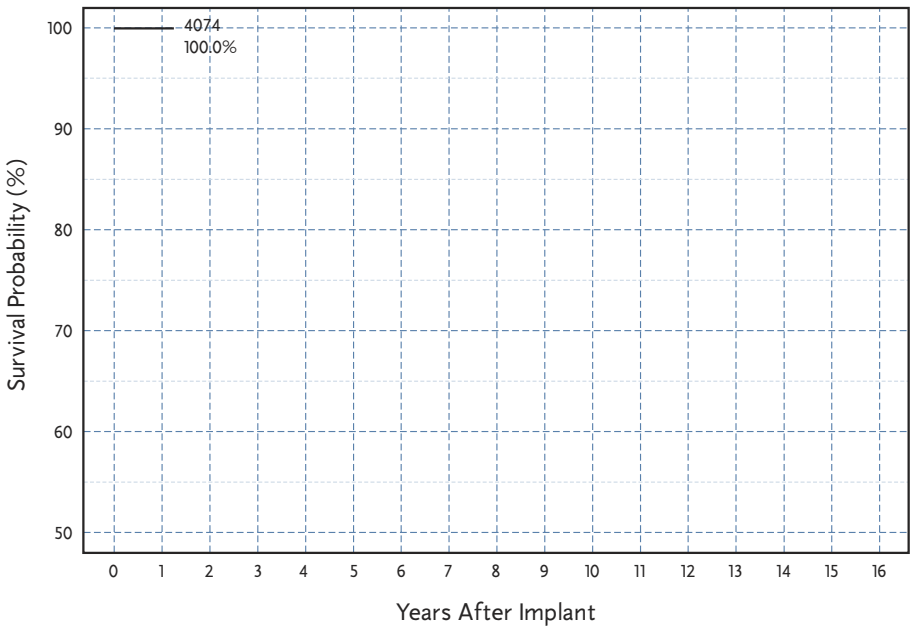
ICD Leads Laboratory Analysis

Model Family	Model	Market Release	Initial Implants	Active Implants	Implant Damage	Electrical	Other
Sprint	6947	Nov-01	95,000	85,000	184	36	8
	6944	Dec-00	23,000	20,000	18	20	8
	6943	Oct-97	21,000	13,000	49	50	8
	6945	Sep-97	44,000	29,000	194	64	11
	6942	Jul-97	18,000	11,000	32	29	5
	6932	Aug-96	15,000	8,000	16	34	7
CapSureFix	6940	Oct-98	27,000	17,000	115	14	3
Transvene RV	6966	Mar-96	5,000	1,000	33	81	3
	6936	Apr-94	19,000	7,000	58	344	16
SVC/CS	6937	Mar-96	3,000	1,000	0	12	0
	6933	Apr-94	9,000	3,000	17	117	5
	6963	Dec-93	5,000	2,000	14	60	8
Sub-Q Patch	6939	Apr-94	1,000	400	2	6	0
	6999	Dec-93	3,000	1,000	2	26	1
Epicardial Patch	6721	Mar-94	2,000	1,000	0	12	0
	6921	Feb-93	7,000	2,000	5	65	0

Brady Leads CLS

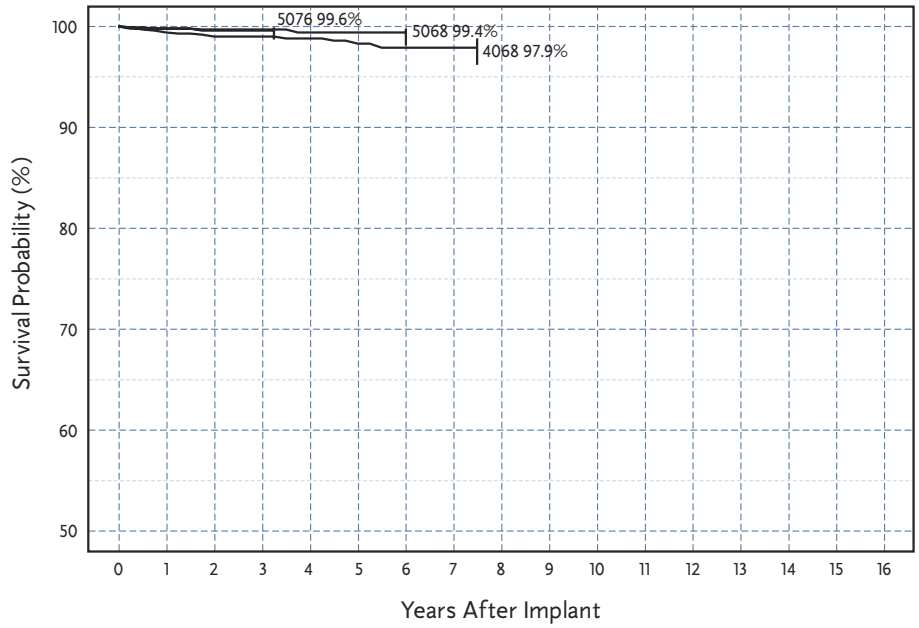
These results are generated based on CLS data through a database cutoff of August 1, 2004.

Ventricular CapSure Sense Leads



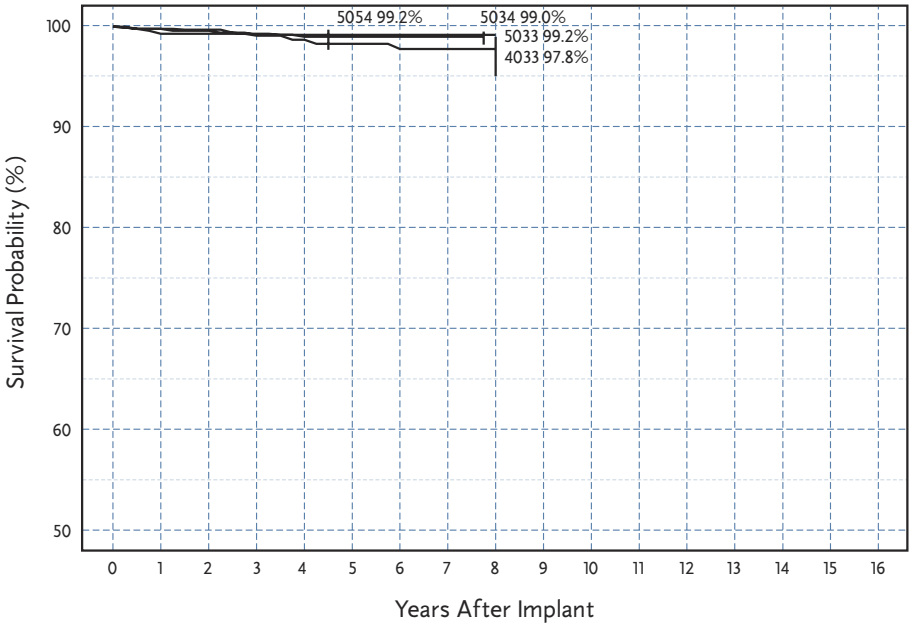
					Lead Survival (95% Confidence Interval)										
Model Family	Model	Market Release	Initial Implants	Complications	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSure Sense	4074	Jun-02	182	0	100 +0/-0	100 +0/-0 at 15 mo.										

Ventricular CapSureFix/CapSureFix Novus Leads



					Lead Survival (95% Confidence Interval)										
Model Family	Model	Market Release	Initial Implants	Complications	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSureFix Novus	5076	Aug-00	1,103	3	99.8 +0.2/ -0.6	99.6 +0.3/ -0.9	99.6 +0.3/ -0.9	99.6 +0.3/ -0.9 at 39 mo.								
CapSureFix	5068	Jan-97	1,360	4	99.8 +0.2/ -0.6	99.7 +0.2/ -0.7	99.7 +0.2/ -0.7	99.4 +0.4/-1.3	99.4 +0.4/-1.3	99.4 +0.4/-1.3						
	4068	Mar-96	1,756	19	99.4 +0.3/ -0.5	99 +0.4/ -0.7	99 +0.4/ -0.7	98.8 +0.5/ -0.7	98.3 +0.7/-1.3	97.9 +0.9/-1.7	97.9 +0.9/-1.7	97.9 +0.9/ -1.7 at 90 mo.				

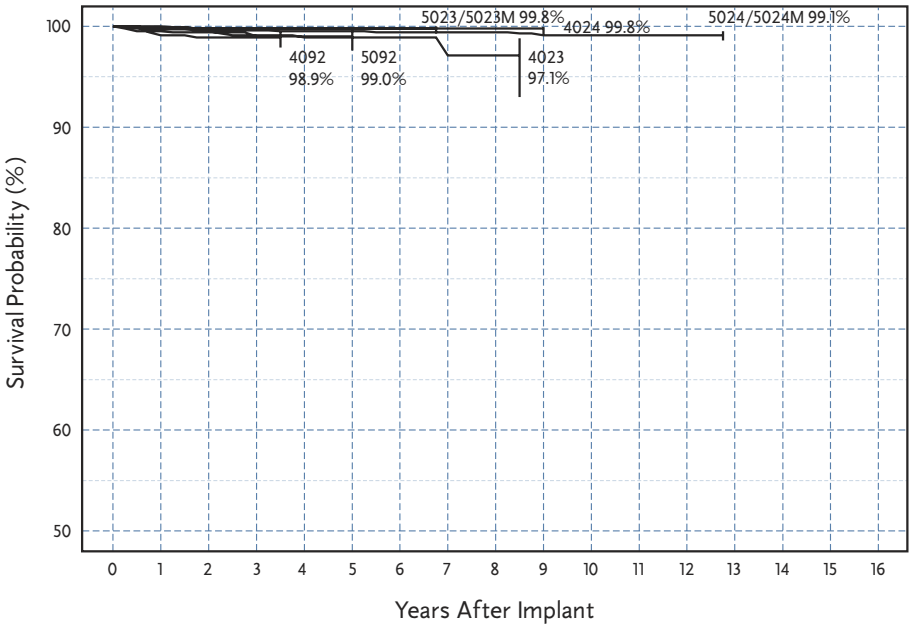
Ventricular CapSure Z/CapSure Z Novus Leads



Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Complications	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSure Z Novus	5054	Jan-98	1,248	8	99.7 +0.2/ -0.6	99.5 +0.3/ -0.6	99.5 +0.3/ -0.6	99.2 +0.5/-1.5	99.2 +0.5/ -1.5 at 54 mo.							
CapSure Z	5034	Feb-96	1,598	11	99.8 +0.1/ -0.4	99.6 +0.2/ -0.6	99.3 +0.3/ -0.7	99 +0.5/-0.8	99 +0.5/-0.8	99 +0.5/-0.8	99 +0.5/-0.8	99 +0.5/-0.8 at 93 mo.				
	5033	Jan-96	1,894	10	99.8 +0.1/ -0.4	99.7 +0.2/ -0.4	99.2 +0.4/ -0.7	99.2 +0.4/ -0.7	99.2 +0.4/ -0.7	99.2 +0.4/ -0.7	99.2 +0.4/ -0.7	99.2 +0.4/ -0.7				
	4033*	Mar-94	539	8	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	97.8 +1.2/-2.7	97.8 +1.2/-2.7	97.8 +1.2/-2.7				

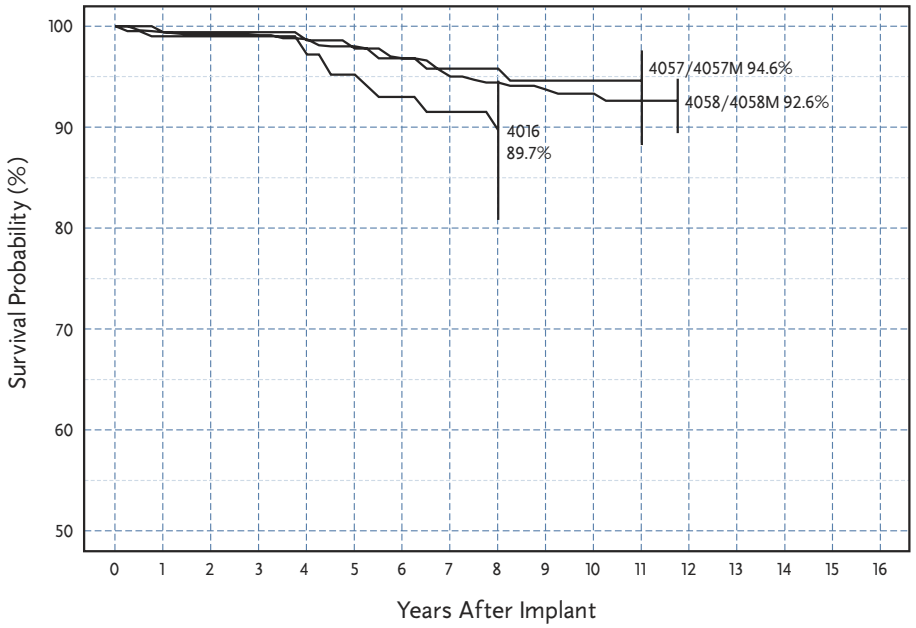
* Not available in the United States.

Ventricular CapSure SP/CapSure SP Novus Leads



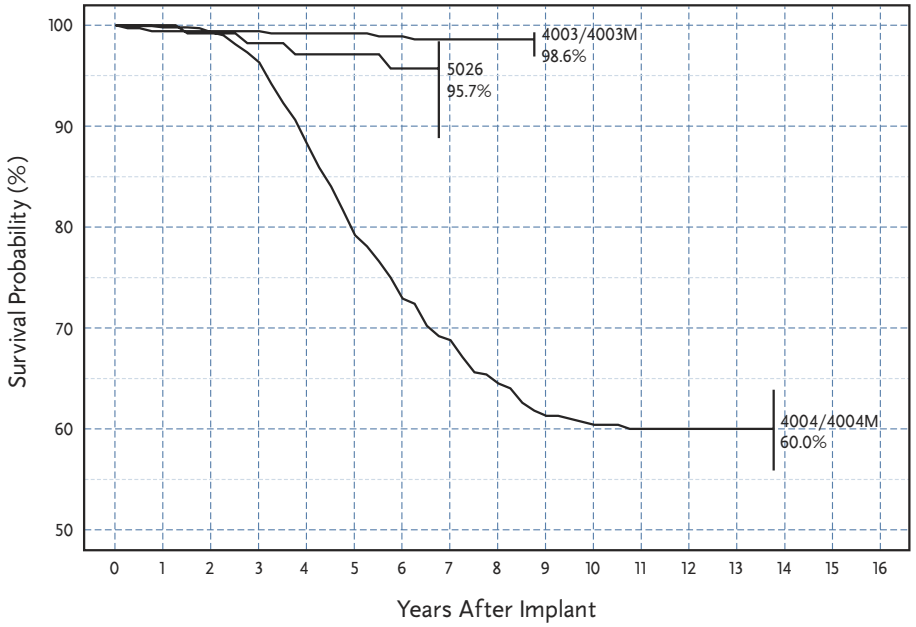
Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Complications	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSure SP Novus	4092	Sep-98	1,015	8	99.1 +0.5/ -0.9	98.9 +0.6/-1	98.9 +0.6/-1	98.9 +0.6/-1 at 42 mo.								
	5092	Jul-98	1,059	6	99.5 +0.3/ -0.7	99.4 +0.3/ -0.9	99 +0.6/-1.4	99 +0.6/-1.4	99 +0.6/-1.4							
CapSure SP	4024	Oct-91	1,214	3	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 108 mo.			
	4023	Aug-91	1,147	10	100 +0/-0	99.5 +0.3/ -0.7	99.1 +0.5/ -0.9	98.9 +0.6/-1.1	98.9 +0.6/-1.1	98.9 +0.6/-1.1	97.1 +1.7/-4.1	97.1 +1.7/-4.1				
	5024/5024M	Mar-90	8,134	37	99.7 +0.1/ -0.2	99.6 +0.1/-0.1	99.6 +0.1/ -0.2	99.5 +0.2/ -0.2	99.5 +0.1/ -0.2	99.4 +0.2/ -0.2	99.4 +0.2/ -0.2	99.4 +0.2/ -0.3	99.1 +0.4/ -0.5	99.1 +0.4/-0.5	99.1 +0.4/-0.5 at 153 mo.	
	5023/5023M	Nov-88	1,234	2	99.8 +0.2/ -0.5	99.8 +0.2/ -0.5	99.8 +0.2/ -0.5	99.8 +0.2/ -0.5	99.8 +0.2/ -0.5	99.8 +0.2/ -0.5	99.8 +0.2/ -0.5 at 81 mo.					

Ventricular Screw-In Leads



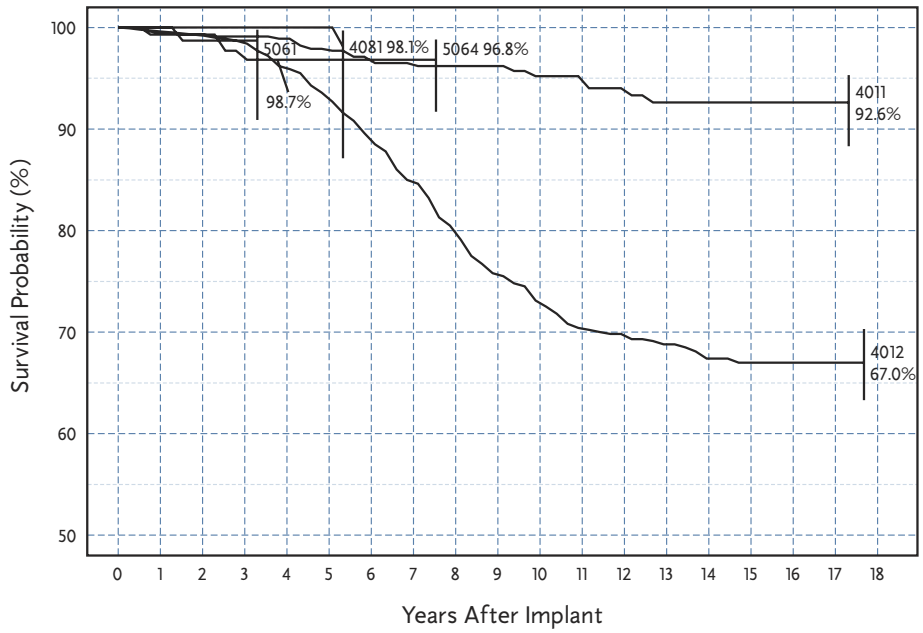
Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Complica-tions	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Screw-In	4057/4057M	Apr-89	259	7	99.4 +0.5/ -3.5	99.4 +0.5/ -3.5	99.4 +0.5/ -3.5	98.6 +1.1/-4	97.8 +1.5/ -4.7	96.8 +2/-5.1	95.8 +2.5/ -5.7	95.8 +2.5/ -5.7	94.6 +3/-6.4	94.6 +3/ -6.4 at 132 mo.		
	4058/4058M	Mar-89	1,689	39	99.4 +0.3/ -0.7	99.2 +0.4/ -0.7	99.1 +0.4/ -0.8	98.7 +0.5/ -0.9	98 +0.7/ -1.2	96.8 +1.1/-1.5	95 +1.5/ -2.2	94.4 +1.7/ -2.3	93.3 +2/ -2.7	92.6 +2.2/ -3.2 at 141 mo.		
	4016	Sep-85	225	13	99 +0.7/-3	99 +0.7/-3	99 +0.7/-3	97.2 +1.8/ -4.8	95.2 +2.7/ -5.8	93 +3.5/ -6.9	91.5 +4.1/ -7.7	89.7 +4.9/ -8.9				

Ventricular CapSure Leads



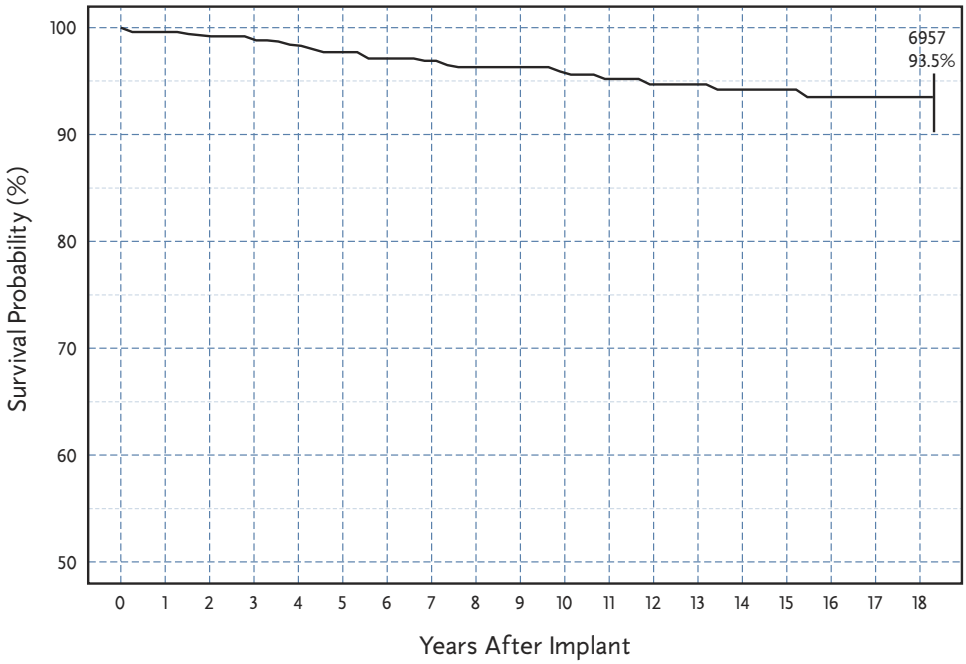
Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Complica-tions	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSure	4004/4004M	Jan-89	1,640	275	99.8 +0.1/ -0.5	99.3 +0.4/ -0.7	96.3 +1/-1.3	88.2 +1.9/ -2.3	79.2 +2.6/ -2.9	72.9 +3/-3.3	68.8 +3.3/ -3.6	64.5 +3.6/ -3.8	60.4 +3.8/-4.1	60 +3.9/ -4.1	60 +3.9/ -4.1 at 165 mo.	
	5026	Mar-88	168	4	100 +0/-0	99.2 +0.7/ -4.7	98.2 +1.4/-5.1	97.1 +2/ -5.8	97.1 +2/ -5.8	95.7 +2.7/ -6.9	95.7 +2.7/ -6.9 at 81 mo.					
	4003/4003M	Nov-86	711	7	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.2 +0.5/-1.2	99.2 +0.5/-1.2	98.9 +0.6/-1.5	98.6 +0.7/-1.7	98.6 +0.7/-1.7	98.6 +0.7/ -1.7 at 105 mo.			

Ventricular Target Tip Leads



Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Complica-tions	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Target Tip	4081	Feb-90	260	3	100 +0/-0	100 +0/-0	100 +0/-0	100 +0/-0	100 +0/-0	98.1 +1.6/ -11 at 63 mo.						
	5064	Jul-85	177	4	99.3 +0.6/ -3.9	99.3 +0.6/ -3.9	96.8 +2/-5.1	96.8 +2/-5.1	96.8 +2/-5.1	96.8 +2/-5.1	96.8 +2/-5.1	96.8 +2/ -5.1 at 90 mo.				
	5061	Apr-85	118	1	100 +0/-0	98.7 +1.1/ -7.8	98.7 +1.1/ -7.8	98.7 +1.1/ -7.8 at 39 mo.								
	4012	Nov-83	2,542	315	99.6 +0.2/ -0.3	99.2 +0.3/ -0.6	98.4 +0.5/ -0.6	95.9 +0.8/-1.1	92.7 +1.2/-1.4	88.5 +1.6/-1.8	84.6 +1.9/ -2.2	79.1 +2.3/ -2.5	72.5 +2.7/-3.1	69.3 +3.1/-3.3	67.4 +3.3/ -3.5	67 +3.3/ -3.7 at 213 mo.
	4011	Feb-83	851	23	99.4 +0.4/-1	99.3 +0.4/-1.1	99.1 +0.5/-1.1	98.9 +0.6/-1.3	97.7 +1/-1.8	96.5 +1.4/ -2.2	96.2 +1.5/ -2.4	96.2 +1.5/ -2.4	95.2 +1.8/ -2.9	93.3 +2.5/ -3.9	92.6 +2.7/ -4.3	92.6 +2.7/ -4.3 at 207 mo.

Ventricular Spectraflex Lead



Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Complica-tions	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Spectraflex	6957	Sep-79	1,853	40	99.6 +0.2/ -0.5	99.2 +0.4/ -0.6	98.8 +0.5/ -0.8	98.3 +0.6/-1	97.7 +0.8/-1.1	97.1 +0.9/ -1.4	96.9 +1/-1.4	96.3 +1.1/-1.7	95.6 +1.4/-2	94.7 +1.7/ -2.4	94.2 +1.9/ -2.8	93.5 +2.2/ -3.3 at 219 mo.

Ventricular Implantable Pacing Leads (Bradycardia)

Actuarial Survival Probability (%)[1] (Including 95% Confidence Interval)[2]

Source: Chronic Lead Study
(Data as of August 1, 2004)

					Lead Survival (95% Confidence Interval)											
Model Family	Model	Market Release	Initial Implants	Complications	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSure Sense	4074	Jun-02	182	0	100 +0/-0	100 +0/-0 at 15 mo.										
CapSureFix Novus	5076*	Aug-00	1,103	3	99.8 +0.2/-0.6	99.6 +0.3/-0.9	99.6 +0.3/-0.9	99.6 +0.3/-0.9 at 39 mo.								
CapSureFix	5068*	Jan-97	1,360	4	99.8 +0.2/-0.6	99.7 +0.2/-0.7	99.7 +0.2/-0.7	99.4 +0.4/-1.3	99.4 +0.4/-1.3	99.4 +0.4/-1.3						
	4068*	Mar-96	1,756	19	99.4 +0.3/-0.5	99 +0.4/-0.7	99 +0.4/-0.7	98.8 +0.5/-0.7	98.3 +0.7/-1.3	97.9 +0.9/-1.7	97.9 +0.9/-1.7	97.9 +0.9/-1.7 at 90 mo.				
CapSure Z Novus	5054	Jan-98	1,248	8	99.7 +0.2/-0.6	99.5 +0.3/-0.6	99.5 +0.3/-0.6	99.2 +0.5/-1.5	99.2 +0.5/-1.5 at 54 mo.							
CapSure Z	5034	Feb-96	1,598	11	99.8 +0.1/-0.4	99.6 +0.2/-0.6	99.3 +0.3/-0.7	99 +0.5/-0.8	99 +0.5/-0.8	99 +0.5/-0.8	99 +0.5/-0.8	99 +0.5/-0.8 at 93 mo.				
	5033	Jan-96	1,894	10	99.8 +0.1/-0.4	99.7 +0.2/-0.4	99.2 +0.4/-0.7	99.2 +0.4/-0.7	99.2 +0.4/-0.7	99.2 +0.4/-0.7	99.2 +0.4/-0.7	99.2 +0.4/-0.7				
	4033**	Mar-94	539	8	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	97.8 +1.2/-2.7	97.8 +1.2/-2.7	97.8 +1.2/-2.7				
CapSure SP Novus	4092	Sep-98	1,015	8	99.1 +0.5/-0.9	98.9 +0.6/-1	98.9 +0.6/-1	98.9 +0.6/-1 at 42 mo.								
	5092	Jul-98	1,059	6	99.5 +0.3/-0.7	99.4 +0.3/-0.9	99 +0.6/-1.4	99 +0.6/-1.4	99 +0.6/-1.4							
CapSure SP	4024	Oct-91	1,214	3	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 108 mo.			
	4023	Aug-91	1,147	10	100 +0/-0	99.5 +0.3/-0.7	99.1 +0.5/-0.9	98.9 +0.6/-1.1	98.9 +0.6/-1.1	98.9 +0.6/-1.1	97.1 +1.7/-4.1	97.1 +1.7/-4.1				
	5024/5024M	Mar-90	8,134	37	99.7 +0.1/-0.2	99.6 +0.1/-0.1	99.6 +0.1/-0.2	99.5 +0.2/-0.2	99.5 +0.1/-0.2	99.4 +0.2/-0.2	99.4 +0.2/-0.2	99.4 +0.2/-0.3	99.1 +0.4/-0.5	99.1 +0.4/-0.5	99.1 +0.4/-0.5 at 153 mo.	
	5023/5023M	Nov-88	1,234	2	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5	99.8 +0.2/-0.5 at 81 mo.					
Screw-In	4057/4057M	Apr-89	259	7	99.4 +0.5/-3.5	99.4 +0.5/-3.5	99.4 +0.5/-3.5	98.6 +1.1/-4	97.8 +1.5/-4.7	96.8 +2/-5.1	95.8 +2.5/-5.7	95.8 +2.5/-5.7	94.6 +3/-6.4	94.6 +3/-6.4 at 132 mo.		
	4058/4058M*	Mar-89	1,689	39	99.4 +0.3/-0.7	99.2 +0.4/-0.7	99.1 +0.4/-0.8	98.7 +0.5/-0.9	98 +0.7/-1.2	96.8 +1.1/-1.5	95 +1.5/-2.2	94.4 +1.7/-2.3	93.3 +2/-2.7	92.6 +2.2/-3.2 at 141 mo.		
	4016*	Sep-85	225	13	99 +0.7/-3	99 +0.7/-3	99 +0.7/-3	97.2 +1.8/-4.8	95.2 +2.7/-5.8	93 +3.5/-6.9	91.5 +4.1/-7.7	89.7 +4.9/-8.9				
CapSure	4004/4004M	Jan-89	1,640	275	99.8 +0.1/-0.5	99.3 +0.4/-0.7	96.3 +1/-1.3	88.2 +1.9/-2.3	79.2 +2.6/-2.9	72.9 +3/-3.3	68.8 +3.3/-3.6	64.5 +3.6/-3.8	60.4 +3.8/-4.1	60 +3.9/-4.1	60 +3.9/-4.1 at 165 mo.	
	5026	Mar-88	168	4	100 +0/-0	99.2 +0.7/-4.7	98.2 +1.4/-5.1	97.1 +2/-5.8	97.1 +2/-5.8	95.7 +2.7/-6.9	95.7 +2.7/-6.9 at 81 mo.					
	4003/4003M	Nov-86	711	7	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.4 +0.4/-1.1	99.2 +0.5/-1.2	99.2 +0.5/-1.2	98.9 +0.6/-1.5	98.6 +0.7/-1.7	98.6 +0.7/-1.7	98.6 +0.7/-1.7 at 105 mo.			
Target Tip	4081	Feb-90	260	3	100 +0/-0	100 +0/-0	100 +0/-0	100 +0/-0	100 +0/-0	98.1 +1.6/-11 at 63 mo.						
	5064	Jul-85	177	4	99.3 +0.6/-3.9	99.3 +0.6/-3.9	96.8 +2/-5.1	96.8 +2/-5.1	96.8 +2/-5.1	96.8 +2/-5.1	96.8 +2/-5.1	96.8 +2/-5.1 at 90 mo.				
	5061	Apr-85	118	1	100 +0/-0	98.7 +1.1/-7.8	98.7 +1.1/-7.8	98.7 +1.1/-7.8 at 39 mo.								
	4012	Nov-83	2,542	315	99.6 +0.2/-0.3	99.2 +0.3/-0.6	98.4 +0.5/-0.6	95.9 +0.8/-1.1	92.7 +1.2/-1.4	88.5 +1.6/-1.8	84.6 +1.9/-2.2	79.1 +2.3/-2.5	72.5 +2.7/-3.1	69.3 +3.1/-3.3	67.4 +3.3/-3.5	67 +3.3/-3.7 at 213 mo.
	4011	Feb-83	851	23	99.4 +0.4/-1	99.3 +0.4/-1.1	99.1 +0.5/-1.1	98.9 +0.6/-1.3	97.7 +1/-1.8	96.5 +1.4/-2.2	96.2 +1.5/-2.4	96.2 +1.5/-2.4	95.2 +1.8/-2.9	93.3 +2.5/-3.9	92.6 +2.7/-4.3	92.6 +2.7/-4.3 at 207 mo.
Spectraflex	6957*	Sep-79	1,853	40	99.6 +0.2/-0.5	99.2 +0.4/-0.6	98.8 +0.5/-0.8	98.3 +0.6/-1	97.7 +0.8/-1.1	97.1 +0.9/-1.4	96.9 +1/-1.4	96.3 +1.1/-1.7	95.6 +1.4/-2	94.7 +1.7/-2.4	94.2 +1.9/-2.8	93.5 +2.2/-3.3 at 219 mo.

[1] "Actuarial survival probability" refers to the proper functioning of the device, not the survival of the patient. For example, a survival probability of 98% is a statistical assessment that, by the point in time indicated, each patient has had a 2% risk of incurring a lead hardware failure or lead-related complication.

[2] Rounded to closest 0.1%.

* Note that Model(s) 4016, 4058/4058M, 4068, 5068, 5076, and 6957 are listed separately under "atrial" and under "ventricular" categories, according to their use.

** Not available in the United States.

FOR BRAND NAMES AND TECHNICAL DETAILS, REFER TO REFERENCE SECTION.

Ventricular Implantable Pacing Leads (Bradycardia)

Laboratory Analysis

Source: U.S. Returned Product Analysis
(Data as of August 1, 2004)

Model Family	Model	Market Release	Initial Implants[1]	Active Implants[2]	Implant Damage[3]	Electrical[4]	Other
CapSure Sense	4074	Jun-02	15,000	14,000	4	1	1
CapSureFix Novus	5076*	Aug-00	405,000	344,000	412	57	36
CapSureFix	4067	Jan-97	1,000	1,000	3	1	1
	5068*	Jan-97	107,000	69,000	455	45	15
	4068*	Mar-96	131,000	78,000	406	59	11
CapSure VDD-2	5038	Sep-98	6,000	5,000	6	2	1
CapSure Z Novus	5054	Jan-98	66,000	48,000	38	9	5
CapSure Z	5034	Feb-96	59,000	31,000	84	30	11
	5033	Jan-96	3,000	1,000	6	1	3
CapSure SP Novus	4092	Sep-98	102,000	80,000	27	5	5
	5092	Jul-98	77,000	59,000	35	11	10
CapSure SP	4024	Oct-91	229,000	112,000	264	77	34
	4023	Aug-91	44,000	20,000	48	18	6
	5024/5024M	Mar-90	211,000	98,000	723	92	29
	5023/5023M	Nov-88	11,000	4,000	15	7	0
CapSure VDD-2	5032	Mar-96	6,000	4,000	24	12	0
Screw-In	4057/4057M	Apr-89	12,000	4,000	39	6	4
	4058/4058M*	Mar-89	111,000	36,000	388	211	23
	4016A	Jul-88	4,000	1,000	19	20	0
	4016*	Sep-85	8,000	1,000	57	59	3
CapSure	4004/4004M	Jan-89	74,000	5,000	55	677	19
	5026	Mar-88	8,000	2,000	60	7	1
	5025	Apr-87	2,000	400	1	3	0
	4003/4003M	Nov-86	40,000	10,000	24	54	2
Target Tip	4081	Feb-90	4,000	1,000	4	5	0
	5064	Jul-85	8,000	2,000	11	15	0
	5061	Apr-85	6,000	1,000	5	1	0
	4012	Nov-83	97,000	8,000	50	823	34
	4011	Feb-83	64,000	10,000	29	135	5
Spectraflex	6957*	Sep-79	29,000	4,000	85	39	25

NOTES:

[1] The number of initial implants is based on using the total number of leads sold.

[2] The number of active implants was estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure.

[3] Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes or conductor fracture due to overtorquing.

[4] 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). (Exception: For bipolar leads, an insulation breach adjacent to the anode ring electrode that does not have the potential to cause pacing or sensing problems, and for which no clinical complication is reported, is considered to be a non-electrical failure.) 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.

*NOTE: Includes both ventricular and atrial use.

FOR BRAND NAMES AND TECHNICAL DETAILS, REFER TO REFERENCE SECTION.

Ventricular Implantable Pacing Leads (Bradycardia)

Lead Complications by Lead Model Families

Source: Chronic Lead Study
(Data as of August 1, 2004)

CapSure Leads				
Lead Failure Mode	**4003/4003M**	**4004/4004M**	**5026**	**Grand Total**
Conductor Fracture	0	7	0	7
Electrical Abandonment	0	1	1	2
Extra Cardiac Stimulation	2	2	0	4
Failure to Capture	4	131	3	138
Failure to Sense	0	62	0	62
Impedance Out of Range	0	31	0	31
Insulation (ESC)	0	4	0	4
Insulation (MIO)	0	4	0	4
Insulation (not further defined)	0	6	0	6
Medical Judgement	0	1	0	1
Oversensing	1	25	0	26
Unspecified Clinical Failure	0	1	0	1
Grand Total	7	275	4	286

CapSureFix/CapSureFix Novus Leads				
Lead Failure Mode	**4068**	**5068**	**5076**	**Grand Total**
Extra Cardiac Stimulation	1	0	0	1
Failure to Capture	15	3	2	20
Failure to Sense	2	0	1	3
Impedance Out of Range	1	0	0	1
Lead Dislodgement	0	1	0	1
Grand Total	19	4	3	26

CapSure SP/CapSure SP Novus Leads							
Lead Failure Mode	**4023**	**4024**	**4092**	**5023/5023M**	**5024/5024M**	**5092**	**Grand Total**
Conductor Fracture	0	0	2	0	3	0	5
Extra Cardiac Stimulation	0	0	1	1	1	0	3
Failure to Capture	8	3	4	1	23	1	40
Failure to Sense	0	0	0	0	1	0	1
Insulation (ESC)	0	0	0	0	1	0	1
Insulation (not further defined)	0	0	0	0	3	0	3
Lead Dislodgement	2	0	1	0	4	5	12
Oversensing	0	0	0	0	1	0	1
Grand Total	10	3	8	2	37	6	66

CapSure Z/CapSure Z Novus Leads					
Lead Failure Mode	**4033***	**5033**	**5034**	**5054**	**Grand Total**
Cardiac Perforation	0	1	0	0	1
Conductor Fracture	1	3	1	0	5
Failure to Capture	7	3	7	5	22
Failure to Sense	0	0	1	0	1
Impedance Out of Range	0	1	0	1	2
Lead Dislodgement	0	2	2	2	6
Grand Total	8	10	11	8	37

* Not available in the United States.

Ventricular Implantable Pacing Leads (Bradycardia)

Lead Complications by Lead Model Families

Source: Chronic Lead Study
(Data as of August 1, 2004)

Screw-In Leads				
Lead Failure Mode	**4016**	**4057/4057M**	**4058/4058M**	**Grand Total**
Conductor Fracture	2	2	2	6
Extra Cardiac Stimulation	0	2	3	5
Failure to Capture	4	2	19	25
Failure to Sense	2	1	7	10
Impedance Out of Range	1	0	3	4
Insulation (not further defined)	1	0	3	4
Lead Dislodgement	0	0	1	1
Oversensing	3	0	1	4
Grand Total	13	7	39	59

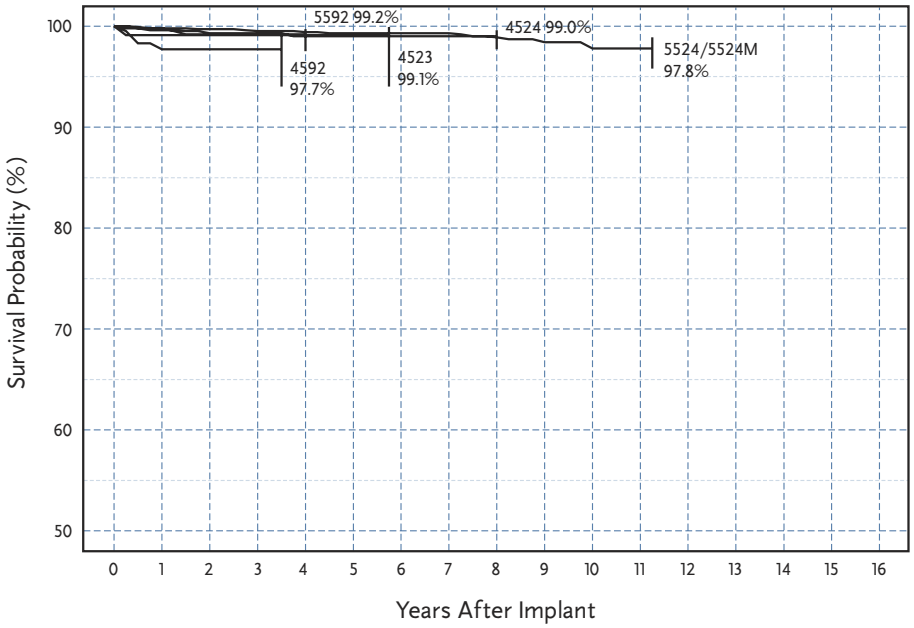
Spectraflex Leads		
Lead Failure Mode	**6957**	**Grand Total**
Conductor Fracture	12	12
Extra Cardiac Stimulation	2	2
Failure to Capture	19	19
Failure to Sense	2	2
Impedance Out of Range	1	1
Insulation (not further defined)	1	1
Oversensing	3	3
Grand Total	40	40

Target-Tip Leads						
Lead Failure Mode	**4011**	**4012**	**4081**	**5061**	**5064**	**Grand Total**
Conductor Fracture	0	6	1	0	0	7
Extra Cardiac Stimulation	4	3	0	0	0	7
Failure to Capture	9	126	0	1	2	138
Failure to Sense	0	76	2	0	1	79
Impedance Out of Range	0	26	0	0	0	26
Insulation (ESC)	0	9	0	0	0	9
Insulation (MIO)	0	4	0	0	0	4
Insulation (not further defined)	9	16	0	0	0	25
Medical Judgement	0	1	0	0	0	1
Oversensing	1	48	0	0	1	50
Grand Total	23	315	3	1	4	346

Tenax Leads			
Lead Failure Mode	**6961**	**6962**	**Grand Total**
Conductor Fracture	0	5	5
Extra Cardiac Stimulation	4	1	5
Failure to Capture	7	27	34
Failure to Sense	6	10	16
Impedance Out of Range	0	2	2
Insulation (not further defined)	2	2	4
Lead Dislodgement	1	1	2
Oversensing	1	3	4
Grand Total	21	51	72

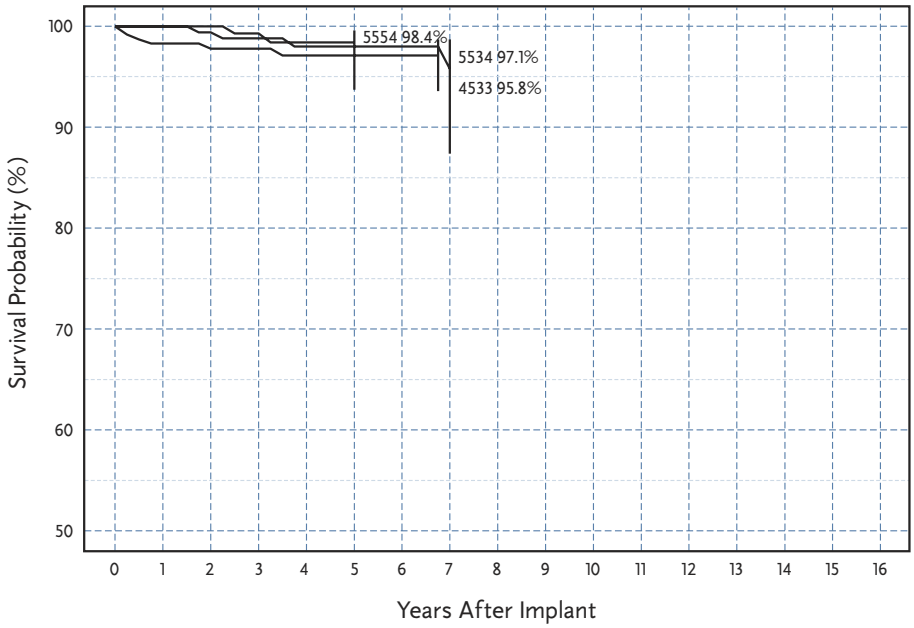
No Brand Name Leads		
Lead Failure Mode	**6907/6907R**	**Grand Total**
Conductor Fracture	1	1
Failure to Capture	5	5
Lead Dislodgement	1	1
Oversensing	2	2
Grand Total	9	9

Atrial CapSure SP/CapSure SP Novus Leads



Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Complica-tions	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSure SP Novus	4592	Oct-98	231	4	97.7 +1.4/ -3.7	97.7 +1.4/ -3.7	97.7 +1.4/ -3.7	97.7 +1.4/ -3.7 at 42 mo.								
	5592	Jul-98	578	3	99.8 +0.2/-1.3	99.2 +0.5/-1.7	99.2 +0.5/-1.7	99.2 +0.5/-1.7								
CapSure SP	4524	Oct-91	910	6	99.6 +0.3/-0.7	99.3 +0.4/-1	99.3 +0.4/-1	99 +0.6/ -1.3	99 +0.6/ -1.3	99 +0.6/ -1.3	99 +0.6/ -1.3	99 +0.6/ -1.3				
	4523	Sep-91	121	1	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1 at 69 mo.						
	5524/5524M	Jun-90	4,427	28	99.8 +0.1/-0.2	99.7 +0.2/-0.2	99.5 +0.2/-0.3	99.4 +0.2/-0.4	99.3 +0.2/-0.4	99.3 +0.2/-0.4	99.3 +0.2/-0.4	98.9 +0.4/-0.7	97.8 +1.1/ -2	97.8 +1.1/ -2 at 135 mo.		

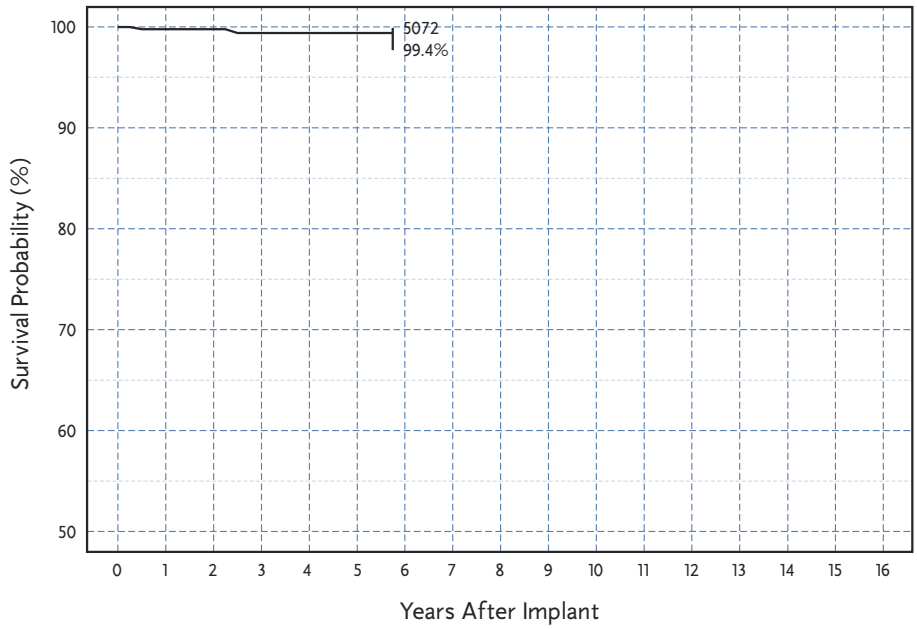
Atrial CapSure Z/CapSure Z Novus Leads



Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Complica-tions	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSure Z Novus	5554	Jul-98	314	2	100 +0/-0	100 +0/-0	99.3 +0.6/-4.1	98.4 +1.2/-4.7	98.4 +1.2/-4.7							
CapSure Z	5534	Jul-98	260	6	98.3 +1.1/ -2.8	97.8 +1.3/-3.1	97.8 +1.3/-3.1	97.1 +1.6/ -3.5	97.1 +1.6/ -3.5	97.1 +1.6/ -3.5	97.1 +1.6/ -3.5 at 81 mo.					
	4533*	Mar-94	205	4	100 +0/-0	99.4 +0.5/-3.5	98.8 +0.9/-3.5	98 +1.3/ -4.3	98 +1.3/ -4.3	98 +1.3/ -4.3	95.8 +2.9/-8.4					

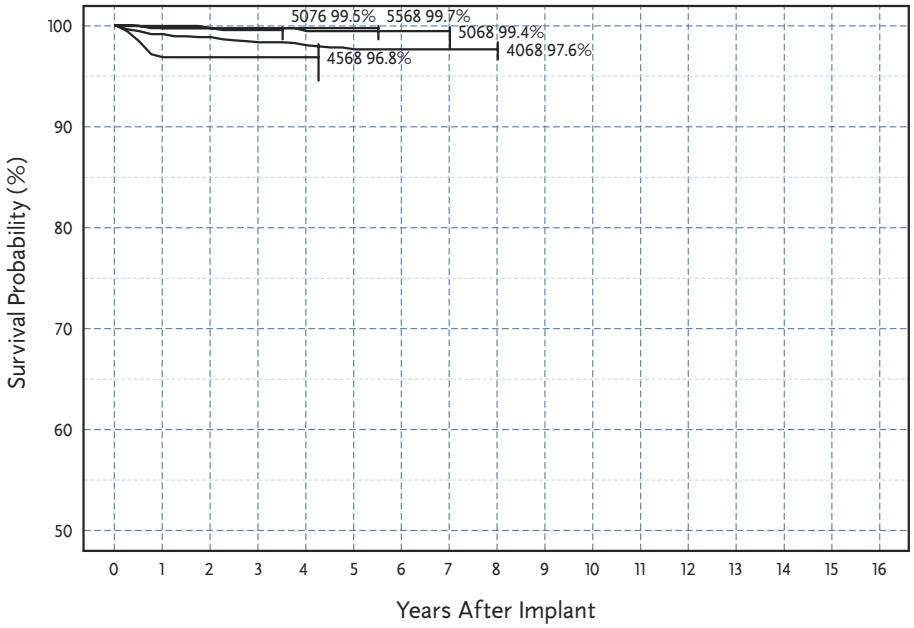
* Not available in the United States.

Atrial SureFix Leads



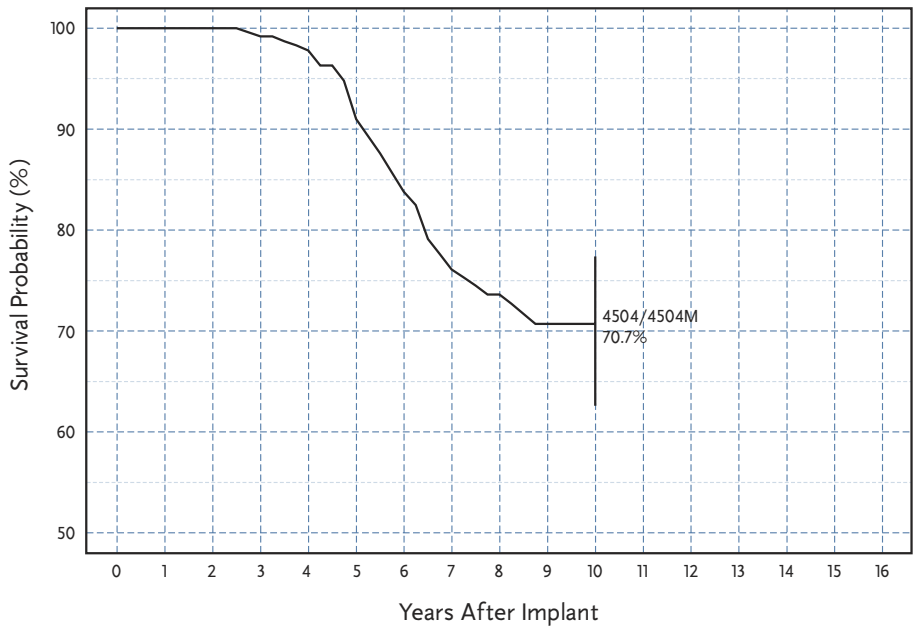
Lead Survival (95% Confidence Interval)															
Model Family	Model	Market Release	Initial Implants	Complica-tions	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
SureFix	5072	Jun-98	449	2	99.8 +0.2/-1.5	99.8 +0.2/-1.5	99.4 +0.5/-1.7	99.4 +0.5/-1.7	99.4 +0.5/-1.7	99.4 +0.5/-1.7 at 69 mo.						

Atrial CapSure Fix/CapSure Fix Novus Leads



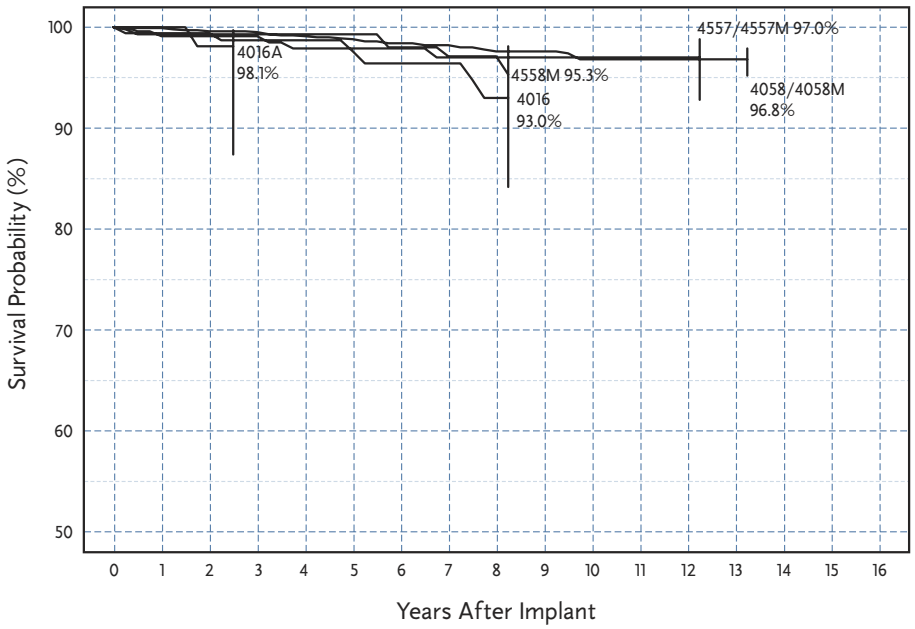
Lead Survival (95% Confidence Interval)															
Model Family	Model	Market Release	Initial Implants	Complica-tions	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSureFix Novus	5076	Aug-00	1,485	5	99.7 +0.2/-0.6	99.7 +0.2/-0.6	99.5 +0.3/-0.9	99.5 +0.3/-0.9 at 42 mo.								
CapSureFix	4568	May-97	505	14	96.8 +1.3/-2.3	96.8 +1.3/-2.3	96.8 +1.3/-2.3	96.8 +1.3/-2.3	96.8 +1.3/-2.3 at 51 mo.							
CapSureFix Novus	5568	Apr-97	797	3	99.9 +0.1/-0.9	99.7 +0.2/-1.1	99.7 +0.2/-1.1	99.7 +0.2/-1.1	99.7 +0.2/-1.1	99.7 +0.2/-1.1 at 66 mo.						
CapSureFix	5068	Jan-97	963	3	99.7 +0.2/-0.8	99.7 +0.2/-0.8	99.7 +0.2/-0.8	99.4 +0.4/-1.6	99.4 +0.4/-1.6	99.4 +0.4/-1.6	99.4 +0.4/-1.6					
	4068	Mar-96	2,366	38	99.1 +0.3/-0.5	98.8 +0.3/-0.6	98.3 +0.5/-0.7	98 +0.6/ -0.8	97.6 +0.7/-1	97.6 +0.7/-1	97.6 +0.7/-1	97.6 +0.7/-1				

Atrial CapSure Leads



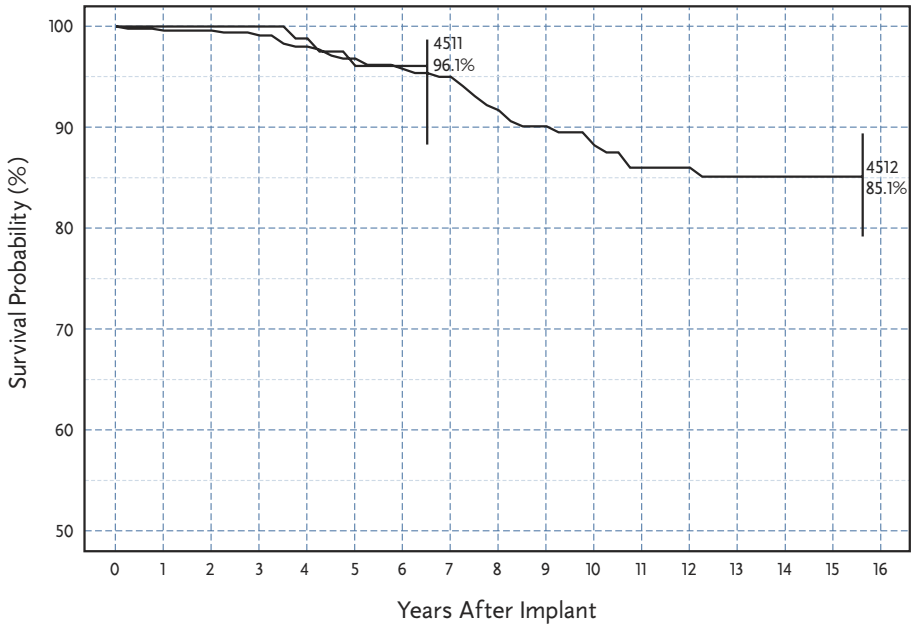
Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Compli-cations	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSure	4504/4504M	Mar-90	368	48	100 +0/-0	100 +0/-0	99.2 +0.6/ -2.4	97.8 +1.3/-3.1	91 +3.2/ -4.9	83.8 +4.7/-6.2	76.1 +5.8/-7.3	73.6 +6.2/-7.7	70.7 +6.7/-8.1			

Atrial Screw-In Leads



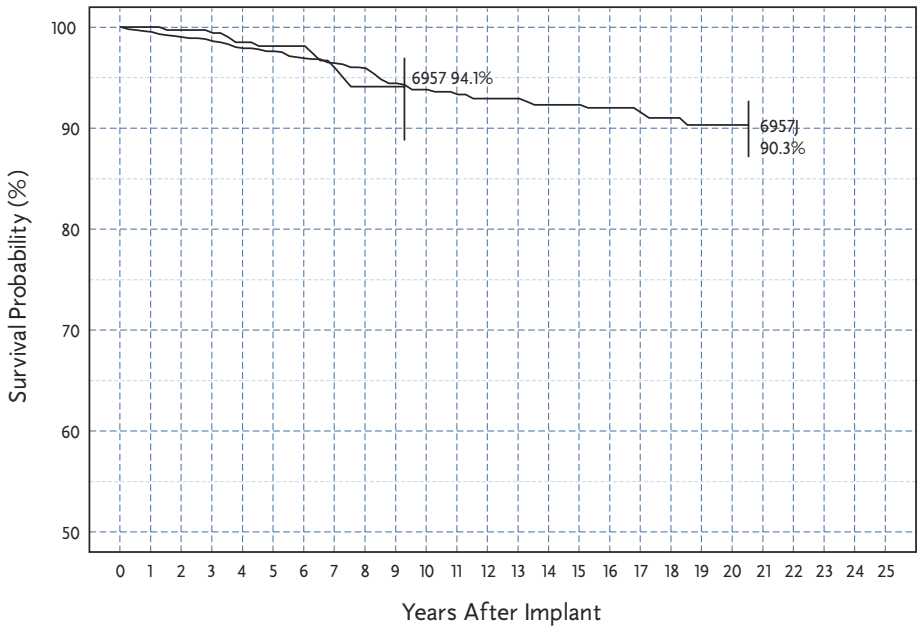
Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Complica-tions	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Screw-In	4558M	Nov-94	539	7	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	98 +1.3/ -3.3	97.1 +1.7/ -4.3	97.1 +1.7/ -4.3	95.3 +2.8/-6.8 at 99 mo.			
	4058/4058M	Mar-89	2,365	30	99.9 +0.1/ -0.3	99.6 +0.2/-0.4	99.5 +0.2/-0.5	99.1 +0.4/ -0.6	98.8 +0.4/-0.8	98.4 +0.5/-0.9	98.2 +0.6/-0.9	97.6 +0.8/-1.1	96.8 +1.1/-1.6	96.8 +1.1/-1.6	96.8 +1.1/ -1.6 at 159 mo.	
	4557/4557M	Aug-88	294	5	99.1 +0.7/ -2.7	99.1 +0.7/ -2.7	99.1 +0.7/ -2.7	97.9 +1.3/-3.5	97.9 +1.3/-3.5	97.9 +1.3/-3.5	97 +1.8/ -4.2	97 +1.8/ -4.2	97 +1.8/ -4.2	97 +1.8/ -4.2	97 +1.8/ -4.2 at 147 mo.	
	4016A	Jul-88	68	3	100 +0/-0	98.1 +1.6/ -10.7	98.1 +1.6/ -10.7 at 30 mo.									
	4016	Sep-85	180	6	99.4 +0.5/-3.4	99.4 +0.5/-3.4	98.7 +1/-4	98.7 +1/-4	97.6 +1.6/-5.3	96.4 +2.3/-6	96.4 +2.3/-6	93 +4/-8.7	93 +4/-8.7 at 99 mo.			

Atrial Target Tip Leads



Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Compli-cations	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Target Tip	4512	Nov-83	599	35	99.6 +0.3/-1.2	99.6 +0.3/-1.2	99.1 +0.6/-1.5	98 +1/ -1.9	96.8 +1.4/-2.3	95.8 +1.7/-2.7	95 +1.9/-3	91.7 +2.7/-4.1	88.2 +3.6/-5	86 +4.1/ -5.6	85.1 +4.3/ -5.9	85.1 +4.3/ -5.9 at 189 mo.
	4511	Mar-83	158	3	100 +0/-0	100 +0/-0	100 +0/-0	98.8 +1/-7.2	96.1 +2.6/ -7.8	96.1 +2.6/ -7.8	96.1 +2.6/-7.8 at 78 mo.					

Atrial Spectraflex Leads



Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Compli-cations	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
Spectraflex	6957J	Feb-81	2,348	81	99.5 +0.2/ -0.5	99 +0.4/ -0.6	98.6 +0.5/ -0.7	97.9 +0.6/ -0.9	97.6 +0.6/-1	96.9 +0.8/-1	96.4 +0.9/-1.2	95.9 +1/-1.3	93.8 +1.4/-1.7	92.9 +1.5/-2	92.3 +1.7/-2.1	90.3 +2.4/ -3.2 at 246 mo.
	6957	Sep-79	676	10	100 +0/-0	99.7 +0.3/-1.5	99.4 +0.4/-1.9	98.5 +1/-2.4	98.1 +1.1/-2.8	98.1 +1.1/-2.8	95.9 +2.1/-4.3	94.1 +2.8/-5.3	94.1 +2.8/-5.3 at 111 mo.			

Atrial Implantable Pacing Leads (Bradycardia)

Actuarial Survival Probability[1] (Including 95% Confidence Interval)[2]

Source: Chronic Lead Study
(Data as of August 1, 2004)

					Lead Survival (95% Confidence Interval)											
Model Family	Model	Market Release	Initial Implants	Complications	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSureFix Novus	5076*	Aug-00	1,485	5	99.7 +0.2/-0.6	99.7 +0.2/-0.6	99.5 +0.3/-0.9	99.5 +0.3/-0.9 at 42 mo.								
CapSure SP Novus	4592	Oct-98	231	4	97.7 +1.4/-3.7	97.7 +1.4/-3.7	97.7 +1.4/-3.7	97.7 +1.4/-3.7 at 42 mo.								
	5592	Jul-98	578	3	99.8 +0.2/-1.3	99.2 +0.5/-1.7	99.2 +0.5/-1.7	99.2 +0.5/-1.7								
CapSure Z Novus	5554	Jul-98	314	2	100 +0/-0	100 +0/-0	99.3 +0.6/-4.1	98.4 +1.2/-4.7	98.4 +1.2/-4.7							
CapSure Z	5534	Jul-98	260	6	98.3 +1.1/-2.8	97.8 +1.3/-3.1	97.8 +1.3/-3.1	97.1 +1.6/-3.5	97.1 +1.6/-3.5	97.1 +1.6/-3.5	97.1 +1.6/-3.5 at 81 mo.					
	4533**	Mar-94	205	4	100 +0/-0	99.4 +0.5/-3.5	98.8 +0.9/-3.5	98 +1.3/-4.3	98 +1.3/-4.3	98 +1.3/-4.3	95.8 +2.9/-8.4					
SureFix	5072	Jun-98	449	2	99.8 +0.2/-1.5	99.8 +0.2/-1.5	99.4 +0.5/-1.7	99.4 +0.5/-1.7	99.4 +0.5/-1.7	99.4 +0.5/-1.7 at 69 mo.						
CapSureFix	5568	Apr-97	797	3	99.9 +0.1/-0.9	99.7 +0.2/-1.1	99.7 +0.2/-1.1	99.7 +0.2/-1.1	99.7 +0.2/-1.1	99.7 +0.2/-1.1 at 66 mo.						
	4568	May-97	505	14	96.8 +1.3/-2.3	96.8 +1.3/-2.3	96.8 +1.3/-2.3	96.8 +1.3/-2.3	96.8 +1.3/-2.3 at 51 mo.							
	5068*	Jan-97	963	3	99.7 +0.2/-0.8	99.7 +0.2/-0.8	99.7 +0.2/-0.8	99.4 +0.4/-1.6	99.4 +0.4/-1.6	99.4 +0.4/-1.6	99.4 +0.4/-1.6					
	4068*	Mar-96	2,366	38	99.1 +0.3/-0.5	98.8 +0.3/-0.6	98.3 +0.5/-0.7	98 +0.6/-0.8	97.6 +0.7/-1	97.6 +0.7/-1	97.6 +0.7/-1	97.6 +0.7/-1				
CapSure SP	4524	Oct-91	910	6	99.6 +0.3/-0.7	99.3 +0.4/-1	99.3 +0.4/-1	99 +0.6/-1.3	99 +0.6/-1.3	99 +0.6/-1.3	99 +0.6/-1.3	99 +0.6/-1.3				
	4523	Sep-91	121	1	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1	99.1 +0.8/-5.1 at 69 mo.						
	5524/5524M	Jun-90	4,427	28	99.8 +0.1/-0.2	99.7 +0.2/-0.2	99.5 +0.2/-0.3	99.4 +0.2/-0.4	99.3 +0.2/-0.4	99.3 +0.2/-0.4	99.3 +0.2/-0.4	98.9 +0.4/-0.7	97.8 +1.1/-2	97.8 +1.1/-2 at 135 mo.		
CapSure	4504/4504M	Mar-90	368	48	100 +0/-0	100 +0/-0	99.2 +0.6/-2.4	97.8 +1.3/-3.1	91 +3.2/-4.9	83.8 +4.7/-6.2	76.1 +5.8/-7.3	73.6 +6.2/-7.7	70.7 +6.7/-8.1			
Screw-In	4558M	Nov-94	539	7	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	99.3 +0.5/-1.4	98 +1.3/-3.3	97.1 +1.7/-4.3	97.1 +1.7/-4.3	95.3 +2.8/-6.8 at 99 mo.			
	4058/4058M	Mar-89	2,365	30	99.9 +0.1/-0.3	99.6 +0.2/-0.4	99.5 +0.2/-0.5	99.1 +0.4/-0.6	98.8 +0.4/-0.8	98.4 +0.5/-0.9	98.2 +0.6/-0.9	97.6 +0.8/-1.1	96.8 +1.1/-1.6	96.8 +1.1/-1.6	96.8 +1.1/-1.6 at 159 mo.	
	4557/4557M	Aug-88	294	5	99.1 +0.7/-2.7	99.1 +0.7/-2.7	99.1 +0.7/-2.7	97.9 +1.3/-3.5	97.9 +1.3/-3.5	97.9 +1.3/-3.5	97 +1.8/-4.2	97 +1.8/-4.2	97 +1.8/-4.2	97 +1.8/-4.2	97 +1.8/-4.2 at 147 mo.	
	4016A	Jul-88	68	3	100 +0/-0	98.1 +1.6/-10.7	98.1 +1.6/-10.7 at 30 mo.									
	4016*	Sep-85	180	6	99.4 +0.5/-3.4	99.4 +0.5/-3.4	98.7 +1/-4	98.7 +1/-4	97.6 +1.6/-5.3	96.4 +2.3/-6	96.4 +2.3/-6	93 +4/-8.7	93 +4/-8.7 at 99 mo.			
Target Tip	4512	Nov-83	599	35	99.6 +0.3/-1.2	99.6 +0.3/-1.2	99.1 +0.6/-1.5	98 +1/-1.9	96.8 +1.4/-2.3	95.8 +1.7/-2.7	95 +1.9/-3	91.7 +2.7/-4.1	88.2 +3.6/-5	86 +4.1/-5.6	85.1 +4.3/-5.9	85.1 +4.3/-5.9 at 189 mo.
	4511	Mar-83	158	3	100 +0/-0	100 +0/-0	100 +0/-0	98.8 +1/-7.2	96.1 +2.6/-7.8	96.1 +2.6/-7.8	96.1 +2.6/-7.8 at 78 mo.					
Spectraflex	6957J	Feb-81	2,348	81	99.5 +0.2/-0.5	99 +0.4/-0.6	98.6 +0.5/-0.7	97.9 +0.6/-0.9	97.6 +0.6/-1	96.9 +0.8/-1	96.4 +0.9/-1.2	95.9 +1/-1.3	93.8 +1.4/-1.7	92.9 +1.5/-2	92.3 +1.7/-2.1	90.3 +2.4/-3.2 at 246 mo.
	6957*	Sep-79	676	10	100 +0/-0	99.7 +0.3/-1.5	99.4 +0.4/-1.9	98.5 +1/-2.4	98.1 +1.1/-2.8	98.1 +1.1/-2.8	95.9 +2.1/-4.3	94.1 +2.8/-5.3	94.1 +2.8/-5.3 at 111 mo.			

[1] "Actuarial survival probability" refers to the proper functioning of the device, not the survival of the patient. For example, a survival probability of 98% is a statistical assessment that, by the point in time indicated, each patient has had a 2% risk of incurring a lead hardware failure or lead-related complication.

[2] Rounded to closest 0.1%.

* Note that Model(s) 4016, 4058/4058M, 4068, 5068, 5076, and 6957 are listed separately under "atrial" and under "ventricular" categories, according to their use.

** Not available in the United States.

FOR BRAND NAMES AND TECHNICAL DETAILS, REFER TO REFERENCE SECTION.

Atrial Implantable Pacing Leads (Bradycardia)

Laboratory Analysis

Source: U.S. Returned Product Analysis
(Data as of August 1, 2004)

Model Family	Model	Market Release	Initial Implants[1]	Active Implants[2]	Implant Damage[3]	Electrical[4]	Other
CapSure SP Novus	4592	Oct-98	54,000	41,000	8	1	0
	5592	Jun-98	16,000	13,000	3	1	0
CapSure SP	4524	Oct-91	107,000	51,000	47	15	8
	4523	Sep-91	12,000	5,000	5	2	1
	5524/5524M	Jun-90	64,000	31,000	66	17	7
CapSure Z Novus	5554	Jul-98	42,000	31,000	7	5	3
CapSure Z	5534	Feb-96	28,000	13,000	29	6	5
SureFix	5072	Jun-98	8,000	5,000	21	2	1
CapSureFix	4568	May-97	67,000	47,000	189	3	4
	5568	Apr-97	35,000	25,000	153	6	6
CapSure	4504/4504M	Mar-90	17,000	2,000	5	167	4
Screw-In	4558M	Nov-94	21,000	9,000	111	9	1
	4557/4557M	Aug-88	22,000	7,000	53	14	4
Target Tip	4512	Nov-83	12,000	2,000	4	81	8
	4511	Mar-83	10,000	1,000	5	22	3
Spectraflex	6957J	Feb-81	30,000	3,000	74	28	30

NOTES:

[1] The number of initial implants is based on using the total number of leads sold.

[2] The number of active implants was estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure.

[3] Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes or conductor fracture due to overtorquing.

[4] 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). (Exception: For bipolar leads, an insulation breach adjacent to the anode ring electrode that does not have the potential to cause pacing or sensing problems, and for which no clinical complication is reported, is considered to be a non-electrical failure.) 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.

FOR BRAND NAMES AND TECHNICAL DETAILS, REFER TO REFERENCE SECTION.

Atrial Implantable Pacing Leads (Bradycardia)

Lead Complications by Lead Model Families

Source: Chronic Lead Study
(Data as of August 1, 2004)

CapSure Leads		
Lead Failure Mode	**4504/4504M**	**Grand Total**
Electrical Abandonment	3	3
Extra Cardiac Stimulation	1	1
Failure to Capture	14	14
Failure to Sense	16	16
Impedance Out of Range	9	9
Insulation (MIO)	1	1
Lead Dislodgement	1	1
Oversensing	3	3
Grand Total	48	48

CapSureFix/CapSureFix Novus Leads						
Lead Failure Mode	**4068**	**4568**	**5068**	**5076**	**5568**	**Total**
Conductor Fracture	0	0	0	1	0	1
Extra Cardiac Stimulation	1	0	0	1	0	2
Failure to Capture	16	9	2	1	2	30
Failure to Sense	8	0	0	0	0	8
Impedance Out of Range	1	0	1	0	0	2
Insulation (ESC)	2	0	0	0	0	2
Lead Dislodgement	8	4	0	2	1	15
Medical Judgement	0	1	0	0	0	1
Oversensing	1	0	0	0	0	1
Unspecified Clinical Failure	1	0	0	0	0	1
Total	38	14	3	5	3	63

CapSure SP/CapSure SP Novus Leads						
Lead Failure Mode	**4523**	**4524**	**4592**	**5524/5524M**	**5592**	**Grand Total**
Conductor Fracture	0	0	0	1	0	1
Failure to Capture	0	3	2	17	2	24
Failure to Sense	0	2	0	2	0	4
Insulation (not further defined)	0	0	0	1	0	1
Lead Dislodgement	1	1	2	4	1	9
Oversensing	0	0	0	3	0	3
Grand Total	1	6	4	28	3	42

CapSure Z/CapSure Z Novus Leads				
Lead Failure Mode	**4533***	**5534**	**5554**	**Grand Total**
Failure to Capture	1	5	1	7
Failure to Sense	1	0	0	1
Impedance Out of Range	0	1	1	2
Lead Dislodgement	1	0	0	1
Oversensing	1	0	0	1
Grand Total	4	6	2	12

* Not available in the United States.

Atrial Implantable Pacing Leads (Bradycardia)

Lead Complications by Lead Model Families

Source: Chronic Lead Study
(Data as of August 1, 2004)

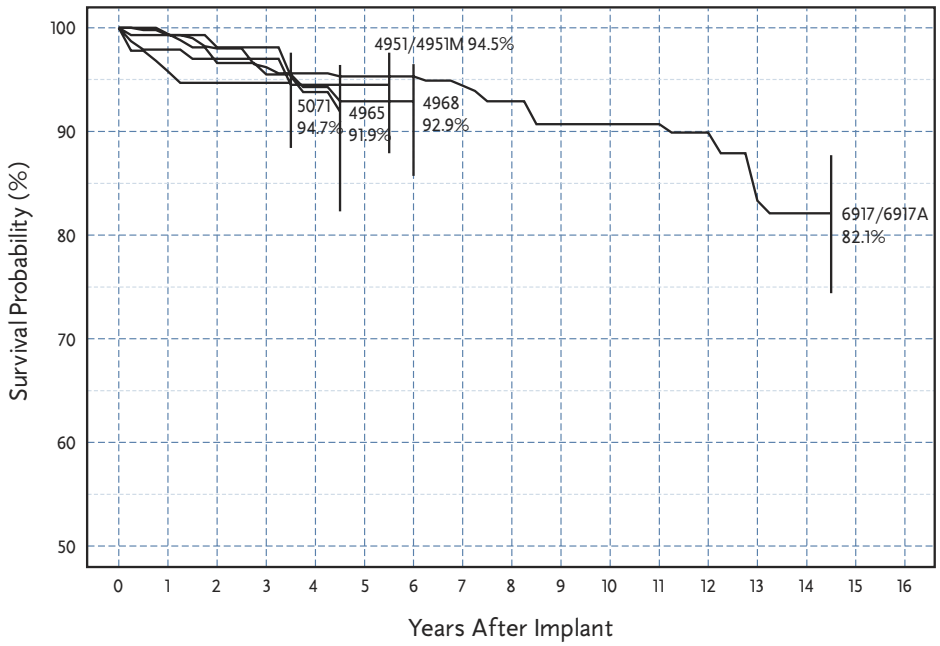
Screw-In Leads						
Lead Failure Mode	4016	4016A	4058/4058M	4557/4557M	4558M	Grand Total
Electrical Abandonment	0	0	0	0	1	1
Extra Cardiac Stimulation	0	0	1	1	0	2
Failure to Capture	2	1	15	3	3	24
Failure to Sense	1	1	6	0	1	9
Impedance Out of Range	0	0	3	0	1	4
Insulation (ESC)	1	0	0	0	0	1
Insulation (not further defined)	2	0	1	0	1	4
Lead Dislodgement	0	0	3	0	0	3
Oversensing	0	1	1	1	0	3
Grand Total	6	3	30	5	7	51

Spectraflex Leads			
Lead Failure Mode	6957	6957J	Grand Total
Conductor Fracture	0	11	11
Extra Cardiac Stimulation	1	3	4
Failure to Capture	3	48	51
Failure to Sense	5	13	18
Insulation (ESC)	0	1	1
Insulation (not further defined)	0	3	3
Lead Dislodgement	0	2	2
Oversensing	1	0	1
Grand Total	10	81	91

SureFix Leads		
Lead Failure Mode	5072	Grand Total
Cardiac Perforation	1	1
Failure to Capture	1	1
Grand Total	2	2

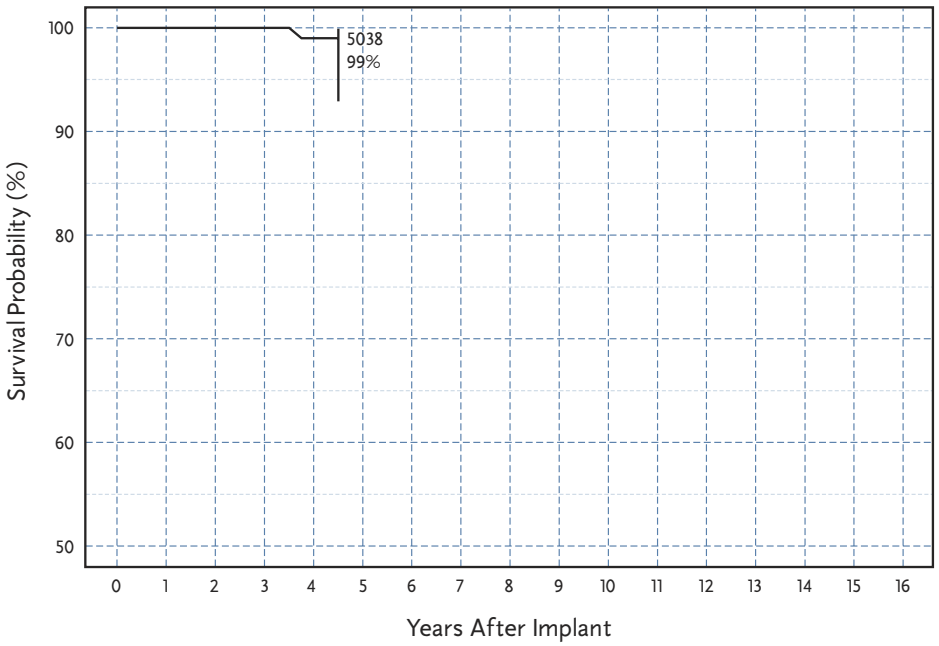
Target-Tip Leads			
Lead Failure Mode	4511	4512	Grand Total
Electrical Abandonment	0	1	1
Failure to Capture	2	6	8
Failure to Sense	0	14	14
Impedance Out of Range	0	3	3
Insulation (ESC)	0	2	2
Insulation (MIO)	0	4	4
Insulation (not further defined)	0	2	2
Lead Dislodgement	0	1	1
Oversensing	1	2	3
Grand Total	3	35	38

EPI/Myocardial Leads



Lead Survival (95% Confidence Interval)																
Model Family	Model	Market Release	Initial Implants	Compli-cations	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSure Epi	4968	Oct-98	189	4	99.4 +0.5/-3.7	96.6 +2/-4.5	95.5 +2.5/-5.4	94.3 +3/-6.3	92.9 +3.6/-7.2	92.9 +3.6/-7.2						
	4965	Sep-96	158	6	99.3 +0.6/-4.4	98.1 +1.4/-5.9	98.1 +1.4/-5.9	93.8 +3.6/-8.4	91.9 +4.5/ -9.6 at 54 mo.							
No Brand Name	5071	Feb-93	158	6	95.8 +2.4/-5.7	94.7 +2.9/-6.3	94.7 +2.9/-6.3	94.7 +2.9/ -6.3 at 42 mo.								
Spetraflex	4951/4951M	Oct-81	177	10	97.9 +1.4/-4.3	97 +1.9/-5	97 +1.9/-5	94.5 +3.1/-6.6	94.5 +3.1/-6.6	94.5 +3.1/-6.6 at 66 mo.						
Tenax	6917/6917A	Jun-73	598	35	99.3 +0.5/-1.5	98 +1/-2	96.2 +1.6/-2.5	95.6 +1.7/-2.6	95.3 +1.8/-2.8	95.3 +1.8/-2.8	94.4 +2/-3.1	92.9 +2.4/-3.7	90.7 +3/-4.4	89.9 +3.3/-4.7	82.1 +5.6/-7.7	82.1 +5.6/ -7.7 at 174 mo.

VDD Single Pass Leads



Model Family	Model	Market Release	Initial Implants	Complications	1 Year	2 Year	3 Year	4 Year	5 Year
CapSure VDD	5038	Sep-98	524	1	100 +0/-0	100 +0/-0	100 +0/-0	99 +0.9/-6.1	99 +0.9/-6.1 at 54 mo.

Epi/Myocardial Implantable Pacing Leads (Bradycardia)

Actuarial Survival Probability (%)[1] (Including 95% Confidence Interval)[2]

Source: Chronic Lead Study
(Data as of August 1, 2004)

					Lead Survival (95% Confidence Interval)											
Model Family	Model	Market Release	Initial Implants	Complica-tions	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	10 Year	12 Year	14 Year	16 Year
CapSure Epi	4968	Oct-98	189	4	99.4 +0.5/ -3.7	96.6 +2/-4.5	95.5 +2.5/ -5.4	94.3 +3/-6.3	92.9 +3.6/ -7.2	92.9 +3.6/ -7.2						
	4965	Sep-96	158	6	99.3 +0.6/ -4.4	98.1 +1.4/ -5.9	98.1 +1.4/ -5.9	93.8 +3.6/ -8.4	91.9 +4.5/ -9.6 at 54 mo.							
No Brand Name	5071	Feb-93	158	6	95.8 +2.4/ -5.7	94.7 +2.9/ -6.3	94.7 +2.9/ -6.3	94.7 +2.9/ -6.3 at 42 mo.								
Spetraflex	4951/4951M	Oct-81	177	10	97.9 +1.4/ -4.3	97 +1.9/-5	97 +1.9/-5	94.5 +3.1/ -6.6	94.5 +3.1/ -6.6	94.5 +3.1/ -6.6 at 66 mo.						
Tenax	6917/6917A	Jun-73	598	35	99.3 +0.5/ -1.5	98 +1/-2	96.2 +1.6/ -2.5	95.6 +1.7/ -2.6	95.3 +1.8/ -2.8	95.3 +1.8/ -2.8	94.4 +2/-3.1	92.9 +2.4/ -3.7	90.7 +3/-4.4	89.9 +3.3/ -4.7	82.1 +5.6/ -7.7	82.1 +5.6/ -7.7 at 174 mo.

[1] "Actuarial survival probability" refers to the proper functioning of the device, not the survival of the patient. For example, a survival probability of 98% is a statistical assessment that, by the point in time indicated, each patient has had a 2% risk of incurring a lead hardware failure or lead-related complication.
[2] Rounded to closest 0.1%.
FOR BRAND NAMES AND TECHNICAL DETAILS, REFER TO REFERENCE SECTION.

Epi/Myocardial Implantable Pacing Leads (Bradycardia)

Lead Complications by Lead Model Families

Source: Chronic Lead Study
(Data as of August 1, 2004)

Lead Failure Mode	4951/4951M	4965	4968	5071	6917/6917A	Grand Total
Conductor Fracture	0	2	2	0	0	4
Failure to Capture	4	1	1	6	26	38
Failure to Sense	3	1	0	0	6	10
Impedance Out of Range	1	0	0	0	0	1
Insulation (ESC)	1	0	0	0	0	1
Insulation (MIO)	0	0	0	0	1	1
Insulation (not further defined)	1	0	0	0	0	1
Oversensing	0	2	1	0	2	5
Grand Total	10	6	4	6	35	61

Epi/Myocardial Implantable Pacing Leads (Bradycardia)

Laboratory Analysis

Source: U.S. Returned Product Analysis
(Data as of August 1, 2004)

Model Family	Model	Market Release	Initial Implants[1]	Active Implants[2]	Implant Damage[3]	Electrical[4]	Other
CapSure Epi	4968	Sep-99	6,000	5,000	1	2	0
	4965	Sep-96	13,000	8,000	7	62	2
No Brand Name	5071	Dec-92	18,000	12,000	9	3	1
Spectraflex	4951/4951M	Oct-81	25,000	5,000	15	93	28
Tenax	6917/6917A	Jun-73	180,000	9,000	115	42	1

NOTES:
[1] The number of initial implants is based on using the total number of leads sold.
[2] The number of active implants was estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure.
[3] Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes or conductor fracture due to overtorquing.
[4] 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). (Exception: For bipolar leads, an insulation breach adjacent to the anode ring electrode that does not have the potential to cause pacing or sensing problems, and for which no clinical complication is reported, is considered to be a non-electrical failure.) 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.
FOR BRAND NAMES AND TECHNICAL DETAILS, REFER TO REFERENCE SECTION.

VDD Single Pass Implantable Pacing Leads (Bradycardia)

Actuarial Survival Probability (%)[1] (Including 95% Confidence Interval)[2]

Source: Chronic Lead Study
(Data as of August 1, 2004)

Model Family	Model	Market Release	Initial Implants	Complications	1 Year	2 Year	3 Year	4 Year	5 Year
CapSure VDD	5038	Sep-98	524	1	100 +0/-0	100 +0/-0	100 +0/-0	99 +0.9/-6.1	99 +0.9/-6.1 at 54 mo.

[1] "Actuarial survival probability" refers to the proper functioning of the device, not the survival of the patient. For example, a survival probability of 98% is a statistical assessment that, by the point in time indicated, each patient has had a 2% risk of incurring a lead hardware failure or lead-related complication.
[2] Rounded to closest 0.1%.
FOR BRAND NAMES AND TECHNICAL DETAILS, REFER TO REFERENCE SECTION.

VDD Single Pass Implantable Pacing Leads (Bradycardia)

Laboratory Analysis

Source: U.S. Returned Product Analysis
(Data as of August 1, 2004)

Model Family	Model	Market Release	Initial Implants[1]	Active Implants[2]	Implant Damage[3]	Electrical[4]	Other
CapSure VDD	5038	Sep-98	6,000	5,000	6	2	1

Lead Complications		
Lead Failure Mode	5038	Grand Total
Failure to Sense	1	1
Grand Total	1	1

NOTES:
[1] The number of initial implants is based on using the total number of leads sold.
[2] The number of active implants was estimated using the total number of leads sold and projections for normal patient mortality, elective replacement, and lead failure.
[3] Typical examples of implant damage are stylet perforation, cut or torn insulation, bent or distorted conductors, over-retracted helixes or conductor fracture due to overtorquing.
[4] 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). (Exception: For bipolar leads, an insulation breach adjacent to the anode ring electrode that does not have the potential to cause pacing or sensing problems, and for which no clinical complication is reported, is considered to be a non-electrical failure.) 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.
FOR BRAND NAMES AND TECHNICAL DETAILS, REFER TO REFERENCE SECTION.

ICD Charge Time Data

Introduction

Medtronic continues to be committed to providing updated information on charge time performance of Medtronic ICDs via the CRM Product Performance Report. The collection of Save-To-Disk files for all Medtronic ICD models, from 7221 (Micro Jewel®) onwards, was implemented in the Tachyarrhythmia Chronic Systems Study (TCSS) on July 1, 1999.

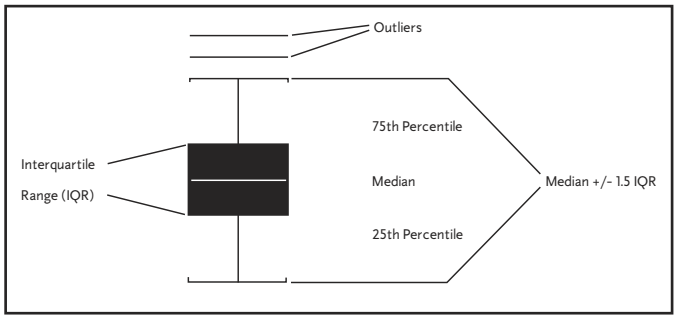
Charge times are normally affected by several factors: (a) the gradual decline in battery voltage and increase in battery resistance that occurs over the life of the device, (b) the deformation of capacitors that occurs normally between capacitor formations, and (c) the different rates of capacitor deformation due to component variability.

Certain early Model 7223Cx and Model 7271 devices have demonstrated longer than typical charge times due to greater component variability in the capacitors used in these devices. This information has been previously communicated directly to physicians (see Safety Advisories). The following data reports TCSS experience with Medtronic ICDs including units experiencing longer than typical charge times as communicated by physician letter.

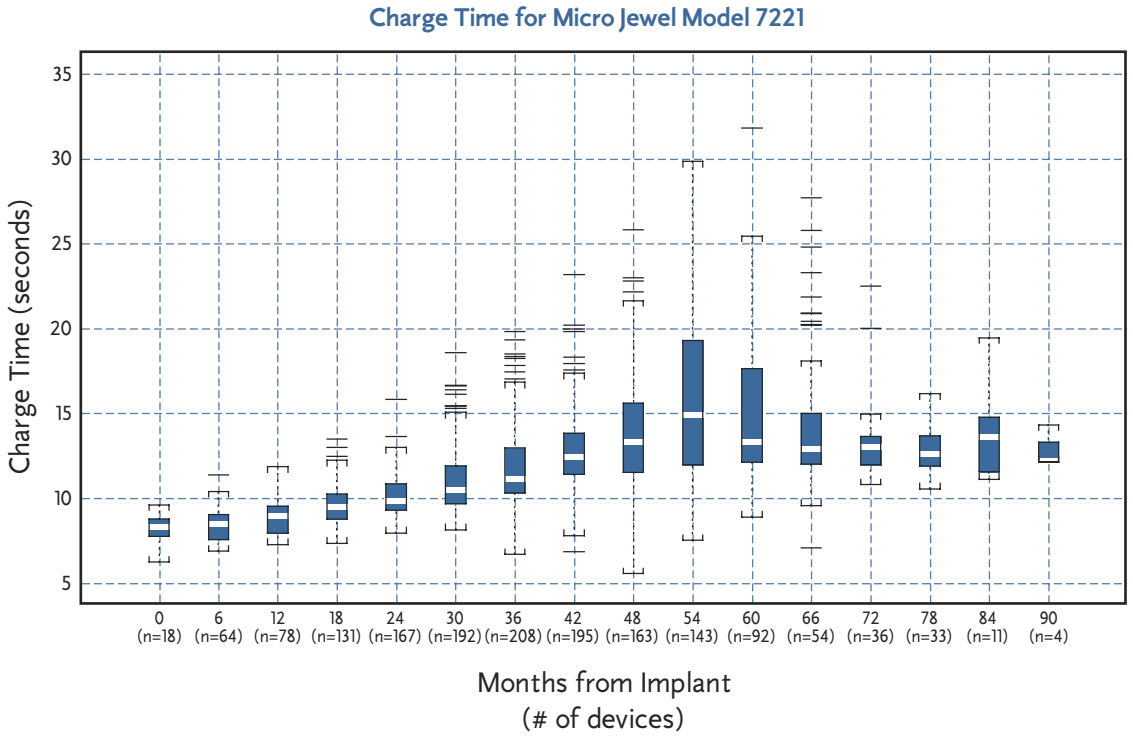
Data Presentation

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.

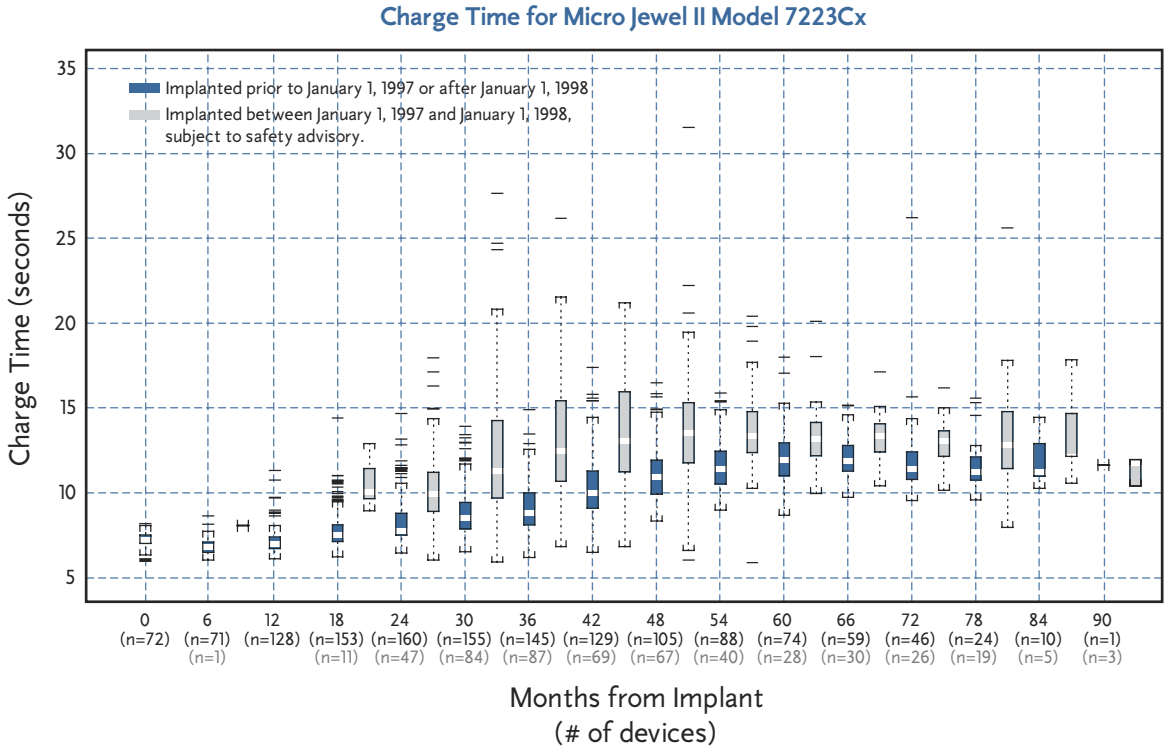
Only charge times resulting from full energy charges are considered. To ensure consistent reporting across devices, the charge time reported at implant represents the last charge time available from date of implant. A conservative approach has been adopted whereby only the maximum charge in each six-month 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.



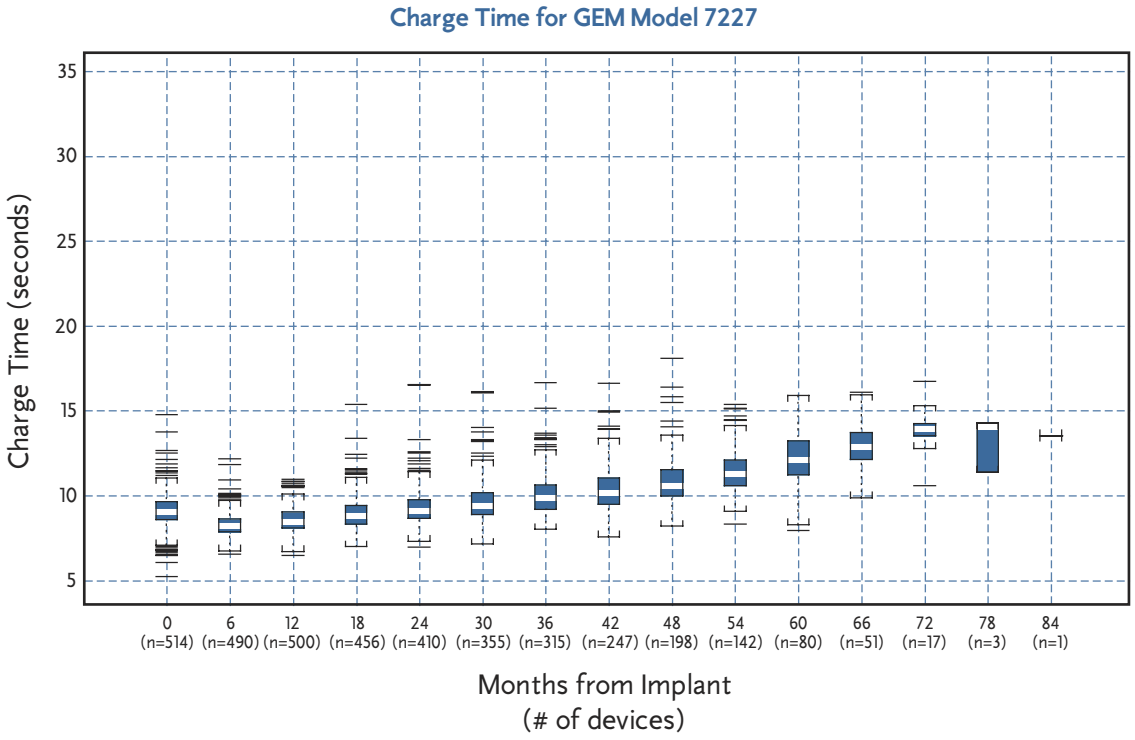
For these devices, charge time increases gradually over the implant time. A maximum charge time of 31.82 seconds is seen at 60 months post-implant.



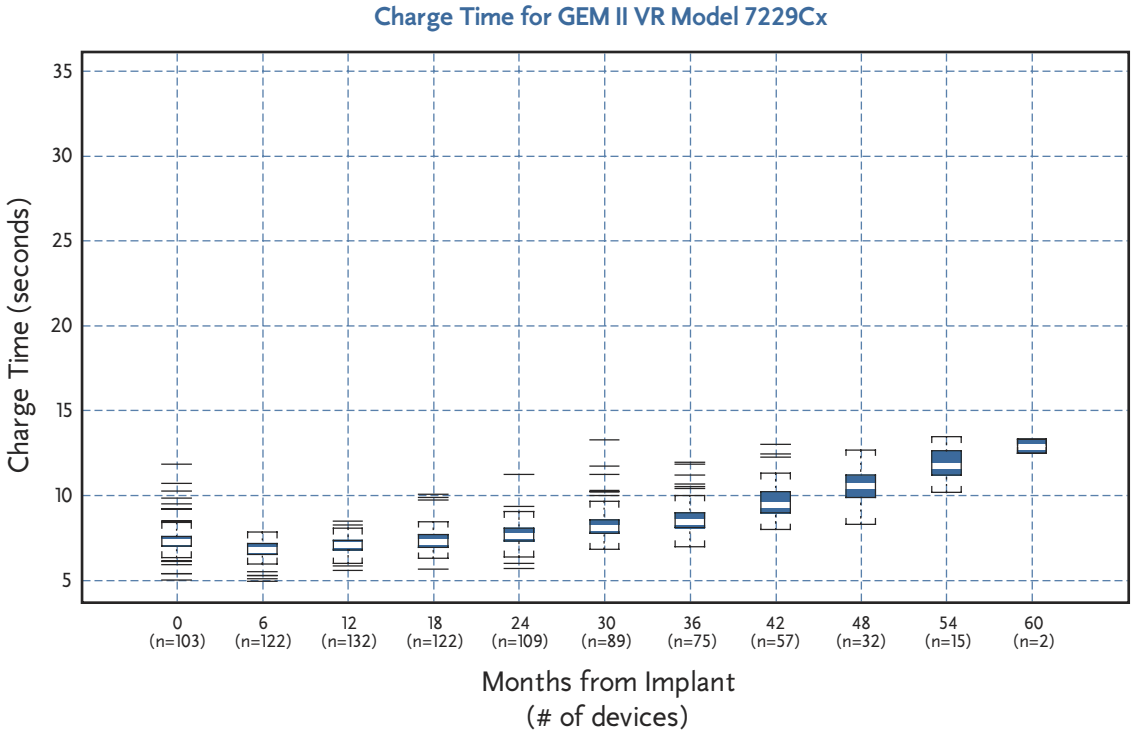
Devices implanted during the calendar year of 1997 demonstrate highly variable charge times at 30, 36, 42, and 48 months post-implant. A maximum charge time of 31.51 seconds is observed at 48 months post-implant. In contrast, charge times for devices implanted outside of this time period are relatively stable through 36 months, with a maximum charge time of 26.20 seconds at 72 months post-implant.



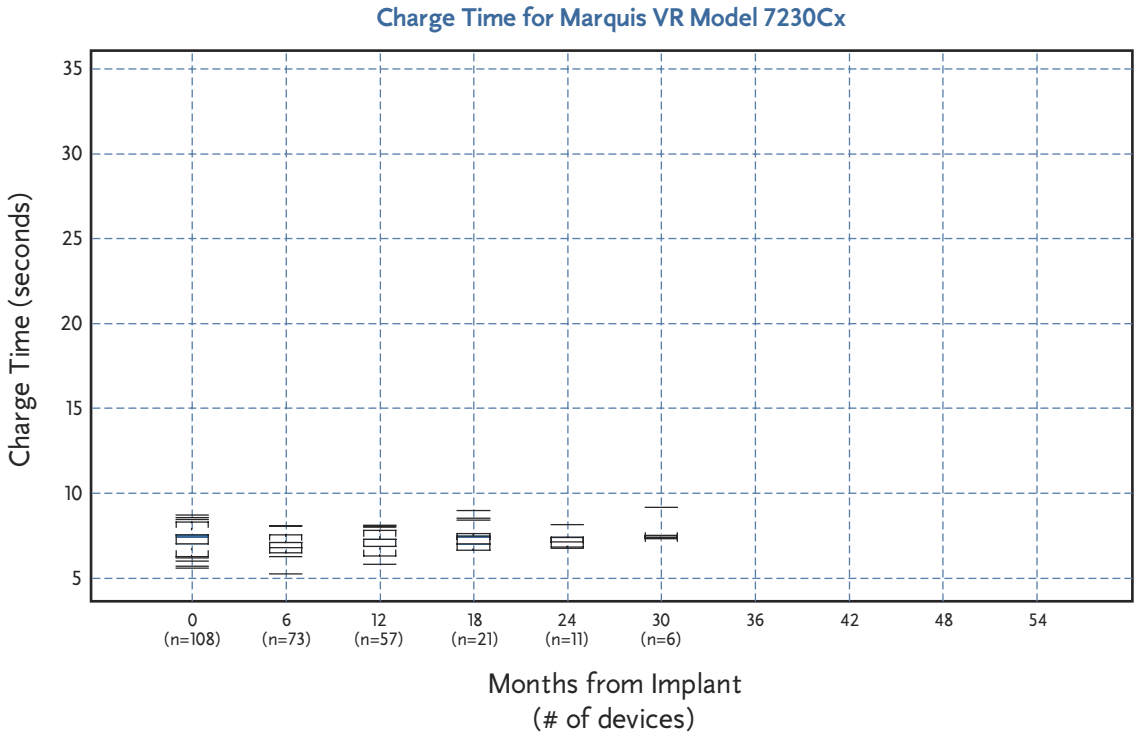
Save-to-Disk files have been collected 84 months post-implant. Charge times are generally below 15 seconds, with a maximum charge time of 18.09 seconds at 48 months.



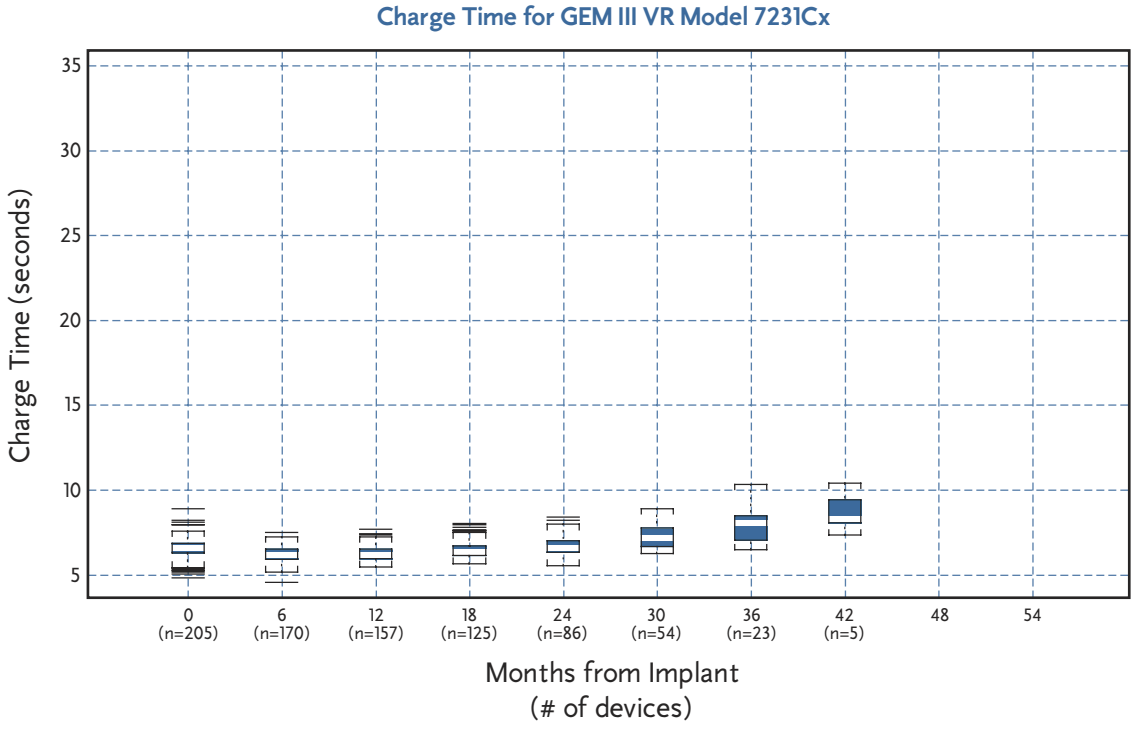
Save-to-Disk files have been collected 60 months post-implant. Charge times are consistently below 15 seconds, with a maximum charge time of 13.5 seconds observed at 54 months post-implant.



Save-to-Disk files have been collected 30 months post-implant. All observed charge times are less than 10 seconds with a maximum of 9.15 seconds observed at 30 months post-implant.

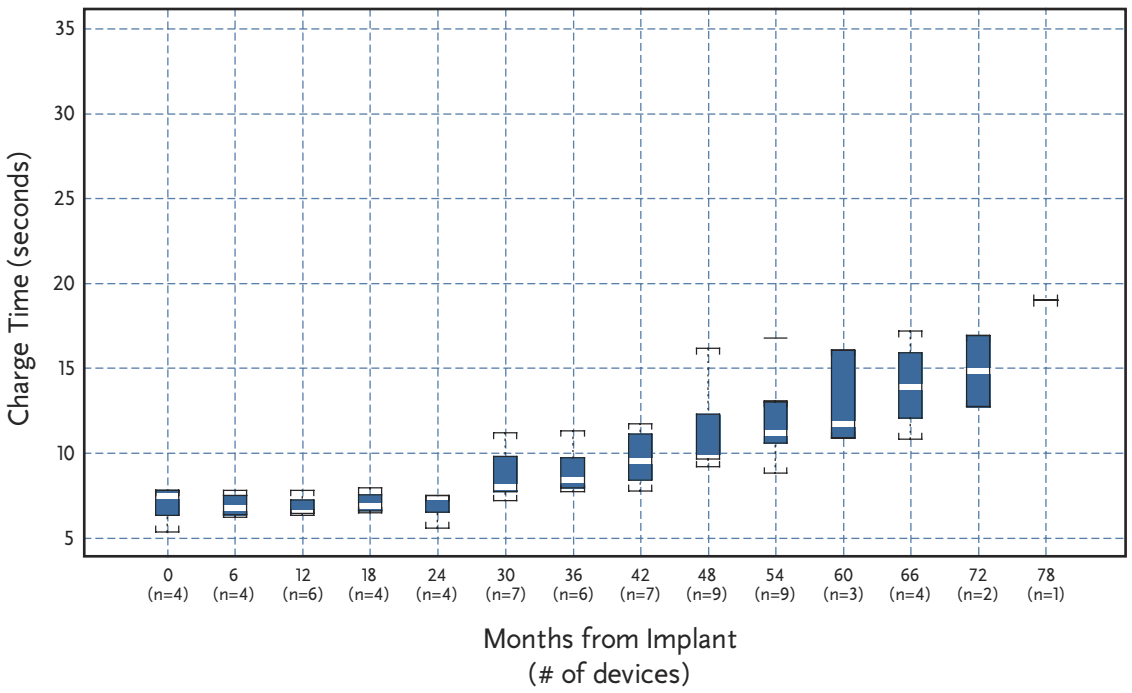


Save-to-Disk files have been collected 42 months post-implant. All observed charge times are less than 12 seconds with a maximum of 10.4 seconds seen at 42 months post-implant.



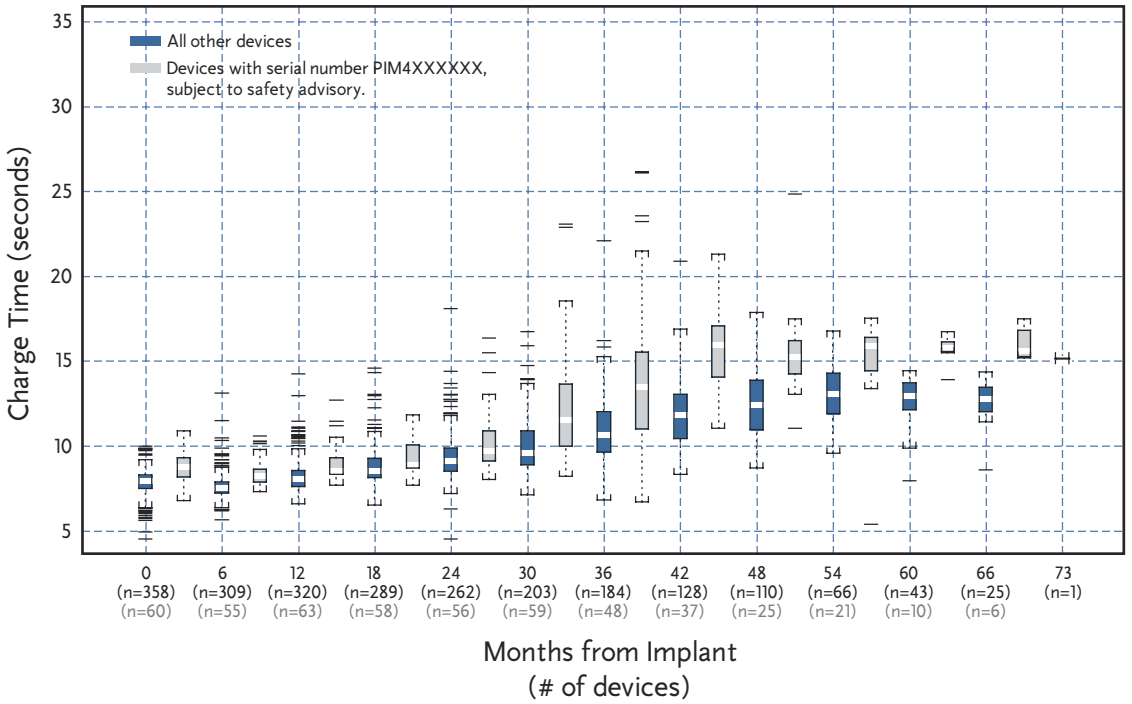
Save-to-Disk files have been collected 78 months post-implant. All observed charge times are less than 20 seconds with a maximum of 18.99 seconds observed at 78 months post-implant.

Charge Time for Jewel AF Model 7250

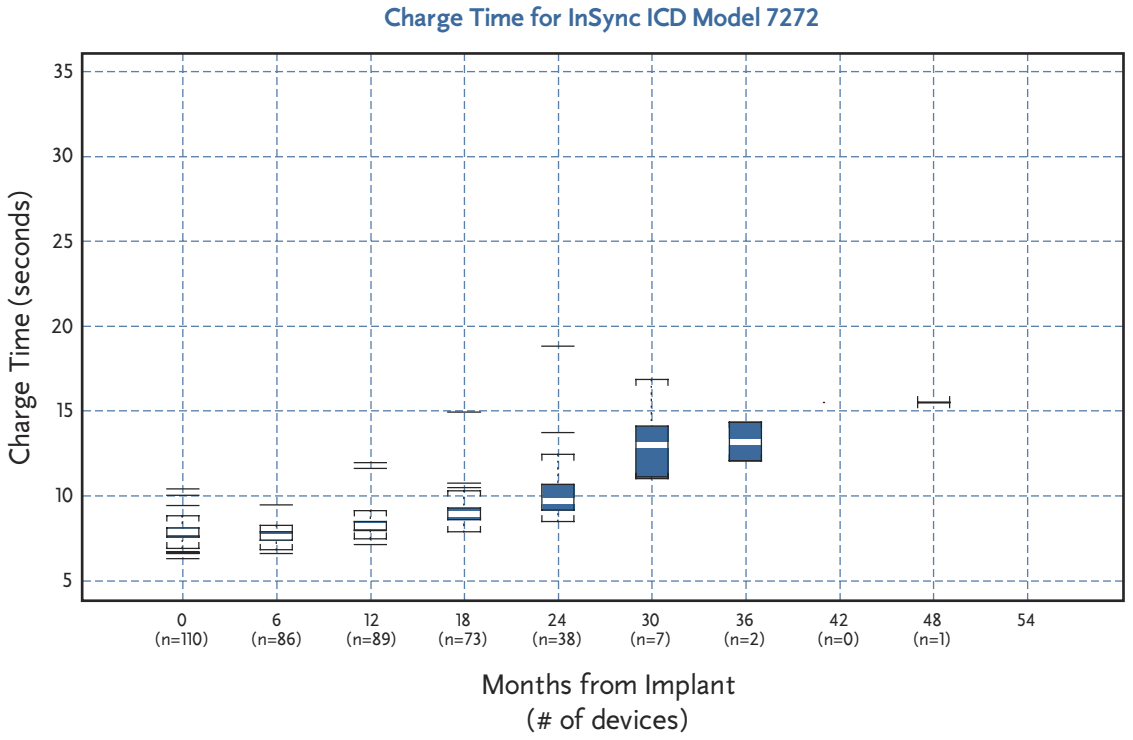


Save-to-Disk files have been collected 73 months post-implant. Charge times for devices implanted between the November 1, 1997 and December 31, 1998 time frame show gradually increasing charge time beyond 24 months with a maximum charge time of 26.15 seconds seen at 36 months. For the devices implanted prior to November 1, 1997, and after December 31, 1998, the charge times have a maximum of 22.07 seconds seen at 36 months post-implant.

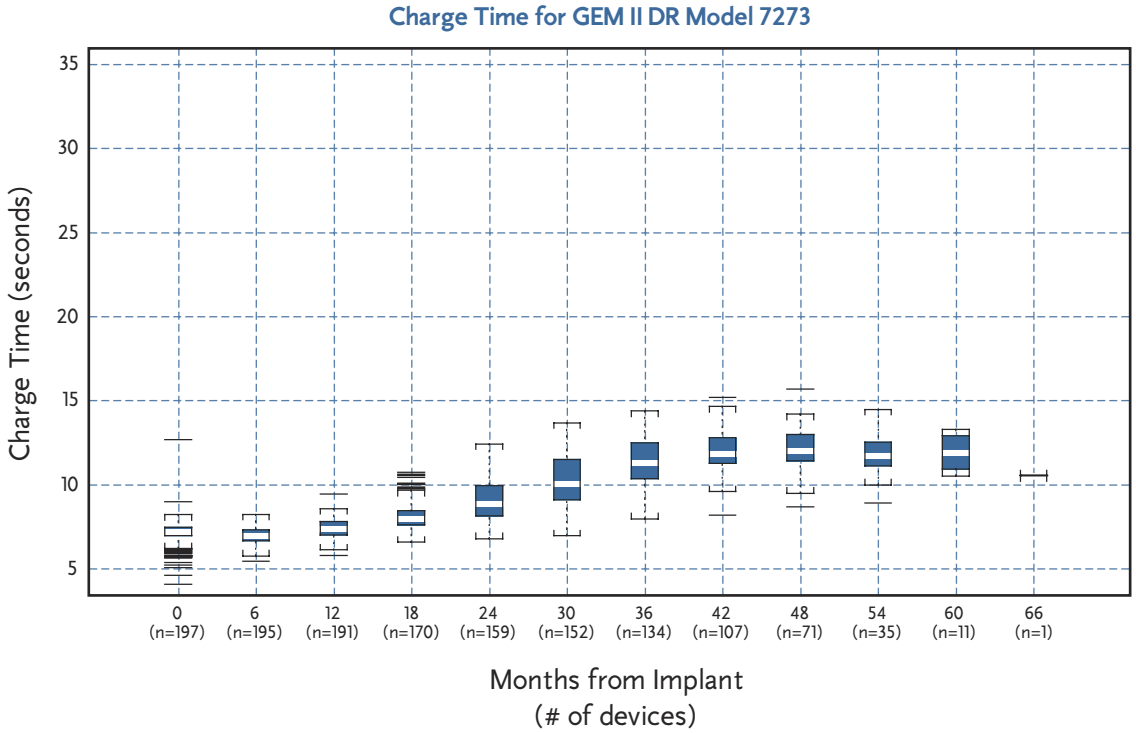
Charge Time for GEM DR Model 7271



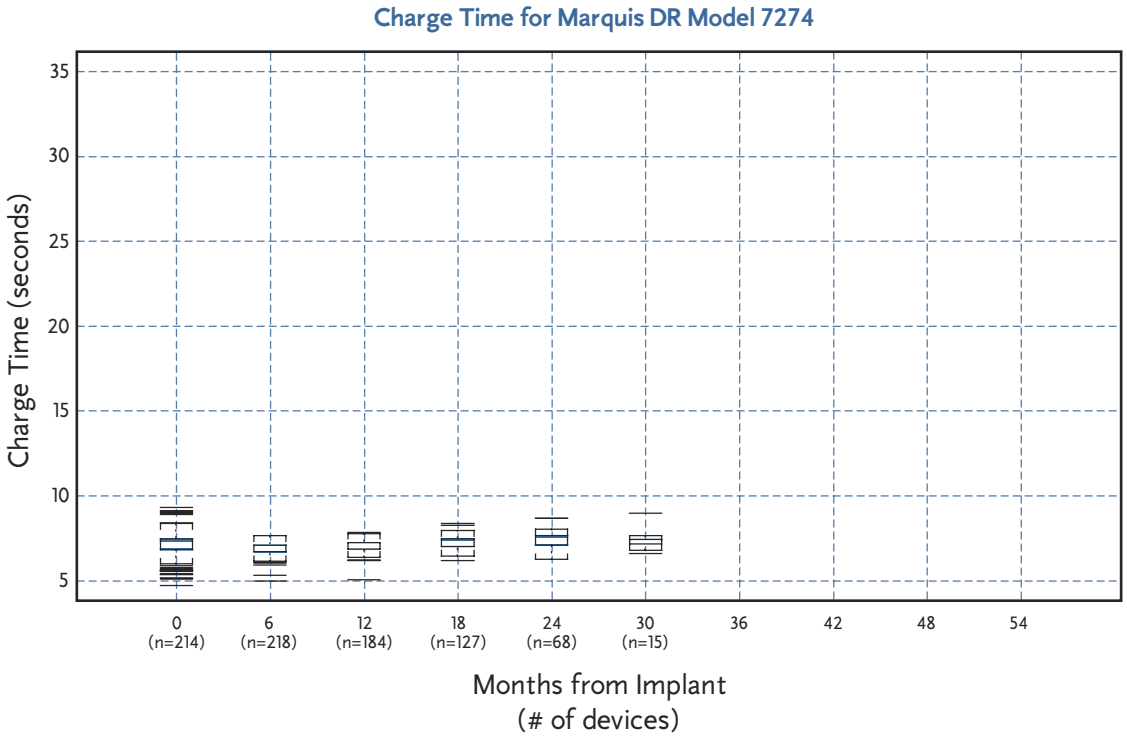
Save-to-Disk files have been collected 42 months post-implant. All observed charge times are less than 20 seconds with a maximum of 18.81 seconds observed at 24 months post-implant.



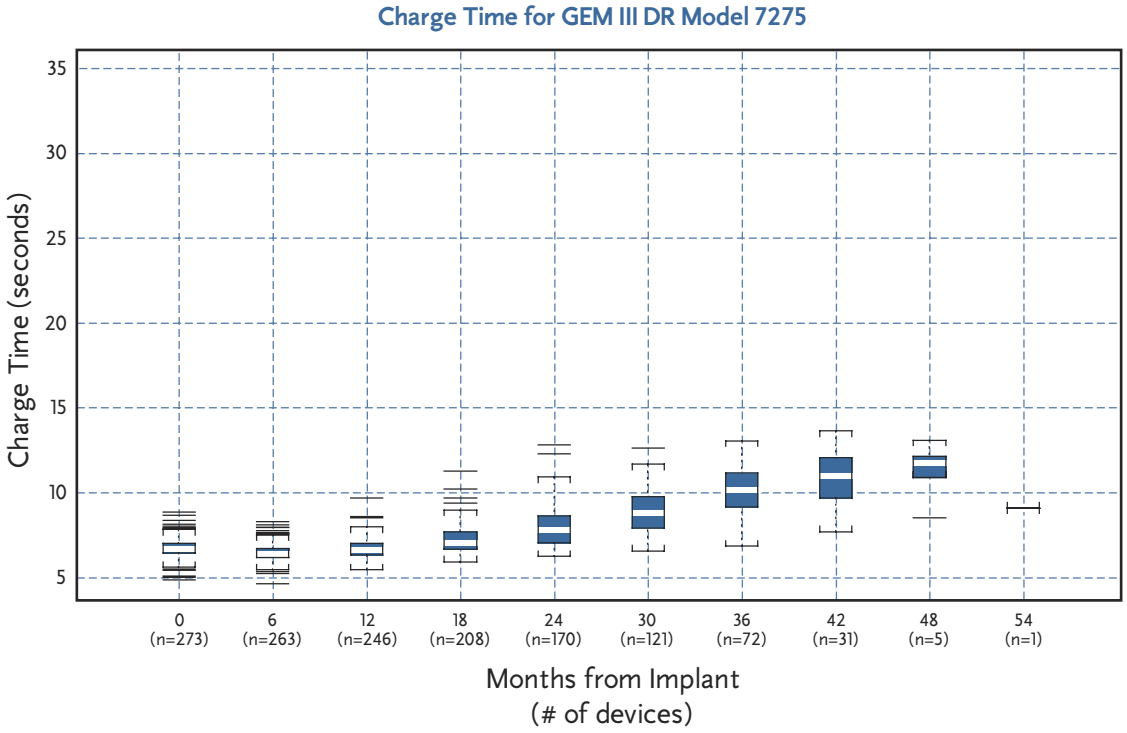
Save-to-Disk files have been collected 66 months post-implant. Charge times are generally below 15 seconds, with a maximum charge time of 15.69 seconds observed at 48 months post-implant.



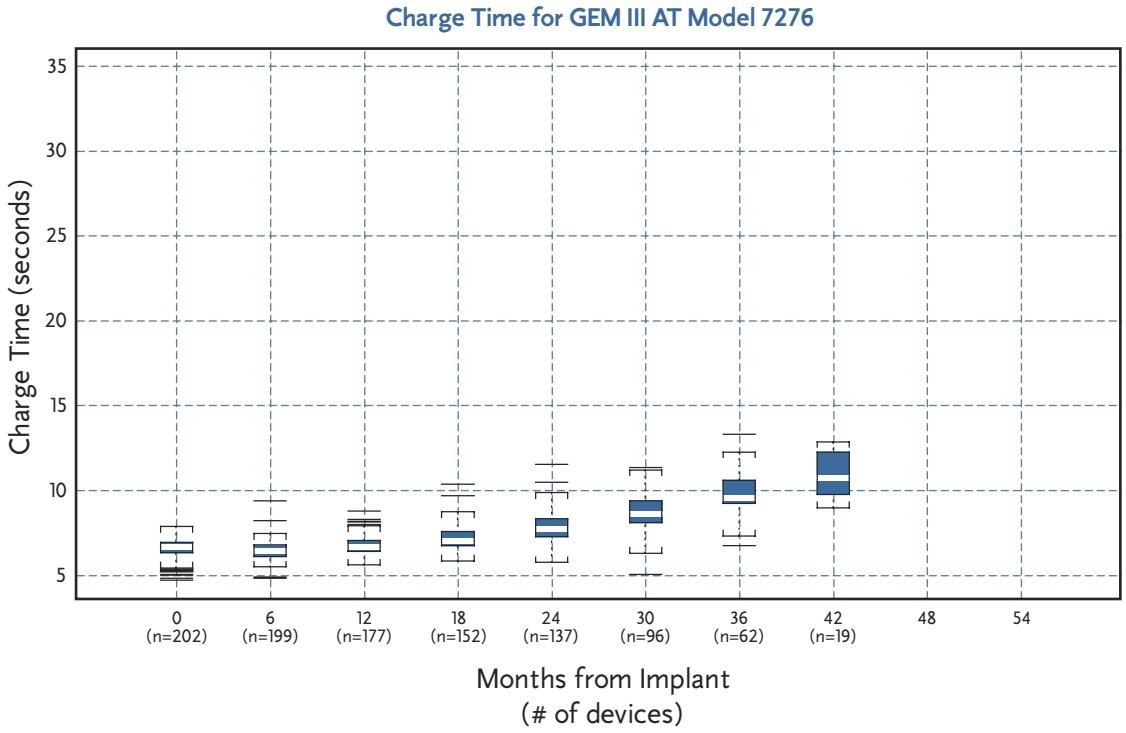
Save-to-Disk files have been collected 30 months post-implant. All observed charge times are less than 10 seconds with a maximum of 9.31 seconds observed at implant.



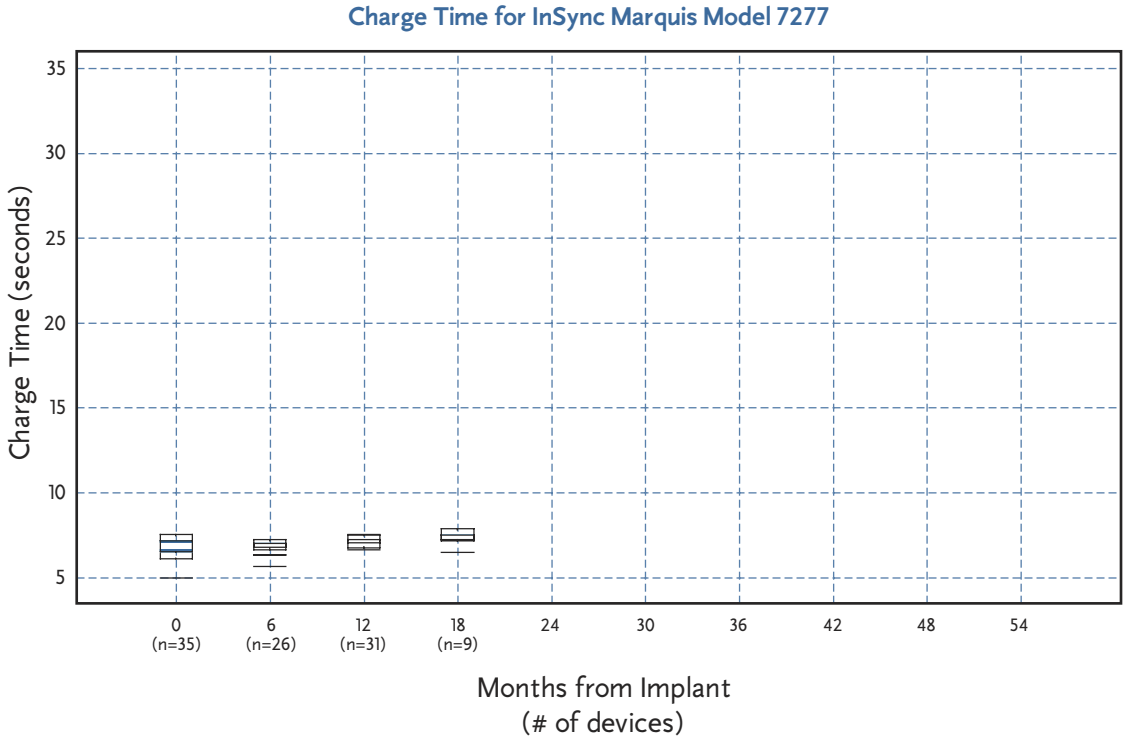
Save-to-Disk files have been collected 54 months post-implant. All observed charge times are less than 15 seconds with a maximum of 13.64 seconds seen at 42 months post-implant.



Save-to-Disk files have been collected 42 months post-implant. All observed charge times are less than 15 seconds with a maximum of 13.31 seconds observed at 36 months post-implant.

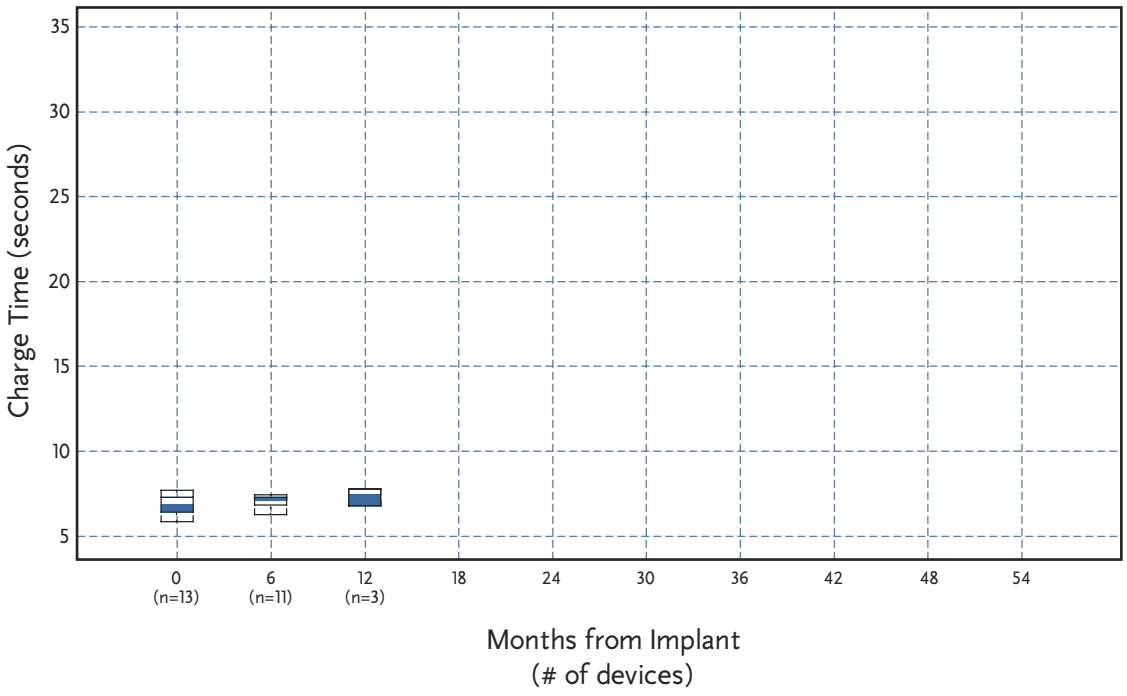


Save-to-Disk files have been collected 18 months post-implant. All observed charge times are less than 8 seconds with a maximum of 7.88 seconds observed at 18 months post-implant.



Save-to-Disk files have been collected 12 months post-implant. All observed charge times are less than 8 seconds with a maximum of 7.76 seconds observed at 12 months post-implant.

Charge Time for InSync II Marquis Model 7289



Advisories (Bradycardia)

Summarized below are advisories, safety alerts, and product recalls which have been issued/communicated to physicians concerning Medtronic bradycardia products, and which currently remain in effect.

Questions pertaining to the performance-related details of any listed or previous advisory or the product problem described should be directed to Medtronic Technical Services at 1-800-723-4636.

PRODUCT	ADVISORY	PATIENT MANAGEMENT RECOMMENDATIONS
AT500™ Pacing System	**September 15, 2003** Voluntary Physician Communication Medtronic has received fourteen 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 has 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 four 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 two-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. The affected devices are limited to a very small number of the AT500 devices 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. No other Medtronic devices are affected, nor are AT500 devices manufactured after October 2001.	There is a simple non-invasive procedure that will permanently correct the memory circuit preventing this 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. If you have 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.

Advisories (Continued)

PRODUCT	ADVISORY	PATIENT MANAGEMENT RECOMMENDATIONS
Kappa® 700/600 Dual Chamber (D, DR, and VDD) Kappa® 700/600 Dual Chamber (D, DR, and VDD) Implantable Pulse Generators with **submuscular implants** locations have been identified by serial numbers. Hospitals and Physicians were notified.	**March 15, 2002** Voluntary Physician Communication. 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.	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.
Sigma Implantable Pulse Generators	**September 27, 1999** Safety Alert letter. 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.	Medtronic representatives provided a list of affected device serial numbers. 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 judgement should, as always, dictate patient care. If you choose to replace the device, Medtronic will provide a new device under the applicable warranty program.
177 Thera Implantable Pulse Generators Worldwide (Models 7940/41/42/50, 8940/41/42/48). The 177 affected Thera Implantable Pulse Generators have been identified by serial number and each respective Physician has been notified. This action was completed in March 1997.	**February 18, 1997**. 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. 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.

Advisories (Continued)

PRODUCT	ADVISORY	PATIENT MANAGEMENT RECOMMENDATIONS
Model 4504/4504M Atrial CapSure Lead and Model 4582 Atrial Target Tip Lead	**October 4, 1996** letter. Lead survival probability is below expectations and is primarily associated with insulation degradation due to Metal Ion Oxidation (MIO).	■ 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.
Legend Plus Models 8446 and 8448 Implantable Pulse Generators	**June 14, 1996**. Potential for improper acceptance of the programming of a rate responsive mode resulting in irregular rate intervals.	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 judgement dictate patient care.
Model 4004/4004M, Ventricular CapSure Lead and Model 4082, Ventricular Target Tip Lead	**October 8, 1993** Health Safety Alert letter. Lead survival probability is below expectations due primarily to polyurethane insulation failure (MIO) and conductor fracture (associated with "subclavian crush").	■ 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. ■ Consider the use of unipolar if the pulse generator has this capability. ■ As always, individual circumstances and medical judgement 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.

Advisories (Continued)

PRODUCT	ADVISORY	PATIENT MANAGEMENT RECOMMENDATIONS
Model 4012, Ventricular Target Tip Lead	**September 26, 1991** Health Safety Alert letter. Lead survival probability beyond five years is below expectations due primarily to polyurethane insulation failure (due to ESC and/or MIO) and conductor fracture (associated with "subclavian crush").	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 judgement must be used to establish the appropriate schedule and course of care for every individual, particularly pacemaker-dependent or other patients at higher risk.
Minix, Minix ST, Micro Minix Implantable Pulse Generators	**May 6, 1991** letter. Possibility of delayed restoration of permanent pacing mode and parameters, after the magnet or programming head is removed under certain conditions.	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.

Advisories (Tachycardia)

Summarized below are advisories, safety alerts, and/or product recalls which have been issued/ communicated to physicians concerning Medtronic Tachyarrhythmia products included in this report, and which currently remain in effect. Questions pertaining to these advisories or any other product problem should be directed to Medtronic Technical Services at 1-800-723-4636.

PRODUCT	ADVISORY	PATIENT MANAGEMENT RECOMMENDATIONS
Micro Jewel® II Model 7223Cx and GEM® DR Model 7271 ICDs 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 V) and continuing through EOL (4.57 V). 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 V 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.	**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. 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.	*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 three months, through review of the patient's medical records. • Schedule replacement for any device with: - Battery voltage of 5.16 V 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 one month. If verified charge time is less than 14 seconds, no additional reprogramming is required. • Follow these patients every three months, at a minimum.
GEM® DR Model 7271 ICDs Affected devices consisting of < 20% of the GEM® DR builds between 1998 to 1999 have suspect batteries that could exhibit sudden increased charge times. Suspect devices are identified by the ICD serial numbers with engineering series number "4" only. For example, PIM4xxxxxx.	**November 14, 2002** letter. A separate written communication has been provided to physicians who have patients implanted with the affected devices, along with serial numbers of those devices. Suspect GEM® DR devices can exhibit sudden increase in charge times greater than 18 seconds at approximately 32 months post implant.	*The following recommendations apply to suspect GEM® DR 7271 devices.* 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 three 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. • Patient Alert™ for Excessive Charge Time should be programmed On. Eighteen seconds is the default setting for Patient Alert™ – Excessive Charge Time. • If the physician identifies any GEM® DR device with an unformed charge time of 18 seconds or greater, replacement of that device should be considered.

Advisories (Continued)

PRODUCT	ADVISORY	PATIENT MANAGEMENT RECOMMENDATIONS
Interchangeable Connector System Model 7227 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 Patient Alert™ 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.	**December 20, 2000** letter. Forty-five instances of this out of 1200 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	• **The Patient Alert™ option for "Lead Impedance Out-of-Range" should be enabled at the next scheduled follow-up for both the pacing and defibrillation lead.** This will support identification of patients with out-of-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 combination of both. The save-to-disk file can be sent as an e-mail attachment to crmtechnicalservices@medtronic.com. Medtronic Technical Services can also be contacted at 1-800-723-4636. • **After a high impedance trigger of the Patient Alert™ 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.
Micro Jewel® II Model 7223Cx ICDs 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. **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.	*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 three 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.
GEM® DR Model 7271 ICDs Affected devices can exhibit unformed charge times >18 seconds 12-24 months post implant.	**December 16, 1999** letter. 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. Devices displaying this behavior contain capacitors from specific component lots.	*The following recommendations apply to 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 one month. *Note: Stabilization and/or reduction in charge times may take 3-6 months to become apparent after programming the formation to one month.*

Advisories (Continued)

PRODUCT	ADVISORY	PATIENT MANAGEMENT RECOMMENDATIONS
GEM® II VR Model 7229Cx & GEM® II DR Model 7273 ICDs Affected devices have solder connection that may weaken over time and can result in loss of telemetry and device therapy output. **IMPORTANT REMINDER:** Medtronic strongly advises physicians who have patients under their care affected by this issue to reprogram the Patient Alert feature "ON" without delay.	**February 11, 2000** letter. Solder connections on a specific component may exhibit loss of integrity. Sixteen hundred devices with potential for this failure mode have been implanted worldwide. Medtronic estimates that this failure mode will affect less than 50 devices worldwide. **This issue does not affect other Medtronic devices or GEM II devices currently being supplied.**	*The following recommendations apply to GEM® II VR Model 7229Cx & GEM® II DR Model 7273 devices.* • Program "Lead Impedance Out-of-Range" to ON within the Patient Alert 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 out-of-range – this will cause an activated Patient Alert tone to sound. The Patient Alert feature will check the lead impedances once each day. • If the Patient Alert 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 Patient Alert tone should be investigated. **The Patient Alert parameter must be programmed ON for the remainder of the device life in order to detect any future occurrences of this failure mode.**
GEM® Model 7227Cx or GEM® II VR Model 7229Cx ICD Devices supplied before October 15, 1999, whose serial number terminates in an "H," e.g., PIPxxxxxxH or PJJxxxxxxH, where x is a variable numeric, may be affected **IMPORTANT REMINDER:** Medtronic strongly advises physicians who have patients under their care affected by this issue to reprogram the Patient Alert feature "ON" without delay.	**October 15, 1999** letter. 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."	• 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 ⇒ AX polarity pathway when compared to AX ⇒ B.* *Devices implanted with functional dedicated bipolar leads such as the 6932, 6934S, 6936, 6943, and 6966 are not affected.*
GEM® Model 7227Cx ICD Affected devices can be identified by reviewing battery voltage: If the battery voltage is >3.03 V and it is at least three months post-implant, then the ICD is not affected. Model 7227Cx devices delivered after April 2, 1999 are not affected.	**April 2, 1999** letter. 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.	Review battery voltage records for each 7227Cx patient. 1) If the battery voltage at implant was • ≤3.07 V or unknown, then bring the patient in for evaluation as soon as possible. • >3.07 V, then review the battery voltage at 3 months post-implant. 2) If the battery voltage at the three month follow-up is • ≤3.03 V, then contact your Medtronic representative for further evaluation. • >3.03 V, then no further action is required.

Technical Articles

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.

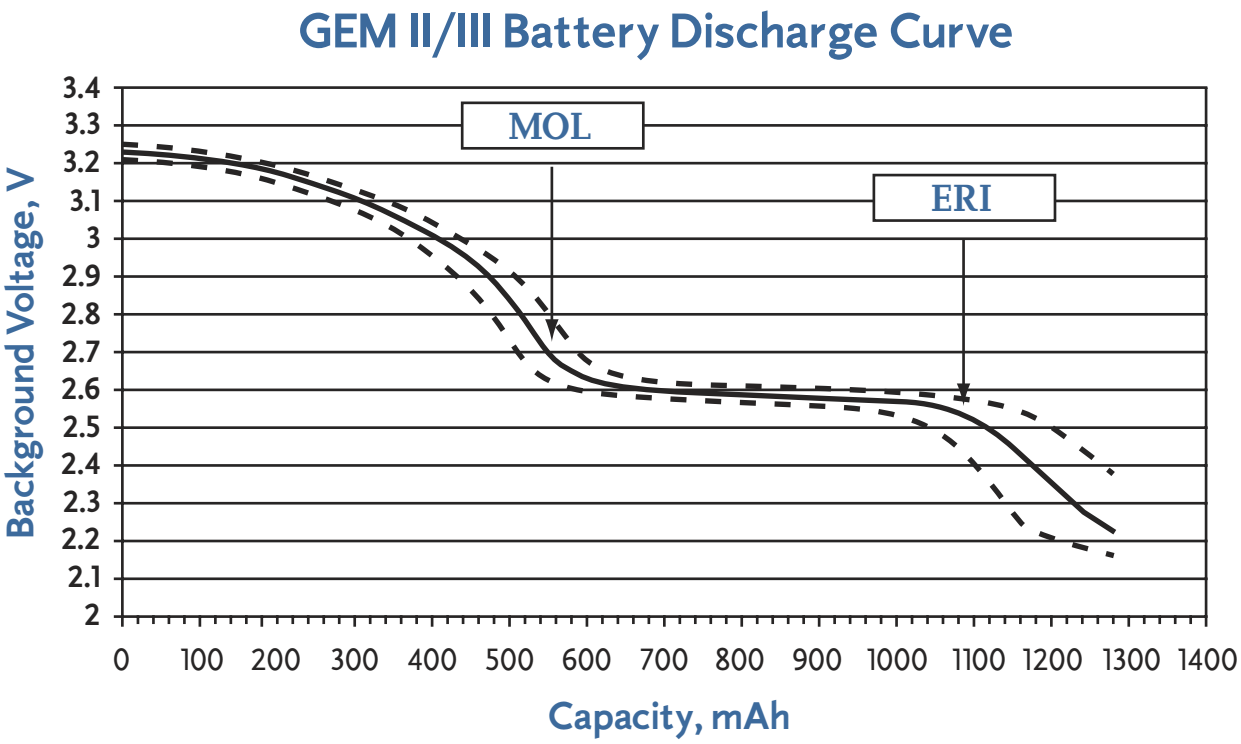
The battery discharge curve (see curve below) is characterized by a significant decrease in the battery voltage approaching middle-of-life (MOL), followed by a plateau (MOL to Elective Replacement Indicator) where the battery voltage remains around 2.6 volts. The transition to the plateau could be easily 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.



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 follow-up 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 Patient Alert™ and performance information from the Tachyarrhythmia Chronic Systems Study (TCSS).

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 five and ten 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 & 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 life-saving 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 six 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 U.S. 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
Pacing Impedance (Telemetered or Measured Invasively)	Sudden and Significant Decrease	Sudden and Significant Increase	Dislodgement ..... Decrease Perforation ..... Increase or Decrease Electrolyte Increase Imbalance ..... or Decrease Improper IPG/ Increase Lead Connection ..... or Decrease
Pacing Thresholds (Telemetered/Programmed or Measured Invasively)	Sudden and Significant Increase Especially in Bipolar System	Sudden and Significant Increase	Dislodgement ..... Increase Exit Block ..... Increase Infarct at Electrode Site ..... Increase Perforation ..... Increase Improper IPG/ Lead Connection ..... 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 ..... Decrease Perforation ..... Decrease Infarct at Electrode Site ..... Decrease Electrolyte Imbalance ..... Decrease Improper IPG/ Lead Connection ..... 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 ..... or Intermittent No Pacer Artifacts (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 ..... Sometimes Discernible
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

References

IPG Elective Replacement Time Indicators

Model		Indicators (Unless otherwise specified, "rate" refers to pacing rate without magnet applied)*
Spectrax 5940, 5940LP, 5941, 5984, 5984LP, 5985, 8420, 8422, 8423, 8423M, 5976, 5977 (SX-HT)		Rate decrease of 10% from preset or programmed rate. Telemetry indication in SXT family devices.
Classix	8436, 8437, 8438	30% increase in pulse width (measured with the Model 9431 transmitter). Rate decrease of 10% from programmed rate. Telemetry indication.
Minix **Minix ST**	8340, 8341, 8341M, 8342 8330, 8331, 8331M	Rate decrease of 10% from programmed rate. Telemetry indication.
Micro Minix	8360	Rate decrease of 10% from programmed rate. Telemetry indication. In a recent Product Education Brief, Medtronic provided an update to the longevity of the Micro Minix Model 8360 pacemaker. Recent 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.
Activitrax	8400, 8402, 8403, 8403M	Rate and mode change to 65 ppm and VVI (non-rate responsive). Telemetry indication.
Activitrax II **Legend** **Legend II**	8412, 8413, 8413M, 8414 8416, 8417, 8417M, 8418, 8419 8424, 8426, 8427	**If programmed to non-rate responsive mode (e.g. VVI), rate decrease of 10% from programmed rate.** Telemetry indication. If programmed to rate responsive mode (e.g. VVIR), rate change to 65 ppm and mode change to VVI. Telemetry indication.
Pasys **Pasys ST** **Prevail**	8320, 8322, 8329 8316, 8317, 8318 8084, 8085, 8086	Rate decrease of 10% from programmed rate. Telemetry indication.
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).
Elite **Elite II** **Minuet** **Symbios** **Thera-S** **Thera-i S** **Thera-SR** **Thera-i SR** **Thera-D** **Thera-i D** **Thera-DR 40** **Thera-i DR** **Thera-DR 50** **Thera-i VDD** **Prodigy D** **Prodigy DR** **Prodigy S** **Prodigy SR** **Preva SR** **Preva D** **Preva DR** **Preva ST** **Prevail S** **Kappa 400 SR** **Kappa 400 DR** **Kappa 700 SR** **Kappa 700 DR** **Kappa 700 D** **Kappa 700 DR** **Kappa 700 VDD** **Kappa 600 DR** **Kappa 600 DR** **Kappa 900 SR** **Kappa 900 DR** **Kappa 920 DR** **Kappa 900 VDD** **Kappa 800 DR** **Sigma 300 SR** **Sigma 300 DR** **Sigma 200 SR** **Sigma 200 DR** **Sigma 300 VDD** **Sigma 100 S** **Sigma 300 S** **Sigma 200 D** **InSync**	7074, 7075, 7076, 7077 7084, 7085, 7086 7107, 7108 7005, 7005C, 7006, 7008 8944, 8945, 8946 8964i, 8965i, 8966i 8940, 8941, 8942 8960i, 8961i, 8962i 7944, 7945, 7946 7964i, 7965i, 7966i 7940, 7941, 7942 7960i, 7961i, 7962i, 7968i 7950, 7951, 7952 8968i 7864, 7865, 7866 7860, 7861, 7862 8164, 8165, 8166 8158, 8160, 8161, 8162 8088, 8089 7068 7088, 7089 DR 7078 8085, 8086 KSR401, KSR403 KDR401, KDR403 KSR701, KSR703, KSR706 KDR701, KDR703, KDR706 KDR701 KDR721 KVDD700, KVDD701 KDR601, KDR603, KDR606 KDR651, KDR653 KSR901, KSR903, KSR906 KDR901, KDR903, KDR906 KDR921 KVDD901 KDR801, KDR803 SSR303, SSR306 SDR303, SDR306 SSR203 SDR203 SVDD303 SS103, SS106 SS303 SD203 8040	- Telemetry indication. - Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).

*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 (see page 2).

References (Continued)

ICD Reference Chart

Model	Connector Style	Volume/ mass*	Delivered Energy	Estimated Longevity					Elective Replacement (ERI)***		End of Life
				Charging Frequency**	100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Battery Voltage	or Charge Time	(EOL) Battery Voltage
GEM III AT 7276	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
GEM III DR 7275	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
GEM III VR 7231	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
GEM II DR 7273	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
GEM II VR 7229	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
GEM DR 7271	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§§
GEM 7227	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§§
Jewel AF 7250	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
Micro Jewel II 7223	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‡‡
Micro Jewel 7221	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‡‡
Jewel 7219	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
Jewel Plus 7220	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
Jewel CD 7202	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
Marquis DR 7274	DR	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		≤ 2.55 V
Marquis VR 7230	Cx	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		≤ 2.55 V
InSync ICD 7272	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
InSync Marquis 7277	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	NA	3 months after ERI
InSync II Marquis 7289	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	NA	3 months after ERI
Maximo DR 7278	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	NA	3 months after ERI
Maximo VR 7232	Cx	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	NA	3 months after ERI

* Volume mass differs by connector style.

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

*** The minimum time between ERI and EOL is three months (100% pacing, bimonthly charges).

‡ Pacing specification is DDD for dual chamber devices and VVI for others:
60 ppm, 3.0 V, 0.4 ms, 510 ohms for 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 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 7271 and 7227 devices, if charge time exceeds 30 seconds, the device is at EOL. Immediate replacement is recommended. If three consecutive charge cycles exceed 30 seconds, the "charge circuit inactive" indicator is tripped and all therapies except emergency VVI pacing are disabled.

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

References (Continued)

ICD Lead Reference Chart

Family	Model	U.S. Market Release Date	Type	Pin Configuration		Lead Body Diameter	Insulation, Lead Body	Fixation, Steroid
				Pace/ Sense	High Voltage			
Sprint Quattro Secure	6947	Nov 2001	Endo RV/SVC (Quadripolar)	IS-1	2 DF-1	8.2 Fr	Silicone† Multilumen	Active Steroid
Sprint Quattro	6944§	Dec 2000	Endo RV/SVC (Quadripolar)	IS-1	2 DF-1	8.2 Fr	Silicone† Multilumen	Passive, Steroid
Sprint	6945+	Mar 1998	Endo RV/SVC	IS-1	2 DF-1	7.8 Fr	Silicone, Multilumen	Active, Steroid
	6943§	Sep 1997	Endo RV	IS-1	DF-1	7.8 Fr	Silicone, Multilumen	Active, Steroid
	6942+	Jul 1997	Endo RV/SVC	IS-1	2 DF-1	7.8 Fr	Silicone, Multilumen	Passive, Steroid
	6932§	Aug 1996	Endo RV	IS-1	DF-1	7.8 Fr	Silicone, Multilumen	Passive, Steroid
Transvene	6934S§	Mar 1996	Endo RV	IS-1	DF-1	12 Fr	Silicone, Coaxial	Passive, Steroid
	6936§	Apr 1994	Endo RV	IS-1	DF-1	10 Fr	Polyurethane, Coaxial	Active
	6966§	Dec 1993	Endo RV	3.2 mm L.P.	6.5 mm	10 Fr	Polyurethane, Coaxial	Active
	6937A	Apr 2001	Endo SVC	—	DF-1	7.5 Fr	Silicone, Single Lumen	Passive
	6937	Mar 1996	Endo SVC	—	DF-1	5.5 Fr	Silicone, Single Lumen	Passive
	6933	Apr 1994	Endo SVC/CS	—	DF-1	7 Fr	Silicone, Single Lumen	Passive
	6963	Dec 1993	Endo SVC/CS	—	6.5 mm	7 Fr	Silicone, Single Lumen	Passive
Sub Q Patch	6939	Apr 1994	SQ Patch	—	DF-1	One Size	Silicone, Single Lumen	Suture
	6999	Dec 1993	SQ Patch	—	6.5 mm	One Size	Silicone, Single Lumen	Suture
Epicardial Patch	6721	Mar 1994	Epi Patch	—	DF-1	S, M, L	Silicone, Single Lumen	Suture
	6921	Feb 1993	Epi Patch	—	6.5 mm	S, M, L	Silicone, Single Lumen	Suture
CapSureFix	6940§	Nov 1998	Pace/Sense	IS-1	—	7.8 Fr	Silicone, Coaxial	Active

+ Integrated bipolar sensing.
§ True bipolar sensing.
† Silicone insulation with Isoglide™ polyurethane overlay.

References (Continued)

Ventricular Pacing Leads Reference Chart

Model[1]	Avail[2]	Type	Brand Name	Insulation[3]	Conductor Material[4]	Tip Electrode	Connector Type
4003/4003M	N	Transvenous Ventricular Tines	CapSure	Polyurethane (80A)	MP35N 4 Filars	Porous/Steroid	5 mm (4003) IS-1 UNI (4003M)
4004/4004M	N**	Transvenous Ventricular Tines	CapSure	Polyurethane (80A)	MP35N 6/4 Filars*	Porous/Steroid	3.2 mm Low Profile (4004) IS-1 BI (4004M)
4011	N	Transvenous Ventricular Tines	Target Tip	Polyurethane (80A)	MP35N 4 Filars	Target Tip Concentric Grooves	5 mm
4012	N**	Transvenous Ventricular Tines	Target Tip	Polyurethane (80A)	MP35N 6/4 Filars	Target Tip Concentric Grooves	3.2 mm Low Profile
4016	N	Transvenous V or A Screw-In	N/A	Polyurethane (80A/55D)	MP35N 4/2 Filars	1.5 mm Helix	3.2 mm Low Profile
4016A	N	Transvenous V or A Screw-In	N/A	Polyurethane (80A/55D)	MP35N 4/2 Filars*	2.0 mm Helix	3.2 mm Low Profile
4023	Y	Transvenous Ventricular Tines	CapSure SP	Polyurethane (55D)	MP35N 4 Filars*	Porous Platinized/Steroid	IS-1 UNI
4024	N	Transvenous Ventricular Tines	CapSure SP	Polyurethane (55D)	MP35N 4/5 Filars*	Porous Platinized/Steroid	IS-1 BI
4033	Y*	Transvenous Ventricular Tines	CapSure Z	Polyurethane (55D)	MP35N 2 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
4057/4057M	N	Transvenous V or A Screw-In	N/A	Polyurethane (80A)	MP35N 1 Filar	2.0 mm Helix	5 mm (4057) IS-1 UNI (4057M)
4058/4058M	N	Transvenous V or A Screw-In	N/A	Polyurethane (80A/55D)	MP35N 4/1 Filars*	2.0 mm Helix	3.2 mm Low Profile (4058) IS-1 BI (4058M)
4067	Y	Transvenous V or A Screw-In	CapSureFix	Polyurethane (80A)	MP35N 3 Filars	1.8 mm Helix/Steroid	IS-1 UNI
4068	Y	Transvenous V or A Screw-In	CapSureFix	Polyurethane (80A/55D)	MP35N 4/3 Filars*	1.8 mm Helix/Steroid	IS-1 BI
4081	N	Transvenous Ventricular Tines	Target Tip	Polyurethane (80A)	MP35N 4 Filars	Target Tip Concentric Grooves	IS-1 UNI w/Removable 5 mm Sleeve
4082	N**	Transvenous Ventricular Tines	Target Tip	Polyurethane (80A)	MP35N 6/4 Filars*	Target Tip Concentric Grooves	IS-1 BI
4092	Y	Transvenous Ventricular Tines	CapSure SP Novus	Polyurethane/Silicone (55D/4719)	MP35N 6/4 Filars	Porous Platinized/Steroid	IS-1 BI
5023/5023M	Y	Transvenous Ventricular Tines	CapSure SP	Silicone	MP35N 4 Filars	Porous Platinized/Steroid	5 mm (5023) IS-1 UNI (5023M)
5024/5024M	N	Transvenous Ventricular Tines	CapSure SP	Silicone	MP35N 4/5 Filars	Porous Platinized/Steroid	3.2 mm Low Profile (5024) IS-1 BI (5024M)
5025	N	Transvenous Ventricular Tines	CapSure	Silicone	MP35N 4 Filars	Porous Platinized/Steroid	5 mm Unipolar
5026	N	Transvenous Ventricular Tines	CapSure	Silicone	MP35N 6/4 Filars	Porous Platinized/Steroid	3.2 mm Low Profile
5032	Y	Transvenous V or A Tines	CapSure VDD	Silicone	MP35N 5/6/1 Filars	Porous Platinized/Steroid	IS-1 BI
5033	N	Transvenous Ventricular Tines	CapSure Z	Silicone	MP35N 4 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
5034	N	Transvenous Ventricular Tines	CapSure Z	Silicone	MP35N 4/5 Filars	CapSure Z Platinized/Steroid	IS-1 BI
5038	Y	Transvenous Ventricular Tines	VDD Single Pass	Silicone	MP35N	Porous Platinized/Steroid	IS-1 Quadripolar
5054	Y	Transvenous Ventricular Tines	CapSure Z Novus	Silicone (4719)	MP35N 5/5 Filars	CapSure Z Porous/Platinized/ Steroid	IS-1 BI
5061	N	Transvenous Ventricular Tines	Target Tip	Silicone	MP35N 4 Filars	Target Tip Concentric Grooves	5 mm
5062	N	Transvenous Ventricular Tines	Target Tip	Silicone	MP35N 6/4 Filars	Target Tip Concentric Grooves	3.2 mm Low Profile
5064	N	Transvenous Ventricular Tines	Target Tip	Silicone	MP35N 4 Filars	Target Tip Concentric Grooves	5 mm Bifurcated
5067	Y	Transvenous V or A Screw-In	CapSureFix	Silicone	MP35N 3 Filars	1.8 mm Helix/Steroid	IS-1 UNI
5068	Y	Transvenous V or A Screw-In	CapSureFix	Silicone	MP35N 4/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
5072	Y	Transvenous V or A Screw-In	SureFix	Silicone	MP35N 4/5 Filars	1.8 mm Helix/Steroid	IS-1 BI
5076	Y	Transvenous V or A Screw-In	CapSureFix Novus	Silicone (4719)	MP35N 4/5 Filars	Porous Platinized/Steroid	IS-1 BI
5092	Y	Transvenous Ventricular Tines	CapSure SP Novus	Silicone (4719)	MP35N 5/5 Filars	Porous Platinized/Steroid	IS-1 BI
6907	N	Transvenous Ventricular Flange	N/A	Silicone	MP35N 2 Filars	Cylinder Tip	5 mm
6907R	N	Transvenous Ventricular Flange	N/A	Silicone	MP35N 2 Filars	Ring Tip	5 mm
6957	N	Transvenous V or A Screw-In	Spectraflex	Polyurethane (80A)	MP35N 1 Filar	2.0 mm Helix	5 mm
6961	N	Transvenous Ventricular Tines	Tenax	Silicone	MP35N 3 Filars	Ring Tip	5 mm
6962	N	Transvenous Ventricular Tines	Tenax	Silicone	MP35N 4 Filars	Ring Tip	5 mm Bifurcated

[1] Even-numbered models are bipolar leads; odd-numbered models are unipolar leads.
[2] Currently available: Y = Yes; N = No. *Not available in the United States. **Indicates past advisory or safety alert.
[3] Polyurethane 55D and 80A are different formulations.
[4] Asterisk indicates leads with barrier coating (Outer/Inner Filars).

References (Continued)

Atrial Pacing Leads Reference Chart

Model[1]	Avail[2]	Type	Brand Name	Insulation[3]	Conductor Material[4]	Tip Electrode	Connector Type
4503/ 4503M	N	Transvenous Atrial-J Tines	CapSure	Polyurethane (80A)	MP35N 4 Filars	Porous/Steroid	5 mm (4503) IS-1 UNI (4503M)
4504/ 4504M	N**	Transvenous Atrial-J Tines	CapSure	Polyurethane (80A)	MP35N 3/4 Filars*	Porous/Steroid	3.2 mm Low Profile (4504) IS-1 BI (4504M)
4511	N	Transvenous Atrial-J Tines	Target Tip	Polyurethane (80A)	MP35N 4/3 Filars	Target Tip Concentric Grooves	5 mm
4512	N	Transvenous Atrial-J Tines	Target Tip	Polyurethane (80A)	MP35N 2/4 Filars	Target Tip Concentric Grooves	3.2 mm Low Profile
4523	Y	Transvenous Atrial-J Tines	CapSure SP	Polyurethane (55D)	MP35N 2 Filars*	Porous Platinized/Steroid	IS-1 UNI
4524	N	Transvenous Atrial-J Tines	CapSure SP	Polyurethane (55D)	MP35N 4/5 Filars*	Porous Platinized/Steroid	IS-1 BI
4533	N*	Transvenous Atrial-J Tines	CapSure Z	Polyurethane (55D)	MP35N 2 Filars	CapSure Z Platinized/Steroid	IS-1 UNI
4557/ 4557M	Y	Transvenous Atrial-J Screw-In	N/A	Polyurethane (80A)	MP35N 1 Filar	1.5 mm Helix	5 mm (4557) IS-1 UNI (4557M)
4558M	Y	Transvenous Atrial-J Screw-In	N/A	Polyurethane (80A/55D)	MP35N 6/3 Filars*	1.8 mm Helix	IS-1 BI
4568	Y	Transvenous Atrial-J Screw-In	CapSureFix	Polyurethane (80A/55D)	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
4592	Y	Transvenous Atrial-J Tines	CapSure SP Novus	Polyurethane/Silicone (55D/4719)	MP35N 6/3 Filars	Porous Platinized/Steroid	IS-1 BI
5524/ 5524M	Y	Transvenous Atrial-J Tines	CapSure SP	Silicone	MP35N 6/5 Filars	Porous Platinized/Steroid	3.2 mm Low Profile (5524) IS-1 BI (5524M)
5534	N	Transvenous Atrial Tines	CapSure Z	Silicone	MP35N 4/5 Filars	CapSure Z Platinized/Steroid	IS-1 BI
5554	Y	Transvenous Atrial	CapSure Z Novus	Silicone (4719)	MP35N 6/5 Filars	CapSure Z Porous Platinized/Steroid	IS-1 BI
5568	Y	Transvenous Atrial-J Screw-In	CapSureFix	Silicone	MP35N 6/3 Filars	1.8 mm Helix/Steroid	IS-1 BI
5592	Y	Transvenous Atrial-J Tines	CapSure SP Novus	Silicone (4719)	MP35N	Porous Platinized/Steroid	IS-1 BI
6957J	N	Transvenous Atrial-J Screw-In	Spectraflex	Polyurethane (80A)	MP35N 1 Filar	1.5 mm Helix	5 mm

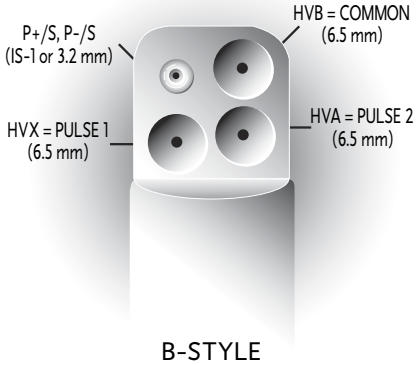
Epi/Myocardial Pacing Leads Reference Chart

Model[1]	Avail[2]	Type	Brand Name	Insulation[3]	Conductor Material[4]	Tip Electrode	Connector Type
4951/ 4951M	Y	Myocardial Stab-In V or A/Peds	Spectraflex	Polyurethane (80A)	MP35N 4 Filars	Barb	5 mm IS-1 UNI (4951M)
4965	Y	Epicardial Suture-On V or A	CapSure Epi	Silicone	MP35N 5 Filars	Porous Platinized Steroid	IS-1 UNI
4968	Y	Epicardial Suture-On V or A	CapSure Epi	Silicone	MP35N 5 Filars	Porous Platinized Steroid	IS-1 BI
5069	Y	Myocardial Screw-In	N/A	Silicone	MP35N Multifilars	3-Turn Helix	IS-1 UNI
5071	Y	Myocardial Screw-In	N/A	Silicone	MP35N Multifilars	2-Turn Helix	IS-1 UNI
6917AT	N	Myocardial Screw-In Ventricular	Tenax	Silicone	Pt Ir Tinsel Wire	2-Turn Helix	5 mm
6917T	N	Myocardial Screw-In Ventricular	Tenax	Silicone	Pt Ir Tinsel Wire	3-Turn Helix	5 mm

[1] Even-numbered models are bipolar leads; odd-numbered models are unipolar leads.
[2] Currently available: Y = Yes; N = No. *Not available in the United States. **Indicates past advisory or safety alert.
[3] Polyurethane 55D and 80A are different formulations.
[4] Asterisk indicates leads with barrier coating (Outer/Inner Filars).

References (Continued)

ICD Connector Styles



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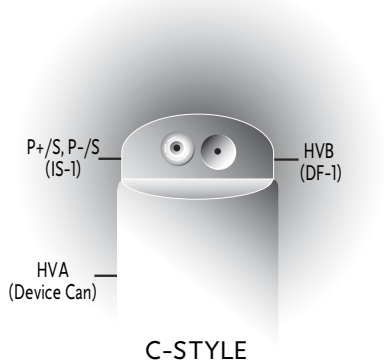

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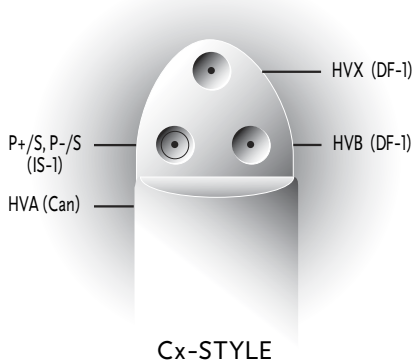

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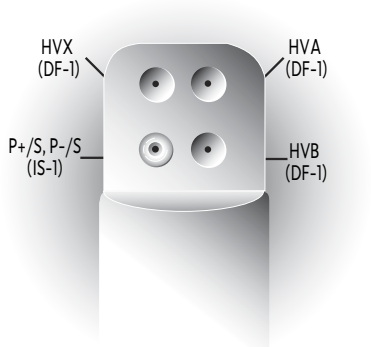

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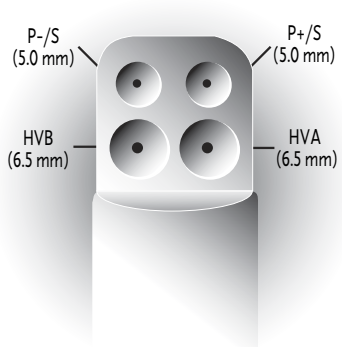

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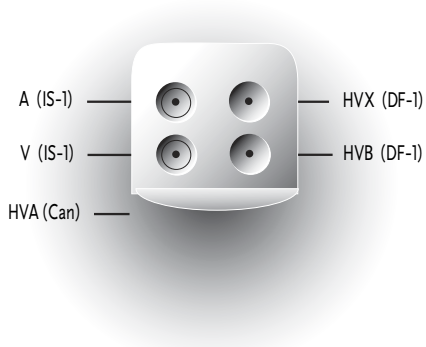

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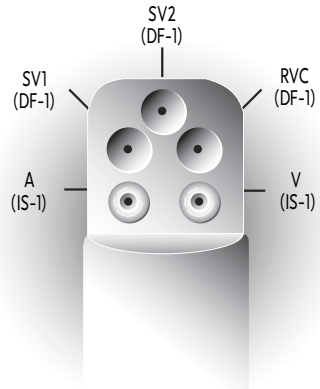

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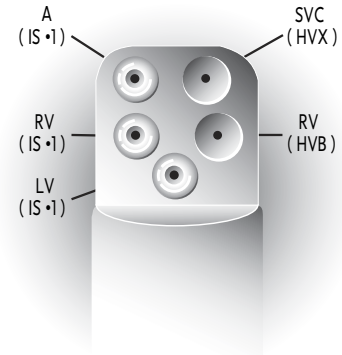

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Medtronic

When Life Depends on Medical Technology

World Headquarters
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879
www.medtronic.com

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for
physicians and medical professionals)

Europe
Medtronic Europe Sàrl
Route du Molliau
CH-1131 Tolochenaz
Switzerland
Tel: (41 21) 802 7000
Fax: (41 21) 802 7900
www.medtronic.com

Canada
Medtronic of Canada Ltd.
6733 Kitimat Road
Mississauga, Ontario L5N 1W3
Canada
Tel: (905) 826-6020
Fax: (905) 826-6620
Toll-free: 1 (800) 268-5346

Asia Pacific
Medtronic International, Ltd.
16/F Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel: (852) 2891 4456
Fax: (852) 2891 6830
enquiryap@medtronic.com
www.medtronic.com

Latin America
Medtronic, Inc.
2700 S. Commerce Parkway Ste. 105
Weston, FL 33331
USA
Tel: (954) 384-4500
Fax: (954) 306-0176
www.medtronic.com

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