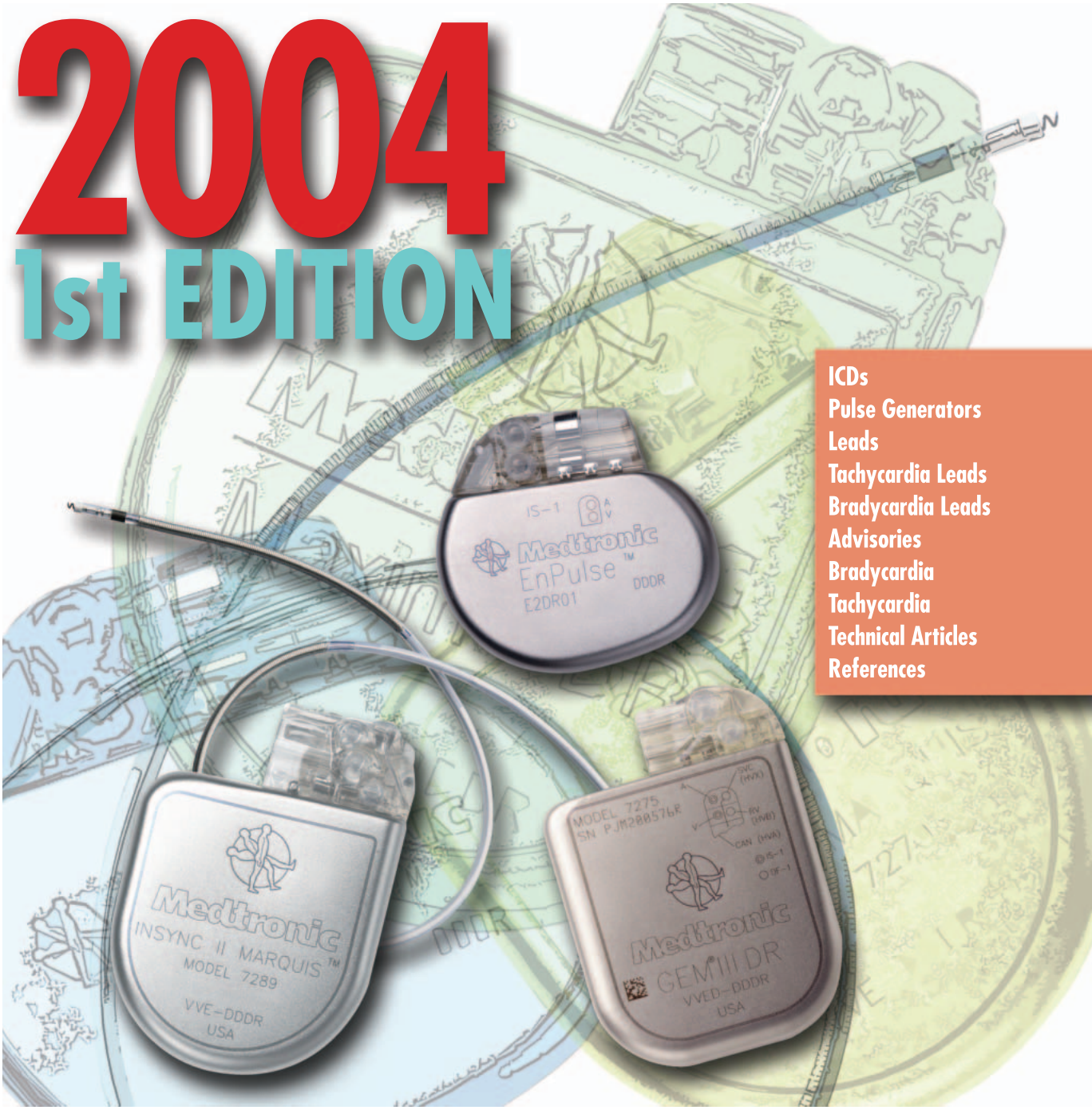
Medtronic

CRM PRODUCT PERFORMANCE REPORT

2004
1st EDITION



ICDs
Pulse Generators
Leads
Tachycardia Leads
Bradycardia Leads
Advisories
Bradycardia
Tachycardia
Technical Articles
References

Important Patient Management Information for Physicians

CRM Product Performance Report
is now available on

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Medtronic Mission:

"To Strive Without Reserve for the Greatest Possible Reliability and Quality in Our Products"

Medtronic insists our customers are well informed about our product performance

The 2004 First Edition of the CRM Product Performance Report introduces a new format. In past publications, Medtronic has published the Brady and Tachy reports separately. Starting with this edition and future issues, they will be combined into one report. This provides you, our customer, the advantage of having all leads and device information in one report.

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 (CLS), 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. is 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.

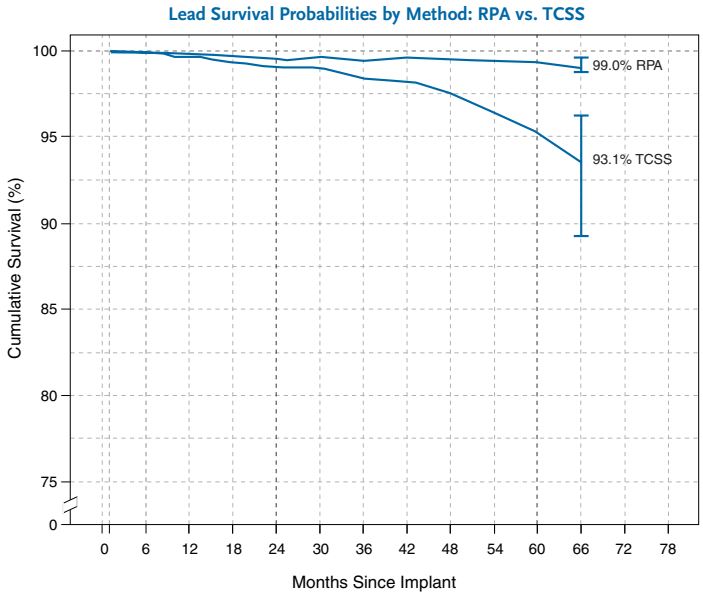
In contrast, because a small percentage of leads are returned to the manufacturer (due to the difficulty of extracting them), a much less accurate estimate of lead survival is generated when the results are based solely on Returned Product Analysis.

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

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

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1st EDITION

2004

New for this edition

Implantable Cardiac Defibrillation

- InSync Marquis Model 7277 has been added to the ICD Returned Product table on page 15 and the survival chart on page 9.
- InSync II Marquis Model 7289 has been added to the ICD Returned Product table on page 15 and the survival chart on page 9.

Pacing Leads

- CapSure Sense Lead Model 4074 has been added to the Lead Survival table on pages 41 and 44 and the Laboratory Analysis table on page 45.
- CRT Lead 4193 has been added to Lead Survival table on pages 36 and 37 and the Laboratory Analysis table on page 38.

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Implantable Cardioverter Defibrillators

Returned Product Analysis

Introduction

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:

- **GEM DR ICD** Model 7271
- **GEM ICD** Model 7227
- **GEM II DR ICD** Model 7273
- **GEM II ICD** Model 7229Cx
- **GEM III AT ICD** Model 7276
- **GEM III DR ICD** Model 7275
- **GEM III VR ICD** Model 7231Cx
- **InSync ICD** Model 7272
- **InSync Marquis** Model 7277
- **InSync II Marquis** Model 7289
- **Jewel AF ICD** Model 7250
- **Jewel Plus ICD** Model 7220
- **Marquis DR ICD** Model 7274
- **Marquis VR ICD** Model 7230Cx
- **Micro Jewel ICD** Model 7221
- **Micro Jewel II ICD** Model 7223Cx

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

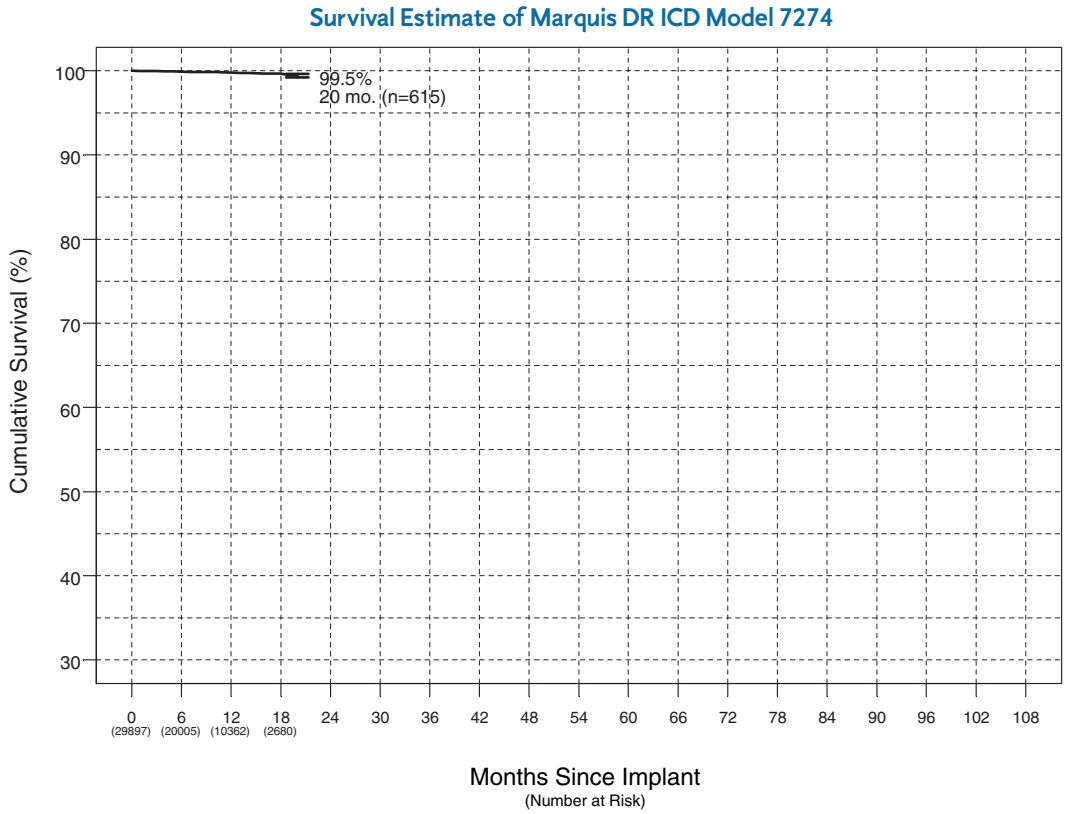
The following results are generated based on returned product data through a database cutoff of February 1, 2004.

Marquis DR ICD

Cumulative survival:
99.5% at 20 months

95% confidence interval:
99.2 to 99.6%

N = 29,897

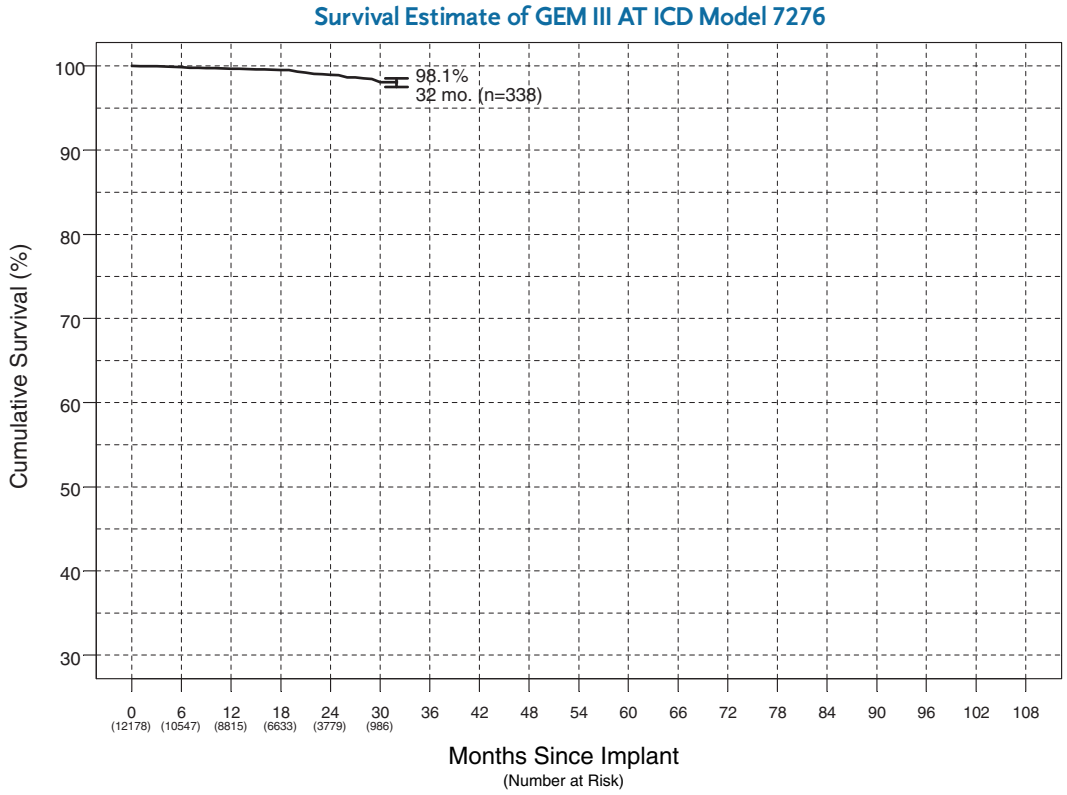


GEM III AT ICD

Cumulative survival:
98.1% at 32 months

95% confidence interval:
97.5 to 98.5%

N = 12,178

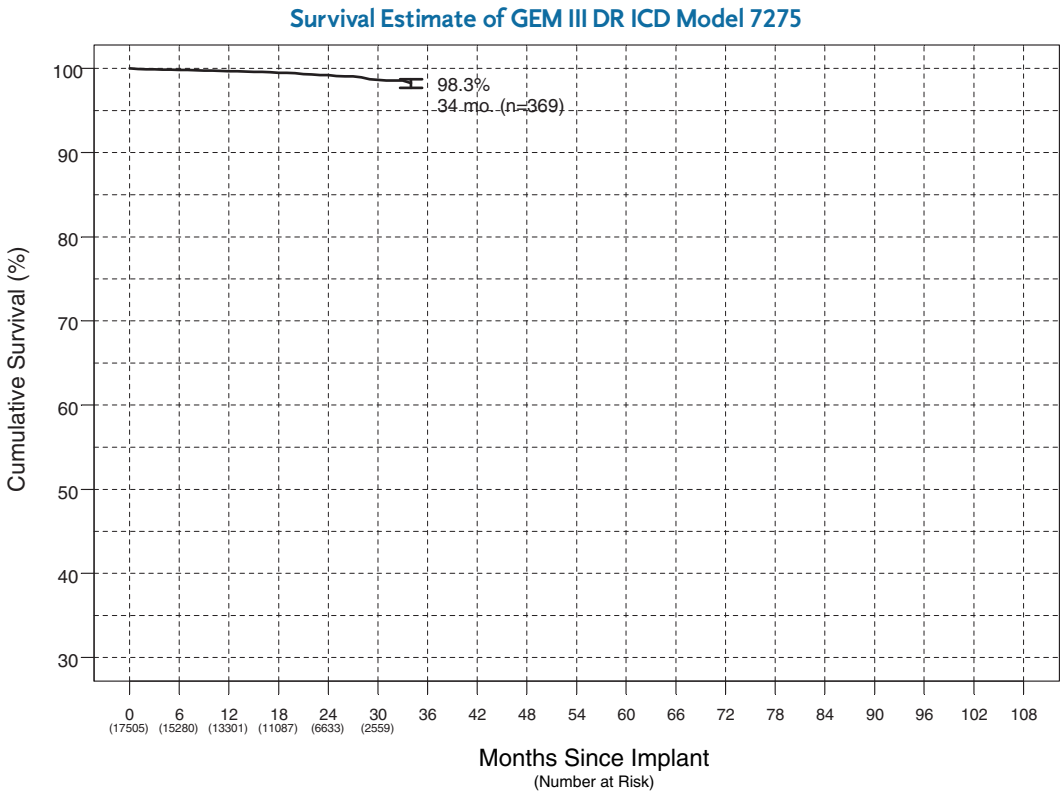


GEM III DR ICD

Cumulative survival:
98.3% at 34 months

95% confidence interval:
97.7 to 98.7%

N = 17,505

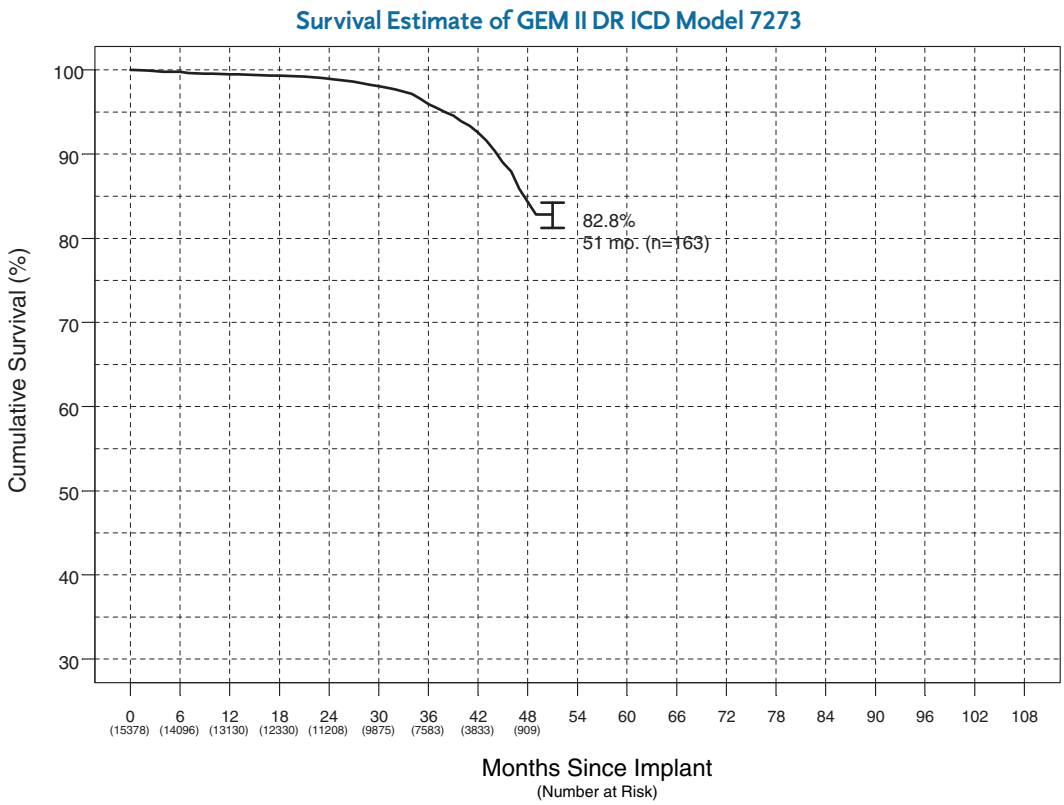


GEM II DR ICD

Cumulative survival:
82.8% at 51 months

95% confidence interval:
81.2 to 84.3%

N = 15,378



GEM DR ICD

*** Population 1**

Cumulative survival:
94.6% at 61 months

95% confidence interval:
93.0 to 95.8%

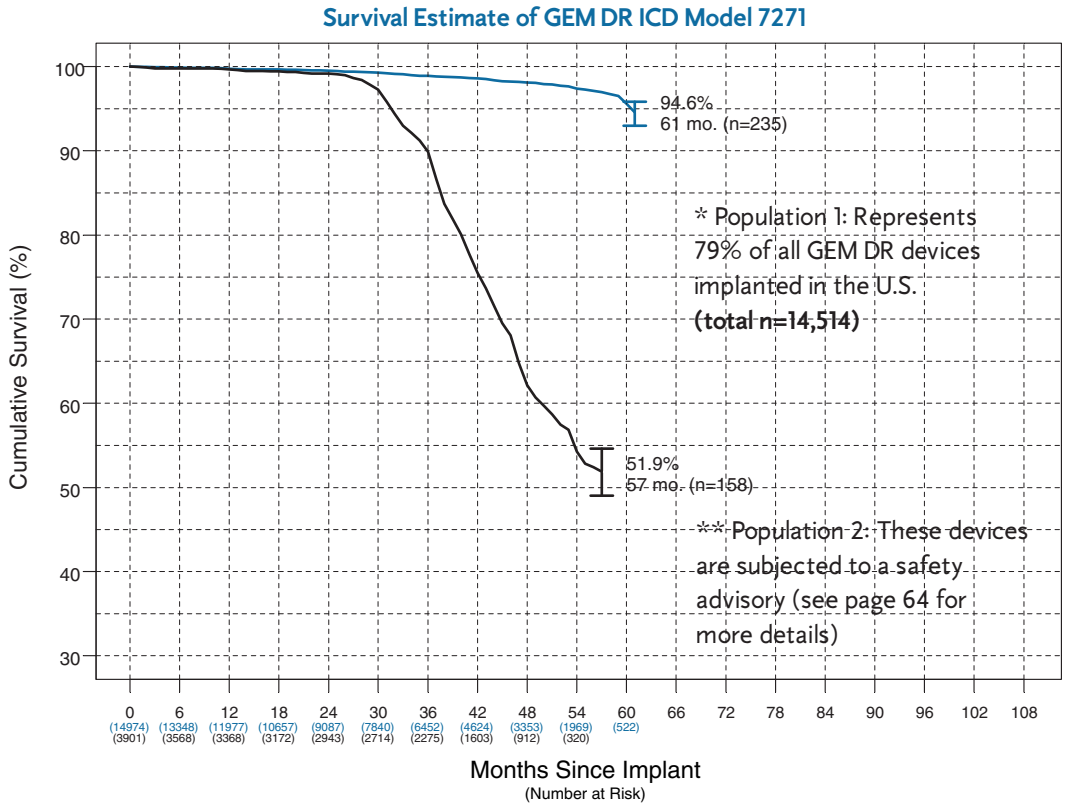
N = 14,974

**** Population 2**

Cumulative survival:
51.9% at 57 months

95% confidence interval:
49.0% to 54.6%

N = 3,899

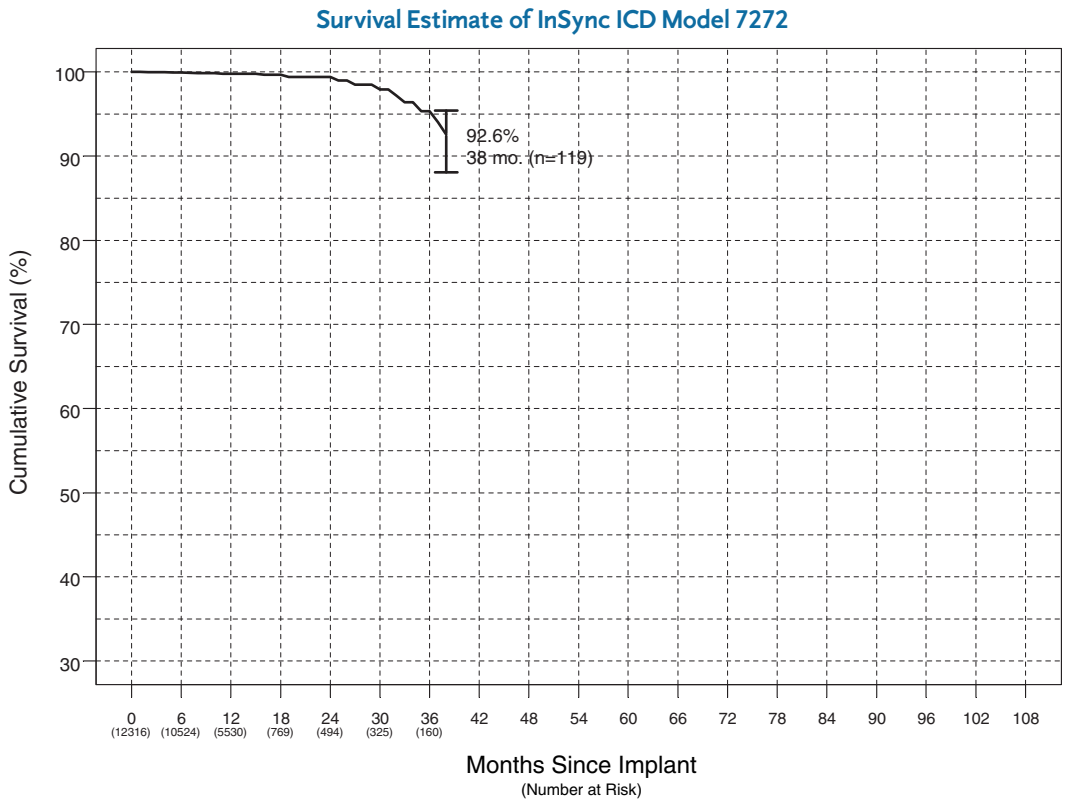


InSync ICD

Cumulative survival:
92.6% at 38 months

95% confidence interval:
88.1 to 95.4%

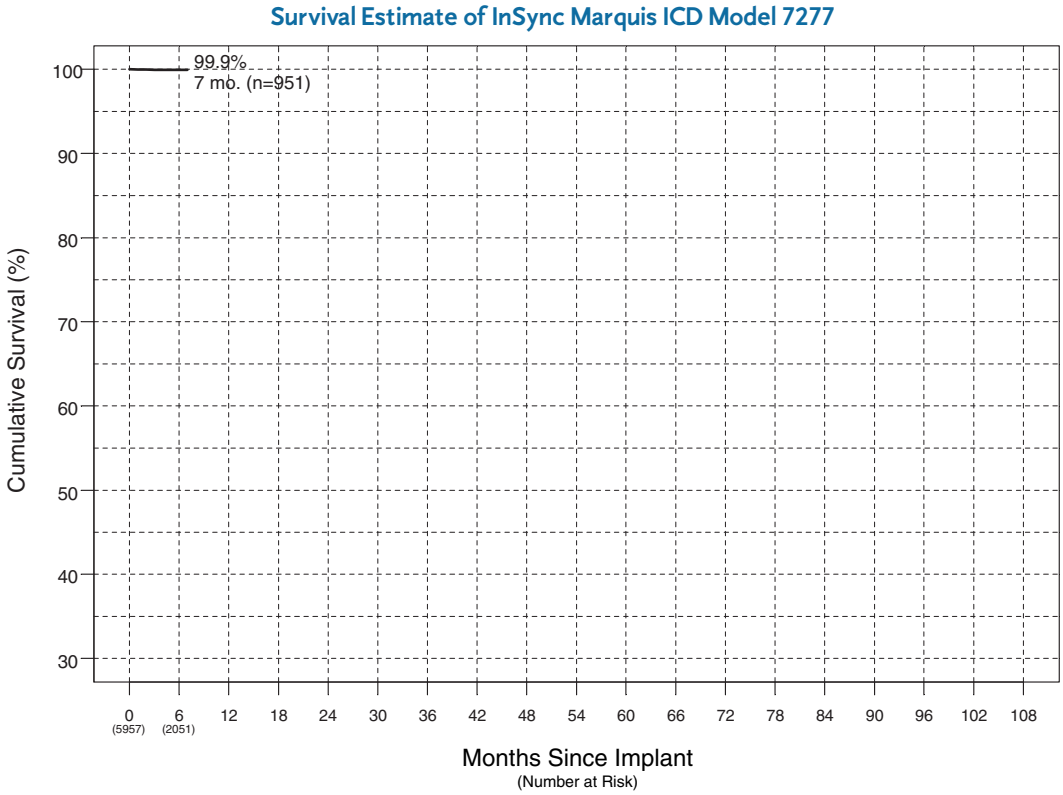
N = 12,316



INSYNC MARQUIS ICD

Cumulative survival:
99.9% at 7 months

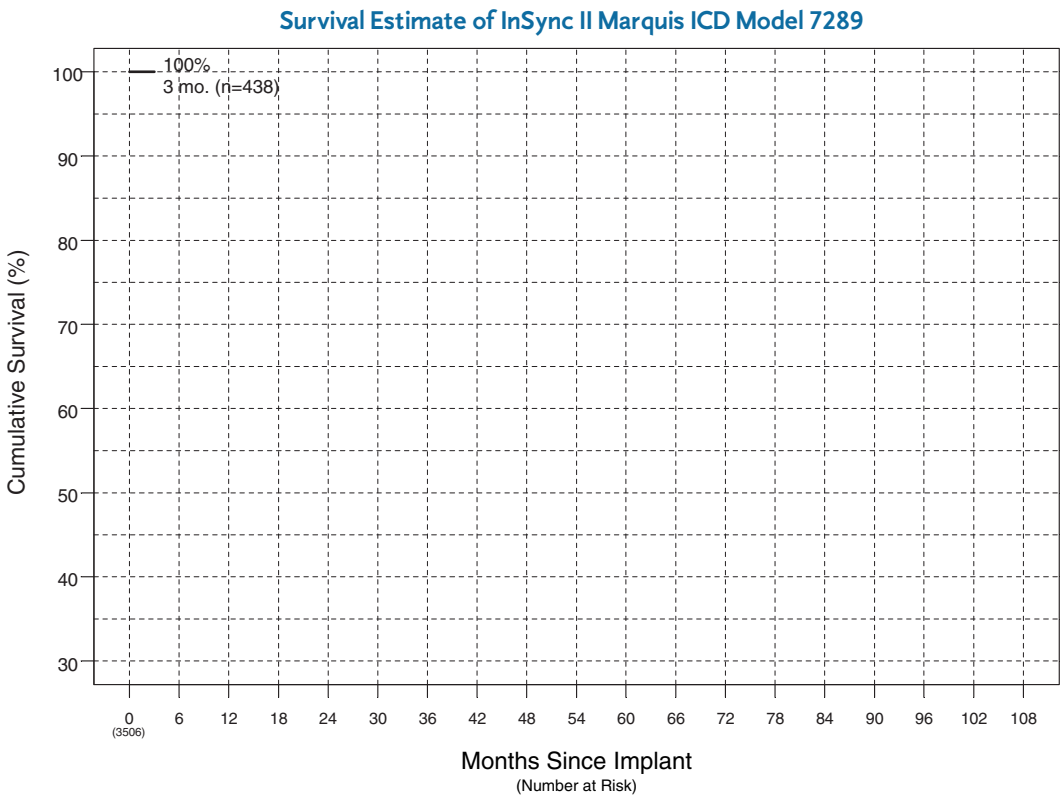
N = 5,957



InSync II MARQUIS ICD

Cumulative survival:
100% at 3 months

N = 3,506

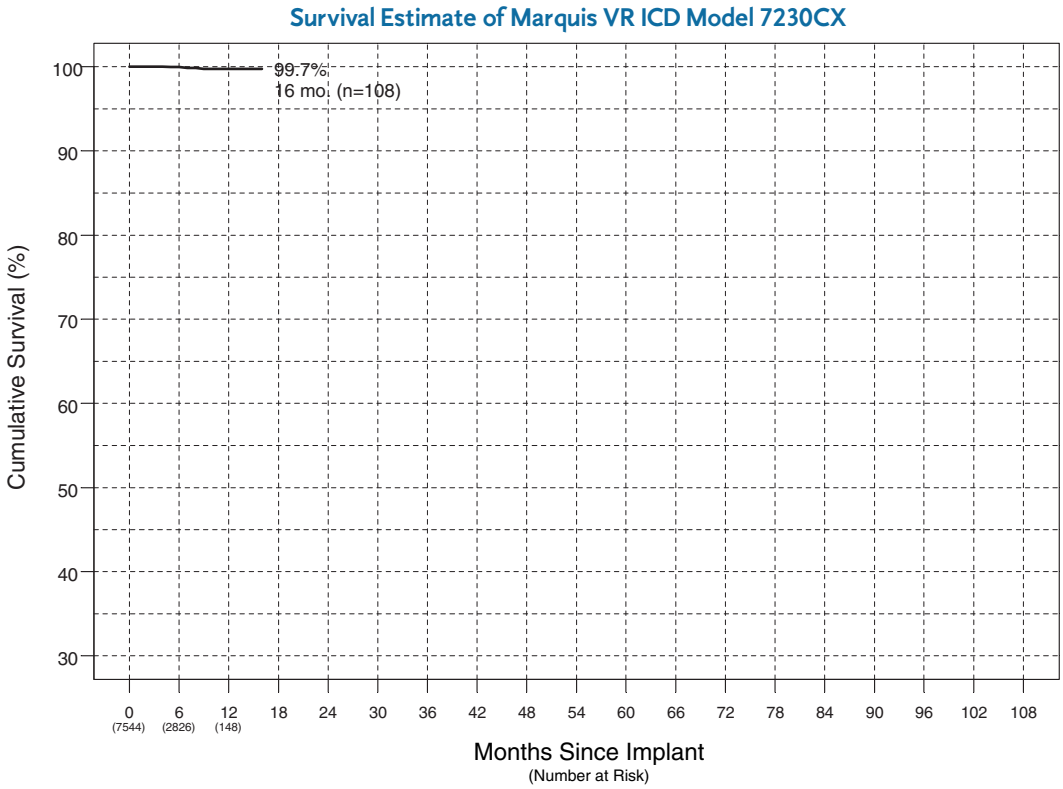


MARQUIS VR ICD

Cumulative survival:
99.7% at 16 months

95% confidence interval:
99.4 to 99.9%

N = 7,544

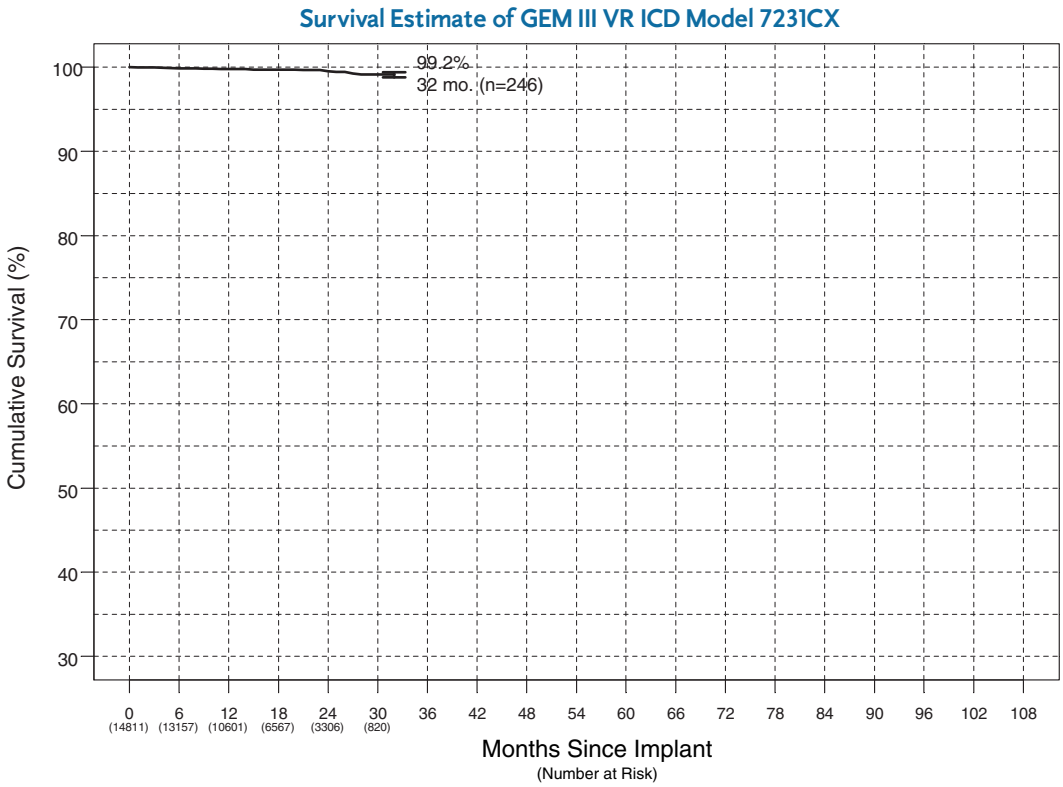


GEM III VR ICD

Cumulative survival:
99.2% at 32 months

95% confidence interval:
98.8 to 99.4%

N = 14,811

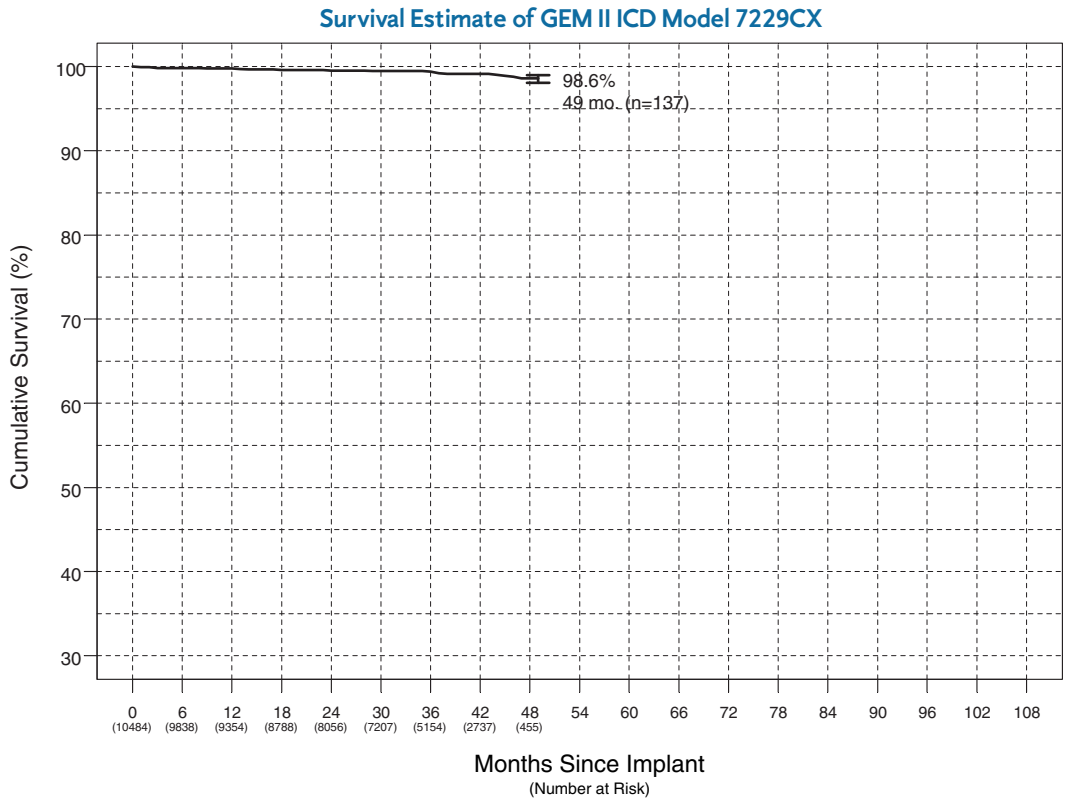


GEM II ICD

Cumulative survival:
98.6% at 49 months

95% confidence interval:
98.1 to 99.0%

N = 10,484



GEM ICD

*** 7227Cx, B, D, E**

Cumulative survival:
98.2% at 61 months

95% confidence interval:
97.9 to 98.4%

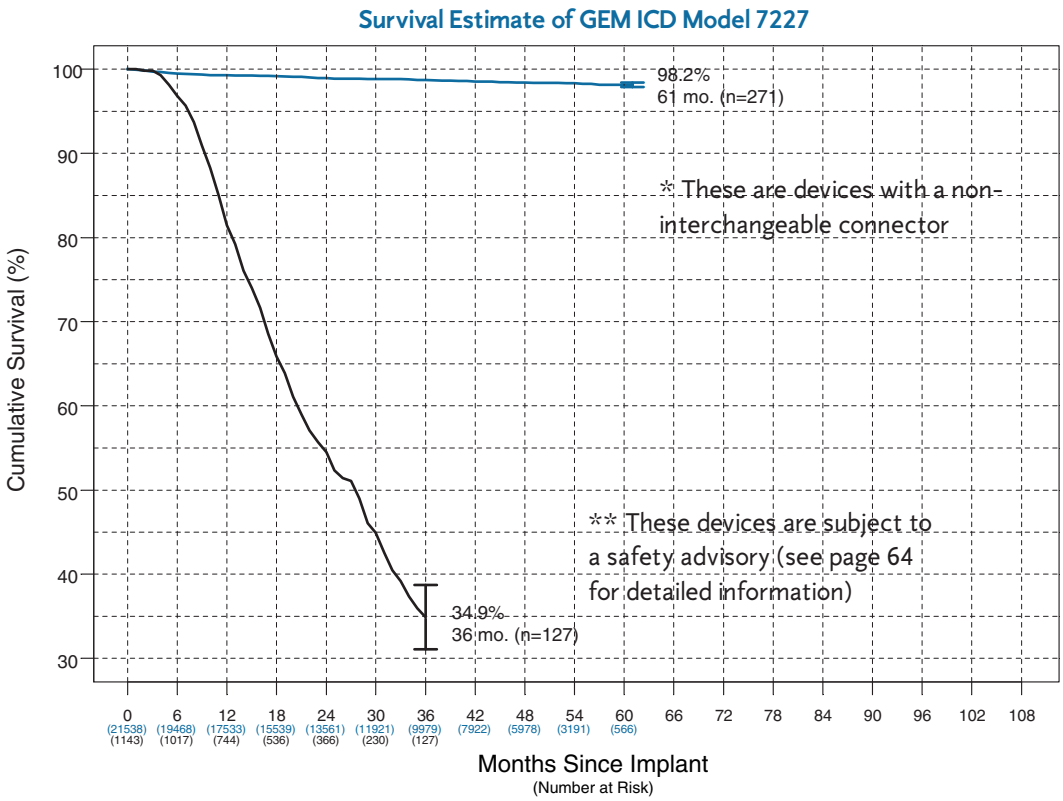
N = 21,538

**** 7227 B, D, E (interchangeable connector devices)**

Cumulative survival:
34.9% at 36 months

95% confidence interval:
31.1 to 38.7%

N = 1,143

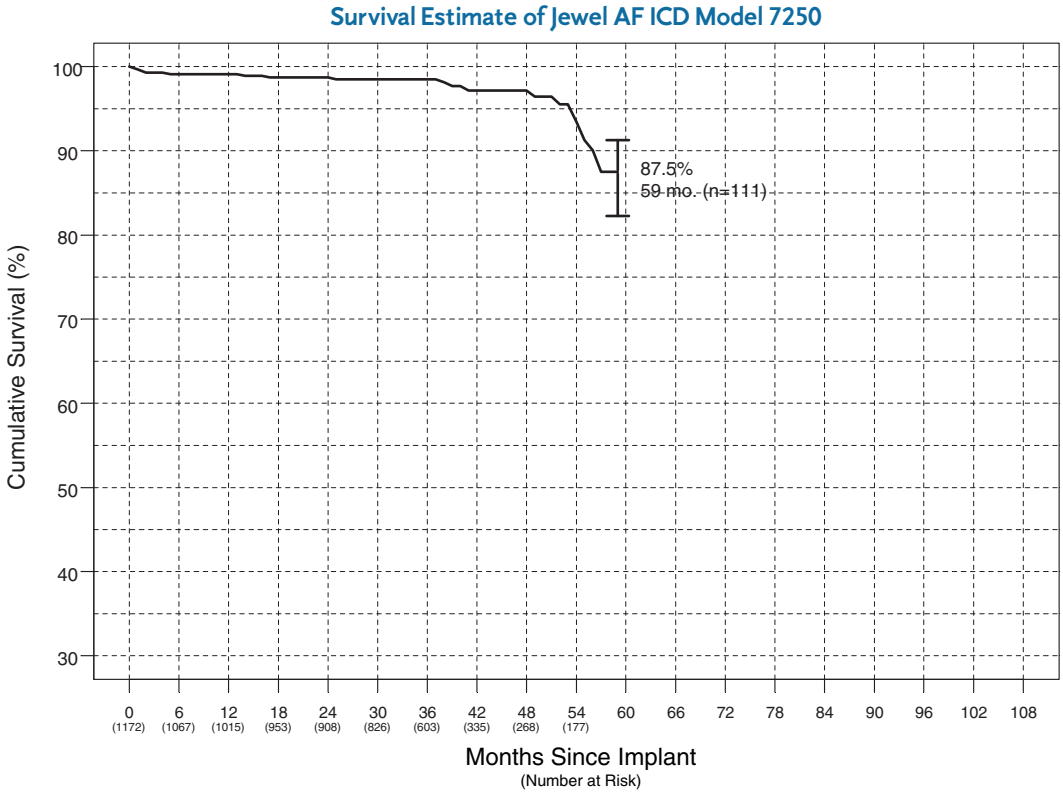


Jewel AF ICD

Cumulative survival:
87.5% at 59 months

95% confidence interval:
82.2 to 91.3%

N = 1,172



Micro Jewel II ICD

*** Population 1**

Cumulative survival:
88.3% at 83 months

95% confidence interval:
85.6 to 90.5%

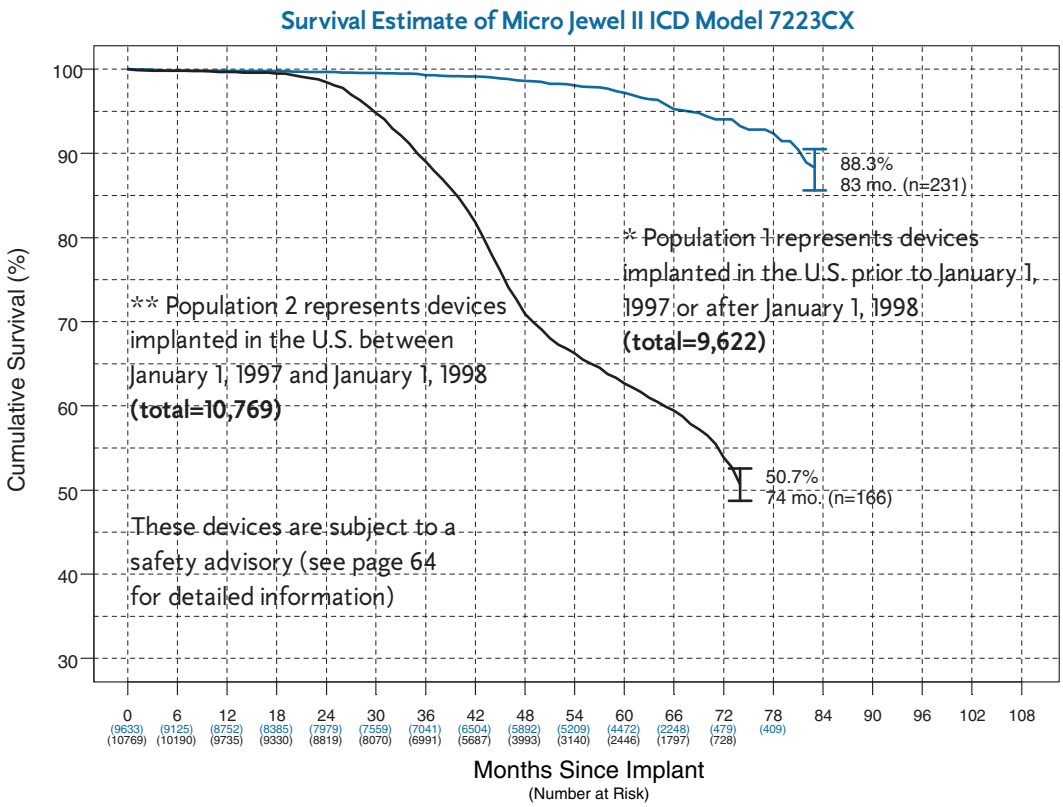
N = 9,633

**** Population 2**

Cumulative survival:
50.7% at 74 months

95% confidence interval:
48.7 to 52.6%

N = 10,769

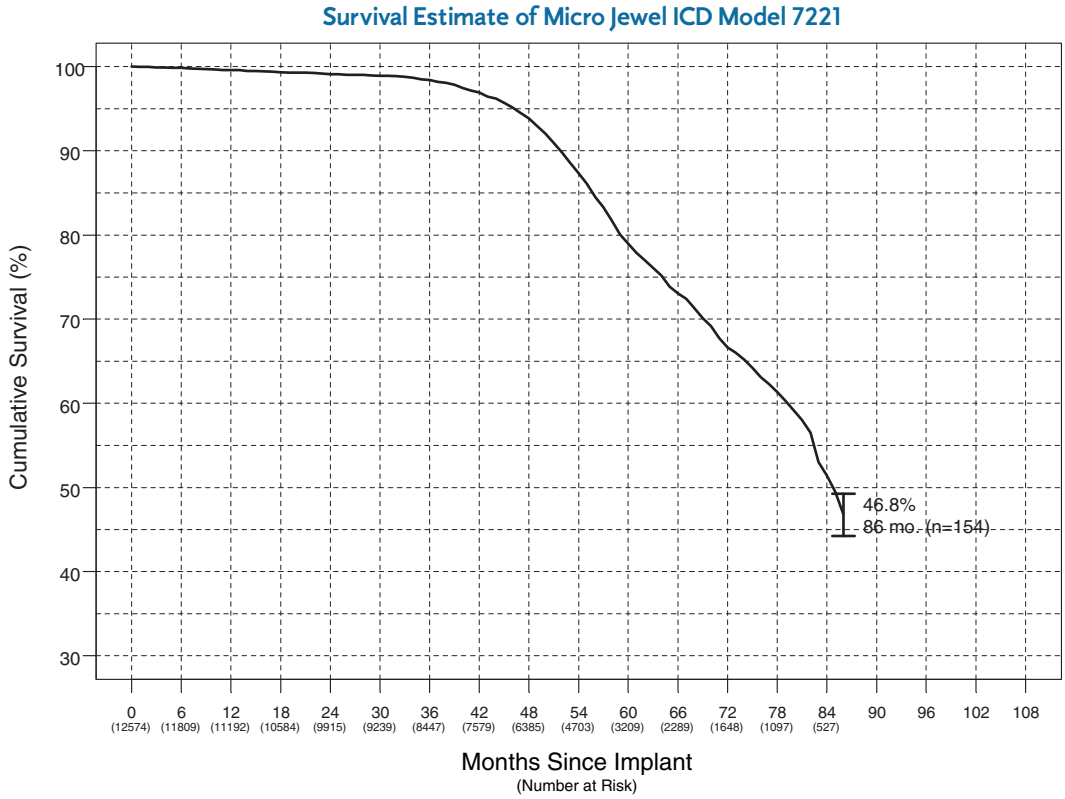


Micro Jewel ICD

Cumulative survival:
46.8% at 86 months

95% confidence interval:
44.3 to 49.3%

N = 12,567

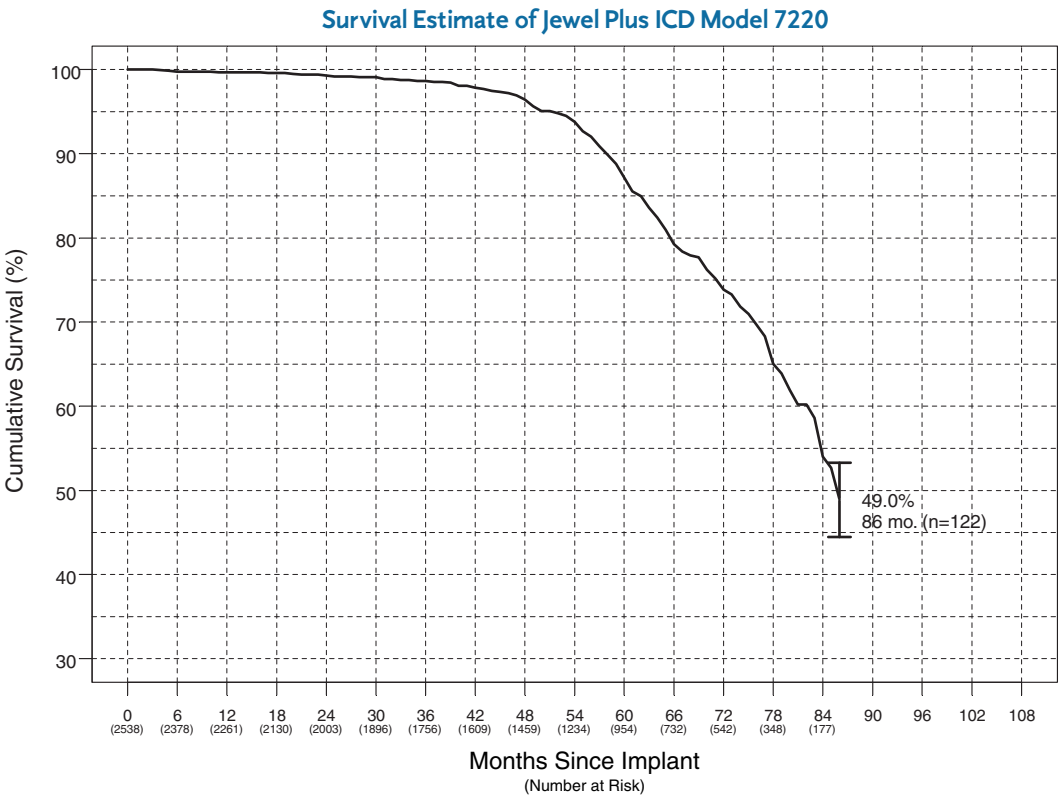


Jewel Plus ICD

Cumulative survival:
49.0% at 86 months

95% confidence interval:
44.5 to 53.3%

N = 2,538



Summary

Estimates of ICD event-free survival from returned product analysis are summarized in Table 1 on page 15.

Determinations of normal battery depletion and electrical failure are summarized in Table 1. The leading edge of the Micro Jewel and Jewel Plus ICD event-free survival curves primarily show the effect of normal battery depletion on page 15.

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Table 1. ICD Survival: Returned Product Analysis Results*

Model	U.S. Market Release Date	U.S. Implants	Active U.S. Implants	Battery Depletion†	Electrical Failures‡	ICD Survival (95% Confidence Interval) 1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year
Marquis DR 7274	Mar 2002	29,897	26,777	11	17	99.8% (99.7% to 99.8%)	99.5% (99.2% to 99.6%) at 20 mo.	NA	NA	NA	NA	NA	NA
GEM III AT 7276	Feb 2001	12,178	9,412	27	20	99.7% (99.5% to 99.8%)	99.0% (98.7% to 99.2%)	98.1% (97.5% to 98.5%) at 32 mo.	NA	NA	NA	NA	NA
GEM III DR 7275	Nov 2000	17,505	13,317	42	21	99.7% (99.6% to 99.8%)	99.2% (99.1% to 99.4%)	98.3% (97.7% to 98.7%) at 34 mo.	NA	NA	NA	NA	NA
GEM II DR 7273	Feb 1999	15,378	7,812	348	67	99.5% (99.4% to 99.6%)	99.0% (98.8% to 99.1%)	96.0% (95.6% to 96.3%)	84.3% (83.0% to 85.6%)	82.8% (81.2% to 84.3%) at 51 mo.	NA	NA	NA
GEM DR 7271 (pop 1)**	Oct 1998	14,974	9,315	38	55	99.7% (99.6% to 99.8%)	99.5% (99.4% to 99.6%)	98.9% (98.7% to 99.1%)	98.1% (97.8% to 98.4%)	95.6% (94.5% to 96.5%)	94.6% (93.0% to 95.8%) at 61 mo.	NA	NA
GEM DR 7271 (pop 2)**	Oct 1998	3,901	760	26	447	99.7% (99.4% to 99.8%)	99.2% (98.8% to 99.4%)	89.9% (88.7% to 91.0%)	62.1% (60.0% to 64.2%)	51.9% (49.0% to 54.6%) at 57 mo.	NA	NA	NA
InSync ICD 7272	Jun 2002	12,316	9,936	7	14	99.8% (99.6% to 99.8%)	99.4% (98.8% to 99.7%)	95.3% (92.2% to 97.2%)	92.6% (88.1% to 95.4%) at 38 mo.	NA	NA	NA	NA
InSync Marquis 7277	Mar 2003	5,957	5,470	1	1	100% (99.8% to 100%) at 7 mo.	NA	NA	NA	NA	NA	NA	NA
InSync II Marquis 7289	Jul 2003	3,506	3,394	0	0	100% at 3 mo.	NA	NA	NA	NA	NA	NA	NA
Marquis VR 7230Cx, B, E	Dec 2004	7,544	7,116	1	2	99.7% (99.4% to 99.9%)	99.7% (99.4% to 99.9%) at 16 mo.	NA	NA	NA	NA	NA	NA
GEM III VR 7231CX	Dec 2000	14,811	12,004	13	12	99.8% (99.7% to 99.9%)	99.5% (99.3% to 99.7%)	99.2% (98.8% to 99.4%) at 32 mo.	NA	NA	NA	NA	NA
GEM II VR 7229CX	Jul 1999	10,484	6,990	13	24	99.8% (99.6% to 99.8%)	99.5% (99.4% to 99.6%)	99.4% (99.2% to 99.5%)	98.6% (98.1% to 99.0%)	98.6% (98.1% to 99.0%) at 49 mo.	NA	NA	NA
GEM 7227 B, D, E	Oct 2001	1,143	66	0	268	81.5% (78.9% to 83.7%)	54.5% (51.1% to 57.8%)	34.9% (31.1% to 38.7%)	NA	NA	NA	NA	NA
GEM 7227Cx, B, D, E	Oct 1998	21,538	14,000	20	108	99.3% (99.1% to 99.4%)	98.9% (98.8% to 99.1%)	98.7% (98.5% to 98.9%)	98.4% (98.2% to 98.6%)	98.2% (97.9% to 98.4%)	98.2% (97.9% to 98.4%) at 61 mo.	NA	NA
Jewel AF 7250	Jun 2000	1,172	653	11	13	99.1% (98.4% to 99.5%)	98.7% (97.8% to 99.2%)	98.5% (97.6% to 99.1%)	97.2% (95.5% to 98.2%)	87.5% (82.2% to 91.3%) at 59 mo.	NA	NA	NA
Micro Jewel II 7223CX (pop 1)**	Nov 1996	9,633	4,670	93	47	99.8% (99.7% to 99.9%)	99.7% (99.5% to 99.8%)	99.3% (99.1% to 99.5%)	98.6% (98.3% to 98.8%)	97.2% (96.8% to 97.6%)	94.0% (93.0% to 94.9%)	88.3% (85.6% to 90.5%) at 83 mo.	NA
Micro Jewel II 7223CX (pop 2)**	Nov 1996	10,769	1,076	268	1,163	99.7% (99.5% to 99.8%)	98.4% (98.2% to 98.7%)	89.0% (88.3% to 89.7%)	70.9% (69.9% to 72.0%)	62.7% (61.5% to 63.9%)	53.8% (52.3% to 55.3%)	50.7% (48.7% to 52.6%) at 74 mo.	NA
Micro Jewel 7221	Jul 1996	12,574	2,061	567	419	99.6% (99.5% to 99.7%)	99.1% (98.9% to 99.3%)	98.4% (98.1% to 98.6%)	93.9% (93.3% to 94.4%)	79.0% (77.9% to 80.0%)	66.6% (65.1% to 68.0%)	51.4% (49.3% to 53.5%)	46.8% (44.3% to 49.3%) at 86 mo.
Jewel Plus 7220	Jun 1995	2,538	153	206	14	99.7% (99.3% to 99.8%)	99.3% (98.8% to 99.6%)	98.7% (98.1% to 99.1%)	96.4% (95.5% to 97.2%)	87.2% (85.3% to 88.9%)	73.9% (71.1% to 76.4%)	54.0% (49.9% to 57.9%)	49.0% (44.5% to 53.3%) at 86 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 February 1, 2004.

** Denotes new advisories since the last Product Performance Report. See Advisory section, page 63.

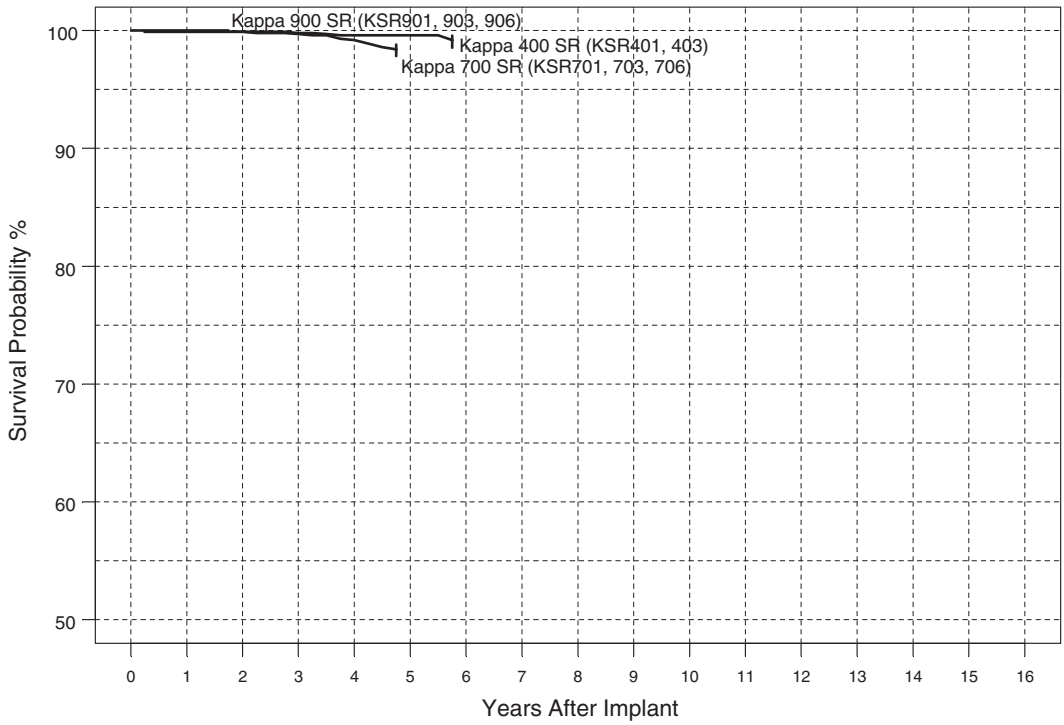
Pulse Generator Performance

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 February 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.

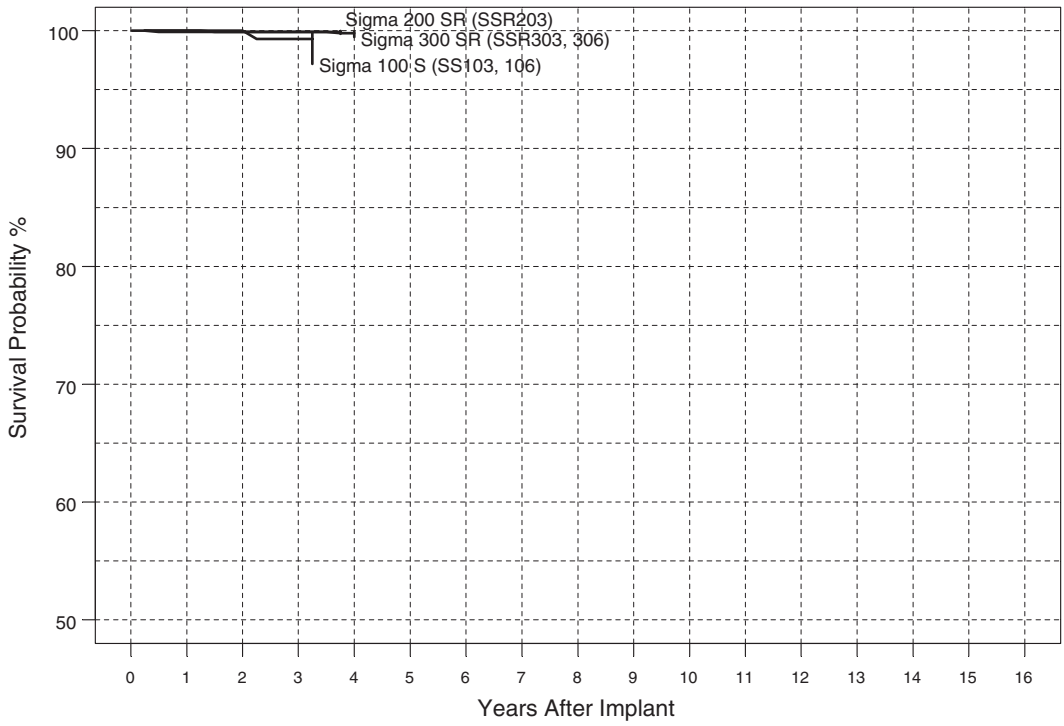
Survival Probability (%) based on Returned Product Analysis. Error bars represent two Standard Errors at the leading 3-month interval. "Survival Probability" refers to proper functioning of the device, not the survival of the patient. (For example: A survival probability of 98% is a statistical assessment 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.

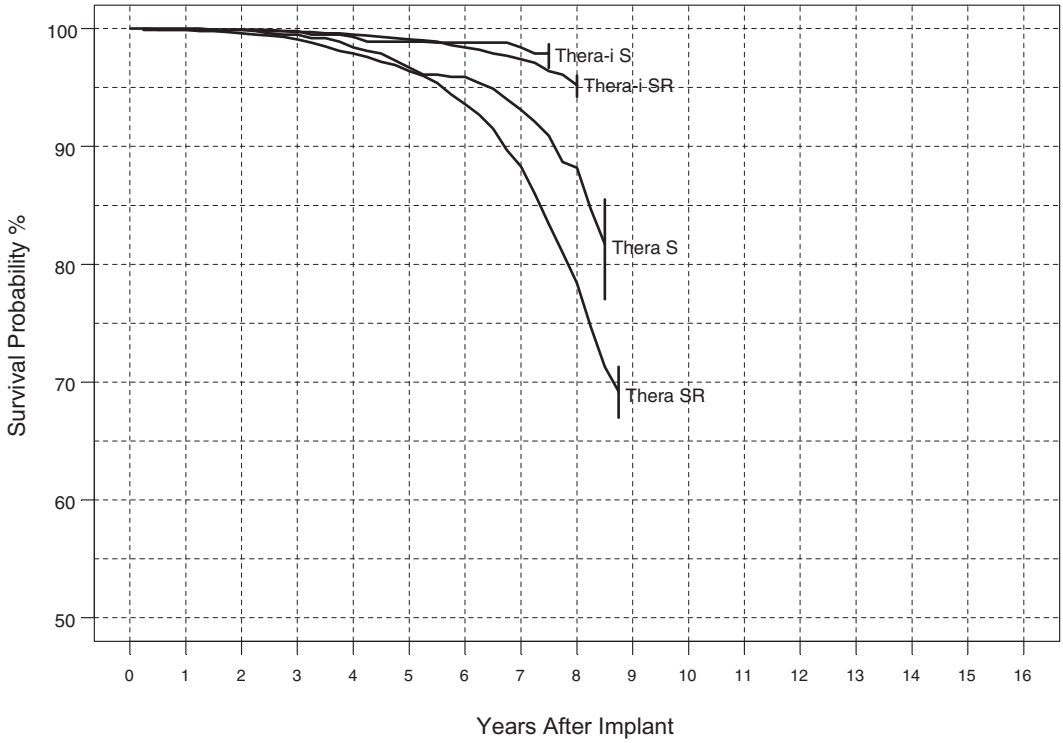
Single Chamber Kappa Pulse Generators



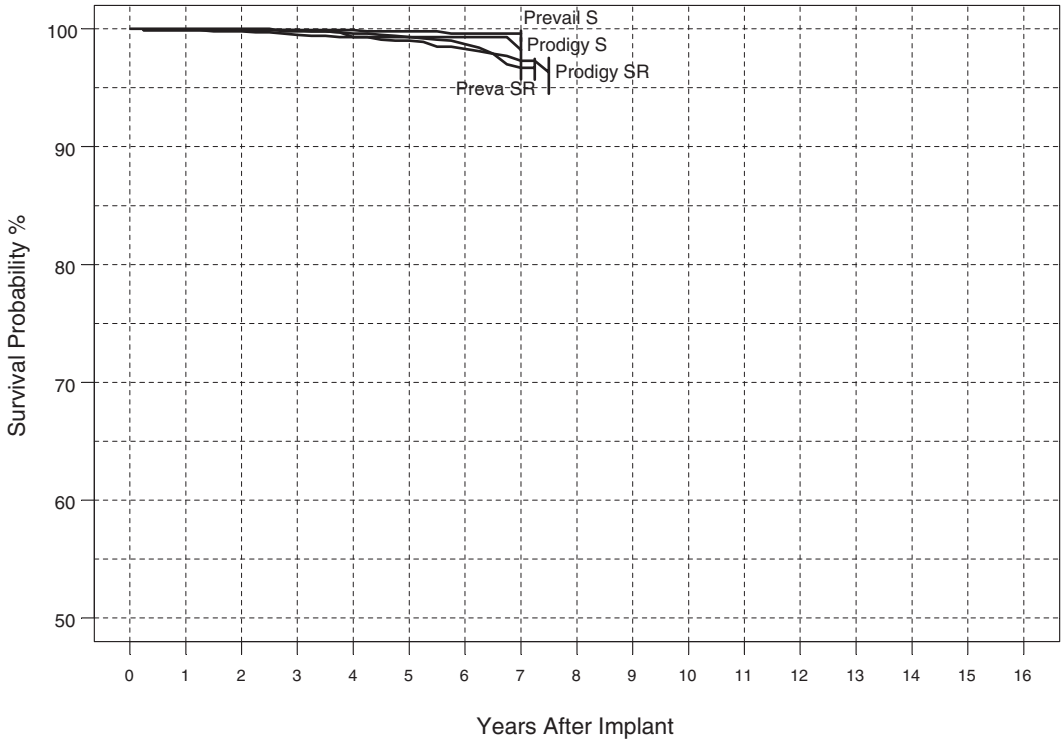
Single Chamber Sigma Pulse Generators



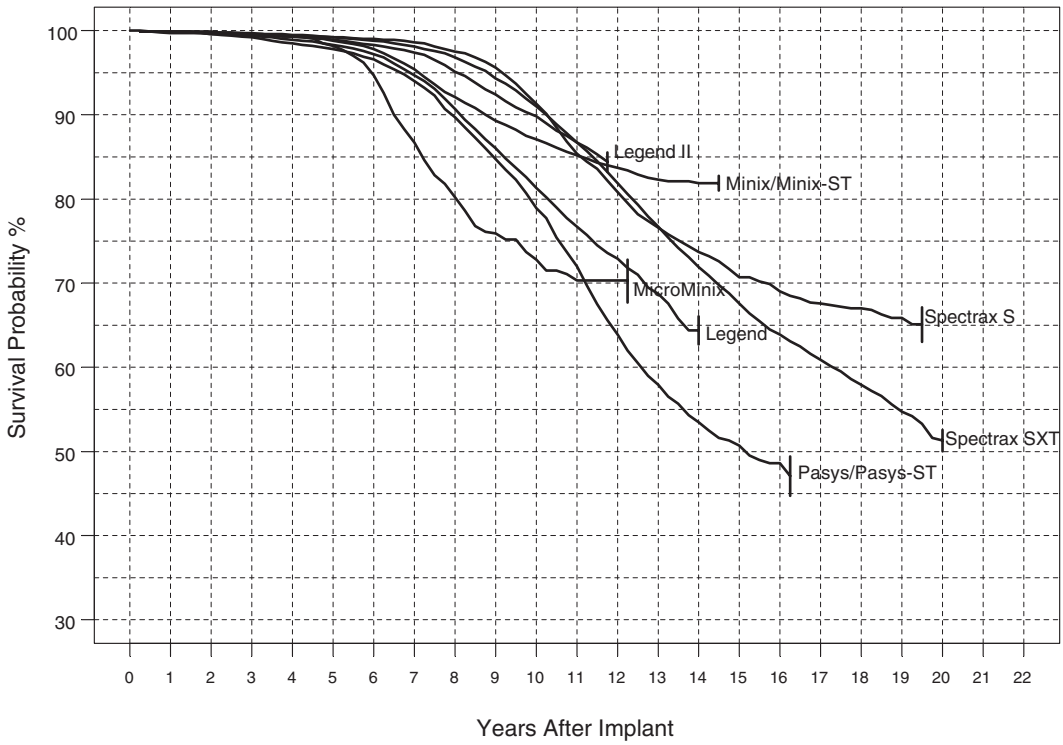
Single Chamber Thera Pulse Generators



Prevail, Preva, & Prodigy Pulse Generators



Single Chamber Pulse Generators



Single Chamber Implantable Pulse Generators

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

Laboratory Analysis and Actuarial Survival Probability (%)[1] (± 2 Standard Errors)[2]

Model Family	Registered Implants	Active Implants[3]	Battery EOL Indicators[4]	Electrical Failures[4]	1 Year Intervals								2 Year Intervals				
					1	2	3	4	5	6	7	8	10	12	14	16	18
Spectrax S 5940, 5940LP, 5941	24,912	1,200	799	97	99.7 ±0.1	99.6 ±0.1	99.5 ±0.1	99.4 ±0.1	99.2 ±0.1	99.0 ±0.2	98.6 ±0.2	97.5 ±0.3	91.3 ±0.6	80.8 ±1.0	73.7 +1.2/-1.3	66.0 +1.8/-1.9 (228 mo.)	
Spectrax SX 5984, 5984LP, 5985	107,171	200	6,095	754	99.7	99.5	99.4 ±0.1	99.2 ±0.1	98.8 ±0.1	98.2 ±0.1	97.2 ±0.1	95.6 ±0.2	87.1 ±0.3	72.5 ±0.5	59.6 ±0.7	26.5 +1.9/-1.8 (201 mo.)	
Spectrax SXT 8420, 8422, 8423, 8423M	111,159	3,600	4,306	566	99.9	99.8	99.7	99.5	99.2 ±0.1	98.8 ±0.1	98.1 ±0.1	96.8 ±0.1	91.0 ±0.3	81.9 ±0.4	71.9 ±0.6	50.5 ±1.6 (240 mo.)	
Pasys/Pasys ST 8320, 8322, 8329 8316, 8317, 8318	27,879	1,200	1,405	173	99.9	99.6 ±0.1	99.2 ±0.1	98.5 ±0.2	97.8 ±0.2	96.6 ±0.3	94.0 ±0.4	89.7 ±0.6	78.9 ±0.9	63.9 ±1.3	53.5 ±1.6	48.6 +1.8/-1.9	47.1 ±2.4 (195 mo.)
Minix/Minix ST 8340, 8341, 8341M 8342, 8330, 8331, 8331M	58,484	8,300	1,252	85	99.9	99.8	99.6 ±0.1	99.3 ±0.1	98.8 ±0.1	97.8 ±0.2	95.4 ±0.3	92.1 ±0.4	87.1 ±0.5	83.7 ±0.7	81.9 ±0.9	81.9 ±0.9 (174 mo.)	
Micro Minix 8360	6,922	500	243	13	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.6 +0.2/-0.3	99.4 ±0.2	98.2 +0.4/-0.6	94.7 +0.8/-1.0	86.7 +1.3/-1.4	80.2 +1.8/-1.9	72.8 +2.3/-2.4	70.3 +2.5/-2.6	70.3 +2.5/-2.6 (147 mo.)		
Legend 8416, 8417, 8417M 8418, 8419	57,067	6,500	2,121	219	99.9	99.7	99.4 ±0.1	98.9 ±0.1	98.3 ±0.1	97.2 ±0.2	94.7 ±0.3	90.7 ±0.4	81.3 ±0.6	72.9 ±0.8	64.4 +1.6/-1.7		
Legend II 8424, 8426, 8427	58,484	12,100	1,099	55	99.9	99.8	99.6 ±0.1	99.3 ±0.1	98.9 ±0.1	98.3 ±0.1	97.4 ±0.2	95.1 ±0.3	89.8 ±0.5	84.4 +1.1/-1.2 (141 mo.)			
Thera-S 8944, 8945, 8946	2,626	400	53	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	88.2 +2.2/-2.7	81.7 +3.8/-4.7 (102 mo.)				
Thera-SR 8940, 8941, 8942	14,059	2,000	599	18	99.9 +0.1/-0.2	99.6 ±0.1	99.1 ±0.2	97.9 ±0.3	96.4 ±0.4	93.6 ±0.6	88.3 ±0.8	78.4 +1.2/-1.3	69.2 +2.1/-2.2 (105 mo.)				
Thera-i S 8964i, 8965i, 8966i	3,823	1,200	13	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	98.8 +0.4/-0.6	98.4 +0.6/-1.0	97.9 +0.8/-1.2 (90 mo.)					
Thera-i SR 8960i, 8961i, 8962i	49,993	18,600	243	14	99.9	99.9	99.7 ±0.1	99.5 ±0.1	99.1 ±0.1	98.4 ±0.2	97.4 ±0.3	95.2 +0.8/-1.0					
Prodigy S 8164, 8165, 8166	2,410	700	6	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	98.2 +1.0/-2.5						
Prodigy SR 8158, 8160, 8161, 8162	21,587	8,800	87	10	99.9	99.8 ±0.1	99.5 ±0.1	99.3 ±0.1	99.0 ±0.2	98.3 ±0.3	97.3 +0.5/-0.7	96.3 +1.2/-1.8 (90 mo.)					
Preva SR 8088, 8089	17,724	6,700	53	3	99.9	99.9	99.9 +0.1/-0.2	99.6 ±0.1	99.3 ±0.2	98.7 ±0.3	96.7 +0.8/-1.0	96.7 +0.8/-1.0 (87 mo.)					
Prevail S 8085, 8086	4,159	1,100	3	0	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.8 +0.1/-0.3	99.6 +0.2/-0.7	99.6 +0.2/-0.7						
Kappa 400 SR KSR401, KSR403	13,661	7,800	16	3	99.9	99.9 +0.1/-0.2	99.8 ±0.1	99.6 +0.2/-0.3	99.6 +0.2/-0.3	99.2 +0.4/-0.7 (69 mo.)							
Kappa 700 SR KSR701, KSR703, KSR706	44,004	28,200	55	7	99.9	99.9	99.7 ±0.1	99.2 ±0.2	98.4 +0.4/-0.6 (57 mo.)								
Sigma 100 S SS103, SS106	751	400	1	0	100	100	99.3 +0.5/-2.1	99.3 +0.5/-2.1 (39 mo.)									
Sigma 200 SR SSR203	10,579	6,600	2	0	100	99.9	99.9 +0.1/-0.2	99.9 +0.1/-0.2 (45 mo.)									
Sigma 300 S SS303	246	100	0	0	100	100	100 (33 mo.)										
Sigma 300 SR SSR303, SSR306	33,698	22,900	5	5	99.9	99.9	99.9 +0.1/-0.2	99.8 +0.1/-0.3									
Kappa 900 SR KSR901 KSR903, KSR906	16,609	14,100	0	0	100	100 (21 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.

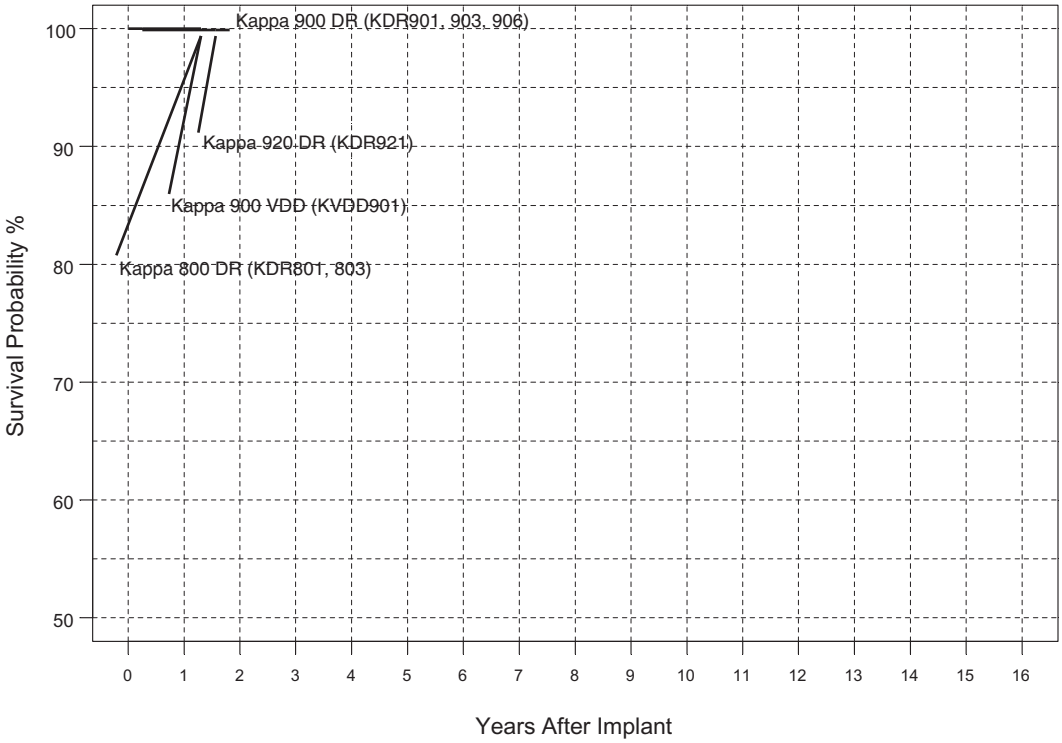
[2] Rounded to closest 0.1%. If no standard error (SE) appears, SE less than 0.1%.

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

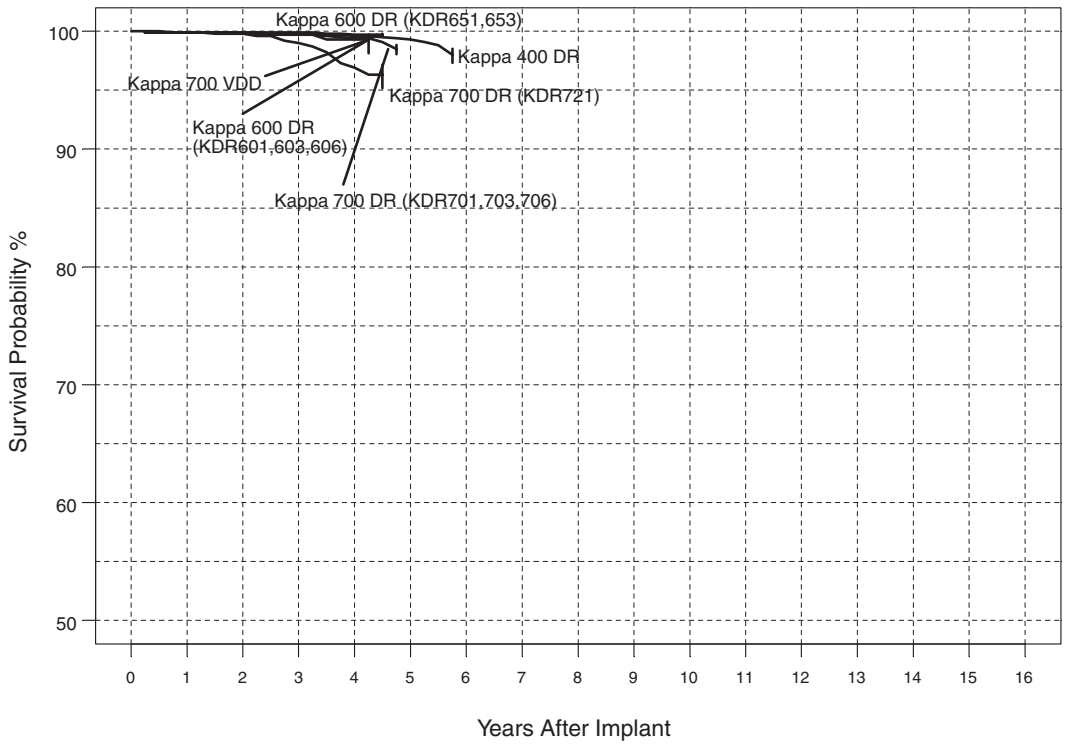
[4] Registered and non-registered devices are included in the number of devices exhibiting battery elective replacement time indicators and the number of devices exhibiting electrical failures.

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

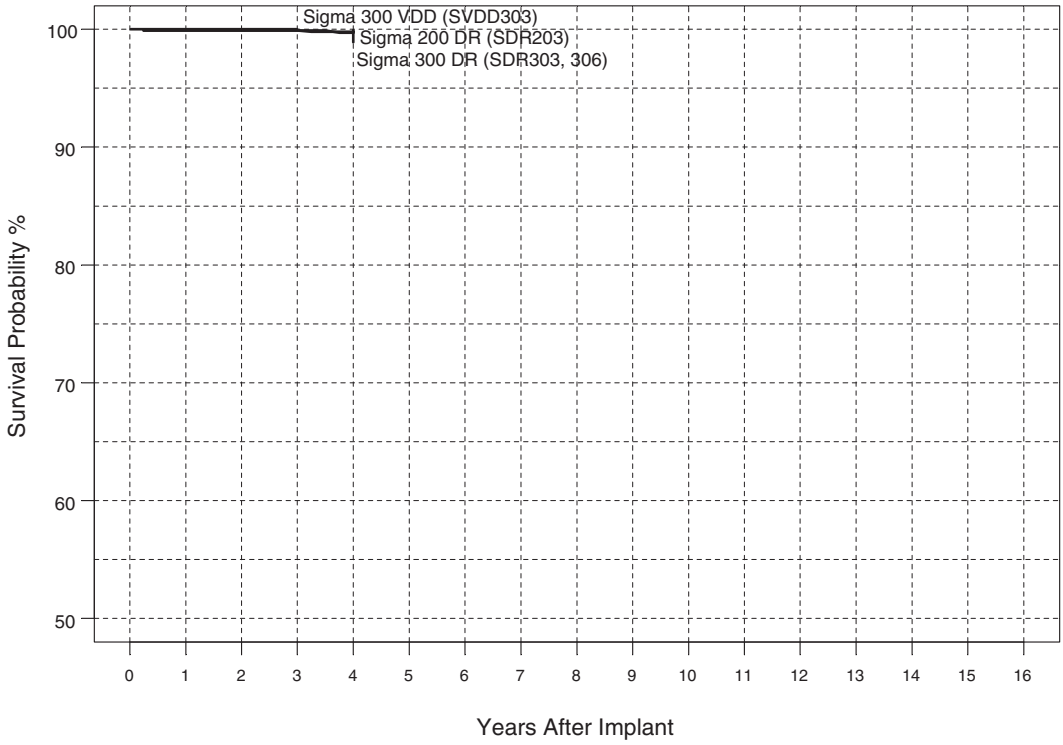
Kappa 800/900 Dual Chamber Pulse Generators



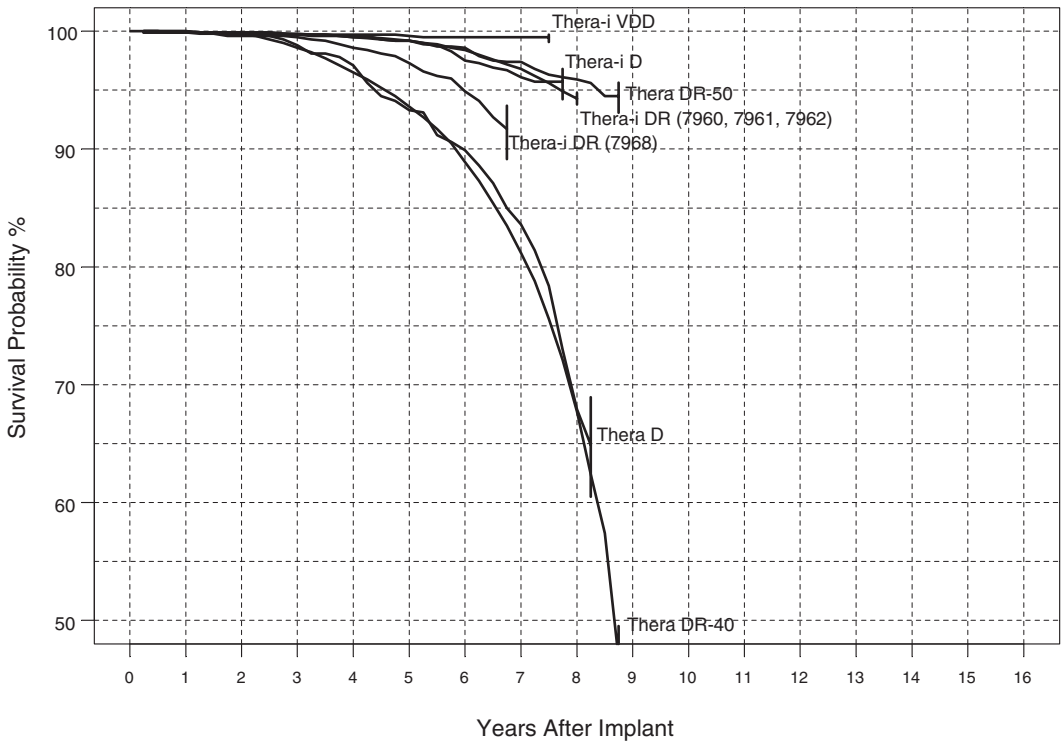
Other Kappa Dual Chamber Pulse Generators



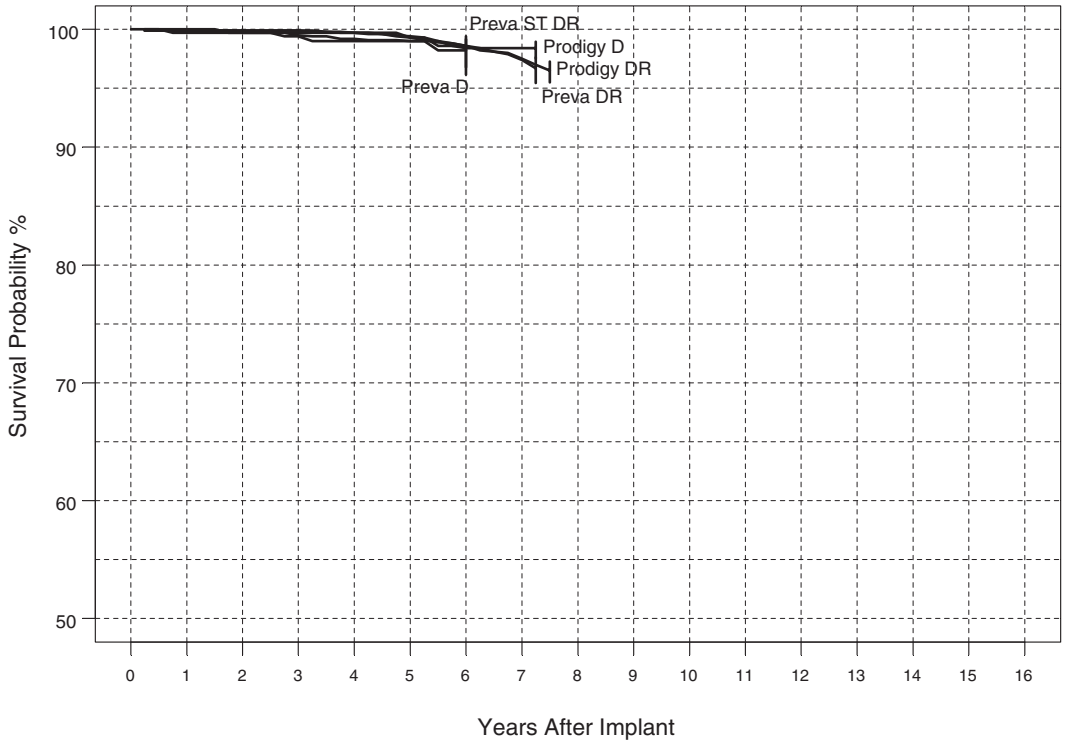
Sigma Dual Chamber Pulse Generators



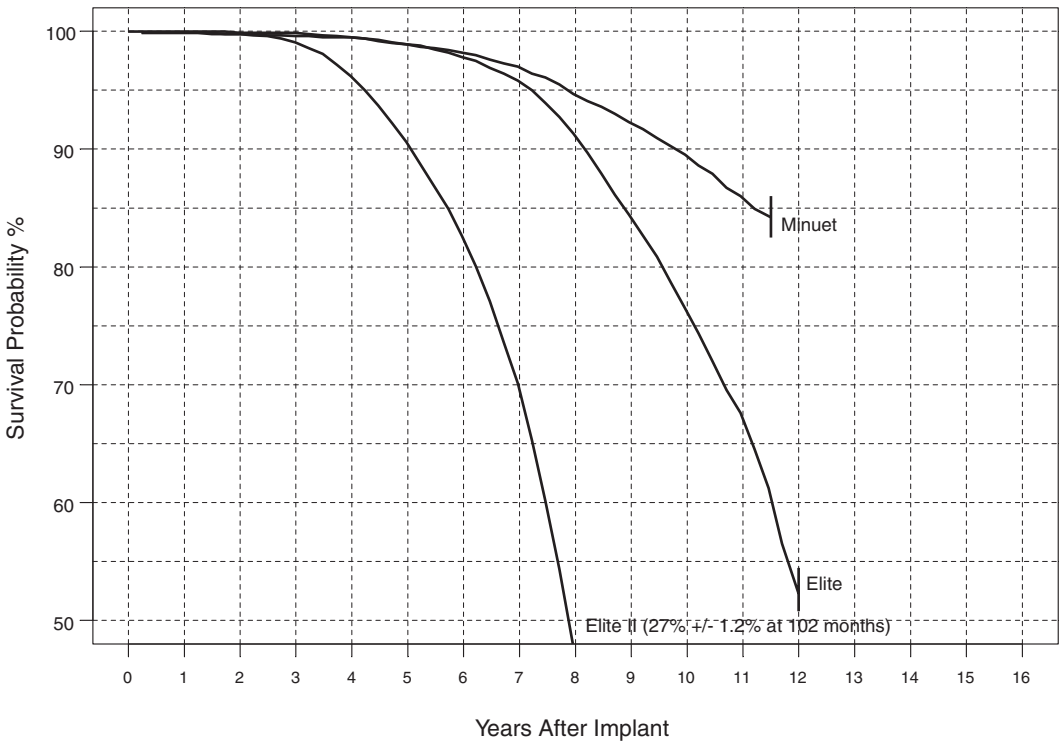
Thera Dual Chamber Pulse Generators



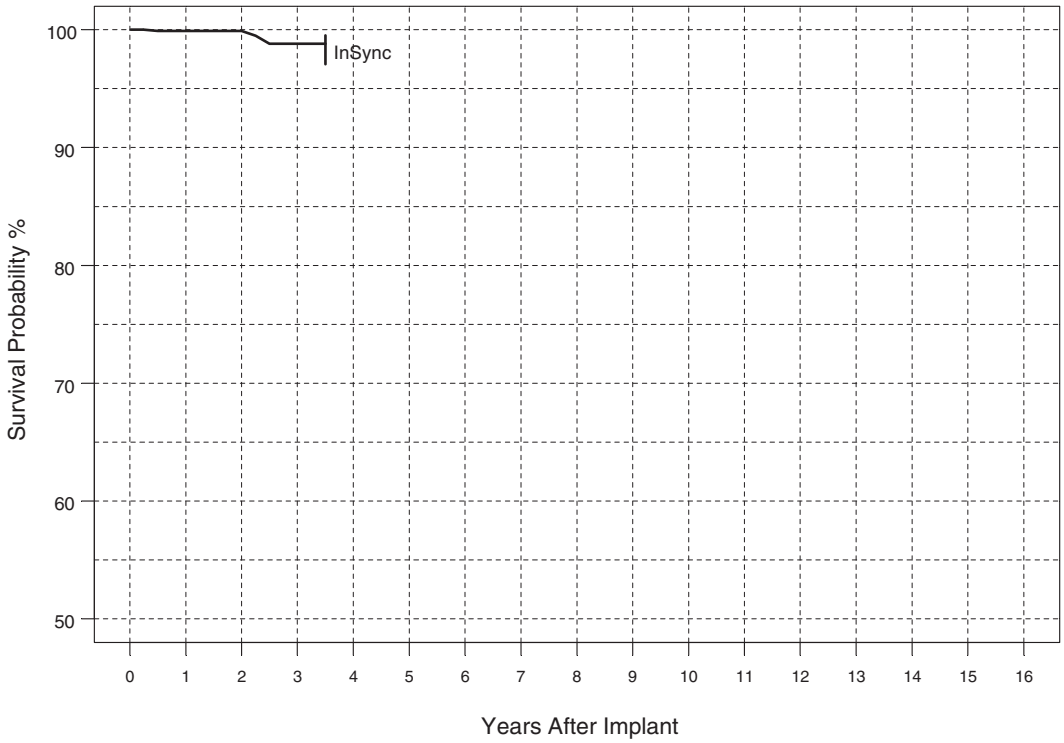
Preva, Prevail, & Prodigy Pulse Generators



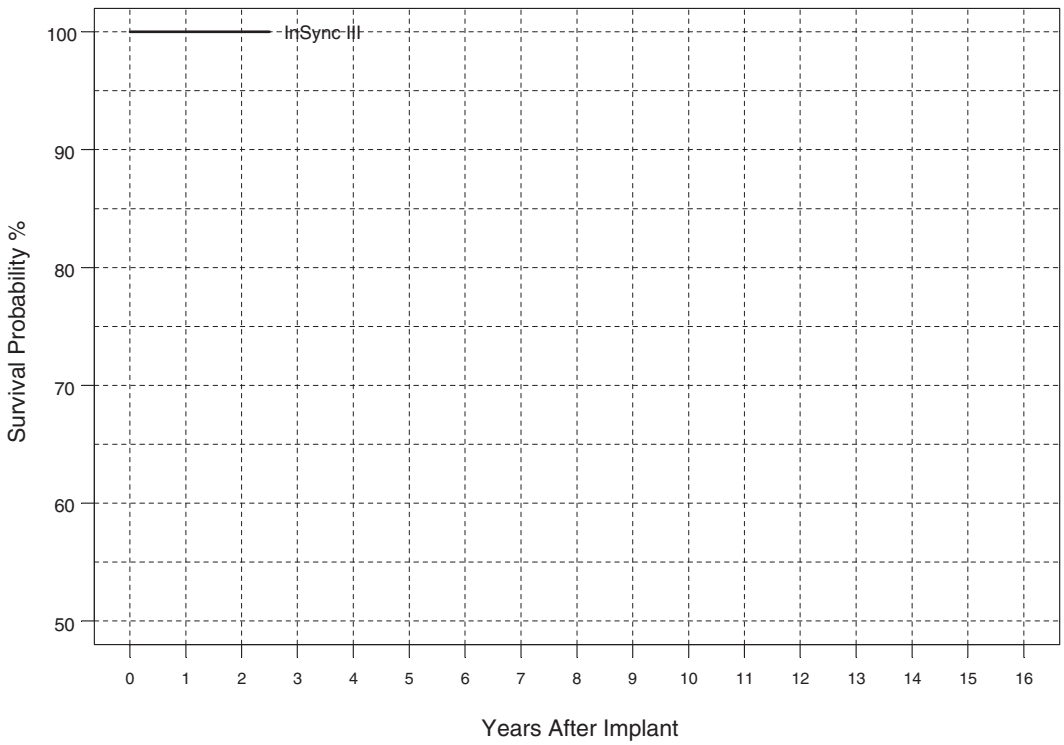
Dual Chamber Pulse Generators



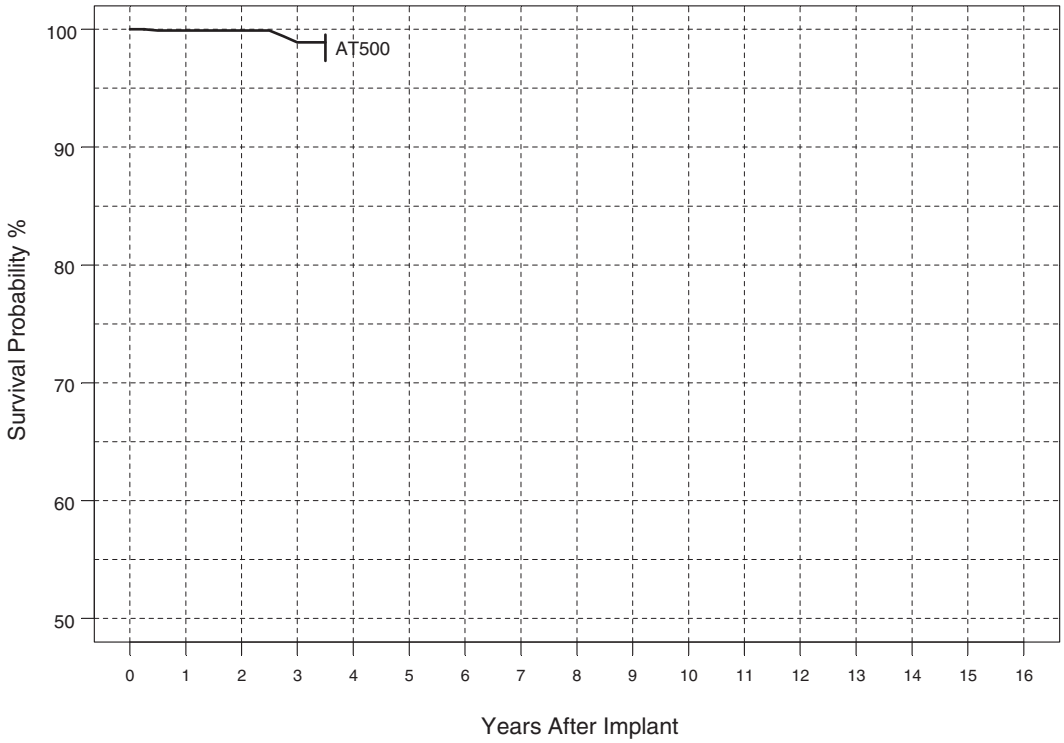
InSync 8040 Pulse Generator



InSync III 8042 Pulse Generator



AT500 7253 Pulse Generator



Dual Chamber Implantable Pulse Generators

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

Laboratory Analysis and Actuarial Survival Probability (%)[1] (± 2 Standard Errors)[2]

Model Family	Registered Implants	Active Implants[3]	Battery EOL Indicators[4]	Electrical Failures[4]	1 Year Intervals								2 Year Intervals			
					1	2	3	4	5	6	7	8	10	12	14	16
Elite 7074, 7075, 7076, 7077	47,718	5,600	2,343	109	99.9	99.8	99.6 ±0.1	99.5 ±0.1	98.9 ±0.1	97.8 ±0.2	95.8 ±0.3	91.3 ±0.4	76.4 ±0.7	52.5 +1.8/-1.9		
Elite II 7084, 7085, 7086	57,442	400	6,804	115	99.9	99.8	99.1 ±0.1	96.2 ±0.2	90.6 ±0.3	82.6 ±0.4	70.0 ±0.6	47.6 ±0.8	27.1 ±1.2 (102 mo.)			
Minuet 7107, 7108	16,742	4,300	345	9	100	99.9	99.9 +0.1/-0.2	99.5 ±0.1	98.9 ±0.2	98.2 ±0.3	97.0 ±0.4	94.7 ±0.5	89.5 +0.8/-0.9	84.3 +1.7/-1.9 (138 mo.)		
Thera-D 7944, 7945, 7946	1,934	300	126	1	99.9 +0.1/-0.6	99.6 +0.2/-0.4	98.8 +0.5/-0.8	97.1 +0.8/-1.0	93.3 +1.3/-1.6	89.9 +1.6/-1.9	83.6 +2.3/-2.6	67.9 +3.7/-4.0	64.9 +4.0/-4.4 (99 mo.)			
Thera-DR 40 7940, 7941, 7942	29,536	3,300	2,250	42	99.9	99.7 ±0.1	98.6 ±0.2	96.5 ±0.3	93.6 ±0.4	88.9 ±0.5	81.2 ±0.6	67.7 ±0.9	46.7 +2.8/-2.9 (105 mo.)			
Thera-DR 50 7950, 7951, 7952	4,493	1,600	52	1	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	97.4 +0.5/-0.7	95.9 +0.7/-0.9	94.5 +1.1/-1.4 (105 mo.)			
Thera-i D 7964i, 7965i, 7966i	3,344	1,400	27	2	100	99.9 +0.1/-0.2	99.7 +0.1/-0.3	99.6 +0.2/-0.4	99.2 +0.3/-0.5	97.5 +0.7/-0.9	96.1 +0.9/-1.2	95.7 +1.1/-1.5 (93 mo.)				
Thera-i DR 7960i, 7961i, 7962i	121,471	58,000	825	58	99.9	99.9	99.8	99.5	99.2 ±0.1	98.4 ±0.1	96.8 ±0.2	94.3 ±0.5				
Thera-i VDD 8968i	4,876	2,300	9	0	99.9 +0.1/-0.2	99.9 +0.1/-0.2	99.7 +0.1/-0.3	99.7 +0.1/-0.3	99.6 +0.2/-0.3	99.5 +0.2/-0.4	99.5 +0.2/-0.4	99.5 +0.2/-0.4 (90 mo.)				
Thera-i DR 7968i	3,586	1,600	40	5	100	99.8 +0.1/-0.3	99.5 +0.2/-0.4	98.6 +0.4/-0.6	97.3 +0.6/-0.8	94.9 +1.1/-1.3	91.7 +2.0/-2.6 (81 mo.)					
Prodigy D 7864, 7865, 7866	2,834	1,300	13	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	98.4 +0.6/-0.9	98.4 +0.6/-0.9	98.4 +0.6/-0.9 (87 mo.)				
Prodigy DR 7860, 7861, 7862	37,393	19,200	132	13	99.9	99.9	99.9	99.7 ±0.1	99.3 ±0.1	98.6 ±0.2	97.5 ±0.4	96.5 +0.8/-1.0 (90 mo.)				
Preva DR 7088, 7089	25,438	12,700	90	4	99.9	99.9	99.9	99.7 ±0.1	99.4 ±0.1	98.6 ±0.2	97.4 +0.5/-0.7	96.7 +0.9/-1.3 (87 mo.)				
Preva D 7068	895	400	3	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	98.2 +1.0/-2.0						
Preva ST DR 7078	826	400	4	0	99.7 +0.2/-0.8	99.7 +0.2/-0.8	99.7 +0.2/-0.8	99.7 +0.2/-0.8	99.3 +0.5/-1.4	98.6 +0.8/-1.8						
Kappa 400 DR KDR401, KDR403	43,784	27,400	84	25	99.9	99.9	99.8 ±0.1	99.6 ±0.1	99.3 ±0.1	98.0 +0.5/-0.7 (69 mo.)						
Kappa 700 D KD701	298	200	0	0	100	100	100	100 (39 mo.)								
Kappa 700 DR KDR701, KDR703, KDR706	157,792	118,000	107	105	99.9	99.9	99.7	99.4 ±0.1	98.5 +0.3/-0.4 (57 mo.)							
Kappa 700 DR KDR721	9,762	6,500	43	4	99.9 +0.1/-0.2	99.8 ±0.1	99.0 ±0.3	96.9 +0.7/-0.9	96.3 +0.9/-1.1 (54 mo.)							
Kappa 700 VDD KVDD701	1,699	1,100	3	2	99.9 +0.1/-0.6	99.9 +0.1/-0.6	99.7 +0.2/-0.5	99.3 +0.4/-1.2	99.3 +0.4/-1.2 (51 mo.)							
Kappa 600 DR KDR601, KDR603, KDR606	23,390	15,800	6	12	99.9	99.9	99.9	99.7 ±0.1	99.7 ±0.1 (54 mo.)							
Kappa 600 DR KDR651, KDR653	14,067	11,200	1	3	99.9	99.9	99.9 (30 mo.)									
Sigma 200 D SD203	218	100	0	0	100	100	100 (30 mo.)									
Sigma 200 DR SDR203	13,667	10,200	1	5	99.9	99.9	99.9	99.7 +0.2/-0.8								
Sigma 300 DR SDR303, SDR306	68,706	53,100	12	14	99.9	99.9	99.9	99.8 ±0.1								
Sigma 300 VDD SVDD303	602	400	0	0	100	100	100									
Kappa 900 DR KDR901, KDR903, KDR906	68,087	61,900	0	9	99.9	99.9 (21 mo.)										
Kappa 920 DR KDR921	10,315	9,100	0	2	99.9	99.9 (18 mo.)										
Kappa 900 VDD KVDD901	452	400	0	0	100	100 (15 mo.)										
InSync 8040	15,012	10,700	3	5	99.9	99.9 +0.1/-0.2	98.8 +0.7/-1.7	98.8 +0.7/-1.7 (42 mo.)								
InSync III 8042	6,649	5,900	0	1	100	100	100 (30 mo.)									
AT500 AT501, 7253**	4,218	3,900	2	1	99.9 +0.1/-0.2	99.9 +0.1/-0.2	98.9 +0.6/-1.6	98.9 +0.6/-1.6 (42 mo.)								
Kappa 800 DR KDR801, KDR803	3,458	3,200	0	0	100	100 (15 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%. If no standard error (SE) appears, SE less than 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).

** Denotes new advisories since the last Product Performance Report. See Advisory section, page 59.

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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 at least one 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. Error bars represent two Standard Errors at the leading 3-month interval. "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.)

Results

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

Sprint Quattro Lead Model 6947

- **Dual Coil (Quadripolar)**
- **Active Fixation**
- **True Bipolar Sensing**
- **Silicone Insulation**
- **Steroid-eluting**

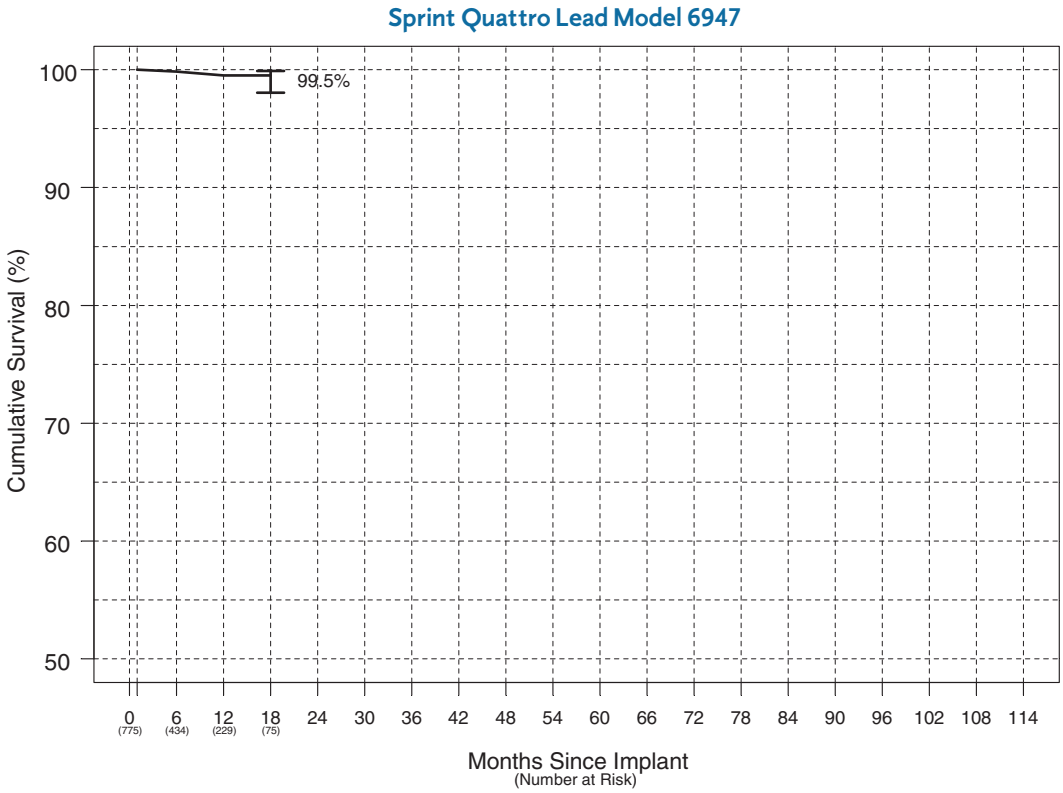
Total device months: **6,621**

Cumulative survival:
99.5% at 18 months

95% Confidence interval:
98.1 to 99.9%

N = 775 leads

Adverse events: 2



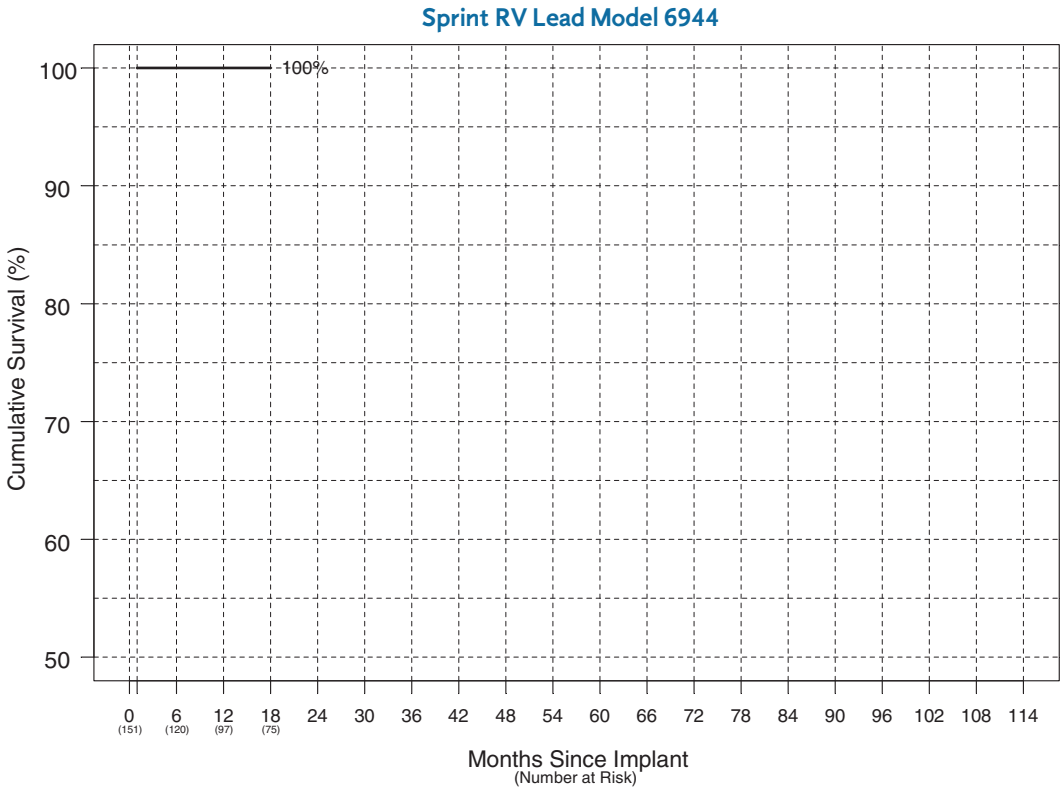
Sprint RV Lead Model 6944

- **Dual Coil (Quadripolar)**
- **Passive Fixation**
- **True Bipolar Sensing**
- **Silicone Insulation**
- **Steroid-eluting**

Total device months: **2,583**

Cumulative survival:
100% at 18 months

N = 151 leads



Sprint RV Lead Model 6943

- **Single Coil (Tripolar)**
- **Active Fixation**
- **True Bipolar Sensing**
- **Silicone Insulation**
- **Steroid-eluting**

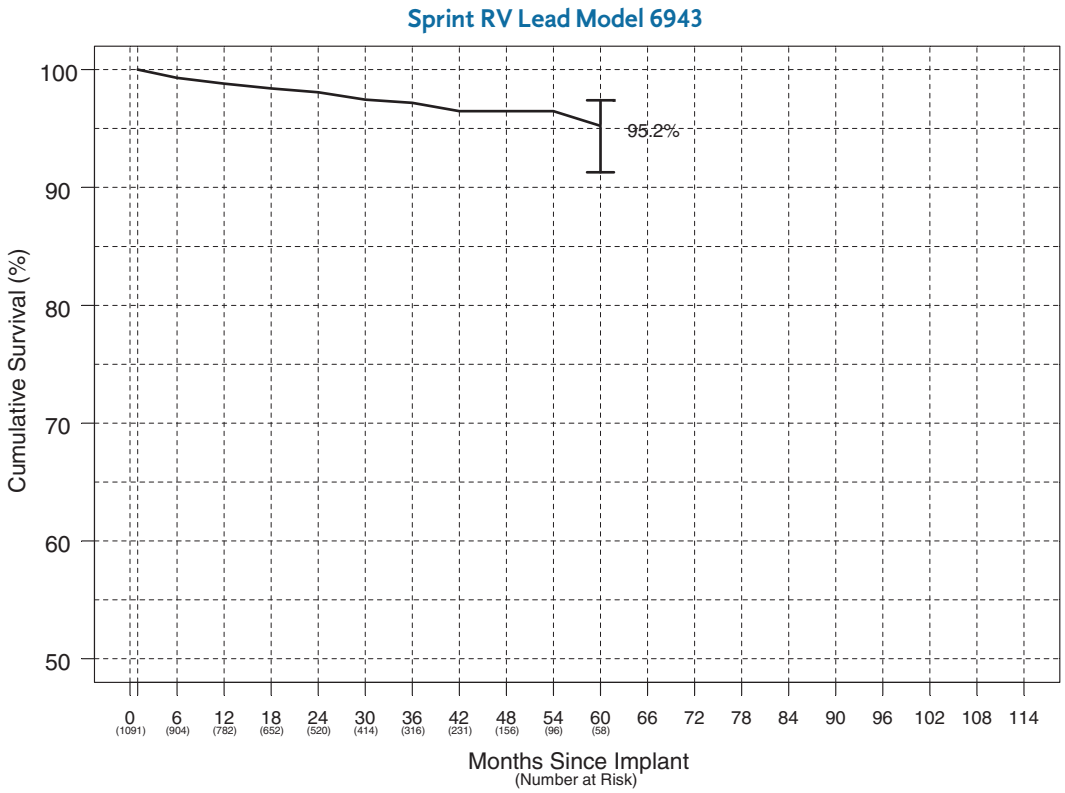
Total device months: **27,947**

Cumulative survival:
95.2% at 60 months

95% confidence interval:
91.3 to 97.4%

N = 1,091 leads

Adverse events: 23



Sprint RV Lead Model 6945

- **Dual Coil (Tripolar)**
- **Active Fixation**
- **Integrated Bipolar Sensing**
- **Silicone Insulation**
- **Steroid-eluting**

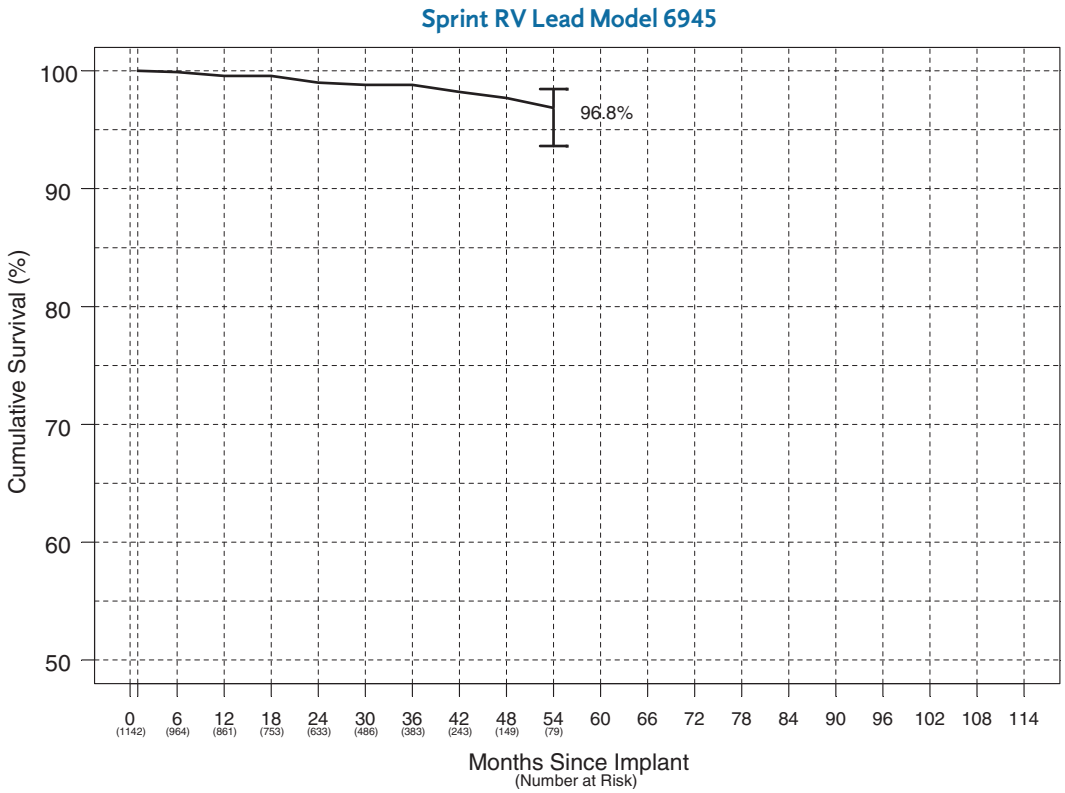
Total device months: **30,771**

Cumulative survival:
96.8% at 54 months

95% Confidence interval:
93.6 to 98.4%

N = 1,142 leads

Adverse events: 14



Sprint RV Lead Model 6942

- **Dual Coil (Tripolar)**
- **Passive Fixation**
- **Integrated Bipolar Sensing**
- **Silicone Insulation**
- **Steroid-eluting**

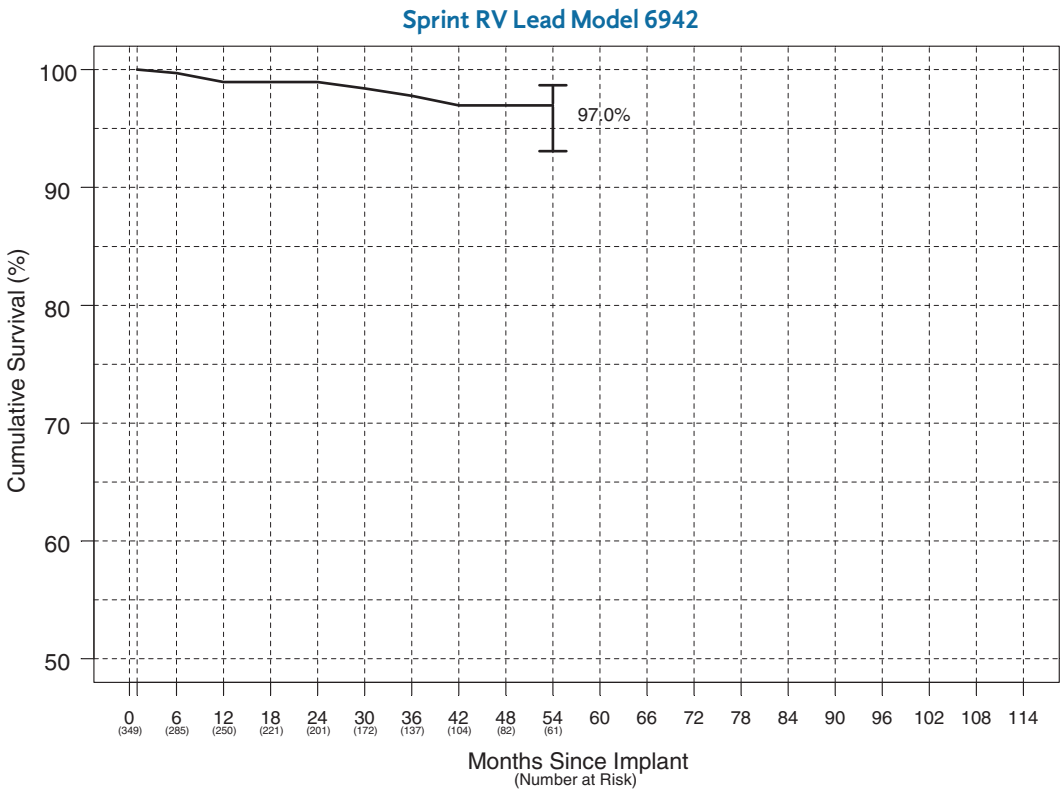
Total device months: **10,469**

Cumulative survival:
97.0% at 54 months

95% confidence interval:
93.1 to 98.7%

N = 349 leads

Adverse events: 7



Sprint RV Lead Model 6932

- **Single Coil (Tripolar)**
- **Passive Fixation**
- **True Bipolar Sensing**
- **Silicone Insulation**
- **Steroid-eluting**

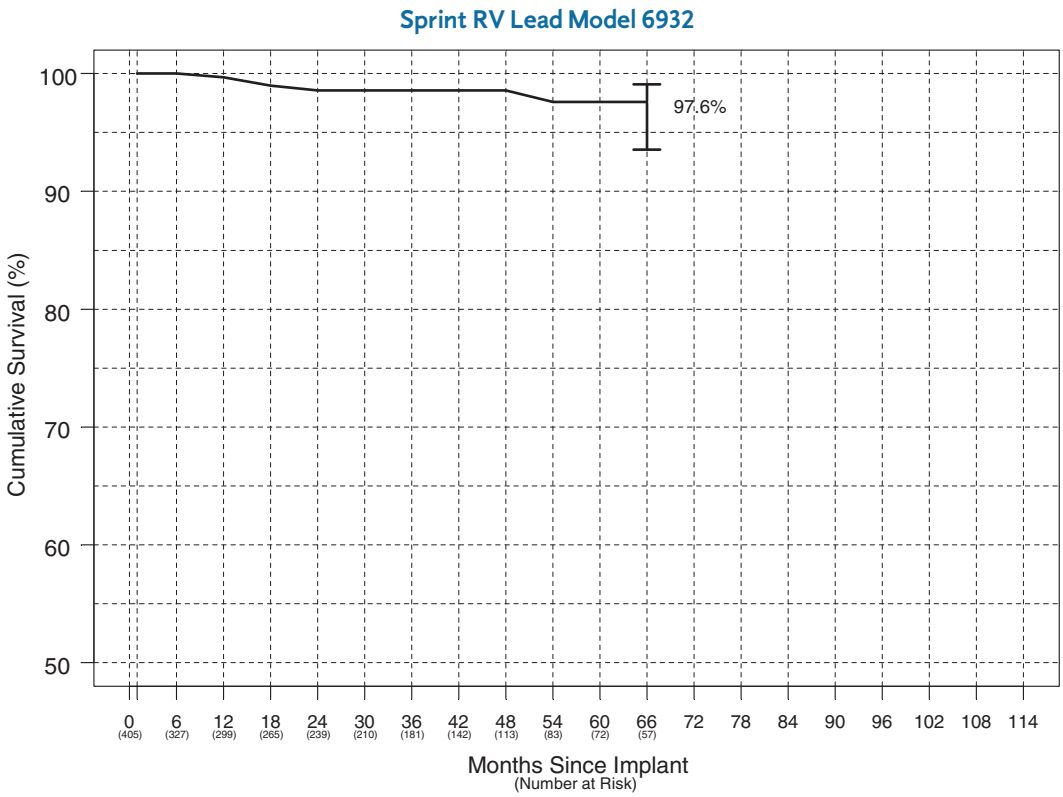
Total device months: **13,330**

Cumulative survival:
97.6% at 66 months

95% confidence interval:
93.6 to 99.1%

N = 405 leads

Adverse events: 5



Transvene RV Leads

- **Single Coil (Tripolar)**
- **Active Fixation**
- **True Bipolar Sensing**
- **Polyurethane Insulation**

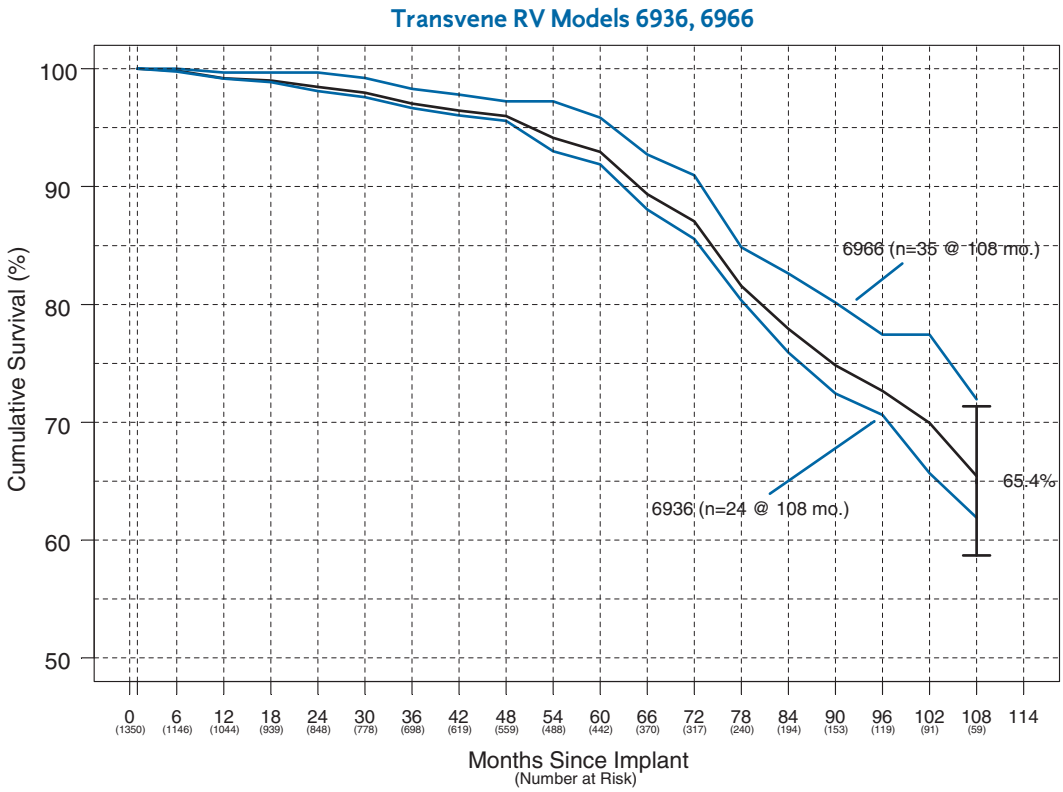
Total device months: **58,782**

Cumulative survival:
65.4% at 108 months

95% confidence interval:
58.7 to 71.4%

N = 1,350 leads

Adverse events: 125



Transvene SVC/CS Leads

- **Single Coil (Unipolar)**
- **High Voltage Only**
- **Silicone Insulation**

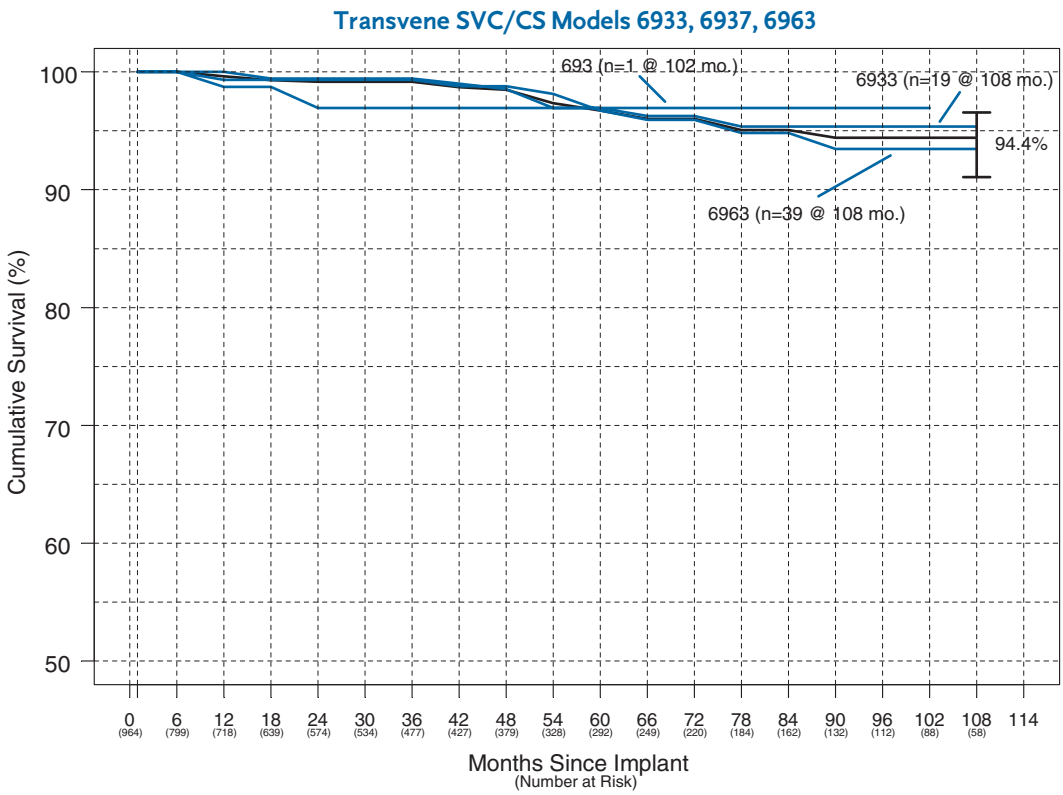
Total device months: **41,254**

Cumulative survival:
94.4% at 108 months

95% confidence interval:
91.1 to 96.6%

N = 964 leads

Adverse events: 20



Note: The blue lines represent individual lead models, as labeled. The numbers in parentheses represent the number of leads followed on the leading edge of the blue survival curves. The black lines represent the overall survival experience for the lead group.

Transvene Sub-Q Patch Leads

- **High Voltage (Unipolar)**
- **Silicone Insulation**

Total device months: **16,499**

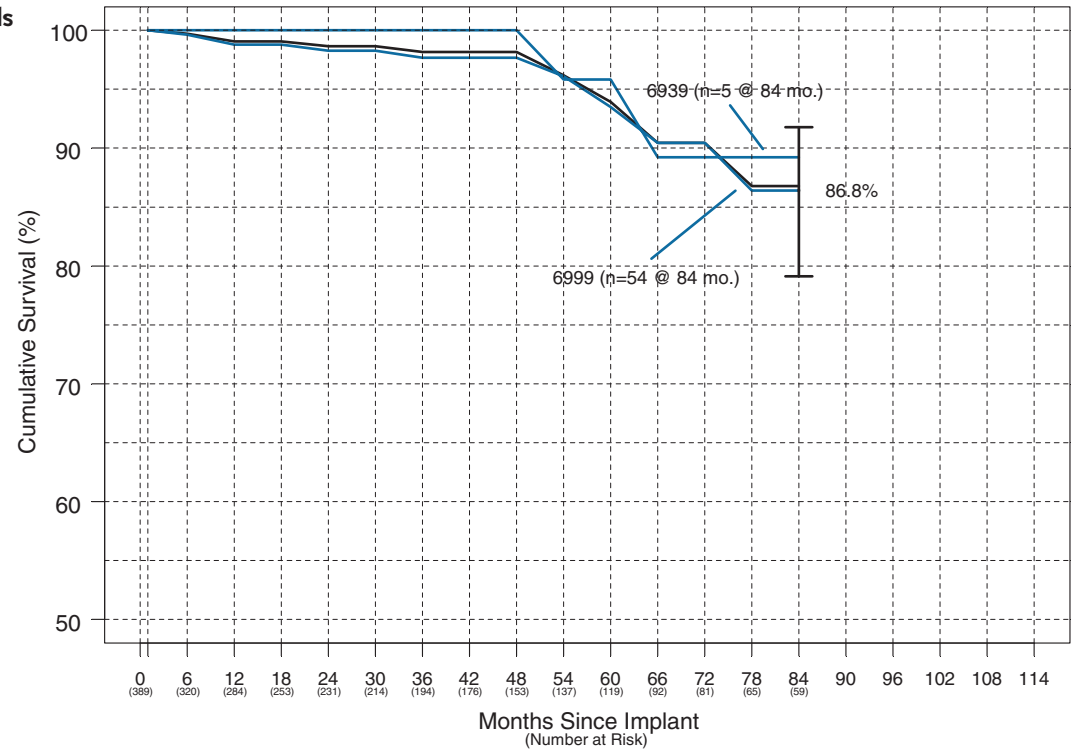
Cumulative survival:
86.8% at 84 months

95% confidence interval:
79.1 to 91.8%

N = 389

Adverse events: 20

Transvene Sub-Q Patch Models 6939, 6999



Epicardial Patch Leads

- **High Voltage (Unipolar)**
- **Silicone Insulation**

Total device months: **16,868**

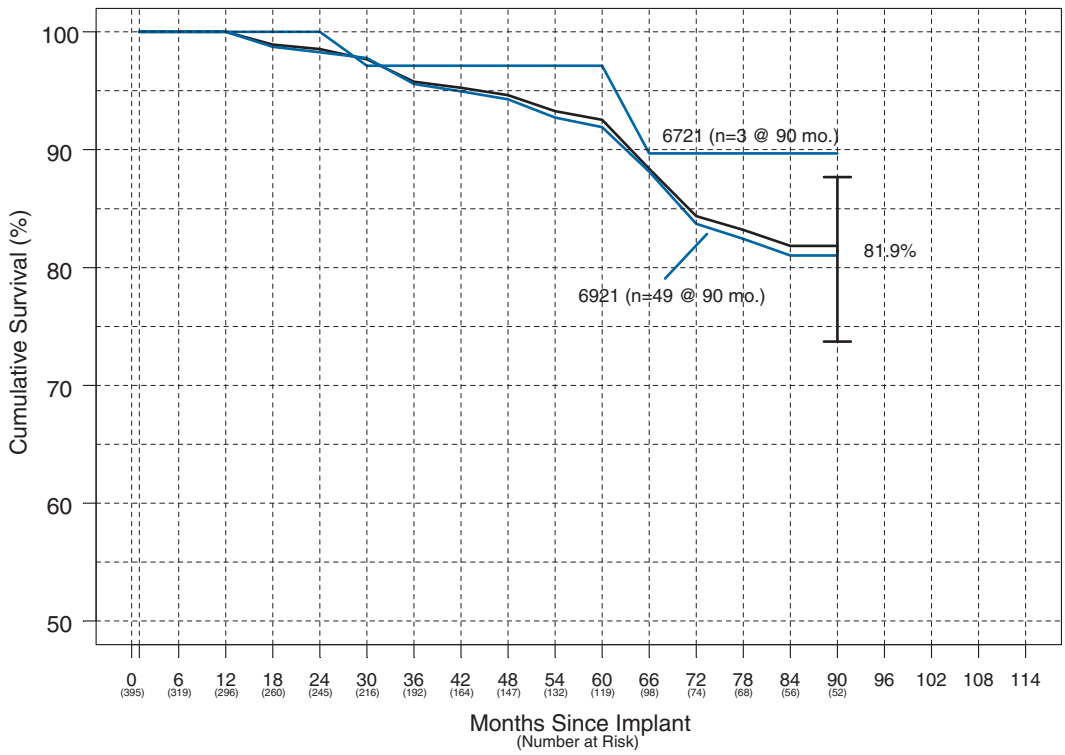
Cumulative survival:
81.9% at 90 months

95% confidence interval:
73.7 to 87.7%

N = 395

Adverse events: 26

Epicardial Patch Models 6721, 6921



Tenax Lead Model 6917

- **Unipolar**
- **Epicardial**
- **Silicone Insulation**

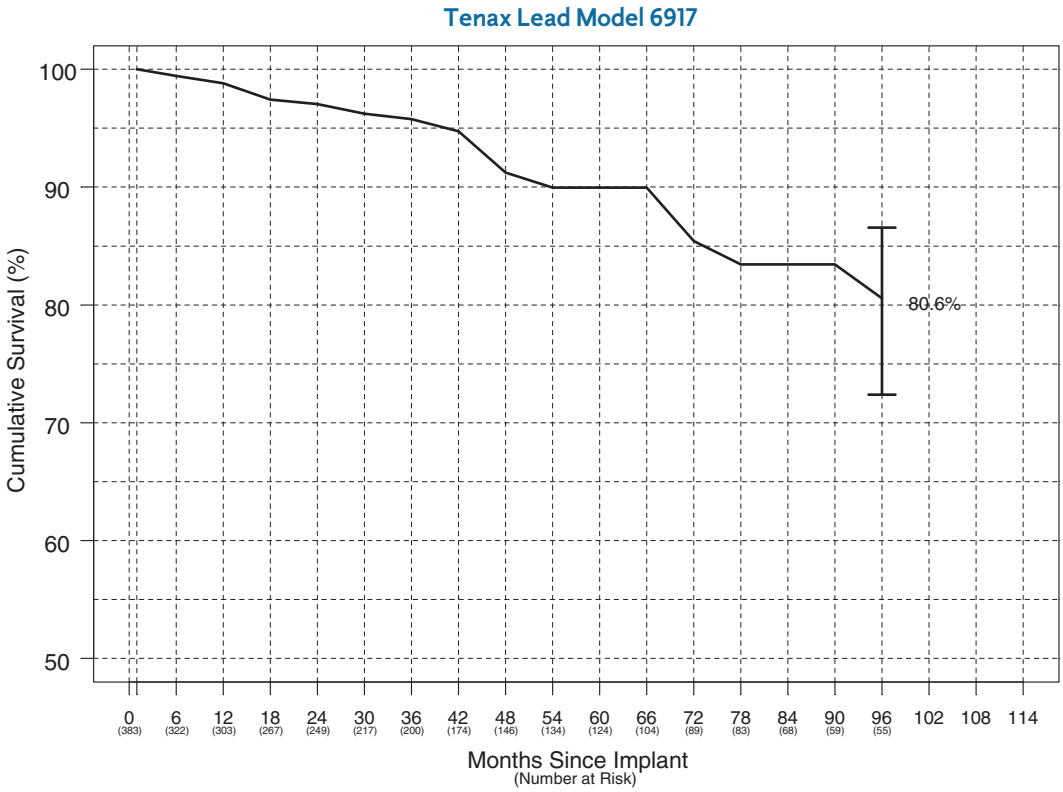
Total device months: **17,511**

Cumulative survival:
80.6% at 96 months

95% confidence interval:
72.3 to 86.5%

N = 383

Adverse events: 35



CapSureFix Lead Model 6940

- **No Coil (Atrial)**
- **Active Fixation**
- **True Bipolar Sensing**
- **Silicone Insulation**
- **Steroid-eluting**

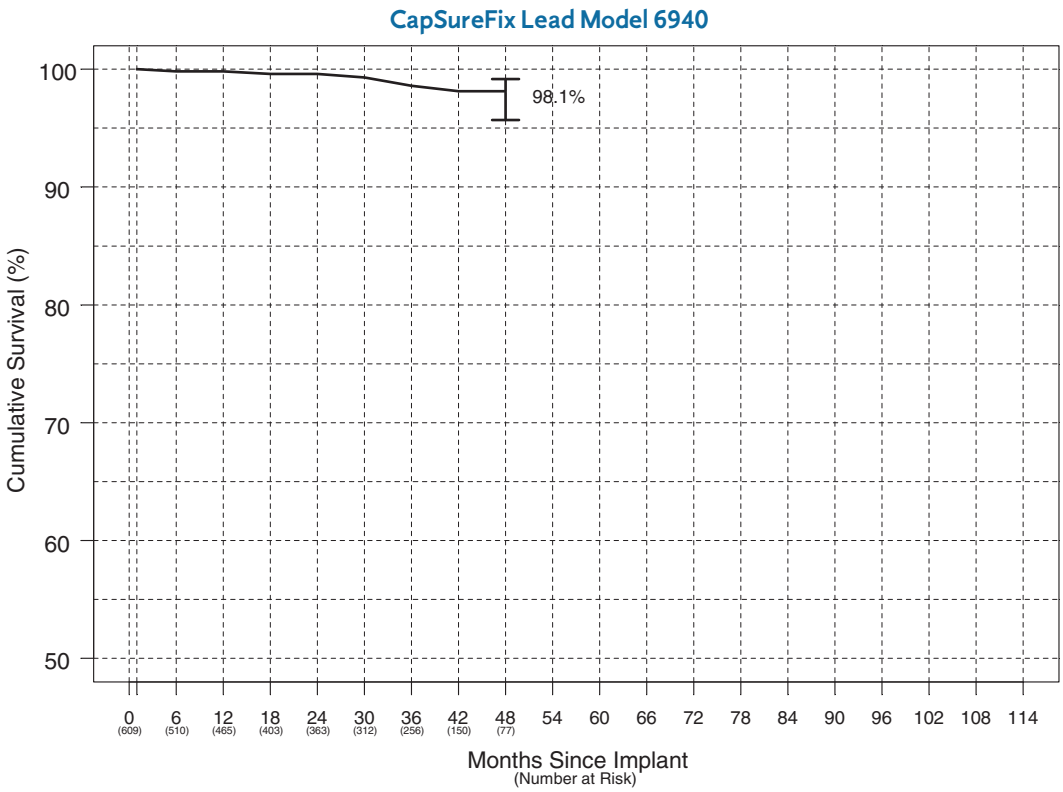
Total device months: **17,157**

Cumulative survival:
98.1% at 48 months

95% confidence interval:
95.7 to 99.2%

N = 609

Adverse events: 6



CapSureFix Novus Lead Model 5076

- **No Coil (Atrial/Ventricle)**
- **Active Fixation**
- **True Bipolar Sensing**
- **Silicone Insulation**
- **Steroid-eluting**

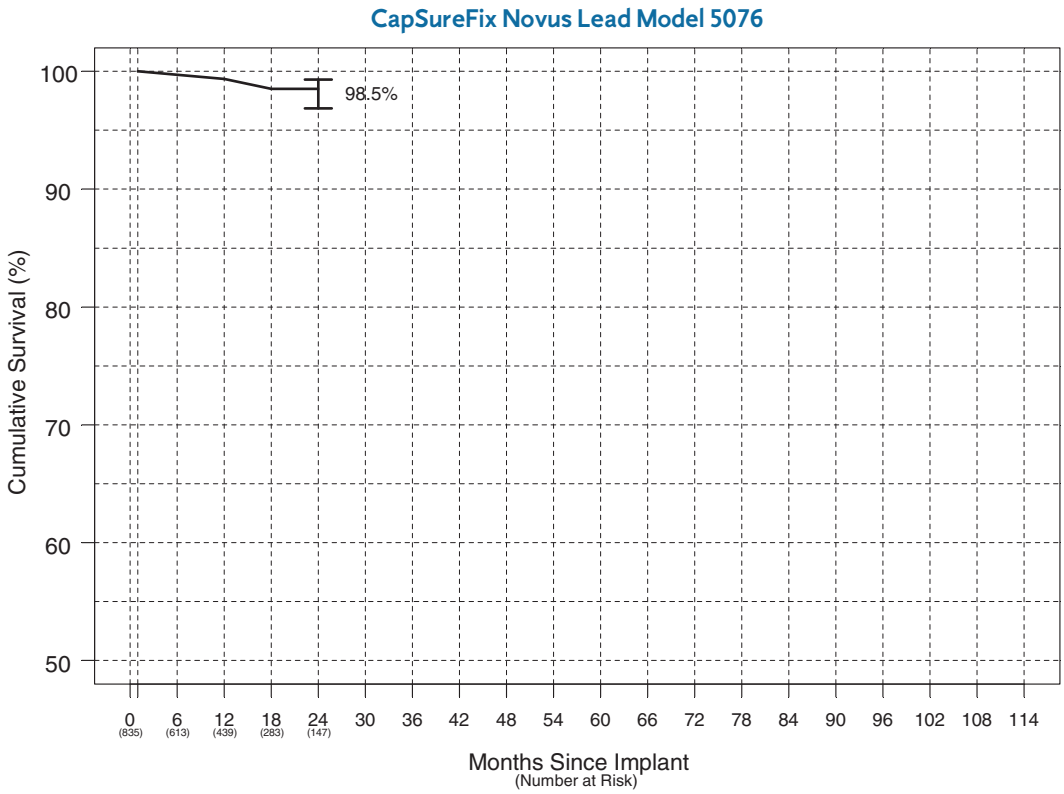
Total device months: **11,751**

Cumulative survival:
98.5% at 24 months

95% confidence interval:
96.8 to 99.3%

N = 835

Adverse events: 7



CapSureFix Novus Lead Model 5568

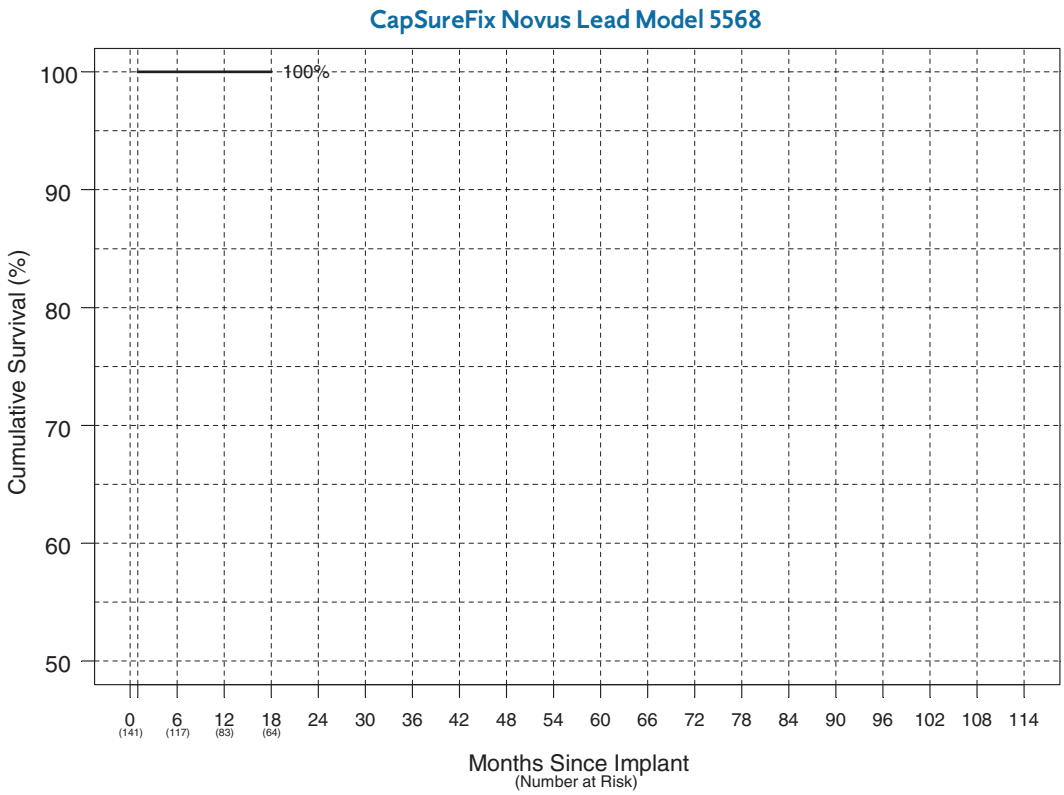
- **No Coil (Atrial/Ventricle)**
- **Active Fixation**
- **True Bipolar Sensing**
- **Silicone Insulation**
- **Steroid-eluting**

Total device months: **2,510**

Cumulative survival:
100% at 18 months

N = 141

Adverse events: 1



4193 LV Lead

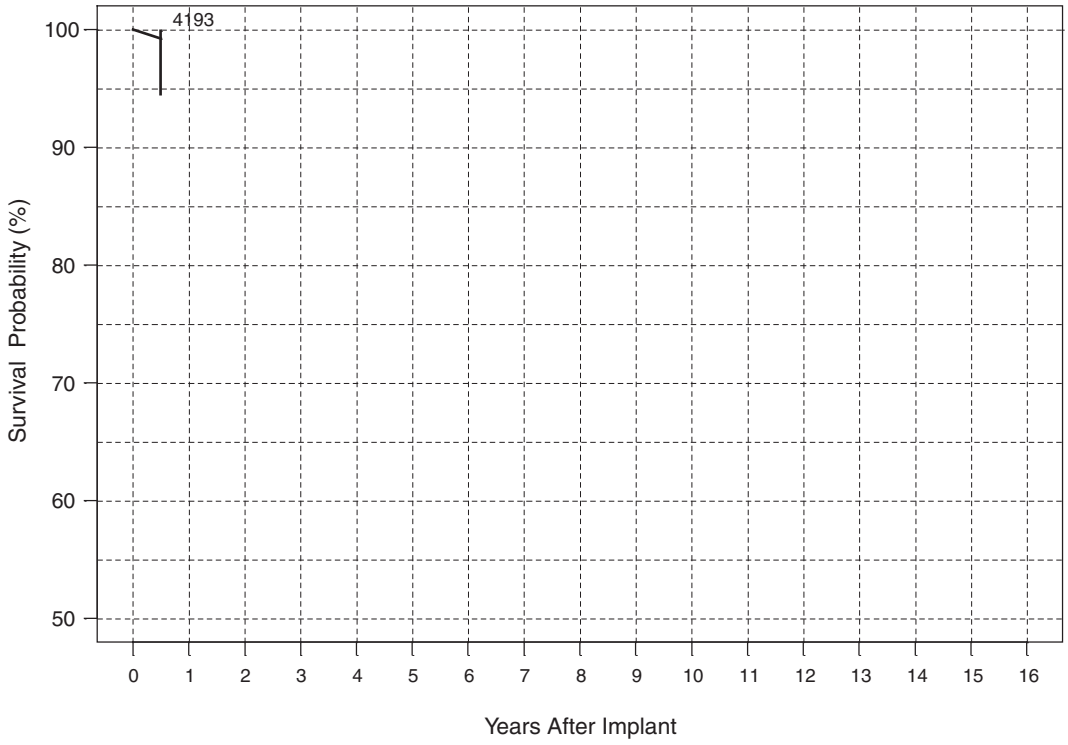

4193
100
90
80
70
60
50
Survival Probability (%)
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
Years After Implant

Table 2. ICD Lead Survival: TCSS Results

Group	Model(s)	Number of Implanted Leads	Cumulative Months of Follow-Up	Lead Survival (95% Confidence Interval)								
				1 Year	2 Year	3 Year	4 Year	5 Year	6 Year	7 Year	8 Year	9 Year
LV	4193	175	1,197	99.2% (94.5% to 99.9%)								
Sprint	6947	775	6,621	99.5% (98.1% to 99.9%)	99.5% (98.1% to 99.9%) @ 18 mo.							
	6945	1,142	30,771	99.6% (98.9% to 99.8%)	99.0% (98.0% to 99.5%)	98.8% (97.7% to 99.4%)	97.7% (95.6% to 98.8%)	96.8% (93.6% to 98.4%) @ 54 mo.				
	6943	1,091	27,947	98.8% (97.9% to 99.4%)	98.1% (96.9% to 98.8%)	97.2% (95.6% to 98.2%)	96.5% (94.5% to 97.7%)	95.2% (91.3% to 97.4%)				
	6944	151	2,583	100%	100% @ 18 mo.							
	6942	349	10,469	98.9% (96.7% to 99.7%)	98.9% (96.7% to 99.7%)	97.8% (94.6% to 99.1%)	97.0% (93.1% to 98.7%)	97.0% (93.1% to 98.7%) @ 54 mo.				
	6932	405	13,330	99.7% (97.8% to 100%)	98.6% (96.3% to 99.5%)	98.6% (96.3% to 99.5%)	98.6% (96.3% to 99.5%)	97.6% (93.6% to 99.1%)	97.6% (93.6% to 99.1%) @ 66 mo.			
Transvene RV	6936, 6966	1,350	58,782	99.2% (98.5% to 99.6%)	98.5% (97.5% to 99.1%)	97.0% (95.7% to 98.0%)	96.0% (94.4% to 97.1%)	92.9% (90.7% to 94.7%)	87.0% (83.8% to 89.7%)	77.9% (73.4% to 81.7%)	72.7% (67.4% to 77.2%)	65.4% (58.7% to 71.4%)
Transvene SVC/CS	6933, 6937, 6963	964	41,254	99.6% (98.8% to 99.9%)	99.2% (98.1% to 99.6%)	99.2% (98.1% to 99.6%)	99.5% (97.0% to 99.2%)	96.7% (94.5% to 98.1%)	96.0% (93.5% to 97.6%)	95.1% (92.1% to 96.9%)	94.4% (91.1% to 96.5%)	94.4% (91.1% to 96.6%)
Transvene Sub-Q	6939, 6999	389	16,499	99.1% (97.1% to 99.7%)	98.7% (96.4% to 99.5%)	98.2% (95.6% to 99.2%)	98.2% (95.6% to 99.2%)	93.9% (89.0% to 96.7%)	90.4% (84.2% to 94.3%)	86.8% (79.1% to 91.8%)		
EPI Patch	6721, 6921	395	16,868	100%	98.9% (96.7% to 99.7%)	95.8% (92.3% to 97.7%)	94.6% (90.7% to 96.9%)	92.5% (87.8% to 95.5%)	84.4% (77.0% to 89.5%)	81.9% (73.7% to 87.7%)	81.9% (73.7% to 87.7%) @ 90 mo.	
Tenax	6917	383	17,511	98.8% (96.8% to 99.5%)	97.1% (94.4% to 98.5%)	95.8% (92.6% to 97.6%)	91.3% (86.6% to 94.4%)	90.0% (84.9% to 93.4%)	85.4% (78.8% to 90.1%)	83.5% (76.4% to 88.6%)	80.6% (72.3% to 86.5%)	
CapSureFix	6940	609	17,157	99.8% (98.8% to 100%)	99.6% (98.4% to 99.9%)	98.6% (96.6% to 99.4%)	98.1% (95.7% to 99.2%)					
	5076	835	11,751	99.4% (98.3% to 99.8%)	98.5% (96.8% to 99.3%)							
	5568	141	2,510	100%	100% @ 18 mo.							

Summary

Lead-related adverse event-free survival estimates are summarized in Table 2.

These estimates are based on reports of 294 lead-related adverse events, summarized in Table 3.

The following clinical responses to these events were made:

- Leads left in place and abandoned
- Leads explanted
- Leads repaired

Discussion

The lead survival estimates presented here are based on data obtained during follow-up visits of TCSS patients, which included collection of data on adverse events, patients lost to follow-up and deaths.

Not all lead fractures can be identified solely on the assessment of pacing and sensing performance. The most reliable methods for evaluating ICD lead integrity are x-ray and defibrillation testing. Medtronic recommends that x-rays be taken every six months as part of routine patient care.

Table 3. ICD Lead-Related Adverse Events: TCSS Results*

Type of Failure	4193	6947	6945	6943	6942	6932	6934	Transvene RV	SVC/CS	SQ Patch	EPI Patch	Tenax 6917	CapSureFix 6940	CapSureFix Novus 5076	CapSureFix 5568	Total
Failure to Capture**	2	0	0	1	0	1	0	0	0	0	0	4	0	4	1	13
Failure to Sense	0	0	2	3	1	2	0	4	0	0	0	5	2	0	0	19
Oversensing	0	0	4	11	3	1	0	67	0	0	0	8	1	2	0	97
Muscle Stimulation	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0	2
Conductor Fracture	0	0	2	2	1	0	1	15	13	10	20	7	1	0	0	72
Insulation Breach	0	1	0	0	0	0	0	12	2	6	1	0	0	0	0	22
Pacing Impedance out-of-range	0	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	0	2	2	0	3	0	0	0	0	7
Failure to Cardiovert/Defibrillation	0	0	0	0	0	1	0	5	1	2	2	0	0	0	0	11
Inappropriate VT	0	0	0	0	0	0	0	1	0	0	0	2	0	0	0	3
Inappropriate VF	0	0	2	2	0	0	0	11	0	0	0	7	0	0	0	22
Dislodgement	0	1	0	1	1	0	0	0	1	0	0	0	1	1	0	6
Misc: Other	0	0	1	1	1	0	0	4	1	2	0	0	1	0	0	11
Total	**2**	**2**	**14**	**23**	**7**	**5**	**1**	**125**	**20**	**20**	**26**	**35**	**6**	**7**	**1**	**294**

* This table represents all qualifying lead-related adverse events reported in the TCSS. ** Failure to capture or abnormal sensing is possible when using the 7217 common port.

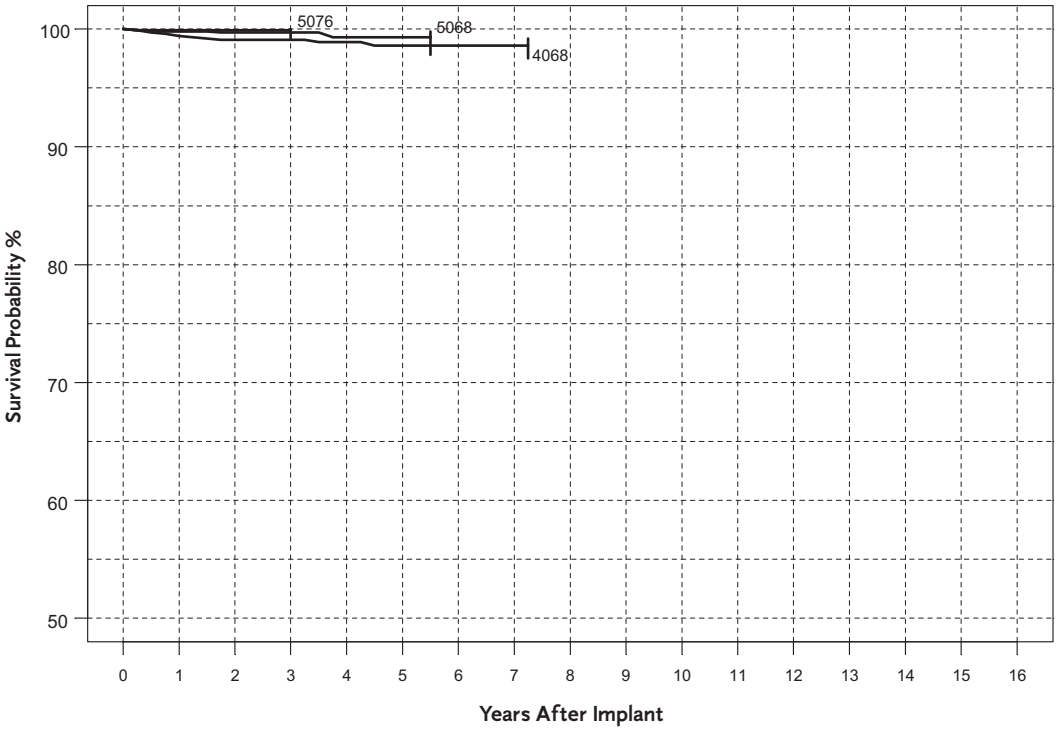
Table 4. Tachy Leads Laboratory Analysis

Model Family	Model	Initial Implants	Active Implants	Implant Damage	Electrical Failures	Other
Sprint	6947	69,183	62,888	138	10	8
	6945	43,673	30,447	191	50	11
	6944	20,461	17,476	18	16	7
	6943	20,305	13,300	48	44	8
	6942	18,106	11,650	32	26	5
	6932	14,868	8,720	15	32	6
Transvene RV	6936	19,394	7,022	58	326	16
	6966	5,231	1,298	34	78	3
SVC/CS	6937	2,506	1,523	0	11	0
	6933	8,541	3,585	17	115	5
	6963	5,350	1,860	14	60	8
Sub-Q Patch	6939	1,178	402	2	6	0
	6999	3,138	956	2	26	1
Epicardial Patch	6721	1,417	718	0	12	0
	6921	6,967	1,656	5	65	0
CapSureFix	6940	26,558	18,164	115	12	3
Tachy	4193	38,757	35,718	32	2	41

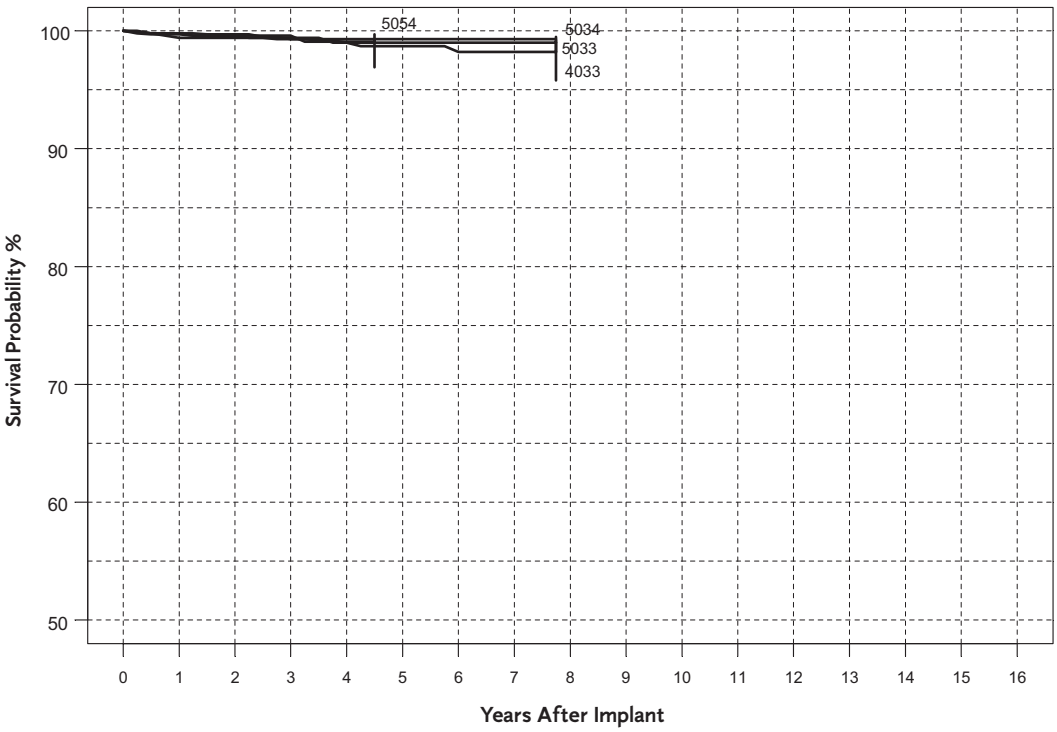
Brady Leads CLS

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

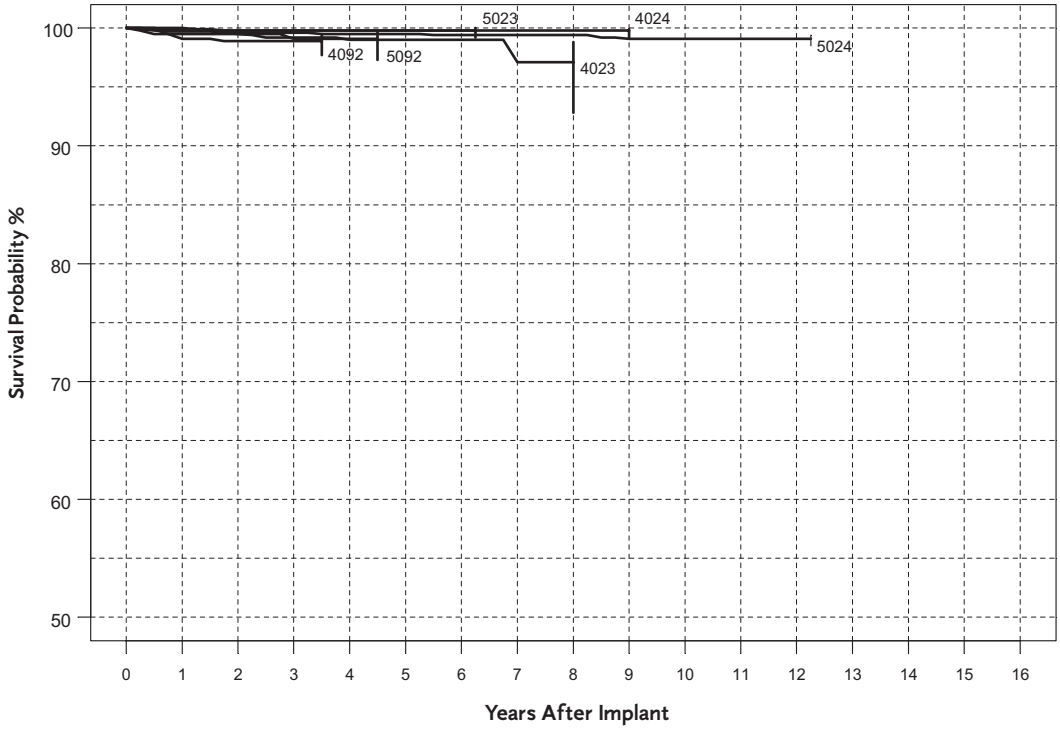
Ventricular CapSureFix Leads



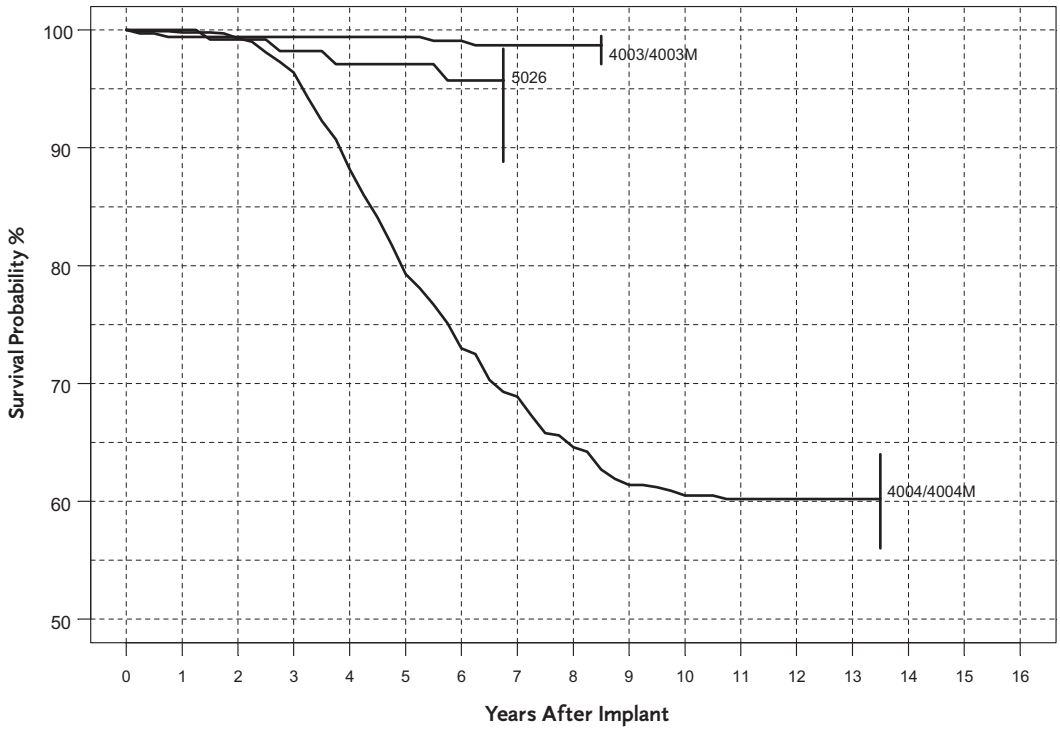
Ventricular CapSure Z/CapSure Z Novus Leads



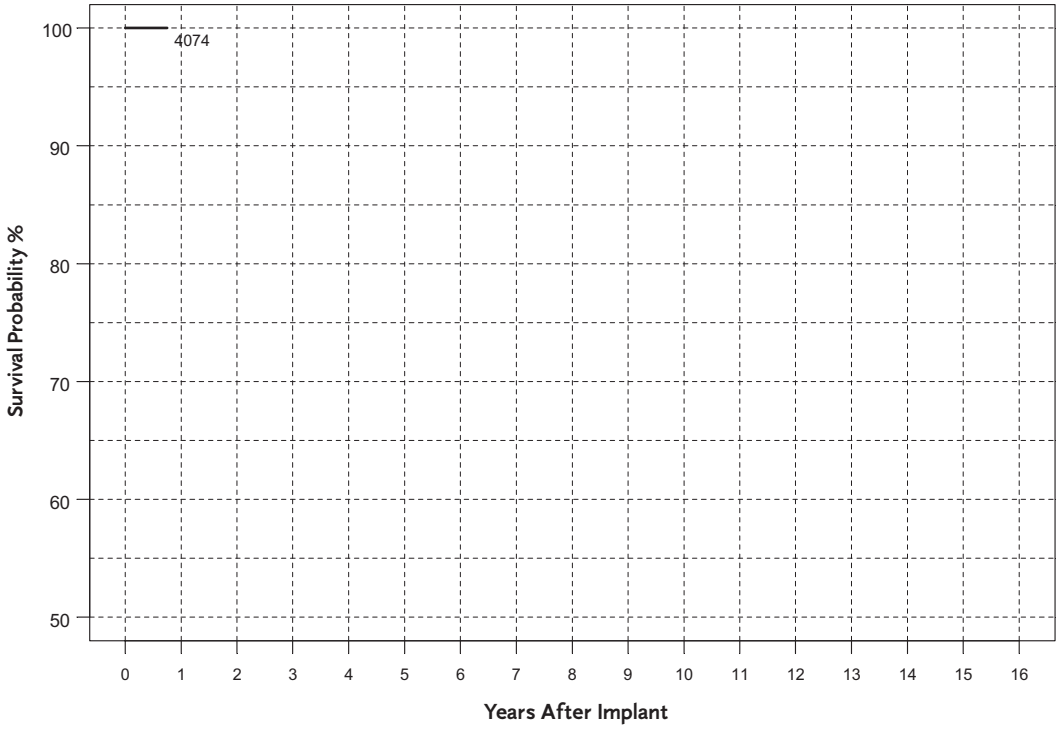
Ventricular CapSure SP/CapSure SP Novus Leads



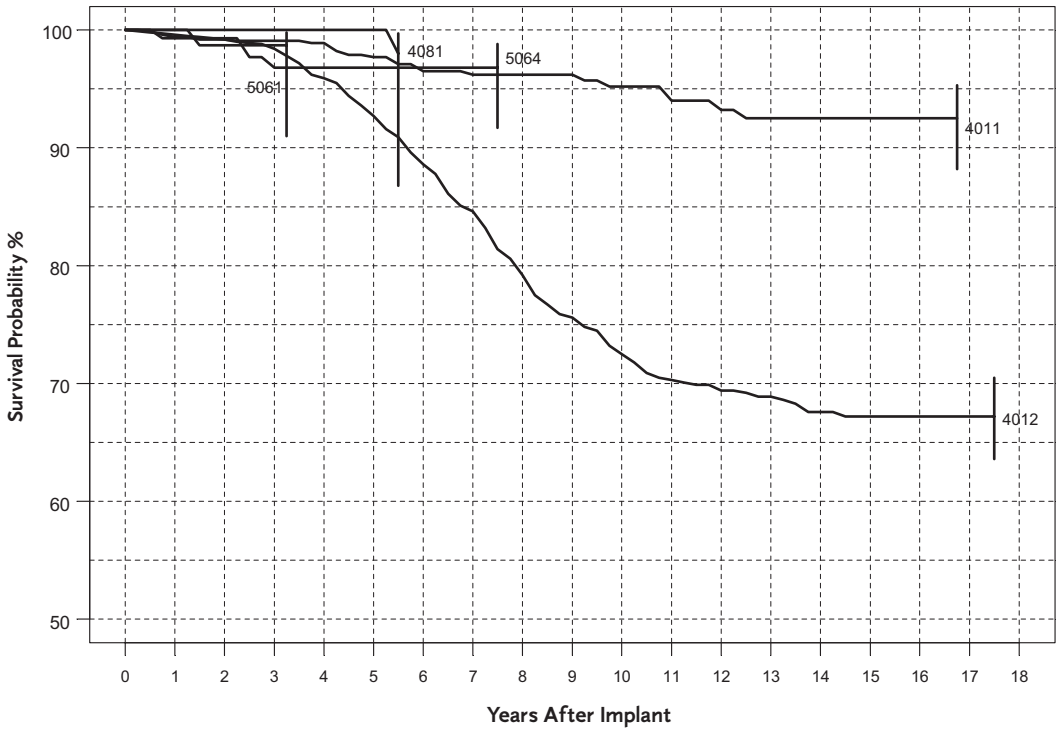
Ventricular CapSure Leads



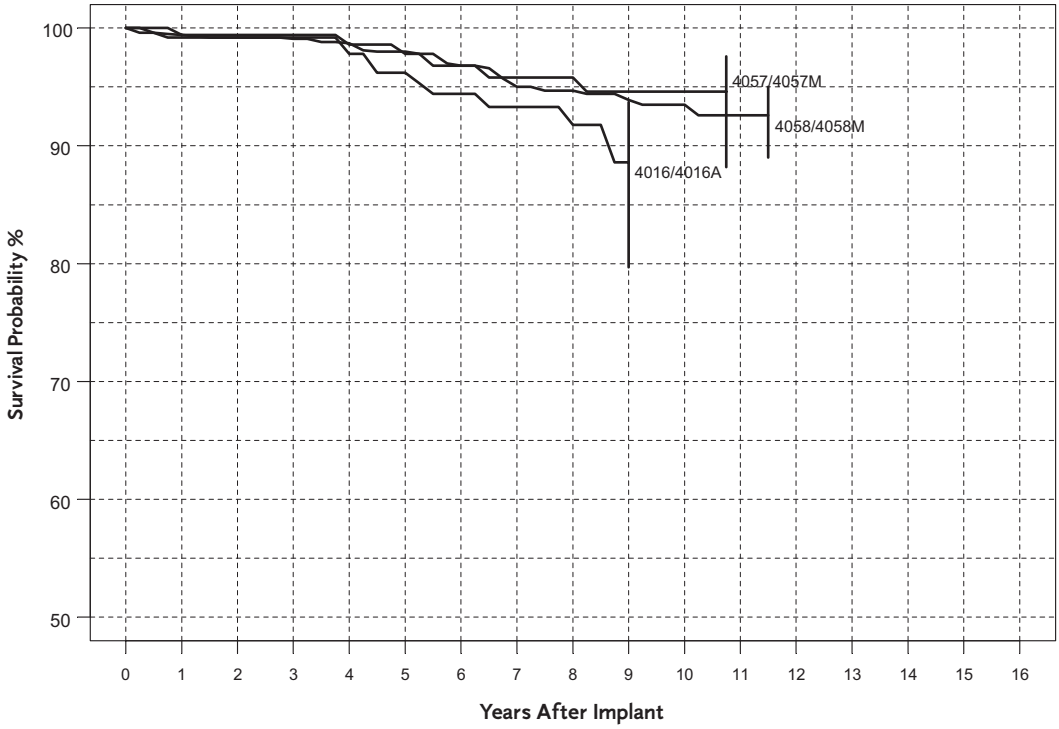
Ventricular CapSure Sense Leads



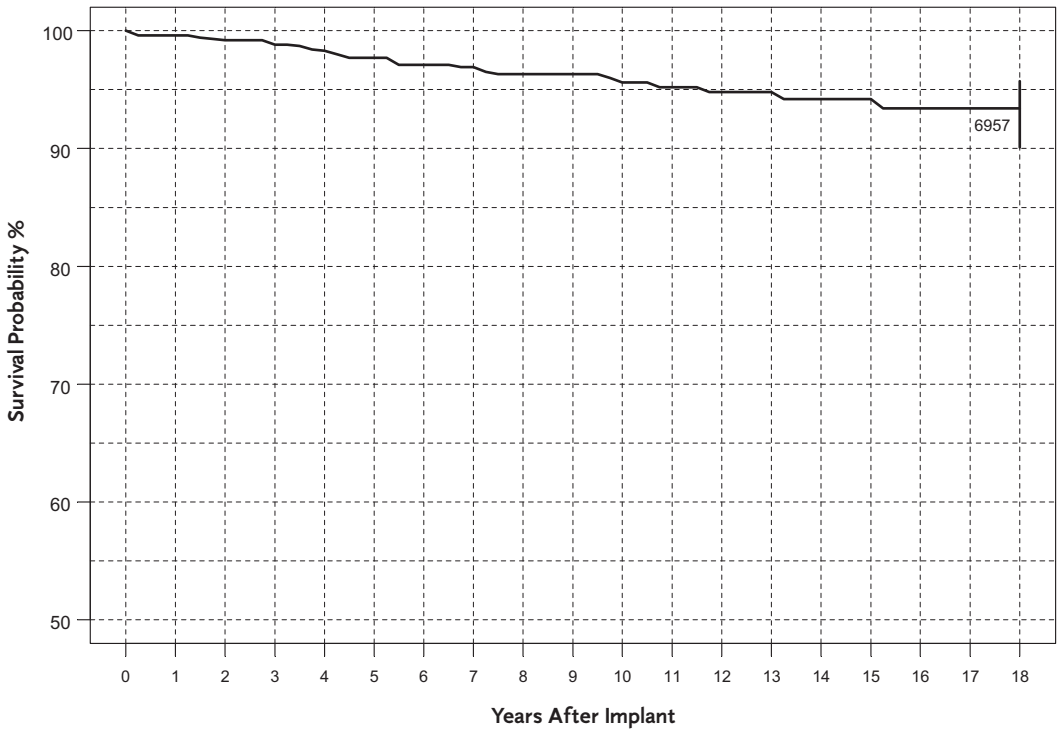
Ventricular Target Tip Leads



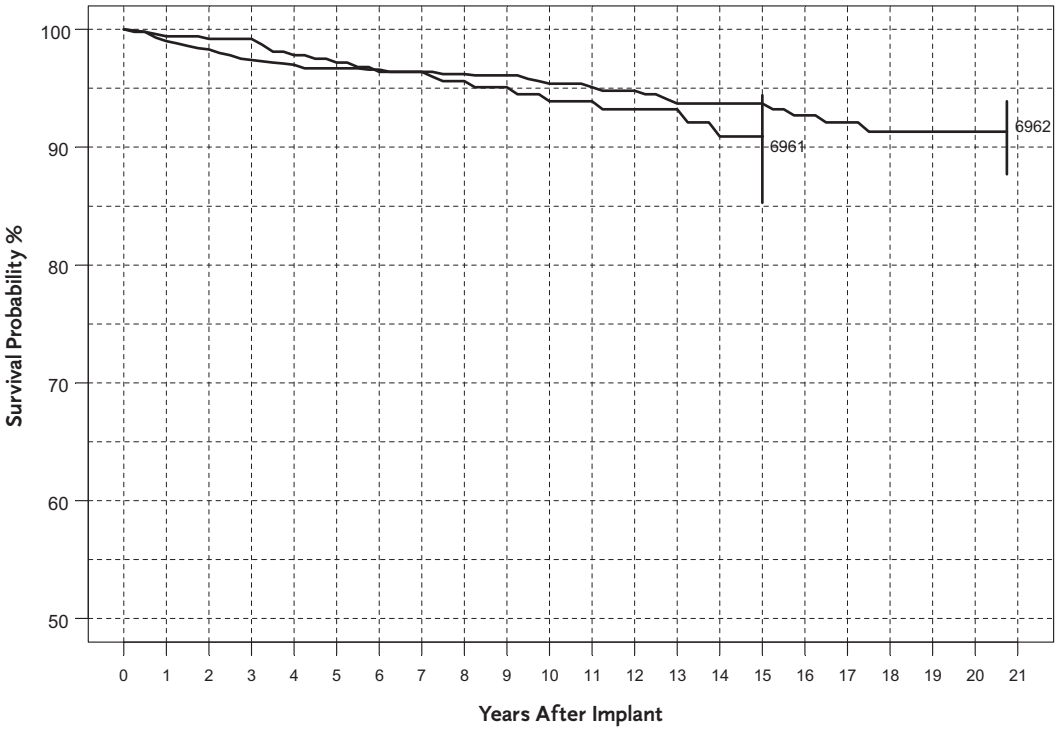
Ventricular Screw-In Leads



Ventricular Spectraflex Leads



Ventricular Tenax Leads



Ventricular Implantable Pacing Leads (Bradycardia)

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

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

Model Family	Model	Avail[3]	Initial Implants	Compli-cations	1 Year Intervals								2 Year Intervals			
					1	2	3	4	5	6	7	8	10	12	14	16
CapSureFix	4068	Y	1,723	16	99.4% (98.8% to 99.7%)	99.1% (98.4% to 99.5%)	99.1% (98.4% to 99.5%)	98.9% (98.1% to 99.4%)	98.6% (97.5% to 99.2%)	98.6% (97.5% to 99.2%)	98.6% (97.5% to 99.2%)	98.6% (97.5% to 99.2%) at 87 mo.				
	5068	Y	1,357	4	99.8% (99.2% to 100%)	99.7% (99% to 99.9%)	99.7% (99% to 99.9%)	99.3% (97.8% to 99.8%)	99.3% (97.8% to 99.8%)	99.3% (97.8% to 99.8%) at 66 mo.						
CapSureFix Novus	5076	Y	946	1	99.9% (99.2% to 100%)	99.9% (99.2% to 100%)	99.9% (99.2% to 100%)									
CapSure Z	4033	Y	538	6	99.4% (98% to 99.8%)	99.4% (98% to 99.8%)	99.4% (98% to 99.8%)	99% (97.4% to 99.6%)	98.7% (96.7% to 99.5%)	98.2% (95.8% to 99.2%)	98.2% (95.8% to 99.2%)	98.2% (95.8% to 99.2%) at 93 mo.				
	5033	Y	1,892	10	99.8% (99.4% to 99.9%)	99.7% (99.3% to 99.9%)	99.3% (98.7% to 99.6%)	99.3% (98.7% to 99.6%)	99.3% (98.7% to 99.6%)	99.3% (98.7% to 99.6%)	99.3% (98.7% to 99.6%)	99.3% (98.7% to 99.6%) at 93 mo.				
	5034	N	1,597	11	99.8% (99.4% to 99.9%)	99.6% (99% to 99.8%)	99.3% (98.6% to 99.6%)	99% (98.2% to 99.5%)	99% (98.2% to 99.5%)	99% (98.2% to 99.5%)	99% (98.2% to 99.5%)	99% (98.2% to 99.5%) at 93 mo.				
CapSure Z Novus	5054	Y	1,195	6	99.7% (99.2% to 99.9%)	99.6% (99% to 99.9%)	99.6% (99% to 99.9%)	99.1% (96.9% to 99.7%)	99.1% (96.9% to 99.7%) at 54 mo.							
CapSure SP	4023	Y	1,140	9	100%	99.5% (98.7% to 99.8%)	99.2% (98.2% to 99.6%)	99% (97.7% to 99.5%)	99% (97.7% to 99.5%)	99% (97.7% to 99.5%)	97.1% (92.8% to 98.8%)	97.1% (92.8% to 98.8%)				
	4024	N	1,214	3	99.9% (99.4% to 100%)	99.8% (99.1% to 99.9%)	99.8% (99.1% to 99.9%)	99.8% (99.1% to 99.9%)	99.8% (99.1% to 99.9%)	99.8% (99.1% to 99.9%)	99.8% (99.1% to 99.9%)	99.8% (99.1% to 99.9%)	99.8% (99.1% to 99.9%) at 108 mo.			
	5023/5023M	Y	1,188	2	99.8% (99.2% to 100%)	99.8% (99.2% to 100%)	99.8% (99.2% to 100%)	99.8% (99.2% to 100%)	99.8% (99.2% to 100%)	99.8% (99.2% to 100%)	99.8% (99.2% to 100%) at 75 mo.					
	5024/5024M	N	8,131	37	99.7% (99.5% to 99.8%)	99.6% (99.5% to 99.7%)	99.6% (99.4% to 99.7%)	99.5% (99.3% to 99.7%)	99.5% (99.3% to 99.6%)	99.4% (99.2% to 99.6%)	99.4% (99.2% to 99.6%)	99.4% (99% to 99.6%)	99.1% (98.5% to 99.4%)	99.1% (98.5% to 99.4%)	99.1% (98.5% to 99.4%) at 147 mo.	
CapSure SP Novus	4092	Y	928	7	99.1% (98.1% to 99.6%)	98.9% (97.7% to 99.5%)	98.9% (97.7% to 99.5%)	98.9% (97.7% to 99.5%) at 42 mo.								
	5092	Y	1,007	5	99.5% (98.7% to 99.8%)	99.5% (98.7% to 99.8%)	99.1% (97.3% to 99.7%)	99.1% (97.3% to 99.7%)	99.1% (97.3% to 99.7%) at 54 mo.							
CapSure	4003/4003M	N	711	6	99.4% (98.3% to 99.8%)	99.4% (98.3% to 99.8%)	99.4% (98.3% to 99.8%)	99.4% (98.3% to 99.8%)	99.4% (98.3% to 99.8%)	99.1% (97.7% to 99.6%)	98.7% (97.1% to 99.5%)	98.7% (97.1% to 99.5%)	98.7% (97.1% to 99.5%) at 102 mo.			
	4004/4004M	N	1,640	275	99.8% (99.3% to 99.9%)	99.3% (98.6% to 99.7%)	96.4% (95% to 97.4%)	88.2% (85.9% to 90.2%)	79.3% (76.3% to 81.9%)	73% (69.7% to 76%)	68.9% (65.4% to 72.2%)	64.6% (60.8% to 68.2%)	60.5% (56.5% to 64.4%)	60.2% (56% to 64%)	60.2% (56% to 64%) at 162 mo.	
	5026	N	168	4	100%	99.2% (94.5% to 99.9%)	98.2% (93.1% to 99.6%)	97.1% (91.3% to 99.1%)	97.1% (91.3% to 99.1%)	95.7% (88.8% to 98.4%)	95.7% (88.8% to 98.4%) at 81 mo.					
CapSure Sense	4074	Y	136	0	100% at 9 mo.											
Target Tip	4011	N	851	23	99.4% (98.4% to 99.8%)	99.2% (98.2% to 99.7%)	99.1% (97.9% to 99.6%)	98.9% (97.6% to 99.5%)	97.7% (95.9% to 98.7%)	96.5% (94.3% to 97.9%)	96.2% (93.8% to 97.6%)	96.2% (93.8% to 97.6%)	95.2% (92.3% to 97%)	93.2% (89.3% to 95.8%)	92.5% (88.2% to 95.3%)	92.5% (88.2% to 95.3%) at 201 mo.
	4012	N	2,543	315	99.6% (99.3% to 99.8%)	99.2% (98.6% to 99.5%)	98.4% (97.8% to 98.9%)	95.9% (94.8% to 96.8%)	92.7% (91.3% to 94%)	88.6% (86.7% to 90.1%)	84.6% (82.5% to 86.5%)	79.2% (76.7% to 81.5%)	72.5% (69.5% to 75.3%)	69.4% (66.2% to 72.5%)	67.6% (64.1% to 70.9%)	67.2% (63.6% to 70.5%) at 210 mo.
	4081	Y	261	2	100%	100%	100%	100%	100%	98% (86.8% to 99.7%) at 66 mo.						
	5061	N	118	1	100%	98.7% (91% to 99.8%)	98.7% (91% to 99.8%)	98.7% (91% to 99.8%) at 39 mo.								
	5064	N	177	4	99.3% (95.4% to 99.9%)	99.3% (95.4% to 99.9%)	96.8% (91.7% to 98.8%)	96.8% (91.7% to 98.8%)	96.8% (91.7% to 98.8%)	96.8% (91.7% to 98.8%)	96.8% (91.7% to 98.8%)	96.8% (91.7% to 98.8%) at 90 mo.				
Screw-In	4016/4016A	N	294	14	99.2% (97% to 99.8%)	99.2% (97% to 99.8%)	99.2% (97% to 99.8%)	97.8% (93.9% to 99.2%)	96.2% (91.5% to 98.3%)	94.4% (88.8% to 97.2%)	93.3% (87% to 96.5%)	91.8% (84.7% to 95.7%)	88.6% (79.7% to 93.7%) at 108 mo.			
	4057/4057M	N	259	7	99.4% (95.9% to 99.9%)	99.4% (95.9% to 99.9%)	99.4% (95.9% to 99.9%)	98.6% (94.6% to 99.7%)	97.8% (93.1% to 99.3%)	96.8% (91.7% to 98.8%)	95.8% (90.1% to 98.3%)	95.8% (90.1% to 98.3%)	94.6% (88.2% to 97.6%)	94.6% (88.2% to 97.6%) at 129 mo.		
	4058/4058M	N	1,689	38	99.4% (98.8% to 99.7%)	99.2% (98.5% to 99.6%)	99.1% (98.3% to 99.5%)	98.7% (97.8% to 99.2%)	98% (96.8% to 98.7%)	96.8% (95.3% to 97.9%)	95% (92.8% to 96.5%)	94.7% (92.5% to 96.3%)	93.5% (90.7% to 95.4%)	92.6% (89% to 95%) at 138 mo.		
Spectraflex	6957	N	1,854	40	99.6% (99.1% to 99.8%)	99.2% (98.6% to 99.6%)	98.8% (98% to 99.3%)	98.3% (97.3% to 98.9%)	97.7% (96.6% to 98.5%)	97.1% (95.7% to 98.1%)	96.9% (95.5% to 97.9%)	96.3% (94.6% to 97.4%)	95.6% (93.6% to 97%)	94.8% (92.3% to 96.4%)	94.2% (91.5% to 96.1%)	93.4% (90.1% to 95.7%) at 216 mo.
Tenax	6961	N	627	21	99.4% (98.3% to 99.8%)	99.2% (97.9% to 99.7%)	99.2% (97.9% to 99.7%)	97.8% (95.8% to 98.9%)	97.2% (94.9% to 98.5%)	96.4% (93.9% to 98%)	96.4% (93.9% to 98%)	95.6% (92.6% to 97.4%)	93.9% (90.2% to 96.2%)	93.2% (89.1% to 95.8%)	90.9% (85.3% to 94.4%)	90.9% (85.3% to 94.4%) at 180 mo.
	6962	N	1,483	51	99% (98.3% to 99.4%)	98.3% (97.3% to 98.9%)	97.4% (96.3% to 98.2%)	97% (95.7% to 97.9%)	96.7% (95.4% to 97.7%)	96.6% (95.2% to 97.5%)	96.4% (95% to 97.4%)	96.2% (94.8% to 97.3%)	95.4% (93.6% to 96.6%)	94.8% (92.9% to 96.2%)	93.7% (91.3% to 95.5%)	91.3% (87.7% to 93.9%) at 240 mo.
No Brand Name	6907/6907R	N	207	9	98.9% (95.6% to 99.7%)	98.9% (95.6% to 99.7%)	98.9% (95.6% to 99.7%)	98.9% (95.6% to 99.7%)	98.1% (94% to 99.4%)	98.1% (94% to 99.4%)	97% (91.7% to 98.9%)	95.7% (89.5% to 98.3%)	91.2% (82.5% to 95.7%)	91.2% (82.5% to 95.7%) at 126 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%. If no standard error (SE) appears, SE less than 0.1%.
[3] Currently available: Y = Yes; N = No.
*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.
FOR BRAND NAMES AND TECHNICAL DETAILS, REFER TO REFERENCE SECTION.

Ventricular Implantable Pacing Leads (Bradycardia)

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

Laboratory Analysis

Model Family	Model	Initial Implants[1]	Active Implants[2]	Implant Damage[3]	Electrical Failures[4]	Other
CapSureFix	4068*	129,888	80,372	406	50	10
	4067	1,208	651	3	1	1
	5068*	105,972	71,376	455	37	15
	5076*	329,258	285,443	314	23	28
CapSure VDD	5032	5,435	3,014	24	11	0
	5038	6,193	4,576	6	2	1
CapSure Z	5033	2,531	1,451	6	1	3
	5034	58,683	32,402	84	30	11
CapSure Z Novus	5054	62,524	47,087	37	7	5
CapSure SP	4023	43,584	21,167	48	18	6
	4024	229,214	117,946	264	70	32
	5023/5023M	10,609	4,129	15	7	0
	5024/5024M	210,537	102,158	723	92	28
CapSure SP Novus	5092	71,014	55,579	32	10	9
	4092	93,758	75,106	26	4	5
CapSure	4003/4003M	39,967	10,114	24	54	2
	4004/4004M	74,485	5,770	55	672	19
	5025	1,643	383	1	3	0
	5026	7,816	1,847	60	7	1
CapSure Sense	4074	9,479	8,892	3	0	1
Target Tip	4011	64,038	10,262	29	135	3
	4012	96,791	8,910	50	817	33
	4081	4,065	1,283	4	5	0
	5061	5,544	1,130	5	1	0
	5064	8,480	1,761	11	15	0
Screw-In	4016*	8,149	1,348	57	58	3
	4016A*	3,848	773	19	19	0
	4057/4057M*	12,126	3,956	39	6	4
	4058/4058M*	111,134	37,678	388	206	21
Spectraflex	6957*	29,117	4,137	85	39	25
Tenax	6961	44,668	3,741	103	27	0
	6962	70,555	6,440	170	84	0
No Brand Name	6907/6907R	87,511	2,481	172	110	2

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 February 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 Sense	0	62	0	62
Failure to Capture	4	131	3	138
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	0	25	0	25
Unspecified Clinical Failure	0	1	0	1
Grand Total	6	275	4	285

CapSureFix Leads

Lead Failure Mode	4068	5068	5076	Grand Total
Extra Cardiac Stimulation	1	0	0	1
Failure to Sense	1	0	0	1
Failure to Capture	13	3	1	17
Impedance Out of Range	1	0	0	1
Lead Dislodgement	0	1	0	1
Grand Total	16	4	1	21

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 Sense	0	0	0	0	1	0	1
Failure to Capture	8	3	4	1	23	2	41
Insulation	0	0	0	0	1	0	1
Insulation (not further defined)	0	0	0	0	3	0	3
Lead Dislodgement	1	0	0	0	4	3	8
Oversensing	0	0	0	0	1	0	1
Grand Total	9	3	7	2	37	5	63

CapSure Z/CapSure Z Novus Leads

Lead Failure Mode	4033	5033	5034	5054	Grand Total
Cardiac Perforation	0	1	0	0	1
Conductor Fracture	0	3	1	0	4
Failure to Sense	0	0	1	0	1
Failure to Capture	6	3	7	3	19
Impedance Out of Range	0	1	0	1	2
Lead Dislodgement	0	2	2	2	6
Grand Total	6	10	11	6	33

Screw-In Leads

Lead Failure Mode	4016/4016A	4057/4057M	4058/4058M	Grand Total
Conductor Fracture	2	2	2	6
Extra Cardiac Stimulation	0	2	3	5
Failure to Sense	2	1	6	9
Failure to Capture	5	2	19	26
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	14	7	38	59

Ventricular Implantable Pacing Leads (Bradycardia)

Lead Complications by Lead Model Families

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

Spectraflex Leads

Lead Failure Mode	6957	Grand Total
Conductor Fracture	12	12
Extra Cardiac Stimulation	2	2
Failure to Sense	2	2
Failure to Capture	19	19
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 Sense	0	76	1	0	1	78
Failure to Capture	9	126	0	1	2	138
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	2	1	4	345

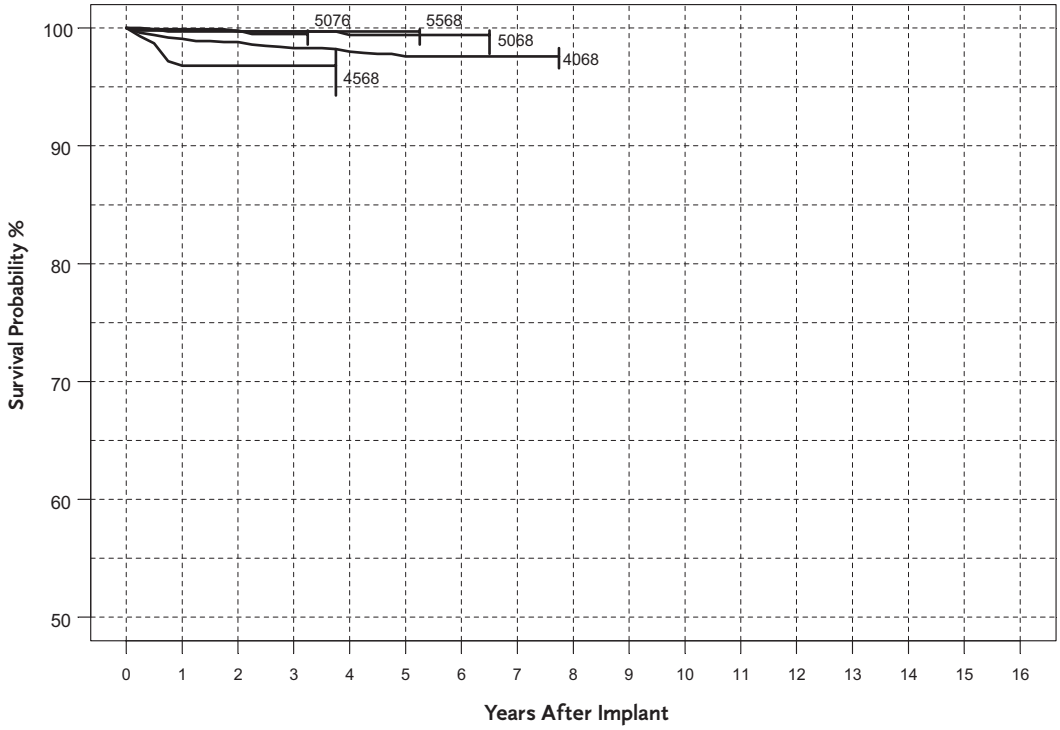
Tenax Leads

Lead Failure Mode	6961	6962	Grand Total
Conductor Fracture	0	5	5
Extra Cardiac Stimulation	4	1	5
Failure to Sense	6	10	16
Failure to Capture	7	27	34
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

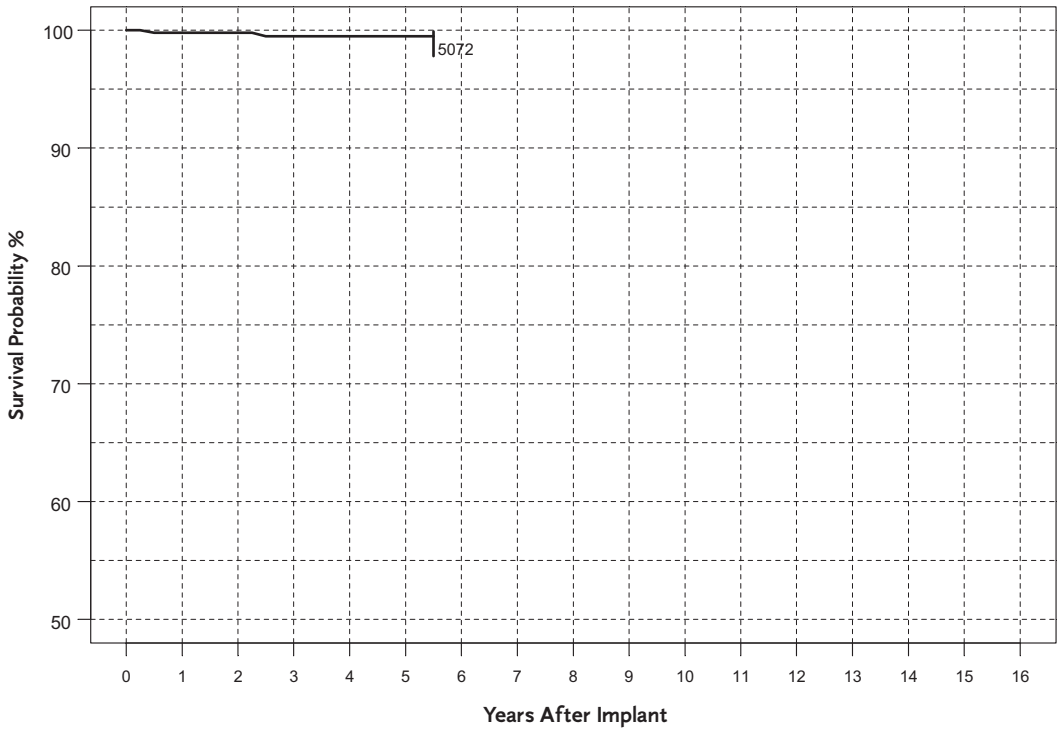
No Brand Name Leads

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

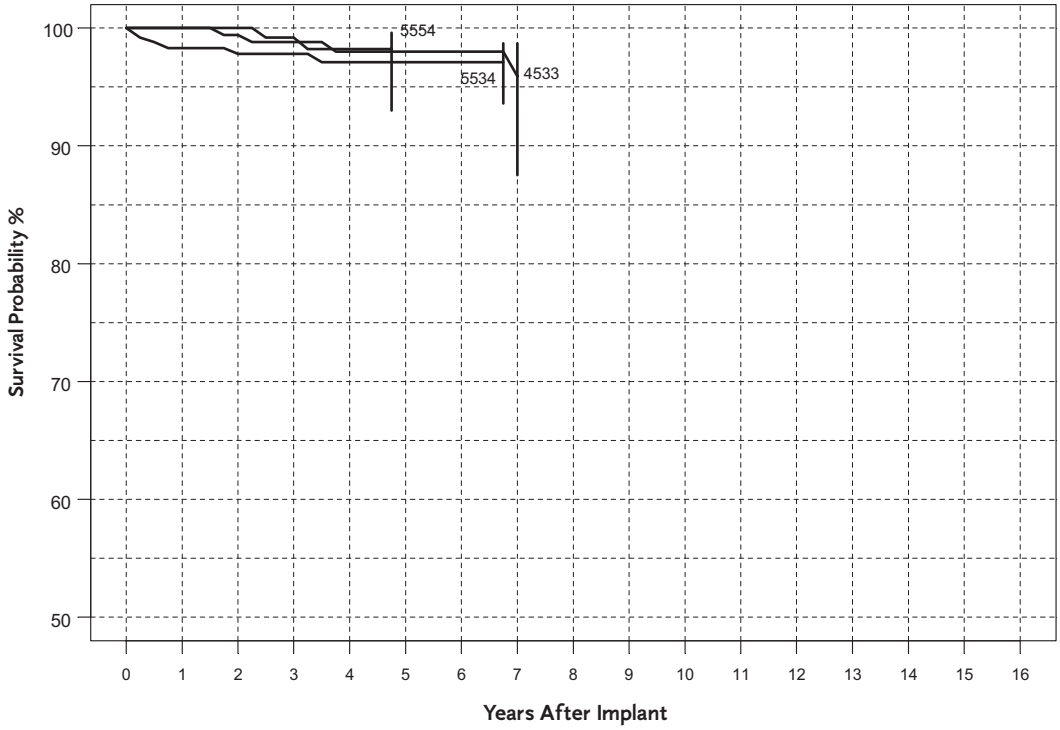
Atrial CapSureFix Leads



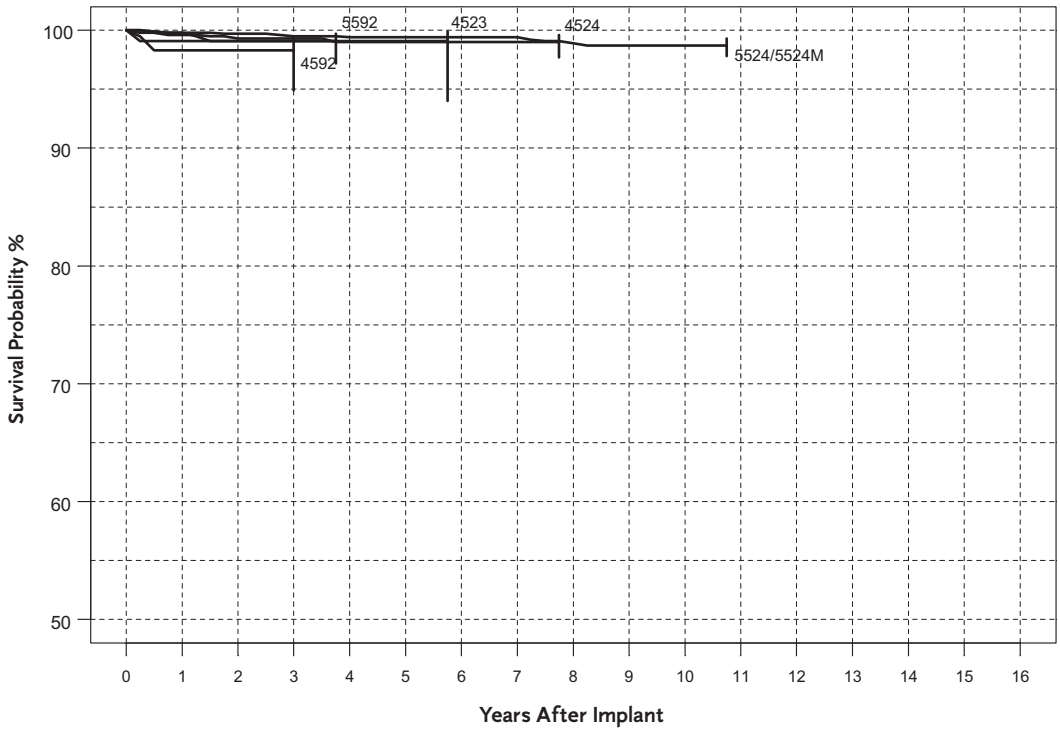
Atrial SureFix Leads



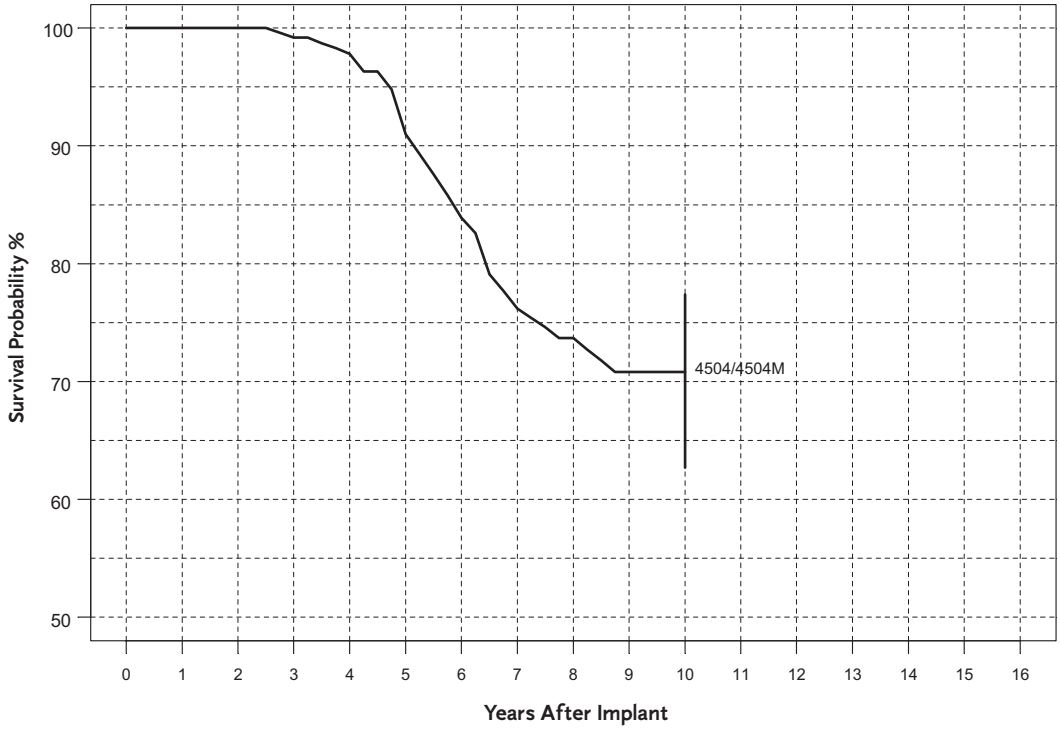
Atrial CapSure Z/CapSure Z Novus Leads



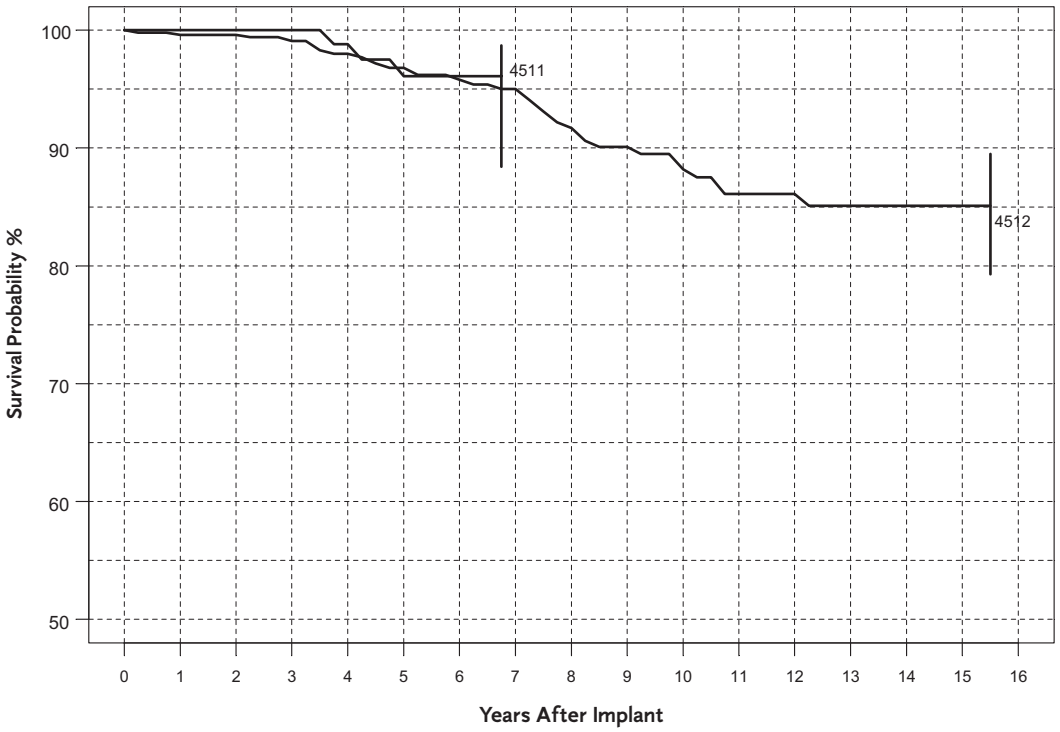
Atrial CapSure SP/CapSure SP Novus Leads



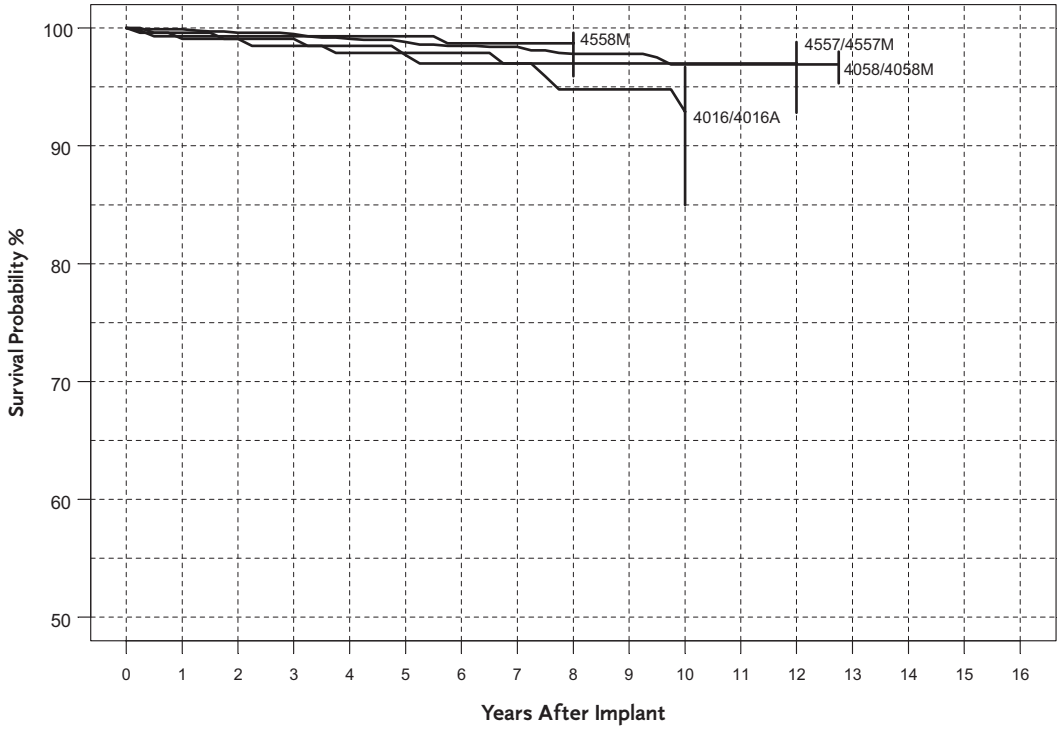
Atrial CapSure Leads



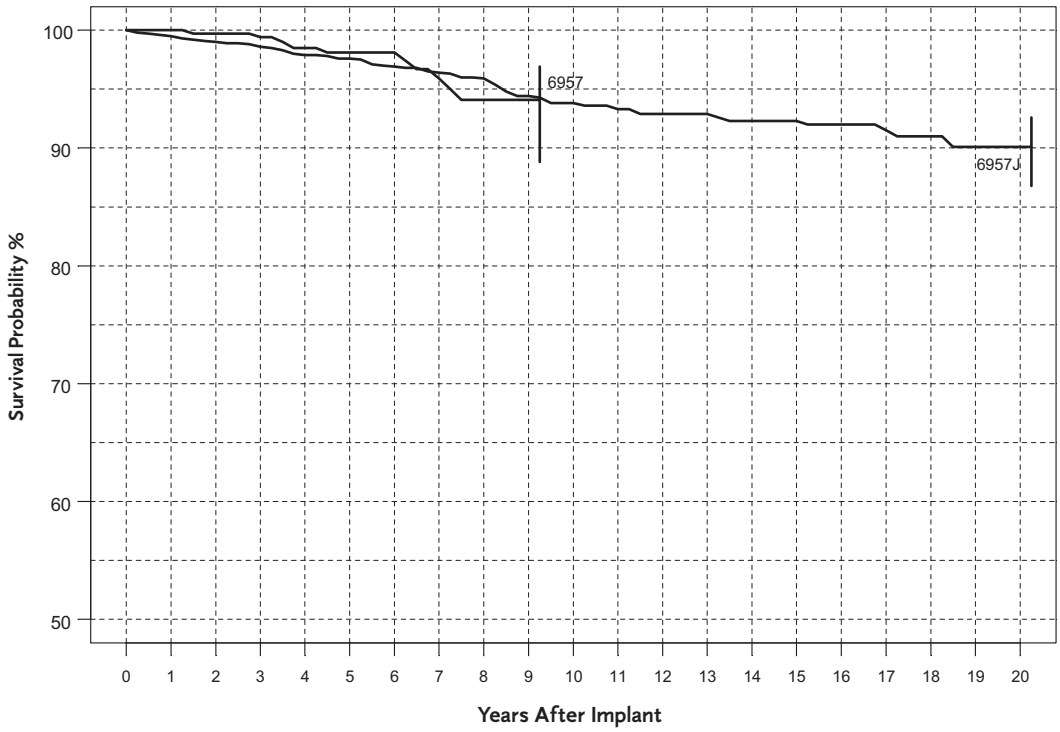
Atrial Target Tip Leads



Atrial Screw-In Leads



Atrial Spectraflex Leads



Atrial Implantable Pacing Leads (Bradycardia)

Actuarial Survival Probability (%)[1] (± 2 Standard Errors)[2]

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

Model Family	Model	Avail[3]	Initial Implants	Compli-cations	1 Year Intervals								2 Year Intervals			
					1	2	3	4	5	6	7	8	10	12	14	16
CapSureFix	4068	Y	2,346	37	99.1% (98.6% to 99.4%)	98.8% (98.2% to 99.2%)	98.3% (97.6% to 98.8%)	98% (97.2% to 98.6%)	97.6% (96.6% to 98.3%)	97.6% (96.6% to 98.3%)	97.6% (96.6% to 98.3%)	97.6% (96.6% to 98.3%) at 93 mo.				
	4568	Y	459	12	96.8% (94.3% to 98.2%)	96.8% (94.3% to 98.2%)	96.8% (94.3% to 98.2%)	96.8% (94.3% to 98.2%) at 45 mo.								
	5068	Y	963	3	99.7% (98.9% to 99.9%)	99.7% (98.9% to 99.9%)	99.7% (98.9% to 99.9%)	99.4% (97.8% to 99.8%)	99.4% (97.8% to 99.8%)	99.4% (97.8% to 99.8%)	99.4% (97.8% to 99.8%) at 78 mo.					
CapSureFix Novus	5076	Y	1,329	4	99.8% (99.2% to 99.9%)	99.8% (99.2% to 99.9%)	99.5% (98.6% to 99.8%)	99.5% (98.6% to 99.8%) at 39 mo.								
	5568	Y	790	3	99.9% (99% to 100%)	99.7% (98.6% to 99.9%)	99.7% (98.6% to 99.9%)	99.7% (98.6% to 99.9%)	99.7% (98.6% to 99.9%)	99.7% (98.6% to 99.9%) at 63 mo.						
CapSure Z	4533	Y	205	4	100% (100% to 100%)	99.4% (96% to 99.9%)	98.8% (95.3% to 99.7%)	98% (94% to 99.4%)	98% (94% to 99.4%)	98% (94% to 99.4%)	95.9% (87.5% to 98.7%)					
	5534	N	259	6	98.3% (95.5% to 99.4%)	97.8% (94.7% to 99.1%)	97.8% (94.7% to 99.1%)	97.1% (93.6% to 98.7%)	97.1% (93.6% to 98.7%)	97.1% (93.6% to 98.7%)	97.1% (93.6% to 98.7%) at 81 mo.					
CapSure Z Novus	5554	Y	313	2	100%	100%	99.2% (94.7% to 99.9%)	98.2% (93% to 99.6%)	98.2% (93% to 99.6%) at 57 mo.							
CapSure SP	4523	Y	121	1	99.1% (94% to 99.9%)	99.1% (94% to 99.9%)	99.1% (94% to 99.9%)	99.1% (94% to 99.9%)	99.1% (94% to 99.9%)	99.1% (94% to 99.9%) at 69 mo.						
	4524	Y	910	6	99.6% (98.9% to 99.9%)	99.3% (98.3% to 99.7%)	99.3% (98.3% to 99.7%)	99% (97.7% to 99.6%)	99% (97.7% to 99.6%)	99% (97.7% to 99.6%)	99% (97.7% to 99.6%)	99% (97.7% to 99.6%) at 93 mo.				
	5524/5524M	Y	4,424	24	99.8% (99.6% to 99.9%)	99.7% (99.5% to 99.9%)	99.5% (99.2% to 99.7%)	99.4% (99.1% to 99.6%)	99.4% (99% to 99.6%)	99.4% (99% to 99.6%)	99.4% (99% to 99.6%)	98.9% (98.2% to 99.4%)	98.7% (97.8% to 99.3%)	98.7% (97.8% to 99.3%) at 129 mo.		
CapSure SP Novus	4592	Y	227	3	98.3% (94.9% to 99.5%)	98.3% (94.9% to 99.5%)	98.3% (94.9% to 99.5%)									
	5592	Y	530	3	99.8% (98.4% to 100%)	99.1% (97.2% to 99.7%)	99.1% (97.2% to 99.7%)	99.1% (97.2% to 99.7%) at 45 mo.								
CapSure	4504/4504M	N	368	48	100%	100%	99.2% (96.8% to 99.8%)	97.8% (94.8% to 99.1%)	91% (86.1% to 94.2%)	83.9% (77.7% to 88.5%)	76.2% (68.9% to 82%)	73.7% (66.1% to 79.9%)	70.8% (62.7% to 77.4%)			
Target Tip	4511	N	158	3	100%	100%	100%	98.8% (91.6% to 99.8%)	96.1% (88.4% to 98.7%)	96.1% (88.4% to 98.7%)	96.1% (88.4% to 98.7%) at 81 mo.					
	4512	N	599	35	99.6% (98.4% to 99.9%)	99.6% (98.4% to 99.9%)	99.1% (97.6% to 99.7%)	98% (96.1% to 99%)	96.8% (94.5% to 98.2%)	95.8% (93.1% to 97.5%)	95% (92% to 96.9%)	91.7% (87.6% to 94.4%)	88.2% (83.2% to 91.8%)	86.1% (80.5% to 90.1%)	85.1% (79.3% to 89.5%)	85.1% (79.3% to 89.5%) at 186 mo.
Screw-In	4016/4016A	N	248	9	99.6% (97% to 99.9%)	99.1% (96.3% to 99.8%)	98.5% (95.4% to 99.5%)	98.5% (95.4% to 99.5%)	97.7% (94% to 99.2%)	97% (92.7% to 98.8%)	97% (92.7% to 98.8%)	94.8% (88.9% to 97.6%)	92.9% (85% to 96.7%)			
Screw-In	4058/4058M	N	2,365	29	99.9% (99.6% to 100%)	99.6% (99.2% to 99.8%)	99.5% (99% to 99.7%)	99.1% (98.5% to 99.5%)	98.8% (98% to 99.2%)	98.5% (97.7% to 99%)	98.4% (97.5% to 98.9%)	97.8% (96.6% to 98.5%)	96.9% (95.3% to 98%)	96.9% (95.3% to 98%)	96.9% (95.3% to 98%) at 153 mo.	
Screw-In	4557/4557M	N	294	5	99.1% (96.4% to 99.8%)	99.1% (96.4% to 99.8%)	99.1% (96.4% to 99.8%)	97.9% (94.4% to 99.2%)	97.9% (94.4% to 99.2%)	97.9% (94.4% to 99.2%)	97% (92.8% to 98.8%)	97% (92.8% to 98.8%)	97% (92.8% to 98.8%)	97% (92.8% to 98.8%)		
Screw-In	4558M	N	540	5	99.3% (98% to 99.8%)	99.3% (98% to 99.8%)	99.3% (98% to 99.8%)	99.3% (98% to 99.8%)	99.3% (98% to 99.8%)	98.7% (95.9% to 99.6%)	98.7% (95.9% to 99.6%)	98.7% (95.9% to 99.6%)				
Spectraflex	6957	N	677	10	100% (100% to 100%)	99.7% (98.2% to 100%)	99.4% (97.5% to 99.8%)	98.5% (96.1% to 99.5%)	98.1% (95.3% to 99.2%)	98.1% (95.3% to 99.2%)	95.9% (91.6% to 98%)	94.1% (88.8% to 96.9%)	94.1% (88.8% to 96.9%) at 111 mo.			
Spectraflex	6957J	N	2,348	81	99.5% (99% to 99.7%)	99% (98.4% to 99.4%)	98.6% (97.9% to 99.1%)	97.9% (97% to 98.5%)	97.6% (96.7% to 98.2%)	96.9% (95.9% to 97.7%)	96.4% (95.2% to 97.3%)	95.9% (94.7% to 96.9%)	93.8% (92.1% to 95.2%)	92.9% (90.9% to 94.4%)	92.3% (90.3% to 94%)	90.1% (86.8% to 92.6%) at 243 mo.
SureFix	5072	N	444	2	99.8% (98.3% to 100%)	99.8% (98.3% to 100%)	99.5% (97.8% to 99.9%)	99.5% (97.8% to 99.9%)	99.5% (97.8% to 99.9%)	99.5% (97.8% to 99.9%) at 66 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%. If no standard error (SE) appears, SE less than 0.1%.
[3] Currently available: Y = Yes; N = No.
*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.
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 February 1, 2004)

Model Family	Model	Initial Implants[1]	Active Implants[2]	Implant Damage[3]	Electrical Failures[4]	Other
CapSureFix	4568	62,487	45,201	163	2	4
	5568	32,423	24,179	138	4	5
CapSure Z	5534	27,651	13,875	29	5	5
CapSure Z Novus	5554	39,793	30,041	7	3	3
CapSure SP	4523	11,938	5,187	5	2	1
	4524	106,879	54,041	47	13	8
	5524/5524M	63,514	32,520	66	15	6
CapSure SP Novus	4592	50,483	39,774	8	1	0
	5592	13,690	11,389	3	1	0
CapSure	4504/4504M	16,637	2,489	5	164	4
Target Tip	4511	10,336	1,280	5	22	2
	4512	11,562	1,587	4	80	7
Screw-In	4557/4557M	22,390	7,733	53	14	4
	4558M	20,964	9,153	111	8	1
Spectraflex	6957J	29,968	3,491	74	28	30
SureFix	5072	7,201	5,194	21	2	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.

Atrial Implantable Pacing Leads (Bradycardia)

Lead Complications by Lead Model Families

Source: Chronic Lead Study
(Data as of February 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 Leads

Lead Failure Mode	4068	4568	5068	5076	5568	Grand Total
Conductor Fracture	0	0	0	1	0	1
Extra Cardiac Stimulation	1	0	0	1	0	2
Failure to Capture	16	8	2	0	2	28
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	7	3	0	2	1	13
Medical Judgement	0	1	0	0	0	1
Oversensing	1	0	0	0	0	1
Unspecified Clinical Failure	1	0	0	0	0	1
Grand Total	37	12	3	4	3	59

CapSure SP/CapSure SP Novus Leads

Lead Failure Mode	4523	4524	4592	5524/5524M	5592	Grand Total
Failure to Capture	0	3	1	16	2	22
Failure to Sense	0	2	0	2	0	4
Insulation (not further defined)	0	0	0	1	0	1
Lead Dislodgement	1	1	2	3	1	8
Oversensing	0	0	0	2	0	2
Grand Total	1	6	3	24	3	37

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

Atrial Implantable Pacing Leads (Bradycardia)

Lead Complications by Lead Model Families

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

Screw-In Leads

Lead Failure Mode	4016/4016A	4058/4058M	4557/4557M	4558M	Grand Total
Electrical Abandonment	0	0	0	1	1
Extra Cardiac Stimulation	0	1	1	0	2
Failure to Capture	3	14	3	3	23
Failure to Sense	2	6	0	0	8
Impedance Out of Range	0	3	0	0	3
Insulation (ESC)	1	0	0	0	1
Insulation (not further defined)	2	1	0	1	4
Lead Dislodgement	0	3	0	0	3
Oversensing	1	1	1	0	3
Grand Total	9	29	5	5	48

Spectraflex Leads

Lead Failure Mode	6957	6957J	Grand Total
Cardiac Perforation	0	0	0
Conductor Fracture	0	11	11
Electrical Abandonment	0	0	0
Extra Cardiac Stimulation	1	3	4
Failure to Capture	3	48	51
Failure to Sense	5	13	18
Impedance Out of Range	0	0	0
Insulation (ESC)	0	1	1
Insulation (MIO)	0	0	0
Insulation (not further defined)	0	3	3
Lead Dislodgement	0	2	2
Medical Judgement	0	0	0
Oversensing	1	0	1
Unspecified Clinical Failure	0	0	0
Grand Total	10	81	91

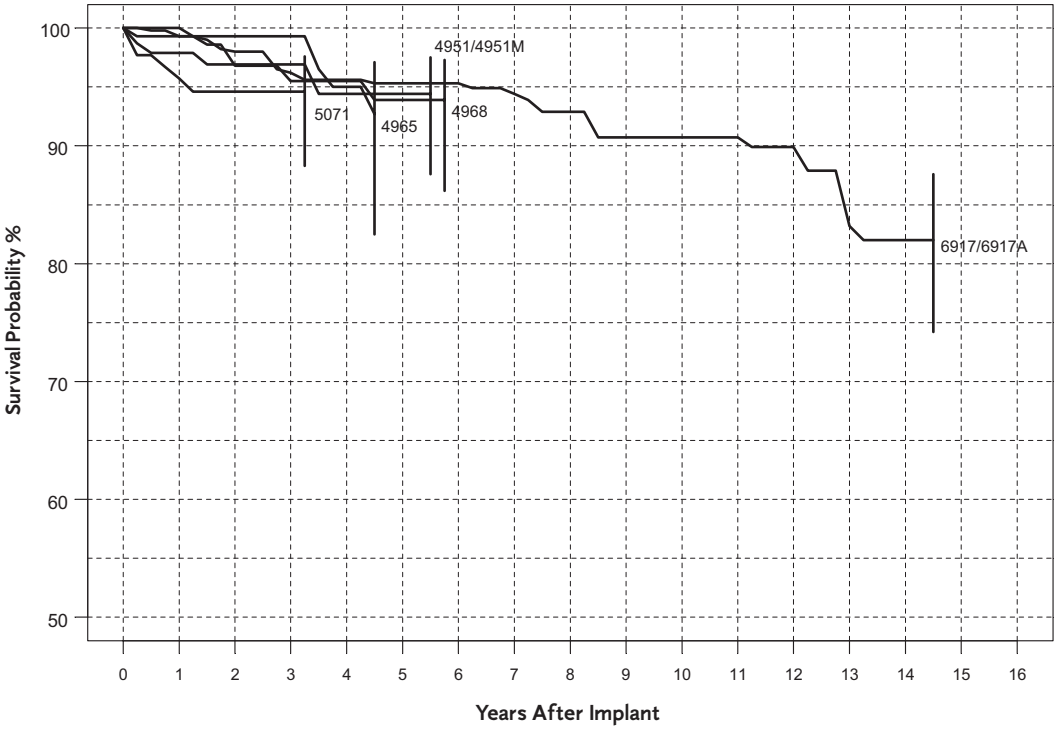
SureFix Leads

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

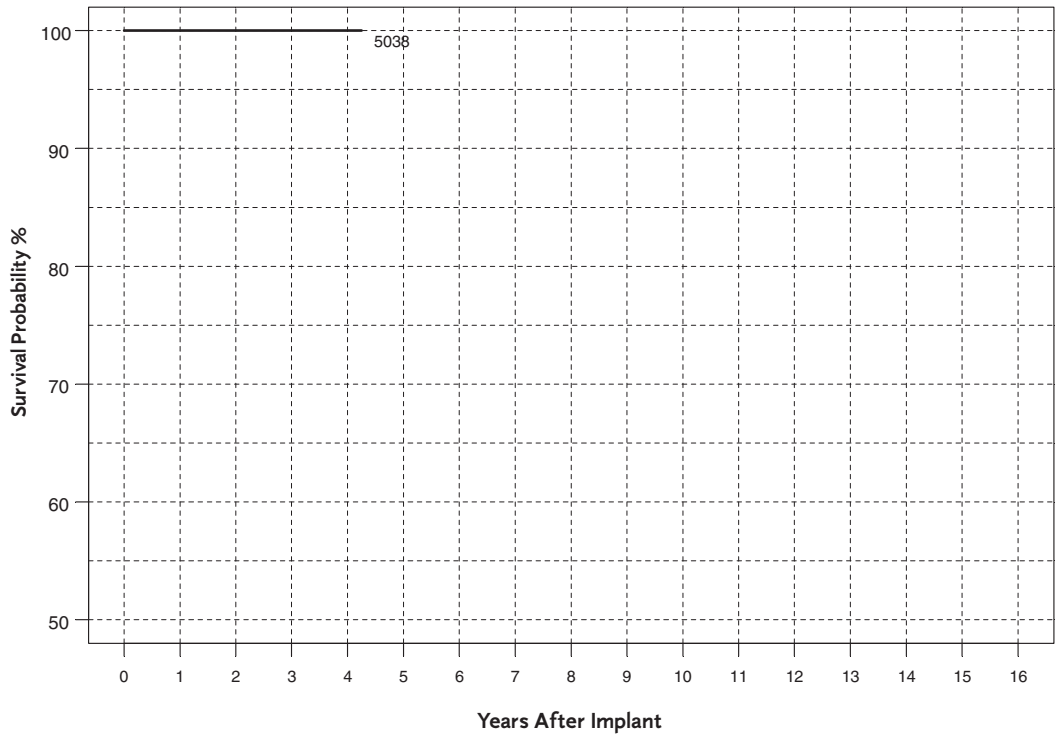
Target-Tip Leads

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



VDD Single Pass Leads



Epi/Myocardial Implantable Pacing Leads (Bradycardia)

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

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

Model Family	Model	Avail[3]	Initial Implants	Compli-cations	1 Year Intervals								2 Year Intervals			
					1	2	3	4	5	6	7	8	10	12	14	16
Spectraflex	4951/4951M	Y	177	10	97.9% (93.6% to 99.3%)	96.9% (91.9% to 98.9%)	96.9% (91.9% to 98.9%)	94.4% (87.6% to 97.5%)	94.4% (87.6% to 97.5%)	94.4% (87.6% to 97.5%) at 66 mo.						
Tenax	6917/6917A	N	598	35	99.3% (97.8% to 99.8%)	98% (96% to 99%)	96.2% (93.7% to 97.8%)	95.6% (93% to 97.3%)	95.3% (92.5% to 97.1%)	95.3% (92.5% to 97.1%)	94.4% (91.3% to 96.4%)	92.9% (89.2% to 95.3%)	90.7% (86.3% to 93.7%)	89.9% (85.2% to 93.2%)	82% (74.2% to 87.6%)	82% (74.2% to 87.6%) at 174 mo.
CapSure Z Novus	5071	Y	156	6	95.7% (89.9% to 98.2%)	94.6% (88.3% to 97.6%)	94.6% (88.3% to 97.6%)	94.6% (88.3% to 97.6%) at 39 mo.								
CapSure Epi	4965	Y	156	5	99.3% (94.8% to 99.9%)	99.3% (94.8% to 99.9%)	99.3% (94.8% to 99.9%)	95% (86.8% to 98.1%)	92.7% (82.5% to 97.1%) at 54 mo.							
	4968	Y	177	6	100% (100% to 100%)	96.8% (91.5% to 98.8%)	95.5% (89.4% to 98.2%)	95.5% (89.4% to 98.2%)	93.9% (86.2% to 97.3%)	93.9% (86.2% to 97.3%) at 69 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%. If no standard error (SE) appears, SE less than 0.1%.
[3] Currently available: Y = Yes; N = No.
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 February 1, 2004)

Lead Failure Mode	4951/4951M	4965	4968	5071	6917/6917A	Grand Total
Conductor Fracture	0	1	1	0	0	2
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	0	0
Insulation (not further defined)	1	0	0	0	1	2
Oversensing	0	2	1	0	2	5
Grand Total	10	5	3	6	35	59

Epi/Myocardial Implantable Pacing Leads (Bradycardia)

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

Laboratory Analysis

Model Family	Model	Initial Implants[1]	Active Implants[2]	Implant Damage[3]	Electrical Failures[4]	Other
Spectraflex	4951/4951M	24,653	4,923	17	92	28
CapSure Epi	4965	11,868	7,921	9	45	2
	4968	4,940	4,049	1	1	0
CapSure Z Novus	5071	14,906	9,856	8	3	1
Tenax	6917/6917A	180,105	9,997	115	40	0

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)

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

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

Model Family	Model	Avail[3]	Initial Implants	Compli-cations	1 Year Intervals								2 Year Intervals			
					1	2	3	4	5	6	7	8	10	12	14	16
CapSure VDD	5038	Y	510	0	100%	100%	100%	100%	100% (51 mo.)							

VDD Single Pass Implantable Pacing Leads (Bradycardia)

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

Laboratory Analysis

Model Family	Model	Initial Implants[1]	Active Implants[2]	Implant Damage[3]	Electrical Failures[4]	Other
CapSure VDD	5038	6,193	4,576	6	2	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.

Advisories (Bradycardia)

Summarized below are advisories, safety alerts, and product recalls which have been issued/communicated to physicians concerning Medtronic Implantable Pulse Generators (this is U.S. only and does not include OUS), and which currently remain in effect. These have been reviewed in past issues of the Product Performance Report.

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 1-800-505-4636.

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. As always, individual circumstances and medical judgement dictate patient care and frequency of follow-up. If the pulse generator has this capability. ■ 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.

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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.

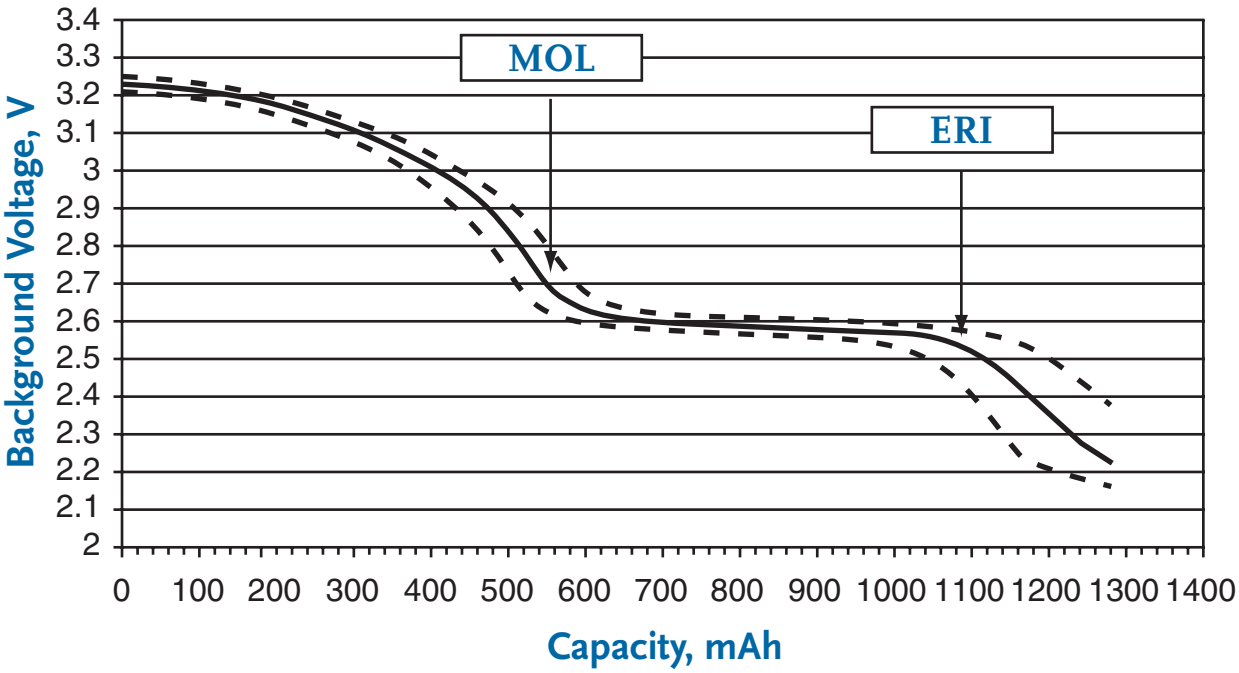
It is important to understand that this battery voltage decrease in the GEM II/III family of ICDs is a normal characteristic of the battery function in these devices and should not create a need for additional follow-up or monitoring.

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.

GEM II/III Battery Discharge Curve



General Follow-Up and Replacement of ICD Leads

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

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

Table 5.

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 msec.) 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/ Intermittent Lead Connection .....or No Pacer Artifacts (even in asynchro-nous mode)
Radiographs (Post-Implant, Recent, Current)	Not Discernible	Visual Observation of Conductor/ Connector/Electrode Fracture (sometimes discernible)	Dislodgement or Perforation Improper IPG/Lead Sometimes Connection ..... 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 Sometimes Connection ..... 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 Sometimes Connection ..... 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 Sometimes Connection ..... 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 Sometimes Connection ..... Discernible
Loss of Capture	See "Pacing Thresholds" Above	See "Pacing Thresholds" Above	See "Pacing Thresholds" Above

Pulse Generator 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	8340, 8341, 8341M, 8342	Rate decrease of 10% from programmed rate. Telemetry indication.
Minix ST	8330, 8331, 8331M	
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	8412, 8413, 8413M, 8414	**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.
Legend	8416, 8417, 8417M, 8418, 8419	
Legend II	8424, 8426, 8427	
Pasys	8320, 8322, 8329	Rate decrease of 10% from programmed rate. Telemetry indication.
Pasys ST	8316, 8317, 8318	
Prevail	8084, 8085, 8086	
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	7074, 7075, 7076, 7077	- Telemetry indication. - Rate and mode change to 65 ppm and VVI respectively (VOO/65 with magnet).
Elite II	7084, 7085, 7086	
Minuet	7107, 7108	
Symbios	7005, 7005C, 7006, 7008	
Thera-S	8944, 8945, 8946	
Thera-i S	8964i, 8965i, 8966i	
Thera-SR	8940, 8941, 8942	
Thera-i SR	8960i, 8961i, 8962i	
Thera-D	7944, 7945, 7946	
Thera-i D	7964i, 7965i, 7966i	
Thera-DR 40	7940, 7941, 7942	
Thera-i DR	7960i, 7961i, 7962i, 7968i	
Thera-DR 50	7950, 7951, 7952	
Thera-i VDD	8968i	
Prodigy D	7864, 7865, 7866	
Prodigy DR	7860, 7861, 7862	
Prodigy S	8164, 8165, 8166	
Prodigy SR	8158, 8160, 8161, 8162	
Preva SR	8088, 8089	
Preva D	7068	
Preva DR	7088, 7089	
Preva ST	DR 7078	
Prevail S	8085, 8086	
Kappa 400 SR	KSR401, KSR403	
Kappa 400 DR	KDR401, KDR403	
Kappa 700 SR	KSR701, KSR703, KSR706	
Kappa 700 DR	KDR701, KDR703, KDR706	
Kappa 700 D	KDR701	
Kappa 700 DR	KDR721	
Kappa 700 VDD	KVDD700, KVDD701	
Kappa 600 DR	KDR601, KDR603, KDR606	
Kappa 600 DR	KDR651, KDR653	
Kappa 900 SR	KSR901, KSR903, KSR906	
Kappa 900 DR	KDR901, KDR903, KDR906	
Kappa 920 DR	KDR921	
Kappa 900 VDD	KVDD901	
Kappa 800 DR	KDR801, KDR803	
Sigma 300 SR	SSR303, SSR306	
Sigma 300 DR	SDR303, SDR306	
Sigma 200 SR	SSR203	
Sigma 200 DR	SDR203	
Sigma 300 VDD	SVDD303	
Sigma 100 S	SS103, SS106	
Sigma 300 S	SS303	
Sigma 200 D	SD203	
InSync	8040	

*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)

Table 6. ICD Reference Chart

Model	Connector Style	Volume/ mass	Delivered Energy	Charging Frequency**	Estimated Longevity 100% Pacing‡	50% Pacing‡	15% Pacing‡	100% Sensing	Elective Replacement (ERI)*** Battery Voltage	or Charge Time	End of Life (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

* Volume mass differs by connector style.

† No longer marketed.

** 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, and 510 ohms for 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)

Table 7. 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

* No longer marketed.
\+ Integrated bipolar sensing.
§ True bipolar sensing.
† Silicone insulation with Isoglide™ polyurethane overlay.

References (Continued)

Medtronic 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	Y	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	Y	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

References (Continued)

Medtronic Atrial Pacing Leads Reference Chart

Model[1]	Avail[2]	Type	Brand Name	Insulation[3]	Conductor Material[4]	Tip Electrode	Connector Type
4503 4503M	Y	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	Y	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	Y	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

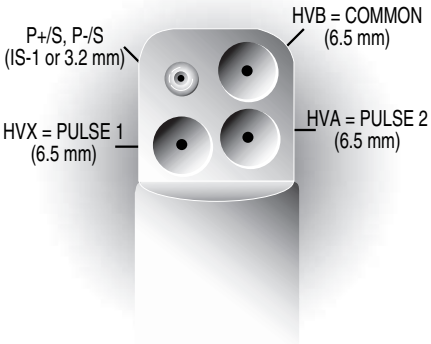
Medtronic Epi/Myocardial Pacing Leads Reference Chart

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	Y	Myocardial Screw-In Ventricular	Tenax	Silicone	Pt Ir Tinsel Wire	2-Turn Helix	5 mm
6917T	Y	Myocardial Screw-In Ventricular	Tenax	Silicone	Pt Ir Tinsel Wire	3-Turn Helix	5 mm

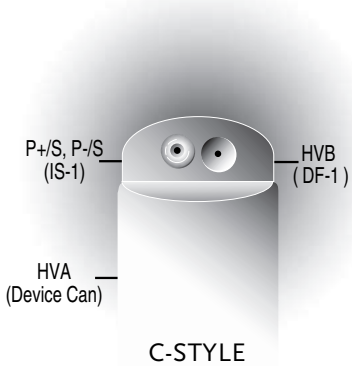
[1] Even-numbered models are bipolar leads; odd-numbered models are unipolar leads.
[2] Currently available: Y = Yes; N = No. **Indicates past advisory or safety alert.
[3] Polyurethane 55D and 80A are different formulations.
[4] Asterisk indicates leads with barrier coating (Outer/Inner Filars).

References (Continued)

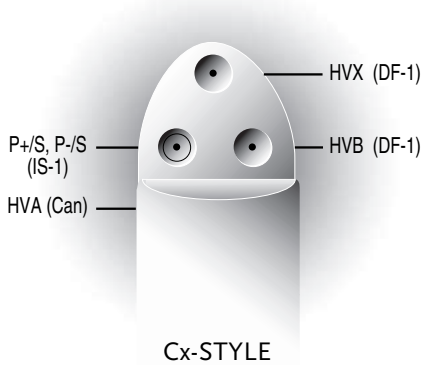
ICD Connector Styles



B-STYLE CONNECTOR



C-STYLE CONNECTOR



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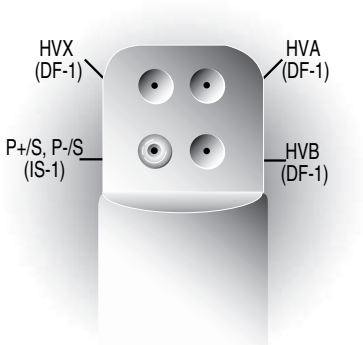
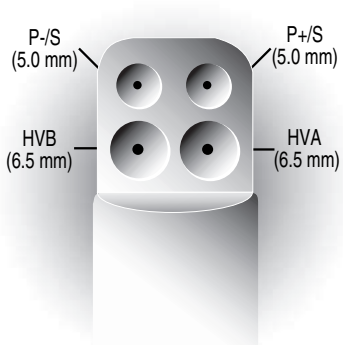
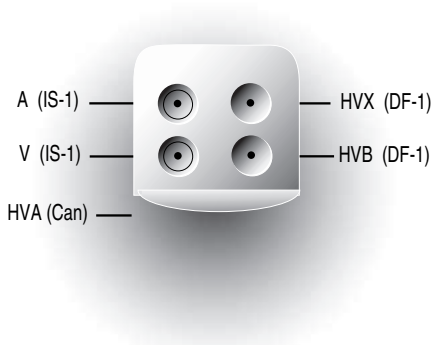


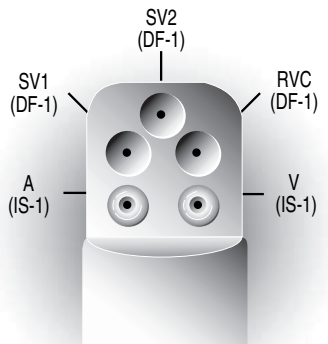
D-STYLE CONNECTOR



E-STYLE CONNECTOR



DR-STYLE CONNECTOR



H-STYLE CONNECTOR

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