

DEFIBRILLATION LEADS

Defibrillation Leads

Customer Reported Performance Data

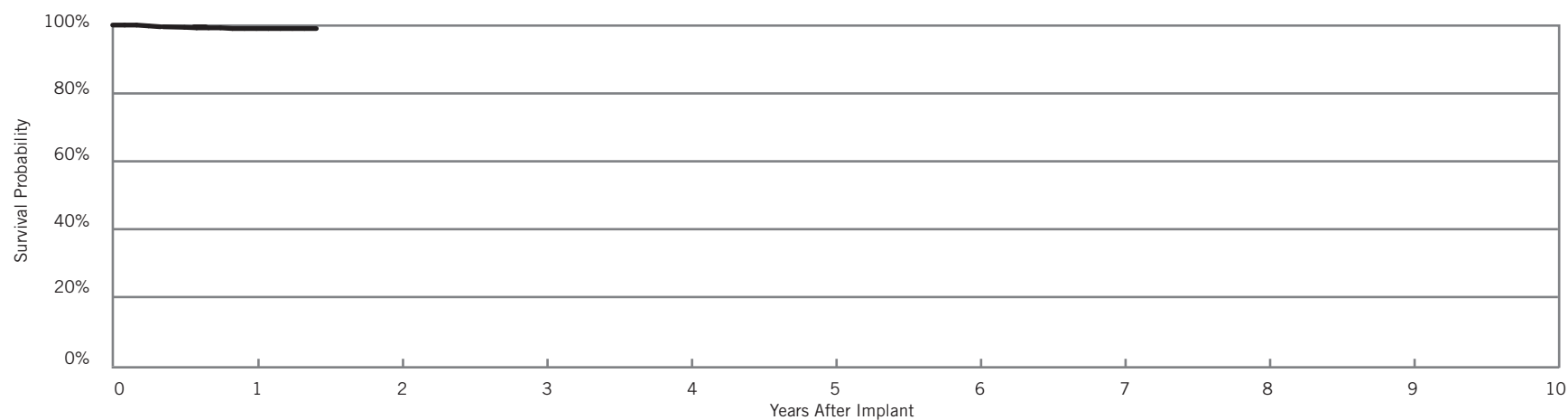
Durata® DF4

Models 7170Q & 7171Q

US Regulatory Approval	July 2009
Registered US Implants	1,740
Estimated Active US Implants	1,538
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	1	0.06%	0	0.00%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	2	0.11%	2	0.11%
Failure to Capture	1	0.06%	6	0.34%
Oversensing	0	0.00%	1	0.06%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	1	0.06%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	4	0.23%	10	0.57%
Total Returned for Analysis	3		6	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	6	0.34%
Total	6	0.34%



Year	1	at 17 months								
Survival Probability	98.95%	98.95%								
± 1 standard error	0.28%	0.28%								
Sample Size	700	200								

*Optim® lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

Customer Reported Performance Data

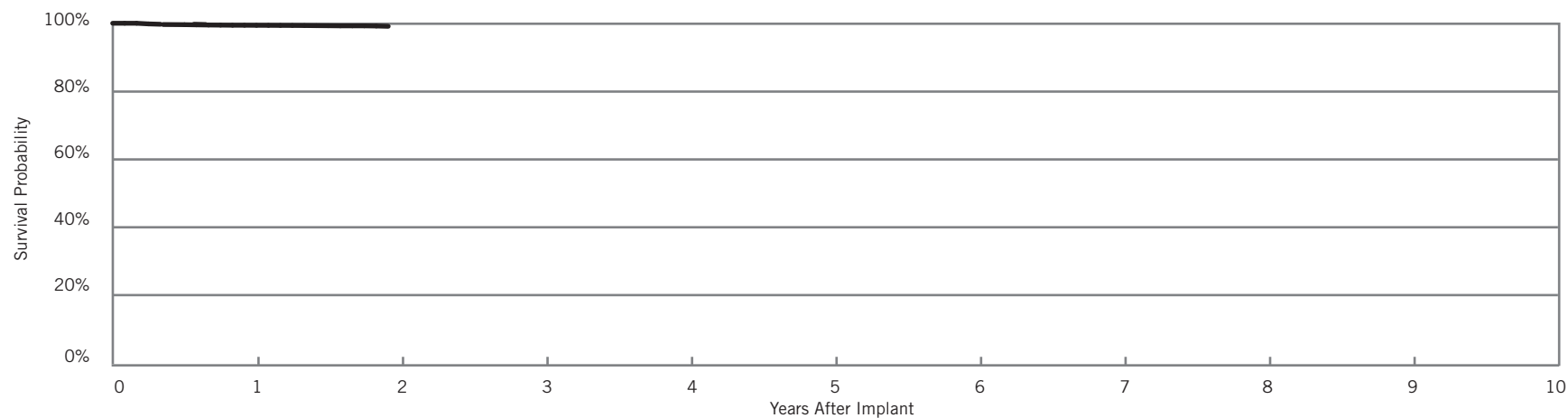
Durata® DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Registered US Implants	42,871
Estimated Active US Implants	37,926
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	23	0.05%	7	0.02%
Conductor Fracture	0	0.00%	6	0.01%
Lead Dislodgement	70	0.16%	112	0.26%
Failure to Capture	34	0.08%	41	0.10%
Oversensing	21	0.05%	20	0.05%
Failure to Sense	6	0.01%	5	0.01%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	<0.01%	1	<0.01%
Abnormal Defibrillation Impedance	1	<0.01%	6	0.01%
Extracardiac Stimulation	1	<0.01%	1	<0.01%
Other	4	0.01%	4	0.01%
Total	162	0.38%	203	0.47%
Total Returned for Analysis	90		171	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	4	0.01%
Clavicular Crush	0	0.00%
In the Pocket	2	<0.01%
Intravascular	2	<0.01%
Insulation Breach	2	<0.01%
Lead-to-Can Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	1	<0.01%
Externalized Conductors	0	0.00%
Others	1	<0.01%
Crimps, Welds & Bonds	0	0.00%
Other	3	0.01%
Extrinsic Factors	122	0.28%
Total	131	0.31%



Year	1	at 23 months								
Survival Probability	99.37%	99.08%								
± 1 standard error	0.04%	0.12%								
Sample Size	30700	600								

*Optim® lead insulation is a copolymer of silicone and polyurethane.

SCORE Registry Performance Data

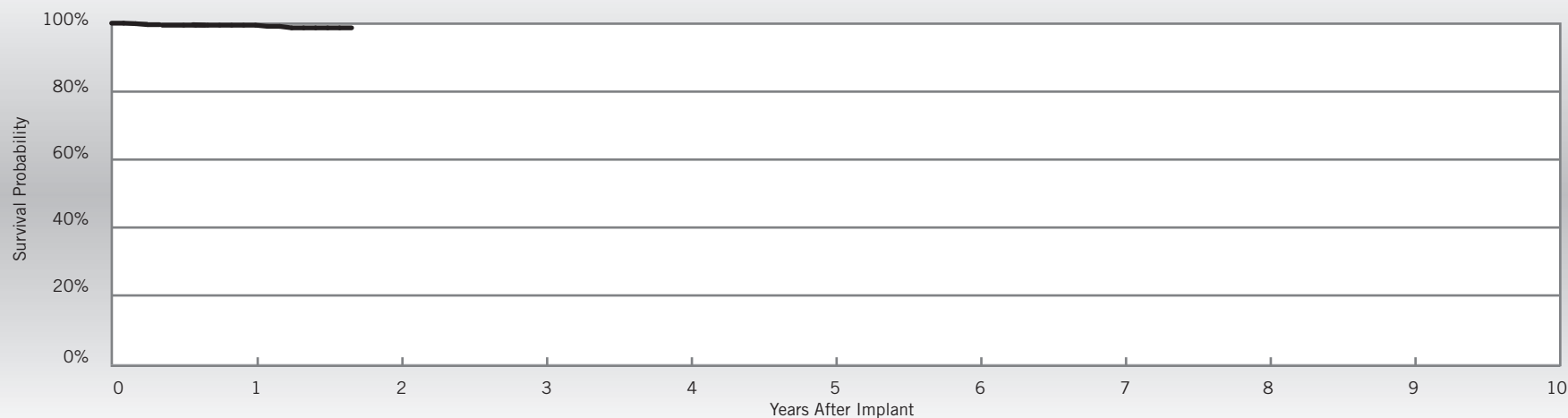
Durata® DF4

Models 7120Q & 7121Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	736
Cumulative Months of Follow-up	8,043
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Defibrillation Impedance	2	0.27%
Failure to Capture	1	0.14%
Lead Dislodgement	3	0.41%

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.68%
Total	5	0.68%



Year	1	at 20 months								
Survival Probability	99.40%	98.60%								
± 1 standard error	0.29%	0.60%								
Sample Size	520	70								

*Optim® lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

Customer Reported Performance Data

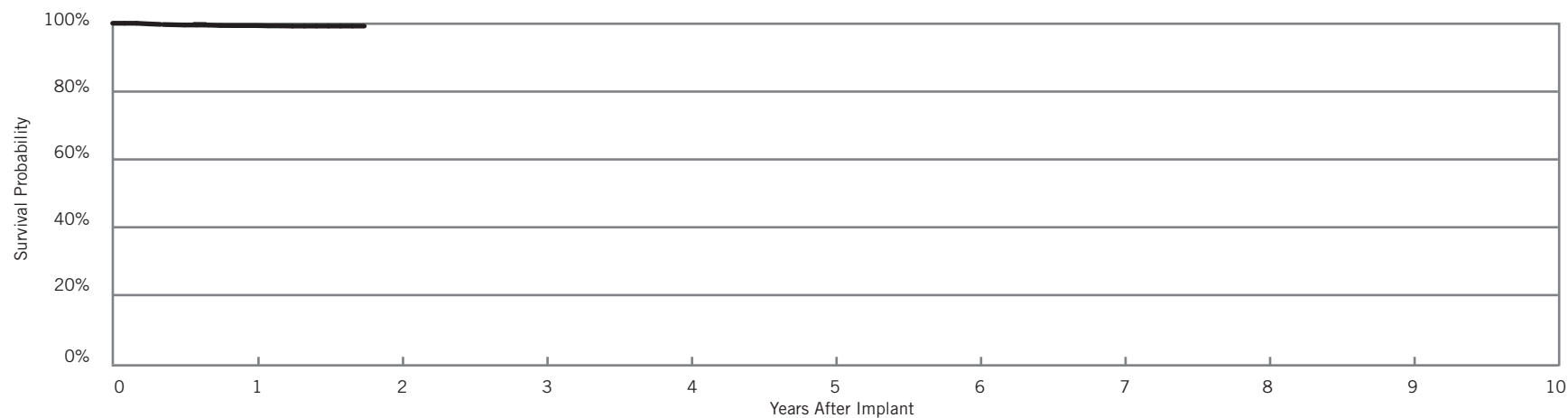
Durata® DF4

Model 7122Q

US Regulatory Approval	January 2009
Registered US Implants	7,403
Estimated Active US Implants	6,602
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	6	0.08%	4	0.05%
Conductor Fracture	0	0.00%	1	0.01%
Lead Dislodgement	11	0.15%	19	0.26%
Failure to Capture	11	0.15%	5	0.07%
Oversensing	4	0.05%	6	0.08%
Failure to Sense	3	0.04%	2	0.03%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	0	0.00%
Abnormal Defibrillation Impedance	1	0.01%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	3	0.04%	0	0.00%
Total	39	0.53%	37	0.50%
Total Returned for Analysis	28		32	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	2	0.03%
Clavicular Crush	0	0.00%
In the Pocket	2	0.03%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	25	0.34%
Total	27	0.36%



Year	1	at 21 months								
Survival Probability	99.21%	99.15%								
± 1 standard error	0.12%	0.14%								
Sample Size	5000	300								

*Optim® lead insulation is a copolymer of silicone and polyurethane.

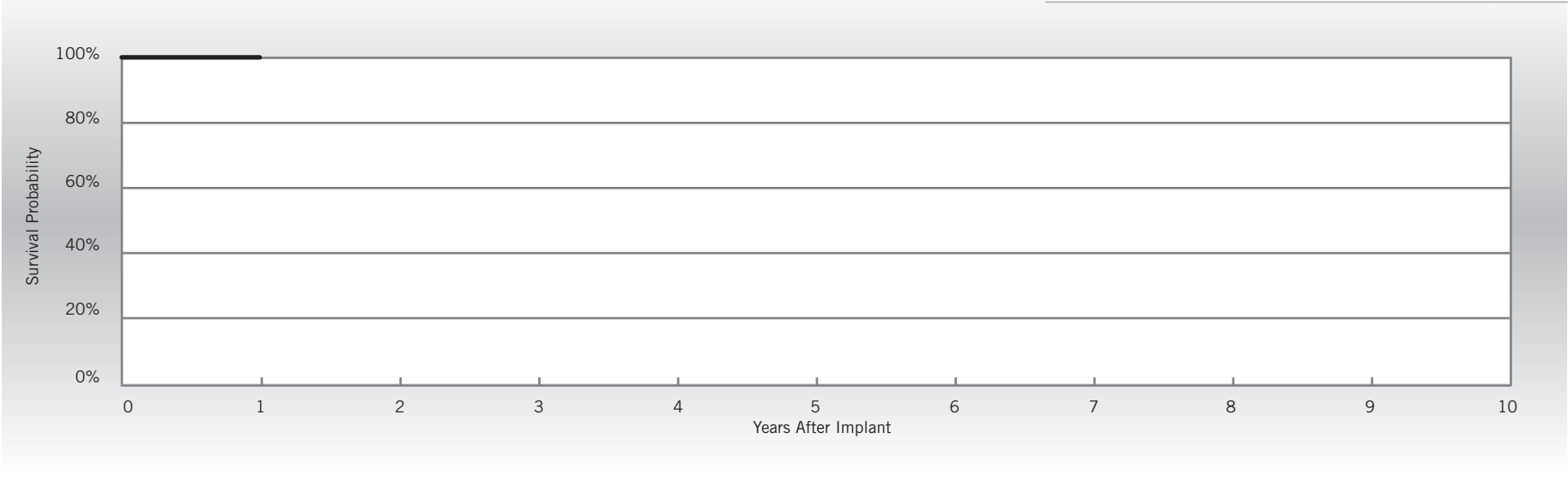
SCORE Registry Performance Data

Durata® DF4
Model 7122Q

US Regulatory Approval	January 2009
Number of Devices Enrolled in Study	145
Cumulative Months of Follow-up	1,526
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications
None Reported

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	0	0.00%



Year	1									
Survival Probability	100.00%									
± 1 standard error	0.00%									
Sample Size	100									

*Optim® lead insulation is a copolymer of silicone and polyurethane.

Customer Reported Performance Data

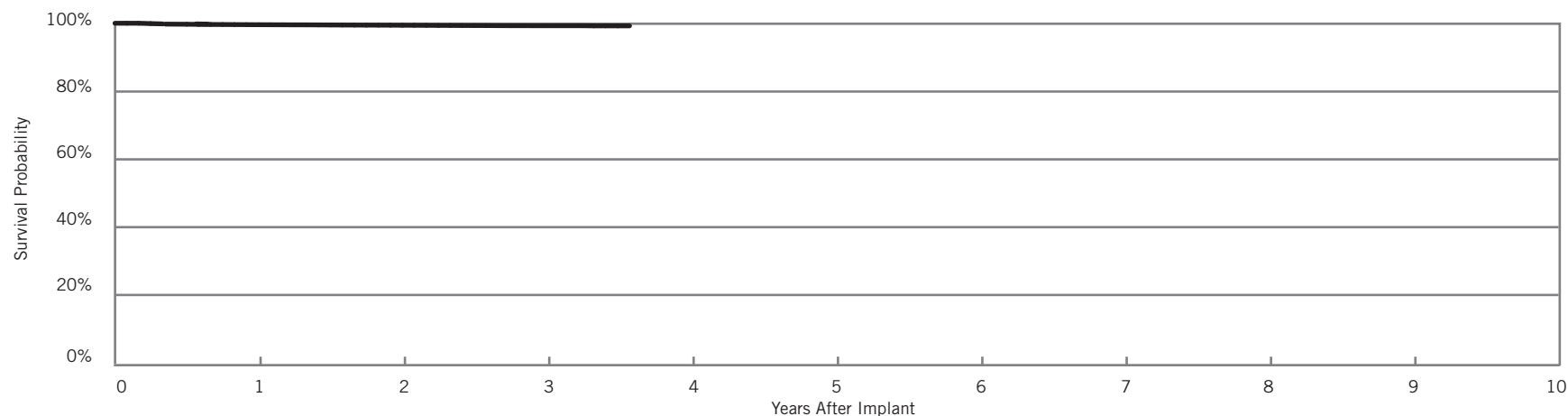
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Registered US Implants	53,161
Estimated Active US Implants	41,241
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	31	0.06%	4	0.01%
Conductor Fracture	1	<0.01%	9	0.02%
Lead Dislodgement	66	0.12%	113	0.21%
Failure to Capture	17	0.03%	50	0.09%
Oversensing	44	0.08%	55	0.10%
Failure to Sense	4	0.01%	11	0.02%
Insulation Breach	0	0.00%	1	<0.01%
Abnormal Pacing Impedance	1	<0.01%	10	0.02%
Abnormal Defibrillation Impedance	17	0.03%	16	0.03%
Extracardiac Stimulation	1	<0.01%	0	0.00%
Other	15	0.03%	11	0.02%
Total	197	0.37%	280	0.53%
Total Returned for Analysis	81		197	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	9	0.02%
Clavicular Crush	0	0.00%
In the Pocket	7	0.01%
Intravascular	2	<0.01%
Insulation Breach	6	0.01%
Lead-to-Can Contacts	2	<0.01%
Lead-to-Lead Contacts	2	<0.01%
Clavicular Crush	1	<0.01%
Externalized Conductors	0	0.00%
Others	1	<0.01%
Crimps, Welds & Bonds	1	<0.01%
Other	2	<0.01%
Extrinsic Factors	120	0.23%
Total	138	0.26%



Year	1	2	3	at 43 months						
Survival Probability	99.55%	99.38%	99.25%	99.21%						
± 1 standard error	0.03%	0.04%	0.05%	0.06%						
Sample Size	49600	35300	16500	300						

SCORE Registry Performance Data

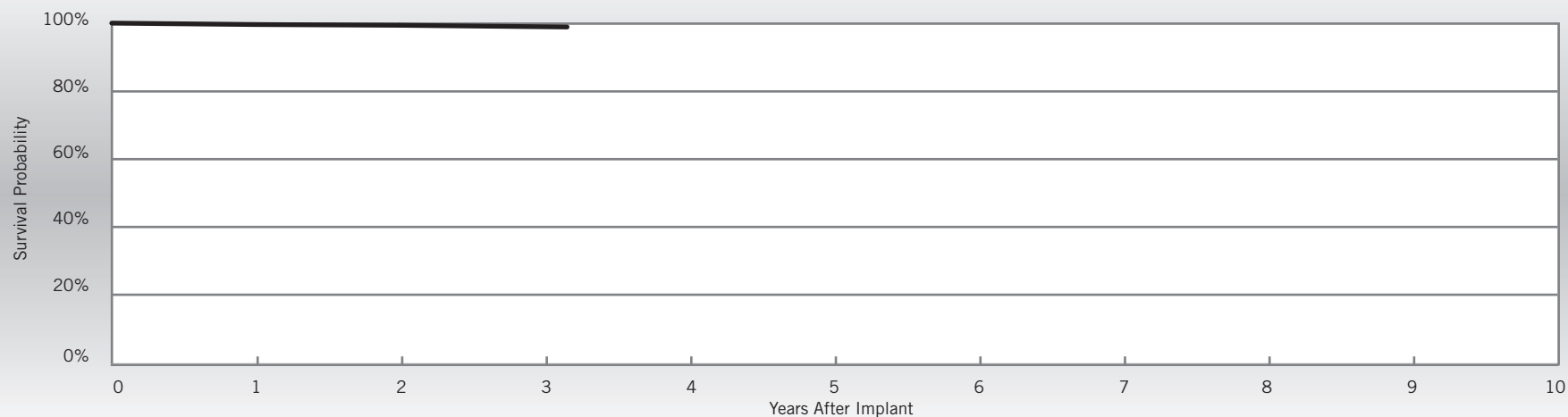
Durata®

Models 7120 & 7121

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	1,490
Cumulative Months of Follow-up	33,880
Insulation	Optim®*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Conductor Fracture	2	0.13%
Extracardiac Stimulation	1	0.07%
Failure to Capture	2	0.13%
Lead Dislodgement	5	0.34%
Oversensing	1	0.07%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.07%
Clavicular Crush	0	0.00%
In the Pocket	1	0.07%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.13%
Total	3	0.20%



Year	1	2	3	at 38 months						
Survival Probability	99.58%	99.36%	98.84%	98.84%						
± 1 standard error	0.17%	0.23%	0.37%	0.37%						
Sample Size	1330	950	430	70						

*Optim® lead insulation is a copolymer of silicone and polyurethane.

Customer Reported Performance Data

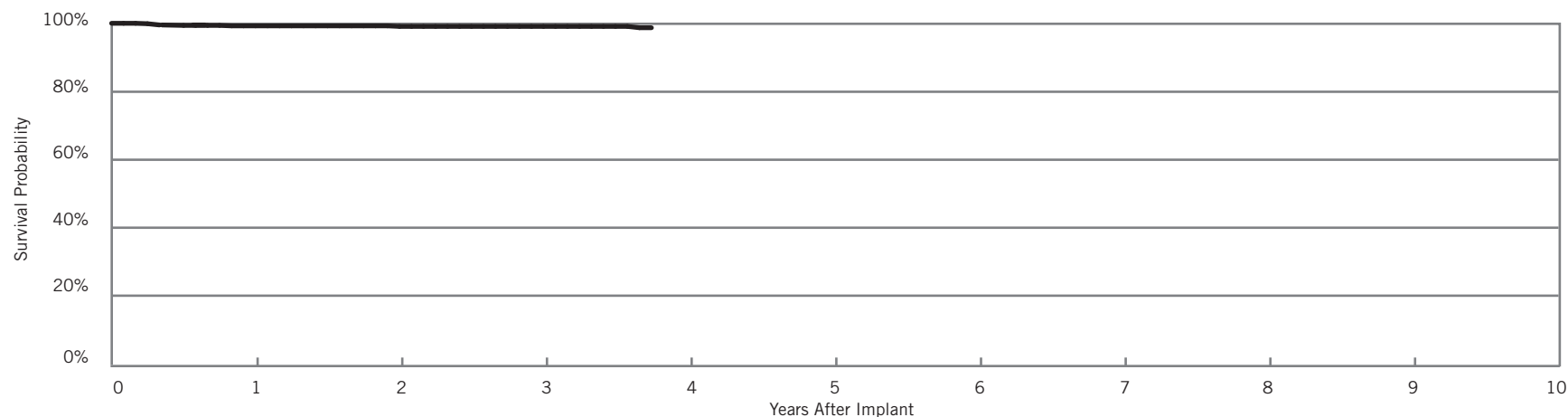
Riata® ST Optim®

Models 7030 & 7031

US Regulatory Approval	July 2006
Registered US Implants	851
Estimated Active US Implants	547
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	0	0.00%	1	0.12%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	5	0.59%	0	0.00%
Failure to Capture	0	0.00%	4	0.47%
Oversensing	2	0.24%	6	0.71%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	1	0.12%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	7	0.82%	12	1.41%
Total Returned for Analysis	3		2	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	3	0.35%
Total	3	0.35%



Year	1	2	3	at 45 months						
Survival Probability	99.23%	99.07%	99.07%	98.67%						
± 1 standard error	0.31%	0.35%	0.35%	0.53%						
Sample Size	800	700	500	200						

*Optim® lead insulation is a copolymer of silicone and polyurethane.

Customer Reported Performance Data

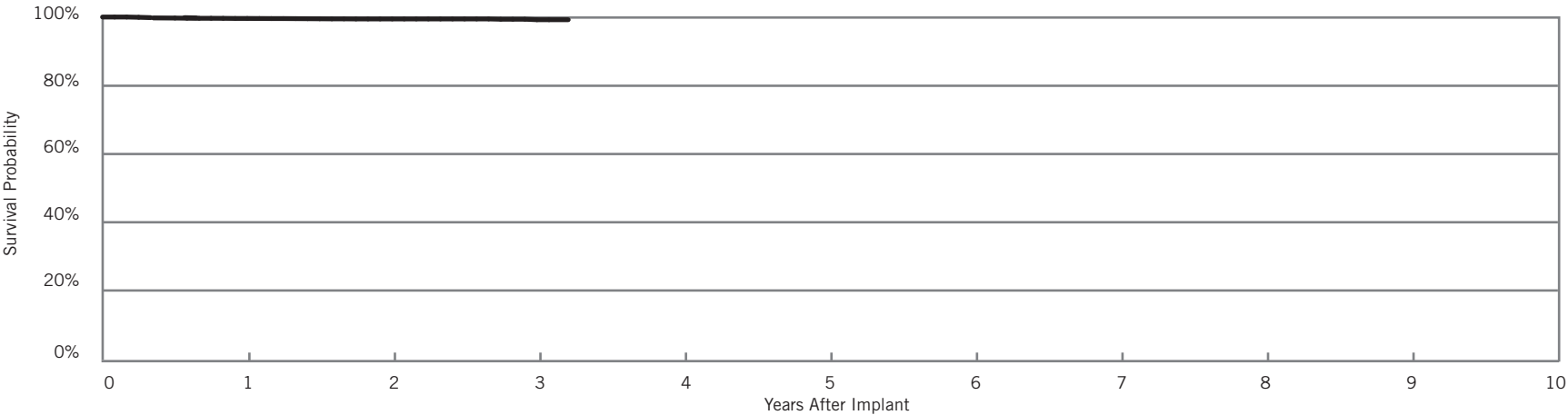
Durata®

Model 7122

US Regulatory Approval	September 2007
Registered US Implants	8,362
Estimated Active US Implants	6,779
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	4	0.05%	1	0.01%
Conductor Fracture	1	0.01%	2	0.02%
Lead Dislodgement	8	0.10%	13	0.16%
Failure to Capture	6	0.07%	10	0.12%
Oversensing	3	0.04%	6	0.07%
Failure to Sense	0	0.00%	3	0.04%
Insulation Breach	0	0.00%	2	0.02%
Abnormal Pacing Impedance	1	0.01%	4	0.05%
Abnormal Defibrillation Impedance	1	0.01%	1	0.01%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	2	0.02%
Total	24	0.29%	44	0.53%
Total Returned for Analysis	12		40	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	3	0.04%
Clavicular Crush	0	0.00%
In the Pocket	2	0.02%
Intravascular	1	0.01%
Insulation Breach	3	0.04%
Lead-to-Can Contacts	1	0.01%
Lead-to-Lead Contacts	2	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	24	0.29%
Total	30	0.36%



Year	1	2	3	at 38 months						
Survival Probability	99.56%	99.43%	99.34%	99.19%						
± 1 standard error	0.08%	0.09%	0.20%	0.20%						
Sample Size	7200	4300	600	300						

*Optim® lead insulation is a copolymer of silicone and polyurethane.

SCORE Registry Performance Data

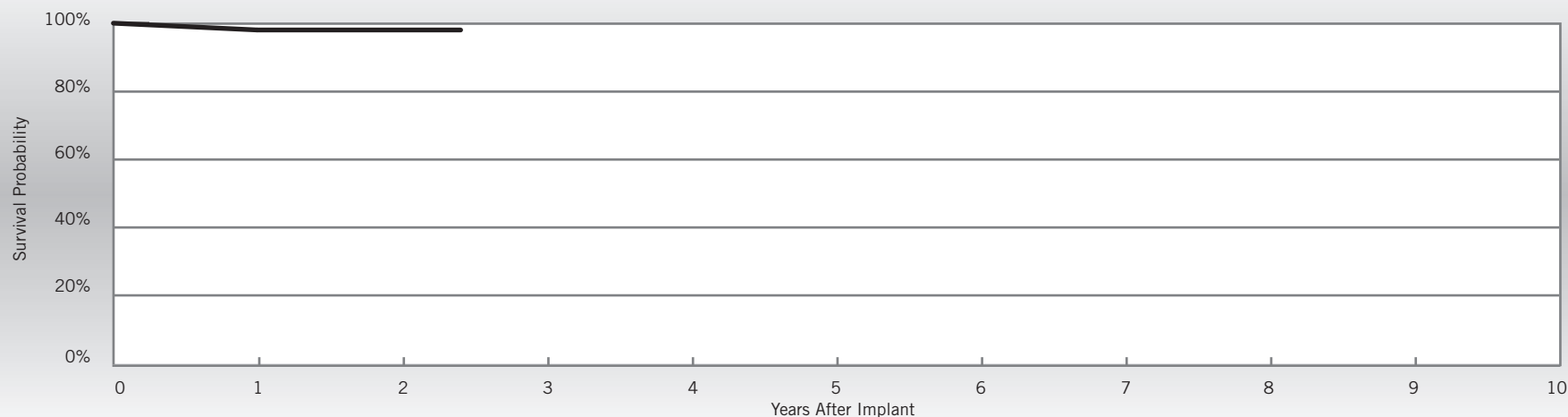
Durata®

Model 7122

US Regulatory Approval	September 2007
Number of Devices Enrolled in Study	251
Cumulative Months of Follow-up	4,509
Insulation	Optim®*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.40%
Lead Dislodgement	3	1.20%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.40%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.40%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	2	0.80%
Total	3	1.20%



Year	1	2	at 28 months							
Survival Probability	97.96%	97.96%	97.96%							
± 1 standard error	1.00%	1.00%	1.00%							
Sample Size	210	120	60							

*Optim® lead insulation is a copolymer of silicone and polyurethane.

Customer Reported Performance Data

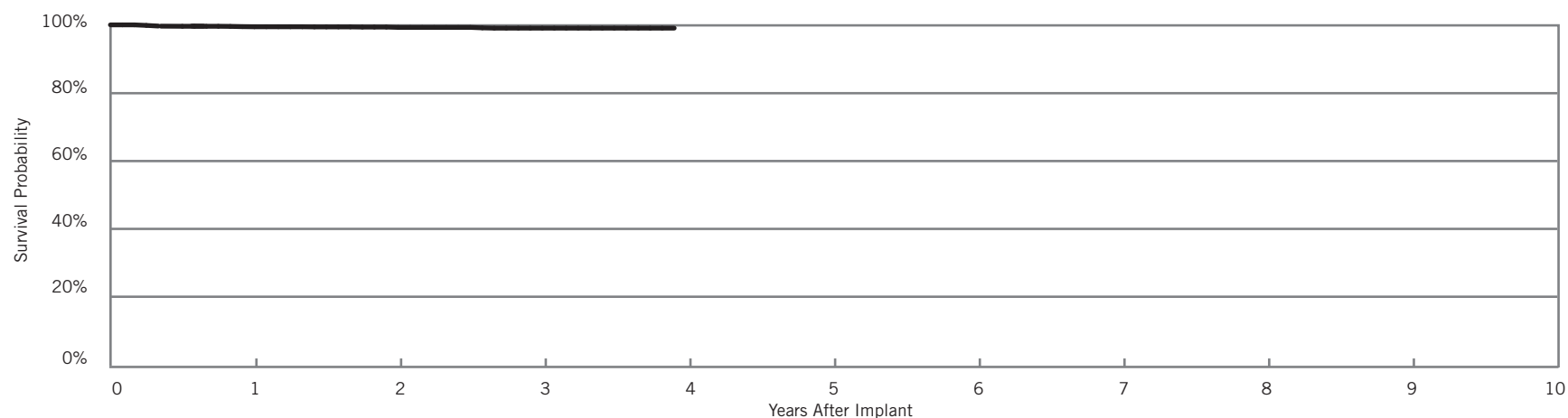
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Registered US Implants	3,296
Estimated Active US Implants	2,423
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	2	0.06%	2	0.06%
Conductor Fracture	1	0.03%	2	0.06%
Lead Dislodgement	3	0.09%	4	0.12%
Failure to Capture	5	0.15%	4	0.12%
Oversensing	4	0.12%	6	0.18%
Failure to Sense	3	0.09%	2	0.06%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	0	0.00%	2	0.06%
Abnormal Defibrillation Impedance	0	0.00%	1	0.03%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	18	0.55%	23	0.70%
Total Returned for Analysis	8		8	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	0.03%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.03%
Insulation Breach	1	0.03%
Lead-to-Can Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	1	0.03%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	5	0.15%
Total	7	0.21%



Year	1	2	3	at 47 months						
Survival Probability	99.42%	99.24%	99.02%	99.02%						
± 1 standard error	0.14%	0.17%	0.21%	0.21%						
Sample Size	3100	2300	1400	200						

*Optim® lead insulation is a copolymer of silicone and polyurethane.

SCORE Registry Performance Data

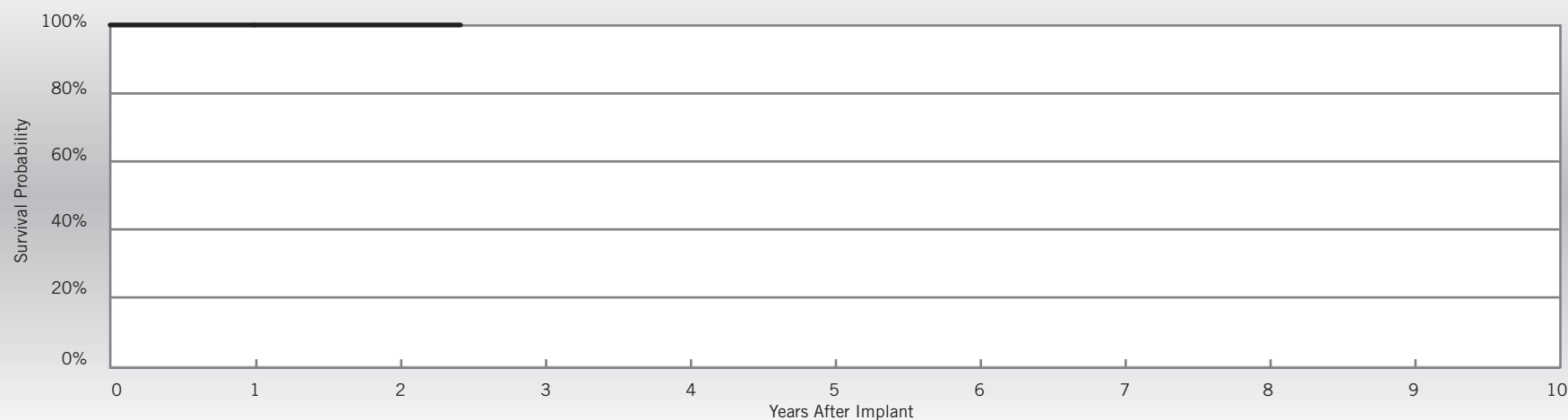
Riata® ST Optim®

Models 7070 & 7071

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	150
Cumulative Months of Follow-up	3511
Insulation	Optim*
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes

Qualifying Complications
None Reported

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.67%
Total	1	0.67%



Year	1	2	at 28 months							
Survival Probability	100.00%	100.00%	100.00%							
± 1 standard error	0.00%	0.00%	0.00%							
Sample Size	140	100	60							

*Optim® lead insulation is a copolymer of silicone and polyurethane.

Defibrillation Leads

Customer Reported Performance Data

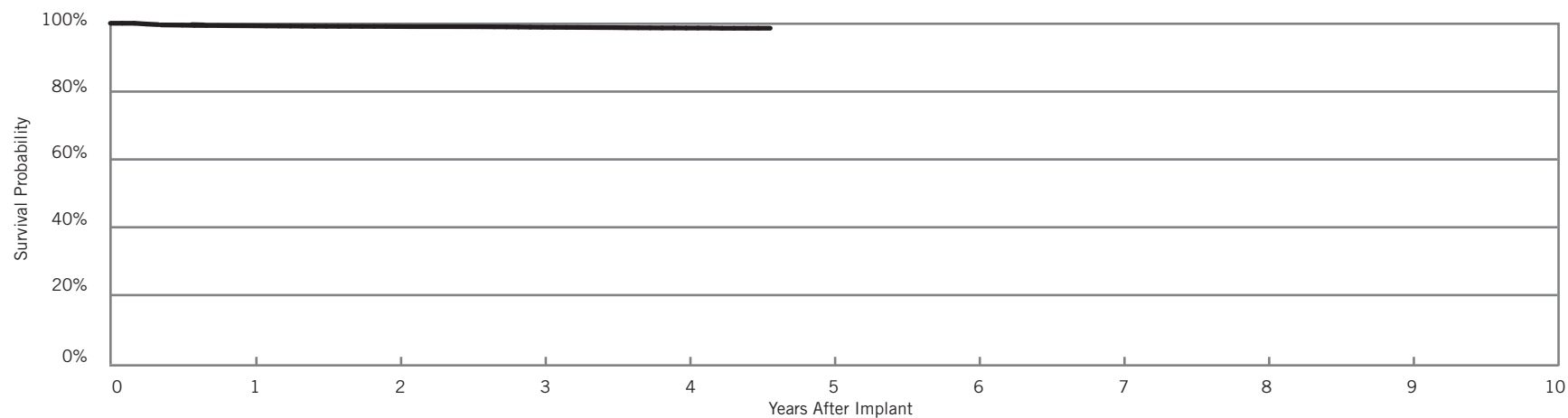
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Registered US Implants	15,461
Estimated Active US Implants	10,148
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	38	0.25%	10	0.06%
Conductor Fracture	0	0.00%	4	0.03%
Lead Dislodgement	34	0.22%	47	0.30%
Failure to Capture	19	0.12%	39	0.25%
Oversensing	19	0.12%	46	0.30%
Failure to Sense	8	0.05%	10	0.06%
Insulation Breach	0	0.00%	2	0.01%
Abnormal Pacing Impedance	1	0.01%	4	0.03%
Abnormal Defibrillation Impedance	4	0.03%	7	0.05%
Extracardiac Stimulation	4	0.03%	2	0.01%
Other	0	0.00%	13	0.08%
Total	127	0.82%	184	1.19%
Total Returned for Analysis	62		132	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	5	0.03%
Clavicular Crush	1	0.01%
In the Pocket	1	0.01%
Intravascular	3	0.02%
Insulation Breach	10	0.06%
Lead-to-Can Contacts	3	0.02%
Lead-to-Lead Contacts	3	0.02%
Clavicular Crush	1	0.01%
Externalized Conductors	0	0.00%
Others	3	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	87	0.56%
Total	102	0.66%



Year	1	2	3	4	at 55 months					
Survival Probability	99.19%	99.00%	98.79%	98.57%	98.51%					
± 1 standard error	0.07%	0.08%	0.09%	0.11%	0.13%					
Sample Size	15100	13000	10900	6100	200					

*Optim® lead insulation is a copolymer of silicone and polyurethane.

SCORE Registry Performance Data

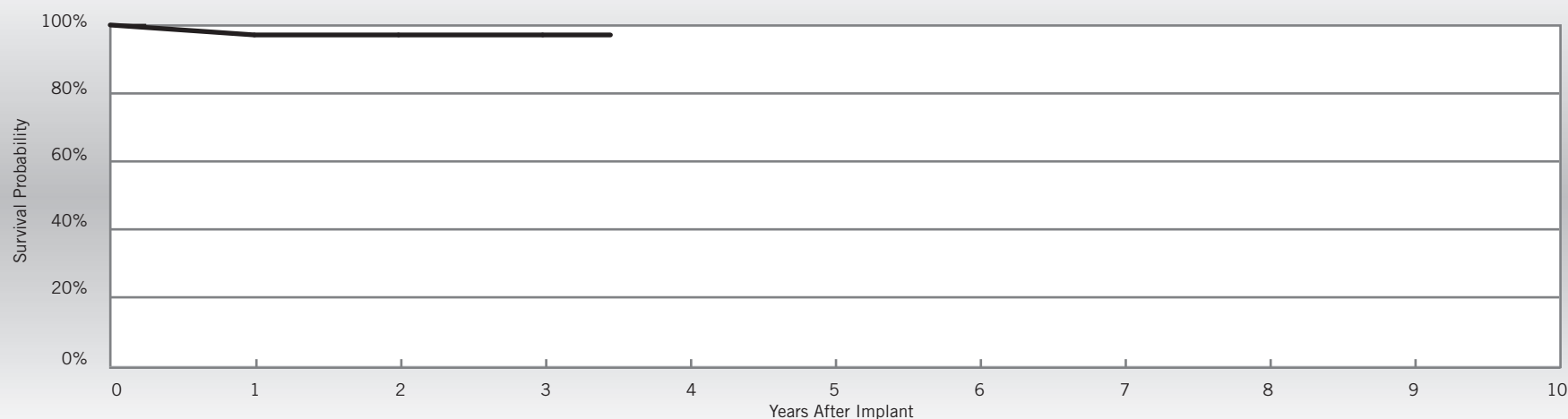
Riata® ST Optim®

Models 7020 & 7021

US Regulatory Approval	July 2006
Number of Devices Enrolled in Study	176
Cumulative Months of Follow-up	5,628
Insulation	Optim*
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.57%
Cardiac Perforation	1	0.57%
Conductor Fracture	2	1.14%
Failure to Sense	1	0.57%

Malfunctions	Qty.	Rate
Conductor Fracture	1	0.57%
Clavicular Crush	0	0.00%
In the Pocket	1	0.57%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	1	0.57%
Total	2	1.14%



Year	1	2	3	at 41 months						
Survival Probability	97.01%	97.01%	97.01%	97.01%						
± 1 standard error	1.31%	1.31%	1.31%	1.31%						
Sample Size	170	140	110	70						

*Optim® lead insulation is a copolymer of silicone and polyurethane.

Customer Reported Performance Data

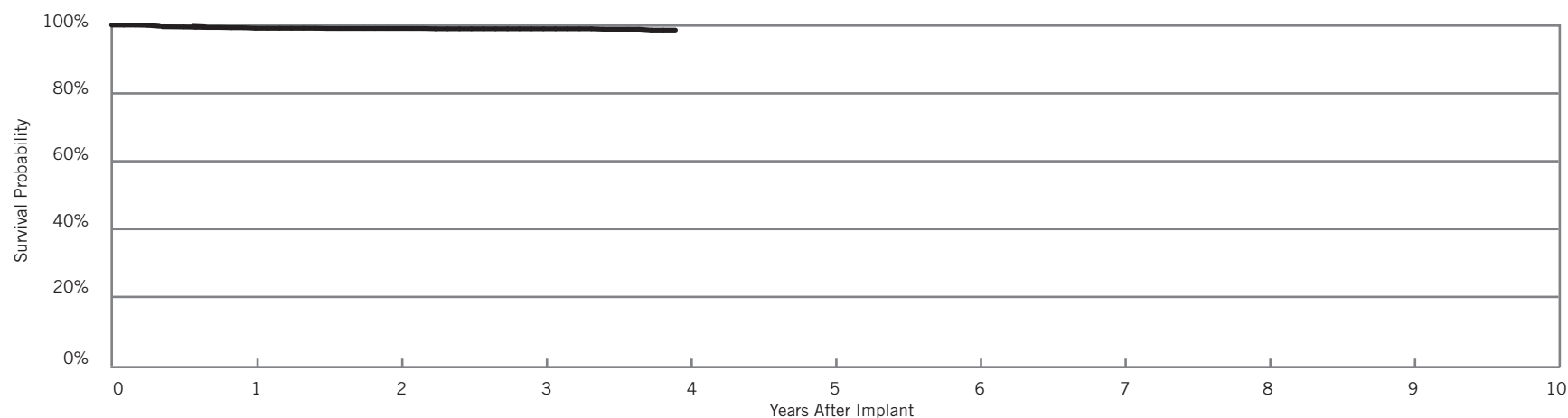
Riata® ST Optim®

Model 7022

US Regulatory Approval	July 2006
Registered US Implants	1,483
Estimated Active US Implants	975
Insulation	Optim*
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	5	0.34%	3	0.20%
Conductor Fracture	0	0.00%	3	0.20%
Lead Dislodgement	3	0.20%	6	0.40%
Failure to Capture	1	0.07%	1	0.07%
Oversensing	0	0.00%	5	0.34%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.13%	0	0.00%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	0	0.00%	0	0.00%
Total	11	0.74%	18	1.21%
Total Returned for Analysis	4		13	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	1	0.07%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	1	0.07%
Insulation Breach	0	0.00%
Lead-to-Can Contacts	0	0.00%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	8	0.54%
Total	9	0.61%



Year	1	2	3	at 47 months						
Survival Probability	99.06%	98.98%	98.89%	97.97%						
± 1 standard error	0.26%	0.27%	0.29%	0.40%						
Sample Size	1400	1300	1000	200						

*Optim® lead insulation is a copolymer of silicone and polyurethane.

Customer Reported Performance Data

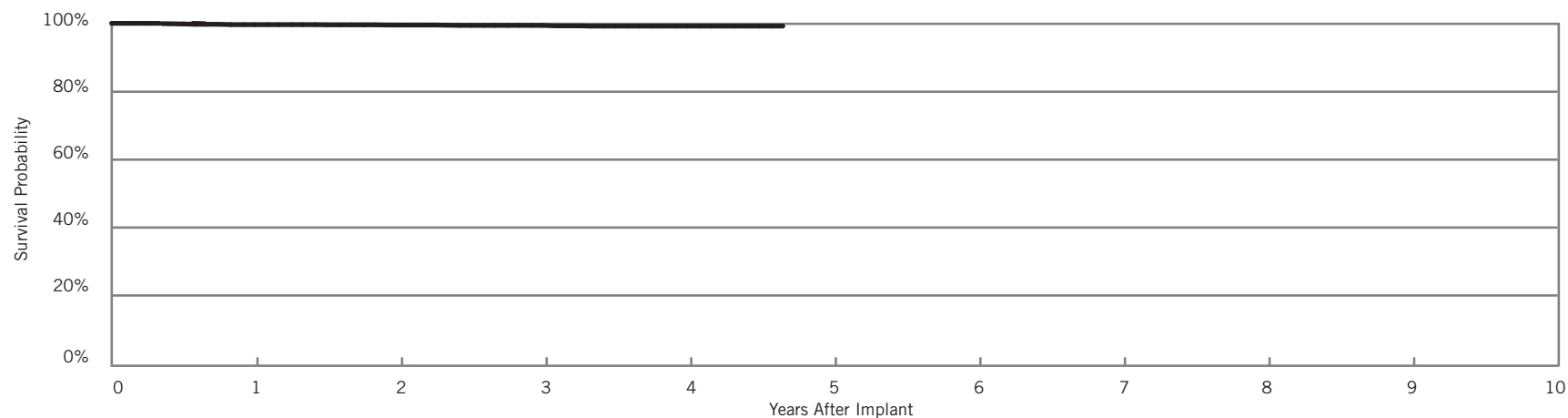
Riata® ST

Models 7010 & 7011

US Regulatory Approval	March 2006
Registered US Implants	2,208
Estimated Active US Implants	1,355
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	3	0.14%	1	0.05%
Conductor Fracture	0	0.00%	0	0.00%
Lead Dislodgement	1	0.05%	5	0.23%
Failure to Capture	3	0.14%	0	0.00%
Oversensing	2	0.09%	4	0.18%
Failure to Sense	1	0.05%	2	0.09%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	1	0.05%	1	0.05%
Abnormal Defibrillation Impedance	0	0.00%	0	0.00%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.05%	1	0.05%
Total	12	0.54%	14	0.63%
Total Returned for Analysis	5		9	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	2	0.09%
Lead-to-Can Contacts	0	0.00%
Lead-to-Lead Contacts	2	0.09%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	4	0.18%
Total	6	0.27%



Year	1	2	3	4	at 56 months					
Survival Probability	99.61%	99.50%	99.38%	99.17%	99.17%					
± 1 standard error	0.14%	0.16%	0.18%	0.22%	0.22%					
Sample Size	2200	1900	1700	1200	200					

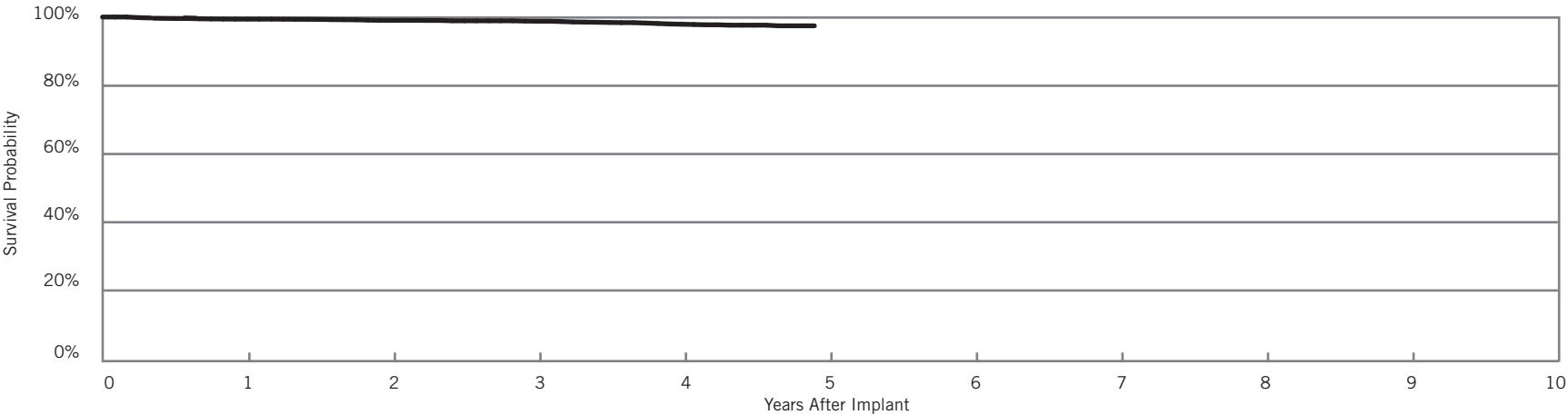
Customer Reported Performance Data

Riata® ST
Models 7040 & 7041

US Regulatory Approval	March 2006
Registered US Implants	4,088
Estimated Active US Implants	2,618
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	4	0.10%	2	0.05%
Conductor Fracture	0	0.00%	6	0.15%
Lead Dislodgement	5	0.12%	3	0.07%
Failure to Capture	1	0.02%	9	0.22%
Oversensing	3	0.07%	19	0.46%
Failure to Sense	0	0.00%	4	0.10%
Insulation Breach	0	0.00%	1	0.02%
Abnormal Pacing Impedance	2	0.05%	3	0.07%
Abnormal Defibrillation Impedance	0	0.00%	3	0.07%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.02%	0	0.00%
Total	16	0.39%	50	1.22%
Total Returned for Analysis	4		20	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	2	0.05%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.05%
Insulation Breach	8	0.20%
Lead-to-Can Contacts	5	0.12%
Lead-to-Lead Contacts	2	0.05%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	1	0.02%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	6	0.15%
Total	16	0.39%



Year	1	2	3	4	at 59 months				
Survival Probability	99.37%	99.01%	98.75%	97.76%	97.37%				
± 1 standard error	0.13%	0.16%	0.19%	0.30%	0.39%				
Sample Size	4000	3400	2800	1800	200				

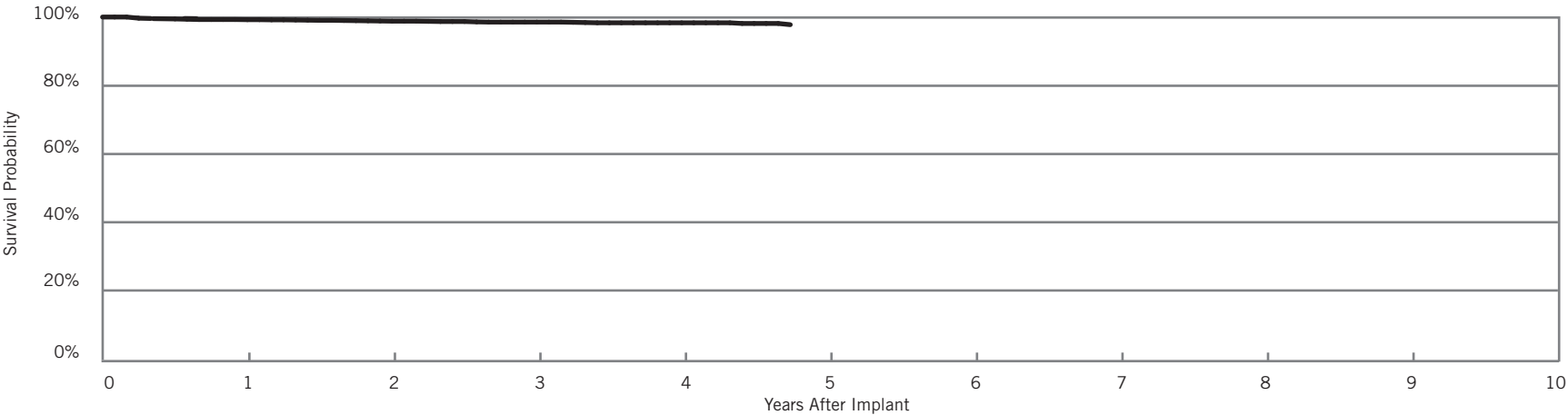
Customer Reported Performance Data

Riata® ST
Model 7002

US Regulatory Approval	June 2005
Registered US Implants	2,413
Estimated Active US Implants	1,508
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	6	0.25%	2	0.08%
Conductor Fracture	0	0.00%	3	0.12%
Lead Dislodgement	3	0.12%	9	0.37%
Failure to Capture	4	0.17%	7	0.29%
Oversensing	4	0.17%	11	0.46%
Failure to Sense	0	0.00%	0	0.00%
Insulation Breach	0	0.00%	0	0.00%
Abnormal Pacing Impedance	2	0.08%	0	0.00%
Abnormal Defibrillation Impedance	1	0.04%	1	0.04%
Extracardiac Stimulation	0	0.00%	0	0.00%
Other	1	0.04%	3	0.12%
Total	21	0.87%	36	1.49%
Total Returned for Analysis	10		18	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	2	0.08%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.08%
Insulation Breach	2	0.08%
Lead-to-Can Contacts	2	0.08%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	10	0.41%
Total	14	0.58%



Year	1	2	3	4	at 57 months				
Survival Probability	99.21%	98.76%	98.49%	98.28%	97.71%				
± 1 standard error	0.19%	0.24%	0.27%	0.29%	0.51%				
Sample Size	2400	2100	1800	1100	200				

Customer Reported Performance Data

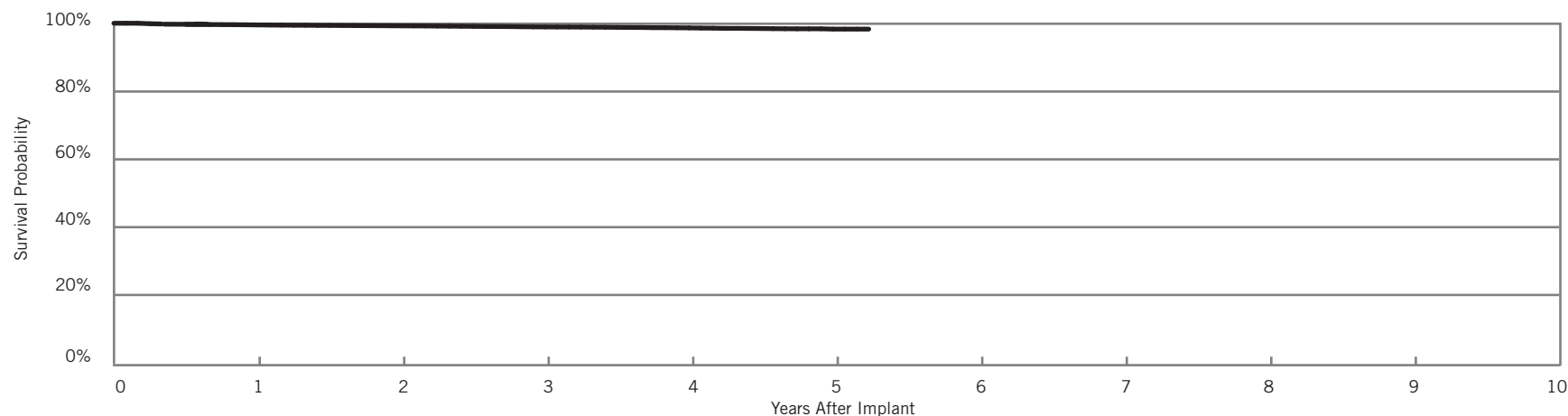
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Registered US Implants	34,925
Estimated Active US Implants	21,523
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

	Acute Observations (Post Implant, ≤30 days)		Chronic Complications (>30 days)	
	Qty.	Rate	Qty.	Rate
Cardiac Perforation	41	0.12%	18	0.05%
Conductor Fracture	0	0.00%	23	0.07%
Lead Dislodgement	37	0.11%	39	0.11%
Failure to Capture	43	0.12%	72	0.21%
Oversensing	40	0.11%	171	0.49%
Failure to Sense	7	0.02%	19	0.05%
Insulation Breach	1	<0.01%	9	0.03%
Abnormal Pacing Impedance	8	0.02%	11	0.03%
Abnormal Defibrillation Impedance	4	0.01%	12	0.03%
Extracardiac Stimulation	4	0.01%	2	0.01%
Other	11	0.03%	29	0.08%
Total	196	0.56%	405	1.16%
Total Returned for Analysis	103		233	

Lead Malfunctions	Qty.	Rate
Conductor Fracture	10	0.03%
Clavicular Crush	2	0.01%
In the Pocket	2	0.01%
Intravascular	6	0.02%
Insulation Breach	80	0.23%
Lead-to-Can Contacts	58	0.17%
Lead-to-Lead Contacts	11	0.03%
Clavicular Crush	2	0.01%
Externalized Conductors	1	<0.01%
Others	8	0.02%
Crimps, Welds & Bonds	1	0.00%
Other	0	0.00%
Extrinsic Factors	94	0.27%
Total	185	0.53%



Year	1	2	3	4	5	at 63 months				
Survival Probability	99.47%	99.20%	98.88%	98.55%	98.23%	98.23%				
± 1 standard error	0.04%	0.05%	0.06%	0.07%	0.10%	0.10%				
Sample Size	34300	30100	26100	19200	2700	500				

SCORE Registry Performance Data

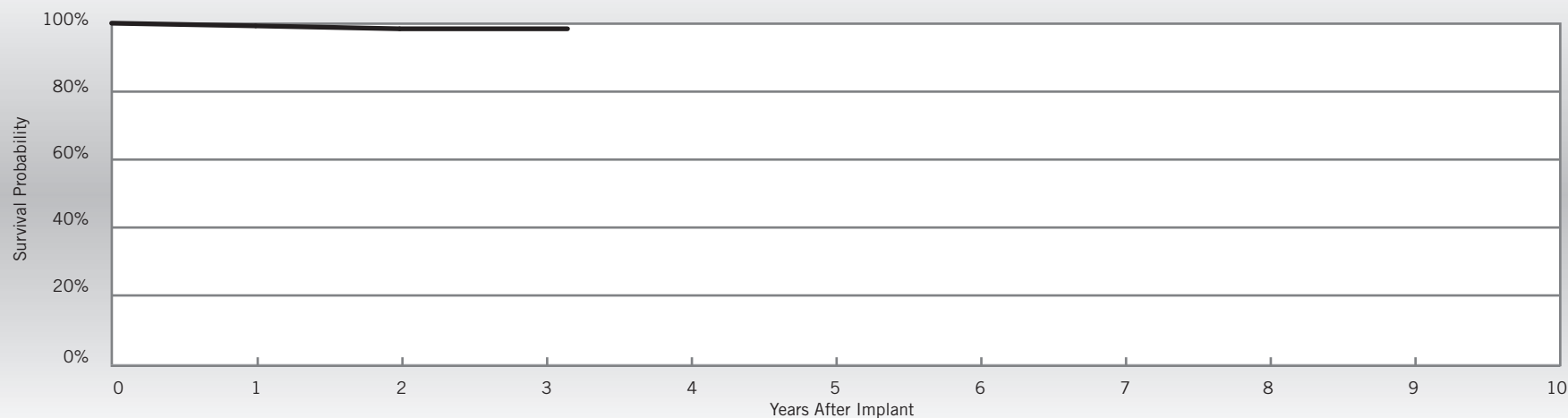
Riata® ST

Models 7000 & 7001

US Regulatory Approval	June 2005
Number of Devices Enrolled in Study	128
Cumulative Months of Follow-up	3,946
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Lead Dislodgement	1	0.78%
Oversensing	1	0.78%

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	2	1.56%
Lead-to-Can Contact	1	0.78%
Lead-to-Lead Contact	1	0.78%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	1	0.78%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	3	2.34%



Year	1	2	3	at 38 months						
Survival Probability	99.20%	98.32%	98.32%	98.32%						
± 1 standard error	0.79%	1.17%	1.17%	1.17%						
Sample Size	120	100	70	50						

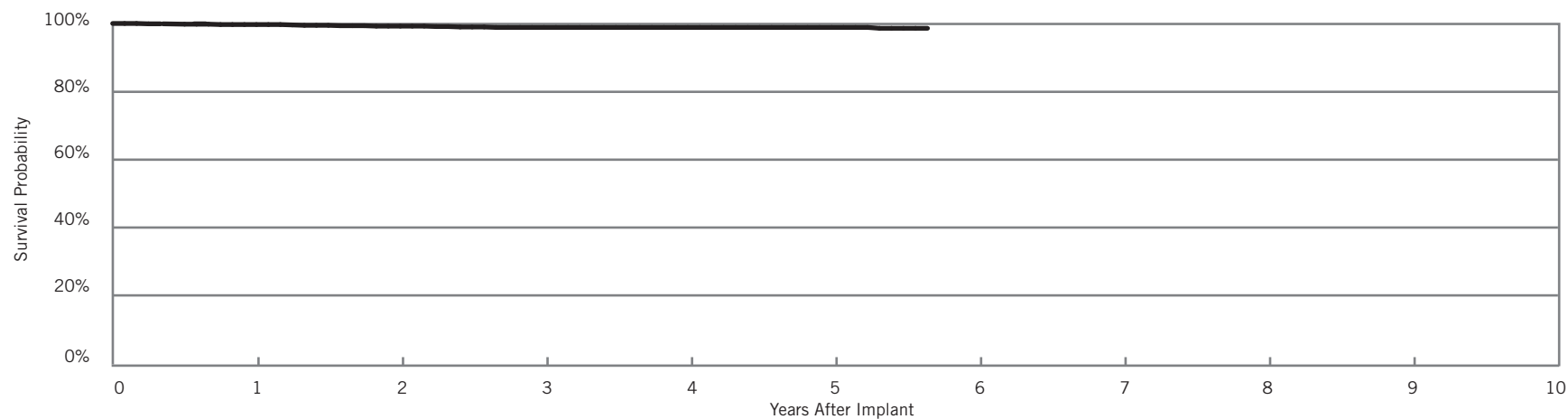
Customer Reported Performance Data

Riata® i

Models 1560 & 1561

US Regulatory Approval	April 2004
Registered US Implants	1,008
Estimated Active US Implants	503
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	1	0.10%
Lead-to-Can Contacts	1	0.10%
Lead-to-Lead Contacts	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	0	0.00%
Total	1	0.10%



Year	1	2	3	4	5	at 68 months				
Survival Probability	99.68%	99.20%	98.81%	98.81%	98.81%	98.55%				
± 1 standard error	0.19%	0.30%	0.38%	0.38%	0.38%	0.45%				
Sample Size	1000	900	800	700	600	200				

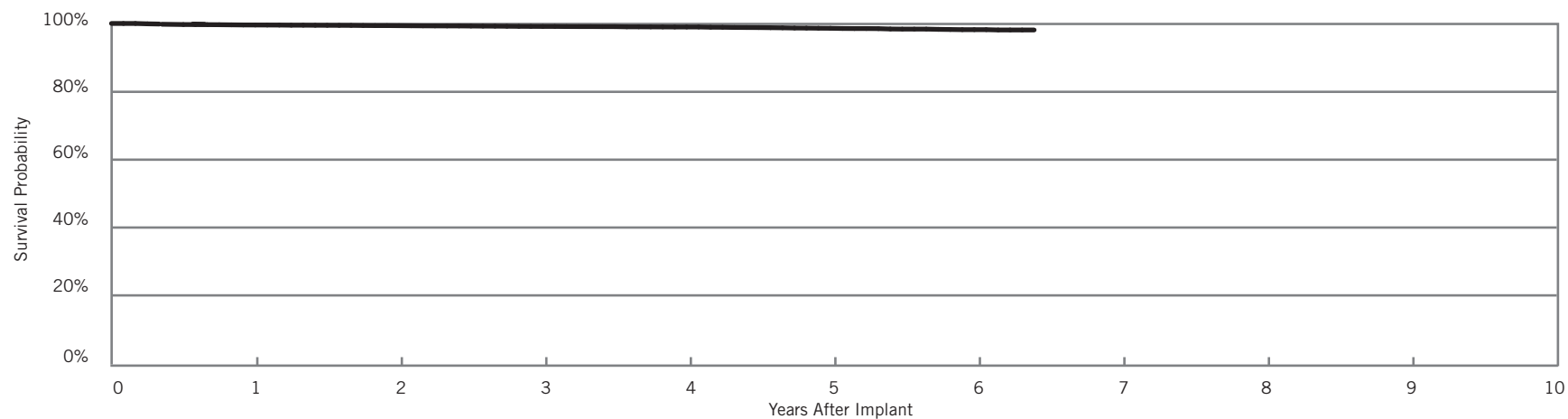
Customer Reported Performance Data

Riata® i

Models 1590 & 1591

US Regulatory Approval	April 2004
Registered US Implants	9,753
Estimated Active US Implants	5,104
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Integrated Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	4	0.04%
Clavicular Crush	1	0.01%
In the Pocket	0	0.00%
Intravascular	3	0.03%
Insulation Breach	14	0.14%
Lead-to-Can Contacts	7	0.07%
Lead-to-Lead Contacts	3	0.03%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Others	4	0.04%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	16	0.16%
Total	34	0.35%



Year	1	2	3	4	5	6	at 77 months			
Survival Probability	99.53%	99.31%	99.11%	98.94%	98.49%	98.04%	97.62%			
± 1 standard error	0.07%	0.09%	0.10%	0.11%	0.14%	0.21%	0.21%			
Sample Size	9600	8500	7700	6700	5500	900	300			

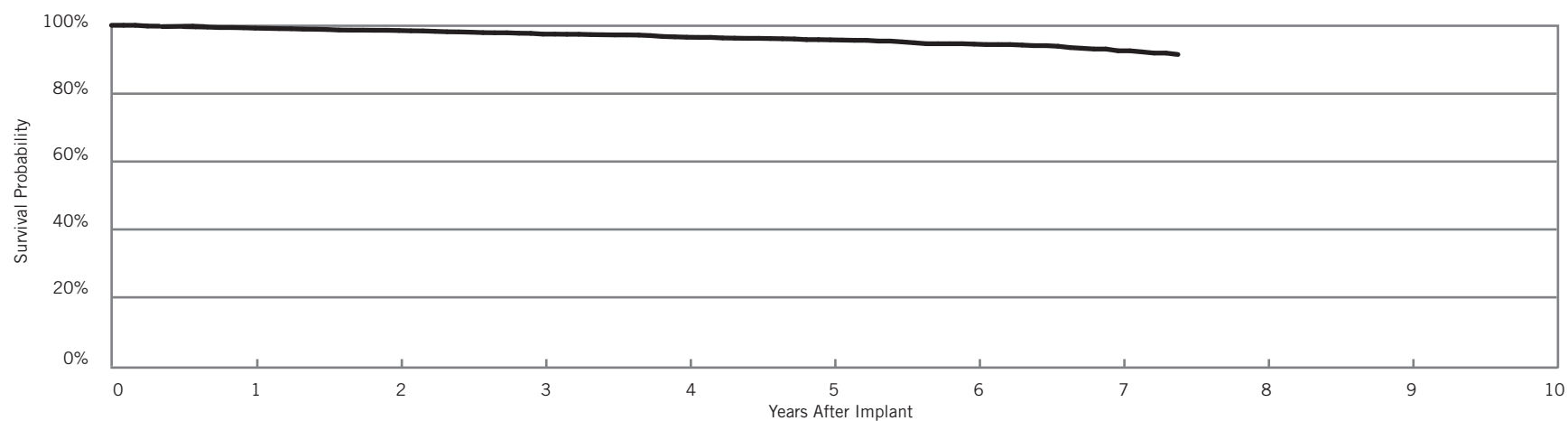
Customer Reported Performance Data

Riata®

Model 1582

US Regulatory Approval	March 2003
Registered US Implants	3,189
Estimated Active US Implants	1,480
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	2	0.06%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	2	0.06%
Insulation Breach	44	1.38%
Lead-to-Can Contacts	24	0.75%
Lead-to-Lead Contacts	4	0.13%
Clavicular Crush	1	0.03%
Externalized Conductors	5	0.16%
Others	10	0.31%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	14	0.44%
Total	60	1.88%



Year	1	2	3	4	5	6	7	at 89 months		
Survival Probability	99.07%	98.34%	97.34%	96.36%	95.55%	94.20%	92.32%	91.21%		
± 1 standard error	0.17%	0.24%	0.32%	0.38%	0.44%	0.55%	0.84%	1.05%		
Sample Size	3100	2700	2400	2000	1600	1100	300	200		

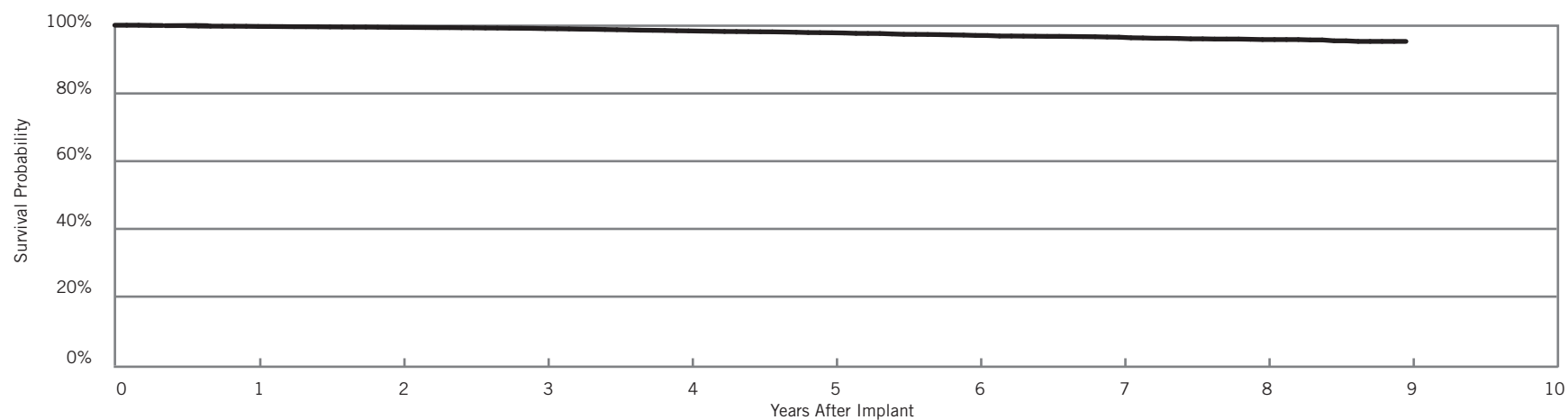
Customer Reported Performance Data

Riata®

Models 1570 & 1571

US Regulatory Approval	March 2002
Registered US Implants	10,529
Estimated Active US Implants	4,795
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	3	0.03%
Clavicular Crush	2	0.02%
In the Pocket	1	0.01%
Intravascular	0	0.00%
Insulation Breach	32	0.30%
Lead-to-Can Contacts	20	0.19%
Lead-to-Lead Contacts	2	0.02%
Clavicular Crush	0	0.00%
Externalized Conductors	3	0.03%
Others	7	0.07%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	19	0.18%
Total	54	0.51%



Year	1	2	3	4	5	6	7	8	9	
Survival Probability	99.62%	99.33%	98.94%	98.23%	97.67%	96.89%	96.21%	95.67%	95.12%	
± 1 standard error	0.06%	0.08%	0.11%	0.15%	0.18%	0.22%	0.26%	0.33%	0.43%	
Sample Size	10200	9000	8000	6900	5700	4300	2800	1600	200	

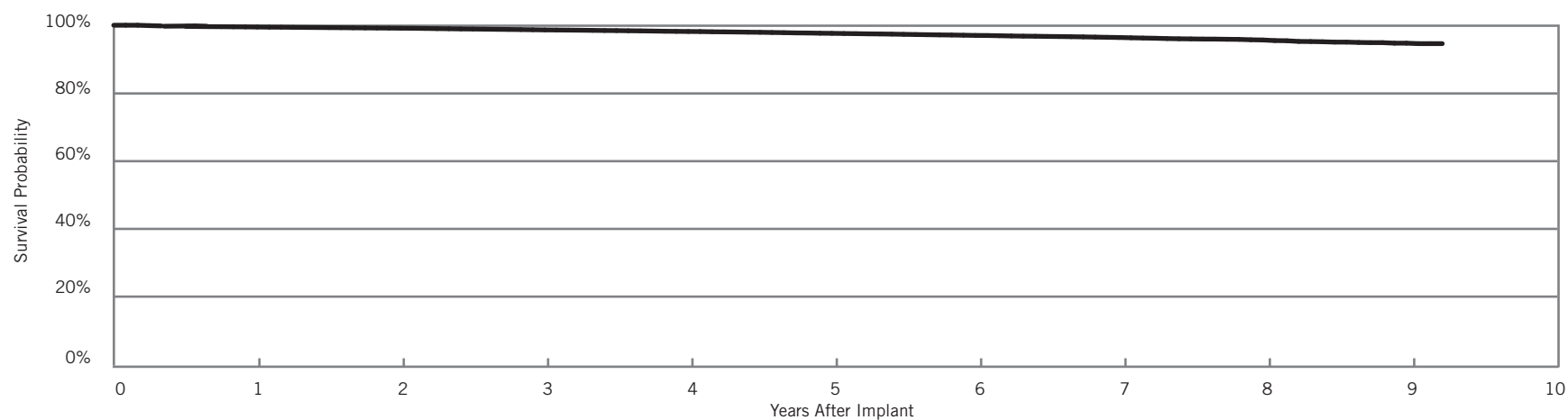
Customer Reported Performance Data

Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Registered US Implants	69,242
Estimated Active US Implants	33,066
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None

Lead Malfunctions	Qty.	Rate
Conductor Fracture	14	0.02%
Clavicular Crush	2	<0.01%
In the Pocket	5	0.01%
Intravascular	7	0.01%
Insulation Breach	267	0.39%
Lead-to-Can Contacts	157	0.23%
Lead-to-Lead Contacts	35	0.05%
Clavicular Crush	6	0.01%
Externalized Conductors	24	0.03%
Others	45	0.06%
Crimps, Welds & Bonds	3	<0.01%
Other	0	0.00%
Extrinsic Factors	207	0.30%
Total	491	0.71%



Year	1	2	3	4	5	6	7	8	9	at 111 months
Survival Probability	99.42%	99.08%	98.56%	98.09%	97.50%	96.90%	96.21%	95.37%	94.45%	94.45%
± 1 standard error	0.03%	0.04%	0.05%	0.06%	0.07%	0.08%	0.11%	0.15%	0.25%	0.28%
Sample Size	68100	60000	53700	46900	39600	28300	15500	7100	800	200

SCORE Registry Performance Data

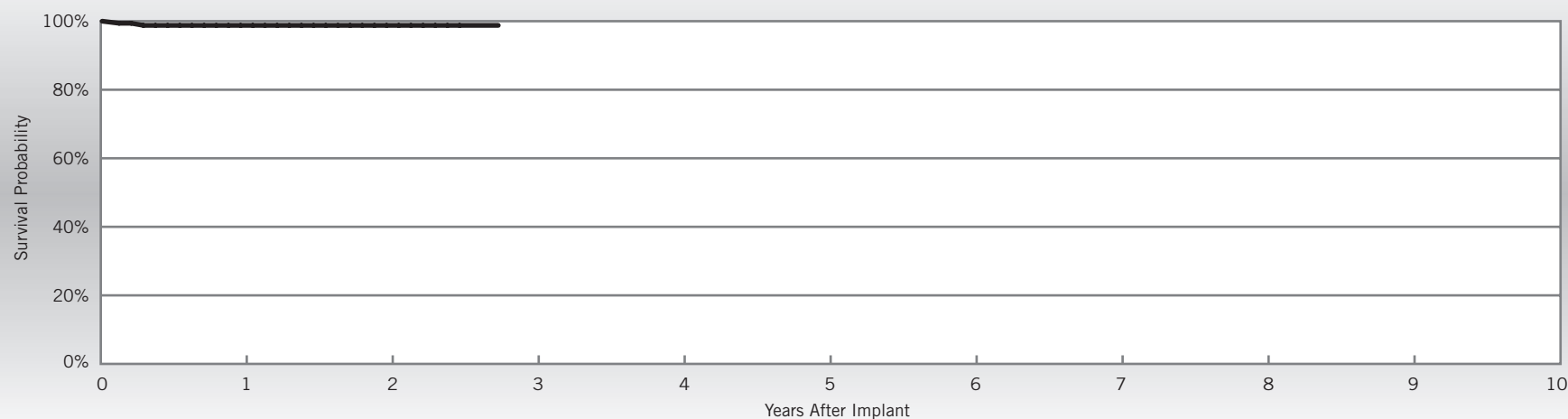
Riata®

Models 1580 & 1581

US Regulatory Approval	March 2002
Number of Devices Enrolled in Study	170
Cumulative Months of Follow-up	4,241
Insulation	Silicone
Type and/or Fixation	Dual Coil, Active
Polarity	Bipolar
Steroid	Yes

Qualifying Complications	Qty.	Rate
Abnormal Pacing Impedance	1	0.59%
Lead Dislodgement	1	0.59%

Malfunctions	Qty.	Rate
Conductor Fracture	0	0.00%
Clavicular Crush	0	0.00%
In the Pocket	0	0.00%
Intravascular	0	0.00%
Insulation Breach	0	0.00%
Lead-to-Can Contact	0	0.00%
Lead-to-Lead Contact	0	0.00%
Clavicular Crush	0	0.00%
Externalized Conductors	0	0.00%
Other	0	0.00%
Crimps, Welds & Bonds	0	0.00%
Other	0	0.00%
Extrinsic Factors	3	1.76%
Total	3	1.76%



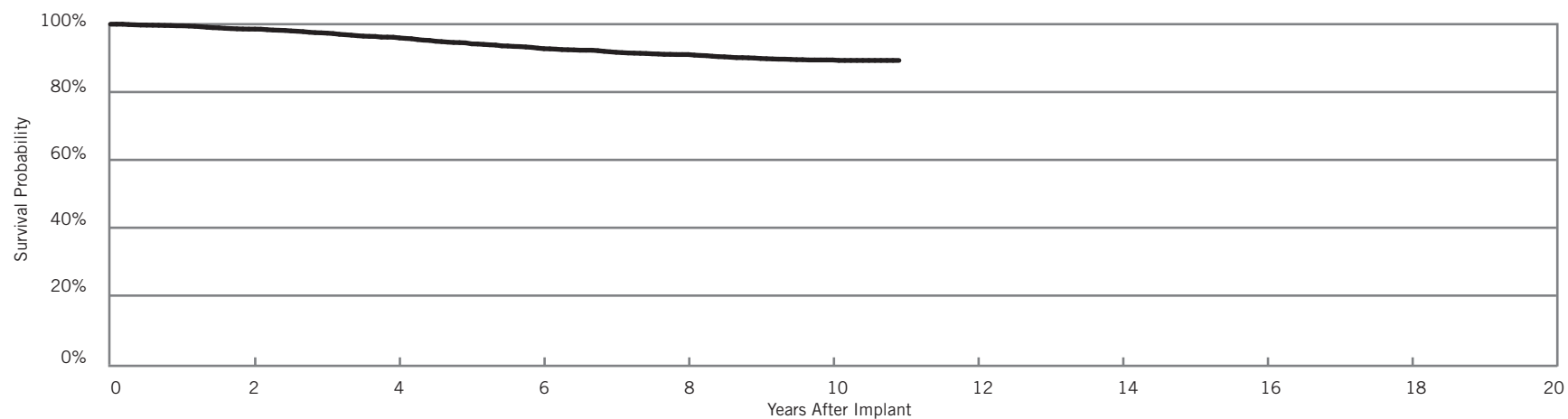
Year	1	2	at 33 months							
Survival Probability	98.81%	98.81%	98.81%							
± 1 standard error	0.83%	0.83%	0.83%							
Sample Size	160	120	50							

Customer Reported Performance Data

TVL™ ADX

Model 1559

US Regulatory Approval	November 1999
Registered US Implants	4,736
Estimated Active US Implants	1,041
Insulation	Silicone
Type and/or Fixation	Single Coil, Active
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



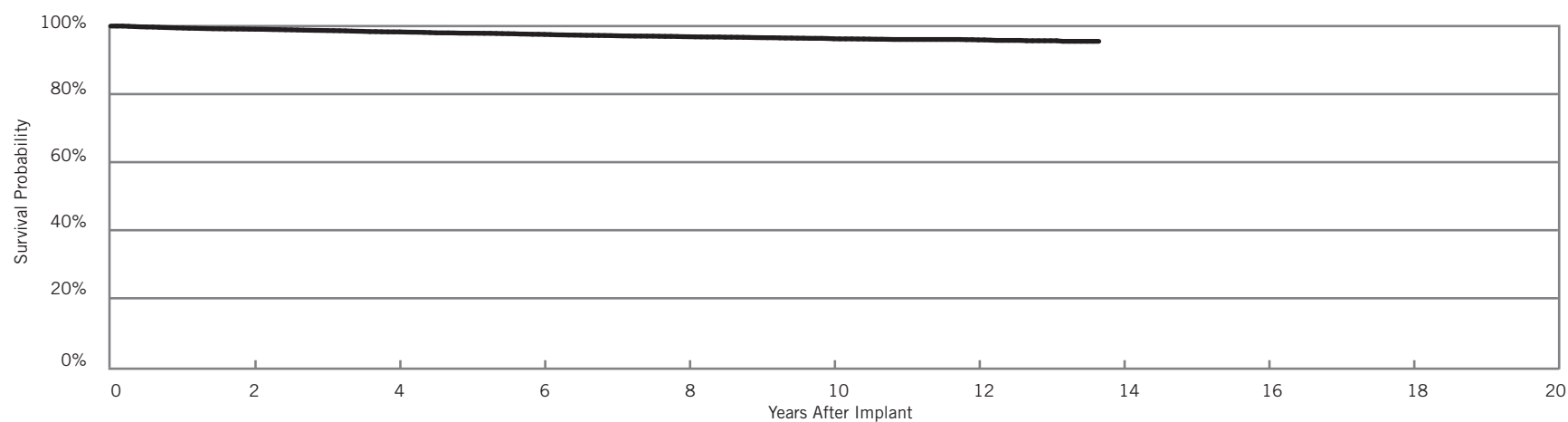
Year	2	4	6	8	10	at 131 months				
Survival Probability	98.51%	95.80%	92.70%	90.86%	89.28%	89.28%				
± 1 standard error	0.19%	0.34%	0.47%	0.54%	0.62%	0.63%				
Sample Size	3900	3100	2400	1900	1100	200				

Customer Reported Performance Data

SPL®

Models SP01, SP02, SP03 & SP04

US Regulatory Approval	September 1997
Registered US Implants	12,642
Estimated Active US Implants	2,940
Insulation	Silicone
Type and/or Fixation	Dual Coil, Passive
Polarity	Bipolar
Steroid	Yes
Number of US Advisories	None



Year	2	4	6	8	10	12	at 164 months			
Survival Probability	99.05%	98.22%	97.49%	96.82%	96.22%	95.92%	95.50%			
± 1 standard error	0.09%	0.13%	0.16%	0.19%	0.22%	0.25%	0.34%			
Sample Size	11000	9000	7300	5800	4200	1900	200			

SUMMARY INFORMATION

Defibrillation Leads

Survival Summary

Models	Family	Survival Probability									
		1 year	2 year	3 year	4 year	5 year	6 year	7 year	8 year	9 year	10 year
7170Q/7171Q	Durata® DF4	98.95%									
7120Q/7121Q	Durata® DF4	99.37%									
7122Q	Durata® DF4	99.21%									
7120/7121	Durata®	99.55%	99.38%	99.25%							
7122	Durata®	99.56%	99.43%	99.34%							
7030/7031	Riata® ST Optim®	99.23%	99.07%	99.07%							
7022	Riata® ST Optim®	99.06%	98.98%	98.89%							
7070/7071	Riata® ST Optim®	99.42%	99.24%	99.02%							
7020/7021	Riata® ST Optim®	99.19%	99.00%	98.79%	98.57%						
7010/7011	Riata® ST	99.61%	99.50%	99.38%	99.17%						
7040/7041	Riata® ST	99.37%	99.01%	98.75%	97.76%						
7002	Riata® ST	99.21%	98.76%	98.49%	98.28%						
7000/7001	Riata® ST	99.47%	99.20%	98.88%	98.55%	98.23%					
1560/1561	Riata® i	99.68%	99.20%	98.81%	98.81%	98.81%					
1590/1591	Riata® i	99.53%	99.31%	99.11%	98.94%	98.49%	98.04%				
1582	Riata®	99.07%	98.34%	97.34%	96.36%	95.55%	94.20%	92.32%			
1570/1571	Riata®	99.62%	99.33%	98.94%	98.23%	97.67%	96.89%	96.21%	95.67%	95.12%	
1580/1581	Riata®	99.42%	99.08%	98.56%	98.09%	97.50%	96.90%	96.21%	95.37%	94.45%	
1559	TVL™ ADX	99.45%	98.51%	97.22%	95.80%	94.14%	92.70%	91.58%	90.86%	89.79%	89.28%
SP01/SP02/SP03/SP04	SPL®	99.36%	99.05%	98.65%	98.22%	97.89%	97.49%	97.10%	96.82%	96.56%	96.22%

Defibrillation Leads

Acute Observation Summary

Post Implant ≤30 Days

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Abnormal Defibrillation Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
7170Q/7171Q	Jul-09	1740	1538	1	0.06%	0	0.00%	2	0.11%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	4	0.23%	3
7120Q/7121Q	Jan-09	42871	37926	23	0.05%	0	0.00%	70	0.16%	34	0.08%	21	0.05%	6	0.01%	0	0.00%	2	<0.01%	1	<0.01%	1	<0.01%	4	0.01%	162	0.38%	90
7122Q	Jan-09	7403	6602	6	0.08%	0	0.00%	11	0.15%	11	0.15%	4	0.05%	3	0.04%	0	0.00%	0	0.00%	1	0.01%	0	0.00%	3	0.04%	39	0.53%	28
7120/7121	Sep-07	53161	41241	31	0.06%	1	<0.01%	66	0.12%	17	0.03%	44	0.08%	4	0.01%	0	0.00%	1	<0.01%	17	0.03%	1	<0.01%	15	0.03%	197	0.37%	81
7122	Sep-07	8362	6779	4	0.05%	1	0.01%	8	0.10%	6	0.07%	3	0.04%	0	0.00%	0	0.00%	1	0.01%	1	0.01%	0	0.00%	0	0.00%	24	0.29%	12
7030/7031	Jul-06	851	547	0	0.00%	0	0.00%	5	0.59%	0	0.00%	2	0.24%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	7	0.82%	3
7022	Jul-06	1483	975	5	0.34%	0	0.00%	3	0.20%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	2	0.13%	0	0.00%	0	0.00%	0	0.00%	11	0.74%	4
7070/7071	Jul-06	3296	2423	2	0.06%	1	0.03%	3	0.09%	5	0.15%	4	0.12%	3	0.09%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	18	0.55%	8
7020/7021	Jul-06	15461	10148	38	0.25%	0	0.00%	34	0.22%	19	0.12%	19	0.12%	8	0.05%	0	0.00%	1	0.01%	4	0.03%	4	0.03%	0	0.00%	127	0.82%	62
7010/7011	Mar-06	2208	1355	3	0.14%	0	0.00%	1	0.05%	3	0.14%	2	0.09%	1	0.05%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	1	0.05%	12	0.54%	5
7040/7041	Mar-06	4088	2618	4	0.10%	0	0.00%	5	0.12%	1	0.02%	3	0.07%	0	0.00%	0	0.00%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	16	0.39%	4
7002	Jun-05	2413	1508	6	0.25%	0	0.00%	3	0.12%	4	0.17%	4	0.17%	0	0.00%	0	0.00%	2	0.08%	1	0.04%	0	0.00%	1	0.04%	21	0.87%	10
7000/7001	Jun-05	34925	21523	41	0.12%	0	0.00%	37	0.11%	43	0.12%	40	0.11%	7	0.02%	1	<0.01%	8	0.02%	4	0.01%	4	0.01%	11	0.03%	196	0.56%	103

Chronic Complication Summary

>30 Days

Models	US Regulatory Approval	Registered US Implants	Estimated Active US Implants	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Abnormal Defibrillation Impedance		Extracardiac Stimulation		Other		Total		Total Returned for Analysis
				Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	
7170Q/7171Q	Jul-09	1740	1538	0	0.00%	0	0.00%	2	0.11%	6	0.34%	1	0.06%	0	0.00%	0	0.00%	0	0.00%	1	0.06%	0	0.00%	0	0.00%	10	0.57%	8
7120Q/7121Q	Jan-09	42871	37926	7	0.02%	6	0.01%	112	0.26%	41	0.10%	20	0.05%	5	0.01%	0	0.00%	1	<0.01%	6	0.01%	1	<0.01%	4	0.01%	203	0.47%	171
7122Q	Jan-09	7403	6602	4	0.05%	1	0.01%	19	0.26%	5	0.07%	6	0.08%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	37	0.50%	32
7120/7121	Sep-07	53161	41241	4	0.01%	9	0.02%	113	0.21%	50	0.09%	55	0.10%	11	0.02%	1	<0.01%	10	0.02%	16	0.03%	0	0.00%	11	0.02%	280	0.53%	197
7122	Sep-07	8362	6779	1	0.01%	2	0.02%	13	0.16%	10	0.12%	6	0.07%	3	0.04%	2	0.02%	4	0.05%	1	0.01%	0	0.00%	2	0.02%	44	0.53%	40
7030/7031	Jul-06	851	547	1	0.12%	0	0.00%	0	0.00%	4	0.47%	6	0.71%	0	0.00%	0	0.00%	1	0.12%	0	0.00%	0	0.00%	0	0.00%	12	1.41%	2
7022	Jul-06	1483	975	3	0.20%	3	0.20%	6	0.40%	1	0.07%	5	0.34%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	18	1.21%	13
7070/7071	Jul-06	3296	2423	2	0.06%	2	0.06%	4	0.12%	4	0.12%	6	0.18%	2	0.06%	0	0.00%	2	0.06%	1	0.03%	0	0.00%	0	0.00%	23	0.70%	8
7020/7021	Jul-06	15461	10148	10	0.06%	4	0.03%	47	0.30%	39	0.25%	46	0.30%	10	0.06%	2	0.01%	4	0.03%	7	0.05%	2	0.01%	13	0.08%	184	1.19%	132
7010/7011	Mar-06	2208	1355	1	0.05%	0	0.00%	5	0.23%	0	0.00%	4	0.18%	2	0.09%	0	0.00%	1	0.05%	0	0.00%	0	0.00%	1	0.05%	14	0.63%	9
7040/7041	Mar-06	4088	2618	2	0.05%	6	0.15%	3	0.07%	9	0.22%	19	0.46%	4	0.10%	1	0.02%	3	0.07%	3	0.07%	0	0.00%	0	0.00%	50	1.22%	20
7002	Jun-05	2413	1508	2	0.08%	3	0.12%	9	0.37%	7	0.29%	11	0.46%	0	0.00%	0	0.00%	0	0.00%	1	0.04%	0	0.00%	3	0.12%	36	1.49%	18
7000/7001	Jun-05	34925	21523	18	0.05%	23	0.07%	39	0.11%	72	0.21%	171	0.49%	19	0.05%	9	0.03%	11	0.03%	12	0.03%	2	0.01%	29	0.08%	405	1.16%	233

Definitions of observations and complications can be found on [pages 8 and 9](#).

Malfunction Summary

		Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total	
Models	Registered US Implants	Clavicular Crush		In the Pocket		Intravascular		Total Conductor Fracture		Lead to Can Contact		Lead to Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach									
		Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate		
7170Q/7171Q	1740	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	6	0.34%	6	0.34%
7120Q/7121Q	42871	0	0.00%	2	<0.01%	2	<0.01%	4	0.01%	0	0.00%	0	0.00%	1	<0.01%	0	0.00%	1	<0.01%	2	<0.01%	0	0.00%	3	0.01%	122	0.28%	131	0.31%
7122Q	7403	0	0.00%	2	0.03%	0	0.00%	2	0.03%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	25	0.34%	27	0.36%
7120/7121	53161	0	0.00%	7	0.01%	2	<0.01%	9	0.02%	2	<0.01%	2	<0.01%	1	<0.01%	0	0.00%	1	<0.01%	6	0.01%	1	<0.01%	2	<0.01%	120	0.23%	138	0.26%
7122	8362	0	0.00%	2	0.02%	1	0.01%	3	0.04%	1	0.01%	2	0.02%	0	0.00%	0	0.00%	0	0.00%	3	0.04%	0	0.00%	0	0.00%	24	0.29%	30	0.36%
7030/7031	851	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	0.35%	3	0.35%
7022	1483	0	0.00%	0	0.00%	1	0.07%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	8	0.54%	9	0.61%
7070/7071	3296	0	0.00%	0	0.00%	1	0.03%	1	0.03%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	1	0.03%	0	0.00%	0	0.00%	5	0.15%	7	0.21%
7020/7021	15461	1	0.01%	1	0.01%	3	0.02%	5	0.03%	3	0.02%	3	0.02%	1	0.01%	0	0.00%	3	0.02%	10	0.06%	0	0.00%	0	0.00%	87	0.56%	102	0.66%
7010/7011	2208	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.09%	0	0.00%	0	0.00%	0	0.00%	2	0.09%	0	0.00%	0	0.00%	4	0.18%	6	0.27%
7040/7041	4088	0	0.00%	0	0.00%	2	0.05%	2	0.05%	5	0.12%	2	0.05%	0	0.00%	0	0.00%	1	0.02%	8	0.20%	0	0.00%	0	0.00%	6	0.15%	16	0.39%
7002	2413	0	0.00%	0	0.00%	2	0.08%	2	0.08%	2	0.08%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.08%	0	0.00%	0	0.00%	10	0.41%	14	0.58%
7000/7001	34925	2	0.01%	2	0.01%	6	0.02%	10	0.03%	58	0.17%	11	0.03%	2	0.01%	1	<0.01%	8	0.02%	80	0.23%	1	<0.01%	0	0.00%	94	0.27%	185	0.53%
1560/1561	1008	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.10%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.10%	0	0.00%	0	0.00%	0	0.00%	1	0.10%
1590/1591	9753	1	0.01%	0	0.00%	3	0.03%	4	0.04%	7	0.07%	3	0.03%	0	0.00%	0	0.00%	4	0.04%	14	0.14%	0	0.00%	0	0.00%	16	0.16%	34	0.35%
1582	3189	0	0.00%	0	0.00%	2	0.06%	2	0.06%	24	0.75%	4	0.13%	1	0.03%	5	0.16%	10	0.31%	44	1.38%	0	0.00%	0	0.00%	14	0.44%	60	1.88%
1570/1571	10529	2	0.02%	1	0.01%	0	0.00%	3	0.03%	20	0.19%	2	0.02%	0	0.00%	3	0.03%	7	0.07%	32	0.30%	0	0.00%	0	0.00%	19	0.18%	54	0.51%
1580/1581	69242	2	<0.01%	5	0.01%	7	0.01%	14	0.02%	157	0.23%	35	0.05%	6	0.01%	24	0.03%	45	0.06%	267	0.39%	3	<0.01%	0	0.00%	207	0.30%	491	0.71%

Definitions of malfunction categories can be found on [pages 10 and 11](#).

Defibrillation Leads

SCORE Summary

Qualifying Complications

Models	Number of Devices Enrolled	Cumulative Months of Follow-Up	Cardiac Perforation		Conductor Fracture		Lead Dislodgement		Failure to Capture		Oversensing		Failure to Sense		Insulation Breach		Abnormal Pacing Impedance		Abnormal Defibrillation Impedance		Extracardiac Stimulation		Other		Total	
			Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7120Q/7121Q	736	8043	0	0.00%	0	0.00%	3	0.41%	1	0.14%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.27%	0	0.00%	0	0.00%	6	0.82%
7122Q	145	1526	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
7120/7121	1490	33880	0	0.00%	2	0.13%	5	0.34%	2	0.13%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.07%	0	0.00%	11	0.74%
7122	251	4509	0	0.00%	0	0.00%	3	1.20%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.40%	0	0.00%	0	0.00%	0	0.00%	4	1.59%
7070/7071	150	3511	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
7020/7021	176	5628	1	0.57%	2	1.14%	0	0.00%	0	0.00%	0	0.00%	1	0.57%	0	0.00%	1	0.57%	0	0.00%	0	0.00%	0	0.00%	5	2.84%
7000/7001	128	3946	0	0.00%	0	0.00%	1	0.78%	0	0.00%	1	0.78%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	1.56%
1580/1581	170	4241	0	0.00%	0	0.00%	1	0.59%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.59%	0	0.00%	0	0.00%	0	0.00%	2	1.18%

Malfunctions

		Conductor Fracture								Insulation Breach												Crimps, Welds & Bonds		Other		Extrinsic Factors		Total			
Models	Number of Devices Enrolled	Clavicular Crush		Extravascular		Intravascular		Total Conductor Fracture		Lead to Can Contact		Lead to Lead Contact		Clavicular Crush		Externalized Conductors		Other		Total Insulation Breach											
																						Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate	Qty.	Rate
7120Q/7121Q	736	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	5	0.68%	5	0.68%
7122Q	145	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
7120/7121	1490	0	0.00%	1	0.07%	0	0.00%	1	0.07%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.13%	3	0.20%
7122	251	0	0.00%	0	0.00%	1	0.40%	1	0.40%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	0.80%	3	1.20%
7070/7071	150	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.67%	1	0.67%
7020/7021	176	0	0.00%	1	0.57%	0	0.00%	1	0.57%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.57%	2	1.14%
7000/7001	128	0	0.00%	0	0.00%	0	0.00%	0	0.00%	1	0.78%	1	0.78%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	2	1.56%	1	0.78%	0	0.00%	0	0.00%	3	2.34%
1580/1581	170	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0.00%	3	1.76%	3	1.76%

Definitions of complications can be found on [page 14](#).

Definitions of malfunction categories can be found on [pages 10 and 11](#).