INSIGNIA Plus DR (downsize) Model 1298

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 77000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 61000

U.S. Normal Battery Depletions: 279
U.S. Unconfirmed Reports of Premature Battery Depletions: 47

U.S. Confirmed Malfunctions: 33
Without Compromised Therapy: 21
With Compromised Therapy: 12

U.S. Average Device Age: 26.3 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Est. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	47000	Depletion & Malfct	99.88 (0.1/+0.0)	99.88 @ 18 mo. (0.1/+0.0)	—					
		Malfunction Only	100.00 (0.0/+0.0)	100.00 @ 18 mo. (0.0/+0.0)	—					
Advisory 22-Sep-05 First Fail Mode*	11000	Depletion & Malfct	99.93 (0.1/+0.0)	99.71 (0.1/+0.1)	99.22 (0.2/+0.2)	98.90 @ 42 mo. (0.4/+0.3)	—			
		Malfunction Only	99.94 (0.1/+0.0)	99.89 (0.1/+0.0)	99.86 (0.1/+0.1)	99.86 @ 42 mo. (0.1/+0.1)	—			
Advisory 22-Sep-05 (Second Fail Mode)*	65000	Depletion & Malfct	99.95 (0.0/+0.0)	99.82 (0.0/+0.0)	99.20 (0.1/+0.1)	97.95 (0.4/+0.4)	97.95 @ 48 mo. (0.4/+0.4)	—		
		Malfunction Only	99.97 (0.0/+0.0)	99.96 (0.0/+0.0)	99.96 (0.0/+0.0)	99.96 (0.0/+0.0)	99.96 @ 48 mo. (0.0/+0.0)	—		

PULSAR MAX II SR (downsize) Model 1180

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 7000
U.S. Approval Date: March 2001
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 48
U.S. Unconfirmed Reports of Premature Battery Depletions: 4

U.S. Confirmed Malfunctions: 1
Without Compromised Therapy: 1
With Compromised Therapy: 0

U.S. Average Device Age: 62.7 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Est. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	2000	Depletion & Malfct	99.98 (0.1/+0.0)	99.94 (0.1/+0.0)	99.87 (0.2/+0.1)	99.04 (0.6/+0.3)	95.38 @ 69 mo. (2.6/+1.7)	—		
		Malfunction Only	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	99.87 (0.2/+0.0)	99.97 (0.2/+0.0)	99.97 @ 69 mo. (0.2/+0.0)	—		

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory.
Survival probability for INSIGNIA Plus DR (downsize) pacemakers subject to the 23-Jun-06 advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Safety Advisory section for more details on this advisory.
Survival probability for PULSAR MAX II SR (downsize) pacemakers subject to 18-Jul-05 and 21-Jan-06 (Original Population) advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Safety Advisory section for more details on this advisory.
Data are representative of Guidant INSIGNIA Plus and Intermedics NEXUS Plus device performance.
Data are representative of Guidant PULSAR MAX II and Intermedics VIRTUS Plus II device performance.

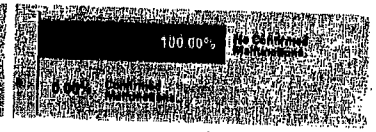
PULSAR MAX II SR Model 1181

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 1,000
U.S. Approval Date: May 2001
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 4
U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 0
Without Compromised Therapy: 0
With Compromised Therapy: 0
U.S. Average Device Age: 39.6 mo



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Reg. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	1,000	Depletion & Malfct.	99.92 (0.0/+0.1)	99.92 (0.0/+0.1)	99.77 (0.0/+0.2)	99.56 (0.1/+0.4)	99.56 @ 53 mo. (0.1/+0.4)	—		
		Malfunction Only	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 @ 53 mo. (0.0/+0.0)	—		

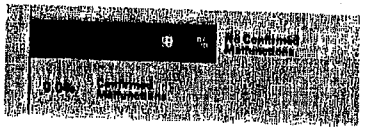
PULSAR MAX II DR Model 1280

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 29,000
U.S. Approval Date: May 2001
U.S. Estimated Active Implants: 20,000

U.S. Normal Battery Depletions: 261
U.S. Unconfirmed Reports of Premature Battery Depletions: 13

U.S. Confirmed Malfunctions: 13
Without Compromised Therapy: 10
With Compromised Therapy: 3
U.S. Average Device Age: 36.9 mo



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Reg. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	29,000	Depletion & Malfct.	99.95 (0.0/+0.0)	99.80 (0.1/+0.2)	99.52 (0.1/+0.3)	99.06 (0.2/+0.3)	97.32 (0.5/+0.4)	97.32 @ 61 mo. (0.5/+0.4)		
		Malfunction Only	99.99 (0.0/+0.0)	99.98 (0.0/+0.0)	99.96 (0.0/+0.0)	99.94 (0.0/+0.0)	99.94 (0.0/+0.0)	99.94 @ 61 mo. (0.0/+0.0)	—	

Survival probabilities for PULSAR MAX II SR and PULSAR MAX II DR pacemakers subject to 18-Jul-05 and 21-Jan-06 (Original Population) advisory not provided because they do not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Safety Advisory section for more details on this advisory.

Data are representative of Guidant PULSAR MAX II and Intermedics VIRTUS Plus II device performance.

DISCOVERY II SR (downsize) Model 1184

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 13,000
U.S. Approval Date: March 2000
U.S. Estimated Active Implants: 6,000

U.S. Normal Battery Depletions: 110
U.S. Unconfirmed Reports of Premature Battery Depletions: 4

U.S. Confirmed Malfunctions: 2
Without Compromised Therapy: 1
With Compromised Therapy: 1

U.S. Average Device Age: 32.8 mo

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Reg. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	13,000	Depletion & Malfct.	99.86 (+0.1/+0.0)	99.83 (+0.1/+0.1)	99.67 (+0.2/+0.0)	99.05 (+0.3/+0.2)	97.95 (+0.5/+0.4)	96.14 @ 70 mo (+0.8/+0.8)	—	—
		Malfunction Only	99.99 (+0.1/+0.0)	99.98 (+0.1/+0.0)	99.98 (+0.1/+0.0)	99.98 (+0.0/+0.0)	99.98 (+0.1/+0.0)	99.98 @ 70 mo (+0.1/+0.0)	—	—
Advisory 21-Jan-06 (Second Population)*	300	Depletion & Malfct.	99.72 (+1.7/+0.2)	99.72 (+1.7/+0.2)	99.36 (+1.9/+0.5)	98.41 @ 43 mo (+2.1/+1.0)	—	—	—	—
		Malfunction Only	100.00 (+0.0/+0.0)	100.00 (+0.0/+0.0)	100.00 (+0.0/+0.0)	100.00 @ 43 mo (+0.0/+0.0)	—	—	—	—

DISCOVERY II SR Models 1186/1187

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 3,000
U.S. Approval Date: March 2000
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 17
U.S. Unconfirmed Reports of Premature Battery Depletions: 1

U.S. Confirmed Malfunctions: 1
Without Compromised Therapy: 0
With Compromised Therapy: 1

U.S. Average Device Age: 32.4 mo

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Reg. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	3,000	Depletion & Malfct.	99.96 (+0.2/+0.1)	99.75 (+0.5/+0.1)	99.49 (+0.6/+0.3)	99.23 (+0.6/+0.3)	99.07 (+0.7/+0.4)	98.70 @ 83 mo (+1.3/+0.7)	—	—
		Malfunction Only	100.00 (+0.0/+0.0)	100.00 (+0.0/+0.0)	100.00 (+0.0/+0.0)	100.00 (+0.0/+0.0)	100.00 (+0.0/+0.0)	100.00 @ 83 mo (+0.0/+0.0)	—	—

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory.
Survival probability for the DISCOVERY II SR (downsize) pacemakers subject to 18-Jul-05 and 21-Jan-06 (Original Population) advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Safety Advisory section for more details on this advisory.
Survival probability for DISCOVERY II SR pacemakers subject to the 18-Jul-05 and 21-Jan-06 (Original and Second Population) advisories not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Safety Advisory section for more details on this advisory.
Data are representative of Guidant DISCOVERY II and Intermedics INTELIS II device performance.

DISCOVERY II DR (downsize) Model 1283

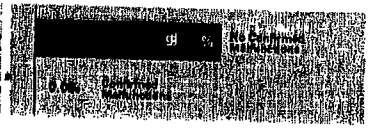
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 33,000
U.S. Approval Date: March 2000
U.S. Estimated Active Implants: 17,000

U.S. Normal Battery Depletions: 2,636
U.S. Unconfirmed Reports of Premature Battery Depletions: 39

U.S. Confirmed Malfunctions: 17
Without Compromised Therapy: 13
With Compromised Therapy: 4

U.S. Average Device Age: 40.2 mo.



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Prob. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	21,000	Depletion & Malfct.	99.91 (-0.0/+0.0)	99.67 (-0.1/+0.1)	99.76 (-0.3/+0.1)	95.93 (-0.3/+0.3)	84.62 (-0.7/+0.7)	65.17 @ 71 mo. (-1.0/+1.0)		
		Malfunction Only	99.97 (-0.0/+0.0)	99.97 (-0.0/+0.0)	99.96 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.93 (-0.0/+0.0)	99.91 @ 71 mo. (-0.1/+0.0)		
Advisory: 18-Jul-05 and 21-Jan-06 (Original Population)*	1,000	Depletion & Malfct.	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.06 (-1.8/+0.8)	94.52 (-2.8/+2.8)	79.13 (-4.6/+4.6)	77.98 @ 61 mo. (-5.0/+4.3)		
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 61 mo. (-0.0/+0.0)		
Advisory: 21-Jan-06	1,000	Depletion & Malfct.	99.90 (-0.0/+0.0)	99.47 (-0.7/+0.5)	98.19 (-1.2/+0.7)	93.64 (-2.0/+1.8)	79.81 (-3.4/+3.0)	65.36 @ 70 mo. (-4.6/+3.4)		
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 70 mo. (-0.0/+0.0)		

DISCOVERY II DR Models 1284/1286

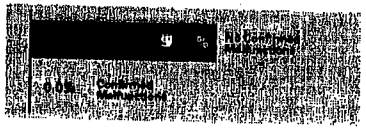
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 23,000
U.S. Approval Date: March 2000
U.S. Estimated Active Implants: 16,000

U.S. Normal Battery Depletions: 264
U.S. Unconfirmed Reports of Premature Battery Depletions: 5

U.S. Confirmed Malfunctions: 6
Without Compromised Therapy: 3
With Compromised Therapy: 3

U.S. Average Device Age: 37.8 mo.



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Prob. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	21,000	Depletion & Malfct.	99.88 (-0.0/+0.0)	99.86 (-0.1/-0.0)	99.82 (-0.1/+0.1)	99.86 (-0.2/+0.2)	97.30 (-0.4/+0.4)	89.20 @ 70 mo. (-1.4/+1.1)		
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.98 (-0.0/+0.0)	99.96 (-0.1/+0.0)	99.96 (-0.1/+0.0)	99.96 @ 70 mo. (-0.1/+0.0)		
Advisory: 21-Jan-06	1,000	Depletion & Malfct.	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.71 (-1.7/+0.3)	99.77 (-2.0/+0.9)	97.63 (-3.0/-1.2)	95.03 @ 56 mo. (-5.6/+2.2)		
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 56 mo. (-0.0/+0.0)		

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory.
Survival probability for DISCOVERY II DR pacemakers subject to 18-Jul-05 and 21-Jan-06 (Original Population) advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Safety Advisory section for more details on this advisory.
Data are representative of Guidant DISCOVERY II and Intermedics INTELIS II device performance.

PULSAR MAX SR (downsize) Model 1170

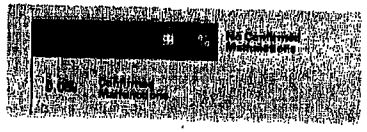
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 11,000
U.S. Approval Date: June 1999
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 660
U.S. Unconfirmed Reports of Premature Battery Depletions: 3

U.S. Confirmed Malfunctions: 6
Without Compromised Therapy: 5
With Compromised Therapy: 1

U.S. Average Device Age: 40.9 mo



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Registered Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	7,000	Depletion & Malfct.	99.94 (-0.1/+0.0)	99.84 (-0.1/+0.1)	99.57 (-0.3/+0.1)	99.62 (-0.4/+0.3)	99.37 (-0.8/+0.7)	64.65 @ 70 mo. (-0.8/+0.8)		
		Malfunction Only	99.96 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 (-0.1/+0.0)	99.97 @ 70 mo. (-0.1/+0.0)		
Advisory: 18-Jul-05 and 21-Jan-06 (Original Population)*	2,000	Depletion & Malfct.	99.84 (-0.3/+0.0)	99.80 (-0.4/+0.1)	99.59 (-0.6/+0.2)	99.59 (-0.8/+0.5)	99.50 (-1.1/+1.3)	70.86 (-3.6/+3.5)	71.89 @ 76 mo. (-3.6/+3.6)	
		Malfunction Only	99.94 (-0.3/+0.0)	99.94 (-0.3/+0.0)	99.94 (-0.3/+0.0)	99.94 (-0.3/+0.0)	99.83 (-0.6/+0.1)	99.66 (-0.8/+0.2)	99.66 @ 76 mo. (-0.8/+0.2)	
Advisory: 21-Jan-06 (Second Population)*	5,000	Depletion & Malfct.	100.00 (-0.0/+0.0)	99.92 (-0.5/+0.1)	99.23 (-0.8/+0.4)	98.29 (-1.1/+0.7)	98.11 (-1.0/+1.3)	76.66 (-3.7/+3.4)	74.09 @ 76 mo. (-4.0/+4.1)	
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.86 (-0.8/+0.1)	99.86 (-0.8/+0.1)	99.86 @ 74 mo. (-0.8/+0.1)	

PULSAR MAX SR Model 1171

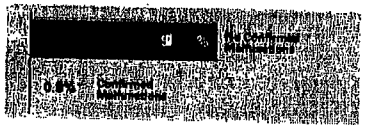
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 2,000
U.S. Approval Date: June 1999
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 30
U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 6
Without Compromised Therapy: 4
With Compromised Therapy: 2

U.S. Average Device Age: 46.6 mo



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Registered Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory*	1,000	Depletion & Malfct.	100.00 (-0.0/+0.0)	99.89 (-0.7/+0.1)	99.76 (-0.7/+0.2)	99.62 (-0.8/+0.3)	99.39 (-1.1/+0.4)	99.03 @ 64 mo. (-1.6/+0.6)		
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.87 (-0.8/+0.1)	99.87 (-0.8/+0.1)	99.87 (-0.8/+0.1)	99.87 @ 64 mo. (-0.8/+0.1)		
Advisory: 18-Jul-05 and 21-Jan-06 (Original Population)*	1,000	Depletion & Malfct.	99.82 (-1.1/+0.2)	99.82 (-1.1/+0.2)	99.66 (-1.3/+0.3)	99.23 (-1.7/+0.5)	99.23 (-1.7/+0.5)	99.23 @ 66 mo. (-1.7/+0.5)		
		Malfunction Only	99.82 (-1.1/+0.2)	99.82 (-1.1/+0.2)	99.82 (-1.1/+0.2)	99.49 (-1.6/+0.4)	99.49 (-1.6/+0.4)	99.49 @ 66 mo. (-1.6/+0.4)		
Advisory: 21-Jan-06 (Second Population)*	1,000	Depletion & Malfct.	100.00 (-0.0/+0.0)	99.82 (-1.1/+0.2)	99.40 (-1.3/+0.4)	98.91 (-1.5/+0.6)	98.91 (-1.5/+0.6)	97.15 (-2.5/+1.9)		
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.76 (-1.5/+0.2)	99.76 (-1.5/+0.2)	99.43 (-1.7/+0.4)		

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory.
Survival probabilities for PULSAR MAX SR (downsize) and PULSAR MAX SR pacemakers subject to the 29-Mar-99 advisory not provided because they do not meet report inclusion criteria (see Statistical Methodology section for more details). Refer to the Safety Advisory section for more details on this advisory.
Data are representative of Guidant PULSAR MAX and Intermedics VIRTUS Plus device performance.

PULSAR MAX DR Model 1270

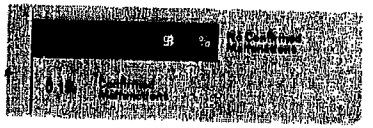
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 41,000
U.S. Approval Date: June 1999
U.S. Estimated Active Implants: 20,000

U.S. Normal Battery Depletions: 2,660
U.S. Unconfirmed Reports of Premature Battery Depletions: 42

U.S. Confirmed Malfunctions: 79
Without Compromised Therapy: 55
With Compromised Therapy: 24

U.S. Average Device Age: 50.4 mo



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Reg. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	26,000	Depletion & Malfct.	99.86 (±0.0/+0.0)	99.79 (±0.1/+0.1)	99.38 (±0.1/+0.1)	98.24 (±0.2/+0.2)	96.59 (±0.4/+0.4)	85.98 (±1.6/±1.6)	—	—
		Malfunction Only	99.98 (±0.0/+0.0)	99.96 (±0.0/+0.0)	99.95 (±0.0/+0.0)	99.94 (±0.0/+0.0)	99.93 (±0.1/+0.0)	99.91 (±0.1/±0.0)	—	—
Advisory: 18-Jul-05 and 21-Jan-06 (Original Population)*	2,000	Depletion & Malfct.	99.97 (±0.1/+0.0)	99.73 (±0.2/±0.1)	99.16 (±0.4/±0.4)	97.98 (±0.6/±0.6)	94.65 (±0.7/±0.7)	79.06 (±1.6/±1.6)	57.09 @ 80 mo. (±2.6/±2.6)	—
		Malfunction Only	99.98 (±0.1/+0.0)	99.98 (±0.1/±0.0)	99.96 (±0.1/±0.0)	99.91 (±0.1/±0.1)	99.58 (±0.3/±0.2)	98.42 (±0.6/±0.4)	97.58 @ 80 mo. (±1.1/±0.8)	—
Advisory: 21-Jan-06 (Second Population)*	3,000	Depletion & Malfct.	99.90 (±0.1/±0.1)	99.65 (±0.2/±0.1)	99.17 (±0.3/±0.2)	98.12 (±0.4/±0.3)	96.23 (±0.6/±0.6)	82.70 (±1.2/±1.1)	60.60 @ 81 mo. (±2.6/±2.6)	—
		Malfunction Only	99.95 (±0.1/±0.0)	99.95 (±0.1/±0.0)	99.87 (±0.1/±0.1)	99.85 (±0.1/±0.1)	99.82 (±0.1/±0.1)	99.77 (±0.2/±0.1)	99.72 @ 81 mo. (±0.2/±0.1)	—

DISCOVERY SR (downsize) Model 1174

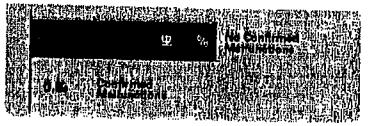
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 10,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 531
U.S. Unconfirmed Reports of Premature Battery Depletions: 8

U.S. Confirmed Malfunctions: 78
Without Compromised Therapy: 47
With Compromised Therapy: 31

U.S. Average Device Age: 45.4 mo



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Reg. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Advisory: 29-Mar-99*	1,000	Depletion & Malfct.	96.64 (±1.4/±1.0)	95.33 (±1.6/±1.2)	94.58 (±1.6/±1.3)	93.65 (±1.7/±1.5)	90.36 (±2.0/±2.1)	86.52 (±2.3/±2.7)	77.45 @ 81 mo. (±4.4/±3.8)	—
		Malfunction Only	97.06 (±1.3/±0.9)	96.00 (±1.5/±1.1)	95.56 (±1.6/±1.2)	94.81 (±1.6/±1.4)	94.14 (±2.0/±1.6)	94.14 (±2.0/±1.6)	93.33 @ 81 mo. (±2.4/±1.6)	—
Advisory: 18-Jul-05 and 21-Jan-06 (Original Population)*	2,000	Depletion & Malfct.	99.31 (±0.3/±0.2)	98.94 (±0.3/±0.2)	98.51 (±0.4/±0.3)	97.57 (±0.5/±0.4)	95.67 (±0.7/±0.6)	92.06 (±1.0/±0.8)	81.66 (±2.1/±1.6)	74.89 @ 91 mo. (±2.6/±2.0)
		Malfunction Only	99.44 (±0.2/±0.2)	99.16 (±0.3/±0.2)	99.04 (±0.3/±0.2)	98.84 (±0.3/±0.3)	98.74 (±0.4/±0.3)	98.61 (±0.4/±0.3)	98.20 (±0.5/±0.4)	98.03 @ 91 mo. (±0.7/±0.5)
Advisory: 21-Jan-06 (Second Population)*	3,000	Depletion & Malfct.	99.89 (±0.2/±0.1)	99.66 (±0.3/±0.2)	99.05 (±0.5/±0.3)	98.54 (±0.7/±0.5)	97.20 (±0.9/±0.7)	92.78 (±1.6/±1.2)	79.59 (±3.5/±2.4)	—
		Malfunction Only	99.92 (±0.2/±0.1)	99.83 (±0.3/±0.1)	99.72 (±0.4/±0.2)	99.72 (±0.4/±0.2)	99.72 (±0.4/±0.2)	99.62 (±0.5/±0.3)	99.62 (±0.5/±0.2)	—

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory.
Survival probability for PULSAR MAX DR pacemakers subject to the 29-Mar-99 advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology section for more details). Refer to the Safety Advisory section for more details on this advisory.
Data are representative of Guidant PULSAR MAX and Intermedics VIRTUS Plus device performance.
Data are representative of Guidant DISCOVERY and Intermedics INTELIS device performance.

DISCOVERY SR Model 1175

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 8,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 43
U.S. Unconfirmed Reports of Premature Battery Depletions: 0

U.S. Confirmed Malfunctions: 1
Without Compromised Therapy: 1
With Compromised Therapy: 0
U.S. Average Device Age: 21.2 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Reg. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	4,000	Depletion & Malfct.	99.87 (0.6/+0.1)	99.72 (0.5/+0.2)	99.72 (0.5/+0.2)	99.68 (0.5/+0.2)	99.68 (0.5/+0.2)	–	–	–
		Malfunction Only	99.94 (0.4/+0.1)	99.94 (0.4/+0.1)	99.94 (0.4/+0.1)	99.94 (0.4/+0.1)	99.94 (0.4/+0.1)	–	–	–
Advisory 18-Jul-05 and 21-Jan-06 (Original Population)*	1,000	Depletion & Malfct.	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	99.26 (-0.6/+0.6)	98.37 (-1.0/+0.9)	94.81 @ 78 mo. (-3.3/+2.1)	–	–
		Malfunction Only	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 @ 70 mo. (0.0/+0.0)	–	–
Advisory 21-Jan-06 (Second Population)*	500	Depletion & Malfct.	100.00 (0.0/+0.0)	99.70 (-1.6/+0.3)	99.36 (-2.1/+0.7)	96.10 (-2.6/+1.1)	96.10 @ 49 mo. (-2.6/+1.1)	–	–	–
		Malfunction Only	00.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 @ 49 mo. (0.0/+0.0)	–	–	–

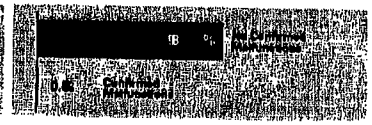
DISCOVERY DR (downsize) Model 1273

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 23,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 6,065
U.S. Unconfirmed Reports of Premature Battery Depletions: 69

U.S. Confirmed Malfunctions: 147
Without Compromised Therapy: 93
With Compromised Therapy: 54
U.S. Average Device Age: 50.0 mo.



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Reg. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Advisory 28-Mar-99*	17,000	Depletion & Malfct.	97.67 (-1.0/+0.7)	96.31 (-1.7/+0.9)	94.38 (-1.9/+1.0)	91.16 (-1.9/+1.0)	88.85 (-2.0/+2.0)	86.24 (-2.0/+2.0)	43.01 @ 78 mo. (-4.1/+4.2)	–
		Malfunction Only	97.75 (-1.0/+0.7)	96.65 (-1.1/+0.9)	95.68 (-1.3/+1.0)	95.33 (-1.4/+1.1)	94.91 (-1.6/+1.1)	94.35 (-1.6/+1.3)	94.35 @ 78 mo. (-1.6/+1.3)	–
Advisory* 18-Jul-05 and 21-Jan-06 (Original Population)*	1,000	Depletion & Malfct.	99.58 (-0.1/+0.1)	99.02 (-0.3/+0.3)	97.60 (-0.4/+0.5)	93.62 (-0.5/+0.6)	91.91 (-0.6/+0.8)	55.17 (-1.2/+1.2)	57.39 (-1.8/+1.8)	33.47 @ 84 mo. (-1.8/+1.8)
		Malfunction Only	99.63 (-0.1/+0.1)	99.39 (-0.1/+0.1)	99.26 (-0.2/+0.1)	99.19 (-0.2/+0.1)	99.11 (-0.2/+0.2)	98.91 (-0.2/+0.2)	98.63 (-0.3/+0.3)	98.47 @ 84 mo. (-0.5/+0.4)
Advisory 21-Jan-06 (Second Population)*	2,000	Depletion & Malfct.	99.85 (-0.1/+0.1)	99.49 (-0.3/+0.3)	97.93 (-0.4/+0.5)	94.72 (-0.7/+0.8)	83.40 (-1.2/+1.1)	56.71 (-1.7/+1.7)	37.21 (-2.0/+2.0)	35.45 @ 87 mo. (-1.8/+1.8)
		Malfunction Only	99.91 (-0.1/+0.1)	99.83 (-0.1/+0.1)	99.69 (-0.2/+0.1)	99.62 (-0.2/+0.1)	99.62 (-0.2/+0.1)	99.62 (-0.2/+0.1)	99.62 (-0.2/+0.1)	99.62 @ 87 mo. (-0.2/+0.1)

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory.
Survival probability for DISCOVERY SR pacemakers subject to 28-Mar-99 advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Safety Advisory section for more details on this advisory.

DISCOVERY DR Models 1274/1275

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 13,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 1,103
U.S. Unconfirmed Reports of Premature Battery Depletions: 16

U.S. Confirmed Malfunctions: 119
Without Compromised Therapy: 74
With Compromised Therapy: 45

U.S. Average Device Age: 34.8 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	11,000	Depletion & Malfct.	99.93 (-0.0/+0.1)	99.67 (-0.0/+0.2)	99.36 (-0.1/+0.3)	97.83 (-1.4/+0.6)	96.07 @ 58 mo. (-2.1/+1.0)			
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 @ 58 mo. (-0.0/+0.0)			
Advisory: 29-Mar-99*	1,000	Depletion & Malfct.	96.69 (-1.6/+1.3)	93.90 (-1.8/+1.8)	92.75 (-2.0/+1.8)	91.30 (-2.2/+1.9)	89.44 (-2.5/+2.1)	88.03 (-2.9/+2.5)	78.42 @ 82 mo. (-4.1/+3.5)	–
		Malfunction Only	98.03 (-1.5/+1.1)	94.23 (-1.8/+1.4)	93.22 (-1.9/+1.5)	92.39 (-2.1/+1.7)	91.81 (-2.2/+1.8)	90.95 (-2.3/+1.9)	90.30 @ 82 mo. (-2.6/+2.1)	–
Advisory: 18-Jul-05 and 21-Jan-06 (Original Population)*	7,000	Depletion & Malfct.	99.84 (-0.2/+0.2)	99.66 (-0.3/+0.3)	99.30 (-0.4/+0.4)	97.03 (-0.9/+0.4)	94.94 (-0.7/+0.8)	89.82 (-1.0/+0.8)	75.82 (-1.6/+1.7)	64.49 @ 93 mo. (-2.8/+2.6)
		Malfunction Only	99.43 (-0.2/+0.2)	99.07 (-0.3/+0.2)	98.91 (-0.3/+0.2)	98.76 (-0.3/+0.2)	98.59 (-0.3/+0.2)	98.03 (-0.4/+0.4)	97.56 (-0.5/+0.5)	96.95 @ 93 mo. (-0.8/+0.7)
Advisory: 21-Jan-06 (Second Population)*	4,000	Depletion & Malfct.	99.94 (-0.2/+0.0)	99.70 (-0.4/+0.1)	99.65 (-0.5/+0.0)	97.97 (-0.6/+0.0)	95.67 (-0.8/+0.7)	90.11 (-1.4/+1.0)	78.74 (-2.0/+2.0)	71.28 @ 69 mo. (-3.3/+3.1)
		Malfunction Only	99.97 (-0.2/+0.0)	99.87 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.83 (-0.2/+0.1)	99.83 @ 69 mo. (-0.2/+0.1)

MERIDIAN DDD Model 0976

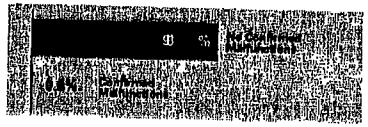
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 2,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 1,000

U.S. Normal Battery Depletions: 35
U.S. Unconfirmed Reports of Premature Battery Depletions: 1

U.S. Confirmed Malfunctions: 4
Without Compromised Therapy: 3
With Compromised Therapy: 1

U.S. Average Device Age: 44.0 mo.



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	500	Depletion & Malfct.	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)				
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)				
Advisory: 18-Jul-05 and 21-Jan-06 (Original Population)*	1,000	Depletion & Malfct.	99.84 (-1.0/+0.1)	99.66 (-1.0/+0.3)	99.44 (-1.2/+0.4)	99.18 (-1.4/+0.6)	97.40 (-2.0/+1.2)	91.78 (-3.1/+2.6)	–	–
		Malfunction Only	99.84 (-1.0/+0.1)	99.66 (-1.0/+0.3)	99.66 (-1.0/+0.3)	99.66 (-1.0/+0.3)	99.66 (-1.0/+0.3)	99.66 (-1.0/+0.3)	–	–
Advisory: 21-Jan-06 (Second Population)*	400	Depletion & Malfct.	100.00 (-0.0/+0.0)	99.26 (-2.0/+0.6)	98.84 (-2.4/+0.8)	98.84 @ 43 mo. (-2.4/+0.8)	–	–	–	–
		Malfunction Only	100.00 (-0.0/+0.0)	99.64 (-2.1/+0.3)	99.23 (-2.3/+0.6)	99.23 @ 43 mo. (-2.3/+0.6)	–	–	–	–

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory.
Survival probability for MERIDIAN DDD pacemakers subject to 29-Mar-99 advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details).
Data are representative of Guidant DISCOVERY and Intermedics INTELIS device performance.

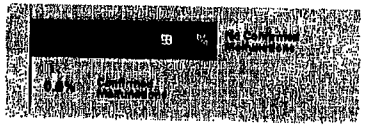
MERIDIAN SR Model 1176

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 9,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 3,000

U.S. Normal Battery Depletions: 200
U.S. Unconfirmed Reports of Premature Battery Depletions: 10

U.S. Confirmed Malfunctions: 18
Without Compromised Therapy: 12
With Compromised Therapy: 6
U.S. Average Device Age: 35.3 mo.



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Reg. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	6,000	Depletion & Malfct.	99.92 (-0.1/+0.1)	99.88 (-0.1/+0.1)	99.80 (-0.2/+0.1)	99.71 (-0.2/+0.1)	99.09 (-0.4/+0.1)	97.03 @ 67 mo. (-1.1/+0.1)	—	—
		Malfunction Only	99.98 (-0.1/+0.0)	99.98 (-0.1/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 (-0.2/+0.0)	99.94 @ 67 mo. (-0.2/+0.0)	—	—
Advisory: 18-Jul-05 and 21-Jan-06 (Original Population)*	2,000	Depletion & Malfct.	99.65 (-0.4/+0.3)	99.41 (-0.5/+0.3)	99.05 (-0.6/+0.4)	98.82 (-0.8/+0.5)	97.14 (-1.1/+0.6)	91.21 (-2.0/+1.5)	83.18 @ 82 mo. (-3.8/+3.0)	—
		Malfunction Only	99.75 (-0.4/+0.1)	99.57 (-0.4/+0.2)	99.42 (-0.5/+0.3)	99.33 (-0.6/+0.3)	99.23 (-0.6/+0.3)	99.05 (-0.6/+0.5)	98.68 @ 82 mo. (-1.1/+0.6)	—
Advisory: 21-Jan-06 (Second Population)*	1,000	Depletion & Malfct.	100.00 (-0.0/+0.0)	99.66 (-0.7/+0.3)	99.59 (-0.9/+0.5)	99.73 (-1.1/+0.6)	97.43 (-1.9/+1.0)	92.20 (-3.9/+2.1)	86.75 @ 77 mo. (-6.8/+3.8)	—
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.87 (-0.8/+0.1)	99.87 (-0.8/+0.1)	99.87 (-0.8/+0.1)	99.87 (-0.8/+0.1)	99.87 @ 77 mo. (-0.8/+0.1)	—

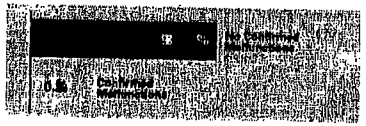
MERIDIAN DR Model 1276

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 16,000
U.S. Approval Date: April 1998
U.S. Estimated Active Implants: 7000

U.S. Normal Battery Depletions: 627
U.S. Unconfirmed Reports of Premature Battery Depletions: 12

U.S. Confirmed Malfunctions: 36
Without Compromised Therapy: 18
With Compromised Therapy: 17
U.S. Average Device Age: 42.7 mo.



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

	Reg. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	10,000	Depletion & Malfct.	99.86 (-0.1/+0.0)	99.82 (-0.1/+0.1)	99.63 (-0.2/+0.1)	99.79 (-0.4/+0.3)	97.80 (-0.7/+0.5)	94.26 @ 70 mo. (-1.6/+1.0)	—	—
		Malfunction Only	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	100.00 (-0.0/+0.0)	99.97 (-0.2/+0.0)	99.97 @ 70 mo. (-0.2/+0.0)	—	—
Advisory: 29-Mar-99*	400	Depletion & Malfct.	99.13 (-1.8/+0.6)	97.81 (-2.3/+1.1)	95.88 (-3.0/+1.8)	94.14 (-3.8/+2.3)	—	—	—	—
		Malfunction Only	99.13 (-1.8/+0.6)	97.81 (-2.3/+1.1)	96.25 (-2.9/+1.7)	94.94 (-3.4/+2.1)	—	—	—	—
Advisory: 18-Jul-05 and 21-Jan-06 (Original Population)*	4,000	Depletion & Malfct.	99.81 (-0.2/+0.1)	99.45 (-0.3/+0.2)	98.83 (-0.4/+0.3)	97.69 (-0.8/+0.5)	95.48 (-1.0/+0.7)	90.58 (-1.9/+1.2)	81.42 (-3.0/+2.3)	79.83 @ 86 mo. (-3.8/+2.8)
		Malfunction Only	99.86 (-0.2/+0.1)	99.65 (-0.3/+0.2)	99.45 (-0.3/+0.2)	99.29 (-0.4/+0.2)	99.20 (-0.4/+0.3)	99.01 (-1.3/+0.3)	98.43 (-1.0/+0.6)	98.43 @ 86 mo. (-1.0/+0.6)
Advisory: 21-Jan-06 (Second Population)*	2,000	Depletion & Malfct.	100.00 (-0.0/+0.0)	99.58 (-0.4/+0.2)	99.27 (-0.6/+0.3)	98.24 (-0.8/+0.5)	96.10 (-1.2/+0.8)	92.17 (-1.7/+1.1)	80.13 (-3.6/+3.2)	—
		Malfunction Only	100.00 (-0.0/+0.0)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.90 (-0.3/+0.1)	99.79 (-0.5/+0.1)	99.79 (-0.5/+0.1)	—

*Devices subject to an advisory. Refer to the Safety Advisories section for more details. Devices may be part of more than one advisory.
Survival probability for MERIDIAN SR pacemakers subject to 29-Mar-99 advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Safety Advisory section for more details on this advisory.

Pacing Leads

FLEXTEND Active Fixation Models 4086/4087/4088

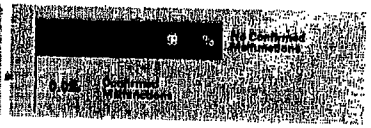
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 127,000
U.S. Approval Date: February 2002
U.S. Estimated Active Implants: 109,000

U.S. Unconfirmed Reports of Lead Complications: 526

U.S. Confirmed Malfunctions: 25
Without Compromised Therapy: 2
With Compromised Therapy: 23

U.S. Average Device Age: 21.6 mo.



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Registered U.S. Implants	Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)	Yr 9 (%)	Yr 10 (%)
127,000	99.76 (-0.0/+0.0)	99.58 (-0.0/+0.0)	99.33 (-0.1/+0.1)	98.93 (-0.1/+0.1)	98.74 @ 63 mo. (-0.2/+0.2)	–	–	–	–	–

FINELINE II/FINELINE II Sterox Passive Fixation (Polyurethane) Models 4452/4453/4456/4457

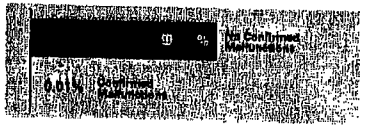
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 90,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 66,000

U.S. Unconfirmed Reports of Lead Complications: 290

U.S. Confirmed Malfunctions: 7
Without Compromised Therapy: 0
With Compromised Therapy: 7

U.S. Average Device Age: 27.2 mo.



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Registered U.S. Implants	Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)	Yr 9 (%)	Yr 10 (%)
90,000	99.83 (-0.0/+0.0)	99.72 (-0.0/+0.0)	99.60 (-0.1/+0.1)	99.42 (-0.1/+0.1)	99.20 (-0.1/+0.1)	99.04 @ 89 mo. (-0.3/+0.2)	–	–	–	–

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Polyurethane) Models 4463/4464/4465/4469/4470/4471

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 174,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 138,000

U.S. Unconfirmed Reports of Lead Complications: 521

U.S. Confirmed Malfunctions: 15
Without Compromised Therapy: 1
With Compromised Therapy: 14

U.S. Average Device Age: 25.8 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

Registered U.S. Implants	Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)	Yr 9 (%)	Yr 10 (%)
174,000	99.86 (-0.0/+0.0)	99.72 (-0.0/+0.0)	99.59 (-0.0/+0.0)	99.39 (-0.1/+0.1)	99.12 (-0.1/+0.1)	98.80 @ 71 mo. (-0.4/+0.3)	–	–	–	–

Data are representative of Guidant FINELINE II (polyurethane) and Intermedics THINLINE II (polyurethane) lead performance.

FINELINE II/FINELINE II Sterox Atrial J (Polyurethane) Models 4477/4478/4479/4480

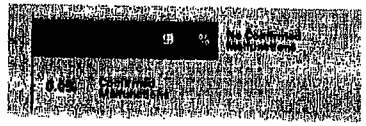
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 28,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 22,000

U.S. Unconfirmed Reports of Lead Complications: 127

U.S. Confirmed Malfunctions: 13
Without Compromised Therapy: 12
With Compromised Therapy: 1

U.S. Average Device Age: 27.2 mo.



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)	Yr 9 (%)	Yr 10 (%)
	29,000	99.68 (-0.1/+0.1)	99.56 (-0.1/+0.1)	99.32 (-0.1/+0.1)	99.20 (-0.2/+0.1)	99.01 (-0.3/+0.3)	99.01 @ 67 mo. (-0.3/+0.2)				

FINELINE II/FINELINE II Sterox Passive Fixation (Silicone) Models 4454/4455/4458/4459

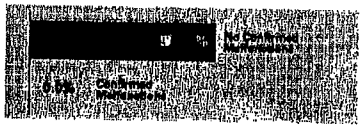
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 10,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 7,000

U.S. Unconfirmed Reports of Lead Complications: 93

U.S. Confirmed Malfunctions: 3
Without Compromised Therapy: 0
With Compromised Therapy: 3

U.S. Average Device Age: 32.4 mo.



U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)	Yr 9 (%)	Yr 10 (%)
	10,000	99.23 (-0.1/+0.1)	99.36 (-0.2/+0.2)	98.95 (-0.3/+0.3)	98.62 (-0.4/+0.3)	98.17 (-0.5/+0.4)	97.87 @ 69 mo. (-0.8/+0.5)				

FINELINE II EZ/FINELINE II Sterox EZ Positive Fixation (Silicone) Models 4466/4467/4468/4472/4473/4474

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 29,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 22,000

U.S. Unconfirmed Reports of Lead Complications: 214

U.S. Confirmed Malfunctions: 13
Without Compromised Therapy: 0
With Compromised Therapy: 13

U.S. Average Device Age: 28.7 mo.

U.S. Survival Probability (with rounded population sizes and corresponding yearly confidence limits)

		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)	Yr 9 (%)	Yr 10 (%)
	29,000	99.70 (-0.1/+0.1)	99.38 (-0.1/+0.1)	99.09 (-0.2/+0.1)	98.71 (-0.2/+0.2)	98.15 (-0.4/+0.3)	97.23 @ 70 mo. (-0.8/+0.7)				

Data are representative of Guidant FINELINE II (polyurethane) and Intermedics THINLINE II (polyurethane) lead performance.
Data are representative of Guidant FINELINE II (silicone) and Intermedics THINLINE II (silicone) lead performance.