VENTAK PRIZM DR HE Models 1853/1858

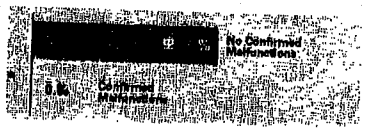
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 10,000
U.S. Approval Date: August 2000
U.S. Estimated Active Implants: 4,000

U.S. Normal Battery Depletions: 1,711
U.S. Unconfirmed Reports of Premature Battery Depletions: 56

U.S. Confirmed Malfunctions: 78
Without Compromised Therapy: 64
With Compromised Therapy: 14

U.S. Average Device Age: 24.6 mo



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

	Est. # of Active Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	4,000	Depletion & Malfct.	99.73 (-0.1/+0.1)	99.61 (-0.2/+0.3)	78.17 (-1.6/+1.8)	29.70 (-4.4/+3.6)	27.24 @ 49 mo. (-4.4/+3.6)			
		Malfunction Only	99.86 (-0.1/+0.1)	99.78 (-0.1/+0.1)	99.01 (-0.2/+0.3)	96.54 (-1.6/+1.1)	96.54 @ 49 mo. (-1.6/+1.1)			
Advisory: 23-Apr-01*	1,000	Depletion & Malfct.	99.65 (-0.7/+0.2)	97.12 (-1.5/+1.0)	69.70 (-3.8/+3.8)	43.91 @ 41 mo. (-4.3/+4.4)				
		Malfunction Only	99.89 (-0.7/+0.1)	99.04 (-1.0/+0.8)	97.15 (-1.8/+1.1)	96.86 @ 41 mo. (-1.9/+1.2)				

VENTAK PRIZM VR HE Models 1852/1857

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 8,000
U.S. Approval Date: August 2000
U.S. Estimated Active Implants: 5,000

U.S. Normal Battery Depletions: 678
U.S. Unconfirmed Reports of Premature Battery Depletions: 9

U.S. Confirmed Malfunctions: 33
Without Compromised Therapy: 19
With Compromised Therapy: 14

U.S. Average Device Age: 24.1 mo

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

	Est. # of Active Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	5,000	Depletion & Malfct.	99.60 (-0.2/+0.1)	99.04 (-0.3/+0.5)	96.78 (-0.7/+0.6)	85.31 (-2.0/+1.8)	47.53 @ 61 mo. (-3.6/+3.6)			
		Malfunction Only	99.77 (-0.2/+0.1)	99.66 (-0.2/+0.1)	99.43 (-0.3/+0.2)	98.99 (-0.6/+0.4)	98.70 @ 61 mo. (-1.0/+0.6)			

*Devices subject to an advisory. Refer to the Safety Advisory section for more details.
Survival probability for VENTAK PRIZM VR HE ICDs subject to the 23-Apr-01 advisory not provided because it does not meet report inclusion criteria (see Statistical Methodology for more details). Refer to the Safety Advisory section for more details on this advisory.

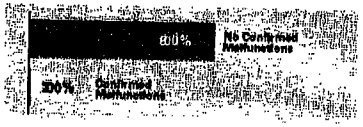
VENTAK PRIZM DR Models 1851/1856

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 13,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 4,479
U.S. Unconfirmed Reports of Premature Battery Depletions: 49

U.S. Confirmed Malfunctions: 260
Without Compromised Therapy: 242
With Compromised Therapy: 18
U.S. Average Device Age: 38.4 mo.



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

	Rem. U.S. Implants		Yr 1 (%)	Yr 2 (%)	Yr 3 (%)	Yr 4 (%)	Yr 5 (%)	Yr 6 (%)	Yr 7 (%)	Yr 8 (%)
Non-Advisory	2,000	Depletion & Malfct.	99.76 (-0.1/+0.1)	99.36 (-0.2/+0.2)	98.88 (-0.5/+0.5)	61.44 (-1.5/+1.5)	20.18 (-1.4/+1.5)	16.62 (-1.4/+1.5)	—	—
		Malfunction Only	99.88 (-0.1/+0.1)	99.76 (-0.1/+0.1)	99.37 (-0.2/+0.2)	96.13 (-0.7/+0.6)	94.00 (-1.3/+1.0)	93.23 (-1.5/+1.3)	—	—
Advisory: 23-Apr-01*	2,000	Depletion & Malfct.	99.11 (-0.3/+0.2)	98.63 (-0.4/+0.3)	96.81 (-0.8/+0.8)	65.32 (-1.9/+1.8)	19.92 (-1.7/+1.8)	17.50 @ 67 mo. (-1.7/+1.8)	—	—
		Malfunction Only	99.16 (-0.3/+0.2)	98.99 (-0.4/+0.3)	98.79 (-0.4/+0.3)	98.25 (-0.5/+0.4)	96.62 (-1.2/+0.9)	96.62 @ 67 mo. (-1.2/+0.9)	—	—

VENTAK PRIZM VR Models 1860/1855

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 6,000
U.S. Approval Date: January 2000
U.S. Estimated Active Implants: 2,000

U.S. Normal Battery Depletions: 2,235
U.S. Unconfirmed Reports of Premature Battery Depletions: 11

U.S. Confirmed Malfunctions: 77
Without Compromised Therapy: 64
With Compromised Therapy: 13
U.S. Average Device Age: 43.9 mo.

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

	Rem. 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.	99.74 (-0.2/+0.1)	99.43 (-0.3/+0.2)	98.75 (-0.6/+0.5)	86.96 (-0.9/-0.9)	61.38 (-2.6/+2.7)	23.20 @ 66 mo. (-2.6/+2.8)	—	—
		Malfunction Only	99.87 (-0.2/+0.1)	99.69 (-0.3/+0.1)	99.34 (-0.4/+0.2)	99.30 (-0.4/+0.2)	98.90 (-0.6/+0.4)	98.69 @ 66 mo. (-0.6/+0.6)	—	—
Advisory: 23-Apr-01*	4,000	Depletion & Malfct.	99.20 (-0.3/+0.2)	98.86 (-0.4/+0.3)	98.62 (-0.5/+0.3)	97.21 (-0.7/+0.6)	69.31 (-2.1/+2.0)	22.80 @ 67 mo. (-2.2/+2.3)	—	—
		Malfunction Only	99.28 (-0.3/+0.2)	99.12 (-0.4/+0.3	98.98 (-0.4/+0.3)	99.00 (-0.4/+0.3)	98.35 (-0.6/+0.4)	97.95 @ 67 mo. (-0.6/+0.6)	—	—

*Devices subject to an advisory. Refer to the Safety Advisory section for more details.

Defibrillation Leads

ENDOTAK RELIANCE G Dual Coil, Active Fixation Models 0184/0185/0186/0187

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 52,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 47,000

U.S. Unconfirmed Reports of Lead Complications: 103

U.S. Confirmed Malfunctions: 0
Without Compromised Therapy: 0
With Compromised Therapy: 0
U.S. Average Device Age: 11.9 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 (%)
52,000	99.78 (-0.1/+0.1)	99.65 (-0.1/+0.1)	99.65 @ 27 mo. (-0.1/-0.1)	–	–	–	–	–	–	–

ENDOTAK RELIANCE G Dual Coil, Passive Fixation Models 0174/0175/0176/0177

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 5,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 4,000

U.S. Unconfirmed Reports of Lead Complications: 20

U.S. Confirmed Malfunctions: 1
Without Compromised Therapy: 0
With Compromised Therapy: 1
U.S. Average Device Age: 13.1 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 (%)
5,000	99.62 (-0.3/+0.2)	99.06 (-0.7/+0.4)	99.06 @ 28 mo. (-0.7/+0.4)	–	–	–	–	–	–	–

ENDOTAK RELIANCE SG Single Coil, Active Fixation Models 0180/0181/0182

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 2,000
U.S. Approval Date: March 2004
U.S. Estimated Active Implants: 2,000

U.S. Unconfirmed Reports of Lead Complications: 4

U.S. Confirmed Malfunctions: 0
Without Compromised Therapy: 0
With Compromised Therapy: 0
U.S. Average Device Age: 11.0 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 (%)
2,000	99.87 (-0.4/+0.1)	99.51 @ 21 mo. (-0.9/+0.3)	–	–	–	–	–	–	–	–

ENDOTAK RELIANCE Dual Coil, Active Fixation Models 0157/0158/0159

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 70,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 56,000

U.S. Unconfirmed Reports of Lead Complications: 333

U.S. Confirmed Malfunctions: 6
Without Compromised Therapy: 1
With Compromised Therapy: 6
U.S. Average Device Age: 23.6 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 (%)
70,000	99.73 (-0.0/+0.0)	99.54 (-0.1/+0.1)	99.26 (-0.1/+0.1)	98.95 @ 48 mo. (-0.3/+0.2)	–	–	–	–	–	–

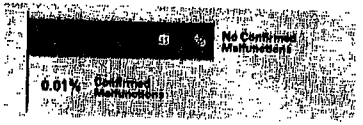
ENDOTAK RELIANCE Dual Coil, Passive Fixation Models 0147/0148/0149

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 30,000
U.S. Approval Date: November 2000
U.S. Estimated Active Implants: 21,000

U.S. Unconfirmed Reports of Lead Complications: 355

U.S. Confirmed Malfunctions: 3
Without Compromised Therapy: 0
With Compromised Therapy: 3
U.S. Average Device Age: 35.2 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 (%)
30,000	99.70 (-0.1/+0.1)	99.36 (-0.1/+0.1)	98.76 (-0.2/+0.1)	98.14 (-0.2/+0.2)	97.69 (-0.3/+0.3)	97.50 @ 66 mo. (-0.5/+0.4)	–	–	–	–

ENDOTAK RELIANCE S Single Coil, Active Fixation Models 0137/0138

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 1,000
U.S. Approval Date: July 2002
U.S. Estimated Active Implants: 1,000

U.S. Unconfirmed Reports of Lead Complications: 12

U.S. Confirmed Malfunctions: 0
Without Compromised Therapy: 0
With Compromised Therapy: 0
U.S. Average Device Age: 23.9 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 (%)
1,000	99.17 (-0.6/+0.4)	98.92 (-0.9/+0.5)	98.50 @ 55 mo. (-1.1/+0.8)	–	–	–	–	–	–	–

ENDOTAK RELIANCE S Single Coil, Passive Fixation Models 0127/0128

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 1,000
U.S. Approval Date: November 2000
U.S. Estimated Active Implants: 400

U.S. Unconfirmed Reports of Lead Complications: 21

U.S. Confirmed Malfunctions: 0
Without Compromised Therapy: 0
With Compromised Therapy: 0
U.S. Average Device Age: 41.0 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 (%)
1,000	99.46 (-0.1/+0.4)	98.43 (-1.5/+0.8)	97.00 (-3.0/+1.2)	94.95 (-2.8/+1.8)	94.95 @48 mo. (-2.8/+1.8)	–	–	–	–	–

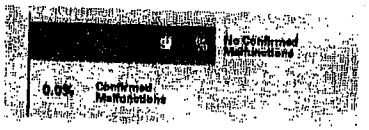
ENDOTAK ENDURANCE EZ Active Fixation Models 0154/0155/0156

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 29,000
U.S. Approval Date: June 1999
U.S. Estimated Active Implants: 17,000

U.S. Unconfirmed Reports of Lead Complications: 188

U.S. Confirmed Malfunctions: 8
Without Compromised Therapy: 4
With Compromised Therapy: 4
U.S. Average Device Age: 45.1 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 (%)
29,000	99.79 (-0.1/+0.0)	99.64 (-0.1/+0.1)	99.48 (-0.1/+0.1)	99.26 (-0.1/+0.1)	99.00 (-0.2/+0.1)	98.84 (-0.2/+0.2)	98.60 @84 mo. (-0.4/+0.4)	–	–	–

ENDOTAK ENDURANCE Rx Passive Fixation, Steroid Eluting Models 0144/0145/0146

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 18,000
U.S. Approval Date: January 1999
U.S. Estimated Active Implants: 10,000

U.S. Unconfirmed Reports of Lead Complications: 295

U.S. Confirmed Malfunctions: 17
Without Compromised Therapy: 3
With Compromised Therapy: 14
U.S. Average Device Age: 54.6 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 (%)
18,000	99.78 (-0.1/+0.1)	99.57 (-0.1/+0.1)	99.23 (-0.3/+0.1)	98.62 (-0.2/+0.2)	97.94 (-0.3/+0.2)	97.41 (-0.3/+0.3)	96.96 (-0.4/+0.4)	96.96 @87 mo. (-0.4/+0.4)	–	–

ENDOTAK ENDURANCE Passive Fixation Models 0134/0135/0136

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 3,000
U.S. Approval Date: August 1998
U.S. Estimated Active Implants: 1,000

U.S. Unconfirmed Reports of Lead Complications: 47

U.S. Confirmed Malfunctions: 3
Without Compromised Therapy: 2
With Compromised Therapy: 1

U.S. Average Device Age: 60.0 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 (%)
	3,000	99.45 (-0.4/+0.2)	99.26 (-0.4/+0.3)	98.89 (-0.5/+0.3)	98.47 (-0.6/+0.5)	98.08 (-0.7/+0.6)	97.63 (-0.8/+0.6)	97.18 (-0.9/+0.7)	97.08 @ 91 mo. (-0.1/+0.1)	--	--

ENDOTAK DSP Passive Fixation Models 0094/0095/0126

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 36,000
U.S. Approval Date: November 1995
U.S. Estimated Active Implants: 15,000

U.S. Unconfirmed Reports of Lead Complications: 824

U.S. Confirmed Malfunctions: 149
Without Compromised Therapy: 37
With Compromised Therapy: 112

U.S. Average Device Age: 66.8 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 (%)
Non-Advisory	16,000	99.71 (-0.1/+0.1)	99.53 (-0.1/+0.1)	99.32 (-0.2/+0.1)	99.06 (-0.2/+0.2)	98.47 (-0.3/+0.3)	98.06 (-0.3/+0.3)	97.74 (-0.3/+0.3)	97.42 (-0.4/+0.3)	97.23 @ 101 mo. (-0.5/+0.4)	--
Advisory: 19-Jul-99*	1,000	99.61 (-0.1/+0.1)	99.14 (-0.1/+0.1)	98.45 (-0.2/+0.2)	97.60 (-0.3/+0.2)	96.46 (-0.3/+0.3)	95.84 (-0.4/+0.3)	95.03 (-0.4/+0.4)	94.56 (-0.4/+0.4)	93.96 (-0.5/+0.4)	93.09 (-0.6/+0.6)

*Devices subject to an advisory. Refer to the Safety Advisory section for more details.

ENDOTAK PLUS Passive Fixation Models 0073/0075/0113/0115

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 4,000
U.S. Approval Date: May 1995
U.S. Estimated Active Implants: 1,000

U.S. Unconfirmed Reports of Lead Complications: 196

U.S. Confirmed Malfunctions: 47
Without Compromised Therapy: 4
With Compromised Therapy: 43
U.S. Average Device Age: 76.0 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 (%)
4,000	99.39 (-0.3/+0.3)	98.66 (-0.4/+0.3)	97.81 (-0.5/+0.4)	96.01 (-0.7/+0.6)	94.30 (-0.8/+0.8)	93.60 (-1.0/+0.9)	93.23 (-1.0/+0.8)	92.52 (-1.1/+1.0)	91.45 (-1.3/+1.1)	89.97 (-1.4/+1.3)

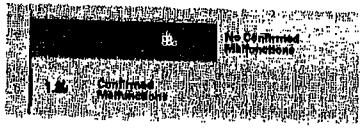
ENDOTAK 70 SERIES Passive Fixation Models 0070/0072/0074

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 6,000
U.S. Approval Date: August 1994
U.S. Estimated Active Implants: 2,000

U.S. Unconfirmed Reports of Lead Complications: 222

U.S. Confirmed Malfunctions: 85
Without Compromised Therapy: 10
With Compromised Therapy: 75
U.S. Average Device Age: 76.8 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 (%)
6,000	99.41 (-0.2/+0.2)	98.60 (-0.3/+0.3)	97.70 (-0.4/+0.4)	96.69 (-0.6/+0.5)	95.55 (-0.7/+0.6)	94.85 (-0.7/+0.6)	94.34 (-0.8/+0.7)	93.34 (-0.8/+0.8)	92.39 (-1.0/+0.9)	91.44 (-1.1/+1.0)

ENDOTAK 60 SERIES Passive Fixation Models 0060/0062/0064

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 11,000
U.S. Approval Date: August 1993
U.S. Estimated Active Implants: 3,000

U.S. Unconfirmed Reports of Lead Complications: 499

U.S. Confirmed Malfunctions: 176
Without Compromised Therapy: 37
With Compromised Therapy: 139
U.S. Average Device Age: 81.7 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 (%)
11,000	99.51 (-0.2/+0.1)	98.73 (-0.2/+0.2)	97.63 (-0.3/+0.3)	95.87 (-0.5/+0.4)	94.59 (-0.6/+0.5)	93.76 (-0.6/+0.5)	92.88 (-0.6/+0.6)	91.64 (-0.7/+0.7)	90.67 (-0.8/+0.7)	89.79 (-0.9/+0.8)

Pacemakers

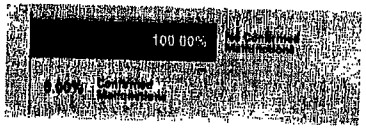
INSIGNIA Ultra SR Model 1190

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 10,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 8,000

U.S. Normal Battery Depletions: 1
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: 9.3 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	8,000	Depletion & Malfct.	99.90 (0.0/+0.1)	99.90 @ 17 mo. (0.0/+0.1)						
		Malfunction Only	100.00 (0.0/+0.0)	100.00 @ 17 mo. (0.0/+0.0)						
Advisory: 22-Sep-05* (Second Fail Mode)*	5,000	Depletion & Malfct.	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)						

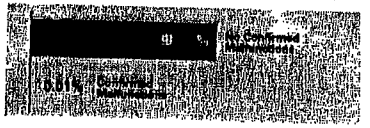
INSIGNIA Ultra DR (downsize) Model 1290

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 33,000
U.S. Approval Date: November 2002
U.S. Estimated Active Implants: 30,000

U.S. Normal Battery Depletions: 3
U.S. Unconfirmed Reports of Premature Battery Depletions: 1

U.S. Confirmed Malfunctions: 3
Without Compromised Therapy: 0
With Compromised Therapy: 3
U.S. Average Device Age: 10.8 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	16,000	Depletion & Malfct.	100.00 (0.0/+0.0)	100.00 @ 19 mo. (0.0/+0.0)						
		Malfunction Only	100.00 (0.0/+0.0)	100.00 @ 19 mo. (0.0/+0.0)						
Advisory: 22-Sep-05 (Second Fail Mode)*	12,000	Depletion & Malfct.	99.97 (0.0/+0.0)	99.91 (0.1/+0.1)	99.91 @ 26 mo. (0.1/+0.1)					
		Malfunction Only	99.98 (0.0/+0.0)	99.98 (0.0/+0.0)	99.98 @ 26 mo. (0.0/+0.0)					
Advisory: 23-Jun-06*	14,000	Depletion & Malfct.	100.00 @ 5 mo. (0.0/+0.0)							
		Malfunction Only	100.00 @ 5 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 probabilities for INSIGNIA Ultra SR pacemakers subject to the 22-Sep-05 (First Failure Mode) and 23-Jun-06 advisories 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 these advisories.
Survival probability for INSIGNIA Ultra DR (downsize) pacemakers subject to the 22-Sep-05 (First Failure Mode) 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 Ultra and Intermedics NEXUS Ultra device performance.

INSIGNIA Ultra DR Model 1291

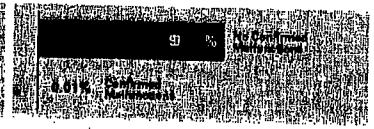
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 12,000
U.S. Approval Date: November 2003
U.S. Estimated Active Implants: 12,000

U.S. Normal Battery Depletions: 1
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: 10.6 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	4,000	Depletion & Malfct	100.00 (0.0/+0.0)	100.00 @ 18 mo. (0.0/+0.0)	—					
		Malfunction Only	100.00 (0.0/+0.0)	100.00 @ 18 mo. (0.0/+0.0)	—					
Advisory 22-Sep-05 (Second Fail Mode)*	8,000	Depletion & Malfct	100.00 (0.0/+0.0)	99.88 (0.4/+0.1)	99.88 @ 28 mo. (0.4/+0.1)	—				
		Malfunction Only	100.00 (0.0/+0.0)	99.95 (0.3/+0.0)	99.95 @ 28 mo. (0.3/+0.0)	—				

INSIGNIA Entra SR Models 1195/1198

U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 9,000
U.S. Approval Date: March 2007
U.S. Estimated Active Implants: 7,000

U.S. Normal Battery Depletions: 9
U.S. Unconfirmed Reports of Premature Battery Depletions: 2

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

U.S. Average Device Age: 16.3 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	2,000	Depletion & Malfct	100.00 (0.0/+0.0)	100.00 @ 16 mo. (0.0/+0.0)	—					
		Malfunction Only	100.00 (0.0/+0.0)	100.00 @ 16 mo. (0.0/+0.0)	—					
Advisory 22-Sep-05 (First Fail Mode)*	5,000	Depletion & Malfct	99.93 (0.1/+0.0)	99.82 (0.5/+0.1)	99.35 @ 35 mo. (1.0/+0.3)	—				
		Malfunction Only	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 @ 35 mo. (0.0/+0.0)	—				
Advisory 22-Sep-05 (Second Fail Mode)*	6,000	Depletion & Malfct	99.98 (0.1/+0.0)	99.90 (0.2/+0.1)	99.53 (0.9/+0.3)	99.53 @ 37 mo. (0.9/+0.3)	—			
		Malfunction Only	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 (0.0/+0.0)	100.00 @ 37 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 then one advisory.
Survival probabilities for INSIGNIA Ultra DR (downsize) pacemakers subject to the 22-Sep-05 (First Failure Mode) and 23-Jun-06 advisories 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 these advisories.
Survival probability for INSIGNIA Entra SR 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.
Data are representative of Guidant INSIGNIA Ultra and Intermedics NEXUS Ultra device performance.
Data are representative of Guidant INSIGNIA Entra and Intermedics NEXUS Entra device performance.

INSIGNIA Entra DR (downsize) Model 1296

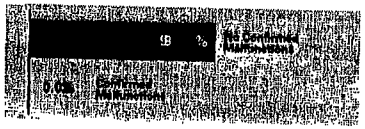
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 18,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 14,000

U.S. Normal Battery Depletions: 14
U.S. Unconfirmed Reports of Premature Battery Depletions: 6

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

U.S. Average Device Age: 16.5 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	3,000	Depletion & Malfct.	99.83 (0.4/+0.1)	99.83 @ 16 mo. (0.4/+0.1)	—					
		Malfunction Only	99.92 (0.2/+0.1)	99.92 @ 16 mo. (0.2/+0.1)	—					
Advisory 22-Sep-05 (First Fail Mode)*	3,000	Depletion & Malfct.	99.93 (0.6/+0.1)	99.89 (0.2/+0.1)	99.48 (0.4/+0.2)	99.48 @ 38 mo. (0.4/+0.2)				
		Malfunction Only	99.96 (0.2/+0.0)	99.96 (0.2/+0.0)	99.96 (0.2/+0.0)	99.96 @ 38 mo. (0.2/+0.0)				
Advisory 22-Sep-05 (Second Fail Mode)*	11,000	Depletion & Malfct.	99.98 (0.1/+0.0)	99.90 (0.1/+0.1)	99.77 (0.3/+0.1)	99.77 @ 39 mo. (0.6/+0.1)				
		Malfunction Only	99.99 (0.1/+0.0)	99.99 (0.1/+0.1)	99.99 (0.3/+0.1)	99.99 @ 39 mo. (0.1/+0.1)				

INSIGNIA Entra DR Models 1294/1295

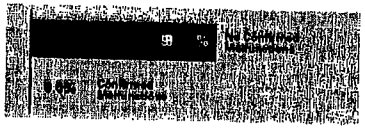
U.S. Summary (with rounded population sizes)

U.S. Registered Implants: 12,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 10,000

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

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

U.S. Average Device Age: 17.3 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	2,000	Depletion & Malfct.	100.00 (0.0/+0.0)	100.00 @ 16 mo. (0.0/+0.0)	—					
		Malfunction Only	100.00 (0.0/+0.0)	100.00 @ 16 mo. (0.0/+0.0)	—					
Advisory 22-Sep-05 (First Fail Mode)*	2,000	Depletion & Malfct.	99.82 (0.4/+0.1)	99.68 (0.4/+0.2)	99.60 (0.5/+0.3)	99.60 @ 37 mo. (0.6/+0.2)				
		Malfunction Only	99.82 (0.4/+0.1)	99.82 (0.4/+0.1)	99.82 (0.4/+0.1)	99.82 @ 37 mo. (0.4/+0.1)				
Advisory 22-Sep-05 (Second Fail Mode)*	7,000	Depletion & Malfct.	99.89 (0.1/+0.0)	99.89 (0.1/+0.1)	99.89 (0.2/+0.1)	—				
		Malfunction Only	99.99 (0.1/+0.0)	99.93 (0.2/+0.0)	99.93 (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 probabilities for INSIGNIA Entra DR (downsize) and INSIGNIA Entra DR pacemakers subject to the 23-Jun-06 advisory not provided because they do not meet report inclusion criteria (see Statistical Methodology for more details). Refer to Safety Advisory section for more on this advisory.
Data are representative of Guidant INSIGNIA Entra and Intermedics NEXUS Entra device performance.

INSIGNIA Plus SR Model 1194

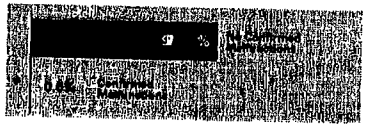
Summary (with rounded population sizes)

U.S. Registered Implants: 23,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 16,000

U.S. Normal Battery Depletions: 32
U.S. Unconfirmed Reports of Premature Battery Depletions: 0

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

U.S. Average Device Age: 22.6 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	4,000	Depletion & Malfct.	100.00 (0.0/+0.0)	100.00 @ 15 mo. (0.0/+0.0)	—	—	—	—	—	—
		Malfunction Only	100.00 (0.0/+0.0)	100.00 @ 15 mo. (0.0/+0.0)	—	—	—	—	—	—
Advisory 22-Sep-05 (First Fail. Mode)*	12,000	Depletion & Malfct.	99.92 (0.2/+0.0)	99.92 (0.2/+0.1)	99.88 (0.2/+0.1)	99.88 @ 30 mo. (0.2/+0.1)	—	—	—	—
		Malfunction Only	99.92 (0.2/+0.1)	99.92 (0.2/+0.1)	99.92 (0.2/+0.1)	99.92 @ 40 mo. (0.2/+0.1)	—	—	—	—
Advisory 22-Sep-05 (Second Fail. Mode)*	12,000	Depletion & Malfct.	99.95 (0.1/+0.0)	99.88 (0.2/+0.1)	99.88 (0.2/+0.1)	99.83 (0.3/+0.1)	—	—	—	—
		Malfunction Only	99.99 (0.0/+0.0)	99.99 (0.0/+0.0)	99.97 (0.1/+0.0)	99.97 (0.1/+0.0)	—	—	—	—

INSIGNIA Plus DR Model 1297

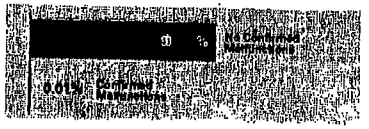
Summary (with rounded population sizes)

U.S. Registered Implants: 21,000
U.S. Approval Date: March 2002
U.S. Estimated Active Implants: 18,000

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

U.S. Confirmed Malfunctions: 3
Without Compromised Therapy: 2
With Compromised Therapy: 1

U.S. Average Device Age: 23.6 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	2,000	Depletion & Malfct.	100.00 (0.0/+0.0)	100.00 @ 18 mo. (0.0/+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)*	12,000	Depletion & Malfct.	99.95 (0.2/+0.0)	99.88 (0.2/+0.1)	99.88 (0.2/+0.1)	99.88 @ 40 mo. (0.2/+0.1)	—	—	—	—
		Malfunction Only	99.97 (0.2/+0.0)	99.97 (0.2/+0.0)	99.97 (0.2/+0.0)	99.97 @ 40 mo. (0.2/+0.0)	—	—	—	—
Advisory 22-Sep-05 (Second Fail. Mode)*	12,000	Depletion & Malfct.	99.97 (0.0/+0.0)	99.92 (0.1/+0.0)	99.44 (0.3/+0.1)	99.73 @ 47 mo. (0.0/+0.0)	—	—	—	—
		Malfunction Only	99.98 (0.0/+0.0)	99.98 (0.0/+0.0)	99.98 (0.0/+0.0)	99.98 @ 47 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 probabilities for INSIGNIA Plus SR and INSIGNIA Plus DR pacemakers subject to the 23-Jun-06 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 INSIGNIA Plus and Intermedics NEXUS Plus device performance.