

# Epi/Myocardial Pacing Leads continued

## US Returned Product Analysis Summary

Model Number	Family	US Market Release	Estimated US Implants	Estimated US Active	Conductor Fracture	Crimp/Weld/Bond	Insulation Breach	Extrinsic	Other
4951, 4951M	Spectraflex	Oct-81	23,100	2,200	56	0	39	7	29
4965	CapSure Epi	Sep-96	18,200	9,000	96	1	24	10	2
4968	CapSure Epi	Sep-99	17,400	10,900	10	0	4	2	0
5071	Screw-in	Dec-92	35,500	13,900	6	0	1	29	4

Source: Returned Product Analysis  
Data as of July 31, 2009

## US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Cardiac Perforation	Conductor Fracture	Lead Dislodgement	Failure to Capture	Impedance Abnormal	Extracardiac Stimulation	Unspecified
4951, 4951M	Spectraflex	23,100	0	1	0	13	0	0	2
4965	CapSure Epi	18,200	0	0	1	2	2	0	0
4968	CapSure Epi	17,400	1	0	3	1	0	0	0
5071	Screw-in	35,500	1	0	0	16	3	1	1

Report Cut-Off Date: July 31, 2009

## Reference Chart

Model Number	Family	Type	Insulation	Conductor Material	Tip Electrode	Connector Type
4951, 4951M	Spectraflex	Myocardial Stab-In V or A/Peds	Polyurethane (80A)	MP35N 4 Filars	Barb	5 mm (4951) IS-1 UNI (4951M)
4965	CapSure Epi	Epicardial Suture-On V or A	Silicone	MP35N 5 Filars	Porous Platinized/ Steroid	IS-1 UNI
4968	CapSure Epi	Epicardial Suture V or A	Silicone	MP35N 5 Filars	Porous Platinized/ Steroid	IS-1 B1
5069	(No brand name)	Myocardial Screw-In	Silicone	MP35N Multifilars	3-Turn Helix	IS-1 UNI
5071	(No brand name)	Myocardial Screw-In Ventricular	Silicone	MP35N Multifilars	2-Turn Helix	IS-1 UNI