

Defibrillation 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
6721, 6921	Epicardial Patch	Feb-93	8,300	1,300	68	1	10	5	1
6930	Sprint Fidelis	Sep-04	400	200	2	0	0	0	0
6931	Sprint Fidelis	Sep-04	8,100	5,800	191	0	0	27	1
6932	Sprint	Aug-96	15,000	5,600	17	0	22	16	8
6933, 6937, 6937A, 6963	SVC/CS	Dec-93	16,800	2,600	166	0	32	31	16
6935	Sprint Quattro Secure	Nov-08	3,600	3,500	0	0	0	9	1
6936, 6966	Transvene	Dec-93	23,600	3,100	177	0	318	90	20
6939, 6999	Sub-Q Patch	Dec-93	3,600	300	28	0	5	4	1
6942	Sprint	Jul-97	17,700	7,200	12	1	21	31	8
6943	Sprint	Oct-97	20,800	8,500	50	1	22	51	9
6944	Sprint Quattro	Dec-00	33,400	20,100	38	2	2	30	8
6945	Sprint	Sep-97	42,800	17,500	96	2	24	200	14
6947	Sprint Quattro Secure	Nov-01	233,200	172,700	115	1	9	534	68
6948	Sprint Fidelis	Sep-04	10,400	7,600	38	0	0	10	6
6949	Sprint Fidelis	Sep-04	186,700	129,700	2,576	2	7	476	51
6996	Sub-Q Lead	Jun-01	2,500	1,700	4	0	0	1	0

US Reports of Acute Lead Observations

Model Number	Family	Estimated US Implants	Cardiac Perforation	Conductor Fracture	Lead Dislodgement	Failure to Capture	Oversensing	Failure to Sense	Insulation Breach	Impedance Abnormal	Extracardiac Stimulation	Unspecified
6721, 6921	Epicardial Patch	8,300	0	0	0	0	0	0	2	3	0	4
6931	Sprint Fidelis	8,100	1	1	1	1	3	1	0	0	0	1
6932	Sprint	15,000	0	0	3	2	0	2	0	1	0	0
6933, 6937, 6937A, 6963	SVC/CS	16,800	0	0	2	0	1	0	2	1	0	1
6935	Sprint Quattro Secure	3,600	1	1	0	0	0	0	0	1	0	0
6936, 6966	Transvene	23,600	7	2	1	6	4	5	1	1	0	4
6939, 6999	Sub-Q Patch	3,600	0	0	0	0	0	0	0	1	0	1
6942	Sprint	17,700	1	0	2	4	1	0	0	2	0	1
6943	Sprint	20,800	1	0	0	2	1	1	1	3	0	0
6944	Sprint Quattro	33,400	1	1	5	7	5	2	0	5	0	5
6945	Sprint	42,800	0	1	4	6	8	2	2	1	1	3
6947	Sprint Quattro Secure	233,200	8	9	26	26	42	11	3	14	0	7
6948	Sprint Fidelis	10,400	0	0	7	6	1	0	0	1	0	0
6949	Sprint Fidelis	186,700	9	12	26	31	29	24	6	23	0	11

Report Cut-Off Date: July 31, 2009