Table I: Classification of significant changes in electrical parameters

Threshold	> 1V increase*
Noise	Oversensing (+/- shock)
R wave	Persistent fall to <2mV Persistent fall of >50%
Pacing impedance	Fall to <300 Ω Rise to >1500 Ω Change +/- 400 Ω**
HV impedance	Fall to <20 Ω Rise to >200 Ω Change +/- 15 Ω

* Threshold increase at fixed pulse width between pacing checks and such that a 2:1 capture safety margin cannot be achieved

** Over a 12 month period

Table II: Demographics

	Riata 1580 N=321	Endotak 0158 N=335
Gender		
Male	223 (69.5%)	237 (70.7%)
Female	98 (30.5%)	98 (29.3%)
Age		
Median	56	64
Range	(16-84)	(18-90)
Lead position		
Apex	283 (88.2%)	300 (89.5%)
Septum	32 (9.9%)	29 (8.7%)
Unknown	6 (1.9%)	6 (1.8%)
Pocket		
Prepectoral	229 (71.3%)	233 (69.6%)
Subpectoral	89 (27.7%)	101 (30.1%)
Unknown	3 (0.9%)	1 (0.3%)
Approach at lead implant		
Cephalic	160 (49.8%)	172 (51.3%)
Subclavian/axillary	144 (44.9%)	141 (42.1%)
Unknown	17 (5.3%)	22 (6.6%)
Number of leads		
1	87 (27.1%)	95 (28.4%)
2	149 (46.4%)	127 (37.9%)
3	71 (22.1%)	101 (30.1%)
4+	14 (4.4%)	11 (3.3%)
Unknown	0 (0.0%)	1 (0.3%)
Aetiology of heart disease		
Ischaemic	95 (29.6%)	125 (37.3%)
DCM	81 (25.2%)	106 (31.6%)
HCM	90 (28.0%)	63 (18.8%)
GUCH	8 (2.5%)	4 (1.2%)
Other	45 (14.0%)	35 (10.4%)
Unknown	2 (0.6%)	2 (0.6%)

Table III: Censored events for the Riata and Endotak leads

	Riata (321)	Endotak (335)
Death	109 (34.0%)	143 (42.7%)
Days: median and range	902 (1-3652)	1247 (1-3915)
Removal or deactivation of lead	38 (11.8%)	24 (7.2%)
Infection	25	14
Transplant	5	5
Disabled at patient or physician request	8	5
Total	147 (45.8%)	167 (49.9%)

Table IV: Comparison of electrical failures

Electrical failure	Riata (n=321)	Endotak (n=335)
Number of leads affected	51 (15.9%)	21 (6.3%)
Threshold increase	21 (6.5%)	0 (0.0%)
Noise With shock Without shock	17 (5.3%) 6 (1.9%) 11 (3.4%)	19 (5.7%) 3 (0.9%) 16 (4.8%)
R wave fall Pacing impedance change HV change	7 (2.2%) 12 (3.7%) 6 (1.9%)	2 (0.6%) 6 (1.8%) 1 (0.3%)

Table V: Table of the yearly estimated survival probabilities by lead type, up to 11 years

All data combined

Year	Endotak 0158			Riata 1580		
	Survival probability	SE	95% CI	Survival probability	SE	95% CI
1	0.987	0.007	0.974, 1	0.982	0.008	0.967, 0.998
2	0.987	0.007	0.974, 1	0.974	0.01	0.956, 0.993
3	0.971	0.01	0.951, 0.991	0.961	0.012	0.938, 0.985
4	0.966	0.011	0.945, 0.988	0.947	0.014	0.919, 0.976
5	0.939	0.016	0.909, 0.969	0.913	0.019	0.877, 0.951
6	0.933	0.016	0.902, 0.966	0.866	0.023	0.822, 0.913
7	0.922	0.018	0.888, 0.958	0.804	0.028	0.75, 0.861
8	0.916	0.019	0.88, 0.954	0.791	0.029	0.736, 0.851
9	0.908	0.02	0.869, 0.949	0.774	0.031	0.715, 0.837
10	0.908	0.02	0.869, 0.949	0.731	0.036	0.664, 0.806
11	0.884	0.031	0.825, 0.947	0.693	0.044	0.612, 0.784

Table VI: Table of the coefficients and hazard ratios for all leads under the final model.

Variable	Factor comparison	Coefficient	SE	HR	HR 95% CI	z-statistic	p-value
Pocket	Sub versus pre	0.4645	0.246	1.5912	(0.982,2.578)	1.89	0.0592
Age at implant	Per year increase	-0.0132	0.007	0.9869	(0.973,1.001)	-1.83	0.0670
Lead type: Time period	R versus E, ≤6 years following implant	0.6182	0.316	1.8556	(0.999,3.448)	1.96	0.0505
	R versus E, >6 years following implant	1.6671	0.499	5.297	(1.991,14.089)	3.34	0.0008

SE = Standard Error, HR = Hazard Ratio, CI = Confidence Interval.

Table VII: Log-rank test of the survival distribution for the leads by lead type.

Lead type	N	Observed	Expected	Test statistic	P value
Endotak	335	21	37.9	15.866	0.0001
Riata	321	51	34.1		

N=Number of leads per group.

Observed is the observed number of lead failures.

Expected is the expected number of lead failures under the assumption that the survival distributions are the same.