Appendix B7. Tipping Point Analysis

We imputed missing event times for patients if their observed length of follow-up was less than half or less than three quarters of expected follow-up (with-in trial maximum follow up time). This sensitivity analysis suggests that all subjects randomized to the device arm censored prior to the end of follow-up (trial-specific maximum) would need to have a **twofold** increase in event hazard (recurrent ischemic stroke) compared with patients randomized to the medical therapy arm for the statistically significant result in favor of the device versus medical therapy to be nullified (the 'tipping point').

Appendix Table 16. Tipping Point Analysis of Primary Outcome.

Impute missing event time if observed follow-up < half of expected follow-up						
Medical therapy	**Impute missing event time**	**N**		**Device delta hazard**	**HR**	**Upper 95% CL**
	No	1318		1.0 (censored at random)	0.410	0.638
	Yes	**533**		1.5	0.508	0.766
Device				2	0.594	0.938
	No	1456		2.5 (tipping point)	0.681	1.170
	Yes	**433**				
Impute missing event time if observed follow-up < three quarters of expected follow-up						
Medical therapy	**Impute missing event time**	**N**		**Device delta hazard**	**HR**	**Upper 95% CL**
	No	955		1.0 (censored at random)	0.405	0.639
	Yes	**896**		1.5	0.524	0.798
Device				2 (tipping point)	0.641	1.051
	No	1122				
	Yes	**767**				

CL, confidence limit; HR indicates hazard ratio.