

Attachment 1

Sample Size Estimates

Assumptions:

Primary endpoint is the rate of stroke and death at 2 years.

- $H_0: P_c = P_t$, where P_c = stroke/death rate for medical therapy (control) and P_t = stroke/death rate for device closure
- $H_a: P_c \neq P_t$

- $\alpha = 0.05$, two-sided
- $\beta = 0.80$
- 1:1 randomization
- No adjustments made to preserve alpha allocation, such as for interim analysis

Estimate for P_c	Estimate for P_t	Estimated Sample Size per arm*
4%	1%	396
4%	2%	1130
6%	2%	358
6%	3%	741
8%	4%	552
10%	5%	432
12%	6%	351

* Exact Sample size estimated using StatXact software (version 6.2.0).