

Appendix B9. Safety Outcomes by PASCAL Classification

Appendix Table 17. Safety Outcomes by PASCAL Classification with 2 year Atrial Fibrillation Rates.

Safety outcome (as-treated population)	Kaplan Meier 2-year rate % (patients with event/n)		Absolute Risk Difference % (95% CI)
	Device	No device	
PASCAL Classification			
Atrial fibrillation (all events)			
Unlikely	7.6 (20/260)	1.8 (5/282)	5.8 (2.2, 9.4)
Possible	3.8 (31/835)	0.3 (3/965)	3.5 (2.1, 4.8)
Probable	2.5 (16/667)	0.5 (3/709)	2.0 (0.6, 3.3)
Atrial fibrillation (present beyond 45 days)			
Unlikely	4.2 (11/260)	1.5 (4/282)	2.7 (-0.2, 5.6)
Possible	1.7 (14/835)	0.3 (3/965)	1.4 (0.4, 2.3)
Probable	1.1 (8/667)	0.5 (3/709)	0.6 (-0.4, 1.6)
Leave out CLOSURE trial			
Atrial fibrillation (all events)			
Unlikely	8.1 (13/159)	1.3 (2/165)	6.8 (2.2, 11.4)
Possible	3.0 (19/640)	0.2 (1/695)	2.8 (1.5, 4.2)
Probable	2.4 (14/564)	0.6 (3/587)	1.9 (0.5, 3.3)
Atrial fibrillation (present beyond 45 days)			
Unlikely	4.4 (7/159)	1.4 (2/165)	3.0 (-0.7, 6.8)
Possible	1.4 (9/640)	0.2 (1/695)	1.2 (0.3, 2.2)
Probable	1.2 (7/564)	0.6 (3/587)	0.6 (-0.5, 1.7)

CI, confidence interval; PASCAL indicates PFO-Associated Stroke Causal Likelihood.