conformal
THE SHAPE OF STROKE PREVENTION

CONFORM Adverse Event Source

Site Number: _____ Subject ID: _____

AE #	AE Term	AE Status	Cause	Date Aware	Date Entered	Severity	Serious	Onset Date	Resolved Date
		☐ New ☐ Pre-Existing				☐ Mild ☐ Moderate ☐ Severe	☐No ☐ Yes **** Circle all that apply*** **1 2 3 4 5 6 7**		
	Relationship to implant?	**Relationship to access sheath?**		**Relationship to delivery system?**		**Relationship to Study Procedure?**		**Relationship to Study Medication?**	
	☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship	☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship	
	Investigator Signature:					**Date (DD/MMM/YYYY):**			

AE #	AE Term	AE Status	Cause	Aware	Notified	Severity	Serious	Onset	Resolved Date
		☐ New ☐ Pre-Exist				☐ Mild ☐ Moderate ☐ Severe	☐ No ☐ Yes **** Circle all that apply*** **1 2 3 4 5 6 7**		
	Relationship to implant?	**Relationship to access sheath?**		**Relationship to delivery system?**		**Relationship to Study Procedure**		**Relationship to Study Medication**	
	☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship	☐ Not related ☐ Possible ☒ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship	
	Investigator Signature:					**Date (DD/MMM/YYYY):**			

*** Serious : 1. Led to chronic disease 2. Led to subject death 3. Resulted in life-threatening illness or injury 4. Resulted in permanent impairment of a body structure or body function 5. Resulted in medical or surgical intervention to prevent life-threatening illness, injury or permanent impairment of body structure or function 6. Required in-subject hospitalization or prolongation of existing hospitalization 7. Led to fetal distress, fetal death or congenital anomaly or birth defect**