conformal
THE SHAPE OF STROKE PREVENTION

CONFORM Adverse Event

☐ Source ☐ Data Transfer Tool

Site Number: _____ Subject ID: _____

AE EDC Event Number	
Status of Adverse Event	☐ New adverse event ☐ Worsening of pre-existing condition
AE Event Term	
AE Description	
Suspected Cause	
Date of Site Awareness of AE	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
Date Sponsor Notified of AE	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
AE Onset Date	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)
Severity *Refer to Protocol Appendix A 21.1.1*	☐ Mild ☐ Moderate ☐ Severe
Action Taken (*Check all that apply*)	☐ None ☐ Hospitalization < 24 hours ☐ Hospitalization > 24 hours ☐ Study Medication prescribed ☐ Study Medication dose changed ☐ Study Medication stopped ☐ Percutaneous intervention Specify: _____ ☐ Surgical intervention Specify: _____ ☐ Transfusion Number of units of red blood cells (xx): _____ Number of units of platelets or FFP *(xx)*: _____ ☐ Other, specify: _____

Were any of the following performed? *(Please ensure any images are uploaded into Imaging Module)*	☐ None ☐ Cardiac Angiography ☐ Cardiac MRI ☐ Cardiac Echo/CT ☐ Brain Imaging ☐ ECG ☐ Ultrasound ☐ Pathologic Examination

Is this a Serious Adverse Event (SAE)?	☐ Yes ☐ No	
	Led to subject death *(If yes, complete Death Form)*	☐ Yes ☐ No
	A life-threatening illness or injury	☐ Yes ☐ No
	A permanent impairment of a body structure or body function, including chronic diseases	☐ Yes ☐ No
	A medical or surgical intervention to prevent life-threatening illness, injury or permanent impairment of body structure or function	☐ Yes ☐ No
	In-subject hospitalization or prolongation of existing hospitalization	☐ Yes ☐ No
	Fetal distress, fetal death or congenital anomaly or birth defect including physical or mental impairment	☐ Yes ☐ No

Is Event cardiovascular or neurological in etiology?	☐ Yes, Cardiovascular ☐ Yes, Neurological ☐ No

Adverse Event of Special Interest?	☐ Yes ☐ No	If yes, check all that apply	☐ Bleeding Event ☐ Myocardial Infarction Were cardiac enzymes drawn? ☐ Yes *(Complete Cardiac Enzyme Form)* ☐ No ☐ Unknown ☐ Pericardial Effusion ☐ Neurological Event ☐ Vascular Complication ☐ Systemic Embolization ☐ Device Embolization

Related to study device?	☐ Yes ☐ No	
	Relationship to implant?	☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship
	Relationship to access sheath?	☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship
	Relationship to delivery system?	☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship
	Relationship to hydraulic loader?	☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship ☐ N/A – Subject did not receive CLAAS
Related to Study Procedure?	☐ Yes ☐ Possible ☐ Probable ☐ Causal relationship ☐ No, Not related	
Related to Study Medication?	☐ Yes ☐ Possible ☐ Probable ☐ Causal relationship ☐ No, Not related	

AE Outcome	☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Ongoing ☐ Fatal *(Complete Death Form and Study Exit Forms)* ☐ Ongoing at end of study
If recovered/resolved, describe how resolution was confirmed:	
AE End Date	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)

_____ __ __ / __ __ __ / __ __ __ __

RC/ RA Signature **Date (DD/MMM/YYYY)**

_____ __ __ / __ __ __ / __ __ __ __

Investigator Signature **Date (DD/MMM/YYYY)**