

AE EDC Event Number	
Status of Adverse Event	<input type="checkbox"/> New adverse event <input type="checkbox"/> 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 <i>Refer to Protocol Appendix A 21.1.1</i>	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe

<p>Action Taken (Check all that apply)</p>	<p><input type="checkbox"/> None  <input type="checkbox"/> Hospitalization &lt; 24 hours  <input type="checkbox"/> Hospitalization &gt; 24 hours  <input type="checkbox"/> Study Medication prescribed  <input type="checkbox"/> Study Medication dose changed  <input type="checkbox"/> Study Medication stopped  <input type="checkbox"/> Percutaneous intervention  Specify: _____  <input type="checkbox"/> Surgical intervention  Specify: _____  <input type="checkbox"/> Transfusion    Number of units of red blood cells (xx): _____    Number of units of platelets or FFP (xx): _____    <input type="checkbox"/> Other, specify: _____</p>
<p>Were any of the following performed? (Please ensure any images are uploaded into Imaging Module)</p>	<p><input type="checkbox"/> None  <input type="checkbox"/> Cardiac Angiography  <input type="checkbox"/> Cardiac MRI  <input type="checkbox"/> Cardiac Echo/CT  <input type="checkbox"/> Brain Imaging  <input type="checkbox"/> ECG  <input type="checkbox"/> Ultrasound  <input type="checkbox"/> Pathologic Examination</p>
<p>Is this a Serious Adverse Event (SAE)?</p>	<p><input type="checkbox"/> Yes  <input type="checkbox"/> No</p>
	<p>Led to subject death (If yes, complete Death Form)</p> <p><input type="checkbox"/> Yes  <input type="checkbox"/> No</p>
	<p>A life-threatening illness or injury</p> <p><input type="checkbox"/> Yes  <input type="checkbox"/> No</p>
	<p>A permanent impairment of a body structure or body function, including chronic diseases</p> <p><input type="checkbox"/> Yes  <input type="checkbox"/> No</p>
	<p>A medical or surgical intervention to prevent life-threatening illness, injury or permanent impairment of body structure or function</p> <p><input type="checkbox"/> Yes  <input type="checkbox"/> No</p>
	<p>In-subject hospitalization or prolongation of existing hospitalization</p> <p><input type="checkbox"/> Yes  <input type="checkbox"/> No</p>

		Fetal distress, fetal death or congenital anomaly or birth defect including physical or mental impairment		<input type="checkbox"/> Yes <input type="checkbox"/> No
Is Event cardiovascular or neurological in etiology?		<input type="checkbox"/> Yes, Cardiovascular <input type="checkbox"/> Yes, Neurological <input type="checkbox"/> No		
Adverse Event of Special Interest?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, check all that apply	<input type="checkbox"/> Bleeding Event <input type="checkbox"/> Myocardial Infarction Were cardiac enzymes drawn? <input type="checkbox"/> Yes ( <i>Complete Cardiac Enzyme Form</i> ) <input type="checkbox"/> No <input type="checkbox"/> Unknown	
			<input type="checkbox"/> Pericardial Effusion <input type="checkbox"/> Neurological Event <input type="checkbox"/> Vascular Complication <input type="checkbox"/> Systemic Embolization <input type="checkbox"/> Device Embolization <input type="checkbox"/> Device Related Thrombus Was subject treated with an oral anticoagulant? <input type="checkbox"/> Yes <input type="checkbox"/> No Was subject treated with ASA? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Related to study device?		<input type="checkbox"/> Yes <input type="checkbox"/> No		
		Relationship to implant?	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	
		Relationship to access sheath?	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	
		Relationship to delivery system?	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	

Related to Study Procedure?	<input type="checkbox"/> Yes <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship <input type="checkbox"/> No, Not related
Related to Study Medication?	<input type="checkbox"/> Yes <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship <input type="checkbox"/> No, Not related

AE Outcome	<input type="checkbox"/> Recovered/Resolved <input type="checkbox"/> Recovered/Resolved with Sequelae <input type="checkbox"/> Ongoing <input type="checkbox"/> Fatal ( <i>Complete Death Form and Study Exit Forms</i> ) <input type="checkbox"/> 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)