

AE #	AE Term	AE Status	Cause	Date Aware	Date Sponsor Notified	Severity	Serious	Onset Date	Resolved Date
		<input type="checkbox"/> New <input type="checkbox"/> Pre-Existing				<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> No <input type="checkbox"/> Yes <i>* Circle all that apply</i> 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?			
	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship		<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship			
Investigator Signature:						Date (DD/MMM/YYYY):			
AE #	AE Term	AE Status	Cause	Date Aware	Date Sponsor Notified	Severity	Serious	Onset Date	Resolved Date
		<input type="checkbox"/> New <input type="checkbox"/> Pre-Exist				<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<input type="checkbox"/> No <input type="checkbox"/> Yes <i>* Circle all that apply</i> 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			
	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship	<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> Causal relationship		<input type="checkbox"/> Not related <input type="checkbox"/> Possible <input type="checkbox"/> Probable <input type="checkbox"/> 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