

For use with Follow Up Visits as needed (45-Day, 12 Months, and Unscheduled).

Reminders:

- **At 45 Days and 12 Months:**
- TEE or CT is mandatory per protocol at 45 Days and 12 Months for Implanted Subjects
- If a CT is completed and shows findings (i.e., leak or thrombus), a TEE is required to confirm the finding as soon as possible

Was Echocardiogram/CT performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No (<i>Complete protocol deviation form</i>)		
Are the required images for this visit available?	<input type="checkbox"/> Yes <input type="checkbox"/> No (<i>Complete protocol deviation form</i>)		
Were images uploaded into the Imaging Module?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Time period of Imaging	<input type="checkbox"/> 45 Day <input type="checkbox"/> 12 Months <input type="checkbox"/> Unscheduled, specify: _____		
Date echocardiogram/CT completed	____ / ____ / ____ (DD/MMM/YYYY)		
Imaging Type	<input type="checkbox"/> TTE – Transthoracic echocardiogram <input type="checkbox"/> TEE – Transesophageal echocardiogram <input type="checkbox"/> Cardiac CT <input type="checkbox"/> Cardiac MRI <input type="checkbox"/> Brain CT <input type="checkbox"/> MRI		
Left atrial appendage visible	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Available		
If available, confirm if the following was noted on echo/CT:			
Dense spontaneous echo contrast consistent with Thrombus?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Available		
Intra-cardiac thrombus	<input type="checkbox"/> Yes (<i>Complete AE form</i>) <input type="checkbox"/> No <input type="checkbox"/> Not available	If yes, confirm location	<input type="checkbox"/> Left atrium <input type="checkbox"/> Left atrial appendage <input type="checkbox"/> Left ventricle <input type="checkbox"/> Right atrium <input type="checkbox"/> Right ventricle <input type="checkbox"/> Other, specify: _____

Intra-cardiac vegetation	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not available	If yes, confirm location	<input type="checkbox"/> Left atrium <input type="checkbox"/> Left atrial appendage <input type="checkbox"/> Left ventricle <input type="checkbox"/> Right atrium <input type="checkbox"/> Right ventricle <input type="checkbox"/> Other, specify: _____
Patent foramen ovale warranting closure?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not available	Is this a high risk PFO?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Atrial septal defect?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not available	If yes, specify	<input type="checkbox"/> Right to left shunt present <input type="checkbox"/> Left to right shunt present <input type="checkbox"/> Bidirectional shunt <input type="checkbox"/> Unable to determine
		If yes, does defect warrant closure?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Left atrial appendage occlusion device position stable and position unchanged?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not available		
Peri-device leak present?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not available	If yes, specify (mm)	_____ mm
	<input type="checkbox"/> Yes (<i>Assess for AE</i>) <input type="checkbox"/> No <input type="checkbox"/> Not available		
Pericardial effusion present?	If yes, select type	<input type="checkbox"/> Circumferential <input type="checkbox"/> Loculated	
	If yes, select size <i>*AE is reportable for pericardial effusions Moderate or larger</i>	<input type="checkbox"/> Trivial <input type="checkbox"/> Small (<1 cm) <input type="checkbox"/> Moderate (1-2 cm) <input type="checkbox"/> Large (>2 cm and <5cm) <input type="checkbox"/> Large (> 5 cm)	
	If yes, do any of the following apply?	<input type="checkbox"/> Symptomatic <input type="checkbox"/> Sign or symptom of acute or chronic pericarditis <input type="checkbox"/> Evidence of tamponade physiology	

Device embolization?

☐ Yes (*Complete AE form*)

☐ No

☐ Not available

Site Personnel Signature

____/____/_____
Date (DD/MMM/YYYY)