

CONFORM Pivotal Trial TEE Checklist – ALL LAAO cases to be

performed by Non-Implanting Physician

TEE FOLLOW-UP

General

- **Confirm 3-beat loops for subjects in sinus rhythm. 3-second loops for arrhythmias and tachycardia**
- □ Color Flow Doppler: Optimize frame rate (>=20fps) for temporal resolution. Ensure gain setting is appropriate
- □ Spectral Doppler: Sweep speed should be 75-100mm/S. 3-beat spectral acquisition for subjects in sinus rhythm, 5-beat acquisition for arrhythmias
- $\hfill\square$ Nyquist limit of LAA at 40 cm/sec and valvular assessment at 60 cm/sec
- DICOM images AND Sonographer Worksheets should be uploaded to the EDC
- □ All images required for the core lab, should be recorded in single-plane unless otherwise specified
- □ PLEASE ENSURE ALL PHI HAS BEEN REMOVED FROM IMAGES PRIOR TO UPLOAD!

TEE FOLLOW-UP ACQUISITION REQUIREMENTS

Pericardial Effusion (if Pericardial effusion observed at baseline obtain similar images)

- □ Transgastric LV (biplane if possible)
- □ 4-Chamber LV biplane

2D LAAO Device Assessment

- □ 0° Acquire clip with/without Color Flow Doppler
- □ 45° Acquire clip with/without Color Flow Doppler
- 90° Acquire clip with/without Color Flow Doppler
- □ 135° Acquire clip with/without Color Flow Doppler

ASD/PFO

 \Box 90-110° Bicaval view with and without color

3D Image of LAAO Device

□ Wide-angled acquisition (at 45°), 1-beat acquisition, 3-beat loop

Left Pulmonary Veins (PW) and Color Flow Doppler

- □ 0-90° Assess LUPV by placing PW 1cm in the LUPV (adjust to scale)
- 90-110° Assess LLPV by placing PW 1cm in the LLPV (adjust to scale)

Mitral Valve

- □ Biplane imaging of the mitral valve with and without color
- □ Confirm severity of MR has not changed

IMPORTANT REMINDERS

- □ Imaging MUST be performed at 0, 45, 90 and 135 degrees
- □ Imaging MUST be performed at 0, 45, 90 and 135 degrees at PREand POST-Release with and without color
- □ Color sector must encompass the whole device
- Acquisition should be at least 3 seconds IF in AF

Please upload the TEE images into the CONFORM Imaging Platform

Questions about Imaging? Please reach out to your Site Manager or Field Clinical Specialist or refer to the CONFORM Manual of Procedures Binder!