

### **CONFORM Pivotal Trial**

# TEE Checklist – ALL LAAO cases to be performed by Non-Implanting Physician

### **TEE BASELINE**

General			
<ul> <li>□ Confirm 3-beat loops for subjects in sinus rhythm. 3-second loops for arrhythmias and tachycardia</li> <li>□ Color Flow Doppler: Optimize frame rate (&gt;=20fps) for temporal resolution. Ensure gain setting is appropriate</li> <li>□ Spectral Doppler: Sweep speed should be 75-100mm/S. 3-beat spectral acquisition for subjects in sinus rhythm, 5-beat acquisition for arrhythmias</li> <li>□ Nyquist limit of LAA at 40 cm/sec and valvular assessment at 60 cm/sec</li> <li>□ DICOM images AND Sonographer Worksheets should be uploaded to the EDC</li> <li>□ All images required for the core lab, should be recorded in single-plane unless otherwise specified</li> <li>□ PLEASE ENSURE ALL PHI HAS BEEN REMOVED FROM IMAGES PRIOR TO UPLOAD!</li> </ul>			
- TELAGE ENGAGE ALETTI TIAG SEEN NEMOVES THOM IMPAGES THICK TO	or Long.		
2D LAA			
□ 0°			
□ 45°			
☐ 90° PW Doppler inside the LAA at 90°	Diameter		
☐ 135°	Diameter		
	Depth-Perpendicular		
2D LAA Ostial and Depth Measurements (perpendicular to ostial plane			
and max depth, for both Treatment and Control cases)	100		
□ 0°	11'0		
□ 45°			
□ 90°	Depth-Max		
□ 135°			
3D Image of LAA			
☐ Wide-angled acquisition at 45°			
Left Pulmonary Veins (PW) and Color Flow Doppler			
<ul> <li>0-90° Assess LUPV by placing PW 1cm in the LUPV (adjust to scale)</li> </ul>			
☐ 90-110° Assess LLPV by placing PW 1cm in the LLPV (adjust to scale)			
ASD/PFO			
☐ 90-110° Bicaval view with and without color			
Device which Effection (The very on evaluation at heading is necessary)			
Pericardial Effusion (Thorough evaluation at baseline is necessary)			
<ul><li>☐ Trans gastric LV (biplane if possible)</li><li>☐ 4-Chamber LV biplane</li></ul>	IMPORTANT REMINDERS		
Mitral Valva	☐ Imaging MUST be performed at 0,		
Mitral Valve	☐ Imaging MUST be performed at 0, 45, 90 and 135 degrees		
$\square$ Biplane imaging of the mitral valve with and without color			
	45, 90 and 135 degrees ☐ Imaging MUST be performed at 0, 45, 90 and 135 degrees at PRE- and		
<ul><li>☐ Biplane imaging of the mitral valve with and without color</li><li>☐ If suspicion of stenosis, formal evaluation with gradient is needed</li></ul>	45, 90 and 135 degrees ☐ Imaging MUST be performed at 0,		
<ul> <li>☐ Biplane imaging of the mitral valve with and without color</li> <li>☐ If suspicion of stenosis, formal evaluation with gradient is needed</li> </ul> Aortic Atheroma	45, 90 and 135 degrees ☐ Imaging MUST be performed at 0, 45, 90 and 135 degrees at PRE- and POST-Release with and without color		
<ul> <li>□ Biplane imaging of the mitral valve with and without color</li> <li>□ If suspicion of stenosis, formal evaluation with gradient is needed</li> <li>Aortic Atheroma</li> <li>□ Upper-esophageal 120-150°</li> </ul>	45, 90 and 135 degrees  ☐ Imaging MUST be performed at 0, 45, 90 and 135 degrees at PRE- and POST-Release with and without color ☐ Color sector must encompass the		
□ Biplane imaging of the mitral valve with and without color □ If suspicion of stenosis, formal evaluation with gradient is needed  Aortic Atheroma □ Upper-esophageal 120-150° □ Upper-esophageal 0°	45, 90 and 135 degrees  ☐ Imaging MUST be performed at 0, 45, 90 and 135 degrees at PRE- and POST-Release with and without color ☐ Color sector must encompass the whole device		
□ Biplane imaging of the mitral valve with and without color □ If suspicion of stenosis, formal evaluation with gradient is needed  Aortic Atheroma □ Upper-esophageal 120-150° □ Upper-esophageal 0° □ Mid-esophageal 0°	45, 90 and 135 degrees  ☐ Imaging MUST be performed at 0, 45, 90 and 135 degrees at PRE- and POST-Release with and without color ☐ Color sector must encompass the whole device ☐ Acquisition should be at least 3		
□ Biplane imaging of the mitral valve with and without color □ If suspicion of stenosis, formal evaluation with gradient is needed  Aortic Atheroma □ Upper-esophageal 120-150° □ Upper-esophageal 0°	45, 90 and 135 degrees  ☐ Imaging MUST be performed at 0, 45, 90 and 135 degrees at PRE- and POST-Release with and without color ☐ Color sector must encompass the whole device		



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### **TEE PRE-RELEASE**

<b>Tug Tes</b>	t		
	Annotate "TUG"		
	Acquire dynamic clip in view of tether insertion (device apex)		
2D LAA	O Device Assessment		
	0° Acquire clip with and without Color Flow Doppler		
	45° Acquire clip with and without Color Flow Doppler		
	90° Acquire clip with and without Color Flow Doppler		
	135° Acquire clip with and without Color flow Doppler		
	TEE POST-RELEASE AND FOLLOW-U	P	
Genera	l		
	<ul> <li>□ Confirm 3-beat loops for subjects in sinus rhythm. 3-second loops for arrhythmias and tachycardia</li> <li>□ Color Flow Doppler: Optimize frame rate (&gt;=20fps) for temporal resolution. Ensure gain setting is appropriate</li> <li>□ Spectral Doppler: Sweep speed should be 75-100mm/s. 3-beat spectral acquisition for subjects in sinus rhythm, 5-</li> </ul>		
	beat acquisition for arrhythmias.		
	□ DICOM images AND Sonographer Worksheets should be uploaded to the EDC		
	PLEASE ENSURE ALL PHI HAS BEEN REMOVED FROM IMAGES PRIOR TO UPLO		
	dial Effusion (if Pericardial effusion observed at baseline obtain similar image	s)	
	Transgastric LV (biplane if possible)		
	4-Chamber LV biplane	IMPORTANT REMINDERS	
2D LAA	O Device Assessment		
	Annotate "POST RELEASE"	☐ Imaging MUST be performed at 0,	
	0° Acquire clip with/without Color Flow Doppler	45, 90 and 135 degrees	
	45° Acquire clip with/without Color Flow Doppler	☐ Imaging MUST be performed at 0,	
	90° Acquire clip with/without Color Flow Doppler	45, 90 and 135 degrees at PRE- and	
	135° Acquire clip with/without Color Flow Doppler	POST-Release with and without	
		color	
ASD/PFO		☐ Color sector must encompass the	
-	90-110° Bicaval view with and without color	whole device	
_		☐ Acquisition should be at least 3	
3D Imag	ge of LAAO Device	seconds IF in AF	
	Wide-angled acquisition (at 45°), 1-beat acquisition, 3-beat loop		
	monary 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)		
Ш	20-110 M33633 FELA DA MIGGILIE LAN TOILI III FILE FELA (GAITASE TO SCORE)		
Mitral \	/alve		
	Biplane imaging of the mitral valve with and without color		
	Confirm severity of MR has not changed		



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### 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!