



## SURGICAL ABLATION VERSUS NO SURGICAL ABLATION FOR PATIENTS WITH PERSISTENT OR LONGSTANDING PERSISTENT ATRIAL FIBRILLATION UNDERGOING MITRAL VALVE SURGERY REV 4.2 PROTOCOL SUMMARY

<b>Objectives</b>	<ul style="list-style-type: none"> <li>○ To compare the effect of mitral valve surgery (MVS) alone or in combination with atrial fibrillation (AF) ablation on postop heart rhythm in patients with MV disease and persistent or longstanding persistent AF</li> <li>○ Compare 2 different techniques for post-ablation heart rhythm monitoring (long-term monitor at 6 and 12 months vs. weekly rhythm strips) to guide follow-up strategies for future studies of rhythm control in AF patients</li> <li>○ Compare quality of life (QoL) in persistent or longstanding persistent AF patients who undergo surgery for mitral valve disease and receive surgical ablation for AF to those who receive MVS alone</li> <li>○ Obtain preliminary estimates of the relative benefit of pulmonary vein isolation (PVI) alone vs. a biatrial lesion set for ablation in MVS patients</li> </ul>
<b>Study Design</b>	Randomized controlled trial; patients randomized with equal allocation to MVS alone or to MVS + ablation for AF; patients randomized to MVS + ablation further randomized (1:1) to PVI or ablation with biatrial lesion set.
<b>Target Population</b>	Adult patients with persistent or longstanding persistent AF who are undergoing MVS.
<b>Rx arms</b>	MVS alone versus MVS + AF ablation
<b>Sample Size</b>	260 patients; provides 90% power to detect a 20% difference (25% versus 45%) in freedom from AF (measured at 6 and 12 months)
<b>Duration</b>	24 months follow-up following randomization.
<b>1° Endpoints</b>	<p>Efficacy: Freedom from AF in patients with mitral valve disease and persistent or longstanding persistent AF; this will be assessed with 3-day continuous monitoring at 6 and 12 months post-ablation.</p> <p>Safety: Composite of death, stroke, serious AEs (cardiac and non-cardiac), and cardiac re-hospitalizations &lt; 30 days post-procedure or hospital discharge.</p>
<b>2° Endpoints</b>	AF load; freedom from any electrocardiographically documented arrhythmic recurrence; anti-arrhythmic interventions;; survival (all-cause mortality); safety (i.e., MACE and incidence of protocol-defined and serious adverse events <i>within 12 months after randomization</i> ); QoL
<b>3° Endpoints</b>	Functional status; hospitalizations; inpatient costs
<b>Inclusion Criteria</b>	Able to sign Informed Consent and Release of Medical Information forms; age ≥ 18; clinical indications for MVS for the following: organic MV disease, functional non-ischemic mitral regurgitation, or ischemic mitral regurgitation with evidence of concomitant structural MV disease; <i>(may include need for surgical management of functional tricuspid regurgitation or patent foramen ovale; may also include concomitant CABG, aortic arch or aortic valve procedure; may include sternotomy or minimally invasive procedure)</i> ; persistent AF (defined as non self-terminating AF lasting greater than 7 days or lasting less than 7 days but necessitating pharmacologic or electrical cardioversion) within 6 months prior to randomization or longstanding persistent AF (a sub-category of persistent AF defined as continuous AF of greater than one year duration); able to use heart rhythm monitor
<b>Exclusion Criteria</b>	AF w/o indication for mitral valve surgery; AF is paroxysmal; evidence of left atrial thrombus by intra-operative transesophageal echocardiography (TEE); active infection; patient does not understand nature, significance and scope of study; surgical management of hypertrophic obstructive cardiomyopathy; previous catheter ablation; life expectancy < 1 year; absolute contraindications for anticoagulation therapy; current enrollment in other drug or device trials; uncontrolled hypo- or hyperthyroidism; patients with FEV1 < 30% of predicted value and/or need for home oxygen therapy; women who are pregnant as evidenced by positive pregnancy test; women of childbearing age who do not agree to be on adequate birth control throughout the period of the trial