

# Repair MR

<b><u>INVESTIGATORS</u></b>	<ul style="list-style-type: none"><li>• Robert Cubeddu, MD-Principal Investigator</li><li>• Luis Paz, MD-Sub Investigator</li><li>• Mazen Albaghdadi, MD Sub-Investigator</li><li>• Brian Solomon, MD Sub-Investigator</li><li>• Viviana Navas, MD Sub-Investigator</li><li>• David Axline, MD Sub-Investigator</li></ul>
<b><u>Trial Objective</u></b>	<ul style="list-style-type: none"><li>• The objective of this randomized controlled trial (RCT) is to compare the clinical outcome of MitraClip™ device versus surgical repair in patients with severe primary MR who are at moderate surgical risk and whose mitral valve has been determined to be suitable for correction by MV repair surgery by the cardiac surgeon on the local site heart team.</li></ul>
<b><u>Randomization</u></b>	<ul style="list-style-type: none"><li>• The trial will randomize approximately 500 eligible subjects in a 1:1 ratio to receive either:<ul style="list-style-type: none"><li>- The MitraClip™ device (Device Group): Subjects will undergo implantation with the MitraClip™ device, or</li><li>- Mitral Valve Repair Surgery (Control Group): Subjects will undergo mitral valve repair surgery</li></ul></li></ul>
<b><u>Key Inclusion</u></b>	<ul style="list-style-type: none"><li>• Subject has severe Primary MR</li><li>• Subject is symptomatic (NYHA Class II/III/IV OR Pulmonary artery systolic pressure &gt;50 mmHG, or LVSED &gt; 40 MM)</li></ul>
<b><u>Key Exclusion</u></b>	<ul style="list-style-type: none"><li>• Concomitant severe tricuspid valve regurgitation</li><li>• Ejection fraction &lt;30%</li><li>• Sever Mitral annular calcification</li><li>• Renal insufficiency requiring dialysis</li></ul>