

# Clasp II F

<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>• David Axline, MD Sub-Investigator</li><li>• Hany Elmahdy, MD Sub-Investigator</li></ul>
<b><u>Trial Objective</u></b>	<ul style="list-style-type: none"><li>• The objectives of this pivotal clinical trial are to evaluate the safety and effectiveness of the PASCAL System for transcatheter mitral valve repair compared to the MitraClip System in the treatment of patients with symptomatic degenerative mitral regurgitation (DMR) and who have been determined to be at prohibitive risk for mitral valve surgery by the Heart Team.</li></ul>
<b><u>Randomization</u></b>	<ul style="list-style-type: none"><li>• Up to 300 eligible patients will be randomized in a 2:1 randomization ratio to the PASCAL System (200 patients) or to the MitraClip System (100 patients).</li></ul>
<b><u>Key Inclusion</u></b>	<ul style="list-style-type: none"><li>• Functional Mitral Regurgitation (MR <math>\geq 3+</math>)</li><li>• Left Ventricular Ejection Fraction is <math>\geq 20\%</math> and <math>\leq 50\%</math></li><li>• Stable heart failure medications</li></ul>
<b><u>Key Exclusion</u></b>	<ul style="list-style-type: none"><li>• Primarily Degenerative MR</li><li>• Severe Tricuspid regurgitation</li><li>• Severe COPD</li></ul>