

Clasp II TR

<u>INVESTIGATORS</u>	<ul style="list-style-type: none">• Robert Cubeddu, MD-Principal Investigator• Mazen Albaghdadi, MD -Sub Investigator• Luis Paz, MD-Sub Investigator• Brian Solomon, MD Sub-Investigator• Viviana Navas, MD Sub-Investigator• David Axline, MD Sub-Investigator• Hany Elmahdy, MD Sub-Investigator
<u>Trial Objective</u>	<ul style="list-style-type: none">• The objectives of this pivotal clinical trial are to evaluate the safety and effectiveness of the PASCAL System for transcatheter tricuspid valve repair with OMT compared to OMT alone in the treatment of patients with symptomatic severe tricuspid regurgitation.
<u>Randomization</u>	<ul style="list-style-type: none">• 2:1 Randomization ratio to the Pascal System and OMT (233 Patients) or OMT alone (117 Patients)
<u>Key Inclusion</u>	<ul style="list-style-type: none">• Functional and/ or degenerative TR graded as sever or greater on TTE assessed by the echo core lab• NYHA Class II-IVa or heart failure hospitalization in the prior 12 months
<u>Key Exclusion</u>	<ul style="list-style-type: none">• LVEF \leq 25%• Primary non degenerative tricuspid disease• Previous tricuspid valve repair or replacement that would interfere with placement of PASCAL• Severe aortic, mitral and/or pulmonic stenosis and /or regurgitation• Known history of untreated severe symptomatic carotid stenosis (>50% by ultrasound) or asymptomatic carotid stenosis (>70% by ultrasound)