Encircle

INVESTIGATORS	• Robert Cubeddu, MD-Principal Investigator • Luis Paz, MD-Sub Investigator • Mazen Albaghdadi, MD Sub-Investigator • Brian Solomon, MD Sub-Investigator • Viviana Navas, MD Sub-Investigator • David Axline, MD Sub-Investigator • Hany Elmahdy, MD Sub-Investigator
Trial Objective	• To establish the safety and effectiveness of the SAPIEN M3 System in subjects with symptomatic, at least 3+ mitral regurgitation (MR) for whom commercially available surgical or transcatheter treatment options are deemed unsuitable due to clinical, anatomic or technical considerations
Randomization	• All patient who meet Inclusion/Exclusion receive Edwards SAPIEN M3 System
Key Inclusion	• MR ≥ 3 • NYHA Functional class ≥ II
Key Exclusion	• Left Ventricular Ejection Fraction <25% • History of heart transplant • Irreversible, severe pulmonary hypertension (e.g., pulmonary artery systolic pressure ≥ 2/3 systemic pressure) • COPD requiring home oxygen therapy or chronic outpatient oral steroid use