EMPOWER

INVESTIGATORS	• Robert Cubeddu, MD-Principal Investigator • Viviana Navas, MD Sub-Investigator • David Axline, MD Sub-Investigator
Trial Objective	• The primary efficacy objective is to demonstrate that the Carillon Mitral Contour System (Intervention) group is superior to the Control group on the composite endpoint of death, heart transplant or LVAD implant, unplanned mitral valve retreatment, unplanned heart failure hospitalization through 24 months (analyzed when the last subject completes 12 months of follow-up), and improvement in six-minute walk distance at 12 months
Randomization	• Patients will be randomized 1(carillon mitral contour system):1 (control/nonintervention)
Key Inclusion	• Diagnosis of ischemic or non-ischemic cardiomyopathy • Symptomatic functional MR of at least 1+ (mild) severity • NYHA II, III, or IV • 6MWT distance ≥ 150 meters and ≤450 meters • Left Ventricular Ejection Fracture ≤ 50%
Key Exclusion	• Class I indication for CRT or anticipated need for CRT within 12 months • Presence of mechanical or bio-prosthetic mitral valve, mitral annuloplasty leaflet repair device • Hypertrophic cardiomyopathy, infiltrative cardiomyopathy, or constrictive pericarditis. • Pre-Existing device • Severe Aortic stenosis