Clinical Study of the BioVentrix Revivent TC System for Treatment of Left Ventricular Aneurysms

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

- 18 to 100 years old - diagnosis of LV Aneurysm or scar - Left Ventricular Ejection Fraction less than 45% - symptoms of heart failure that aren't improving with treatment - for people in the comparison group: have had previous pericardiotomy, left thoracotomy, or open heart surgery OR the location of the LV aneurysm or scar does not permit treatment with the study device

Exclusion Criteria:

- valvular heart disease which will require surgery - contact study staff for additional criteria

Conditions & Interventions

Conditions:
Heart & Vascular
Keywords:
Left Ventricular Dysfunction. Left Ventricular Aneurysm, Clinics and Surgery Center (CSC)

More Information

Description: The purpose of the study is to demonstrate the safety and effectiveness of the BioVentrix Revivent TC System for the treatment of LV antero-septal aneurysms/scars in patients with symptomatic heart failure. This study is prospective, multi-center, dual-arm with 2:1 study vs. control pool allocation ratio, pivotal study designed to evaluate the safety and effectiveness of the BioVentrix Revivent TC System for treatment of Left Ventricular (LV) Antero-Septal Aneurysms/Scars in Patients with Symptomatic Heart Failure. Patients will be selected for enrollment by a Heart Team at each clinical site that will be minimally composed of a heart failure specialist, an Interventional cardiologist, and a cardiac surgeon, one of whom is the site PI. The Heart Team will guide patient selection by pre-procedural agreement of the entire heart team regarding anatomic suitability and eligibility prior to selection of the patient by the Study PI. The Heart Team will optimize procedural performance (joint Interventionalist and cardiac surgical participation), and provide optimal and equivalent Guideline Directed Medical Therapy for residual or ongoing heart failure symptoms in test (post-procedural) and control group patients as determined by the heart failure specialist and referring physician
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