

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

**Status:** Recruiting

### Eligibility Criteria

**Sex:** Male or Female

**Age Group:** 18 years and over

This study is NOT accepting healthy 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

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#### Exclusion Criteria:

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

### Conditions & Interventions

#### Conditions:

Heart & Vascular

#### Keywords:

Clinics and Surgery Center (CSC), Left Ventricular Dysfunction. Left Ventricular Aneurysm

### More Information

**Description:** The Revivent TC System study is being conducted to test an investigational device that can repair a Left Ventricular Aneurysm without the use of a heart-lung machine, or opening the chest/heart chamber. The device works by placing a tuck in the heart where there is scar. This has the effect of shortening the distance across the heart and decreasing the stress on the working heart muscle. Follow up will last for 5 years after the device is placed.

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**Principal Investigator:** Tamas Alexy

**Phase:** Phase 2/Phase 3

**IRB Number:** 1703M11122

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