BioVentrix

ALIVE

American Less Invasive Ventricular Enhancement

A Clinical Study for Heart Failure Patients with Left Ventricular Scars/Aneurysms

Eligible Patients

- Patients suffering from symptomatic heart failure (NYHA functional class III or ambulatory class IV).
- Referred for treatment of left ventricular antero-septal scars/aneurysms that are contiguous.

Note: Control Group enrollment available for patients who may not meet all requirements.

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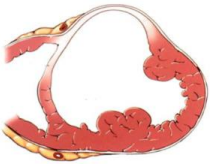
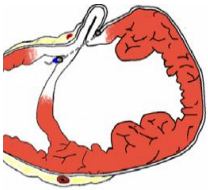
LIVE Procedure

Designed to reduce the wall stress of the left ventricle (LV) and stop the progression of heart failure caused by formation of an LV scar or aneurysm, the LIVE procedure is performed by an Interventional Cardiologist (IC) and Cardiac Surgeon (CS) using the Revivent TC System to oppose the walls of the heart and exclude the non—functioning heart tissue from the cavity of the LV. The LIVE procedure is based on a well-defined law of physics which describes how the shape and pressure inside the LV can create stress on the heart. The procedure is performed off-pump, without a ventriculotomy, and through the internal jugular (IC) and a 4cm thoracotomy (CS).

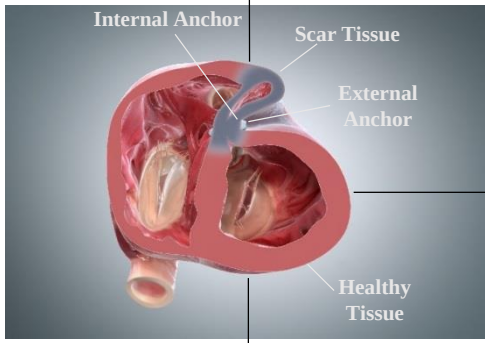
Ischemic Cardiomyopathy





Revivent TC Implant

Excludes the scar tissue (grey) from the healthy tissue (red) reducing the stress on the left ventricle.



Reshapes the heart back to a more normal shape and size.

May improve pumping efficiency, thereby increasing blood flow to the rest of the body.

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Patient inclusion/exclusion criteria

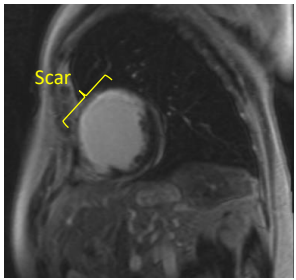
Key inclusion criteria

- Scar involving septum and/or anterior, apical or anterolateral regions of the left ventricle
- Contiguous acontractile (akinetic and/or dyskinetic) scar
- Viability of myocardium in regions remote from area of intended scar exclusion
- Left Ventricular Ejection Fraction < 45%
- Left ventricular end-systolic volume index ≥50 mL/m2
- NYHA functional class III – IV (ambulatory)

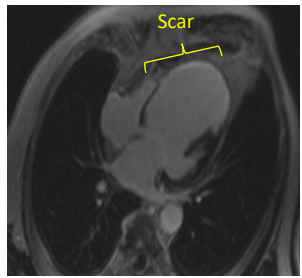
Key exclusion criteria

- CRT device placement ≤ 60 days prior to enrollment
- Peak Systolic Pulmonary Arterial Pressure > 60 mm Hg
- Myocardial Infarction within 90 days prior to enrollment
- Chronic renal failure with a serum creatinine >2.5 mg/dL and/or GFR<30ml/min
- Previous pericardiotomy, left thoracotomy, or open heart surgery*

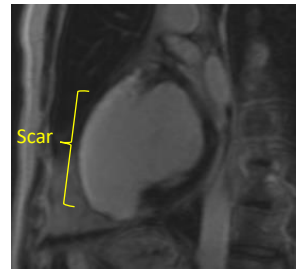
Short Axis view



Four Chamber View



Two Chamber View



* Patients can be enrolled in the control group.

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Key Trial Endpoints

Efficacy

- No hospital readmission for new or worsening heart failure
- Improvement in MLHF Quality of Life score by >10 points
- Improvement in 6 Minute Walk Distance by >25 meters
- Improvement in NYHA Classification >1 grade

Safety

Composite primary safety endpoint of all cause death, placement of a mechanical support device intra or post-op (IABP, VAD, or ECMO), emergent cardiac surgery including reoperation for bleeding or tamponade, prolonged mechanical ventilation, renal failure and clinically important stroke (Rankin Score of 4 or higher) through 30 days post procedure. Data from patients treated with the Revivent TC System will be compared to surgical outcomes data from the Society for Thoracic Surgery database for surgical LV aneurysm or scar repair.

Composite secondary safety endpoint of all cause of death, placement of a mechanical support device and operation (or re-operation) for HF, bleeding or tamponade from 1 through 12 months (day 31 through 365) post procedure. Data from patients treated with the Revivent TC System will be compared to data from control patients who meet all eligibility criteria and are not treated with the investigational devices remain on Guideline Directed Medical Therapy (GDMT).