LESS INVASIVE VENTRICULAR ENHANCEMENT

ALIVE

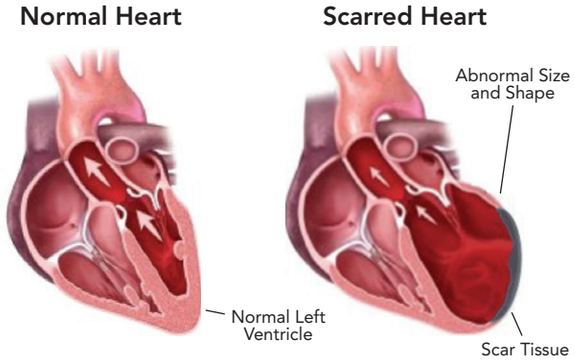
A Clinical Study for Heart Failure Patients with Left Ventricular Aneurysms

BioVentrix

Have You Suffered a Heart Attack?

A heart attack is caused by a narrowing or blockage of the coronary arteries which supply blood to the heart. As a result, the pumping muscle of the left side of the heart becomes damaged or scarred. The left side of the heart is also called the "left ventricle" and is the main portion of the heart which pumps blood to the body.

The scarred muscle does not contract as well as healthy heart muscle and causes the heart to become less efficient. To compensate, the heart grows larger in size and becomes abnormal in shape.



Heart Failure Symptoms

As a result of your heart attack, the heart may pump an insufficient amount of blood to the body resulting in a failing heart and you may experience the following symptoms:

- Shortness of breath
- Fatigue
- Reduced ability to perform physical activity
- Lightheadedness
- Fluid in the lungs and swelling in the legs
- Rapid or irregular heartbeat

Introducing the LIVE Procedure using the Revivent TC™ TransCatheter Ventricular Enhancement System

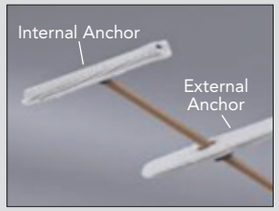
The Less Invasive Ventricular Enhancement (LIVE) procedure is based on a well-defined law of physics which describes how the shape and pressure inside of the left ventricle can create stress on the heart. Heart failure symptoms worsen as the stress on the left ventricle increases, and the only way to stop the progression of heart failure is to reduce the stress on the left ventricle. The LIVE procedure is uniquely designed to reduce this wall stress by restoring the functionality of the left ventricle.

Performed by both an Interventional Cardiologist and Cardiac Surgeon, the LIVE procedure uses the Revivent TCTM System to implant micro-anchor pairs into the scar tissue of your heart. The anchors are composed of a small titanium bar covered by polyester cloth.

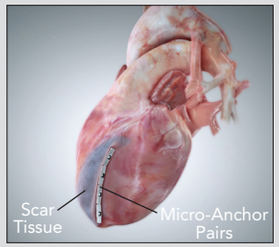
The internal anchor is placed inside the right side or "right ventricle" of your heart through the jugular vein in your neck. The external anchor is placed on the outside of the left ventricle through a small incision on the left side of your chest. Once the anchors are in position, your doctors will gently pull them toward each other resulting in the anchor pairs excluding the scar tissue from the healthy tissue on the left ventricle. This isolates the non-functioning part of your heart muscle and allows the remaining healthy tissue to work more effectively.

An average of 2-3 anchor pairs are typically implanted and remain in the heart once the procedure is finished. For more information about the LIVE procedure, please consult with your cardiologist.

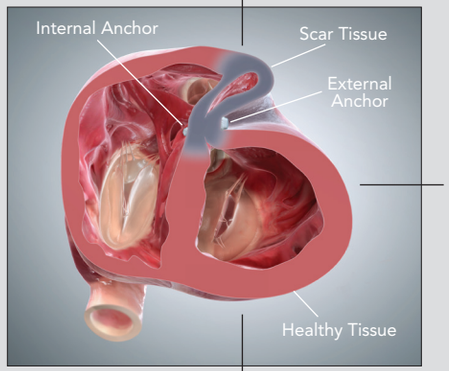
Micro-Anchor Pair



Revivent TC™ System 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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What Can I Expect Before the Procedure?

Certain investigations will need to be performed before the procedure. These include, but are not limited to the following:

- Cardiac examination including heart rate, blood pressure, NYHA class, bloodwork, ECG, and review of cardiac medications
- Neurological examination
- Transthoracic or Transesophageal echocardiogram (ultrasound test for the heart)
- CT/MRI Scans – imaging assessment of the heart and identification of the scar location to determine accurate implant using the Revivent TC™ System

What Happens After the Procedure?

Once the LIVE Procedure is complete, you will be transferred to the cardiac monitoring unit for about 1-2 days. After this, your cardiologist may transfer you to the regular hospital ward before discharge. Additional tests may be performed after the procedure to ensure all structures in your heart are working properly. You will be given blood thinners, such as Coumadin for 90 days.

As part of the clinical study, you will be required to follow up with your cardiologist at 1, 6, and 12 months and annually for 5 years after your procedure to get a routine patient cardiac exam and undergo an echocardiogram (ultrasound). At 12 months, you will also be required to have a chest X-ray, which will be repeated on an annual bases until year 5. Your cardiologist may also determine that additional tests are required.

CAUTION: Investigational Device. Limited by United States law to investigational use. The patient is enrolling in a study to determine whether the LIVE procedure results in the changes/benefits desired and that whether or not this will be achieved is unknown.

ALIVE

Revivent TC™ Clinical Trial Center

The LIVE Procedure is performed in the United States at participating clinical trial centers as part of an Investigational Study. It is important you consult with your doctor to determine if the Revivent TCTM System and participation in its clinical trial is appropriate for you. You and your doctor will discuss the risks and potential benefits of this and other treatments for your heart failure.

Should you choose to participate in the clinical trial, your doctors may perform additional tests and request you visit the hospital several times to meet with your doctors and research team.

Your local Revivent TCTM System Research Team is:

Place sticker/label here

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TALK TO YOUR DOCTOR OR VISIT BIOVENTRIX.COM TO LEARN MORE

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Potential Risks/Complications of the Procedure: Air Embolism, Allergic reaction, Angina (chest pain),Arrhythmias (irregular heartbeat, Sustained Ventricular Tachycardia, Ventricular Fibrillation requiring Cardioversion), Bleeding complications requiring transfusion, Cardiac arrest , Cardiac tamponade, Coagulation disorder, Death, Device embolization/migration, Device Thrombosis, Endocarditis or device infection , Emergent or urgent cardiac surgery caused by the device or procedure (conversion to sternotomy), Erosion of device through the LV, possibly causing a hole between two main heart chambers, Hematoma, Hypo or hypertension (low or high blood pressure), Intra aortic balloon pump, ECMO or inotropic support required, Infection , Kidney Failure , Left Ventricular Assist Devices (insertion either surgically or interventional catheter access), Low cardiac output, Myocardial infarction (heart attack), Neurological deficit (stroke), Perforation, Pericardial effusion requiring drainage, Peripheral embolism/thrombus (blood clot), Pleural Effusion (fluid around the lungs), Post-operative pain requiring intravenous narcotic administration, Pulmonary embolism (clots in the lungs), Renal compromise, Stroke/TIA, Thrombosis - Blood clot formed in blood vessel, Valve damage, Vascular complications, Ventricular Septal Defect, and Worsening heart failure.