Less Invasive Ventricular Enhancement™

For Heart Attack Patients

Revivent TC™

TransCatheter Ventricular Enhancement System

BioVentrix

This patient booklet is for those who have suffered a heart attack resulting in damage to the left side of the heart causing it to scar. This information will help you learn more about your heart's dysfunction due to your heart attack and your treatment options, which includes a procedure called Less Invasive Ventricular Enhancement™ (LIVE™).

Be sure to ask your doctor to explain all of the treatment options as well as the benefits and risks.

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THE HEART

The heart is a muscular organ in your chest and is about the size of a closed fist. Its primary purpose is to pump blood to the rest of the body. The heart pumps blood following an electrical signal that causes a contraction of the heart. The heart is divided into four chambers:

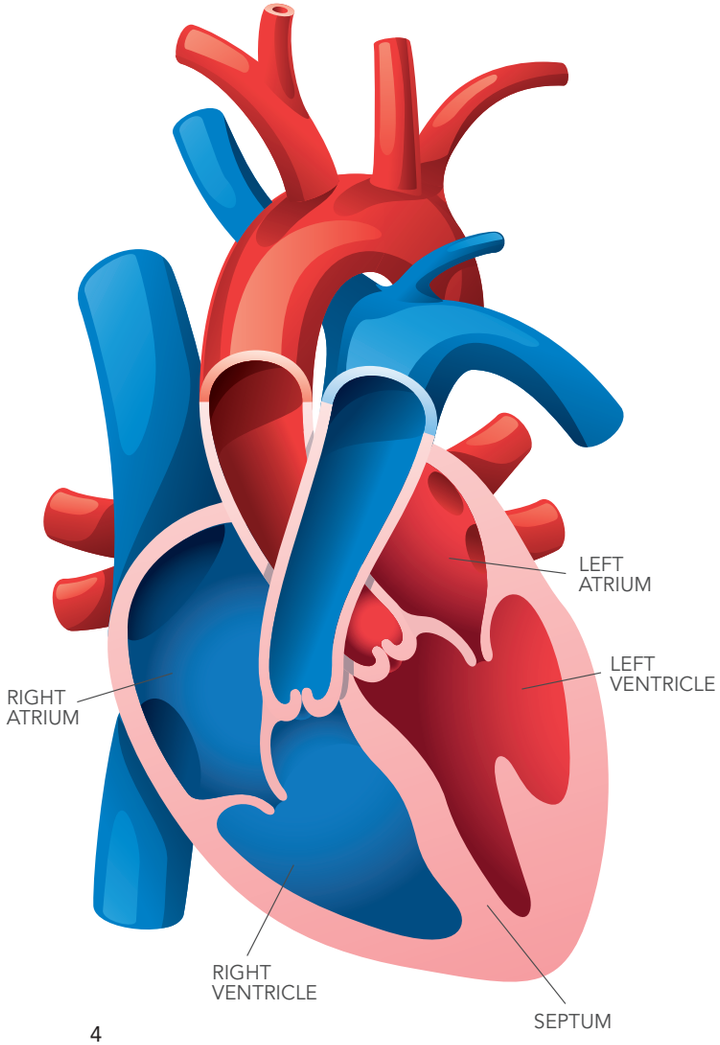
Right Atrium: receiving chamber for deoxygenated blood entering the heart

Right Ventricle: pumping chamber for deoxygenated blood to the lungs

Left Atrium: receiving chamber for oxygenated blood from the lungs

Left Ventricle: pumping chamber for oxygenated blood to the organs in the body

The left ventricle is the most important chamber in the heart as it is responsible for supplying a sufficient amount of blood to the rest of the body's organs. It is important that it is functioning properly to support the overall well-being of the body.



HEART ATTACK

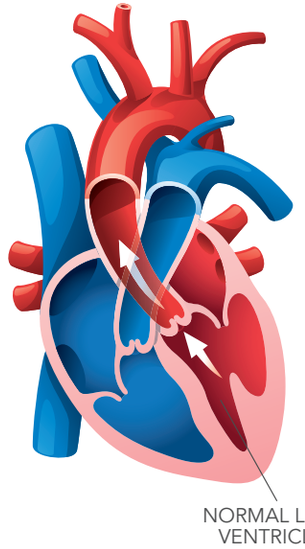
A heart attack is caused by a narrowing or blockage of the coronary arteries which supply blood to the heart. This causes structural damage to the heart's left ventricle.

There are two problems that may occur to the structure of the left ventricle after a heart attack:

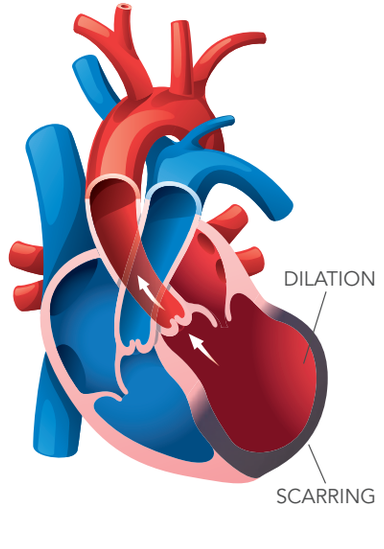
Scarring: part of the left ventricle tissue is damaged and does not function.

Dilation: the left ventricle grows over time to compensate for the scarred tissue and becomes abnormal in shape and size.

NORMAL HEART



HEART ATTACK VICTIM



FACT: Globally, about 1.4M people suffer from a heart attack each year and are looking for solutions to help improve their health. Of those who have a heart attack, 84% survive.

THE HEART'S ELECTRICAL SYSTEM

Did you know the heart has an electrical system that gives it the ability to contract? With each contraction, blood is pumped throughout the body. After a heart attack, the electrical system can become negatively affected, due to the structural damage that has occurred to the heart. The correction of the structural damage may result in an improvement to the electrical system, which will enhance the flow of blood throughout the heart and into the body.

As a precaution and attempt to enhance contractility in the heart, doctors may treat with Cardiac Resynchronization Therapy (CRT). A CRT device delivers electrical energy to the heart to restore the normal timing of beats and causes the ventricles to pump together more efficiently. Although this may improve part of the heart's contractility, there is still a scar which may require treatment.

HEART FAILURE SYMPTOMS

As a result of your heart attack, the heart may pump an insufficient amount of blood to the body from a failing heart. 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**

HEART FAILURE MEDICATIONS

These medications each perform a specific function to help you feel better, but they will not cure your heart failure. Your doctor may have you on one or more of the following medications:

- **ACE inhibitors:** lowers blood pressure and increases the amount of blood your heart pumps
- **Digoxin:** slows your heart rate in patients with atrial fibrillation
- **Beta blockers:** manages abnormal heart rhythms and protects the heart from having another heart attack
- **Diuretics:** helps relieve fluid and swelling that may occur as a result of your heart failure

CLASSIFYING YOUR HEART FAILURE

After your heart attack, your doctor will assess your heart and put you in a specific class based on your heart failure symptoms. This is known as a New York Heart Association (NYHA) class and is used to track your heart's health and support suggested treatment options based on your symptoms.

NYHA Classification	Patient Characteristics
I (Mild)	Structural heart disease but without symptoms of heart failure
II (Mild) III (Moderate)	Structural heart disease with prior or current symptoms of heart failure
IV (Severe)	Structural heart disease with severe symptoms of heart failure

UNDERSTANDING YOUR TREATMENT OPTIONS FOR A SCARRED HEART

If you have been diagnosed with a scarred left ventricle after your heart attack, the damage to your heart may require a structural intervention at some point during the progression of heart failure. Structural interventions may include the following:

- Open-heart surgery
- LIVE™ procedure (closed-chest)

SURGERY FOR A SCARRED HEART

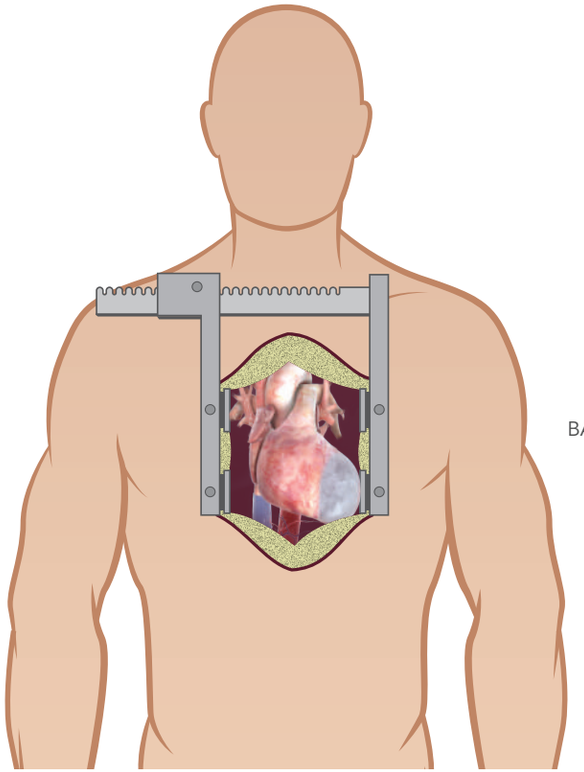
Open-heart surgery is performed through an 20-25 cm cut into the center of your chest to gain full access to the heart. This incision is called a median sternotomy which is how most surgical heart procedures are performed.

Open-heart surgery typically requires a heart-lung machine which temporarily takes over the function of the heart and lungs to maintain circulation of blood to the body. This is called cardiopulmonary bypass.

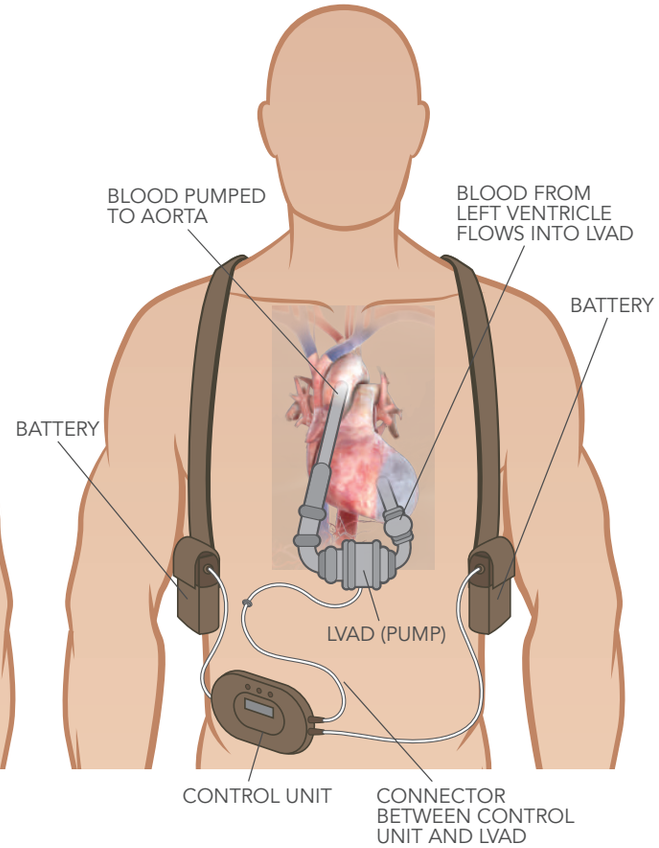
Typical surgical procedures for scarred hearts:

- **Surgical Ventricular Reconstruction:** an invasive procedure that cuts out the scarred portion of your heart and stiches the healthy tissue together. Since this is often viewed as a very invasive procedure, doctors rarely refer patients for this form of treatment as the risk is too high.
- **LVAD:** Left Ventricular Assist Device (LVAD) is an invasive procedure that requires a battery operated device to be inserted into the bottom of the left ventricle to enhance blood circulation throughout the body. The device may be used temporarily until a heart is available for transplant or as a permanent therapeutic solution. The patient is required to wear a battery pack at all times as it activates the device inside the heart.
- **Heart Transplant:** an extremely invasive procedure for end-stage heart failure patients that will replace their scarred heart with a healthy donor heart. Patients will be placed on a list until a compatible heart is available and there is no guarantee as to when they may receive their new heart.

MEDIAN STERNOTOMY



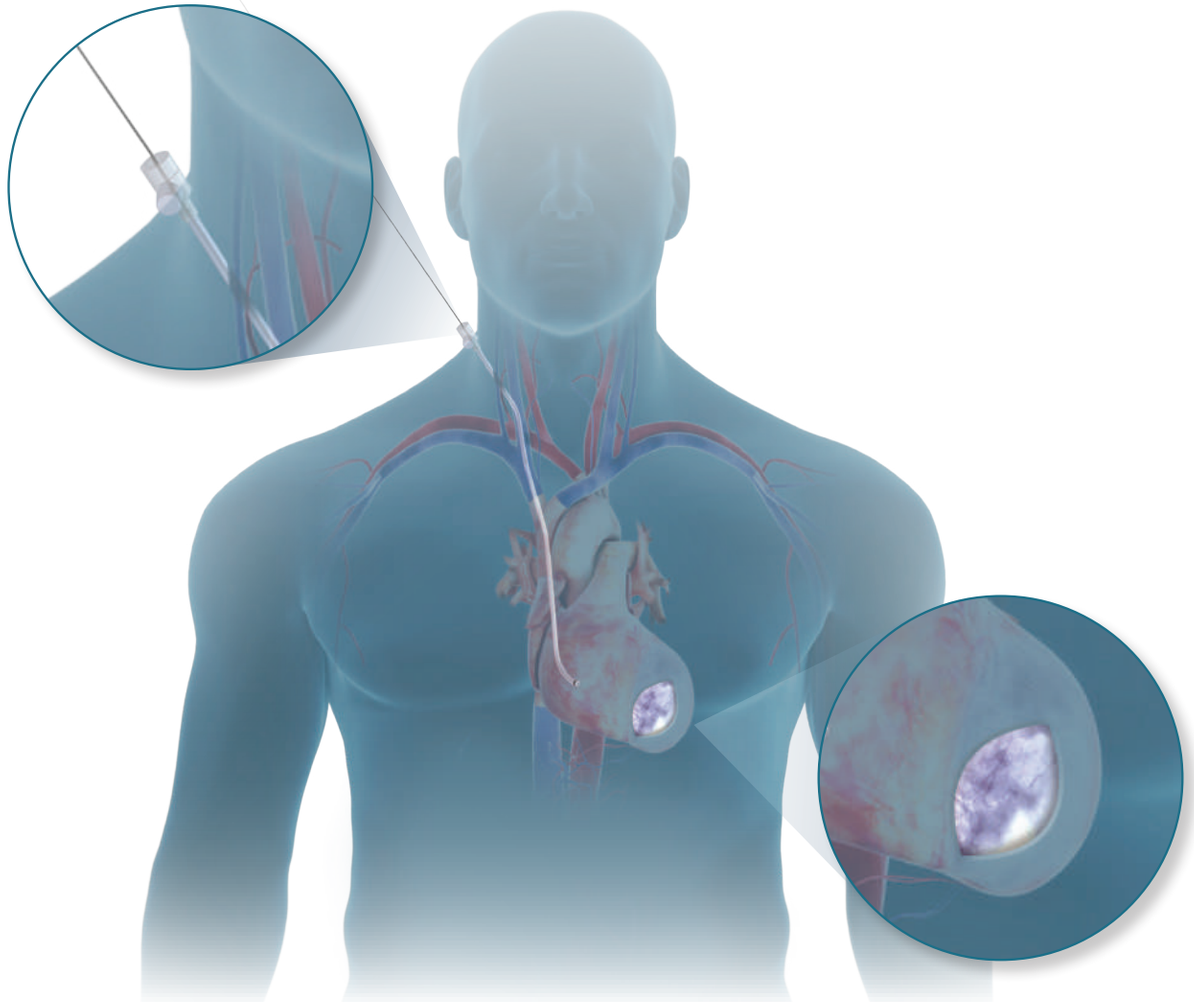
LVAD IMPLANT



INTRODUCING THE LIVE™ PROCEDURE FOR A SCARRED HEART

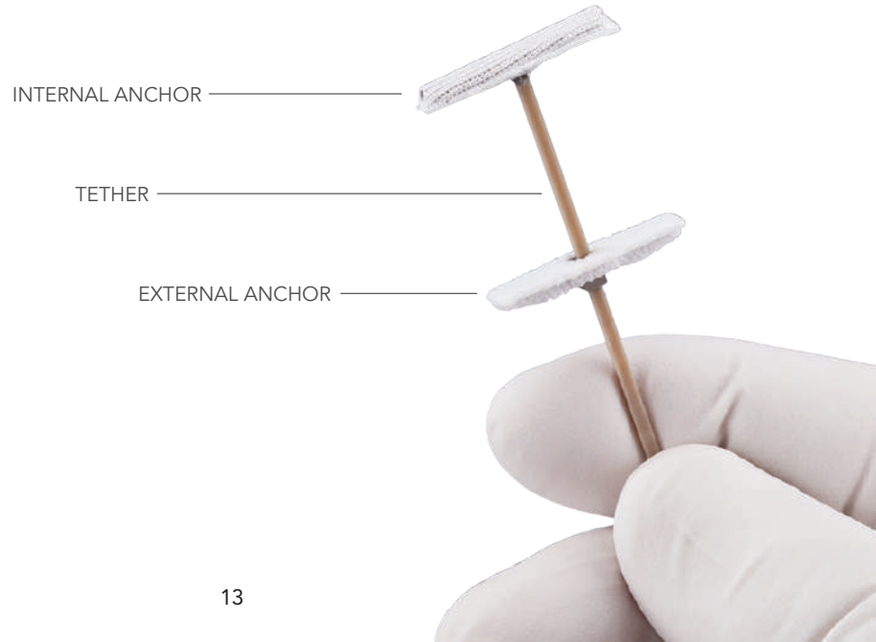
Less Invasive Ventricular Enhancement™ or the LIVE™ procedure is a closed-chest, catheter-based technique for excluding the scar from the cavity of the left ventricle. An interventional cardiologist along with a cardiothoracic surgeon will work together to reconstruct the left ventricle using the Revivent TC™ Transcatheter Ventricular Enhancement System. The interventional cardiologist will operate from the right side of the neck through the jugular vein and the cardiothoracic surgeon will maneuver through a small 4 cm incision on the left side of the chest. They will guide the Revivent TC™ Transcatheter Ventricular Enhancement System into position along the scarred portion of the left ventricle utilizing x-ray and ultrasound, while the heart is still beating. This approach removes the need for cardiopulmonary bypass and increases the safety of the procedure.

The LIVE™ procedure, since it is less-invasive, gives more heart attack patients an opportunity to seek treatment of their left ventricle when open-heart surgery is too high of a risk. The closed-chest, catheter-based technique also allows for a much quicker recovery time as neither the left ventricle itself nor the breastbone will be cut open and cardiopulmonary bypass is not required.



THE REVIVENT TC™ TRANSCATHETER VENTRICULAR ENHANCEMENT SYSTEM

The LIVE™ procedure uses the Revivent TC™ Transcatheter Ventricular Enhancement System to exclude the scar on your left ventricle by implanting anchor pairs on the scar along the septum of the right ventricle and outer surface of the left ventricle. Excluding the scar allows the remaining functional portion of the left ventricle to operate more efficiently. There is an internal anchor (IA) and an external anchor (EA) that are connected by a tether that will be implanted through the scar on the heart. The implant will help remodel the heart back to a more regular shape and size, which may result in an improvement in blood flow throughout the body and benefit the rest of the organs. On average, patients receive 3 anchor pairs. However, your doctor will determine how many anchor pairs are right for you.

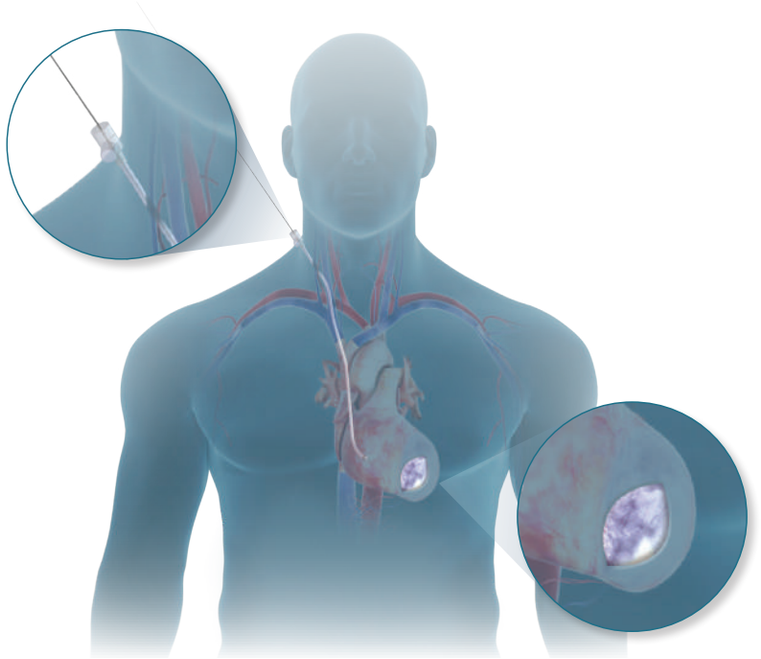


WHAT CAN I EXPECT BEFORE THE LIVE™ PROCEDURE?

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

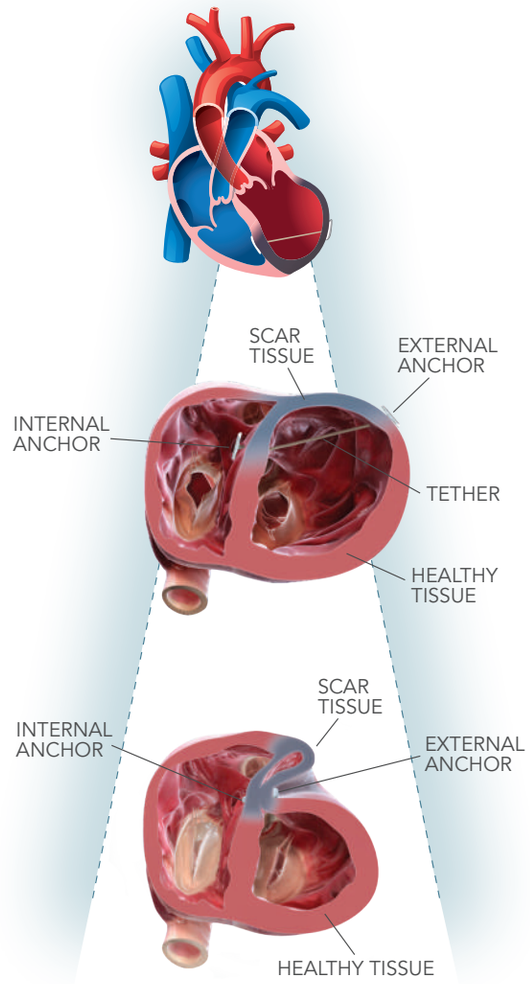
- Cardiac examination including heart rate, blood pressure, NYHA class, bloodwork, ECG, and review of cardiac medications
- Ultrasound examination of the heart
- CT/MRI Scans–imaging assessment of the heart and identification of the scar location to determine accurate implant using the Revivent TC™ Transcatheter Ventricular Enhancement System

Average Procedure Time:
2-3 Hours



THE LIVE™ PROCEDURE USING THE REVIVENT TC™ TRANSCATHETER VENTRICULAR ENHANCEMENT SYSTEM

1. You will be placed under anesthesia.
2. A small incision will be made at the neck to access the jugular vein by your cardiologist to deliver the internal anchor. The cardiothoracic surgeon will make a 4 cm incision on the left side of your chest to access the scar on the outside of your heart to implant the external anchor.
3. The cardiologist will put the internal anchor along the septum in the right ventricle and the tether will be pushed outside the left side of your heart. The cardiothoracic surgeon will put the external anchor over the tether to connect the anchor pairs.
4. The cardiothoracic surgeon will push the external anchor toward the internal anchor to lock the anchor pairs. This will exclude the scarred portion of your left ventricle from the remaining healthy working tissue.
5. The doctors will close up the incision and the procedure will be complete.

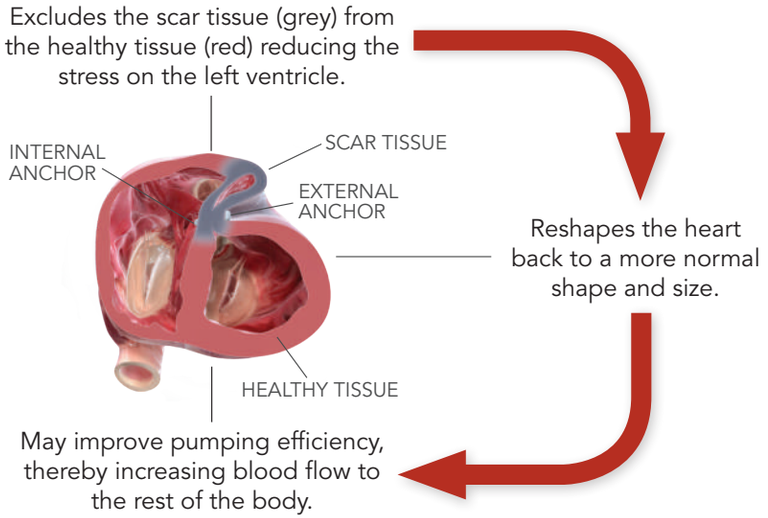


WHAT ARE THE BENEFITS OF THE LIVE™ PROCEDURE?

The LIVE™ procedure should help your heart work better and you may experience improvements to your:

QUALITY OF LIFE | NYHA FUNCTIONAL CLASS | BLOOD FLOW | ACTIVITY LEVEL

THE LIVE™ PROCEDURE:



WHAT HAPPENS AFTER THE PROCEDURE?

Once the procedure is complete, you may be transferred to the cardiac monitoring unit or 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.

Your doctor will discuss your after-care plan and give you specific instructions to help with your recovery. This may include a specific diet, exercise routine, and medication. Regular post-operation check-ups with your doctor are very important.

Always tell your doctor about your anchor implants before any medical, dental, or cardiac imaging procedures.

WHAT ARE THE RISKS OF THE LIVE™ PROCEDURE?

As with any medical procedure, there are risks associated that may cause complications.

The most serious complications that may occur with the LIVE™ procedure include:

- Death
- Stroke
- Bleeding complications requiring transfusion
- Vascular Complications

Additional potential risks associated with the LIVE™ procedure include:

- Ventricular Septal Defect
- Heart Attack
- Irregular Heartbeat
- Infection
- Erosion of the device
- Hypertension
- Blood clot in the heart or lungs
- Fluid around the lungs
- Renal compromise

Improve your Quality of Life by

39%

Improve your Symptoms by

28%

Improve your Activity by

23%

CLINICAL DATA FOR THE LIVE™ PROCEDURE

To date, over 150 patients have undergone the LIVE™ procedure. The following table summarizes a group of 57 patients from a clinical study who reached 1 year follow-up and were treated with the Revivent TC™ Transcatheter Ventricular Enhancement System.

PATIENT DATA AT 1 YEAR	
Quality of Life Improved by:	39%
NYHA Class Improved by:	28%
6 Minute Walk Test Improved by:	23%
Pumping Efficiency Improved by:	12%
Major Stroke Occurrence:	0%
Secondary Heart Attack Occurrence:	0%
CRT Implant:	0%
LVAD Implant:	0%
Heart Transplant:	0%

FAQs

Is heart failure the same as heart a attack?
No. A heart attack occurs (usually quickly) when the artery that supplies blood to the heart becomes blocked (by a clot or plaque) and prevents fresh blood from reaching and refreshing the heart. After a heart attack, the affected part may be permanently damaged. Heart failure occurs when the heart cannot circulate enough blood to meet the body's needs. Heart failure may take years to develop, and is often a consequence of one or more heart attacks that have left the heart muscle scarred and damaged.

How long does it take for heart failure to develop?
It can take years for heart failure to develop or it can come on quickly, particularly after a heart attack. Changes to the heart's size, structure and function may precede noticeable symptoms by several months or even years. If you suspect your heart may be failing, consult your physician immediately.

Is the LIVE™ procedure approved?
Yes. The LIVE™ procedure Revivent TC™ Transcatheter Ventricular Enhancement System has been CE Marked in the European Union (EU), allowing for the technology to be widely accessed by doctors commercially throughout Europe. This means that as a result of a successful clinical trial in the EU, all hospitals in Europe can access the Revivent TC™ Transcatheter Ventricular Enhancement System as a resource to treat patients who have had a heart attack. The device is currently under clinical investigation in the U.S.A. with the hopes of gaining FDA approval once the clinical trial is complete.

What kind of relief does the LIVE™ procedure provide to people who have had a heart attack?
In a clinical study that concluded in 2016, people who have had a heart attack and underwent the LIVE™ procedure showed they could walk an average of 417 meters in 6 minutes at 1 Year post-operation. This was a significant improvement prior to the LIVE™ procedure as patients could only walk an average 339 meters in 6 minutes. The 23% increase is a direct indicator of a patient's improved quality of life as their heart failure symptoms were relieved by excluding the damage done from the heart attack.

Are there other risks?
Like any surgery, the LIVE™ procedure comes with risks, including bleeding, infection, stroke, and death. Talk to your doctor to better understand the risks and benefits of the LIVE™ procedure. See page 19 for a conclusive list.

How long does the Revivent TC™ Transcatheter Ventricular Enhancement System implant last and what happens if it fails?
The Revivent TC™ Transcatheter Ventricular Enhancement System implant was designed to last for the remainder of your life. However, if there is a problem, the implant does not prevent you from future interventions like an LVAD or a Heart Transplant, if necessary.

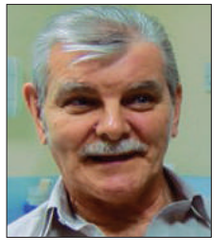
PATIENT TESTIMONIALS

*"I have recovered **30-40% of my heart's functionality** and my health has benefited greatly… **It really changes your life**."*

– Civil Hospital of the University of Brescia Medical School (Italy)

*"**I feel good now**…When I came back home after 12 days, I was able to walk about half-way up a hill…**Now I walk normally**."*

– NA Holmoce Hospital (Prague)



*"**Go for it!** Without a shadow of a doubt. **You have nothing to lose and everything to gain**."*

– Freeman Hospital in Newcastle upon Tyne (The UK)

Watch full Patient Testimonials at www.bioventrix.com

QUESTIONS TO ASK YOUR HEART TEAM

Do I qualify for LIVE™ procedure?

How will my life change from the LIVE™ procedure?

What are the clinical benefits of the LIVE™ procedure? How do they compare to drugs, an LVAD, or heart transplant?

What is the survival rate? What are the potential complications?

What additional tests do you need to do prior to the procedure?

Is there a patient I can speak to about their experience with the LIVE™ procedure?

Do you have a consenting form I can sign?

NOTES

CONTACT INFORMATION

For more information about the LIVE™ procedure:

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If you have suffered from a heart attack, contact your doctor to learn more about how the LIVE™ procedure using the Revivent TC™ Transcatheter Ventricular Enhancement System can change your life. Your doctor will determine if the system is suitable to treat your condition.

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