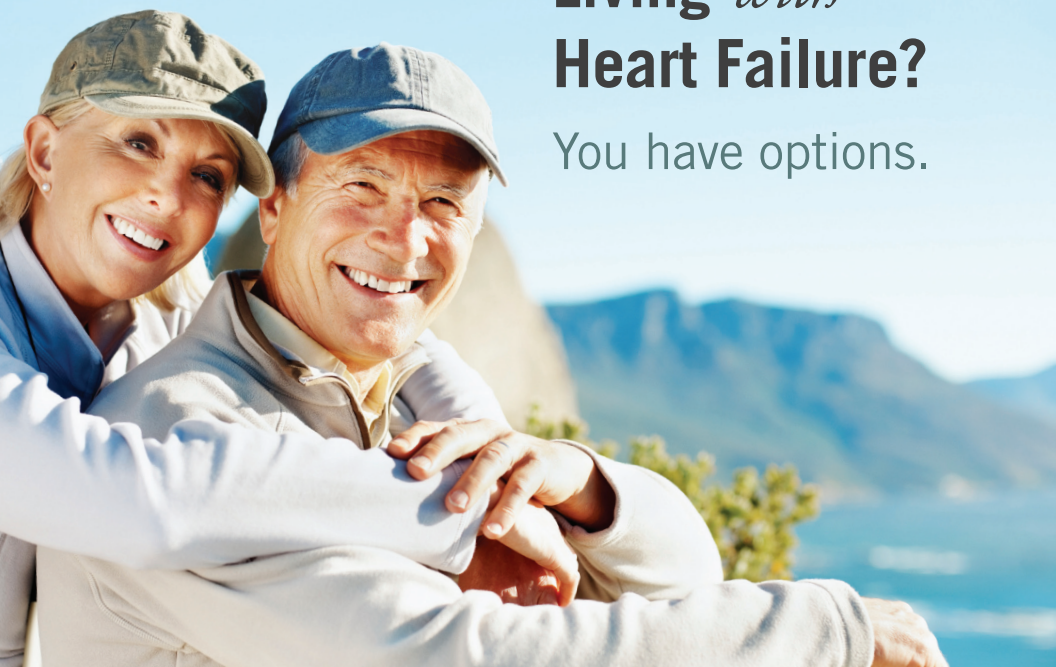




SUNSHINE  
HEART

# Living *with* Heart Failure?

You have options.



 COUNTER HF™  
CLINICAL STUDY

## What is heart failure?

Although the term “heart failure” makes it sound as if the heart has stopped working, it really means your heart isn’t pumping as well as it should. Heart failure is a progressive condition that develops slowly as the heart muscle weakens and needs to work harder to keep blood flowing through the body. Heart failure can affect the left side, right side or both sides of your heart.

## What are the symptoms of heart failure?

As the heart struggles to keep up with the demands of the body people experience a range of symptoms, such as:

- ✓ Feeling tired and weak
- ✓ Shortness of breath
- ✓ Reduced ability to walk or exercise
- ✓ Swelling of the legs and ankles

## How common is heart failure?

Heart failure affects over 5 million Americans of all ages and is responsible for more than 1 million hospitalizations in the United States each year.<sup>1,2</sup> Nearly 500,000 new cases are reported annually - yet many people with heart failure are not aware they have it, since some of the most common symptoms are often mistaken for normal signs of aging.<sup>1</sup> Among those currently diagnosed with heart failure, approximately 1.2 million are Class III (Moderate HF).<sup>1,3</sup>

## How severe is my heart failure?

The severity of heart failure depends on how well your heart is still able to pump blood to your body. There are four categories of heart failure based on standards from the New York Heart Association (NYHA), which focus on how your cardiac disease limits your physical activity.<sup>4</sup>

NYHA Class	Patient Symptoms
<b>Class I (Mild)</b>	You have no limits to your daily activities. You are able to do all of your normal daily activities without becoming tired, short of breath or having heart palpitations.
<b>Class II (Mild)</b>	You have some limits to your daily activities. You are comfortable at rest, but normal activities may cause you to be tired, short of breath or have heart palpitations.
<b>Class III (Moderate)</b>	You are very limited in your daily activities. You are comfortable at rest, but are unable to do your daily activities without becoming tired, short of breath or having heart palpitations.
<b>Class IV (Severe)</b>	You are unable to do any physical activity without discomfort. You become tired, short of breath and possibly have heart palpitations even when you are at rest. Any physical activity makes your discomfort worse.

## How is heart failure treated?

Heart failure is a serious illness that can affect how long you live. However, with proper treatment and careful management, you can live longer and feel better. Generally, treatment for heart failure depends on your NYHA classification and underlying medical condition. The major types of heart failure treatments include:

- Lifestyle changes
- Heart medications
- Surgery for correctable problems
- Implantable devices
- Heart transplant

<sup>1</sup> Heart Disease and Stroke Statistics. American Heart Association – 2013 Update. *Circulation*. 2013;127: e6-e245.

<sup>2</sup> Blecker S, et al. *J Am Coll Cardiol*. 2013;61(12):1259-1267.

<sup>3</sup> Farwell D, et al. *Eur Heart J*. 2000;21:1246-1250.

<sup>4</sup> Lindenfeld J, et al. *J Card Fail*. 2010;16(6)e1-194.



## Lifestyle changes

Lifestyle changes are recommended for all patients. Following recommendations about diet, exercise and other habits can help to alleviate symptoms, slow your disease's progression and improve your everyday life.

## Heart medications

Heart failure patients often need multiple medications. These medications treat different symptoms or causes of heart failure. Your doctor will help determine which medications are most appropriate for your specific condition. It is important to take all of your medications correctly to ensure maximum benefit.

## Surgical procedures to correct heart problems

Surgical procedures will be used when your doctor can identify a correctable problem that's causing heart failure – such as a heart defect or a blocked coronary artery. Coronary artery bypass and balloon/stent procedures are used to treat blocked coronary arteries. Patients with defective valves can have their valves repaired or replaced.

## Implantable Devices

There are a number of implantable devices that are used to treat heart failure, including:

### ▶ Cardiac Resynchronization Device (CRT or CRT-D)

This device sends tiny electrical pulses to the lower chambers of your heart to help them beat in a more coordinated or “synchronized” fashion. This may help improve the pumping efficiency of the heart. Patients with serious heart rhythm problems will get a CRT device with defibrillation capabilities (CRT-D) to help treat abnormal fast rhythms.

### ▶ Left Ventricular Assist Device (LVAD)

This device is a pump attached to the heart that helps the patient's own heart pump blood through the body. This treatment is generally reserved for patients with severe heart failure (NYHA Class IV).

## Heart Transplant

Some patients have severe, progressive heart failure that can't be helped by lifestyle changes, medications, or implantable devices. In such cases a heart transplant may be the only effective treatment option.

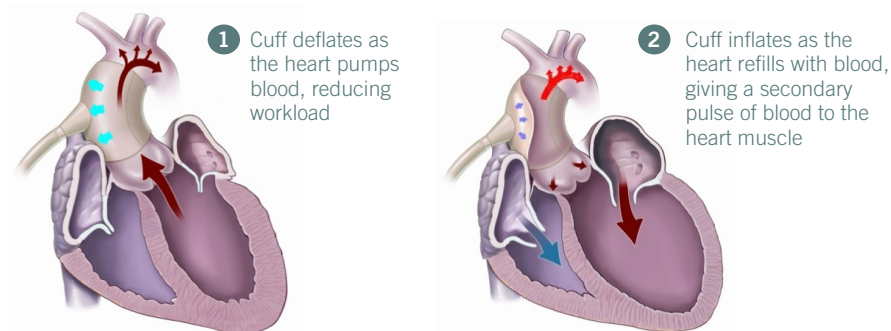
## The C-Pulse® Heart Assist System

The C-Pulse System is an investigational treatment option designed for patients with moderate to severe heart failure. The C-Pulse System works to assist your heart to pump blood, rather than “replacing” the heart function, and can be disconnected for short periods as required. The C-Pulse System is being offered as part of the COUNTER HF™ Clinical Study, currently being conducted at select treatment centers throughout North America.

## How does the C-Pulse System work?

The C-Pulse System's Cuff wraps around the outside of the ascending aorta (the main artery coming out of the heart that delivers blood to the body), much like a blood pressure cuff around your arm.

The C-Pulse Cuff pumps in rhythm with the natural heartbeat, which is monitored using a pacemaker-type wire. The Cuff deflates just before the heart pumps blood, reducing the workload of the heart. The Cuff is timed to re-inflate inbetween heartbeats, once the heart has finished pumping blood - this allows the Cuff to act like a second heartbeat, producing a surge of blood flow to the heart muscle. Reducing the workload of the heart and increasing blood flow to the heart muscle are important in assisting the heart to pump blood.



## C-Pulse is designed to treat heart failure symptoms by:

- ✓ Reducing the workload for the heart
- ✓ Providing more oxygen-rich blood going to the heart muscle
- ✓ Improving heart function





- ▶ **The Extra-Aortic Cuff** wraps around the aorta and is connected to the Driver (the pump) by a tube (interface lead) that passes through a small hole in the skin.
- ▶ **The ECG Sensing Lead** (pacemaker-type wire) is used as a timing guide that allows the Driver to control the Cuff inflation/deflation timing.
- ▶ **The Driver** moves air in and out of the Cuff and is powered by a small rechargeable battery or electrical outlet. The Driver is carried inside a specially designed bag for ease of portability.

## How is the C-Pulse System designed to improve heart function?

The C-Pulse System is designed to assist your heart to pump blood by reducing the workload for the heart, while increasing blood flow to the heart muscle. The C-Pulse System does not replace the heart function, but rather is designed to assist the heart in doing its job.

## How is the C-Pulse System implanted?

To implant the C-Pulse System, the cardiac surgeon will make an incision in the chest and wrap the C-Pulse Cuff around the aorta, while attaching the ECG Sensing Lead to the outside of the heart. The surgeon does not make an incision on the heart itself or to any major vessels. Therefore, the heart is beating during the surgery and a heart-lung bypass machine is not necessary.

## How long is the hospital stay after the procedure?

The expected stay after surgery is 7 - 14 days. Prior to discharge, you and your caregiver will be taught how to handle the Driver and care for the exit site dressings. Discharge from the hospital is determined by your doctor based on your medical condition.

## Are blood thinners required after the procedure?

No. Since the C-Pulse System does not come in contact with your blood stream, blood-thinning medications are not required. Your doctor will determine what medications you will be taking after the implant surgery.

## Do I need to be connected to the C-Pulse System all the time?

Since the C-Pulse System works to assist the heart, rather than “replacing” the heart function, the system can safely be turned off and disconnected for short periods of time. However, your doctor will request that you stay connected to the C-Pulse System at all times except for personal hygiene.

## Can I have the C-Pulse System implanted if I already have a cardiac resynchronization device, or an implantable cardioverter defibrillator?

Yes, the C-Pulse System may be used in combination with other approved devices and/or medications for treating heart failure.

## The COUNTER HF Clinical Study

Doctors from up to 40 centers throughout North America are conducting a clinical research study to evaluate the safety and effectiveness of the C-Pulse System for the treatment of moderate to severe heart failure.

### Step 1: Screening Phase

To be eligible for the COUNTER HF Study, you must meet specific study criteria. These criteria have been carefully selected to include those patients most suitable for the study. During the screening phase, your doctor will review your overall health, health history, and current heart medications. In addition, you will be asked to have a chest x-ray and CT scan to examine the condition of your aorta (if you have not had one recently). Following this, you will be asked to complete a few additional standard tests and questionnaires to confirm your eligibility for the study.

### Step 2: Treatment Phase

If you meet all of the criteria for the study and decide you are ready to participate, you will be placed into one of two groups – the C-Pulse Group or the Optimal Medical Therapy Group. Your group assignment is determined at random, like flipping a coin.

- ▶ **If you are assigned to the C-Pulse Group (50% chance)**, you will be scheduled for your surgery to receive the C-Pulse System. Following your surgery, you will meet with your study doctor a minimum of 6 times over the next 2 years for study purposes (you will continue to see your doctor regularly for medical care). During these visits, you will be asked about your recent medical history and will complete questionnaires and tests to monitor your condition. Also during these visits, your C-Pulse System will be checked to ensure optimal performance and usage. Following your 2-year visit, you will continue to meet with your study doctor once every year over the next 3 years to further monitor your overall health and heart condition.
- ▶ **If you are assigned to the Optimal Medical Therapy Group (50% chance)**, you will not undergo surgery to implant the C-Pulse System. However, your study doctor will work closely with you to review your current heart medications, and possibly recommend changes to certain medications in an effort to further optimize your therapy. As part of the study you will meet with your study doctor a minimum of 6 times over the next 2 years for study purposes (you will continue to see your doctor regularly for medical care). During these visits, you will be asked about your recent medical history and will complete questionnaires and tests to monitor your condition. Following your 2-year visit, you will continue to meet with your study doctor once every year over the next 3 years to further monitor your progress.

## Who is eligible for the COUNTER HF Study?

If you meet the following criteria, you may be a potential candidate for the COUNTER HF Study. However, please note that only your study doctor can determine your eligibility.

- ✓ Class III or early Class IV heart failure
- ✓ Ejection fraction  $\leq 35\%$
- ✓ Taking appropriate HF medications as prescribed by your doctor
- ✓ Have been evaluated for CRT or ICD therapy

## Can I receive the C-Pulse System without joining the COUNTER HF Study?

No, the C-Pulse System is an investigational device and is currently available in North America only through the COUNTER HF Study.

## Can I pursue other treatments for my heart failure during the study?

Regardless of whether you are in the C-Pulse group or the optimal medical therapy group, your participation does not keep you from receiving other treatment options. Your study doctor will closely monitor your specific condition and recommend these options if necessary.

It is important to know that all clinical studies involve some risks (complications or side effects from the study treatment). Prior to joining the study, your doctor will discuss the risks and potential benefits with you in detail to help you decide whether this study may be right for you.



CAUTION: C-Pulse is an Investigational device. The device is limited by Federal (or United States) Law to Investigational use only. It is not available for sale in the United States.

C-Pulse is a registered trademark of Sunshine Heart, Inc.

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