



The C-PULSE[®]
Heart Assist System
For Treating Heart Failure

Patient Information



CAUTION: C-Pulse is an investigational device. The device is limited by federal (United States) law to investigational use only. It is not available for sale in the United States.

What is Heart Failure?

Heart Failure (HF), is a progressive disease that makes the heart weak or stiff, leaving the heart unable to pump normally or supply enough blood to meet the body's needs. As a patient's HF gets worse, the heart grows larger and larger since it must work harder to pump the blood needed for the body to function properly. These patients usually have shortness of breath, low blood pressure, extra fluid and may become tired with normal activities.

Who is affected by Heart Failure?

About 5 million people in the United States have Heart Failure (HF). Each year there are 500,000 new cases reported. Among those currently diagnosed with Heart Failure, approximately 1.4 million are Class III (Moderate HF). Unfortunately, even with the medications available today in this area and other surgical options, many patients continue to get worse.

What are the causes of Heart Failure?

Common causes of Heart Failure include: heart attack; high blood pressure; heart muscle infection; lung disease; diabetes and valvular disorders. Sometimes the exact cause of Heart Failure is unknown.

How do I know how bad my Heart Failure is?

The severity of Heart Failure depends on how well your heart is still able to pump blood to your body. There are four (4) levels of Heart Failure that are based on standards from the New York Heart Association or NYHA. The NYHA guidelines are shown below.

NYHA Class	Patient Symptoms
Class I (Mild)	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
Class II (Mild)	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.
Class III (Moderate)	You have a great amount of limit to 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.
Class IV (Severe)	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.

What is the C-Pulse System for treating Heart Failure?

The C-Pulse System is a new Heart Assist Device that is currently being studied in seven hospitals in the United States under the Food and Drug Administration (FDA) guidelines. Patients must meet the study requirements and only doctors that have been approved to participate in the study may use the System.

THE C-PULSE SYSTEM

How does the C-Pulse System work?

The C-Pulse System's Cuff wraps around the outside of the ascending aorta, much like a blood pressure cuff around your arm. A balloon inside the Cuff inflates and deflates in time with the heart's pumping.

The C-Pulse System pumps in rhythm with the natural heart beat. A pacemaker wire is used to monitor signals from the heart and to assist with the timing of the balloon inflating and deflating. The balloon inflates to help push blood to the body and the arteries of the heart. When the cuff deflates it may reduce the work needed for the heart to pump the blood out.

The C-Pulse is designed to improved heart function in three ways:

1. To provide more blood flow from the heart, called increased cardiac output
2. To provide more oxygen-rich blood going to the heart muscle, called increased coronary blood flow
3. To reduce the work for the heart, called decreased afterload

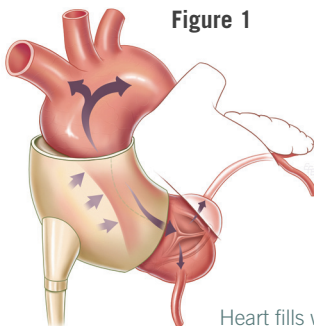


Figure 1

Heart fills with blood then the cuff inflates

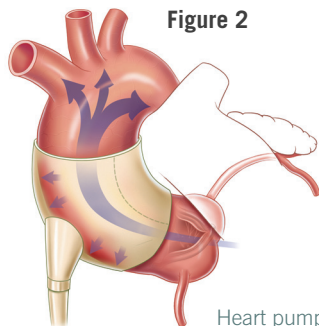


Figure 2

Heart pumps as the cuff deflates

How is the C-Pulse System designed to improve the way the heart functions?

As the heart fills with blood, the C-Pulse Cuff inflates to push blood from the aorta to the rest of the body then to the heart muscle and to the coronary arteries. Just before the heart pumps, the C-Pulse Cuff deflates to open up the aorta and reduce the heart's workload. This allows the heart to pump with less effort.

How does the surgeon implant the C-Pulse System?

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. 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 will I be in the hospital after the implant of the C-Pulse System?

Following surgery, the expected stay in the ICU is 2-3 days. The stay on the ward is usually 7-14 days. Prior to discharge, you and your care-giver will be taught how to handle the Driver and care for the exit site dressings. Discharge from the hospital will be determined by your Surgeon and Cardiologist based on your medical condition and your ability to walk without aid for short distances.

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 Heart Failure Cardiologist will determine what medications you will be taking after the implant surgery.

Will I always need to be connected to the C-Pulse System Driver?

For the study, you are asked to be connected to the C-Pulse System approximately 20 hours a day. You may safely disconnect for short periods of time, however, it is recommended that you not be disconnected for longer than 15 minutes at a time or you may see a return of your Heart Failure symptoms, such as shortness of breath.

THE C-PULSE SYSTEM COMPONENTS

The C-Pulse System includes several major parts (see figure 3).

- The Cuff wraps around the aorta and is connected to the Driver (the pump) by a tube that passes through a small hole in the skin.
- The Driver moves air in and out of the Cuff and may be powered by a small rechargeable battery or an electrical outlet.
- The Battery and Driver can be worn on a belt or placed inside a System carrying bag.

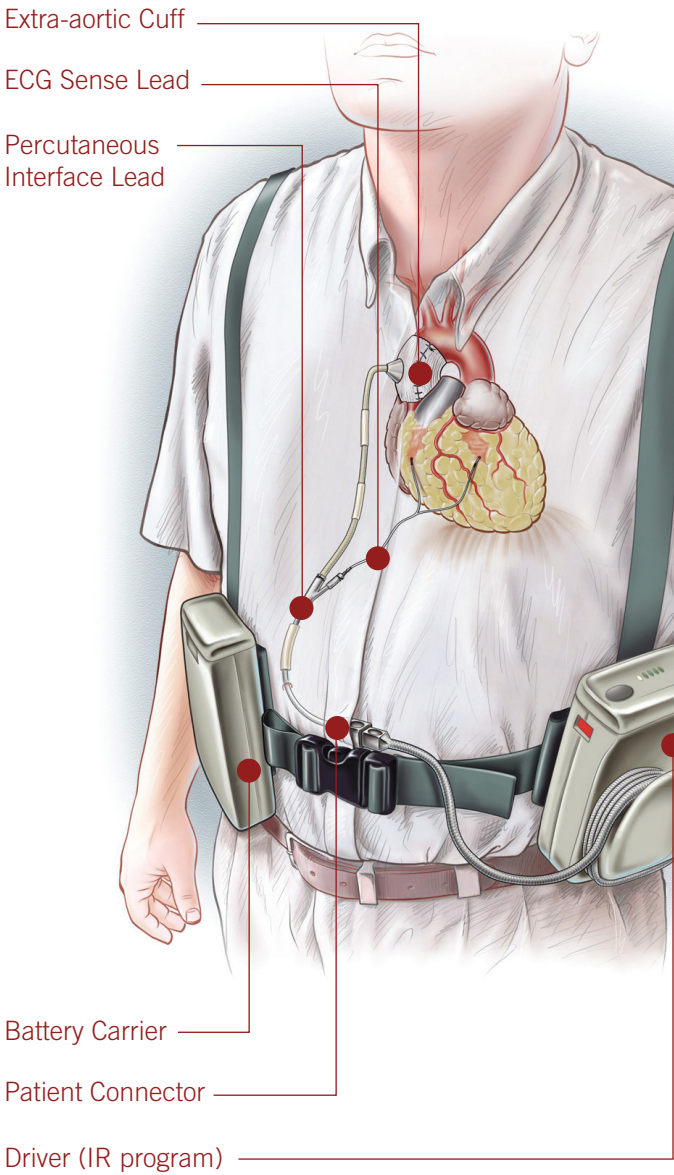


Figure 3
C-Pulse System
components

Extra-aortic Cuff

ECG Sense Lead

Percutaneous
Interface Lead

Battery Carrier

Patient Connector

Driver (IR program)

Who qualifies to participate in this clinical trial?

Your doctor will determine if you are a suitable candidate for the clinical trial by using the FDA approved study criteria. Your doctor will first evaluate your medical history to determine if you are a possible candidate.

You will then be given detailed information about the C-Pulse System, how it is implanted and how it works. You will also be given information about what to expect during the trial, such as what tests and visits are required. You will have time to ask questions and talk with your family. If you decide to participate in the trial, you will be asked to sign a consent form. The doctor will help you understand the consent form, the study testing, device and surgical risks, possible benefits and the study requirements. If your doctor determines you meet all of the study criteria, you will see the surgeon and the surgery will be scheduled.

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