The Counter HF™ Clinical Study for Heart Failure

CAUTION: C-Pulse is an investigational device. It is limited by Federal (or United States) Law to investigational use only.
Agenda

- Heart Failure
- C-Pulse® Heart Assist System
- Counter HF™ Clinical Study
What is Heart Failure?

• **Heart Failure**, also known as congestive heart failure (CHF), means your heart cannot pump enough blood to meet your body’s needs

• The heart muscle becomes weak and works harder to keep blood flowing to the rest of your body
Heart Failure Symptoms

- Feeling tired and weak
- Shortness of breath
- Reduced ability to walk or exercise
- Swelling of legs and ankles
How Common is Heart Failure?

- Affects over 5 million Americans¹
- Each year 500,000 new cases are reported¹
- 1.2 million suffer from moderate or Class III heart failure¹,²
- Responsible for more than 1 million hospitalizations in the United States each year³
- Many people are not aware they have it because symptoms are mistaken for aging

# Heart Failure Classifications

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>Patients with Cardiac Disease – Description of HF Related Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (Mild)</td>
<td>You have no limits on daily activities. You are able to do all your normal daily activities without becoming tired, short of breath, or having heart palpitations.</td>
</tr>
<tr>
<td>Class II (Mild)</td>
<td>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.</td>
</tr>
<tr>
<td>Class III (Moderate)</td>
<td>You are very limited in your daily activities. You are comfortable at rest, but unable to do your daily activities without becoming tired, short of breath, or having heart palpitations.</td>
</tr>
<tr>
<td>Class IV (Severe)</td>
<td>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.</td>
</tr>
</tbody>
</table>
Heart Failure Treatments

• Heart failure is a serious illness that can affect how long you live

• Proper treatment and careful management can help you feel better and live longer

• In general, your treatment will depend on your NYHA classification and underlying medical condition

• Your doctor will help determine the best treatments for your heart failure condition
Heart Failure Treatments

• Lifestyle changes

• Heart medications

• Surgery for correctable problems:
  ‣ Coronary artery bypass
  ‣ Balloon/stents
  ‣ Heart valve repair or replacement

• Implantable devices
  ‣ Cardiac resynchronization therapy (CRT, CRT-D)
  ‣ Implantable Cardioverter Defibrillator (ICD)
  ‣ Left ventricular assist device (LVAD)

• Heart transplant (reserved for NYHA Class IV)
C-Pulse Heart Assist System

- Investigational treatment designed for patients with moderate to severe heart failure

- Implanted system that is intended to help the heart pump blood

C-Pulse cuff and balloon

C-Pulse Driver

Note: Images not to scale
C-Pulse System Components

- Extra-Aortic Cuff
- ECG Sensing Lead
- Interface Lead
- Driver
The Cuff wraps around the outside of the ascending aorta. It inflates and deflates in time with the heart’s pumping motion, using information from the Sensing Lead that monitors the heart’s rhythm.

When the cuff inflates, it produces a surge of blood that flows to the heart muscle.
C-Pulse System - Potential Benefits

C-Pulse is designed to treat HF symptoms by:

- Reducing the workload of the heart
- Providing more oxygen-rich blood going to the heart muscle
- Improving overall heart function
C-Pulse System - Potential Benefits

✓ Allows you to remain active when in use

✓ Blood thinner medications not required unless otherwise indicated by your doctor

✓ “Assists” heart rather than “replaces” heart - device can be disconnected if needed

✓ Has the potential to reduce the need for hospital visits resulting from your HF condition

✓ Has the potential to delay the progression of your HF condition
C-Pulse System - Potential Risks

Some potential risks associated with participation in this clinical study include:

- Risks related to the screening tests and procedures
- Risks related to the surgery to implant the device including general anesthesia and the surgical procedure itself
- Risks related to the investigational device
- There may be additional risks, which are unknown

More information on potential risks is provided in the Informed Consent Document. Your doctor will discuss these with you.
An incision is made in the chest and the Cuff is wrapped around the aorta. The Sensing Lead is attached to the outside of the heart. No incisions are made into the heart and a heart-lung bypass machine is not required.

Q. How long is the hospital stay after the procedure?
A. 7 to 14 days. You and your caregiver will be educated on how to manage the Driver and care for the exit site dressings. Your doctor will determine your discharge date, based on your medical condition.

Q. Are blood thinners required after the procedure?
A. No. The C-Pulse System does not come in contact with the blood stream, you are not required to be on blood thinners. Your doctor will determine what medications are needed after your surgery.
C-Pulse System FAQs

Q. Do I need to stay connected to the C-Pulse System at all times?

A. Because the system works to “assist” the heart and not “replace” the heart function, it can be safely disconnected for short periods of time. However, your doctor will want you to stay connected to the system at all times except for personal hygiene.

Q. Can I have a CRT, CRT-D, or ICD device if I have the C-Pulse System implanted?

A. Yes. The C-Pulse System can be used in combination with other approved devices and/or medications for treating heart failure.
The COUNTER HF Clinical Study

- Study to evaluate the safety and effectiveness of the C-Pulse System for the treatment of moderate to severe heart failure
- Up to 40 clinical sites in North America are participating in the study
- Up to 388 patients will be enrolled in the study
COUNTER HF Study Phases

Screening & Eligibility
- Eligibility qualifications
- Chest X-ray and CT scan information
- Standard tests and questionnaires to confirm eligibility

Randomized Treatment
- C-Pulse Group (50% chance)
- Optimal Medical Therapy Group (50% chance)

Study Follow-up
- Doctor visits 6 times over first 2 years for study purposes
- Doctor visits once/year for next 3 years for study purposes
Key Qualification Criteria

✓ Class III or early Class IV heart failure

✓ Left ventricular ejection fraction (LVEF) ≤ 35%

✓ Taking appropriate HF medications as prescribed by your doctor

✓ Have been evaluated for CRT, CRT-D, or ICD therapy
COUNTER HF Study FAQs

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

A. No, it is an investigational device and is only available through this study to those that are randomized to the C-Pulse System group.

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

A. Yes, your doctor will closely monitor your condition and recommend other HF treatments if necessary.
Further Information

To learn more about the COUNTER HF Clinical Study, and to see if you might qualify, please contact: