C-Pulse®
Heart Assist System
Counterpulsation System for the Treatment of
Moderate to Severe Heart Failure

Information for Medical Professionals
Heart Failure
Heart failure affects over 5 million Americans and is responsible for more than 1 million hospitalizations in the United States each year.\textsuperscript{1,2} It is a costly disease, with an estimated $32 billion associated with it in the United States.\textsuperscript{1} Patients with heart failure have a poor quality of life, and many with advanced heart failure have few effective treatment options. Heart failure is associated with a poor prognosis with almost 50% dying within 5 years of diagnosis.\textsuperscript{3,4} It is estimated that 1.2 million Americans suffer from moderate (NYHA Class III) heart failure.\textsuperscript{1,5}

What is the C-Pulse\textsuperscript{®} 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 the heart to pump blood, rather than “replacing” the heart function, and can be disconnected for short periods as required.

How does the C-Pulse System work?
The C-Pulse consists of a polyurethane balloon and a polyester wrap fitted to conform to the ascending aorta. The C-Pulse System pumps in counterpulsation to the intrinsic heartbeat. The Cuff deflates prior to systole, reducing afterload. The Cuff is timed to re-inflate during diastole, increasing perfusion to the coronary arteries. The bipolar epicardial ECG sensing lead is attached to the heart for timing.

The C-Pulse System “assists” the heart rather than “replaces” it; allowing the device to be turned off if needed. Patients can remain active while it is in use. Anticoagulation medications are not required because the system is placed outside the bloodstream. It may be implanted in a minimally invasive procedure during off pump bypass surgery.

For More Information
To learn more about the COUNTER HF Clinical Study, or to refer a patient, please contact us:

What is the C-Pulse System designed to do?

The C-Pulse System is designed to improve heart function by decreasing left ventricular afterload and increasing coronary perfusion. If the C-Pulse System is able to improve the function of the heart, it has the potential to reduce the need for hospital level care and delay the progression of the disease. It could also help reduce symptoms related to heart failure and improve quality of life.

The Extra-Aortic Cuff wraps around the ascending aorta and is connected to the Driver (the pump) by a percutaneous interface lead that passes through a small hole in the skin. The percutaneous Interface Lead is connected to the ECG Sensing Lead as a timing guide, allowing the Driver to control Cuff inflation/deflation timing. The Interface Lead is also connected to the Cuff to provide an airline to inflate/deflate the Cuff.

The Driver moves air in and out of the Cuff balloon and is powered by a small rechargeable battery or electrical outlet. The Driver is carried inside a specially designed bag for ease of portability.

Secondary Objectives

To demonstrate the superiority of C-Pulse therapy as compared to OMT in improvement in the following categories (mean values):

- 6MHW
- LVEF
- Total number of days hospitalized for worsening heart failure
- Total days alive out of the hospital for worsening heart failure relative to the total observed follow-up days
- KCCQ scores

Principal Investigator and Clinical Advisors

- National Principal Investigators:
  - William Abraham, MD (Cardiology)
    The Ohio State University Medical Center
  - Margarita Camacho, MD (Surgical)
    Newark Beth Israel Medical Center

- Clinical Surgical Advisor:
  - Benjamin Sun, MD
    Minneapolis Heart Institute

- Clinical Heart Failure Advisor:
  - Jeffrey Teuteberg, MD
    University of Pittsburgh Medical Center

COUNTER HF Trial - Primary Objectives

- Primary Efficacy Endpoint
  Evaluate the efficacy of the C-Pulse therapy by measuring freedom from worsening heart failure events resulting in hospitalization, LVAD implantation, cardiac transplantation or death as compared to OMT.

- Primary Safety Endpoint:
  The number of all serious procedure, device, or therapy related adverse events as determined by Clinical Event Committee adjudication.
C-Pulse® System Feasibility Study Results

The C-Pulse System was evaluated in a feasibility study. A total of 20 subjects were enrolled at 7 North American centers. The subjects in the study had the following clinical characteristics: NYHA Class III or ambulatory Class IV; LVEF ≤ 35%; on optimal medical therapy and had either a cardiac resynchronization (CRT or CRT-D) or implantable cardioverter defibrillator (ICD) device.

Primary Efficacy Findings

The table below summarizes the key efficacy parameter measures in this study. Overall, there were improvements on these parameters at 6 months. Subjects who continued on device therapy to 12 months maintained or improved in these efficacy measures.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean ± SD (p-value)</th>
<th>Baseline</th>
<th>6-month</th>
<th>12-month</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NYHA Class</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1 ± 0.3 (n=20)</td>
<td>1.9 ± 0.7 (&lt;0.0001)</td>
<td>1.9 ± 0.7 (0.0005)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MLWHF</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>64.4 ± 17.6 (n=20)</td>
<td>40.2 ± 23.2 (0.0003)</td>
<td>36.4 ± 21.7 (0.0003)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Six Minute Hall Walk (6MHW)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>275.5 ± 64.0 (n=20)</td>
<td>296.4 ± 104.9 (0.1574)</td>
<td>336.5 ± 91.8 (0.0295)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Safety Results

There were no device related strokes, myocardial infarctions or major bleeds through 12 months of follow-up. There were no deaths at 30 days. There were 8 exit site infections and one internal percutaneous lead infection. There was one aortic disruption during a re-do surgery at approximately 3 months post-implant resulting from a sternal wound infection.

Additional Observations

No subjects were re-hospitalized due to their heart failure condition during the 30 day period after the procedure. One subject was re-hospitalized for worsening heart failure through 6 months of follow-up. The use of diuretics was discontinued, reduced or unchanged in all subjects. All subjects who were on inotropes discontinued using the drug within 48 hours of the C-Pulse System implant procedure.

COUNTER HF Clinical Trial

Sunshine Heart, Inc. is sponsoring the COUNTER HF Clinical Trial. It is a prospective, multi-center, randomized trial designed to assess the safety and efficacy of the C-Pulse® System in NYHA Class III and ambulatory Class IV patients.

Key Study Qualifications

- NYHA Class III/ambulatory Class IV
- Left Ventricular Ejection Fraction (LVEF) ≤ 35%
- On optimal medical therapy and remains symptomatic
- Had been evaluated for or have CRT or CRT-D therapy and remains symptomatic or ICD therapy (narrow QRS)
- 6MHW 175 - 375 m
- At least one hospitalization for decompensated HF, while on HF medications, within 12 months prior to randomization OR BNP level > 300 or NTproBNP > 1500

Study Design

Up to 40 centers throughout North America will participate in the study. Patients will be randomized 1:1 to the C-Pulse System or Optimal Medical Therapy (OMT). Up to 388 patients will participate in the study and will be followed up to 5 years.