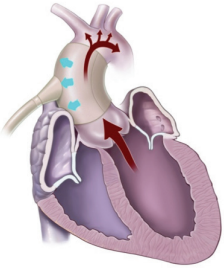
COUNTER HF
CLINICAL STUDY

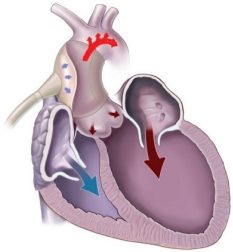
Physician Quick Guide

C-Pulse® System

The C-Pulse System is an extravascular counterpulsation device designed to improve heart function by decreasing left ventricular afterload and increasing coronary perfusion. The C-Pulse System works to assist the heart to pump blood, rather than "replacing" the heart function, does not require anticoagulation and can be disconnected for short periods of time. 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 the symptoms related to heart failure and improve quality of life.



1 Cuff deflates as the heart pumps blood, reducing workload



2 Cuff inflates as the heart refills with blood, giving a secondary pulse of blood to the heart muscle

COUNTER HF™ Clinical Trial

Sunshine Heart, Inc. is sponsoring the COUNTER HF Clinical Trial. The study is designed to assess the safety and efficacy of the C-Pulse System in patients with moderate to severe heart failure. It is a prospective, multi-center study with up to 40 centers participating throughout North America. 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 be followed up to 5 years.

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Primary Study Objectives

- **Primary Efficacy Endpoint:** Survival free 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.

Key Study Qualifications

Major Inclusion Criteria

- √ LVEF ≤ 35%
- √ NYHA Class III/Ambulatory Class IV
- √ On optimal medical therapy and remain symptomatic
- √ Evaluated for or have CRT/CRT-D but remain symptomatic or ICD (narrow QRS)
- √ 6MWT 175 to 375 meters
- √ At least one hospitalization for decompensated HF, while on HF meds, within 12 months prior to randomization OR
  BNP level > 300 or NTproBNP > 1500

Major Exclusion Criteria

- ✗ Ascending aortic calcification or ascending aorto-coronary artery bypass grafts
- ✗ Inability to wean from inotropic therapy
- ✗ Non-ambulatory NYHA Class IV
- ✗ Body Mass Index (BMI) < 18 or > 45 kg/m^2

For More Information

To learn more, or to refer a patient, please contact us at anytime: