SUNSHINE HEART

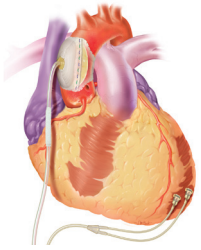
Medical Brief

Learn More About the C-Pulse® Heart Assist System for Heart Failure Patients - COUNTER HF™ Clinical Study Now Enrolling

The Technology

It is well established that a mode of circulatory support, known as counterpulsation, works by reducing the workload on the heart, augmenting heart pump function, and increasing both coronary artery and total body perfusion. Unlike LVADs, counterpulsation devices act to augment native heart function rather than replace it. Counterpulsation has two main benefits to heart function:

- When the aortic valve is closed and the balloon is inflated, diastolic pressure is increased ("diastolic augmentation"): There is augmentation of flow to the coronary arteries.
- The balloon deflates prior to systole. The reduction in impedance reduces aortic pressure and thus the workload of the heart by reducing the pressure-head which the heart has to eject against. This allows the heart to contract more vigorously and with greater efficiency.



Comparative Safety Profile

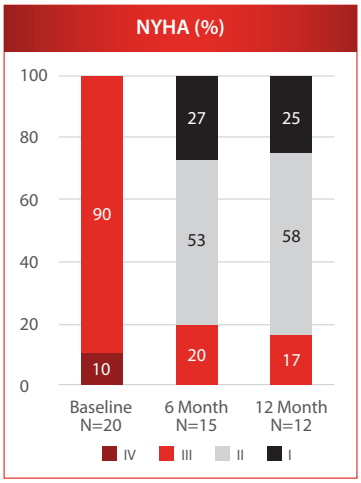
While LVADs have shown benefit to NYHA Class III and Class IV HF patients, there is growing evidence that there is a need for lower risk, lower cost devices that allow for long-term chronic therapy in less sick patients. In a feasibility study of 20 patients that received C-Pulse therapy, there were no 30-day post-operative deaths reported in the study. Additionally, there were no device related strokes, myocardial infarctions, neurological events or major bleeds through 12 months. Exit site infections accounted for the highest number of adverse events reported. Improved exit site management practices have been implemented. At 12 months, there was one adjudicated device-related death. The device-related death was attributed to complications arising from a sternal wound infection in a patient who underwent repeated sternotomies and attempted sternectomy.

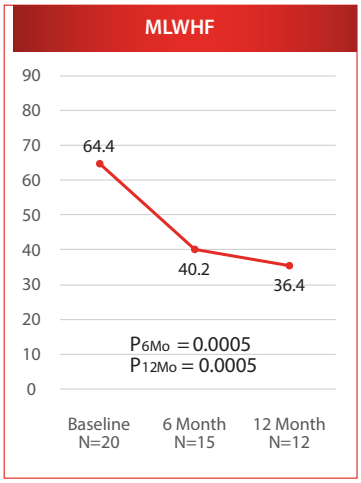
The Device in Trial

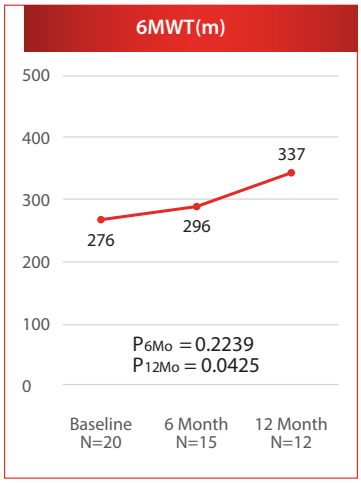
The C-Pulse® Heart Assist System for patients in the COUNTER HF™ Clinical Study takes advantage of counterpulsation benefits, yet the device is extra-vascular and can be implanted through a minimally invasive surgical procedure. The device consists of a polyurethane balloon and a polyester wrap fitted to conform to the ascending aorta. As 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 system uses a bipolar epicardial ECG sensing lead which is attached to the heart for timing.

Efficacy Findings

Overall, most subjects saw improvements at six months with the C-Pulse System. Those who continued on device therapy maintained or improved their efficacy at 12 months.







COUNTER HF™ CLINICAL STUDY

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Device Features

The C-Pulse Heart Assist System features:

- Simple technology that takes advantage of counterpulsation therapy
- Minimally invasive surgery
- Extra-vascular system, no anti-coagulation therapy required
- Ability for patient to safely disconnect the unit for brief periods of time

Trial Now Enrolling

Sunshine Heart, Inc. is sponsoring the COUNTER HF Clinical Study to assess the safety and efficacy of the C-Pulse System in NYHA Class III and ambulatory Class IV patients.

Patient Profile

Patient qualifications for the COUNTER HF Clinical Study include:

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

Patient Testimonial

Emmette from Fort Deposit, Alabama, was diagnosed with NYHA Class IV Heart Failure and received C-Pulse therapy for eleven months. After significant improvement, he was weaned from the device and has been without it for more than three years.

"The very first time that I got C-Pulse, I stopped having feelings where I couldn't breathe," explained Emmette. "I knew something was getting better before I even left the hospital. I started walking up the street, blocks, and I'd find out I can walk another block...I just started walking and realized I wasn't short of breath. It got so much better, I felt like I didn't have heart problems."

To learn more about the potential to refer patients for participation in the COUNTER HF Clinical Study, visit www.sunshineheart.com.

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