The C-Pulse® Heart Assist System

Non-blood contacting, therefore patients do not require anticoagulation medication

Unlike LVAD, the system is non-obligatory allowing patients to disconnect for short periods of time contributing to a better quality of life

May be implanted through a minimally invasive lateral thoracotomy

C-Pulse® Heart Assist System

Counterpulsation System for the Treatment of Moderate to Severe Heart Failure

Key Attributes of the C-Pulse System

- Non-blood contacting, therefore patients do not require anticoagulation medication
- Unlike LVAD, the system is non-obligatory allowing patients to disconnect for short periods of time contributing to a better quality of life
- May be implanted through a minimally invasive lateral thoracotomy

Mechanism of Action

Supports Myocardial Perfusion: The ascending aorta acts as reservoir for the heart to eject blood into. The inflation of the C-Pulse balloon during diastole creates a second pulse, increasing coronary flow and perfusion through the body.

Influence on Aortic Baroreceptors: Previous studies using the intra-aortic balloon pump have shown hemodynamic effects which have been attributed to stimulation of baroreceptors in the aortic arch.¹ ²

Effects on Left Ventricular Wall Stress: Preliminary results of the C-Pulse therapy have shown to reduce arterial afterload in the ascending aorta leading to improved cardiac performance through increased velocity of shortening of the left ventricle.³

NYHA Class III Heart Failure Treatment Gap

Unmet Need

Optimal Medical Therapy

CRT / ICD

Unmet Need

C-Pulse

LVAD / Heart Tx

NYHA Class III

NYHA Class IV

NYHA Class IV (± other devices)

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 on 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

Caution: C-Pulse is an Investigational device. The device is limited by Federal (United States) Law to investigational use only.

Sunshine Heart, Inc. is sponsoring the COUNTER HF Clinical Study. 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. Subjects will be randomized 1:1 to the C-Pulse System or Optimal Medical Therapy (OMT). Up to 388 subjects will participate in the study and be followed up to 5 years.

Primary Study Objectives

➤ Primary Efficacy Objective: Survival free from worsening heart failure events resulting in hospitalization, LVAD implantation, cardiac transplantation or death as compared to OMT.

➤ Primary Safety Objective: Evaluate freedom from serious adverse events that are adjudicated as definitely related to device, therapy or procedure and resulting in either surgical intervention or death.

References

³Leggett et al. 112:1-26. 2005