

Full Title OPTIMIZER Smart Post-Approval Study

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Study Objectives The purpose of this post approval study (PAS) is to evaluate the safety of the long-term use of the OPTIMIZER Smart device and Cardiac Contractility Modulation therapy on the quality of life and heart failure symptoms for patients who remain symptomatic despite optimized guideline directed heart failure medications.

Inclusion Criteria Individuals must meet all of the following inclusion criteria to be eligible to participate:

- Patient or legally authorized representative provides written authorization and/or consent per institution and geographical requirements
- Male or non-pregnant female, aged 18 or older
- Left ventricular ejections fractions of 25-45% (inclusive)
- NYHA Class III heart failure symptoms
- Stated willingness to comply with all study procedures and availability for the duration of the study
- Patient has been treated with guideline-directed heart failure therapies with stable doses for at least 1 month

Exclusion Criteria

- Infiltrative or inflammatory cardiomyopathy (e.g., amyloid, hemochromatosis, myocarditis, hypertrophic cardiomyopathy, Fabry disease, cardiac tumor)
- Primary heart failure due to uncorrected mitral valve disease, or mitral valve repair or clip within 3 months of enrollment



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- IV inotropes, hemofiltration, or any form of positive inotropic support within 30 days before enrollment, including continuous IV inotrope therapy
- Myocardial infarction within 3 months of enrollment
- Undergone a CABG procedure within 3 months or a PRCA procedure within 30 days of enrollment
- Persistent (>7 days) or permanent (>1 year) atrial fibrillation or atrial flutter, or cardioverted within 30 days of enrollment
- Prior heart transplant, ventricular assist device, or mechanical tricuspid valve
- Receiving cardiac resynchronization therapy (CRT) or has a Class I indication for CRT implantation according to the ACCF/AHA/HRS guidelines for device-based therapy
- Currently on dialysis or undergoing treatment for cancer

Affiliations & Sponsors

Impulse Dynamics (USA), Inc.

Status

Open to Enrollment

Keywords

CHF, CMM, NYHA Class III, Quality of Life, congestive heart failure