1. ***CCM*® Therapy delivered by the Optimizer® System: Fast Facts**

The Unmet Need: Heart Failure

- Heart failure affects an estimated 6.5 million Americans and nearly 26 million people worldwide.[1]
- By 2030, heart failure is expected to affect 8 million Americans.[2]
- Heart failure is a condition in which the heart slowly weakens and is not able to pump with the force required to supply oxygen-rich blood to meet the body's needs.
- Patients with heart failure experience debilitating symptoms including breathlessness, fatigue, confusion, and swelling in the legs that make everyday activities challenging and significantly diminishes their quality of life.
- Traditional treatments for heart failure provide limited, or no, improvement to the heart's pumping forcefulness and nearly 50 percent of people with heart failure die within five years of being diagnosed.[2]
- Today, most heart failure patients are prescribed medications intended to slow the progression of the disease and manage their symptoms.
- As the condition progresses, these treatments lose their effectiveness and the quality of life for heart failure patients will continue to decline.
- The total annual cost for heart failure is projected to reach $70 billion by 2030.[2]

***CCM*® Therapy: A Breakthrough Approach**

- ***CCM***® therapy is delivered by the Optimizer®, a minimally invasive, implantable device. The innovative therapy is the first of its kind designed to improve contraction of the heart, allowing more oxygen-rich blood to reach the body.[3]
- Studies evaluating the FDA-approved therapy have demonstrated the device is safe and is proven to improve quality of life for suitable patients.[3]
- The Optimizer delivers ***CCM***® therapy, or cardiac contractility modulation, the company's proprietary technology, to the heart.[3]
- ***CCM***® therapy delivers precisely timed electrical pulses to the heart during the absolute refractory period of the beating cycle, just after the heart contracts.
- The approach was proven to be safe and effective in numerous clinical studies, including several randomized controlled trials, and the results have been published in over 80 articles appearing in leading medical journals.[4]
- The Optimizer system was granted Breakthrough Device designation by the FDA and is the first and only FDA-approved (March 2019) device in the United States or elsewhere for the delivery of ***CCM***® therapy.
- The Optimizer has been used to treat over 4,500 patients and is currently available in the United States, Europe (obtained CE Mark in October 2016), China, Brazil, India and more than 40 other countries around the world.

***CCM*® Therapy: A New and Effective Option for Millions of Heart Failure Patients**

- ***CCM***® therapy is a breakthrough that has the potential to improve the lives of the large number of heart failure patients who continue to experience symptoms despite receiving medical therapy.[3]
- The therapy is a new option that improves quality of life for patients that are no longer adequately responding to medications to manage symptoms or slow the progression of heart failure.[3]
- ***CCM***® therapy may be an appropriate treatment option for the approximately 70 percent of NYHA Class III heart failure patients who remain symptomatic despite guideline-directed medical therapy.[3]

How it Works:

- The Optimizer device is similar in size to a pacemaker and is implanted during a minimally invasive procedure while the patient is under light sedation.
- During the procedure, the device is implanted under the skin of the upper chest, along with electrical leads that are placed in the heart's right ventricle through the veins (transcatheter).
- After the procedure, the physician programs the delivery of ***CCM***® therapy for each patient and activates the device.
- The implanted device then sends electrical pulses to the heart muscle for a total of five hours a day, in one-hour treatments separated by regular intervals.

- From the comfort of their home, the patient charges the device each week for one hour using an external charger.
- The Optimizer has been rigorously tested and it is expected to provide ***CCM***® therapy for up to 15 years before requiring replacement.

Is Optimizer® like a pacemaker or defibrillator?

- In some ways yes, for example, both are implanted under the skin of the upper chest, and they each use leads to deliver therapy to the heart muscle. But that's where the similarities end.
- Unlike a pacemaker or defibrillator, Optimizer® devices deliver ***CCM***® therapy during the non-excitatory or absolute refractory period of the cardiac cycle. Instead of actually causing a contraction, ***CCM***® therapy is designed to cause subsequent beats of the heart to be stronger or more forceful, which can result in more oxygen rich blood to be delivered to the body with each beat.
- A pacemaker is used to treat slow heart rhythm disturbances which are symptomatic. Defibrillators can do that and can deliver lifesaving therapy when/if patients experience life-threatening electrical disturbances called arrhythmias. Cardiac contractility modulation is used to treat patients with heart failure to make their hearts beat stronger and make them feel better.

Impulse Dynamics: Determined to Improve the Lives of Heart Failure Patients through *CCM*® Therapy

- Impulse Dynamics is dedicated to improving the lives of people with heart failure by transforming how the condition is treated.
- ***CCM***® therapy (cardiac contractility modulation), which is delivered by the company's Optimizer system, a breakthrough, FDA-approved treatment that is proven to improve the quality of life for heart failure patients.[3]
- ***CCM***® therapy is a safe and effective minimally invasive treatment option for many heart failure patients who otherwise have few effective options available to them.[3]
- The company is headquartered in Marlton, New Jersey, and has offices in Pearl River, New York, and Stuttgart, Germany.
- To learn more visit www.impulsedynamics.com, or follow the company on LinkedIn and Twitter.
- The company has 95 employees.

[1] Savarese G, Lund LH. Global Public Health Burden of Heart Failure. Card Fail Rev. 2017 Apr; 3(1): 7–11.
[2] Benjamin E.J., Blaha M.J., Chiuve S.E., et al. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. Circulation 2017; 135: pp. e146-e603
[3] Abraham WT, Kuck KH, Goldsmith RL, et al. A randomized controlled trial to evaluate the safety and efficacy of cardiac contractility modulation. JACC Heart Failure. 6(10), 874-883 (2018).
[4] Clinical evidence on file: https://impulse-dynamics.com/providers/clinical-trials/