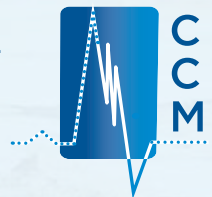


CCM[®] Therapy

An implant procedure that is designed to improve cardiac function and reduce heart failure symptoms.¹



“ I continue to struggle with my heart failure symptoms despite being on multiple medications. I feel like I don't have enough energy to do my usual everyday activities that I enjoy. ”



Approximately 5.7 million people have Heart Failure in the United States.

Heart Failure may start suddenly, and you may feel symptoms immediately, or it may start slowly and progress unnoticed for some time. Some patients do not realize that they have heart failure because they believe that their symptoms are just indications of getting older. The condition typically starts after there is some sort of injury to the heart (e.g. a heart attack), and over time, the unusual stresses placed on the heart cause the disease to progressively worsen. The heart can be affected in two ways, either becoming weak and losing the ability to pump enough blood on each beat, or it can become stiff and unable to adequately fill with blood before each beat. In either case, the heart may reach the point where it is unable to pump enough blood to the body's organs and tissues. When the body cannot get enough blood, adequate supplies of oxygen and nutrients cannot be delivered, and symptoms will start to emerge.

Your symptoms may include:

- Shortness of breath
 - Fatigue and weakness
 - Swelling in your abdomen or lower extremities
 - Rapid weight gain from fluid retention
-



The OPTIMIZER® Implantable Pulse Generator (IPG) is a programmable device that delivers electrical impulses to the heart muscle, **CCM**® therapy, or cardiac contractility modulation, was designed to increase the contractility (squeeze) of the heart and improve quality of life. The electrical impulses are delivered to the cardiac tissue at specific times throughout the day and has been studied to show benefits in patients with NYHA Class III, with an ejection fraction of 25% – 45%, and that are not indicated for Cardiac Resynchronization Therapy.

Optimizer® Safety

In more than **800** patients included in randomized studies, as well as **5,500** patients in registries and regular use, **CCM**® has been shown to offer meaningful benefits to heart failure patients. **CCM**® reduces symptoms caused by heart failure and improves quality of life in patients with NYHA Class III and LVEF 25-45%.

The Optimizer® was the first therapeutic device alternative for select NYHA Class III patients that remain symptomatic despite guideline directed medical therapy (GDMT), and that are not indicated for cardiac resynchronization therapy (CRT).

CCM[®] Implant Procedure Overview

The Optimizer[®] IPG is implanted via a minimally invasive procedure (usually under local anesthesia) by a cardiologist or other qualified implanter.

Here's what happens during the procedure.⁴

1



To implant the Optimizer[®] your doctor makes a small incision in your upper chest area (just below the collar bone) and creates a "pocket" where the device will be placed.

2



A lead is an insulated wire that is connected to the pulse generator on one end, with the other end placed against the center wall (septum) of the heart. The lead delivers electrical impulses to the heart when the heart is not "excitable" or able to accept any signal. This energy that is delivered to the "cardiac muscle" is designed to increase contractility or force of the heart beat.

3



The procedure is done under local anesthesia and you will be awake during the implant procedure. Patients who get the Optimizer[®] device usually stay in the hospital overnight and go home the next day.

4

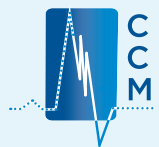


You should be able to return to your daily routine within a few days. Your doctor will tell you if you will need to take more time in returning to your normal activities. You should not do any lifting or pulling on anything for a few weeks. You may be instructed to limit movement of the arm on the side that the Optimizer[®] was placed, based on your doctor's preferences.

5



Once you are home, you need to charge your Optimizer device once per week. You will be given a charger device. It is very easy and you can even do this sitting in your favorite chair, watching a television show you enjoy! Simply lay the wand over your device and start charging.



Is CCM[®] therapy right for you?

Questions to help determine if **CCM[®]** therapy is right for you or your loved one

Has your doctor told you that you have a weakened or failing heart and prescribed you medications for it?

Have you experienced any of the following?

- Difficulty breathing
- Trouble climbing a flight of stairs
- Fatigue or tiredness during the day
- Swelling in your legs

Do your symptoms make it hard for you to accomplish your normal daily activities?

Do you have an ejection fraction (a measurement of the heart's pumping efficiency) of 25%-45%?

If you answered yes to a majority of these questions, **CCM[®]** therapy may be right for you or your loved one.

*Please note that if you have a mechanical tricuspid valve, or are someone that has issues with vascular access (Leads cannot be implanted or obtained) then **CCM[®]** may not be the right solution for you.*

Visit our website at <https://ccm.impulse-dynamics.com> to find out if **CCM[®]** is for you and to get in contact with a physician that can answer your questions.

For more information, visit our website at impulsedynamics.com or contact us at 856-642-9933.

1 Campbell CM, Kahwash R, & Abraham WT. Optimizer Smart in the treatment of moderate-to-severe chronic heart failure. *FutureCardiol.* 16(1), 13–25 (2020)

2 Creaser JW, DePasquale EC, Vandenbogaart E, Rourke D, Chaker T, Fonarow GC. I. Team-Based Care for Outpatients with Heart Failure. *Heart Failure Clin* 11 (2015) 379–405.

3 Brunckhorst CB, Shemer I, Mika Y, Ben-Haim SA, Burkhoff D. Cardiac contractility modulation by nonexcitatory currents: studies in isolated cardiac muscle. *Eur J Heart Fail* 2006; 8:7e15

4 Kuschyk J, Kloppe A, Schmidt-Schweda S, Bonnermeier H, Rousso B, Röger S. Cardiac Contractility Modulation: A Technical Guide for Device Implantation. *Rev Cardiovasc Med.* 2017;18(1):1-13.

*Indications for Use: The Optimizer[®] System, which delivers **CCM[®]** therapy, is indicated to improve 6 minute hall walk, quality of life, and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, are not indicated for CRT, and have a left ventricular ejection fraction ranging from 25% to 45%.*

