

Parameter Adjustment Period

Three to five weeks after the implantation, doctors will begin the stimulation process. The appropriate stimulation level is determined according to your comfort level and heart rate. Generally, the stimulation current is raised slowly to minimize discomfort over a period of four weeks. Fine tuning of the parameters may be conducted later in the study as required.

Long Term Treatment

Whether or not you receive the device, you will be asked to attend follow up visits every three months for the first eighteen months and thereafter every six months for a total period of up to five and a half years. During these visits you will be required to complete questionnaires and undergo similar tests to those undertaken during the evaluation stage.

ABOUT CARDIAC RESEARCH

There are many new treatments that may help people live longer and healthier lives. Clinical trials are conducted according to strict regulations to protect the rights and ensure the safety of the volunteers. Clinical studies compare new treatments to the current medical treatments. Ideally, the CardioFit® system will decrease heart failure symptoms and slow the progression of HF. The goal is to improve the heart's performance and increase the overall health and quality of life of patients.

While the treatment offered in this trial may be of benefit to you, there are no guarantees. We are committed to ensuring that this trial will provide invaluable information that will help to create better treatments in the future for patients with heart failure.

HOW TO PARTICIPATE

If you or someone you know is interested in additional information about this trial, please consult with your physician.



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AT THE HEART OF IT ALL

INOVATE-HF is seeking participants in a global clinical trial to determine the safety and efficacy of a **new approach to treating heart failure.**

CAUTION: Investigational Device. Limited by Federal (or United States) law to investigational use.



AT THE HEART OF IT ALL



Approximately 23 million people worldwide suffer from heart failure (HF), and 2 million new cases are diagnosed each year worldwide¹. The incidence of heart failure is on the rise and it is the most rapidly growing cardiovascular disorder in the United States.

If you or someone in your family has been diagnosed with heart failure, the **INOVATE-HF** trial may be of interest to you. Talk to your doctor about the possibility of participating.

WHAT IS THE INOVATE-HF TRIAL?

INOVATE-HF is a worldwide clinical trial designed to evaluate the safety and effectiveness of a new treatment for heart failure. The trial is seeking up to 650 patients, aged 18 and over, at selected group of hospitals/ medical centers across the U.S. and Europe. Our investigators are doctors who specialize in treating patients with heart failure. Potential candidates will have been diagnosed with HF and are being treated with a combination of medications, but continue to have symptoms such as shortness of breath and fatigue. In patients with heart failure the autonomic nervous system is out of balance. There are two branches of the autonomic nervous system: the sympathetic and parasympathetic. Medications can be used to treat the overactivity of the sympathetic nervous system but to date there are no medications that directly modulate the parasympathetic branch in patients with heart failure.

¹ Congestive Heart Failure: Worldwide Drug and Medical Device Market – Kalorama Information available through MarketResearch.com

THE CARDIOFIT® SYSTEM **cardiofit™**

The CardioFit® system is the investigational device being evaluated in the **INOVATE-HF** trial. The CardioFit® is designed to stimulate the vagus nerve in the neck to treat the parasympathetic branch of the automatic nervous system, which may lessen the workload on the heart and as such, may help in alleviating heart failure symptoms.

In Europe, the system has been in use within an experimental framework for over five years².

The purpose of the **INOVATE-HF** trial is to determine whether the CardioFit® system is beneficial and safe for the treatment of heart failure (HF). In addition, the trial aims to investigate whether the combination of the implanted device together with medical therapy is more effective than just medical therapy alone.

The CardioFit® system comprises of three main components:

- 1 Sensing lead is a standard pacemaker lead that passes through a vein into the right ventricle of the heart.
- 2 Stimulator: similar to a pacemaker, a small sealed case housing the electronics of the system.
- 3 Stimulation lead: flexible lead that transmits electrical signals from the stimulator to the vagus nerve.



The CardioFit® System

² Chronic vagus nerve stimulation: a new and promising therapeutic approach for chronic heart failure - Gaetano M. De Ferrari et al. European Heart Journal 2010; doi: 10.1093/eurheartj/ehq391

TRIAL PROCESS

Participation in a clinical trial is voluntary. Ask your doctor to explain the trial in detail to you. Make sure your doctor answers all your questions and explains the possible risks and potential benefits.

Prior to being accepted into the trial you will be asked to provide a full medical history and undergo a complete physical examination. Depending on what tests you have had recently, you may undergo an echocardiogram, Holter monitoring, ultrasound test of the right carotid artery, chest x-rays, blood and urine tests and a standard 6 minute walk test. In addition, you will be required to complete several questionnaires pertaining to your daily activities and health status.

3 out of every 5 patients will be randomly assigned to receive the CardioFit device; the other 2 out of every 5 patients will be randomly assigned to receive ongoing optimal medical therapy. Neither you nor your doctor can influence the group assignment; the selection is based on an independent statistical computer program that is designed to ensure that by the end of the trial 60% of patients will have received the device and 40% will not.

THREE PHASES OF THE TRIAL

The study will consist of three phases: the implant phase, parameter adjustment period, and long term treatment.

Implant Phase

During the implant phase, the active group will be implanted with the device. The procedure can be undertaken using local or general anesthesia.

Five to ten days after the procedure, you will be required to visit the clinic for a post surgery check.