

eHEART™

EXTRA VENTRICULAR ASSIST DEVICE

Company Profile



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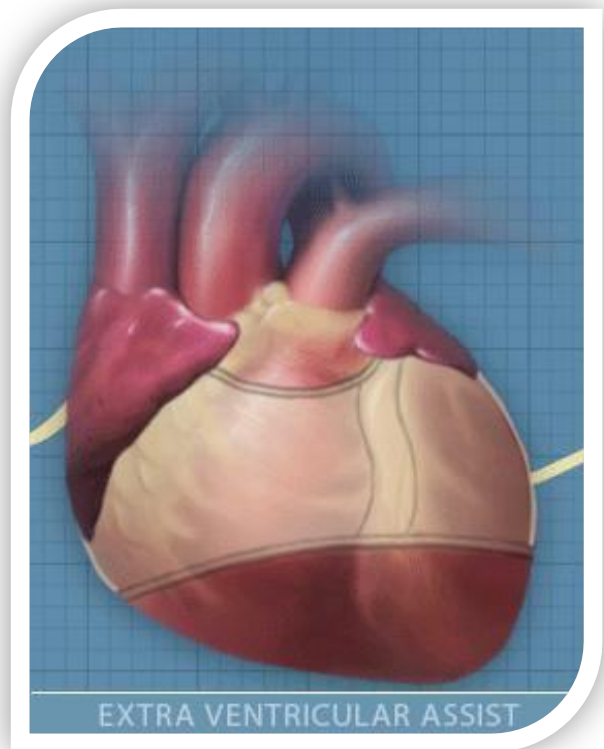
Company Profile

I. The Company

NeoCardial Technologies, LLC (“the company”) is an early-stage medical device company, founded to innovate and offer improved treatment options and results for patients suffering from late stage heart failure.

NeoCardial’s first product for commercialization, the eHeart™ will be a non-blood contact, direct compression, extra-ventricular assist device (eVAD). Implanted using a thoracotomy procedure, it provides immediate cardiac output assistance to a failing heart.

The eHeart™ minimizes the complications associated with both surgery and direct blood contact, while providing a dynamic means of sustaining circulation and physiological parameters that current and prior products have been unable to deliver.





II. Market

Cardiovascular disease kills one in three Americans. Particularly desperate is the plight of severely ill heart failure patients who have few options. The shortage of donor hearts for transplant has increased the need for functional and safe heart assist device technology. The goal of this technology should be twofold: Not only to keep patients alive, but also to extend and improve the quality of their lives.

Each year In the United States there are nearly 6 million people suffering with congestive heart failure (CHF); globally, that number doubles to 12 million. Of these patients, between 1.6 and 2 million, are in the class 3B and class 4 heart failure categories. These are patients who are still ambulatory, but no longer derive significant benefit from drugs and electrical stimulation assist devices. The drugs and devices available to patients in this category are failing to maintain adequate cardiac output, moving them toward candidacy for Ventricular assist device (VAD) assistance.

Worldwide, over 500,000 patients are in late stage Class 4 heart failure and in need of VAD assist for either Destination Therapy or to suffice as a Bridge to Transplant. A large percentage of these patients could be candidates for the eHeart™.

Annually approximately 2500 to 3000 VADs are implanted. Comparatively, 2000 to 2500 Total Heart transplants are performed in the United States. This is approximately 63% of total annual procedures worldwide. Perhaps more striking, however, is that less than 2% of the patients who could benefit from ventricular assist intervention, receive it.

For the 2 million Class 3B and Class 4 ambulatory, home bound patients, the eHeart™ will supplement native heart function by maintaining partial support on an *as-needed* basis. During the last decade several reports have indicated that earlier intervention of the less sick, class 3B, non ischemic patient, is medically justified. These patients have shown a high percentage of reverse remodeling of the heart (healing of the heart), effectively returning the patient to Class 2 and even Class 1 levels.

There still remains a significant concern among clinicians about the invasiveness of current device implant procedures, and the potential complications of direct blood contact required by most current devices. Unique to the eHeart™ is an innovative approach to addressing these issues.

The eHeart™ System:

- 1) Augment patient's native remaining heart function.**
- 2) Requires a Thoracotomy to implant.**
- 3) No surgical intervention into the heart or aorta, no need for a heart-lung bypass machine.**
- 4) No direct blood contact.**
- 5) Power failure or disconnection is not catastrophic -> patients supported by their remaining cardiac output until the system is restored.**



III. Technology Overview

The eHeart™ was invented by Ted Lillehei, MD, a cardiothoracic surgeon practicing in Minnesota, and Allan Robinson, a research perfusionist and medical device developer. The eHeart™ is a direct compression heart assist device, with a noninvasive circulatory support system. The design is intended to work in conjunction with the native heart, enhancing clinical outcomes and improving quality of life for patients and their families.

The eHeart™ is a thoracotomy–implanted device that will consist of several key components:

- A. Implanted around the outside of the ventricles of the heart is the dual chambered (right and left ventricle) expandable compression jacket. Once expanded, it can become a totally implantable passive constraint device to assist in the maintenance of the outer wall parameters of the ventricles; When connected to the Controller/Driver, it will assist the heart during systole as either a left ventricular assist, right ventricular assist or a bi–ventricular assist device. The ventricular chamber jacket and drive line are made of proven bio–compatible implant materials.
- B. The Controller/Driver systems will be constructed primarily from components presently used in pulsation or counter pulsation devices. It will consist of a bedside console and a battery operated wearable ambulatory unit.
- C. The controller/driver units will auto adjust to patient cardiac demand via ECG and pressure sensors on the patient. The unit will include adjustable controls for passive constraint pressure and compression assisted pulsation rates.

The company believes that the eHeart™ will dramatically improve the adoption of eVAD assist for the underserved patient populations, respectively falling into the Class 3B ambulatory, and Class 4 categories of congestive heart failure. This is due to the potential of eHeart™ to mitigate complication concerns related to current VAD products on the market.

Circulatory support design attributes unique to eHeart™:

- 1) **Designed for use with drug therapy for the Reversal of heart failure, a bridge to recovery**
- 2) **Engineered to be in-line with the cost-saving and outcome-improving goals of the modern U.S. healthcare system**
- 3) **Engineered to be a dominant, cost-effective technology for a large, challenging and underserved patient population**
- 4) **Designed to supplement native cardiac output without surgical intervention into the heart or aorta**
- 5) **Elimination of direct blood contact complications**
- 6) **Designed for implant without the need of cardiopulmonary bypass**



IV. Technology Design

eHeart™ is a non-blood contact direct compression ventricular support system designed to work with the native heart that offers the potential of new treatment options for patients with chronic heart failure who are no longer responding to standard medical care.

The eHeart™ requires a less invasive implant procedure, and is intended to reduce the surgical risks associated with present day implant procedures that require cardiopulmonary bypass support. In addition, the non-blood contact design will reduce the potential complications associated with present day direct blood contact devices such as bleeding, hemolysis, thrombosis, stroke and mechanical breakdown potentially causing death. eHeart™ is intended to reduce symptoms of heart failure and associated re-hospitalizations, as well as to improve exercise tolerance, with the potential to assist in the reverse remodeling of the heart and recovery to a better quality of life.

The eHeart™ is comprised of NeoCardial's proprietary ventricular compression chamber jacket, adjustable subcutaneous pressure module and chamber inlet line for passive constraint application, inflow and outflow fluid line with a percutaneous lead line that is connected to a bedside or wearable external controller/driver, and a light-weight, rechargeable dual-battery pack system. The eHeart™ ventricular assist

chamber jacket has a proprietary compression design that provides adjunct external pressure to enhance the ventricles' ejection fraction (EF percentage of blood volume moved out of the heart per beat of the heart). This attempts to return the EF as close to normal as possible, reducing heart work load and permitting recovery while improving blood flow to vital organs. The eHeart™ supplements the native pumping capacity of the heart, preserves the heart in its native entirety, as well as its own ability to respond to the cardiac demands of the patient.



V. Product development

Product development began in Q3 2011. Several design iterations of the implantable compression chamber ventricular wrap have been developed and constructed, and are in different phases of testing.

Design iterations based on bench testing, adherence to customer requirements and physician feedback will continue until the design is frozen, expected in mid-2015. Functional prototypes are being tested in animal and bench test models that began in Q3 2012.

The design and testing is being conducted in-house and at American Preclinical Services located in Coon Rapids, Minnesota.

VI. Intellectual Property

The company has one issued patent from the U.S. Patent and Trademark Office:

Patent No.: US 8,795,149 B2

Date: Aug. 5, 2014

The company has two U.S. patent applications pending. One in Japan and Europe, and also one worldwide patent application.

The company expects it will file more patent applications as the design of the first commercial product is refined and finalized.



VII. Core Business Proposition

NeoCardial will focus on the patient provider specialties of the Interventional Cardiologist and the Thoracic/Cardiovascular Surgeon that would have the primary diagnosis and treatment responsibilities for the heart failure patient in need of a Ventricular Assist Device (VAD).

This will include other specialties, such as that of the primary care Cardiologist, in-hospital VAD nurse coordinator and team plus the at-home VAD service specialists. Currently these specialties have been established for the VAD and Transplant specialty institutions that constitute approximately 156 hospitals in the U.S. and a near number in Europe.

There is a significant opportunity to create vastly expanded treatment opportunities in these institutions and in new facilities as the patient population increases with age.

The eHeart™ system, bi-ventricular assist system employs characteristics that would now involve at least 3 different ventricular assist devices. The key advantages of the eHeart™ all in one system is its ability to offer the patient and physician an artificial cardiomyoplasty with distinct advantages over the existing VADs of today.

The company will leverage these key elements to create value:

- 1) **A disruptive evolution in technology**
- 2) **Cost effective solution with better patient outcomes**
- 3) **Favorable reimbursement environment**
- 4) **Founders and Directors have experience in Medical device start-up leadership**
- 5) **Intellectual property protection**