HeartMate 3™ Left Ventricular Assist System (LVAS)

Fact Sheet

WHAT IS THE HEARTMATE 3™ LEFT VENTRICULAR ASSIST SYSTEM (LVAS)?
The Thoratec HeartMate 3™ LVAS is a small implantable device that is designed to supplement the pumping function of the heart and helps circulate blood throughout the body for patients whose hearts are too weak to pump blood adequately on their own. It is intended for a broad range of advanced heart failure patients and is designed to restore blood flow, improve survival, functional status and quality of life.

CE MARK
In Europe, the HeartMate 3 LVAS received CE Mark on Oct. 8, 2015 for the following uses:
- a long-term support option (years) for patients who are not candidates for cardiac transplantation (also known as Destination Therapy).
- a short-term support option (months), for patients awaiting transplantation (Bridge-to-Transplantation)
- myocardial (heart) recovery

CE MARK TRIAL RESULTS1
- Exceptional 30-day and six-month patient survival: 98 percent at 30-days survival and 92 percent at 6-months, respectively
- No incidence of the following key adverse events: pump thrombosis, haemolysis, pump malfunctions or exchange at 30 and 180 days.
- Progressive, sustained Quality of Life improvements
- 83 percent of patients demonstrated a significant reduction in heart failure symptoms at six months, improving to New York Heart Association (NYHA) Class I or II from NYHA Class IIIB or IV
- Significant improvement in six-minute walk distance: greater than two times longer compared to baseline

BENEFITS
The goals of LVAD therapy include:
- Survival: Provide a survival benefit over non-device therapies.
- Quality of Life: Allow patients to live a fulfilling life.
- Active Patient Lifestyle: Facilitate life at home, potentially providing significant psychological and social benefits to the patient as well as cost savings for both the patient and the hospital.
- The HeartMate 3 is designed to minimise the risk of complications and improve device durability while enhancing patient outcomes.

1 Netuka I, et al. HeartMate 3 fully magnetically levitated LVAD for the treatment of advanced heart failure: results from the CE Mark Trial. Presented at the 19th Annual Meeting of the Heart Failure Society of America (HFSA); September 26-29, 2015; Washington, D.C.
FEATURES

- Blood compatibility: The design of the HeartMate 3 includes large, consistent blood flow gaps - 10 to 20 times greater than other LVADs - designed to reduce blood cell trauma.
  - Textured Blood-Contacting Surfaces. Encourages a tissue-to-blood interface that potentially reduces complications. Like inside the heart, blood is in contact with tissue and not an artificial material.
  - Full MagLev™ (magnetically-levitated) technology allows the device’s rotor to be “suspended” by magnetic forces. Since the parts “float,” there is no friction and therefore less wear and tear on the rotor. This contact-free environment is designed to optimise haemocompatibility and reduce blood trauma through gentle blood handling.
  - Artificial Pulse technology is designed to promote washing of the pump to prevent the formation of zones of recirculation and stasis.
- Advanced design for surgical ease. HeartMate 3 incorporates advanced technology to enhance the surgical experience and allow for ease of implantation.
- Designed for an Active Lifestyle. The controller provides a small, safe, smart patient interface for the HeartMate 3 LVAS. It features single-sided cables, so it discreetly slips into a front pocket for easier manageability.
- Full range of operation. Provides flow from 2.5 to 10 L/min to accommodate a broad range of clinical needs

HOW IT WORKS

The HeartMate 3 LVAS includes a blood pump (LVAD) that is implanted directly onto a patient’s native heart and designed to supplement the pumping ability of the weakened heart’s left ventricle, which is responsible for pumping oxygen-rich blood from the lungs throughout the body. The device is implanted above the diaphragm, immediately next to the native heart, and is attached to the aorta (the main artery that feeds blood into the entire body), leaving natural circulation in place while providing all of the energy necessary to propel blood throughout the body. The patient wears an external, wearable controller and battery system that powers the pump. The HeartMate 3 LVAS can pump up to 10 liters of blood per minute.
HeartMate 3™ Left Ventricular Assist System (LVAS) CE Mark Clinical Trial

Fact Sheet

CE MARK CLINICAL TRIAL OVERVIEW
The HeartMate 3™ Left Ventricular Assist System (LVAS) CE Mark Clinical Trial was a single arm, prospective, multi-center, non-blinded and non-randomized study. The study involved 50 patients at nine sites in Europe, Australia and Canada.

PRODUCT
The HeartMate 3 LVAS is a small, implantable device intended for a broad range of advanced heart failure patients. It is designed to restore blood flow while improving survival, functional status and quality of life.

PRIMARY STUDY OBJECTIVE
To evaluate the performance and safety of the HeartMate 3 LVAS at six months of support in subjects with advanced heart failure.

STUDY POPULATION
The HeartMate 3 LVAS was implanted in patients with refractory advanced left ventricular heart failure who required either short or long term support. Hospital discharge was allowed based on the patient’s condition.

PRIMARY ENDPOINT
The primary outcome measure for the HeartMate 3 LVAS CE Mark Clinical Trial was a comparison of survival at six months of left ventricular assist device (LVAD) support to a performance goal established using matched HeartMate II INTERMACS data.

SECONDARY ENDPOINT
The following secondary objectives were evaluated:

1. Quality of Life measured by the EuroQol-5D-5L (EQ-5D-5L)
2. Functional status as measured by the Six Minute Walk Test (6MWT) and New York Heart Association (NYHA) classification
3. Frequency and incidence of pre-defined anticipated adverse event rates
4. Frequency and incidence of device malfunction rates
5. Frequency and incidence of reoperations
6. Frequency and incidence of rehospitalizations
7. Survival free of debilitating stroke (Modified Rankin Score > 3)
STUDY DURATION
Subjects were followed to the primary endpoint of six months or outcome (transplant, explant or death), whichever occurred first. Subjects that remained in the study after six months continue to be followed to 24 months post-implant or outcome, whichever occurred first.

CE MARK TRIAL RESULTS

- Exceptional 30-day and six-month patient survival: 98 percent at 30-days survival and 92 percent at 6-months.
- No incidence of the following key adverse events: pump thrombosis, haemolysis, pump malfunctions or exchange at 30 and 180 days.
- Progressive, sustained Quality of Life improvements
- 83 percent of patients demonstrated a significant reduction in heart failure symptoms at six months, improving to New York Heart Association (NYHA) Class I or II from NYHA Class III or IV.
- Significant improvement in 6-minute walk distance: greater than two times longer than baseline.

STATUS
The device received CE Mark on Oct. 8, 2015 for use as a long-term support option (years) for patients who are not candidates for cardiac transplantation (also known as Destination Therapy). It is also approved for short-term support options (months), for patients awaiting transplantation (Bridge-to-Transplantation) and for myocardial (heart) recovery.

INVESTIGATIVE SITES
Australia – The Alfred Hospital  
Austria – Medical University of Vienna  
Canada – Toronto General Hospital  
Czech Republic – The Institute for Clinical and Experimental Medicine (IKEM)  
Kazakhstan – National Research Center for Cardiac Surgery  
Germany - Heart and Diabetes Center NRW in Bad Oeynhausen, German Heart Institute Berlin, Hannover Medical School, Herzzentrum Leipzig, Universitäts-Herzzentrum Freiburg

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