THORATEC®
CORPORATION

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HeartMate II® Left Ventricular Assist Device (LVAD) Fact Sheet

Product: The Thoratec HeartMate II Left Ventricular Assist Device (LVAD) is a mechanical circulatory support (MCS) device intended for a broad range of advanced-stage heart failure patients. HeartMate II is designed to restore blood flow, improve survival, functional status, and quality of life.

Current Indications: Based on the impressive clinical outcomes of the landmark HeartMate II clinical trial initiated in 2003, the HeartMate II received FDA approval for Bridge-to-Transplantation (BTT) in April 2008.

On January 20, 2010, FDA approval was received for Destination Therapy (DT), or long-term support, for those who do not qualify for heart transplantation due to age or other circumstances.

Benefits: The HeartMate II incorporates many features specifically intended to minimize the risk of complications and improve device durability while enhancing patient outcomes.

- Survival. Major clinical studies have shown HeartMate II to provide long-term survival that is up to six times greater than previously reported outcomes with medical therapy alone, and more than two times greater than the previous DT-approved device.
- Quality of Life. The HeartMate II is an implantable device that facilitates freedom of movement, routine daily activities, travel and even some sports like golf - leading to an improved quality of life for patients.
- Home Discharge. HeartMate II patients can be discharged from the hospital, providing significant psychological and social benefits to the patient as well as cost savings to the patient and hospital alike.
- Low Incidence of Thromboembolic (TE) Complications - Stroke. The blood flow path has been optimized to ensure thorough washing of surfaces and eliminate stagnation. And blood-contacting surfaces are designed to avoid blood damage. As a result, the HeartMate II is exceptionally durable, dependable and thromboresistant.
- Simplicity/Ease-of-Use. The simple design - with one moving part - contributes substantially to reliable operation.
- Durability. The device was designed for long-term support.

- Lightweight. HeartMate II measures approximately three inches in length and weighs approximately 10 ounces.
- Active Lifestyle. In May 2013, the FDA approved Thoratec's next-generation HeartMate II Pocket Controller™, which lighter and more compact than previous LVAD system controllers in order to support the active lifestyle that patients with HeartMate II are leading.

How it Works:

The HeartMate II is implanted alongside a patient's native heart and designed to take over 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 placed just below the diaphragm in the abdomen. It is attached to the aorta (the main artery that feeds blood into the entire body) from the natural heart, leaving natural circulation in place while providing all of the energy necessary to propel blood throughout the body. An external, wearable system that includes a controller and batteries is attached via an external driveline. A power cable connects the device to a small monitor, a power base unit.

The HeartMate II LVAS can pump up to 10 liters of blood per minute, covering the full output of a healthy heart. The HeartMate II is designed to provide long-term cardiac support for patients who have advanced-stage heart failure. An axial flow device, the HeartMate II is designed to have a much longer functional life than the previous generation of devices and to operate more simply and quietly. It is also smaller and designed to be easier to implant.

In total, more than 18,000 patients have been implanted with HeartMate II through trial enrollment and commercial use worldwide.[1]

Outcomes:

The HeartMate II offers significant and sustained improvements in quality of life and is the most widely studied device of its kind in the world with over 400 peer-reviewed publications.

The HeartMate II BTT Post-Approval Study included 169 patients across 77 institutions. Data demonstrated 91% survival at six months and 85% survival at one year.[2]

The latest multicenter results with HeartMate II for destination therapy demonstrate 75% survival at one year.[3]

There are more than 350 medical centers worldwide that are implanting HeartMate II. For a list of centers visit: http://www.thoratec.com/patients-caregivers/about-heartmateII.aspx

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[1] Thoratec data on file

[2] *Results of the Post-U.S. Food and Drug Administration-Approval Study With a Continuous Flow Left Ventricular Assist Device as a Bridge to Heart Transplantation; Journal of American College of Cardiology; R. Starling, R., Naka, Y., Boyle, A., Gonzalez-Stawinski, G., John, R., Jorde, U., Russell, S., Conte, J., Aaronson, K., McGee, E.; 2011; 57-1890-1898, doi:10.1016/j.jacc2010.10.062*

[3] *Park SJ, et al. Outcomes in Advanced Heart Failure Patients with Left Ventricular Assist Devices for Destination Therapy. Circulation Heart Failure. 2012.*

DEVICE	REGION	STATUS
HeartMate II LVAS	• United States	• Bridge-to-Transplantation – Received FDA approval in April 2008. • Destination Therapy – Received FDA approval in January 2010.
	• Europe	• Authorized to bear the Conformité Européenne (CE) Mark in November 2005.

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