



T H O R A T E C[®]
C O R P O R A T I O N

FOR USE ANYTIME

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ROADMAP Study - Fact Sheet

Overview: ROADMAP (Risk Assessment and Comparative Effectiveness Of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients) is a prospective, multi-center, non-randomized, controlled, observational study to evaluate the effectiveness of the Thoratec[®] HeartMate II[®] Left Ventricular Assist System (LVAS) versus Optimal Medical Management (OMM).

Population: The study will involve ambulatory advanced heart failure patients who are not yet dependent on intravenous inotropic support and are typically categorized as INTERMACS profiles 4-6, within the existing FDA-approved indication for Destination Therapy. It will include 200 patients at up to 50 sites, including experienced HeartMate II implant centers as well as community centers that care for a large volume of advanced heart failure patients.

Design: Subjects will be enrolled in one of two cohorts: LVAS or OMM. Clinical investigators and the patients will decide which cohort a patient will enter based on the center's standard of care and patient acceptance of therapy options. Baseline risk assessment profiles will allow for stratification of expected risk and severity of illness.

HeartMate II: The HeartMate II is intended for a broad range of advanced heart failure patients and is the only continuous-flow left ventricular assist device (LVAD) approved by the FDA for both Bridge-to-Transplantation and Destination Therapy. The device is designed to provide long-term cardiac support, pumping up to 10 liters of blood per minute for full support of the circulation, or to supplement the native function of the patient's left ventricle. The HeartMate II is placed just below the diaphragm and is connected to the left ventricle, returning blood flow to the aorta, the main artery that carries oxygenated blood to the entire body. An external, wearable system that includes a small controller and two batteries is attached by an external driveline. HeartMate II is small and easy to implant, and with only one moving part, it is designed to provide exceptional reliability and improved patient quality of life. In total, more than 20,000 patients have been implanted with HeartMate II.

OMM: Subjects who elect to remain on optimal medical management per established heart failure guidelines for this subject population including ACE inhibitors, beta blockers and aldosterone antagonists 45 out of the last 60 days or an inability to tolerate neurohormonal antagonists.

Primary Objective: To evaluate and compare the effectiveness of HeartMate II LVAS support versus OMM in ambulatory New York Heart Association (NYHA) Class IIIB/IV heart failure patients who are not dependent on IV inotropic support and meet the FDA-approved indication for HeartMate II LVAS destination therapy.

Secondary Objectives:

- Determine the accuracy of risk prediction models of a population appropriate for HeartMate II and to establish equipoise.
- Determine factors related to patient and physician decisions for HeartMate II.
- Determine the frequency of cross-over to other advanced heart failure therapies.
- Compare results of early versus delayed LVAD implantation.
- Determine the feasibility of enrolling target population.
- Use information to design follow-up studies; randomized trials, or additional observational studies and registries.

Endpoints: The primary endpoint will be a composite of survival and functional improvement, as measured by the six-minute walk test (6-MWT), distance from a baseline of ≥ 75 meters, at one year. Secondary endpoints include actuarial survival, quality of life, pump replacement, adverse events and rehospitalizations. Subjects who undergo transplantation or explant will be followed for current status six-months and one-year post transplant or explant.

Duration: Patients will be followed for two years. The study’s estimated completion date is December 2015.

For more information: Visit: <http://clinicaltrials.gov> - ID# NCT01452802.

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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