



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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Heart Failure Treatment Options: Frequently Asked Questions

1. **Q:** What is heart failure?

A: Heart failure is a widespread condition that develops when the heart muscle weakens and is unable to pump sufficient amounts of blood throughout the body. Heart failure is a chronic condition that worsens over time and is typically caused by persistent high blood pressure, heart attack, valve disease and other forms of heart disease or birth defects. Left untreated, the lack of adequate blood flow causes the organs to progressively fail, resulting in numerous medical complications that erode a person's quality of life and often leads to death.

Heart failure can involve both sides of the heart or be localized to the left or right side. The left ventricle, which supplies oxygenated blood to the body, accounts for approximately 80 percent of all heart failure cases.

2. **Q:** How common is heart failure?

A: According to the American Heart Association (AHA) and the Heart Failure Society of American (HFSA), nearly six million Americans are living with heart failure, and 670,000 new cases are diagnosed each year. In the United States, the number of deaths from this condition has more than doubled since 1979, averaging 250,000 annually.

3. **Q:** What are the different stages of heart failure?

A: The New York Heart Association (NYHA) created a classification system to help physicians determine the best course of therapy for their patients. This system compares symptoms to daily activities and the patient's quality of life.

Class	Patient Symptoms
Class I (Mild)	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation or dyspnea (shortness of breath).
Class II (Mild)	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation or dyspnea.

Class III (Moderate)	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation or dyspnea.
Class IV (Severe)	Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

4. Q: How is heart failure treated?

A: Symptoms of advanced-stage heart failure are generally managed with the use of medications, including diuretics, angiotensin converting enzyme (ACE) inhibitors, beta-blockers and digoxin combined with strict diet and exercise programs. For many, a heart transplant is necessary for survival, but advanced-stage heart failure sufferers are frequently ineligible for transplant because of age or other extenuating health reasons. Between 2,000 and 2,500 Americans receive a heart transplant each year, while another 25,000-50,000 Americans die waiting for a donor heart to become available.

Recent guidelines from the American College of Cardiology (ACC) and the AHA recommend that physicians consider ventricular assist devices (VADs) as a treatment option for advanced-stage patients and those with refractory heart failure who might be eligible for specialized advanced treatment, including transplantation.

5. Q: What are VADs?

A: Ventricular Assist Devices are mechanical pumps that are implanted alongside a patient's own heart and designed to assist the heart's pumping function to restore hemodynamic function, or the flow of oxygenated blood throughout the body.

6. Q: What is the HeartMate II® Left Ventricular Assist System (LVAS)?

A: The HeartMate II LVAS is a miniaturized heart assist device designed to supplement or take over the pumping function of the heart. The HeartMate II LVAS has one moving part, a continuously spinning rotor that helps circulate up to 10 liters of blood per minute, 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.

7. Q: Which patients might be helped by this device?

A: The HeartMate II LVAS is FDA-approved for Bridge-to-Transplantation (BTT) and Destination Therapy (DT). A BTT indication allows the HeartMate II to be used for temporary support to restore adequate hemodynamics while a patient is waiting for heart transplant. A DT indication allows the HeartMate II to be used for long-term or permanent support for advanced-stage heart failure patients who are not eligible for heart transplantation.

8. Q: How does the HeartMate II differ from other heart assist pumps?

A: The HeartMate II LVAS provides blood flow to the body through the circulatory system on a continuous basis with only one moving part. 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 small and designed to be easier to implant than the previous generation of devices.

9. Q: What is the HeartMate II Pivotal Clinical Trial?

A: The Thoratec® HeartMate II Left Ventricular Assist System (LVAS) pivotal clinical trial incorporates a number of unique elements, including the use of the device for both Bridge-to-Transplantation (BTT) and Destination Therapy (DT). This was the first time the FDA approved a clinical trial with both indications in one protocol.

BTT Study - The BTT pivotal clinical trial was a non-randomized trial in which all subjects received the HeartMate II LVAS and was compared to an objective performance criterion (OPC). Study enrollment ended with FDA approval in April 2008. The BTT Pivotal Clinical Trial results were published in the *Journal of the American College of Cardiology* by HeartMate II investigators Francis D. Pagani, MD, PhD, Leslie W. Miller, MD, Stuart Russell, MC, et al.

DT Study - The DT pivotal clinical trial was a prospective, randomized evaluation of the HeartMate II LVAS. Patients were randomly assigned to treatment with the HeartMate® XVE LVAS (control group) or to treatment with the HeartMate II LVAS. The DT arm of the study initially involved 200 patients in its primary cohort at 38 sites, randomizing the HeartMate II LVAS to the HeartMate XVE LVAS on a 2-1 basis, respectively. The objective of the DT arm of the trial was to determine the safety and efficacy of the HeartMate II LVAS as DT in advanced heart failure patients who did not qualify for cardiac transplantation. The DT arm of the Pivotal Clinical trial was published in the *New England Journal of Medicine* by HeartMate II investigators Mark S. Slaughter, MD, Joseph G. Rogers, MD, Carmelo A. Milano, MD, et al.

10. Q: How many patients were enrolled in the trial?

A: Enrollment in the DT arm of the trial reached 939 patients. In total, 1,429 patients were enrolled in the pivotal trial, by far the largest VAD study ever conducted. FDA Approval of HeartMate II for Destination Therapy was announced on January 20, 2010.

11. Q: What criteria did patients need to meet in order to be considered for trial enrollment?

A: Enrollment for BTT was limited to advanced-stage heart failure patients who were on the heart transplant list and who met certain criteria. The DT arm included patients who were not candidates for heart transplantation due to age or other health conditions. Most candidates were classified as NYHA Class IV. The criteria of the trial allowed the DT arm to enroll some late-stage NYHA Class IIIB heart failure patients.

12. Q: Does insurance reimburse the HeartMate II for Bridge to Transplantation and Destination Therapy?

A: The majority of private payors cover LVAD procedures when performed according to the FDA-approved indications. Multiple private payors, including Blue Cross plans, Aetna, Cigna, Humana, Optum Health Group, have published positive coverage decisions related to Thoratec products. The Centers for Medicare & Medicaid Services (“CMS”) covers any procedures using Thoratec VADs for FDA-approved indications, including reimbursement for the use of the Left Ventricular Assist System for Destination Therapy at

Joint Commission certified centers.

13. Q: Where can I find clinical information about VADs?

A: Clinical information on Thoratec's ventricular assist devices is available in the "VAD Trials and Outcomes" section at www.thoratec.com.

14. Q: Which centers currently offer HeartMate II?

A: There are more than 350 medical centers implanting HeartMate II worldwide. For a list of centers, visit <http://www.thoratec.com/careers/find-a-center.aspx>

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