



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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HeartMate[®] XVE LVAS Fact Sheet

Product: The HeartMate XVE Left Ventricular Assist System (LVAS) is implanted alongside a patient's native heart and designed to take over the pumping ability of the weakened heart's left ventricle. The HeartMate XVE is the only wearable, pulsatile LVAD available to patients who cannot tolerate systemic anticoagulation.

Current Indications:

- **Destination Therapy (DT).** Based on the impressive clinical outcomes of the landmark REMATCH clinical trial, the HeartMate XVE is the only device approved by the FDA for permanent use, called Destination Therapy (DT). This indication serves advanced-stage heart failure patients who, due to age or extenuating medical circumstances, are not eligible for heart transplantation. The device can potentially treat the sickest heart failure patients among the 100,000 Americans each year who have no alternative for their debilitating disease.

- **Bridge-to-Transplantation (BTT).** HeartMate XVE is FDA-approved to serve as a Bridge-to-Transplantation (BTT), keeping critically ill patients alive until donor hearts become available.

Benefits:

- **Survival.** Given the extreme shortage of donor hearts, the HeartMate XVE provides life-sustaining support to BTT patients until an appropriate donor heart is found. Additionally, the HeartMate XVE offers a new lease on life to DT patients who are not eligible for heart transplantation. The REMATCH clinical trial demonstrated that patients with the device had two times the rate of survival as those on optimal medical management treatment of drug therapy, diet and exercise.

- **Quality of Life.** The HeartMate XVE is an implantable device with wearable system components 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 XVE patients can be discharged home 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 HeartMate XVE is widely recognized as having a low rate of blood clot complications among major VAD manufacturers.
- **Minimal Anti-Coagulation Requirements.** The HeartMate XVE's proprietary textured blood contacting surfaces encourage the deposit of a lining derived from the patient's own blood. As blood comes into contact with the surface, it deposits a lining of blood components resembling the inner surfaces of arteries and veins. This lining strives to protect blood cells. As a result, there is a reduced incidence of clot formation and thromboembolism, and complicated and costly anticoagulation therapy is not required. Today, no other assist device can provide the same level of support as the HeartMate XVE without systemic anti-coagulation.

How it Works:

The HeartMate XVE is designed to assist the 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.

The HeartMate XVE is pulsatile (which simulates the motion of the natural heart) and is approximately four inches in diameter, less than two inches in depth and weighs about two and a half pounds. It can pump up to 10 liters of blood per minute, which restores critical circulation, reverses end-organ dysfunction and can greatly reduce mortality in patients who do not qualify for a heart transplant or who are waiting for a heart transplant.

In December 2001, Thoratec Corporation introduced the HeartMate XVE LVAS for Bridge-to-Transplantation, followed by its Destination Therapy indication in April 2003.

The enhancements of the HeartMate XVE were based on extensive clinical experience, customer feedback, technological advances, critical product evaluation and Thoratec’s commitment to complete customer satisfaction. The modifications were designed to improve pump reliability and durability, ease of use, patient comfort and to decrease complications.

The HeartMate XVE enhancements include a longer, smaller diameter and more flexible lead designed to improve patient comfort and enable surgeons to treat larger patients. In addition, a rotating tunneling bullet was added to ease implantation and facilitate tunneling of the driveline through the exit site on the patient. Other improvements include graft redesigns to reduce kinking and battery module improvements to increase battery life.

Thoratec’s HeartMate XVE and HeartMate II (which was recently FDA-approved for BTT) allow patients to be discharged from the hospital and go home with a fully portable, wearable system and return to a near-normal lifestyle. Both of the devices have wearable components that include the belt-worn system controller and two rechargeable batteries, which provide approximately six hours of mobile patient support.

The XVE features a variety of accessories designed for ease of patient use and flexibility, including the Power Base Unit (PBU), which charges the batteries required for patient support, provides connections for system diagnostics and provides a direct power connection for the patient when non-battery operating support is desired.

DEVICE	INDICATION	STATUS
HeartMate XVE LVAS	<ul style="list-style-type: none"> • Bridge-to-Transplantation • Destination Therapy 	<ul style="list-style-type: none"> • Conformité Européenne (CE) mark authorized, June 2003. • Approved by the FDA in 2001. • Conformité Européenne (CE) mark authorized, June 2003 • Approved by the FDA, April 2003.

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