



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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Thoratec[®] PVAD[™] & Thoratec[®] IVAD[™] Fact Sheet

About PVAD: The Thoratec PVAD (Paracorporeal Ventricular Assist Device) provides maximum versatility for physicians in meeting the left, right or bi-ventricular support needs of advanced heart failure patients requiring acute (weeks) or intermediate (months) support with the opportunity for home discharge. With more than 20 years of clinical use, the PVAD can support a wide range of patients with advanced heart failure. The device is approved in the U.S. for Bridge-to-Transplantation (BTT) and Post-Cardiotomy Recovery from open-heart surgery.

About IVAD: The Thoratec IVAD (Implantable Ventricular Assist Device) is based on the reliable and clinically established Thoratec PVAD. The result is an implantable VAD with proven technology that can support an extensive array of patients. The IVAD is the only implantable biventricular support option for advanced heart failure patients requiring intermediate (months) or chronic (years) support.

PVAD & IVAD Systems: Each PVAD and IVAD system includes three major components: Blood pump, Cannulae and Pneumatic Driver (Dual Drive Console or TLC-II[®] Portable VAD Driver). This system offers partial or total circulatory assistance when the heart cannot maintain adequate circulation to the body. Today, more than 7,400 Thoratec PVAD and IVAD devices have been used in the treatment of nearly 4,900 patients across more than 240 medical centers worldwide.

TLC-II[®] Portable VAD Driver: To improve patient mobility and patient quality of life, Thoratec developed the TLC-II Portable VAD Driver, an electromechanical device that pneumatically powers the PVAD and IVAD devices. This driver is a compact and lightweight (9.8 kg/20 lbs) unit that allows easier patient movement and increased portability. In Europe and North America, it is approved for use in the hospital and discharge setting including a patient's home. This enables patients to be discharged from the hospital while awaiting heart transplantation or recovery of the natural heart. For greater convenience, the TLC-II is also approved for both ground and air travel, which includes helicopter and fixed-wing aircraft.

Current Indications:

- Bridge-to-Transplantation. The Thoratec PVAD and IVAD are approved for Bridge-to-Transplantation, keeping critically ill patients alive until donor

hearts become available.

- **Post-Cardiotomy Recovery.** Open-heart surgery patients sometimes have difficulty being weaned off bypass machines, and a VAD can provide much needed rest to the heart while it recovers.
- **Home Discharge.** The Thoratec PVAD and IVAD are the first and only biventricular support systems that are approved for home discharge, allowing patients to be discharged from the hospital while awaiting heart transplantation or recovery of the natural heart.

Benefits:

- **BiVAD Support.** Thoratec is the only U.S. company to offer biventricular (i.e. left and right heart support) VADs approved for home discharge, and where the IVAD is the only approved implantable option for these patients where myocardial recovery of the native heart is possible. This gives physicians more versatility in treating severe heart failure, which can increase a patient's chance of survival. It is estimated that approximately 20-30 percent of all heart failure patients will suffer from right ventricular failure, either in isolation or in combination with left ventricular failure.
- **Home Discharge.** The Thoratec PVAD and IVAD are unique in the industry, since they are the only FDA approved biventricular VADs that allows patients to be discharged home. With the use of the TLC-II Portable VAD Driver, patients can regain the freedom to await transplant or recover in the comfort of their home. This aspect alone is perhaps one of the greatest benefits for these advanced heart failure patients.
- **Acute to Chronic Support.** The Thoratec PVAD system has supported patients from weeks to over three years. However, due to the option of external placement of the system, the PVAD is also ideal for both post-cardiotomy recovery and Bridge-to-Transplantation situations.
- **Use in Smaller Size Patients.** Since the Thoratec PVAD is placed outside the body (usually resting on the patient's abdomen), smaller patients can be supported. It has been used to treat small patients, weighing as little as 40 pounds and as young as five years old.
- **Proven Biocompatible Materials.** At the heart of the Thoratec PVAD and IVAD systems is Thoralon[®], a proprietary biocompatible material developed at Thoratec that minimizes blood clotting and inflammation. Two major components of Thoralon are surface modifying additives (SMAs) and BPS-215 polyurethaneurea, an elastomer, that allows Thoralon to flex for long periods of time without sacrificing device performance, as demonstrated by patients supported as long as three years without failure.
- **Manufactured and supported by Thoratec.** As the industry leader in mechanical circulatory support (MCS) for advanced heart failure patients, Thoratec is committed to providing extensive programs and services,

including reimbursement support, education and training, clinical support and product and technical support.

How it Works:

The pulsatile Thoratec PVAD System works by allowing blood to flow from the natural heart to the PVAD, outside the body, through an implanted atrial or ventricular cannula. It then pumps blood back to the body through another implanted arterial cannula. The PVAD pumps are prosthetic ventricles consisting of a smooth, seamless pumping chamber enclosed in a rigid polysulfone case.

The cannula is manufactured with Thoralon, a polymer base, which provides strength, flexibility and durability. A sensor, that detects when the PVAD is full of blood, triggers the ejection of blood from the pump. In the clinical setting, this sensor allows the PVAD pump(s) to automatically adjust its rate to pump faster during exertion and slower when a patient is sleeping, just as the natural heart does.

The Thoratec IVAD is an implantable version of the Thoratec PVAD and works in the same manner, however unlike the PVAD, the IVAD pump(s) reside in the patient's chest cavity. Weighing less than a pound and utilizing the same internal components as the already approved Thoratec PVAD, the IVAD is one of the smallest implantable VADs available.

DEVICE	LONGEVITY	INDICATION	STATUS
Thoratec Paracorporeal VAD (PVAD)	<ul style="list-style-type: none"> • Days to weeks • Weeks to years 	<ul style="list-style-type: none"> • Post-Cardiotomy Recovery • Bridge-to-Transplantation 	<ul style="list-style-type: none"> • Conformité Européenne (CE) mark authorized • FDA Approval: <ul style="list-style-type: none"> - Bridge-to-Transplantation (1995) - Post-Cardiotomy Recovery (1998)
Thoratec Implantable VAD (IVAD)	<ul style="list-style-type: none"> • Days to weeks • Weeks to years 	<ul style="list-style-type: none"> • Post-Cardiotomy Recovery • Bridge-to-Transplantation 	<ul style="list-style-type: none"> • Conformité Européenne (CE) mark authorized (2003) • FDA Approval (2004)

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