



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

FOR USE ANYTIME

CONTACT: Susan Benton Russell
Phone: 310.697.3488
susan@bentoncommunications.com

Thoratec Corporation[®] Fact Sheet

- Established:** Thoratec Corporation was incorporated in March of 1976 and began publicly selling shares of its stock in the spring of 1981 (NASDAQ:THOR). In February 2001, Thoratec completed a merger with Thermo Cardiosystems Inc. (AMEX: TCA).
- Mission:** Thoratec innovates and delivers technologies that enable a full range of therapies to save, support and restore failing hearts, allowing patients to reclaim their lives.
- Overview:** Thoratec develops, manufactures and markets proprietary medical devices used for circulatory support. Thoratec is the world leader in mechanical circulatory support with the broadest portfolio of devices to treat a wide range of patients and their clinical needs - spanning the spectrum from acute to chronic support in adults as well as children.

Thoratec Product Portfolio

Commercially Available:

- Thoratec[®] HeartMate II[®] LVAS (Left Ventricular Assist System):** The HeartMate II LVAS is a miniaturized mechanical circulatory support device designed to restore hemodynamic function by pumping oxygenated blood throughout the body. As the only device approved by the FDA for both Bridge-to-Transplantation (BTT) and Destination Therapy (DT), the HeartMate II is the leading chronic continuous-flow device, offering proprietary textured surfaces, open flow paths, and a flexible inflow conduit to optimize outcomes. Designed to provide long-term cardiac support for patients who have advanced heart failure, in total, more than 20,000 patients have been implanted with HeartMate II through trial enrollment and commercial use worldwide.¹ The HeartMate II was FDA-approved for BTT in April 2008 and DT in January 2010, and CE-Mark approved in November 2005. There are nearly 400 medical centers worldwide that are implanting HeartMate II. For a list of centers visit: <http://www.thoratec.com/patients-caregivers/hm2-find-a-center.aspx>

¹ Thoratec data on file

**Thoratec®
CentriMag®
and PediMag®
Blood Pump:**

The Thoratec CentriMag Blood Pump is an external device for short-term circulatory support consisting of a single-use blood pump, a motor and a device console. As the first and only magnetically levitated blood pump cleared by the FDA in 2008, the CentriMag is a technologically advanced acute circulatory support device that provides rapid hemodynamic stabilization. PediMag is a smaller version of the CentriMag specifically designed for pediatric short-term circulatory support. The PediMag (called the PediVAS® outside the U.S.) operates on the same hardware platform as the CentriMag. Both devices received CE-Mark approval in 2002 and 2007, respectively.

**Thoratec®
PVAD™
(Paracorporeal
Ventricular
Assist Device):**

The Thoratec PVAD 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 30 years of proven clinical results, the PVAD can support a wide range of patients with advanced heart failure for short- to mid-term support. Today, more than 5,000 patients have received PVAD implants at nearly 280 heart centers worldwide. The device is FDA-approved for Bridge-to-Transplantation (BTT) and Post-Cardiotomy Recovery from open-heart surgery. It received FDA approval for both indications in 1995 and 1998, respectively, and CE-Mark approval in 1998.

Commercially Available (in Europe Only):

**Thoratec®
HeartMate
PHP™
(Percutaneous
Heart Pump)**

The HeartMate PHP system is a percutaneous heart pump designed to provide hemodynamic left ventricular support. This device disrupts the relationship between size and flow traditionally found in percutaneous hemodynamic support devices to provide care without compromise. Upon insertion into the femoral artery via a 14F introducer sheath, the PHP catheter is advanced into the left ventricle where the distal end of the catheter is then expanded to 24F, allowing for enhanced blood flow with low levels of hemolysis. Thoratec has designed the PHP system to facilitate rapid insertion using an intuitive control console and to provide 4-5 liters per minute of mean flow. The HeartMate PHP system is intended to provide short-term mechanical circulatory support for patients in or at risk of acute heart failure. It received CE-Mark approval in July 2015.

Currently In Clinical Trial:

**Thoratec®
HeartMate 3™
LVAS (Left
Ventricular
Assist System)*:** The HeartMate 3 LVAS is an investigational chronic mechanical circulatory support (MCS) device intended for a broad range of advanced heart failure patients. HeartMate 3 is designed to restore blood flow, improve survival, functional status, and quality of life. ^{**+^**} In the U.S., the MOMENTUM 3 (Multi-center study of Maglev technology in patients undergoing MCS therapy with HeartMate 3) Clinical Trial, is evaluating the device for use as long-term support (years) for patients who are not candidates for cardiac transplantation (also known as Destination Therapy, or DT). It will also be evaluated for short-term support options (months), for patients awaiting transplantation (Bridge-to-Transplantation, or BTT).

In the HeartMate 3 CE Mark Clinical Trial, the device is being evaluated for myocardial (heart) recovery, in addition to DT and BTT.

**Thoratec®
HeartMate
PHP™ (U.S.)*** In May, 2015, Thoratec received conditional approval from the FDA for a U.S. IDE clinical trial to investigate the use of the HeartMate PHP acute catheter-based heart pump in patients undergoing a high-risk percutaneous coronary intervention.* The SHIELD II (Supporting patients undergoing High-risk PCI using a high-flow percutaneous Left ventricular support Device) U.S. clinical trial will randomize up to 425 patients at up to 60 sites against the Impella® 2.5 at a 2:1 ratio.

Employees: More than 1,000 worldwide

**World
Headquarters:** Thoratec Corporation
6035 Stoneridge Drive
Pleasanton, CA 94588
Phone: 1 (800) 528-2577
Fax: (925) 847-8574

Thoratec is based in Pleasanton, California, with facilities in Burlington, Massachusetts; Fremont, Rancho Cordova and Sunnyvale, California; Gainesville, Florida (Continuum); Ann Arbor, Michigan; Huntingdon, Cambridgeshire, UK; and Zurich, Switzerland.

Internet: www.thoratec.com

* US: Caution: Investigational Device: Limited by Federal United States law to investigational use.

+ EU: exclusively for clinical investigations

^ AU: for clinical trial use only

**CANADA: Investigational Device To be Used by Qualified Investigators Only.

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