



# Heart Failure and Transplantation Program

## Ventricular Assist Devices

The Heart Failure and Transplantation Program at California Pacific Medical Center offers leading-edge medical and surgical therapies for patients with end-stage heart disease. The program is actively involved in research clinical trials, allowing patients the unique opportunity of direct access to some of the newest medications, innovative surgical treatments, and therapeutic devices. With these advanced therapies we can help heart failure patients lead longer and fuller lives.

Our heart failure program provides patients with a wide variety of advanced therapies best suited to their individual needs. Working closely with patients and their referring physicians, our team of heart failure experts assist patients by encouraging lifestyle modifications, developing individual medical treatment plans and, if appropriate, implanting state-of-the-art heart assist devices that restore and synchronize the heart's rhythm.

We focus on providing experienced, multidisciplinary care, managing the entire spectrum of heart failure care to an excellent outcome.

## Advanced Surgical Treatment Options

Advanced surgical treatment options include ventricular assist devices (VAD), an implanted mechanical device assisting the heart's pumping function. VADs are used as a bridge-to-transplant—supporting the circulation in patients who have run out of options while waiting for a donor organ—or as destination therapy—permanent, long-term therapy for patients who are not eligible for heart transplant.

### VENTRICULAR ASSIST DEVICES

Left ventricular assist devices (LVAD), or heart pumps, are used to treat patients with severe heart failure. The devices are temporary for some and permanent for others. The pump is surgically attached to a patient's own heart and simulates the work of the left ventricle. The pump is placed just below the diaphragm in the abdomen or above the diaphragm in the chest. It collects blood from the left ventricle and pumps it through the aorta. Typically, an LVAD has two tubes connected to an electric pump, an electronic controller, and an energy supply. One tube goes into the left ventricle, emptying blood from the ventricle into the pump. The pump then sends blood into the aorta, the large blood vessel leaving the ventricle, effectively "bypassing" the weakened ventricle. Another tube attached



Image courtesy of Thoratec

Thoratec's HeartMate® XVE Left Ventricular Assist Device (LVAD)

to the pump is brought out of the abdominal wall and attached to the external pump control system. Natural circulation continues as the implant provides additional support, pumping blood throughout the body.

LVADs are one of the most innovative therapies for end-stage heart failure. Sometimes referred to as a bridge-to-transplant because the LVAD can sustain a patient's weakened heart while waiting for organ transplantation, LVADs are normally used from a few weeks to several months prior to a heart transplant. In patients who are not transplant candidates, LVADs can be used as "destination therapy," providing permanent mechanical circulatory support.

### THORATEC HEARTMATE® LVAD

One LVAD currently available is the Thoratec HeartMate®. The HeartMate is fist-sized, FDA approved, and made of titanium. It can be used for short-term bridge-to-transplantation, or indefinitely in patients who are not candidates for transplantation. A tube attaches the implanted HeartMate to an external controller and is powered by batteries which are worn by the patient, similar to a shoulder bag. Patients can move about freely, exercise, and even be discharged from the hospital, allowing patients a greatly improved quality of life.

## HEART HOPE™ CENTER

In November 2002, the FDA approved the HeartMate LVAD for destination therapy, a long-term permanent implant for patients with end-stage heart failure who are not heart transplant candidates. As a Heart Hope™ Center, we offer these heart failure patients the option of surgically implanting Thoratec's HeartMate LVAD heart assist device for destination therapy. Currently, California Pacific's Heart Transplant Program is the only program in Northern California that is a designated Heart Hope Center.

California Pacific Medical Center was invited to become a Heart Hope Center based on a number of selection criteria including:

- demonstrated leadership in education, research, and the treatment of heart disease;
- staff credentials with a dedicated team of physicians, scientists, nurses, and support staff;
- experience with the Thoratec HeartMate XVE LVAD and a low frequency of medical complications and deaths associated with use of this device; and
- the hospital's methods for monitoring and evaluating care.

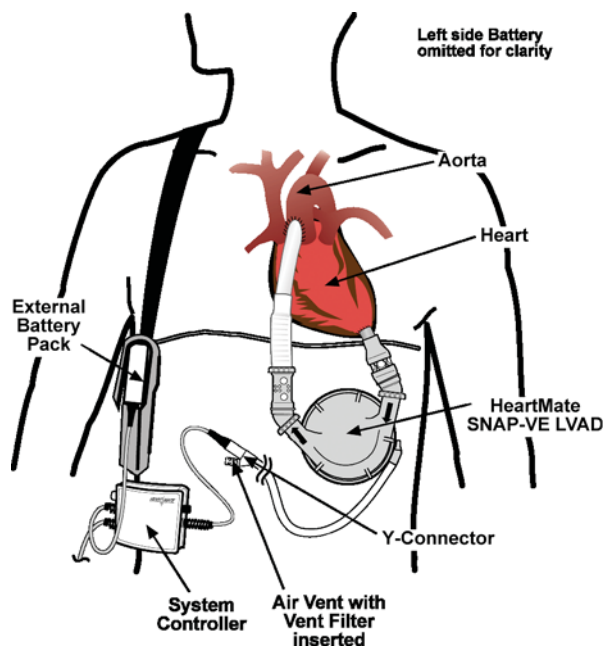
All Heart Hope Centers are Medicare approved for destination therapy and meet the Centers for Medicare and Medicaid Services's (CMS's) strict criteria for coverage, which includes VAD experience and demonstrated professional and facility quality performance. In addition, each center has agreed to participate in a national registry to track adverse events and clinical outcomes. Therefore, the facility can compare its LVAD experience against that of other implanting facilities to assess the quality of its performance overall as well as to determine whether an individual patient's care and progress in recovering from the procedure is meeting normative standards. Research has shown that hospitals performing a high volume of other cardiac procedures and that vigilantly monitor their own performance typically achieve the best results for its patients.

The Heart Hope Initiative is a partnership between Thoratec Corporation and Heart Hope Centers to focus on exceptional customer service to patients and referring physicians to advance clinical outcomes with use of mechanical circulatory assist devices and other advanced therapies used in the treatment of heart failure.

## MICROMED DEBAKEY VAD® CLINICAL TRIAL

California Pacific Medical Center is one of 20 sites currently participating in MicroMed Technology's bridge-to-transplant clinical trial. This is a new device with promising axial flow technology and it may improve patient outcomes. Clinical trials will be an important step toward establishing the safety and efficacy of such a device. California Pacific is one of only a handful of clinical trial sites for MicroMed's DeBakey VAD®. The DeBakey VAD, under study for destination therapy and bridge-to-transplantation, is intended to be a lower-cost, less-invasive alternative to the commercially available larger LVADs. The DeBakey VAD, designed for long-term use by end-stage heart failure patients who can no longer provide necessary blood flow with their native heart, is a silent, miniaturized VAD, about the size of a C cell battery. It is one-tenth the size of LVADs currently on the market, and weighs less than four ounces. To date, more than 200 patients have been implanted with the MicroMed DeBakey LVAD.

The MicroMed DeBakey VAD was pioneered by Drs. Michael DeBakey, George Noon, and NASA engineer David Saucier. The device applies spacecraft technology and, in 1996, MicroMed Technology, Inc., received an exclusive license from NASA for the VAD.



HeartMate® XVE LVAS