# About Mechanical Circulatory Support and LVADs Fact Sheet

### **About Mechanical Circulatory Support**

Many patients with advanced heart failure are not eligible for a heart transplant or do not receive a transplant heart quickly enough. In fact, while transplants offer hope for approximately 2,000 advanced heart failure patients each year in the U.S., more than 250,000 advanced heart failure patients in the U.S. have no viable treatment option and are considered at high risk for repeated hospitalization, poor quality of life and even death.<sup>1</sup>

Mechanical Circulatory Support (MCS) is the process of implanting a mechanical device that is designed to restore blood flow throughout the body when the heart is too weak to pump blood adequately on its own. MCS provides a treatment option for these advanced heart failure patients, either to support patients and improve their quality of life while awaiting a donor heart ("Bridge-to-Transplant") or as a permanent therapy for patients who are not eligible for heart transplantation ("Destination Therapy").

### MCS treatments include:

- Ventricular Assist Device (left or right ventricular)
- Total Artificial Heart
- Extra Corporeal Life Support
- Intra-Aortic Balloon Pump

# **About LVADs**

A left ventricular assist device or "LVAD" (sometimes called a "VAD" or "heart pump") is a commonly used MCS device. An LVAD attaches to the heart and is designed to assist, or take over, the pumping function of the patient's left ventricle – the main pumping chamber of the heart.

LVADs circulate blood throughout the body when the heart is too weak to pump blood adequately on its own, often resulting in improved breathing, reduced fatigue, and improved organ function in heart failure patients.

The LVAD is placed just below the diaphragm in the abdomen and attached to the left ventricle and the aorta, the main artery that carries the oxygenated blood from the left ventricle to the entire body. People with an LVAD also wear part of the system outside of their bodies, including a small controller and two batteries, all of which are connected to the LVAD through wiring inserted during the LVAD surgery. The portable, wearable system is either worn under or on top of clothing.

### Benefits of an LVAD

The AHA estimates there are 50,000 to 100,000 advanced heart failure patients in the U.S. today who could benefit from an LVAD, without which most would have poor prospects for survival and significantly limited lifestyles."

Further, studies have demonstrated that the one-year survival rate for someone with end-stage heart failure is just 10 percent without an LVAD. This is in contrast to a 68 percent one-year survival rate for patients who

receive continuous flow LVADs. iii Recent research shows that some LVAD patients are living more than eight years post implant. iv

LVADs have demonstrated the ability to help extend the lives of heart-failure patients and improve their quality of life, with many LVAD patients reporting that they can resume their normal activities after surgery. Still, many patients who have experienced heart failure are unaware of LVADs as a treatment option, and report a lack of education and resources.

# By The Numbers: Heart Failure and LVADs in the U.S.

**5 Million**: Total Americans currently living with heart failure. *In fact, 670,000 new cases are diagnosed each year.* v

Approximately 50% will die within 5 years of diagnosis.vi

2,000 advanced heart failure patients receive transplants each year. vii

**Still...** More than 250,000 advanced heart failure patients in the U.S. have no viable treatment option and are considered at high risk for repeated hospitalization, poor quality of life and even death. viii

Approximately 50,000-100,000 of these patients could benefit from an LVAD. ix

#### **Potential Risks**

Complications of LVAD surgery are similar to the potential complications of any open heart surgery procedure. A surgeon will discuss potential risks and benefits with the patient prior to the procedure. Risks may include blood clots, bleeding, infection, device malfunction, right heart failure or death.

Possible serious adverse events include the following:

- Death
- Bleeding, during surgery or after surgery
- Cardiac arrhythmia (irregular heartbeat)
- Local infection
- Respiratory failure
- Device malfunction
- Sepsis (serious infection)
- · Right heart failure
- Driveline or pocket infection
- Renal failure (inability of the kidneys to remove waste from the blood)
- Stroke
- Neurologic dysfunction (problems affecting the brain or nervous system)
- Psychiatric episode
- Thromboembolic event, peripheral (blood clots)
- Hemolysis (breakdown of red blood cells)
- Hepatic dysfunction (liver problems)

- Device thrombosis (formation of a blood clot inside the device)
- Myocardial infarction (heart attack)

#### **More Information**

Mended Hearts is the oldest peer-to-peer support group in the United States that seeks to provide hope to heart disease patients, their families and caregivers. Together with support from St. Jude Medical, Mended Hearts launched the "Thanks to an LVAD..." Video Contest in February 2016. Visit www.ThanksLVAD.com to learn more and see inspirational stories of patients who have benefited from an LVAD.

<sup>&</sup>lt;sup>1</sup> Slaughter, M.S., Rogers, J.G., et al. Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device. N Engl J Med. 2009 Dec 3; Vol 361:2241-2251

<sup>&</sup>quot; American Heart Association, HeartMate II: A Reliable Destination; Feb. 2010

iii McIlvennan CK, Magid KH, Ambardekar AV, Thompson JS, Matlock DD, Allen LA. Clinical Outcomes Following Continuous-Flow Left Ventricular Assist Device: A Systematic Review. Circ. Heart Fail. Oct 7 2014.

iv Data on file, Pleasanton, Calif., Thoratec Corporation.

<sup>&</sup>lt;sup>v</sup> Go AS, Mozaffarian D, Roger VL, Benjamin EJ, Berry JD, et al. <u>Heart disease and stroke statistics—2013 update: a report from the American Heart Association</u>. 2013;127:e6–e245.

vi Go AS, Mozaffarian D, Roger VL, Benjamin EJ, Berry JD, et al. <u>Heart disease and stroke statistics—2013 update: a report from the American Heart Association</u>. *Circulation*. 2013;127:e6—e245.

vii Slaughter, M.S., Rogers, J.G., et al. Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device. N Engl J Med. 2009 Dec 3; Vol 361:2241-2251

viii Slaughter, M.S., Rogers, J.G., et al. Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device. N Engl J Med. 2009 Dec 3; Vol 361:2241-2251

ix American Heart Association, HeartMate II: A Reliable Destination; Feb. 2010