Abbott

# HEARTMATE II™ LEFT VENTRICULAR ASSIST SYSTEM


**HeartMate II™**
Left Ventricular Assist Device

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# UNPARALLELED REAL-WORLD EXPERIENCE

Over 25,000 heart failure patients have received the HeartMate II™ LVAD. Many have passed the 5-year milestone on therapy, with some still on therapy after 10-plus years — living proof for over a decade that HeartMate II LVAD delivers predictable surgical and clinical performance for improved outcomes.[1-5]

The HeartMate II LVAD, along with the HeartMate 3™ LVAD, make up the HeartMate™ LVAD Portfolio to deliver innovation, experience and outstanding outcomes[4-7, 8] — setting the standard in heart failure LVAD therapy.

# EXPERIENCE MAKES A DIFFERENCE

HeartMate II™ LVAD is the most widely used and extensively studied LVAD in the world, with more patients treated and multiple clinical data published in top peer-reviewed journals.[7]

## UNPARALLELED REAL-WORLD EXPERIENCE

OVER
**25,000** Patients implanted with the HeartMate II™ LVAD[6]

## UNMATCHED CLINICAL EVIDENCE[1,7,9-13]

OVER
**900**
CLINICAL OR SCIENTIFIC PUBLICATIONS[7*]

**ROADMAP Trial (2017)**
*Journal of the American College of Cardiology: Heart Failure*[9]

**PREVENT Trial (2016)**
*Journal of Heart and Lung Transplantation*[10]

**DT Post-Approval Study (2014)**
*Journal of the College of Cardiology*[1]

**BTT Post-Approval Study (2011)**
*Journal of the American College of Cardiology*[11]

**DT Trial (2009)**
*New England Journal of Medicine*[12]

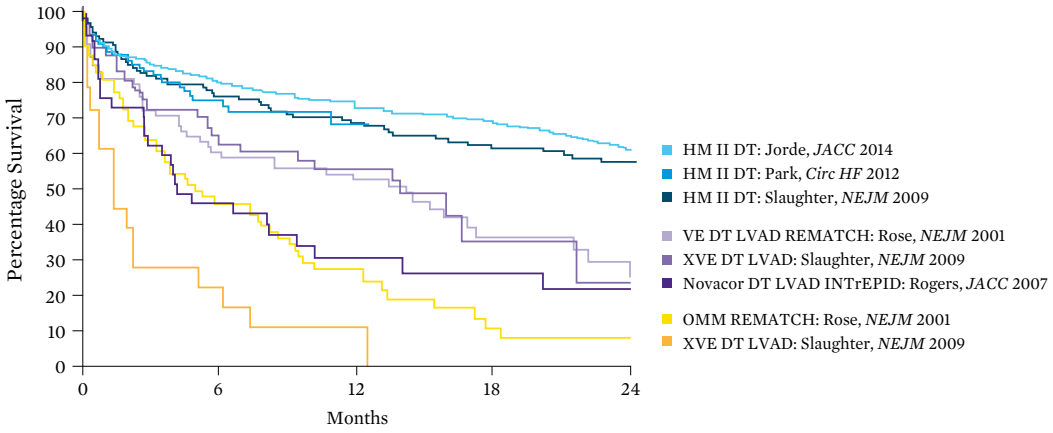
**BTT Trial (2007)**
*New England Journal of Medicine*[13]

*HeartMate II LVAD publications as of July 11, 2017. Above numbers are cumulative. The total number of publications in 2016 include the publications from prior years.

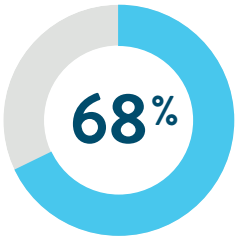
# PREDICTABLE PERFORMANCE FOR IMPROVED OUTCOMES

The HeartMate II™ LVAD delivers predictable surgical and clinical performance for improved outcomes in both bridge-to-transplantation and destination therapy.[1-5]

## HEARTMATE II LVAD SHOWS IMPROVED SURVIVAL OVER TIME IN LVAD TRIALS**[4]

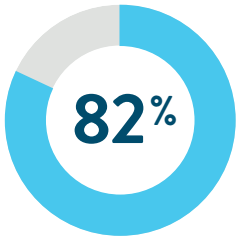



## HEARTMATE II LVAD LONG-TERM SURVIVAL RATES APPROACH THOSE OF TRANSPLANTATION**[4,14]




**HEARTMATE II™ LVAD SURVIVAL RATES[4]**

2-year survival




**TRANSPLANTATION SURVIVAL RATES[14]**

2-year survival

**Based on published data from multicenter experience and separate studies, which may involve different patient populations and other variables. Not a head to head comparison. Data presented for informational purposes only.

Please refer to the HeartMate II LVAD Instructions for Use about indications, contraindications, adverse events, warnings, and precautions.

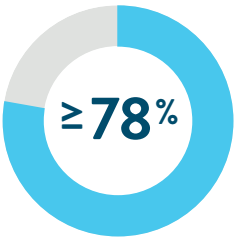
# SIGNIFICANT IMPROVEMENTS IN FUNCTIONAL CLASS AND QUALITY OF LIFE

**80% of HeartMate II™ LVAD recipients** reverse many of the symptoms of their heart failure condition.[15]

## HEARTMATE II LVAD OFFERS PATIENTS IMPROVEMENT IN NYHA CLASS[15]

More than 80% of patients improved to NYHA Class I/II from NYHA Class IIIB/IV by 6 months, with sustained improvement of 78% through 24 months. [15]

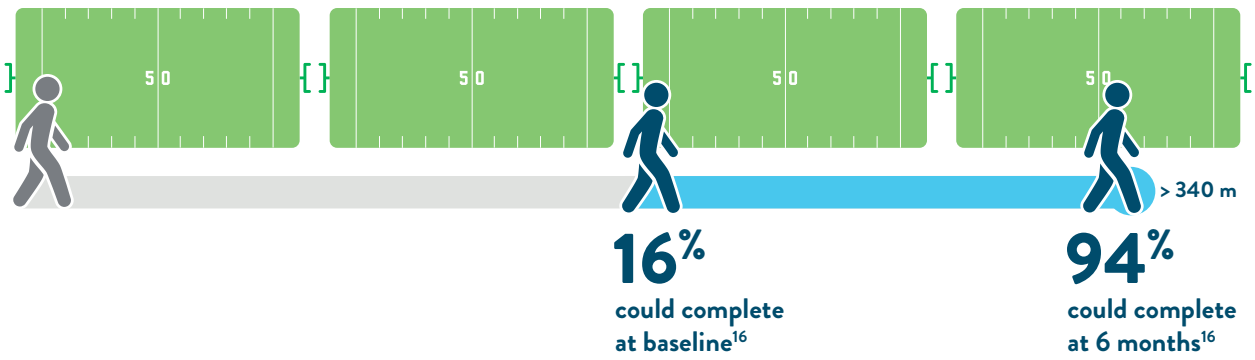

**6 MONTHS**
(n = 276)




**24 MONTHS**
(n = 162)

## HEARTMATE II LVAD OFFERS PATIENTS IMPROVEMENT IN 6-MINUTE WALK DISTANCE[16]

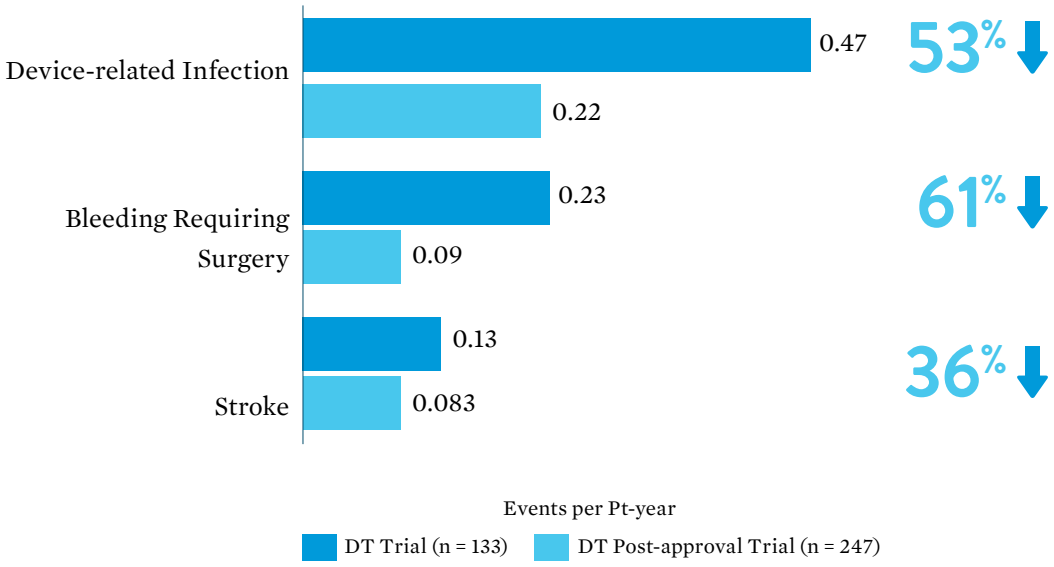
At baseline, only 16% of those tested completed the 6-minute walk test at an average of ~200 meters. At six months, 94% of those tested completed the test at an average of ~340 meters.[16]



# PREDICTABLE ADVERSE EVENT PROFILE

The HeartMate II™ LVAD adverse event profile allows surgeons to implant with confidence.

## LOWERED ADVERSE EVENTS WITH COMMERCIAL USE[1]




## REDUCTION IN THROMBUS WITH ADHERENCE TO PREVENT RECOMMENDATIONS[10]

**4.8%** **CONFIRMED PUMP THROMBOSIS EVENTS**
at 6 months[10]

## LOW PUBLISHED STROKE RATES***

| HeartMate™ II LVAD Recent Studies | ENDURANCE[4] N = 148 2 Years 204 PT YEARS | ROADMAP[9] N = 94 2 Years 68.7 PT YEARS | PREVENT[10] N = 300 6 Months | MOMENTUM 3[8] N = 138 6 Months |
|---|---|---|---|---|
| **Stroke (%/EPPY)** | **12.1% / 0.09** | **11.7% / 0.09** | **6.7%** | **10.9%** |
| Ischemic (%/EPPY) | 8.1% / 0.06 | 8.5% / 0.06 | 4.0% | 6.5% |
| Hemorrhagic (%/EPPY) | 4.0% / 0.03 | 4.3% / 0.03 | 2.7% | 5.8% |

***Based on published data from multicenter experience and separate studies, which may involve different patient populations and other variables.
Please refer to the HeartMate II LVAD Instructions for Use about indications, contraindications, adverse events, warnings, and precautions.

# FLEXIBILITY TO TREAT MORE PATIENTS

HeartMate II™ LVAD is indicated for patients in NYHA Class IIIB and IV, and is clinically proven for both short and long-term support.

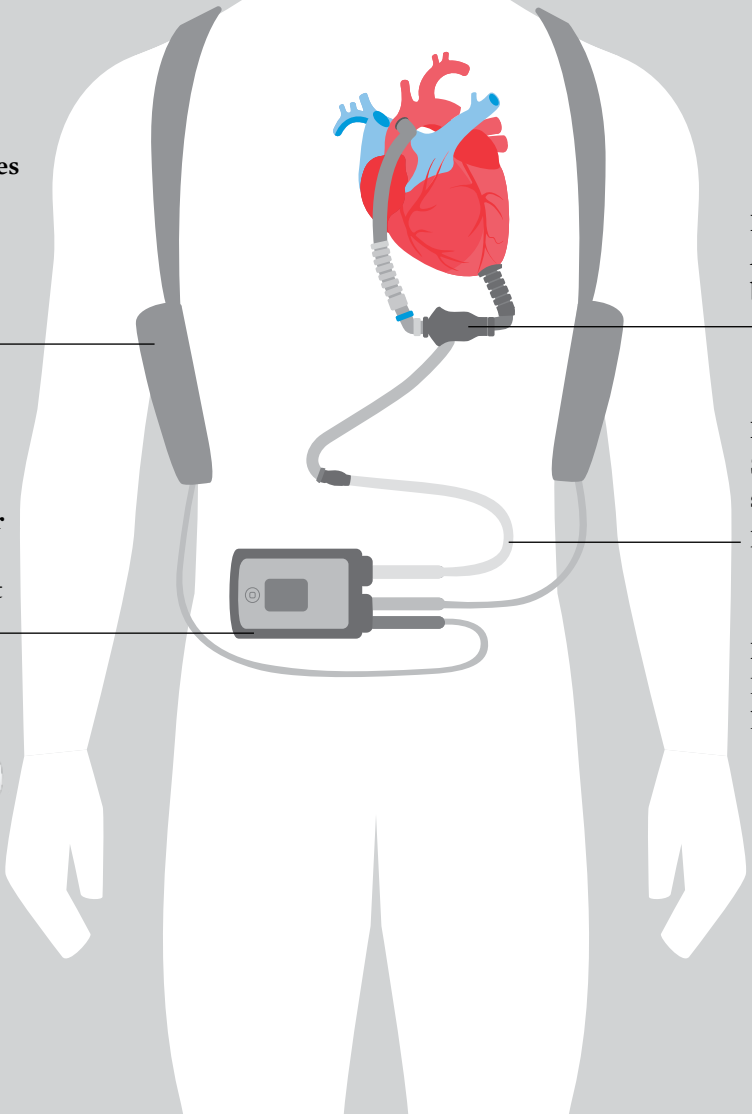
### Bridge-to-Transplantation (BTT)

Mechanical circulatory support for certain cardiac transplantation candidates who are at risk of imminent death from non-reversible left ventricular failure.

### Destination Therapy (DT)

Mechanical circulatory support for certain patients in end-stage left ventricular failure who are not candidates for cardiac transplantation.

## THE HEARTMATE II LVAD SYSTEM IS DESIGNED FOR AN ACTIVE LIFESTYLE[15,16]

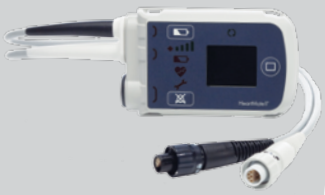


**Wearable external batteries**
Two rechargeable 1-pound batteries deliver up to 12 hours of uninterrupted support on a single charge

**HeartMate II™ LVAD**
Assists the heart in circulating blood throughout the body

**Durable, percutaneous driveline**
Sends power and operating signals to the LVAD from the pocket controller

**External pocket controller**
Controls the LVAD, and is small and light enough to fit in a pocket



**Mobile Power Unit**
Lightweight, discreet and highly portable

1. Jorde, U. P., Kushwaha, S. S., Tatooles, A. J., Naka, Y., Bhat, G., Long, J. W., ... & Birks, E. J. (2014). Results of the destination therapy post-food and drug administration approval study with a continuous flow left ventricular assist device: a prospective study using the INTERMACS‡ registry (Interagency Registry for Mechanically Assisted Circulatory Support). *Journal of the American College of Cardiology*, *63*(17), 1751-1757.
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3. Estep, J. D., Starling, R. C., Horstmanshof, D. A., Milano, C. A., Selzman, C. H., Shah, K. B., ... & Kasirajan, V. (2015). Risk assessment and comparative effectiveness of left ventricular assist device and medical management in ambulatory heart failure patients: results from the ROADMAP study. *Journal of the American College of Cardiology*, *66*(16), 1747-1761.
4. Rogers, J. G., Pagani, F. D., Tatooles, A. J., Bhat, G., Slaughter, M. S., Birks, E. J., ... & Gregoric, I. D. (2017). Intrapericardial Left Ventricular Assist Device for Advanced Heart Failure. *New England Journal of Medicine*, *376*(5), 451-460.
5. Grady, K. L., Naftel, D., Stevenson, L., Dew, M. A., Weidner, G., Pagani, F. D., ... & Young, J. (2014). Overall quality of life improves to similar levels after mechanical circulatory support regardless of severity of heart failure before implantation. *The Journal of Heart and Lung Transplantation*, *33*(4), 412-421.
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7. Based on clinical or scientific publications on HeartMate II LVAD as of July 24, 2017. SJM-HM-0817-0090.
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9. Starling RC, Estep JD, Horstmanshof DA, Milano CA, et al; ROADMAP Study Investigators (2017). Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients: The ROADMAP Study 2-Year Results. *JACC Heart Fail*, 2017 Mar 30.
10. Maltais S., et al. PREVENTion of HeartMate II Pump Thrombosis Through Clinical Management: The PREVENT multi-center study. *J Heart Lung Transplant*, 2017 Jan;36(1):1-12. Epub 2016 Nov 16.
11. Starling, R. C., Naka, Y., Boyle, A. J., Gonzalez-Stawinski, G., John, R., Jorde, U., et al (2011). Results of the post-U.S. Food and Drug Administration-approval study with a continuous flow left ventricular assist device as a bridge to heart transplantation. A prospective study using the INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support). *Journal of the American College of Cardiology*, *57*(19), 1890-1898.
12. Slaughter, M. S., Rogers, J. G., Milano, C. A., Russell, S. D., Conte, J. V., et al (2009). Advanced heart failure treated with continuous-flow ventricular assist device. *New England Journal of Medicine*, *361*(23), 2241- 2251.
13. Miller, L. W., Pagani, F. D., Russell, S. D., John, R., Boyle, A. J., et al (2007). Use of a continuous-flow device in patients awaiting heart transplantation. *New England Journal of Medicine*, *357*(9), 885-896.
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Caution: US federal law restricts this device to sale by or on the order of a physician.

**Abbott**

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SJM.com

St. Jude Medical is now Abbott.

**Rx Only**

**Brief Summary:** Prior to using these devices, please review the Instructions for Use (IFU) for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

**Indications:** The HeartMate II™ Left Ventricular Assist System is indicated for use as a "bridge to transplantation" for cardiac transplant candidates who are at risk of imminent death from non-reversible left ventricle failure. It is also indicated for use in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure, who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II Left Ventricular Assist System is intended for use both inside and outside of the hospital, or for transportation of Left Ventricular Assist Device patients via ground ambulance, airplane, or helicopter.

**Contraindications:** The HeartMate II Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

**Adverse Events:** Adverse events that may be associated with the use of the HeartMate II Left Ventricular Assist System are listed below. Adverse events are listed in decreasing order of frequency, except for death, which appears first because it is a non-reversible complication:

Death, Bleeding (perioperative or late), Cardiac arrhythmia, Local infection, Respiratory failure, Device malfunction, Sepsis, Right heart failure, Driveline or pump pocket infection, Renal failure, Stroke, Neurologic dysfunction, Psychiatric episode, Peripheral thromboembolic event, Hemolysis, Hepatic dysfunction, Device thrombosis, Myocardial infarction

**Warnings:** A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using the HeartMate II Left Ventricular Assist System. Read the IFU before attempting implantation of the Left Ventricular Assist Device or before caring for HeartMate II patients. Completion of Thoratec's HeartMate II LVAD Surgical Training Program is also required prior to use. Understanding the operating and safety aspects of the HeartMate II Left Ventricular Assist System is critical for safe and successful use. All users, including clinicians, patients, and caregivers, must be trained on system operation and safety before use. All users, including clinicians, patients, and caregivers, must be trained on any HeartMate II power accessories (Power Module, Battery Charger, or HeartMate™ 14 Volt Lithium-Ion batteries) before use. Do not use the HeartMate II™ Left Ventricular Assist Device in pregnant women or in women likely to become pregnant. A growing fetus may dislodge the pump, which may result in device failure, catastrophic bleeding, or death. Instruct women of childbearing age to use reliable contraception if sexually active. Blood thinners have been associated with birth defects. Anticoagulation regimens are contraindicated during pregnancy. Certain parts of the HeartMate II Left Ventricular Assist System are not compatible with other HeartMate systems (such as the XVE Left Ventricular Assist System). Only use HeartMate II parts with the HeartMate II system. Do not try to repair any of the HeartMate II system components. If components need service, contact appropriate personnel.

Please consult your doctor or the St. Jude Medical website for a complete list of risks.

Please refer to the HeartMate II Left Ventricular Assist System Instructions for Use for additional warnings and precautions (http://www.thoratec.com/medical-professionals/resource-library/ifus-manuals/heartmate-ll-lvad.aspx).



22774-SJM-HM-0317-0061a | Item approved for global use.

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