HEARTMATE II™ LEFT VENTRICULAR ASSIST SYSTEM
HeartMate II™
Left Ventricular Assist Device

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.¹–⁶

The HeartMate II LVAD, along with the HeartMate 3™ LVAD, make up the HeartMate™ LVAD Portfolio to deliver innovation, experience and outstanding outcomes⁴–⁷,⁸ — 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™ LVAD⁶

UNMATCHED CLINICAL EVIDENCE¹,⁷,⁹-¹³

ROADMAP Trial (2017)
Journal of the American College of Cardiology: Heart Failure⁶

PREVENT Trial (2016)
Journal of Heart and Lung Transplantation¹⁰

DT Post-Approval Study (2014)
Journal of the College of Cardiology¹

BTT Post-Approval Study (2011)
Journal of the American College of Cardiology¹¹

DT Trial (2009)
New England Journal of Medicine¹²

BTT Trial (2007)
New England Journal of Medicine¹³

⁷HeartMate 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**

HEARTMATE II LVAD LONG-TERM SURVIVAL RATES APPROACH THOSE OF TRANSPLANTATION**

68% HEARTMATE II™ LVAD SURVIVAL RATES**
2-year survival

82% TRANSPLANTATION SURVIVAL RATES**
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.
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 CLASS15

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

HEARTMATE II LVAD OFFERS PATIENTS IMPROVEMENT IN 6-MINUTE WALK DISTANCE16

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 USE¹

<table>
<thead>
<tr>
<th>Event</th>
<th>DT Trial (n = 133)</th>
<th>DT Post-approval Trial (n = 247)</th>
<th>Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device-related Infection</td>
<td>0.22</td>
<td>0.47</td>
<td>53%</td>
</tr>
<tr>
<td>Bleeding Requiring Surgery</td>
<td>0.23</td>
<td>0.09</td>
<td>61%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0.13</td>
<td>0.083</td>
<td>36%</td>
</tr>
</tbody>
</table>

Events per Pt-year

REDUCTION IN THROMBUS WITH ADHERENCE TO PREVENT RECOMMENDATIONS¹⁰

4.8% CONFIRMED PUMP THROMBOSIS EVENTS at 6 months¹⁰

LOW PUBLISHED STROKE RATES***

<table>
<thead>
<tr>
<th>HeartMate™ II LVAD Recent Studies</th>
<th>ENDURANCE* N = 148 2 Years 204 PT YEARS</th>
<th>ROADMAP* N = 94 2 Years 68.7 PT YEARS</th>
<th>PREVENT* N = 300 6 Months</th>
<th>MOMENTUM 3* N = 138 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke (%/EPPY)</td>
<td>12.1% / 0.09</td>
<td>11.7% / 0.09</td>
<td>6.7%</td>
<td>10.9%</td>
</tr>
<tr>
<td>Ischemic (%/EPPY)</td>
<td>8.1% / 0.06</td>
<td>8.5% / 0.06</td>
<td>4.0%</td>
<td>6.5%</td>
</tr>
<tr>
<td>Hemorrhagic (%/EPPY)</td>
<td>4.0% / 0.03</td>
<td>4.3% / 0.03</td>
<td>2.7%</td>
<td>5.8%</td>
</tr>
</tbody>
</table>

***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.
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**

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

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

- **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

- **Mobile Power Unit**
  Lightweight, discreet and highly portable
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, Neuropsychologic dysfunction, Psychiatric episode, Peripheral thromboembolic event, Hemolysis, Hepatic dysfunction, Device thrombosis, Myocardial infarction

Indications: The HeartMate II Left Ventricular Assist System is intended for use as a “bridge to transplantation” for cardiac transplant candidates who are at risk of imminent death from heart failure. It is also indicated for use in patients with New York Heart Association (NYHA) Class III 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.