Abbott

HEARTMATE 3™ LEFT VENTRICULAR ASSIST SYSTEM

A New Milestone in LVAD Therapy

HeartMate 3™
Left Ventricular Assist Device

Introducing the new

HEARTMATE 3™ LVAD WITH FULL MAGLEV™ FLOW TECHNOLOGY

HeartMate 3™ LVAD with Full MagLev™ Flow Technology delivers better blood handling through meaningful innovation.**[1]

VIVIAN
HeartMate 3™ LVAD
Recipient

SETTING A NEW STANDARD FOR HEMOCOMPATIBILITY

The HeartMate 3™ LVAD with Full MagLev™ Flow Technology sets a new standard of LVAD performance by significantly improving the hemocompatibility-related adverse event (HRAE) profile.

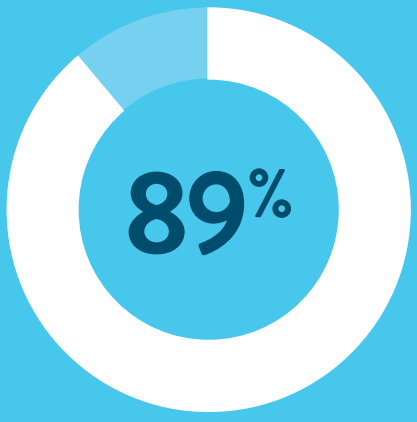
IMPROVED HRAE PROFILE

0% PUMP THROMBOSIS[1]

At the 6-month primary endpoint in the MOMENTUM 3 trial.[1]

The HeartMate 3™ LVAD addresses the complex interconnectivity of hemocompatibility events by minimizing pump thrombosis without significantly impacting† stroke or gastrointestinal bleeding.

EXCELLENT 6-MONTH SURVIVAL[1]



†There is no significant difference between the HeartMate 3 and HeartMate II LVADs with regard to stroke or gastrointestinal bleeding in the MOMENTUM 3 study: 7.9% and 15.9% for the HeartMate 3 LVAD, respectively, vs 10.9% and 15.2% for the HeartMate II™ LVAD in the MOMENTUM 3 trial at 6 months.[1]

Meaningful innovation driven by

FULL MAGLEV™ FLOW TECHNOLOGY

Full MagLev™ Flow Technology is designed to provide better blood handling to minimize complications.

UNIQUE HEMODYNAMIC ELEMENTS

- **Frictionless design,** with the absence of mechanical bearings, may help to eliminate friction, heat buildup and the potential for thrombus
- **Wide blood flow pathways** intended to minimize hemolysis, blood shearing and stasis
- **Intrinsic pulsatility** to enable pump washing and help minimize areas of stasis in the pump

DESIGNED TO DELIVER

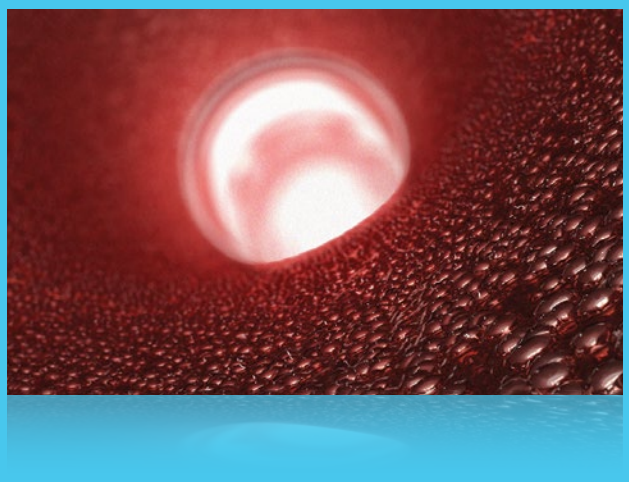
MINIMAL PUMP THROMBOSIS[1]

LOW HEMOLYSIS[1]

REDUCED BLOOD SHEARING AND STASIS[3]

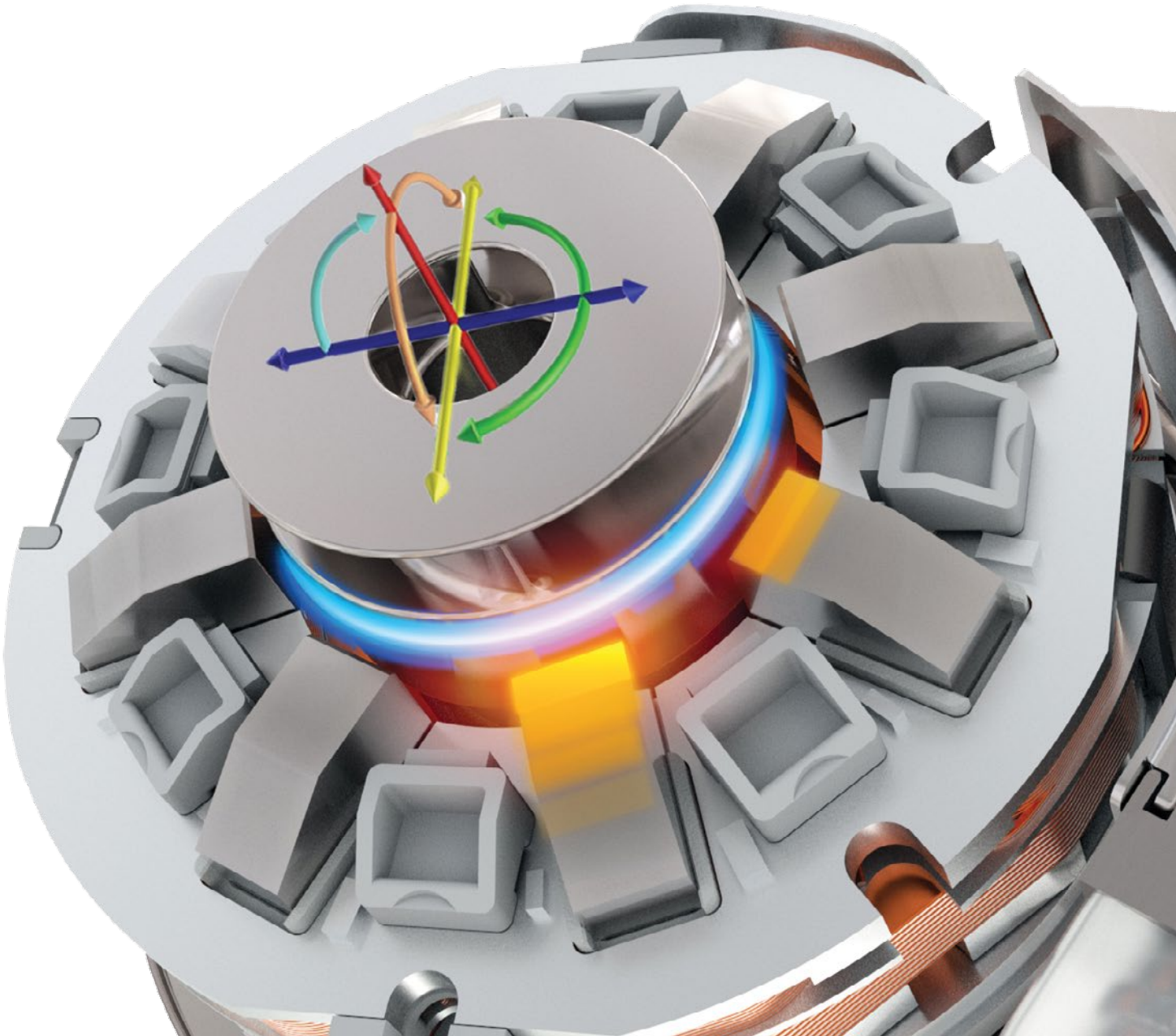
SINTERED TITANIUM SURFACES

Designed to promote hemocompatibility on blood contacting surfaces inside the pump, generating a hemocompatible surface layer that can reduce the potential for thrombus formation.



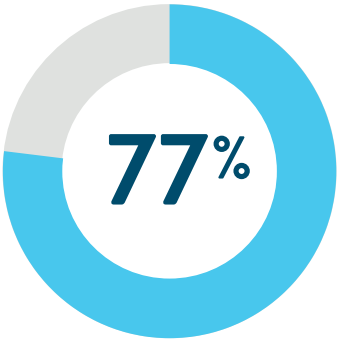
FEATURING
LEVITATING SELF-CENTERING ROTOR

Rotor self-diagnostics are performed tens of thousands of times per second to ensure consistent centering. HeartMate 3™ LVAD rotor will remain suspended and centered, regardless of its orientation, even at zero speed.



MAKING A REAL DIFFERENCE
in patients' lives

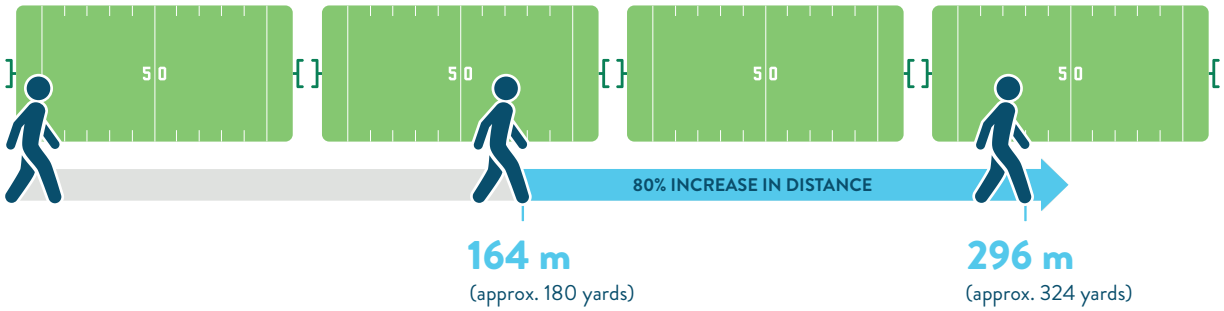
SIGNIFICANT IMPROVEMENT
IN NYHA CLASS[1]



PATIENTS IMPROVED
to NYHA Class I or II from NYHA Class III or IV (n = 127) at 6 months ($p < 0.0001$ compared to baseline)

SIGNIFICANT IMPROVEMENT
IN 6-MINUTE WALK DISTANCE[1]

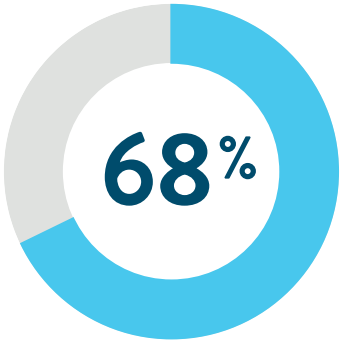
Average 6-minute walk distance in patients implanted with the HeartMate 3™ LVAD (n = 114) ($P < 0.001$ compared to baseline)[1]



Note: One football field = 91 m (100 yards)

MEANINGFUL IMPROVEMENT IN QUALITY OF LIFE[1]

Kansas City Cardiomyopathy Questionnaire Overall Score Increase from Baseline



IMPROVEMENT
in mean KCCQ score (standard QoL scale) from baseline****

ADVERSE EVENT PROFILE[1]

Adverse events through six months for patients implanted with the HeartMate 3™ LVAD (n = 151).

Device thrombosis	0	0%	0
Hemolysis not associated with pump thrombosis	1	0.7%	1
GI bleeding	24	15.9%	47
Stroke*	12	7.9%	12
Ischemic	8	5.3%	8
Hemorrhagic	4	2.6%	4
Bleeding requiring surgery	15	9.9%	15
Device malfunction requiring reoperation	1	0.7%	1
Driveline infection	18	11.9%	21
RVAD usage	4	2.6%	4

A BETTER EXPERIENCE
for clinicians and patients

Abbott continues to set new standards with the world's most comprehensive portfolio of innovative, evidence-based solutions for heart failure therapy supported by a deep commitment to the success of your heart failure program.

- Offers up to 17 hours of battery life for greater patient confidence and convenience
- Designed for intrapericardial placement
- Features a thin, mechanical apical cuff lock for quick and easy pump attachment
- Incorporates a modular driveline that facilitates simple replacement of externalized portion

The HeartMate 3™ LVAS

TO LEARN MORE

about the HeartMate 3™ LVAD with Full MagLev™ Flow Technology, please contact your Abbott representative or visit **www.HeartMate3.com**.

EMPOWERING THE TRANSFORMATION OF HEART FAILURE

From treatment to ongoing patient management, Abbott is committed to working with you to transform heart failure and improve more patient lives.

BEAT AS ONE™

*At the 6-month primary endpoint in the MOMENTUM 3 trial. (MOMENTUM 3 = Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HeartMate 3).
**As defined by zero incidence of pump thrombosis in the MOMENTUM 3 trial at 6 months.
***As seen in the MOMENTUM 3 trial.
****Kansas City Cardiomyopathy Questionnaire.

1. Mehra MR, Naka Y, Uriel N, et al; for the MOMENTUM 3 investigators. A fully magnetically levitated circulatory pump for advanced heart failure. *N Engl J Med. 2017;* 376:440-450.
2. Uriel N, Colombo PC, Cleveland JC, et al. Hemocompatibility-related outcomes in the MOMENTUM 3 trial at 6 months. *Circulation. 2017;*135(21):2003-2012.
3. Bourque, K., Cotter, C., Dague, C., Harjes, D., Dur, O., Duhamel, J., Spink, K., Walsh, K., and Burke, E. Design Rationale and Preclinical Evaluation of the HeartMate 3 Left Ventricular Assist System for Hemocompatibility. *American Society of Artificial Internal Organs* 2016; 62:375-383.
4. Park S. J., Milano, C. A., Tatooles, A. J., Rogers, J. G., Adamson, R. M., Steidley, D. E., et al (2012). Outcomes in advanced heart failure patients with left ventricular assist devices for destination therapy. *Circulation Heart Failure, 5*(2), 241-248.
5. 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.
6. 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
7. 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.

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HeartMate3.com
St. Jude Medical is now Abbott.

Rx Only

Brief Summary: Prior to using these devices, please review the User's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The HeartMate 3 Left Ventricular Assist System is indicated for providing short-term hemodynamic support (e.g., bridge to transplant or bridge to myocardial recovery) in patients with advanced refractory left ventricular heart failure.

Contraindications: The HeartMate 3 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 3 Left Ventricular Assist System are listed below. Adverse events are listed in anticipated decreasing order of frequency, except for death, which appears first as it is a non-reversible complication: death, bleeding, cardiac arrhythmia, localized infection, right heart failure, respiratory failure, device malfunctions, driveline infection, renal dysfunction, sepsis, stroke, other neurological event (not stroke-related), hepatic dysfunction, psychiatric episode, venous thromboembolism, hypertension, arterial non-central nervous system (CNS), thromboembolism, pericardial fluid collection, pump pocket or pseudo pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis), possible pump thrombosis (has not occurred with HeartMate 3™ in the MOMENTUM 3 short term clinical study through 180 days).

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

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Item approved for U.S. use only.

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