

Open a new world
for your advanced heart
failure patients



HeartMate II[®]
Left Ventricular Assist System

Change the trajectory of Advanced Heart Failure (AHF) in your practice

Lead your AHF patients on a different course of action with HeartMate II®

You know your patients depend on you for answers throughout the disease process, whether you've been treating them for many years or have just diagnosed their heart condition. When medical options are no longer enough to provide meaningful benefits, take heart in knowing there is more you can do.

- Mechanical circulatory support (MCS) through a left ventricular assist device (LVAD) is the established standard of care for advanced heart failure by the American Heart Association¹
- HeartMate II, the LVAD market leader, shows survival benefit 7 times that of optimal medical management alone^{2,3}
- LVAD education and early identification of appropriate candidates can make the difference for you and your patients

Understanding the life-changing potential of LVADs, the experience and benefits of HeartMate II, and how to identify appropriate patients for timely referral reflects your commitment to your advanced heart failure patients' long-term outcomes.



Industry best practices for Advanced Heart Failure treatment

American Heart Association (AHA) guidelines identify appropriate therapeutic alternatives for each stage of heart disease

New York Heart Association (NYHA) Classification⁴

	I	II	III	IV
Lifestyle changes	Risk factor reduction		Dietary restrictions	
Medications	ACE inhibitors	Beta-blockers	Diuretics	Palliative care (eg, inotropes)
	ARBs		Aldosterone	
			Digoxin	
Interventional and surgical procedures			Nesiritide	
			CRT	
			Revascularization	
			Mitral valve repair or replacement	
			VAD: Acute, BTT, or DT	
			Transplantation	

Evaluate for advanced assessment & care

Other than heart transplantation, an LVAD is the only option that can significantly and meaningfully improve the symptoms of AHF⁵

- Donor organ supply limits the availability of heart transplants⁶; as a result, more LVADs are implanted each year than heart transplants performed⁷

Leading experts stress the importance of patient selection for early intervention¹

- Studies demonstrate earlier referral and LVAD implantation result in shorter hospitalizations and greater survival,⁸ which may lead to lower adverse events, lower cost of care, and improved quality of life

Recognizing the Advanced Heart Failure patient as an LVAD patient

AHA guidelines establish LVADs as standard of care for AHF patients¹

Patients may be considered for an LVAD for either:

- Bridge to Transplantation (BTT), which supports patients awaiting organ donation
- Destination Therapy (DT), which supports patients ineligible for heart transplant
- Also recommended for use in a less severe patient population or in those who may elect DT

The Destination Therapy patient: A growing population

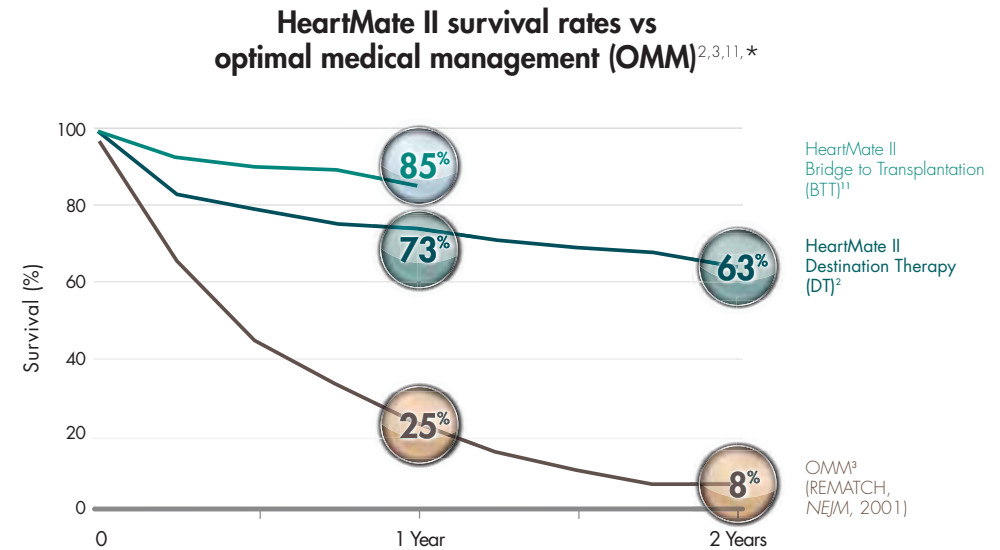
DT patients are ineligible for a heart transplant for reasons such as^{9,10}:

- Advanced age (ie, over 70)
- Cardiac comorbidities such as pulmonary hypertension
- Obesity
- Other serious comorbidities such as renal failure, diabetes, and recent cancer diagnosis

Patients eligible for DT fall into a particular window of health, compromised enough to require an LVAD, but otherwise healthy enough to survive and thrive through the procedure.⁹

Only HeartMate II offers the confidence of long-term survival data

Years of clinical experience show a high percentage survival rate in both DT and BTT patients



*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 Instructions for Use about indications, contraindications, adverse events, warnings, and precautions (<http://www.thoratec.com/medical-professionals/resource-library/ifus-manuals/heartmate-ii-lvad.aspx>).



"With heart failure, it was not a matter of if I would get worse, it was a matter of when; and when it did, my doctors pointed me in the right direction to the HeartMate II."

John

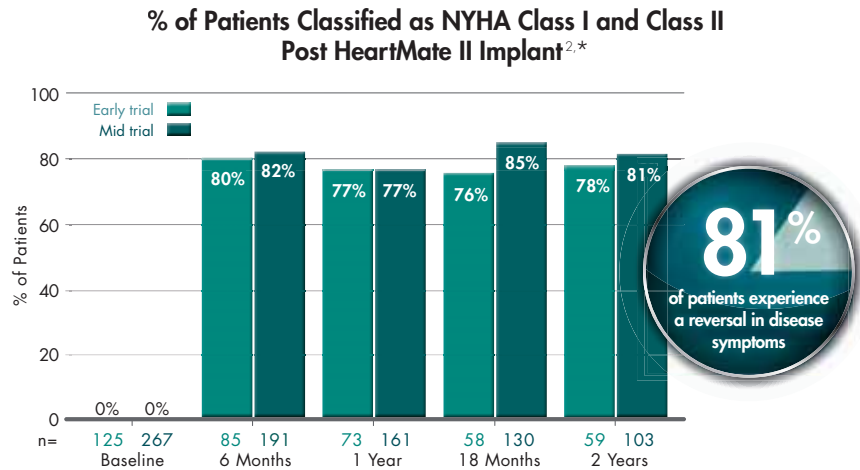
Received HeartMate II as Destination Therapy

HeartMate II[®]
Left Ventricular Assist System



HeartMate II delivers dramatic, sustained functional improvement²

Vast majority of patients return to NYHA Class I or Class II over time²



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HeartMate II allows patients to get moving again¹²

The 6-minute walk test (6MWT) is an objective tool designed to measure activity intolerance in patients with heart failure.¹³

- Prior to implantation, 84% of patients could not complete the 6MWT¹²
- At 6 months post implantation, 94% could complete the test and walked an average of 345 meters¹²

"I felt like my time had really run out until I found out about the HeartMate II. I wish I'd known about it sooner."

Aleta
Received HeartMate II as Destination Therapy



HeartMate II offers assurance regarding complications, especially stroke

HeartMate II has the lowest published stroke rate of any continuous flow LVAD^{11,14,15,*}

Long-term survival anchored in low stroke rates over 1,500 patient years^{2,14}

HeartMate II Stroke Rates in Postapproval Studies

Stroke Rates	BTT ¹⁷	DT ¹⁶
(Events/Patient Years)	2011 N = 1,496 1,082 Patient Years	2013 N = 247 385.5 Patient Years
Ischemic	0.06	0.05
Hemorrhagic	0.02	0.03
Unknown type	0.02	0.0
Total	0.10	0.08

Take confidence in referring patients for an LVAD with HeartMate II

The most widely used and extensively studied LVAD in the world^{17,18}

- Over 17,000 implants (as of June 2014)¹⁹
- Over 7,000 patients currently supported (as of June 2014)¹⁹
- Over 350 HeartMate II Centers in 41 countries¹⁹
- Patients are living over 10 years, and more than 400 have been going strong for more than 5 years¹⁹

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Put your patients on a path to a longer, better life: Refer them for an LVAD evaluation

The world's leading LVAD

- Survival advantage 7 times greater than optimal medical management alone^{2,3}
- Immediate and sustained reduction of heart failure symptoms^{2,*}
- Dramatic and sustained improvements in functional capacity and quality of life^{2,*}
- Lowest published stroke rate of any continuous flow LVAD^{11,14,15,*}
- The only LVAD approved for both DT and BTT, with a proven track record in each^{2,10,12,14,19}



References:

1. Peura JL, Colvin-Adams M, Francis GS, et al. Recommendations for the use of mechanical circulatory support: device strategies and patient selection: a scientific statement from the American Heart Association. *Circulation*. 2012;126(22):2648-2667. 2. Park SJ, Milano CA, Tatroles AJ, et al; for the HeartMate II Clinical Investigators. Outcomes in advanced heart failure patients with left ventricular assist devices for destination therapy. *Circ Heart Fail*. 2012;5(2):241-248. 3. Rose EA, Gelijns AC, Moskowitz AJ, et al; for the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term use of a left ventricular assist device for end-stage heart failure. *N Engl J Med*. 2001;345(20):1435-1443. 4. Jessup M, Brozena S. Heart failure. *N Engl J Med*. 2003;348(20):2007-2018. 5. Miller LV. Left ventricular assist devices are underutilized. *Circulation*. 2011;123(14):1552-1558. 6. Fang JC. Rise of the machines—left ventricular assist devices as permanent therapy for advanced heart failure. *N Engl J Med*. 2009;361(23):2282-2285. 7. Data on file. Thoratec Estimates: Average analyst projections for VAD market [Wells Fargo, JP Morgan, Credit Suisse, Oppenheimer]. 2013. Pleasanton, CA. Thoratec Corp. 8. Boyle AJ, Ascheim DD, Russo MJ, et al. Clinical outcomes for continuous-flow left ventricular assist device patients stratified by preoperative INTERMACS classification. *J Heart Lung Transplant*. 2011;30(4):402-407. 9. Flint KM, Mallock DD, Lindenfeld J, Allen LA. Frailty and the selection of patients for destination therapy left ventricular assist device. *Circ Heart Fail*. 2012;5(2):286-293. 10. HeartMate II Left Ventricular Assist System: Instructions for Use. 105747.B. Pleasanton, CA: Thoratec Corp.; 2013. 11. Starling RC, Naka Y, Boyle AJ, et al. 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 INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support). *J Amer Coll Cardiol*. 2011;57(19):1890-1898. 12. John R, Naka Y, Smedira NG, et al. Continuous flow left ventricular assist device outcomes in commercial use compared with the prior clinical trial. *Ann Thorac Surg*. 2011;92(4):1406-1413. 13. Guazzi M, Dickstein K, Vicenzi M, Arena R. Six-minute walk test and cardiopulmonary exercise testing in patients with chronic heart failure. *Cir Heart Failure*. 2009;2(6):549-555. 14. Boyle AJ, Russell SD, Teuteberg JJ, et al. Low thromboembolism and pump thrombosis with the HeartMate II left ventricular assist device: analysis of outpatient anti-coagulation. *J Heart Lung Transplant*. 2009;28(9):881-887. 15. Aaronson KD, Slaughter MS, Miller LV, et al. Use of an intrapericardial, continuous-flow, centrifugal pump in patients awaiting heart transplantation. *Circulation*. 2012;125(25):3191-3200. 16. Jorde UP, Kushwaha SS, Tatroles AJ, et al. 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). *J Am Coll Cardiol*. 2014;63(17):1751-1757. 17. Lund H, Gabrielsen A, Tirén L, Hallberg A, El Karlsson K, Eriksson MJ. Derived and displayed power consumption, flow, and pulsatility over a range of HeartMate II left ventricular assist device settings. *ASAIO J*. 2012;58(3):183-190. 18. Rodriguez LE, Suarez EE, loebe M, Bruckner BA. Ventricular assist devices (VAD) therapy: new technology, new hope? *Methodist DeBakey Cardiovasc J*. 2013;9(1):32-37. 19. Data on file. June 2014. Pleasanton, CA. Thoratec Corp.

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www.HeartMatePro.com

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