When should patients be considered for HeartMate™ LVAD therapy?

Patients with the following should be referred for evaluation for advanced heart failure therapies, including LVAD therapy.

1 NYHA CLASS IIIB OR IV HEART FAILURE (INTERMACS‡ 1-6):

NYHA CLASS	CLASS III		CLASS IIIB/IV		CLASS IV			
		7	6	5	4	3	2	1
INTERMACS‡ registry advanced heart failure profiles		**Advanced NYHA III symptoms.** *Living comfortably with limited physical activity*	**Exertion limited.** *Walking wounded*	**Exertion intolerant.** *Housebound*	**Resting symptoms.** *Frequent flyer*	**Stable but inotrope dependent.** *Dependent stability*	**Progressive decline on inotropic support.** *Sliding on inotropes*	**Critical cardiogenic shock.** *Crash and burn*

2 ANY ONE OF THE FOLLOWING HIGH-RISK CLINICAL TRIGGERS[1]:

I	IV Inotropes
N	NYHA IIIB/IV or persistently elevated natriuretic peptides
E	End-organ dysfunction (Cr > 1.8 mg/dL or BUN > 43 mg/dL)
E	Ejection fraction ≤ 35%
D	Defibrillator shocks
H	Hospitalizations > 1
E	Edema (or elevated PA pressure) despite escalating diuretics
L	Low blood pressure, high heart rate
P	Prognostic medication — progressive intolerance or down-titration GDMT

Additional patient referral considerations:

- CRT nonresponder
- Physical activity limited or impaired quality of life

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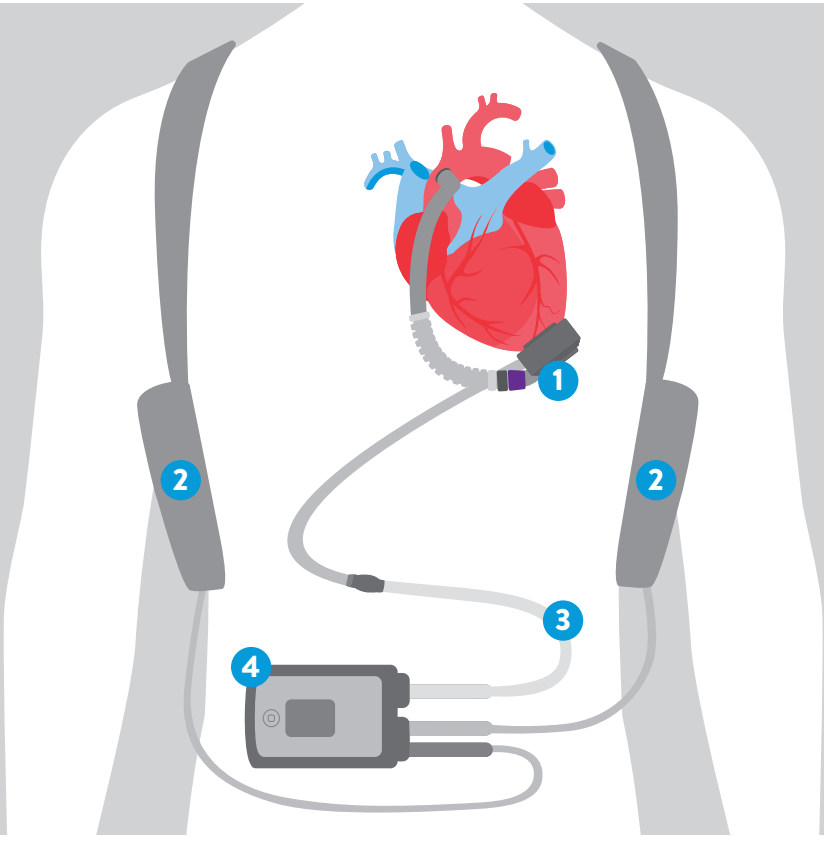
UNDERSTAND THE HEARTMATE™ LVAD SYSTEM

HeartMate 3™
Left Ventricular Assist Device

HeartMate II™
Left Ventricular Assist Device



1. HEART PUMP (LVAD)*
2. BATTERIES
3. DRIVELINE
4. CONTROLLER

*HeartMate 3™ LVAD shown

1. 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. Yancy CW, Januzzi JL Jr, Allen LA, Butler J, Davis LL, Fonarow GC, Ibrahim NE, Jessup M, Lindenfeld J, Maddox TM, Masoudi FA, Motiwala SR, Patterson JH, Walsh MN, Wasserman A. *J Am Coll Cardiol.* 2018 Jan 16;71(2):201-230. doi: 10.1016/j.jacc.2017.11.025. Epub 2017 Dec 22.

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One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000
HeartMate.com
St. Jude Medical is now Abbott.

Rx Only

Important Safety Information

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

HeartMate 3™ LVAS 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.

HeartMate II™ LVAS 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 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.

HeartMate 3 LVAS and HeartMate II LVAS Contraindications: The HeartMate 3 and HeartMate II Left Ventricular Assist Systems are contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.

HeartMate 3 LVAS and HeartMate II LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 or HeartMate II Left Ventricular Assist System are listed below: 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 pump pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) and possible pump thrombosis.

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