NEW HEARTMATE 3^{TM} with Full MagLev flow technology

RESPECTS THE FLOW



with Full MagLev™

New HeartMate 3[™] with Full MagLev[™] flow technology

HAEMOCOMPATIBILITY MAKES THE DIFFERENCE



Full MagLev flow technology is designed to optimise haemocompatibility and reduce blood trauma through gentle blood handling.



Remarkably low incidence of key adverse events



Excellent 30-day and 6-month survival

98% 30-day survival¹

Study description: Single-arm, prospective, multicentre, nonblinded, nonrandomised study to evaluate the performance and safety of HeartMate 3 Left Ventricular Assist System after 6 months of support. Patients were adults with an ejection fraction \leq 25% and cardiac index \leq 2.2 L/min/m² while not on inotropes. Patients must have also met one of the following: on optimal medical management, based on current heart failure practice guidelines, for at least 45 out of the previous 60 days and were failing to respond; or in NYHA class IIIB or IV heart failure for at least 14 days AND dependent on intra-aortic balloon pump for at least 7 days; or inotrope-dependent/unable to wean from inotropes; or listed for transplant.¹

Patient population: Fifty patients were enrolled and implanted with HeartMate 3 at 10 centres. Patients were representative of an advanced heart failure population and were a mix of bridge-to-transplant (54%) and destination therapy (46%). Twenty-six patients (52%) were in INTERMACS profiles 2 and 3, and 24 patients (48%) were in profiles 4 to 6. No patients were in profiles 1 or 7.





GENTLE BLOOD HANDLING with Full MagLev[™] flow technology

Large, consistent blood-flow pathways Blood-flow gaps 10 to 20 times greater than those of

hydrodynamic-bearing pumps

Full MagLev blood-flow pathway

DESIGNED FOR HAEMOCOMPATIBILITY with the goal of minimising complications



- Rotor is completely suspended by magnetic forces, preventing surface-to-surface contact that could cause blood trauma
- Designed for: -Low haemolysis
- -Minimised blood shearing and stasis



Stacked red blood cells

Dimensions are approximate for illustration purposes only. The use of a red blood cell as a measuring unit is for illustration purposes and is not meant to imply actual blood-flow quantities during operation.

GAP

Full range of operation

Provides flow from 2.5 to 10 L/min to accommodate a broad range of clinical needs



Artificial pulsatility Designed to promote pump washing and minimise areas of stasis in the pump



PERFORMANCE-LEADING **OUTCOMES**

with Heart Mate 3^{TM}

Reach significant improvements in NYHA class¹

Patients improved to NYHA class I or II from NYHA class IIIB or IV at month 6 (P < 0.0001 compared to baseline)

Gain significant improvement in 6-minute walk distance²

Average 6-minute walk distance in patients implanted with HeartMate 3 (n = 36)



NYHA: New York Heart Association.

See progressive, sustained QoL improvements¹

EQ-5D Visual Analog Scale



Confirm a favourable safety profile¹

Adverse events through 6 months for patients implanted with HeartMate 3 (N = 50)

ADVERSE EVENTS	Number of Patients	Percentage of Patients	Number of Events
Device thrombosis	0	0%	0
Haemolysis	0	0%	0
Stroke*			
Ischaemic	4	8%	4
Haemorrhagic	2	4%	2
Bleeding requiring surgery	7	14%	8
GI bleeding	4	8%	6
Device malfunction	0	0%	0
Driveline infection	5	10%	5
Right heart failure	5	10%	5

*Includes 3 procedure-related events: 1 implant issue (difficulty engaging inflow conduit); 1 following anaphylactic shock from contrast media; 1 following transcatheter aortic valve implantation procedure.

Mean baseline values for paired analyses were 52.4, 52.1, and 51.4 at 1, 3, and 6 months, respectively.



Discover a better experience

- Built to the highest standards of Swiss engineering
- Designed for intrapericardial placement
- Features a thin, mechanical apical cuff lock for quick and easy pump attachment
- Incorporates a modular driveline for straightforward replacement of external portion
- Offers an advanced controller and extended battery life for simplified patient management



HeartMate 3[™] treats blood with the respect that it deserves, for optimised outcomes and better patient lives.



References: 1. Netuka I, et al. HeartMate 3 fully magnetically levitated LVAD for the treatment of advanced heart failure: results from the CE Mark Trial. Presented at 19th Annual Meeting of the Heart Failure Society of America; September 26-29, 2015; Washington, DC. 2. Data on file. Thoratec Corporation, 2015. © 2015 Thoratec Corporation. All rights reserved. EU-HM3-08150343

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