

HeartMate 3™

Left Ventricular Assist System



INDICATIONS

The HeartMate 3^{TM} Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in adult and pediatric patients with advanced refractory left ventricular heart failure and with an appropriate body surface area.

DEVICE SPECIFICATIONS

MODEL#	DESCRIPTION
106524US	HeartMate 3™ LVAD Implant Kit, Includes 1 HeartMate 3™ LVAD Controller
106531US	HeartMate 3™ LVAD Controller Includes Emergency Backup Battery
106525US	HeartMate 3™ LVAD Modular Cable
106526US	HeartMate 3™ LVAD Modular Cable Cap (package of 3)
105581US	HeartMate 3™ LVAD Outflow Graft With Bend Relief
100010372GBL	HeartMate 3™ LVAD Tunneling Tools
10002222US	HeartMate 3™ LVAD Surgical Hand Tools
1340	Power Module
1286	System Monitor (configured for HeartMate 3™ LVAD)
107754	Mobile Power Unit [™] Module and Locking Power Cord
107760	Locking AC Power Cord for Mobile Power Unit™ Module
2465	14V Batteries (set of 4)
1440	Battery Charger
2865	14V Battery Clips (set of 2)
104234	Battery Holster
104229/ 104230/104231	Holster Vest (small, medium, large)
104232	Shower Bag (package of 2)
106449/104233	Consolidated Bag (left, right)

MODEL#	DESCRIPTION
10008189	HeartMate 3™ LVAD Functional Training Kit
10008190	HeartMate 3™ LVAD Controller Training Kit
10003212	HeartMate 3™ LVAD Mock Pump (non-functional replica)
10005877	Mini Apical Cuff Kit (Mini Apical Cuff and Apical Cuff Holder)
10005872	HeartMate 3™ Coring Tool
1050	Apical Coring Knife
10010901	HeartMate 3™ Apical Cuff (package of 3)
СН5877	HeartMate 3™ Apical Cuff Holder
106534US	HeartMate 3™ Tunneling Adapters (package of 3)
106532US	HeartMate 3^{TM} Thread Protector Set (package of 5)
106528US	HeartMate 3™ Skin Punch
HMT1100	HeartMate Touch™ Communication System
HMT1100-R	HeartMate Touch™ Communication System, Rental
HMT2100	HeartMate Touch™ Communication System Bluetooth® Wireless Technology Adapter
НМТ2900	Flash Drive for HeartMate Touch™ Communication System
HMT2133	Power Adapter for HeartMate Touch™ Communication System
HMT2166	USB Cable for HeartMate Touch™ Communication System

HeartMate Touch™ Communication System Overview: The HeartMate Touch™ Communication System is intended for use by clinicians in the hospital to wirelessly monitor a patient's HeartMate II™ Left Ventricular Assist System or HeartMate 3™ Left Ventricular Assist System. The HeartMate Touch Communication System is required during implant procedures and any time close monitoring of system operation is needed. It provides clinicians with the ability to program system parameters such as pump speed, assess and track alarm conditions, and view and save performance data.

Abbott

6101 Stoneridge Dr., Pleasanton, CA 94588 USA, Tel: 1 925 847 8600 Cardiovascular.Abbott/HeartMate3

Rx Only

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™ Coring Tool Indications: For the HeartMate 3™ Left Ventricular Assist System (LVAS) Indications for Use, please refer to the HeartMate 3 LVAS Instructions for Use. The HeartMate 3™ Coring Tool is intended for use with the HeartMate 3 LVAS. The HeartMate 3 Coring Tool provides a means to resect a plug of myocardium from the left ventricle, which allows for HeartMate 3 inflow cannula insertion.

HeartMate 3™ Coring Tool Contraindications: The use of the HeartMate 3 Coring Tool is contraindicated in patients who are contraindicated for HeartMate 3 Left Ventricular Assist System (LVAS) therapy.

HeartMate 3™ Coring Tool Adverse Events: The following adverse events may be associated with the use of the HeartMate 3 Coring Tool. 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 (perioperative or late), local infection, local ischemia, cardiac arrhythmia, stroke, peripheral thromboembolic event, neurologic dysfunction, hemolysis, sepsis.

HeartMate 3^{TM} LVAS Indications: The HeartMate 3^{TM} Left Ventricular Assist System is indicated for providing short- and long-term mechanical circulatory support (e.g., as bridge to transplant or myocardial recovery, or destination therapy) in adult and pediatric patients with advanced refractory left ventricular heart failure and with an appropriate body surface area.

 $\textbf{HeartMate 3} \ \textbf{TMLVAS Contraindications} : The \ \textbf{HeartMate 3} \ \textbf{Left Ventricular Assist System is contraindicated for patients who cannot tolerate, or who are allergic to, anticoagulation therapy.}$

HeartMate 3™ LVAS Adverse Events: Adverse events that may be associated with the use of the HeartMate 3 Left Ventricular Assist System are: 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) or pump thrombosis.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner.

Bluetooth and Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

© 2022 Abbott. All Rights Reserved.

MAT-1901625 v6.0 | Item approved for U.S. use only.

