HeartMate III™ LVAS

OR overview

CAUTION: Investigational device. Limited by federal (U.S.) law to investigational use.
Our Product Vision:
A 10 Year, Forgettable System.
HeartMate III: Design Goals

- Build upon the highly successful HeartMate II LVAS
- Enhanced AE profile
- Increased surgical ease
- Elevate the patient experience
HeartMate III

Designed to be Hematologically-Compatibile
Leverages Fully Magnetically Levitated Technology

Features
• Fully Magnetically Levitated
  • Large pump gaps designed to reduce blood trauma
  • Artificial pulse
• Textured blood contacting surfaces
• Wide range of operation
  • Full support (2 – 10 L/min)
• Advanced Design for Surgical Ease
  • Engineered apical attachment
  • Modular Driveline
• Designed for an Active Lifestyle
  • Pocket Controller
HeartMate III Blood Pump

Sealed Outflow Graft (14 mm) w/Bend Relief

Inflow Conduit (20 mm)

Percutaneous Cable

Rotor & Mag-Lev - Blood path with Textured Surfaces
Introduction

• You will find many similarities between the HeartMate III LVAS and the HM II LVAS
• Throughout these training materials we will highlight for you where something is new or unique for the HeartMate III system using the following:

*New for HM III
HeartMate III LVAD

- Pump Cable w/Modular Connector*
- Sealed Outflow Graft w/Bend Relief*
- Inflow*
- Cuff Lock*
- Apical Cuff*

*New for HM III

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Other HeartMate III Items*

- Tunneling Lances & Handle
- Modular Cable
- 6 mm Skin Punch

*New for HM III
HM III is Different from the HM II.....

Implantation

• No pump pocket is required.
• The apical cuff is thinner and has a larger-diameter.
• A quick connection to the cuff replaces tie bands and sutures.
  – The cuff locking mechanism is easily accessible with the pump in place.
• A 2 piece Externally Modular Driveline allows for replacement of external portion of the Driveline
  – The HM III does not utilize the braided metal shielding
  – The Modular Cable is constructed of durable polyurethane
  – Conductors made from a high-flex and high-strength alloy
HM III is Different from the HM II.....

Implantation

• The HM III Outflow Graft and Bend Relief is unique to the HM III Pump
  – It only connect to a HM III pump.
  – The HM II Outflow Graft and Bend Relief will only connect to a HM II pump.

• The Bend Relief is removable with the assistance of a surgical instrument
  – The use of the HM II Collar is not required

• A new Tunneler enables the inside-out or outside-in approach.
  – An OR Cap is provided for the Modular Cable; a Tunneling Adapter is provided for the Pump Cable.

• The pump may temporarily stop during the use of the ESU
  – Function recovers automatically once ESU use has stopped
HM III is Different from the HM II.....

System Controller

• It may take up to 10 seconds for the HM III pump to start once connected to an externally powered System Controller

• The HM III LVAS will not start on the Emergency Battery alone
  – Must be connected to an external power source (14 Volt Batteries, Power Module, or Mobile Power Unit)
Product Configuration*

*New for HM III
HM III Implant Kit

• HM III VAD*
  – Pump, Apical Cuff, Coring Knife, 6 mm Coring Punch, Thread Protectors, Tunneling Adapter

• HM III System Controller*
  – Non-sterile 11V Li-Ion Backup Battery

• Modular Cable*
  – w/cap

• HM III Outflow Graft w/Bend Relief*
  – No collar needed

• GoGear accessories

• IFU & Patient Handbook

*Sterile

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HM III System Controller

- Standalone HM III System Controller*
  - Non-sterile 11V Li-Ion Backup Battery
  - Patient Handbook

*Sterile
HM III Modular Cable

• Standalone Modular Cable*
  – w/cap

*Sterile

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HM III Outflow Graft /Bend Relief

• Standalone HM III Outflow Graft w/Bend Relief*
  – No collar needed

*Sterile

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HM III Tunneling Lance & Handle

• Includes a long & short lance w/Handle
  – Supplied non-sterile
  – Includes cleaning and sterilization instructions
HeartMate III™
OR Device Preparation & Implantation

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Required Thoratec Equipment

Sterile Items

• HM III Implant kit
  – Left Ventricular Assist Device (LVAD) Assembly
  – 14mm Sealed Outflow Graft with Bend Relief
  – Apical Cuff
  – Apical Coring Knife (20mm)
  – Skin Coring Punch (6mm)
  – Outflow Thread Protectors (1 set)
  – Modular Cable (with Modular Cable Cap)
  – Tunneling Adapter
  – System Controller

• HM III System Controller
Required Thoratec Equipment

Non Sterile Items

- Tunneling lance and handle (sterilized at hospital)
- Power Module (PM) with Patient Cable
- System Monitor with SM cable
- Battery Clips (set of 2) for HM 14 v Li-ion batteries
- HM batteries (set of 4) 14 v Li-ion batteries (fully charged)
- Backup Battery (packed with SC)
Other Supplies & Equipment for Implant

- Small Drip Basin
- Graduate Pitcher*
- Emesis Basins (2)
- Vent Needle
- CV Major Surgical Set
- Heavy Non-Absorbable Ligature
- Catheter-Tipped Syringe with Sterile Normal Saline
- 12 pledgeted horizontal mattress 2-0 braided sutures

*New for HM III
Workflow

Day before Implant

– Clean & Sterilize Tunneling Lance and Handle
– Charge 14V Li-Ion Batteries

Day of Implant

– Configure System Monitor & Power Module
  • Set SM date and time
Unpackage Sterile Items*

*New for HM III
Pre-Implant Pump Operation*

• Insert Modular Cable into the System Controller
• Place pump in a sterile graduate pitcher, minimum of 1 L sterile saline
• Connect the Modular in-line connector (preserve caps & plugs) to the Modular Cable – keep dry
• Start pump and run at 3000 rpm for a minimum of 5 minutes – activate extended alarm silent (audio)
• Set patient hematocrit
• Stop pump, disconnect Modular in-line connector from the Modular Cable, replace caps & plugs
• Remove pump from graduate pitcher, place thread protector, fill with sterile saline, glove tip, place with antibiotic laps
• Secure the System Controller and attached Modular Cable (so both maintain sterility) – leave connected to the Power module

*New for HM III
**Driveline Protection**

- Minimize Modular In-line Cable and Modular Cable connectors exposure to fluids
- Place the Modular Cable Cap onto the Modular In-Line Connector by inserting the connector into the cap. Press firmly until the connector bottom is inside the cap.
- Protect the capped Modular Cable Connector with a clean, dry and sterile towel
- Prior to removing the Modular Cable Cap from the Modular Cable, orient it downward and dry it with a clean, dry, and sterile towel
- Prior to removing the Tunneling Adapter from the Modular In-line Cable, orient it downward and dry it with a clean, dry, and sterile towel

*New for HM III*
Key Verifications*

- Observe sterile technique when handling the System Controller, LVAD, Modular Cable and the other sterile system components
- Ensure the Modular Cable (when attached to the System Controller) stays within the sterile field
- All caps and adapters are properly affixed
  - Place a clean, dry, sterile towel to cover the capped end of the Modular Cable
- Remove air bubbles from the sterile saline filled pump by gently tapping

*New for HM III
HeartMate III LVAS Implantation
Pump Cable Placement*

- Choose externalization location – consider stabilization
- Utilize skin punch (6 mm)
- Utilize HM III Tunneling Lance & Handle
  - Tunneling Adapter must be fully engaged – yellow line not visible
  - Attach Lance to Adapter (see next slide)
- May tunnel “Inside – Out” or “Outside – In”
- Long Percutaneous Cable tunnel path – no sharp bends or kinks
  - Dry off connectors
  - Anticipate changes in subject’s anatomy post LVAD recovery
- Velour or silicone skin interface

*New for HM III
Using the Tunneler Handle*

- **Lance Insertion**
  - Retract the handle flange
  - Insert the tip of the tunneling lance and hex shaped feature until captured in the handle

- **Lance Removal**
  - Retract the handle flange
  - Remove lance from handle

*New for HM III*
Apical Anastomosis*

- Choose apical coring location – anticipate cannula position for optimal filling and the position of pump within the chest
- May choose “Cut then Sew” or “Sew then Cut” method for apical cannulation
- While coring, position knife towards the Mitral valve. Avoid cutting the septum and remove core and inspect ventricular cavity
- Use 12 sutures for attaching the Apical Cuff to the myocardium, ensure that the black markings are visible for proper orientation
- Retract Cuff Lock fully, remove glove tip and the advance the Inflow Cannula into the ventricle/apical Cuff
- Radially orient the pump in the desired position, then fully engage the Cuff Lock
  - Verify pump is locked in place
- Place the pump, graft and Driveline in final position
- Connect Modular In-line Cable to the Modular Cable – verify complete engagement and locking (dry off connectors)

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Key Verifications*

- Verify ventricular cored hole is free of obstructive tissue and intraventricular thrombus is removed
- Make sure the cuff lock is fully retracted before inserting into the cored hole
- All 12 sutures must be placed in the Apical Cuff between the black radial line and the metal collar
  - If using the “Sew then Cut” method, place sutures to avoid being cut during coring
- Ensure the Inflow Cannula is positioned in the ventricle without obstruction to flow
- The Cuff Lock is fully engaged in the locked position – no yellow markings visible
- Do not pull on the driveline such that the pump changes position (may also damage PEBR)
- Ensure the Outflow Graft is completely connected to the pump
- Leave Outflow Graft clamps in place

*New for HM III
Attach Outflow Graft to Pump

- Remove thread protectors and attach the Outflow Graft to the pump housing
Modular Cable Connection

• To connect Pump and Modular Cables:
  – Push together firmly
  – Rotate locking nut

• CONFIRM: No Yellow Line is Visible
Modular Cable Disconnection

• To disconnect the Pump and Modular Cables:
  – Rotate the locking nut
  – Until it spins freely

• Pull cables apart
De-Airing & Hemostasis*

- Goal is to remove entrapped air from the LVAD, Outflow Graft, and native heart – use echocardiography to assist in verification

- Place a venting needle in the Outflow Graft to allow trapped air to vent – elevate the graft to the highest position

- Reduce CPB and initiate HM III Pump operation at 3000 rpm – continue to vent until the heart and LVAD are free of air

- Remove Outflow Graft clamp to allow for full LVAD operation

- Inspect the Aortic and Apical anastomosis, Outflow Graft to Pump for hemostasis – address any bleeding

- Slide the OGBR over metal fitting of the Outflow Graft toward screw ring until it is fully engaged – perform verification (next slide)

- Address any non-LVAD bleeding

*New for HM III
Outflow Graft Bend Relief Placement and Verification*

- Advance the Outflow Graft Bend Relief firmly towards the Pump until it engages.

- Verify engagement by moving the OGBR axially multiple times. The OGBR will move approximately 0.5 mm between the pump and the aorta if properly engaged.

*New for HM III
Key Verifications*

- Outflow Graft is fully tightened to the pump
- The OGBR is fully engaged to the Outflow Graft metallic hardware—failure to do so may result in abrasion or kinking of the Outflow Graft
  - Verify engagement – See previous slide
- All air is removed from the blood path
- Verify LVAD & surgical hemostasis
- Do not clamp the OGBR
- No inflow cannula obstruction

*New for HM III
Closing

- Ensure hemostasis of LVAD connections and surgical incisions
- De-cannulate CPB
- Close surgical wounds using CV surgical techniques
- Immobilize externalized cable
  - Ensure System Controller will not pull the driveline
- Install EBB in System Controller once the chest is closed and the sterile field has been broken