# HEART FAILURE
# PRODUCT CATALOG

Abbott

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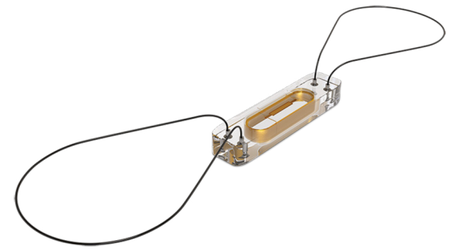
# HEMODYNAMIC MONITORING



# HEMODYNAMIC MONITORING

# CARDIOMEMS™ HF SYSTEM

# HOSPITAL

In the hospital setting, the implanting physician will use the Hospital System (CM3100) to zero the sensor, based upon simultaneous readings from the PA catheter during implant. It can also be used by healthcare professionals to record PA pressure from the sensor, eliminating the need for patients to carry their electronics unit to the hospital or doctor's office.

## CardioMEMS™ Hospital System

| MODEL NUMBER | DESCRIPTION |
|---|---|
| CM3100 | CardioMEMS™ Hospital System |
| CM3150 | CardioMEMS™ Hospital System Cart |
| CM3120 | CardioMEMS™ Hospital System U.S. Power Cord |





# HOME

## CardioMEMS™ Patient Electronics System

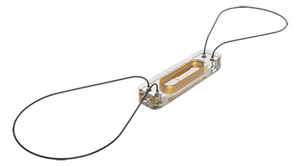
The CardioMEMS™ Patient Electronics System is designed for patients to use at home. Patient-initiated sensor readings are wirelessly transmitted to the Merlin.net™ Patient Care Network for clinicians to securely access and review patient data.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| CM1100 | CardioMEMS™ Patient Electronics System |
| CM1170 | CardioMEMS™ Fabric Cover |
| CM1050 | CardioMEMS™ Orientation Ball |
| CM3040 | CardioMEMS™ Wi-Fi Adapter |
| CM1120 | CardioMEMS™ Travel Case |
| CM3020 | CardioMEMS™ U.S. Power Cord |
| CM1110 | CardioMEMS™ Power Supply |
| CM3026 | CardioMEMS™ Power Cord Clip |

# SENSOR

## CardioMEMS™ PA Sensor and Delivery System

The CardioMEMS™ PA Sensor is implanted in the pulmonary artery using a delivery system via a right heart catheterization procedure.



| MODEL NUMBER | DESCRIPTION |
|---|---|
| CM2000 | CardioMEMS™ PA Sensor and Delivery System |

# ORDERING INFORMATION

## U.S. orders only:

**Customer Service:** 1-800-681-9293 (option 5)
**Email:** CMEMSCustomerService@abbott.com

**Technical Support:** 1-844-692-6367

**Payment:** According to terms of agreement

**Shipment:** FOB Shipping Point

*All Abbott products are supported with a comprehensive warranty, including parts and labor.*



# MECHANICAL CIRCULATORY SUPPORT

# ACUTE






# ACUTE

**CentriMag™ Acute Circulatory Support System**

# CENTRIMAG™ ACUTE CIRCULATORY SUPPORT SYSTEM

# CONSOLES AND HARDWARE

## CentriMag™ 2nd Generation Console with 3/8 in Flow Probe

Contents:

- 1 CentriMag™ console for use with both CentriMag™ and PediMag™ pumps
- 1 Adult flow probe for 3/8 in tubing (separate flow probe for 1/4 in tubing required for PediMag™ pump)
- 1 Power cord
- 1 Monitor cable
- 1 Console standoff set

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-90411 | CentriMag™ 2nd Generation Console with 3/8 in Flow Probe |

## CentriMag™ Motor

Reusable motor attaches to CentriMag™ Console. For use with both CentriMag™ and PediMag™ pumps.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 102956 | CentriMag™ Motor |

## CentriMag™ Motor Bracket

Attaches CentriMag™ Motor to IV pole.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 102961 | CentriMag™ Motor Bracket |

## CentriMag™ Monitor Kit

Compatible with CentriMag™ 2nd Generation Console. For use with both CentriMag™ and PediMag™ pumps.

Contents:

- 1 CentriMag™ Monitor
- 1 Monitor Arm Clamp
- 1 Monitor Arm

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-90404 | CentriMag™ Monitor Kit |

## CentriMag™ System Cart

Cart accommodates up to three CentriMag™ Consoles, one CentriMag™ Monitor, three CentriMag™ Motors and Motor Brackets and one oxygen tank (size D or E).

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 107533 | CentriMag™ System Cart |

## Oxygenator Holder

Articulating arm and holder for AMG PMP Oxygenators. Clamps onto vertical posts such as IV poles.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| US2257 | Oxygenator Holder |

## CentriMag™ System Transporter

Designed to provide the convenience and protection needed to safely transport patients. Space for core system components, including console, pump/motor and oxygenator.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| CM2TR00 | CentriMag™ System Transporter |





## CentriMag™ System Transporter

Allows for simple and safe transportation of the system. Transporter accommodates one CentriMag™ 2nd Generation Console, one CentriMag™ Motor, one oxygen tank (size M9, C or smaller) and one oxygenator. Oxygenator bracket not included.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-50140 | CentriMag™ System Transporter |

## Square Oxygenator Bracket for Transporter

To fit adult, square-format oxygenators (e.g., Maquet Quadrox®).

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-50144 | Square Oxygenator Bracket for Transporter |

## Oxygenator Bracket for Transporter

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-50143 | Large-sized Oxygenator Bracket for Transporter<br>To fit adult, tubular-format oxygenators (diameter of 3.5 in/90 cm) (e.g., Eurosets AMG PMP Adult Oxygenator). |
| 201-50142 | Medium-sized Oxygenator Bracket for Transporter<br>To fit pediatric, tubular-format oxygenators (diameter of 2.2 in/55 cm). |
| 201-50141 | Small-sized Oxygenator Bracket for Transporter<br>To fit neonatal, tubular-format oxygenators (diameter of 2.2 in/55 cm). |

# DISPOSABLES

## CentriMag™ Blood Pump

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 102953 | CentriMag™ Blood Pump |

## PediMag™ Blood Pump

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-90052 | PediMag™ Blood Pump |

## AMG PMP Oxygenators

Supplied sterile. Box of 4.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| US5062 | AMG PMP Adult Oxygenator, Box of 4 |
| US5087 | AMG PMP Pediatric Oxygenator, Box of 4 |
| US5088 | AMG PMP Infant Oxygenator, Box of 4 |

## AMG PP Adult Oxygenator

Supplied sterile. Box of 4.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| US5400 | AMG PP Adult Oxygenator, Box of 4 |





## CentriMag™ Pre-connected Pack

Contains all required components for initiation of cardiopulmonary support. All components provided are sterile and disposable.

Contents:

- CentriMag™ Blood Pump
- CentriMag™ Adult Oxygenator
- Priming Bag
- Tubing
- Accessories (includes a gas line, 3/8 in connectors with luer, high-flow pigtails with 3-way stopcock, tie bands, tubing clamps and cutter)

Gas Line (1)

3/8 in Connectors With Luer (2)

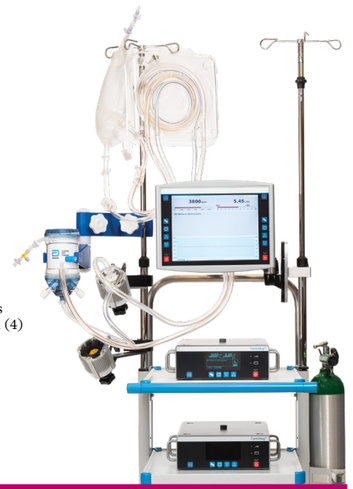
High-flow Pigtails With 3-way Stopcock (4)



Tie Bands (8)

Tubing Clamps (5)

Cutter (1)



| MODEL NUMBER | DESCRIPTION |
|---|---|
| CMAEK00 | CentriMag™ Pre-connected Pack |

## CentriMag™ 34 Fr Drainage (Venous) Cannula Kit

Supplied sterile. Cannula and assertion/fixation accessories.
For adult central cannulation only.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-50067 | CentriMag™ 34 Fr Drainage (Venous) Cannula Kit, 56 cm length |

## CentriMag™ 24 Fr Return (Arterial) Cannula Kit

Supplied sterile. Cannula and assertion/fixation accessories.
For adult central cannulation only.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-50068 | CentriMag™ 24 Fr Return (Arterial) Cannula Kit, 56 cm length |

## DTXPlus‡ Pressure Transducers

Supplied sterile. Box of 10. Suitable for use with BD pressure cables.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 104304 | DTXPlus‡ Pressure Transducers, Box of 10 |

# SYSTEM ACCESSORIES AND SERVICE PARTS

## CentriMag™ Monitor-Console Cable

Connects CentriMag™ Monitor to CentriMag™ 2nd Generation Console.
Replacement part: also included with CentriMag™ 2nd Generation Consoles.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-52147 | CentriMag™ Monitor-Console Cable |

## CentriMag™ RS Data Cable

The CentriMag™ RS Data Cable allows transfer of live data stream by the CentriMag™ Monitor.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-52261 | CentriMag™ RS Data Cable |

## Monitor Arm

Attaches to CentriMag™ Monitor and Monitor Clamp.
Replacement part: also included with CentriMag™ Monitor Kit.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-52170 | Monitor Arm |

## Monitor Clamp

Attaches to Monitor Arm, and clamps onto IV poles.
Replacement part: also included with CentriMag™ Monitor Kit.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-52171 | Monitor Clamp |





## Flow Probes for Use with CentriMag™ 2nd Generation Console

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-30105 | 3/8 in Flow Probe for Use with CentriMag™ 2nd Generation Console |
| 201-30107 | 1/4 in Flow Probe for Use with CentriMag™ 2nd Generation Console |

## Lithium-ion Console Battery

Replacement battery for use with CentriMag™ 2nd Generation Console.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-50207 | Lithium-ion Console Battery |

## CentriMag™ Pressure Cable for BD DTXPlus‡ Transducer

For use with CentriMag™ Console and BD DTXPlus‡ transducers. Reusable.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 104303 | CentriMag™ Pressure Cable for BD DTXPlus‡ Transducer |

## Power Cord

Replacement cord for use with CentriMag™ 2nd Generation Consoles.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 102964 | Power Cord |

## CentriMag™ Training Loop

Supplied as 1 non-clinical pump attached to a reservoir. Includes gate clamp.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 102963 | CentriMag™ Training Loop |

## PediMag™ Training Loop

Supplied as 1 non-clinical pump attached to a reservoir. Includes gate clamp.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 201-50134 | PediMag™ Training Loop |

# ORDERING INFORMATION

## U.S. orders only:

**Customer Service:** HeartLine™ Support — Toll Free: 800 456 1477
**Email:** MCSCustomerService@abbott.com

**Technical Support:** HeartLine™ Support — Toll Free: 800 456 1477
**Email:** TTECHServices@abbott.com

**Payment:** According to terms of agreement

**Shipment:** FOB Shipping Point

*All Abbott products are supported with a comprehensive 1-year manufacturer's warranty, including parts and labor.*

*The CentriMag System can be further supported with an extended warranty for up to 5 years, or with a Preservation Plan for equipment greater than 5 years.*



# CHRONIC

# CHRONIC

# HEARTMATE 3™ LVAD

# SURGICAL PROCEDURE

## HeartMate 3™ Left Ventricular Assist System (LVAS) Implant Kit

Supplied sterile. Contents:

- 1 HeartMate 3™ Left Ventricular Assist Device (LVAD) with Tunneling Adapter
- 1 HeartMate 3™ LVAD System Controller with 11-Volt Lithium-ion Backup Battery (non-sterile)
- 1 Outflow Graft with Bend Relief
- 1 Apical Cuff
- 1 Skin Punch (6 mm)
- 1 Thread Protector Set
- 1 Modular Cable
- 1 Apical Coring Knife

Supplied non-sterile. Contents:

- 1 Wearables Accessory Kit (1 System Controller Neck Strap, 1 Belt Attachment, 1 Protection Bag)
- 1 Instructions for Use
- 1 Patient Handbook


| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106524US | HeartMate 3™ LVAS Implant Kit |

## HeartMate 3™ LVAD Tunneling Tools

Supplied non-sterile. Contents:

- 1 Long Tunneling Lance
- 1 Short Tunneling Lance
- 1 Handle
- 1 Instructions for Use

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 100010372GBL | HeartMate 3™ LVAD Tunneling Tools |

## HeartMate 3™ LVAD Outflow Graft with Bend Relief

Supplied sterile. Contents:

- 1 Outflow Graft
- 1 Outflow Graft Bend Relief

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 105581US | HeartMate 3™ LVAD Outflow Graft with Bend Relief |

## HeartMate 3™ LVAD Outflow Graft Clip

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 10012390GBL | HeartMate 3™ LVAD Outflow Graft Clip |

## HeartMate 3™ LVAD Surgical Hand Tools

Supplied non-sterile, reusable. Contents:

- 1 Unlock Tool
- 1 Pliers
- 1 Instructions for Use
- 1 Cleaning and Sterilization Instructions

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 10002222US | HeartMate 3™ LVAD Surgical Hand Tools |

## HeartMate 3™ LVAD Modular Cable

Supplied sterile. Modular Cable with Cap.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106525US | HeartMate 3™ LVAD Modular Cable |

## HeartMate 3™ LVAD Modular Cable Cap (package of 3)

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106526US | HeartMate 3™ LVAD Modular Cable Cap (package of 3) |

## Apical Coring Knife

Supplied sterile. Can be used for HeartMate II™ and HeartMate 3™ LVADs.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 1050 | Apical Coring Knife |





## HeartMate™ Explant Kit

For explanted pump return. Can be used for HeartMate II™ and HeartMate 3™ LVADs.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 28717 | HeartMate™ Explant Kit |

## HeartMate 3™ Mini Apical Cuff Kit

Supplied sterile. Contents:

- 1 Mini Apical Cuff
- 1 Apical Cuff Holder

Supplied non-sterile. Contents:

- 1 Instructions for Use

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 10005877 | HeartMate 3™ Mini Apical Cuff Kit |

## HeartMate 3™ Apical Cuff Holder

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| CH5877 | HeartMate 3™ Apical Cuff Holder |

## HeartMate 3™ Coring Tool

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 10005872 | HeartMate 3™ Coring Tool |

## HeartMate 3™ Apical Cuff (package of 3)

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106522US | HeartMate 3™ Apical Cuff (package of 3) |

## HeartMate 3™ Skin Punch

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106528US | HeartMate 3™ Skin Punch |

## HeartMate 3™ Thread Protector Set (package of 5)

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106532US | HeartMate 3™ Thread Protector Set (package of 5) |

## HeartMate 3™ Tunneling Adapters (package of 3)

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106534US | HeartMate™ Tunneling Adapters (package of 3) |





# SYSTEM OPERATIONS

## HeartMate 3™ LVAD System Controller with 11-Volt Lithium-ion Backup Battery


Supplied sterile. Contents:

- 1 System Controller with 11-Volt Lithium-ion Backup Battery (non-sterile)

Supplied non-sterile. Contents:

- 1 Patient Handbook

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106531US | HeartMate 3™ LVAD System Controller with 11-Volt Lithium-ion Backup Battery |

## 11-Volt Lithium-ion System Controller Backup Battery

Supplied non-sterile. Can be used with HeartMate II™ System Controller and HeartMate 3™ System Controller.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106128 | 11-Volt Lithium-ion System Controller Backup Battery |

# PATIENT SUPPORT KITS

## HeartMate 3™ LVAD Patient Support Kit with Mobile Power Unit™ Module and Battery Charger

Contents:

- 1 Mobile Power Unit™ Module with Locking Power Cord, North America
- 1 Battery Charger
- 1 HeartMate 3™ LVAD System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)


Mobile Power Unit Module


System Controller


Battery Charger


Battery Set


Battery Clip Set


Travel Bag


Shower Bag

| MODEL NUMBER | DESCRIPTION |
|---|---|
| B10002193 | HeartMate 3™ LVAD Patient Support Kit with Mobile Power Unit™ Module and Battery Charger |

## HeartMate 3™ LVAD Patient Support Kit

Contents:

- 1 HeartMate 3™ System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)


System Controller


Travel Bag


Shower Bag


Battery Clip Set


Battery Set

| MODEL NUMBER | DESCRIPTION |
|---|---|
| B10002194 | HeartMate 3™ LVAD Patient Support Kit |





# HEARTMATE II™ LVAD

# SURGICAL PROCEDURE

## HeartMate II™ LVAS Implant Kit with Sealed Grafts and System Controller*

Supplied sterile. Contents:

- 1 HeartMate II™ LVAD with Tunneling Bullet
- 1 HeartMate II™ Sealed Inflow Conduit
- 1 HeartMate II™ Sealed Outflow Graft with Bend Relief, 4 in (10.2 cm)
- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery (non-sterile)
- 1 Apical Coring Knife
- 1 HeartMate II™ Apical Sewing Ring
- 1 HeartMate II™ Skin Coring Punch
- 1 HeartMate II™ Thread Protector Set

Supplied non-sterile. Contents:

- 1 Wearable Accessories Kit (includes 1 System Controller Neck Strap, 1 Belt Attachment and 1 Protection Bag)
- 1 HeartMate II™ LVAS Instructions for Use
- 1 HeartMate II™ LVAS Patient Handbook


| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106015 | HeartMate II™ LVAS Implant Kit with Sealed Grafts and System Controller* |

## HeartMate II™ Sealed Outflow Graft Bend Relief Collar

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 107315 | HeartMate II™ Sealed Outflow Graft Bend Relief Collar |

*HeartMate II Outflow Graft Bend Relief Collar must be ordered separately, #107315.

# HeartMate II™ LVAS Mini Implant Kit (Used for pump exchange)

Supplied sterile. Contents:

- 1 HeartMate II™ LVAD with Tunneling Bullet
- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery (non-sterile)
- 1 HeartMate™ Apical Coring Knife
- 1 HeartMate II™ Apical Sewing Ring
- 1 HeartMate II™ Skin Coring Punch
- 1 HeartMate II™ Thread Protector Set

Supplied non-sterile. Contents:

- 1 HeartMate II™ LVAS Instructions for Use
- 1 HeartMate II™ LVAS Patient Handbook


| MODEL NUMBER | DESCRIPTION |
|---|---|
| 107801 | HeartMate II™ LVAS Mini Implant Kit (Used for pump exchange) |

# HeartMate II™ Sealed Inflow Conduit, Standalone

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 104142 | HeartMate II™ Sealed Inflow Conduit, Standalone |

# HeartMate II™ Sealed Outflow Graft with Bend Relief, Standalone

Supplied sterile. 4 in (10.2 cm) bend relief.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 103393 | HeartMate II™ Sealed Outflow Graft with Bend Relief, Standalone |

# HeartMate II™ Short Outflow Graft Bend Relief, Standalone

Supplied sterile. 3 in (7.6 cm) bend relief.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 104692 | HeartMate II™ Short Outflow Graft Bend Relief, Standalone |





# HeartMate II™ Skin Coring Punch

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 105557 | HeartMate II™ Skin Coring Punch |

# HeartMate II™ Thread Protectors Set

Supplied sterile.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 105558 | HeartMate II™ Thread Protectors Set |

# HeartMate II™ Driveline Tunneler

Supplied non-sterile, reuseable.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 102137 | HeartMate II™ Driveline Tunneler |

# HeartMate II™ Sizer

Supplied non-sterile, reuseable.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 102772 | HeartMate II™ Sizer |

# HeartMate II™ Spanner Wrench

Supplied non-sterile, reuseable.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 102138 | HeartMate II™ Spanner Wrench |

## HeartMate II™ Apical Sewing Ring with Centering Fixture

Supplied sterile. 3 per box.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 1065 | HeartMate II™ Apical Sewing Ring with Centering Fixture |

## Apical Coring Knife

Supplied sterile. Can be used for HeartMate II™ and HeartMate 3™ LVADs.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 1050 | Apical Coring Knife |

## HeartMate™ Explant Kit

For explanted pump return. Can be used for HeartMate II™ and HeartMate 3™ LVADs.

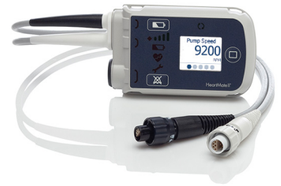
| MODEL NUMBER | DESCRIPTION |
|---|---|
| 28717 | HeartMate™ Explant Kit |





# SYSTEM OPERATIONS

## HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery




Supplied sterile. Contents:

- 1 HeartMate II™ System Controller

Supplied non-sterile. Contents:

- 1 HeartMate II™ System Controller 11-Volt Lithium-ion Backup Battery
- 1 HeartMate II™ LVAS Patient Handbook

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106762 | HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery |

## 11-Volt Lithium-ion System Controller Backup Battery

Supplied non-sterile. Can be used with HeartMate II™ System Controller and HeartMate 3™ System Controller.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106128 | 11-Volt Lithium-ion System Controller Backup Battery |

# PATIENT SUPPORT KITS

## HeartMate II™ Patient Support Kit* with Power Module

- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)
- 1 Power Module
- 1 Power Module Automobile DC Power Cable
- 1 Power Module Patient Cable (14-Volt)
- 1 HeartMate II™ LVAS Patient Handbook
- 1 Battery Charger


Battery Charger


System Controller


Travel Bag


Shower Bag


Battery Set

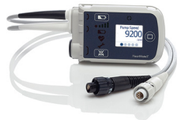

Battery Clip Set


Power Module

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106101 | HeartMate II™ Patient Support Kit* with Power Module |

## HeartMate II™ Patient Support Kit* with Automobile DC Power Cable and Power Module Patient Cable

- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)
- 1 Power Module Automobile DC Power Cable


System Controller


Travel Bag


Shower Bag


Battery Set


Battery Clip Set

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106102 | HeartMate II™ Patient Support Kit* with Automobile DC Power Cable and Power Module Patient Cable |

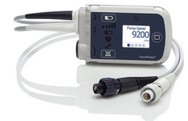
*For convenience, Abbott offers a number of patient accessories in different sizes. These accessories must be ordered separately from patient support kits.





## HeartMate II™ Patient Support Kit*

- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)


System Controller


Battery Set


Battery Clip Set


Travel Bag


Shower Bag

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 10002192 | HeartMate II™ Patient Support Kit |

## HeartMate II™ Patient Support Kit* with Mobile Power Unit™ Module

- 1 Mobile Power Unit™ Module with Locking Power Cord
- 1 Battery Charger
- 1 HeartMate II™ System Controller with 11-Volt Lithium-ion Backup Battery
- 2 14-Volt Lithium-ion Battery Sets (set of 4)
- 2 14-Volt Lithium-ion Battery Clip Sets (set of 2)
- 1 Travel Bag
- 1 Box of Shower Bags (set of 2)


System Controller


Battery Charger


Mobile Power Unit


Travel Bag


Shower Bag


Battery Set


Battery Clip Set

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 10002191 | HeartMate II™ Patient Support Kit with Mobile Power Unit™ Module |

*For convenience, Abbott offers a number of patient accessories in different sizes. These accessories must be ordered separately from patient support kits.

# WEAR AND CARE ACCESSORIES

## Stabilization Belts

Supplied non-sterile. 2 Stabilization Belts with 6 Lead Locks.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 100760 | Stabilization Belts, Large/ Extra-Large |
| 100759 | Stabilization Belts, Small/ Medium |





# COMMON HEARTMATE™ LVAD COMPONENTS

# HEARTMATE TOUCH™ COMMUNICATION SYSTEM

## HeartMate Touch™ Communication System


The HeartMate Touch™ Communication System is an intuitive and user-friendly tool setting a new standard in left ventricular assist device (LVAD) patient care for more clinical independence in patient management.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| HMT1100 | HeartMate Touch™ Communication System |

## HeartMate Touch™ Communication System Rental

| MODEL NUMBER | DESCRIPTION |
|---|---|
| HMT1100-R | HeartMate Touch™ Communication System Rental |

## HeartMate Touch™ Communication System Bluetooth® Wireless Technology Adapter

| MODEL NUMBER | DESCRIPTION |
|---|---|
| HMT2100 | HeartMate Touch™ Communication System Bluetooth® Wireless Technology Adapter |

## Flash Drive for HeartMate Touch™ Communication System


| MODEL NUMBER | DESCRIPTION |
|---|---|
| HMT2900 | Flash Drive for HeartMate Touch™ Communication System |

## Power Adapter for HeartMate Touch™ Communication System

| MODEL NUMBER | DESCRIPTION |
|---|---|
| HMT2133 | Power Adapter for HeartMate Touch™ Communication System |

## USB Cable for HeartMate Touch™ Communication System

| MODEL NUMBER | DESCRIPTION |
|---|---|
| HMT2166 | USB Cable for HeartMate Touch™ Communication System |





# POWER SUPPLIES

## Mobile Power Unit™ Module and Locking Power Cord

Mobile Power Unit™ Module with Integrated Patient Cable and Locking Power Cord


| MODEL NUMBER | DESCRIPTION |
|---|---|
| 107754 | Mobile Power Unit™ Module and Locking Power Cord |

## Locking AC Power Cord for Mobile Power Unit™ Module

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 107760 | Locking AC Power Cord for Mobile Power Unit™ Module |

## Power Module

Contents:

- 1 Power Module with Patient Cable
- 1 Power Module Backup Battery
- 1 Power Cord

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 1340 | Power Module |

## Power Module Backup Battery

A backup power source inside the HeartMate™ Power Module that provides up to 30 minutes of support if power to the HeartMate Power Module fails or is disconnected.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 109200 | Power Module Backup Battery |

## Power Module Patient Cable

Connects the HeartMate II™ or HeartMate 3™ System Controller to the HeartMate™ Power Module.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 103426 | Power Module Patient Cable |

## Power Module Automobile DC Power Cable*

Connects the Power Module to automobile DC power.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 2230 | Power Module Automobile DC Power Cable |

## AC Power Cord for Power Module or Battery Charger

AC power cord that is compatible with both the HeartMate™ Power Module and Battery Charger.

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 103860 | AC Power Cord for Power Module or Battery Charger |

## Battery Charger

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 1440 | Battery Charger |

## 14-Volt Lithium-ion Battery Set

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 2465 | 14-Volt Lithium-ion Battery Set (set of 4) |
| 2865 | 14-Volt Lithium-ion Battery Clip Set (set of 2) |

*Approved for use with HeartMate II LVAS only.





# WEAR AND CARE ACCESSORIES

## Consolidated Bag

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106449 | Left-handed Consolidated Bag |
| 104233 | Right-handed Consolidated Bag |

## Holster Vest

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 104229 | Holster Vest, Small — Recommended for patients weighing less than 160 pounds. |
| 104230 | Holster Vest, Medium — Recommended for patients weighing 160–240 pounds. |
| 104231 | Holster Vest, Large — Recommended for patients weighing more than 240 pounds. |

## Wearable Accessories Kit

Supplied non-sterile. Contents:

- 1 System Controller Neck Strap
- 1 Belt Attachment
- 1 Protection Bag

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 106129 | Wearable Accessories Kit |

## Battery Holster

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 104234 | Battery Holster |

## Shower Bag (package of 2)

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 104232 | Shower Bag (package of 2) |

## Travel Bag

| MODEL NUMBER | DESCRIPTION |
|---|---|
| 1260 | Travel Bag |



# RENTAL PROGRAMS


# RENTAL PROGRAMS

# CENTRIMAG™ ACUTE CIRCULATORY SUPPORT SYSTEM AND HEARTMATE™ LVAD RENTAL PROGRAMS

The Abbott MCS Rental Program includes same-day shipping (when available) and delivery. Rate includes installation, inspection and standby or active use. All services, repairs and/or replacement, if any, throughout the rental period are included.

The Abbott MCS Rental Program has been established to help hospitals defer the cost/inventory of capital equipment during sporadic increases in clinical caseload. **This is not a Rent-to-Own Program.**

- The length of rental may be unknown at the time of ordering, but must be for a minimum of seven (7) days for the HeartMate™ LVAD, and a minimum of thirty (30) days for the CentriMag™ System. A valid purchase order with monetary value must be issued by the hospital. The value should cover at least the first six (6) months of rental charges. The PO must be amendable should the rental exceed that length of time/rental charges.

- The hospital is responsible for contacting Abbott Customer Service to obtain a returned material authorization (RMA) number prior to returning rental or other products to Abbott. Purchase Order for Rental charges will terminate upon receipt and complete inspection of product at Abbott.

- All products noted on “Delivery Note” of rental equipment must be returned to Abbott. Rental charges continue until all components of the rental are received at Abbott.

- Customer responsibility for charges begins as soon as product leaves Abbott’s shipping dock. Seven (7) days of the Daily Rate Fee, regardless of whether product is used, returned unopened, refused at customer dock or canceled in transit, will be applied.

- If needed, Abbott’s Technical Service personnel will schedule installation of equipment based on time of arrival and urgency.

- The customer is responsible to retain console, cart or other product packaging for return of any product. Packaging must be stored in a dry, secure environment throughout the rental period by customer. Shipping charges will apply to any packaging replacement.





# CENTRIMAG™ SYSTEM PRODUCT RENTALS

## CentriMag™ Motor

Reuseable motor attaches to CentriMag™ Console.
For use with both CentriMag™ and PediMag™ pumps.

| CATALOG NUMBER | PRODUCT NAME AND DESCRIPTION |
|---|---|
| 9-1509DR | CentriMag™ Motor |

## CentriMag™ 2nd Generation Console

For use with both CentriMag™ and PediMag™ pumps. Separate flow probe required for PediMag™ pump.

Supplied non-sterile. Contents:

- 1 CentriMag™ Console
- 1 Flow Probe (3/8 in)
- 1 Power Cord
- 1 Console Standoff Set
- 1 Monitor-Console Cable

| CATALOG NUMBER | PRODUCT NAME AND DESCRIPTION |
|---|---|
| 9-1511DR | CentriMag™ 2nd Generation Console |

## CentriMag™ Monitor Kit

Compatible with 2nd Generation Console.

Contents:

- 1 CentriMag™ Monitor
- 1 Monitor Arm Clamp
- 1 Monitor Arm

| CATALOG NUMBER | PRODUCT NAME AND DESCRIPTION |
|---|---|
| 9-1512DR | CentriMag™ Monitor Kit |

# HEARTMATE™ LVAD PRODUCT RENTALS

## Power Module

Provides power to the HeartMate™ system when connected via a power cord to a functioning AC electrical outlet. Connects to the HeartMate™ System Monitor for purposes of transferring data from the HeartMate II™ or HeartMate 3™ System Controller for display on the HeartMate™ System Monitor screen.

Connects to HeartMate II™ or HeartMate 3™ System Controller through the HeartMate™ Power Module Patient Cable (14 Volt).

| CATALOG NUMBER | PRODUCT NAME AND DESCRIPTION |
|---|---|
| 9-1340DR | Power Module |

## Battery Charger

Used to charge, calibrate and test the HeartMate™ 14-Volt Lithium-ion Batteries used to power the HeartMate™ System during battery-powered operation.

| CATALOG NUMBER | PRODUCT NAME AND DESCRIPTION |
|---|---|
| 9-1440DR | Battery Charger |

AMG PMP Oxygenators and Oxygenator Holder are manufactured by Eurosets s.r.l. and distributed by Abbott.

AMG PP Adult Oxygenator and Oxygenator Holder are manufactured by Eurosets s.r.l. and distributed by Abbott.

**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.

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**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.

**CardioMEMS™ HF System Indications and Usage:** The CardioMEMS HF System is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and reducing heart failure hospitalizations.

**CardioMEMS™ HF System Contraindications:** The CardioMEMS™ HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

**CardioMEMS™ HF System Potential Adverse Events:** Potential adverse events associated with the implantation procedure include, but are not limited to, the following: air embolism, allergic reaction, infection, delayed wound healing, arrhythmias, bleeding, hemoptysis, hematoma, nausea, cerebrovascular accident, thrombus, cardiovascular injury, myocardial infarction, death, embolization, thermal burn, cardiac perforation, pneumothorax, thoracic duct injury and hemothorax.

**myCardioMEMS™ Mobile App Limitations:** Patients must use their own Apple‡ or Android‡ mobile device to receive and transmit information to the myCardioMEMS™ Mobile App. To do so the device must be powered on, app must be installed and data coverage (cellular or Wi-Fi‡) available. The myCardioMEMS™ Mobile App can provide notification of medication adjustments and reminders, requests for lab work and acknowledgement that the PA pressure readings have been received. However, there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of the notifications and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, clinic environment, schedule/configuration changes, or data processing.

**CentriMag™ Circulatory Support System Indications [PMA Approval; 30-day use]:** Temporary circulatory support for up to 30 days for one or both sides of the heart to treat post-cardiotomy patients who fail to wean from cardiopulmonary bypass, providing a bridge to decision when it is unclear whether the patient's heart will recover or whether the patient will need alternative, longer-term therapy.

**CentriMag™ Circulatory Support System Contraindications [PMA Approval; 30-day use]:** The CentriMag™ Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

**CentriMag™ Circulatory Support System Adverse Events [PMA Approval; 30-day use]:** Adverse events that may be associated with mechanical circulatory support can include, but are not limited to, the following: bleeding on device support, hemolysis, infection, renal failure/dysfunction/complication, respiratory dysfunction, hepatic dysfunction, cardia arrhythmias (atrial or ventricular), thromboembolism (venous and arterial non-CNS), hypotension, hypertension, device malfunction or failure, psychiatric events, right heart failure, and death.

**CentriMag™ RVAS Indications [Humanitarian Exemption Device (HDE) Approval; 30-day use]:** The CentriMag Circulatory Support System is intended to provide temporary circulatory support for up to 30 days for patients in cardiogenic shock due to acute right ventricular failure.

**CentriMag™ RVAS Contraindications [Humanitarian Exemption Device (HDE) Approval; 30-day use]:** The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

**Humanitarian Device Statement:** Caution: Humanitarian Device. The CentriMag Circulatory Support System is authorized by Federal Law for temporary circulatory support for up to 30 days for patients in cardiogenic shock due to right ventricular failure. The effectiveness of this device for this use has not been demonstrated.

**AMG PMP Oxygenator Indications [510(k) Clearance; 6-hour use]:** The AMG MODULE PMP NO T.P. STERILE is intended for use in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours. The AMG MODULE PMP NO T.P. STERILE is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration. Contact with blood for a longer period of time is unadvisable. AMG MODULE PMP NO T.P. STERILE is an adult oxygenator. The AMG MODULE PMP NO T.P. STERILE should be used in combination with medical devices listed in section "Medical devices for use with the AMG MODULE PMP NO T.P. STERILE."

**AMG PMP Oxygenator Contraindications [510(k) Clearance; 6-hour use]:** This device used for any other purposes than for the indicated intended use is the responsibility of the user. See Instructions for Use.

**AMG PMP Pediatric Oxygenator Indications [510(k) Clearance; 6-hour use]:** The device is indicated for patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for 6 hours or less with a maximum blood flow rate of 4 liters/minute.

**AMG PMP Pediatric Oxygenator Contraindications [510(k) Clearance; 6-hour use]:** No contraindications are known if the device is used for the purpose described and in accordance with the stated operating conditions. Do no use the device for any purpose other than indicated.

**AMG PMP Infant Oxygenator Indications [510(k) Clearance; 6-hour use]:** The device is indicated for patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for 6 hours or less with a maximum blood flow rate of 1.5 liters/minute.

**AMG PP Oxygenator Indications [510(k) Clearance; 6-hour use]:** The A.M.G. MODULE PP NO T.P. STERILE is intended for use in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours. The A.M.G. MODULE PP NO T.P. STERILE is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration. Contact with blood for a longer period of time is unadvisable. A.M.G. MODULE PP NO T.P. STERILE is an adult oxygenator. The A.M.G. MODULE PP NO T.P. STERILE should be used in combination with medical devices listed in section "Medical devices for use with the A.M.G. MODULE PP NO T.P. STERILE."

**AMG PP Oxygenator Contraindications [510(k) Clearance; 6-hour use]:** Do not use the device for any purpose other than indicated. This device used for any other purposes than for the indicated intended use is the responsibility of the user. Relative contraindications to CPB procedures applies.

**CentriMag™ Blood Pump with CentriMag™ Acute Circulatory Support System for ECMO Indications [ECMO, 510(k) Clearance; >6-hour use]:** The CentriMag™ Blood Pump for use with CentriMag™ Acute Circulatory Support System (Motor, Monitor, Console, and Flow Probes) is indicated for controlling blood flow as part of an extracorporeal membrane oxygenation (ECMO) circuit. ECMO is intended to provide assisted extracorporeal circulation and physiologic gas exchange of the patients' blood for adult patients with acute respiratory failure and/or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent.

**CentriMag™ Blood Pump with CentriMag™ Acute Circulatory Support System for ECMO Contraindications [ECMO, 510(k) Clearance; >6-hour use]:** The CentriMag™ System is contraindicated for use as a cardiotomy suction device. The System is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

**CentriMag™ Blood Pump with CentriMag™ Acute Circulatory Support System for ECMO Adverse Events [ECMO, 510(k) Clearance; >6-hour use]:** Potential adverse events associated with the use of extracorporeal membrane oxygenation include, but are not limited to the following: Death, Mechanical Failures/Dysfunction, Bleeding (including Cardiac Tamponade), Hemolysis (including Hemoglobinuria, Anemia, Hyperbilirubinemia), Neurologic Dysfunction (including Stroke, Seizures), Cardiac Dysfunction (including Myocardial Infarction, Arrythmias, Right/Left Heart Failure), Hypertension, Hypotension, Vascular (including Air Embolism, Thromboembolism (venous/arterial), Limb Ischemia, Vascular Damage) Pulmonary Dysfunction (including Pulmonary Embolism, Respiratory Failure), Renal Dysfunction, Cardiogenic Shock, Hypovolemia, Hypervolemia, Hepatic Dysfunction, Coagulation Disorders (including Thrombocytopenia, DIC), Infection (including Wound Dehiscence), Metabolic/Respiratory Acidosis, Psychiatric Disorder.

**CentriMag™ Blood Pump Indications [510(k) Clearance; 6-hour use]:** The CentriMag Circulatory Support System is indicated to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours). It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.).

**CentriMag™ Blood Pump Contraindications [510(k) Clearance; 6-hour use]:** The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

**PediMag™ Blood Pump Indications for Use [510(k) Clearance; 6-hour use]:** The PediMag Blood Pump is indicated for use with the CentriMag Circulatory Support System console and motor to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to six hours) for surgical procedures such as mitral valve reoperation. It is also indicated for use in extracorporeal support systems (for periods up to six hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants etc.).

**PediMag™ Blood Pump Contraindications [510(k) Clearance; 6-hour use]:** The PediMag Blood Pump is contraindicated for use as a cardiotomy suction device. The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

**CentriMag™ Drainage (Venous) Cannula Kit Indications for Use [510(k) Clearance; 6-hour use]:** The CentriMag Drainage (Venous) Cannula is indicated for use with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.

**CentriMag™ Drainage (Venous) Cannula Kit Contraindications [510(k) Clearance; 6-hour use]:** The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative. The CentriMag Drainage (Venous) Cannula is not intended for peripheral cannulation.

**CentriMag™ Return (Arterial) Cannula Kit Indications for Use [510(k) Clearance; 6-hour use**]: The CentriMag Return (Arterial) Cannula is indicated for use as an arterial return cannula with an extracorporeal bypass circuit for extracorporeal circulatory support for periods up to six hours.

**CentriMag™ Return (Arterial) Cannula Kit Contraindications [510(k) Clearance; 6-hour use]:** The CentriMag Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative. The CentriMag Return (Arterial) Cannula is not intended for peripheral cannulation.

**CentriMag™ Pre-connected Pack Indications for Use [510(k) Clearance; 6-hour use]:** The CentriMag™ Pre-connected Pack is indicated for use with the CentriMag™ Acute Circulatory Support System to provide physiologic gas exchange of the blood and to pump a patient's blood through an extracorporeal circuit for periods lasting less than six (6) hours for the purpose of providing either: (i) Full or partial cardiopulmonary bypass during open surgical procedures on the heart or great vessels; or (ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

**CentriMag™ Pre-connected Pack Contraindications [510(k) Clearance; 6-hour use]:** The CentriMag™ Acute Circulatory Support System is contraindicated for use as a cardiotomy suction device. The system is also contraindicated for adult patients who are unable or unwilling to be treated with an appropriate anticoagulant such as Heparin or a comparable alternative.

**CentriMag™ Pre-connected Pack Adverse Events [510(k) Clearance; 6-hour use]:** Potential adverse events associated with the use of any extracorporeal circuit include, but are not limited to the following: Death, Respiratory Failure, Cardiac Arrhythmias, Right Heart Failure, Left Heart Failure, Thrombocytopenia, Hyper-anticoagulation, Therapeutic Management Hypo-anticoagulation, Exsanguination, Hyper-anticoagulation Bleeding, Vascular Access Sites, Phrenic Nerve Damage and Diaphragm Paralysis, Vagus Nerve Damage and Larynx Muscle Dysfunction, Pneumothorax, Renal Failure/Dysfunction, Neurologic Dysfunction, Hemolysis, Hepatic Dysfunction, Hypotension, Cardiac Tamponade, Pericardial Effusion, Wound Dehiscence, Psychiatric Episode, Myocardial Infarction, Hyperthermia, Hypothermia, Anoxia, Hypercarbia.

**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™ LVAS Indications:** The HeartMate 3™ 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.

**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 left 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™ 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™ 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 pocket infection, myocardial infarction, wound dehiscence, hemolysis (not associated with suspected device thrombosis) and possible pump thrombosis.

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