MECHANICAL CIRCULATORY SUPPORT (MCS) CODING GUIDE

LEFT VENTRICULAR ASSIST DEVICE (LVAD), HEARTMATE II™ OR HEARTMATE 3™ (LVADS), ACUTE MCS (CENTRIMAG™ PUMPS)

Effective October 1, 2025

MECHANICAL CIRCULATORY SUPPORT (MCS)

Effective October 1, 2025

INTRODUCTION

The Mechanical Circulatory Support (MCS) Coding Guide is intended to provide coding and reimbursement information for providers regarding the implantable HeartMate II™ Left Ventricular Assist Device (LVAD), HeartMate 3™ LVAD and the CentriMag™ acute circulatory support system including the CentriMag™ pump and the PediMag™ pump procedures.

REIMBURSEMENT HOTLINE

In addition, Abbott offers a reimbursement hotline, which provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement support is available from 8 a.m. to 5 p.m. Central Time, Monday through Friday at (855) 569-6430 or hce@abbott.com. This guide and all supporting documents are available https://www.cardiovascular.abbott/us/en/hcp/reimbursement/hf.html. Coding and reimbursement assistance is provided subject to the disclaimers set forth in this guide.

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LEFT VENTRICULAR ASSIST DEVICE (LVAD)

HEARTMATE II™ OR HEARTMATE 3™ LVADS

Effective October 1, 2025

CODING AND REIMBURSEMENT FOR LVAD

PHYSICIAN[1]

CPT‡ CODE	DESCRIPTION	WORK RVU	NATIONAL MEDICARE FACILITY RATE
Left Ventricular Assist Device (LVAD) Procedures			
LVAD IMPLANT*			
33979	Insertion of ventricular assist device, implantable, intracorporeal, single ventricle	37.50	$1,841
LVAD REMOVAL			
33980	Removal of ventricular assist device, implantable, intracorporeal, single ventricle	33.50	$1,691
LVAD REPLACEMENT			
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass	37.86	$1,841
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass	44.54	$2,165
LVAD INTERROGATION**			
93750	Interrogation of ventricular assist device (VAD), in person, with physician analysis of device parameters (e.g., drivelines, alarms, power surges), review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report	0.75	$39

* Please note that LVAD implant, removal, and replacement procedures are restricted by Medicare to the inpatient hospital site of service.

**Surgeons are able to bill for post implant visits and VAD interrogation starting the day after the VAD implantation, when documented appropriately, as there is a zero-day global period. Please consult your professional coding staff for documentation guidelines. This code is not reported with any of the surgical implantation codes (33975, 33976, 33979, 33981-33983), but is typically reported in conjunction with an evaluation and management visit code (e.g., 99211-99215) and is reimbursed in addition to the visit code. Documentation in the patient's chart must support both the level chosen for the visit as well as the VAD interrogation code. There are no Correct Coding Initiative (CCI) edits for the interrogation code. It can be billed once, per day, per patient, per specialty, if medical necessity is adequately documented. Nurse Practitioners should check both with their compliance department as well as their state-specific scope of services before independently billing for a VAD interrogation.

It is incumbent upon the physician to determine which, if any modifiers should be used first.

Effective Dates: January 1, 2025 - December 31, 2025

CODING AND REIMBURSEMENT FOR LVAD

HOSPITAL INPATIENT[2]

Effective Dates: October 1, 2025 - September 30, 2026

ICD-10-PCS	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
LEFT VENTRICULAR ASSIST DEVICE (LVAD) IMPLANT FOR HEARTMATE II™ LVAD AND HEARTMATE 3™ LVAD			
02HA0QZ	Insertion of implantable heart assist system into heart, open approach	001 Heart transplant or implant of heart assist system with MCC	$203,923
		002 Heart transplant or implant of heart assist system without MCC	$82,459

HOSPITAL OUTPATIENT[8]

Effective Dates: January 1, 2025 - December 31, 2025

CPT‡ CODE	DESCRIPTION	APC	NATIONAL MEDICARE RATE
LVAD INTERROGATION			
93750	Interrogation of ventricular assist device (VAD), in person, with physician analysis of device parameters (e.g., drivelines, alarms, power surges), review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report	5742	$92

CMS restricts chronic and acute mechanical circulatory support procedures to the inpatient hospital site of service. Regardless of how many procedures are furnished, a single hospitalization receives a single MS-DRG payment. For Medicare beneficiaries, per CMS Program Transmittal 613, inpatient reimbursement for LVAD accessories and supplies is included in the MS-DRG payment to hospitals for the implant admission. Therefore, all accessories and supplies needed by LVAD patients during the inpatient stay and post-discharge at home should be included on the inpatient bill. Replacement accessories and supplies are payable in the physician office or hospital outpatient setting, and are not considered Durable Medical Equipment per CMS Program Transmittal 1159.

CODING AND REIMBURSEMENT FOR LVAD

LVAD REPLACEMENT SUPPLY AND ACCESSORY CODES[4]

HCPCS	DESCRIPTION	MEDICALLY UNLIKELY EDIT	DMEPOS FEE SCHEDULE NATIONAL AVG
LVAD REPLACEMENT ACCESSORIES AND SUPPLIES - HOSPITAL OUTPATIENT OR PHYSICIAN OFFICE SETTING*			
Q0477	Power module patient cable for use with electric or electric/pneumatic ventricular assist device, replacement only	1	$910
Q0478	Power adapter for use with electric or electric/pneumatic ventricular assist device, vehicle type	1	$216
Q0479	Power module for use with electric/pneumatic ventricular assist device, replacement only	1	$14,071
Q0481	Microprocessor control unit for use with electric ventricular assist device, replacement only	1	$17,131
Q0483	Monitor/display module for use with electric ventricular assist device, replacement only	1	$22,104
Q0486	Monitor control cable for use with electric/pneumatic ventricular assist device, replacement only	1	$345
Q0489	Power pack base for use with electric/pneumatic ventricular assist device, replacement only	1	$19,163
Q0491	Emergency power source for use with electric/pneumatic ventricular assist device, replacement only	1	$1,303
Q0495	Battery/power pack charger for use with electric or electric/pneumatic ventricular assist device, replacement only	1	$4,924

*DMEPOS fee schedule is updated on a quarterly basis and providers are encouraged to check the most recent DMEPOS fee schedule on CMS's website. If you have a question on the most recent payment rates for your locality, please email VADReimbursement@abbott.com for more information. These HCPCS codes all have coverage and payment jurisdiction with the local Medicare Administrative Contractor (MAC); they do not have coverage and payment jurisdiction at the DMEMAC. The HCPCS codes listed above have a defined DMEPOS fee schedule payment rate with the exception of HCPCS Q0508 and Q0509 whose payment rate is based on individual consideration with the local Medicare contractor. HCPCS Q0508 and Q0509 will require an invoice and supporting documentation for payment consideration. The Medically Unlikely Edit (MUE) for HCPCS code Q0508 (usually reported for driveline stabilization systems) is "24" units for outpatient hospital providers. CMS is working to ensure the same MUE edit for Q0508 furnished by practitioners and we will provide an update when that becomes available. Q0509 is reported for anything provided for a Medicare patient who was not a Medicare beneficiary at the time of LVAD implant.

All items must have documentation of medical necessity for payment; if any item not under warranty is lost, stolen, or damaged prior to one year post discharge, the-RA modifier should be used.

CODING AND REIMBURSEMENT FOR LVAD

LVAD REPLACEMENT SUPPLY CODES[4]

HCPCS	DESCRIPTION	MEDICALLY UNLIKELY EDIT	DMEPOS FEE SCHEDULE NATIONAL AVG
LVAD REPLACEMENT ACCESSORIES AND SUPPLIES - HOSPITAL OUTPATIENT OR PHYSICIAN OFFICE SETTING*			
Q0496	Battery, other than lithium-ion, for use with electric or electric/pneumatic ventricular assist device, replacement only	1	$1,767
Q0497	Battery clips for use with electric or electric/pneumatic ventricular assist device, replacement only	2	$552
Q0498	Holster for use with electric or electric/pneumatic ventricular assist device, replacement only	1	$606
Q0499	Belt/vest/bag for use to carry external peripheral components of any type ventricular assist device, replacement only	1	$197
Q0501	Shower cover for use with electric or electric/pneumatic ventricular assist device, replacement only	1	$602
Q0506	Lithium Ion battery for use with electric or electric/pneumatic ventricular assist device, replacement only	8	$1,007
Q0508	Miscellaneous supply or accessory for use with any implanted ventricular assist device	4: physician's office 24: outpatient hospital	Paid on invoice
Q0509	Miscellaneous supply or accessory for use with implanted ventricular assist device for which payment was not made under Medicare Part A	2	Paid on invoice

*DMEPOS fee schedule is updated on a quarterly basis and providers are encouraged to check the most recent DMEPOS fee schedule on CMS's website. If you have a question on the most recent payment rates for your locality, please email VADReimbursement@abbott.com for more information. These HCPCS codes all have coverage and payment jurisdiction with the local Medicare Administrative Contractor (MAC); they do not have coverage and payment jurisdiction at the DMEMAC. The HCPCS codes listed above have a defined DMEPOS fee schedule payment rate with the exception of HCPCS Q0508 and Q0509 whose payment rate is based on individual consideration with the local Medicare contractor. HCPCS Q0508 and Q0509 will require an invoice and supporting documentation for payment consideration. The Medically Unlikely Edit (MUE) for HCPCS code Q0508 (usually reported for driveline stabilization systems) is "24" units for outpatient hospital providers. CMS is working to ensure the same MUE edit for Q0508 furnished by practitioners and we will provide an update when that becomes available. Q0509 is reported for anything provided for a Medicare patient who was not a Medicare beneficiary at the time of LVAD implant.

All items must have documentation of medical necessity for payment; if any item not under warranty is lost, stolen, or damaged prior to one year post discharge, the-RA modifier should be used.

CODING AND REIMBURSEMENT FOR LVAD

HEARTMATE II™ LVAD AND HEARTMATE 3™ LVAD SUPPLY AND ACCESSORY HCPCS CROSSWALK[3]

HEARTMATE II™ LVAD	HEARTMATE 3™ LVAD	DESCRIPTION	HCPCS
PART NUMBERS			
106762	106531US	Pocket Controller including emergency back-up battery	Q0481
106128	106128	Backup Battery for (11v) (for controller)	Q0506
107754	107754	Mobile Power Unit™	Q0479
1340	1340	Power Module	Q0479
103426	103426	Power Module Patient Cable	Q0477
1286	1286	Display Module	Q0483
2865	2865	14V Battery Clips (set of 2)	Q0497
2465	2465	14V Batteries (set of 4)	Q0506
104229, 30, 31	104229, 30, 31	HeartMate™ LVAD Holster Vest, (small, medium, large)	Q0498
104232	104232	HeartMate™ LVAD Shower Bag	Q0501
104234	104234	HeartMate™ LVAD Battery Holster	Q0498
1440	1440	Universal Battery Charger (UBC)	Q0495

CODING AND REIMBURSEMENT FOR LVAD

HEARTMATE II™ LVAD AND HEARTMATE 3™ LVAD SUPPLY AND ACCESSORY HCPCS CROSSWALK[3]

HEARTMATE II™ LVAD	HEARTMATE 3™ LVAD	DESCRIPTION	HCPCS
PART NUMBERS			
1260	1260	HeartMate™ LVAD Travel Bag	Q0508
100760	NA	HeartMate II™ LVAD Stabilization Belts	Q0508
104233 106449	104233 106449	HeartMate™ LVAD Consolidated Bag, (right, left)	Q0499
NA	NA	Driveline Management System (e.g., dressings)	Q0508

CODING AND REIMBURSEMENT FOR LVAD

ICD-10-CM DIAGNOSIS CODES[5]

Diagnosis codes are used by both hospitals and physicians to document the medical necessity of the procedure. For Mechanical Circulatory Support patients, there are many possible diagnosis code scenarios and a wide variety of possible combinations. The limited diagnosis list is not meant to be an exhaustive representation of the diagnosis options for the procedure. It is always the responsibility of health care providers to choose the most appropriate diagnosis code(s) representative of the patient's clinical condition. The customer should check with their local carriers or intermediaries and should consult with legal counsel or a financial, coding or reimbursement specialist for coding, reimbursement or billing questions related to ICD-10-CM diagnosis codes.

ICD-10-CM	DESCRIPTION	ICD-10CM	DESCRIPTION
ICD CODES THAT MAY APPLY		ICD CODES THAT MAY APPLY	
I23.0 - I23.9	Certain current complications following ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction (within the 28 day period)	I97.190	Other postprocedural cardiac functional disturbances following cardiac surgery
I50.1 - I50.9	Heart failure	R57.0	Cardiogenic shock
I97.0	Postcardiotomy syndrome	T82.897	Other specified complication of cardiac prosthetic devices, implants and grafts
I97.110	Postprocedural cardiac insufficiency following cardiac surgery	T86.298	Other complications of heart transplant
I97.120	Postprocedural cardiac arrest following cardiac surgery	Z76.82	Awaiting organ transplant status (awaiting heart transplant)
I97.130	Postprocedural heart failure following cardiac surgery	Z95.811	Presence of heart assist device

CODING AND REIMBURSEMENT FOR LVAD

COVERAGE FOR HEARTMATE 3™ LVAD

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.

On December 1, 2020, the Centers for Medicare and Medicaid Services (CMS) finalized NCD 20.9.1 for Ventricular Assist Devices (VADs) to remove the pre-implant designations (bridge-to-transplant and destination therapy) in favor of one central criteria for qualification of VAD candidacy for the purposes of coverage and payment. The patient criteria leverage the clinical evidence supported by the MOMENTUM 3 clinical trial.

Specifically, the patient criteria for VAD coverage are the following:

- Have New York Heart Association (NYHA) Class IV heart failure; and
- Have a left ventricular ejection fraction (LVEF) ≤ 25%; and
- Are inotrope dependent

  OR

  have a Cardiac Index (CI) < 2.2 L/min/m2, while not on inotropes, and also meet one of the following:
  - Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; or
  - Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days.

The facility requirements of NCD 20.9.1 remain the same, and facilities performing VAD implants for short or long-term mechanical circulatory support need to have accreditation from an approved CMS certifying body and maintain an appropriate multi-disciplinary team to support VAD procedures.

NCD 20.9.1 that reflect the updated changes as of December 1, 2020 is effective for dates of service on and after December 1, 2020.

To access the full NCD 20.9.1 updated on December 1, 2020 and the associated CMS analysis, please click here.

Most commercial payer policies reflect similar guidance as the Medicare NCD, but it is important that providers and institutions check their payer policies and seek prior authorization to ensure appropriate adherence to their LVAD coverage criteria especially in light of the December 1, 2020 NCD update. Medicare Advantage Plans are required to align with the coverage criteria in NCD 20.9.1 based on the latest December 1, 2020 update.

ACUTE MECHANICAL CIRCULATORY SUPPORT

Effective October 1, 2025

CODING AND REIMBURSEMENT FOR ACUTE MCS PROCEDURES

PHYSICIAN[1]

CPT‡ CODE	DESCRIPTION	WORK RVU	NATIONAL MEDICARE RATE FACILITY
ACUTE MCS SYSTEM IMPLANT			
33975	Insertion of ventricular assist device; extracorporeal, single ventricle	25.00	$1,240
33976	Insertion of ventricular assist device; extracorporeal, biventricular	30.75	$1,494
ACUTE MCS SYSTEM REMOVAL			
33977	Removal of ventricular assist device; extracorporeal, single ventricle	20.86	$1,071
33978	Removal of ventricular assist device; extracorporeal, biventricular	25.00	$1,262
ACUTE MCS SYSTEM REPLACEMENT			
33981	Replacement of extracorporeal ventricular assist device; single or biventricular, pump(s), single or each pump	16.11	$783

The CPT‡ codes above describe possible surgeon services in the hospital inpatient setting where the Acute MCS system procedure (e.g., CentriMag™ Pumps) occurs. These services are restricted to the inpatient hospital site of service.

PMA approval for 30-day use of CentriMag™ System components include: CentriMag™ Pump, CentriMag™ Console, CentriMag™ Motor, Mag Monitor, flow probe, and CentriMag™ Drainage Cannula and CentriMag™ Return Cannula. Optional accessories include: CentriMag™ System Cart, CentriMag™ System Transporter and Pressure Transducer. PMA approval for 30-day use of CentriMag™ System excludes: PediMag™ Blood Pump.

It is incumbent upon the physician to determine which, if any modifiers should be used first.

Effective Dates: January 1, 2025- December 31, 2025

CODING AND REIMBURSEMENT FOR ACUTE MCS PROCEDURES

HOSPITAL INPATIENT[2]
EXTERNAL ASSIST DEVICE SHORT-TERM HEART ASSIST SYSTEM

ICD-10 PCS CODE[4]	DESCRIPTION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON CLINICAL TYPE			
02HA0RZ*	Insertion of Short-term External Heart Assist System into Heart, Open Approach		
CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON DURATION OR SUPPORT TYPE		001 w/MCC	$203,923
5A02116	Assistance with cardiac output using other pump, intermittent	002 w/o MCC	$82,459
5A02216	Assistance with cardiac output using other pump, continuous		

*The Centrimag™ Blood Pump is listed as a short term external heart assist system in the heart and great vessels in the 2026 ICD-10 PCS code set under Appendix C: Device Key. It is important to document and code the Centrimag™ Acute Circulatory Support System as an external heart assist device with the appropriate approach, even if other concomitant procedures are performed.

According to the CMS manuals, the transferring hospital receives a per diem, prorated from the expected MS-DRG. The per diem is derived from the MS-DRG's average length of stay when the transferring facility submits a claim to Medicare with the discharge status code of 02, "discharged/transferred to another short term general hospital for inpatient care." The geometric mean length of stay (LOS) and arithmetic mean LOS in FY2026 for MS-DRG 215 are 4.7 and 8.1 days, respectively.

The second hospital can expect full MS-DRG payment, even if the MS-DRG assignment turns out to be different from the transferring hospital. Hospital-specific factors-such as an ownership relations between the transferring and receiving hospital-could affect payment.

Refer to the CMS Medicare Claims Processing Manual Chapter 3 - Inpatient Hospital Billing "Transfers".[13]

Effective Dates: October 1, 2025 - September 30, 2026

CODING AND REIMBURSEMENT FOR ACUTE MECHANICAL CIRCULATORY SUPPORT SYSTEM

HOSPITAL INPATIENT[2]

INTRAOPERATIVE SHORT-TERM EXTERNAL HEART ASSIST SYSTEM*

ICD-10 PCS CODE[4]	DESCRIPTION	USE OF CARDIAC CATHETERIZATION	TYPICAL MS-DRG ASSIGNMENT	NATIONAL MEDICARE RATE
CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON APPROACH AND SUPPORT TYPE				
CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON APPROACH TYPE		Yes	216 w/MCC	$71,187
			217 w/CC	$47,847
02HA0RJ*	Insertion of Short-term External Heart Assist System in Heart and Great Vessels, Intraoperative, Open Approach		218 w/out CC/MCC	$47,847
CHOOSE THE APPROPRIATE ICD-10 PROCEDURE CODE BASED ON SUPPORT TYPE				
5A02116	Assistance with cardiac output using other pump, intermittent	No	219 w/MCC	$55,873
			220 w/ CC	$38,806
5A02216	Assistance with cardiac output using other pump, continuous		221 w/out MCC	$36,676

*The qualifier “intraoperative” was added effective October 1, 2017 (FY 2018) to the procedure codes describing the insertion of short-term external heart assist system procedures to distinguish between procedures where the device was only used intraoperatively and was removed at the conclusion of the procedure versus procedures where the device was not removed at the conclusion of the procedure and for which that qualifier would not be reported.”

Insertion approach and Support type do not take into consideration the utilization of cardiac catheterization. Cardiac Catheterization should be separately coded as appropriate and supported by the clinical documentation.

Effective Dates: October 1, 2025 - September 30, 2026

CODING AND REIMBURSEMENT FOR ACUTE MCS PROCEDURES

ICD-10-CM DIAGNOSIS CODES[5]

Diagnosis codes are used by both hospitals and physicians to document the medical necessity of the procedure. For Mechanical Circulatory Support patients, there are many possible diagnosis code scenarios and a wide variety of possible combinations. The limited list represented below is not meant to be an exhaustive representation of diagnosis options for the procedure. It is always the responsibility of health care providers to choose the most appropriate diagnosis code(s) representative of the patients' clinical condition. The customer should check with their local carriers or intermediaries and should consult with legal counsel or a financial, coding or reimbursement specialist for coding, reimbursement or billing questions related to ICD-10-CM diagnosis codes.

ICD-10-CM	DESCRIPTION	ICD-10-CM	DESCRIPTION
ICD CODES THAT MAY APPLY		ICD CODES THAT MAY APPLY	
I23.0 - I23.9	Certain current complications following ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction (within the 28 day period)	I97.190	Other postprocedural cardiac functional disturbances following cardiac surgery
I50.1 - I50.9	Heart failure	R57.0	Cardiogenic shock
I97.0	Postcardiotomy syndrome	T82.897	Other specified complication of cardiac prosthetic devices, implants and grafts
I97.110	Postprocedural cardiac insufficiency following cardiac surgery	T86.298	Other complications of heart transplant
I97.120	Postprocedural cardiac arrest following cardiac surgery	Z76.82	Awaiting organ transplant status (awaiting heart transplant)
I97.130	Postprocedural heart failure following cardiac surgery	Z95.811	Presence of heart assist device

PMA approval for 30-day use of CentriMag™ System components include: CentriMag™ Pump, CentriMag™ Console, CentriMag™ Motor, Mag Monitor, flow probe, and CentriMag™ Drainage Cannula and CentriMag™ Return Cannula. Optional accessories include: CentriMag™ System Cart, CentriMag™ System Transporter and Pressure Transducer. PMA approval for 30-day use of CentriMag™ System excludes: PediMag™ Blood Pump.

IMPORTANT SAFETY INFORMATION

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™ 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.

IMPORTANT SAFETY INFORMATION

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.

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.

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.

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.

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.

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.

REFERENCES

1. Physician Prospective Payment-Final rule with Comment Period and Final CY2025 Payment Rates. CMS-1807-F: https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1807-f
2. Hospital Inpatient Prospective Payment-Final Rule Home Page FY 2026 CMS-1833-F: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page
3. HCPCS Release and Code Sets: https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system
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