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CentriMag™ Drainage and Return Cannula Kits

PRODUCT HIGHLIGHTS

Designed for optimal flow characteristics that minimize thrombus formation based on computational fluid dynamics analysis

Drainage Cannula Kit Key Features

- Optimized tip design
- Minimal cannulae tip stasis
- Convenient depth markers
- Malleable wire-reinforced tip
- Atrial or apical placement option
- Cap designed for easy tunneling
- Simple insertion and placement
- Radiopaque tip marker

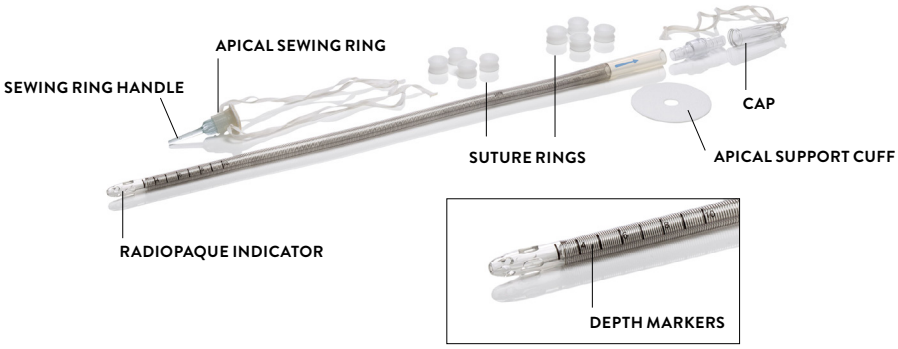
Return Cannula Kit Key Features

- Convenient depth markers on tip
- Tunneling bullet optimized for easy tunneling
- Simple insertion and placement
- Can be placed direct or over the wire

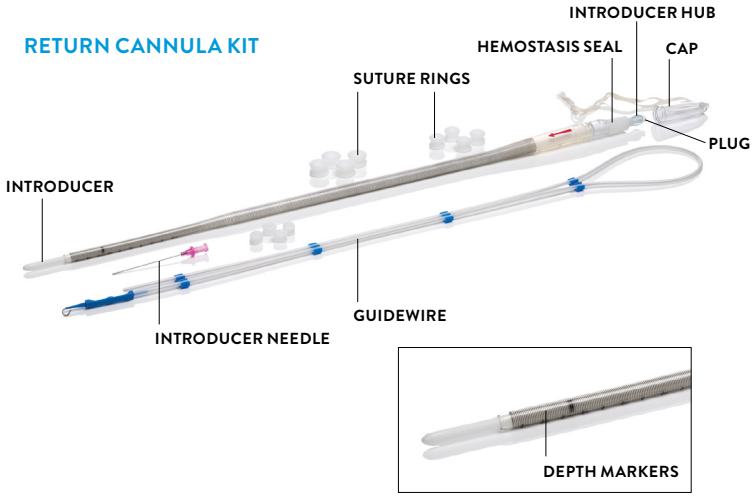
PRODUCT SPECIFICATIONS

PART NUMBER	DESCRIPTION
201-50067	CentriMag™ 34 F Drainage (Venous) Cannula Kit, 56 cm length
201-50068	CentriMag™ 24 F Return (Arterial) Cannula Kit, 56 cm length

DRAINAGE CANNULA KIT



RETURN CANNULA KIT



***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 and any other pediatric components or accessories.

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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.

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™ Acute Circulatory Support System Temporary Expanded Indication: The FDA issued an enforcement policy guidance document in April 2020 allowing for FDA-cleared or approved cardiopulmonary bypass devices to be used in an ECMO circuit to treat patients who are experiencing acute respiratory failure and/or acute cardiopulmonary failure during the COVID-19 public health emergency. The CentriMag™ System including the CentriMag™ Blood Pump and PediMag™ Blood Pump are indicated for use as part of an ECMO circuit for longer than 6 hours to treat patients with acute respiratory failure and/or acute cardiopulmonary failure.

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.

MAT-1900198 v2.0 | Item approved for U.S. use only.

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