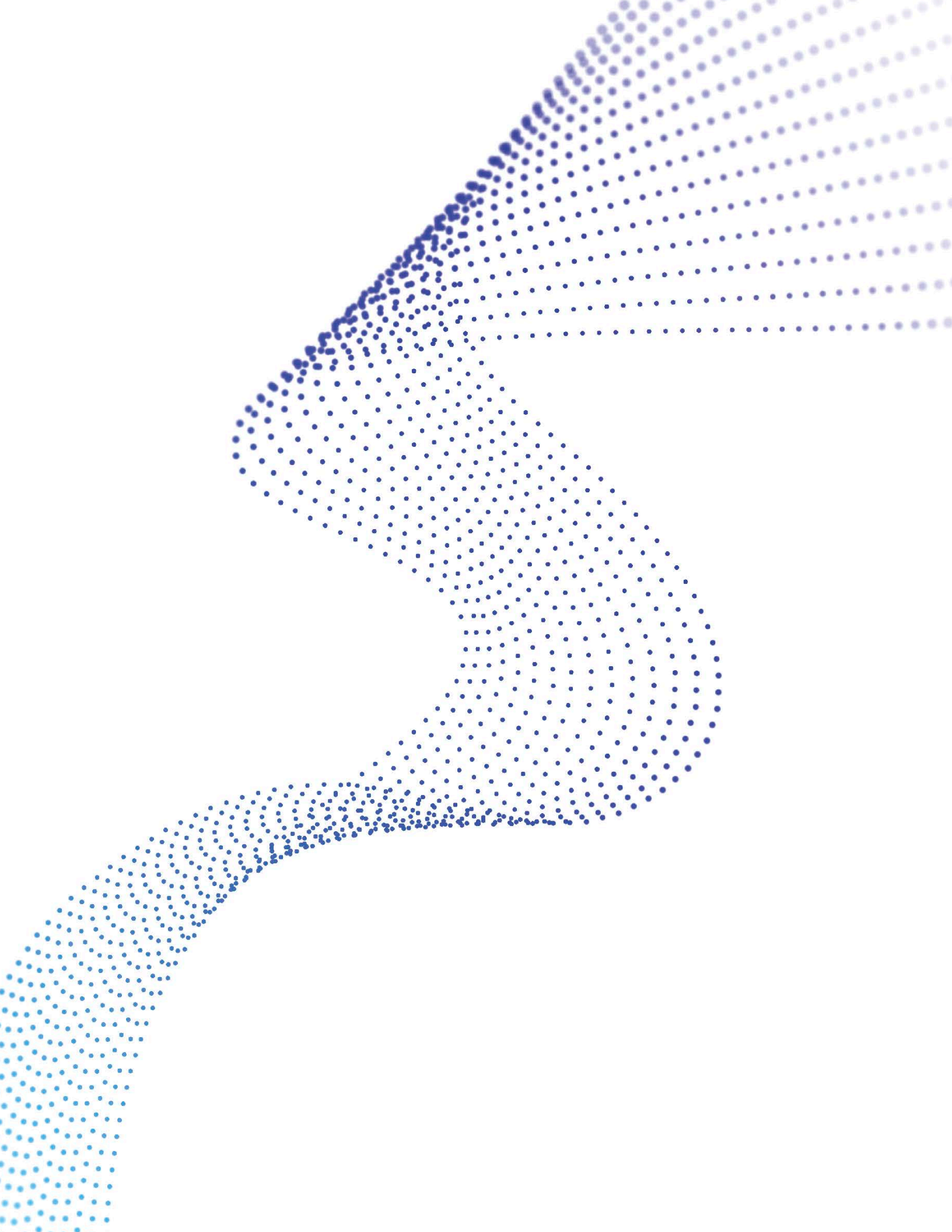
Medtronic

Extracorporeal Membrane Oxygenation (ECMO)

U.S. product catalog

Table of contents



Elevating ECMO every day

Innovative like no other

Extracorporeal membrane oxygenation (ECMO) is a rapidly growing therapy used to help support patients experiencing acute cardiac and/or respiratory failure in their journey toward recovery.

Together with our partners in healthcare, we are helping shape a comprehensive ECMO solution. We provide products designed specifically for ECMO and a wide breadth of support products that can be used with patients in critical care settings.

VitalFlow ECMO system

Easier, smarter ECMO†

Engineered for ECMO. Designed for simplicity and performance, the VitalFlow ECMO system can be configured to accommodate your clinical preferences and hospital protocols.[1] Streamline and simplify your program with the VitalFlow system – reset your expectations for ECMO care.

A configurable, one-system ECMO solution

† Medtronic usability data and design reports on file. Compared to Nautilus Smart technology.

Configurability

Flexible and versatile, allowing you to configure the system to meet your needs.

VitalFlow caddy

Centralizes the VitalFlow motor drive and emergency hand crank, while providing portability, visibility, and access to the pump and oxygenator

VitalFlow ECMO cart‡

Configurable cart with quick-release mounts and compact design, supports both caddy and traditional holder setups.

Console mounting shelf
Rotate and adjust the height of the VitalFlow console

VitalFlow caddy shelf
Mount and securely lock the VitalFlow caddy

Heater cooler shelf
Sliding and lockable shelf, with securement straps

‡ VitalFlow™ ECMO cart is manufactured by Pryor Products and distributed by Medtronic.

VitalFlow ECMO system

VitalFlow centrifugal pump[1]

- Low profile fins for efficient blood flow at low RPMs
- Ceramic pivot bearings yield low heat generation
- Centrifugal design leads to low shear and low hemolysis

Nautilus VF oxygenator[1]

- Circular flow path reduces areas of low flow and stasis
- Guided inlet design increases blood and fiber contact
- Filling vanes aid in even fill and distribution across the membrane
- Integrated sensors provide real-time performance data to the VitalFlow console

Simplified blood flow, simplified workflow

VitalFlow set with Balance™ BioSurface

Tested and indicated for use in ECMO§

§ Indicated in the United States for use up to 48 hours.

Easier, smarter ECMO◊

Product ordering information			
CFN	**Description**	**Details**	**Image**
58100	Console includes: 58150 Flow and bubble sensor 58131 AC power cord	Verified for intra-hospital transport,[2] Weight: 8.86 kg	
58150	Flow and bubble sensor	3/8" x 3/32", 2 m length	
58131	AC power cord	3 m length	
58103	Emergency hand crank	Includes optional pole mount holder Weight: 3.08 kg	
58102	Motor drive and holder	DC external drive motor Includes optional pole mount holder	
58130	Nautilus VF oxygenator cable	Compatible with Nautilus VF oxygenator, 2.4 m length	
ECM-9688-1	VitalFlow ECMO cart¶	Configurable cart	
58120	VitalFlow caddy	Configurable for disposables Weight: 4.3 kg	
48160	Nautilus oxygenator holder	Optional pole mount	
58112	VitalFlow Set with Balance BioSurface	Complete disposable set with prime bag, table tray, tubing, Nautilus VF ECMO oxygenator and VitalFlow centrifugal pump# DEHP free blood contacting materials	

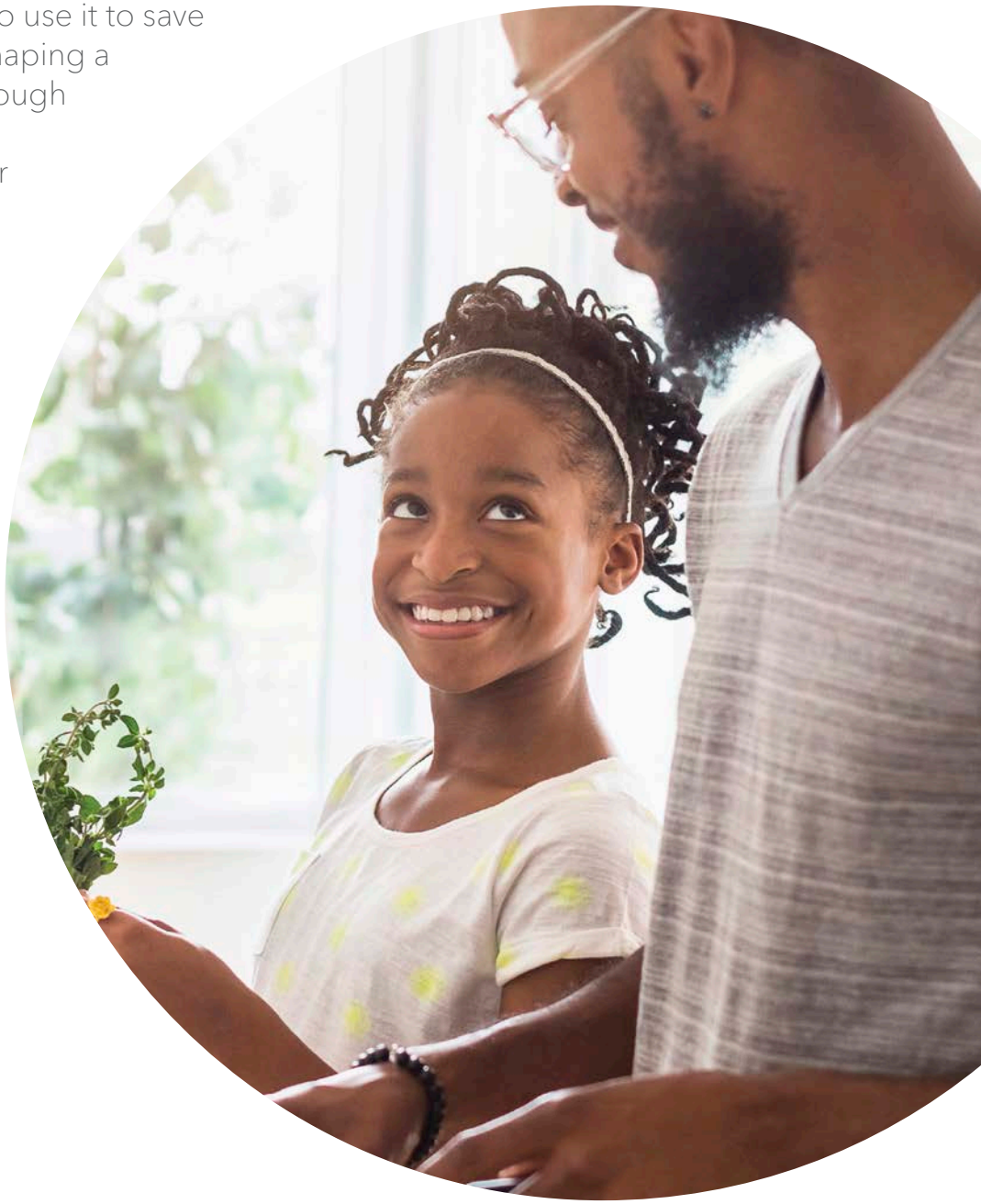
Potential complications related to the use of ECMO devices include, but are not limited to, heart, vessel, or lung damage, hypoxia, anemia, irritation, toxic reaction, infection, hemorrhage, liver or kidney failure, stroke, and death. The benefits of extracorporeal support must be weighed against the risk of systemic anticoagulation and must be assessed by the prescribing physician.
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.
Only clinicians thoroughly trained in extracorporeal life support procedures should use this device.

Balance™ is a trademark of Medtronic. Technology licensed under agreement from BioInteractions, Limited, United Kingdom.

◊ Medtronic usability data and design reports on file. Compared to Nautilus Smart technology.
¶ VitalFlow ECMO cart is manufactured by Pryor Products and distributed by Medtronic.
# Prime bag contains phthalates.

ECMO oxygenators

Extracorporeal membrane oxygenation (ECMO) provides long-term heart and/or lung support to critically ill patients. We are committed to learning and developing this therapy together with those healthcare professionals who use it to save patient lives. Medtronic is shaping a comprehensive solution through standardized, easy-to-use, advanced technologies. Our Nautilus and Nautilus Smart oxygenators were designed specifically for ECMO.



Risks of ECMO include heart, vessel, or lung damage, hypoxia, anemia, infection, hemorrhage, liver or kidney failure, stroke, and death.

Nautilus ECMO oxygenators

Designed for ECMO

- Long-term ECMO indication[Δ]
- PMP fiber
- Balance Biosurface[∞]
- Circular flow-path design

Nautilus Smart ECMO Module

Nautilus ECMO Oxygenator

Δ Indicated in the United States for use up to 48 hours.
∞ Technology licensed under agreement from BioInteractions, Limited, United Kingdom.

Nautilus Smart ECMO module

Simplify your circuit with the first oxygenator featuring integrated monitoring. The Nautilus Smart ECMO module improves long-term gas transfer[3] while providing real-time device performance data that's accessible from an intuitive touch screen.

Performance predictability

- View monitored parameters on the interactive touch screen.
- Pressure in/pressure out/Δ P
- O_2 saturation in/O_2 saturation out
- Temperature out
- Set alarm limits.
- Receive visual and audio alert notifications.

Circuit simplicity

- Integrated sensors may eliminate the need for pressure transducers and in-line blood saturation monitoring.[4-6]
- Simplify the circuit for patient transport, ambulation, and rehabilitation.[4-6]
- Fewer connections minimizes number of areas prone to blood clot formation and air entrainment.[4-6]

Streamlined workflow

- Light bar provides at-a-glance assessment of oxygenator performance.
- Reduce need to look at multiple devices to obtain oxygenator-related performance data
- Visual and audio alerts when limits are exceeded
- Displayed data allows clinicians to clearly communicate oxygenator status among ECMO team members.

Nautilus ECMO oxygenator

Designed for ECMO

Circular flow-path technology

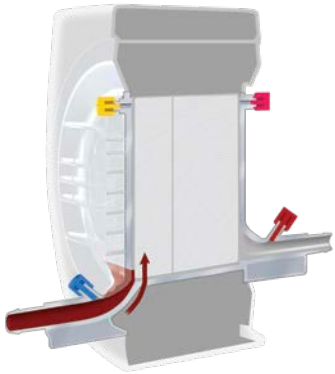
The Nautilus ECMO oxygenator has a transverse flow path with a circular profile. Transverse flow minimizes surface contact area while achieving a low blood-side pressure drop. The circular profile eliminates corners where low flow and stasis are known to occur.

Circular shape

Eliminates corners, areas known for clotting.

Guided inlet††

Reduces velocity changes at the inlet where low flow and stasis may occur.



Filling vanes

Aid in even filling and even flow distribution across the membrane.

†† Patent pending.

Nautilus ECMO oxygenator specifications

Membrane material	Polymethylpentene (PMP)
Membrane surface area	1.8 m^2
Heat exchange material	Polyethylene terephthalate (PET)
Heat exchange surface area	0.3 m^2
Static priming volume	226 mL
Recommended blood flow rate	0.5–7 L/min
Maximum blood pressure	750 mmHg
Recommended gas flow rate (gas:blood)	0.5:1 to 3:1
Maximum water side pressure	1,125 mmHg
Arterial outlet port	3/8"
Venous inlet port	3/8"
Delta P at 4 L/min	38 mmHg
O^2 at 4 L/min	266 mL/min
CO^2 at 4 L/min	186 mL/min
Heat exchange performance at 4 L/min	0.77

Nautilus ordering information

CFN	
48135	Nautilus Smart ECMO module
48160	Nautilus oxygenator holder
48150	Power supply
48155	Power cord

CFN	
48145	Nautilus ECMO oxygenator with Balance Biosurface‡‡
48160	Nautilus ECMO oxygenator holder

Nautilus oxygenator holder

Power cord

Power supply

‡‡ Technology licensed under agreement from BioInteractions, Limited, United Kingdom.

Catheters

As ECMO therapy evolves and expands, so does the variety of patients you treat. Medtronic catheters are designed for the duration and support requirements of patients on VV and/or VA ECMO. Developed with extensive user input, the breadth of our dual lumen and single lumen catheter portfolio offers more lengths, sizes, and configurations than any other brand[7] – giving you the choices you need to individualize your patients' ECMO care.

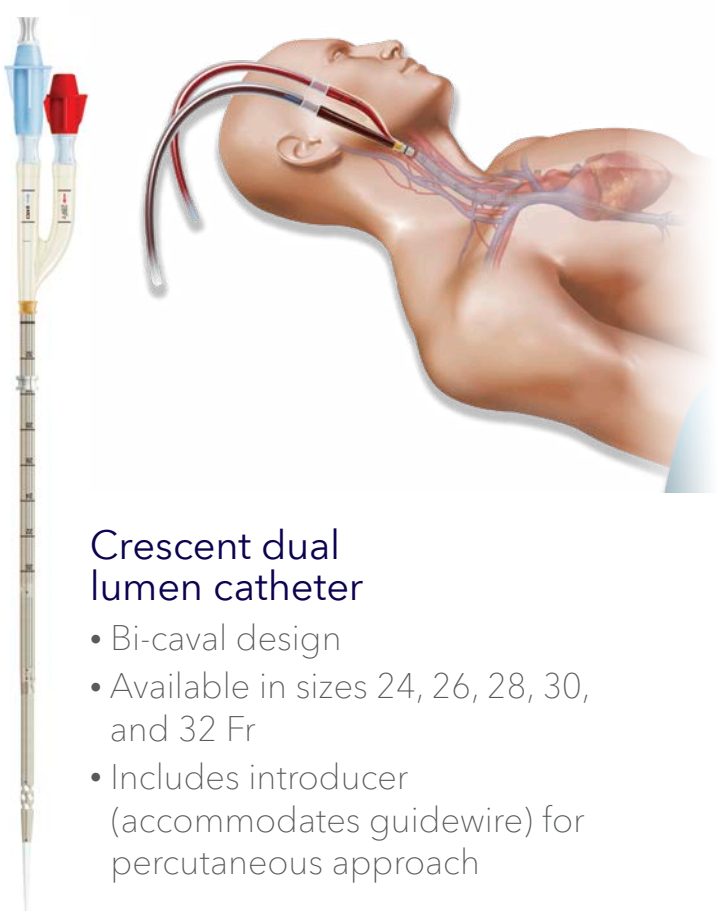
Risks of ECMO include heart, vessel, or lung damage, hypoxia, anemia, infection, hemorrhage, liver or kidney failure, stroke, and death.

Crescent jugular dual lumen catheters

Game-changing flow[8] for ECMO

The Crescent portfolio is the first FDA-cleared, jugular dual lumen long-term ECMO line of catheters. The catheters allow for more accurate placement[9] with just one cannulation site, deliver enhanced flow dynamics, and help maintain optimal flow once placed.

- Correct placement made easier[9]
- Optimized flow rates[8]
- Durable securement[10]



Crescent dual lumen catheter

- Bi-caval design
- Available in sizes 24, 26, 28, 30, and 32 Fr
- Includes introducer (accommodates guidewire) for percutaneous approach

Crescent RA jugular dual lumen catheter

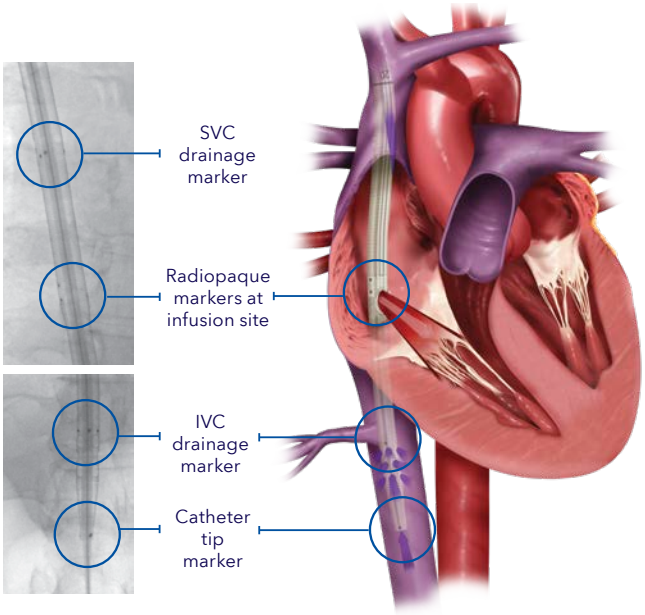
- Right atrial design
- Available in sizes 13, 15, and 19 Fr
- Includes obturator (short blunt tip) for an open technique and introducer (accommodates guidewire) for percutaneous technique

Only physicians with previous training and experience with venous catheterization and extracorporeal life support should use this device.

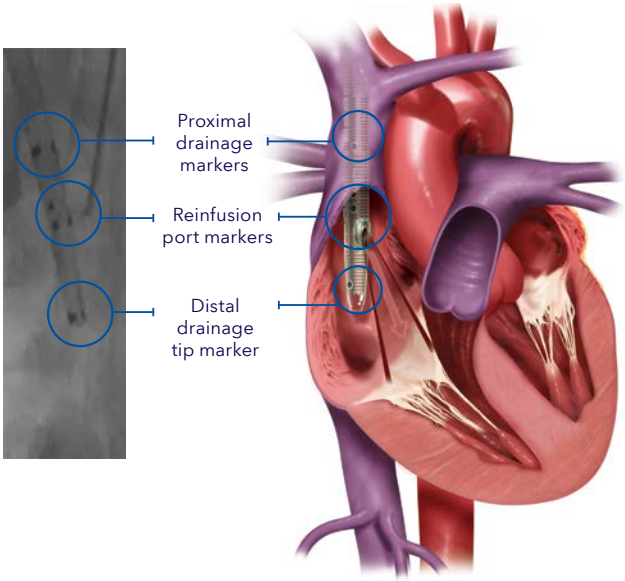
Correct placement made easier[9]

Optimal flow begins with correct placement, and that can be challenging. The Crescent jugular dual lumen catheters were designed to address those challenges with features that make positioning and securement easier.[9]

Crescent jugular dual lumen catheter



Crescent RA jugular dual lumen catheter



Radiopaque markers for improved visualization

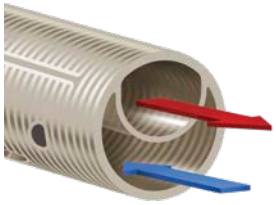
Visible under radiographic imaging, radiopaque markers aid in positioning the catheter and identifying drainage sites, infusion port, catheter tip, and axial orientation of the port.

Only physicians with previous training and experience with venous catheterization and extracorporeal life support should use this device.

Crescent jugular dual lumen catheters

Optimized flow rates[8]

Enhancements in port placement, lumen design, and tip geometry give these catheters optimal flow efficiency.[8] This enables you to achieve higher flow at lower pressure and allows for lower rates of hemolysis and recirculation.



Enhancements for optimal flow

Crescent-shaped lumen helps optimize pressure flow performance, and advanced materials make the catheter strong, flexible, and kink resistant.[10]

Promotes directional efficiency

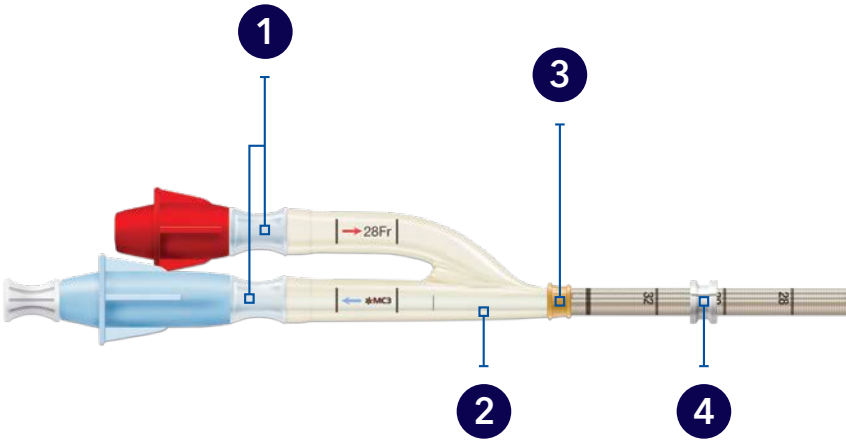
Large infusion port, combined with radiopaque markers for placement accuracy, helps ensure flow is directed toward the tricuspid valve.

Helps minimize recirculation

Drainage and reinfusion ports are designed to mimic the body´s natural flow ratios to minimize recirculation while maintaining flow.

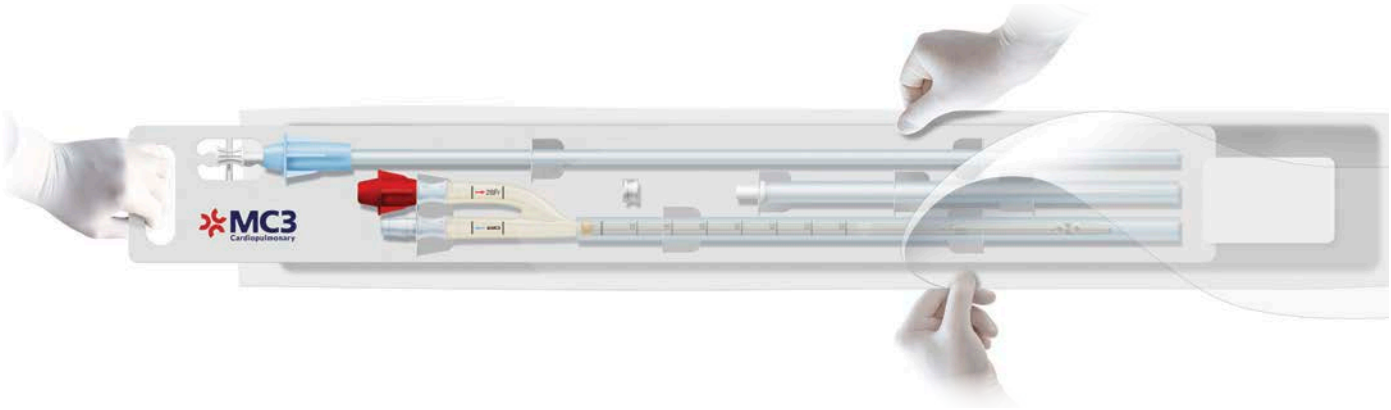
Durable securement[10]

1. In select circumstances, sutures may be placed on the connectors.
2. **Bifurcation suture site** provides security against catheter translations.
3. **Integrated suture site** contains special reinforcement to protect against catheter damage.
4. **Optional suture collar** can be placed at a desired location on the catheter body before or after catheter insertion.



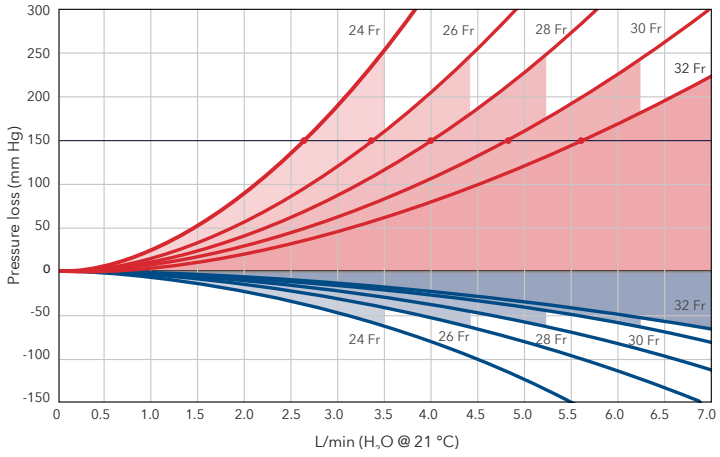
Only physicians with previous training and experience with venous catheterization and extracorporeal life support should use this device.

The Crescent catheter is the first FDA-cleared, jugular dual lumen long-term ECMO catheter. It allows for more accurate placement with just one cannulation site, delivers enhanced flow dynamics, and helps maintain optimal flow[8] once placed.



The Crescent catheter, introducer with drainage cap, suture collar, and matching dilator are provided on a holding card and sealed in a sterile pouch.

Crescent flow curves



Non-vented 3/8 in (0.95 cm) connector		
		Insertion length
70124	24 Fr (8.0 mm)	30.0 cm
70126	26 Fr (8.7 mm)	30.0 cm
70128	28 Fr (9.3 mm)	34.0 cm
70130	30 Fr (10.0 mm)	34.0 cm
70132	32 Fr (10.7 mm)	34.0 cm

One unit per carton.

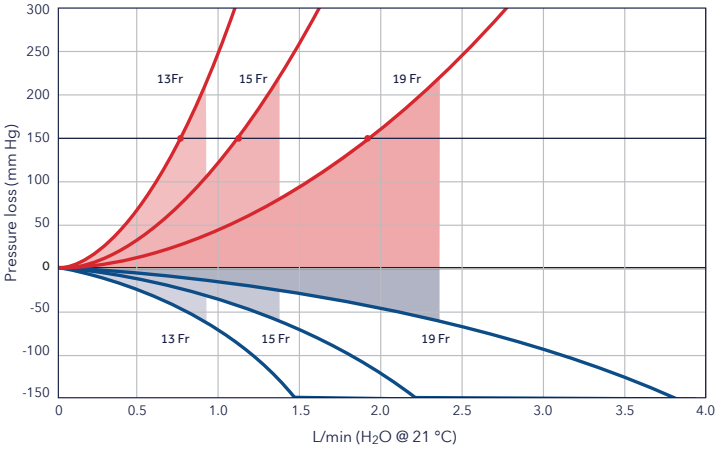
Only physicians with previous training and experience with venous catheterization and extracorporeal life support should use this device.

Crescent RA jugular dual lumen catheter

We understand the value of VV ECMO therapy, and now you have the option to provide your pediatric patients with the same game-changing flow[8] you expect from the Crescent catheter name. The Crescent RA jugular dual lumen catheter offers a right atrial design and includes both an introducer for a percutaneous technique and a blunt tip obturator for a surgical cut-down technique.

The Crescent RA catheter, introducer (accommodates a guidewire to facilitate a percutaneous approach), obturator (short, blunt tip to facilitate an open approach), stylet, optional suture collar, and matching dilator are affixed to a holding card and sealed in a sterile pouch.

Crescent right atrial flow curves



Non-vented 1/4 in (0.64 cm) connector		
		Insertion length
70413	13 Fr (3.7 mm)	8.9 cm
70415	15 Fr (4.3 mm)	9.7 cm
70419	19 Fr (5.0 mm)	14.5 cm

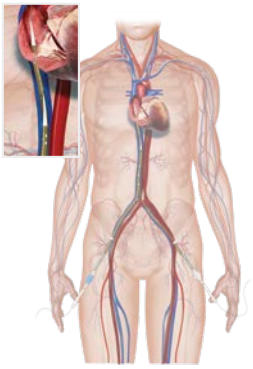
One unit per carton.

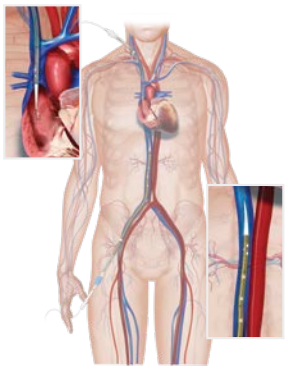
Bio-Medicus Life Support catheters

Developed with extensive user input, the Bio-Medicus Life Support catheter offers more lengths, sizes, and configurations than any other brand.[7] Life Support catheters provide clinicians with choices and options to individualize patients' ECMO care.

- French sizes 9 to 29
- Insertion lengths from 10 to 61 cm
- Configurations for VA and VV ECMO

Veno-venous





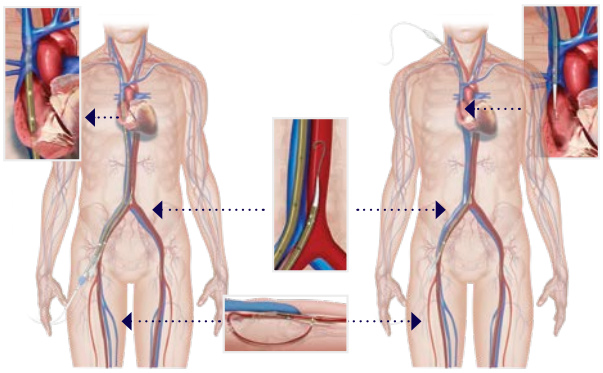
FEM-FEM VV

- Femoral-venous drainage
- Femoral-venous return

FEMORAL-JUGULAR VV

- Femoral-venous drainage
- Jugular return

Veno-arterial



FEM-FEM VA

- Femoral-venous drainage
- Femoral-arterial return

FEMORAL-JUGULAR VA

- Jugular-venous drainage
- Femoral-arterial return

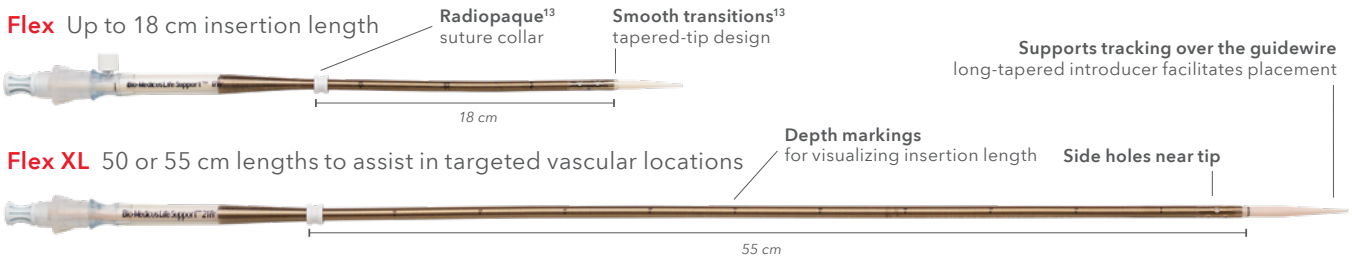
Bio-Medicus Life Support cannulae are made with Elast-Eon™* polymers, a biocompatible and biostable polyurethane/silicone copolymer.§§ Elast-Eon is commonly used in prolonged use and implantable medical devices, including ECMO dual lumen catheters. Features such as fingerlet-tip supports create a no-step transition, allowing for smooth insertion.[11] The kink-resistant wall design promotes optimized flow rates.[12]

§§ Elast-Eon™* is a siloxane urethane copolymer.

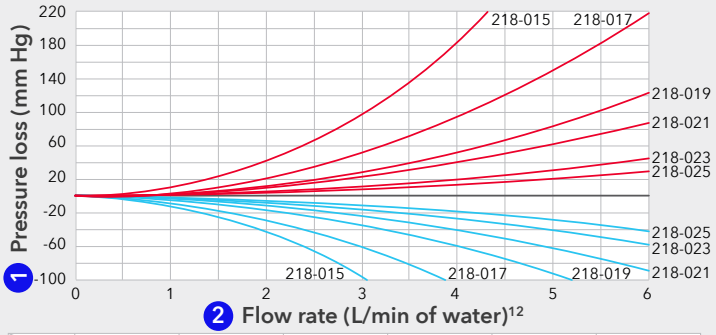
Bio-Medicus Life Support catheters

Flex and Flex XL

Designed for drainage or return at different insertion lengths, with side holes only near the tip.

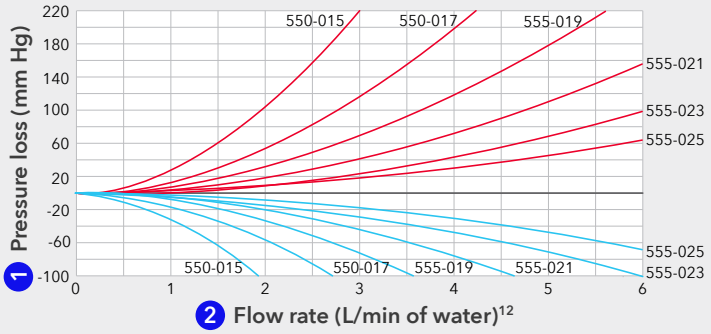


Flex return/drainage catheters **LS96**218-[12]



1 \ 2	218-015	218-017	218-019	218-021	218-023	218-025
100	3.0	4.1	5.5	> 6.0	> 6.0	> 6.0
-40	1.9	2.4	3.5	4.0	4.9	5.9

Flex XL return/drainage catheters **LS96**550-, **LS96**555-[12]



1 \ 2	550-015	550-017	555-019	555-021	555-023	555-025
100	2.0	2.8	3.7	4.7	> 6.0	> 6.0
-40	1.2	1.7	2.2	2.9	3.7	4.5

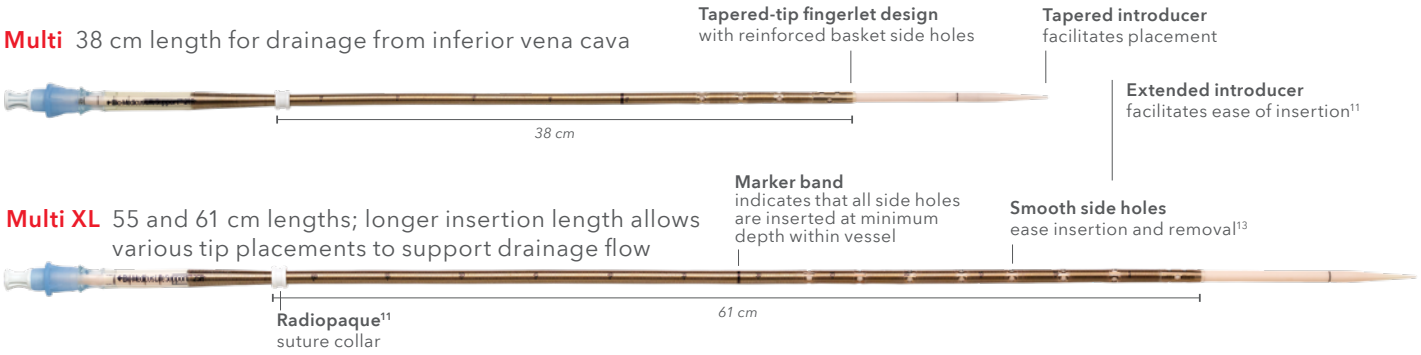
Ordering information

Bio-Medicus Life Support catheters and introducers	Catheter code	French size	Tip length	Connector
Return or drainage **Flex**	LS96218-015	15 Fr (5.0 mm)	18 cm	3/8 in (0.95 cm) vented
	LS96218-017	17 Fr (5.7 mm)	18 cm	3/8 in (0.95 cm) vented
	LS96218-019	19 Fr (6.3 mm)	18 cm	3/8 in (0.95 cm) vented
	LS96218-021	21 Fr (7.0 mm)	18 cm	3/8 in (0.95 cm) vented
	LS96218-023	23 Fr (7.7 mm)	18 cm	3/8 in (0.95 cm) vented
	LS96218-025	25 Fr (8.3 mm)	18 cm	3/8 in (0.95 cm) vented
Return or drainage **Flex XL**	LS96550-015	15 Fr (5.0 mm)	50 cm	3/8 in (0.95 cm) non-vented
	LS96550-017	17 Fr (5.7 mm)	50 cm	3/8 in (0.95 cm) non-vented
	LS96555-019	19 Fr (6.3 mm)	55 cm	3/8 in (0.95 cm) non-vented
	LS96555-021	21 Fr (7.0 mm)	55 cm	3/8 in (0.95 cm) non-vented
	LS96555-023	23 Fr (7.7 mm)	55 cm	3/8 in (0.95 cm) non-vented
	LS96555-025	25 Fr (8.3 mm)	55 cm	3/8 in (0.95 cm) non-vented

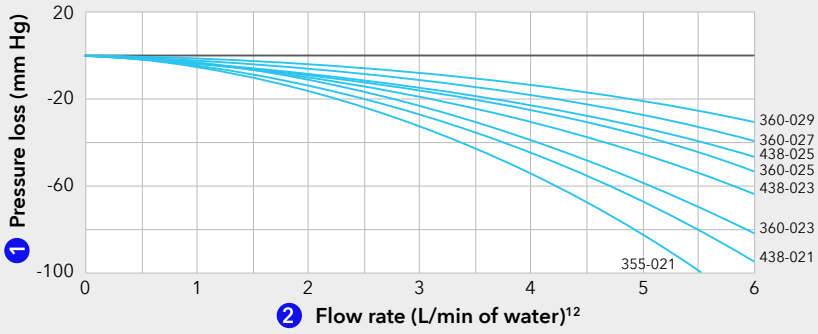
Bio-Medicus Life Support catheters

Multi and Multi XL

Designed for efficient drainage and optimized flow dynamics.[12]



Multi and Multi XL drainage catheters
LS96438-, **LS96**355-, **LS96**360-[12]



1 \ 2	355-021	438-021	360-023	438-023	360-025	438-025	360-027	360-029
-40	3.4	3.7	4.1	4.6	5.1	5.5	> 6.0	> 6.0

Ordering information

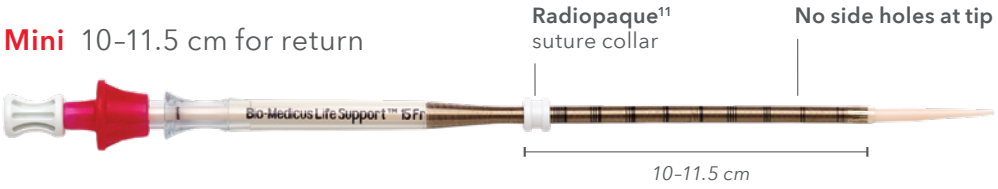
Bio-Medicus Life Support catheters and introducers	Catheter code	French size	Tip length	Connector
Drainage Multi	LS96438-021	21 Fr (7.0 mm)	38 cm	3/8 in (0.95 cm) non-vented
	LS96438-023	23 Fr (7.7 mm)	38 cm	3/8 in (0.95 cm) non-vented
	LS96438-025	25 Fr (8.3 mm)	38 cm	3/8 in (0.95 cm) non-vented
Drainage Multi XL	LS96355-021	21 Fr (7.0 mm)	55 cm	3/8 in (0.95 cm) non-vented
	LS96360-023	23 Fr (7.7 mm)	61 cm	3/8 in (0.95 cm) non-vented
	LS96360-025	25 Fr (8.3 mm)	61 cm	3/8 in (0.95 cm) non-vented
	LS96360-027	27 Fr (9.0 mm)	61 cm	3/8 in (0.95 cm) non-vented
	LS96360-029	29 Fr (9.7 mm)	61 cm	3/8 in (0.95 cm) non-vented

Bio-Medicus Life Support catheters

Mini

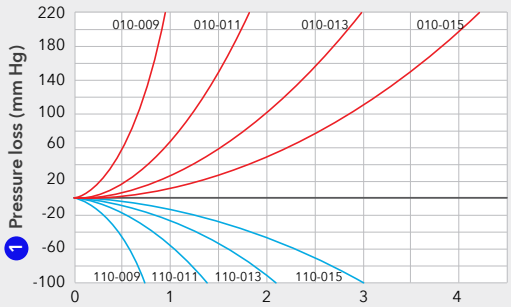
Designed for catheter placement configurations that require smaller sizes and shorter insertable lengths.

Mini 10–11.5 cm for return

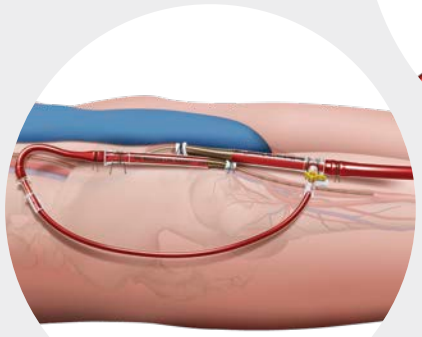


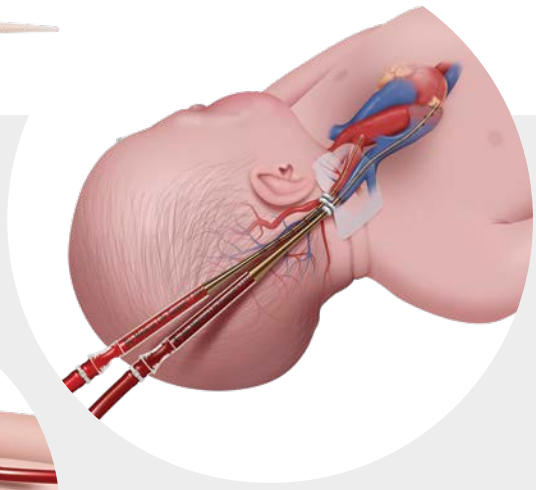
Mini 10–11.5 cm for drainage

Mini return/drainage catheters **LS96**010-, **LS96**110-[12]



1 \ 2	010-009 110-009	010-011 110-011	010-013 110-013	010-015 110-015
100	0.6	1.2	2.0	2.8
-40	0.4	0.8	1.3	1.8





Ordering information

Bio-Medicus Life Support catheters and introducers	Catheter code	French size	Tip length	Connector
Return **Mini**	LS96010-009	9 Fr (3.0 mm)	10 cm	1/4 in (0.64 cm) non-vented
	LS96010-011	11 Fr (3.7 mm)	10.5 cm	1/4 in (0.64 cm) non-vented
	LS96010-013	13 Fr (4.3 mm)	11 cm	1/4 in (0.64 cm) non-vented
	LS96010-015	15 Fr (5.0 mm)	11.5 cm	1/4 in (0.64 cm) non-vented
Drainage **Mini**	LS96110-009	9 Fr (3.0 mm)	10 cm	1/4 in (0.64 cm) non-vented
	LS96110-011	11 Fr (3.7 mm)	10.5 cm	1/4 in (0.64 cm) non-vented
	LS96110-013	13 Fr (4.3 mm)	11 cm	1/4 in (0.64 cm) non-vented
	LS96110-015	15 Fr (5.0 mm)	11.5 cm	1/4 in (0.64 cm) non-vented

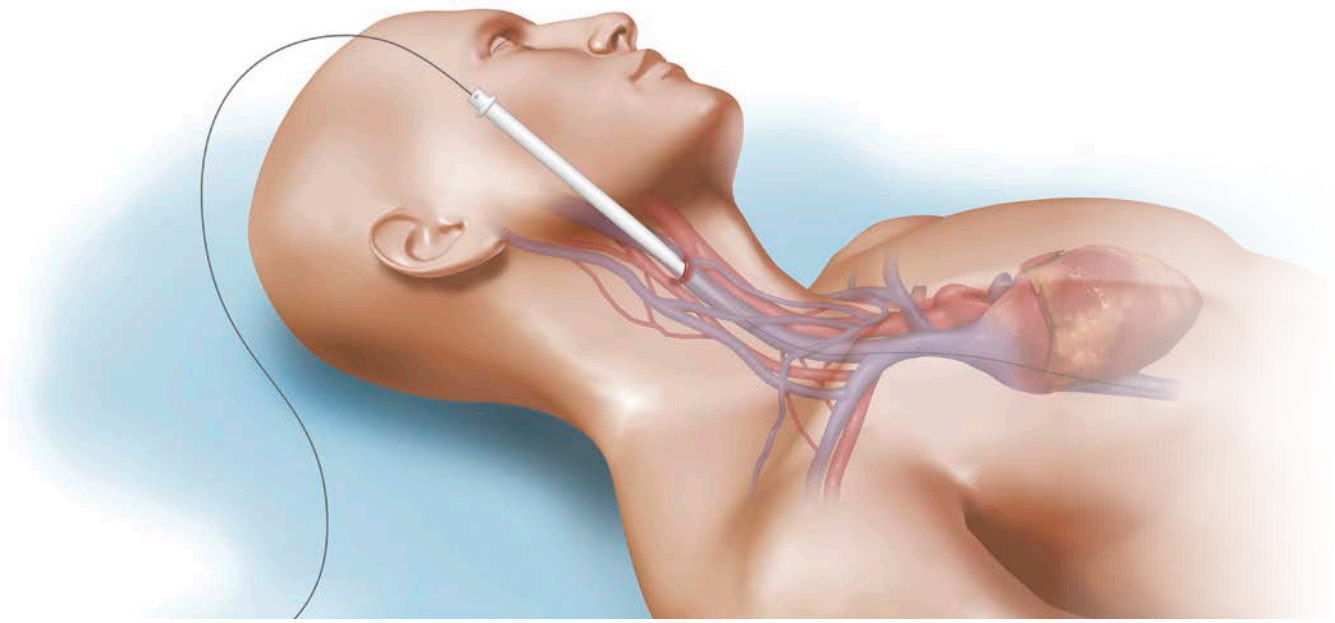
Opus vascular access kit

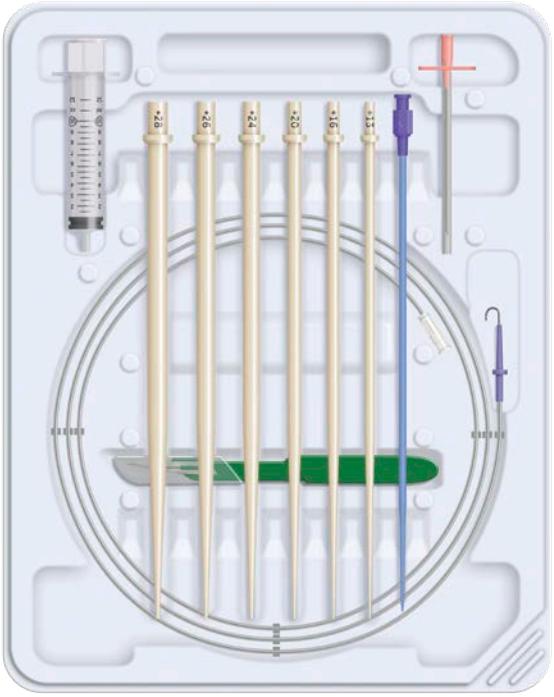
Expanding options for vascular access

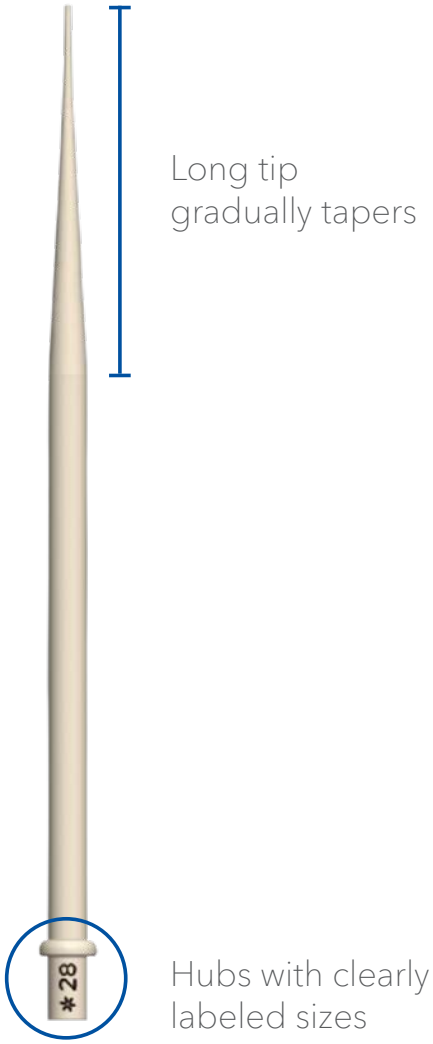
The Opus vascular access kit offers a convenient solution for the access you need. Our kits are thoughtfully composed to meet your preferences and techniques. Each Opus kit includes a complete set of instruments, along with dilators specifically designed to facilitate a smooth insertion[14] – while allowing for gradual dilation of the fascia. A versatile performer, the Opus kit is compatible with single lumen arterial and venous cannulae – and Crescent jugular dual lumen catheters.

- Selection of dilator sizes can accommodate varying patient anatomies
- Flexible-tip dilators support tracking along the guidewire[15]
- Hub helps with handling during insertion and removal
- Safety scalpel features clear protective shield that locks into place with a one-handed activation

Experience smooth insertion[15] and guidewire tracking with flexible, long, tapered-tip dilators.







Ordering information

Code	Configuration	Kit contents
21030	Box of 5	Stepped vessel dilator, 8/10 Fr, 13 Fr, 16 Fr, 20 Fr, 24 Fr, 26 Fr, 28 Fr
		Guidewire, J-tip 0.038 in (0.97 mm) x 71 in (180 cm) with depth mark increments
		Scalpel, #11 safety
		Needle, 18 gauge
		Syringe, 10 cc

Acute care and monitoring solutions

The INVOS system is the most widely studied regional oximeter on the market.[16] It was designed to respond quickly – so you can, too.

INVOS regional oximetry system

INVOS regional oximetry guided management may help you detect and resolve regional tissue desaturation during ECMO that may otherwise go unrecognized in these difficult-to-treat patients.[16,17]

The INVOS system can play an important role as a valuable "first alert"[18] because it monitors for hemodynamic changes and deteriorating patient conditions. It features:

- A touch screen for easily reviewing and marking patient data
- Automatic baseline setting – ensuring a reference value is taken
- LEDs in the reusable sensor cable to enable quick identification of sensors and channel label
- Perforated sensor design to keep sensors in place
- Up to four channels to measure cerebral and somatic tissue perfusion

The INVOS regional oximetry system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

INVOS system ordering information

Ordering information

SKU no.	Description	Quantity
PM7100	PM7100 patient monitor	1
PMPAMP71	Preamplifier	1
PMAC71RSC	Reusable sensor cable for PM7100	1
PMAC71DOC	Docking station	1
PMAC71STAND	Monitor stand	1
PMSENS71-A-20	Adult rSO_2 sensor, > 40 kg	20/box
PM71IFTD	PM7100 field test device	1
PMSENS71-P-20	Pediatric rSO_2 sensor, 4-40 kg	20/box
IS	Infant regional saturation sensor, < 40 kg	10/box
PMAC71RIC	Reusable infant cable	1

Technical specifications

INVOS 7100 monitor	
Size	20 x 30.75 x 5.1 cm (7.87 x 12.1 x 2 in)
Weight	1270g (2.8 lb)
Power	AC power adapter, Li-ion battery (30 minutes)
Screen size	25.7 cm (10.1 in.), measured diagonally
Screen type	FT LCD, projected capacitive multi-touch
Resolution	1280 x 800 pixels
Ports	USB 3.0, USB 2.0, DC In, docking port

INVOS 7100 preamplifier	
Size	12.8 x 8.7 x 2.8cm (5.04 x 3.43 x 1.1 in) with hook folded down
Weight	294 g (0.65 lb)
Indicator	Reusable sensor cable (RSC) connection prompt
Cable length	428.4 cm (14 ft) (approximate)
Cable connector	Amphenol 8-pin
Defibrillation	Defibrillator proof

INVOS 7100 adult rSO_2 and 7100 pediatric rSO_2 sensors	
Material	Medical grade acrylic adhesive, latex, DEHP and BPA free
Packaging	Packaged non-sterile for single use

INVOS infant regional saturation sensor (OxyAlert NIRSensor)	
Material	Medical grade hydrocolloid adhesive, latex and PVC free
Packaging	Packaged non-sterile for single use

Important Safety Information

VitalFlow ECMO System

Potential complications related to the use of ECMO devices include, but are not limited to, heart, vessel, or lung damage, hypoxia, anemia, irritation, toxic reaction, infection, hemorrhage, liver or kidney failure, stroke, and death. The benefits of extracorporeal support must be weighed against the risk of systemic anticoagulation and must be assessed by the prescribing physician.

Important safety information: For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

Nautilus Smart ECMO module and Nautilus ECMO Oxygenator

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

Only clinicians thoroughly trained in extracorporeal life support procedures should use this device.

Nautilus™ Smart ECMO Module and Nautilus are manufactured by Medtronic.

Balance™ is a trademark of Medtronic. Technology licensed under agreement from BioInteractions, Limited, United Kingdom.

Crescent, Crescent RA jugular dual lumen catheters, and Opus vascular access kit

Care and caution should be taken to avoid damage to vessels and cardiac tissue during cannulation or other cardiac surgery procedures. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Crescent™ Jugular Dual Lumen Catheter, Crescent™ RA, and Opus™ vascular access kit are manufactured by Medtronic.

Only physicians with previous training and experience with venous catheterization and extracorporeal life support should use this device.

Crescent™ Jugular Dual Lumen Catheters, Crescent™ RA, and Opus™ vascular access kit are not approved in every geography.

Bio-Medicus Life Support Catheters

- Only physicians trained and experienced in using percutaneous catheterization techniques (such as the Seldinger technique), ECMO, and ECLS should use this device.
- Note: The benefits of catheterization for extracorporeal circulation must be weighed against the risk of systemic anticoagulation and subsequent propensity for hemorrhage.

- **Caution:** Ensure that the catheter size selected is of adequate size for the vessel to allow distal perfusion of the limb when the catheter is in place. Improper catheter size may be difficult to advance. The vessel must be large enough to ensure perfusion and venous return.

Care and caution should be taken to avoid damage to vessels and cardiac tissue during cannulation or other cardiac surgery procedures. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

The INVOS Regional Oximetry System should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

For more information, contact your local Medtronic cannula products representative. U.S. Customer Service: 1-800-328-1357.

For a listing of indications, contraindications, precautions, and warnings, please refer to the Instructions for Use.

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1.Medtronic design verification data on file for VitalFlow ECMO system. May not be indicative of clinical performance.

2. ISO 60601-1 data on file.

3. Design verification and validation data on file for Nautilus Smart ECMO module. These tests may not be indicative of clinical performance.

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5. Alwardt CM, Wilson DS, Alore ML, Lanza LA, Devaleria PA, Pajaro OE. Performance and safety of an integrated portable extracorporeal life support system for adults. *J Extra Corpor Technol.* March 2015;47(1):38–43.

6. Lequier L, Horton SB, McMullan DM, Bartlett RH. Extracorporeal membrane oxygenation circuitry. *Pediatr Crit Care Med.* June 2013;14(5 Suppl 1):S7–12.

7. Maquet HLS brochure – Flow Rate l/min (H2O) at ambient temperature. Characterization bench data on file, may not be indicativeof clinical performance. Flow curve data on file. Maquet is a registered trademark of Maquet GmbH Catalogue – products and pictures may differ from the actual product appearance. Specifications are subject to change without prior notice. MCP_ BR_10018_EN_1 (as of 2015-03).

8. Bench and animal data on file for Crescent jugular dual lumen catheters. These tests may not be indicative of clinical performance.

9. Compared to products without radiopaque markers. Design verification and validation data on file for Crescent jugular and Crescent RA jugular dual lumen catheters. These tests may not be indicative of clinical performance.

10. Design verification and validation data on file for Crescent jugular and Crescent RA jugular dual lumen catheters. These tests may not be indicative of clinical performance.

11. Design Validation Report on file for Bio-Medicus Life Support catheters. Medtronic data on file. These tests may not be indicative of clinical performance.

12. Based on Medtronic flow rate/pressure loss data on file for Bio-Medicus Life Support catheters. Clinical results will vary due to the patient's condition and blood composition.

13. Design Validation and Verification Report for Bio-Medicus Life Support catheters. Medtronic data on file. These tests may not be indicative of clinical performance.

14. Design verification and validation data on file for Opus vascular kit. These tests may not be indicative of clinical performance.

15. Compared to a stepped vessel dilator. May not be indicative of clinical performance.

16. Wong JK, Smith TN, Pitcher HT, Hirose H, Cavarocchi NC. Cerebral and lower limb near-infrared spectroscopy in adults on extracorporeal membrane oxygenation. *Artif Organs.* August 2012;36(8):659–667.

17.Kim DJ, Cho Y-J, Park SH, et al. Near-Infrared Spectroscopy Monitoring for Early Detection of Limb Ischemia in Patients on Veno-Arterial Extracorporeal Membrane Oxygenation. *ASAIO J.* September/October 2017;63(5):613–617.

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UC202501365 EN
03/2025