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ORDIN DE PLATA NR.: 187                                TIP.DOC. 1 :
                                DATA EMITERII:mar?i, 18 martie 2:
=====:
PLATITI: 25000-00          LEI: Douazeci si Cinci Mii lei 00 b :
ani                                                                :
=====:
PLATITOR: (R) "BIOSISTEM          CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L.                MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
=====:
PRESTATORUL PLATITOR          CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau          :MOLDMD2X329:
=====:
BENEFICIAR (R) Institutul          CONTUL DE PLATI/CODUL IBAN :
de Medicina Urgenta IMSP          MD55VI022510300000002MDL :
                                CODUL FISCAL :1003600152606 / :
=====:
PRESTATORUL BENEFICIAR          CODUL BANCII:
B.C."VICTORIABANK"S.A.          :VICBMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizitie public: NORMAL/URGENT :N:
a nr. ocds-b3wdp1-MD-1740568454463 din : :
19.03.2025 : :
                                : L.S. :
=====:
                                CODUL TRANZACTIEI:001: :
                                DATA PRIMIRII:18/03/2025 : SEMNATURILE :
                                DATA EXECUTARII: : EMITENTULUI :
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(semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
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L.S. (semnatura electronica) :
CONducATOR: (semnatura manuala) :
CONTABIL-SEF: (semnatura manuala) :
SEMnATURA PRESTATORUL L.S. :
MOTIVUL REFUZULUI : L.S. :
-----:

```

REPUBLICA



MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

**Societatea cu Răspundere Limitată "BIOSISTEM MLD"**  
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

*Numărul de identificare de stat - codul fiscal*  
**1010600028048**

*Data înregistrării*

**12.08.2010**

*Data eliberării*

**12.08.2010**

**Svirepova Ludmila, registrator**

*Funcția, numele, prenumele persoanei  
care a eliberat certificatul*

*L. Svirepova*  
semnătura

MD 0101250





## AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

### EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**

Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei.**

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **15.09.2023.**

**Registrator în domeniul  
înregistrării de stat**

Digitally signed by Rusu Diana  
Date: 2023.09.15 16:44:17 EEST  
Reason: MoldSign Signature  
Location: Moldova



**Rusu Diana**



**EB 0461494**



# BC "MOLDINDCONBANK" S.A. Filiala "Invest"

Republica Moldova, MD-2068  
mun. Chişinău, bd. Moscovei, 14/1  
Tel. : (373-22) 43-44-81, 43-46-24  
Fax : (373-22) 43-44-22  
cod: MOLDM2X329

Data 14. IAN. 2016  
Nr. 03/2 - 19/23

Республика Молдова, MD-2068  
мун. Кишинэу, бул. Московей, 14/1  
Тел. : (373-22) 43-44-81, 43-46-24  
Факс : (373-22) 43-44-22  
код: MOLDM2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent  
in moneda nationala al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu  
**IBAN MD95ML000000002251429243.**

Codul băncii MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza  
Tel. 43-45-96

## **Lista fondatorilor Biosistem-mld SRL**

<b>Nr.</b>	<b>Nume, Prenume</b>	<b>IDNP</b>
<b>1.</b>	<b>Vitalie Poiata</b>	<b>0983103892591</b>
<b>2.</b>	<b>Alexandr Nasedchin</b>	<b>2002001070747</b>
<b>3.</b>	<b>Dmitrii Kojevnikov</b>	<b>0972305012362</b>

## HEATER COOLER

TAILORED AND RELIABLE  
TEMPERATURE MANAGEMENT  
FOR ECLS



## HEATER COOLER

### THE MOST **COMPLETE, SECURE & INTUITIVE** SOLUTION TO MANAGE THE PATIENT'S BLOOD TEMPERATURE DURING ECLS PROCEDURES

The Heater-Cooler is a system designed to facilitate patient thermo-regulation during ECMO. This innovative device is part of the ECLS portfolio and is capable of warming/cooling the patient in the range of 15-39°C, making it suitable to respond to different clinical needs. Aligned with the safety standards defining the entire ECLS portfolio, our Heater Cooler utilizes a fully "closed" water circulation system. "In this type of closed heater cooler, air born transmission of *Mycobacterium chimaera* could not be demonstrated"<sup>1</sup>.

#### Key Features:

- Performs both cooling and warming functions in a wide set of temperature ranges (15°-39°)
- Easy to set up and use with a dedicated workstation in the Leonardo/Leonardo Slim Trolley
- Fully "closed" water circulatory system to reduce infection risk
- Incorporates automatic functional tests and alarms for enhanced safety
- Offers enhanced protection when used in combination with Eurosets Oxygenators to reduce the risk of disinfectant solution migration

1) Trudzinski F.C., Schlotthauer U., Kamp A., Hennemann K., Muellenbach R.M., Reischl U. Gärtner B., Wilkens H., Bals R., Herrmann M., Lepper P.M. and Becker S.L. (2016) - **Clinical implications of *Mycobacterium chimaera* detection in thermo-regulatory devices used for extracorporeal membrane oxygenation (ECMO)** - Germany, 2015 to 2016', in Euro Surveillance, p. 6.



RATED VOLTAGE	230 VAC 50 Hz
NOMINAL VALUE RANGE	15-39°C
PUMP CAPACITY	Max. 5.5 l/min. max. 0.21 bar
WARM-UP TIME	Approx. 5-10 mins. (20-37°C)
COOLING-DOWN TIME	Approx. 5-10 mins. (20-15°C)
TANK VOLUME	0.5/0.8 l (min./max.)
DIMENSIONS (w x h x d)	200 x 290 x 440 mm
WEIGHT	17 kg (empty)

## HEATER COOLER



# HEATER COOLER

## ORDERING GUIDE

CODE	DESCRIPTION	N°/PACK
EU3941	includes: <ul style="list-style-type: none"><li>• HC Unit</li><li>• UK and EU Power supply cables</li><li>• Hoses 1,5m (x2)</li><li>• Hanes connection tube</li><li>• Water discarghe hose (female)</li></ul> 	1 *
EU3943	Hoses 3m (x2) 	1 *

- \* The code EU3941 is CE 0123 Certified
- \* The code EU3943 is certified by EUROSETS S.r.l.

### EUROSETS EUROPE

#### ITALY

Eurosets S.r.l.  
Strada Statale 12, 143  
41036 Medolla (MO)  
Italy  
Ph: +39 0535 660311  
Fax: +39 0535 51248  
info@eurosets.com

#### BENELUX

Eurosets Benelux  
Winstar Park,  
Rue Provinciale, 62  
1301 Bierges (Wavre)  
Belgium  
Ph: +32 10237993  
info.nl@eurosets.com  
info.be@eurosets.com

#### FRANCE

Eurosets France Sarl  
Immeuble LE FONTENOY  
96, Boulevard Vivier  
Merle  
69423 LYON Cedex 03  
Ph: +33 962191542  
Fax: +33 970066573  
info.fr@eurosets.com

#### GERMANY

Eurosets GmbH  
Industriestr. 29  
82194 Gröbenzell  
Ph: +49 81426671227  
Fax: +4981426671229  
info.de@eurosets.com

### EUROSETS ASIA

#### CHINA

Eurosets (Suzhou) Medical Device Ltd.  
Suite 1308-2, The Summit (South Block)  
No. 119, Suzhou Avenue West,  
Suzhou Industrial Park - 215000, Greater China.  
苏州工业园区苏州大道西119  
号苏悦广场南楼1308-2, 215000,  
更大的中国  
info.cn@eurosets.com

   [eurosets.com](https://www.eurosets.com)

Prodotto da  
Manufactured by  
Fabriqué par  
Hersteller  
Fabricado por

Eurosets s.r.l.  
Strada Statale 12, n°143  
41036 Medolla (MO) Italy  
Tel: +39 0535 660311  
Fax: +39 0535 51248  
E-mail: info@eurosets.com  
eurosets.com



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Distribuido por



Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

No. G2 14 05 24169 025

**Manufacturer:** Eurosets s.r.l.  
Strada Statale 12, 143  
41036 Medolla (MO)  
ITALY

**Facility(ies):** Eurosets s.r.l.  
Via Dei Mestieri, 4/6/8, 41030 Bastiglia (MO), ITALY

**Product Category(ies):** Medical devices for transfusion (Micro-aggregates filters), Autotransfusion (Intra-operative and post-operative reservoir, Vacuum reducer, Anticoagulant and aspiration lines, Post-operative Autotransfusion systems), Drainage (Cardio-thoracic drainage systems, wound drainage systems with suction), Washing (Wound Washing, aspiration and cleaning systems, Pressure reducer), Vacuum Generators (for autotransfusion and post-operative drainage, wound drainage with suction), blood oxygenating devices for extracorporeal circulation (Oxygenators, venous reservoirs and Cardiotomy), Circuits and components for extracorporeal and infusional circulation (blood circuits with or without oxygenators, reservoirs, centrifugal blood pump, connector for transducer for flow monitoring system; cardioplegia and infusional circuits with or without heat exchanger; Connectors, Gas filters, Pre by-pass filters, cardioplegia and infusional solution filters, heat exchangers, Vascular tourniquet, one way valves; arterial filters)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** ITA 244421  
**Valid from:** 2021-07-28  
**Valid until:** 2026-07-12



*H.-H.*

Date, 2021-07-29

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1





# free life ECMO/ECLS Blood Heater Unit FT2800pro

Hochleistungs- elektronische Heater Unit

# free life ECMO/ECLS Blood Heater Unit FT2800pro

In Temperatursensoren integrierte Mikroprozessoren bieten eine hochpräzise Steuerung des Gerätes.

## Funktionen:

- Dauerbetrieb Selbsttests, 24 Stunden Dauerbetrieb
- Doppelter unabhängiger Überhitzungsschutz und automatische Abschaltung
- Optischer und akustischer Alarm bei Hochtemperatur- / Niedertemperatur- / Sensorfehler
- Jeder Kanal kann unabhängig mit seiner eigenen Temperatur arbeiten. Einstellung und Temperaturregelung jedes einzelnen Kreislaufes möglich.
- Zwei Kanäle können kombiniert werden, um die Wärmekapazität und das aufwärmen des Patienten zu steigern.
- Die Schläuche sind vollständig eingehüllt, dadurch kein Wärmeverlust

## Technische Spezifikationen

**Modell:** FT2800pro

**Einstellung der Temperatur:** 33 - 41°C

**Stromversorgung:** a.c.100~240V/50~60 HZ

**Leistungsaufnahme:** Max.180 VA

**Art des Schutzes gegen elektrischen Schlag:** Klasse I

**Schutzgrad gegen elektrischen Schlag:**  
BF Anwendungsteil; Defibrillationsgeschützt

**Schutzgrad gegen das Eindringen von Flüssigkeiten:**  
IPX2

**Temperaturgenauigkeit:** ±1,0°C

**Überhitzungsschutz:** 42°C/43°C

**Niedrigtemperatur-Alarm:** 32°C

**Aufwärmzeit:** von 20°C auf 36°C ca. 2 min.

**Betriebsart:** Kontinuierlich

**Abmessungen (B\*T\*H):** 200 x 130 X 250mm

**Nettogewicht:** 2,3 kg

**Warming profile:**  
length 1300mm, für 3/8" Schläuche,  
optional für 1/4" Schläuche erhältlich



Kontaktieren Sie uns für weitere Optionen.

\*Vorbehaltlich technischer Änderungen  
ohne vorherige Ankündigung.

## Benutzerfreundliches Bedienfeld:

- Großer LED-Bildschirm mit:
  - Vorwahl Temperatur
  - tatsächlicher Temperatur
  - Heizzeit
  - und Fehler Anzeige
- Einfach und schnell einzurichten, innerhalb von Minuten einsatzbereit.
- Akzeptiert Standard 3/8" Schläuche



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

**No. G1 039709 1263 Rev. 00**

**Manufacturer:**

**Medtronic, Inc.**

710 Medtronic Parkway  
Minneapolis MN 55432  
USA

**Product Category(ies):**

- **Autotransfusion Systems and Associated Disposables**
- **Centrifugal Blood Pumps**
- **Bio-Console Drive Units**
- **Flow Monitoring Systems**
- **Bio-Cal Blood Temperature Controller**
- **Temperature Monitoring Systems and Associated Disposables**
- **Blood Monitoring Systems**
- **Cardioplegia Delivery Systems**
- **Disposable Blood Handling Devices used for Open Heart Surgery**
- **Arterial Filters**
- **Oxygenators including Heat Exchangers, with and without Cardiotomy Reservoirs**
- **Cardiotomy Venous Reservoirs**
- **Venous Reservoir Bags**
- **Perfusion Equipment and Disposable Perfusion Devices**
- **Disposable Medical Devices for Drainage Systems**
- **Disposable Medical Devices for use in Cardiopulmonary Surgery: Cardioplegia, Cannulae, Venting, Suction**
- **Pressure Display System & related accessories of class IIa**
- **Tissue Positioning/Stabilizing Devices**
- **Surgical Site Clearing Devices**
- **Intravascular Shunts**
- **Surgical Retractors**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final

Page 1 of 3

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



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Product Service

# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

**No. G1 039709 1263 Rev. 00**

inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 72150396

**Valid from:** 2020-02-12

**Valid until:** 2024-05-26

**Date,** 2020-02-12

Christoph Dicks  
Head of Certification/Notified Body



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Product Service

# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

**No. G1 039709 1263 Rev. 00**

## Facility(ies):

Medtronic Mexico S.de R.L.de CV  
Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja  
California, MEXICO

Medtronic Perfusion Systems  
7611 Northland Drive, Minneapolis, MN 55428, USA

Medtronic, Inc.  
710 Medtronic Parkway, Minneapolis MN 55432, USA

**Medtronic**

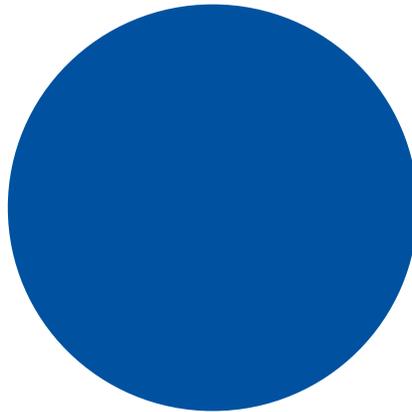
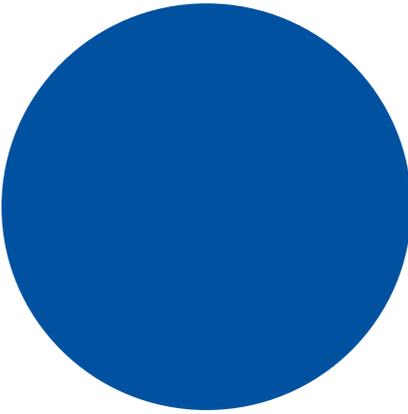
Bio-Medicus Life Support™ Catheters

# Individualized ECLS care

Indicated for long-term† ECLS



†21CFR870.4100.



# For the full range of patients you treat.

Bio-Medicus Life Support portfolio is part of our ongoing commitment to ECLS.

As ECLS therapy evolves and expands, so does the variety of patients you treat. This makes it challenging to provide the best individualized care for each patient.

The Bio-Medicus Life Support catheter portfolio helps address many of these challenges.

Developed with extensive user input, the Bio-Medicus Life Support catheter offers more lengths, sizes, and configurations than any other brand, giving you the choices you need to individualize your patient's ECLS care.

# Designed for performance<sup>1</sup>

## Optimizing flow

Thin, kink-resistant wall design promotes optimized flow rates.

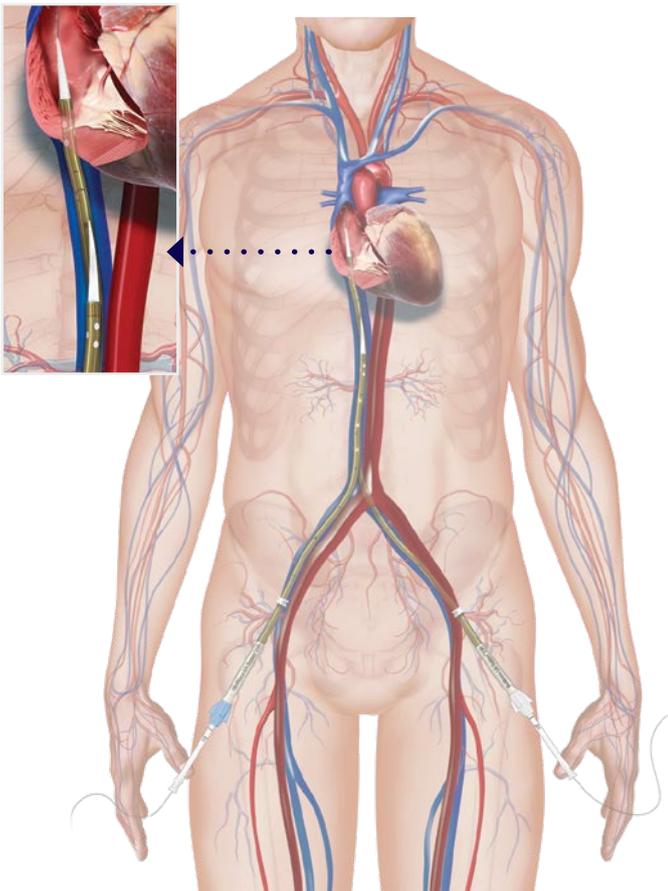
## Ease of insertion

Features such as fingerlet tip supports create a no-step transition allowing for smooth insertion.

## Configuration options

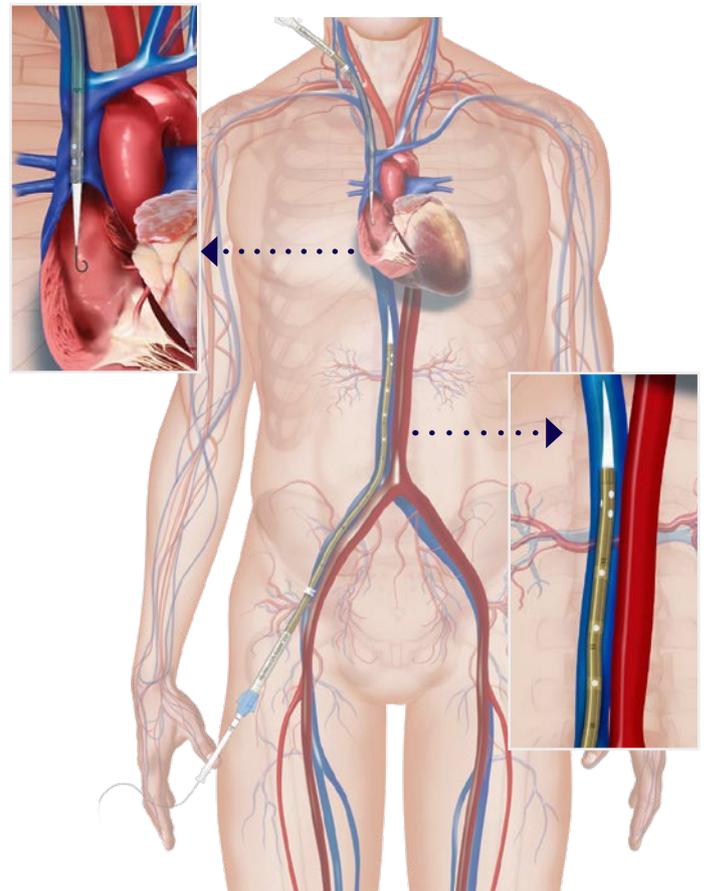
We developed the Bio-Medicus Life Support catheter by listening to the needs of ECLS physicians regarding technique and configurations.

## Veno-venous



### FEMORAL-FEMORAL VV

Femoral-venous drainage  
Femoral-venous return



### FEMORAL-JUGULAR VV

Femoral-venous drainage  
Jugular return

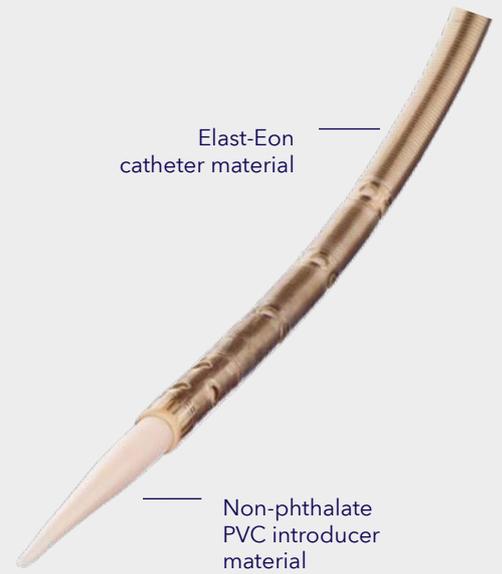
## Advanced biostable material

Bio-Medicus Life Support cannulae are made with Elast-Eon™, a biocompatible and biostable polyurethane/silicone copolymer.†

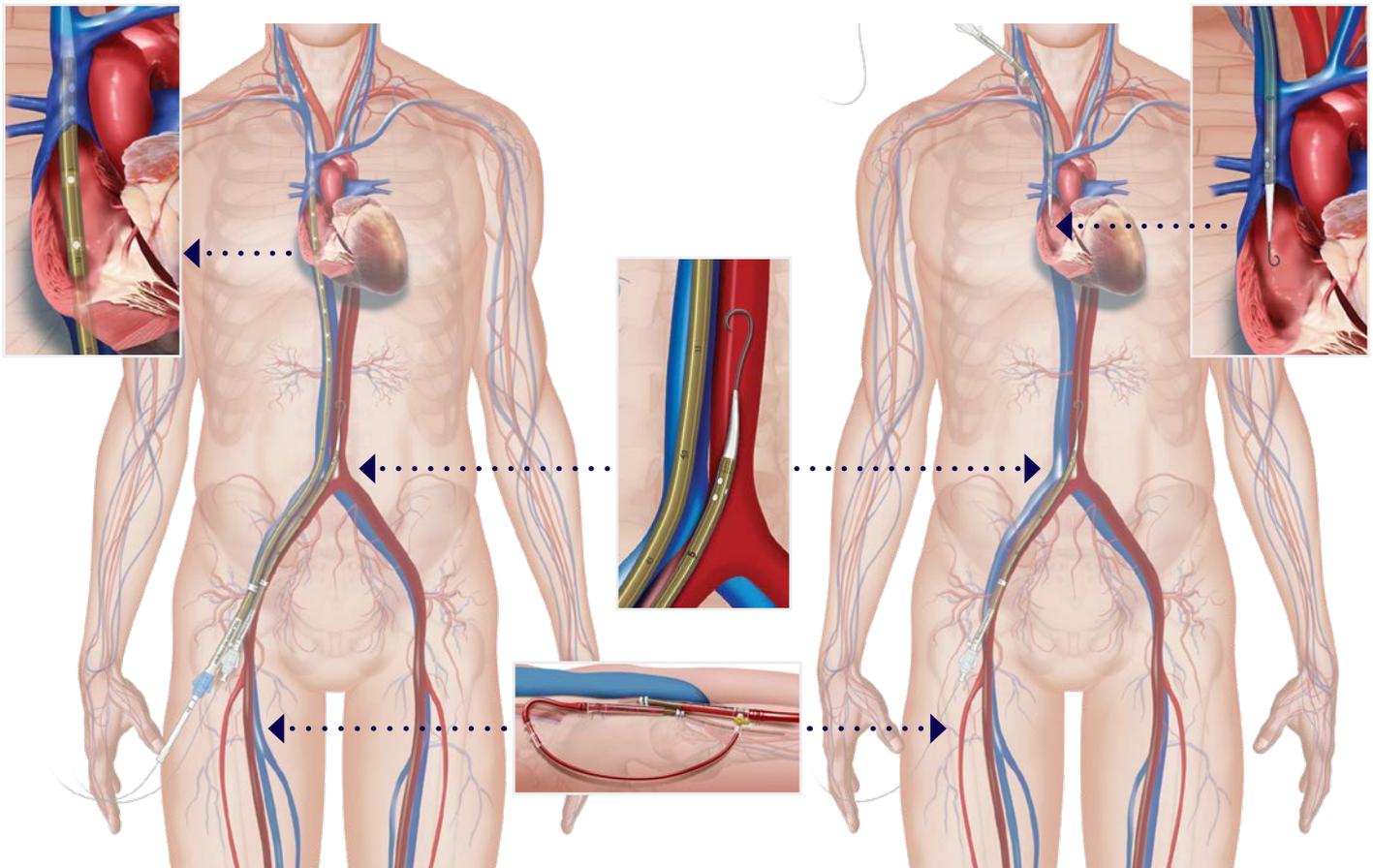
Elast-Eon is commonly used in prolonged-use and implantable medical devices, including ECLS dual lumen catheters.

†Elast-Eon™ is a siloxane urethane copolymer.

<sup>1</sup> Bench data on file, may not be indicative of clinical performance.



## Veno-arterial



### FEMORAL-FEMORAL VA

Femoral-venous drainage  
Femoral-arterial return

### JUGULAR-FEMORAL VA

Jugular-venous drainage  
Femoral-arterial return

# More sizes. More lengths. More options.

## Drainage or return catheters – Flex

Used for VA or VV configurations

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

**Flex** Up to 18 cm insertion length (See Figure A below for flow data)



**Flex XL** 50 or 55 cm lengths to assist in targeted vascular locations



## Drainage catheters – Multi

Designed for efficient drainage and optimized flow dynamics<sup>1</sup>

**Multi** 38 cm length for drainage from inferior vena cava



**Multi XL** 55 and 61 cm lengths; longer insertion length allows various tip placements to support drainage flow



<sup>1</sup> Bench data on file, may not be indicative of clinical performance.

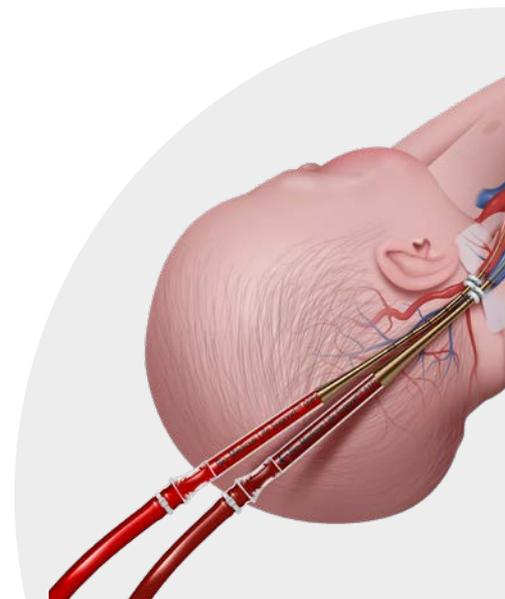
## Drainage or return catheters – Mini

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



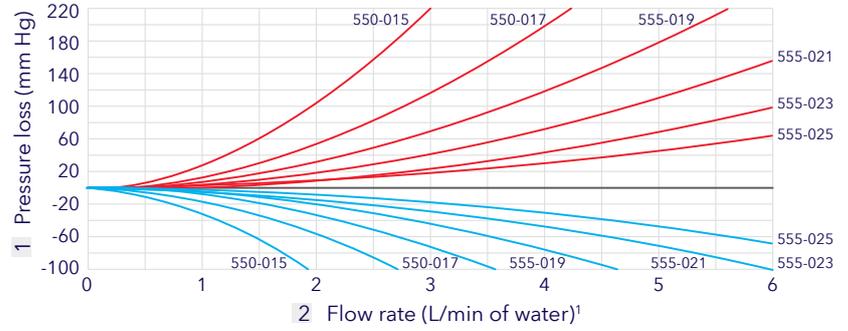
Bio-Medicus Life Support offers catheter options so that you have the flexibility to uniquely treat each patient – smallest to largest, youngest to oldest – with varying extracorporeal support needs.

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

### Flex XL return/drainage catheters LS96550-, LS96555-<sup>1</sup>

**Supports tracking over the guidewire**  
Long-tapered introducer facilitates placement

**Smooth transitions**  
Tapered tip design



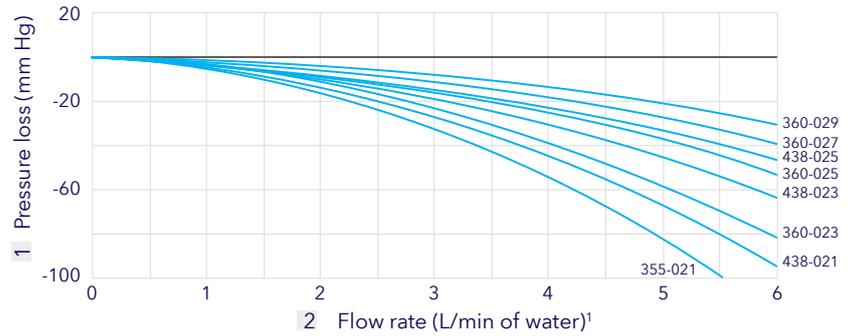
1 \ 2	550-015	550-017	555-019	555-021	555-023	555-025
100	2.0	2.8	3.7	4.7	>6.0	>6.0
-40	1.2	1.7	2.2	2.9	3.7	4.5

### Multi and Multi XL drainage catheters LS96438-, LS96355-, LS96360-<sup>1</sup>



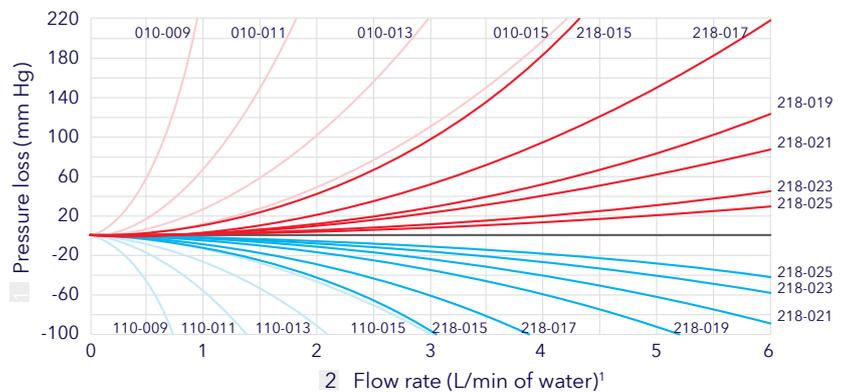
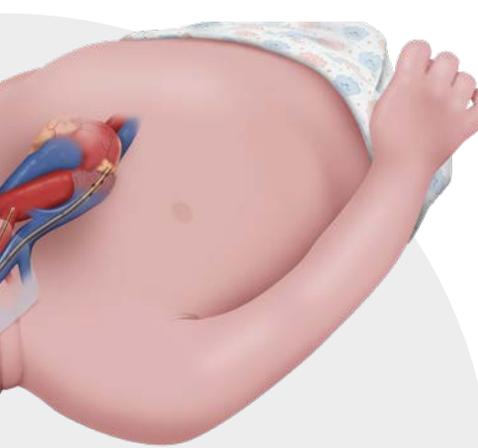
**Extended introducer**  
Facilitates ease of insertion

**Smooth side holes**  
Ease insertion and removal



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

### Figure A Flex and Mini return/drainage catheters LS96010-, LS96110-, LS96218-<sup>1</sup>



1 \ 2	010-009 110-009	010-011 110-011	010-013 110-013	010-015 110-015	218-015	218-017	218-019	218-021	218-023	218-025
100	0.6	1.2	2.0	2.8	3.0	4.1	5.5	>6.0	>6.0	>6.0
-40	0.4	0.8	1.3	1.8	1.9	2.4	3.5	4.0	4.9	5.9

<sup>1</sup>Bench data on file, may not be indicative of clinical performance.

## 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
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
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

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at [www.medtronic.eu](http://www.medtronic.eu).

For applicable products, consult instructions for use on [www.medtronic.com/manuals](http://www.medtronic.com/manuals).

Manuals can be viewed using a current version of any major internet browser.

For best results, use Adobe Acrobat® Reader with the browser.

This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

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**Medtronic**

# Extracorporeal life support (ECLS)

U.S. product catalog



# Elevating ECLS every day

## Innovative like no other

Extracorporeal life support (ECLS) is a rapidly growing therapy used to bridge patients experiencing acute cardiac and/or respiratory failure to recovery, or to bridge patients to a destination therapy.

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

- Catheters
- ECMO Oxygenators
- Patient Monitoring Solutions
- Blood Diagnostics
- Appendix



# Catheters

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As ECLS 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 – giving you the choices you need to individualize your patients' ECLS care.



## ● Catheters

- Crescent™ Jugular Dual Lumen
  - Crescent™
  - Crescent™ RA
- Bio-Medicus Life Support™
  - Flex
  - Multi
  - Mini
- Opus™ Vascular Access Kit

○ ECMO Oxygenators

○ Patient Monitoring Solutions

○ Blood Diagnostics

○ Appendix



# Crescent™ Jugular Dual Lumen Catheters

## ● Catheters

### • Crescent™ Jugular Dual Lumen

- Crescent™
- Crescent™ RA

### • Bio-Medicus Life Support™

- Flex
- Multi
- Mini

### • Opus™ Vascular Access Kit

## ○ ECMO Oxygenators

## ○ Patient Monitoring Solutions

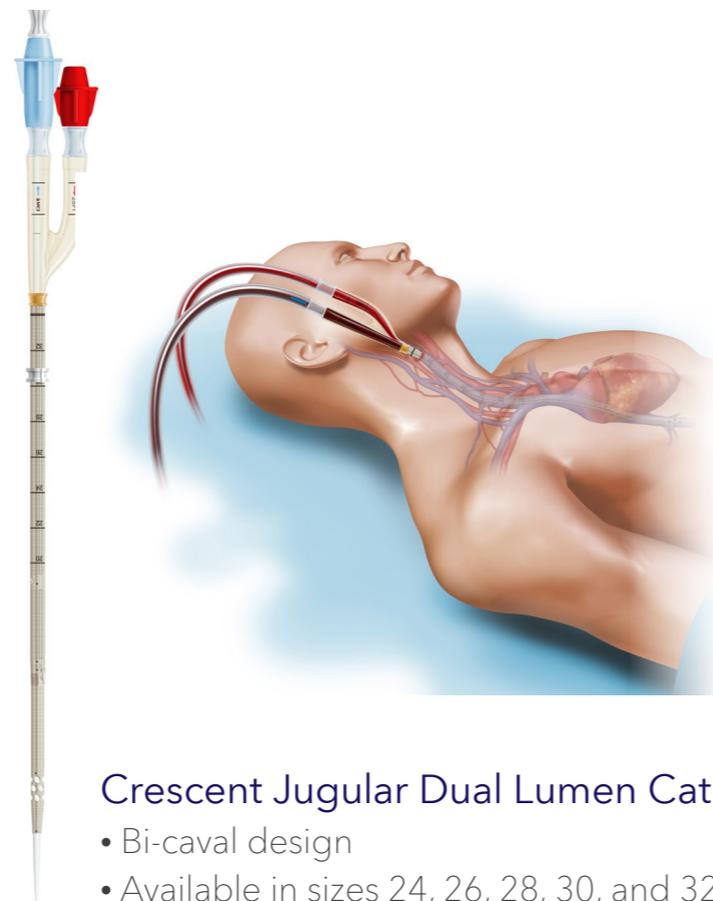
## ○ Blood Diagnostics

## ○ Appendix

## Game-changing flow† for ECMO

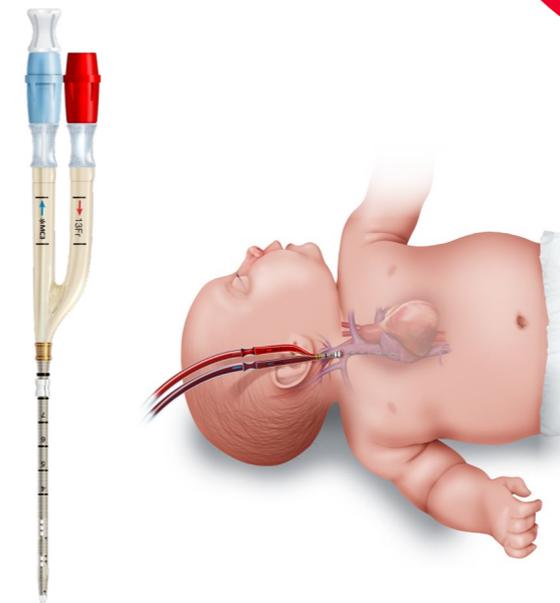
The Crescent portfolio is the first FDA-cleared, jugular dual lumen long-term ECMO line of catheters. The catheters allow for more accurate placement with just one cannulation site, deliver enhanced flow dynamics, and help maintain optimal flow once placed.

- Correct placement made easier
- Optimized flow rates†
- Durable securement



### Crescent Jugular 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. Crescent™ jugular dual lumen catheter and Crescent™ RA jugular dual lumen catheter are manufactured by MC3, Inc., and exclusively distributed by Medtronic.

™Third-party brands are trademarks of their respective owners.

†Bench and animal data on file at MC3. These tests may not be indicative of clinical performance.



# Crescent™ Jugular Dual Lumen Catheters

## ● Catheters

### • Crescent™ Jugular Dual Lumen

- Crescent™
- Crescent™ RA

### • Bio-Medicus Life Support™

- Flex
- Multi
- Mini

### • Opus™ Vascular Access Kit

○ ECMO Oxygenators

○ Patient Monitoring Solutions

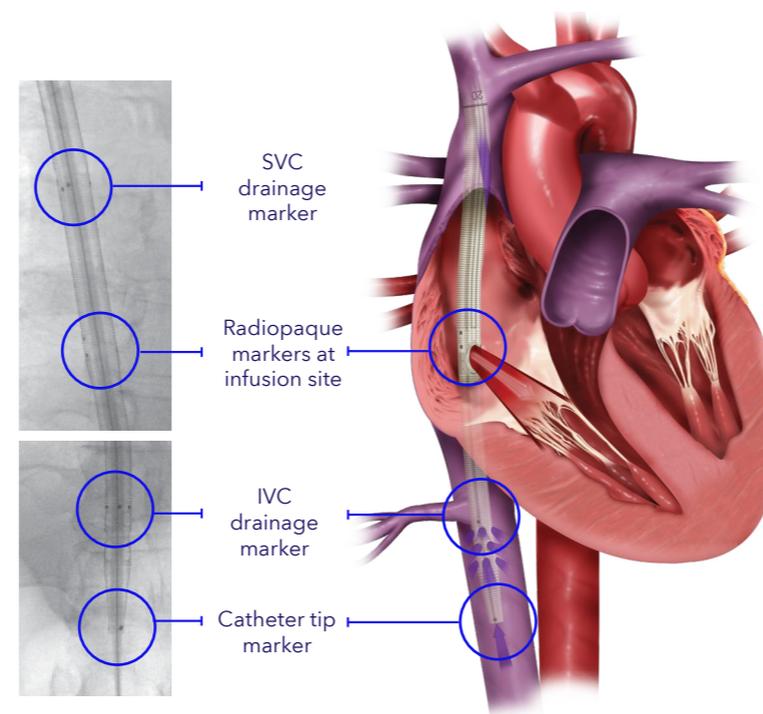
○ Blood Diagnostics

○ Appendix

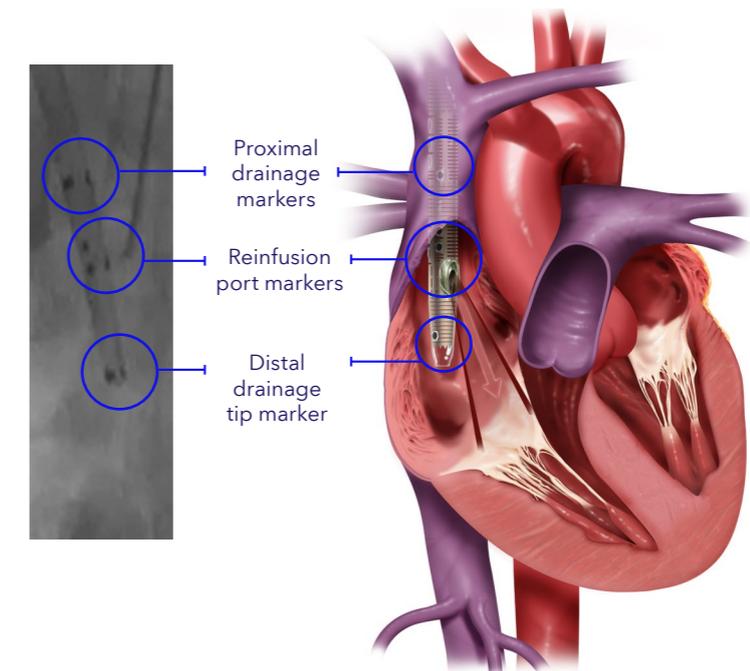
## Correct placement made easier

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 for you.

### 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 catheter and Crescent™ RA jugular dual lumen catheter are manufactured by MC3, Inc., and exclusively distributed by Medtronic.

™Third-party brands are trademarks of their respective owners.



# Crescent™ Jugular Dual Lumen Catheters

## ● Catheters

### • Crescent™ Jugular Dual Lumen

- Crescent™
- Crescent™ RA

### • Bio-Medicus Life Support™

- Flex
- Multi
- Mini

### • Opus™ Vascular Access Kit

## ○ ECMO Oxygenators

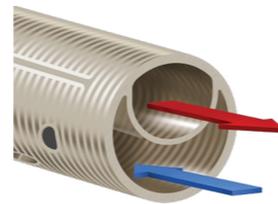
## ○ Patient Monitoring Solutions

## ○ Blood Diagnostics

## ○ Appendix

## Optimized flow rates†

Enhancements in port placement, lumen design, and tip geometry give these catheters optimal flow efficiency. This enables you to realize 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.



### Promotes directional efficiency

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

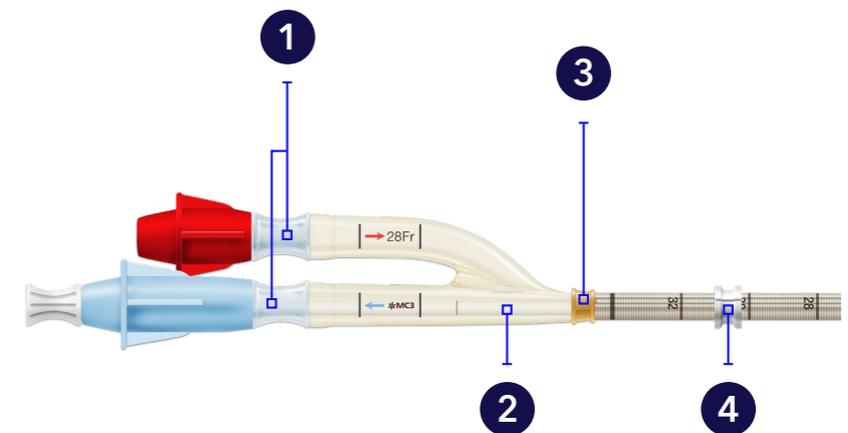


### Helps minimize recirculation

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

## Durable securement

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. Crescent™ jugular dual lumen catheter and Crescent™ RA jugular dual lumen catheter are manufactured by MC3, Inc., and exclusively distributed by Medtronic.

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†Data on file at MC3. These tests may not be indicative of clinical performance.



# Crescent™ Jugular Dual Lumen Catheter

## ● Catheters

- Crescent™ Jugular Dual Lumen
  - Crescent™
  - Crescent™ RA
- Bio-Medicus Life Support™
  - Flex
  - Multi
  - Mini
- Opus™ Vascular Access Kit

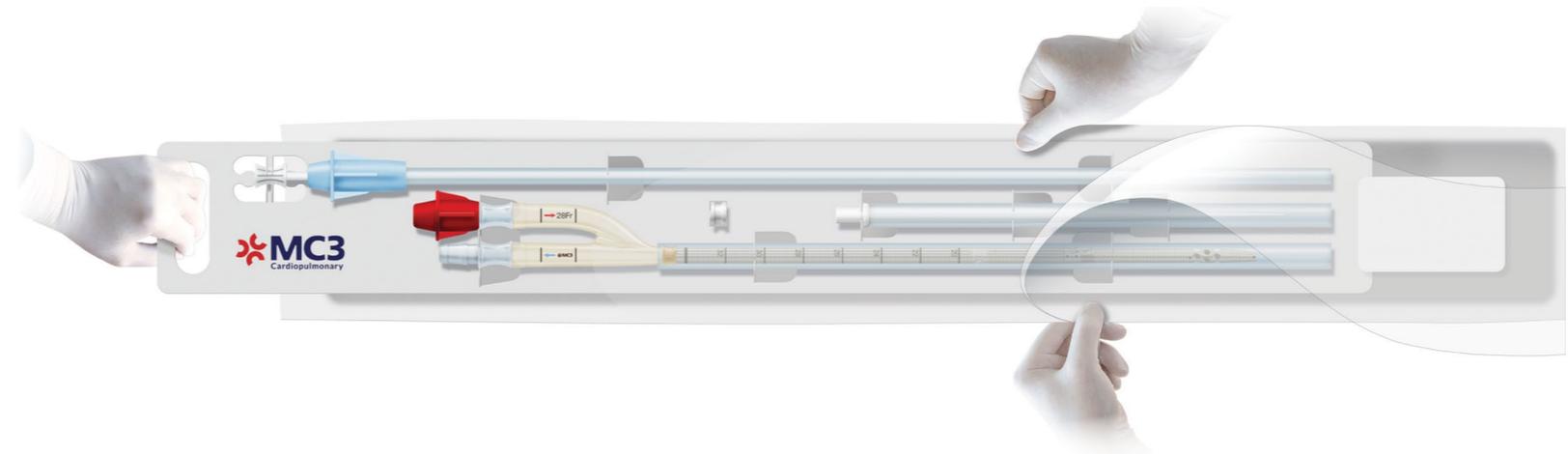
○ ECMO Oxygenators

○ Patient Monitoring Solutions

○ Blood Diagnostics

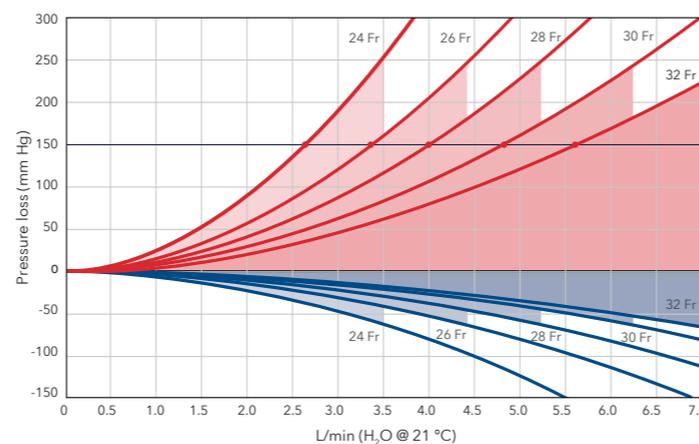
○ Appendix

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† 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™ jugular dual lumen catheter and Crescent™ RA jugular dual lumen catheter are manufactured by MC3, Inc., and exclusively distributed by Medtronic.

™Third-party brands are trademarks of their respective owners.

†Bench and animal data on file at MC3. These tests may not be indicative of clinical performance.



# Crescent™ RA Jugular Dual Lumen Catheter

## ● Catheters

- Crescent™ Jugular Dual Lumen
  - Crescent™
  - Crescent™ RA
- Bio-Medicus Life Support™
  - Flex
  - Multi
  - Mini
- Opus™ Vascular Access Kit

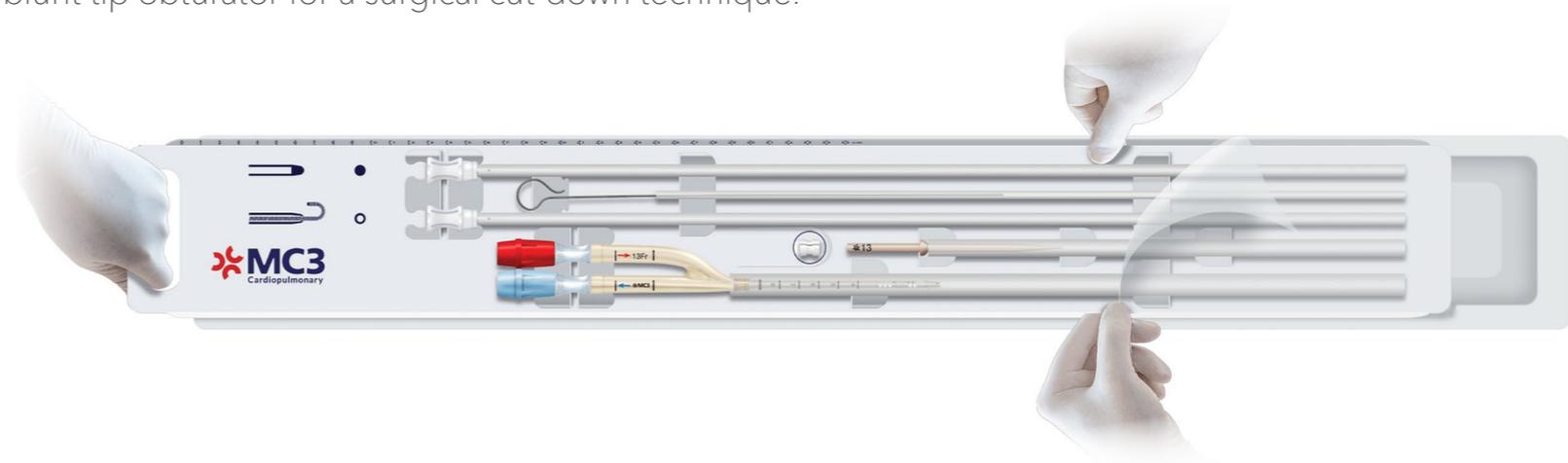
○ ECMO Oxygenators

○ Patient Monitoring Solutions

○ Blood Diagnostics

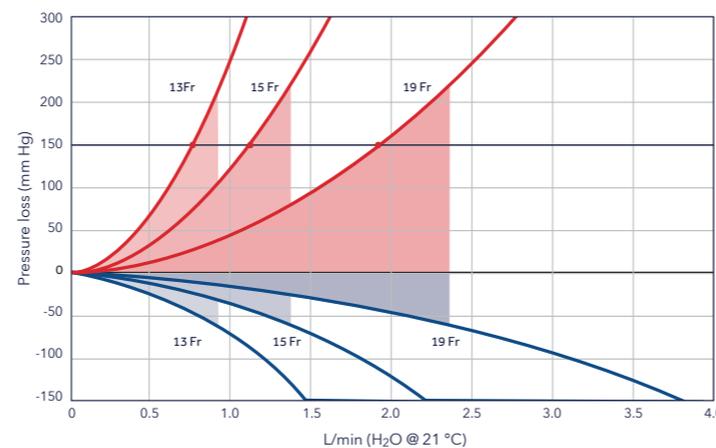
○ Appendix

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† 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.

Crescent™ jugular dual lumen catheter and Crescent™ RA jugular dual lumen catheter are manufactured by MC3, Inc., and exclusively distributed by Medtronic.

™Third-party brands are trademarks of their respective owners.

†Bench and animal data on file at MC3. These tests may not be indicative of clinical performance.



# 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. Life Support catheters provide clinicians with choices and options to individualize patients' ECLS care.

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

## ● Catheters

- Crescent™ Jugular Dual Lumen
  - Crescent™
  - Crescent™ RA
- Bio-Medicus Life Support™
  - Flex
  - Multi
  - Mini
- Opus™ Vascular Access Kit

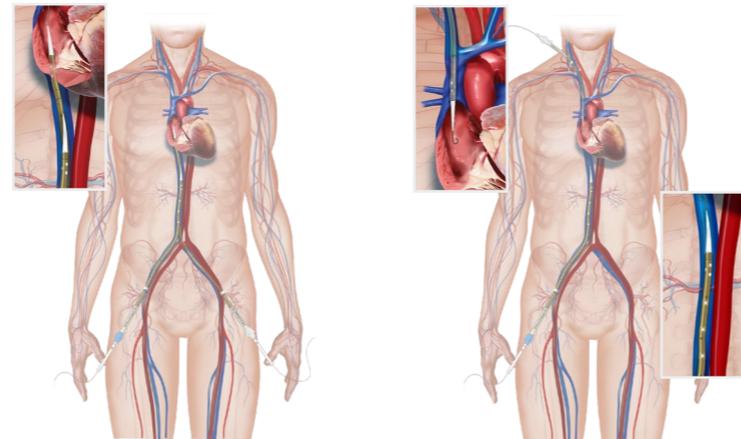
## ○ ECMO Oxygenators

## ○ Patient Monitoring Solutions

## ○ Blood Diagnostics

## ○ Appendix

### Veno-venous



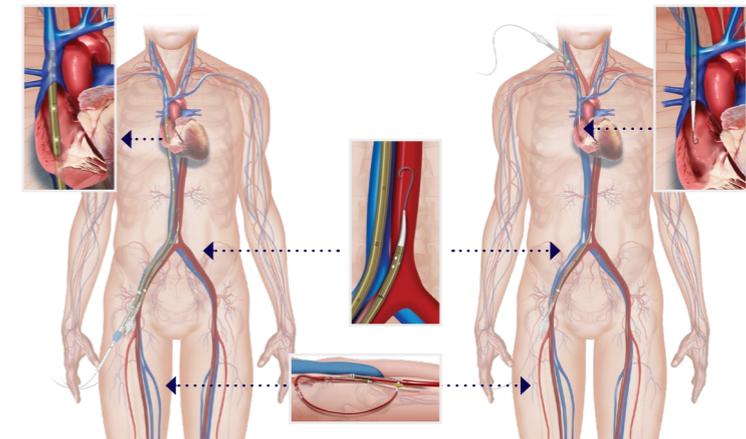
#### FEM-FEM VV

- 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™, a biocompatible and biostable polyurethane/silicone copolymer.<sup>1</sup> Elast-Eon is commonly used in prolonged use and implantable medical devices, including ECLS dual lumen catheters. Features such as fingerlet-tip supports create a no-step transition, allowing for smooth insertion. The kink-resistant wall design promotes optimized flow rates.

<sup>™</sup>Third-party brands are trademarks of their respective owners.

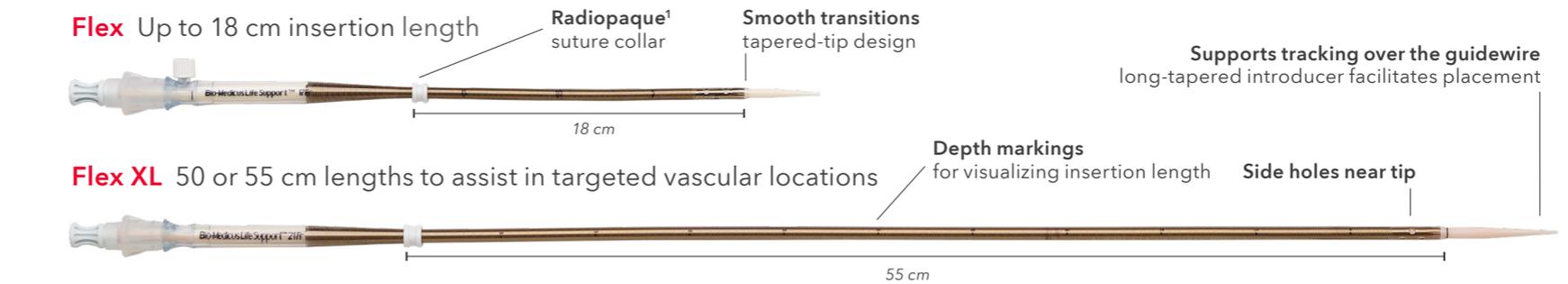
<sup>1</sup>Elast-Eon™ is a siloxane urethane copolymer.



# 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.



### ● Catheters

- Crescent™\* Jugular Dual Lumen
  - Crescent™\*
  - Crescent™\* RA
- Bio-Medicus Life Support™
  - Flex
  - Multi
  - Mini
- Opus™\* Vascular Access Kit

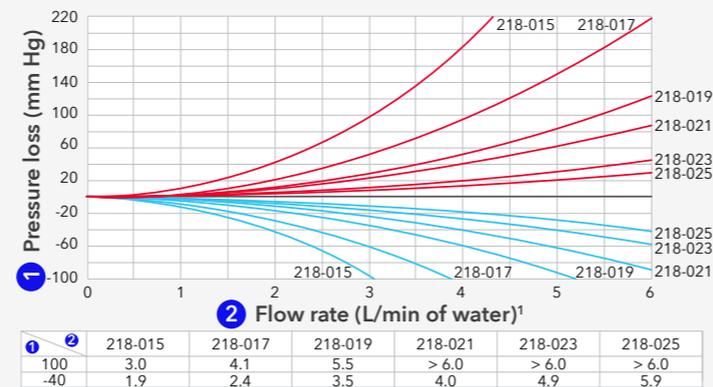
### ○ ECMO Oxygenators

### ○ Patient Monitoring Solutions

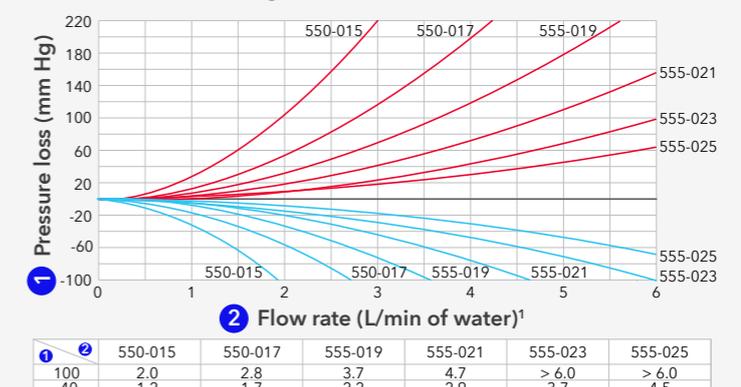
### ○ Blood Diagnostics

### ○ Appendix

Flex return/drainage catheters LS96218-<sup>1</sup>



Flex XL return/drainage catheters LS96550-, LS96555-<sup>1</sup>



## Ordering information

Bio-Medicus Life Support catheters and introducers	Catheter code	French size	Tip length	Connector
Return or drainage <b>Flex</b>	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 <b>Flex XL</b>	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

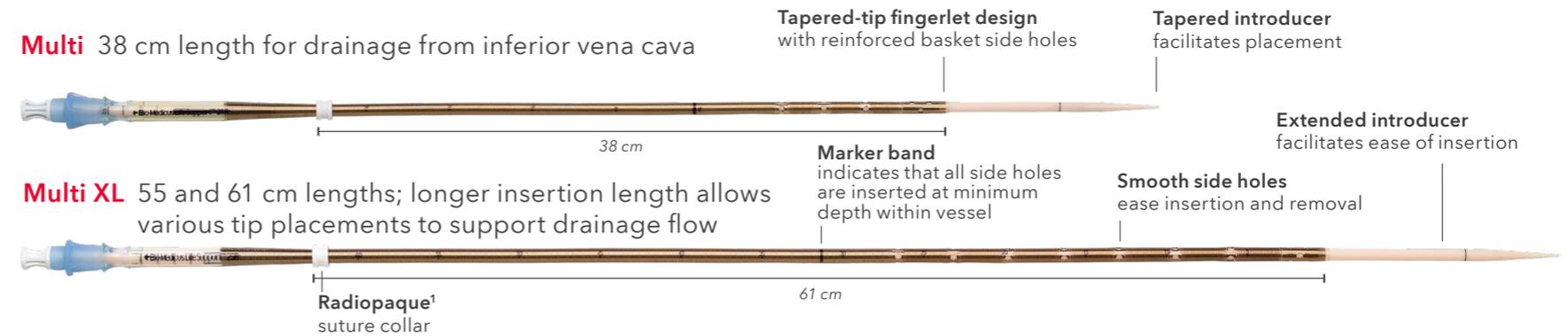
<sup>1</sup>Bench data on file, may not be indicative of clinical performance.



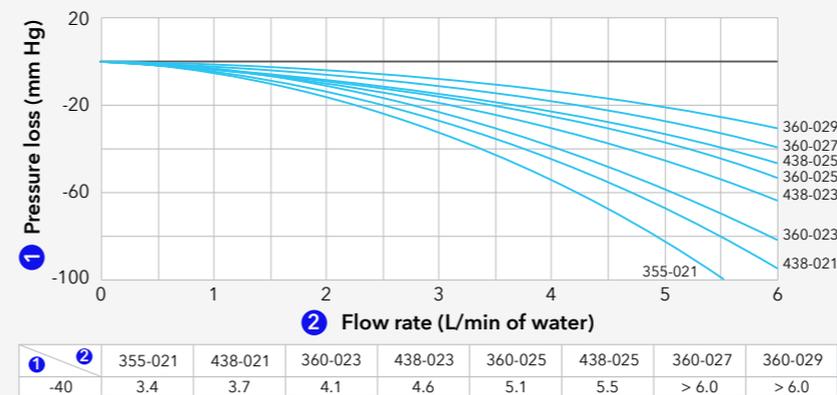
# Bio-Medicus Life Support™ Catheters

## Multi and Multi XL

Designed for efficient drainage and optimized flow dynamics.<sup>1</sup>



Multi and Multi XL drainage catheters LS96438-, LS96355-, LS96360-<sup>1</sup>



## Ordering information

Bio-Medicus Life Support catheters and introducers	Catheter code	French size	Tip length	Connector
Drainage <b>Multi</b>	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 <b>Multi XL</b>	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

<sup>1</sup>Bench data on file, may not be indicative of clinical performance.



### ● Catheters

- Crescent™\* Jugular Dual Lumen
  - Crescent™\*
  - Crescent™\* RA
- Bio-Medicus Life Support™
  - Flex
  - **Multi**
  - Mini
- Opus™\* Vascular Access Kit

### ○ ECMO Oxygenators

### ○ Patient Monitoring Solutions

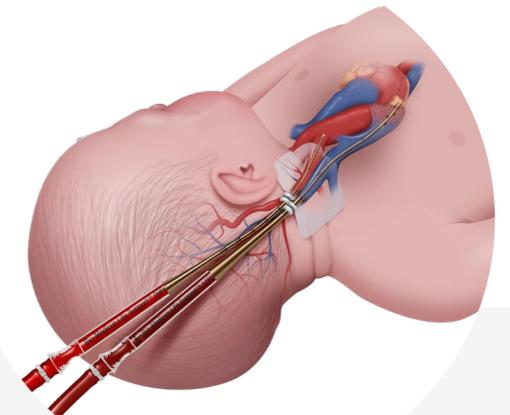
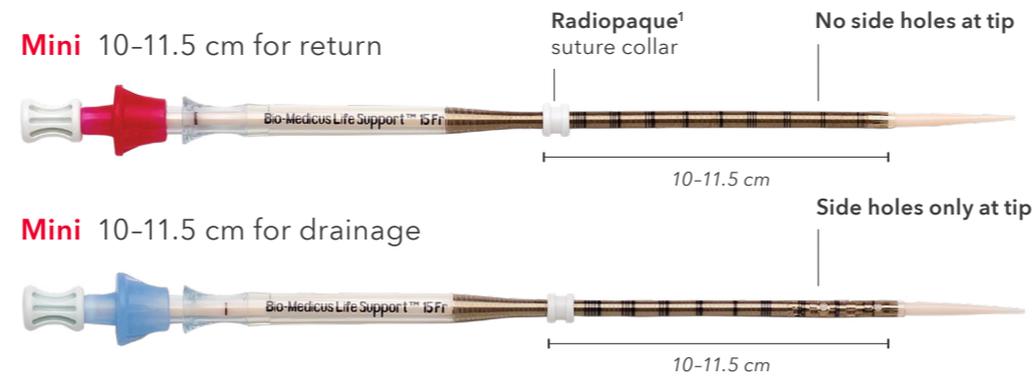
### ○ Blood Diagnostics

### ○ Appendix

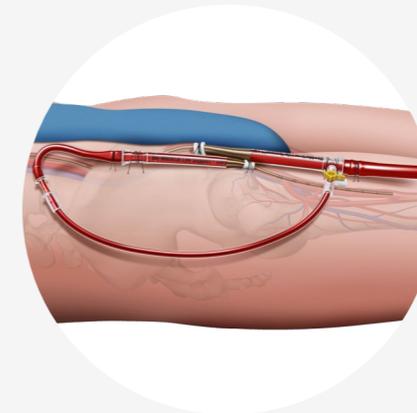
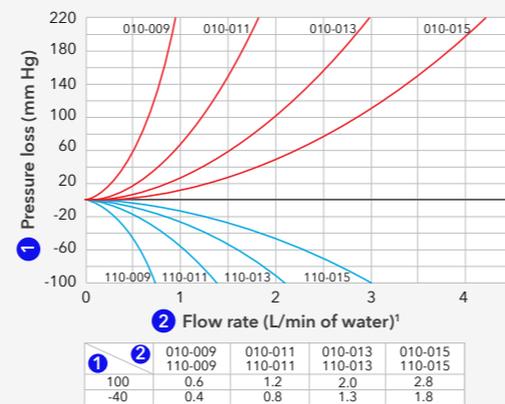
# Bio-Medicus Life Support™ Catheters

## Mini

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



Mini return/drainage catheters LS96010-, LS96110-<sup>1</sup>



### ● Catheters

- Crescent™\* Jugular Dual Lumen
  - Crescent™\*
  - Crescent™\* RA
- Bio-Medicus Life Support™
  - Flex
  - Multi
  - **Mini**
- Opus™\* Vascular Access Kit

### ○ ECMO Oxygenators

### ○ Patient Monitoring Solutions

### ○ Blood Diagnostics

### ○ Appendix

## Ordering information

Bio-Medicus Life Support catheters and introducers	Catheter code	French size	Tip length	Connector
Return <b>Mini</b>	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 <b>Mini</b>	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

<sup>1</sup>Bench data on file, may not be indicative of clinical performance.



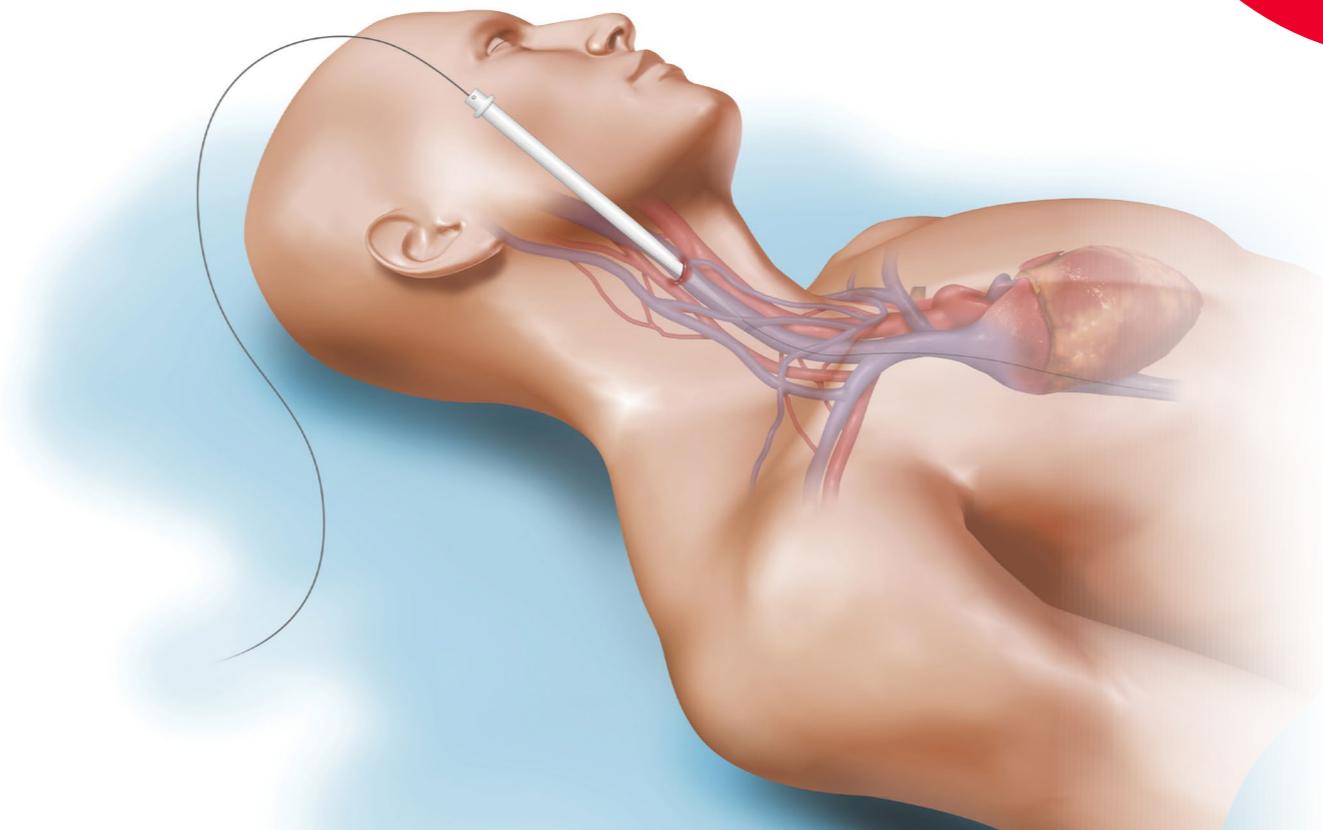
# Opus™ Vascular Access Kit

## 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 – 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.

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

- Selection of dilator sizes can accommodate varying patient anatomies
- Flexible-tip dilators support tracking along the guidewire<sup>1</sup>
- Hub helps with handling during insertion and removal
- Safety scalpel features clear protective shield that locks into place with a one-handed activation



Crescent™ jugular dual lumen catheter and Opus™ vascular access kit are manufactured by MC3, Inc., and exclusively distributed by Medtronic.

™Third-party brands are trademarks of their respective owners.

<sup>1</sup>Bench data on file at MC3. These tests may not be indicative of clinical performance.



## ● Catheters

- Crescent™ Jugular Dual Lumen
  - Crescent™
  - Crescent™ RA

- Bio-Medicus Life Support™
  - Flex
  - Multi
  - Mini

- **Opus™ Vascular Access Kit**

○ ECMO Oxygenators

○ Patient Monitoring Solutions

○ Blood Diagnostics

○ Appendix

# Opus™\* Vascular Access Kit

## ● Catheters

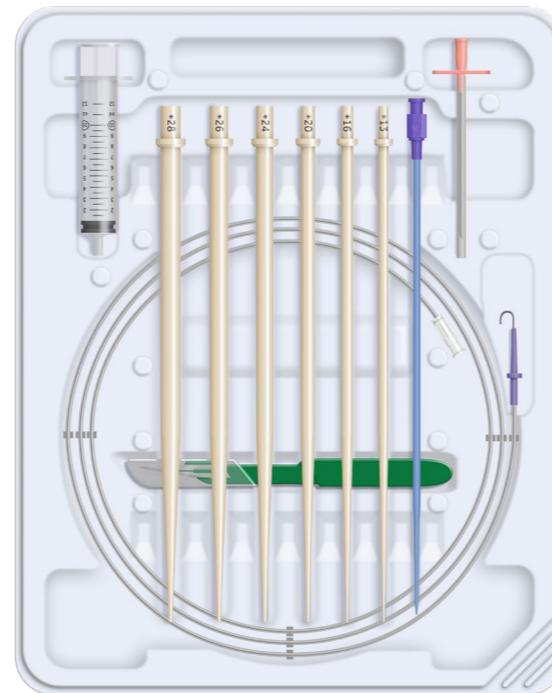
- Crescent™\* Jugular Dual Lumen
  - Crescent™\*
  - Crescent™\* RA
- Bio-Medicus Life Support™
  - Flex
  - Multi
  - Mini
- Opus™\* Vascular Access Kit

○ ECMO Oxygenators

○ Patient Monitoring Solutions

○ Blood Diagnostics

○ Appendix



Hubs with clearly labeled sizes

Long tip gradually tapers



## 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

Crescent™\* jugular dual lumen catheter and Opus™\* vascular access kit are manufactured by MC3, Inc., and exclusively distributed by Medtronic.™\*Third-party brands are trademarks of their respective owners.



# ECMO Oxygenators

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○ Catheters

● **ECMO Oxygenators**

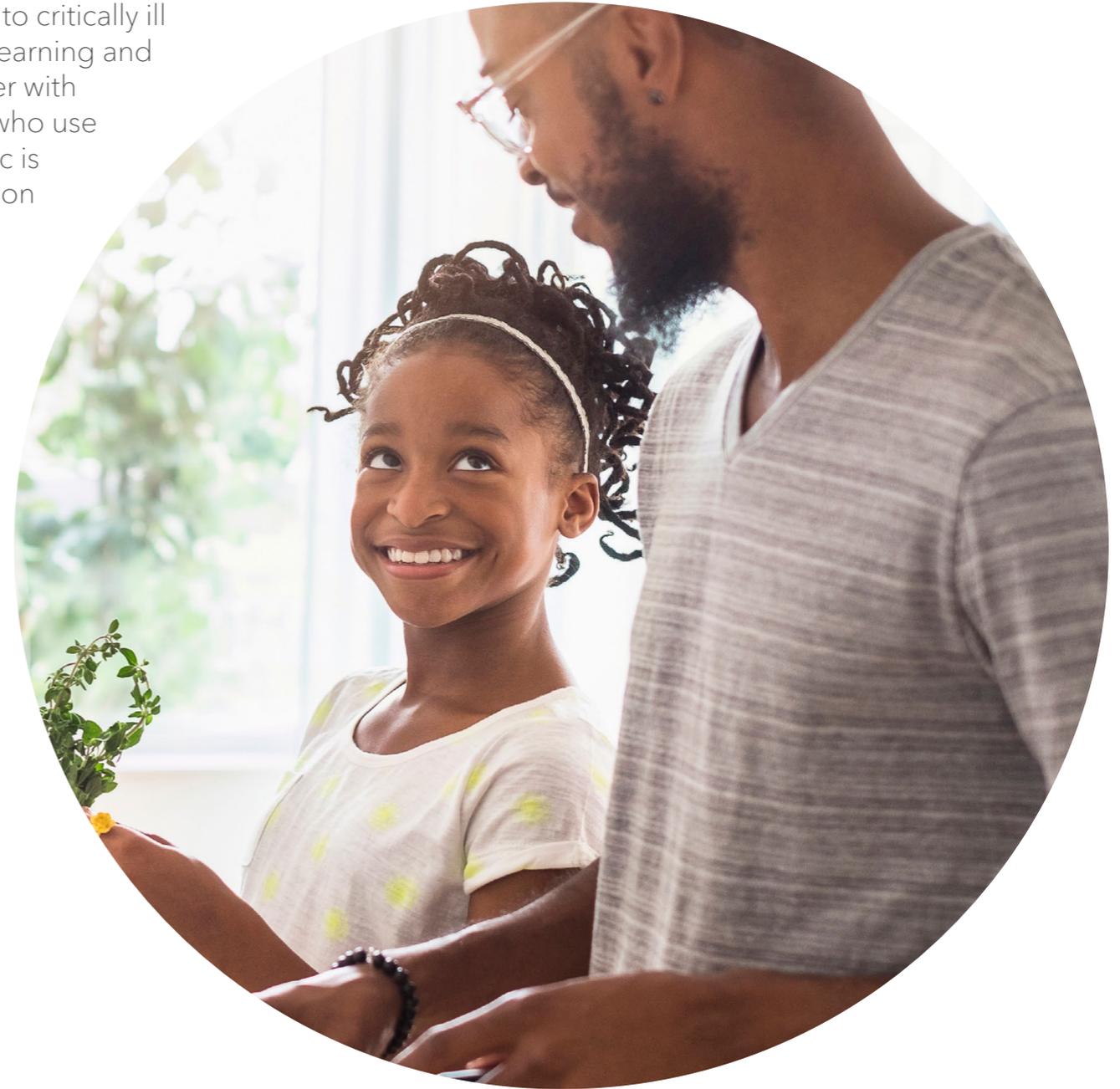
- Nautilus™\* Smart ECMO Module
- Nautilus™\* ECMO Oxygenator

○ Patient Monitoring Solutions

○ Blood Diagnostics

○ Appendix

Extracorporeal life support (ECLS) 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 extracorporeal membrane oxygenation (ECMO).



# Nautilus™ ECMO Oxygenators

○ Catheters

● **ECMO Oxygenators**

- Nautilus™ Smart ECMO Module
- Nautilus™ ECMO Oxygenator

○ Patient Monitoring Solutions

○ Blood Diagnostics

○ Appendix

## Designed for ECMO

- Long-term ECMO indication†
- PMP fiber
- Balance™ Biosurface‡
- Circular flow-path design



Nautilus™ Smart ECMO Module



Nautilus™ ECMO Oxygenator

Nautilus™ ECMO oxygenator is manufactured by MC3, Inc., and exclusively distributed by Medtronic.

™Third-party brands are trademarks of their respective owners.

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

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



# Nautilus™ Smart ECMO Module

○ Catheters

● **ECMO Oxygenators**

- Nautilus™ Smart ECMO Module
- Nautilus™ ECMO Oxygenator

○ Patient Monitoring Solutions

○ Blood Diagnostics

○ Appendix

Simplify your circuit with the first oxygenator featuring integrated monitoring. The Nautilus Smart ECMO module improves long-term gas transfer<sup>1</sup> 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/ $\Delta P$
- O<sub>2</sub> saturation in/O<sub>2</sub> 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
- Simplify the circuit for patient transport, ambulation, and rehabilitation
- Fewer connections minimizes number of areas prone to blood clot formation and air entrainment

## Streamlined workflow

- Light bar provides at-a-glance assessment of oxygenator performance
- Reduce need to look at multiple devices to get 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



™Third-party brands are trademarks of their respective owners.

<sup>1</sup> Data on file at MC3. These tests may not be indicative of clinical performance.

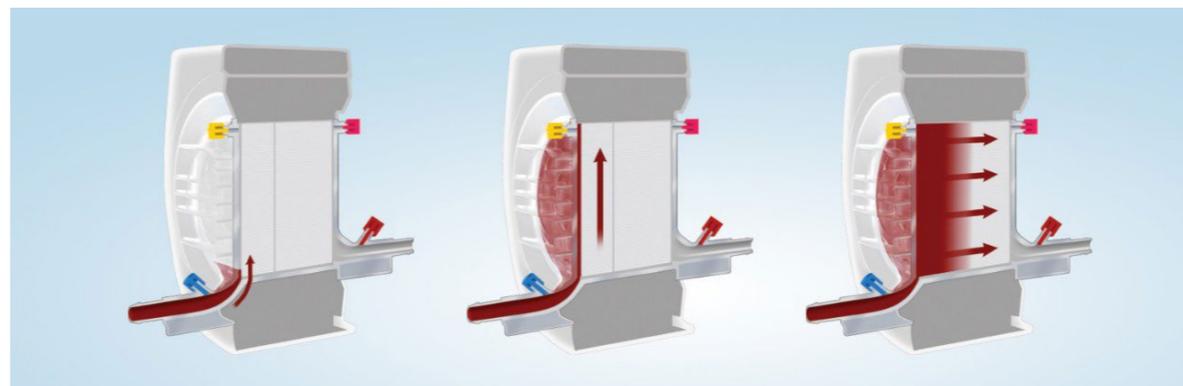


# Nautilus™\* ECMO Oxygenator

Designed for ECMO

## Circular flow-path technology

The Nautilus ECMO oxygenator has a transverse flow-path with a circular profile.<sup>1</sup> 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.



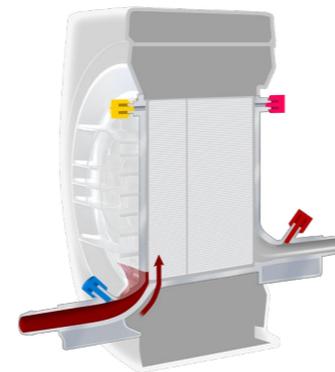
## Circular shape

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.



\*Third-party brands are trademarks of their respective owners.

†Patent pending.

<sup>1</sup>Data on file at MC3. These tests may not be indicative of clinical performance.



○ Catheters

## ● ECMO Oxygenators

- Nautilus™\* Smart ECMO Module
- Nautilus™\* ECMO Oxygenator

○ Patient Monitoring Solutions

○ Blood Diagnostics

○ Appendix

# Nautilus™\* specifications

○ Catheters

● **ECMO Oxygenators**

- Nautilus™\* Smart ECMO Module
- Nautilus™\* ECMO Oxygenator

○ Patient Monitoring Solutions

○ Blood Diagnostics

○ Appendix

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

™\*Third-party brands are trademarks of their respective owners.



# Nautilus™ ordering information

○ Catheters

● **ECMO Oxygenators**

- Nautilus™ Smart ECMO Module
- Nautilus™ ECMO Oxygenator

○ Patient Monitoring Solutions

○ Blood Diagnostics

○ Appendix



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**



Nautilus™ ECMO oxygenator is manufactured by MC3, Inc., and exclusively distributed by Medtronic.  
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# Patient Monitoring Solutions

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The INVOS™ system is the most widely studied regional oximeter on the market.<sup>1</sup> It was designed to respond quickly – so you can, too.



○ Catheters

○ ECMO Oxygenators

● **Patient Monitoring Solutions**

• INVOS™ Regional Oximetry System

○ Blood Diagnostics

○ Appendix

<sup>1</sup>Yu Y, et al. *Cochrane Database Syst Rev.* 2018;1:CD010947.



# INVOS™ Regional Oximetry System

○ Catheters

○ ECMO Oxygenators

● **Patient Monitoring Solutions**

• **INVOS™ Regional Oximetry System**

○ Blood Diagnostics

○ Appendix

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.<sup>1,2</sup>

The INVOS system can play an important role as a valuable "first alert"<sup>3</sup> 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

[See the evidence](#)



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.

<sup>1</sup>Wong JK, et al. *Artif Organs*. 2012;36:659-667.

<sup>2</sup>Kim DJ, et al. *ASAIO J*. 2017;63:613-617.

<sup>3</sup>Avery EG. Cerebral oximetry is frequently a "first alert" indicator of adverse outcomes [white paper]. Medtronic; 2016.



# INVOS™ system ordering information

○ Catheters

○ ECMO Oxygenators

● **Patient Monitoring Solutions**

• INVOS™ Regional Oximetry System

○ Blood Diagnostics

○ Appendix

## 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 <sub>2</sub> sensor, > 40 kg	20/box
PM71IFTD	PM7100 field test device	1
PMSENS71-P-20	Pediatric rSO <sub>2</sub> 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<sub>2</sub> and 7100 pediatric rSO<sub>2</sub> sensors

Material	Medical grade acrylic adhesive, latex, DEHP & BPA free
Packaging	Packaged non-sterile for single use

### INVOS™ infant regional saturation sensor (OxyAlert NIRSensor)

Material	Medical grade hydrocolloid adhesive, latex & PVC free
Packaging	Packaged non-sterile for single use



# Blood Diagnostics

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- Catheters
- ECMO Oxygenators
- Patient Monitoring Solutions
- **Blood Diagnostics**
  - HMS Plus Hemostasis Management System
- Appendix

Medtronic Perfusion Systems remains the pioneer and leader providing both a heparin dose response test and the only point-of-care heparin assay for individualized heparin and protamine management. Our technology is guideline-recommended per the 2007 Society of Thoracic Surgeons (STS) guidelines.<sup>1</sup> The HMS Plus hemostasis management system is a reliable, versatile, and effective platform for improved heparin and protamine management resulting in lower associated procedural and operational costs.<sup>2</sup>



<sup>1</sup>Society of Thoracic Surgeons. Sts.org. Available at: <https://www.sts.org/sites/default/files/documents/BloodConservationUpdate0311.pdf>. Accessed May 12, 2022.  
<sup>2</sup>Khan JH, et al. *J Extra Corpor Technol.* 2017;49:273-282.



# HMS Plus Hemostasis Management System

- Catheters
- ECMO Oxygenators
- Patient Monitoring Solutions
- **Blood Diagnostics**
  - HMS Plus Hemostasis Management System
- Appendix

## When measuring the ACT is not enough

The HMS Plus hemostasis management system performs multiple tests for anticoagulation management and allows user to measure actual circulating heparin concentration and assess a patient's response to heparin.<sup>1</sup>



Instrument	
Height	40 cm (15.75")
Depth	38 cm (15.0")
Width	33 cm (13.0")
Weight	15.47 kg (34.1 lb)
Serial port data	19200 baud, 8 data bits, 1 stop bit, no parity
Voltage	100-240 V ~ single phase
Frequency	50-60 Hz
Maximum current	1.2/0.6 A (100-120/200-240)

Cartridges	
Tests	ACT, heparin dose response (HDR), heparin/protamine titration (HPT)
Channels	2-channel ACT, 6-channel HDR, 4- and 6-channel HPT
Controls	Liquid, electronic

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

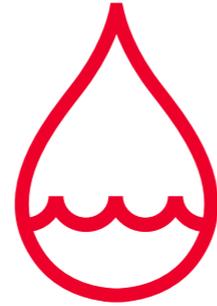
The HMS Plus instrument and cartridges must only be used in the manner and purpose for which they are intended. Instructions for proper use are included in the manual and in the cartridge package inserts. Read all warnings, precautions, and Instructions for Use carefully prior to use.

<sup>1</sup>Bench data on file at Medtronic.



# HMS Plus Hemostasis Management System

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## Benefits of improved hemostasis management

- Fewer complications associated with excessive blood loss<sup>1</sup>
- Preservation of the coagulation system, resulting in fewer transfusions<sup>2</sup>
- Decrease in packed red blood cells, fresh frozen plasma, cryoprecipitate, and platelet usage, thus decreasing associated costs<sup>2</sup>
- Trends toward reductions in hospital length of stay and intensive care unit stay<sup>2</sup>

The following risks are known to be associated with activated clotting time and hemostatic management devices: coagulopathy, hypovolemia, infection, and ischemia.

For risks associated with the HMS Plus system, please refer to the instructions for use.

- Catheters
- ECMO Oxygenators
- Patient Monitoring Solutions
- **Blood Diagnostics**
  - HMS Plus Hemostasis Management System
- Appendix

<sup>1</sup>Despotis GJ, et al. *J Thorac Cardiovasc Surg.* 1995;110:46-54.  
<sup>2</sup>Khan JH, et al. *J Extra Corpor Technol.* 2017;49:273-282.



# HMS Plus Hemostasis Management System

- Catheters
- ECMO Oxygenators
- Patient Monitoring Solutions
- **Blood Diagnostics**
  - **HMS Plus Hemostasis Management System**
- Appendix

## HMS Plus system

CFN	Product	Units per case
30514	HMS Plus system	1 per case
R30514	Refurbished HMS Plus system	1 per case

## HMS Plus cartridges

4-channel heparin assay includes 9 syringes and 9 blunt tip needles

CFN	Product	Units per case
304-01POR	Red 0.0-0.9 mg/kg	9 per case
304-02POR	Yellow 0.0-1.5 mg/kg	9 per case

## HMS Plus cartridges

6-channel heparin assay includes 9 syringes and 9 blunt tip needles

CFN	Product	Units per case
304-07POR	Orange 0.0-2.5 mg/kg	9 per case
304-08POR	Gold 1.5-4.0 mg/kg	9 per case

## HMS Plus accessories

CFN	Product	Units per case
HMSPLUSSC	Bar code scanner	1 per case
300-01	Monoject™ syringes, 3 mL	100 per case
300-02	Blunt needles, 1 7/16", 19 GA	100 per case
313-51	HEPtrac™ electronic control for HMS Plus	1 per case
300-04	Thermal printer paper	5 rolls per case
300-10	Temperature verification cartridge for the HMS Plus	1 per case
300-19	HMS Plus cleaning kit	1 per case
30032	HMS Plus cart	1 per case
31506	HMS Plus salvage reservoir cups	100 per case
313-50	HEPline kit	1 per case
HMSPLUSEDM	HMS Plus and ACT Plus external data manager software	1 per case



- Catheters
- ECMO Oxygenators
- Patient Monitoring Solutions
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## Important Safety Information

### Nautilus Smart and Nautilus

**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 MC3, Inc. and exclusively distributed by Medtronic.

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

### Crescent, Crescent RA, 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 MC3, Inc. and exclusively distributed 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

- 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.

### HMS Plus

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

The HMS Plus instrument and cartridges must only be used in the manner and purpose for which they are intended. Instructions for proper use are included in the manual and in the cartridge package inserts. Read all warnings, precautions and Instructions for Use carefully prior to use.

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

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