ThruPort Systems

Edwards Cardiac Cannulae

Product Guides

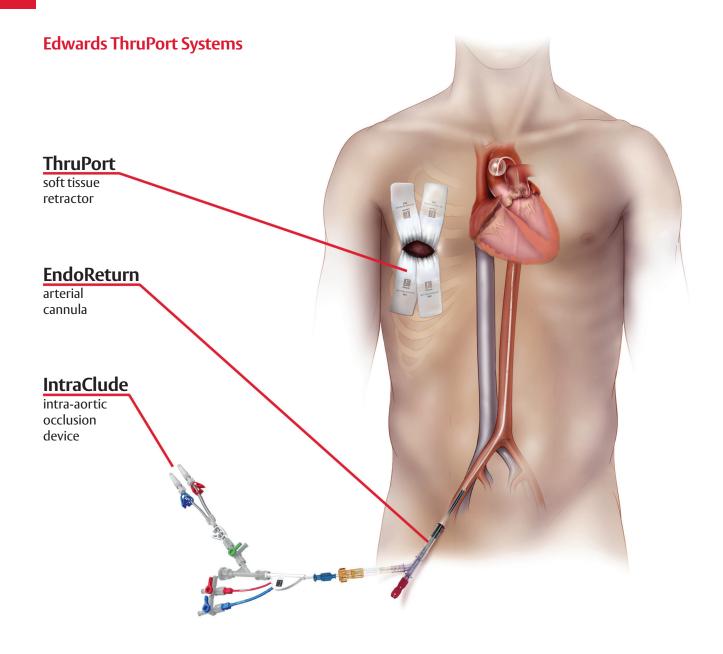


ThruPort Systems and Edwards Cardiac Cannulae

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ThruPort Systems

Disposable Products for Minimal Incision Surgery



IntraClude Intra-Aortic Occlusion Device

The IntraClude intra-aortic occlusion device is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude intra-aortic occlusion device occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart. The pressure lumen allows monitoring of the aortic root pressure.

- 10.5 Fr (3.5 mm), triple-lumen, 100 cm long catheter
- Designed to occlude the ascending aorta in order to partition the aortic root from arterial circulation
- Balloon expands to occlude a range of aorta sizes from 20 to 40 mm
- Designed to be used in the femoral approach with the Edwards EndoReturn (ER21B or ER23B) arterial cannula or the Edwards introducer sheath (IS19A)
- The shaft is provided with an extended strain relief designed to prevent kinking

1 unit per case

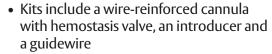
39.4 inch (100 cm) overall length

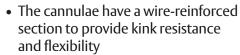
ICF100

0.038 inch (200 cm) guidewire
Y-connector
Red and blue pressure lines

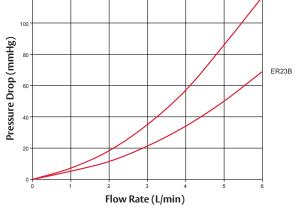
EndoReturn Arterial Cannula

The FndoReturn arterial cannula and 19 Fr (6.3 mm) arterial cannula are indicated for patients undergoing cardiopulmonary bypass. They are intended to deliver oxygenated blood for cardiopulmonary bypass during surgery. The EndoReturn arterial cannula with hemostasis valve also allows the hemostatic introduction and removal of vascular catheters such as the EndoClamp aortic catheter.





FR21B



Arterial: Pressure Drop vs. Flow*

- Tapered tips to aid in insertion and advancement into the femoral artery
- Hemostasis valve designed to allow passage of catheters, such as the EndoClamp aortic catheter

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- The introducers accept a .038 inch (0.97 mm) guidewire and are marked to simplify assembly and indicate alignment
- A lubricious coating is applied to the surface of the cannula body, designed to ease insertion and retraction of catheters and introducers

1 unit per case

3.7 inch (9.4 cm) effective length

ER21B 21 Fr (7.0 mm)

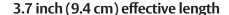
0.038 inch (100 cm) guidewire

Introducer Connector hub

ER23B 23 Fr (7.6 mm)

0.038 inch (100 cm) guidewire

Introducer Connector hub



IS19A 19 Fr (6.3 mm)

0.038 inch (100 cm) guidewire

Introducer



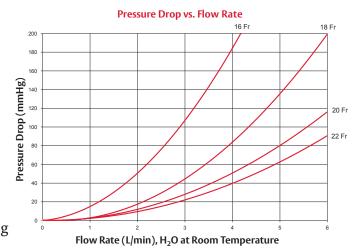
^{*} Mean value derived from in vitro testing performed with water at 21°C. The actual pressure gradients encountered in a clinical situation may vary from those shown, depending on perfusion techniques.

OptiSite Arterial Cannula

The Edwards Lifesciences arterial perfusion cannulae are indicated for arterial perfusion in the extracorporeal circuit for < 6 hours. Cannulation site selection is left to the discretion of the surgeon and may include the femoral artery or the aortic arch.

- Smoothly rounded tips to facilitate atraumatic insertion
- The proximal ends of the cannulae are designed to accept 3/8 inch (9.5 mm) tubing
- Lock introducer is designed for use with 0.038 inch (0.96 mm) guidewires
- Removable vented luer cap designed to allow cannula venting when guidewire is not in use





15 cm effective length 20.8 cm overall length

Vented 3/8 inch connector

OPTI16	16 Fr (5.3 mm)
OPTI18	18 Fr (6.0 mm)
OPTI20	20 Fr (6.7 mm)
OPTI22	22 Fr (7.3 mm)

Blunt tip introducer with guidewire



Soft Tissue Retractor

The ThruPort soft tissue retractor is used to allow visualization of intrathoracic structures and provide entry for the instruments into the thoracic cavity during specific cardiac surgical procedures. The ThruPort soft tissue retractor is designed to be inserted into an intercostal incision and retract tissue to form a port.

- Available in three sizes
- Fabric tabs designed to retract tissue from the incision
- Soft, polyester fabric conforms to intercostal incision
- Metallic ring compresses for insertion into thorax

Model	Description	Ring diameter	Tab length	Tab width		
TRS	Soft tissue retractor, small	2.2 inch (6.0 cm)	6.0 inch (15.2 cm)	1.5 inch (3.8 cm)		
TRM	Soft tissue retractor, medium	3.0 inch (7.5 cm)	6.0 inch (15.2 cm)	2.0 inch (5.1 cm)		
TRL	Soft tissue retractor, large	3.5 inch (9.0 cm)	6.0 inch (15.2 cm)	2.5 inch (6.4 cm)	III	1 /6

Knot Pusher

• Knot pusher facilitates extracorporeal knot tying of valve sutures

KP1 12.9 inch (33 cm) length

Edwards Cardiac Cannulae

- Arterial Cannulae
- Venous Cannulae
- Femoral Cannulae
- Cardioplegia Catheters

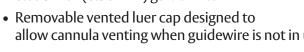
Arterial Cannulae

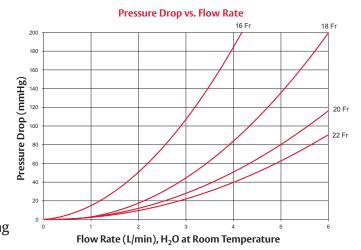
Aortic perfusion cannulae may be used in pediatric or adult populations based on the flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.

OptiSite Arterial Cannula

The Edwards Lifesciences arterial perfusion cannulae are indicated for arterial perfusion in the extracorporeal circuit for < 6 hours. Cannulation site selection is left to the discretion of the surgeon and may include the femoral artery or the aortic arch.

- Smoothly rounded tips to facilitate atraumatic insertion
- The proximal ends of the cannulae are designed to accept 3/8 inch (9.5 mm) tubing
- Lock introducer is designed for use with 0.038 inch (0.96 mm) guidewires
- allow cannula venting when guidewire is not in use





1 unit per case

Blunt tip introducer with guidewire

15 cm effective length 20.8 cm overall length

Vented 3/8 inch connector

OPTI16	16 Fr (5.3 mm)
OPTI18	18 Fr (6.0 mm)
OPTI20	20 Fr (6.7 mm)
OPTI22	22 Fr (7.3 mm)

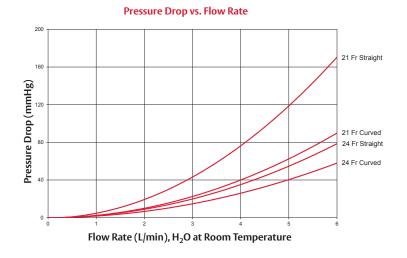


EZ Glide Aortic Perfusion Cannula

The EZ Glide aortic perfusion cannula is intended to create a dispersive flow.

- Tip design disperses return flow in a conical spray pattern
- Unique auto-dilating tip

10 units per case



Straight cannula

14 inch (35 cm) overall length

3/8 inch vented connector

EZS21TA 21 Fr (7.0 mm) EZS24TA 24 Fr (8.0 mm)

3/8 inch non-vented connector

EZS21A 21 Fr (7.0 mm) EZS24A 24 Fr (8.0 mm)



6 III

EZ Glide Aortic Perfusion Cannula (continued)

Curved cannula with suture bump

14.8 inch (37.6 cm) overall length

3/8 inch vented connector

EZC21TA 21 Fr (7.0 mm) EZC24TA 24 Fr (8.0 mm)

3/8 inch non-vented connector

EZC21A 21 Fr (7.0 mm) EZC24A 24 Fr (8.0 mm)

Curved cannula with suture flange

14.8 inch (37.6 cm) overall length

3/8 inch vented connector

EZF21TA 21 Fr (7.0 mm) EZF24TA 24 Fr (8.0 mm)

3/8 inch non-vented connector

EZF21A 21 Fr (7.0 mm) EZF24A 24 Fr (8.0 mm)





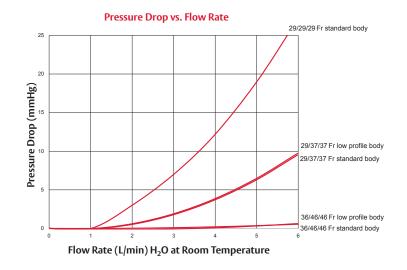
Venous Cannulae

Venous cannulae may be used in pediatric populations or adult populations based on flow rate requirements and patient anatomy. Please see labeling for maximum flow rate information.

Triple Stage Venous Cannula

- Thin-Flex triple stage venous cannula offers 34% reduction in wall thickness compared to traditional technology*
- Open lighthouse tip for high flow rates
- Compatible with vacuum assist venous drainage systems
- Optional Trim-Flex low profile venous cannula offers a flattened design*

10 units per case



Trim-Flex low profile triple stage venous cannula

14.5 inch (37 cm) overall length

1/2 inch non-vented connector

TRF2937O2A 29/37/37 Fr

(9.6/12.3/12.3 mm)

1/2 inch acceptance

TRF2937O2 29/37/37 Fr

(9.6/12.3/12.3 mm)

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16 inch (40 cm) overall length

1/2 inch non-vented connector

TRF3646O2A 36/46/46 Fr

(12.0/15.3/15.3 mm)

1/2 inch acceptance

TRF3646O2 36/46/46 Fr

(12.0/15.3/15.3 mm)

^{*} As compared to standard venous cannulae, data on file

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Triple Stage Venous Cannula (continued)

Thin-Flex triple stage venous cannula

14.5 inch (37 cm) overall length

1/2 inch non-vented connector

TF293702A 29/37/37 Fr

(9.6/12.3/12.3 mm)

1/2 inch acceptance

TF293702 29/37/37 Fr

(9.6/12.3/12.3 mm)

16 inch (40 cm) overall length

1/2 inch non-vented connector

TF292902A 29/29/29 Fr

(9.6/9.6/9.6 mm)

3/8 inch acceptance

TF292902 29/29/29 Fr

(9.6/9.6/9.6 mm)

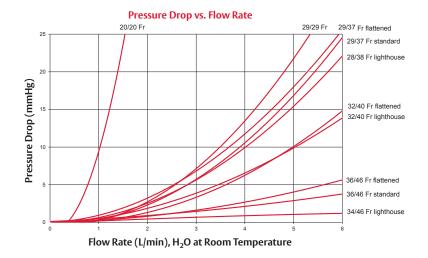
1/2 inch acceptance

TF3646O2 36/46/46 Fr

(12.0/15.3/15.3 mm)

Dual Stage Venous Cannula

- Features patented dual stage drainage baskets designed to provide increased resistance to collapse
- Multiple port tip designed to increase drainage
- Wire-reinforcement helps reduce kinking and twisting
- Optional Thin-Flex dual stage venous cannula with proprietary thin-wall technology designed to maximize flow rates and available space



10 units per case

Trim-Flex low profile dual stage cannula

14.5 inch (37 cm) overall length

1/2 inch non-vented connector

TRF2937OA 29/37 Fr (9.6/12.3 mm)

1/2 inch acceptance

TRF2937O 29/37 Fr (9.6/12.3 mm)

0001100

16 inch (40 cm) overall length

1/2 inch non-vented connector

TRF3646OA 36/46 Fr (12.0/15.3 mm)

1/2 inch acceptance

TRF3646O 36/46 Fr (12.0/15.3 mm)



Dual Stage Venous Cannula (continued)

Thin-Flex dual stage venous cannula

14.5 inch (37 cm) overall length

1/2 inch non-vented connector

TF2937OA 29/37 Fr (9.6/12.3 mm)

1/2 inch acceptance

TF2937O 29/37 Fr (9.6/12.3 mm)

16 inch (40 cm) overall length

3/8 inch acceptance

TF292901 29/29 Fr (9.6/9.6 mm)

1/2 inch non-vented connector

1/2 inch acceptance

Dual Stage Venous Cannula (continued)

Open lighthouse tip

16 inch (40 cm) overall length

1/2 inch non-vented connector

TR3240OA 32/40 Fr (10.6/13.3 mm)

1/2 inch acceptance

TR32400 32/40 Fr (10.6/13.3 mm)

Lighthouse tip

16 inch (40 cm) overall length

1/2 inch acceptance

Bullet tip

16 inch (40 cm) overall length

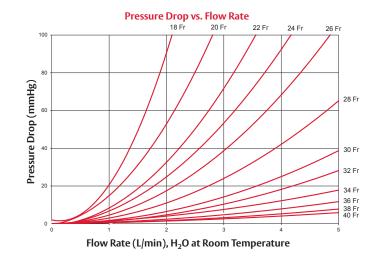
1/2 inch acceptance

TR3651B 36/51 Fr (12.0/17.0mm)

Single Stage Venous Cannula

- One piece wire reinforced cannula
- Proprietary thin-wall design to maximize venous drainage
- Multiple port tip designed to increase drainage
- Thin-Flex venous cannula with proprietary thin-wall technology designed to maximize flow rates

10 units per case



Thin-Flex straight open lighthouse tip

14 inch (35 cm) overall length

1/4 inch or 3/8 inch acceptance

TF018L	18 Fr (6.0 mm)
TF020L	20 Fr (6.7 mm)
TF022L	22 Fr (7.3 mm)
TF024L	24 Fr (8.0 mm)

3/8 inch acceptance

TF026L	26 Fr (8.7 mm)
TF028L	28 Fr (9.3 mm)

16 inch (40 cm) overall length

3/8 inch acceptance	
TF030L	30 Fr (10.0 mm)
TF032L	32 Fr (10.7 mm)
TF034L	34 Fr (11.3 mm)

TF036L 36 Fr (12.0 mm)
TF038L 38 Fr (12.6 mm)
TF040L 40 Fr (13.3 mm)

Single Stage Venous Cannula (continued)

Thin-Flex right angled open lighthouse tip

14 inch (35 cm) overall length

1/4 inch or 3/8 inch acceptance

TF024L90 24 Fr (8.0 mm)

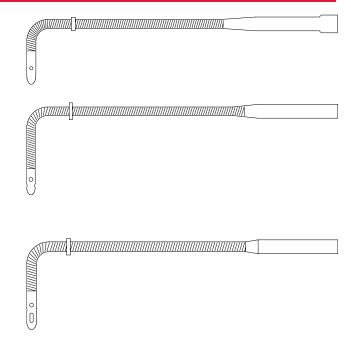
3/8 inch acceptance

TF026L90 26 Fr (8.7 mm) TF028L90 28 Fr (9.3 mm)

16 inch (40 cm) overall length

3/8 inch acceptance

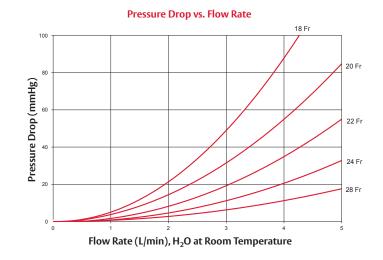
TF030L90	30 Fr (10.0 mm)
TF032L90	32 Fr (10.7 mm)
TF034L90	34 Fr (11.3 mm)
TF036L90	36 Fr (12.0 mm)
TF038L90	38 Fr (12.6 mm)



Single Stage Venous Cannula

- One piece wire reinforced cannula
- Proprietary thin-wall design to maximize venous drainage
- Multiple port tip designed to increase drainage
- Thin-Flex venous cannula with proprietary thin-wall technology designed to maximize flow rates

10 units per case



Thin-Flex 90° plastic tip with side holes

14 inch (35 cm) overall length

3/8 inch acceptance

TF018O90 18 Fr (6.0 mm) TF02OO90 20 Fr (6.7 mm)

15 inch (38 cm) overall length

3/8 inch acceptance

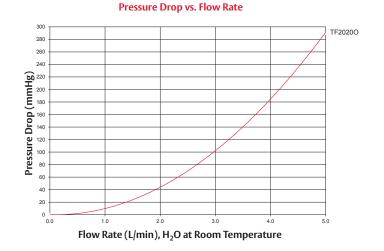
TF022O90 22 Fr (7.3 mm) TF024O90 24 Fr (8.0 mm) TF028O90 28 Fr (9.3 mm)



Small Size Dual Stage Venous Cannula

- Thin-Flex venous cannula with proprietary thin-wall technology designed to maximize flow rates
- Patented dual stage drainage baskets designed to provide increased resistance to collapse
- Wire-reinforcement helps reduce kinking and twisting

10 units per case



Thin-Flex dual stage venous cannula

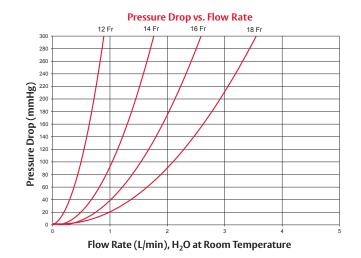
14 inch (35 cm) overall length

1/4 inch or 3/8 inch acceptance TF20200 20/20 Fr (6.7/6.7 mm)

Small Size Single Stage Venous Cannula

 Thin-Flex venous cannula with proprietary thin-wall technology designed to maximize flow rates

10 units per case



Thin-Flex straight open lighthouse tip

11 inch (28 cm) overall length

1/4 inch acceptance

TF012L 12 Fr (4.0 mm) TF014L 14 Fr (4.7 mm) TF016L 16 Fr (5.3 mm)

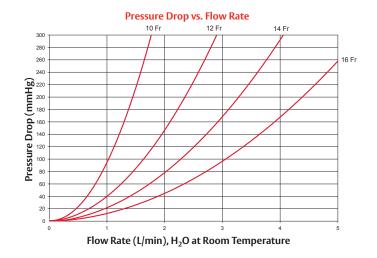
14 inch (35 cm) overall length

1/4 or 3/8 inch inch acceptance TF018L 18 Fr (6.0 mm)

Small Size Single Stage Venous Cannula

 Thin-Flex venous cannula with proprietary thin-wall technology designed to maximize flow rates

10 units per case



Thin-Flex 90° plastic tip with side holes

11 inch (28 cm) overall length

1/4 inch acceptance

TF010O90 10 Fr (3.3 mm)

13 inch (33 cm) overall length

1/4 inch or 3/8 inch acceptance

TF012O90 12 Fr (4.0 mm) TF014O90 14 Fr (4.7 mm) TF016O90 16 Fr (5.3 mm)

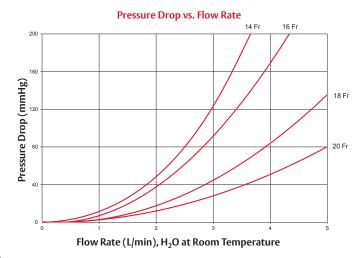
Femoral Cannulae

Femoral access cannulae may be used in pediatric populations or adult populations based on flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.

Fem-Flex II Femoral Arterial Cannula

Fem-Flex II femoral arterial cannula is designed with thin-wall technology for enhanced flow and flexibility.

- Tapered tip and smooth dilator to cannula transition facilitates insertion
- Polyurethane body with wire reinforcement helps reduce kinking
- Radiopaque striping for visualization during placement
- Accommodates up to 0.038 inch guidewire



1 unit per case

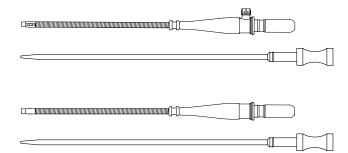
9.5 inch (24 cm) overall length 6.0 inch (15 cm) effective length

3/8 inch vented connector

FEMII016A 16 Fr (5.3 mm) FEMII018A 18 Fr (6.0 mm) FEMII020A 20 Fr (6.7 mm)

3/8 inch non-vented connector

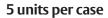
FEMII016AS 16 Fr (5.3 mm) FEMII018AS 18 Fr (6.0 mm) FEMII020AS 20 Fr (6.7 mm)



Percutaneous Insertion Kit

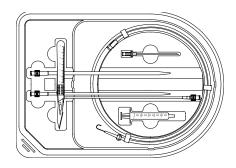
The percutaneous insertion kit is designed to facilitate percutaneous insertion of a femoral cannula. The kit includes the following components:

- Number 11 scalpel
- 18 ga. insertion needle
- 5 mL syringe
- \bullet Three dilators: 8 Fr / 12 Fr / 16 Fr
- 0.038 inch guidewire



Arterial insertion kit

PIKA 100 cm guidewire



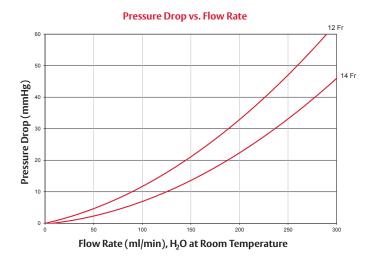
Cardioplegia Catheters

Retrograde coronary sinus cardioplegia catheters may be used in pediatric or adult populations based on the requirements of individual patient anatomy.

Self-Inflating Retrograde Cardioplegia Catheter with Retractaguard Anti-Retraction Technology

The self-inflating retrograde cardioplegia catheter is designed to maximize patient protection by providing global myocardial protection.

- Balloon self-inflates when cardioplegia is being delivered
- Variety of handle and stylet designs that facilitate insertion for a variety of surgical techniques
- Utilizes proprietary Retractaguard anti-retraction technology, which helps the cannula retain its shape after deployment and prevent balloon slippage



10 units per case

Pre-shaped stylet and handle

10.6 inch (27 cm) overall length

18 mm textured balloon

RC2014S 14 Fr (4.7 mm)

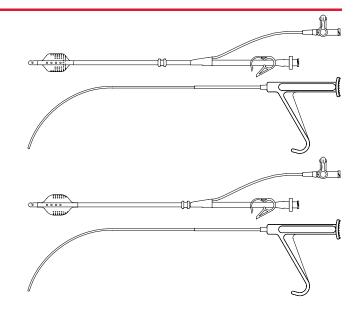
12.5 inch (32 cm) overall length

18 mm textured balloon

RC2012 12 Fr (4.0 mm) RC2014 14 Fr (4.7 mm)

20 mm textured balloon

RC2014LB 14 Fr (4.7 mm)



Cardioplegia Catheters

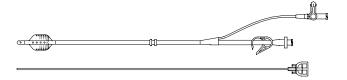
Self-Inflating Retrograde Cardioplegia Catheter with Retractaguard Anti-Retraction Technology (continued)

Guidewire stylet

12.5 inch (32 cm) overall length

18 mm textured balloon

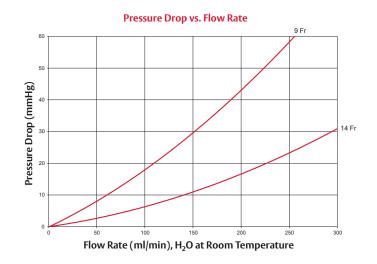
RC2012M 12 Fr (4.0 mm) RC2014M 14 Fr (4.7 mm)



Self-Inflating Retrograde Cardioplegia Catheter

The self-inflating retrograde cardioplegia catheter is designed to maximize patient protection by providing global myocardial protection.

- Balloon self-inflates when cardioplegia is being delivered
- Variety of handle and stylet designs that facilitate insertion for a variety of surgical techniques



Pre-shaped stylet and handle

5 units per case 8 inch (20 cm) overall length

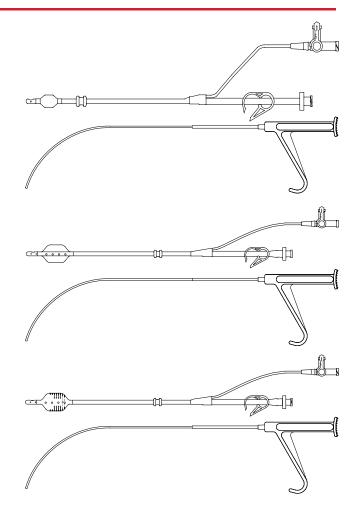
9 mm smooth balloon RC09 9 Fr (3.0 mm)

10 units per case 10.6 inch (27 cm) overall length

18 mm smooth balloon RC014 14 Fr (4.7 mm)

14 mm textured balloon RC014IT 14 Fr (4.7 mm)

18 mm textured balloon RC014T 14 Fr (4.7 mm)



Cardioplegia Catheters

Self-Inflating Retrograde Cardioplegia Catheter (continued)

Guidewire stylet

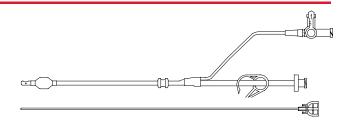
5 units per case 8 inch (20 cm) overall length

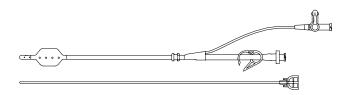
 $9\,mm\,smooth\,balloon$

RC09M 9 Fr (3.0 mm)

10 units per case 10.6 inch (27 cm) overall length

18 mm smooth balloon RC014M 14 Fr (4.7 mm)

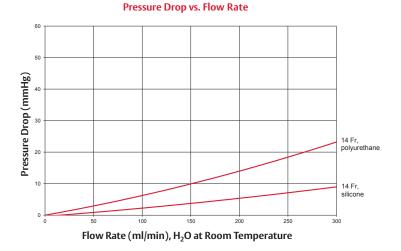




Manually Inflating Retrograde Cardioplegia Catheter

The manually inflating retrograde cardioplegia catheter is designed to maximize patient protection by providing global myocardial protection.

- Manual inflation of the balloon allows surgical control over balloon inflation
- Variety of handle and stylet designs that facilitate insertion for a variety of surgical techniques
- Optional Retractaguard anti-retraction technology to prevent balloon slippage



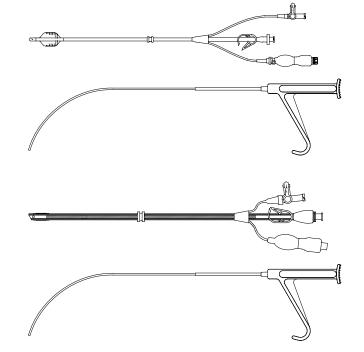
10 units per case

Pre-shaped stylet and handle

12.5 inch (32 cm) overall length

Textured polyurethane balloon and retractaguard lumen RC2014MIBB 14 Fr (4.7 mm)

Smooth silicone balloon RC014MIBB 14 Fr (4.7 mm)



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ThruPort Systems

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TF020L		TF3646OA		RC2012M	
TF020O90		TF3646O2		RC2014	
TF022L		TR2838L		RC2014LB	
TF022O90		TR3240L		RC2014M	
TF024L		TR3446L		RC2014MIBB	
TF024L90		TR3240O		RC2014S	
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Customer Service Policies

Customer service US only

Edwards Lifesciences
One Edwards Way
Irvine, California 92614
1-949-250-2500 24-Hour Customer Service
1-800-4-A-HEART (424-3278) Toll Free
1-800-422-9329 or 1-949-250-3489 Fax
edwards.com

For next day delivery, non-emergency, orders must be received by 3:00pm Pacific Time.

Edwards Lifesciences is a partner of the Global Healthcare Exchange (GHX). You may also place orders online with My Account, Edwards web ordering system at www.edwards.com.

For more information about buying Edwards Lifesciences products using My Account or GHX, please speak with a Customer Service Representative.

Terms and conditions

Prices: Subject to change without prior notice. All applicable taxes will be charged. All prices are quoted FOB shipping port. Payment: Net 30 days

Returned goods policy

- **1.** Edwards Lifesciences is committed to providing our customers with quality products and service. Therefore, we will accept for return and full credit and product that:
 - a. Is a result of an error by Edwards Lifesciences
 - b. Does not perform satisfactorily for the purposes and indications described in the labeling
- 2. Authorization is required for all returns and may be obtained through Customer Service. A Returned Goods Authorization number will be issued and this number must be referenced on all returned packages. Freight on all returns must be prepaid by the customer except for returns listed in section one.
- **3.** All returned product will be subject to a 20% handling and restocking fee except for returns listed in section one.
- **4.** The following material is not acceptable for return:
 - a. Sterile items that are returned without the manufacturing seals intact
 - **b.** Custom products (SPC, ISP)
 - c. Incomplete kits or cases
 - d. Product which has less than 13 month shelf life
 - **e.** Product which has been marked or labeled with anything other than the standard Edwards label
- **5.** As part of an ongoing effort to improve the quality of our products, we would like any defective product to be returned for evaluation. Credit or replacement will be issued by Edwards upon receipt of the defective product.

Return address for all products

Edwards Lifesciences 12050 Lone Peak Parkway Draper, Utah 84020

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

Edwards, Edwards Lifesciences, the stylized E logo, 1-800-4-A-Heart, EndoReturn, EZ Glide, Fem-Flex II, IntraClude, OptiSite, Retractaguard, Thin-Flex, ThruPort, and Trim-Flex are trademarks or service marks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

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