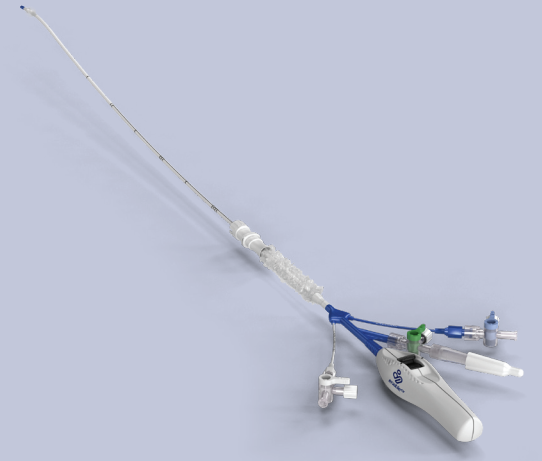
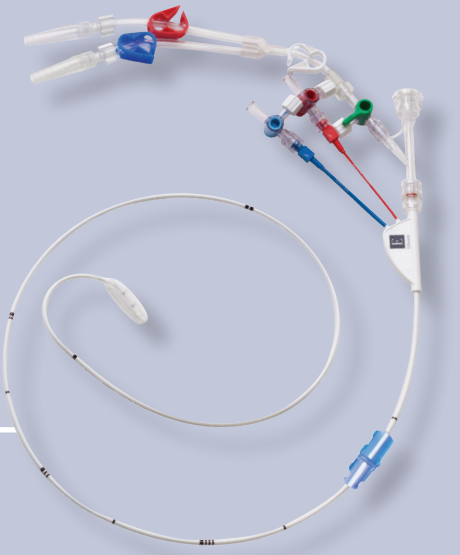
enable CV





Minimally Invasive Devices

Cardiac Cannulae

Product Catalog

enableCV

enableCV is a wholly-owned subsidiary of Edwards Lifesciences. The mission of this highly focused organization is to bring continued innovation that enhances cardiovascular surgical procedures and techniques. enableCV's product portfolio consists of devices that enable minimally invasive surgical approaches, as well as cannulae, all of which are used and respected by surgeons worldwide.

Our Vision

Lead transformative and enabling innovation in Cardiac Surgery

Our Mission

Enable a broad spectrum of cardiovascular surgeries and advance minimally invasive surgical approaches.

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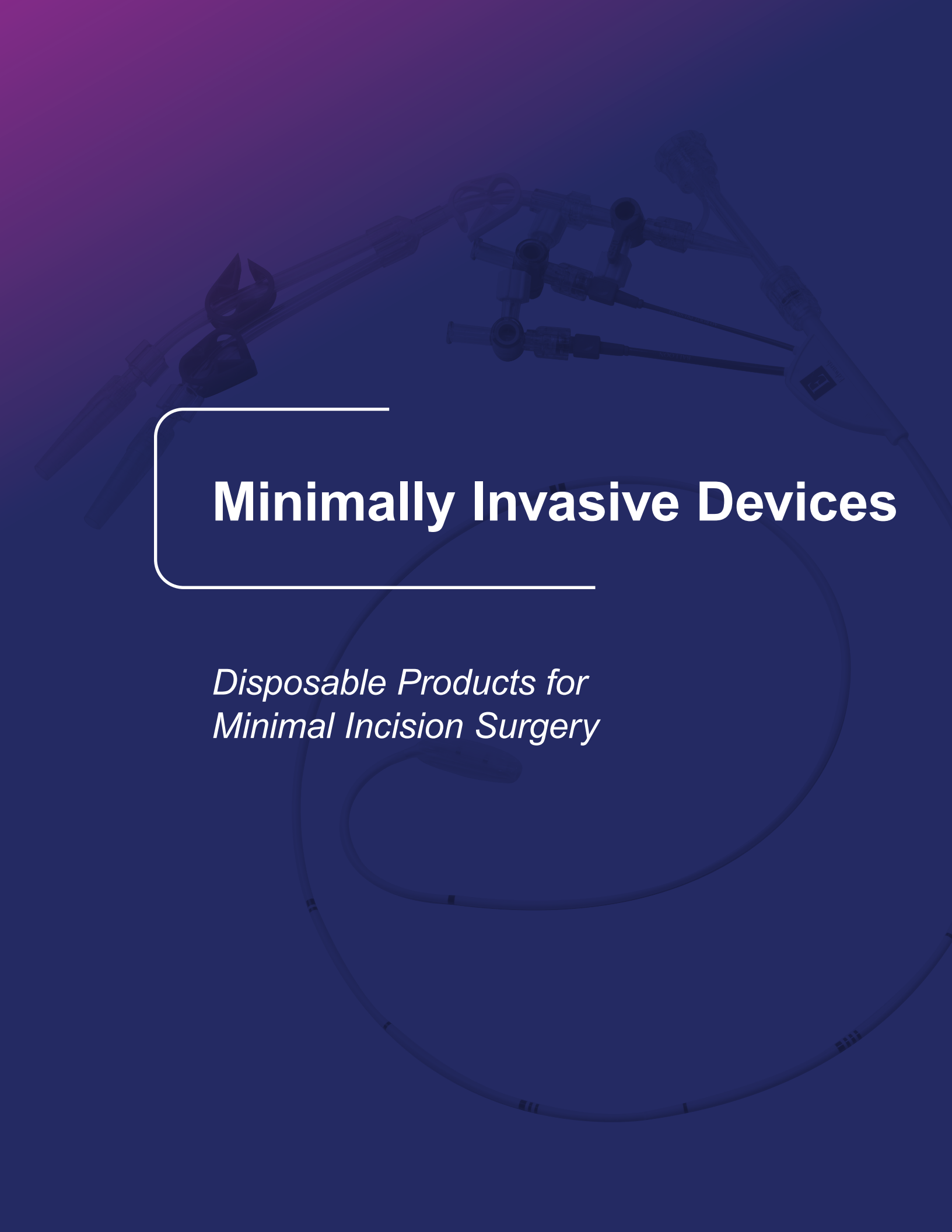
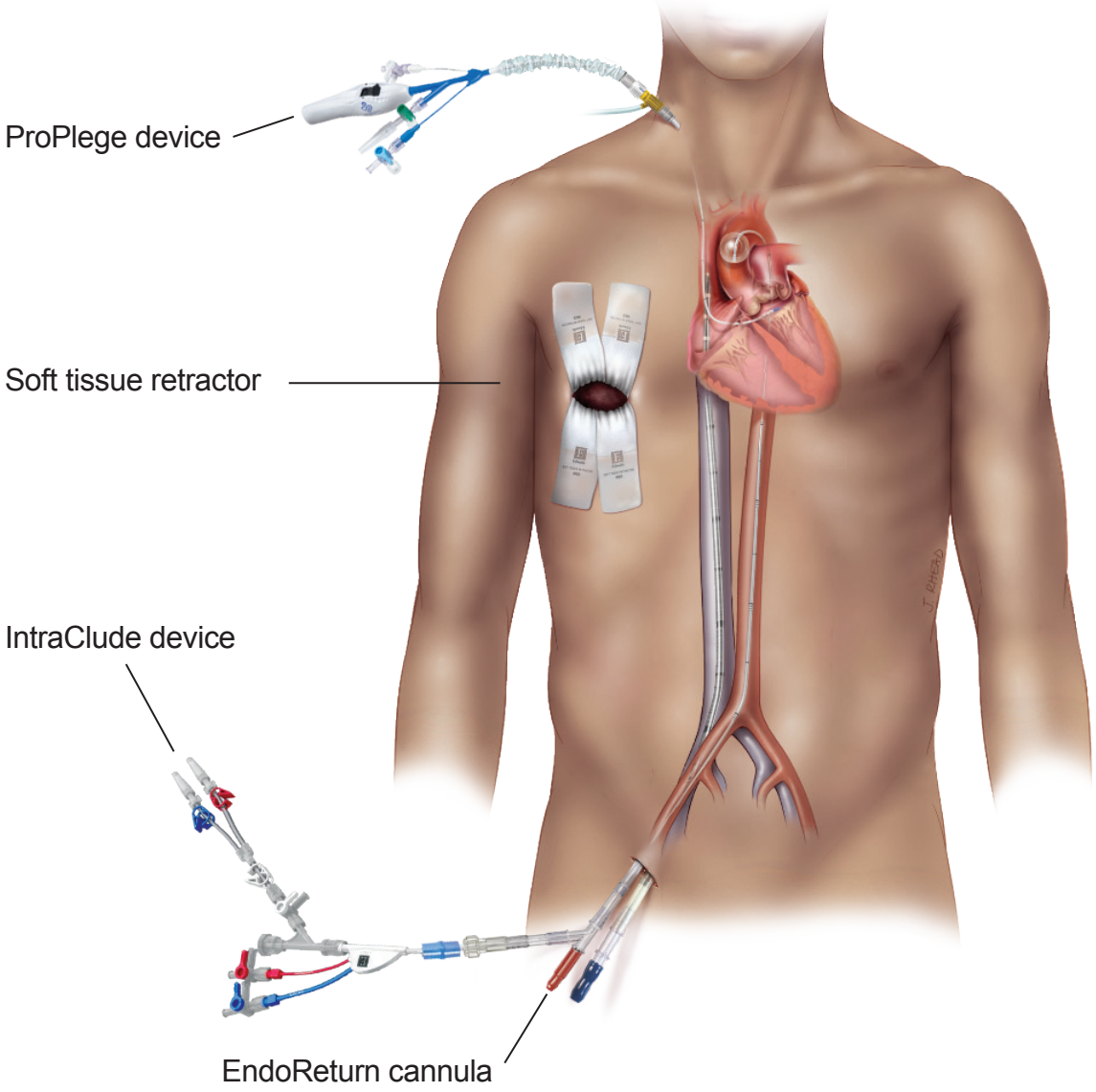
Minimally Invasive Devices and Cardiac Cannulae



Minimally Invasive Devices

Disposable Products for
Minimal Incision Surgery

Minimally Invasive Devices



ProPlege Peripheral Retrograde Cardioplegia Device

The ProPlege device is indicated for occlusion of the coronary sinus, delivery of cardioplegia solution, and monitoring of coronary sinus pressure during cardiopulmonary bypass.

- 9 Fr (3.1 mm), 59 cm long, triple-lumen, articulating device
- Designed for occluding the coronary sinus for retrograde perfusion of the coronary circulation
- Balloon expands to occlude a range of coronary sinus diameters
- The large central lumen of the ProPlege device delivers cardioplegic solution to the coronary sinus
- The two remaining lumens serve as conduits for balloon inflation and coronary sinus pressure monitoring distal to the balloon
- The shaft features an articulation mechanism which changes the curvature of the distal end when the positioning dial is manipulated
- The ProPlege device is provided with a contamination guard, which connects to the introducer sheath

1 unit per case

23.2 inch (59 cm) effective length
32.3 inch (82 cm) overall length

PR9 9 Fr (3.1 mm) catheter

IntraClude Intra-Aortic Occlusion Device

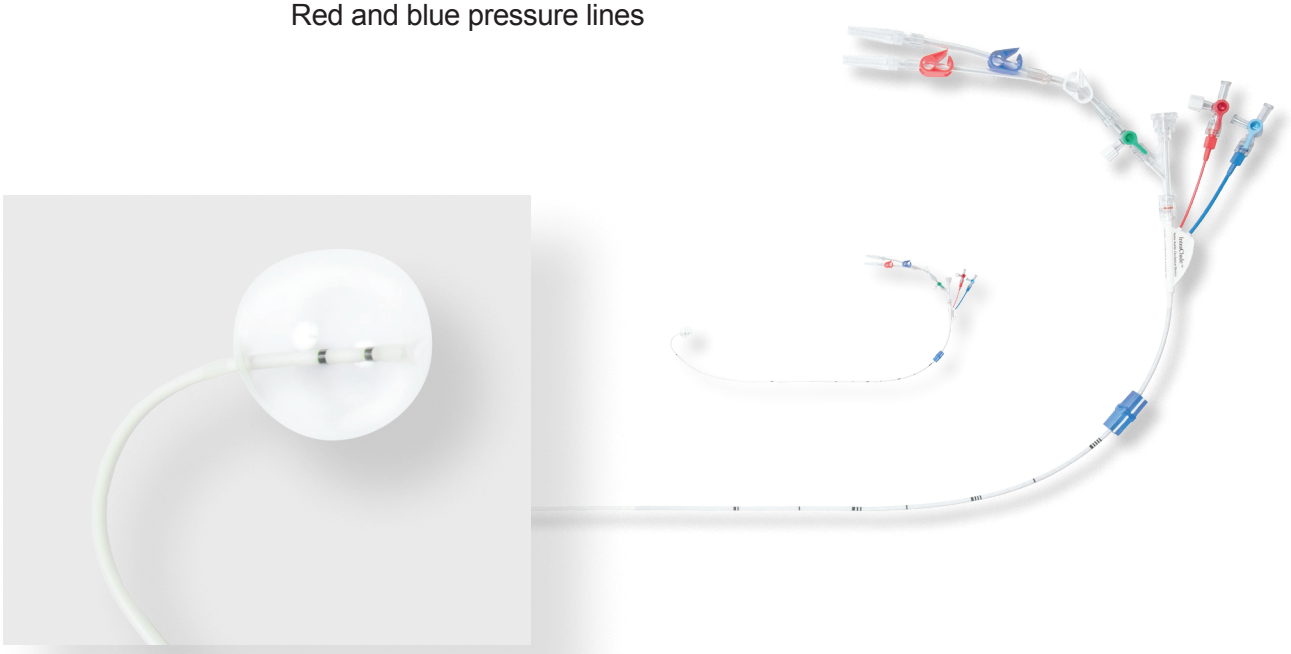
The IntraClude intra-aortic occlusion device is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude intra-aortic occlusion device occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart.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

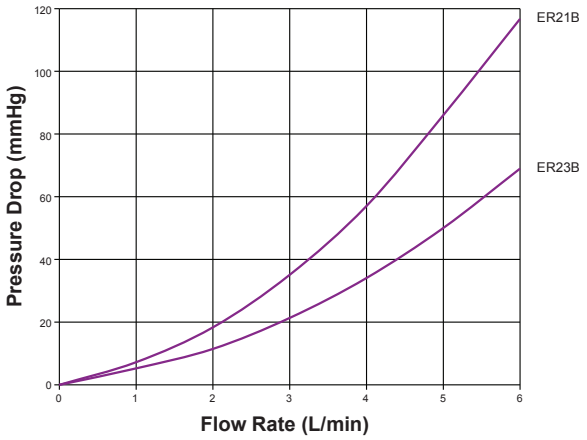
ICF100	0.038 inch (200 cm) guidewire Y-connector Red and blue pressure lines



EndoReturn Arterial Cannula

The EndoReturn 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.

Arterial: Pressure Drop vs. Flow*



** 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.*

- Kits include a wire-reinforced cannula with hemostasis valve, an introducer and a guidewire
- The cannulae have a wire-reinforced section to provide kink resistance and flexibility
- 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
- 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

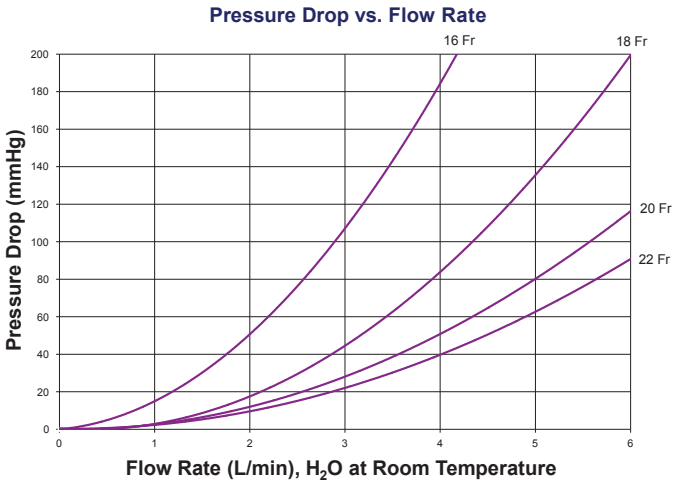
ER21B	21 Fr (7.0 mm) 0.038 inch (100 cm) guidewire Introducer Connector hub
ER23B	23 Fr (7.6 mm) 0.038 inch (100 cm) guidewire Introducer Connector hub

3.7 inch (9.4 cm) effective length

IS19A	19 Fr (6.3 mm) 0.038 inch (100 cm) guidewire Introducer

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

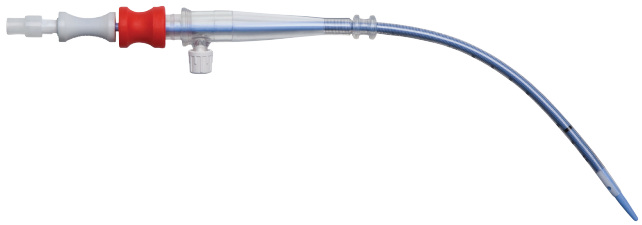
1 unit per case

Blunt tip introducer

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)



Soft Tissue Retractor

The 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 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)

Knot Pusher

- Knot pusher facilitates extracorporeal knot tying of valve sutures

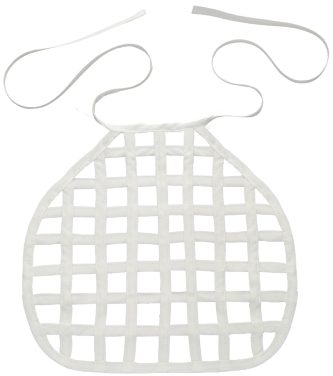
KP1	12.9 inch (33 cm) length	

Janke-Barron Heart Support

The Janke-Barron heart support is designed for effective and convenient support of the heart during coronary artery surgery, specifically bypass operations on the circumflex artery system.

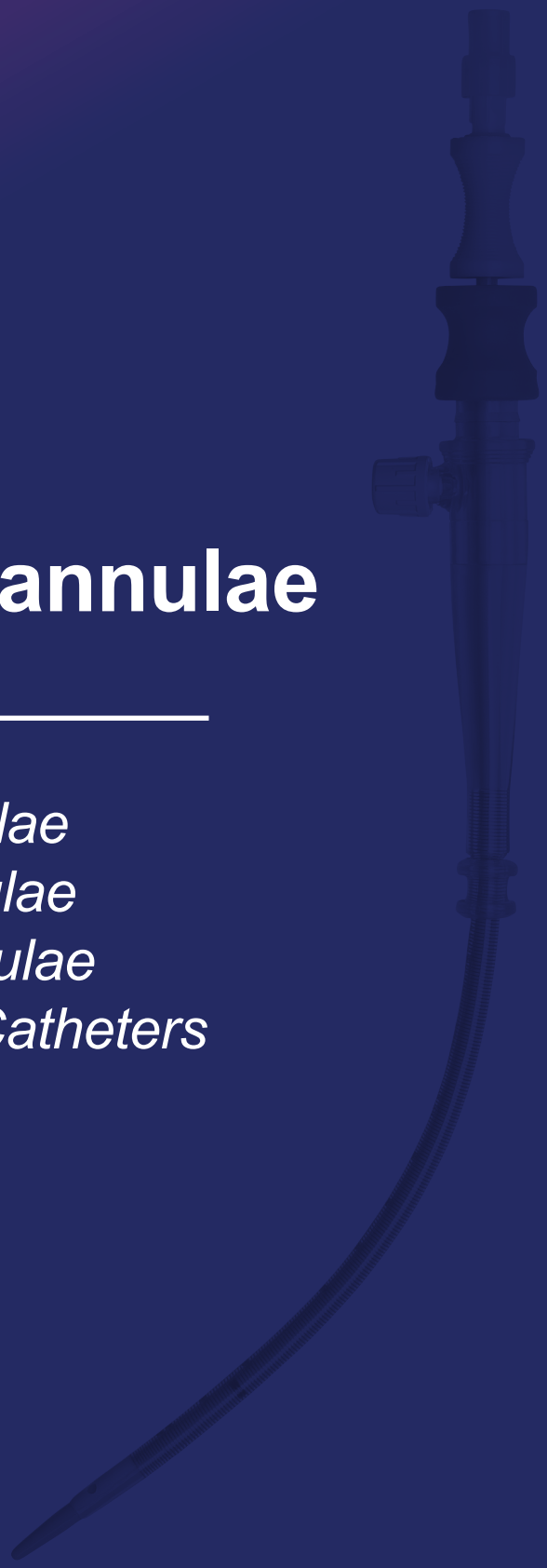
- Configuration: Openwork pattern, square openings, approximately 1.5 cm
- Width: Approximately 20 cm
- Length: Approximately 20 cm
- Tapes: 6 mm wide, folded from 2.5 cm strips
- Thread: Polyester, approximately 5 stitches per cm

Model	Description	Size
4800	Janke-Baron heart support	Individual supports are supplied 6 to a box



Cardiac Cannulae

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

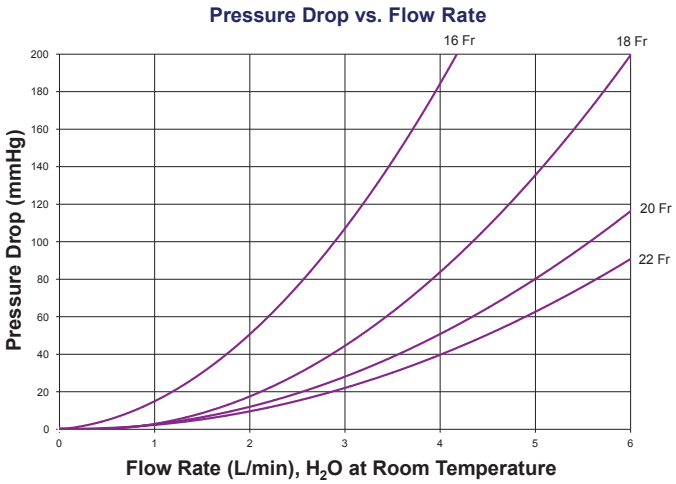


Arterial Cannulae

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
- Removable vented luer cap designed to allow cannula venting when guidewire is not in use

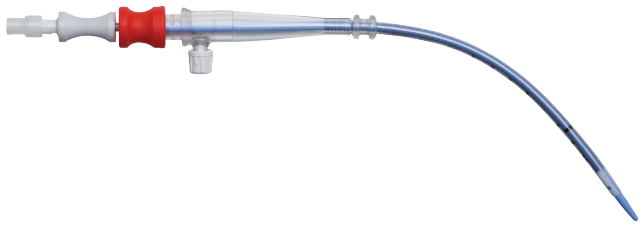
1 unit per case

Blunt tip introducer

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)

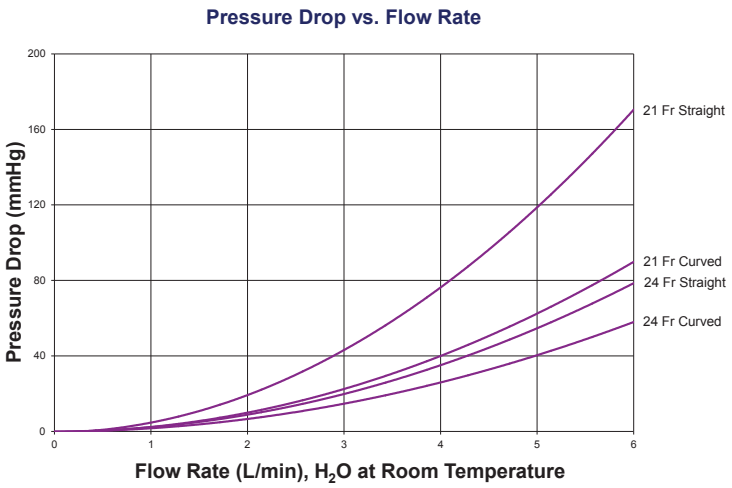


EZ Glide Aortic Perfusion Cannula

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)

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

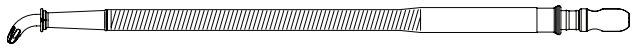
14.8 inch (37.6 cm) overall length

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)



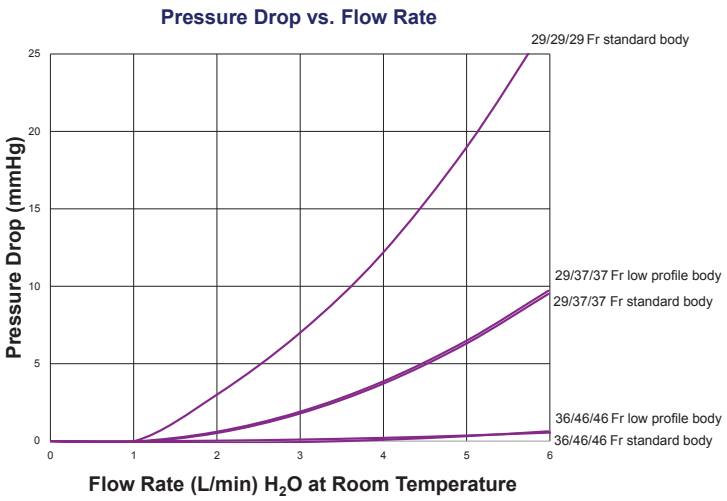
Venous Cannulae

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

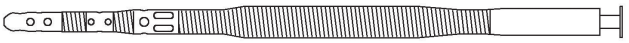
1/2 inch non-vented connector
TRF2937O2A 29/37/37 Fr (9.6/12.3/12.3 mm)

1/2 inch acceptance
TRF2937O2 29/37/37 Fr (9.6/12.3/12.3 mm)

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

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)

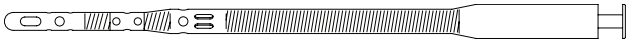
1/2 inch acceptance
TF293702 29/37/37 Fr (9.6/12.3/12.3 mm)

16 inch (40 cm) overall length

1/2 inch non-vented connector
TF292902A 29/29/29 Fr (9.6/9.6/9.6 mm)

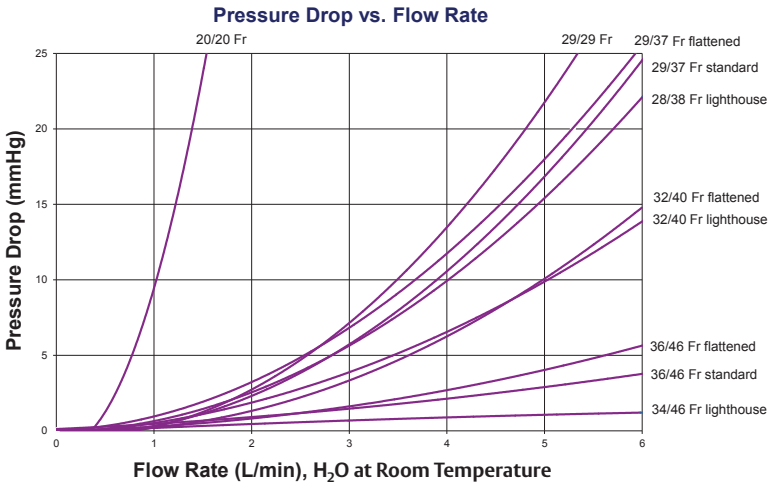
3/8 inch acceptance
TF292902 29/29/29 Fr (9.6/9.6/9.6 mm)

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

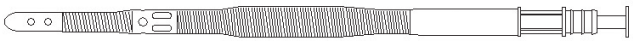
14.5 inch (37 cm) overall length

1/2 inch non-vented connector
TRF2937OA 29/37 Fr (9.6/12.3 mm)

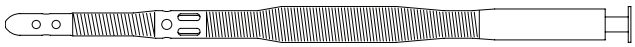
1/2 inch acceptance
TRF2937O 29/37 Fr (9.6/12.3 mm)

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

TF3646OA	36/46 Fr (12.0/15.3 mm)
TF3343OA	33/43 Fr (11.0/14.3 mm)

1/2 inch acceptance

TF3646O	36/46 Fr (12.0/15.3 mm)
TF3343O	33/43 Fr (11.0/14.3 mm)

Thin-Flex dual stage venous cannula angled

14 inch (35 cm) overall length

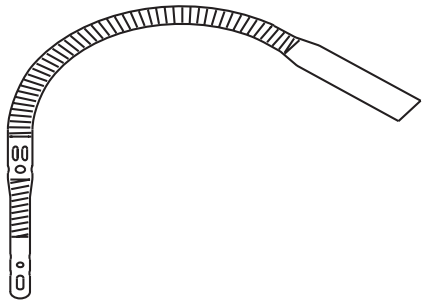
1/2 inch acceptance

TF2937O120	29/37 Fr (9.6/12.3 mm)

15 inch (37.5 cm) overall length

1/2 inch acceptance

TF3646O120	36/46 Fr (12.0/15.3 mm)



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

TR3240O	32/40 Fr (10.6/13.3 mm)

Lighthouse tip

16 inch (40 cm) overall length

1/2 inch acceptance

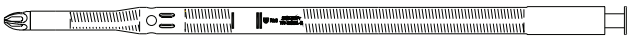
TR2838L	28/38 Fr (9.3/12.6 mm)
TR3240L	32/40 Fr (10.6/13.3 mm)
TR3446L	34/46 Fr (11.3/15.3 mm)

Bullet tip

16 inch (40 cm) overall length

1/2 inch acceptance

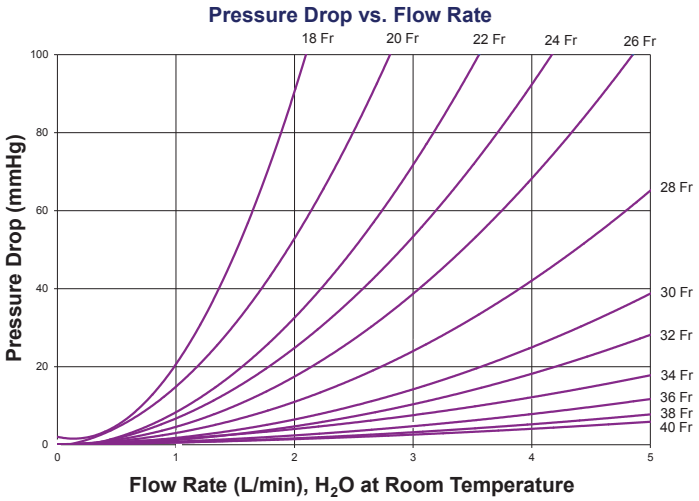
TR3651B	36/51 Fr (12.0/17.0mm)



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 single stage venous cannula 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

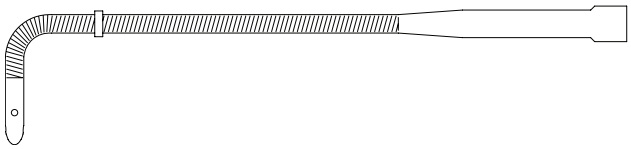
3/8 inch acceptance

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 single stage venous cannula 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)

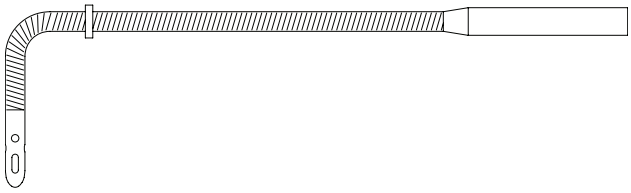
3/8 inch acceptance

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

16 inch (40 cm) overall length

3/8 inch acceptance

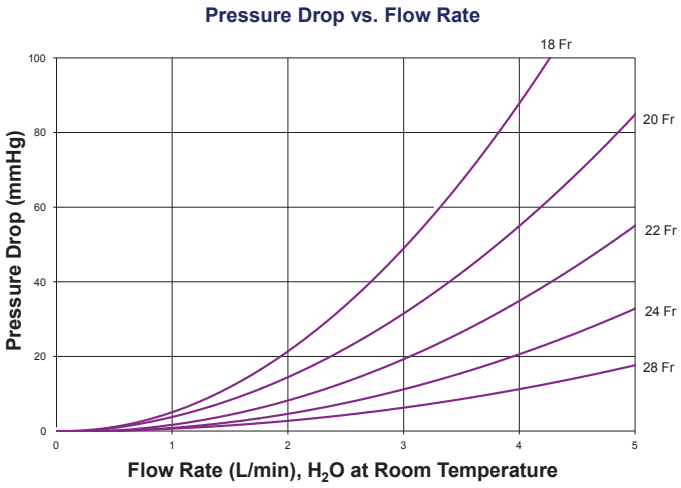
TF030L90	30 Fr (10.0 mm)
TF032L90	32 Fr (10.7 mm)
TF034L90	34 Fr (11.3 mm)
TF036L90	36 Fr (12.0 mm)
TF038L90	38 Fr (12.6 mm)



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 single stage venous cannula 90° plastic tip with side holes

14 inch (35 cm) overall length

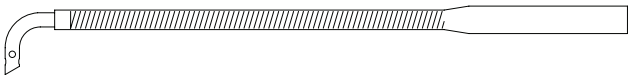
3/8 inch acceptance

TF018O90	18 Fr (6.0 mm)
TF020O90	20 Fr (6.7 mm)

15 inch (38 cm) overall length

3/8 inch acceptance

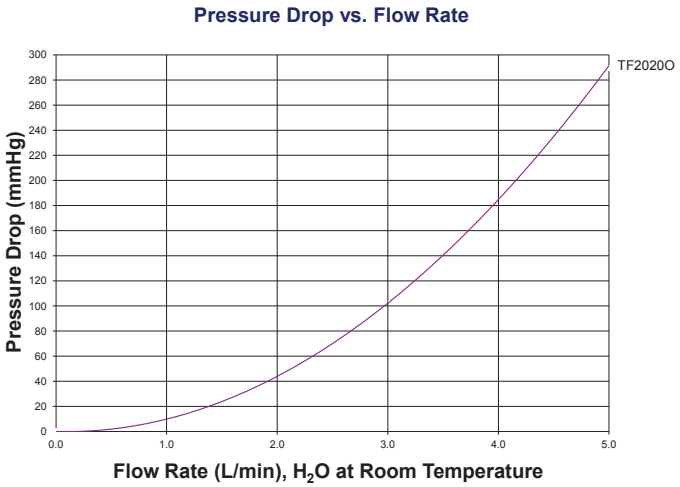
TF022O90	22 Fr (7.3 mm)
TF024O90	24 Fr (8.0 mm)
TF028O90	28 Fr (9.3 mm)



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

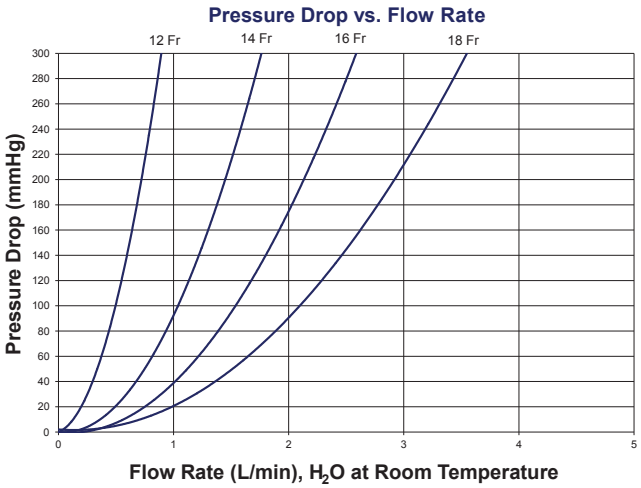
1/4 inch or 3/8 inch acceptance

TF2020O	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 single stage venous cannula 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

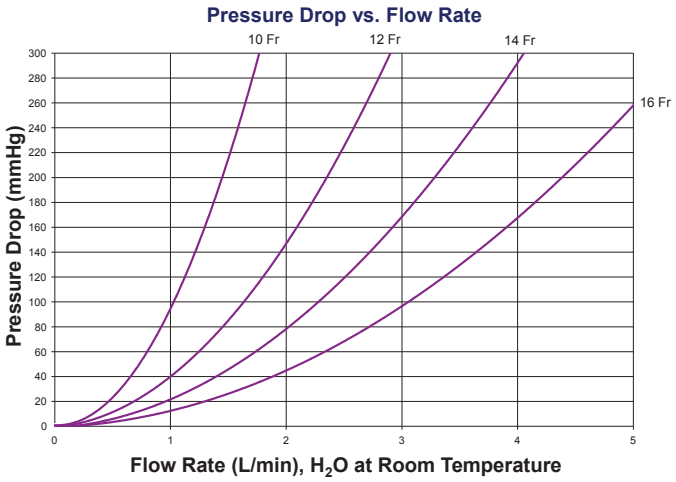
1/4 or 3/8 inch inch acceptance

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 single stage venous cannula 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

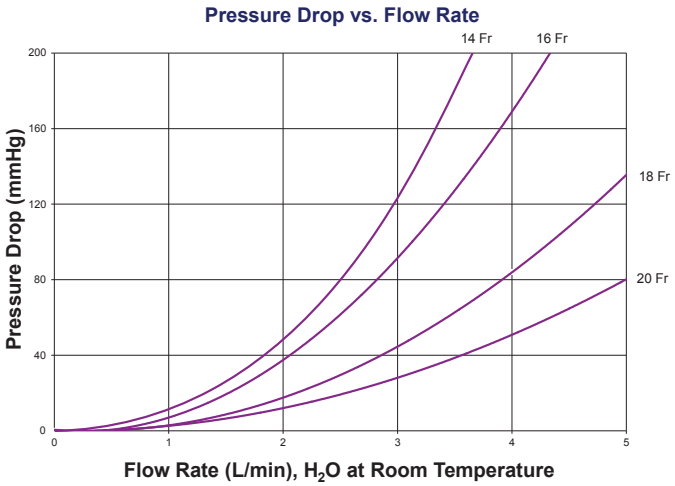
Femoral access cannulae may be used in pediatric populations or adult populations based on flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.

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



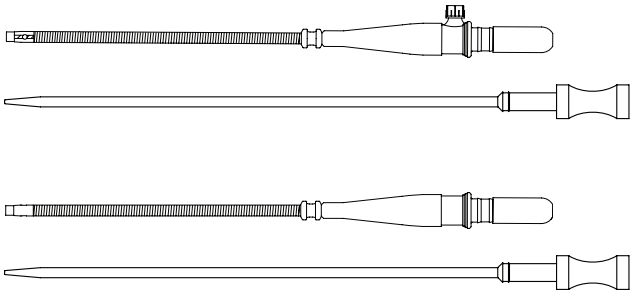
9.5 inch (24 cm) overall length
6.0 inch (15 cm) effective length

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

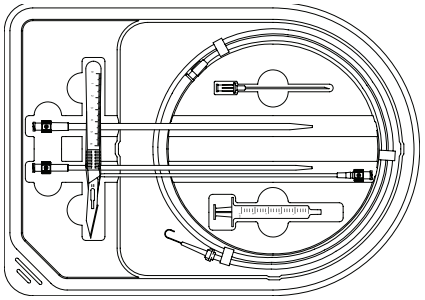
FEMII016AS	16 Fr (5.3 mm)
FEMII018AS	18 Fr (6.0 mm)
FEMII020AS	20 Fr (6.7 mm)



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
- Three dilators: 8 Fr / 12 Fr / 16 Fr
- 0.038 inch guidewire



5 units per case

Arterial insertion kit

PIKA	100 cm guidewire

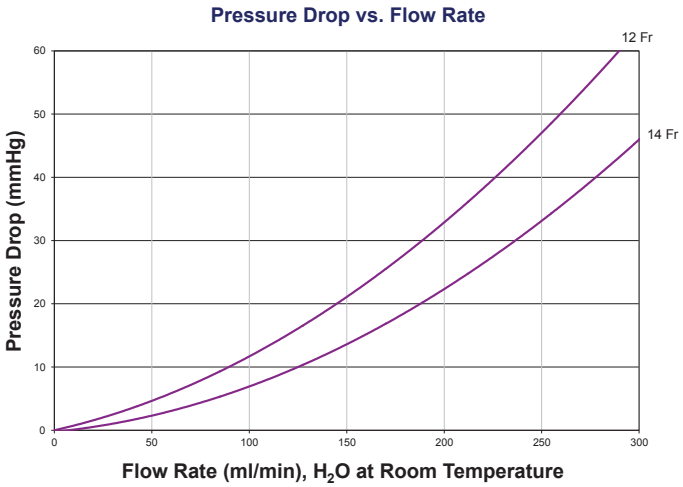
Cardioplegia Catheters

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)

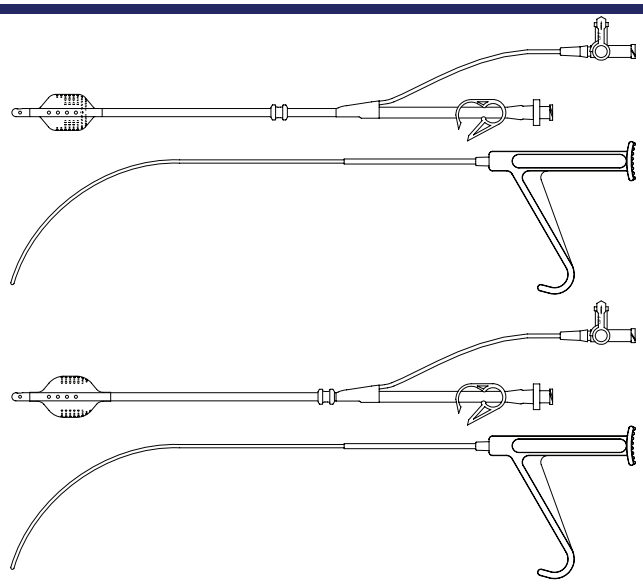
12.5 inch (32 cm) overall length

18 mm textured balloon

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

20 mm textured balloon

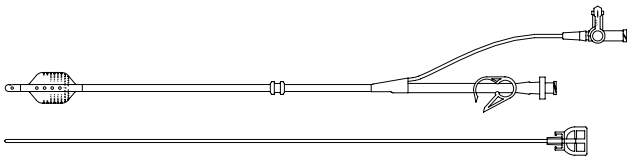
RC2014LB	14 Fr (4.7 mm)



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

Guidewire stylet

12.5 inch (32 cm) overall length



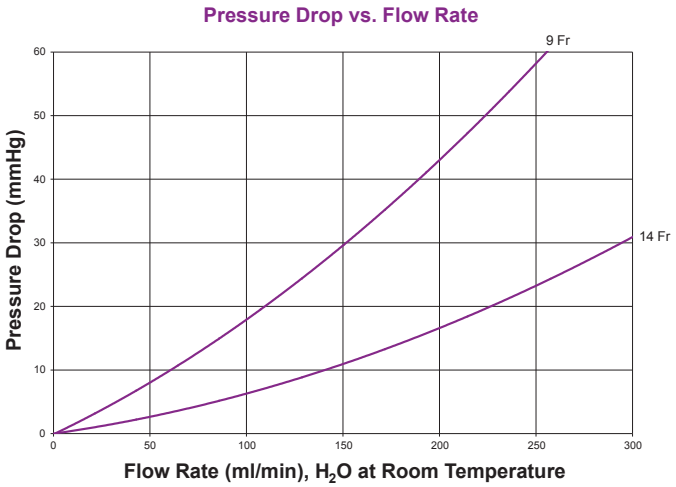
18 mm textured balloon

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.

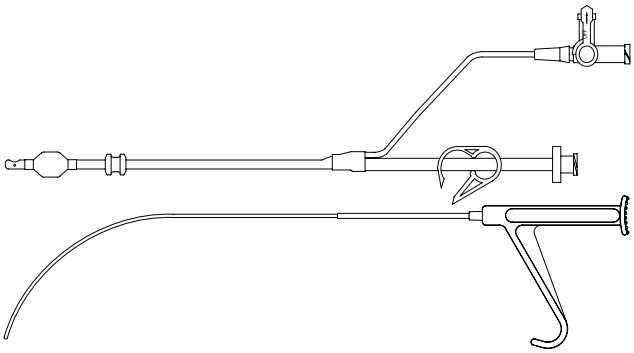
- Balloon self-inflates when cardioplegia is being delivered
- Variety of handle and stylet designs that facilitate insertion for a variety of surgical techniques



Pre-shaped stylet and handle

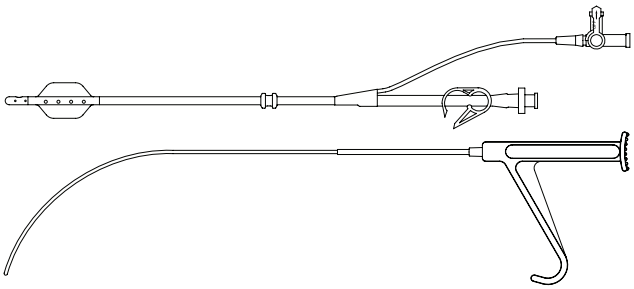
5 units per case
8 inch (20 cm) overall length

9 mm smooth balloon
RC09 9 Fr (3.0 mm)



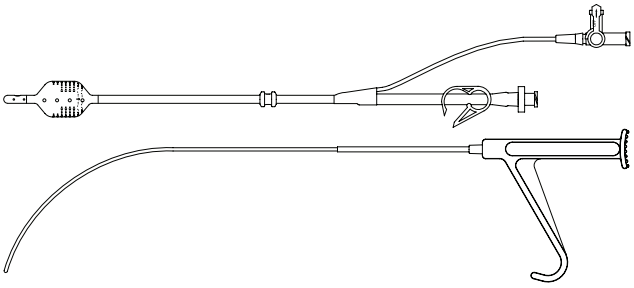
10 units per case
10.6 inch (27 cm) overall length

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)

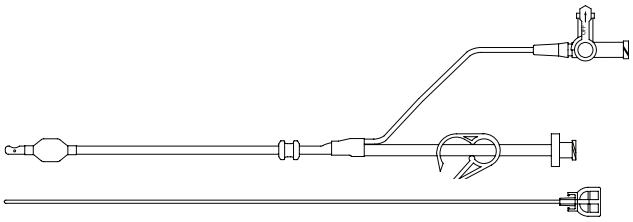


Self-Inflating Retrograde Cardioplegia Catheter (continued)

Guidewire stylet

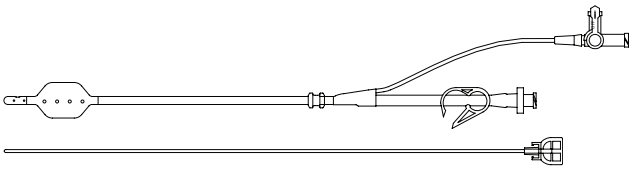
5 units per case
8 inch (20 cm) overall length

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)



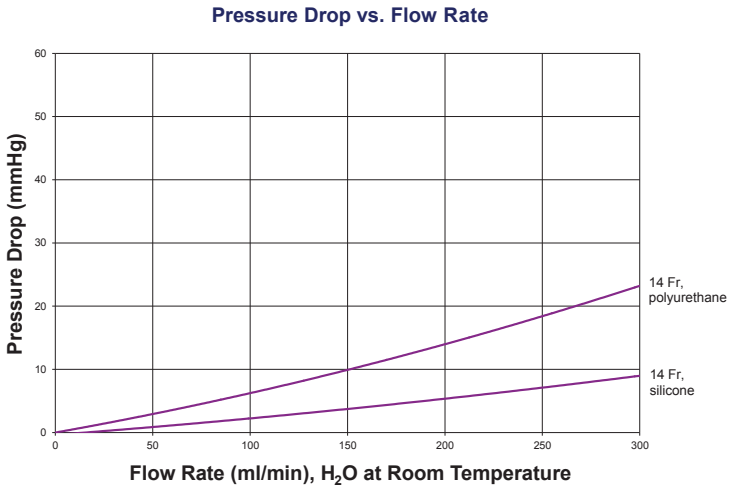
Manually Inflating Retrograde Cardioplegia Catheter

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

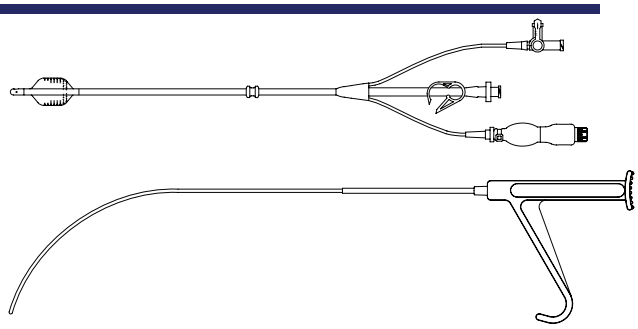
Pre-shaped stylet and handle



12.5 inch (32 cm) overall length

Textured polyurethane balloon and retractaguard lumen

RC2014MIBB	14 Fr (4.7 mm)



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Cardiac Cannulae

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   - **b.** Does not perform satisfactorily for the purposes and indications described in the labeling
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3. All returned products 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.** Incomplete cases
   - **c.** Product which has less than 13-month shelf life
   - **d.** Product which has been marked or labeled with anything other than the standard enableCV / Edwards labels
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