ThruPort Systems

Edwards Cardiac Cannulae

Product Guides

Edwards

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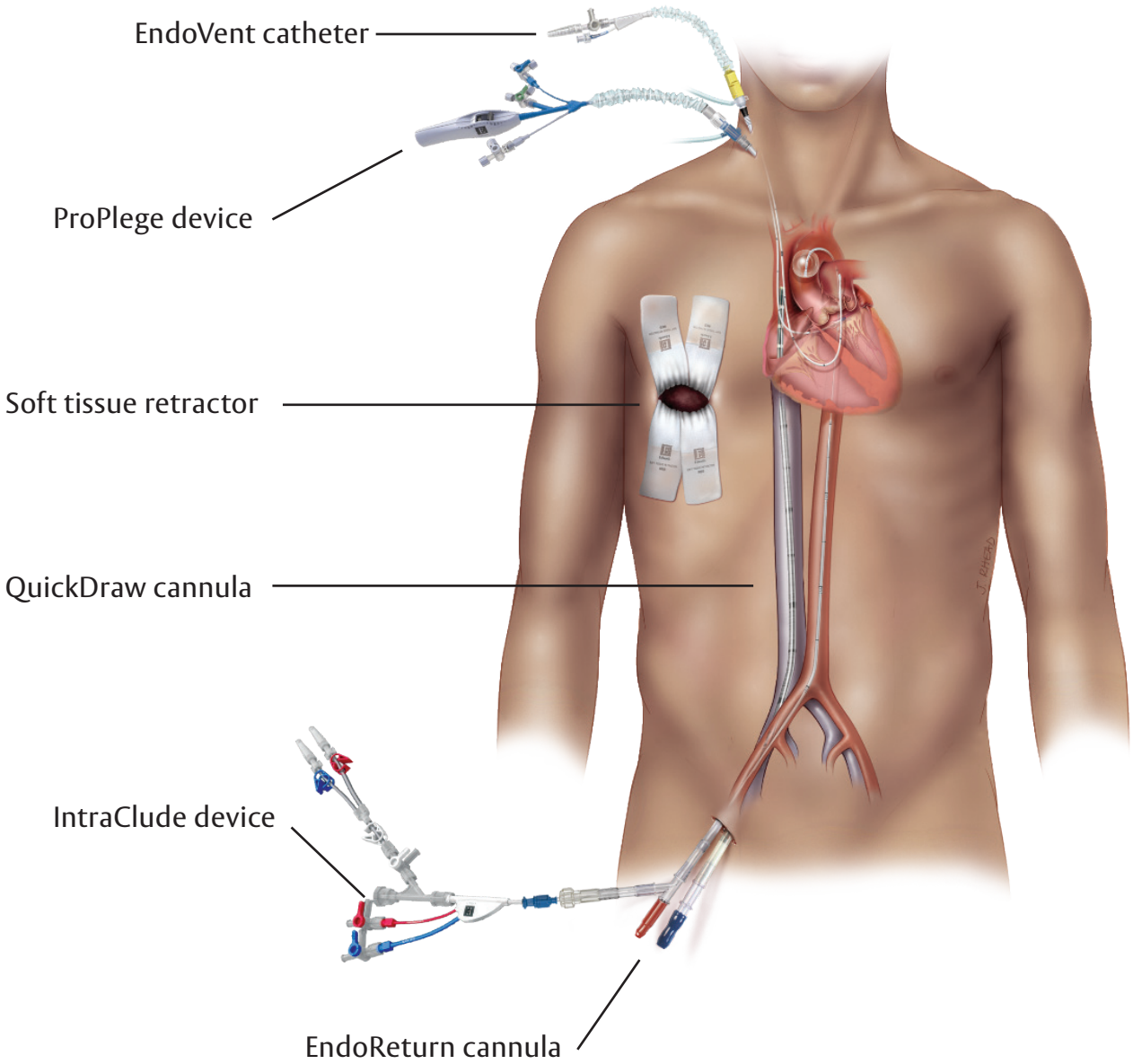
ThruPort Systems

Disposable Products for Minimal Incision Surgery

Edwards ThruPort Systems



ProPlege Peripheral Retrograde Cardioplegia Device

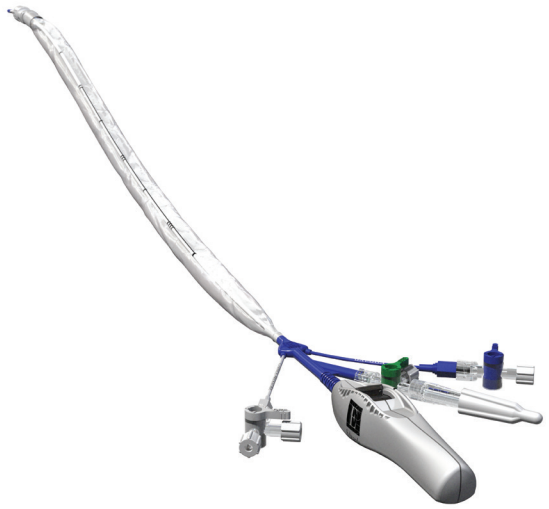
The ProPlege device is indicated for occlusion of the coronary sinus, delivery of cardioplegia solution, and monitoring of coronary sinus pressure during cardiopulmonary bypass.

- 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 11 Fr (3.7 mm) introducer



EndoVent Pulmonary Catheter

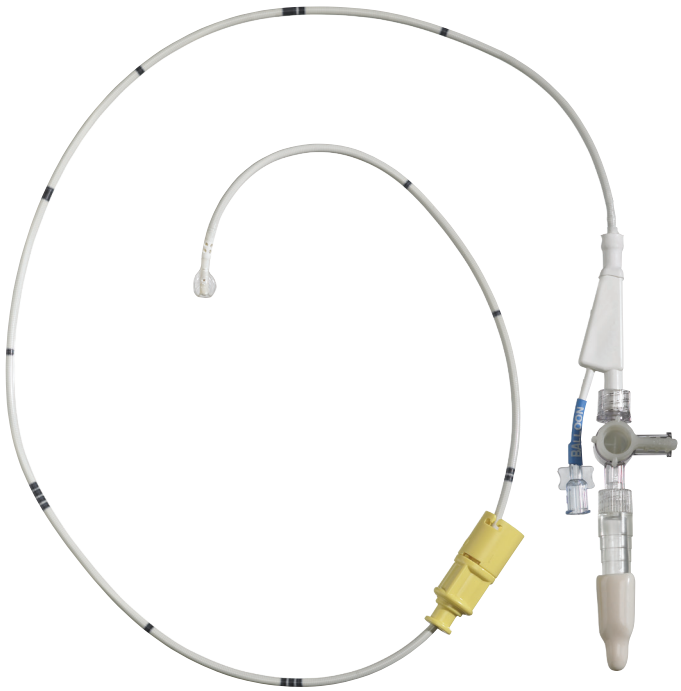
The EndoVent pulmonary catheter is indicated for use in patients undergoing cardiopulmonary bypass. It is intended to remove blood from the pulmonary artery and assist in decompressing the heart.

- 8.3 Fr (2.8 mm), double lumen catheter intended to vent the pulmonary artery
- Preshaped and flexible to facilitate percutaneous placement through the internal jugular vein or the subclavian vein
- An integrated balloon designed to flow-direct the catheter into the pulmonary artery
- The EndoVent pulmonary catheter is protected by a contamination guard which is compatible with the supplied introducer sheath

1 unit per case

25.5 inch (65 cm) overall length

EV	8.3 Fr (2.8 mm) catheter 9 Fr (3.0 mm) introducer



IntraClude Intra-Aortic Occlusion Device

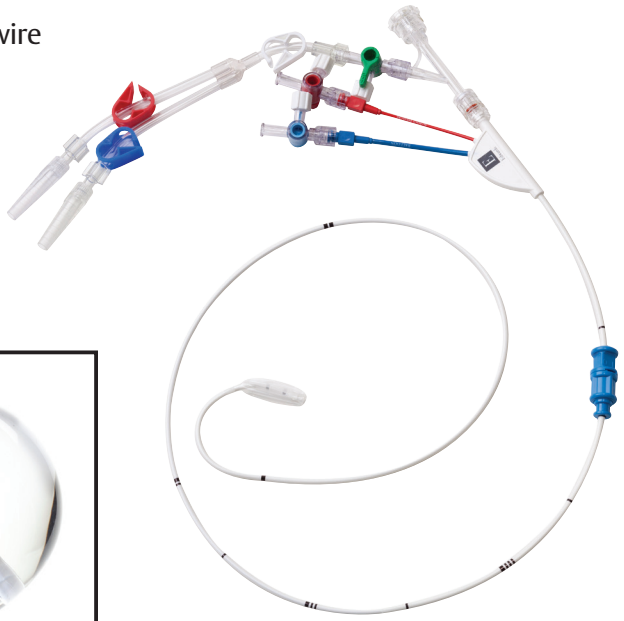
The IntraClude intra-aortic occlusion device is indicated for use in patients undergoing cardiopulmonary bypass. The IntraClude intra-aortic occlusion device occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart.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

39.3 inch (100 cm) overall length

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



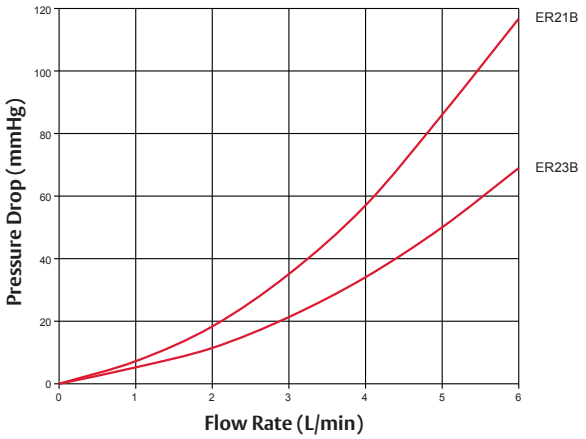
Close up of tip

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.

- 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

Arterial: Pressure Drop vs. Flow*

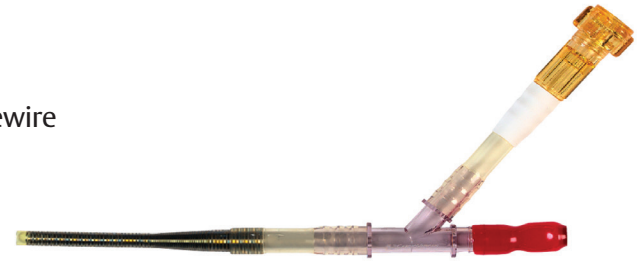


** Mean value derived from in vitro testing performed with water at 21°C. The actual pressure gradients encountered in a clinical situation may vary from those shown, depending on perfusion techniques.*

- 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



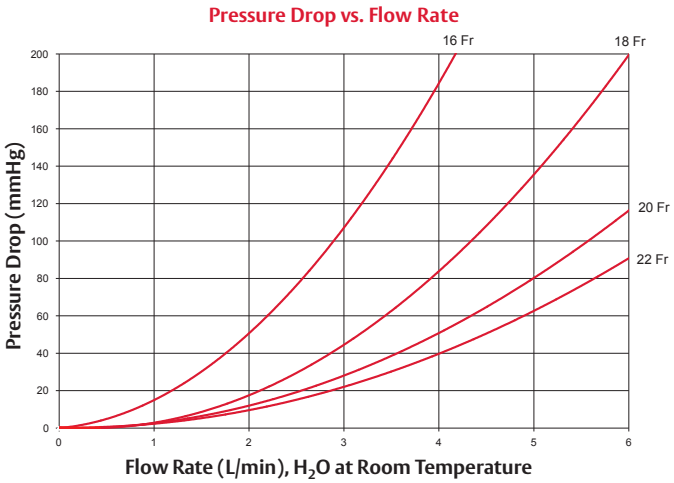
ER21B	21 Fr (7.0 mm) 0.038 inch (100 cm) guidewire Introducer Connector hub
ER23B	23 Fr (7.6 mm) 0.038 inch (100 cm) guidewire Introducer Connector hub

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

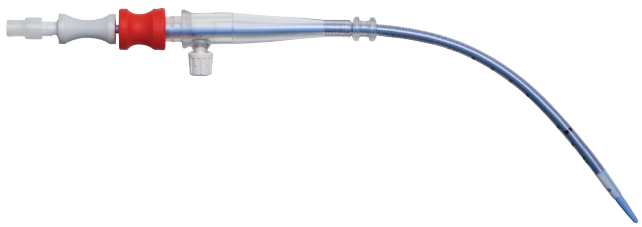
1 unit per case

Blunt Tip Introducer with Guidewire

15 cm effective length
20.8 cm overall length

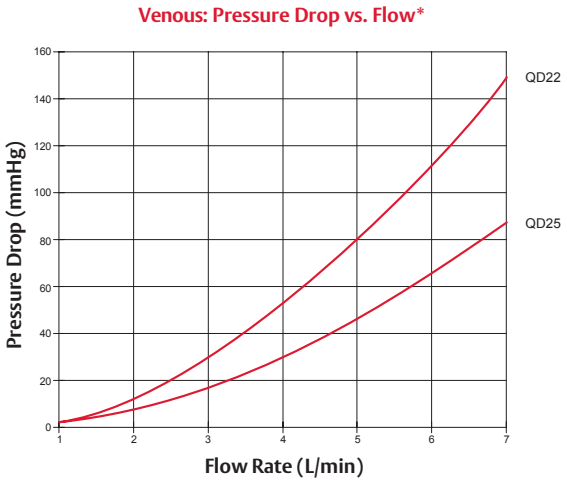
Vented 3/8 inch connector

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



QuickDraw Venous Cannula

Use of the QuickDraw venous cannula is indicated for patients undergoing cardiopulmonary bypass. The QuickDraw venous cannula serves to drain nonoxygenated blood from the venae cavae or right atrium during cardiopulmonary bypass.



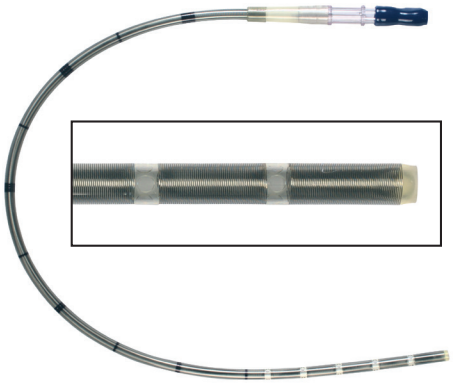
** Mean value derived from in vitro testing performed with water at 21°C. The actual pressure gradients encountered in a clinical situation may vary from those shown, depending on perfusion techniques.*

- The QuickDraw venous cannula kit includes: a wirewound cannula; introducer(s); guidewire; connector hub; percutaneous insertion components
- The cannula and introducer(s) have tapered tips to aid in insertion and advancement into the femoral vein
- The cannula is marked at 5 cm intervals from the first marker band to indicate the depth of insertion
- The soft, clear tubing near the barbed end of the cannula allows visualization of air and blood and provides a non-reinforced clamp site
- The cannula connector is a 3/8 inch (9.5 mm) barbed connector
- The introducers accept a 0.038 inch (0.97 mm) guidewire for assistance in cannula insertion
- The connector hub secures and immobilizes the introducer within the cannula for easier, one-person insertion of the cannula/introducer assembly
- For percutaneous insertion, percutaneous insertion components are provided

1 unit per case

25.5 inch (65 cm) effective length

QD22	22 Fr (7.3 mm) 0.375 inch (9.5 mm) barbed connector Introducer 0.038 inch (180 cm) guidewire Percutaneous insertion kit 5 mL syringe
QD25	25 Fr (8.3 mm) 0.375 inch (9.5 mm) barbed connector Introducer 0.038 inch (180 cm) guidewire Percutaneous insertion kit 5 mL syringe



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)

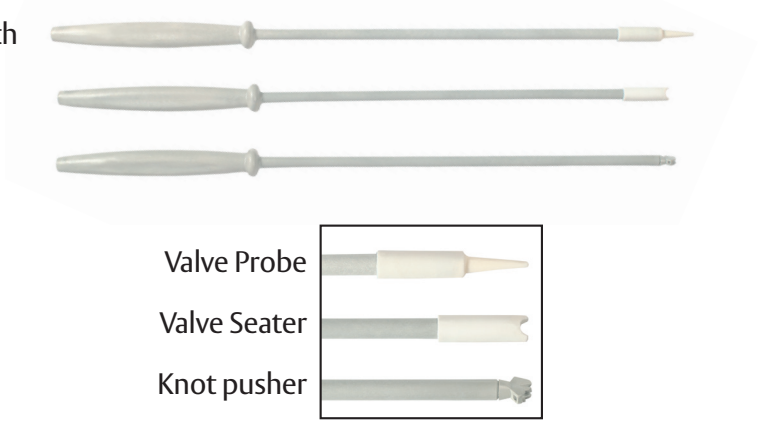
Knot Pusher

- Knot pusher facilitates extracorporeal knot tying of valve sutures

KP1	12.9 inch (33 cm) length	

Valve Placement Pack

- Valve probe has a soft, atraumatic tip for testing mechanical prosthetic valve leaflet motion
- Valve seater has a soft, silicone rubber tip designed to seat mechanical prosthetic valves
- Knot pusher facilitates extracorporeal knot tying of valve sutures

VPP	12.9 inch (33 cm) length	

Close up of tips

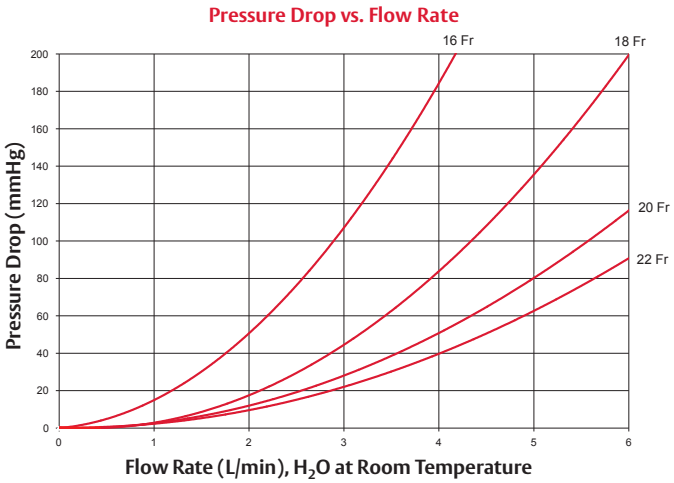
Edwards Cardiac Cannulae

- Arterial Cannulae
- Venous Cannulae
- Femoral Cannulae
- Cardioplegia Catheters
- Blood Management

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.

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- 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

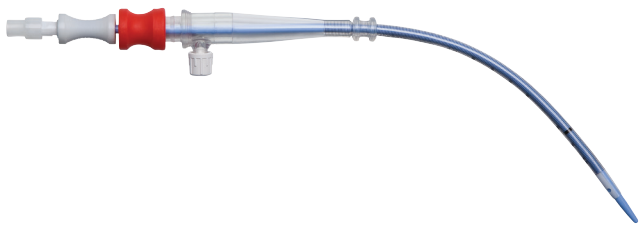
1 unit per case

Blunt Tip Introducer 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)

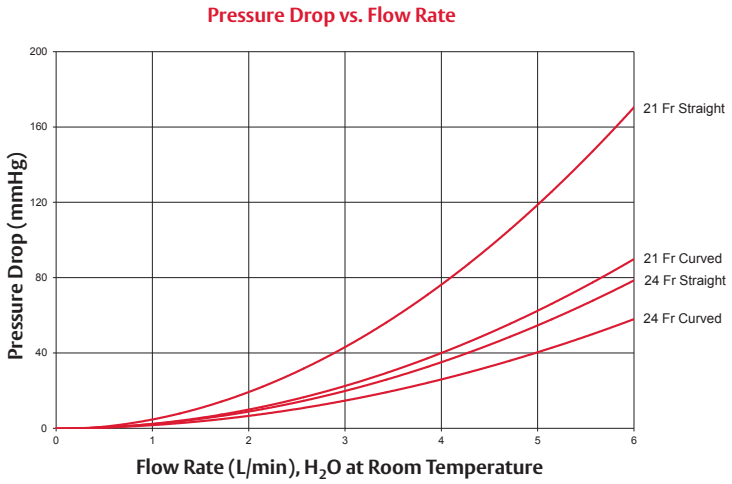


EZ Glide Aortic Perfusion Cannula

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

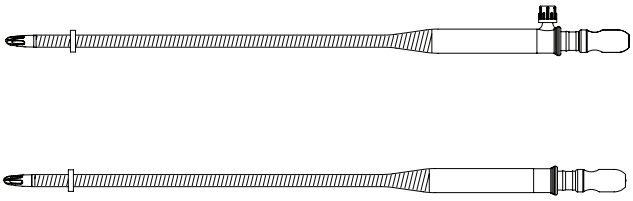
14 inch (35 cm) overall length

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)



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

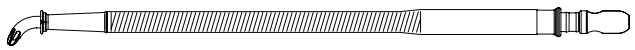
14.8 inch (37.6 cm) overall length

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)



Arterial Cannula Accessories

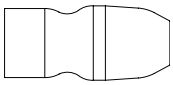
These accessories can be used in conjunction with Edwards arterial cannulae.

10 units per case

Vent caps

Compatible with 3/8 inch connector

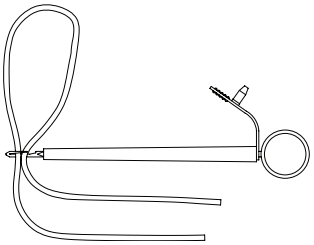
SPC2063	20 micron porous vent cap



Vascular Tourniquet

2 per pouch

TK2	5 inch (12.7 cm) sheath



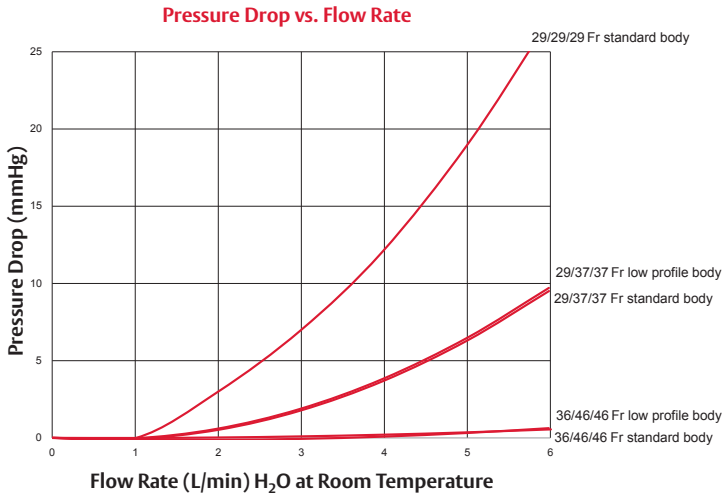
Venous Cannulae

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

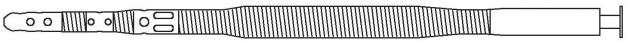
1/2 inch non-vented connector
TRF2937O2A 29/37/37 Fr (9.6/12.3/12.3 mm)

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)

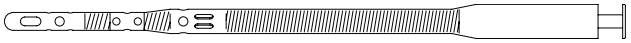
1/2 inch acceptance
TF293702 29/37/37 Fr (9.6/12.3/12.3 mm)

16 inch (40 cm) overall length

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

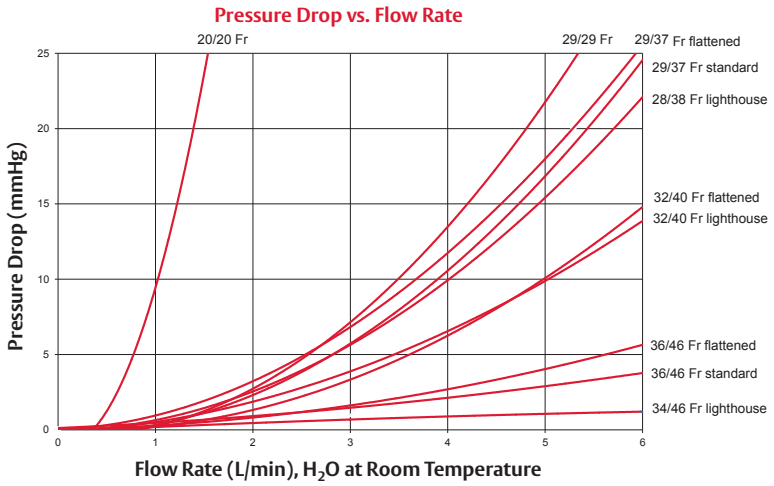
3/8 inch acceptance
TF292902 29/29/29 Fr (9.6/9.6/9.6 mm)

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

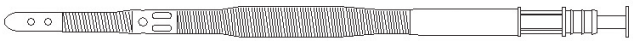
14.5 inch (37 cm) overall length

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 n



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)

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

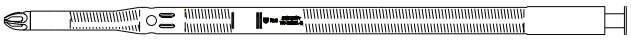
TR2838L	28/38 Fr (9.3/12.6 mm)
TR3240L	32/40 Fr (10.6/13.3 mm)
TR3446L	34/46 Fr (11.3/15.3 mm)

Bullet Tip

16 inch (40 cm) overall length

1/2 inch acceptance

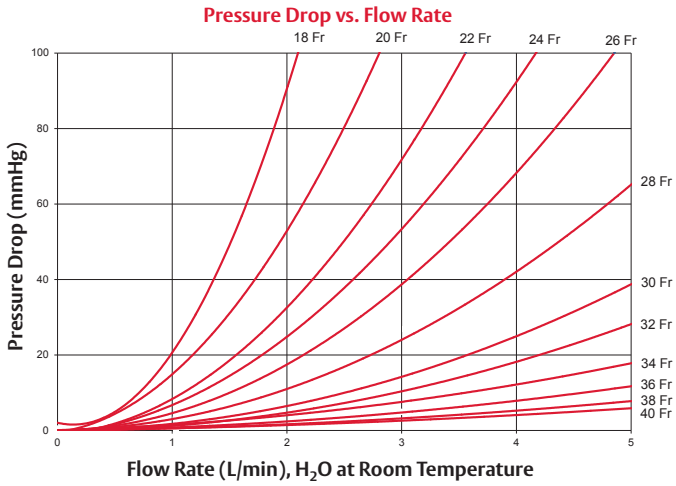
TR3651B	36/51 Fr (12.0/17.0mm)



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 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

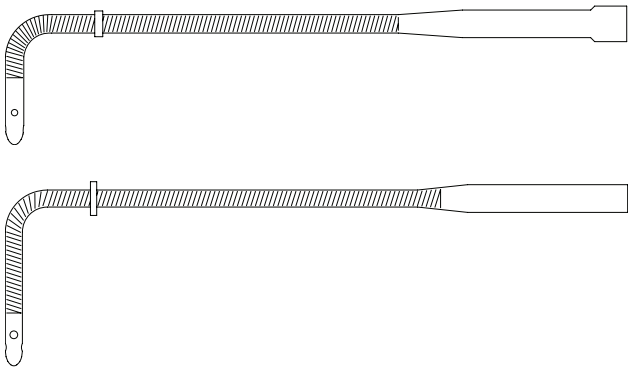
14 inch (35 cm) overall length

1/4 inch or 3/8 inch acceptance

TF024L90	24 Fr (8.0 mm)

3/8 inch acceptance

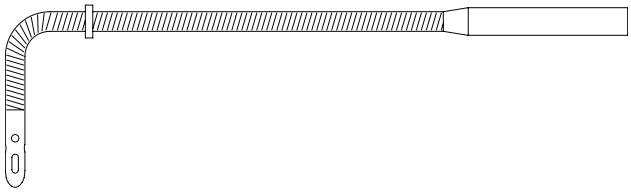
TF026L90	26 Fr (8.7 mm)
TF028L90	28 Fr (9.3 mm)



16 inch (40 cm) overall length

3/8 inch acceptance

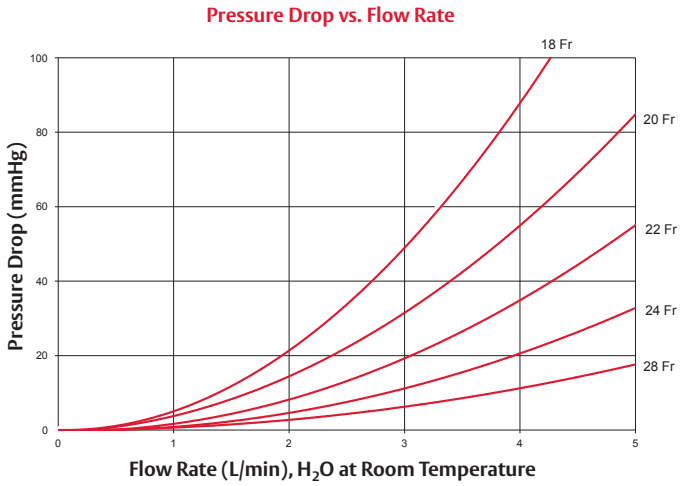
TF030L90	30 Fr (10.0 mm)
TF032L90	32 Fr (10.7 mm)
TF034L90	34 Fr (11.3 mm)
TF036L90	36 Fr (12.0 mm)
TF038L90	38 Fr (12.6 mm)



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

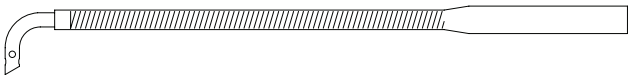
3/8 inch acceptance

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

15 inch (38 cm) overall length

3/8 inch acceptance

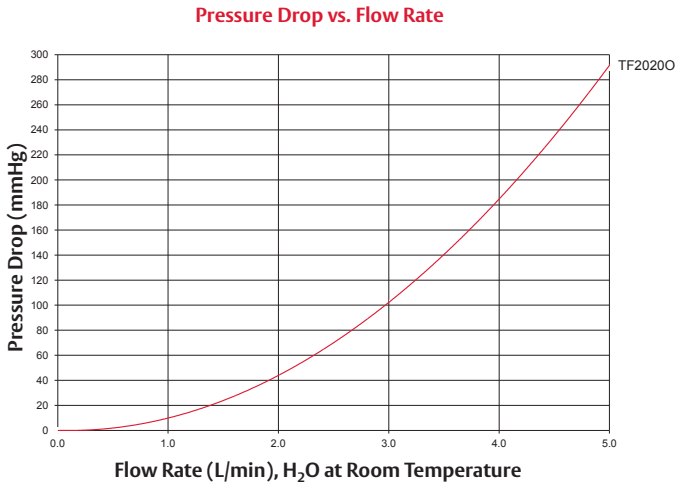
TF022O90	22 Fr (7.3 mm)
TF024O90	24 Fr (8.0 mm)
TF028O90	28 Fr (9.3 mm)



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

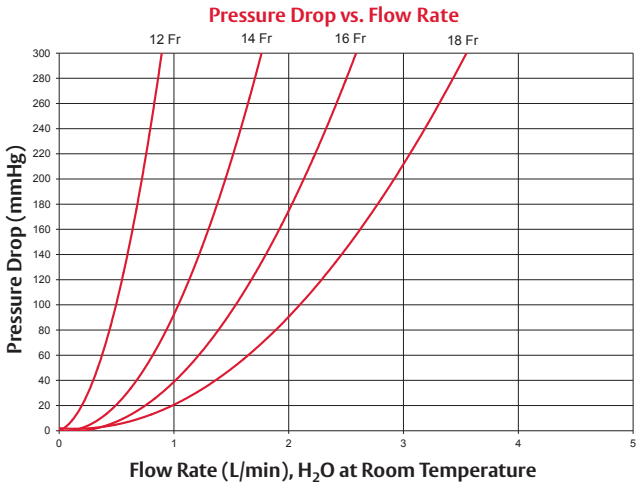
1/4 inch or 3/8 inch acceptance

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 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

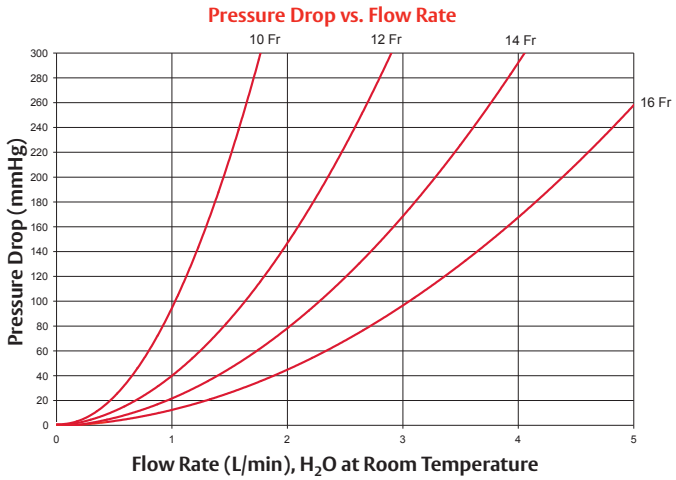
1/4 or 3/8 inch inch acceptance

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

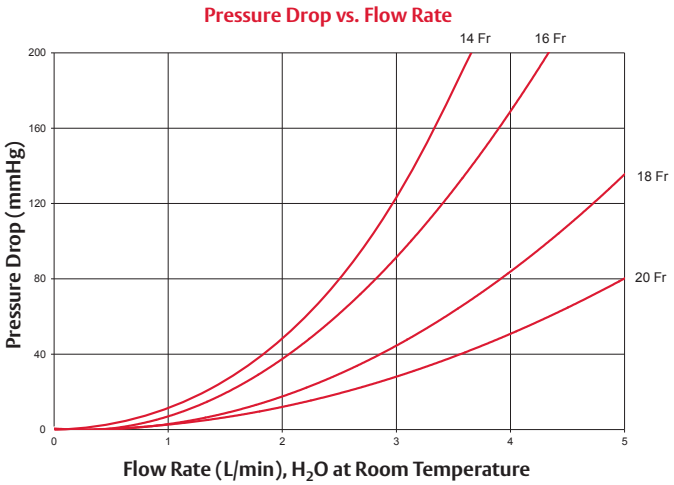
Femoral access cannulae may be used in pediatric populations or adult populations based on flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.

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

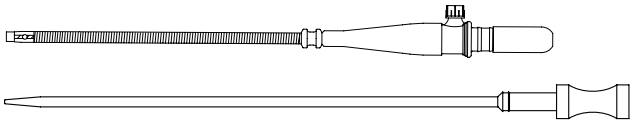
1 unit per case



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

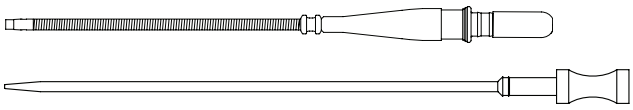
3/8 inch vented connector

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)



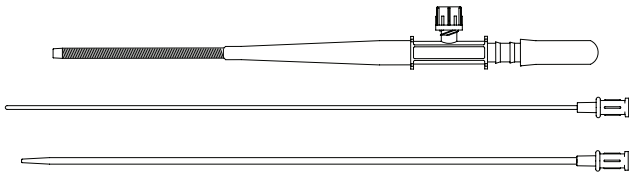
5 units per case

Small Size

7.75 inch (19.7 cm) overall length
2.6 inch (6.5 cm) effective length

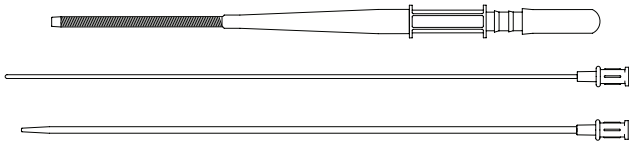
1/4 inch vented connector

FEMII014AT	14 Fr (4.7 mm)



1/4 inch non-vented connector

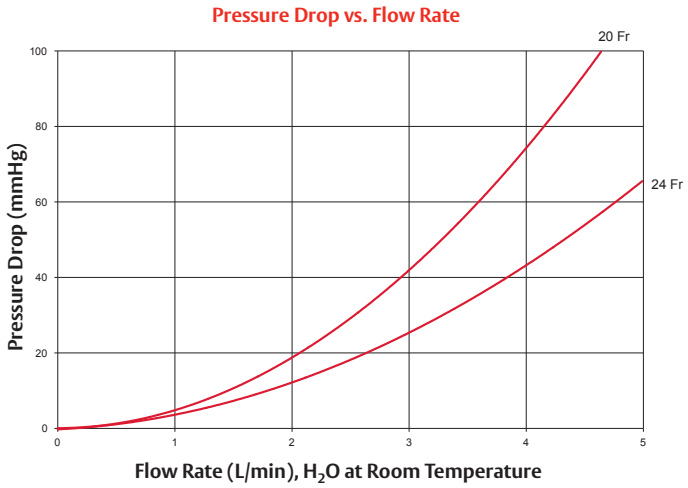
FEMII014A	14 Fr (4.7 mm)



FemTrak Femoral Venous Cannula

- Wire-reinforced thin-wall body that helps minimize kinking and maximize flow rates
- Metal ferrule tipped cannula to provide an atraumatic and smooth transition between cannula and introducer
- Soft, flexible tip on the introducer

1 unit per case

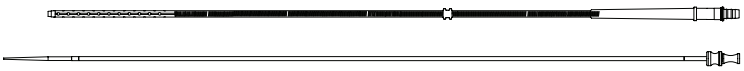


29 inch (74 cm) overall length
21.6 inch (55 cm) effective length

3/8 inch non-vented connector
FTV020 20 Fr (6.7 mm)

34 inch (86 cm) overall length
26.8 inch (68 cm) effective length

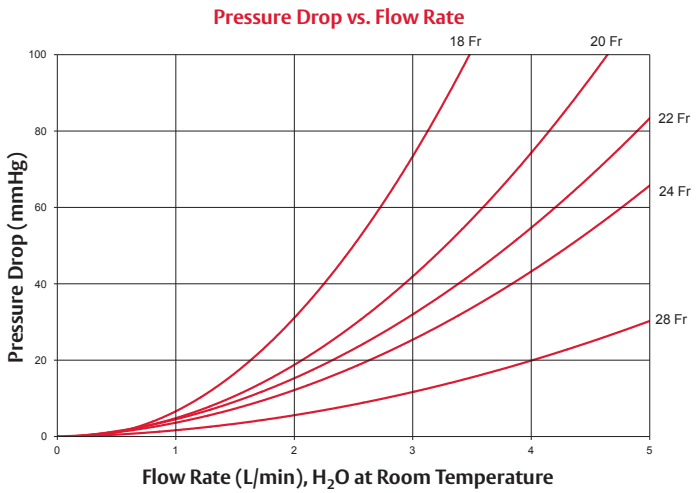
3/8 inch non-vented connector
FTV024 24 Fr (8.0 mm)



VFEM Femoral Venous Cannula

- Thin-wall technology enhances venous drainage and provides flexibility for a variety of surgical applications
- Wire-reinforced body to help reduce kinking
- A tapered tip and smooth dilator-to-cannula for ease of insertion
- Extended section of drainage holes designed to maximize venous drainage

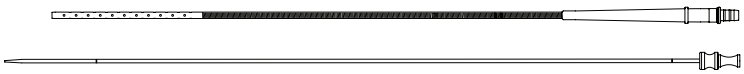
1 unit per case



29 inch (74 cm) overall length
21.6 inch (55 cm) effective length

3/8 inch non-vented connector

VFEM018	18 Fr (6.0 mm)
VFEM020	20 Fr (6.7 mm)
VFEM022	22 Fr (7.3 mm)



34 inch (86 cm) overall length
26.8 inch (68 cm) effective length

3/8 inch non-vented connector

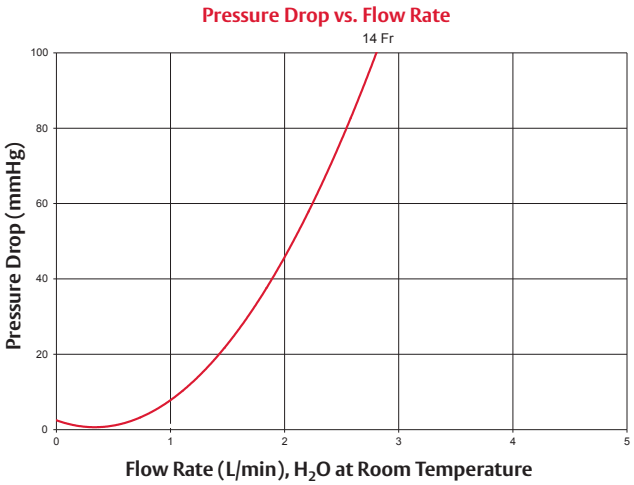
VFEM024	24 Fr (8.0 mm)
VFEM028	28 Fr (9.3 mm)

Fem-Flex II Small Size Femoral Venous Cannula

Fem-Flex II femoral venous 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
- Extended section of drainage holes designed to maximize venous drainage

5 units per case

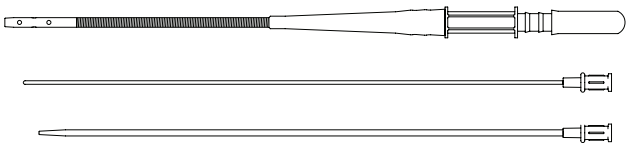


Small Size

9.5 inch (24 cm) overall length
4.5 inch (11.5 cm) effective length

1/4 inch non-vented connector

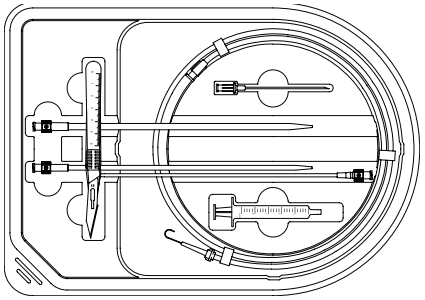
FEMII014V	14 Fr (4.7 mm)



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

Venous Insertion Kit

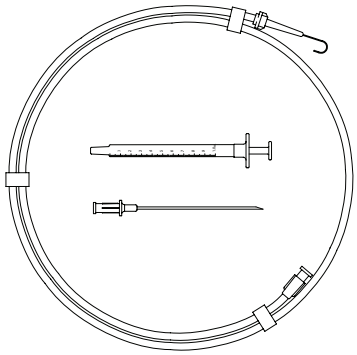
PIKV	210 cm guidewire

Femoral Cannulae Accessories

10 units per case

Guidewire Kit

ART100	0.038 inch (0.97 mm) guidewire - 100 cm (39.4 inch) overall length, 1 ml syringe and 18 ga. insertion needle
VEN210	0.038 inch (0.97 mm) guidewire - 210 cm (82.7 inch) overall length, 1 ml syringe and 18 ga. insertion needle



Cardioplegia Catheters

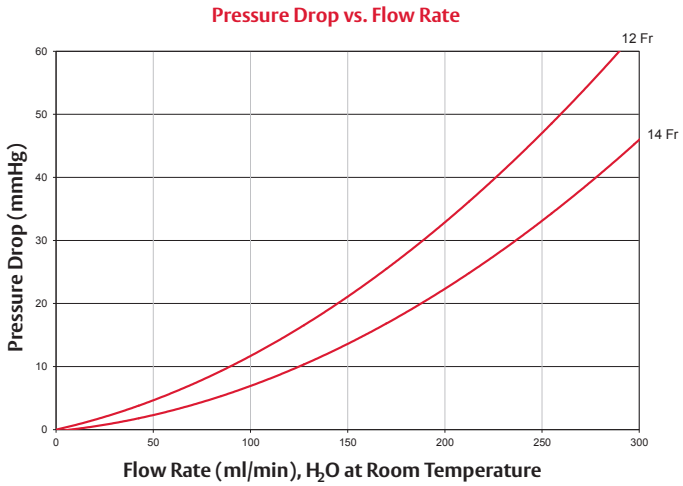
Retrograde coronary sinus cardioplegia catheters may be used in pediatric or adult populations based on the requirements of individual patient anatomy.

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)

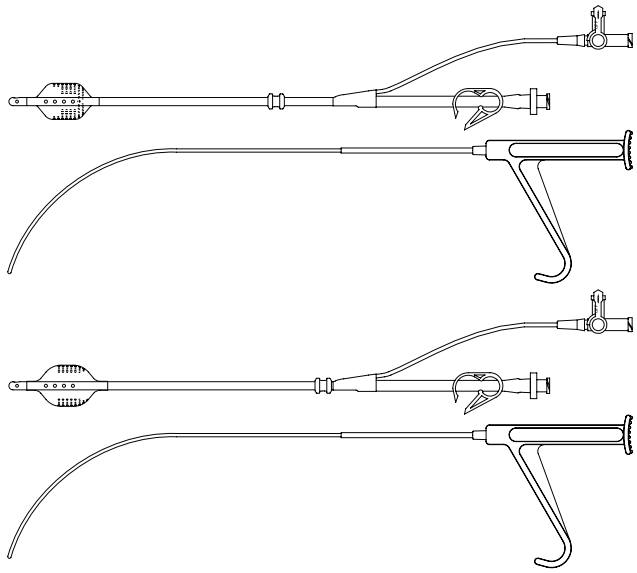
12.5 inch (32 cm) overall length

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)



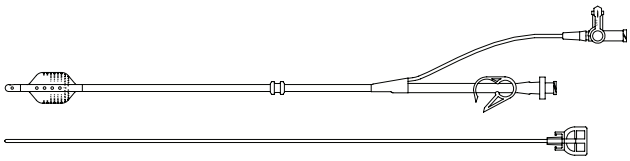
Self-Inflating Retrograde Cardioplegia Catheter with Retractaguard Anti-Retraction Technology (continued)

Guidewire Stylet

12.5 inch (32 cm) overall length

18 mm textured balloon

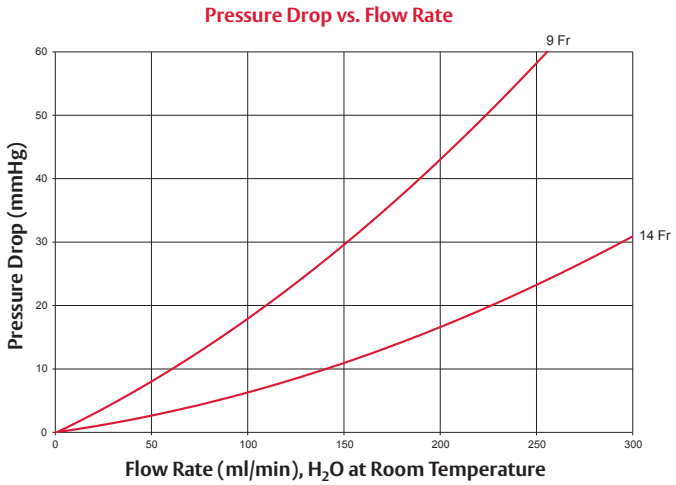
RC2012M	12 Fr (4.0 mm)
RC2014M	14 Fr (4.7 mm)



Self-Inflating Retrograde Cardioplegia Catheter

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

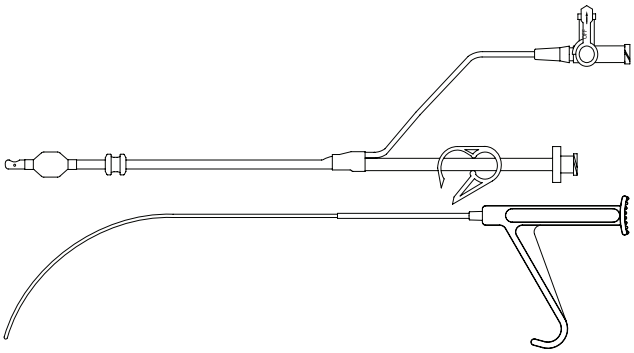
- Balloon self-inflates when cardioplegia is being delivered
- Variety of handle and stylet designs that facilitate insertion for a variety of surgical techniques



Pre-Shaped Stylet and Handle

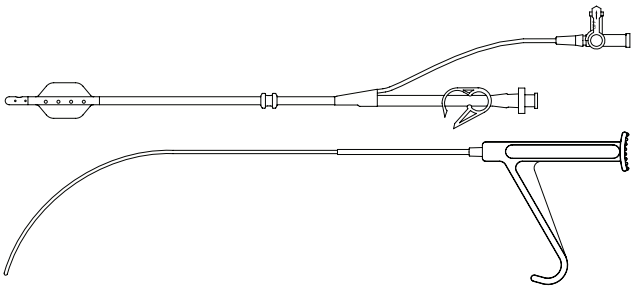
5 units per case
8 inch (20 cm) overall length

9 mm smooth balloon
RC09 9 Fr (3.0 mm)



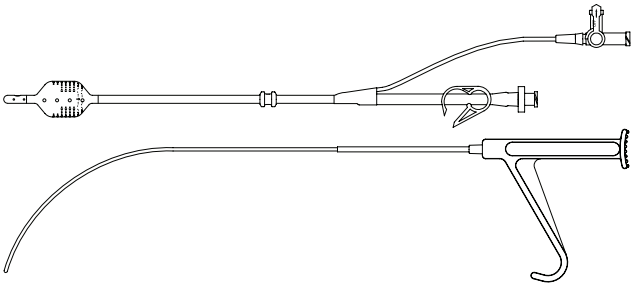
10 units per case
10.6 inch (27 cm) overall length

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)



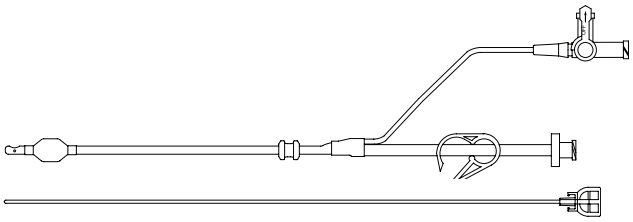
Self-Inflating Retrograde Cardioplegia Catheter (continued)

Guidewire Stylet

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

9 mm smooth balloon

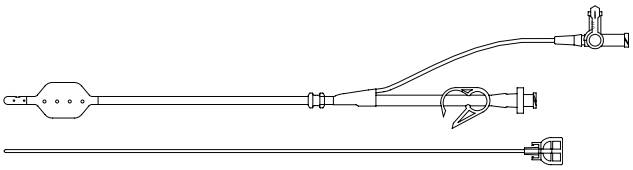
RC09M	9 Fr (3.0 mm)



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

18 mm smooth balloon

RC014M	14 Fr (4.7 mm)

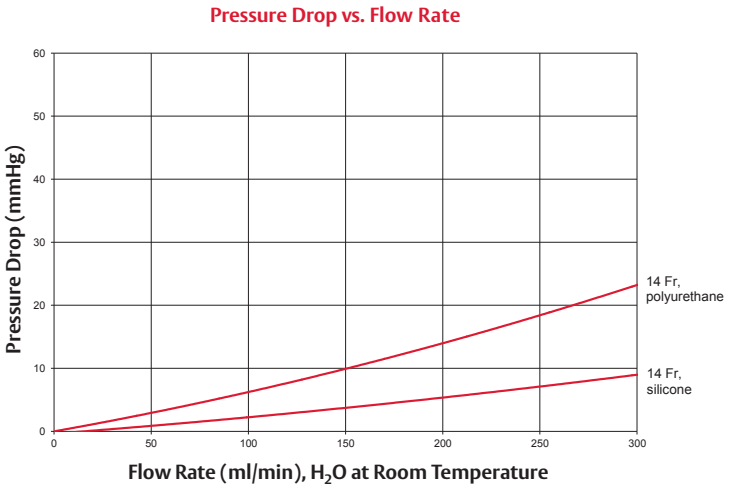


Manually Inflating Retrograde Cardioplegia Catheter

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

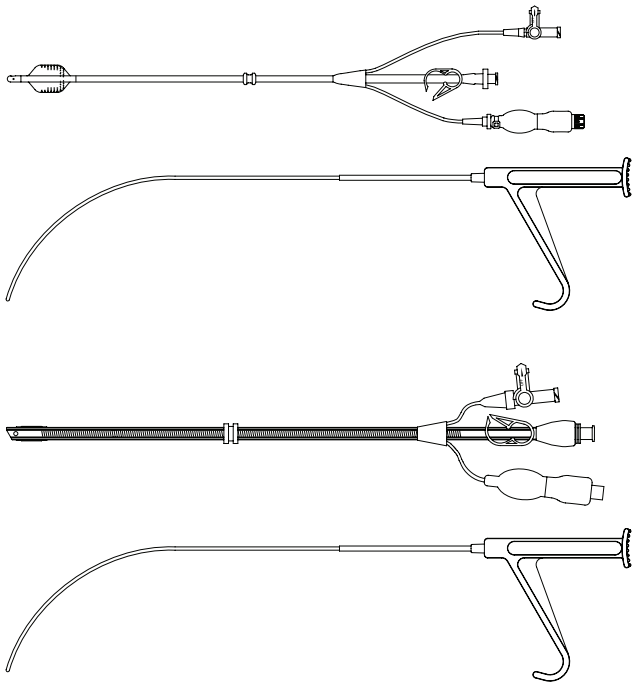


Pre-shaped Stylet and Handle

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)



Manually Inflating Retrograde Cardioplegia Catheter (continued)

Guidewire Stylet

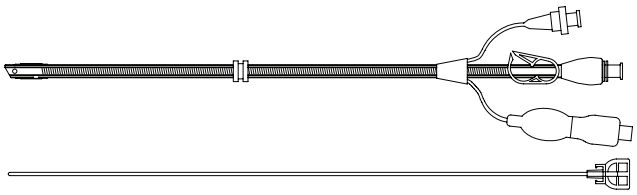
12.5 inch (32 cm) overall length

Smooth silicone balloon

PLD014MIBH	14 Fr (4.7 mm)*

*Female luer instead of stopcock

RC014MIB	14 Fr (4.7 mm)



Blood Management

Vent catheters may be used in pediatric or adult populations based on individual patient anatomy.

Vent Catheter

10 units per case

Guidewire Stylet and Silicone Catheter Body

1/4 inch connector
15.5 inch (39.4 cm) overall length

E063	20 Fr (6.7 mm) 6 cm of drainage holes	

Blood Flow Monitoring

The FLOtector ultrasonic blood flow detector is a battery powered pulsed Doppler ultrasound system designed for the evaluation of blood velocity in vessels.

- A varying audible signal is produced
- The signal pitch is proportional to to blood velocity in the vessel
- Specifically designed for the evaluation of blood velocity in vessels

FLOtector Intraoperative Surgical Blood Flow Detector

1 unit per case

FLO001	Transceiver

FLOtector Detector Probes

4 units per case

FLO002S	8 Fr (2.7 mm) Curved tip

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ThruPort Systems

ThruPort Systems

ThruPort Systems

Edwards Cardiac Cannulae

Edwards
Cardiac
Cannulae

Edwards Cardiac Cannulae

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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
   a. 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, UT 84020

For professional use. CAUTION: Federal (United States) law restricts this device 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 Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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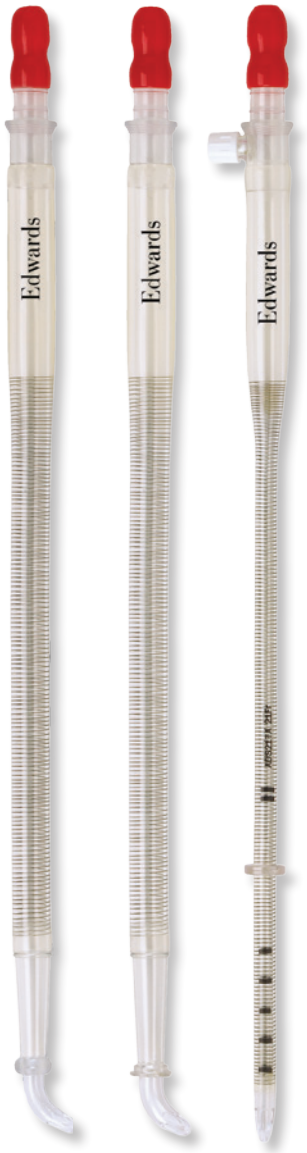
Edwards

EZ Glide

Aortic Cannulae

Gentle, dispersive flow

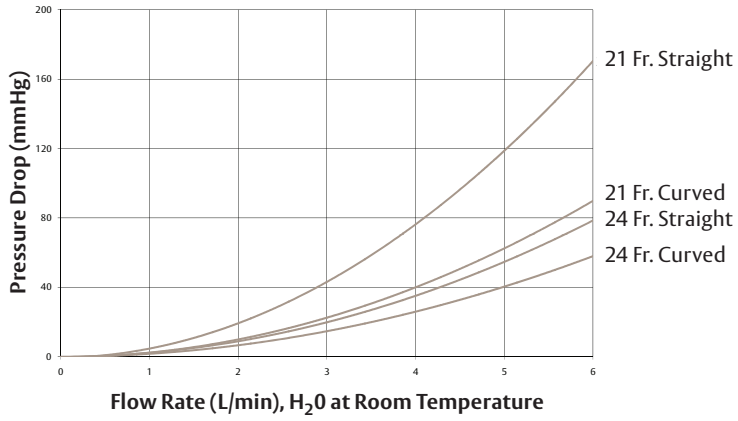


When cardiovascular surgery requires aortic cannulae, EZ Glide aortic cannulae are intended to help protect patients from the potential dangers of embolic dislodgement.

The unique auto dilating tip disperses flow in a gentle, conical spray pattern which reduces the likelihood of embolic disruption by reducing the exit force and line pressure.

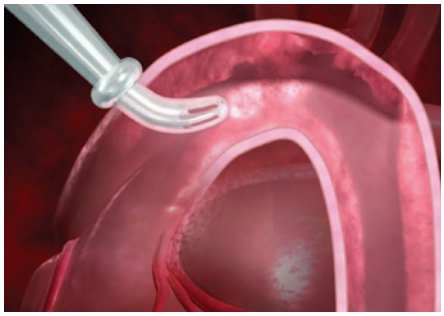
- Optimized tip angle provides centered flow inside the aorta, away from the vessel wall
- Unique, auto-dilating tip enables ease of insertion
- Available with suture bump, suture flange, or moveable suture ring
- Depth markings aid in placement

Pressure Drop vs Flow

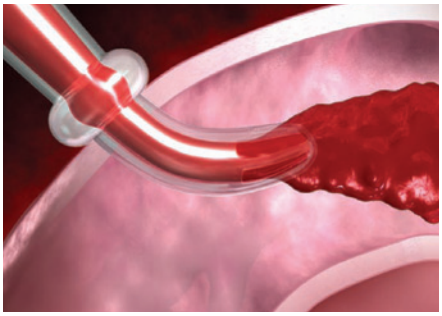


Edwards

Flow through EZ Glide aortic cannulae



Central orientation of aortic cannula



Central fan shaped dispersive flow

By putting a new level of gentle, dispersive flow into a cannula, our enhanced EZ Glide aortic cannulae help you protect patients from the potential dangers of embolic dislodgement.

EZ Glide aortic cannulae offer:

- Central orientation designed to reduce jetting against the aortic wall
- Central fan shaped dispersive flow

EZ Glide aortic cannulae models

Model Number	Tip Configuration	Size	Connector	Vent Cap
EZC21A	Curved tip with suture bump	21 Fr. (7.0 mm)	3/8" Non-vented	Standard
EZC24A		24 Fr. (8.0 mm)		Standard
EZC21TA		21 Fr. (7.0 mm)	3/8" Vented	Standard
EZC24TA		24 Fr. (8.0 mm)		Standard
EZF21A	Curved tip with suture flange	21 Fr. (7.0 mm)	3/8" Non-vented	Standard
EZF24A		24 Fr. (8.0 mm)		Standard
EZF21TA		21 Fr. (7.0 mm)	3/8" Vented	Standard
EZF24TA		24 Fr. (8.0 mm)		Standard
EZS21A	Straight tip with suture flange	21 Fr. (7.0 mm)	3/8" Non-vented	Standard
EZS24A		24 Fr. (8.0 mm)		Standard
EZS21TA		21 Fr. (7.0 mm)	3/8" Vented	Standard
EZS21QTA		21 Fr. (7.0 mm)		Quick venting cap
EZS24TA		24 Fr. (8.0 mm)		Standard

CAUTION: Federal (United States) law restricts this device 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.

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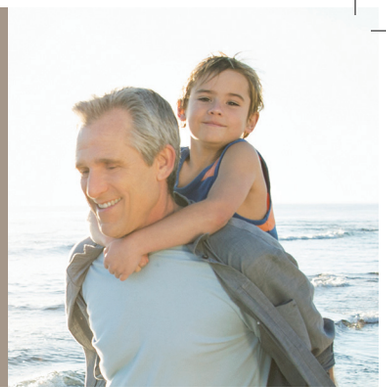
OptiSite

Aortic Cannulae



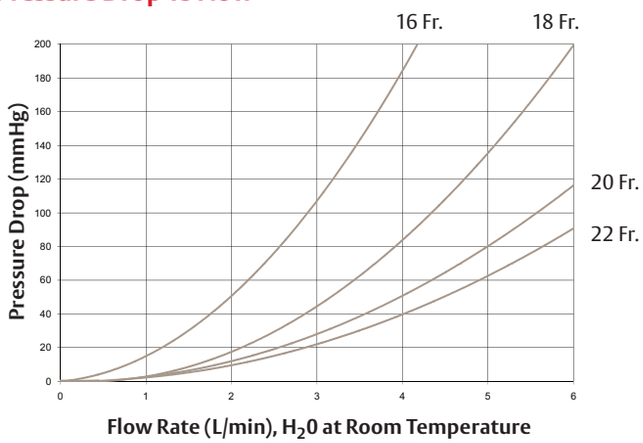
Designed to go where you need it

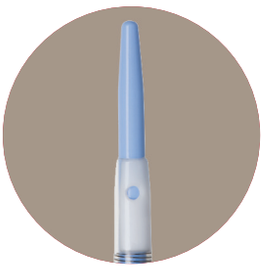
Every patient and surgical situation is different, which is why you need an arterial cannula that gives you options. OptiSite arterial cannulae incorporate easy-to-use thin-wall technology to provide you with a variety of cannulation site options, designed to accommodate multiple surgical techniques and clinician preferences.

Indicated for cannulation in various arterial sites such as the aorta, femoral, axillary and subclavian.

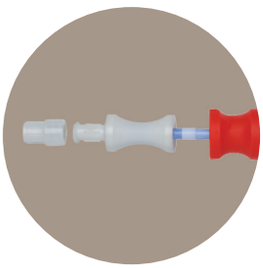
- Smooth rounded introducer tip allows for atraumatic insertion
- Locking introducer reduces retraction during insertion
- Vent cap reduces back-bleed during aortic cannulation
- Depth markings aid in placement
- Fr. sizes include 16, 18, 20 and 22

Pressure Drop vs Flow





Smooth Rounded Tip of the OptiSite arterial cannula



Vent Cap reduces back-bleed

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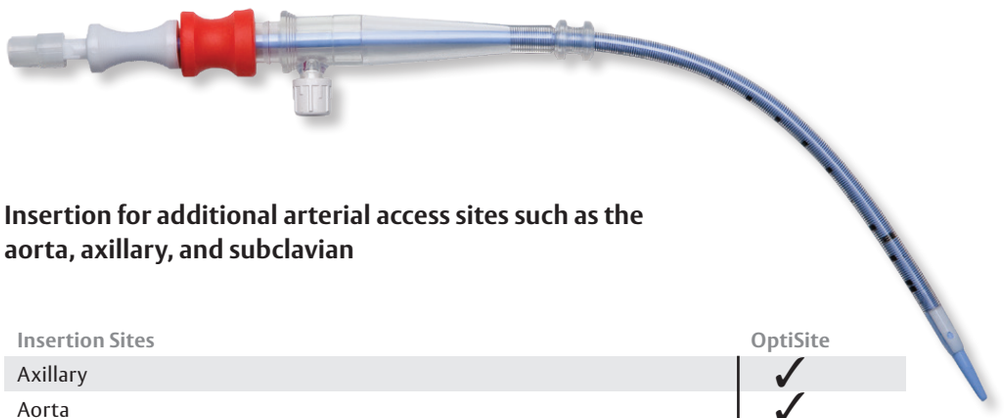
OptiSite cannulae models

Model Number	Size	Effective Length	Connector
OPTI16	16 Fr. (5.3 mm)	6.0” (15 cm)	3/8” Vented
OPTI18	18 Fr. (6.0 mm)	6.0” (15 cm)	3/8” Vented
OPTI20	20 Fr. (6.7 mm)	6.0” (15 cm)	3/8” Vented
OPTI22	22 Fr. (7.3 mm)	6.0” (15 cm)	3/8” Vented



Insertion for additional arterial access sites such as the aorta, axillary, and subclavian

Insertion Sites	OptiSite
Axillary	✓
Aorta	✓
Subclavian	✓
Femoral	✓

CAUTION: Federal (United States) law restricts this device 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.

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DECLARATION OF CONFORMITY

Manufacturer	*Edwards Lifesciences LLC* *One Edwards Way* *Irvine, CA 92614, USA*
European Representative	*Edwards Lifesciences Services GmbH* *Edisonstrasse 6* *85716 Unterschleissheim, Germany*
Product Category **Classification**	*Arterial Cannula* *Class III - Annex IX, Rule 7 (AutoIncisor Rule 6)*
Conformity Assessment	*Annex II*
UMDNS / GMDN Nomenclature	*See following pages*

We hereby declare that the distributed CE marked products, specified in the annexed product list, meet the provisions of the Council Directive 93/42/EEC, as amended by 2007/47/EC concerning Medical Devices and that this Declaration of Conformity is issued under the sole responsibility of Edwards Lifesciences LLC. All supporting documentation is retained under the premises of the production location.

The manufacturer has established and is maintaining a quality system which meets the requirements of ISO 13485:2016 and EN ISO 13485:2016, per certificates **3817373** and **3821948** valid until 07 January 2021.

Notified Body	*DEKRA Certification B.V* *Meander 1051* *6825 MJ Arnhem, The Netherlands* *Identification Number 0344*
EC Certificate	*2016183CE01* *(Valid until 7 January 2023)* *2016183DE10* *(Valid until 26 May 2024)*
Signed for and on behalf of Manufacturer	*Edwards Lifesciences LLC* *Irvine, CA*

Ashwini Jacob

Digitally signed by Ashwini Jacob
DN: cn=Ashwini Jacob, o=Edwards Lifesciences, ou=Sr. Director, Regulatory Affairs, email=ashwini_jacob@edwards.com, c=US
Date: 2019.08.08 15:05:34 -07'00'

Ashwini Jacob
Sr. Director, Regulatory Affairs
Irvine, CA USA

Edwards

PRODUCT LIST
Arterial Cannula

This product list belongs to the Declaration of Conformity identified by ***Arterial Cannula*****,** and specifies that these CE marked products distributed by Edwards Lifesciences are in conformity with the provisions of the Council Directive 93/42/EEC amended by 2007/47/EC concerning medical devices. The following list identifies the catalog number and description. Refer to the Essential Requirements Checklist for a list of relevant harmonized standards.

Start Date of CE Marking: Devices covered by this section of the Declaration were first CE Marked in 1998.

Catalog Number	**Description**
Arterial Cannula	**UMDNS: 15768 Cannulae, Aortic** **GMDN: 34893 Cardiopulmonary bypass cannula, arterial**
EZC21A	EZ Glide Aortic Cannula: Curved w/Suture Bump w/straight connector, 21 Fr.
EZC21TA	EZ Glide Aortic Cannula: Curved w/Suture Bump w/T connector, 21 Fr.
EZC24A	EZ Glide Aortic Cannula: Curved w/Suture Bump w/straight connector, 24 Fr.
EZC24TA	EZ Glide Aortic Cannula: Curved w/Suture Bump w/T connector, 24 Fr.
EZF21A	EZ Glide Aortic Cannula: Curved w/Suture Flange w/straight connector, 21 Fr.
EZF21TA	EZ Glide Aortic Cannula: Curved w/Suture Flange w/T connector, 21 Fr.
EZF24A	EZ Glide Aortic Cannula: Curved w/Suture Flange w/straight connector, 24 Fr.
EZF24TA	EZ Glide Aortic Cannula: Curved w/Suture Flange w/T connector, 24 Fr.
EZS21A	EZ Glide Aortic Cannula: Straight w/straight connector, 21 Fr.
EZS21TA	EZ Glide Aortic Cannula: Straight w/T connector, 21 Fr.
EZS24A	EZ Glide Aortic Cannula: Straight w/straight connector, 24 Fr.
EZS24TA	EZ Glide Aortic Cannula: Straight w/T connector, 24 Fr.
Catalog Number	**Description**
Arterial Cannula	**UMDNS: 10564 Cannulae, Arterial** **GMDN: 34893 Cardiopulmonary bypass cannula, arterial**
OPTI16	OptiSite Arterial Perfusion Cannula, 16 Fr., blunt tip, vented introducer
OPTI18	OptiSite Arterial Perfusion Cannula, 18 Fr., blunt tip, vented introducer
OPTI20	OptiSite Arterial Perfusion Cannula, 20 Fr., blunt tip, vented introducer
OPTI22	OptiSite Arterial Perfusion Cannula, 22 Fr., blunt tip, vented introducer

ThruPort Systems Arterial Cannulae All lots manufactured prior to August 10, 2011 will still be branded with PORT ACCESS Systems.

Start Date of CE Marking: Devices covered by this section of the Declaration were first CE Marked in 1999.

Catalog Number	Description	
Arterial Cannula		**UMDNS: 10564 Cannulae, Arterial** **GMDN: 34893 Cardiopulmonary bypass cannula, arterial**
ER21B	EndoReturn Arterial Cannula Kit: (Y- connector w/smooth, inner radius), 21 Fr, with Guidewire	
ER23B	EndoReturn Arterial Cannula Kit: (Y- connector w/smooth, inner radius), 23 Fr, with Guidewire	

EC CERTIFICATE

Number: 2016183CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

For the product category(ies)

Devices for Cardiac Surgery and Accessories

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2103732CN, initially dated 31 August 2007
Addendum, initially dated 1 March 2002

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 7 January 2023
Issued for the first time: 1 March 2002

Revised: 4 January 2019
Reissued: 7 January 2017

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

Belonging to certificate: 2016183CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Devices for Cardiac Surgery and Accessories

Issued to:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
United States Of America

This certificate covers the following product(s):

Cardioplegia
- Retrograde and Antegrade Cardioplegia Catheter (Class IIa)

Cardiopulmonary Bypass
- Arterial Cardiopulmonary Bypass Cannula (Class III)
- Heart Bypass Venous Drainage Cannula (Class III)
- Cardiopulmonary Bypass Vent Catheter (Class III)
- Atrial Vent Catheters (Class III)
- Cardiopulmonary Bypass Cannula Kits (Class III)

Accessories
- Valve Placement Devices (Class IIa)
- Vascular Tourniquet Sheath (Class IIa)
- Peripheral Venous Guidewire (Class IIa)
- Peripheral Arterial Guidewire (Class IIa)
- Introducer Sheath (Class IIa)
- Soft Tissue Retractors (Class IIa)
- Knot Pushers (Class IIa)
- Dilators (Class IIa)

Initial date: 1 March 2002
Revision date: 11 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

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EC DESIGN-EXAMINATION CERTIFICATE

Number: 2016183DE10

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
United States Of America

For the product

Arterial Cardiopulmonary Bypass Cannula

Documents, that form the basis of this certificate:

Certification Notice 2103732CN, initially dated 31 August 2007
Addendum, initially dated 23 April 2019

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.
The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 23 April 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2016183DE10

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Arterial Cardiopulmonary Bypass Cannula

Issued to:

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614
United States Of America

This certificate covers the following product(s):

EZ Glide Aortic Cannula models: EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A, EZS24TA

OptiSite Arterial Perfusion Cannula models: OPTI16, OPTI18, OPTI20, OPTI22

EndoReturn Arterial Cannula models: ER21B, ER23B

Initial date: 23 April 2019
Revision date: 26 April 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

CERTIFICATE

Number: 3821948

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

including the implementation meets the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

Scope: Design, development, production and distribution of:

- biological surgical heart valves and accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device);
- transcatheter heart valve systems (biological heart valves, delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers);
- transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate);
- annuloplasty rings and accessories (handles, sizers, and trays);
- biologic pericardial patches for the area of heart valve replacement, repair and reconstruction;
- catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.

Certificate expiry date: 7 January 2024
Certificate effective date: 8 June 2021
Certified since: 13 December 2018

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

To certificate: 3821948

The management system of the organization(s) and/or location(s) of:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

Certified organization(s) and/or locations:

Location	Certification scope / Activity
Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614 USA	Design, development, production and distribution of: • biological surgical heart valves and accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device); • transcatheter heart valve systems (biological heart valves, delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers); • transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate); • annuloplasty rings and accessories (handles, sizers, and trays); • biologic pericardial patches for the area of heart valve replacement, repair and reconstruction; • catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.
Edwards Lifesciences LLC 12050 Lone Peak Parkway Draper, UT 84020 USA	Production and distribution of: • biological surgical heart valve accessories (delivery system and inflation device, handles, sizers, trays, suture fasteners, heart support device); • transcatheter heart valve systems (biological heart valve delivery systems, balloon catheters) and accessories (access devices, inflation devices and crimpers); • transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate); • annuloplasty rings and accessories (handles, sizers, and trays); • catheters, cannula and occlusion devices and accessories (introducer sheaths, percutaneous insertion kits.

ADDENDUM

To certificate: 3821948

The management system of the organization(s) and/or location(s) of:

Edwards Lifesciences LLC

One Edwards Way
Irvine, CA 92614
United States Of America

Certified organization(s) and/or locations: continued

Location	Certification scope / Activity
Edwards Lifesciences (Singapore) Pte Ltd 35 Changi North Crescent Singapore 499641 Singapore	Production and distribution of: • biological surgical heart valves; • transcatheter heart valve systems; • transcatheter valve repair and replacement systems (implants).
Edwards Lifesciences Costa Rica S.R.L. La Lima Zona Franca, Edificio Multitenant Modulos 1-3, La Lima, Cartago, Costa Rica	Production and distribution of: • biological heart valve replacement subassemblies.
Edwards Lifesciences Costa Rica S.R.L. Zona Franca La Lima de la entrada de Pequeño Mundo 100 mts oeste y 200 mts sur, Finca 31 y 32, Guadalupe Cartago, Costa Rica	Production and distribution of: • transcatheter heart valves.
Edwards Lifesciences LTD 10 Earhart Ave Shannon Industrial Estates Shannon, County Clare V14 P638 Ireland	Production and distribution of: • transcatheter valve repair and replacement systems (implants, delivery system) and accessories (insertion accessories, loading system, dilator kit, stabilizer incl. base and plate).

Addendum expiry date: 7 January 2024
Addendum effective date: 8 June 2021