Edwards

AORTIC PERFUSION CANNULA

Instructions for Use

CAUTION: Federal law (U.S.A.) restricts this device to sale by, or on the order of, a physician.

1.0 Description

Edwards Lifesciences aortic perfusion cannulae terminate in a connector acceptance of 3/8" (9.5 mm) or 1/4" (6.3 mm). The catalog identifies models that are supplied with a 3/8" (9.5 mm), 1/4" (6.3 mm) connector, or vent plug.

Cannulae are available in wire-reinforced and non-reinforced product codes with a wide variety of tip styles, including the EZ Glide tip.

The exterior and/or inner-luminal cannula surfaces of product codes containing a "D" or "DII" are treated with Duraflo heparin.

Each Edwards Lifesciences device is packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

2.0 Indications for Use

Aortic perfusion cannulae are intended for perfusion of the ascending aorta during short-term (< 6 hours) cardiopulmonary bypass procedures. Aortic cannulae in sizes 6 Fr. (2 mm) to 18 Fr. (6 mm) can be used in pediatric patient populations.

Extracorporeal circuit components with a Duraflo treatment are intended for use in cardiopulmonary bypass when a heparin treated cannula is desired upon initial placement.

3.0 Contraindications for Use

Devices with a Duraflo treatment are contraindicated in patients with a known sensitivity to heparin.

This device is not intended for use other than as indicated and should not be used when any physical impairment would contraindicate its use.

4.0 Complications

The following complications may occur during or following use of the arterial perfusion cannula:

- Aortic dissection
- Death

5.0 Warnings and Precautions

Supplied sterile and non-pyrogenic in undamaged package. Do not use if device shows signs of damage (i.e., cuts, kinks, crushed areas, leakage), or if package is damaged or open as this may indicate compromised sterility and/or product damage.

This device is designed, intended, and distributed for single use only. Do not re-sterilize or reuse this device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing.

Products are known to contain phthalates, which may be found in device materials containing plasticizers such as DEHP and BBP. High exposure to such phthalates during medical treatments in children and pregnant or nursing women may raise a concern. A review of available data and literature supports the conclusion that the benefits outweigh the overall residual risk.

DO NOT PRECOOL the EZ Glide cannula in an ice bath prior to use. Precooling can cause the tip to become brittle and prone to damage.

Orient curved tip of the cannula to direct flow away from the aortic valve. Improper orientation may lead to patient harm or excessive line pressures. Cannula with a curved tip will have a printed orientation line on the cannula body; do not use if line is missing or illegible.

When using small diameter cannulae, do not exceed the maximum pressure limit while increasing flow. A rapid pressure rise may result.

Keep the vent plug dry prior to use. The porous vent plug is designed to vent air when dry and may not function as intended if wet.

Line pressure exceeding acceptable clinical limits may result from incorrect catheter tip position and/or restricted tip patency. Confirm proper placement to minimize risk of injury.

Wire-reinforced cannulae should be clamped in the non-reinforced section located at the connector end since clamping of the reinforced section may produce permanent cannula deformation, thereby impeding flow through the cannula and risking puncture or tearing of the cannula.

Ensure proper levels of anticoagulant therapy are maintained prior to insertion of the cannula and throughout cardiopulmonary bypass, to prevent thrombus formation on or within the cannula, and in the blood stream.

Securely tie-band the connector to cannula junction prior to initiating bypass to protect against tubing slippage.

Prior to initiating cardiopulmonary bypass, completely expel air from the system. Failure to eliminate air from the system could result in an air embolus.

Proper surgical procedures and techniques are the responsibility of the medical profession. Described procedures are provided for informational purposes only. Each physician must determine the appropriate use of this device for each patient based on medical training, experience, the type of procedure employed, and the benefits and risks associated with device use.

Dispose of used product in accordance with established hospital protocols for biohazards to minimize risk of exposure.

6.0 Directions for Use

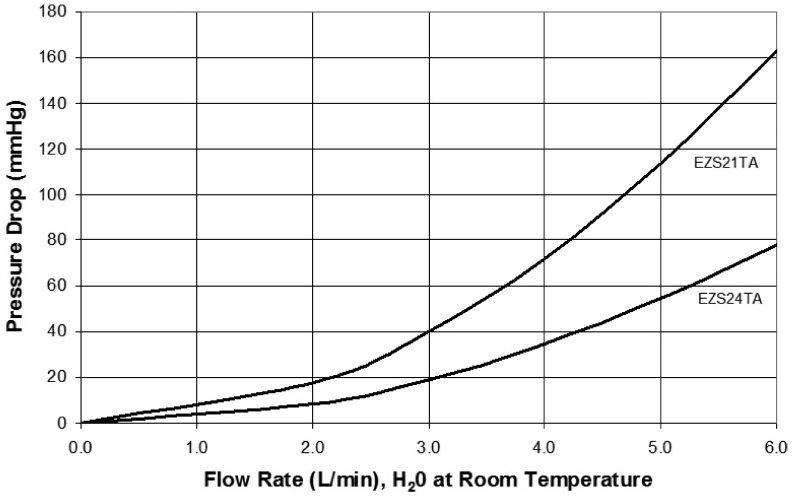
Note: If suture ring assembly is required prior to aortic cannulation, remove suture ring from pouch and slide over cannula tip to desired location.

When using small diameter cannulae, do not exceed the maximum pressure limit while increasing flow. A rapid pressure rise may result.

Step	Procedure
1	Using standard surgical technique, place cannula so that proper perfusion can take place.
2	For cannulae marked with an orientation line, tip direction is indicated by referencing the orientation mark on the cannula body in relationship to the direction of flow as it exits the cannula tip. Orient the curved tip so the flow is directed superiorly, away from the aortic valve.
3	If supplied, the white porous vent plug is designed to fit securely into the back of the lumen of aortic perfusion cannulae without a pre-attached connector. For cannulae with a pre-attached connector, the red vent cap is designed to fit securely around the connector barb. Use the appropriate porous vent plug or vent cap to ensure proper function.
4	Products that state "quick venting cap" on the label (EZQ) contain a vent cap designed to allow venting while wet. This cap may leak blood while venting.
5	Secure cannula. Connect to circuit tubing and securely tie-band all line connections.
6	Upon completion of procedure, remove cannula and repair aortotomy. Graphs of Pressure-Flow relationships are provided at the end of these instructions.

Figures

EPC001



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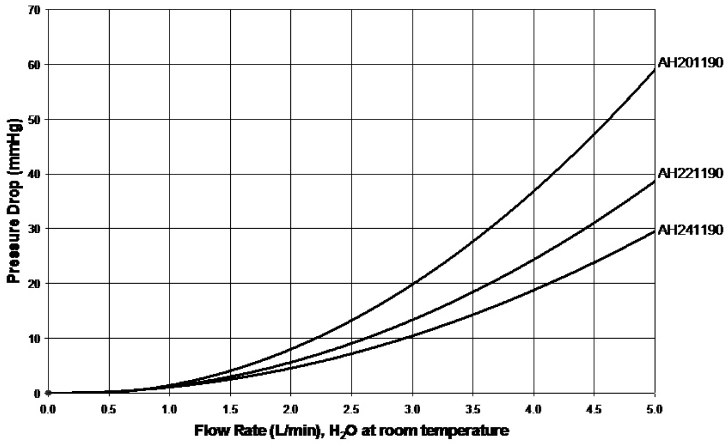

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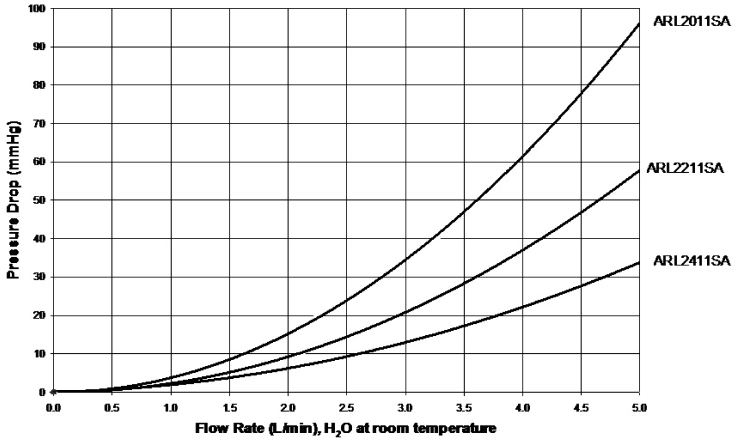

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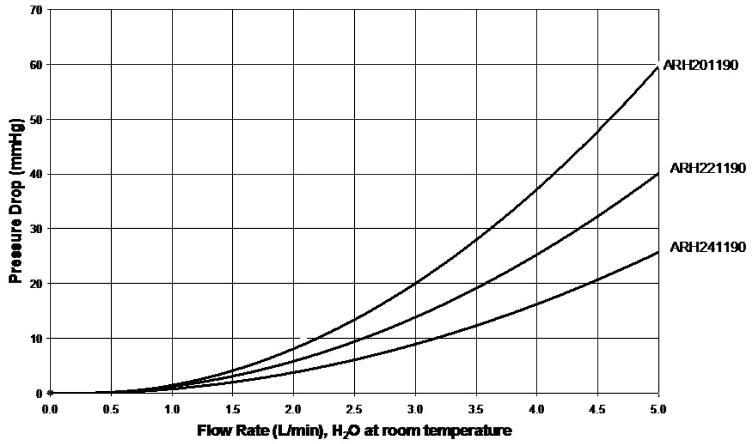

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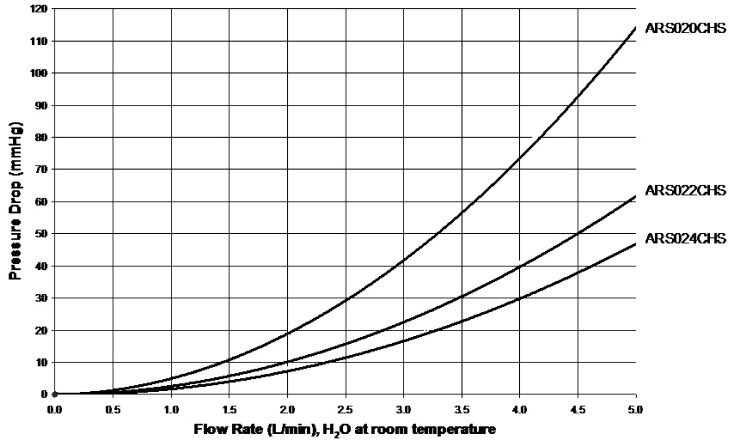

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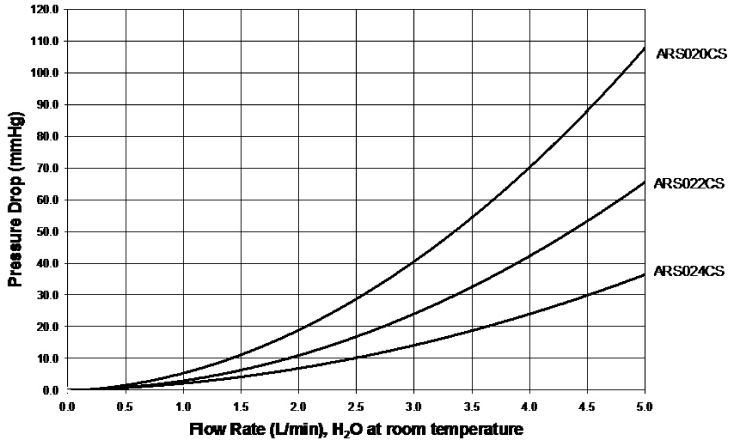

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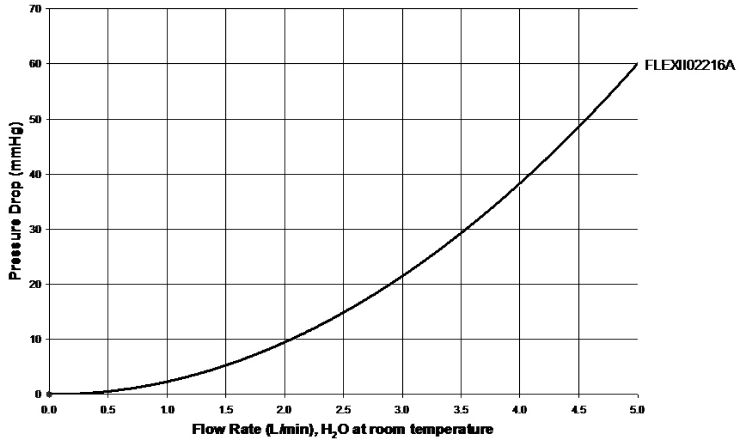

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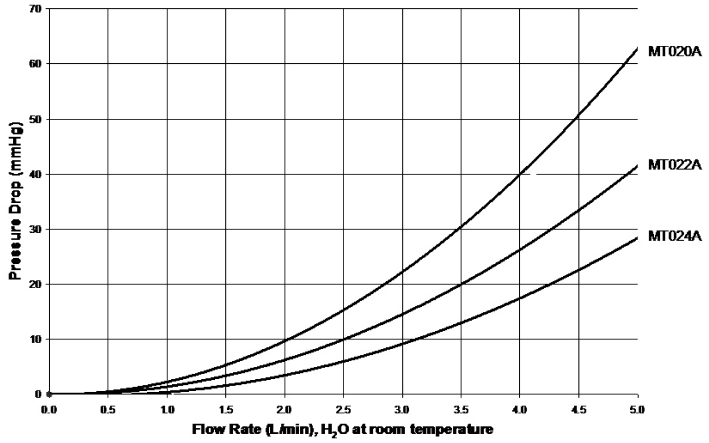

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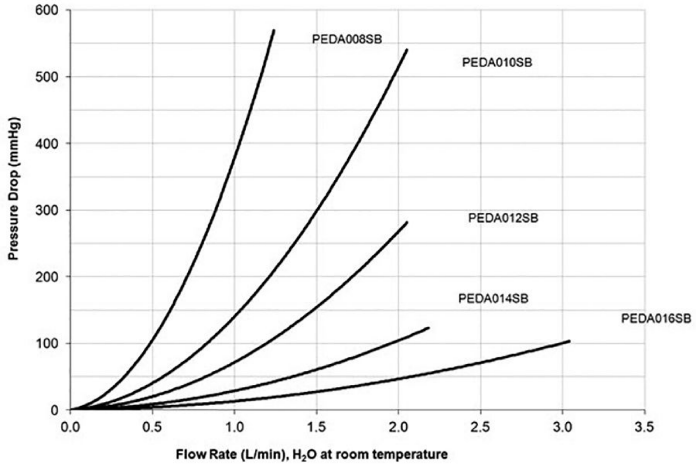

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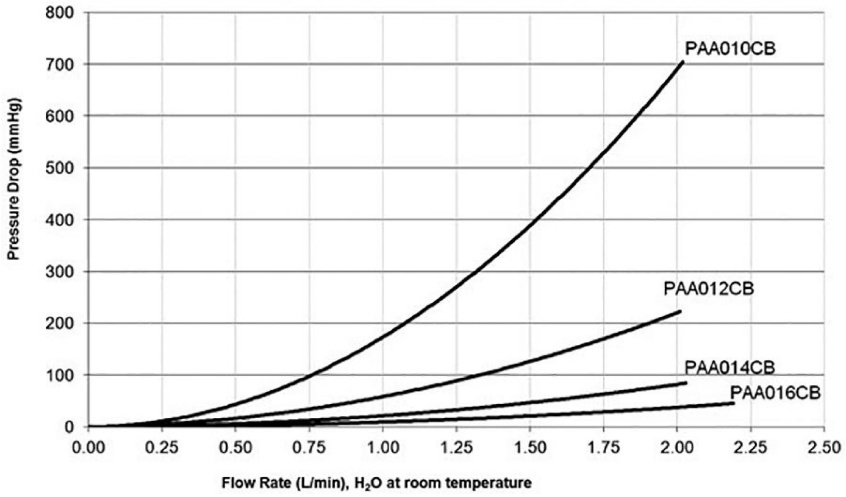
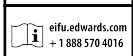
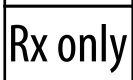

800
700
600
500
400
300
200
100
0
Pressure Drop (mmHg)
PAA010CB
PAA012CB
PAA014CB
PAA016CB
0.00
0.25
0.50
0.75
1.00
1.25
1.50
1.75
2.00
2.25
2.50
Flow Rate (L/min), H2O at room temperature

Symbol Legend

	English
	For Single Use Only
	Ethylene Oxide Sterilized
	Non-pyrogenic
	Do not use if package is damaged
	Lot Number

	English
	Use-by date
	European Authorized Representative
	Consult instructions for use on the website
	Consult instructions for use
	Caution

	English
	Manufacturer
	Quantity
	Contains phthalates
	Catalogue Number
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

Note: Not all symbols may be included in the labeling of this product.

EC REP

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