Edwards

Instructions for Use

ARTERIAL PERFUSION CANNULA

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

1.0 Description

The Edwards Lifesciences arterial perfusion cannulae have smoothly rounded tips to facilitate atraumatic insertion. The proximal ends of the cannulae are designed to accept 3/8" (9.5 mm) tubing.

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

Introducers are provided with some arterial cannulae codes. Introducers are designed for use with 0.038" (0.96 mm) guidewires. Each introducer is provided with a removable vented luer cap. Leave the vented cap in place to allow venting of the cannula for use without a guidewire. Remove the cap to allow cannula use with a guidewire.

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

2.0 Indications for Use

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.

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 Injury
- Vessel Puncture Site Hematoma

5.0 Warnings and Precautions

- Do not use if device shows signs of damage (i.e., cuts, kinks, crushed areas), or if package is damaged or open.
- 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.
- This device is intended for short-term use only (< 6 hours).
- To minimize potential vessel damage, a 45° insertion angle is recommended.
- When using small diameter cannulae, do not exceed the maximum pressure limit while increasing flow. A rapid pressure rise may result.
- When cannulating the axillary artery, dissect the artery around the brachial plexus cords carefully to avoid brachial plexus injury. Damage to the brachial plexus may lead to weakness and/or numbness in the patient's hand.
- The leg used for femoral drainage/perfusion may receive inadequate collateral circulation resulting in severe ischemia. CLOSELY MONITOR THE INVOLVED EXTREMITY FOR ANY SIGN OF DEVELOPING ISCHEMIA.
- Monitor vessel patency and hemostasis after removal of cannula.
- For cut-down procedures, directly visualize vessel during insertion and removal to minimize vessel damage.
- Use fluoroscopy and/or TEE during the procedure.
- Use guidewire to ensure proper cannula placement.
- Cannulate for femoral bypass using standard surgical techniques, including Seldinger technique and cut-down under direct visualization to ensure proper placement.
- If pressures exceed acceptable clinical limits, check the position of the device tip and/or cannula patency.
- 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.
- Dispose of used product in accordance with established hospital protocols for biohazards.
- 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.
- During cardiopulmonary bypass, ensure proper levels of anticoagulant therapy are maintained.
- Securely tie-band the connector to cannula junction prior to initiating bypass.
- If provided, the porous vent plug is designed to vent air when dry and may not function as intended if wet. Keep the vent plug dry prior to use.

6.0 Directions for Use

Using either a cut-down or Seldinger technique, cannulate patient for arterial access bypass.

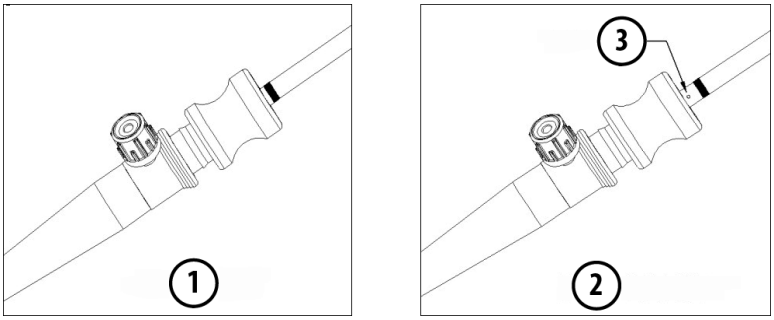
Complete standard de-airing procedures, then connect the Edwards Lifesciences arterial perfusion cannula to the arterial perfusion line.

CAUTION: Ensure that the vessel used is of adequate size to allow sufficient perfusion distal to the cannula after insertion.

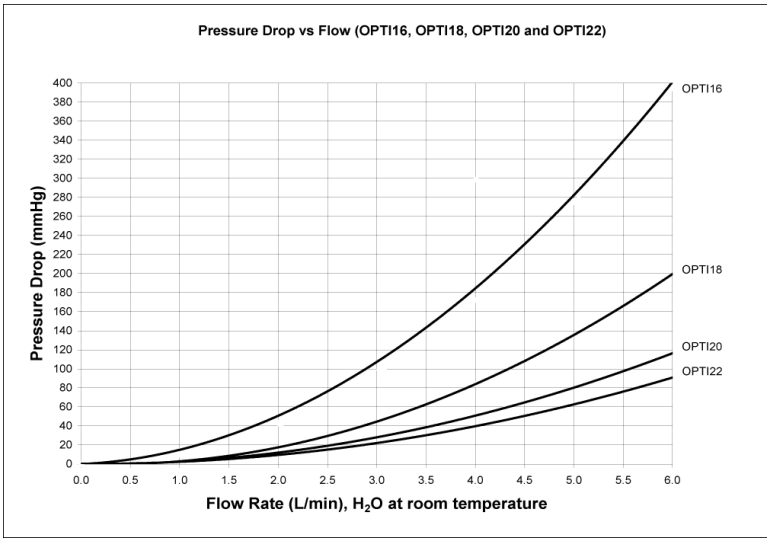
For arterial perfusion cannula provided with an introducer:

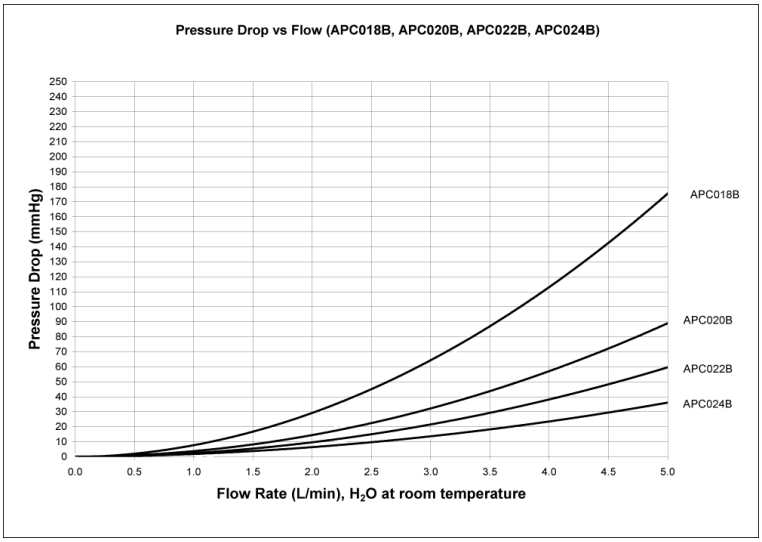
Step	Procedure
1	Insert cap/introducer into cannula. Seat red cap past second barb of connector.
2	Ensure that introducer is fully engaged in cannula by advancing introducer until locking ring engages with red cap (red cap will be flush with white introducer hub). This orientation will ensure a smooth cannula/introducer transition.
3	If a guidewire is not used, ensure that proximal porous luer vent cap is adequately secured.
4	The marking located 2 inches (5.0 cm) from tip of introducer shaft indicates when introducer tip has cleared the cannula clamping area. Once this marking is external to the red cap, clamp the cannula. **Blood spray may occur** if the cannula is not clamped and the introducer's vent holes are exposed (see graphic below).
5	Following cannula placement and introducer removal, cannula may be clamped in the area between the wire reinforcement and the 3/8" (9.5 mm) connector. Remove red cap from end of connector prior to connection to extracorporeal circuit.

Figures



1. CORRECT
2. INCORRECT
3. VENT HOLE





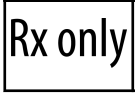
EN.

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

Symbol Legend

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

	English
	Use By
	Consult instructions for use
	Consult instructions for use on the website
	Caution

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

EC REP

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