RETROGRADE CORONARY SINUS CARDIOPLEGIA CATHETER WITH SEMI-RIGID CURVED STYLET

Instructions for Use

Directory

English (EN)

Retrograde Coronary Sinus Cardioplegia Catheter With Semi-Rigid Curved Stylet

Instructions for Use

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

DESCRIPTION

Edwards Lifesciences retrograde cardioplegia, Retroplegia, and Retroplegia II catheters are dual lumen catheters with self-inflating smooth or textured occlusion balloons. The self-inflating balloon surrounding the distal catheter body (proximal to the infusion holes) inflates in response to the differential pressure that is created within the catheter during infusion. The balloon deflates spontaneously when flow is stopped. The distal tip contains multiple infusion holes and an opening into the separate pressure monitoring lumen which extends from the soft tip to a 3-way stopcock at the proximal end. A curved, semi-rigid or malleable insertion stylet is provided with each catheter.

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

INDICATIONS FOR USE

Retrograde coronary sinus cardioplegia catheters are intended for delivery of blood or cardioplegia solution intraoperatively to avoid cardiac damage and aid in myocardial protection.

CONTRAINDICATIONS FOR USE

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

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.

Pre-inflate all catheter balloons with sterile saline to ensure proper balloon inflation per directions (below).

To avoid entry of air into right atrium or coronary sinus, place catheter prior to initiation of full bypass.

Cardiac arrhythmias may occur when catheter is introduced into the coronary sinus. Monitor ECG for any indication of patient intolerance.

To minimize trauma to the coronary sinus, exercise care during placement of the catheter and manipulation of the heart while the catheter is in place.

Reinsert stylet only if tip of device is visible to avoid potential vessel damage.

To prevent tissue damage, take care when repositioning the catheter and do not reposition the catheter with the balloon inflated.

Air remaining in pressure lumen will result in a dampened pressure waveform.

To minimize the risk of coronary sinus injury, maintain sinus pressure at no greater than 50 mmHg.

Flows in excess of 120 ml/min may result in balloon overinflation and/or coronary sinus injury.

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.

To ensure accurate pressure readings, periodically flush pressure line in accordance with standard pressure monitoring techniques.

Vent the aorta or left ventricle during retrograde cardioplegia infusion to prevent distension and possible injury to the left ventricle.

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.

This device is intended for short-term use only (≤ 6 hours). There are no data to support the function and performance of the device beyond six hours of use.

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.

COMPLICATIONS

The following complications may occur during or following use of this device:

- Injury to the coronary sinus
- Infection
- Bleeding
- Insufficient perfusion of cardioplegia
- Pulmonary embolism
- Arrhythmia

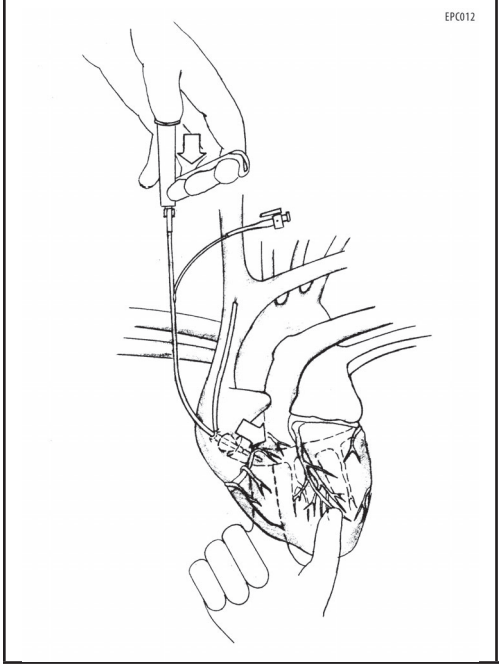
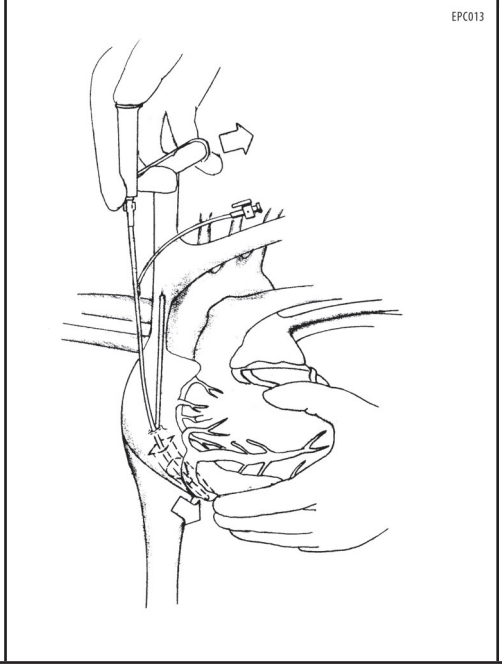
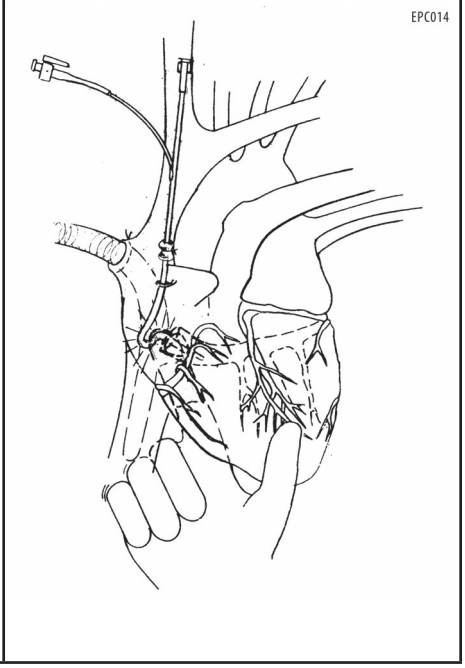
DIRECTIONS FOR USE

1. To ensure proper function of self-inflating balloon, remove introducer stylet, occlude distal tip of cannula, and inflate balloon using a sterile saline solution until balloon inflates. Replace stylet.
2. Flush air from the pressure lumen using a sterile saline solution and close the 3-way stopcock to hold prime or connect to a primed and calibrated monitoring line to monitor pressure.
3. Place a separate small purse string suture with a tourniquet into the lower right atrium opposite the coronary sinus orifice.
4. INSERT THE RETROGRADE CATHETER INTO THE CORONARY SINUS:
   Note: The retrograde catheter can be placed in the coronary sinus from the patient's right side (Diagram A) or from the patient's left side (Diagram B).
   a) Make an incision (0.5 cm) in the center of the purse string suture for insertion and control bleeding with the tourniquet.
   b) Release the tourniquet and insert the retrograde catheter through the incision in the center of the purse string until the balloon is fully within the atrium.
   c) Snug the tourniquet gently to prevent bleeding through the insertion site. Do not over tighten because the catheter must be advanced further.
   d) Place a hand on the diaphragmatic surface of the heart with the index and long fingers placed to adequately palpate the coronary sinus.
   e) Advance the retrograde catheter toward the coronary sinus and as the catheter tip enters the coronary sinus; it will be felt by the fingers. Using these fingers, guide the tip into the coronary sinus.
   f) Remove the insertion stylet while holding the catheter in place close to the purse string to prevent movement and clamp off the retrograde catheter above the junction with the pressure line.

   Note: Dark, pulsatile blood issuing from the catheter confirms placement in the coronary sinus.
5. Slide moveable suture ring to desired location and secure catheter to the tourniquet with a suture.
   Note: DO NOT OCCLUDE PRESSURE MONITORING LINE.
   Note: Once secured in this manner, double-check the placement of the catheter (Diagram C).
6. Connect pressure line stopcock to a primed and calibrated monitoring line to monitor pressure. Turn stopcock handle to open the line if it was previously turned closed and de-air.
7. Attach a 10 ml (minimum) syringe to the female luer, open clamp and slowly aspirate enough blood to fill the cannula. Re-clamp.
8. Connect cardioplegia line to infusion lumen female luer connector and unclamp retrograde catheter.
9. Verify correct placement and confirm catheter position in the coronary sinus during initial and all subsequent infusions by continuously monitoring coronary sinus pressures. Continually monitor coronary sinus pressures during infusion. Coronary sinus pressure less than 20 mmHg may indicate malposition of the device or balloon loss of integrity. If coronary sinus pressure is below 20 mmHg, one or more of the following steps should be taken:
10. By direct vision or palpation:
    a) Advance the cannula approximately one centimeter further into the coronary sinus.
       Note: Reaffirm that the coronary sinus pressure drops below 20 mmHg when infusion is stopped to assure tip patency.
    b) If pressure remains below 20 mmHg during infusion, stop infusion, remove the cannula. Then occlude distal tip and pressurize the cannula to verify balloon inflation.
    c) Reinsert cannula.

REMOVAL

Prior to releasing the aortic cross clamp, remove all fluid from the balloon. The catheter may be removed per surgeon protocol.

A	B	C
		

SYMBOL LEGEND

								
EN	Single use	Sterilized Using Ethylene Oxide	Non-pyrogenic	Do not use if package is damaged	Lot Number	Use By	Authorized Representative in the European Community	Date of Manufacture

							Rx Only
EN	Consult instructions for use	Caution	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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