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 coronary sinus cardioplegia catheters are triple lumen catheters that include a manually inflated/ deflated smooth or textured occlusion balloon with a check valve and pilot (safety) balloon at the inflation port. A separate pressure monitoring lumen extends from the soft, open 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.

The pressure monitoring and balloon inflation lines are affixed to the catheter body by a piece of white paper tape. Remove and discard tape prior to device use. DO NOT CUT THE TAPE: DAMAGE TO THE CATHETER COULD RESULT.

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.

Monitor cardioplegia line pressure while infusing to minimize the 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 reduce the risk of complications due to 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. Prior to catheter insertion, insert an appropriate sized syringe (to match balloon size) into the check valve and test the balloon with air or saline. (Refer to the Balloon Inflation Table below). Visually examine the blue pilot balloon for inflation indicating proper inflation of the manually inflating coronary sinus balloon. If the pilot balloon fails to remain inflated, replace catheter. If saline is used for inflation, note that balloon expansion will be approximately 25% greater. Do not inflate manually inflated balloon with more volume than balloon size, 3 cc of AIR is equal to 2.25 cc of saline and 5 cc of AIR is equal to 3.75 cc of saline.
2. Remove cap, if present on pilot balloon check valve. Withdraw all of the air from the balloon and remove the syringe from the luer check valve to maintain the balloon in a completely deflated condition before insertion.
3. Flush and fill the pressure monitoring lumen using a sterile saline solution prior to placement. If desired, the 3-way stopcock may be closed to hold prime or connected to a primed and calibrated monitoring line to monitor pressure.
4. Place a separate small purse string suture with a tourniquet into the lower right atrium opposite the coronary sinus orifice.
5. 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.
6. 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).
7. 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.
8. Attach a 10 ml (minimum) syringe to the female luer, open clamp and slowly aspirate enough blood to fill the cannula. Re-clamp.
9. Connect cardioplegia line to infusion lumen female luer connector and unclamp retrograde catheter.
10. 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 loss of balloon integrity. If coronary sinus pressure is below 20 mmHg, one or more of the following steps should be taken:
11. By direct vision or palpation:
    a) Following aortic cross clamping, inject air or saline into the balloon infusion port according to the instructions in the following Table. Inflate the balloon to a volume that provides appropriate occlusion of the coronary sinus and confirm by monitoring pressure. DO NOT INFLATE BEYOND THE POINT OF RETENTION IN THE CORONARY SINUS. Visually examine the blue pilot balloon for inflation which indicates inflation of the coronary sinus balloon. Should the pilot balloon fail to hold inflation, replace catheter.

Table 1: BALLOON INFLATION TABLE

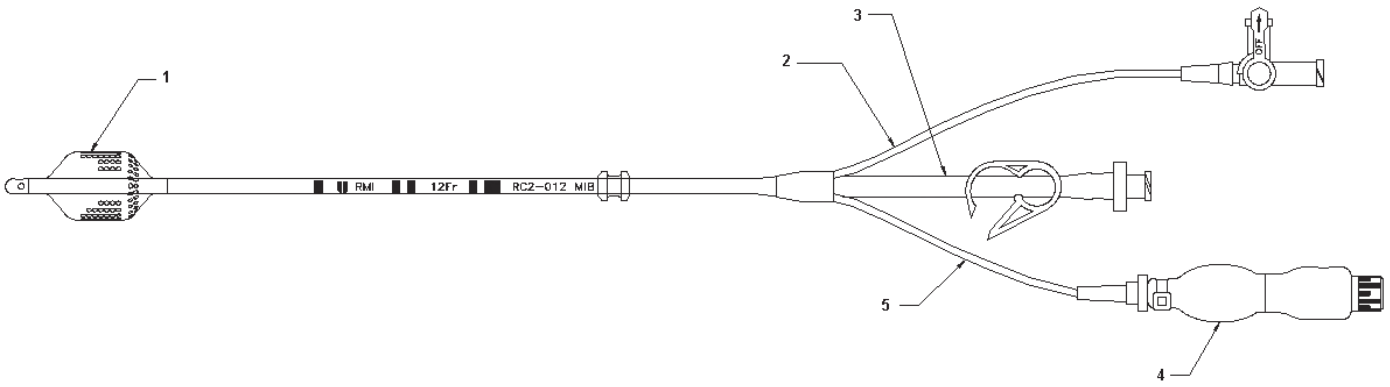
Using the syringe, remove air from the balloon, then fill the balloon using the following chart			
Catalog Part Numbers *Manually Inflated Versions Only	**Balloon**	**Air or Saline****	**Balloon Inflation Instructions**
RC014* PLD014* SRT014	Smooth Smooth Textured Smooth	3 ml Air or Saline	3 ml is recommended
RC2012* RC2014*	18 mm Smooth 18 mm Smooth	5 ml Air only	3 ml of air leaves balloon slightly under inflated and very soft 4 ml of air fully inflates balloon to approximately 18 mm diameter 5 ml inflates balloon to approximately 19 mm diameter & firm
**** Note: Balloon Expansion Will Be 25% Greater Using Saline Than With Air.**			

   b) Slowly start cardioplegia infusion and increase the infusion rate per surgeon protocol.
   c) The pressure in the coronary sinus must rise. If it does not, the catheter is not in the coronary sinus and must be repositioned.
12. Confirm catheter position in the coronary sinus during initial and all subsequent infusions by continuously monitoring the coronary sinus pressures or palpation of the coronary sinus (Diagram C).

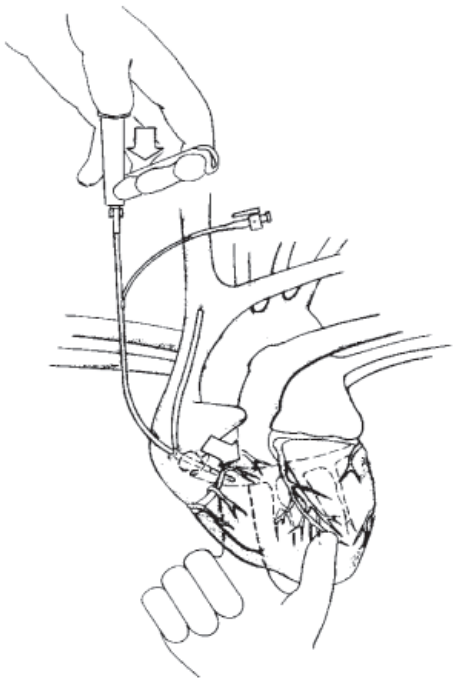
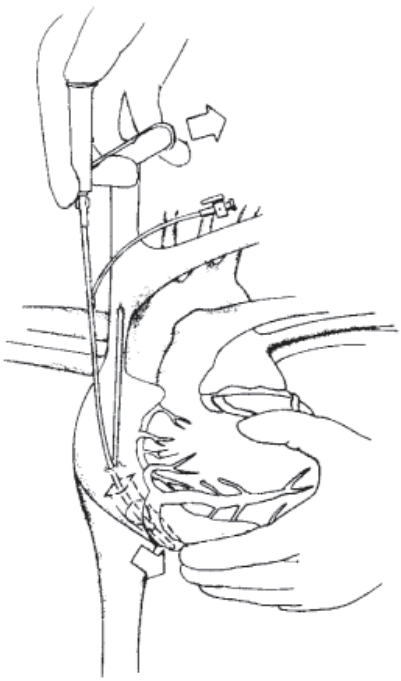
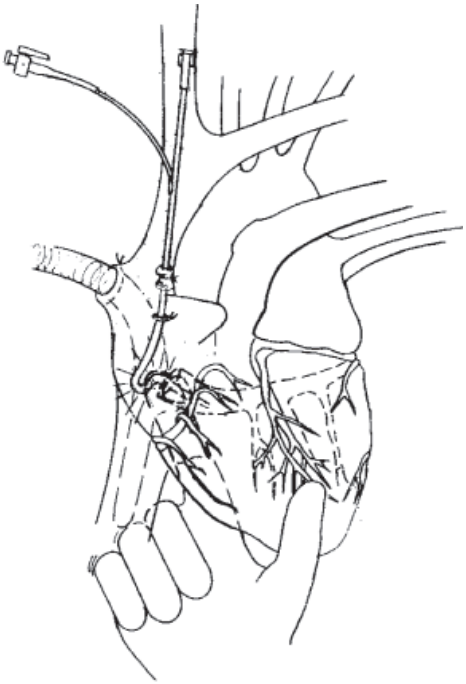
REMOVAL

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

EPC011



	1	2	3	4	5
EN	Manually inflated balloon	Pressure monitoring line	Main lumen	Pilot Balloon	Manually inflated balloon line

A	B	C
EPC012 	EPC013 	EPC014 

SYMBOL LEGEND

							
EN	Single use	Sterilized Using Ethylene Oxide	Non-pyrogenic	Do not use if package is damaged	Lot Number	Use By	Date of Manufacture

SYMBOL LEGEND

							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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