PROPLEGE PERIPHERAL RETROGRADE CARDIOPLEGIA DEVICE

Instructions for Use

Directory

English (EN)

ProPlege Peripheral Retrograde Cardioplegia Device

Instructions for Use

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

See Figures at the end of the Instructions for Use.

DESCRIPTION

The ProPlege peripheral retrograde cardioplegia device (ProPlege device) is a 9 Fr (3.1 mm), 59 cm long, triple-lumen, articulating device with an elastomeric balloon near its tip for occluding the coronary sinus for retrograde perfusion of the coronary circulation (see Figure 1). The balloon is expandable to occlude a range of coronary sinus diameters. The large central lumen of the ProPlege device serves to deliver cardioplegic solution to the coronary sinus. The two additional lumens serve as conduits for balloon inflation and coronary sinus pressure monitoring distal to the balloon. To assist in device placement, the shaft is imprinted with a deflection orientation line and marked at 5 cm intervals beginning 15 cm from the tip of the device and features an articulation mechanism which changes the curvature of the distal end when the positioning dial is pulled (see Figures 2, 3, 4). The ProPlege device is protected by a contamination guard, which allows for device manipulation without directly contacting the catheter shaft. A distal connector allows for connection of the contamination guard to a Cordis (R) AVANTI+(R) 11 Fr (3.7 mm) introducer, which provides access to the central venous circulation to facilitate device and guidewire insertion.

The ProPlege device is packaged with the following accessories (see Figure 1):

- 3-way stopcock with blue handle connected to the inflation / deflation extension line of the ProPlege device for controlling the fluid pathway to the balloon inflation lumen
- 3-way stopcock with white handle connected to the pressure monitoring extension line of the ProPlege device for controlling the fluid pathway to the pressure monitoring lumen
- 3-way stopcock with green handle connected to the cardioplegia hub of the ProPlege device for controlling the fluid pathway to the cardioplegia lumen
- 30 mL syringe for flushing and priming the ProPlege device and contrast injection
- 3 mL syringe for balloon inflation / deflation
- Hose barb adapter to connect the cardioplegia line to cardioplegic pump solution line
- Hemostasis valve adapter for guidewire placement (guidewire not provided)

HOW SUPPLIED

STERILE and NON-PYROGENIC in unopened, undamaged package. Do not use if device shows signs of damage (i.e., cuts, kinks, crushed areas), or if package is damaged or open.

Note: All blood contacting components are supplied phthalate free.

INDICATIONS FOR USE

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

COMPLICATIONS

The following complications may occur during or following use of the ProPlege device:

- Injury to the internal jugular vein including perforation
- Injury to the vena cavae or right atrium
- Injury to the coronary sinus including perforation
- Injury to the tricuspid valve
- Injury to the right ventricle including perforation
- Pneumothorax
- Arrhythmia
- Hemorrhage
- Infection / sepsis
- Pain at the insertion site
- Hematoma at insertion site
- Venous thrombosis
- Embolism
- Cardiac failure
- Death
- Reaction to contrast media (refer to contrast media manufacturer's package insert for appropriate use and risks)

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

WARNINGS AND PRECAUTIONS

FOR SINGLE USE ONLY. 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, non-pyrogenicity, and functionality of the device after reprocessing. Such action could lead to illness or an adverse event, as the device may not function as originally intended.

Patients with fragile tissue and/or abnormal anatomy may be more prone to coronary sinus injury.

Ensure proper levels of anticoagulant therapy are maintained prior to insertion of the device and throughout cardiopulmonary bypass, to reduce the risk of complications due to thrombus formation on or within the device, and in the blood stream.

Failure to administer anticoagulants may result in formation of thrombus on or within the ProPlege device.

Once placed in the body, the device should only be manipulated while being observed using fluoroscopy and/or ultrasound imaging and while monitoring pressure at the device tip. Failure to do so may result in vessel damage and/or device damage.

Care should be used when handling the devices. Damage may result from kinking or stretching the devices.

The distal end of the ProPlege device should not be directly manipulated in an effort to change the curvature as damage to the device may occur.

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 to blood borne pathogens.

INSTRUCTIONS FOR USE

REQUIRED EQUIPMENT

The ProPlege device should only be used in an operating room equipped for cardiac surgery. Additional equipment should include:

- Pressure transducer line
- Cordis (R) AVANTI+(R) 11 Fr (3.7 mm) introducer
- Heparinized saline solution
- Ultrasound Imaging and/or fluoroscopy capabilities
- Cardiopulmonary bypass pump capable of delivering cardioplegia solution
- Radiopaque contrast medium, diluted with heparinized saline at a 6:1 physiological sterile solution : contrast ratio for balloon inflation (note - this is only for use with fluoroscopy and not needed if only ultrasound imaging is used)
- Pressure transducer and monitor

WARNING: Failure to dilute the contrast media as recommended may result in formation of crystals of contrast medium that could delay or prevent balloon deflation.

HANDLING AND PREPARATION

Follow sterile techniques during device preparation and use.

PREPARE THE PROPLEGE DEVICE FOR USE

Visually examine the ProPlege device and sterile packaging for evidence of damage (e.g. rips, tears, etc.). If damaged, DO NOT USE.

1. Remove all components from the package and place on sterile prep table.
2. Visually inspect all the components for damage. Do not use if there are signs of damage.
3. Make sure that all pre-assembled luer connections are tight.
4. Articulate the tip with the positioning dial to ensure the device is functioning properly.
5. Prime the balloon and lumens:

   Note: When shipped, all lumens, including the balloon lumen, contain air. This air must be displaced prior to insertion to ensure that only fluid fills these lumens. This is accomplished in the following manner:

   - Attach the empty 3 mL syringe to the blue stopcock on the balloon inflation port. Withdraw the syringe plunger to remove the air in the balloon. Turn the blue stopcock position "off" to the balloon lumen.
   - Fill the 3 mL syringe with heparinized saline solution and attach it to the blue stopcock on the balloon inflation port. Inflate the balloon with a maximum of 1.4 mL of heparinized saline solution to verify proper inflation.

   WARNING: Do not exceed maximum inflation volume of 1.4 mL as balloon burst may occur.

   - Gently inject and aspirate small amounts of heparinized saline solution (1.4 mL) until all air is removed from the balloon and the balloon inflation lumen. Point the ProPlege device tip upward to facilitate this process.
   - With the syringe fully withdrawn, turn the stopcock position "off" to the balloon lumen.
   - Verify that the balloon is collapsed for balloon insertion through the introducer sheath. Check the balloon just prior to insertion to ensure that the vacuum has been maintained.

   CAUTION: If the balloon vacuum is lost, check the ProPlege device and accessories for leaks before inserting the ProPlege device. Failure to do so may result in unexpected balloon deflation and loss of occlusion.

   WARNING: Air left in the balloon may embolize if the balloon ruptures. Air left in any lumen may embolize during or after device insertion.

   - Attach the 30 mL syringe filled with heparinized saline solution to the white stopcock on the pressure monitoring lumen. Flush the pressure monitoring lumen with heparinized saline solution to remove air. Turn the white stopcock position "off" to the pressure monitoring lumen, then remove the 30 mL syringe.
   - Attach the 30 mL syringe filled with heparinized saline solution to the green stopcock on the cardioplegia infusion lumen. Flush the cardioplegia infusion lumen with heparinized saline solution to remove air. Turn the green stopcock position "off" to the cardioplegia lumen, then remove the 30 mL syringe.

INSERTING THE PROPLEGE DEVICE

1. Administer anticoagulants as appropriate according to hospital protocol.
2. Attach a pressure transducer line to the white stopcock on the pressure monitoring port of the ProPlege device.
3. Flush the pressure transducer to remove any air. Calibrate the transducer, then open the stopcock to the device to begin recording pressure.
4. Insert the ProPlege device through the introducer sheath with the handle in the introduction position (positioning dial pushed all the way forward) (see Figure 2). Insert device up to the first depth marker.

   WARNING: If resistance is met, stop and re-evaluate ProPlege device position. The ProPlege device should not be advanced if resistance is felt, as doing so would cause the ProPlege device to bend or buckle. Aggressive advancement in an attempt to engage the ostium may result in perforation or other injury.

POSITIONING THE PROPLEGE DEVICE

POSITIONING USING ULTRASOUND IMAGING AND PRESSURE MONITORING:

1. Position the ultrasound imaging probe to obtain a mid-esophageal bicaval view. Transition to a modified bicaval view, which will typically include the superior vena cava and coronary sinus (see Figure 5). Alternatively, a deep four chamber view will show the right atrium, right ventricle and the ostium of the coronary sinus (see Figure 6). These are optimal views for guiding the ProPlege device into the ostium of the coronary sinus.
2. Once the ProPlege device can be seen in the right atrium, advance gently while applying counter clockwise torque to align the curve of the device with the intra-atrial septum to place the ProPlege device tip at the ostium of the coronary sinus.

   WARNING: Continuously monitor the pressure at the tip of the device. A pressure change that indicates the device has entered the right ventricle should be noted. Do not advance the device further if the tip is in the right ventricle as perforation or other injury can occur.

3. Place the ProPlege device tip in the optimal engagement position (see Figure 3) by pulling on the positioning dial until it aligns with the mark on the handle. If engagement of the ostium cannot be obtained, further pulling on the positioning dial into the additional articulating position (see Figure 4) will increase the curve of the tip. Use small, slow, and deliberate movements to engage the ostium.

   Note: Once the positioning dial is released, the device will return to the optimal engagement position. The positioning dial may also be pushed forward into the introduction position to achieve less curvature of the distal tip, if the anatomy dictates less curvature.

POSITIONING USING FLUOROSCOPY AND PRESSURE MONITORING:

1. While monitoring pressure at the ProPlege device tip, advance the device into the right atrium. With the device tip pointed posteriorly, advance the device to the level of the tricuspid valve. Position the device tip in the optimal engagement position (see Figure 3) by pulling on the positioning dial until it aligns with the mark on the handle.
2. Slowly withdraw and gently advance the ProPlege device until the coronary sinus is engaged. If the tricuspid valve is crossed and the pressure indicates ventricular pressure, rotate the device tip posteriorly with a counter-clockwise rotation and slowly withdraw until atrial pressure returns. Advancing the device in this plane usually results in the placement of the device tip into the coronary sinus. Placement in the coronary sinus is indicated by constant atrial pressure as the device is advanced across the cardiac shadow. If engagement of the coronary sinus cannot be obtained, further pulling on the positioning dial (see Figure 4) will increase the curve of the tip. Use small, slow, and deliberate movements to engage the ostium. Note: Once the positioning dial is released, device will return to the optimal engagement position (see Figure 3). The positioning dial may also be pushed back into the introduction position to achieve less curvature of the distal tip, if the anatomy dictates less curvature.

   WARNING: The device should not be advanced when the tip is in the right ventricle to reduce the risk of ventricular perforation.

3. Once the ProPlege device is engaged in the coronary sinus, positioning can be assessed by the following technique:

   A straight AP view will show the device in a reversed "J" shape crossing the cardiac shadow.

   Note: Additional fluoroscopic views may provide further information concerning device position (e.g. 30° RAO, 30° LAO).

4. A non-occlusive venogram can be performed to assess coronary anatomy by performing the following:

   - Fill the 30 mL syringe with a 1:1 ratio of contrast and heparinized saline

solution.

- Ensure that the tip of the device is within the coronary sinus.
- Under fluoroscopic guidance, inject contrast through the cardioplegia stopcock. Small volumes (5 - 10 mL) of contrast per imaging loop are typically sufficient to identify the borders of the coronary sinus.

CAUTION: To ensure proper use, follow the contrast medium manufacturer's insert thoroughly.

Note: Recommended for use with a water soluble contrast medium intended and approved for venography.

POSITIONING: USING A GUIDEWIRE FOR CORONARY SINUS ADVANCEMENT

Note: The ProPlege peripheral retrograde cardioplegia device is designed to be used with a soft tip .035" (.89 mm) guidewire with a minimum length of 100 cm.

WARNING: Guidewire assisted device advancement should only be performed with fluoroscopic monitoring of adjustments to either guidewire or device position. Failure to do so may result in perforation or other injury.

1. Remove the hose barb from the green stopcock at the back end of the ProPlege device (place on sterile field for future use).
2. Attach the hemostasis valve adapter to the stopcock (see Figure 1, item 19).
3. Turn the stopcock position to the opposite side to the sideport (see Figure 8).
4. Insert a guidewire through the hemostasis valve adapter and advance the guidewire through the device until the guidewire reaches the device tip. Tighten hemostasis valve adapter as needed to reduce the risk of blood loss while maintaining ability to move guidewire as necessary.
5. Ensure that the tip of the ProPlege device is placed at the coronary sinus ostium or engaged in the coronary sinus. If the guidewire is engaged in the coronary sinus, ensure that the tip of the ProPlege device is not forcefully contacting the wall of the coronary sinus (e.g. withdraw slightly under fluoroscopic guidance until device bowing is removed and the tip is aligned with the desired direction of device advancement).
6. Gently advance the guidewire past the tip of the ProPlege device into the coronary sinus. Slightly retract the ProPlege device and then re-advance the ProPlege device over the guidewire into the coronary sinus.

   WARNING: Guidewire should only be used with fluoroscopy to avoid coronary sinus injury.

   WARNING: Aggressive advancement of the guidewire in an attempt to engage the ostium may result in perforation or other injury.
7. Once the tip of the ProPlege device is in place, remove the guidewire.
8. Turn the green stopcock position "off" towards the tip of the catheter and remove the the hemostasis valve. Reconnect the hose barb adapter to the green stopcock.

CONFIRMING PLACEMENT OF THE PROPLEGE DEVICE WITHIN THE CORONARY SINUS / DETERMINING BALLOON INFLATION VOLUME

CAUTION: Coronary sinus sizes are variable and require different balloon diameters for occlusion. In addition, complete occlusion of the coronary sinus is not essential for cardioplegia delivery. Balloon inflation volumes should be based on ventricularization of the pressure wave form within the coronary sinus or via contrast injection.

WARNING: Overinflation may result in injury to the coronary sinus. If the patient becomes hemodynamically unstable, the possibility of pericardial tamponade may be assessed with appropriate ultrasound imaging views (e.g. midesophageal 4 chamber, midesophageal 2 chamber, etc.).

Note: Inflation volumes exceeding 1 mL are unusual for coronary sinus occlusion unless the coronary sinus is abnormally large. For a graph showing the approximate relationship between inflation volume and balloon outer diameter, see Figure 7.

WARNING: Do not exceed maximum inflation volume of 1.4 mL as balloon burst may occur.

WARNING: The contrast medium manufacturer's insert should be followed thoroughly.

1. Attach a 3 mL syringe filled with 1.4 mL of 1:6 (contrast : saline) diluted contrast to the blue stopcock on the balloon inflation lumen.
2. Inflate the balloon slowly and incrementally with active observation of coronary sinus pressures. Pressure wave form changes can take a few seconds to manifest.
3. Stop inflating the balloon at the first sign of ventricularization. Inflation volumes in excess of 1 mL are unusual unless the coronary sinus appears to be abnormally large. Turn the blue stopcock handle "off" to the balloon lumen to maintain inflation.

   WARNING: Do not exceed maximum inflation volume of 1.4 mL as balloon burst may occur.
4. To confirm placement via an occlusive venogram:
   - Fill the 30 mL syringe with 1:1 ratio of contrast and heparinized saline solution.
   - Connect the syringe to the cardioplegia lumen stopcock.
   - Under fluoroscopic guidance, inject contrast through the cardioplegia stopcock. Small volumes (5-10 mL) of contrast per imaging loop are often sufficient to identify the borders of the coronary sinus.
   - Using fluoroscopy, ensure that the balloon adequately occludes the coronary sinus, and that contrast is distributed throughout the coronary vasculature.

   WARNING: The contrast medium manufacturer's insert should be followed thoroughly.
5. Ensure that the ProPlege device tip is in the desired location within the main lumen of the coronary sinus. If repositioning of the device tip is required, deflate balloon prior to adjustment.

   Note: Injection of contrast via an occlusive venogram will display details of coronary venous anatomy, including whether the ProPlege device is positioned in the main lumen or a side branch.
6. After final positioning is achieved, attach the distal connector to the introducer sheath.
7. To reduce the risk of device movement, twist the locking mechanism so that the two halves (proximal and distal) align.
8. Keep the catheter in its introduction position.
9. Flush cardioplegia lumen with heparinized saline per hospital protocol and turn stopcock "off" to the cardioplegia lumen.

PROPLEGE DEVICE PERFUSION TECHNIQUE

WARNING: Do not arbitrarily re-inflate the balloon with the volume used previously, as this may cause the ProPlege device to migrate during surgical manipulation and decompression of the heart. Overinflation may result in injury to the coronary sinus. Underinflation may cause inadequate occlusion.

1. Remove the cap of the hose barb adapter. Attach retrograde cardioplegia solution tubing to the hose barb or remove the hose barb and connect a male luer to the female luer on the green stopcock connection.
2. Remove the cap on the sideport of the green stopcock, turn the green stopcock position "off" to the patient, and flush line with cardioplegic solution until all air is removed from the stopcock. Replace the cap on the sideport.
3. Turn the green stopcock position "off" to the sideport and open to the ProPlege device lumen. Start retrograde perfusion at a low flow rate (< 50 mL/min).
4. Increase flow while observing pressure. Do not exceed 40 mmHg. If flow cannot be increased to acceptable levels without exceeding 40 mmHg, the ProPlege device may be placed too deep within the coronary sinus. If this occurs, stop perfusion, deflate the balloon, retract the ProPlege device approximately 1 cm, and inflate the balloon as previously instructed. Begin cardioplegia infusion as previously instructed.

   WARNING: High cardioplegia line pressure at low flow rates and/or inadequate delivery of cardioplegic solution may indicate excessively deep placement of the ProPlege device within the coronary sinus or within a side branch of the coronary sinus. This may increase the risk of inadequate myocardial protection and/or vascular damage.

   WARNING: Careful monitoring of the electrocardiogram (ECG) will demonstrate the effectiveness of cardioplegia. Early return of cardiac activity suggests either inadequate initial cardioplegia or inadequate coronary sinus occlusion, which may increase the risk of inadequate myocardial protection. Inadequate coronary sinus occlusion is often associated with low coronary sinus pressure.
5. Repeat infusions of cardioplegic solution may be given to maintain arrest and myocardial cooling.

WITHDRAWING THE PROPLEGE DEVICE

1. ProPlege device removal should occur prior to or coincident with the reversal of anticoagulation.
2. Fully deflate balloon by pulling vacuum with the 3 mL syringe twice. Unlock the distal connector from the device shaft; place the positioning dial in the introduction position (see Figure 2). Withdraw the device until the contamination guard is fully extended, disconnect the distal connector from the introducer sheath, and completely remove the ProPlege device from the introducer.

   Note: If there is a reduction in valve hemostasis, insert the tip of the catheter into the valve and withdraw it slowly.

   WARNING: If resistance is felt when removing the catheter through the catheter introducer sheath, do not exert excessive force. Verify that the balloon is fully deflated and the stopcock is closed. If necessary, position the fluoroscope over the heart, and then remove the catheter and catheter introducer sheath as a unit to reduce the risk of damage to the catheter or injury to the patient.

   WARNING: The ProPlege device must be removed when anticoagulant therapy is neutralized. Failure to do so may produce thrombus and thrombo-embolism.
3. Dispose of used product in accordance with established hospital protocols for biohazards.

STORAGE AND HANDLING

Store sterile packaged device in a cool, dry place until ready to use. Do not expose to organic solvents, ionizing radiation, or ultraviolet light.

TECHNICAL ASSISTANCE

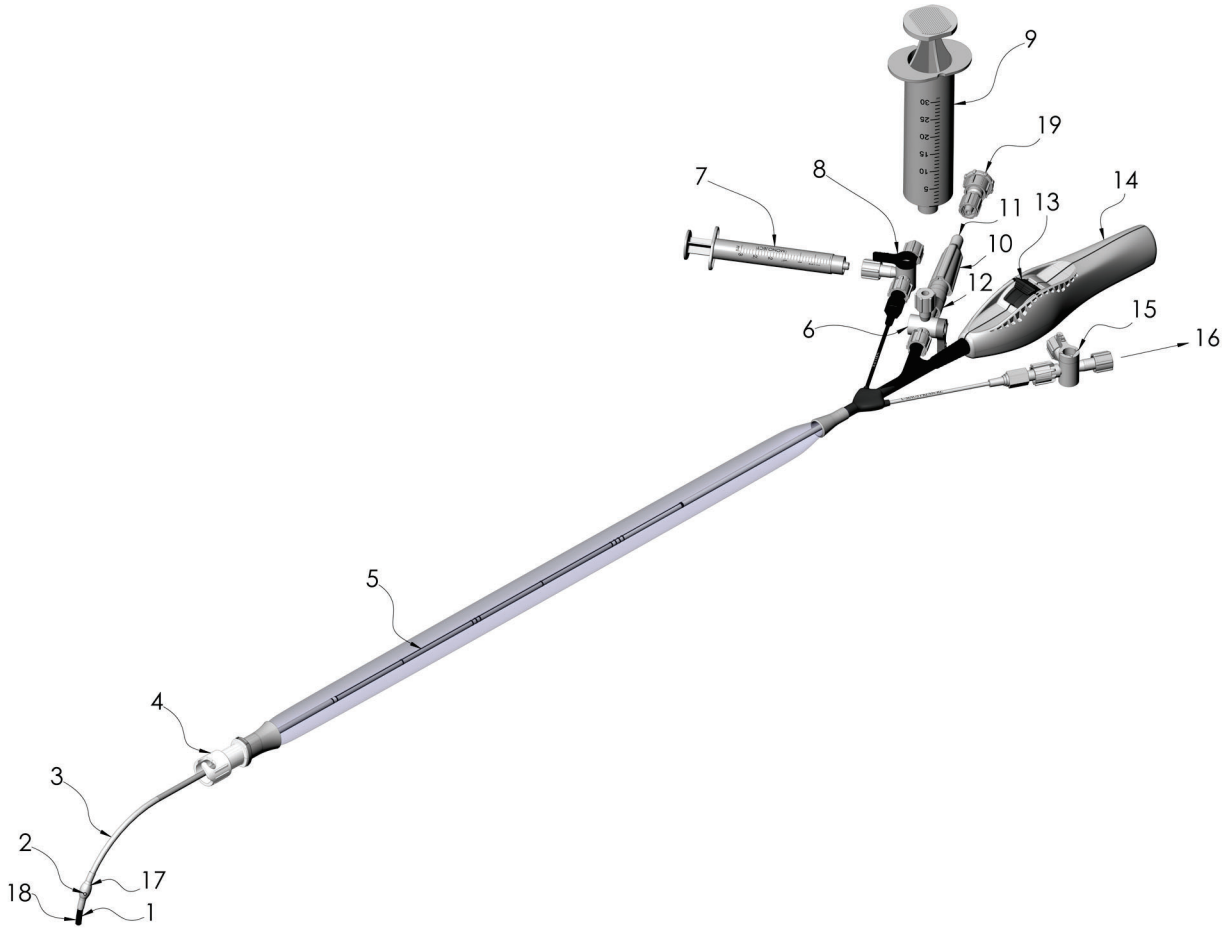
For technical assistance, please call enableCV customer service at the following telephone number: 1.888.943.2783 (1.888.9HEART3)

enableCV.com

Made in the USA.

This product is manufactured and sold under one or more of the following US patent(s): US Patent No. 9,314,587. Likewise, additional US and foreign patents are pending.

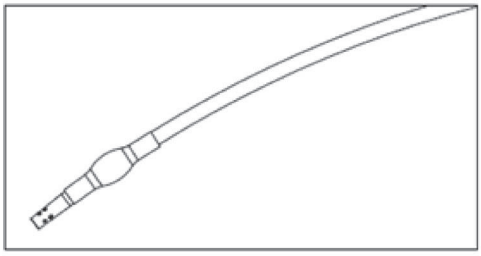
FIGURE 1



	1	2	3	4	5	6	7	8	9	10
en	Pressure monitoring hole	Balloon inflation hole	Distal curve	Introducer sheath adapter (Distal connector)	Deflection orientation line	Cardioplegia infusion stopcock	3 mL Syringe	Balloon inflation stopcock	30 mL syringe	Cardioplegia cap

	11	12	13	14	15	16	17	18	19
en	Cardioplegia line from perfusionist	¼" (0.64 cm) hose barb adapter	Positioning Dial	Handle	Pressure monitoring stopcock	To coronary sinus pressure line	Balloon	Device tip	Hemostasis valve

FIGURE 2



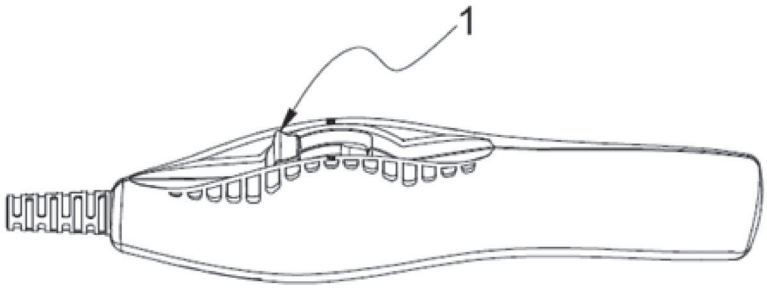
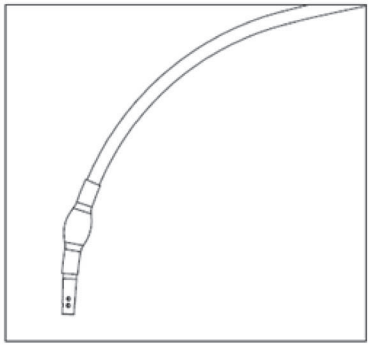


FIGURE 3



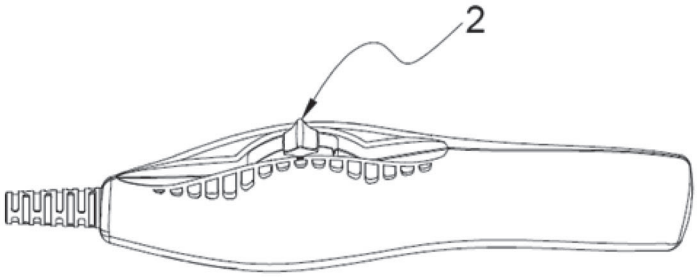
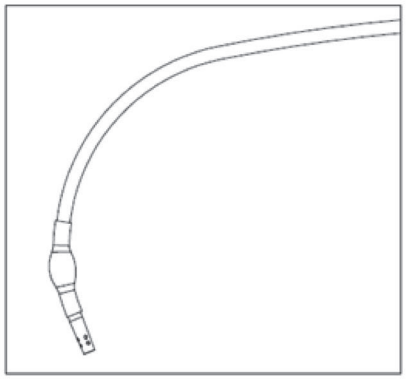
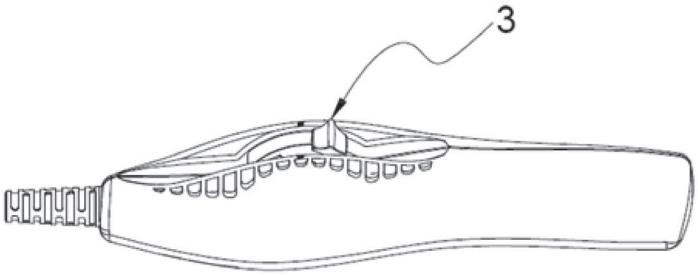


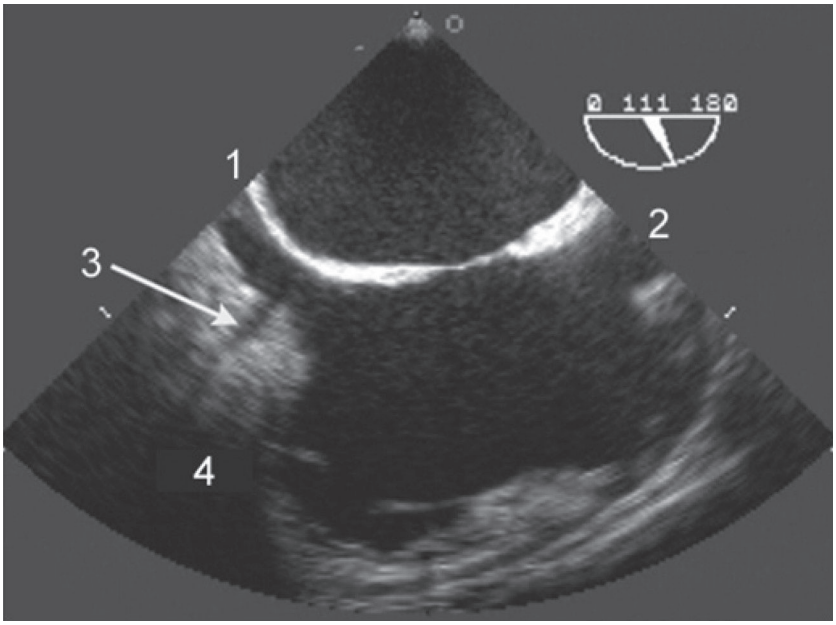
FIGURE 4





en	Figure 2, Device in Position 1 - Introduction Position	Figure 3, Device in Position 2 - Optimal Engagement Position	Figure 4, Device in Position 3 - Additional Articulation Position

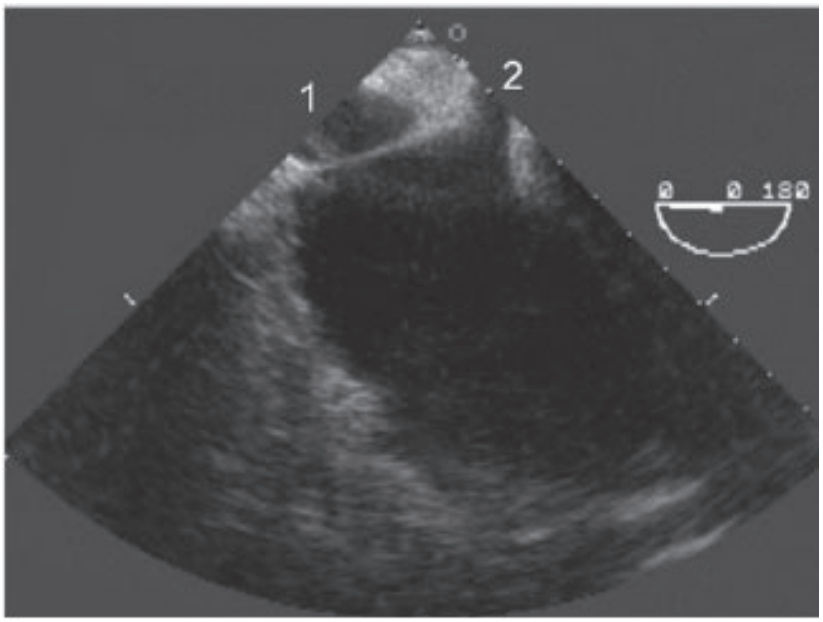
FIGURE 5



en	Figure 5, Modified Bicaval View

	1	2	3	4
en	Coronary Sinus	Superior Vena Cava	Middle Cardiac Vein	Tricuspid Valve

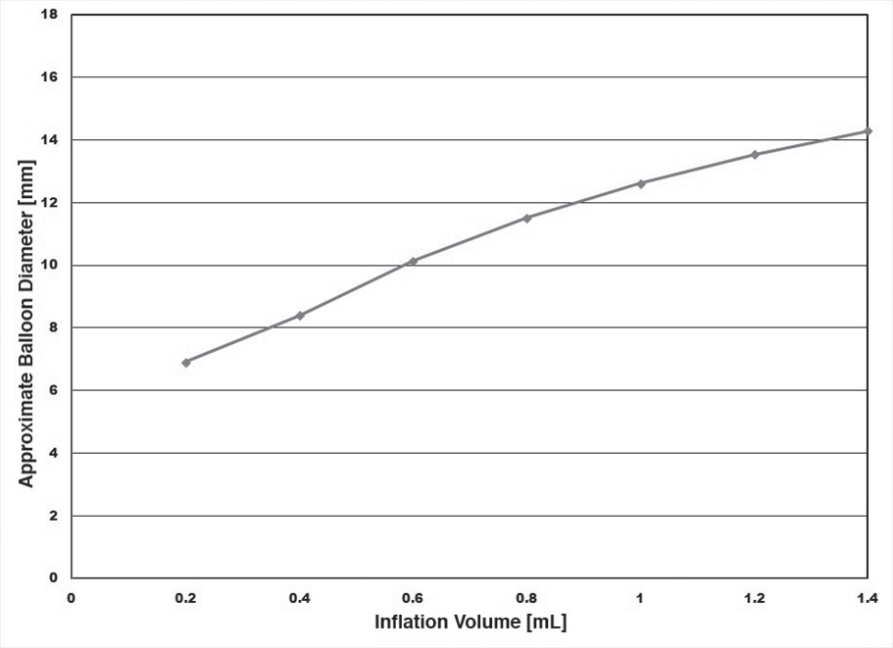
FIGURE 6



en	Figure 6, Deep 4 Chamber View

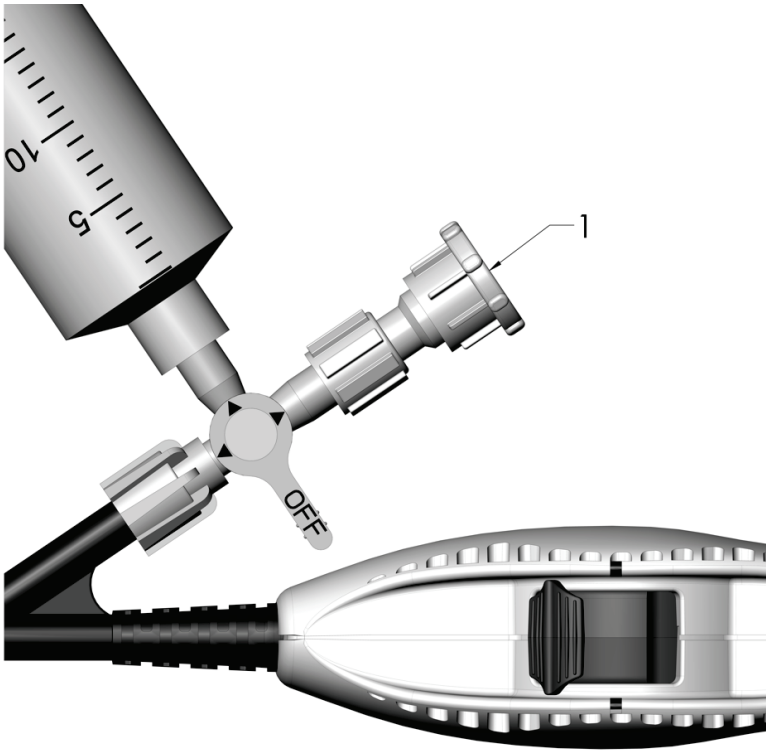
	1	2
en	Inferior Vena Cava	Coronary Sinus

FIGURE 7



en	Figure 7, Balloon Inflation Volume and Diameter	Approximate Balloon Diameter (mm)	Inflation Volume (mL)

FIGURE 8



	1
en	Figure 8, Guidewire Insertion Point

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	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.

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