



Least Invasive Cardiac Surgery™

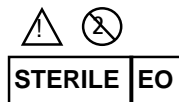
ESTECH Remote Access Perfusion Cannula™ NB 21fr

Instructions for Use

Model 103-400

WARNING: READ ALL INSTRUCTIONS AND WARNINGS BEFORE USE!

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Instructions for Use

The ESTECH Arterial Remote Access Perfusion Cannula is sterilized with Ethylene Oxide. The ESTECH Arterial Remote Access Perfusion Cannula is sterile and non-pyrogenic prior to opening of the packaging until the expiration date indicated on the product label, unless the packaging is damaged.

The ESTECH Arterial Remote Access Perfusion Cannula is for single use only. Store packaged product in a dry place.

DO NOT RE-USE OR RE-STERILIZE THE ESTECH ARTERIAL REMOTE ACCESS PERFUSION CANNULA.

1. Description

The ESTECH Arterial Remote Access Perfusion Cannula is a disposable 64 cm long flexible polyurethane tube with two (2) active lumens. The outside diameter of the cannula is 21 Fr. (7 mm). The cannula has a central lumen for the delivery of arterial blood through multiple distal outlets and a lumen that communicates with the cannula tip for guide wire insertion and aortic pressure monitoring and sampling. Distal radio-opaque segment of cannula and insertion depth marks aid in positioning the device.

Each package contains one RAP Cannula Assembly and Separately packaged Strain Relief (Longitudinally cut 1/4" tubing segment).

Transesophageal Echocardiography (TEE) monitoring is recommended for cannula positioning. Fluoroscopic monitoring may be used if desired.

2. Indications for use

This device is indicated for use in aortic perfusion via a femoral artery for cardiopulmonary bypass (CPB) with required blood flow rates of one (1) to five (5) liters per minute. Maximum recommended blood flow rate is five (5) liters per minute.

3. Contraindications

This device is not intended for use except as indicated above. This device is contraindicated for use in patients with significant aortic and/or peripheral vascular disease, aortic dissection, coarctation of the aorta or the presence of thoracic or abdominal aneurysmal disease.

4. Warnings

- Attempts to insert this device in patients with significant atherosclerotic aortoiliac disease may result in arterial injury.
- Surgical cut down and use of an open femoral arteriotomy is recommended for introduction of this device.
- The obturator should be completely inserted into the cannula before advancing the cannula over the guide wire.
- The cannula should only be inserted over a guide wire. Attempted insertion of the cannula without the use of a guide wire may result in malposition of the device or arterial injury.
- Manipulation of device within the aorta or peripheral arteries may result in dislodgement of atherosclerotic debris or mural thrombus, resulting in arterial thromboembolism, dissection or arterial occlusion.

5. Precautions

NOTE: Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The described procedure is furnished for information purposes only. Each surgeon must, of course, evaluate the appropriateness of the procedure based on their own medical training and experience, the type of surgical procedure, and the type of systems utilized.

The device is designed and intended for single use only. **DO NOT REUSE.**

CAUTION: Federal Law (USA) restricts the sale, distribution, or use of this device to, by, or on the lawful order of a physician.

6. Adverse Effects

The following complications may occur during or following the use of the Remote Access Perfusion Cannula:

- Vascular injury (femoral artery, iliac artery or aorta), including intimal disruption, thrombosis, dissection, perforation or rupture.
- Embolization of atherosclerotic debris or thrombus.
- Wound infection, hematoma, or pain (at insertion site).

7. Directions for Use

1. Preoperative screening of patients includes evaluation by sufficient methods (such as clinical examination, segmental doppler examination, aortogram) to exclude those with aortoiliac disease or anatomy that would preclude safe introduction of the ESTECH arterial perfusion cannula into the aorta from a femoral artery.
2. The patient is anesthetized, positioned, prepped and draped for cardiovascular surgery requiring cardiopulmonary bypass. Intra-operative monitoring with transesophageal echocardiography (TEE) is recommended. Fluoroscopy with capability of imaging the thoracic aorta may be used. Utilizing TEE the ascending aorta should be evaluated for the presence of atherosclerotic disease associated with luminal projections, a contraindication for use of the ESTECH arterial perfusion cannula.
3. Remove the ESTECH arterial perfusion cannula from the package using sterile technique. Loosen Hemostatic valve and insert a .035 x 180 cm stiff guide-wire through valve into lumen until the guide-wire is visible at the aortic root lumen outlet. Tighten Hemostatic valve as much as possible while still allowing the guide wire to travel freely within the lumen. The arterial perfusion cannula with the obturator and guide-wire inserted is placed to the side for later insertion.
4. Verify that the obturator is inserted completely into the cannula; if optional insertion sheath is used, insert the balloon tip into the sheath (sheath should be dipped in sterile saline to ease insertion of balloon tip into sheath).
5. The common femoral artery on the side selected for introduction of the cannula is surgically exposed, obtaining proximal and distal control of the vessel and any significant branches.
6. Estimate cannula placement in patient by placing cannula on outside of patient and noting location of distance marking on patient. NOTE: If all blood outlet ports will not fit within patient alternative cannulation technique must be employed.
7. The patient is systemically anticoagulated as appropriate for cardiopulmonary bypass using heparin administered intravenously, with activated clotting times (ACT) determined in the routine fashion.
8. During brief occlusion 1 cm transverse arteriotomy is created across the anterior arterial wall. Use a soft-jaw clamp to control blood loss at femoral artery insertion site is recommended.
9. The arterial perfusion cannula is advanced into the femoral artery while insuring that the arterial blood outlet closest to balloon is outside of the artery. The guide wire is introduced through the cannula and advanced cephalad up the aorta. TEE imaging should be used to verify proper guide wire placement. Fluoroscopic visualization of the guide wire placement may also be used if desired. The arterial perfusion cannula (with obturator) is advanced over the guide-wire in a retrograde fashion up the iliac artery, abdominal aorta and thoracic aorta. If fluoroscopic visualization is desired; the radio-opaque segment of the cannula can be used to assist placement. The obturator is removed from the cannula, which is de-aired by allowing back bleeding, and then clamped at the 3/8 tubing area provided for clamping (see figure 1, for diagram of port, lumen and component locations). The arterial cannula obturator may be removed when the black indicator ring on the cannula reaches the insertion site indicating that all arterial blood outlet ports are within the artery; the obturator should be appropriately set aside for reinsertion, if required.
10. The arterial perfusion lumen of the cannula is attached to the arterial blood supply line from the CPB machine, taking care not to introduce air at the site of connection (see figure 1, for diagram of port, lumen and component locations).
11. The Strain Relief (longitudinally cut segment of 3@ I.D. Tubing) may be placed around the cannula shaft to provide additional resistance to kinking of the segment of the cannula that is outside the insertion site.
12. Pressure line from suitable pressure monitoring device should be attached to remaining valve port to monitor aortic root pressure.
13. Venous cannulation is performed by direct cannulation of the right atrium with single or dual-stage cannula, selected cannulation of the superior and inferior vena cava, or cannulation of the right atrium via the femoral, jugular or Subclavian Vein.
14. Cardiopulmonary bypass is initiated.

15. To remove cannula after conclusion of bypass, clamp Cannula at 3/8 tubing section provided for clamping using tube-occluding forceps and withdraw cannula to indicator mark (indicating distal blood outlet port is one inch from arterial access incision). A sterile towel should be wrapped around cannula covering exposed portion of cannula between indicator mark and distal end of cannula; this will control blood loss during cannula withdrawal. If obturator reinsertion is desired, obturator may now be inserted back into cannula up to position of clamp. Clamp should be removed and obturator advanced to incision site. Cannula can now be withdrawn on to obturator and access incision closed.

8. Cannula Change-out

Should change out of ESTECH Remote Access Arterial Cannula be required during cardiopulmonary bypass:

1. Insert .035 x 260-cm exchange guide-wire through hemostatic valve, adjust valve to control bleed-back while still allowing free movement of guide wire. Use TEE and/or fluoroscopic imaging to position tip of guide wire in ascending aorta at tip of aortic cannula.
2. Prepare new arterial cannula for introduction as specified in directions for use item 3 and 4.
3. Discontinue arterial blood flow from cardiopulmonary bypass machine.
4. Clamp arterial cannula at 3/8 tubing section provided for clamping. Clamp cardiopulmonary bypass machine arterial line just distal of the arterial perfusion cannula connection. Separate connection between arterial perfusion cannula and cardiopulmonary bypass machine arterial line.
5. Withdraw arterial perfusion cannula over guide wire and remove arterial perfusion cannula from guide wire taking care not to change position of guide wire in aorta.
6. Advance new arterial perfusion cannula over guide wire into the femoral artery. The arterial perfusion cannula (with obturator) is advanced in a retrograde fashion up the iliac artery, abdominal aorta and thoracic aorta. When the arterial perfusion cannula has been advanced past the black port indicator markers, the obturator can be removed from the cannula, which is de-aired by allowing back bleeding, and then clamped at the 3/8 tubing area provided for clamping.
7. The cardiopulmonary bypass machine arterial line may now be connected to the cannula, taking care not to introduce any air into the line while connecting.
8. Bypass may now be reinitiated.

Disclaimer Of Warranty

The following disclaimer of warranty applies to United States Customers only:

Disclaimer of Warranty

Although the ARTERIAL PERFUSION CANNULA, hereafter known as "product" has been manufactured under carefully controlled conditions, ESTECH has no control over the conditions under which the product is used. ESTECH, provides no warranties, either express or implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ESTECH shall not be liable to any person or entity for medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind ESTECH to any representation or warranty with respect to the product.

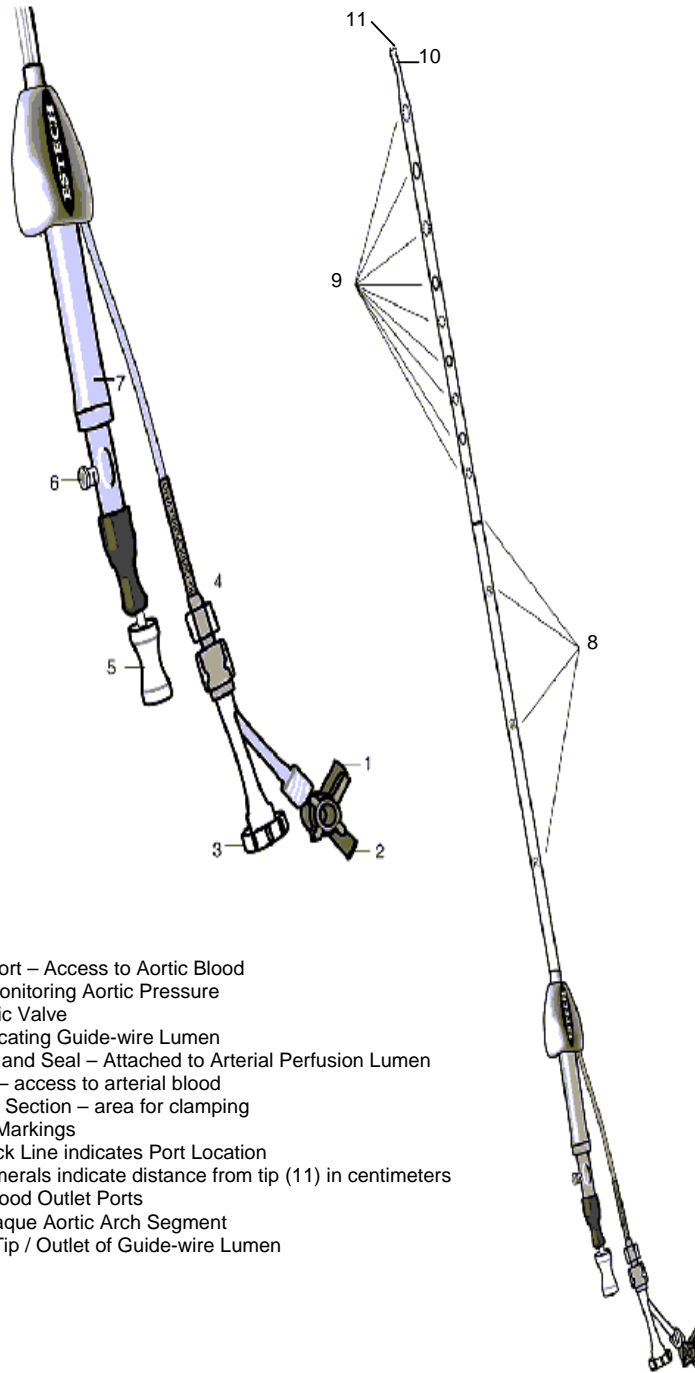
The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this DISCLAIMER OF WARRANTY is held to be illegal, unenforceable or in conflict with applicable law, by a court of competent jurisdiction, the validity of the remaining portions of this DISCLAIMER OF WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this DISCLAIMER OF WARRANTY did not contain the particular part or term held to be invalid.

The following disclaimer of warranty applies to customers outside the United States:

Although the ARTERIAL PERFUSION CANNULA, hereafter known as "product" has been manufactured under carefully designed, manufactured and tested prior to sale, the product may fail to perform its intended function satisfactorily for a variety of reasons. The warnings contained in the product labeling provide more detailed information and are considered an integral part of this disclaimer of warranty. ESTECH, provides no warranties, either express or implied, with respect to the product. ESTECH shall not be liable for any incidental or consequential damages caused by any use, defect, or failure of the product, whether the claim is based on warranty, contract, tort or otherwise.

The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. If any part or term of this Disclaimer Of Warranty is held to be illegal, unenforceable or in conflict with applicable law, the validity of the remaining portions of this Disclaimer Of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer Of Warranty did not contain the particular part or term held to be invalid.

Figure 1 – Product Diagram – Model 103-400



1. Sample Port – Access to Aortic Blood
2. Port for Monitoring Aortic Pressure
3. Hemostatic Valve
4. Label indicating Guide-wire Lumen
5. Obturator and Seal – Attached to Arterial Perfusion Lumen
6. Luer port – access to arterial blood
7. 3/8 tubing Section – area for clamping
8. Indicator Markings
 Black Line indicates Port Location
 Numerals indicate distance from tip (11) in centimeters
9. Arterial Blood Outlet Ports
10. Radio-opaque Aortic Arch Segment
11. Cannula Tip / Outlet of Guide-wire Lumen