DESCRIPTION / INDICATIONS:

This cannula is for use by trained physicians only, and is intended for use as a venous drainage cannula during extracorporeal bypass for up to 6 hours. The cannula has a balloon actuated, expandable, funnel-shaped distal tip to facilitate flow, and to facilitate en-bloc removal of undesirable intravascular material during the performance of extracorporeal circulation. Standard surgical or percutaneous insertion techniques can be employed. This product is intended for use of six hours or less.

CONTRAINDICATIONS:

Alone, this cannula is not a medical treatment device. Selection of the patient as a candidate for use with this device and for such procedures as it is intended is the physicians' sole responsibility. The outcome is dependent on many variables including, patient pathology, surgical procedure, and perfusion procedure/technique. Do not use if the patient has severe arterial or venous vascular disease.

WARNING:

- Do not use if product or sterile packaging is damaged.
- For single use only, do not resterilize or reuse.
- Do not autoclave.
- Do not use in conjunction with a power injector.
- Do not alter the Vortex Cannula in any way.
- Instructions for use and manuals for all related extracorporeal circulatory devices should be read prior to use and used as indicated.
- DO NOT reuse or resterilize and discard after use.
- DO NOT use alcohol or alcohol-based fluids for lubrication.

PRECAUTIONS:

Insert, attach and manipulate cannula in such a manner as to prevent extravascular placement, kinking, compression or in a way that may alter or restrict flow. Caution should be used when connecting the cannula to other devices in the extracorporeal circuit so as not to damage the device being connected or the cannula. Caution should be used when clamping the cannula to avoid damage to the cannula or to the connector to the circuit. DO NOT clamp wire-reinforced sections of the cannula. Clamping of wire-reinforced areas may result in permanent cannula wall distortion and/or lumen collapse. Ensure that, once inserted and in an appropriate intravascular position, the cannula is completely free of air prior to connecting to the extracorporeal circuit. Caution should be used in positioning the cannula as undue pressure exerted by the tip can cause perforation of, or damage to vessels and intravascular structures. Care must be taken when positioning the cannula to avoid impingement of the tip against vessel walls that can obstruct flow and damage the vessel. Care must be taken to avoid over inflation of the balloon and over expansion of the cannula tip greater that the diameter of the target vessel as damage to the vessel wall may occur. The use of cold solutions administered externally may increase the stiffness of the cannula and alter/increase the pressure exerted on the tip during manipulation. Forcing an inappropriate size connector into the cannula may damage the cannula or the connector. DO NOT attempt to clamp the cannula with the introducer/obturator in place. Carefully monitor for both inflow and outflow obstruction/occlusion of the cannula during use.

User assumes responsibility for any variations in the extracorporeal circulation/procedures that could compromise the intended use of this device. Thoroughly inspect the cannula prior to use to verify that the lumen is patent and that the cannula has not been damaged or kinked prior to use. Thoroughly inspect and test the balloon tip and expandable end to ensure that it has not been damaged and for proper inflation and function prior to use. As with all medical devices, this device is to be used by trained physicians only. Initiate adequate systemic anticoagulation therapy prior to patient cannulation. A strict anticoagulation protocol should be followed and anticoagulation should be carefully monitored during all procedures. The benefits of use of this device must be weighed against the risk of systemic anticoagulation and must be assessed by the prescribing physician. Only physicians trained and experienced using surgical and/or percutaneous (Seldinger) vascular access techniques should use this device. Ischemia or vascular congestion may occur with the use of this device. Cannula tip placement and positioning should be guided and confirmed using fluoroscopy.

Adverse Affects:

This device, as do all extracorporeal blood vessel devices, has possible side effects, which include but are not limited to infections, blood loss, thrombus formation, embolic events, vessel damage and complications of percutaneous or surgical insertion techniques. These may occur if the Instructions for Use are not followed.

Complications:

Possible complications include those normally associated with large bore surgical and/or percutaneous vessel catheterization/cannulation, anticoagulation and extracorporeal circulation.

Sterilization:

All Vortex cannula are sterilized (EO) prior to shipment. The Lot Number is designated on the outer package label. This device should not be used if the sterile package has been damaged or if the seal has been broken. Resterilization is not recommended under any circumstances as this device is intended for single-use only.

Flow rate per Pressure lost

Flow Rate Graph

Instructions for Use:

1) The patient should be prepared and draped in the usual and typical sterile manner for percutaneous/surgical vascular procedures.

2) Sterile cannula should be placed into the vascular system utilizing typical percutaneous/surgical techniques. Various components may be included in this kit to assist in the access of the vessel and placement of the cannula. Various sizes of guidewires and dilators are available in order to provide the physician the opportunity of selecting the most appropriate device for each specific procedure.

3) Carefully open the sterile pouch containing the cannula and components. Remove Balloon sheath from end of cannula.

4) Assemble the cannula/obturator
   a. Lubricate the obturator with saline solution.
   b. Insert the obturator into the cannula until the hub is firmly seated in the cannula at the distal end.

5) If desired for use, assemble the introducer sheath/obturator
   a. Lubricate the obturator with saline solution.
   b. Insert the obturator into the introducer sheath until the hub is well seated in the catheter and secured in that position.
6) Identify the vessel to be cannulated and ensure that it is of adequate size to allow for introduction of the introducer sheath and/or cannula. In a percutaneous fashion or into the exposed vessel, introduce an 18g needle into the vessel and aspirate blood. If free flow of blood in not present upon aspiration, repurpose the needle and aspirate. Repeat as needed until adequate blood flow is established.

7) Insert a "J" tip guidewire through the needle into the vessel. NOTE: The guidewire should advance without resistance and should be done under fluoroscopic guidance. CAUTION: Do not withdraw the guidewire back into the needle in the vessel as shearing of the wire may occur. Always remove the needle first.

8) Advance the guidewire into the vessel and position it at or just beyond the desired cannula tip position.

9) Hold the guidewire in place and remove the introducer needle by sliding it away from and out of the patient over the guidewire.

10) Enlarge the insertion site of the wire into the skin or vessel with an #11 blade scalpel to approximate the size of the sheath and/or cannula.

11) Hold the guidewire firmly in position and pass a smaller stepped dilator over the guidewire into the vessel to enlarge the tract to the largest part of the dilator.

12) Remove the vessel dilator by sliding it away from and out of the patient over the guidewire. Be sure to apply digital pressure to the entrance site for hemostasis and hold the guidewire firmly in position.

13) Repeat steps 8 through 10 with larger dilators as appropriate to allow placement of the sheath/cannula.

14) If an introducer sheath is used pass the introducer sheath/obturator assembly over the guidewire, advancing until the guidewire can be grasped beyond the introducer hub.

15) Holding the guidewire firmly in position, advance the introducer sheath/obturator assembly over the guidewire into the vessel to the desired depth. NOTE: Advancement of the introducer sheath/obturator assembly with a rotating motion make placement easier. Do not advance if resistance is met.

16) While holding the guidewire and introducer sheath in place, remove the obturator from the sheath sliding it over the guidewire away from and out of the patient.

17) Secure the introducer sheath in place by suturing it to the skin at the point of insertion.

18) Place the cannula/obturator over the guidewire and advance until the guidewire can be grasped as it exits the distal end of the obturator.

19) While holding the guidewire firmly in position, advance the cannula/obturator over the guidewire and through the introducer sheath into the vessel.

20) If the cannula is used without an introducer sheath, once the vessel and/or insertion tract has been dilated to the appropriate size, place the cannula/obturator assembly over the guidewire and advance into the vessel while holding the guidewire firmly in the appropriate position. NOTE: Advancement of the cannula/obturator assembly with a rotating motion make placement easier. Do not advance if resistance is met.

21) Using fluoroscopy, advance the cannula/obturator into the desired position over the guidewire.

22) Once the optimal position of the cannula has been achieved, remove the guidewire by sliding it out of and away from the patient through the obturator. Once the guidewire has been removed, remove the obturator from the cannula completely by pulling it out and away from the patient.

23) Allow the cannula to back fill with blood and remove all air and clamp the cannula. NOTE: Perfusion tubing clamps must be used. Other clamps may be too weak to ensure complete occlusion of the cannula. DO NOT clamp the wire reinforced portion of the cannula.

24) Slowly fill the remainder of the cannula tube distal to the clamp with sterile priming fluid displacing any remaining air.

25) Attach the cannula to the extracorporeal circuit using the appropriate connector making sure to obtain a light, secure, air free connection.

26) Inflate the balloon to the desired amount using a mixture of contrast media and sterile saline solution. Do not exceed 1 atm to expand balloon. Do Not Over Infl ate.

27) Prior to removal of cannula deflate balloon.

Disclaimer of Warranty:
Although the Vortex cannula hereafter referred to as the “product” has been manufactured under carefully controlled conditions, Vortex Medical has no control over the conditions under which this product is used. Vortex Medical therefore disclaims all warranties of merchantability or fitness for a particular purpose. Vortex Medical shall not be liable to any person or entity for any 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 Vortex Medical to any representation or warranty with respect to the product.

PRECAUTIONS:
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

• The intravascular introducer system should only be used by a physician trained in endovascular procedures and familiar with the medical literature regarding techniques, complications, and hazards associated with the use of intravascular introducer systems.

• Prior to use, confirm that the cannula size is appropriate for the vessel to be accessed and for all instruments used during the procedure.

• A complete understanding of the principles and techniques involved in electrosurgical procedures is necessary to avoid shock and burn hazards to the patient and medical personnel as well as damage to the device or other instruments. For more information refer to the medical literature (1).

• If difficulty or resistance is encountered during placement or withdrawal, the cause should be determined and corrected before proceeding. Failure to do so may result in damage to the vessel.

COMPLICATIONS:
Potential complications associated with the use of intravascular introducer systems include but are not limited to: air embolism, infection, damage to the vessel in the form of, vessel perforation, vessel spasm, hemorrhage, hematoma, and vascular thrombosis.

SPECIFICATION TABLE:
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<th>Part number</th>
<th>VTX-3000</th>
<th>VTX-3022</th>
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<td>Sheath Size</td>
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<tr>
<td>Inflation Volume</td>
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<td>Guide wire</td>
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</table>

HOW SUPPLIED:
Nonpyrogenic
STERILE EO

DO NOT REUSE

STORAGE AND HANDLING:
Handle with care. Product should be stored in a clean, cool dry area away from chemical fumes.

IMPORTANT WARRANTY INFORMATION:
1. Limited Warranty. Vortex warrants that Product will: (i) conform to the written specifications furnished to the Purchaser; and (ii) comply at the time of shipment with the then-applicable requirements of the U.S. Food, Drug and Cosmetic Act and regulations promulgated thereunder.

2. Warranty Claims. For any Product that does not comply with the Limited Warranty set forth above, vortex will, in its discretion: (i) repair or replace the Product at its sole expense, or (ii) refund the full purchase price of the Product. Vortex’s obligations under this section are subject to Purchaser’s compliance with all instructions and requirements regarding the use of the Product.

3. EXCLUSION OF OTHER WARRANTIES AND REMEDIES. EXCEPT AS PROVIDED ABOVE, VORTEX EXCLUDES ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL VORTEX BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM THE USE OF ANY PRODUCT. VORTEX NEITHER ASSUMES, NOR AUTHORIZES, ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THE PRODUCTS. IN NO EVENT SHALL VORTEX’S LIABILITY UNDER THIS LIMITED WARRANTY EXCEED THE PURCHASE PRICE OF THE PRODUCT.

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U.S. and foreign patents pending.
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