

**WARNING** - Only a physician should attempt the following procedures.

- Reposition the catheter including rotation and withdrawal, while observing the effect on pressures. Caution: Do not insert the catheter farther into the vein.
- Temporarily reverse the flow. Caution: As the smaller lumen will now be used for drainage, a significantly higher flow speed through this lumen will occur. Hemolysis and increased regurgitation may result during reversed flow

### Thrombus Formation

**WARNING: NEVER FORCIBLY FLUSH AN OCCLUDED LUMEN.** If a thrombus is suspected, first attempt to aspirate the clot with a syringe. If aspiration fails, consider using medical treatment to dissolve the clot, or replace the catheter.

**CAUTION:** US Federal law restricts the sale and use of this device by or on the order of a physician.

### Disclaimer of Warranties

OriGen Biomedical warrants that reasonable care has been used in the manufacture of this device and that it was free from defects in workmanship or materials at the time of shipment from OriGen. OriGen's sole obligation shall therefore be to repair or replace any device which it determines was defective at the time of shipment. Because no product is completely effective under all circumstances, and because the actual use and handling of this device is beyond our control, OriGen cannot warrant for a good effect or against a bad effect in the application and use of this device. The buyer therefore assumes all liability arising from any cause for damages resulting from use, misuse, use other than as intended, or resterilization of this product. OriGen therefore gives no warranty of merchantability or fitness for a particular purpose. OriGen shall not be liable for incidental or consequential loss, damage or expense resulting from the use or application of this product. This warranty is in lieu of all other warranties, whether implied, express, oral or written, and no individual has the authority to vary the terms of this warranty.

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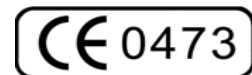
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1. Peek GJ, Firmin RK, Moore HM, Sosnowski AW. Cannulation of neonates for venovenous extracorporeal life support. Annals of Thoracic Surgery 1996;61: 1851-52

2. Extracorporeal Cardiopulmonary Support in Critical Care, Chapter 14, 2nd Edition, ELSO, 2000

## OriGen Dual Lumen Catheters

### Indications

The OriGen Dual Lumen Cannula is indicated for use as a single cannula for both venous drainage and arterial re-infusion of blood in the internal jugular vein during extracorporeal life support procedures.

**Sterile:** Sterile and non-pyrogenic when package unopened or undamaged. This device is intended for single use only. Do not re-sterilize. Store in a cool, dry place.

### Device Description

The OriGen Dual Lumen Cannula is a solid polyurethane catheter providing a divided lumen allowing for simultaneous drainage and return of blood during procedures using only a single catheter.

The two lumens are connected via a "Y" to clear polyurethane tubes which provide access for drainage and re-infusion of blood during the procedure. To assist in connection of the lines, barbed tubing connectors are pre-attached to the tubing. The area ratio of the lumens is approximately 2 to 1, the larger lumen indicated for drainage. The drainage (venous) lumen is marked with a blue band and is supplied with a blunt obturator.

Holes in the lumens provide simultaneous "venous" drainage from the patient and "arterial" re-infusion. The catheter is marked in 1 cm increments and the inserted tip portion is radiopaque. The smaller lumen is the re-infusion (arterial) port. It has a red band on the connector, and is fitted with a self-sealing vent plug. The vent plug is designed to vent air from the infusion side of the catheter and seal off when blood contacts it, making clamping of the catheter tubes unnecessary.

### Product Dimensions

Product Code	Tip diameter	Tip length, cm	Tubing Connector
V V12F	12F	8	1/4"
V V15F	15F	10	1/4"
V V18F	18F	15	1/4"
V V22F	22F	20	3/8"
V V27F	27F	25	3/8"
V V32F	32F	30	3/8"

### Contraindications

There are no known contraindications when used as indicated. Usage other than as indicated is the sole responsibility of the user.

### Potential complications

Atheroembolization, air embolism, brachial plexus injury, cardiac arrhythmia, cardiac tamponade, central venous thrombosis, exit site infection, hemorrhage, hemothorax, luminal thrombosis, pneumothorax, right atrial puncture, sepsis, sinus tract infection, subclavian artery puncture, subcutaneous hematoma

## Instructions for Use

## WARNINGS/PRECAUTIONS

1. **Physician Control:** This device should be used only by or under the direction of a licensed and qualified physician.
2. **Damage:** Do not use catheter if package has been damaged or previously opened. Do not use catheter if it is damaged in any way.
3. **Aseptic Technique:** Observe sterile technique at all times when handling and inserting or removing the catheter.
4. **Heparin:** Adequate heparinization must be maintained during the procedure. The risk of systemic anticoagulation must be weighed against the benefits of extracorporeal circulation.
5. **Air Embolism:** The patient must be paralyzed or on positive pressure ventilation when the jugular vein is open as spontaneous breathing can result in aspiration of air into the venous system.
6. **Debubble:** With each tubing connection, purge air from the catheter and all connecting tubing.
7. **Position:** Use X-ray or ultrasound to verify that the catheter tip is positioned in the mid right atrium before use. Incorrect insertion may result in puncture of the right atrium or vein. Observe patient carefully for signs of arrhythmia caused by passage of the catheter into the right atrium. If symptoms occur, withdraw the catheter slightly and reposition.
8. **Ligature:** Ligature of the cannula can cause the wall of the larger lumen to collapse inwards, resulting in a massive, uncontrollable leak. Ligature can also act as a fulcrum causing kinking, and is therefore not recommended. Instead, a method which does not use ligature is recommended<sup>1,2</sup>. Secure the catheter to the patient with sutures in the tie-downs provided.
9. **Clamping:** Do not clamp the tip portion of the catheter. Use only smooth-jawed forceps for clamping and clamp only near the middle of the clear tubing. Repeated clamping in the same site may weaken the tubing; change the position of the clamps slightly to prolong the life of the tubing. Do not clamp near the connectors, as they may fracture.
10. **Blockage:** Do not infuse against a closed clamp or forcibly infuse a blocked catheter: excess pressure could cause connections to burst open.
11. **Venous return:** For jugular insertion, it should be determined that neither the catheter nor the flow from the catheter is interfering with the venous return from the coronary sinus or inferior vena cava. **N.B.** Vacuum suction on the venous side may cause the catheter to collapse.
12. **Suction: WARNING:** The unreinforced catheter may collapse if suction pressure less than -50 mm Hg is applied to the drainage lumen
13. **Damage:** Inspect the catheter frequently for nicks, scrapes, cuts, etc. which could impair its performance.
14. **Solvents:** Do not use acetone or alcohol-based cleaners (tinctures) on any part of the catheter tubing. Aqueous-based povidone-iodine is recommended.
15. **Replacement:** Remove the catheter as soon as it is no longer needed. Discard after use: the catheter is for single use only.
16. **Protocol:** The medical techniques and procedures described in these instructions are presented as an example only, and do not represent all medically acceptable protocols. They are not intended as a substitute for the physician's experience and judgment in treating any specific patient.

## Suggested Cannulation Technique (CUTDOWN PROCEDURE)

Note: For percutaneous introduction, use the Origen "PCTa" set for 12F to 18F catheters, and the "PCTb" set for 22F to 32F catheters, and refer to the instructions included with that set. Note: These instructions are for informational purposes only. Each surgeon must evaluate the use and performance of this device based on experience and training, local protocol and the type of procedure to be used.

1. **Sterile Field:** Provide a sterile operative field: use sterile drapes, instruments, and accessories. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have the patient wear a mask.
2. **Position Patient:** Place the patient in a supine position and expose the upper chest or the groin side to be

accessed.

3. **Prep site:** Turn the patient's head slightly to the side to expose the insertion site. The Trendelenberg position may facilitate insertion. Prep the access site and scrub the area with an appropriate antiseptic.
4. **Incision:** Using aseptic technique, the neck should be minimally hyperextended and an incision made over the sternocleidomastoid muscle for exposure.
5. **Expose vein:** Expose internal jugular vein using standard surgical technique, taking extra care to assure hemostasis, and prepare for catheter insertion. The physician should measure the vein diameter carefully to Oselect the correct size of catheter
6. **Heparin:** Ensure that Heparin has been given, and enough time allowed for recirculation. **Check catheter:** Remove the catheter from the package using aseptic technique and remove the clear sheath covering the tip. If the self-sealing vent plug in the re-infusion line has come loose from the arterial connector, replace it. This vent plug will vent air in the arterial line so this line does not need to be clamped during insertion or priming. The tapered vent plug can be replaced with a standard luer type syringe to flush the cannula if desired. Do not use if the packaging or product is damaged.
7. **Prepare for Insertion:** The patient should be paralyzed before insertion to prevent air aspiration. A blunt introducer is provided in the return lumen to aid in insertion into the venotomy. If the introducer is removed, clamp the clear drainage line.
8. **Insert:** Gently insert catheter into the internal jugular venotomy, while advancing the catheter slowly into the right atrium. Slow, continuous pressure with slight rotation of the catheter will help advancement. Slight lubrication of the catheter with sterile saline may also assist in placement.
9. **Position:** The tip of the catheter should be in the mid right atrium: verify position of the catheter in the right atrium using X-ray or ultrasound. Orient the catheter with the arterial (red) connector anteriorly, to point the re-infusion ports towards the tricuspid valve.
10. **Debubble:** Remove connector plugs, purge air and attach connectors to the lines of extracorporeal circuit. The connector bands are color-coded to aid in connection, and there are flow arrows on the catheter "Y".
11. **Secure:** Attach the catheter to the skin using the tabs on the catheter and the suture groove just above the tip. Tying around the catheter is not recommended<sup>1,2</sup>. The use of a topical hemostatic agent to control bleeding is recommended
12. **Orientation:** Recirculation can be minimized by orienting the catheter with the ports in the arterial lumen pointed at the tricuspid valve.
13. **Pressures:** Monitor the supply pressure between the pump and the dual lumen catheter. Circuit pressures greater than 500 mm Hg damage the catheter, increase the risk hemolysis, and make disastrous circuit disconnections more likely. If the pressure is significantly higher than the expected pressure at any given flow, there may be an obstruction in the circuit or the catheter (Note: pressure/flow curves are available at our website: [www.origen.com](http://www.origen.com)). The circuit and catheter should be examined and checked for obstructions to flow. Never allow a **vacuum** of more than 50 mm Hg to be applied to the catheter as collapse of the lumens can occur resulting in cessation of flow, leaks and air embolism.

## Suggested Decannulation Technique

1. Discontinue extracorporeal circulation following standard protocol.
2. Clamp both clear drainage and re-infusion lines.
3. Decannulation is carried out in the usual fashion.
4. Close incision using standard surgical technique.

## Inlet Obstruction

Complete obstruction of the inlet ports is unlikely as the catheter has inlet ports in all three axes. However; should the inlet flow be reduced, one or more of the ports may have aspirated tissue. The following adjustments may resolve the obstruction:

- Reposition the patient.