

Percutaneous Introducer Kit; Product Code PCTa

Instructions for Use

Description

The OriGen Biomedical Percutaneous Introducer kit (PCT) is a collection of puncture cannula, guidewires and dilators necessary to place the OriGen Dual Lumen cannula percutaneously.

Sterile:

The kit is sterile and non-pyrogenic, and packaged in a peel pouch.

Indications for Use

The OriGen PCT kit is indicated only as an aid for percutaneous placement of the OriGen Biomedical dual lumen cannula.

Contraindications

The OriGen PCT kit is not designed, sold or intended for any use other than as indicated. It is the responsibility of the physician to determine whether any physical impairment of the patient would contraindicate the use of this device.

Potential Complications

Jugular vein insertion: 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, vein dissection

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 the device if the package or contents appear 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. **Position:** For jugular insertion, use X-ray or echo 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.
7. **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.

General Instructions, Jugular insertion

Prepare the Patient - expose and prep the insertion site. Turn the patient's head slightly to the left to aid in insertion. **WARNING:** Heparinize patient per local protocol.

If the 0.018 guidewire is to be used Start with Step 1. If not, proceed to Step 2.

Step 1: Place the 0.018" Guidewire

1. **Unpack Sharps:** open the pouch containing the sharps. Included is a 21 ga. needle, a 22 ga (blue) IV catheter, and 18 ga. (green) IV catheter and a 5F guidewire switcher. Place them on the sterile field.
2. **Puncture the vein:** Using either the 21 ga. needle or the blue 22 ga. IV cannula, puncture the jugular vein. For patients less than 3 kg, an "exposure assisted" method has been recommended {1}. Venous blood will fill the needle portion confirming placement in the vein.
3. **Insert the Guidewire:** If the IV cath was used, remove the sharp and insert the 0.018 guidewire in the IV catheter. If the 21 ga. needle was used, the guidewire may be inserted directly into the needle lumen.

The .018" guide wire has a pink tip. Pull the pink guidewire lock a few mm out of the coil to release the guidewire. Pull the J-tip back into the pink portion to straighten it and advance the guidewire into the needle or the IV catheter. Continue advancing the guidewire to the mid-right atrium. Note: the guidewire is marked at 10, 20 and 30 cm distances from the J-tip. Use echo, radiography or other means to confirm the tip position.

4. **Remove the sheath:** Once the guidewire is in place, remove the IV catheter or needle, leaving only the 0.018 guidewire in place.

Step 2: Place the 0.035" guidewire

If the .018 guidewire has **NOT** been used:

1. **Unpack Sharps:** open the pouch the sharps. Included is a 21 ga. needle, a 22 ga (blue) IV catheter, and 18 ga. (green) IV catheter and a 5F guidewire switcher. Place them on the sterile field.
2. **Puncture the vein:** Insert the 18 ga. (Green) IV catheter into the vein. Blood will fill the needle section, indicating entry into the vein. Remove the inner sharp, leaving just the green IV cath sheath in place.
3. **Insert the Guidewire:** The .035" guide wire has a blue tip. Pull the blue guidewire lock a few mm out of the coil to release the guidewire. Pull the J-tip back into the blue

portion to straighten it and advance the 0.035" guidewire into the IV catheter.

Note: the guidewire is marked at 10, 20 and 30 cm distances from the J-tip. Use echo, radiography or other means to confirm the tip position.

4. **Remove the sheath:** Once the .035 guidewire is in place, remove the green IV catheter sheath, leaving just the guidewire.

If the .018 guidewire is already in place:

Use the Guidewire Switcher:

1. **Insert 5F:** Slide the complete 5F guidewire switcher over the .018" guidewire, and into the skin opening.
2. **Remove Inner:** Unscrew the small hub on the Guidewire switcher, and remove both the .018" guidewire and the inner part of the Guidewire Switcher, leaving just the outer sheath in place.
3. **Insert .035":** The .035" guide wire has a blue tip. Pull the blue guidewire lock out of the coil slightly to release the guidewire. Pull the J-tip of the guidewire back into the blue portion to straighten it and advance the 0.035" guidewire into the IV catheter.
Note: the guidewire is marked at 10, 20 and 30 cm distances from the J-tip. Use echo, radiography or other means to confirm the tip position.
4. **Remove Sheath:** Remove the guidewire switcher sheath and leave just the 0.035" guidewire in place.

Step 3- Place the straight introducer

Each kit has a straight introducer provided in three sizes, and each is color coded to the catheter to be used. The straight introducer is easily placed and will reinforce the guidewire, making kinking of the guidewire when placing the cannula less likely.

1. **Unpack:** Remove the straight introducers from the packaging. If the desired one has been curved to fit in the package, wrap sterile gauze over it, and pull the gauze across the bend a few times to straighten it.
2. **Match Size:** Select the proper introducer for the size cannula to be used:
 - 12F - Tan Introducer
 - 15F - Blue Introducer
 - 18F - Green Introducer**N.B.** Match the straight introducer to the color of the blunt introducer supplied with the catheter.
3. **Place Introducer:** Insert the matching introducer over the .035 guidewire, and advance it to the opening of the right atrium.
N.B. The J-tip of the guidewire will produce a slight increase in insertion drag when the introducer is moved over the J-section. This is intended as an additional aid in determining the introducer position, and is not intended as a positive stop.

WARNING:

Advancing the introducer beyond the end of the guidewire can result in atrial puncture

- Place Catheter:** Remove and discard the blunt introducer supplied with and already inserted in the catheter. Prime the catheter per your local protocol. Advance the catheter over the straight introducer, holding the straight introducer to prevent it from advancing further. When the catheter is in place, remove the straight introducer and guidewire while holding the catheter in place. Connect and de-air the catheter per your regular protocol.

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 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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