

PERCUTANEOUS CATHETER INTRODUCER with STANDARD PEEL-AWAY SHEATH

Norfolk  Medical

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

Instructions for Use

This device is intended for one time use only.
Read instructions prior to use.

Indications

For use when catheters must be introduced into a vessel.

Warnings

- Intended for **single patient use. DO NOT REUSE.**
- Norfolk Medical Products, Inc. products are single use devices and should never be reimplanted. Any device that has been contaminated by blood should not be reused or resterilized.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- Hold thumb over exposed opening of sheath to prevent air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

Precautions

- Do not use forceps to break handle and/or peel the sheath and cause its withdrawal from the body. The peel-away sheath should withdraw freely from the body.
- If resistance is encountered, do not force the peeling action of the sheath or its

withdrawal. Make procedural corrections, then continue.

- Do not attempt to use the guidewire over maximum diameter specified on the package label.
- Individual patient anatomy and physician technique may require procedural variations.
- Insertion into artery may cause excessive bleeding and/or other complications.
- Damage to the guidewire may result if withdrawn through the needle.
- The need for symmetrical peeling of the sheath cannot be overemphasized.
- If catheter withdrawal is a problem when the sheath is peeled, completely withdraw the sheath from the introduction site while holding the catheter in position, then peel the sheath symmetrically from the catheter by grasping both handles.

Instructions

1. Use sterile technique.
2. Peel open package and place contents on sterile field.
3. Prep skin and drape in area of anticipated puncture site.
4. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site.
5. Attach introducer needle to the syringe and insert into vessel.

Continued on Reverse Side →

6. Aspirate gently as the insertion is made. If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.
7. When the vein has been entered, remove the syringe leaving the needle in place. Place a finger over the hub of the needle to minimize blood loss and the risk of air aspiration.
8. The risk of aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
9. Straighten the “J” tip of the guidewire with the tip straightener and insert tapered end of the tip straightener into the needle.
10. Remove the tip straightener and advance the guidewire as far as appropriate for the procedure. Verify correct positioning, using fluoroscopy, or appropriate technology.
11. Gently withdraw and remove needle. **If the guidewire must be withdrawn while the needle is inserted, remove both the guidewire and needle as a unit to help prevent the needle from damaging or shearing the guidewire.**
12. Make a small incision (approx. 1cm wide) parallel to the guidewire to permit introduction of the vessel dilator and sheath introducer.
13. Advance the vessel dilator and sheath introducer as a unit over the exposed wire using a rotational motion. Advance it into the vein as a unit, leaving at least 2cm of sheath exposed.
14. Release the locking mechanism and gently withdraw the vessel dilator and “J” tip guidewire, leaving the sheath in place.
15. Insert catheter into sheath. Advance the catheter through the sheath into the vessel to the desired site.
16. Grasp the two handles of the peel-away sheath and pull outward and upward at the same time.
17. Peel the sheath away from the catheter completely. Make sure the catheter is not dislodged from the vessel.

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