Peel-Apart Percutaneous Introducer Kits for

- Bard Implanted Ports
- Hickman*, Leonard*, Broviac*, Tenckhoff*, and Groshong* Catheters

Instructions For Use
Introduction

Description

Bard Access Systems Peel-Apart Percutaneous Introducer Kits are custom fitted introducers used in the placement of Bard Implanted Ports and Hickman*, Leonard*, Broviac*, Tenckhoff* and Groshong* catheters.

Peel-Apart Percutaneous Introducer Kit Contents

- Peel-Apart Sheath Introducer with Tapered Vessel Dilator
- Disposable Syringe
- Extra Thin Wall Needle
- Flexible Stainless Steel “J” Guidewire with Tip Straightener
- Instructions For Use

Indications For Use

The Bard Access Systems Percutaneous Introducer Kit is designed for insertion of the indicated catheter of Bard Access Systems Implanted Ports, and Hickman*, Leonard*, Broviac*, Tenckhoff*, and Groshong* Catheters into the vascular system.

All Bard Access Systems central venous catheters are designed for the administration of I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as blood withdrawal.

Contraindications, Warnings, Cautions and Precautions

Contraindications

The device is contraindicated whenever:

- The presence of device related infection, bacteremia, or septicemia is known or suspected.
- Severe chronic obstructive lung disease exists.
- Past irradiation of prospective insertion site.
- Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.

Warnings

- Intended for Single Patient Use. DO NOT REUSE. Bard Access Systems products are single use devices and should never be reimplanted. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Resterilization of incompletely cleaned devices may not be effective. 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.
- Pinch-off Prevention: Catheters placed percutaneously or through a cut-down, into the subclavian vein, should be inserted at the junction of the outer and middle thirds of the clavicle, lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and the clavicle, which can cause damage and even severance of the catheter. A radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle. 1,2
- 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.
- Avoid vessel perforation.
- Hold thumb over exposed orifice 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.
- Avoid positioning the catheter tip in the right atrium. The preferred location of the catheter tip is at the junction of the superior vena cava and the right atrium.

Cautions:
- Carefully read and follow all instructions prior to use.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only qualified healthcare practitioners should insert, manipulate and remove these devices.
- Do not insert guidewire beyond the bevel of the needle while removing straightener from the needle hub in order to prevent guidewire damage or shearing.
- If the guidewire must be withdrawn while the needle is inserted, remove both the needle and guidewire as a unit to help prevent the needle from damaging or shearing the guidewire.

Precautions:

I. Prior to beginning placement procedure, do the following:
- Examine package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a double sterile package and is non-pyrogenic. Do not use if package is damaged, opened or the expiration date has passed. Sterilized by ethylene oxide. Do not Resterilize.
- Inspect kit for inclusion of all components.
- When using an introducer kit, verify that the catheter fits easily through the introducer sheath.
- Carefully read follow all instructions for the Bard Access Systems product to be placed using the Bard Access Systems Percutaneous Introducer Kit.

II. To avert device damage and/or patient injury during placement:
- Avoid accidental device contact with sharp instruments and mechanical damage to the catheter material. Use only smooth-edged atraumatic clamps or forceps.
- Avoid perforating, tearing or fracturing the catheter when using a guidewire.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- When using percutaneous introducers:
  - Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
  - To avoid blood vessel damage, do not allow the percutaneous introducer sheath to remain indwelling in the blood vessel without the internal support of a catheter or dilator.
  - Simultaneously advance the sheath and dilator with rotational motion to help prevent sheath damage.

Possible Complications

The use of an indwelling central venous catheter provides an important means of venous access for critically ill patients; however, the potential exists for serious complications including the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter or Port Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression Between the Clavicle and First Rib
- Catheter or Port-related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothorax
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Inflammation, Necrosis, or Scarring of Skin over Implant Area
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature and should be carefully considered before placing the catheter.
Implantation Instructions

1. Create sterile field and open tray.
2. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site.
3. Locate desired vessel using a small needle attached to a syringe. Note: The subclavian vein is entered percutaneously at the point that identifies the junction of the outer and middle thirds of the clavicle using the needle and syringe.

Refer to the “Warnings” section concerning Catheter Pinch-off.

4. Insert introducer needle with attached syringe into vein. Confirm placement by aspirating blood.
5. Aspirate gently as the insertion is made. Warning: 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.

6. When the subclavian 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. The risk of air aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

7. Straighten “J” tip of guidewire with tip straightener and insert tapered end of tip straightener into the needle. Tip straightener should not be advanced over the guidewire beyond the guidewire tip. Caution: Do not insert guidewire beyond the bevel of the needle while removing straightener from the needle hub in order to prevent guidewire damage or shearing. Remove the tip straightener and advance the guidewire as far as appropriate for the procedure. Verify correct positioning radiographically.

8. Gently withdraw and remove needle. Caution: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and guidewire as a unit to help prevent the needle from damaging or shearing the guidewire.

9. Make a small (approx. 1 cm wide) incision parallel to the clavicle, positioning the guidewire at the center of the incision to permit proper entry of vessel dilator and sheath introducer.

10. Advance the vessel dilator and sheath introducer as a unit over the exposed guidewire using a rotational motion. Advance it into the vein as a unit, leaving at least 2 cms of sheath exposed. Warning: Avoid vessel perforation.
11. Release the locking mechanism and gently withdraw the vessel dilator and “J” guidewire, leaving the sheath in place.

12. **Warning:** Hold thumb over exposed orifice 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.

13. Insert catheter into lumen of sheath and advance to desired position in vessel.

14. Verify catheter tip location radiographically. **Warning:** Avoid positioning the catheter tip in the right atrium. The preferred location of the catheter tip is at the junction of the superior vena cava and the right atrium.

15. Grasp the two handles of the peel-apart sheath and pull outward and upward at the same time.

16. Peel the sheath away from the catheter completely. Make sure the catheter is not dislodged from vessel as sheath is removed.

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**References**


An issued or revision date for these instructions is included for the user’s information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems to see if additional product information is available.

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