with Safety Microintroducer
Instructions For Use
Product Description

The Poly Per-Q-Cath® Triple Lumen PICC is a triple lumen peripherally placed central catheter. Each Poly Per-Q-Cath® Triple Lumen PICC is made from specially formulated and processed polyurethane and other medical grade materials. The Poly Per-Q-Cath® Triple Lumen PICC catheters feature a thin wall design with one large and two smaller lumens. Catheters are packaged in a tray with accessories for reliable long (greater than 30 days) or short (less than 30 days) term vascular access. This microintroducer kit is an introducer system designed for access of peripheral veins using a minimal insertion techniques for the placement of Bard Access Systems Peripherally Inserted Central Catheters and Midline Catheters.

New Important Information:

• **Warning:** When using alcohol or alcohol containing antiseptics with polyurethane PICCs, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

• **Warning:** Alcohol should not be used to soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

• The Poly Per-Q-Cath® Triple Lumen PICC catheter features a reverse-taper catheter design. **Caution:** Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of Poly Per-Q-Cath® Triple Lumen PICC above antecubital fossa is recommended.

• For Superior Vena Cava (SVC) placement, measure from the planned insertion site to the right clavicular head, then down to the third intercostal space. Use the zero mark as reference for point of insertion.

• Catheter does not require “s” curve for dressing and securement.

Indications

The Poly Per-Q-Cath® Triple Lumen PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. For blood therapy, it is recommended that a 4 french or larger catheter be used.

Contraindications:

The device is contraindicated whenever:

• The presence of device-related infection, bacteremia, or septicemia is known or suspected.

• The patient’s body size is insufficient to accommodate the size of the implanted device.

• The patient is known or is suspected to be allergic to materials contained in the device.

• Past irradiation of prospective insertion site.

• Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.

• Local tissue factors will prevent proper device stabilization and/or access.

Warnings:

• When using alcohol or alcohol containing antiseptics with polyurethane PICCs, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

• Alcohol should not be used to soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

• Acetone and polyethylene glycol containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.
• This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade.

• 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.

Chloraprep® One-Step Applicator

• Flammable. Keep away from fire or flame.

• Do not use with electrocautery procedures.

• For external use only.

• When using this product keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a physician.

• Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

• Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Precautions:

• 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.

• The Poly Per-Q-Cath™ Triple Lumen PICC catheter features a reverse-taper catheter design. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of the Poly Per-Q-Cath™ Triple Lumen PICC above antecubital fossa is recommended.

• Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and repeat stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into the desired position (zero mark).

• To minimize the risk of catheter breakage and embolization, the catheter must be secured in place.

• Do not cut the stylet.

• Follow Universal Precautions when inserting and maintaining the catheter.

• Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.

• The fluid level in the catheter will drop if the catheter connector is held above the level of the patient’s heart and opened to air. To help prevent a drop in the fluid level (and thus air entry) while changing injection caps, hold the connector below the level of the patient’s heart before removing the injection cap.

I. Prior to beginning placement procedure, do the following:

• Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a 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.

• Flush the catheter with sterile normal saline or heparinized saline prior to use. Catheter stylet must be wetted prior to stylet repositioning or withdrawal.

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-edgedatraumatic clamps or forcecs.

• Avoid perforating, tearing, or fracturing the catheter when using a stylet.

• Do not use the catheter if there is any evidence of mechanical damage or leaking.

• Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.

• Avoid sharp or acute angles during implantation which could compromise the patency of the catheter lumen(s).

• Do not suture around the catheter as sutures may damage the catheter or compromise catheter patency.

• Do not cut the stylet.

III. After placement, observe the following precautions to avoid device damage and/or patient injury:

• Do not use the device if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation and possible embolism and surgical removal.

• Accessories and components used in conjunction with this device should incorporate luer lock connections.

• If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.

• Infusion pressure greater than 25 psi (172 kPa) may damage blood vessels and visscus and is not recommended. DO NOT USE A SYRINGE SMALLER THAN 10 ml.

• For further information or questions, please call 800-443-3385 or 801-595-0700.

Possible Complications

The potential exists for serious complications including the following:

• Air Embolism

• Bleeding

• Brachial Plexus Injury

• Cardiac Arrythmia

• Cardiac Tamponade

• Catheter Erosion

• Through the Skin

• Catheter Embolism

• Catheter Occlusion

• Catheter-related

• Sepsis

• Endocarditis

• Exit Site Infection

• Exit Site Necrosis

• Extravassation

• Fibrin Sheath Formation

• Hematoma

• Intolerance Reaction to Implanted Device

• Laceration of Vessels or Viscus

• Myocardial Erosion

• Perforation of Vessels or Viscus

• Phlebitis

• Spontaneous Catheter Tip Malposition or Retraction

• Thromboembolism

• Venous Thrombosis

• Ventricular Thrombosis

• Vessel Erosion

• Risks Normally Associated with Local or General Anesthesia, Surgery and Post Operative Recovery

Poly Per-Q-Cath™ Triple Lumen PICC
**Insertion Instructions**

1. **Identify the Vein and Insertion Site**
   - Apply a tourniquet above the anticipated insertion site.
   - Select a vein based on patient assessment. Recommended veins are basilic, cephalic and median cubital veins.
   - **Caution:** Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis.
   - Placement of a Poly Per-Q-Cath™ Triple Lumen PICC above antecubital fossa is recommended.
   - Release tourniquet.

2. **Patient Position / Catheter Measurement**
   - Position the arm at a 90° angle.
   - For SVC placement, measure from the planned insertion site to the right clavicular head, then down to the third intercostal space. Use zero mark as reference for point of insertion. Note that the external measurement can never exactly duplicate the internal venous anatomy.

3. **Preflush the Catheter**
   - Flush all lumens of the catheter with heparinize saline solution.
   - Attach prefilled syringe to the luer attachment on the extension set.
   - Preflush catheter with sterile normal saline or heparinized saline to wet hydrophilic stylet.
   - Leave syringe attached during procedure.

4. **Modification of Catheter Length**
   - **Note:** Catheters can be cut to length if a different length is desired due to patient size and desired point of insertion according to hospital protocol. Catheter depth markings are in centimeters.
   - Measure the distance from the zero mark to the desired tip location.
   - **Retract the stylet to well behind the point the catheter is to be cut.**
   - Using a sterile scalpel or scissors, carefully cut the catheter according to institutional policy if necessary.
   - **Caution:** Do not cut stylet.
   - Inspect cut surface to assure there is no loose material.
   - Re-advance the stylet to the distal end of the trimmed catheter.

5. **Prepare for Insertion**
   - Set-up the sterile field.
   - Prepare the site with the ChloraPrep™ One-Step Applicator or according to institutional policy using sterile technique.
   - Pinch the wings on the ChloraPrep™ One-Step Applicator to break the ampule and release the antiseptic. Do not touch the sponge.
   - Wet the sponge by repeatedly pressing and releasing the sponge against the treatment area until fluid is visible on the skin.

6. **Apply Tourniquet and Drape**
   - Apply the tourniquet above the intended insertion site to distend the vessel.
   - Drape the patient by placing the fenestrated drape over the anticipated puncture site.

7. **Perform Venipuncture**
   - Identify the insertion site for the catheter and prepare the site using proper aseptic technique and local anesthesia as required.
   - Insert the safety introducer needle into the desired vein.
   - **Alternate Technique:** The safety IV catheter may be used as an alternate to the safety introducer needle. Remove the needle from the catheter after the vein is accessed.
   - **WARNING:** If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
   - Remove the guidewire tip protector from the guidewire hoop and insert the flexible end of the guidewire into the introducer needle or catheter and into the vein. Advance the guidewire to the desired depth.
   - Advance the small sheath and dilator together as a unit over the guidewire, using a slight rotational motion. If necessary, a small incision may be made adjacent to the guidewire to facilitate insertion of the sheath and dilator. Verify institutional guidelines concerning the use of a safety scalpel prior to making incision.
   - Withdraw the dilator and guidewire, leaving the small sheath in place.
   - **WARNING:** Place a finger over the orifice of the sheath to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.

   **Caution:** Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
   - **Caution:** Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of PICC above antecubital fossa is recommended.

   - Gently withdraw and remove the safety introducer needle or catheter, while holding the guidewire in position. **CAUTION:** If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
8. Insert and Advance the Catheter
   - Insert the catheter into the PTFE Introducer sheath.
   - Advance the catheter slowly. When the catheter tip has
     advanced at least 10 cm, the sheath may be removed.

9. Retract and Remove the PTFE Introducer Sheath
   - Stabilize the catheter position by applying pressure to the
     vein distal to the PTFE Introducer sheath.
   - Withdraw the PTFE Introducer sheath from the vein and away
     from the site.
   - Split the PTFE Introducer sheath and peel it away from the
     catheter.

10. Complete Catheter Insertion
    - Continue to advance the catheter. For central placement, when
        the tip has advanced to the shoulder, have the patient turn head
        (chin on shoulder) toward the insertion side to prevent possible
        cannulation into the jugular vein.
    - The Poly Per-Q-Cath™ Triple Lumen PICC catheter features a
      reverse-taper catheter design.
    - Caution: Placement of larger catheters at or below antecubital
      fossa may result in an increased incidence of phlebitis.
      Placement of PICC above antecubital fossa is recommended.
    - Position the arm at a 90° angle, maintaining sterility. Complete
      catheter advancement into the desired position (zero mark).
    - Warning: This is not a right atrium catheter. Avoid positioning the
      catheter tip in the right atrium. Placement or migration of the
      catheter tip into the right atrium may cause cardiac arrhythmia,
      myocardial erosion or cardiac tamponade.

11. Remove the Stylet/ T-Lock Assembly
    Disconnect the T-Lock from the catheter Luer connector.
    - Stabilize the catheter position by applying light pressure to the
      vein distal to the insertion site.
    - Slowly remove the T-Lock and stylet.
    - Caution: Never use force to remove the stylet. Resistance can
      damage the catheter. If resistance or bunching of the catheter is
      observed, stop stylet withdrawal and allow the catheter to return
      to normal shape. Withdraw both the catheter and stylet togeth-
      er approximately 2 cm and reattempt stylet removal. Repeat this
      procedure until the stylet is easily removed. Once the stylet is
      out, advance the catheter into the desired position (zero mark).

12. Aspirate and Flush
    - Attach primed extension set and/or saline-filled syringe.
    - Aspirate for adequate blood return and flush each
      lumen of the catheter to ensure patency.

13. Verify Placement
    - Verify catheter tip location radiographically.

14. Securing the Poly Per-Q-Cath™ Triple Lumen PICC:
The StatLock® stabilization device is included in Poly Per-Q-Cath™ Triple Lumen PICC kits.
Please refer to Instructions For Use on the proper use and removal.
The StatLock® stabilization device should be monitored daily and replaced at least every seven days.
- Caution: To minimize the risk of catheter breakage and embolization, the catheter must be secured
  in place.
- Warning: When using alcohol or alcohol containing antiseptics with polyurethane PICCs, care
  should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely
  dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the
  suggested antiseptics to use.
- Warning: Alcohol should not be used to soak or declot polyurethane PICCs because alcohol is
  known to degrade polyurethane catheters over time with repeated and prolonged exposure.
- Warning: Acetone and polyethylene glycol containing ointments should not be used with polyurethane
  catheters, as these may cause failure of the device.
The StatLock® Stabilization Device Procedure

1. Secure catheter with the StatLock® stabilization device.
2. Cover site and the StatLock® stabilization device with transparent dressing.
3. Place 1st anchor tape sticky side up, under one extension leg. Wedge tape between hub and wings. Chevron anchor tape on top of transparent dressing.
4. Place 2nd and 3rd anchor tapes sticky side up under remaining hubs. Wedge tape between hubs and wings. Chevron anchor tape on top of transparent dressing.

Tape Strip Securement Procedure

1. Place 1st anchor tape over wings or trifurcation.
2. Cover site and 1st anchor tape with transparent dressing up to hub, but not over hub.
3. Place 2nd anchor tape sticky side up under hub and close to transparent dressing. Wedge tape between hub and wings. Chevron anchor tape on top of transparent dressing.
4. Place 2nd and 3rd anchor tapes sticky side up under remaining hubs. Wedge tape between hubs and wings. Chevron anchor tape on top of transparent dressing.

Suggested Catheter Maintenance

The catheter should be maintained in accordance with standard hospital protocols. Suggested catheter maintenance is as follows:

- **Dressing Changes**
  Assess the dressing in the first 24 hours for accumulation of blood, fluid or moisture beneath the dressing. During all dressing changes, assess the external length of the catheter to determine if migration of the catheter has occurred. Periodically confirm catheter placement, tip location, patency and security of dressing.

- **Flushing**
  Flush each lumen of the catheter with heparinized saline every 12 hours or after each use. Usually, one ml per lumen is adequate.

- **Occluded or Partially Occluded Catheter**
  Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against resistance. If the lumen will neither flush nor aspirate and it has been determined that the catheter is occluded with blood, a declotting procedure per institution protocol may be appropriate.

- **When cleaning the exit site**
  - **WARNING:**
  - Do not wipe the catheter with acetone based solutions or polyethylene glycol containing ointments. These can damage the polyurethane material if used over time.
  - **DO:**
  - Maintain according to hospital protocol. Avoid using acetone based solutions, or ointment. These substances are known to degrade polyurethane.
  - Use Chlorhexidine gluconate or povidone iodine to clean the exit site around the catheter.
  - Allow all cleaning agents / antiseptics to dry completely before applying dressing.

Catheter Removal

- Remove dressing.
- Grasp catheter near insertion site.
- Remove slowly. Do not use excessive force.
- If resistance is felt, stop removal. Apply warm compress and wait 20 - 30 minutes.
- Resume removal procedure.
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, Inc. to see if additional product information is available.

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*CloraPrep is a registered trademark of MediFlex Hospital Products.

Covered by one or more of the following U.S. Patents: 4,828,547; 5,009,624; 5,221,263; 5,951,520.

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