Product Description

The Poly Per-Q-Cath™ catheters are a family of single and dual-lumen peripherally placed central catheters. Each catheter is made from specially formulated and processed polyurethane and other medical grade materials. Poly Per-Q-Cath™ catheters have a thicker wall, are kink resistant, and feature a reverse tapered design. Catheters are packaged in a tray with accessories for reliable long (greater than 30 days) or short (less than 30 days) term vascular access.

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. Chlordexidine 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™ 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.
• 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™ 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:**

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- Alcohol should not be used to soak or declo 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. The risk of these complications may be more likely in neonatal patients.
- 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.

**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.
- The Poly Per-Q-Cath® 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 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 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).
- To minimize the risk of catheter breakage and embolization, the catheter must be secured in place.
- Do not cut stylet.
- For those unfamiliar with the procedure, published studies and a video are available from Bard Access Systems depicting insertion and maintenance techniques.
- For further information or questions, please call 800-443-3385 or 801-595-0700.

**Precautions:**

- Follow Universal Precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, cautions, precautions and instructions for all infusates as specified by their manufacturer.
- 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-edged atraumatic clamps or forceps.
- 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 viscus and is not recommended. DO NOT USE A SYRINGE SMALLER THAN 10 ml.

**Possible Complications**

The potential exists for serious complications including the following:

• Air Embolism
• Bleeding
• Brachial Plexus Injury
• Cardiac Arrhythmia
• Cardiac Tamponade
• Catheter Erosion Through the Skin
• Catheter Embolism
• Catheter Occlusion
• Catheter-related Sepsis
• Endocarditis
• Exit Site Infection
• Exit Site Necrosis
• Extravasation
• 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

**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, median cubital veins. The Poly Per-Q-Cath® 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.
   - 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 cannot exactly duplicate the internal venous anatomy.

3. **Preflush the Catheter**
   - 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.
  - Use repeated back-and-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to dry for approximately 30 seconds. **Do not blot or wipe away.**
  - Maximum treatment area for one applicator is approximately 130 cm² (approximately 4 x 5 in). Discard the applicator after a single use.
- Remove and discard gloves.
- When alcohol is used as a skin prep, it must be allowed to completely air dry.

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**

- Remove the needle guard.
- Grip only the needle hub during insertion. Do not apply excessive pressure to the wings.
- Perform venipuncture and observe for flashback.
- Holding the needle stationary, advance the Safety Excalibur® Introducer sheath into the vessel by pushing forward.

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

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8. **Withdraw the Safety Excalibur® Introducer Needle**

- Support the Safety Excalibur® Introducer sheath to avoid displacement.
- Apply slight pressure on the vessel above the insertion site to minimize blood flow.
- Release the tourniquet.
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9. Insert and Advance the Catheter

- Insert the catheter into the Safety Excalibur* Introducer sheath.
- Advance the catheter slowly. When the catheter tip has advanced at least 10 cm, the sheath may be removed.

10. Retract and Remove the Safety Excalibur* Introducer Sheath

- Stabilize the catheter position by applying pressure to the vein distal to the Safety Excalibur* Introducer sheath.
- Withdraw the Safety Excalibur* Introducer sheath from the vein and away from the site.
- Split the Safety Excalibur* Introducer sheath and peel it away from the catheter.

11. 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.

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- 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. The risk of these complications may be more likely in neonatal patients.

Note: Resistance may be felt approximately 7cm distal of catheter hub when introducing the catheter into the sheath due to an increase in O.D. The introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.

12. 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.
13. 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.

14. Verify Placement

- Verify catheter tip location radiographically.

15. Securing the Poly Per-Q-Cath* Catheter:

StatLock* stabilization device is included in Poly Per-Q-Cath* kits. Please refer to Instructions For Use on the proper use and removal. 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.
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 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.