Per-Q-Cath® PICC
and MIDLINE Catheters
with Excalibur Introducer®
System

Instructions For Use
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Product Description

A family of single and dual-lumen peripherally placed and central catheters made from specially formulated and processed medical grade materials, in a tray with accessories for reliable long (greater than 30 days) or short (less than 30 days) term vascular access.

Indications

The Per-Q-Cath PICCs are indicated for short or long term peripheral access to the central venous system for intravenous therapy and blood sampling. The Per-Q-Cath Midline catheters are indicated for short or long term peripheral access to the peripheral venous system for selected intravenous therapies and blood sampling. (See Contraindications) 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.
• A midline catheter placement is contraindicated for patients requiring any of the following:
  • Solutions with final glucose concentrations above 10 percent;
  • Solutions with protein concentrations above 5 percent;
  • Continuous infusion of vesicants.
Warnings:

- Use of ointments with polyurethane Per-Q-Cath* catheters can cause failure of the device.
- Alcohol or acetone based solutions should not be used to clean the polyurethane Per-Q-Cath* catheter or skin site as the catheter may be adversely affected. Povidone iodine is the recommended antiseptic solution to be used.
- When alcohol is used as a skin prep, it must be allowed to completely air dry.
- 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.
- Povidone-iodine is the suggested antiseptic to use. Acetone and tincture of iodine should not be used. 10% acetone/70% isopropyl alcohol swabsticks used for dressing changes may be used for silicone Per-Q-Cath* catheters.
- 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.
- 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.
- To minimize the risk of catheter breakage and embolization, the catheter must be secured in place.
Precautions

- 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 its 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 sharp or acute angles during implantation which could compromise the patency of the catheter lumen(s).
Precautions & Possible Complications

- Do not place 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 CC!

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
- Endocarditis or Viscus
Insertion Instructions

1. Identify the Vein and Insertion Site
   - Apply a tourniquet above the anticipated insertion site.
   - Select a vein based on patient assessment. Veins of the antecubital fossa are recommended (basilic, cephalic median cubital veins) with the basilic preferred.
   - 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 clavicle head, then down to the third intercostal space. Note that the external measurement can never 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

• To modify the length of the catheter due to patient size, measure the distance from the insertion site to the desired tip location. Catheter depth markings are in centimeters.

Retract the stylet to well behind the point the catheter is to be cut.

• Using a sharp scalpel or sterile scissors, carefully cut the catheter according to institutional policy.

• Caution: Do not cut stylet.

• Inspect cut surface to assure there is no loose material.

5. Prepare for Insertion

• Set-up the sterile field.

• Prepare the site according to institution policy using sterile technique.

• 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.
**Insertion Instructions**

### 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 **Excalibur Introducer** sheath into the vessel by pushing forward.

### 8. Withdraw the Excalibur Introducer* Needle

- Support the **Excalibur Introducer** sheath to avoid displacement.
- Apply slight pressure on the vessel above the insertion site to minimize blood flow.
- Release the tourniquet.
- Withdraw the needle from the **Excalibur Introducer** sheath.
9. Insert and Advance the Catheter
- Insert the catheter into the 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 Excalibur Introducer* Sheath
- Stabilize the catheter position by applying pressure to the vein distal to the Excalibur Introducer* sheath.
- Withdraw the Excalibur Introducer* sheath from the vein and away from the site.
- Split the 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.

- Position the arm at a 90° angle, maintaining sterility. Complete catheter advancement to the desired position.

- **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.

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.

- **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 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.
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 Per-Q-Cath* Catheter:
- **Caution:** To minimize the risk of catheter breakage and embolization, the catheter must be secured in place.
- **Warning:** Use of ointments with the polyurethane Per-Q-Cath* catheter can cause failure of the device.
- **Warning:** Alcohol or acetone based solutions should not be used to clean polyurethane Per-Q-Cath* catheters or skin site as the catheter may be adversely affected. Povidone iodine is the recommended antiseptic solution to be used.

### Single Lumen

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1. S-Curve</td>
<td>![S-Curve Image]</td>
</tr>
<tr>
<td>2. Place 1st anchor tape over wings or bifurcation.</td>
<td>![Anchor Tape Image]</td>
</tr>
<tr>
<td>3. Cover site and 1st anchor tape with transparent dressing up to hub, but not over hub.</td>
<td>![Dressing Image]</td>
</tr>
<tr>
<td>4. Place 2nd anchor tape sticky side up under hub and close to transparent dressing. Wedge tape between hub and wings. Anchor only one hub of dual lumen catheter.</td>
<td>![Wedge Tape Image]</td>
</tr>
<tr>
<td>5. Chevron 2nd anchor tape on top of transparent dressing and place 3rd anchor tape over hub.</td>
<td>![Chevron Anchor Image]</td>
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### Dual Lumen

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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**
  For intermittent use, 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.

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 to see if additional product information is available.

Revised date: November 2007

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