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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Table of Contents

1 Product Description, Indications, and Contraindications

2 Warnings

3-4 Cautions and Precautions

5 Possible Complications

5-13 Insertion Instructions
   1. Identify the Vein and Insertion Site
   2. Preflush the Catheter and Stylet
   3. Apply Tourniquet and Drape
   4. Perform Venipuncture
   5. Advance Guidewire
   6. Remove Needle
   7. Introduce Microintroducer
   8. Measure Distance to Tip Location
   9. Removing Dilator and Guidewire
  10. Modification of Catheter Length
  11. Insert and Advance the Catheter
  12. Retract and Remove Microintroducer Sheath
  13. Complete Catheter Insertion
  14. Aspirate and Flush
  15. Dress Catheter
  16. Verify Placement

13 Suggested Catheter Maintenance and Catheter Removal
A family of peripherally placed central catheters made from specially formulated and processed medical grade materials. Poly RadPICC™ catheters have a thicker wall, kink resistant, and reverse tapered catheter. Catheters are packaged in a tray with accessories necessary for a percutaneous micro introducer introduction. (Seldinger technique).

New Important Information:

- 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.
- The Poly RadPICC™ 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 RadPICC™ catheter 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 they may damage the device.
- Intended for Single Patient Use. DO NOT REUSE. Bard Access Systems products are single use devices and must never be re-implanted. 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 must not be reused or re-sterilized.
- 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.
- 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.
- When the dilator and guidewire are withdrawn from the sheath, place a finger over the sheath opening 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 or by attaching a syringe or injection cap to the dilator to reduce blood flow while trimming the catheter.
- Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- 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 (allowing air entry) while changing injection caps, hold the connector below the level of the patient’s heart before removing the injection cap.
- Place a finger over the needle to minimize blood loss and risk of air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient holding his breath until the guidewire is inserted into the needle.
Bard Access Systems

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 this catheter.
• The Poly RadPICC® 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.
• For those unfamiliar with the procedure, published studies and a video are available from Bard Access Systems depicting insertion and maintenance techniques.
• 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).
• When trimming the catheter, do not cut the stylet.
• Do not advance the guidewire past the axilla without fluoroscopic guidance.
• The catheter must be secured in place to minimize the risk of catheter breakage and embolization.
• For further information or questions, please call 800-443-3385 or 801-595-0700.

Precautions:

• Only medical practitioners licensed by law, trained and experienced in proper positioning of catheters in the central venous system using percutaneous entry (Seldinger technique) should place this catheter.
• 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.
• Precautions are intended to help avoid catheter damage and/or patient injury.

I. Prior to placement:

• Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The catheter 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 presence of all components.
• Flush the stylet with sterile normal saline or heparinized saline to wet the stylet prior to use, repositioning or withdrawal.

II. During placement:

• Do not allow device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
• Do not perforate, tear, or fracture 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.
• Do not bend the catheter at sharp angles during implantation as this can compromise patency of the catheter.
• Do not place suture around the catheter. Sutures may damage the catheter or compromise catheter patency.
• Do not cut the stylet.
• Do not advance the guidewire into superior vena cava except under x-ray or fluoroscopy. Assure proper tip position in order to prevent erosion or perforation of central venous system.

III. After placement:

• WARNING: Do not use the device if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.
• Accessories and components with Luer Lock connections should be used with this device.
• WARNING: If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
• DO NOT USE A SYRINGE SMALLER THAN 10ml! Infusion pressure greater than 25psi may damage blood vessels or viscus.
• Tip position should be verified by x-ray and monitored on a routine basis.
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

   1. Apply a tourniquet above the anticipated insertion site.
   2. Select a vein by assessing patient anatomy and condition. Recommended veins are with the basilic or median cubital basilic. The PolyRadPICC* 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.
   3. Release tourniquet.
   4. Set up the sterile field.

2. Preflush the Catheter and Stylet

   1. Flush the catheter with heparinized saline solution or sterile water. Note: The catheter may be trimmed if a shorter length is required.
   2. Attach a syringe with heparinized saline solution or sterile normal saline to the Luer Lock fitting of the flush through stylet hub.
   3. Inject enough solution to wet the Hydro-Glide* stylet surface entirely. This will activate the hydrophilic coating, making the stylet surface very lubricious.
   4. Remove the stylet from its holder and insert it into the catheter. If the catheter has been trimmed, only advance the stylet to the distal end of the catheter. Note: If the surface of the stylet becomes dry after removal from the holder, wetting with additional heparinized saline or sterile normal saline will renew the hydrophilic effect.
   5. The catheter stylet assembly can now be introduced as described in the following information.

3. Apply Tourniquet and Drape

   1. Position arm at 90° angle.
   2. Re-apply the tourniquet above the intended insertion site to distend the vessel.
   3. Prepare the site according to institution policy using sterile technique.
   4. Drape the patient by placing the fenestrated drape over the anticipated puncture site.
   5. When alcohol is used as a skin prep, it must be allowed to completely air dry.
4. Perform Venipuncture

1. Remove the needle guard and attach a syringe.
2. Introduce the needle into the vessel and observe for flashback.
3. When the vein has been entered, remove the syringe leaving the needle in place.

**WARNING:** Place a finger over the needle to minimize blood loss and risk of air aspiration. The risk of air aspiration is reduced by performing this part of the procedure with the patient holding his breath until the guidewire is inserted into the needle.

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

**Caution:** The Poly RadPICC* 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.

5. Advance Guidewire

1. Introduce the guidewire through the needle; advance the guidewire 15 to 20cm into the vessel.

**Caution:** Do not advance the wire past the axilla without fluoroscopic guidance.

6. Remove Needle

1. Release tourniquet. Apply slight pressure on the vessel above the insertion site, to minimize blood flow.
2. If necessary, enlarge the puncture site with a #11 scalpel blade.
3. Leaving the guidewire in place, withdraw the needle.

7. Introduce Microintroducer

1. Introduce the microintroducer assembly over the guidewire. Using a twisting motion, advance the assembly into the vessel.

8. Measure Distance to Tip Location

1. Using fluoroscopic control, determine the correct catheter length by advancing the guidewire to the desired catheter tip location in the SVC.
2. Once the guidewire tip is in proper position, mark the length by clamping forceps onto the guidewire at the skin site.
9. Removing Dilator and Guidewire

1. Rotate locking collar of dilator and remove dilator from sheath.
2. Withdraw the dilator and guidewire, leaving the small sheath in place. **WARNING:** Place a finger over the sheath opening 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 or by attaching a syringe or injection cap to the dilator to reduce blood flow while trimming the catheter.

10. 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.

1. Measure the distance from the insertion site (zero mark) to the desired tip location.
2. Using the guidewire to indicate desired length, retract the stylet behind the point the catheter is to be cut.
3. Using a sterile scalpel or scissors, carefully cut the catheter according to institutional policy if necessary.
4. **Caution:** Do not cut stylet.
5. Inspect cut surface to assure there is no loose material.
6. Re-advance the stylet to the distal end of the trimmed catheter.

11. Insert and Advance the Catheter

1. Insert the catheter and stylet as a unit into the microintroducer sheath.
2. Advance the catheter slowly.

12. Retract and Remove the Microintroducer Sheath

1. Stabilize the catheter position by applying pressure to the vein distal to the microintroducer sheath.
2. Withdraw the microintroducer sheath from the vein and away from the site.
3. Split the microintroducer sheath and peel it away from the catheter.
13. Complete Catheter Insertion

1. 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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2. 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.

3. Stabilize the catheter position by applying light pressure to the vein distal to the insertion site. Slowly remove the stylet.

4. Place a finger over the catheter opening to minimize blood loss.

14. Aspirate and Flush

1. Attach primed extension set and/or saline-filled syringe.

2. Aspirate for adequate blood return and flush each lumen of the catheter to ensure patency.

15. Dress Catheter

**StatLock** Stabilization Device Procedure

**Single Lumen**

1. Secure catheter with StatLock stabilization device.

2. Cover site and StatLock stabilization device with transparent dressing.

3. Place anchor tape sticky side up, under hub. Wedge tape between hub and wings.

4. Chevron anchor tape on top of transparent dressing.

**Dual Lumen**

1. Secure catheter with StatLock stabilization device.

2. Cover site and 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 anchor tape sticky side up under hub. Wedge tape between hub and wings. Chevron anchor tape on top of transparent dressing.

**Tape Strip Securement Procedure**

**Single Lumen**

1. Place 1st anchor tape over wings or bifurcation.

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. Anchor only one hub of dual lumen catheter.

4. Chevron 2nd anchor tape on top of transparent dressing and place 3rd anchor tape over hub

**Dual Lumen**

1. Place 1st anchor tape over wings or bifurcation.

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. Anchor only one hub of dual lumen catheter.

4. Chevron 2nd anchor tape on top of transparent dressing and place 3rd anchor tape over hub.
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 ointment. 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 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.

**Important:** Please fill out the patient information card and separate from booklet. Fold on the crease provided and give to the patient for them to keep at all times.

**Note:** See other side for special instructions for care and maintenance.