

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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U.S. Patent Pending.

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The Power of Purple\*

***Polyurethane Radiology  
Catheters with  
Microintroducer Set***

Instructions For Use

**BARDD**

**Bard Access Systems, Inc.**

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**BARDD**

**Bard Access Systems**



## New Important Information:

- Contrast media should be warmed to body temperature prior to power injection.  
**Warning:** Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Vigorously flush the **PowerPICC\*** catheter using a 10 ml or larger syringe and sterile normal saline prior to and immediately following the completion of power injection studies. In addition, lock each lumen of the catheter with heparinized saline. Usually one ml per lumen is adequate. This will ensure the patency of the **PowerPICC\*** catheter and prevent damage to the catheter. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed with power injection study until occlusion has been cleared.  
**Warning:** Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Use only lumens marked "Power Injectable" for power injection of contrast media.  
**Warning:** Use of lumens not marked "Power Injectable" for power injection of contrast media may cause failure of the catheter.
- Do not exceed the maximum flow rate of 5 ml/sec.  
**Warning:** Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter, which may lead to catheter failure.  
**Warning:** Exceeding the maximum flow rate of 5 ml/sec or the maximum pressure of power injectors of 300 psi, may result in catheter failure and/or catheter tip displacement.
- **Warning:** **PowerPICC\*** catheter indication for power injection of contrast media implies the catheter's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

## Power Injection Procedure

1. Remove the injection/needleless cap from the **PowerPICC\*** catheter.
2. Attach a 10 ml or larger syringe filled with sterile normal saline.
3. Aspirate for adequate blood return and vigorously flush the catheter with the full 10 ml of sterile normal saline.  
**Warning:** Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
4. Detach syringe.
5. Attach the power injection device to the **PowerPICC\*** catheter per manufacturer's recommendations.
6. Contrast media should be warmed to body temperature prior to power injection.  
**Warning:** Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
7. Use only lumens marked "Power Injectable" for power injection of contrast media.  
**Warning:** Use of lumens not marked "Power Injectable" for power injection of contrast media may cause failure of the catheter.
8. Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum flow rate of 5 ml/sec.  
**Warning:** Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter, which may lead to catheter failure.  
**Warning:** Exceeding the maximum flow rate of 5 ml/sec or the maximum pressure of power injectors of 300 psi may result in catheter failure and/or catheter tip displacement.
9. Disconnect the power injection device.
10. Replace the injection/needleless cap on the **PowerPICC\*** catheter.
11. Flush the **PowerPICC\*** catheter with 10 ml of sterile normal saline, using a 10 ml or larger syringe. In addition, lock each lumen of the catheter with heparinized saline. Usually one ml per lumen is adequate.

## Product Description

A family of peripherally inserted central catheters made from specially formulated and processed medical grade materials. **PowerPICC\*** catheters have a kink resistant reverse tapered design. Catheters are packaged in a tray with accessories necessary for a percutaneous microintroducer introduction (Seldinger technique).

**Contents are supplied sterile. Sterilized by ethylene oxide. DO NOT RESTERILIZE.**

## Indications

The **PowerPICC\*** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. The maximum recommended infusion rate is 5 ml/sec for power injection of contrast media. For central venous pressure monitoring, it is recommended that a catheter lumen of 20 gauge or larger be used.

## **Contraindications, Warnings and Precautions:**

*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.
- There has been past irradiation of prospective insertion site.
- There have been previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
- There are local tissue factors that may 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 lock, soak or de clot polyurethaneCs 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 must 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.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Use of lumens **not** marked "Power Injectable" for power injection of contrast media may cause failure of the catheter.
- Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may lead to catheter failure.
- Exceeding the maximum flow rate of 5 ml/sec or the maximum pressure of power injectors of 300 psi, may result in catheter failure and/or catheter tip displacement.
- **PowerPICC**<sup>®</sup> catheter indication for power injection of contrast media implies the catheter's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.
- If the artery is entered, withdraw the needle and apply manual pressure for the several minutes.
- 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 until the guidewire is inserted into the needle.
- 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.
- Central venous pressure monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

## **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, including contrast media, as specified by their manufacturer.
- 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 health care practitioners should insert, manipulate and remove these devices.
- The **PowerPICC**<sup>®</sup> 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 **PowerPICC**<sup>®</sup> 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).
- When trimming the catheter, do not cut stylet.
- Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
- 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.

### 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 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 securing 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 10 ml!** Prolonged infusion pressure greater than 25psi may damage blood vessels or viscus.
- **WARNING:** Exceeding the maximum flow rate of 5 ml/sec may result in catheter failure and/or catheter tip displacement.

## 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
- 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 cephalic, basilic or median cubital basilic. The **PowerPICC<sup>®</sup>** 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 **PowerPICC<sup>®</sup>** catheter above antecubital fossa is recommended.
3. Release tourniquet.
4. Set up the sterile field.



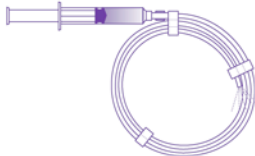
### 2. Preflush the Catheter and Stylet

1. Flush the catheter with heparinized saline solution or sterile normal saline.

**Note:** The catheter may be trimmed if a shorter length is required.

**Optional: For use only when the catheter is not inserted using the over the wire insertion technique.**

2. Attach a syringe with sterile normal saline to the Luer Lock fitting of the flush through stylet hub.
3. Inject enough solution to wet the stylet surface entirely. This will activate the hydrophilic coating, making the stylet surface very lubricious.



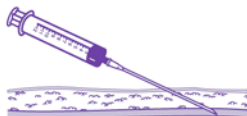
- Remove the stylet from its holder and insert it into the catheter. If the catheter has been trimmed, only advance the stylet to the distal end of the catheter. **Note:** If the surface of the stylet becomes dry after removal from the holder, wetting with additional sterile normal saline will renew the hydrophilic effect.
- The catheter stylet assembly can now be introduced as described in the following information.

### 3. Apply Tourniquet and Drape

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

### 4. Perform Venipuncture

- Remove the needle guard and attach a syringe.
  - Introduce the needle into the vessel and observe for flashback.
  - 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.

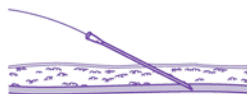


**Caution:** Avoid placement or securing of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.

**Caution:** The **PowerPICC**® 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 **PowerPICC**® catheter above antecubital fossa is recommended.

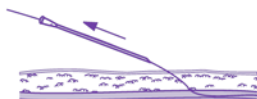
### 5. Advance Guidewire

- Introduce the guidewire through the needle; advance the guidewire 15 to 20 cm into the vessel.
- Caution:** Do not advance the wire past the axilla without fluoroscopic guidance.



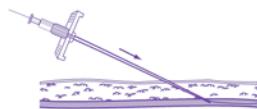
### 6. Remove Needle

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



### 7. Introduce Microintroducer

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



### 8. Measure Distance to Tip Location

- Using fluoroscopic control, determine the correct catheter length by advancing the guidewire to the desired catheter tip location in the SVC.
- 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

- Rotate locking collar of dilator and remove dilator from sheath.
  - 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.

- Measure the distance from the insertion site (zero mark) to the desired tip location.
- Using the guidewire to indicate desired length, retract the stylet 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:** When trimming the catheter, 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.



## 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 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

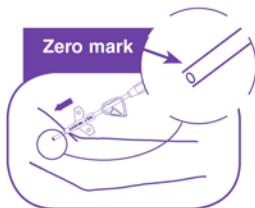
1. Continue to advance the catheter. For central placement, when the tip has advanced to the shoulder, have the patient turn head (chin on shoulder) toward the insertion side to prevent possible cannulation into the jugular vein.

**Caution:** The **PowerPICC**<sup>®</sup> 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 **PowerPICC**<sup>®</sup> catheter above antecubital fossa is recommended.

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.



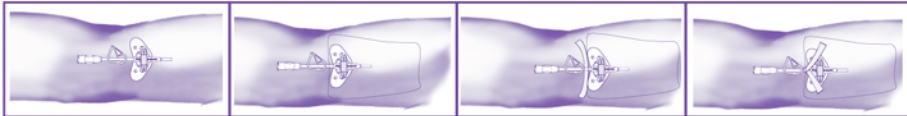
## 14. Aspirate and Flush

1. Attach primed extension set and/or sterile normal saline-filled syringe.
2. Aspirate for adequate blood return and flush each lumen of the catheter to ensure patency. In addition, lock each lumen of the catheter with heparinized saline. Usually, one ml per lumen is adequate.

## 15. Dress Catheter

### StatLock<sup>®</sup> Catheter Stabilization Device Procedure

#### Single Lumen



1. Secure catheter with **StatLock**<sup>®</sup> catheter stabilization device.
2. Cover site and **StatLock**<sup>®</sup> catheter 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**<sup>®</sup> catheter stabilization device.
2. Cover site and **StatLock**<sup>®</sup> catheter 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.

### Triple Lumen



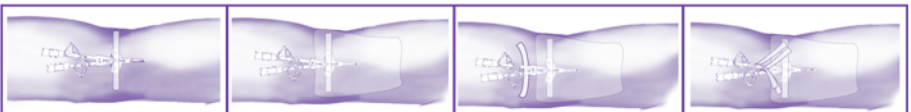
1. Secure catheter with **StatLock\*** catheter stabilization device.
2. Cover site and **StatLock\*** catheter stabilization device with transparent dressing.
3. Place 1st anchor tape sticky side up, under one extension leg. Wedge tape between hub and wings. Chevron anchor tape on top of transparent 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

#### Single Lumen



#### 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. Wedge tape between hub and wings. 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.

**Caution:** The catheter must be secured in place to minimize the risk of catheter breakage and embolization.

**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 lock, soak or de clot 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 damage the device.



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.

## 16. Verify Placement

- Verify catheter tip location radiographically.

## ***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 10 ml of saline every 12 hours or after each use. In addition, lock each lumen of the catheter with heparinized saline. 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 povidone iodine to clean the exit site around the catheter.
- Allow all cleaning agents / antiseptics to dry completely before applying dressing.

- **Power Injections**

The **PowerPICC**<sup>®</sup> catheter testing included 10 power injection cycles.

## ***Central Venous Pressure Monitoring***

- Prior to conducting central venous pressure monitoring:

- Ensure proper positioning of the catheter tip.
- Flush catheter vigorously with sterile normal saline
- Ensure the pressure transducer is at the level of the right atrium.

- It is recommended that a continuous infusion of saline (3 ml/hr) is maintained through the catheter while measuring CVP to improve the accuracy of CVP results.

- Use your institution's protocols for central venous pressure monitoring procedures.

- **Warning:** Central venous pressure monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

## ***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.