POWERPICC® PROVENA™

Radiology Polyurethane Catheter

with SOLO™2 Valve Technology and Microintroducer

BARD

ACCESS SYSTEMS

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Manufacturer:
Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 USA
801-522-5000
Clinical Information Hotline: 1-800-443-3385
Ordering Information: 1-800-545-0890
www.powerpicc.com
www.bardaccess.com

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Recommended Flushing/Maintenance Procedure(s)
The catheter should be maintained in accordance with standard hospital protocols. Recommended catheter flushing/maintenance is as follows:

1. Flush each lumen of the catheter after every use, or at least weekly when not in use. Use a 10 mL or larger syringe.
2. Flush each lumen of the catheter with a minimum of 10 mL of preservative-free 0.9% sodium chloride USP (sterile saline), using a "pulse" or "stop/start" technique. Use of heparin flush solution to lock each lumen of the catheter is optional.
3. Disconnect the syringe and attach a sterile end cap to the catheter hub and tighten securely.
4. Prior to blood sampling when infusing TPN, follow routine maintenance procedure except use 20 mL of sterile saline and flush to clear TPN from the catheter.
5. If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with possible embolization. Refer to institution protocol for clearing occluded catheters.

NOTE: When injecting or infusing medications that are incompatible, always flush the catheter with a minimum of 10 mL of sterile saline before and after each medication.
NOTE: When maintained in accordance with these instructions, the PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology does not require the use of heparin flush solution to lock the catheter lumens. However, use of heparin flush solution will not adversely affect the catheter and may be necessary based on patient status or use of alternate flushing and locking techniques.
Caution: To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the last 0.5 mL of sterile saline.
Caution: Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
Caution: The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology is designed for use with needleless injection caps or "direct-to-hub" connection technique. Apply a sterile end cap on the catheter hub to prevent contamination when not in use. **Use of a needle longer than 1.6 cm may cause damage to the valve.**
WARNING: Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

Product Description
A family of peripherally inserted central catheters made from specially-formulated and processed medical grade materials. Each PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology has a kink resistant, 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.

Sterilized by ethylene oxide. Do not re-sterilize.

PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology
The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology controls the flow of fluids to provide clamp-free infusion therapy. Positive pressure into the catheter (gravity, pump, syringe) will open the valve, allowing fluid infusion. When negative pressure (aspiration) is applied, the valve opens allowing for the withdrawal of blood into a syringe.

Indications
The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology 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
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
General 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 declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

- 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.
- Do not wipe the catheter with acetone-based solutions, tincture of iodine or polyethylene glycol-containing ointments. These can damage the polyurethane material if used over time.
- Intended for Single Patient Use. DO NOT REUSE. The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology is a single use device and should never be re-implanted. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Re-sterilization of incompletely cleaned devices may not be effective. Any device that has been contaminated by blood must not be reused or re-sterilized.
- 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 (CVP) monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

Placement Warnings
- If the artery is entered, withdraw the needle and apply manual pressure for 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 catheter is inserted into the sheath.
- 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.
- Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and/or risk of patient injury.

Power Injection Warnings
- 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.
- Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
- Failure to warm contrast media to body temperature prior to power injection 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 cause catheter failure.
- PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology 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.

Precautions

General Precautions
- Sterilized by ethylene oxide. Do not re-sterilize.
- Carefully read and follow all instructions prior to use.
- Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- Only qualified health care practitioners should insert, manipulate and remove these devices.
- 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.
- Precautions are intended to help avoid catheter damage and/or patient injury.
- Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
- 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.
- Inspect kit for inclusion of all components.
- Accessories and components used in conjunction with this device should incorporate luer lock connections.
- DO NOT USE A SYRINGE SMALLER THAN 10 mL TO FLUSH AND CONFIRM PATENCY. Patency should be assessed with a 10 mL syringe or larger filled with preservative-free 0.9% sodium chloride (sterile saline). Upon confirmation of patency, administration of medication should be given in a syringe appropriately sized for the dose. Do not infuse against resistance.
- Prolonged infusion pressure greater than 25 psi may damage blood vessels or viscus.
- Some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their catheter locked with heparin flush solution.

- As reported in literature, anaphylactic or anaphylactic-like reactions occur in a small percentage of the population during placement[1], positioning[1], flushing[2] of central venous catheters or cleaning of catheter exit site[3]. These reactions are reported in association with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some patients. Be aware of the potential symptoms or signs of these reactions and take precautionary steps as dictated by institution protocol for their prevention or treatment.
- If CHG allergy is suspected, confirmatory testing is recommended[4,5].

Precautions Related to Device Placement Procedure

- The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology 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® Provena™ Catheter with SOLO™2 Valve Technology above antecubital fossa is recommended.
- Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
- Flush each lumen of the catheter with sterile saline prior to use. Catheter stylet must be wetted prior to stylet repositioning or withdrawal.
- Do not advance the guidewire past the axilla without fluoroscopic guidance or other tip locating methods.
- 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.
- 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.
- 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 guidewire.
- Avoid sharp or acute angles during implantation which could compromise the patency of the catheter lumen.
- The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology is designed for use with needleless injection caps or "direct-to-hub" connection technique. Apply a sterile end cap on the catheter hub to prevent contamination when not in use. **Use of a needle longer than 1.6 cm may cause damage to the valve.**
- Do not use scissors to remove dressing to minimize the risk of cutting catheter.
- Do not suture through or around any part of the catheter's tubing (shaft or extension legs). If using sutures to secure catheter **USE THE SUTURE WINGS** and make sure they do not occlude, puncture, or cut the catheter.
- The catheter must be secured in place to minimize risk of catheter breakage and embolization.
- To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the last 0.5 mL of sterile saline.
- Do not withdraw dilator from microintroducer sheath until sheath is within vessel to minimize the risk of damage to sheath tip.
- Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.
- Do not cut guidewire to alter length.
- Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
- Keep sufficient guidewire length exposed at hub to allow for proper handling. A non-controlled guidewire can lead to wire embolism.
- Do not use excessive force when introducing guidewire or microintroducer as this can lead to vessel perforation and bleeding.
- Never leave stylet or stiffening wire in place after catheter insertion; injury may occur. Remove stylet or stiffening wire and T-lock (as applicable) after insertion.
- The stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet or stiffening wire.

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
- Heparin Induced Thrombocytopenia
- Hypersensitivity, anaphylactic or anaphylactic-like reaction during placement[1], positioning[1], flushing[2] of catheter or cleaning of catheter exit site[3]
- 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

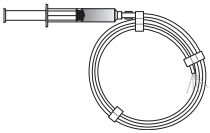
A. Apply a tourniquet above the anticipated insertion site.

B. Select a vein by assessing patient anatomy and condition. Recommended veins are cephalic, basilic or median cubital basilic.
Caution: The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology 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 PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology above antecubital fossa is recommended.
Caution: Avoid placement where kinking may occur to minimize stress on the catheter, patency problems or patient discomfort .

C. Release tourniquet.

D. Set up the sterile field.

2. Preflush the Catheter and Hydrate Stylet



A. Flush the catheter with heparin flush solution solution or sterile saline.
Hydrate stylet (**Note:** The use of the stiffening stylet is optional.)

B. Attach a syringe with sterile saline to the luer lock fitting of the flush through stylet hub.

C. Inject enough solution to wet the stylet surface entirely. This will activate the hydrophylic coating, making the stylet surface very lubricious.

D. Remove the stylet from its holder and insert it 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 saline will renew the hydrophylic effect.

E. The catheter stylet assembly can now be introduced.

3. Apply Tourniquet and Drape

A. Position arm at 90° angle.

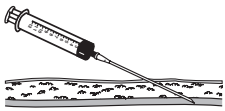
B. Re-apply the tourniquet above the intended insertion site to distend the vessel.

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

D. Drape the patient by placing the fenestrated drape over the anticipated puncture site.

E. When alcohol is used as a skin prep, it must be allowed to completely air dry.

4. Perform Venipuncture



A. Anesthetize with local anesthesia as required.

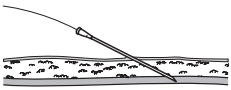
B. Remove the needle guard.

C. Introduce the needle into the desired vein and observe for flashback.
WARNING: If the artery is entered, withdraw the needle and apply manual pressure for several minutes.

D. Release tourniquet.

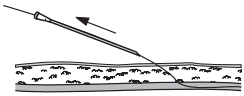
E. When the vein has been entered, remove the syringe leaving the needle in place.
Caution: Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
Caution: The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology 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® Provena™ Catheter with SOLO™2 Valve Technology above antecubital fossa is recommended.

5. Advance Guidewire



A. 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 or other tip locating methods.
Caution: Do not cut guidewire to alter length.
Caution: Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
Caution: Keep sufficient guidewire length exposed at hub to allow for proper handling. A non-controlled guidewire can lead to wire embolism.
Caution: Do not use excessive force when introducing guidewire or microintroducer as this can lead to vessel perforation and bleeding.

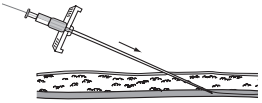
6. Remove Needle



A. Apply slight pressure on the vessel above the insertion site to minimize blood flow.

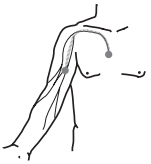
B. Leaving the guidewire in place, withdraw the needle.
Caution: If the guidewire must be withdrawn while the needle is inserted, remove both needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.

7. Introduce Microintroducer



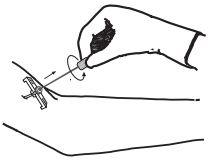
A. Introduce the microintroducer assembly over the guidewire. Using a twisting motion, advance the assembly into the vessel.
B. If necessary, a small incision may be made adjacent to the guidewire to facilitate insertion of the sheath and dilator.

8. Measure Distance to Tip Location



A. Using fluoroscopic control, determine the correct catheter length by advancing the guidewire to the desired catheter tip location in the Superior Vena Cava (SVC).
B. Once the guidewire tip is in proper position, mark the length by clamping forceps onto the guidewire at the skin site.

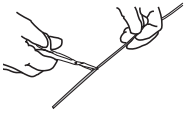
9. Removing Dilator and Guidewire



A. Rotate locking collar of dilator to remove dilator from sheath.
Caution: Do not withdraw dilator from microintroducer sheath until sheath is within vessel to minimize the risk of damage to sheath tip.
B. 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 until the catheter is inserted into the sheath.

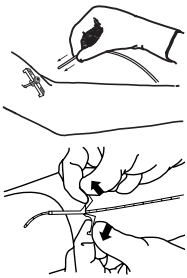
10. Modification of Catheter Length

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.



A. Measure the distance from the insertion site (zero mark) to the desired tip location.
B. Using the guidewire to indicate desired length, retract the stylet behind the point the catheter is to be cut (if applicable).
C. Using a sterile trimming device (e.g. scalpel, scissors, etc.) carefully cut the catheter according to institutional policy if necessary.
Caution: The stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet or stiffening wire.
D. Inspect cut surface to assure there is no loose material.
E. Re-advance the stylet to the distal end of the trimmed catheter (if applicable).
WARNING: Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and/or risk of patient injury.

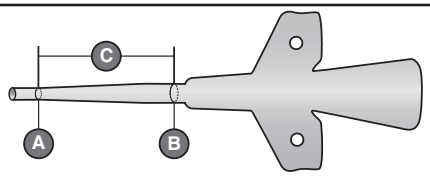
11. Insert and Advance the Catheter



A. Position the arm at a 90° angle, maintaining sterility.
B. Insert the catheter (and stylet, if applicable) into the microintroducer sheath.
C. Advance the catheter slowly.
D. Stabilize the catheter position by applying pressure to the vein distal to the microintroducer sheath.
E. Withdraw the microintroducer sheath from the vein and away from the site.
F. Split the microintroducer sheath and peel it away from the catheter.
Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.

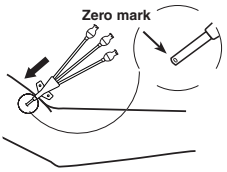
12. Complete Catheter Insertion

A. 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 insertion into the jugular vein.
Note: The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology features a reverse-taper catheter design. Resistance may be felt approximately 7 cm distal of catheter hub when introducing the catheter into the sheath due to an increase in outer diameter (O.D.) The introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.



	A OD (Fr)	B OD at Zero (Fr)	C Taper Length (cm)
PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology	5	7	4

B. Complete catheter advancement into the desired position.
Note: Maximum recommended insertion is to the zero mark on the catheter shaft.
Note: PICCs should be positioned with the catheter tip in the lower 1/3 of the SVC. Verify correct catheter tip position using radiography or other appropriate technology.
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.



C. Stabilize the catheter position by applying light pressure to the vein distal to the insertion site. Slowly remove the stylet, if applicable.
Caution: Never leave stylet or stiffening wire in place after catheter insertion; injury may occur. Remove stylet or stiffening wire and T-lock (as applicable) after insertion.
D. Place a finger over the catheter opening to minimize blood loss.

13. Aspirate and Flush

A. Attach primed extension set and/or sterile saline-filled syringe.
B. Aspirate for adequate blood return and flush catheter with 10 mL sterile saline to ensure patency.
Caution: The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology is designed for use with needleless injection caps or "direct-to-hub" connection technique. Apply a sterile end cap on the catheter hub to prevent contamination when not in use. **Use of a needle longer than 1.6 cm may cause damage to the valve.**
Caution: To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the last 0.5 mL of sterile saline.
Caution: As reported in literature, anaphylactic or anaphylactic-like reactions occur in a small percentage of the population during placement[1], positioning[1], flushing[2] of central venous catheters or cleaning of catheter exit site[3]. These reactions are reported in association with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some patients. Be aware of the potential symptoms or signs of these reactions and take precautionary steps as dictated by institution protocol for their prevention or treatment.
C. Cap catheter.
WARNING: 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.

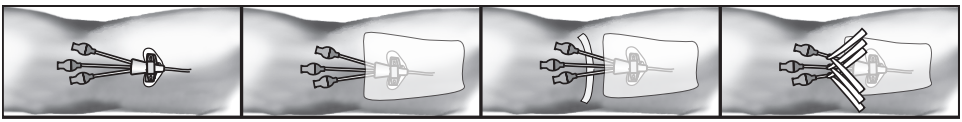
14. Dress Catheter

Caution: Do not suture through or around any part of the catheter's tubing (shaft or extension legs). If using sutures to secure catheter **USE THE SUTURE WINGS** and make sure they do not occlude, puncture, or cut the catheter.
Caution: The catheter must be secured in place to minimize 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 declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
WARNING: Do not wipe the catheter with acetone-based solutions, tincture of iodine or polyethylene glycol-containing ointments. These can damage the polyurethane material if used over time.

The StatLock® stabilization device is included in PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology kits. Please refer to Statlock® stabilization device Instructions For Use on the proper use and removal. The StatLock® stabilization device should be monitored daily and replaced at least every seven days.

The StatLock® Stabilization Device Procedure

Triple Lumen



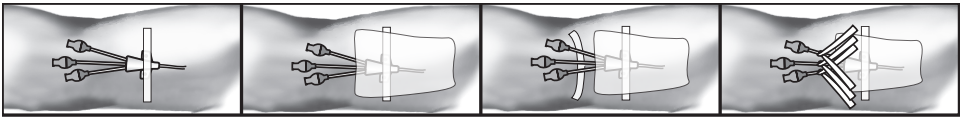
1. Secure catheter with StatLock® stabilization device.

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 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 Stabilization Procedure
Triple Lumen



1. Place 1st anchor tape over wings.

2. Cover site and 1st anchor tape with transparent dressing up to hub, but not over hub.

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.

15. Verify Placement

A. PICCs should be positioned with the catheter tip in the lower 1/3 of the SVC. Verify correct catheter tip position using radiography or other appropriate technology.

16. Power Injection Procedure

WARNING: PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology indication for power injection of contrast media implies the catheter's ability to with stand 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.

A. Remove the injection/needleless cap from the PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology.
B. Attach a 10 mL or larger syringe filled with sterile saline.
C. Aspirate for adequate blood return and vigorously flush each lumen of the catheter with the full 10 mL of sterile saline. This will ensure the patency of the PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology 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.
D. Detach syringe.
E. Attach the power injection device to the PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology per manufacturer's recommendations.
F. 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.
G. Use only lumens marked "Power Injectable" for power injection of contrast media.
WARNING: Use of lumens <u>not</u> marked "Power Injectable" for power injection of contrast media may cause failure of the catheter.
H. 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: 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: Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may cause catheter failure.
I. Disconnect the power injection device.
J. Replace the injection/needleless cap on the PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology.
K. Flush the PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology with 10 mL of sterile saline, using a 10 mL or larger syringe. Use of heparin flush solution to lock each lumen of the catheter is optional.

- The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology testing included 10 power injection cycles.

17. Suggested Catheter Maintenance

Caution: As reported in literature, anaphylactic or anaphylactic-like reactions occur in a small percentage of the population during placement[1], positioning[1], flushing[2] of central venous catheters or cleaning of catheter exit site[3]. These reactions are reported in association with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some patients. Be aware of the potential symptoms or signs of these reactions and take precautionary steps as dictated by institution protocol for their prevention or treatment.
Caution: If CHG allergy is suspected, confirmatory testing is recommended[4,5].

A. **Dressing Changes/ Exit Site Cleaning**
Caution: Do not use scissors to remove dressing to minimize the risk of cutting catheter.
Caution: Do not suture through or around any part of the catheter's tubing (shaft or extension legs). If using sutures to secure catheter **USE THE SUTURE WINGS** and make sure they do not occlude, puncture, or cut the catheter.
Caution: The catheter must be secured in place to minimize risk of catheter breakage and embolization.

1. 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.
   WARNING: Do not wipe the catheter with acetone-based solutions, tincture of iodine or polyethylene glycol-containing ointments. These can damage the polyurethane material if used over time.
   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.

B. **Flushing**
   Caution: Some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their catheter locked with heparin flush solution.

1. Flush each lumen of the catheter after every use, or at least weekly when not in use. Use a 10 mL or larger syringe.
2. Flush each lumen of the catheter with a minimum of 10 mL of sterile saline, using a "pulse" or "stop/start" technique. Use of heparin flush solution to lock each lumen of the catheter is optional.
3. Disconnect the syringe and attach a sterile end cap to the catheter hub and tighten securely.
4. Prior to blood sampling when infusing TPN, follow routine maintenance procedure except use 20 mL of sterile saline and flush to clear TPN from the catheter.
5. If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with possible embolization. Refer to institution protocol for clearing occluded catheters.
   Note: When injecting or infusing medications that are incompatible, you should always flush the catheter with a minimum of 10 mL of sterile saline before and after the medication.
   Note: When maintained in accordance with these instructions, the PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology does not require the use of heparin flush solution to lock the catheter lumens. However, use of heparin flush solution will not adversely effect the catheter and may be necessary based on patient status or use of alternate flushing and locking techniques.
   Caution: To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the last 0.5 mL of sterile saline.
   Caution: Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
   Caution: The PowerPICC® Provena™ Catheter with SOLO™2 Valve Technology is designed for use with needleless injection caps or "direct-to-hub" connection technique. Apply a sterile end cap on the catheter hub to prevent contamination when not in use. **Use of a needle longer than 1.6 cm may cause damage to the valve.**
   WARNING: Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

C. **Occluded or Partially Occluded Catheter**
1. 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.

18. Central Venous Pressure Monitoring (CVP)

Prior to conducting central venous pressure monitoring:
- Ensure proper positioning of the catheter tip.
- Flush catheter vigorously with sterile saline.
- Ensure the pressure transducer is at the level of the right atrium.

A. It is recommended that a continuous infusion of sterile saline (3 mL/hr) is maintained through the catheter while measuring CVP to improve accuracy of CVP results.
B. Use your institution's protocols for central venous pressure monitoring procedures.

WARNING: CVP Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

19. Catheter Removal

A. Remove dressing and StatLock® stabilization device or tape securement strips.
   Caution: Do not use scissors to remove dressing to minimize the risk of cutting catheter.
B. Grasp catheter near insertion site.
C. Remove slowly. Do not use excessive force.
D. If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.
E. Resume removal procedure.
F. Examine catheter tip to determine that the entire catheter has been removed.

References

1 Halpern M.D., Georges. "Allergic and Toxic Reactions." Adverse Events During Infusion Therapy Symposium, University of California, Davis School of Medicine. (1993)

2 Findlay, Steven R. et al,. "Hyperosmolar Triggering of Histamine Release from Human Basophils." Journal of Clinical Investigation. (1981)

3 Benjamin, Richard J. et al,. "Skin Disinfection with Single-Step 2% Chlorhexidine Swab is more Effective than a Two-Step Povidone-Iodine Method in Preventing Bacterial Contamination of Apheresis Platelets." Transfusion. (2010)

4 "FDA Public Health Notice: Potential Hypersensitivity to Chlorhexidine-Impregnated Medical Devices." FDA U.S. Food and Drug Administration. <http://www.fda.gov>. (accessed March, 1998).

5 Beaudouin, E. et al,. "Immediate Hypersensitivity to Chlorhexidine: literature review." European Annals of Allergy and Clinical Immunology. 36, no. 4 (2004)

Non-pyrogenic