Instructions For Use

PowerGroshong*

Peripherally Inserted Central Catheter

BARD

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 **PowerGroshong*** catheter using a 10 ml or larger syringe and sterile normal saline prior to and immediately following the completion of power injection studies. This will ensure the patency of the **PowerGroshong*** 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.
- Do not exceed the maximum flow rate of 4 ml/sec.
  Warning: Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may cause catheter failure.
  Warning: Exceeding the maximum flow rate of 4 ml/sec, or the maximum pressure of 300 psi, may result in catheter failure and/or catheter tip displacement.
- **Warning: PowerGroshong*** 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.

New Important Information:

Power Injection Procedure

1. Remove the injection/needleless cap from the **PowerGroshong*** 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 **PowerGroshong*** catheter per manufacturer's recommendations.
6. Complete power injection study taking care not to exceed the flow rate limits.
   Warning: Exceeding the maximum flow rate of 4 ml/sec, or the maximum pressure of 300 psi, may result in catheter failure and/or catheter tip displacement.
7. Disconnect the power injection device.
8. Flush the **PowerGroshong*** catheter with 10 ml of sterile normal saline, using a 10 ml or larger syringe.
9. Replace the injection/needleless cap on the **PowerGroshong*** catheter.

Product Description

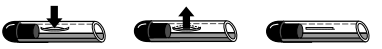
A family of peripherally inserted central catheters made from specially formulated and processed medical grade materials. Each **PowerGroshong*** catheter has a kink resistant, reverse tapered design. Catheters are packaged in a tray with accessories for reliable long (greater than 30 days) or short (less than 30 days) term vascular access.

Groshong Valve Function

The Groshong catheter incorporates a 3-position, pressure-sensitive Groshong valve. The valve is located near the rounded, closed, radiopaque catheter tip and allows fluid infusion and blood aspiration. When not in use, the valve restricts blood backflow and air embolism by remaining closed.

The Groshong valve is designed to remain closed between -7 and 80 mm Hg. Since the normal central venous pressure range in the superior vena cava is 0 to 5 mm Hg, the valve remains closed at normal central venous pressure. Pressure in the superior vena cava must exceed 80 mm Hg to open the valve inward. Also, negative pressure (vacuum) will cause the valve to open inward, allowing blood aspiration.

Positive pressure into the catheter (gravity, pump, syringe) will open the valve outward, allowing fluid infusion. The need for the anticoagulant effect of heparin is eliminated because the closed valve prevents blood from entering the catheter and clotting. If the catheter is aspirated, pulling the valve inward, it must be flushed with normal saline to clear blood from the lumen and allow the valve to return to its normal closed position.



ASPIRATION Negative Pressure | **INFUSION** Positive Pressure | **CLOSED** Neutral Pressure

The benefits provided by the Groshong valve are:

1. Increased patient safety due to reduced risk of air embolism or bleedback.
2. Elimination of the need for heparin flushing to maintain catheter patency.
3. Reduced need for catheter clamping.
4. Reduced need for flushing when the catheter is not in use.

Indications

The **PowerGroshong*** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. The maximum recommended infusion rate is 4 ml/sec for power injection of contrast media.

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.

ChloraPrep® One-Step Applicator Contraindications:

- Do not use in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption.
- Do not use on patients with known allergies to chlorhexidine gluconate or isopropyl alchohol.
- Do not use for lumbar puncture or in contact with meninges.
- Do not use on open skin wounds or as a general skin cleanser.

Warnings

- 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.
- Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may cause catheter failure.
- Exceeding the maximum flow rate of 4 ml/sec, or the maximum pressure of power injectors of 300 psi, may result in catheter failure and/or catheter tip displacement.
- **PowerGroshong*** 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 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.
- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.

ChloraPrep® One-Step Applicator

- Flammable, keep away from fire or flame.
- Do not use with electrocautery procedures.
- For external use only.
- When using this product keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a physician.
- Stop use and ask a doctor if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.
- Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Precautions

- 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 **PowerGroshong*** 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 **PowerGroshong*** catheter 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.
- To minimize the risk of catheter breakage and embolization, the catheter must be secured in place.

- 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.
- Do not advance the guidewire past the axilla without fluoroscopic guidance.
- 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.
- Precautions are intended to help avoid catheter damage and/or patient injury.
- 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.
- To reduce potential for blood backflow into the catheter tip, always remove needles or needleless caps slowly while injecting the last 0.5 ml of saline.
- Use aseptic techniques whenever the catheter lumen is opened or connected to other devices. Chlorhexidine gluconate is the suggested antiseptic to use. Acetone and tincture of iodine should not be used. 2% Chlorhexidine gluconate /70% isopropyl alcohol swabsticks may be used for dressing changes. Povidone-iodine may also be used as an antiseptic.
- Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.

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 guidewire.
- 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.
- Use suture wings to secure the catheter without compromising catheter patency.
- Do not place sutures around catheter.

III. After placement, observe the following precautions to avoid device damage and/or patient injury:

- **Warning:** Do not use the catheter 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.
- **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 25 psi may damage blood vessels or viscus.
- **Warning:** Exceeding the maximum flow rate of 4 ml/sec, or the maximum pressure of 300 psi, may result in catheter failure and/or catheter tip displacement.
- For further information or questions, please call 800-443-3385 or 801-595-0700.

Possible Complications

The potential exists for serious complications including the following:

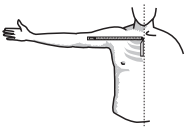
- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- 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

- Apply a tourniquet above the anticipated insertion site.
- Select and mark the vein based on patient assessment. Recommended veins are basilic, cephalic and median cubital veins.
  Caution: The **PowerGroshong*** 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 **PowerGroshong*** catheter above antecubital fossa is recommended.
  Caution: Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
- Release tourniquet.

2. Patient Position / Catheter Measurement



- Position the arm at a 90˚
- For SVC placement, measure from the planned insertion site to the right clavicular head, then down to the third intercostal space.

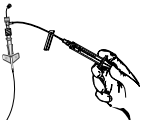
Note: The external measurement can never exactly duplicate the internal venous anatomy.

3. Skin Preparation

- Don prep gloves.
- Apply underdrape.
- Prepare the site with the **ChloraPrep** One-Step Applicator or according to institutional policy using sterile technique.
  - Pinch the wings of the **ChloraPrep** One-Step Applicator to break the ampule and release the antiseptic. **Do not touch the sponge**.
  - Wet the sponge by repeatedly pressing and releasing the sponge against the treatment area until fluid is visible on the skin.
  - Use repeated back-and-forth strokes of the sponge for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to dry for approximately 30 seconds. **Do not blot or wipe away**.
  - Maximum treatment area for one applicator is approximately 130 cm^2 (approximately 4 x 5 in.). Discard the applicator after a single use.
- Remove and discard gloves.

4. Sterile Field Preparation

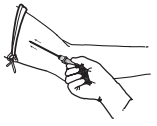
- Apply the tourniquet above the intended insertion site to distend the vessel.
- When alcohol is used as a skin prep, it must be allowed to completely air dry before proceeding with insertion.
- Don sterile gloves.
- Apply fenestrated drape & complete sterile field preparation.



5. Preflush the Catheter

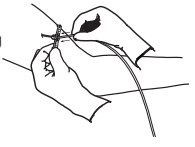
- Attach prefilled syringe to the luer attachment on flushable stylet.
- Preflush catheter with sterile normal saline or heparinized saline to wet stylet.
- The syringe may be left attached during procedure.

6. Perform Venipuncture



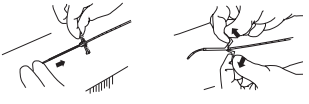
- Anesthetize with local anesthesia as required.
- Insert the safety introducer needle into the desired vein.
  Alternate Technique: The safety IV catheter may be used as an alternate to the safety introducer needle. Remove the needle from the catheter after the vein is accessed.
  Warning: If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
- Release tourniquet.
- Remove the guidewire tip protector from the guidewire hoop and insert the flexible end of the guidewire into the introducer needle or catheter and into the vein. Advance the guidewire to the desired depth.
  Caution: Do not advance the guidewire past the axilla without fluoroscopic guidance.

- Gently withdraw and remove the safety introducer needle or catheter, while holding the guidewire in position.
  Caution: 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.
- Advance the small sheath and dilator together as a unit over the guidewire, using a slight rotational motion. If necessary, a small incision may be made adjacent to the guidewire to facilitate insertion of the sheath and dilator. Verify institutional guidelines concerning the use of a safety scalpel prior to making incision.
- Withdraw the dilator and guidewire, leaving the small sheath in place.
  Warning: 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.



7. Insert and Advance the Catheter

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



8. 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. The **PowerGroshong*** catheters feature a reverse-taper catheter design.
- Position the arm at a 90˚ angle, maintaining sterility. Complete catheter advancement into 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.

9. Retract and Remove the Introducer Sheath

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

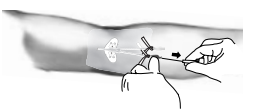
10. Attach Suture Wings

A. If the catheter **is not** inserted to the winged junction/connector;
   - Remove the suture wing from the delivery card
   - Squeeze the suture wing together so that it splits open
   - Place the suture wing around the catheter near the venipuncture site
   - Apply **StatLock*** stabilization device to the suture wing and secure to skin (see **Statlock*** Stabilization Device Procedure)

B. If the catheter **is** inserted to the junction/connector;
   - Apply **StatLock*** stabilization device to the catheter and secure to skin (see **Statlock*** Stabilization Device Procedure)

Caution: To minimize the risk of catheter breakage and embolization, the suture wing, junction, and/or connector must be secured in place. See step 13.

11. Remove the Stylet / T-Lock Assembly



Disconnect the T-Lock from the catheter luer connector.

- Stabilize with suture wing prior to stylet removal.
- 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.

12. Aspirate and Flush

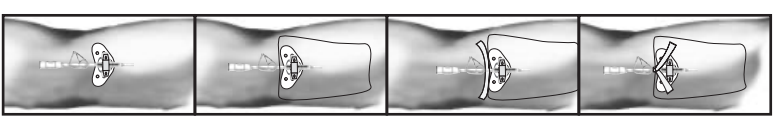
- Attach primed extension set and/or saline-filled syringe.
- Aspirate for adequate blood return and flush catheter with 10ml normal saline to ensure patency.
  Note: When infusion volume is a concern in small or pediatric patients, flush with 3ml per lumen.
- **Caution:** To reduce potential for blood backflow into the catheter tip, always remove needles or needleless caps slowly while injecting the last 0.5 ml of saline.
- Cap catheter.
- **Caution:** 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.

13. Securing the PowerGroshong* Catheter

The **StatLock*** stabilization device is included in **PowerGroshong*** catheters kits. Please refer to Instructions For Use on the proper use and removal. The **StatLock*** stabilization device should be monitored daily and replaced at least every seven days.

- **Caution:** To minimize the risk of catheter breakage and embolization, the catheter must be secured in place.

The StatLock* Stabilization Device Procedure



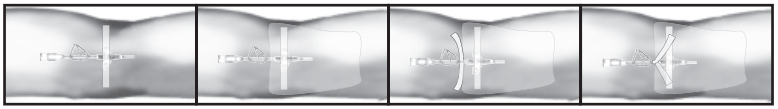
1. Secure catheter with **StatLock*** stabilization device.

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.

Tape Strip Stabilization Procedure



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

14. 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**
  For intermittent use, flush the catheter with saline once each week or after each use.
  Note: When infusion volume is a concern in small or pediatric patients, flush with 3 ml.
  Caution: To reduce potential for blood backflow into the catheter tip, always remove needles or needleless caps slowly while injecting the last 0.5 ml of saline.
- **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**
  - Maintain according to hospital protocol.
  - Use chlorhexidine gluconate or povidone iodine to clean the exit site around the catheter. 2% Chlorhexidine gluconate /70% isopropyl alcohol swabsticks may be used for dressing changes.
- **Caution:** Acetone and tincture of iodine should not be used.

Power Injections

- The **PowerGroshong*** catheter testing included 10 power injection cycles.

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.
- Examine catheter tip for completeness and to determine that the entire catheter has been removed.

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.

Revised date: February 2007

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Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA
Clinical Information Hotline: 1-800-443-3385
Ordering Information: 1-800-545-0890
www.bardaccess.com

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PowerGroshong*
Peripherally Inserted Central Catheter

Silicone Valved PICC

with Microintroducer

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