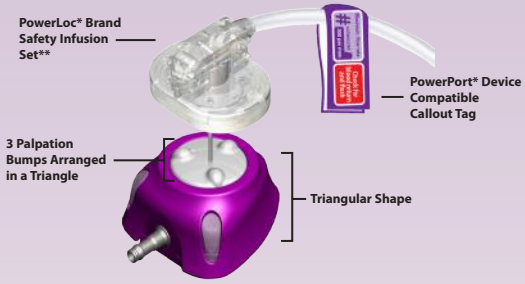
PowerPort* Implantable Port Features



Examples of Radiopaque Identifiers

Radiopaque identifiers for PowerPort* devices aid in identification as a Bard power injectable port.

Description

The PowerPort* implantable port is an implantable access device designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. Power injection is performed using a PowerLoc* Brand Safety Infusion Set** only. The PowerPort* device consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Single lumen PowerPort* implantable ports can be identified subcutaneously by feeling the top of the septum which includes three palpation bumps arranged in a triangle and by palpating the sides of the port, which is also triangular. Dual lumen PowerPort* implantable ports can be identified subcutaneously by feeling the top of each septum; each septum features three palpation bumps arranged in a triangle. All materials are biocompatible, can be used with virtually all injectable solutions intended for medicinal use, including the power injection of contrast media. For implantable ports with Groshong* catheters, the Groshong* catheter valve helps provide security against blood reflux and air embolism into the port/catheter system. The Groshong* catheter may be flushed with normal saline, and it does not require heparin to maintain patency.

Indications For Use

The PowerPort* implantable port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples.

When used with a PowerLoc* Brand Safety Infusion Set**, the PowerPort* device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

Contraindications, Warnings, and Precautions

Contraindications

This device is contraindicated for:

- Catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off.[1,2] Port may be placed in lateral subclavian vein based on evaluation by a qualified practitioner.
- When the presence of device-related infection, bacteremia, or septicemia is known or suspected.
- When the patient's body size is insufficient for the size of the implanted device.
- When the patient is known or is suspected to be allergic to materials contained in the device.
- If severe chronic obstructive lung disease exists.
- If the prospective insertion site has been previously irradiated.
- If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures.
- If local tissue factors will prevent proper device stabilization and/or access.

Warnings

I. During Placement:

- Intended for Single Use. Do not reuse. Reuse and/or repackaging may create risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure and/or lead to injury, illness or death of the patient.
- Alcohol should not be used to soak or declot a polyurethane catheter because alcohol is known to degrade the polyurethane catheter over time with repeated and prolonged exposure.
- 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.
- Place thumb over exposed opening of sheath or needle or attach syringe filled with sterile normal saline solution to minimize blood loss and prevent air embolism. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver and/or in Trendelenburg position.
- Do not suture catheter to port, port stem, or surrounding tissue. Any damage or constriction of catheter may compromise power injection performance and catheter integrity. Bard Access Systems, Inc. does not recommend suturing around the catheter as doing so could compress, kink, or damage catheter, including catheter fragmenting and/or fracturing.
- Do not manipulate a pre-assembled or pre-connected catheter/port connection, as the catheter could become disconnected from the port, or system damage could occur.
- Do not attempt to measure the patient's blood pressure on the arm in which a peripheral system is located, since catheter occlusion or other damage to the catheter could occur.
- Avoid vessel perforation.
- Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
- For implantable ports with Groshong* catheters, do not cut stylet. Withdraw stiffening stylet from catheter prior to cutting.
- Failure to completely advance the catheter on the dual lumen stem may result in subcutaneous leakage.

II. During Port Access:
- Do not use a syringe smaller than 10 mL. Flushing occluded catheters with small syringes can create excessive pressures within the port system.
- PowerPort* implantable ports are only power injectable when accessed with a PowerLoc* Brand Safety Infusion Set**.
- Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
- Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
- Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
- PowerPort* device indication for power injection of contrast media implies the port's ability to withstand the procedure, but it does not imply appropriateness of the procedure for a particular patient nor for a particular infusion set. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any infusion set used to access the port.
- Do not exceed a 300 psi pressure limit setting on the power injection machine, or the maximum recommended flow rate on the PowerLoc* needle, if power injecting through the PowerPort* device.
- If local pain, swelling or signs of extravasation are noted during power injection, the injection should be stopped immediately.

Signs of Pinch-off

Clinical:
- Difficulty with blood withdrawal
- Resistance to infusion of fluids
- Patient position changes required for infusion of fluids or blood withdrawal

Radiologic:
- Grade 1 or 2 distortion on chest X-ray. Pinch-off should be evaluated for degree of severity prior to explantation. Patients indicating any degree of catheter distortion at the clavicle/first rib area should be followed diligently. There are grades of pinch-off that should be recognized with appropriate chest x-ray as shown in the table at right.[3,4]

Grade	Severity	Recommended Action
Grade 0	No distortion	No action
Grade 1	Distortion present without luminal narrowing	Chest x-ray should be taken every one to three months to monitor progression of pinch-off to grade 2 distortion. Shoulder positioning during chest x-rays should be noted as it can contribute to changes in distortion grades.
Grade 2	Distortion present without luminal narrowing	Removal of the catheter should be considered.
Grade 3	Catheter transection or fracture	Prompt removal of the catheter.

Precautions
- Carefully read and follow all instructions in these instructions for use.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Only qualified healthcare practitioners should insert, manipulate and remove these devices.
- Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
- 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.
- Use only non-coring needles with the port.
- Prior to advancing the catheter lock, ensure that the catheter is properly positioned. A catheter not advanced to the proper region may not seat securely and lead to dislodgment and extravasation. The catheter must be straight with no sign of kinking. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter. Do not hold the catheter or cathlock with any instruments that could potentially damage either piece (e.g. hemostats).
- Follow universal precautions when inserting and maintaining the catheter.
- Follow all contraindications, warnings, precautions and instructions for all infusates as specified by their manufacturers.
- Precautions are intended to help avoid catheter damage and/or patient injury.

I. Prior to Placement:
- Examine package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a double 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.
- Check patient's records, and ask patient, whether they have any known allergies to chemicals or materials that will be used during the placement procedure.
- Fill (prime) the device with sterile normal saline solution to help avoid air embolism.
- When using an introducer kit, verify that the catheter fits easily through the introducer sheath.
- When utilizing port for arm placement, the port should not be placed in the axillary cavity.
- Bard Access Systems, Inc. recommends the use of components provided in the kit. If additional items are to be used, check for proper fit prior to utilization.
  Note: Port body, catheter and catheter lock cannot be replaced with components outside the provided kit.

II. During Placement:
- Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
- Take care not to perforate, tear, or fracture the catheter during placement. After assembling catheter to port, check assembly for leaks or damage.
- Do not use the catheter if there is any evidence of mechanical damage or leaking.
- Do not bend catheter at sharp angles during implantation. This can compromise catheter patency.
- Carefully follow the connection technique given in these instructions to ensure proper catheter connection and to avoid catheter damage.
- Do not use sutures to secure catheter to the port stem as it could collapse or damage the catheter.
- When using peel-apart introducers:
  - Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
  - Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apart introducer.
  - Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.
- Never use a catheter lock that appears cracked or otherwise damaged.

III. After Placement:
- Encourage patient to keep patient ID card and present it to clinicians accessing their port.
- Care should be taken to avoid excessive force when accessing an implanted port.

Possible Complications

The use of a subcutaneous port provides an important means of venous access for critically ill patients. However, the potential exists for serious complications, including the following:

- Air Embolism
- Allergic Reaction
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Puncture
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter or port-related Sepsis
- Damage or Breakage due to Compression between the Clavicle and First Rib
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Guidewire Fragment Embolism
- Hematoma
- Hemothorax
- Hydrothorax
- Infection, including but not limited to pocket, catheter tunnel, and/or blood stream
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Intolerance or Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Pain at or around port pocket site
- Perforation of Vessels or Viscus
- Pneumothorax
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion

These and other complications are well documented in medical literature and should be carefully considered before placing the port.

Implantation Instructions

Please read through complete implantation instructions before implanting port, noting "Contraindications, Warnings, and Precautions" and "Possible Complications" sections of this manual before beginning procedure.

Preventing Pinch-Off

The risk of pinch-off syndrome can be avoided by inserting the catheter via the internal jugular vein (IJ). Subclavian insertion of the catheter medial to the border of the first rib may cause catheter pinch-off, which in turn results in occlusion causing port system failure during power injection.

If you choose to insert the catheter into the subclavian vein, it should be inserted lateral to the border of the first rib or at the junction with the axillary vein because such insertion will avoid compression of the catheter, which can cause damage and even sever the catheter. The use of image guidance upon insertion is strongly recommended. A radiographic confirmation of catheter insertion should be made to ensure that the catheter is not being pinched.

Implantation Preparation

1. Select implantation procedure to be used.
2. Select the site for port placement.
   Note: Port pocket site selection should allow for port placement in an anatomic area that provides good port stability, does not interfere with patient mobility or daily activities, does not create pressure points, has not previously been irradiated, does not show signs of infection, and does not interfere with clothing. Ideally choose an implantation site in the lateral infraclavicular region for cosmesis and functionality. For arm port placement, port site should be distal to the desired vein insertion site. Patient's arm movement should be considered when determining the length of the catheter and the final tip location. Consider the amount of cutaneous tissue over the port septum, as excessive tissue will make access difficult. Conversely, too thin a tissue layer over the port may lead to tissue erosion. A tissue thickness of 0.5 cm to 2 cm is appropriate.
3. Complete patient implant record, including length of catheter implanted, product reorder number and lot number.
4. Perform adequate anesthesia.
5. Create sterile field and open tray.
   Note: The catheter and port may be soaked in sterile normal saline prior to placement.
6. Surgically prep and drape the implantation site.

7a. For Attachable Catheters: Flush each lumen of open-ended catheters with sterile normal saline, through the flushing connector and clamp the catheter closed several centimeters from the distal (port) end.
   Note: Clamped catheter segments will be cut off prior to attachment.

7b. For Pre-Attached Catheters: Use a non-coring needle to flush the port and catheter system with sterile normal saline.

7c. For Groshong* catheters: Flush catheter with sterile normal saline through the pre-loaded stylet connector.

8. Place patient in the Trendelenburg position with head turned away from the intended venipuncture site. For arm port placement, position the arm in an abducted, externally rotated position.
   Note: Recommended veins for arm placement are cephalic, basilic, or medial cubital basilic.
   Note: Recommended veins for chest placement are internal jugular or lateral subclavian. Refer to the "Warnings" section covering catheter pinch-off if inserting the catheter via the subclavian vein.

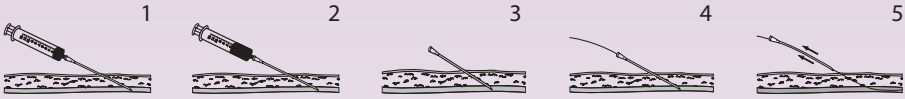
Percutaneous Procedure

1. Locate and access vessel with introducer needle attached to a syringe.
2. Aspirate gently as the insertion is made. If the artery is entered, withdraw the needle and apply manual pressure for several minutes. If the pleural space is entered, withdraw the needle and evaluate patient for possible pneumothorax.
3. When the vein has been entered, remove the syringe leaving the needle in place.
   Warning: Place thumb over exposed opening of sheath or needle or attach syringe filled with sterile normal saline solution to minimize blood loss and prevent air embolism. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver and/or in Trendelenburg position.

If using a micropuncture set, insert the flexible end of the micropuncture guidewire into the introducer needle. Advance the guidewire as far as appropriate. Verify correct positioning, using fluoroscopy or appropriate technology. Gently withdraw and remove the needle, while holding the micropuncture guidewire in position. Advance the small sheath and dilator together as a unit over the micropuncture guidewire, using a slight rotational motion. Withdraw the dilator and guidewire, leaving the microintroducer sheath in place.

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.
Warning: Place thumb over opening of sheath to minimize blood loss and prevent air embolism. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver and/or in Trendelenburg position.

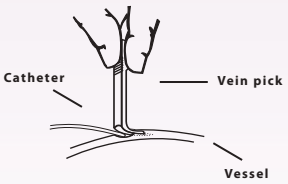
4. Straighten "J" tip of standard guidewire with tip straightener and insert tapered end of tip straightener into the needle (or microintroducer sheath if using a micropuncture set).
   Note: Do not advance guidewire if obstruction is encountered.
5. Remove the tip straightener and advance the guidewire into the superior vena cava. Advance the guidewire as far as appropriate for the procedure. Verify correct positioning using fluoroscopy or appropriate technology.
6. Gently withdraw and remove needle (or microintroducer sheath if using micropuncture set).
   Caution: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to help prevent the needle from damaging or shearing the guidewire.



Peel-Apart Sheath Introducer Instructions

1. Advance the vessel dilator and sheath introducer as a unit over the exposed wire using a rotational motion. Advance it into the vein as a unit, leaving at least 2 cm of sheath exposed.
   Note: Placement may be facilitated by making a small incision to ease introduction of vessel dilator and sheath introducer.
   Warning: Avoid vessel perforation.
2. Release the locking mechanism and gently withdraw the vessel dilator and "J" wire, leaving the sheath in place.
   Warning: Place thumb over exposed opening of sheath to minimize blood loss and prevent air embolism. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver and/or in Trendelenburg position.
3. Insert catheter into the sheath. Advance the catheter through the sheath into the vessel to the desired infusion site. Catheters should be positioned with the catheter tip at the junction of the superior vena cava and the right atrium.
4. Verify correct catheter tip position using fluoroscopy or appropriate technology.
5. Grasp the two handles of the peel-apart sheath and pull outward and upward at the same time. Peel the sheath away from the catheter completely. Make sure the catheter is not dislodged from vessel.

Cut-Down Procedure



1. Use a cut-down incision to expose the entry vein of choice.
2. Perform vessel incision after vessel is isolated and stabilized to prevent bleeding and air embolism.
3. If using a vein pick, insert its tapered end through the incision and advance it into the vessel. Then slide the catheter tip into the grooved underside of the pick.
4. Advance the catheter tip into the vessel.
5. Withdraw the vein pick, if used.
6. Advance the catheter into the vessel to the desired infusion site.
   Note: Catheters should be positioned with the catheter tip at the junction of the superior vena cava and the right atruim. Verify correct catheter tip position using fluoroscopy or appropriate technology.

Catheter Tunneling Procedure

1. Create a subcutaneous pocket using blunt dissection.
   Note: Do a trial placement to verify that the pocket is large enough to accommodate the port and that the port does not lie beneath the incision.

Attachable Catheters

Create a subcutaneous tunnel from the venous site to the port pocket site using tunneler or long forceps per the following:

a. Make a small incision at the venous entry site.
b. Insert tip of tunneler into the small incision.
c. Form tunnel by advancing tip of tunneler from the venous entry site to the port pocket site.
   Caution: Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.

d. Remove catheter lock from the catheter. For implanted ports with Groshong* catheters, remove the catheter lock and stiffener stylet from the catheter prior to cutting catheter to appropriate length.
Warning: Do not cut stiffening stylet. Withdraw stiffening stylet from catheter prior to cutting.
Caution: Never use a catheter lock that appears cracked or otherwise damaged.
e. Attach end of catheter onto the tunneler barb with a twisting motion.
Note: Barb threads must be completely covered by the catheter to adequately secure the catheter as it is pulled through the tunnel. A suture may be tied around the catheter between the tunneler body and the large barb to hold it more securely.
f. Pull the tunneler through to the port pocket site while gently holding the catheter.
Note: The catheter must not be forced.
g. Cut off end of the catheter attached to tunneler.

Pre-Attached Catheters

Create subcutaneous tunnel from the port pocket site to the venous entrance site per the following:

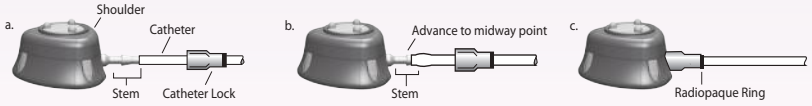
a. Form tunnel by advancing the tip of the tunneler from the port pocket site to the venous entry site.
Caution: Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler.
b. Connect the catheter tip into the end of the tunneler.
c. Pull the tunneler through to the venous entry site while gently holding the catheter.
Note: The catheter must not be forced.
d. Cut off end of the catheter attached to tunneler.
e. Estimate the catheter length required for the tip placement at the junction of the superior vena cava and right atrium by placing the catheter on the chest along the venous path to the right atrium. Cut catheter to length at a 90˚ angle.

Connect Catheter To Port For Attachable Catheters

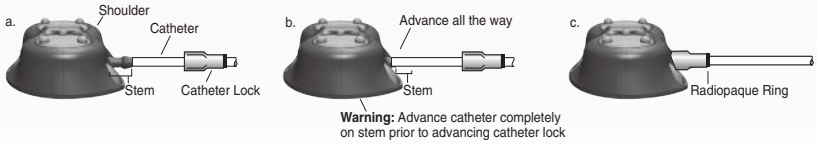
1. Flush all air from each lumen of the port body using a 10 mL syringe with a non-coring needle filled with sterile normal saline. Insert the needle through the septum and inject the fluid while pointing the stem up.
2. Cleanse all system components with irrigation solution.
Caution: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. A catheter not advanced to the proper region may not seat securely and lead to dislodgement and extravasation. The catheter must be straight with no sign of kinking. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter. Do not hold the catheter or cathlock with any instruments that could potentially damage either piece (e.g. hemostats).
3. Connect catheter to port:
   a. Place catheter lock back onto catheter, ensuring the black radiopaque ring on the catheter lock faces away from the port body.
   b. Cut the catheter to the proper length at a 90˚ angle, allowing sufficient slack for body movement and port connection. Check catheter for any damage. If any damage is noted, cut damaged section off before connecting catheter to port.
   Note: Ensure that no guidewires or stiffening wires remain in the catheter lumen prior to cutting and adjusting catheter to desired length.
   c. For single lumen ports, align port stem with catheter. When placing dual lumen ports, align the port stem with both lumens.
   Note: If the catheter and catheter lock are connected and then disconnected, the catheter end must be re-trimmed to ensure a secure re-connection. **Note:** When using the catheter lock, be sure the end containing a colored radiopaque ring faces away from the port. The catheter lock should be sufficient to secure catheter to port. **Note:** Sterile gauze may be used to facilitate stem to catheter connection.
   d. **For single lumen ports:** Advance catheter over port stem to midway point. **Note:** Advancing catheter too far along port stem could lead to "mushrooming" of tubing when the catheter lock is advanced. Should this occur, it is advisable to stop advancing the catheter lock, pull the catheter back along the stem away from the port, trim end of catheter and re-assemble the connection.
   e. **For dual lumen ports:** Advance catheter completely on stem prior to advancing catheter lock. **Warning:** Failure to completely advance the catheter on the dual lumen stem may result in subcutaneous leakage.

Warning: Do not suture catheter to port, port stem, or surrounding tissue. Any damage or constriction of catheter may compromise power injection performance and catheter integrity. Bard Access Systems, Inc. does not recommend suturing around the catheter as doing so could compress, kink, or damage catheter.

Single Lumen PowerPort* Device:



Dual Lumen PowerPort* Device:



Position Port And Close Incision Site

1. Place the port in the subcutaneous pocket away from the incision line. Secure the port to the underlying fascia using non-absorbable, monofilament sutures. Leave sufficient slack in the catheter to permit slight movement, and verify that the catheter is not kinked. This will reduce the risk of port migration and the possibility of it flipping over.
Note: When suturing a port with a silicone port body, place suture through at least 2 mm of silicone.
2. After suturing the port in the pocket, flush the wound with an appropriate antibiotic solution, per institutional protocol.

3. Conduct flow studies on each lumen of the catheter using a non-coring needle and 10 mL syringe to confirm that the flow is not obstructed, that no leak exists, and that the catheter is correctly positioned.
4. Aspirate to confirm the ability to draw blood.
5. Flush and lock each lumen of the port system as described under heparin lock procedure for open-ended catheters or saline lock procedures for implantable ports with Groshong* catheters. Close clamp while injecting last 0.5 mL of flush solution.
   Caution: Remember that some patients may be hyper-sensitive to heparin or suffer from heparin induced thrombocytopenia (HIT). These patients must not have their port locked with heparinized saline.
6. Close the incision site, so that the port does not lie beneath the incision.
7. Apply dressing according to hospital practice.

Power Injection Procedure

1. Access the PowerPort* device with a PowerLoc* Brand Safety Infusion Set**. Make certain that the needle is long enough to be inserted fully within the port and that the needle tip has made contact with the bottom of the port reservoir.
   Warning: The PowerPort* device is only power injectable when accessed with a PowerLoc* Brand Safety Infusion Set**.
   Note: Follow institutional protocol to verify correct catheter tip position prior to power injection.
2. Attach a syringe filled with sterile normal saline.
3. Instruct the patient to assume the position they will be in during the power injection procedure, before checking for patency. If possible, the patient should receive power injection with his or her arm vertically above the shoulder with the palm of the hand on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
4. Aspirate for adequate blood return and vigorously flush the port with at least 10 mL of sterile normal saline.
   Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
5. Detach syringe.
6. Warm contrast media to body temperature.
7. Attach the power injection device to the PowerLoc* Brand Safety Infusion Set** ensuring connection is secure. Check indicated flow rate of safety infusion set and confirm power injector settings.
   Warning: Do not exceed a 300 psi pressure limit setting on the power injection machine, or the maximum recommended flow rate on the PowerLoc* needle, if power injecting through the PowerPort* device.

PowerLoc* Brand Safety Infusion Set Gauge Size**	19 Ga.	20 Ga.	22 Ga.
PowerLoc* Brand Safety Infusion Set Gauge Color**	Cream	Yellow	Black
Maximum Recommended Flow Rate Setting	5 mL/s	5 mL/s	2 mL/s

8. Instruct the patient to communicate immediately any pain or change in feeling during the injection.
9. Inject contrast media warmed to body temperature, taking care not to exceed the flow rate limits.
   Warning: If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately.
   Warning: Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
10. Disconnect the power injection device.
11. After therapy completion, flush each lumen of the port per institutional protocol. Close clamp while injecting last 0.5 mL of flush solution.
12. Perform heparin lock procedure or saline lock procedures for implanted ports with Groshong* catheters. For dual lumen PowerPort* devices, flush each lumen separately and perform locking procedures on each septum.
    Caution: Remember that some patients may be hyper-sensitive to heparin or suffer from heparin induced thrombocytopenia (HIT). These patients must not have their port locked with heparinized saline.
13. To remove PowerLoc* Brand Safety Infusion Set** from the port, activate safety mechanism while withdrawing needle until you hear or feel a "click" at which time the needle should be captured within the safety mechanism of the PowerLoc* Brand Safety Infusion Set**.

Determining Port System Volumes for Port Lock Procedures

For port system volumes and locking procedures, please refer to the packaging insert.

Heparin Lock Procedure For Open-Ended Catheters

To help prevent clot formation and catheter blockage, each lumen of the implanted ports with open-ended catheters should be filled with sterile heparinized saline after each use. If the port remains unused for long periods of time, the heparin lock should be changed at least once every four weeks.

Caution: Remember that some patients may be hyper-sensitive to heparin or suffer from heparin induced thrombocytopenia (HIT). These patients must not have their port locked with heparinized saline.

If the port catheter length is not known, the following are recommended flushing volumes for open-ended catheters, otherwise follow institutional protocol.

Flushing and Locking Volumes (each lumen)	
Procedure	**Volume**
When port not in use	5 mL heparinized saline every 4 weeks (100 U/mL)
After each infusion of medication or TPN	10 mL sterile normal saline then 5 mL heparinized saline (100 U/mL)
After blood withdrawl	20 mL sterile normal saline then 5 mL heparinized saline (100 U/mL)
After power injection of contrast media	10 mL sterile normal saline then 5 mL heparinized saline (100 U/mL)

Equipment:

- Non-coring needle
- 10 mL syringe filled with sterile saline per lumen
- 10 mL syringe filled with 5 mL heparinized saline (100 U/mL) per lumen

  Note: Other concentrations of heparinized saline (10 to 1000 U/mL) have been found to be effective. Determination of proper concentration and volume should be based on patient's medical condition, laboratory tests, and prior experience.

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Attach a 10 mL syringe filled with sterile normal saline to needle.
3. Aseptically locate and access port.
4. After therapy completion, flush port per institutional protocol, then lock with 5 mL 100 U/mL heparinized saline, or with port system volume calculated on page 6. Close clamp while injecting last 0.5 mL of lock solution.

   Warning: Alcohol should not be used to soak or declot polyurethane catheters because alcohol is known to degrade the polyurethane catheters over time with repeated and prolonged exposure.

Saline Lock Procedure For Groshong* Catheters

To help prevent clot formation and catheter blockage, implanted ports with Groshong* catheters should be filled with sterile normal saline after each use. If the port remains unused for long periods of time, the saline lock should be changed by flushing at least once every four weeks.

If the port catheter length is not known, the following chart outlines the recommended flushing volumes for Groshong* catheters – otherwise follow institutional protocol.

Flushing and Locking Volumes (each lumen)	
Procedure	**Volume**
When port not in use	5 mL sterile normal saline every 4 weeks
After each infusion of medication or TPN	10 mL sterile normal saline
After blood withdrawl	20 mL sterile normal saline
After power injection of contrast media	10 mL sterile normal saline

Equipment:

- Non-coring needle
- 10 mL syringe filled with sterile normal saline

Procedure:

Review Site Preparation and Accessing Implanted Port sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site.
2. Attach a 10 mL syringe filled with sterile normal saline to needle.
3. Aseptically locate and access port.
4. After therapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5 mL of flush solution.

References

1. Jacobs, D. M. et. al., "Anatomical and Morphological Evaluation of Pacemaker Lead Compression". PACE. 1993 Mar; 16(1):434-444.
2. Magney, J. E. et. al., "Anatomical Mechanisms Explaining Damage to Pacemaker Leads, Defibrillator Leads and Failure of Central Venous Catheters Adjacent to the Stemoclavicular Joint". PACE. 1993 Mar; 16(1):445-457.
3. Hinke, D,H.; Zandt-Stastny, D.A.; Goodman, L.R.; et.al. Pinch-off syndrome: A complication of implantable subclavian venous access devices. Radiology 177: 353-356, 1990.
4. Ingle, Rebecca; Nace, Corinne. "Venous Access Devices: Catheter Pinch-off and Fracture". 1993, Bard Access Systems, Inc.
5. Camp-Sorrell, Dawn. "Access Device Guidelines." 2nd Ed. Oncology Nursing Society, 2004.

Note: The PowerPort* device testing included at least 36 power injection cycles with a PowerLoc* Brand Safety Infusion Set** and 11.8 cP viscosity contrast solution.

Further Reading

- See PowerPort* Implantable Port Nursing Guide and/or PowerPort* Implantable Port CT Guide for more details.
- Bard Access Systems, Inc. is proud to offer "Your Port Access Advantage"* patient education module for helping patients select their best access option.
- www.powerportadvantage.com
- www.portadvantage.com
- www.veins4life.com

See Bard Access Systems' Sales Representative for more information about any of these products. 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.

** e.g., PowerLoc*, PowerLoc* Clear, PowerLoc* EZ, and PowerLoc* MAX Safety Infusion Sets

Revised date: December 2011.

This product and packaging do not contain natural rubber latex.	This device does not contain DEHP.

CT Contrast Enhanced Computed Tomography Information

CT injector pressure limit should be set at a maximum of 300 psi.

Notes

Notes

BARD

ACCESS SYSTEMS

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Instructions For Use

BARD
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