

*feel and see the
standard of care**

Power Port^{*}
IMPLANTABLE PORT

Power Loc^{*}
Safety Infusion Set

Nursing Guide

BAIRD

ACCESS SYSTEMS



This product and packaging do not
contain natural rubber latex

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Introduction

Bard Access Systems' PowerPort* power-injectable port and PowerLoc* Safety Infusion Set Family† devices not only facilitate infusions, but they are the first port and needle system indicated for the power injection of contrast media for CECT scans.

Contrast enhanced computed tomography (CECT) scans are simple, safe and non-invasive procedures that provide quick and accurate diagnostic information to help track tumor markers or diagnose pulmonary embolisms, for example. The scans are many times more sensitive than conventional x-rays. Radiologists can distinguish small differences in soft tissues that may not be detected with x-rays.

Before performing a CECT scan, the CT team will inject a contrast agent, which is a special fluid that acts like a dye, into the patient to help produce clearer pictures during the CECT scan procedure. For best results, the contrast agent is infused at a high rate into the bloodstream. This process is called power injection.

Bard's PowerPort* power-injectable port used with a PowerLoc* Safety Infusion Set Family† device has the unique ability to allow clinicians to perform power-injected CECT scans without having to use peripheral I.V. needles.

PowerPort* Implantable Port

Description - PowerPort* Implantable Port

The PowerPort* Implantable Port and PowerLoc* Safety Infusion Set Family† devices are access devices 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* Safety Infusion Set Family† device. 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, also in a triangular shape. Dual lumen PowerPort* implantable ports can be identified subcutaneously by feeling the tops of each septum. Each septum has three palpation bumps arranged in a triangle. All materials are biocompatible, can be used with virtually all injectable solutions and can be safely used with CECT.

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 sterile normal saline and does not require heparin to maintain patency.

† PowerLoc*, PowerLoc* Clear, and PowerLoc* MAX Safety Infusion Sets (SIS)

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* Safety Infusion Set Family† device, 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/second.

Warnings

- 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.
- Intended for Single Patient Use. DO NOT REUSE. Bard Access Systems, Inc. products are single use devices and should never be reimplanted. Any device that has been contaminated by blood should 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.
- The use of an infusion set other than a PowerLoc* Safety Infusion Set Family† device during power injection may lead to system failure and possibly patient injury.
- Do not use a syringe size smaller than 10 mL. Flushing occluded catheters with small syringes can create excessive pressure within the port system and lead to port system failure.

Precautions

- Carefully read and follow all instructions prior to use.
- Follow Universal Precautions when accessing the port.
- Follow all contraindications, warnings, precautions and instructions for all infusates as specified by their manufacturers.
- Precautions are intended to help avoid product damage and/or patient injury.
- Only accessories and components with luer lock connections should be used with this device.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- Use only non-coring needles with the 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, but not limited to the following:

- Air Embolism
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression between the Clavicle and First Rib
- Catheter or Port related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothorax
- Hydrothorax
- Intolerance Reaction to Implanted Device
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Vascular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature.

PowerPort* Devices

Use and Maintenance

Site Preparation

Always inspect and aseptically prepare the injection site prior to accessing the port.

Note: It is recommended that catheter tip placement is verified through institutional protocol.

Equipment:

- Alcohol or chlorhexidine wipe
- Antiseptic swabs (3)
- Sterile gloves

Procedure:

1. Explain procedure to patient. Warn of needle prick sensation. (Sensation of needle insertion decreases over time. Use of a topical anesthetic may be appropriate.)
2. Wash hands thoroughly.
3. Put on sterile gloves.
4. Cleanse or scrub the area according to the cleansing agent manufacturer's instructions. We suggest an area of at least 10 – 13 cm (approximately 4 x 5 in.) diameter at the port insertion site.

Directions for the use of ChloraPrep* preoperative skin preparation:

Prepare the site with ChloraPrep* One-Step Applicator Solution or according to institutional policy using sterile technique. "Pinch-Off" the wings on the ChloraPrep* One-Step Applicator Solution to break the ampule and release the antiseptic. Do not touch the sponge. Wet the sponge against the treatment area until fluid is visible on the skin. Use repeated back-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 cm² (approximately 4 x 5 in.). Discard the applicator after use.

Note: Follow established hospital or institutional policy for changing I.V. tubing and accessing cannula. The Center for Disease Control (CDC) or Oncology Nursing Society (ONS) may have recommended guidelines.

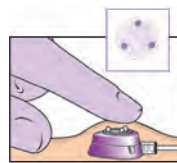
Accessing Implantable Ports

Equipment:

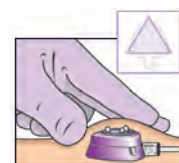
- Syringe
- If the port will be accessed for power injection, it must be accessed with a PowerLoc* Safety Infusion Set Family[†] device. If not power injecting, it can be accessed with any non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.

Procedure for single lumen PowerPort* devices:

1. Perform aseptic site preparation.
2. Locate port septum by palpation.
 - a. Locate base of port with non-dominant hand.
 - b. Triangulate port between thumb and first two fingers of non-dominant hand. Aim for center point of these three fingers.



Feel the soft top of the port to locate the three palpation bumps arranged in a triangle.



Feel the sides of the port to identify its unique triangle shape.

3. Insert PowerLoc* Safety Infusion Set Family[†] device or other non-coring safety needle perpendicular to port septum. Advance needle through the skin and septum until reaching bottom of reservoir. Make certain that needle tip is inserted fully within the port.
4. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
5. Always flush the port reservoir following injection.
6. Perform heparin lock procedure for open-ended catheters. For implantable ports with Groshong* catheters, a sterile normal

saline lock may be used. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.

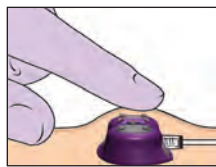
- When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting. If using a PowerLoc* Safety Infusion Set Family† device, activate safety mechanism while withdrawing the needle.

Procedure for dual lumen PowerPort* devices:

- Perform aseptic site preparation.
- Locate port septum by palpation.
 - Locate base of port with non-dominant hand.
 - Locate center of dual lumen port by palpating Septum-Finder* Ridge on top of port and place index finger of dominant hand to mark.
 - Triangulate right or left side of dual lumen port between thumb and first two fingers of non-dominant hand. Aim for center point of these three fingers.



Palpate port housing.



Locate Septum-Finder* Ridge and palpation bumps.

- Insert needle perpendicular to port septum. Advance PowerLoc* Safety Infusion Set Family† device through the skin and septum until reaching bottom of reservoir.
- Confirm correct needle placement by blood aspiration.
- Flush each lumen separately following injection.
- Perform heparin lock separately on each lumen.
- When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting. If using a PowerLoc* Safety Infusion Set Family† device, activate safety mechanism while withdrawing the needle.

Bolus Injection Procedure Other Than Power Injection

Equipment:

- PowerLoc* Safety Infusion Set Family† device. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Syringe filled with sterile normal saline
- Extension set with clamp

Procedure:

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

- Explain procedure to patient and prepare injection site. Remember to check patient's records and ask the patient to determine whether they have any known allergies to chemicals or materials that will be used during the injection procedure.
- Attach PowerLoc* Safety Infusion Set Family† device or other non-coring safety needle to extension set and syringe filled with sterile normal saline. Expel all air and clamp extension.
- Aseptically locate and access port. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
- Flush port with 10 mL sterile normal saline. Clamp the extension set and remove the syringe.
- Connect syringe containing the drug to extension set. Release clamp and begin to administer injection.
- Examine the injection site for signs of extravasation; if noted, immediately discontinue the injection and initiate appropriate intervention.
- When the injection is completed, clamp the extension set.
- Flush after each injection with 10 mL of sterile normal saline to help prevent interaction between incompatible drugs.
- For open-ended catheters:** Flush port with 5 mL heparinized saline after every use and at least once every 4 weeks.

For dual lumen catheters: Flush each lumen with 5 mL heparinized saline to help prevent interaction between incompatible drugs after every use and at least once every 4 weeks.

For Groshong* catheters: A sterile normal saline lock may be used. Flush port with 5 mL of sterile normal saline at least once every 4 weeks.

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

Note: For **Groshong*** and open-ended catheters, the needle hub should not be left open to air while it is in the port. Do not manipulate the needle once it is in the septum.

- When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Continuous Infusion Procedure

Caution: Do not use a syringe size smaller than 10 mL. Flushing occluded catheters with small syringes can create excessive pressures within the port system.

Equipment:

- Prescribed I.V. solution
- Extension set with clamp
- 10 mL syringe filled with sterile normal saline
- PowerLoc* Safety Infusion Set Family† device, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing

beneath the bend of the needle.

- I.V. pole
- I.V. pump (if ordered)
- Transparent dressing
- 2 in. x 2 in. (5 cm x 5 cm) gauze pads

Procedure:

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

1. Explain procedure to patient and prepare injection site. Remember to check patient's records, and ask the patient, to determine whether they have any known allergies to chemicals or materials that will be used during the injection procedure.
2. Attach a PowerLoc* Safety Infusion Set Family† device or other non-coring safety needle to extension set and syringe filled with sterile normal saline. Expel all air and clamp the extension set.
3. Aseptically locate and access port. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
4. Secure needle with transparent dressing to help prevent inadvertent dislodgement. **Note:** For continuous access, change non-coring needle and transparent dressing every week.
5. Open clamp and flush port with sterile normal saline. Clamp extension set and remove syringe.
6. Connect fluid delivery system (I.V. set or infusion pump as indicated). **Note:** Always use Luer lock connections on all tubings and connections. Never use a slip tip connection. Pumps must incorporate a functional automatic pressure limiting switch which will shut pump off before pressure exceeds 25 psi.
7. Release clamp and initiate infusion. Examine the infusion site for signs of extravasation; if noted, or if patient experiences pain, immediately discontinue infusion and initiate appropriate intervention.
8. When infusion is completed, clamp extension set and then remove the fluid delivery system.
9. Flush after each infusion with 10 mL sterile normal saline to help prevent interaction between incompatible drugs.
10. **For open-ended catheters:** Flush port with 5 mL heparinized saline after every use and at least once every 4 weeks. **For dual lumen catheters:** Flush each lumen with 5 mL heparinized saline after every use and at least once every four weeks. **For Groshong* catheters:** A sterile normal saline lock may be used. Flush port with 5 mL of sterile normal saline at least once every 4 weeks. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline. **Note:** For **Groshong*** and open-ended catheters, the needle hub should not be left open to air while it is in the port. Do not manipulate the needle once it is in the septum.
11. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Blood Sampling Procedure

Equipment:

- Extension set with clamp
- PowerLoc* Safety Infusion Set Family† device or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Syringe filled with sterile normal saline
- Syringe (2) or evacuated blood collection vials (2)
- Sterile normal saline

Procedure:

Review Site Preparation and Accessing Implantable Ports sections before proceeding with this section.

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access port with a PowerLoc* Safety Infusion Set Family† device or other non-coring safety needle. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
3. Flush port with sterile normal saline.
4. Withdraw at least 5 mL of blood and discard syringe.
5. Aspirate desired blood volume into second syringe or evacuated blood collection system.
6. Once sample is obtained, perform saline lock procedure by immediately flushing the system with 20 mL of sterile normal saline.
7. Transfer sample into appropriate blood sample tubes.
8. Perform heparin lock procedure for open-ended catheters. **For implantable ports with Groshong* catheters, a sterile normal saline lock may be used.** **Caution:** Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.
9. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

Lock Procedure for Catheters

To help prevent clot formation and catheter blockage, implantable ports should be flushed per institutional protocol using a turbulent push-pause flushing method after each use. Clamp the tubing while infusing the last 0.5 mL of fluid to reduce potential for blood back-flow into the catheter tip, which could encourage catheter clotting. If the port remains unused for long periods of time, the 5 mL heparin solution or **sterile normal saline solution** should be changed at least every four weeks, per lumen. **Caution:** Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port locked with heparinized saline.

Determining Port Volumes

For PowerPort* implantable ports, you will need to check the patient's chart to determine the length of catheter used for each individual patient. For PowerPort* implantable port catheters, use the formula and tables below:

Port System Volume = Catheter length: _____ cm x $\frac{\text{catheter volume}}{\text{cm}}$
+ reservoir volume.

| Catheter Volumes | |
|-------------------------------|--------------------------|
| Procedure | Volume cm (per lumen) |
| 6F Chronoflex* catheter | 0.014 mL |
| 8F Chronoflex* catheter | 0.02 mL |
| 9.6F Silicone | 0.02 mL |
| 8F Groshong* catheter | 0.02 mL |
| 9.5F Chronoflex* (dual lumen) | 0.02 mL |

| Reservoir Volumes | |
|--|---------------------------------|
| Port | Reservoir Volume (per lumen) |
| PowerPort*, PowerPort* lsp, PowerPort* Duo implantable port | 0.6 mL |
| PowerPort* Slim implantable port | 0.5 mL |

Recommended Flushing Volumes, Open-Ended Catheters

Equipment:

- PowerLoc* Safety Infusion Set Family† device, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- 10 mL syringe filled with sterile heparinized saline (100 U/mL).

| Flushing Volumes - Open-Ended Catheters (per lumen) | |
|---|--|
| Procedure | Volume (100 U/mL) |
| When port is not in use | 5 mL heparinized saline every 4 weeks |
| After each infusion of medication or TPN | 10 mL sterile normal saline then 5 mL heparinized saline |
| After blood withdrawal | 20 mL sterile normal saline then 5 mL heparinized saline |
| After power injection of contrast media | 10 mL sterile normal saline then 5 mL heparinized saline |

Recommended Flushing Volumes, Groshong* Catheters

Equipment:

- PowerLoc* Safety Infusion Set Family† device, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- 10 mL syringe filled with sterile normal saline

| Flushing Volumes - Groshong* Catheters (per lumen) | |
|--|--|
| Procedure | Volume (100 U/mL) |
| When port is 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 withdrawal | 20 mL sterile normal saline |
| After power injection of contrast media | 10 mL sterile normal saline |

Procedure:

Review Site Preparation and Accessing Implantable Port sections before proceeding with the following:

- Explain procedure to patient and prepare injection site.
- Attach a syringe filled with sterile normal saline or heparinized saline (as applicable) to needle.
- Aseptically locate and access port with a PowerLoc* Safety Infusion Set Family† device or other non-coring safety needle. Confirm correct positioning of the needle within the port reservoir by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
- After therapy completion, flush port per institutional protocol. Close clamp while injecting last 0.5 mL of flush solution.
- To deaccess a PowerLoc* Safety Infusion Set Family† device from the port, activate safety mechanism while withdrawing needle.

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

MRI Scans



MR Conditional

Non-clinical testing has demonstrated the device is MR conditional. It can be scanned safely under:

- Static magnetic field of 3 tesla or less
- Spacial gradient field of 330 Gauss/cm or less
- Maximum specific absorption rate (SAR) of 4 W/kg for 30 minutes of scanning

In non-clinical testing, the PowerPort* device produced a temperature rise of less than 0.5°C at a maximum specific absorption rate (SAR) of 4 W/kg for 30 minutes of MR scanning in a 3T Siemens Trio with software version VA25.

For Minimal Image Artifact

- MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

PowerLoc* Safety Infusion Set Family† Devices

Description - PowerLoc* Safety Infusion Set Family Devices

PowerLoc* Safety Infusion Set Family† Devices are power injectable safety infusion sets ideal for accessing power injectable ports. This power-combo enables contrast agents to be power-injected. As a result, tissues show up more clearly in CECT scans, making it easier to monitor patient condition.

Indications For Use

The PowerLoc* Safety Infusion Set Family† of devices is intended for use in the administration of fluids and drugs, as well as blood sampling through surgically implanted vascular ports. The PowerLoc* Safety Infusion Set Family† of devices are also indicated for power injection of contrast media into the central venous system only with an implantable port that is also indicated for power injection. The maximum recommended infusion rate at 11.8 cPs is 5 mL/second for 19 Ga. needles, 5 mL/second for 20 Ga. needles, and 2 mL/second for 22 Ga. needles.

Contraindications

- **DO NOT USE**, if the presence of a device related infection, bacteria or septicemia is known or suspected.
- **DO NOT USE**, if local tissue factors will prevent proper device stabilization and/or access.

When used with an implantable power injectable port for contrast media infusion, the following warnings apply:

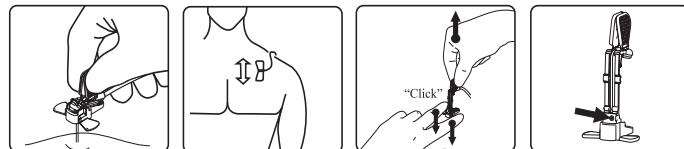
- When a PowerLoc* Safety Infusion Set Family† device is used for power injection of contrast media, it must be used in conjunction with an implantable power-injectable port, such as the Bard PowerPort* device. All Bard PowerLoc* Safety Infusion Set Family† devices have been tested and verified for power injection with Bard PowerPort* devices.
- Verify patient has an implanted power injectable port. When used specifically for power-injection, a PowerLoc* Safety Infusion Set Family† device may be used only in tandem with an appropriate power-rated port.
- **Bard PowerPort* device:** A Bard PowerPort* device can be identified by any two of the following methods:
 - Palpation bumps, triangular shape, radiopaque CT identifier, PowerPort* device patient ID card, ID bracelet, keychain, or PowerPort* device medical record.
- **Other Power-Injectable Ports:** Verify identification methods per port manufacturer's instructions.
- Do not power inject through a PowerLoc* Safety Infusion Set Family† device unless blood return is confirmed.
- Failure to warm contrast media to body temperature prior to power injection may result in device failure.

- Exceeding the indicated maximum flow rate, and the maximum recommended pressure limit setting of the power injector may result in device failure. Refer to individual product labeling for maximum pressure setting of the power injector.
- When power injecting through a PowerLoc* Safety Infusion Set Family† device with a Y-site, replace any needleless cap on the unused extension leg with a dead-end cap and tighten.
- Vigorously flush the device using a 10 mL or larger syringe and sterile normal saline prior to and immediately following the completion of power injection studies.
- The PowerLoc* Safety Infusion Set Family† device indication for power injection of contrast media implies the ability of the system 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.

Insertion

1. Prepare the port site for sterile accessing following institutional protocol.
2. Prime infusion set using aseptic technique following institutional protocol.
3. Verify correct needle placement by aspirating for blood.
4. Flush per institutional protocol and close clamp on extension tubing.
5. Secure needle to site following institutional protocol. Do not manipulate the tubing once it is in the septum.

PowerLoc* Device



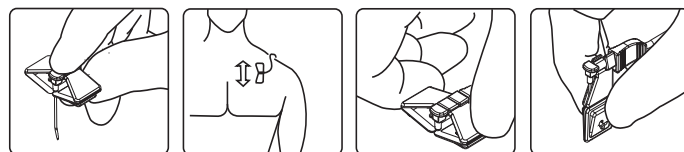
Access: Insert needle perpendicular to the port septum. Note: It is not necessary to push downward on front of device while accessing the port.

Orient wings in single or dual ports as shown.

Deaccess: Firmly pull the wings up until you hear or feel a "click".

Safe: Visually observe the orange dot. Dispose of set in a sharps container.

PowerLoc* Clear Device



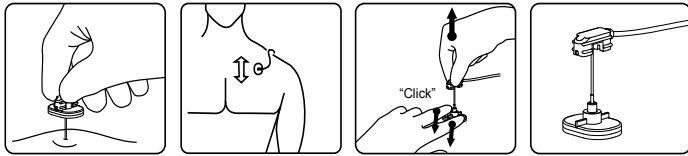
Access: Grasp grip area between thumb and middle finger. Press down with index finger.

Orient wings in single or dual ports as shown.

Deaccess: Grasp wing edges with thumb and inside knuckle of index finger, lift and squeeze until you hear, see, or feel a "click".

Safe: Dispose of set in a sharps container.

PowerLoc* MAX Device



Access: Insert needle perpendicular to the port septum. Note: The textured handle and base are not connected. You may position the base on the skin as needed.

Orientation: Orient device in single or dual ports as shown.

Deaccess: Firmly pull the textured handle up until you feel a firm stop and the needle is locked in the safety position.

Safe: Dispose of set in a sharps container.

Removal

1. After therapy completion, flush port per institutional protocol. Close clamp while injecting the last 0.5 mL of solution.
2. With non-dominant hand, stabilize the port.
3. Deaccess per instructions of the appropriate device listed above.

MRI Scans



MR Conditional

Non-clinical testing has demonstrated the device is MR conditional. It can be scanned safely under:

- Static magnetic field of 3 tesla or less
- Maximum specific absorption rate (SAR) of 4 W/kg for 15 minutes of scanning
- Spatial gradient field of 360 Gauss/cm or less

In non-clinical testing, the **PowerLoc*** device produced a temperature rise of less than 1.2 °C at a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3 Tesla Siemens Trio using software version VA25.

In non-clinical testing, the **PowerLoc* Clear** device produced a temperature rise of less than 1.4 °C at a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3 Tesla Siemens Trio using software version VB15.

In non-clinical testing, the **PowerLoc* MAX** device produced a temperature rise of less than 1.6 °C at a maximum whole body averaged specific absorption rate (SAR) of 4 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3 Tesla Siemens Trio using software version VB15.

For Minimal Image Artifact

- MR image quality may be compromised if the area of interest is within the distance, specified in the table below, to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

| PowerLoc* Family Device | Image Artifact Distance |
|-------------------------|-------------------------|
| PowerLoc* SIS | 5.5 cm |
| PowerLoc* Clear SIS | 6.0 cm |
| PowerLoc* MAX SIS | 7.3 cm |

Troubleshooting Guide

I. Aspiration Difficulties: **Do not power inject if you cannot aspirate as patient injury may result.**

A. Possible Causes

1. Failure to flush adequately, resulting in lumen obstruction.
2. Catheter tip sucking up to vein wall with aspiration.
3. Blood clot, fibrin sheath, or particulate matter obstructing lumen when catheter is aspirated.
 - A clot or other obstruction in the catheter lumen can produce a one-way valve effect. During infusion, the catheter wall expands slightly and allows fluid to flow around the plug. During aspiration, the catheter wall contracts slightly, tightening down around the obstruction and preventing aspiration.
 - Fibrin sheaths usually begin to form within a few days after the insertion of a central venous catheter. If it has grown enough to extend beyond the tip of the catheter, it may be pulled into and obstruct the catheter opening when aspiration is attempted, but not resist infusion.
4. Compression or transection of the catheter between the clavicle and first rib ("pinch-off area").
5. Kinked catheter.
 - Catheter may be pulled too tight through skin tunnel, causing kink at vessel insertion site, or where it curves into the subcutaneous tunnel.
 - Catheter may be curled or kinked within the vessel, or under the dressing.
6. Malposition of catheter tip (i.e. jugular vein, outside of vein).
7. Improper catheter length selection for patient size.

B. Possible Solutions

1. If no resistance to infusion is felt, attempt to flush with 10 mL normal saline. Then pull back gently on syringe plunger 2-3 mL, pause and proceed with aspiration.
2. If resistance to infusion is felt, check for signs of extravasation. If present, notify physician of possible catheter leakage or transection and embolization. If not present, see step 4.
3. Attempt to aspirate with a 20 mL syringe.
4. Move patient's arm, shoulder and head to see if a change in position will allow aspiration. If aspiration can only be accomplished with the patient in a certain position, the patient should be examined to see if the catheter has been placed in the "pinch-off" area.
5. Obtain physician's order for a chest x-ray to determine the position of the catheter.
 - If the catheter tip is not in the superior vena cava, the catheter should be repositioned.
 - If the catheter tip is not in a vein, the catheter should be replaced.
 - If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

II. Patient with Fever and/or Infection:

A. Symptoms:

- Inflammation at incision site
- Fever
- Positive site culture and/or blood cultures

B. If signs of infection are present:

- Notify physician

III. Insufficient Flow: **Do not power inject if resistance to flushing seems excessive.**

Excessive force must not be used to flush an obstructed lumen. Insufficient blood flow may be caused by the catheter contacting the wall of the vein or an occluding clot. The physician may attempt to dissolve the clot with a fibrinolytic agent before power injecting. Physician discretion advised.

A. Equipment:

- PowerLoc* Safety Infusion Set Family† device, or other non-coring safety needle. Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
- Syringe containing port priming volume of a fibrinolytic agent.
- Syringe filled with sterile normal saline.

B. Procedure:

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

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access the desired septum with needle attached to syringe, void of air and filled with port priming volume of fibrinolytic agent. **Warning:** If accessing a PowerPort* port with PowerLoc* Safety Infusion Set Family† device, do not affix the PowerLoc* Safety Infusion Set Family† device sticker that indicates the system can be power injected. Power injecting a blocked catheter could lead to catheter damage and patient injury.
3. Gently instill fibrinolytic solution. Use a gentle pull-push action on the syringe plunger to maximize solution mixing within port and catheter.

Warning: Occluded catheters may not accept all of the solution. If strong resistance is felt, do not attempt to force into catheter.

4. Leave solution in place according to drug manufacturer's recommendation and/or doctor's orders.
5. Attempt to aspirate solution and the clot(s).
6. If the clot(s) cannot be aspirated, repeat procedure.
7. Once the blockage has been aspirated and discarded, flush catheter with at least 20 mL of sterile normal saline.
8. Perform heparin lock procedure for open-ended catheters. **For implantable ports with Groshong* catheters, a sterile normal saline lock may be used.**

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

9. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

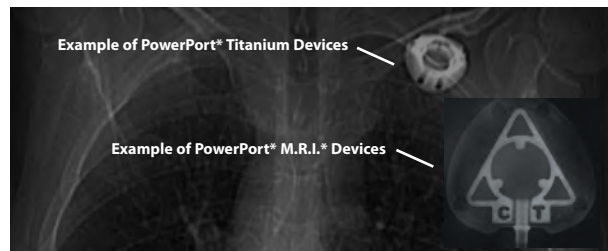
IV. Catheter Occlusion: **Do not power inject an occluded device.**

A. Possible Causes

1. Blood clot completely obstructing lumen.
2. May be kinked, coiled, damaged, or compressed between the clavicle and the first rib.
3. Catheter tip may not be within vein.
4. May be partially or completely transected. Transection can occur from the repeated pressure of the clavicle and the first rib on the catheter during normal movement if it is placed through the "pinch-off" area.
5. Improper catheter length for patient size.
6. Catheter can be blocked from lipid and/or protein deposition.

B. Possible Solutions

1. Ask responsible nurse or physician to attempt to aspirate blood clot.
2. Move patient's arm, shoulder and head to see if position change affects ability to infuse.
3. Obtain physician's order for a chest x-ray to determine the position of the catheter to rule out "Pinch-off". The patient's arms should be down the patient's side to rule out "Pinch-off" syndrome.



A PowerPort* device implanted in patient.

- If the catheter tip is not in the superior vena cava, the catheter should be repositioned.
- If the catheter tip is not in a vein, the catheter should be replaced.
- If the catheter has been placed through the "pinch-off" area, between the clavicle and the first rib, and is being compressed enough to interfere with infusion or aspiration, it is at risk for catheter transection and embolization. The physician should evaluate the patient for catheter replacement.

V. Signs of Pinch-off

A. Clinical:

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

B. 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 follows: ^{2,3}

| 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 with luminal narrowing | Removal of the catheter should be considered. |
| Grade 3 | Catheter transection or fracture | Prompt removal of the catheter. |

VI. Use of Fibrinolytic Agent for Catheter Blockage

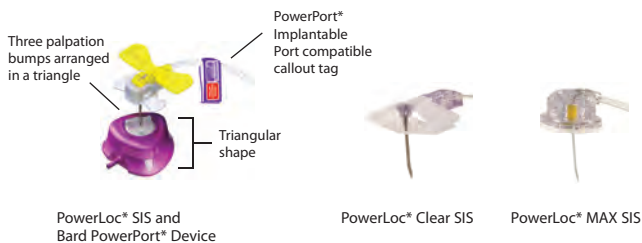
Use of a fibrinolytic agent has successfully cleared clotted catheters when gentle irrigation and aspiration have failed. The instructions provided by the drug manufacturer should be followed.

Alcohol should not be used to soak or de clot polyurethane catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

Power Injection Information

Important Information

- A PowerLoc[®] Safety Infusion Set Family[†] device (SIS) must always be used to access the PowerPort[®] implantable port for power injecting contrast media.
- A PowerLoc[®] Safety Infusion Set Family[†] device may also be used to access a power-rated port for power injecting contrast media if indicated by the port manufacturer.



- 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 port system failure.

- Check for patency, via aspiration, then vigorously flush the PowerPort[®] device using at least 10 mL of sterile normal saline prior to and immediately following the completion of power injection studies. It is important to ensure the patency of the PowerPort[®] device to 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 port system failure.

Warning: 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.

Warning: Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.

Warning: Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort[®] device:

| | | | |
|--|----------|----------|----------|
| PowerLoc [®] Safety Infusion Set Family [†] Device Gauge Size | 19 Ga. | 20 Ga. | 22 Ga. |
| PowerLoc [®] Safety Infusion Set Family [†] Device Gauge Color | Cream | Yellow | Black |
| Maximum Recommended Flow Rate Setting | 5 mL/sec | 5 mL/sec | 2 mL/sec |

- Exceeding the indicated maximum flow rate and the maximum pressure limit setting of the power injector may result in device failure.

Warning: The PowerPort[®] implantable port indication for power injection of contrast media implies the device's ability to withstand the procedure, but it 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. The PowerPort[®] device is only power injectable when accessed with a PowerLoc[®] Safety Infusion Set Family[†] device.

Power Injectable Port & Needle Identification

Always verify that the patient has a PowerPort[®] Implantable Port by at least two means. Ensure the port is accessed with a PowerLoc[®] Safety Infusion Set Family[†] device, and verification tag is affixed to the PowerLoc[®] Safety Infusion Set Family[†] device extension tubing, prior to power injection.

Bard PowerPort[®] devices can be distinguished from non-power injectable ports through the following means:

- Patient implant record
 - Check patient's chart for a PowerPort[®] device patient record sticker.

A. Patient Chart



- Patient discharge packet
 - Ask patient to see the patient identification card, bracelet or key chain received when the port was implanted.

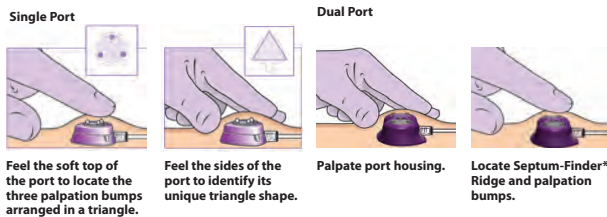
B. ID Items



Keychain Identification card ID Bracelet

- Palpation of the port
 - Palpate each septum on the port to identify a triangular arrangement of three palpation bumps. Palpate sides of a single lumen port to identify triangular port housing.

C. Port Palpation



Single Port
Feel the soft top of the port to locate the three palpation bumps arranged in a triangle.

Dual Port
Feel the sides of the port to identify its unique triangle shape.

Palpate port housing.

Locate Septum-Finder® Ridge and palpation bumps.

- Radiopaque identifier
 - Symbols on the bottom of the plastic and titanium ports are visible under X-ray, fluoroscopy or other appropriate imaging technology.
 - If port is flipped, the letters "CT" on the symbol may be reversed.

D. Radiopaque Identifier



PowerPort* M.R.J.* devices

Titanium PowerPort* device

PowerPort* duo device

- PowerLoc* Safety Infusion Set Family[†] device verification sticker.
 - The sticker is placed on extension tubing when a port is initially identified and accessed. This tag instructs CT to power inject through the PowerPort*/PowerLoc* system.

E. Verification Tag for the PowerLoc* Safety Infusion Set Family[†] needle



Power Injection Procedure

1. Access the port with a PowerLoc* Safety Infusion Set Family[†] device. Make certain that the needle tip is inserted fully within the port.
Warning: A PowerLoc* Safety Infusion Set Family[†] device must always be used to access the PowerPort* implantable port for power injecting contrast media. **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. 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.
4. Detach syringe.
5. After confirming the presence of a PowerPort* device and confirming patency, affix the PowerLoc* Safety Infusion Set Family[†] device purple sticker to the PowerLoc* Safety Infusion Set Family[†] device to inform CT that a power-injectable system is in place.
6. Warm contrast media to body temperature. **Warning:** Failure to warm contrast to body temperature prior to power injection may result in port system failure.
7. If possible, the patient should receive power injection with arms vertically above the shoulder with the palms of the hands 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.
8. Attach the power injection device to the PowerLoc* Safety Infusion Set Family[†] device ensuring connection is secure. All connections should be luer lock connections.

Warning: Do not exceed a 300 psi pressure limit setting, or the maximum flow rate setting shown below, on the power injection machine if power injecting through the PowerPort* device:

| | | | |
|--|----------|----------|----------|
| PowerLoc* Safety Infusion Set Family [†] Device Gauge Size | 19 Ga. | 20 Ga. | 22 Ga. |
| PowerLoc* Safety Infusion Set Family [†] Device Gauge Color | Cream | Yellow | Black |
| Maximum Recommended Flow Rate Setting | 5 mL/sec | 5 mL/sec | 2 mL/sec |

- Exceeding the indicated maximum flow rate and the maximum pressure limit setting of the power injector may result in device failure.
9. Instruct the patient to communicate immediately any pain or change in feeling during the injection. Inject warmed contrast, taking care not to exceed the flow rate limits.
Warning: If local pain, swelling or signs of extravasation are noted, the injection should stop immediately.
Warning: Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
 10. Disconnect the power injection device. Always flush each lumen of the port following power injection with 10 mL of sterile normal saline followed by 5 mL heparinized saline for open-ended catheters or 10 mL sterile normal saline for **Groshong*** catheters.
 11. Perform heparin lock procedure on each lumen for open-ended catheters. For implantable ports with **Groshong*** catheters, a sterile normal saline lock may be used.

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

- After therapy completion, flush port per institutional protocol, and close clamp while injecting last 0.5 mL of flush solution. When deaccessing the port, the needle should be removed using the positive pressure technique. Positive pressure is maintained while flushing the accessed port by clamping the infusion set tubing, while still flushing the line. This helps reduce the potential for blood backflow into the catheter tip, which could encourage catheter clotting.

CT Contrast Enhanced Computed Tomography Information

This product and packaging do not contain natural rubber latex.

This device does not contain DEHP

MR MR Conditional

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

References

- Bard Access Systems; "Your Port Access Advantage: What Patients and Nurses Say About Ports", 2005, 0710420.
- 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.
- Ingle, Rebecca; Nace, Corinne, Venous Access Devices: Catheter Pinch-off and Fracture, 1993, Bard Access Systems, Inc.
- Venousaccess.com
- www.nursingcenter.com
- Camp-Sorrell, Dawn; "Access Device Guidelines: Recommendation for Nursing Practice and Education." 2004

Further Reading

- See PowerPort* device IFU, PowerPort* device Nursing Guide, PowerPort* Patient Guide, PowerLoc* Safety Infusion Set Family† device IFU, and PowerLoc* Safety Infusion Set Family† device wall chart for more details.
- Bard Access Systems is proud to offer "Your Port Access Advantage"* patient education module for helping patients select their best access option.
- See www.powerportadvantage.com



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: March 2010

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