Instructions For Use

BardPort* Implantable Ports

SlimPort* Implantable Ports

X-Port* Implantable Ports

with Open-Ended and Groshong* Catheters
ACCESS SYSTEMS

BardPort* Implantable Ports

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Description

The BardPort*, SlimPort*, and X-Port* implantable ports are implantable access devices designed to provide repeated access to the vascular system. Port access is performed by percutaneous needle insertion using a non-coring needle. The system consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. All materials are biocompatible and can be used with virtually all injectable solutions. 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.

Indication For Use

The BardPort*, SlimPort*, and X-Port* implantable ports are 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.

Contraindications, Warnings, and Precautions

Contraindications

This device is contraindicated:

• 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

During Placement:

• Intended for Single Use. **DO NOT REUSE.** Reuse and/or repackaging may create a 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.

• 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 the 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.

• Failure to completely advance the catheter on the dual lumen stem may result in subcutaneous leakage.

• Avoid vessel perforation.

• For Implantable ports with Groshong* catheters, do not cut stylet. Withdraw stiffening stylet from catheter prior to cutting.

• Pinch-off Prevention: Catheters placed percutaneously or through a cut-down, into the subclavian vein, should be inserted at the junction of the outer and middle thirds of the clavicle, lateral to the thoracic outlet. The catheter should not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and the clavicle, which can cause damage and even sever the catheter. A radiographic confirmation of catheter placement should be made to ensure that the catheter is not being pinched by the first rib and clavicle.\(^1,2\)

• Do not attempt to measure the patient’s blood pressure on the arm in which the peripheral port system is located since catheter occlusion or other damage to the port system could occur.

• Do not access arm in which a peripheral port system is located, proximal to the port pocket as catheter puncture or other damage to the port system could occur.

• Alcohol should not be used to soak or declot polyurethane catheters because alcohol is known to degrade the polyurethane catheters.
• Once needle is positioned in the septum do not tilt or rock needle as this may cause leakage or damage the port system.
• Do not manipulate catheter/port connection of pre-assembled or preconnected port system as the catheter could become disconnected from the port, or system damage could occur.

During Port Access:
• Do not use a syringe smaller than 10 mL. Flushing occluded catheters with small syringes can create excessive pressure within the port system.
• Exceeding maximum flow rate may result in port system failure and/or catheter tip displacement.
• Failure to ensure the patency of the catheter prior to infusion may result in port system failure.
• If local pain, swelling or signs of extravasation are noted during infusion, 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 follows:\textsuperscript{3,4}

<table>
<thead>
<tr>
<th>Grade</th>
<th>Severity</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No distortion</td>
<td>No action.</td>
</tr>
<tr>
<td>Grade 1</td>
<td>Distortion present without luminal narrowing</td>
<td>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.</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Distortion present with luminal narrowing</td>
<td>Removal of the catheter should be considered.</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Catheter transection or fracture</td>
<td>Prompt removal of the catheter.</td>
</tr>
</tbody>
</table>

**Precautions**

- Carefully read and follow all instructions in these instructions for use (IFU).
- 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.
- When utilizing the Arm Placement via Brachia/Basilic approach, the port should not be placed in the axillary cavity.
- 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 the wire as a unit to prevent the needle from damaging or shearing the guidewire.
- Use only non-coring needless 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.

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.
- If vessel has been used for previous port placement evaluate for patency prior to placing port.

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-apartment introducers:
  o Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
  o Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apartment introducer.
  o 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.
• Care should be taken to avoid excessive contact between the needle and port base.

After Placement:
• Encourage patient to keep patient ID card and present it to clinicians accessing their port.
• Do not use the device if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism, and surgical removal.
• Accessories and components with Luer Lock connections should be used with this device.
• If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
• DO NOT USE A SYRINGE SMALLER THAN 10 mL! Infusion pressure greater than 25 psi (172 kPa) may damage blood vessels and viscus and is not recommended.
• Use only non-coring needles with the port.
• Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle.
• Confirm correct positioning of the needle within the port reservoir by aspiration of blood before infusion of any substance. If there is doubt regarding proper needle placement, perform a radiographic dye procedure to confirm placement.

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
• 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
• Guidewire Fragment Embolism
• Hematoma
• Hemothorax
• Hydrothorax
• Infection, including but not limited to pocket, catheter tunnel and/or bloodstream
• 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.

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, does not create pressure points, has not previously been irradiated, does not show signs of infection, and does not interfere with clothing. 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 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 Trendelenberg 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 the needle 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.

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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.

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**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 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.
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 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.
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 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 atrium. Verify correct catheter tip position using fluoroscopy or appropriated 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 onto 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, and re-assemble the connection.
   e. For dual lumen ports: Advance catheter completely onto the 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 catheter integrity. Bard Access Systems, Inc. does not recommend suturing around the catheter as doing so could compress, kink, or damage catheter.

**Single Lumen Port Device:**

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.
2. After suturing the port in the pocket, flush the wound with sterile normal saline or 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.

**Dual Lumen Port Device:**

**Warning:** Advance catheter completely on stem prior to advancing catheter lock.

**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.
2. After suturing the port in the pocket, flush the wound with sterile normal saline or 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.

Determining Port System Volumes For Port Lock Procedures

To calculate a close approximation of port system volume for each lumen, you will need to determine the length of catheter used for each individual patient. (For future reference, it will be helpful to record this information on the patient’s chart and/or patient ID card.)

For BardPort*, SlimPort* and X-Port* implantable port catheters, use the formula and tables below:

Port System Volume = Catheter length: \( \frac{\text{catheter volume}}{\text{cm}} \) + reservoir volume.

<table>
<thead>
<tr>
<th>Catheter</th>
<th>Volume (per lumen)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6F ChronoFlex* catheter</td>
<td>0.01 mL/cm</td>
</tr>
<tr>
<td>6.6F Silicone catheter</td>
<td></td>
</tr>
<tr>
<td>7F Silicone (dual lumen)</td>
<td>0.01 mL/cm</td>
</tr>
<tr>
<td>7F Groshong* catheter</td>
<td></td>
</tr>
<tr>
<td>9.5F Groshong* (dual lumen)</td>
<td>0.02 mL/cm</td>
</tr>
<tr>
<td>10F Silicone (dual Lumen)</td>
<td></td>
</tr>
<tr>
<td>8F ChronoFlex* catheter</td>
<td></td>
</tr>
<tr>
<td>9.6F Silicone catheter</td>
<td></td>
</tr>
<tr>
<td>8F Groshong* catheter</td>
<td></td>
</tr>
<tr>
<td>9.5F ChronoFlex* (dual lumen)</td>
<td></td>
</tr>
<tr>
<td>12F Silicone (dual lumen)</td>
<td></td>
</tr>
</tbody>
</table>
**Reservoir Volumes**

<table>
<thead>
<tr>
<th>Port</th>
<th>Per Reservoir Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>SlimPort* Port</td>
<td>0.2 mL</td>
</tr>
<tr>
<td>X-Port* Port</td>
<td></td>
</tr>
<tr>
<td>Titanium Low Profile Port</td>
<td>0.3 mL</td>
</tr>
<tr>
<td>M.R.I.* Low-Profile</td>
<td></td>
</tr>
<tr>
<td>SlimPort* Ultra Low Profile</td>
<td></td>
</tr>
<tr>
<td>Dual SlimPort* Rosenblatt* Port</td>
<td>0.27 Dist. 0.34 Prox. mL</td>
</tr>
<tr>
<td>M.R.I.* Port</td>
<td></td>
</tr>
<tr>
<td>M.R.I.* Hard Base Port</td>
<td></td>
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<tr>
<td>X-Port isp* Port</td>
<td>0.6 mL</td>
</tr>
<tr>
<td>X-Port duo* Port</td>
<td></td>
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<tr>
<td>Titanium Port</td>
<td></td>
</tr>
<tr>
<td>M.R.I.* Dual-Port</td>
<td>0.8 mL</td>
</tr>
<tr>
<td>Dome* Port</td>
<td>1.2 mL</td>
</tr>
</tbody>
</table>

**Note:** This calculated volume represents the port system volume for each port reservoir.

**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 hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and 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.
**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 repeat with 5 mL 100 U/mL heparinized-saline, or with volume calculated above. Close clamp while injecting last 0.5 mL of flush 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.

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<table>
<thead>
<tr>
<th>Flushing Volumes, Open-Ended Catheters</th>
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<tbody>
<tr>
<td><strong>Procedure</strong></td>
</tr>
<tr>
<td>When port not in use</td>
</tr>
<tr>
<td>After each infusion of medication or TPN</td>
</tr>
<tr>
<td>After blood withdrawal</td>
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</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>When port not in use</td>
<td>5 mL sterile normal saline every 4 weeks</td>
</tr>
<tr>
<td>After each infusion of medication or TPN</td>
<td>10 mL sterile normal saline</td>
</tr>
<tr>
<td>After blood withdrawal</td>
<td>20 mL sterile normal saline</td>
</tr>
</tbody>
</table>

**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


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Implantable ports are classified as “MR Safe” and “MR Conditional”. To determine whether a BAS port is “MR Safe” or “MR Conditional”, refer to the patient identification card, patient implant record and/or the device unit label for these images:

- MR Safe
- MR Conditional

These classifications are described below.

**MR Safe**

Non-clinical testing has demonstrated that the device is “MR Safe”. A patient with this device can be scanned safely immediately after placement under any conditions.

“MR Safe” implantable ports will not create displacement, torque or local heating, and will give minimal or no MR image artifact.

**MR Conditional**

Non-clinical testing has demonstrated that the device is “MR Conditional”. A patient with this device can be scanned safely immediately after placement under the following conditions:

**Static Magnetic Field**
- Static Magnetic Field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less

**MRI-Related Heating**

In non-clinical testing, the device produced a temperature rise of up to 1.9°C during MRI performed for 15 minutes of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system.

Therefore, the MRI-related heating experiments for the device at 3 Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged specific absorption rate (SAR) of 2.9 W/kg (i.e., associated with a calorimetry-measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than 1.9°C.
Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device (within 4 – 40 cm², depending on port size and materials). Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.