Bard Port
Titanium Implanted Ports
With Peritoneal Catheter

Instructions For Use
Introduction

The BardPort Titanium Implanted Port with peritoneal catheter is a totally implantable access device designed to provide repeated access to the peritoneal cavity for the delivery of medications and other fluids. Port access is performed by percutaneous needle insertion using a non-coring needle.

Product Description

The system consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque silicone rubber catheter. All materials are biocompatible and can be used with virtually all injectable solutions.
Tray Configurations

The basic sterile tray of each BardPort Titanium Implanted Port with Peritoneal catheter includes the following:

- Indicated Port
- Catheter with Catheter Lock
- Flushing Connector for Catheter
- Implant Record
- Instructions For Use
- Needles, Non-coring
- Patient I.D. Card
- Vein Pick

Indications For Use

The BardPort Titanium Implanted Port with Peritoneal Catheter is indicated for patient therapy requiring repeated access to the peritoneal cavity. The port system can be used for infusion of medications and other fluids.

Cautions

- Read Instructions prior to use.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Contraindications

The BardPort Titanium Implanted Port with Peritoneal Catheter is contraindicated for implantation whenever:

- The presence of infection, bacteremia, or septicemia is known or suspected.
- The patient’s body size is insufficient to accommodate the size of the implanted port or catheter.
- The patient is known or is suspected to have an allergic reaction to materials contained in the device or has exhibited a prior intolerance to implanted devices.
Precautions

- Only physicians qualified in the implantation of peritoneal access devices should implant these devices.
- All Bard Access Systems Ports are supplied in double sterile packages. Examine the package carefully prior to opening to confirm sterility. If package is opened or damaged do not use the device.
- Be careful when implanting the port system to avoid mechanical damage to the delicate silicone material of the catheter. Clamp catheters only with smooth-edged atraumatic clamps or forceps. Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture and may require surgical removal.
- Implant the port system carefully to avoid any sharp or acute angles which could compromise the patency of the catheter lumen.
- Purge all air from the device by filling the port system and catheter with sterile normal saline solution prior to insertion to avoid air embolism.
- Be careful when using insertion techniques which require guidewires, since mechanical damage can be inflicted upon the delicate catheter lumen during insertion or removal of the wire, resulting in possible perforation, tear, or fracture of the catheter.
- Be careful when placing catheters through percutaneous introducers to avoid inadvertent penetration of vital structures by the introducer. Instructions for use are provided with all Bard Access Systems kits and should be carefully followed to help provide proper catheter connection and avoid catheter damage.
- Use only non-coring needles with the port. Do not use standard hypodermic needles because they may cause premature loss of septal integrity.

Note: Smaller syringes generate more pressure than larger syringes. A three pound force on the plunger of a 3cc syringe generates pressure in excess of 25 psi whereas the same three pound force on the plunger of 10cc syringe generates less than 10 psi of pressure. It is recommended to use no smaller than a 10 cc syringe with Bard Access Systems implanted ports.

- Choose a needle length based on reservoir depth, tissue thickness, and the thickness of any dressing beneath the bend of the needle. Too short a needle will compress the tissue and bandage which may cause the needle to back out of the reservoir. Too long a needle may create a lever action which can cause needle instability.
- Do not reuse non-coring needles. Tip deformation may tear or damage the port septum.
- If sutures are used to secure the catheter, be careful to avoid occluding or cutting the catheter.
- Do not infuse at pressures in excess of 25 psi because high pressure may damage blood vessels or viscus.
**Possible Complications**

- Air Embolism
- Bleeding
- Cardiac Arrhythmia
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter or Port Occlusion
- Catheter or Port-Related Sepsis
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- 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
- Spontaneous Catheter Tip Malposition or Retraction
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature and should be carefully considered before placing the port. Placement and care of the implanted port should only be performed by persons knowledgeable of the risks involved and qualified in the procedures.

**Implantation Instructions**

A number of techniques are available for inserting peritoneal catheters. The techniques described below employ the use of a **Bard Access Systems** Percutaneous Introducer Kit (#0601510).

**Caution:** The extent of peritoneal disease and/or prior abdominal surgery may contribute to formation of adhesions within the peritoneal cavity. Direct visualization may be required to implant peritoneal catheters.

- Complete patient implant record, including product reorder number and lot number.
- Select the site for port placement. The port is typically placed over the lower ribs on either side, but the actual site selected will vary based on individual patient factors. Port pocket site selection should allow for port placement in an anatomic area that provides good port stability, does not interfere with patient mobility, create pressure points, or interfere with clothing. Placement should consider the amount of cutaneous tissue over the port septum as excessive tissue will make location of the septum and needle insertion difficult. Conversely, too thin a tissue layer may lead to port erosion. A tissue thickness of 0.5 cm to 2 cm is generally considered appropriate.
- The catheter may be inserted into the peritoneum either directly through the pocket incision or via a subcutaneous tunnel to a remote entry site.
- The patient’s bladder should be decompressed with an indwelling catheter.
- Surgically prep and drape the operative site.
- Moderately distend patient’s abdomen by infusing sterile normal saline into the peritoneum through a needle. The volume of saline required will vary from less than 200 ml in newborn infants to approximately 3000 ml in obese adults.
Implantation Instructions

Warning: Care must be exercised to avoid bowel perforation when advancing the needle.

- Insert the guidewire through the same needle used to distend the abdomen. Remove the needle.
- Advance the introducer over the guidewire using a gentle rotating motion. Remove the guidewire and dilator as a unit leaving the sheath in place.
- Introduce the catheter into the sheath. Use a gentle, rotating motion to advance the tip of the catheter through the sheath and into the peritoneal cavity. **Note:** Continue to advance the catheter until resistance is met in the pelvis. Spongy resistance may indicate an extra-peritoneal position. Tilt the sheath cephalad to give the catheter a caudal direction. If the patient complains of discomfort in the bladder area, the catheter is placed too anteriorly. Pull the catheter back a few centimeters and reposition more posteriorly. If the patient complains of discomfort in the rectal area, withdraw the catheter a few centimeters until the sensation subsides.
- As the cuff advances, the sheath is split by rolling the handle ends away from each other in a downward direction. Continue to peel apart the sheath while withdrawing it. Be careful not to withdraw the catheter as the sheath is being removed.
- Check the catheter for free infusion and aspiration of saline solution and verify catheter position by x-ray, if appropriate. **Caution:** Verify that all catheter side holes remain within the peritoneal cavity to avoid injection into the subcutaneous tissue. If employing a purse string suture at the peritoneal puncture site, use caution to avoid cutting or occluding the catheter.
- Create a subcutaneous tunnel to the desired port pocket site using the **Bard Access Systems** Tunneler (#0601930).
- Create a subcutaneous pocket using blunt dissection. Do a trial placement to verify that the pocket is large enough to accommodate the port and that the port does no lie beneath the incision.

CAUTION: Prior to advancing the catheter lock, ensure that the catheter is properly positioned. The catheter must be straight with no sign of kinking prior to advancing the catheter lock. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter.

1. **Align Port Stem with Catheter Lumen**

   ![Diagram of Align Port Stem with Catheter Lumen]

2. **Advance Catheter to this Region**

   ![Diagram of Advance Catheter to this Region]

- Remove the catheter lock from the catheter and attach the end of the catheter to the end of the tunneler to pull it through the subcutaneous tunnel. **Note:** After pulling the catheter through the tunnel, it is easier to replace the catheter lock on the catheter by cutting the end at an acute (45°) angle. After replacing the catheter lock, cut the catheter to the proper length at a 90° angle allowing sufficient slack for body movement and port connection.
- Flush all air from the port using a 10 ml syringe filled with heparinized saline (100 USP U/ml). Insert the non-coring needle through the septum and inject the fluid while pointing the port stem upward.
- Cleanse all system components with irrigation solution.

1. **Align Port Stem with Catheter Lumen**

   ![Diagram of Align Port Stem with Catheter Lumen]

2. **Advance Catheter to this Region**

   ![Diagram of Advance Catheter to this Region]
Site Preparation

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

Equipment:
- Alcohol 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. Paint area with alcohol wipe starting at the port and working outward in a spiral motion over an area 4-5 inches in diameter.
5. Repeat Step 4 with antiseptic swabs three times.
Accessing BardPort\textsuperscript{*} Implanted Ports

Equipment:

- Non-coring needle
- Syringe, 10 ml or larger

Procedure:

1. Perform aseptic site preparation.
2. Utilizing a sterile gloved hand, 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.
3. Insert needle perpendicular to port septum. Advance needle through the skin and septum until reaching bottom of reservoir.
4. Verify correct needle placement by fluid aspiration.
5. Always flush the port following injection.
6. Perform heparin lock procedure.

NOTE: It is recommended that the dressing and infusion components be changed every 24-48 hours during infusion therapy.

Deaccessing BardPort\textsuperscript{*} Implanted Ports

To reduce potential for backflow into the catheter tip and possible catheter clotting, always remove a non-coring needle slowly, while injecting the last .5ml of solution. Stabilize the port with two fingers during needle withdrawal.
**Continuous Infusion Procedure**

**Equipment:**
- Prescribed I.V. solution
- Extension set with clamp
- 10 ml syringe filled with sterile normal saline
- Non-coring needle
- I.V. pole
- I.V. pump (if ordered)
- Transparent dressing
- Antibacterial ointment
- 2 in. x 2 in. gauze pads

**Procedure:**
1. Explain procedure to patient and prepare injection site.
2. Attach non-coring needle to extension set and 10 ml syringe filled with sterile normal saline. Expel all air and clamp extension.
3. Aseptically locate and access port.
4. Apply antibacterial ointment to injection site and place a rolled gauze pad under needle hub. Secure needle with transparent dressing to help prevent inadvertent dislodgement.
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:** To provide additional security during pump infusion, tape all tubing connections. Pumps must incorporate a functional automatic pressure limiting switch which will shut pump off before pressure exceeds 25 p.s.i.

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.

**Bolus Injection Procedure**

**Equipment:**
- Non-coring needle
- 10 ml syringe filled with sterile normal saline
- Extension set with clamp

**Procedure:**
1. Explain procedure to patient and prepare injection site.
2. Attach non-coring needle to extension set and 10 ml syringe filled with sterile normal saline. Expel all air and clamp extension.
3. Aseptically locate and access port.
4. Flush port with 10 ml sterile normal saline. Clamp the extension set and remove the syringe.
5. Connect syringe containing the drug to extension set. Release clamp and administer injection.
6. Examine the injection site for signs of extravasation; if noted, immediately discontinue the injection and initiate appropriate intervention.
7. When the injection is completed, clamp the extension set.
8. Flush after each injection with 10 ml of sterile normal saline to help prevent interaction between incompatible drugs.

**NOTE:** 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.
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. Perform heparin lock procedure.

**Heparin Lock Procedure**

To help prevent clot formation and catheter blockage, implanted ports with peritoneal 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.

Recommended flushing volumes:

<table>
<thead>
<tr>
<th>FLUSHING VOLUMES</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROCEDURE</td>
</tr>
<tr>
<td>Port not in use</td>
</tr>
<tr>
<td>After each infusion of medication</td>
</tr>
</tbody>
</table>

**Equipment:**

- Non-coring needle
- 10ml syringe filled with sterile heparinized saline (100 U/ml)

**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.
Use of Urokinase for Catheter Obstruction

Use of a fibrinolytic agent such as urokinase may clear obstructed catheters when gentle irrigation and aspiration have failed. The following procedure may be employed on the order of a physician. Additional instructions provided by the drug manufacturer should be followed.

Equipment:

- Non-coring needle
- 10ml syringe containing 3.2 ml of 5,000 U/ml urokinase
- 20ml syringe filled with sterile normal saline.

Procedure:

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access the desired septum with needle attached to 10 ml syringe, void of air and filled with 3.2 ml of 5,000 U/ml urokinase.
3. Gently instill urokinase solution. Use a gentle pull-push action on the syringe plunger to maximize solution mixing within port and catheter.

WARNING: If strong resistance is felt, do not attempt to force entire 3.2 ml into catheter.

4. Leave solution in place for 15 minutes.
5. Attempt to aspirate urokinase.
6. If the catheter cannot be aspirated, repeat procedure.
7. Once the blockage has been cleared, flush catheter with at least 20 ml of sterile normal saline.
8. Perform heparin lock procedure.

Single Use Medical Device

Bard Access Systems products are single use devices and should never be reimplanted or resterilized. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Resterilization of incompletely cleaned devices may not be effective. Any device that has been contaminated by blood should not be reused or resterilized.
WARNING: 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 to see if additional product information is available.

Revised date: January 2007

© 2007 C. R. Bard, Inc.

*Bard and BardPort are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.

Bard Access Systems, Inc.
Salt Lake City, UT 84116
801-595-0700
Clinical Information Hotline: 1-800-443-3385
Ordering Information: 1-800-545-0890