POWERFLOW™

Implantable Apheresis IV Port

BARD


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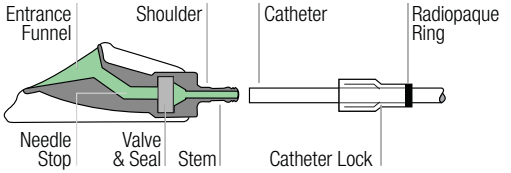
PowerFlow™ Implantable Apheresis IV Port

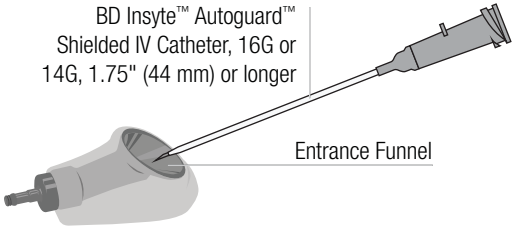
Description

The PowerFlow™ Implantable Apheresis IV Port is a totally implantable vascular access device designed to provide repeated access to the vascular system and flow rates as high as 150 mL/min. It is designed for easy placement, easy access, and continuous flow for apheresis procedures.

The PowerFlow™ IV Port consists of two primary components: a titanium access funnel with soft silicone body and a 9.6F radiopaque ChronoFlex™ polyurethane catheter. The two components are connected with a radiopaque catheter lock. A unique silicone valve and seal assembly inside the access funnel keeps the port system closed. The PowerFlow™ IV Port can be identified subcutaneously by finding the high point of the device and palpating the funnel as it slopes down and away from this point. This area is the entrance to the device and will feel concave and hollow.



PowerFlow™ IV Port access is performed at a shallow angle by the percutaneous insertion of an over-the-needle intravenous (IV) catheter (BD Insyte™ Autoguard™ Shielded IV Catheter, 16G or 14G, 1.75 inches (44 mm) or longer). The access funnel helps guide the IV needle into the angled pathway and to the needle stop. The needle cannot pass beyond the needle stop by design; however, once the needle is separated from the flexible IV catheter and pulled away slightly, the IV catheter can be advanced through the access pathway to open the valve and gain access.



The PowerFlow™ IV Port is not accessed with Huber non-coring needles. All materials are biocompatible and can be used with a broad range of injectable solutions intended for medicinal use, including the power injection of contrast media. The unique radiopaque identifier on the bottom of the port helps identify it as power injectable and accessed with an IV.

Indications for Use

The PowerFlow™ Implantable Apheresis IV Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for long-term therapeutic apheresis, withdrawal of blood, and infusion of medications, IV fluids, parenteral nutrition solutions, blood and blood products. The PowerFlow™ IV Port system is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

Please consult product IFU for full indications, contraindications, hazards, warnings, precautions, and directions for use.

Contraindications

This device is contraindicated for:

- Hemodialysis, as the safety and effectiveness has not been established for this therapy.

Warnings

- Failure to confirm IV catheter placement may result in infiltration/extravasation.
- If high dose heparin (1,000 – 5,000 units/ml) is used, aspirate the solution out of the device before use to prevent systemic heparinization of the patient.
- DO NOT USE A SYRINGE SMALLER THAN 10 mL TO FLUSH AND CONFIRM PATENCY. Patency should be assessed with a 10 mL syringe or larger with sterile normal saline. Upon confirmation of patency, administration of medication should be given in a syringe appropriately sized for the dose. Do not infuse against resistance.
- PowerFlow™ IV Ports are only power injectable when accessed with the BD Insyte™ Autoguard™ Shielded IV Catheter.
- Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
- Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
- Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
- Exceeding the maximum power injection flow rate may result in port system failure.
- PowerFlow™ IV Port system indication for power injection of contrast media implies the port's ability to withstand the procedure, but it does not imply appropriateness of the procedure for a particular patient nor for a particular IV catheter. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any IV catheter used to access the port.

- Do not exceed a 300 psi pressure limit setting on the power injection machine, or the maximum recommended flow rate on the IV catheter, if power injecting through the POWERFLOW™ IV Port (max infusion rate is 5 mL/s).
- If local pain, swelling or signs of extravasation are noted during power injection, the injection should be stopped immediately.

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.
- Encourage patient to keep patient ID card and present it to clinicians accessing their port.
- Care should be taken to avoid excessive force when accessing an implanted port.
- POWERFLOW™ IV Port is not accessed with Huber non-coring needles. To access the POWERFLOW™ IV Port, use BD Insyte™ Autoguard™ Shielded IV Catheters, 16G or 14G, 1.75 inches (44 mm) or longer. The exact IV catheter length should be determined by the clinical situation.
- Use only non-hydrophilic IV catheters.
- Do not bend the needle while using the product.
- Do not reuse or reinsert the needle into the IV catheter. Reinsertion of the needle may cause damage to the IV catheter, which may lead to extravasation.
- If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
- For safety needles, if needle retraction does not occur, depress button again. Dispose of any unshielded needles immediately. Keep needlepoint away from body and fingers at all times.
- The IV catheter hub should not be left open to air while it is in the port.
- 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.

- During MRI, RF heating behavior for the Bard PowerFlow™ Apheresis IV Port does not scale with static field strengths and has not been evaluated for static field strengths above 3 T.

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
- Allergic Reaction
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Puncture
- Cardiac Tamponade
- Catheter or Port Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter or Port-related Sepsis
- Damage or Breakage due to Compression between the Clavicle and First Rib
- Device Rotation or Extrusion
- Endocarditis
- Extravasation
- Fibrin Sheath Formation
- Guidewire Fragment Embolism
- Hematoma
- Hemothorax
- Hydrothorax
- Infection, including but not limited to pocket, catheter tunnel, and/or blood stream
- Inflammation, Necrosis, or Scarring of Skin Over Implant Area
- Intolerance or Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Pain at or around 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

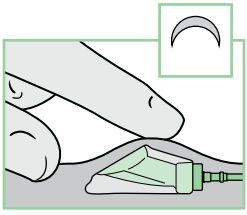
These and other complications are well documented in medical literature.

PowerFlow™ Implantable Apheresis IV Port Use and Maintenance

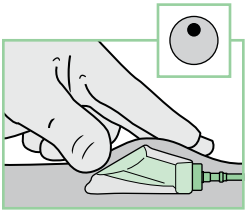
Site Preparation

Always inspect and aseptically prepare the access site prior to accessing the port. Observe universal precautions on all patients.

Locate and identify the port via palpation with gloved hands. Place your finger on the high point of the port to identify the top of the funnel and palpate the funnel as it slopes down and away from this point. This area is the entrance to the port and should feel concave and hollow.



Place your finger on the high point of the port to identify the top of the funnel.



Palpate the funnel, which should feel concave and hollow.

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

Equipment

- BD Insyte™ Autoguard™ Shielded IV Catheter, 16G or 14G, 1.75 inches (44 mm) or longer

  Caution: Use only non-hydrophilic IV catheters.
- 10 mL or larger syringe filled with sterile normal saline
- Primed extension set with clamps
- Sterile gloves
- Masks
- Chlorhexidine Gluconate 2% or other antiseptic solution per facility policy
- Additional items for cleaning and dressing the access site e.g. alcohol wipe, antiseptic swabs, gauze & dressing

Procedure

1. Explain procedure to patient. Warn of needle stick sensation. (Use of a topical anesthetic may be used per facility protocol.)
2. Wash hands thoroughly.
3. Don sterile gloves.
4. Cleanse or scrub the area according to the cleansing agent manufacturer's instructions or institutional policy, as appropriate. We suggest an area of at least 10 – 13 cm (approximately 4 x 5 in.) diameter at the port insertion site.

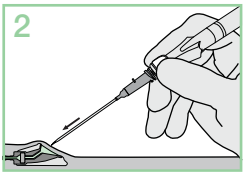
Directions for the Use of ChloraPrep™ Preoperative Skin Preparation

Prepare the site with ChloraPrep™ One-Step Applicator Solution or according to institutional policy using sterile technique. Pinch 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 cm^2 (approximately 4 x 5 in.). Discard the applicator after use.

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

Accessing the PowerFlow™ Implantable Apheresis IV Port for Therapeutic Apheresis Procedure

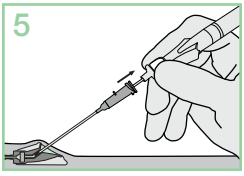
1. Stabilize the port with non-dominant sterile gloved hand and palpate the funnel-shaped entrance.
2. Using a shallow angle of access, (approximately 30 degrees) relative to the skin, insert a 16G or 14G over-the-needle IV catheter into the funnel.



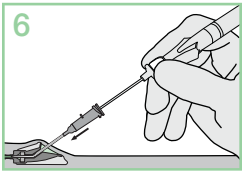
Caution: PowerFlow™ IV Port is not accessed with Huber non-coring needles. To access the PowerFlow™ IV Port, use BD Insyte™ Autoguard™ Shielded IV Catheters, 16G or 14G, 1.75 inches (44 mm) or longer. The exact catheter length should be determined by the clinical situation.

Caution: Do not bend the needle while using the product.

3. Slide the needle to the stop at the center of the funnel where resistance will be felt.
4. Slightly separate the needle from the IV catheter hub.
5. Pull the needle slightly away from the stop (approximately 5 mm) to create space for catheter advancement.



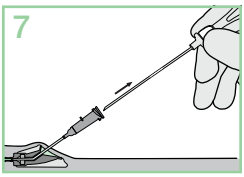
6. Advance the IV catheter completely through the valve assembly, continuing to pull the needle slightly away, as needed.



Note: A minimum of 1.5 cm of catheter advancement past the stop is required to assure adequate passage through the valves.

Note: The risk of air aspiration is reduced by proceeding with this part of the procedure with the patient performing the Valsalva maneuver.

7. Once the IV catheter is in place, withdraw the needle and engage the needle safety mechanism.



Caution: For safety needles, if needle retraction does not occur, depress button again. Dispose of any unshielded needles immediately. Keep needlepoint away from body and fingers at all times.

8. Immediately attach syringe or extension set to the IV catheter.

   Caution: The IV catheter hub should not be left open to air while it is in the port.

   Warning: Do not reuse or reinsert the needle into the IV catheter. Reinsertion of the needle may cause damage to the IV catheter, which may lead to extravasation. Dispose of the needle according to hospital guidelines.

9. Aspirate to confirm the ability to draw blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement. Flush with normal saline.

   Warning: Failure to confirm IV catheter placement may result in infiltration/extravasation.

   Warning: If high dose heparin (1,000 - 5,000 units/mL) is used, aspirate the solution out of the device before use to prevent systemic heparinization of the patient

   Note: Catheters used for apheresis procedures are larger bore catheters and require rapid flow rates. If used for apheresis, follow your facility's apheresis protocol for flushing and locking after each apheresis procedure.

10. Securely dress insertion site and proceed with treatment protocol.

    Note: Folded gauze used to support the catheter hub may help with optimizing flows. Check to ensure there are no kinks in the IV catheter at the skin line that may restrict flows.

    Note: For continuous access, change IV catheter and transparent dressing every 72-96 hours, or when clinically indicated.

De-accessing the IV Port

1. Following the treatment procedure, flush with normal saline.
2. Perform locking solution procedure and withdraw IV catheter while flushing continuously with locking solution.

   Note: Maintaining positive pressure via continuous flush during IV withdrawal will help reduce potential for blood backflow into the catheter tip and possible catheter clotting.

   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.
3. After IV catheter removal, apply pressure if bleeding occurs and apply dressing per hospital protocol.

Bolus Injection Procedure Other Than Power Injection

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

Equipment

- BD Insyte™ Autoguard™ Shielded IV Catheter, 16G or 14G, 1.75 inches (44 mm) or longer

  Caution: Use only non-hydrophilic IV catheters.
- 10 mL or larger syringe filled with sterile normal saline
- Primed extension set with clamps

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 IV catheter to extension set and syringe filled with sterile normal saline. Expel all air and clamp extension.
3. Aseptically locate and access port. Confirm correct positioning of the IV catheter within the port funnel by aspiration of blood ("flashback"). If there is doubt regarding proper IV catheter placement, have a radiographic dye procedure done to confirm placement.
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 begin to 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 15 mL of sterile normal saline to help prevent interaction between incompatible drugs.
9. Flush port with 5 mL heparin or citrate flush solution after every use and at least once every 28 days.

Note: Maintaining positive pressure via continuous flush during IV withdrawal will help reduce potential for blood backflow into the catheter tip and possible catheter clotting.

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 heparin flush solution.

Continuous Infusion Procedure

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

Equipment

- Primed extension set with clamps
- 10 mL or larger syringe filled with sterile normal saline
- BD Insyte™ Autoguard™ Shielded IV Catheter, 16G or 14G, 1.75 inches (44 mm) or longer

  Caution: Use only non-hydrophilic IV catheters.
- IV pole
- IV pump (if ordered)
- Transparent dressing
- 2" x 2" (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 IV catheter 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 IV catheter within the port funnel by aspiration of blood ("flashback"). If there is doubt regarding proper IV catheter placement, have a radiographic dye procedure done to confirm placement.
4. Secure IV catheter with transparent dressing to help prevent inadvertent dislodgement.

   Note: For continuous access, change IV catheter and transparent dressing every 72-96 hours, or when clinically indicated.
5. Open clamp and flush port with sterile normal saline. Clamp extension set and remove syringe.
6. Connect fluid delivery system (IV 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 15 mL sterile normal saline to help prevent interaction between incompatible drugs.
10. Flush port with 5 mL heparin or citrate flush solution after every use and at least once every 28 days.

Note: Maintaining positive pressure via continuous flush during IV withdrawal will help reduce potential for blood backflow into the catheter tip and possible catheter clotting.

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 heparin flush solution.

Blood Sampling Procedure

Equipment

- Primed extension set with clamps
- BD Insyte™ Autoguard™ Shielded IV Catheter, 16G or 14G, 1.75 inches (44 mm) or longer.

  Caution: Use only non-hydrophilic IV catheters.
- Syringe filled with sterile normal saline
- Syringe (2) or evacuated blood collection vials (2)
- Sterile normal saline

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 port with an over the needle polyurethane IV catheter. 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 15 mL of sterile normal saline.
7. Transfer sample into appropriate blood sample tubes.
8. Perform heparin or citrate lock procedure for open-ended catheters.

Note: Maintaining positive pressure via continuous flush during IV withdrawal will help reduce potential for blood backflow into the catheter tip and possible catheter clotting.

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 heparin flush solution.

Lock Procedure for Catheters

The PowerFlow™ Apheresis Port may be used as a regular port for long-term therapeutic apheresis, withdrawal of blood, and infusion of medications, IV fluids, parenteral nutrition solutions, blood and blood products. The type of locking solution and volume depends on how the device is used. To help prevent clot formation and catheter blockage, the port's open-ended catheter should be filled with sterile locking solution after each use. If the port remains unused for long periods of time, the locking solution 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). These patients must not have their port locked with heparinized saline.

Equipment

- BD Insyte™ Autoguard™ Shielded IV Catheter, 16G or 14G, 1.75 inches (44 mm) or longer.
- 10 mL syringe filled with sterile saline
- 10 mL syringe filled with 5 mL locking solution (100 U/mL)

Note: 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. Follow your facility protocol for heparin concentrations for apheresis catheters.

Procedure

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

1. Explain procedure to patient and prepare injection site.
2. Aseptically locate and access port. Confirm correct positioning of the IV catheter within the port by aspiration of blood ("flashback"). If there is doubt regarding proper needle placement, have a radiographic dye procedure done to confirm placement.
3. Attach a 10 mL syringe filled with sterile normal saline to IV catheter.

4. After therapy completion, flush port with 15 mL of sterile normal saline, then lock with 5 mL (100 U/mL) locking solution, or per your apheresis protocol with port system volume calculated below. Withdraw IV catheter while flushing continuously with locking solution.

Note: Maintaining positive pressure via continuous flush during IV withdrawal will help reduce potential for blood backflow into the catheter tip and possible catheter clotting.

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

Priming Volume Calculation

For determining the priming volume of the PowerFlow™ Implantable Apheresis IV Port, you will need to check the patient's chart or ID card to determine the length of catheter used for each individual patient. Typically the 45 cm catheter is cut down to the desired length before insertion. For PowerFlow™ Implantable Apheresis IV Port catheter priming volume, use the formula and tables below:

$$\text{Apheresis IV Port System Volume} = \text{Catheter Length: } \_\_\_\_\_ \text{ cm} \times \frac{\text{Catheter Volume}}{\text{cm}} + \text{Reservoir Volume}$$

Catheter Volume	
Catheter	$\frac{\text{Catheter Volume}}{\text{cm}}$
9.6F Polyurethane Catheter	0.034 mL/cm

Reservoir Volume	
Apheresis Port	Reservoir Volume
PowerFlow™	0.06 mL

Post Apheresis

Follow your facility's apheresis protocol for flushing and locking after each apheresis procedure.

Follow your facility protocol for heparin concentrations or other locking solutions for apheresis catheters. If high dose heparin (1,000-5,000 units/mL) is used to lock the catheter, the heparin solution must be aspirated prior to each use. Please follow institutional procedures or protocols regarding the documentation of device volume as well as locking solution concentrations.

Warning: If high dose heparin (1,000-5,000 units/mL) is used, aspirate the solution out of the device before use to prevent systemic heparinization of the patient.

Flushing Volume	
Procedure	**Volume Heparin (100 U/mL)**
When port is not in use	5 mL heparin flush solution every 28 days
After each infusion of medication of TPN	15 mL sterile normal saline, then 5 mL heparin flush solution
After blood withdrawal	15 mL sterile normal saline, then 5 mL heparin flush solution
After power injection of contrast media	15 mL sterile normal saline, then 5 mL heparin flush solution

PowerFlow™ Implantable Apheresis IV Port System Average Recirculation Rates if Two Systems Placed		
Catheter Tips	**Forward (n=40)**	**Reverse (n=40)**
Even	3.1%	3.2%
Offset by 2 cm	0.5%	8.3%
Offset by 4 cm	0.1%	4.3%

Note: Recirculation rates were measured on the benchtop using a blood simulant with viscosity of 3.5 centipoise (cP). Flow rate was consistently held at 120 mL/min.

MR Conditional

MRI Scans

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

Static Magnetic Field

- Static Magnetic Field of 3 Tesla (T) or less
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Bard PowerFlow™ Apheresis IV Port is expected to produce a maximum temperature rise of less than 6.0°C after 15 minutes of continuous scanning.

Caution: RF heating behavior for the Bard PowerFlow™ Apheresis IV Port does not scale with static field strengths and has not been evaluated with static field strengths above 3 T.

Artifact Information

In non-clinical testing, the image artifact caused by the device extends approximately 14 mm from the Bard PowerFlow™ Apheresis IV Port when imaged with a gradient-echo pulse sequence in a 3 T MRI system.

Troubleshooting Guide

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 10 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.

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

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:

- BD Insyte™ Autoguard™ Shielded IV Catheter, 16G or 14G, 1.75 inches (44 mm) or longer.

  Caution: Use only non-hydrophilic IV catheters.

- 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 port with IV catheter attached to syringe, void of air and filled with port priming volume of fibrinolytic agent.

   Warning: 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 locking procedure.

Note: Maintaining positive pressure via continuous flush during IV withdrawal will help reduce potential for blood backflow into the catheter tip and possible catheter clotting.

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 heparin flush solution.

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. Catheter 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.
   - 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.

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:[1,2]

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

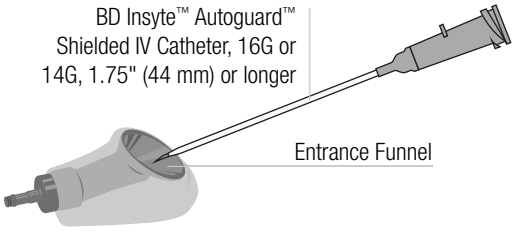
Use of Fibrinolytic Agent for Catheter Blockage

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, declot, or lock the device or some of the components because alcohol is known to degrade some of the components over time with repeated and prolonged exposure.

Power Injection Information

Important Information

Warning: The port device is only power injectable when accessed with the BD Insyte™ Autoguard™ Shielded IV Catheter.



- 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 PowerFlow™ Implantable Apheresis IV Port 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 PowerFlow™ Apheresis IV Port 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: Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.

Warning: Exceeding the maximum power injection flow rate may result in port system failure.

Warning: PowerFlow™ IV Port system indication for power injection of contrast media implies the port's ability to withstand the procedure, but it does not imply appropriateness of the procedure for a particular patient nor for a particular IV catheter. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any IV catheter used to access the port.

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 **PowerFlow™ Implantable Apheresis IV Port (max infusion rate is 5 mL/s):**

Peripheral IV Catheter Device Gauge Size	14G	16G
Peripheral IV Catheter Device Gauge Color	Orange	Grey
Maximum Recommended Flow Rate Setting	5 mL/sec	
Maximum Pressure Setting	300 psi	

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: If local pain, swelling or signs of extravasation are noted during power injection, the injection should be stopped immediately.

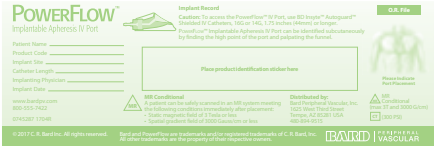
Port Identification

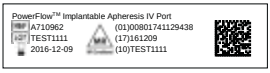
Always verify that the patient has a POWERFLOW™ Implantable Apheresis IV Port by at least two means. Ensure the port is accessed with a BD Insyte™ Autoguard™ Shielded IV catheter prior to power injection.

POWERFLOW™ Implantable Apheresis IV Ports can be distinguished from standard implantable ports through the following means:

Patient Implant Record

- Check patient's chart for a POWERFLOW™ Implantable Apheresis IV Port patient record sticker.





Patient Discharge Packet

Ask patient to see the patient identification card, bracelet or key chain received when the port was implanted

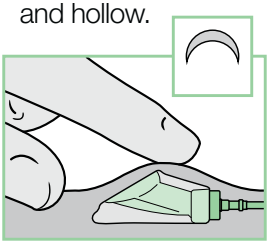
Identification Card

Identification Bracelet

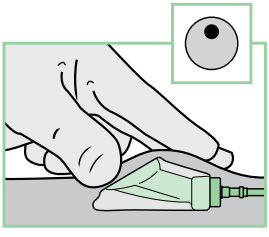
Key chain

Palpation of the Port

- Place your finger on the high point of the port to identify the top of the funnel and palpate the funnel as it slopes down and away from this point. This area is the entrance to the port and should feel concave and hollow.



Place your finger on the high point of the port to identify the top of the funnel.



Palpate the funnel, which should feel concave and hollow.

Radiopaque Identifier

- Symbols on the bottom of the port are visible under X-ray, fluoroscopy or other appropriate imaging technology.
- If port is flipped, the letters “IV CT” on the symbol may be reversed.
- Radiopaque identifiers for PowerFlow™ IV Port aid in identification as a Bard PowerFlow™ Implantable Apheresis IV Port.

Power Injection Procedure

1. Access the PowerFlow™ IV Port with the BD Insyte™ Autoguard™ Shielded IV Catheter following the access steps in the section above. Make certain that the IV catheter is long enough to be inserted fully within the port and that the IV catheter has gone through the valve assembly.

Warning: The port device is only power injectable when accessed with the BD Insyte™ Autoguard™ Shielded IV Catheter.

Note: Follow institutional protocol to verify correct catheter tip position prior to power injection.

2. Attach a syringe filled with sterile normal saline.
3. Instruct the patient to assume the position they will be in during the power injection procedure, before checking for patency. If possible, the patient should receive power injection with his or her arm vertically above the shoulder with the palm of the hand on the face of the gantry during injection. This allows for uninterrupted passage of injected contrast through the axillary and subclavian veins at the thoracic outlet.
4. Aspirate for adequate blood return and vigorously flush the port with at least 10 mL of sterile normal saline.

Warning: Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.

5. Detach syringe.
6. Warm contrast media to body temperature.
7. Attach the power injection device to the power-injection rated IV catheter ensuring connection is secure. Check indicated flow rate of safety infusion set and confirm power injector settings.

Peripheral IV Catheter Device Gauge Size	14G	16G
Peripheral IV Catheter Device Gauge Color	Orange	Grey
Maximum Recommended Flow Rate Setting	5 mL/sec	
Maximum Pressure Setting	300 psi	

Warning: Do not exceed a 300 psi pressure limit setting on the power injection machine, or the

maximum recommended flow rate on the IV catheter, if power injecting through the POWERFLOW™ IV Port (max infusion rate is 5 mL/s):

8. Instruct the patient to communicate immediately any pain or change in feeling during the injection.
9. Inject contrast media warmed to body temperature, taking care not to exceed the flow rate limits.

Warning: If local pain, swelling or signs of extravasation are noted, the injection should be stopped immediately.

Warning: Exceeding the maximum flow rate may result in port system failure.

10. Disconnect the power injection device.
11. After therapy completion, flush the port per institutional protocol. Withdraw IV catheter while flushing continuously with locking solution.
12. Perform locking procedure.

Note: Maintaining positive pressure via continuous flush during IV withdrawal will help reduce potential for blood backflow into the catheter tip and possible catheter clotting.

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

Note: The POWERFLOW™ IV Port testing included at least 36 power injection cycles with a power injection rated IV catheter and 11.8 cP viscosity contrast solution.

Power Injection Information for POWERFLOW™ Implantable Apheresis IV Port System

Catheter Description	9.6F SL Polyurethane Catheter
Maximum Indicated CT Flow Rate[a]	5 mL/s
Operating Pressure at the IV Port Stem[b]	20 psi
Average IV Port-Catheter Static Burst Pressure[c]	113 psi
Range of IV Port-Catheter Static Burst Pressures[c]	107-117 psi

Note: CT injector pressure limit should be set at a maximum of 300 psi. Flow rates less than 5 mL/s and/or lower viscosity contrast will generate lower pressures in the IV port and catheter.

[a] Represents flow capability of IV port and catheter assembly for power injection of contrast media.

[b] Worst case internal IV port operating pressure during maximum indicated CT flow rate using contrast media with 11.8 cP viscosity.

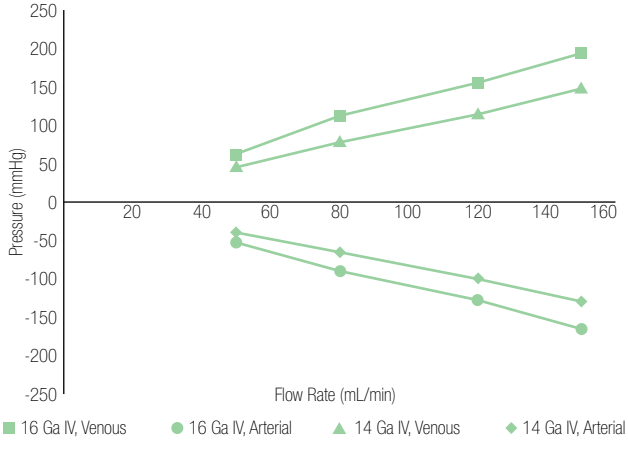
[c] Worst case static hydraulic burst pressure of the IV port-catheter assembly.

Note: The pressure provided are worst case for any IV port from our current product offering, with the catheter configuration specified.

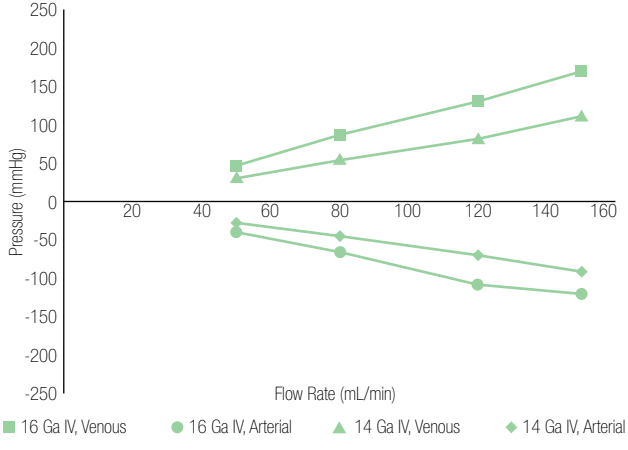
Apheresis Flow Rate Information for POWERFLOW™ Implantable Apheresis IV Port System

POWERFLOW™ allows for flow rates as high at 150 mL/min.

Flow Rates, 45 cm Catheter*



Flow Rates, 25 cm Catheter*



* Mean values, sample size n=30 for each data point.
As suggested by in vitro data, using a blood simulant with viscosity of 3.5cP, approximating the viscosity of whole blood. Changes in blood viscosity, catheter length and IV type will affect achievable flow rates.

See a Bard Peripheral Vascular Sales Representative for more information about any of these products.

References

1. 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.
2. Ingle, Rebecca; Nace, Corinne. Venous Access Devices: Catheter Pinch-off and Fracture, 1993, Bard Access Systems, Inc.

Further Reading

- See POWERFLOW™ Implantable Apheresis IV Port IFU or POWERFLOW™ Apheresis IV Port Patient Guide for more details.
- Bard Peripheral Vascular is proud to offer the Port Ready® Program, an initiative designed to provide resources for patient education and clinician training.
- See www.bardpv.com
- Camp-Sorrell, Dawn; Matey, Laurl. "Access Device Standards of Practice for Oncology Nursing." Oncology Nursing Society, 2017.

CT Contrast Enhanced Computed Tomography Information

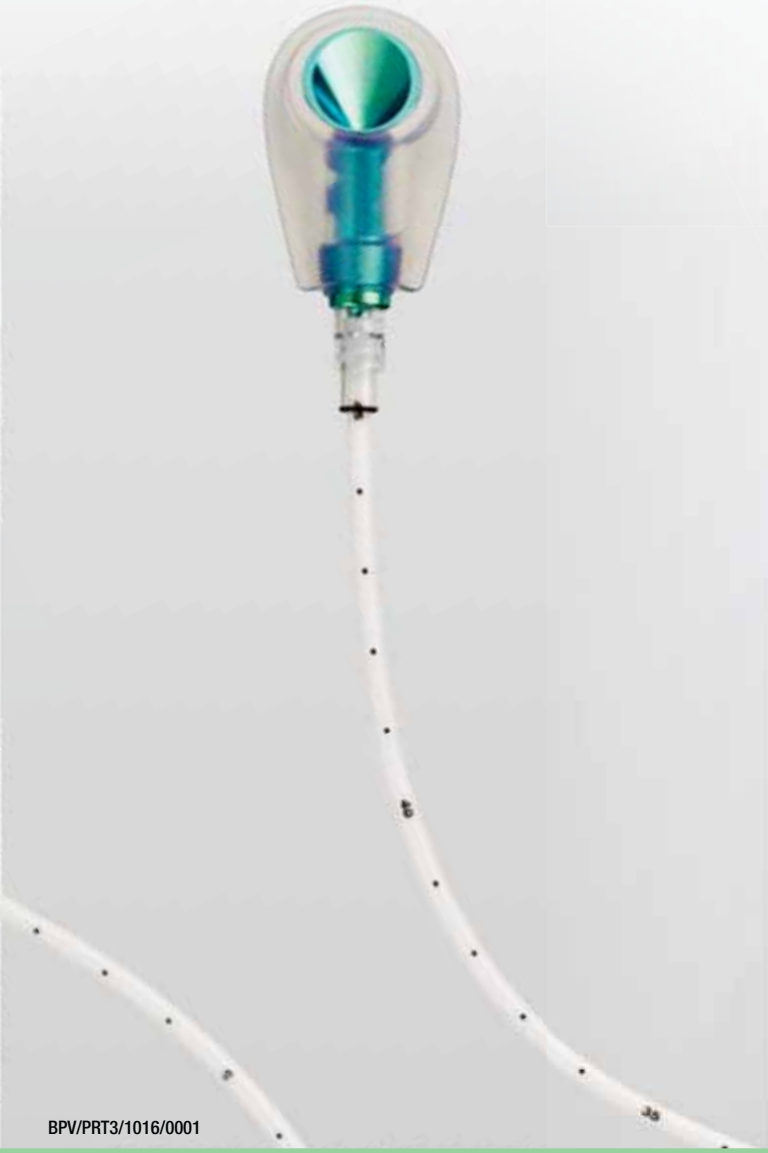
MR MR Conditional

Not made with natural rubber latex.

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 Peripheral Vascular, Inc. to see if additional product information is available.

Revised date: May 2017

Bard Peripheral Vascular, Inc.
www.bardpv.com | 1 800 321 4254
1625 W 3rd St. Tempe, AZ 85281



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