

POWERFLOW™

Implantable Apheresis IV Port



**POWERFLOW™ Implantable Apheresis IV Port
Summary Safety Information**

Description	2
Indications for Use	3
Contraindications	4
Warnings	4
Precautions	5

**Accessing the POWERFLOW™ Implantable
Apheresis IV Port for Power Injection**

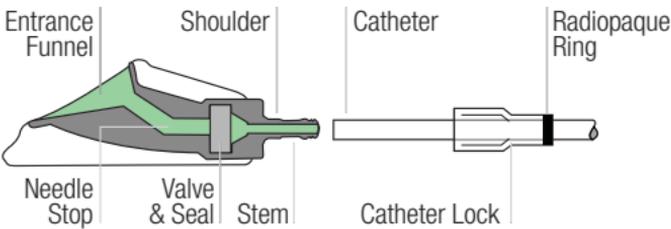
Identification	6
Preparing to Access the POWERFLOW™ IV Port	8
Power Injection Checklist	9
Accessing the POWERFLOW™ IV Port	10
Power Injection Procedure	12
De-accessing the POWERFLOW™ IV Port	14
Locking	15
Flushing	18
MR Safety Information	19
Troubleshooting Guide	20
References	24
Further Reading	24

POWERFLOW™ Implantable Apheresis IV Port

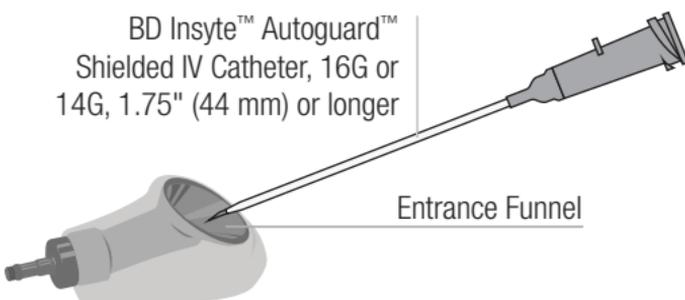
Description

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.
- 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 hypersensitive 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.

Refer to “Power Injection Information for POWERFLOW™ Implantable Apheresis IV Port System” insert for power injection information.

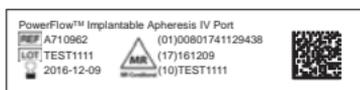
Port Identification

Always verify that the patient has a POWERFLOW™ Implantable Apheresis IV Port by at least two means. Ensure the port is accessed with the 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



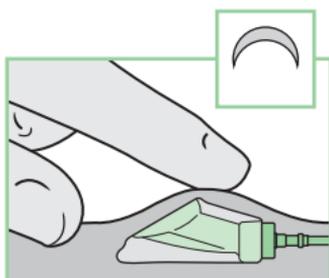
Identification Bracelet



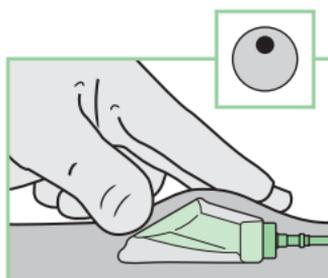
Key chain

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

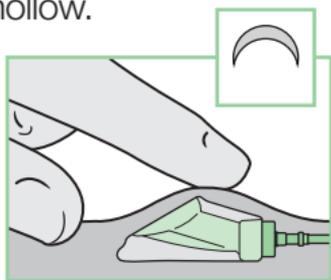
- Symbols on the bottom of the port are visible under X-ray, fluoroscopy or other appropriate imaging technology.
- If port is flipped, the letters “IV CT” on the symbol may be reversed.
- Radiopaque identifiers for POWERFLOW™ IV Port aid in identification as a Bard POWERFLOW™ Implantable Apheresis IV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



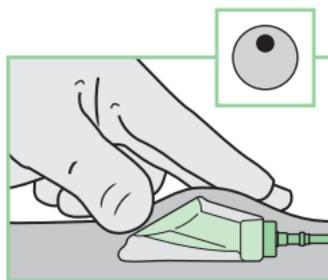
Site Preparation

Always inspect and aseptically prepare the injection 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.

Equipment

Collect and prepare the following equipment for use:

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

Caution: Use only non-hydrophilic IV catheters.

- If the port will be accessed for power injection, POWERFLOW™ IV Ports are only power injectable when accessed with the BD Insyte™ Autoguard™ Shielded IV Catheter.
- 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

Power-Injection Checklist

<input type="checkbox"/>	Ensure patient has a Power Injectable IV Port
<input type="checkbox"/>	Access with BD Insyte™ Autoguard™ Shielded IV catheter, 16G or 14G, 1.75 inches (44 mm) or longer
<input type="checkbox"/>	Check blood return and flush
<input type="checkbox"/>	Check maximum recommended flow rate for port and infusion set

Procedure

1. Explain procedure to patient. Warn of needle stick sensation.
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

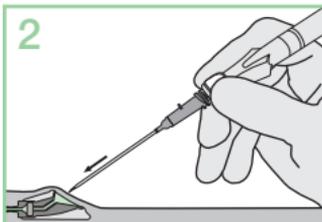
Prepare the site with Chloraprep™ One-Step Applicator Solution or according to institutional policy using sterile technique. Pinch the wings on the Chloraprep™ One-Step Applicator Solution to break the ampule and release the antiseptic. Do not touch the sponge. Wet the sponge against the treatment area 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 cm² (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) have recommended guidelines.

Accessing the POWERFLOW™ Implantable Apheresis IV Port

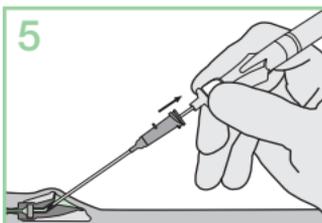
1. Stabilize the port with non-dominant sterile gloved hand and palpate the funnel-shaped entrance.
2. Using a shallow angle of access, (approximately 30 degrees) relative to the skin, insert a 16G or 14G over-the-needle IV catheter into the funnel.

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.

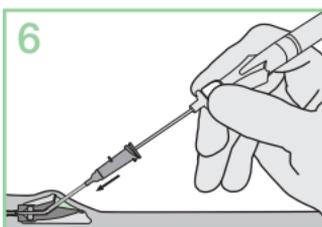


Caution: Do not bend the needle while using the product.

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.



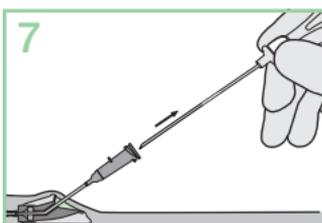
6. Advance the IV catheter completely through the valve assembly, continuing to pull the needle slightly away, as needed.



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 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 power injection 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.

Power Injection Procedure

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.

1. Attach a syringe filled with sterile normal saline.
2. 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.
3. Aspirate for adequate blood return and vigorously flush the port with at least 10 mL of sterile normal saline.

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

4. Detach syringe.
5. Warm contrast media to body temperature.
6. 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):

7. Instruct the patient to communicate immediately any pain or change in feeling during the injection.
8. 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.

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

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.

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.

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.

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.

Warning: Alcohol should not be used to soak or de clot 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:

$$\text{Apheresis IV Port System Volume} = \text{Catheter Length: } \underline{\hspace{2cm}} \text{ cm} \times \frac{\text{Catheter Volume}}{\text{cm}} + \text{Reservoir Volume}$$

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

Recommended Flushing Volumes

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.

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.

Recommended Flushing Volumes if Heparin 100 U/mL is Used

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

MRI Safety Information



MR Conditional

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.

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, de clot, 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.

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

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

An issued or revision date for these instructions is included for the user's information. In the event two years have elapsed between this date and product use, the user should contact Bard Peripheral Vascular, Inc. to see if additional product information is available.

Revised date: May 2017

Bard, PowerFlow, the radiopaque identifier, and PortReady are trademarks and/or registered trademarks of C. R. Bard, Inc or an affiliate. ChronoFlex is a trademark and/or registered trademark of AdvanSource Biomaterials Corp. All other trademarks are the property of their respective owners. Copyright © 2017. All Rights Reserved.



Bard Peripheral Vascular, Inc.

www.bardpv.com | 1 800 321 4254

1625 W 3rd St. Tempe, AZ 85281

BPV/PRT3/0117/0013