PowerFlow™ Implantable Apheresis IV Port

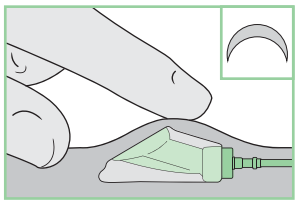
VS

PowerPort® Implantable Port

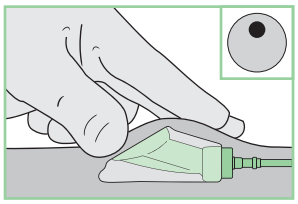
Indications for Use

PowerFlow™ Implantable Apheresis IV Port	PowerPort® Implantable Port
The Bard 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 Bard PowerFlow™ Implantable Apheresis IV Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.	The PowerPort® implantable port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc™ Safety Infusion Set, the PowerPort® implantable port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

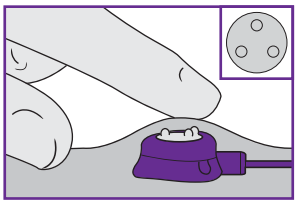
Identification



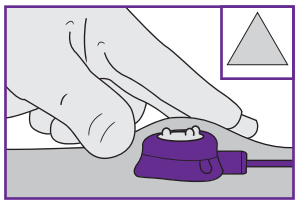
Funnel top



Funnel Entry



Palpation Bumps



Triangle Shape

Radiopaque Identifier

Access

PowerFlow™ Implantable Apheresis IV Port	PowerPort® Implantable Port
Access Device: Over-the-Needle IV Catheter[1]	**Access Device:** Huber Needle
Angle of Access: Approx. 30°	**Angle of Access:** 90°
Method of Entry: Needle breaks skin & IV catheter opens pre-cut valve	**Method of Entry:** Needle breaks skin & pierces silicone septum
Puncture: 1000 accesses[2] (16G and 14G IV catheter)	**Puncture:** 208 punctures[4] (19G Huber needle)

Flow

PowerFlow™ Implantable Apheresis IV Port		PowerPort® Implantable Port	
Flow Rate at -100 mmHg:	118.9 mL/min (16G IV catheter)[3]	**Flow Rate at -100 mmHg:**	69.7 mL/min (16G needle)[5]
Power Injection Flow Rate:	5 mL/sec at 300 psi (16G IV catheter)	**Power Injection Flow Rate:**	5 mL/sec at 300 psi (19G needle)

1 To access the PowerFlow™ IV Port, use BD Insyte™ Autoguard™ Shielded IV Catheters, 16 G or 14 G, 1.75 inches (44 mm) or longer.

2 After 1,000 IV catheter insertions, benchtop leak testing was successfully performed both with the device accessed (both 14G and 16G IV catheters tested separately) and with no IV catheter present. Data on file, Bard Peripheral Vascular, Inc., Tempe, AZ.

3 When tested with a 16G IV catheter and 25 cm 9.6F ChronoFlex™ Catheter in a benchtop model using a blood simulant with viscosity of 3.5cP, N=27.

4 After 208 septum punctures, benchtop leak and power injection testing were successfully performed. Data on file, Bard Peripheral Vascular, Inc., Tempe, AZ.

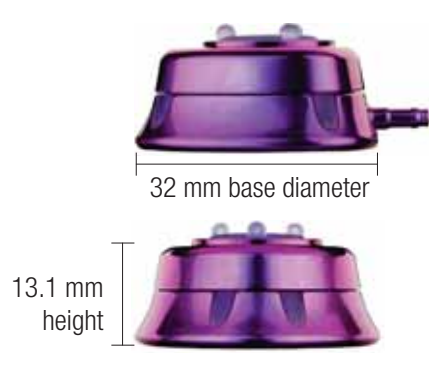
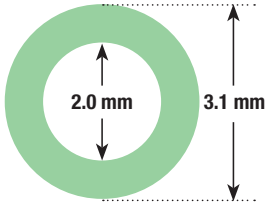
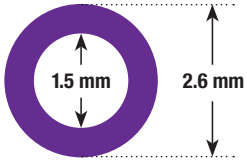
5 When tested with a 16G non-coring needle and 25 cm 8F Polyurethane Catheter in a benchtop model using a blood simulant with viscosity of 3.5cP, N=5. Changes in blood viscosity, catheter length, and IV type will affect achievable flow rates. Data on file, Bard Peripheral Vascular, Inc., Tempe, AZ.

Simulated and bench testing may not be indicative of actual clinical performance. Different test methods may yield different results.

PowerFlow™ vs PowerPort®

Implantable Apheresis IV Port

Implantable Port

	PowerFlow™ Implantable Apheresis IV Port	PowerPort® Implantable Port
Dimensions		
Catheter	**9.6F ChronoFlex™** Polyurethane Catheter 	**8F ChronoFlex™** Polyurethane Catheter 

PowerFlow™ Implantable Apheresis IV Port

Indications For Use: The Bard 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 Bard PowerFlow™ Implantable Apheresis IV Port is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 mL/s.

Contraindications: 1) Catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off. Port catheter may be placed in lateral subclavian vein based on evaluation by a qualified practitioner. **2)** When the presence of infection, bacteremia, or septicemia is known or suspected at the prospective port placement site. **3)** When the patient's vasculature and/or body size is insufficient for the size of the implanted device. **4)** Placement in the patient arm, due to device size and potential heating effect in an MR system. **5)** When the patient is known or is suspected to be allergic to materials contained in the device or placement components. The implanted device is primarily composed of titanium, silicone, polycarbonate and/or polyurethane. **6)** If severe chronic obstructive pulmonary disease exists. **7)** If the prospective insertion site has been previously irradiated. **8)** If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures. **9)** If local tissue factors will prevent proper device stabilization and/or access. **10)** Hemodialysis, as the safety and effectiveness has not been established for this therapy.

Warnings: 1) Needle access should be accomplished using Seldinger technique. Passage of the guidewire, sheath, introducer, and catheter should also be performed with Seldinger technique with careful attention to the signs and symptoms of vessel perforation. Should there be concern for vessel perforation, appropriate diagnostic testing should be performed. **2)** 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. **3)** Failure to confirm IV catheter placement may result in infiltration/extravasation. **4)** 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. **5) 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. **6)** PowerFlow™ IV Ports are only power injectable when accessed with the BD Insyte™ Autoguard™ Shielded IV Catheter. **7)** Failure to warm contrast media to body temperature prior to power injection may result in port system failure. **8)** Failure to ensure patency of the catheter prior to power injection studies may result in port system failure. **9)** Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter. **10)** Exceeding the maximum power injection flow rate may result in port system failure. **11)** 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. **12)** 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 5mL/s). **13)** If local pain, swelling or signs of extravasation are noted during power injection, the injection should be stopped immediately.

Precautions: 1) Check patient's records, and ask patient, whether they have any known allergies to chemicals or materials that will be used during the placement procedure. **2)** Fill (prime) the device with sterile normal saline solution to help avoid air embolism. **3)** Bard recommends the use of components provided in the kit. If additional items are to be used, check for proper fit prior to utilization. **4)** Carefully follow the connection technique given in the IFU to ensure proper catheter connection and to avoid catheter damage. **5)** Remember that some patients may be hyper-sensitive to heparin or suffer from heparin induced thrombocytopenia (HIT). These patients must not have their port locked with heparinized saline. **6)** Encourage patient to keep patient ID card and present it to clinicians accessing their port. **7)** Care should be taken to avoid excessive force when accessing an implanted port. **8)** 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 (44mm) or longer. The exact IV catheter length should be determined by the clinical situation. **9)** Do not bend the needle while using the product. **10)** 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. **11)** The IV catheter hub should not be left open to air while it is in the port. **12)** 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 3T.

Possible Complications: Air embolism · Allergic Reaction · Catheter or port erosion through the skin · Device rotation or extrusion · Extravasation · Fibrin sheath formation · Infection, including, but no limited to, pocket, catheter tunnel, and/or blood stream.

Please consult package insert for more detailed safety information and instructions for use.

For technical inquiries, contact the Bard Clinical Information Hotline at 800 555 7422

PowerPort® Implantable Port

Indications for Use: The PowerPort® Implantable Port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medication, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a PowerLoc® Brand Safety Infusion Set, the PowerPort® device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended rate is 5 mL/s.

Contraindications: 1) Catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off. Port may be placed in lateral subclavian vein based on evaluation by a qualified practitioner. **2)** When presence of device-related infection, bacteremia, or septicemia is known or suspected. **3)** When the patient's body size is insufficient for the size of the implanted device. **4)** When the patient is known or is suspected to be allergic to materials contained in the device. **5)** If severe chronic obstructive lung disease exists. **6)** If the prospective insertion site has been previously irradiated. **7)** If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures. **8)** If local tissue factors will prevent proper device stabilization and/or access.

Precautions: 1) Check patient's records, and ask patient, whether they have any known allergies to chemicals or materials that will be used during the placement procedure. **2)** Fill (prime) the device with sterile normal saline solution to help avoid air embolism. **3)** Carefully follow the connection technique given in the IFU to ensure proper catheter connection and to avoid catheter damage. **4)** Care should be taken to avoid excessive force when accessing an implanted port.

Warnings: 1) Avoid vessel perforation. **2)** Do not power inject through a port system that exhibits signs of clavicle-first reib compression or pinch-off as it may result in port system failure. **3)** PowerPort® Implantable Ports are only power injectable when accessed with a PowerLoc® Brand Safety Infusion Set. **4)** Failure to ensure patency of the catheter prior to power injection studies may result in port system failure. **5)** Exceeding maximum flow rate may result in port system failure and/or catheter tip displacement. **6)** PowerPort® implantable port 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 infusion set. 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 infusion set used to access the port. **7)** Do not exceed a 300 psi pressure limit setting on the power injection machine, or the maximum recommended flow rate on the PowerLoc® needle, if power injecting through the PowerPort® implantable port. **8)** If local pain, swelling or signs of extravasation are noted during power injection, the injection should be stopped immediately. **9)** Do not use a syringe smaller than 10ml to access the port. Flushing occluded catheters with small syringes can create excessive pressure within the port system.

Potential Adverse Reactions: Air Embolism • Device rotation or extrusion • Allergic reactions • Extravasation • Catheter or port erosion through the skin • Fibrin sheath formation.

Please consult package insert for more detailed safety information and instructions for use.

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