The High-Flow Port Designed & Indicated for Apheresis

PowerFlow™
Implantable Apheresis IV Port
The PowerFlow™ Implantable Apheresis IV Port is a high-flow, power-injectable port designed and indicated specifically for therapeutic apheresis.

With an ever-growing number of apheresis procedures and a rising chronic apheresis patient population, there is a need for long-term vascular access options. BD is the global leader in ports and we have listened to the challenges and needs of the apheresis community. Users asked for a durable device that can provide easy, reliable access to the vascular system and deliver ideal flow rates that apheresis procedures demand. The PowerFlow™ Implantable Apheresis IV Port is engineered to meet these needs, designed for long device life, maximum flow, and patient comfort.

Optimized for Long Device Life
Bench Tested up to 1,000 Accesses

1 After 1000 IV catheter insertions, bench top leak testing was successfully performed both with the device accessed (both 0.046 and 0.046G IV catheters tested separately) and with no IV catheter present. Bench testing may not be indicative of actual clinical performance. Different test methods may yield different results. Data on file, Bard Peripheral Vascular, Inc., Tempe, Arizona.
Engineered for Maximum Flow & Patient Comfort

9.6F ChronoFlex™
Large inner diameter polyurethane catheter designed for high flows

Silicone Body
Soft and lightweight to help address patient comfort

IV Access
Replaces needle with IV catheter

Totally Implantable
To help address patient lifestyle

8F ChronoFlex™
Polyurethane Catheter

9.6F ChronoFlex™
Polyurethane Catheter

BD’s Largest Inner Diameter Polyurethane Port Catheter

Comparison of other BD catheters; catheter depiction for reference only, not drawn to scale.
Bench Tested for **High Flow Performance**

**Bench Testing Results**

<table>
<thead>
<tr>
<th>Flow Rate (mL/min)</th>
<th>Inlet</th>
<th>Flow Rate (mL/min)</th>
<th>Inlet</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>When Accessed with 14G IV Catheter</td>
<td></td>
<td>When Accessed with 16G IV Catheter</td>
</tr>
<tr>
<td>150.6</td>
<td></td>
<td>118.9</td>
<td></td>
</tr>
</tbody>
</table>

-100 mmHg

**PowerFlow™**

IV Port Access System

A. Face Masks (2)
B. Gloves (2)
C. Hand Sanitizer (2)
D. Saline Syringes (2)
E. BD Insyte™ Autoguard™ Shielded IV Catheter (1) - 16 G or 14 G
F. Absorbent Towel (1)
G. Chloraprep™ (1)
H. Two-Legged Extension Set (1)
I. Prep Pad, Skin Protectant (1)
J. 2 x 2 Gauze Pads (4)
K. GuardIVa™ Antimicrobial Hemostatic Dressing (1)
L. Tape Strips (3)
M. Transparent Dressing (1)

Unique design and access delivers **high flow rates at low pressures**

Organized to **facilitate sterile “best practices”** that comply with nursing society and CDC guidelines for port access

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*Mean flow rates, 25 cm catheter, when tested in a benchtop model using a blood simulant with viscosity of 3.5cP. Simulated testing may not be indicative of actual clinical performance. Changes in blood viscosity, catheter length, and IV type will affect achievable flow rates.
The PowerFlow™ IV Port is part of the PortReady™ Program, an initiative designed to provide resources for patient education and clinician training. Learn more at www.portready.com

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**PowerFlow™ Implantable Apheresis IV Port**

**Indications For Use:** The BD 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™ 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. A patient who is known or is suspected to be allergic to titanium, silicone, polycarbonate and/or polyurethane.
2. Placement in the patient arm, due to device size.
3. When the patient is known or is suspected to be allergic to chemicals or materials that will be used during the placement procedure.
4. 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)
5. If the prospective placement site has been previously irradiated.
6. If severe chronic obstructive pulmonary disease exists.
7. If the prospective insertion site has been previously irradiated.
8. If local tissue factors will prevent proper device stabilization and/or access.
9. If there is concern for vessel perforation.
10. Please consult respective manufacturer product label and inserts for a complete list of all possible complications.

**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 clotting, as this 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 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 5 mL/s).
13. If local pain, swelling or signs of extravasation are noted during power injection, the injection should be stopped immediately.

**Possible Complications:**
- Air embolism
- Allergic Reaction
- Catheter or port erosion through the skin
- Device rotation or extrusion
- Extravasation
- Fibrous sheath formation
- Infection, including, but not limited to, pocket, catheter tunnel, and/or blood stream.

Please consult respective manufacturer product label and inserts for a complete list of all indications, contraindications, hazards, warnings, precautions and directions for use.

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**PowerFlow™ IV Port Access Systems**

**Description**
- **PowerFlow™ IV Port Access System**
- **PowerFlow™ IV Port Access System**

**Needle Gauge**
- 16G
- 14G

**Product Code**
- AIV16
- AIV14

Sold as: Case of 10

**Product and Packaging**
- Do Not Contain Natural Rubber Latex

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**French Size**
- 9.6F

**Tray Type**
- Intermediate

**Product Code**
- A710962

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