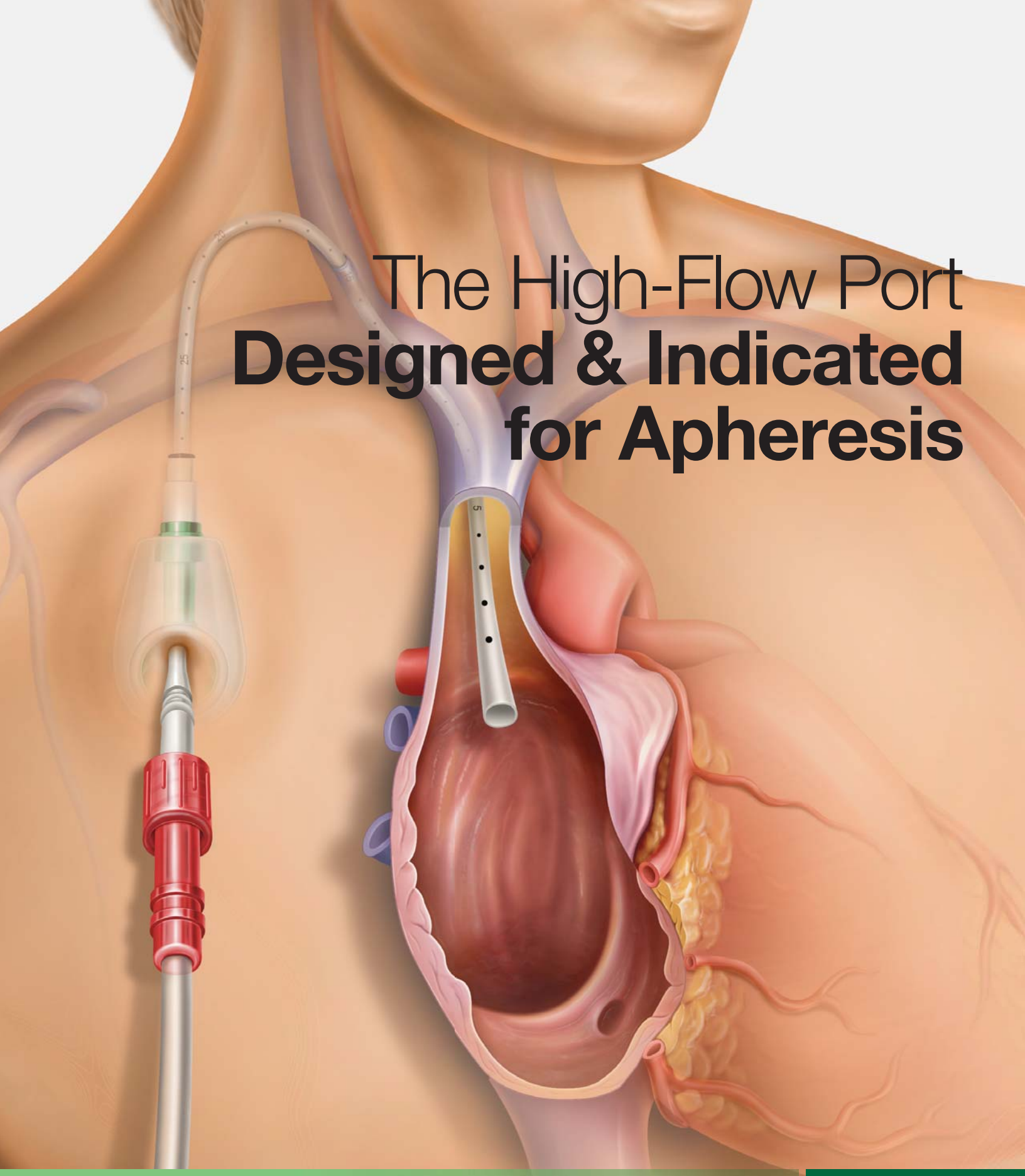
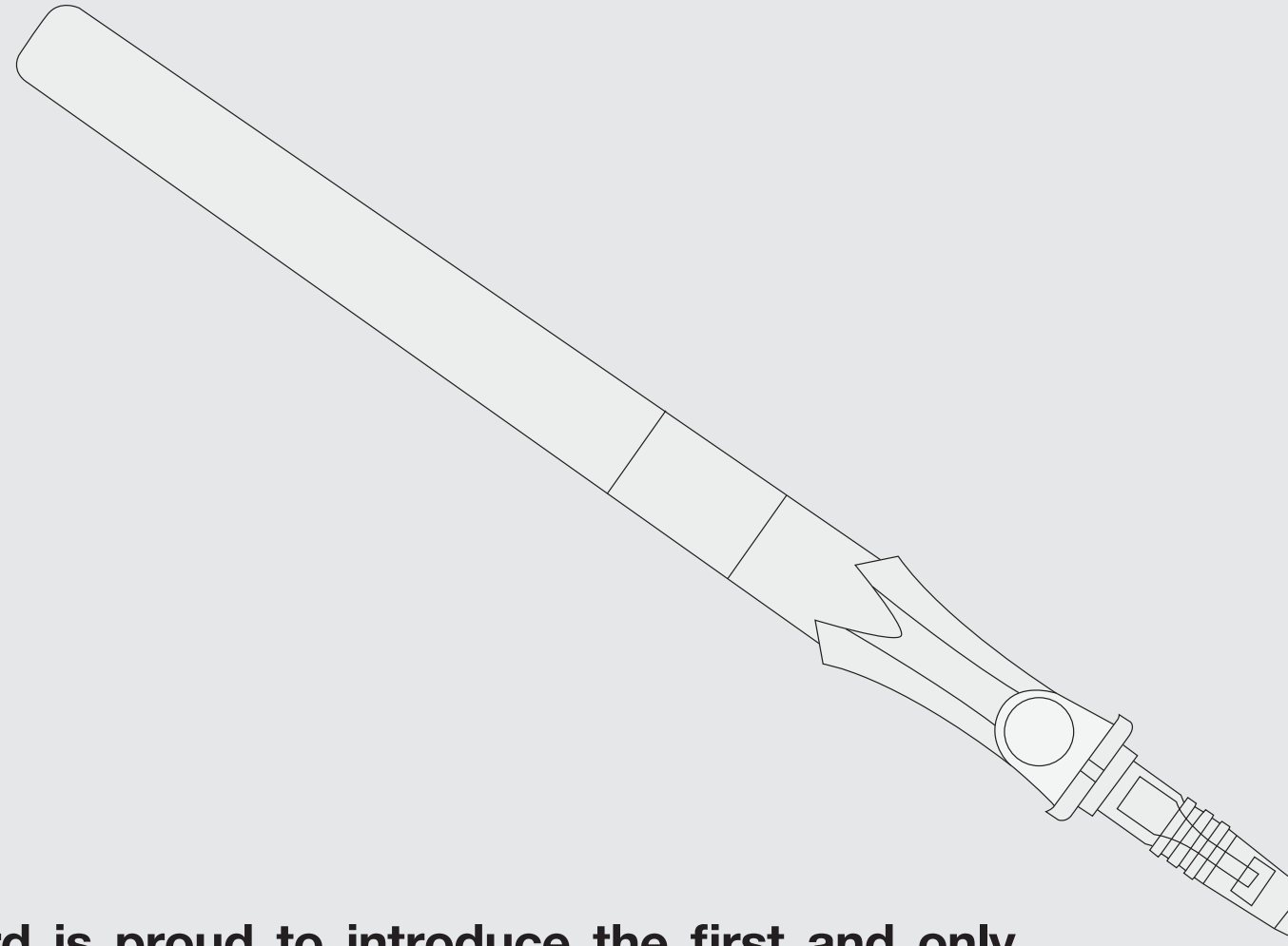


The High-Flow Port **Designed & Indicated for Apheresis**

PowerFlow®
Implantable Apheresis IV Port

BARD

Advancing Lives and the Delivery of Health Care™



Bard is proud to introduce the first and only 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's a need for long-term vascular access options. Bard is the global leader in ports and we've 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.

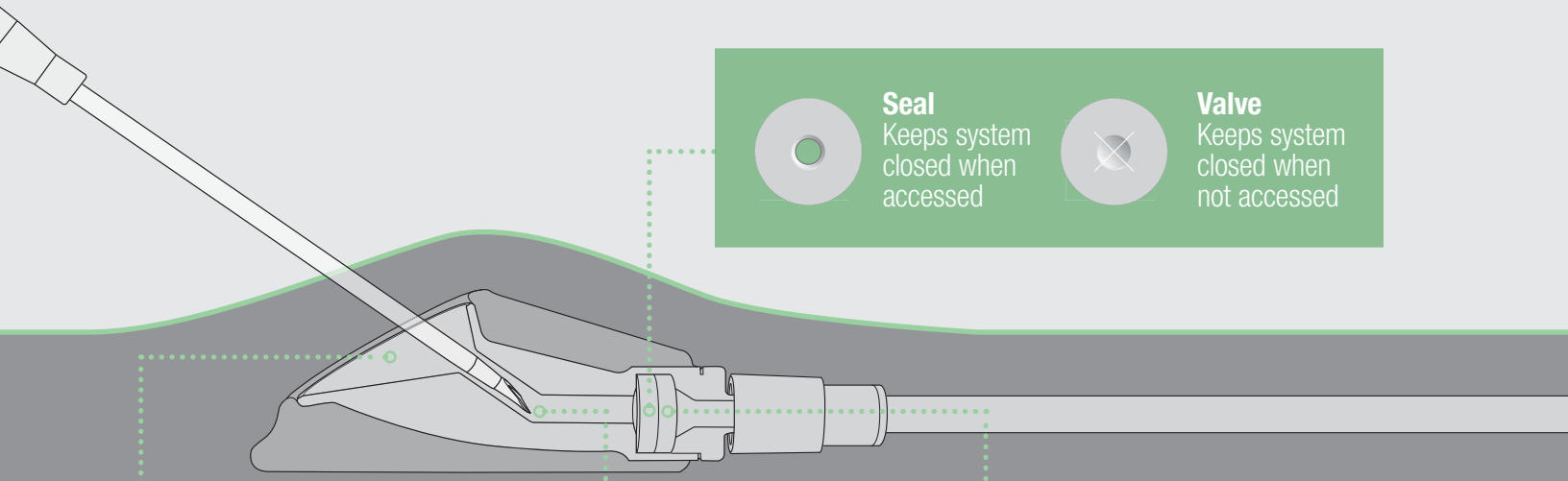
* As of April 2017

PowerFlow®

Implantable Apheresis IV Port

Optimized for Long Device Life

Bench Tested up to 1,000 Accesses[1]



Robust Titanium

Funnel guides IV catheter for reliable and quick access

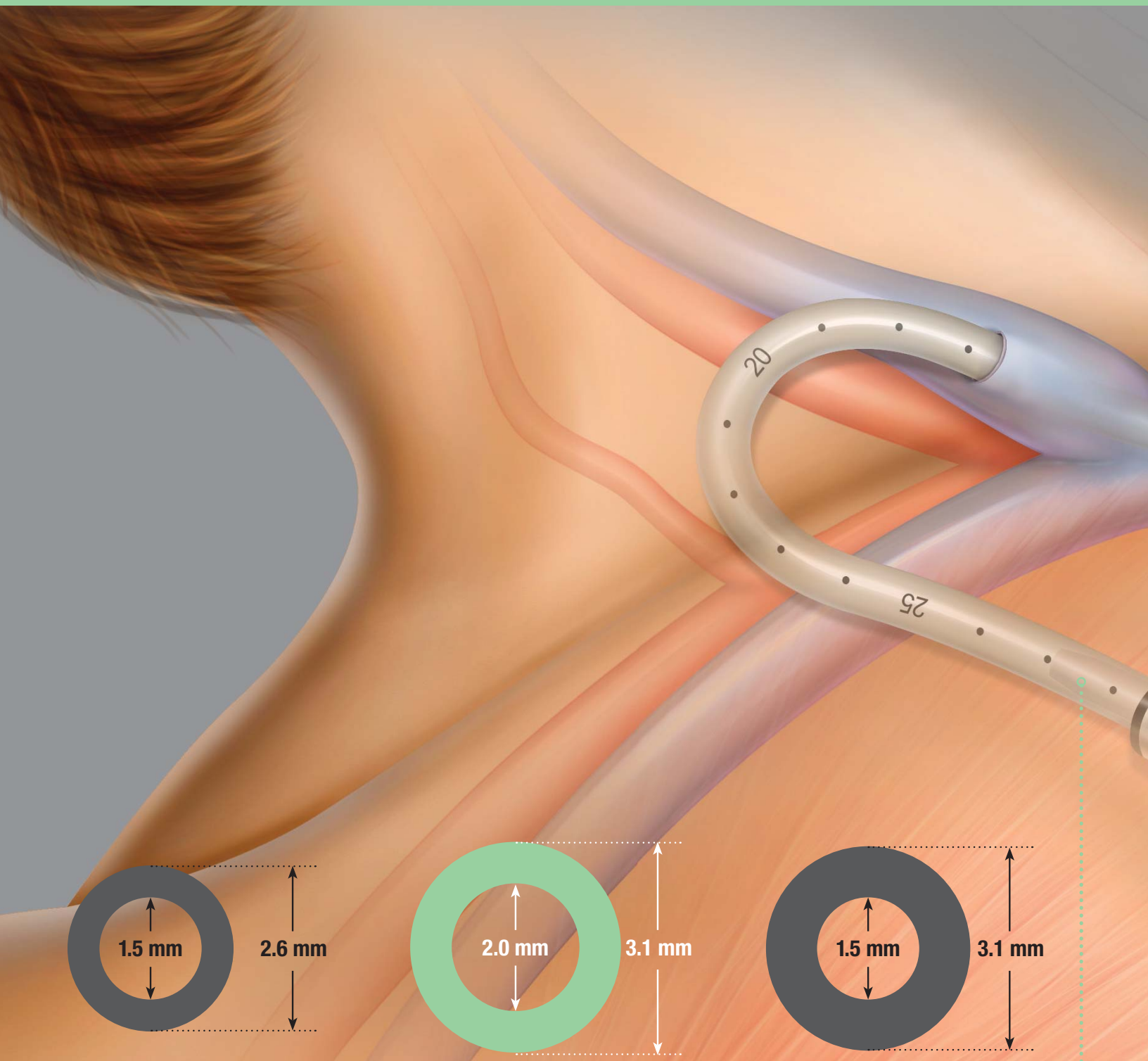
Needle Stop

Prevents needle from piercing the valve

Pre-cut Silicone

Valve accepts 16 and 14 gauge IV catheters

[1] After 1000 IV catheter insertions, bench top leak testing was successfully performed both with the device accessed (both 14G and 16G 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.



8F ChronoFlex™
Polyurethane Catheter

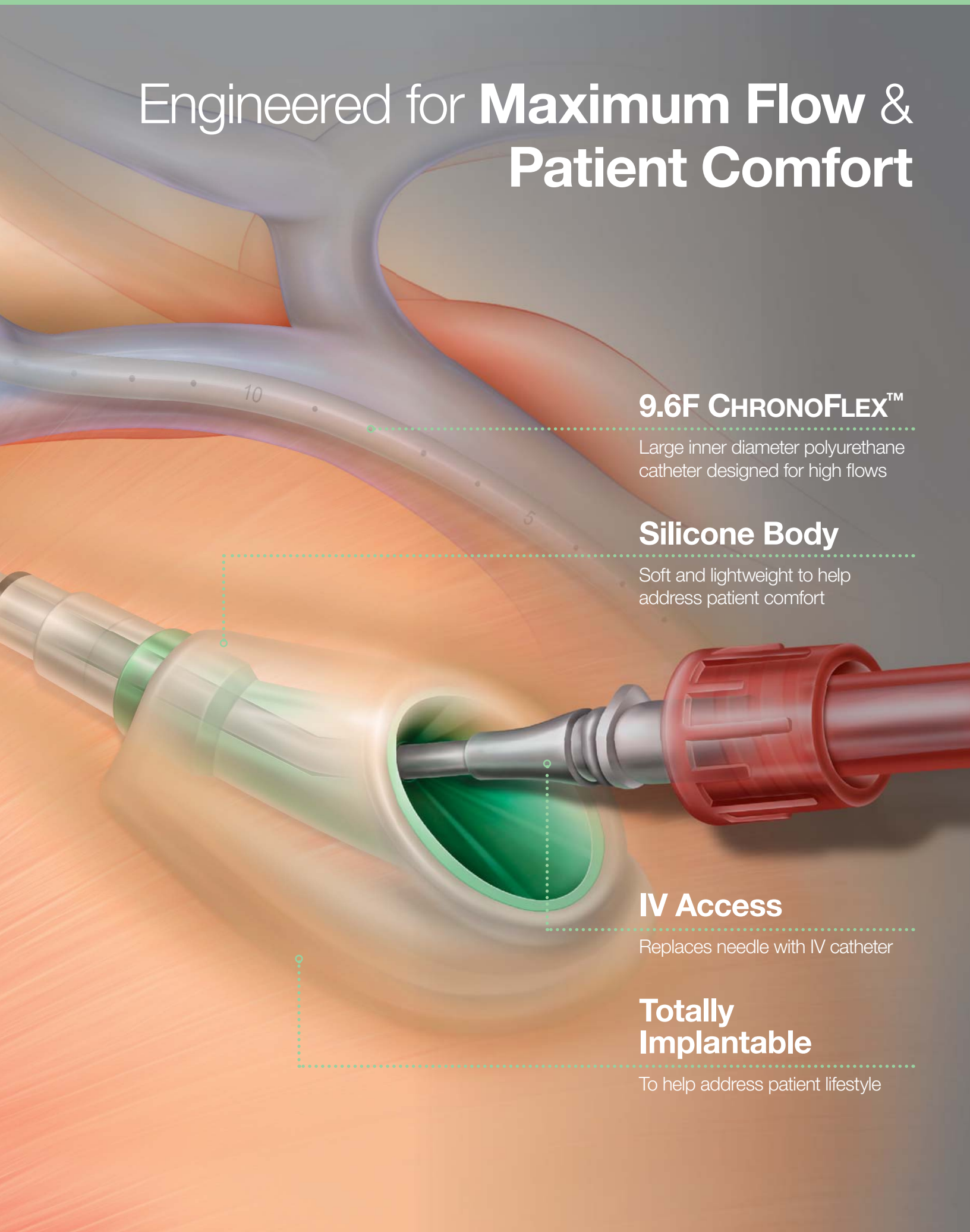
9.6F ChronoFlex™
Polyurethane Catheter

9.6F
Silicone Catheter

Bard's Largest Inner Diameter Polyurethane Port Catheter

Comparison of other Bard catheters; catheter depiction for reference only, not drawn to scale.

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

Bench Tested for **High Flow Performance**

Bench Testing Results

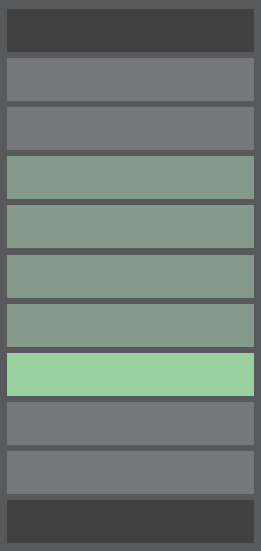
	Inlet
Flow Rate (mL/min)	150.6*

When Accessed with 14G IV Catheter

	Inlet
Flow Rate (mL/min)	118.9*

When Accessed with 16G IV Catheter

-100 mmHg



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

* Mean flow rates, 25 cm catheter, when tested in a benchtop model using a blood simulant with viscosity of 3.5cP, N=27. Simulated testing may not be indicative of actual clinical performance. Changes in blood viscosity, catheter length, and IV type will affect achievable flow rates.

All-in-One Convenience
for Easy Access

PowerFlow™
IV Port Access System

(Not packaged as shown)

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)

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

PowerFlow®

Implantable Apheresis IV Port

The PowerFlow® IV Port is part of the Bard PortReady™ Program, an initiative designed to provide resources for patient education and clinician training. **Learn more at www.portready.com**

PORT READY™

PowerFlow® Apheresis IV Port

Description	French Size	Tray Type	Product Code
PowerFlow® Apheresis IV Port	9.6F	Intermediate	☐ A710962

Intermediate Tray Components

- PowerFlow® Apheresis IV Port
- ChronoFlex™ Radiopaque Polyurethane Single-Lumen Catheter, 9.6F, 45 cm Length
- 2 BD Insyte™ Autoguard™ Shielded IV Catheters, 16 G (1.7 mm OD) x 45 mm
- AirGuard® Valved Introducer, 10F, Peel-Apart Sheath
- Syringe, 12 mL
- Introducer Needle, 18 G x 70 mm
- Tunneler
- 2 Catheter Locks
- StruXure™ Guidewire, 3 mm radius, "J" tip with Straightener
- Flushing Connector, 17 G

PowerFlow™ IV Port Access Systems

Description	Needle Gauge	Product Code
PowerFlow™ IV Port Access System	16G	☐ AIV16
PowerFlow™ IV Port Access System	14G	☐ AIV14

Sold as: Case of 10

Product and Packaging Do Not Contain Natural Rubber Latex

REPRESENTATIVE'S NAME

CONTACT PHONE NUMBER

PHYSICIAN'S SIGNATURE

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

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

 BPV/PRT3/1016/0002(2)