Power Injection Procedure

1. Remove the end cap from the catheter.
2. Attach a 10 mL or larger syringe filled with sterile normal saline.
3. Aspirate for adequate blood return and vigorously flush the catheter with the full 10 mL of sterile normal saline.
   **WARNING:** Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
4. Detach syringe.
5. Attach the power injection device to the catheter per manufacturer’s recommendations.
6. Contrast media should be warmed to body temperature (37°C) prior to power injection.
   **WARNING:** Failure to warm contrast media to body temperature (37°C) prior to power injection may result in catheter failure (e.g. catheter rupture).
7. Use only the lumen marked “Power Injectable” for power injection of contrast media.
   **WARNING:** Do not use lumens not marked “Power Injectable” for power injection of contrast media.
8. Do not exceed the maximum flow rate of 5 mL/sec.
   **WARNING:** Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may lead to catheter failure.
9. Complete power injection study taking care not to exceed the flow rate limits.
   **WARNING:** Exceeding the maximum flow rate of 5 mL/sec or the maximum pressure of power injectors of 300 psi may result in catheter failure and/or catheter tip displacement.
10. Disconnect the power injection device.
11. Flush the catheter with 10 mL of sterile normal saline, using a 10 mL or larger syringe. In addition, lock the lumen marked “Power Injectable” per institution protocol for central lines. Usually one mL is adequate.
12. Close clamp and replace the end cap on the catheter.

Description

**Power-Trialysis™** Short-Term Dialysis Catheters are made of thermosensitive polyurethane, which softens when exposed to body temperature. The catheter is divided into three separate lumens permitting continuous blood flow. Both the venous (blue) and the arterial (red) lumens may be used for hemodialysis, hemoperfusion, and apheresis treatments. The distal (purple) lumen is completely independent from the two dialysis lumens and may be used for intravenous therapy, power injection of contrast media, and central venous pressure monitoring. The distal lumen can also be accessed for blood draws and infusion of medications.
Indications For Use
The Power-Trialysis™ Short-Term Dialysis Catheter, with a third internal lumen for intravenous therapy, power injection of contrast media, and central venous pressure monitoring, is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis, hemoperfusion, and apheresis treatments. The catheter is intended to be inserted in the jugular, femoral, or subclavian vein as required. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.

Contraindications
The catheter is intended for short-term vascular access only and is not to be used for any purpose other than indicated in these instructions.

The device is also contraindicated:
- When the presence of device-related infection, bacteremia, or septicemia is known or suspected.
- When the patient’s body size is insufficient to accommodate the size of the implanted device.
- When the patient is known or is suspected to be allergic to materials contained in the device.
- If the prospective insertion site has been previously irradiated.
- If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures.
- If local tissue factors may prevent proper device stabilization and/or access.

Warnings
- **SUBCLAVIAN ONLY.** Percutaneous insertion of the catheter must be made into the axillary-subclavian vein at the junction of the outer and mid-third of the clavicle lateral to the thoracic outlet. The catheter must not be inserted into the subclavian vein medially, because such placement can lead to compression of the catheter between the first rib and clavicle and can lead to damage or fracture and embolization of the catheter. Fluoroscopic or radiographic confirmation of catheter tip placement can be helpful in demonstrating that the catheter is not being pinched by the first rib and clavicle.
- Fluoroscopic or radiographic confirmation of catheter tip placement can be helpful in demonstrating that the catheter is not being pinched by the first rib and clavicle.

**SIGNS OF PINCH-OFF**

**Clinical:**
- Difficulty with blood withdrawal.
- Resistance to infusion of fluids.
- Patient position changes required for infusion of fluids or blood withdrawal.

**Radiologic:** (see table)
- 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:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No distortion</td>
<td>No action.</td>
</tr>
<tr>
<td>1</td>
<td>Distortion present <strong>without</strong> luminal narrowing</td>
<td>Chest x-ray should be taken 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.</td>
</tr>
<tr>
<td>2</td>
<td>Distortion present <strong>with</strong> luminal narrowing</td>
<td>Removal of the catheter should be considered.</td>
</tr>
<tr>
<td>3</td>
<td>Catheter transection or fracture</td>
<td>Prompt removal of the catheter.</td>
</tr>
</tbody>
</table>

- The catheter must not be left in the femoral vein longer than three days. It is recommended that jugular and subclavian catheters be replaced after four weeks.
- Alcohol or alcohol-containing antiseptics (such as chlorhexidine gluconate) may be used to clean the catheter/skin site; however, care should be taken to avoid prolonged or excessive contact of the catheter with the solution(s). Solutions should be allowed to completely dry before applying an occlusive dressing.
- Acetone and Polyethylene Glycol (PEG)-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments are the preferred alternative.
- Do not resterilize the catheter or components by any method. The manufacturer will not be liable for any damages caused by re-use of the catheter or accessories.
- Intended for Single Use. DO NOT REUSE. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.
- Place all clamps near the center of the polyurethane extension pieces. Polyurethane may develop cuts or tears if subjected to excessive pulling or contact with rough edges. Repeated clamping near or on the Luer-lock connectors may cause tubing fatigue and possible disconnection.
- Repeated over-tightening of bloodlines, syringes and caps will reduce connector life and may lead to connector failure.
- Enzymes in blood and heparin may cause temporary sticking of the extensions when clamped for extended periods of time. To release, open clamp and slide away, gently rotating the tube between finger and thumb until the tubing separates.
**Warnings (cont.)**

- To avoid damage to vessels and viscus, prolonged infusion pressures must not exceed 25 psi (172 kPa). The use of a 10 mL or larger syringe is recommended because smaller syringes generate more pressure than larger syringes.
  
  NOTE: A three pound (13.3 Newton) force on the plunger of a 3 mL syringe generates pressure in excess of 30 psi (206 kPa) whereas the same three pound (13.3 Newton) force on the plunger of a 10 mL syringe generates less than 15 psi (103 kPa) of pressure.
- Accessories and components used in conjunction with this catheter must incorporate Luer-lock adapters in order to avoid inadvertent disconnection.
- Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the opening of the catheter lumens.
- Before dialysis begins, all connections to the extracorporeal circuit must be checked carefully. During all dialysis procedures frequent visual inspection must be conducted to detect leaks and prevent blood loss or entry of air into the extracorporeal circuit. Excess blood leakage may lead to patient shock.
- In the rare event of a leak, the catheter must be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis procedure.
- If the catheter is not used immediately for treatment, follow the suggested Catheter Patency Guidelines.
- Failure to clamp extensions when not in use may lead to air embolism.
- Verification of the catheter tip location must be confirmed by x-ray to ensure proper placement.
- To prevent systemic heparinization of the patient, the heparin solution must be aspirated out of the lumens immediately prior to using the catheter.
- For jugular and subclavian insertion, the patient must be placed on a cardiac monitor during this procedure. Cardiac arrhythmia may result if the guidewire is allowed to pass into the right atrium. The guidewire must be held securely during the procedure.
- The risk of infection is increased with femoral vein insertion.
- Recirculation in femoral catheters was reportedly significantly greater than in internal jugular catheters.
- Before attempting the insertion of the catheter, ensure that you are familiar with the possible complications listed below and their emergency treatment should they occur.

### Cannulation of the left internal jugular vein

- Cannulation of the left internal jugular vein was reportedly associated with a higher incidence of complications compared to catheter placement in the right internal jugular vein.

### Failure to warm contrast media to body temperature (37°C) prior to power injection may result in catheter failure

### Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.

### Do not use lumens not marked “Power Injectable” for power injection of contrast media.

### Power injection machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may lead to catheter failure.

- Exceeding the maximum flow rate of 5 mL/sec or the maximum pressure of power injectors of 300 psi may result in catheter failure and/or catheter tip displacement.
- Catheter indication for power injection of contrast media implies the catheter’s ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.
- Do not power inject through a catheter that exhibits signs of clavicle-first rib compression or pinch-off, as it may result in catheter failure.
- If local pain, swelling, or signs of extravasation are noted, the injection should be stopped immediately.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
- CVP Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.
- CVP Monitoring should not be performed during hemodialysis, hemoperfusion or apheresis.

### Cautions

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Carefully read and follow all instructions prior to use.
- Only qualified health care practitioners should insert, manipulate, and remove these devices.
- Strict aseptic technique must be used during the insertion, maintenance, and catheter removal procedures.
- Do not pull back guidewire over needle bevel as this may sever the end of the guidewire. The introducer needle must be removed first. Also, if unusual resistance is met during manipulation of the guidewire, discontinue the procedure and determine the cause of resistance before proceeding. Withdraw needle and guidewire if cause of resistance cannot be determined.
- Do not allow the guidewire to inadvertently advance totally into the vessel.
- For jugular and subclavian insertion, the catheter tip should not be located in the right atrium.
- Sterile, non-pyrogenic unless package is damaged or opened.
- Left sided placement in particular, may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the left SVC.
- Follow all contraindications, warnings, precautions, and instructions for all infusates, including contrast media, as specified by their manufacturer.
- In vitro flow data indicates flow rates above 350 mL/min for Alphacurve™ Catheter configurations may exceed -250 mmHg prepump pressure as per K/DOQI (2006) guidelines.
Possible Complications
The use of an indwelling central venous catheter provides an important means of venous access for critically ill patients; however, the potential exists for serious complications including the following:

- Air Embolism
- Arterial Puncture
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression between the Clavicle and First Rib
- Catheter-Related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemomediatinum
- Hydrothorax
- Inflammation, Necrosis or Scarring of Skin Over Implant Area
- Intolerance Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Pneumothorax
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Venous Stenosis
- Venous Thrombosis
- Ventricular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

These and other complications are well documented in medical literature and must be carefully considered before placing the catheter. Placement and care of the catheter must be performed only by persons knowledgeable of the risks involved and qualified in the procedures.

Instructions for Catheter Insertion
CATHETERS MUST BE INSERTED UNDER STRICT ASEPSTIC CONDITIONS.

**WARNING:** Cannulation of the left internal jugular vein was reportedly associated with a higher incidence of complications compared to catheter placement in the right internal jugular vein. 1

**CAUTION:** As reported in literature, left sided catheter placement may provide unique challenges due to the right angles formed by the innominate vein and at the left brachiocephalic junction with the SVC. 3

1. The catheter must be inserted only under strict aseptic conditions in which the operator must wear a cap, mask, sterile gown, sterile gloves, and use a large sterile drape to cover the patient. For jugular or subclavian insertion, the patient must be in a modified Trendelenburg position, with the head turned to the side opposite that of the insertion site. A small rolled towel may be inserted between the shoulder blades. For femoral insertion, place patient in supine position to expose the side of the groin to be accessed.

2. Prepare the access site using standard surgical technique and drape the prepped area with sterile towels. If hair removal is necessary, use clippers or depilatories. Next, scrub the entire area preferably with chlorhexidine gluconate unless contraindicated, in which case, povidone-iodine may be used. Use a back-and-forth friction scrub for at least 30 seconds.4 Do not wipe or blot. Allow antiseptic to air dry completely before puncturing the site. Remove and discard gloves. If using the Chloraprep™ Solution One-Step Applicator perform skin preparation using the following steps:

- Prepare the site with the Chloraprep™ Solution One-Step Applicator or according to institution protocol using sterile technique.
- Pinch the wings of the Chloraprep™ Solution One-Step Applicator to break the ampule and release the antiseptic. Do not touch the sponge.
- Wet the sponge by repeatedly pressing and releasing the sponge against the treatment area until fluid is visible on the skin.
- Use repeated back-and-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 a single use.
- Remove and discard gloves.

3. Prepare a sterile field.

4. The insertion site is identified. A local anesthetic is injected over the site.

5. A syringe is attached to an introducer needle that will permit passage of the guidewire. The maximum guidewire that may be used is 0.035 in (0.89 mm).

6. The introducer needle is inserted into the identified vein.

7. The syringe is removed leaving the introducer needle in place.

**WARNING:** For jugular and subclavian insertion, the patient must be placed on a cardiac monitor during this procedure. Cardiac arrhythmia may result if the guidewire is allowed to pass into the right atrium. The guidewire must be held securely during the procedure.

8. The guidewire can be inserted into the needle hub and passed through the needle. Advance the guidewire to the desired location in the vessel.

**CAUTION:** Do not pull back guidewire over needle bevel as this may sever the end of the guidewire. The introducer needle must be removed first. Also, if unusual resistance is met during manipulation of the guidewire, discontinue the procedure and determine the cause of resistance before proceeding. Withdraw needle and guidewire if cause of resistance cannot be determined.
9. Holding the guidewire securely in place, remove the introducer needle.  
   **CAUTION:** Do not allow the guidewire to inadvertently advance totally into the vessel.

10. The introducer needle tract is widened by creating a small surgical incision at the skin exit site. The incision should be slightly larger than the wide/flat side of the catheter.

11. Use the Dualator™ Vessel Dilator(s) to dilate the subcutaneous tissues. Dilate 2-3 times with slow gradual movements. The larger portion of the Dualator™ Dilator device must enter the vein prior to catheter insertion.

12. Flush each lumen of the catheter with saline or heparinized saline filled syringes and clamp the venous (blue) and arterial (red) lumens.

13. The catheter is passed over the proximal end of the guidewire by inserting the guidewire tip into the tapered end of the catheter. The distal (purple) lumen clamp must be in the open position to allow the catheter to pass completely over the guidewire and into the vein. Insert the catheter flat side to the skin.

14. Pinch guidewire and catheter together, advance together in 5 to 10 cm increments (retract wire as needed). Do not twist the catheter during over-the-guidewire insertion.

15. The depth markings in one cm increments may be used to determine insertion depth.

16. The catheter tip must be in the lower superior vena cava for optimal performance. If placed femorally, the catheter tip should be placed in the inferior vena cava to minimize recirculation. Catheters greater than 24 cm are intended for femoral vein insertion.

   **CAUTION:** For jugular and subclavian insertion, the catheter tip should not be located in the right atrium.

17. The guidewire is removed, and the distal (purple) lumen clamp is closed. Flush the lumens again with saline or heparinized saline filled syringes. It is necessary to open the extension clamps during the flush procedure. Close clamps on all lumens and place end caps over the ends of each Luer-lock connector.

18. The rotatable, pre-attached suture wing is oriented to the skin surface and the catheter is attached using a suture.

19. The catheter is now ready for use. For hemodialysis, hemoperfusion, or apheresis the arterial (red) lumen of the catheter is connected to the arterial side of the extracorporeal circuit. The venous (blue) lumen of the catheter is connected to the venous side of the extracorporeal circuit.

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**CENTRAL VENOUS PRESSURE MONITORING (CVP)**

- Prior to conducting central venous pressure monitoring.
  - Ensure proper positioning of the catheter tip.
  - Flush catheter vigorously with sterile normal saline.
  - Ensure the pressure transducer is at the level of the right atrium.
  - It is recommended that a continuous infusion of saline (3 mL/hr) is maintained through the catheter while measuring CVP to improve accuracy of CVP results.
  - CVP Monitoring is intended to be performed through the distal (purple) lumen.
  - Use your institution’s protocols for central venous pressure monitoring procedures.

   **WARNING:** CVP Monitoring should always be used in conjunction with other patient assessment metrics when evaluating cardiac function.

   **WARNING:** CVP Monitoring should not be performed during hemodialysis, hemoperfusion, or apheresis.

---

**Care and Maintenance**

The care and maintenance of the catheter requires well-trained, skilled personnel following a detailed protocol. The protocol should include a directive that the catheter is not to be used for any purpose other than the prescribed therapy.

**Accessing Catheter, Cap Changes, Dressing Changes**

- Experienced personnel
- Use aseptic technique
- Proper hand hygiene
- Clean gloves to access catheter and remove dressing and sterile gloves for dressing changes
- Surgical mask (1 for the patient and 1 for the healthcare professional)

- Catheter exit site should be examined for signs of infection and dressings should be changed at each dialysis treatment.
- Catheter Luer-lock connectors with end caps attached should be soaked for 3 to 5 minutes in povidone iodine and then allowed to dry before separation.
- Carefully remove the dressing and inspect the exit site for inflammation, swelling and tenderness. Notify physician immediately if signs of infection are present.
Exit Site Cleaning

- Use aseptic technique (as outlined above).
- Clean the exit site at each dialysis treatment with chlorhexidine gluconate unless contraindicated. Apply antiseptic per manufacturer’s recommendations. Allow to air dry completely.
- Cover the exit site with sterile, transparent, semipermeable dressing or per hospital protocol.

Recommended Cleaning Solutions

Catheter Luer-lock Connectors/End Caps:

- Povidone iodine

WARNING: Alcohol should not be used to lock, soak or declot polyurethane Dialysis Catheters because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

Exit Site:

- Chlorhexidine gluconate 2% solution (preferred)
- Chlorhexidine gluconate 4% solution
- Dilute aqueous sodium hypochlorite
- 0.55% sodium hypochlorite solution
- Povidone iodine
- Hydrogen peroxide
- Chlorhexidine patches
- Bacitracin zinc ointments in petrolatum bases

WARNING: Acetone and Polyethylene Glycol (PEG)-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine patches or bacitracin zinc ointments (e.g., Polysporin™ ointment) are the preferred alternative.

POST DIALYSIS

Use aseptic technique (as outlined above).

1. Flush arterial and venous lumens with a minimum of 10 mL of sterile saline.

WARNING: To avoid damage to vessels and viscus, infusion pressures must not exceed 25 psi (172 kPa). The use of a 10 mL or larger syringe is recommended because smaller syringes generate more pressure than larger syringes.

2. Inject heparin solution into both the arterial and venous lumens of the catheter. The appropriate heparin solution concentration and flushing frequency should be based on hospital protocol. Heparin solution of 1,000 to 5,000 units/mL has been found to be effective for maintaining the patency of hemodialysis and apheresis catheters. When injecting heparin solution, inject quickly and clamp extension while under positive pressure. Heparin solution volume to lock each lumen must be equal to the priming volume of each lumen. Priming volumes are marked on each lumen. In most instances, no further heparin solution injection is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.

3. Maintain patency of distal (purple) lumen per institution protocol for central lines.

4. Clean catheter Luer-lock connectors per hospital protocol. Attach sterile end caps to both the arterial and the venous clamping extension pieces.

WARNING: To prevent systemic heparinization of the patient, the heparin solution must be aspirated out of both lumens immediately prior to using the catheter.

POWER INJECTIONS

Catheter testing included 10 power injection cycles.

CATHETER REMOVAL

Evaluate the catheter routinely and promptly remove any nonessential catheter per physician’s orders. Catheter removal must be performed by persons knowledgeable of the risks involved and qualified in the removal protocol. After removing the catheter, apply manual pressure to the puncture site for 10-15 minutes until no signs of bleeding are present. Then apply sterile, transparent, semipermeable dressing or dressing per hospital protocol for a minimum of 8 hours. Follow hospital protocol regarding bedrest after catheter removal.

DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and all applicable local, state and federal laws and regulations.

Troubleshooting

PATIENT WITH FEVER

Patient with fever and chills following the procedure may be indicative of catheter-related bacteremia. If bacteremia is present, removal of the catheter may be indicated.

INSUFFICIENT FLOW

Excessive force must not be used to flush an obstructed lumen. Insufficient blood flow may be caused by an occluded tip resulting from a clot or by contacting the wall of the vein. If manipulation of the catheter or reversing arterial and venous lines does not help, then the physician may attempt to dissolve the clot with a thrombolytic agent (e.g., TPA, Cathflo™ Activase™ thrombolytic). Physician discretion advised.

CATHETER EXCHANGE

Do not routinely replace dialysis catheters to prevent catheter-related infections. It may become necessary to exchange the indwelling catheter due to a persistent rise in pressures or decrease of flow rates which cannot be rectified through troubleshooting. Catheter exchanges should be performed under strict aseptic conditions in which the physician should wear a cap, mask, sterile gown, sterile gloves, and use a large sterile drape to cover the patient.
**Flow Performance Guidelines For Bard Access Systems Power-Trialysis™ Short-Term Dialysis Catheter**

Performance Guidelines: (As suggested by In Vitro data):

### Power Injection Flow Information

*Injection pressure should be set at a maximum of 300 psi*

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Max Indicated Power Injections Flow-Rate</th>
<th>Average Max Catheter Pressure During Max Indicated Power Injection Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 cm Straight &amp; Curved Extension Legs</td>
<td>5 mL/sec</td>
<td>107 psi</td>
</tr>
<tr>
<td>24 cm Alphacurve™</td>
<td>5 mL/sec</td>
<td>126 psi</td>
</tr>
</tbody>
</table>

1 Represents maximum indicated flow rate for power injection of contrast media.

2 Internal catheter pressure during power injection of contrast media at 11.8cP with safety cut-off at 300 psi.

### Maximum Static Burst Pressure Information

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Average Max Static Burst Pressure</th>
<th>Range of Max Static Burst Pressures</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 cm Straight &amp; Curved Extension Legs</td>
<td>358 psi</td>
<td>356-360 psi</td>
</tr>
<tr>
<td>24 cm Alphacurve™</td>
<td>333 psi</td>
<td>315-348 psi</td>
</tr>
</tbody>
</table>

3 Maximum burst pressure is the static burst pressure failure point of the power injectable lumen of the catheter when fully occluded. The margin of safety for power injection is demonstrated comparing the average static burst pressure to the catheter pressure during power injection at 5 mL/sec flow rate, assuming patency of the catheter has been verified.

### Dialysis Lumen Flow Information

*(Flow Rate vs. Lumen Pressure)*

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Average Pressures (400 mL/min Flow Rate)</th>
<th>Average Pressures (350 mL/min Flow Rate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 cm Straight</td>
<td>Venous (mmHg) 216</td>
<td>Arterial (mmHg) -221</td>
</tr>
<tr>
<td>24 cm Curved Ext. Legs</td>
<td>197</td>
<td>-204</td>
</tr>
<tr>
<td>24 cm Alphacurve™</td>
<td>239</td>
<td>-216</td>
</tr>
</tbody>
</table>

4 In Vitro flow data indicates flow rates above 350 mL/min for the Alphacurve configuration may exceed a prepump pressure of - 250 mmHg as per K/DOQI (2006) guidelines.

5 Flow Rate vs Lumen Pressure data obtained using a blood simulant of water and glycerin at 3.4cP.

### Center Lumen Flow Information (Gravity Flow Rate (1 Meter of Water Infusion Pressure))

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Insertion Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 cm Straight &amp; Curved Extension Legs (mL/hr)</td>
<td>2258 2634 2830 3333 3721</td>
</tr>
<tr>
<td>Alphacurve™ (mL/hr)</td>
<td>2149 2387 2539 3092</td>
</tr>
</tbody>
</table>

### Priming Volumes

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Insertion Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 cm Straight &amp; Curved Extension Legs (mL)</td>
<td>1.8 1.6 1.4 1.2 1.1</td>
</tr>
<tr>
<td>Alphacurve™ (mL)</td>
<td>2.0 1.8 1.6 1.5</td>
</tr>
</tbody>
</table>

### Recirculation Rates

<table>
<thead>
<tr>
<th>Configuration</th>
<th>Forward</th>
<th>Reverse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straight &amp; Curved Extension Legs</td>
<td>&lt; 2%</td>
<td>&lt; 2%</td>
</tr>
<tr>
<td>Alphacurve™</td>
<td>&lt; 2%</td>
<td>&lt; 2%</td>
</tr>
</tbody>
</table>

6 Recirculation Rates obtained using a saline dilution technique with a blood simulant of water and glycerin at 3.4 cP.
REFERENCES


Other references available upon request.

Bard Access Systems, Inc. warrants to the original purchaser that this product will be free from defects in material and workmanship for a period of one (1) year from the date of purchase. If this product proves to be so defective, purchaser may return same to Bard Access Systems, Inc. for repair or replacement, at Bard Access Systems, Inc.’s option. All returns must be authorized in advance in accordance with Bard Access Systems, Inc.’s Returned Goods Policy found in its then current Price List. The liability of Bard Access Systems, Inc. under this limited product warranty does not extend to any abuse or misuse of this product or its repair by anyone other than an authorized Bard Access Systems, Inc. representative.

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Revised date: February 2015

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