**INSTRUCTIONS FOR USE**

For GlidePath™ Straight and Alphacurve™ Configuration Catheters

**DESCRIPTION**

The GlidePath™ catheters are made of radopaque polyurethane, and allow for flow rates as high as 500 ml/min. The catheter shaft is divided internally into two separate lumens by a septum allowing hemodialysis without the use of a "single needle" system. The catheter comes with a white retention cuff for tissue ingrowth to anchor the catheter.

**INDICATIONS FOR USE**

The GlidePath™ long-term hemodialysis catheters are indicated for use in attaining short-term or long-term vascular access by allowing quicker guidewire passage into the venous system to improve patient comfort. The catheter is designed to be disposable, sterile, and non-pyrogenic.

**CONTRAINDICATIONS**

This device is contraindicated for patients exhibiting severe, uncontrolled thrombosis, sepsis, or coagulopathy.

**WARNINGS**

- Percutaneous insertion of the catheter should be made into the axillary-subclavian vein at the junction of the outer and mid-thirds of the clavicle. The catheter should 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 of the subclavian vein.
- Fluoroscopic or radiographic confirmation of catheter tip placement should be helpful in demonstrating that the catheter is not being pinched by the first rib and clavicle.

**RECOMMENDED CLEANING SOLUTIONS**

Catheter Luer-lock Connectors/End Caps:

- Povidone iodine
- Hydrogen peroxide
- Chlorhexidine solutions
- Bacitracin zinc ointments in petrolatum bases

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

**POST DIALYSIS**

Use asceptic technique (as outlined above).

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

2. Warm saline or avoid damage to vessels and veins. Pressure should not exceed 25 psi (172 kPa). The use of 10 or larger syringes is recommended because smaller syringes generate more pressure than larger syringes.

3. Inject heparin solution into both arterial and venous lumens of the catheter. The appropriate heparin solution concentration and frequency should be determined by hospital protocol. An injection of 1.0 to 5.0 units/ml has been found to be effective for maintaining the patency of hemodialysis and apheresis catheters.10

4. To prevent systemic heparinization of the patient, the heparin solution must be aspirated out of both lumens immediately prior to use. If further heparin solution injection is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.

4. This catheter may contain a Heparin solution - aspirate based on the priming volume or as appropriate for each specific catheter.

**CATHETER REMOVAL**

Evaluate the catheter routinely and promptly remove any nonessential catheter1 per physician’s orders. The white retention cuff facilitates tissue in growth. The catheter must be surgically removed. Free the cuff from the tissue and pull the catheter gently and smoothly. 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 practices 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 suspected, immediately remove the catheter. If the patient is without fever or chills but is suspected of having bacteremia, remove the catheter and culture the catheter 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 elect to dissolve the clot with a thrombolytic agent (e.g., TPA Cathflo Activase®). Thrombolytic physician advised.

**CATHETER EXCHANGE**

Do not routinely replace dialysis catheters to prevent catheter-related infections1,11. Therefore, it is not 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.

**REFERENCES:**


**An issued or revised date for these instructions is included for the users information. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems, Inc. to see if additional product information is available.**

**Revision date: March 2020**

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PERCUTANEOUS INSERTION (1) Percutaneous Placement Procedure of the GlidePath™ catheter with cuff using the split sheath introducer:

For percutaneous placement, the catheter is inserted into either the subclavian vein or internal jugular vein through a small incision in the skin. The placement area is aseptically prepared and the patient is placed in a suitable position (e.g., Trendelenburg position) to facilitate the insertion procedure. The patient should be placed in Trendelenburg position with the head turned to the opposite side of the entry site.

A (COMMON STEPS).

CATHETERS MUST BE INSERTED UNDER STRICT ASEPTIC CONDITIONS.

WARNING: Manipulation 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.

CAUTION: In patients with a history of prior irradiation, radiation therapy or other hypoplastic challenges due to the fragile bone, the right side, internal jugular placement is the preferred initial location.

1. Provide a sterile field throughout the procedure. The operator should wear a cap, mask, sterile gown, sterile gloves, and use a sterile large drape to cover the patient.

2. Prepare the access site using standard surgical technique and drape the prep 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 solution may be used. Use a back-and-forth friction scrub for at least 30 seconds. Do not wet the area. After scrubbing the site, allow the site to dry or air dry completely before puncturing the site.

3. (If applicable) Administer local anesthesia to the insertion site and the path for subcutaneous tunnel.

CAUTION: Do not administer anesthesia for 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:

- Catheter Occlusion
- Hematoma
- Perforation of Vessels
- Vessel Erosion
- Normal Vessels
- Local and General Anesthesia, Surgery, and Post-Operative Recovery

4. Withdraw the vessel dilator and guidewire, leaving the introducer sheath in place.

5. Remove thumb and feed distal section of catheter into the sheath introducer. Advance the catheter tip. Catheter tip location is at the junction of the superior vena cava/right atrium (SVC/RA) or in the mid right atrium. All tip placements should be confirmed by fluoroscopy.

6. Verify the catheter tip location with x-ray or fluoroscopy.

RECOMMENDED DRESSING TECHNIQUE:

1. Secure the catheter to the skin using one or two sterile tape strips.

Optional: Place a pre-cut gauze dressing over the exit site, fitting it snugly around the catheter. Place a 2 in. x 2 in. (5 cm x 5 cm) gauze over the pericatheter area.

2. Apply a cover dressing, leaving the extension legs exposed. If using a sterile, transparent, semipermeable dressing, the following is recommended:

2a. Cut a 1-2 inch (3 - 5 cm) slit in the short side of the dressing using sterile scissors. Remove the backing sheet.

2b. Viewing the catheter site through the dressing on the skin so that the slit is over the catheter hub, press one side of the slit down while holding the other side off the skin.

3. Optional: Suture the entire entry site, or use a Stattlock™ Catheter Stabilization device to anchor the catheter.

WARNING: Suture the entire entry site, or use a Stattlock™ Catheter Stabilization device to anchor the catheter.

4. Follow your hospital protocol for dressing change and exit site care. Allow alcohol-containing agents to air dry completely before placing the dressing.

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

INSERTION TECHNIQUE (2) Sheathless Procedure:

For sheathless placement, the catheter is preferably inserted into the internal jugular vein. For the sheathless procedure, the patient should be placed in Trendelenburg position with the head turned to the opposite side of the entry site.

1. Go to A (Common Steps).

2. Go to B (Common Steps).

3. Skip C (Insertion Technique (1) Percutaneous Placement).

4. Sequentially dilate (guiding dilators over the guidewire) the venous puncture site to accommodate the catheter (dilate vessel to at least the same French size as the catheter, and preferably to 1.5 French larger).

5. After removing the dilator, keep the guidewire in the venous system while applying digital compression at the puncture site to maintain hemostasis.

6. If not using a styptic, the proximal end of the guidewire must be inserted into the end hole of the catheter tip and it is advanced through the arterial lumen. The guidewire must be pushed through the arterial lumen and extended out the arterial Luer-lock connector (red). If using styptic, thread the proximal end of the guidewire through the distal tip of the stylet until the guidewire extends out the stylet Luer-lock connector.

7. To minimize the risk of air embolism, clamp the venous extension leg (indicated by the blue Luer-lock connector).

8. Advance the catheter over the wire, until the tip reaches the desired location. Note that some resistance may be experienced when passing the catheter through the soft tissues, but this should subside once the catheter tip is in the correct position.

CAUTION: For optimal product performance, do not insert any portion of the cuff into the vein.

WARNING: Ensure that the catheter does not move out of the vein while removing the insertion styptic.

Go to D (Common Steps).

INSERTION TECHNIQUE (3) Femoral Venous Placement Procedure:

For femoral placement, the patient should be positioned supine, and the catheter tip should be inserted to the junction of the iliac vein and inferior vena cava.** WARNING: The risk of infection is increased with femoral vein insertion.

Note: Catheters greater than 40 cm are intended for femoral vein insertion.

1. Assess the right and left femoral areas for suitability for catheter placement. Ultrasound may be helpful.

2. On the same side as the insertion site, the patient’s knee should be flexed, and the thigh abducted with the foot placed across the opposing leg.

3. Locate the femoral vein, posterior/medial to the femoral artery.

4. Go to A (Common Steps).

5. Go to B (Common Steps), directing tunnel laterally to decrease the risk of infection.**

6. Go to C (Insertion Technique (1) Percutaneous Placement).

GlidePath™ Catheter Flow Rates, Venous and Arterial Pressures – Please refer to the insert for complete Flow Rate Information and Charts.