CARE AND MAINTENANCE

1. Povidone iodine, dilute aqueous sodium hypochlorite solution, chlorhexidine gluconate 4%, or chlorhexidine gluconate 2% solution are the suggested antiseptics to use.
   WARNING: Acetone and 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.
2. 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.
3. The exit site should be checked daily. Aseptic technique, including facemasks, for nurse and patient hand washing, and gloves must be used for these procedures.
4. Carefully remove the dressing and inspect the exit site for inflammation, swelling and tenderness. Notify physician immediately if signs of infection are present.
5. Clean the exit site with an antimicrobial solution following your institution's protocol. Clean from the catheter working outward in a circular motion.
6. Dress the catheter as described above under "D (Common Steps)." See Nursing Guide for more details.

TROUBLESHOOTING

PATIENT WITH FEVER

Unusual signs or symptoms (i.e., fever, chills) occurring immediately following the procedure may indicate septic thrombosis. If this does result, the catheter should be removed.

INSUFFICIENT FLOW

Excessive force should not be used to flush an obstructed lumen. Insufficient blood flow may be caused by occluded arterial 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 (i.e., TPA). Physician discretion advised.

CATHETER EXCHANGE

It may become necessary to exchange the indwelling catheter due to infection or a persistent rise in pressures or decrease of flow rates which cannot be rectified through troubleshooting.

REFERENCES:

1 Aitken, D.R. and Minton, J.P. "The Pinch-Off Sign: A Warning of Impending Problems with Permanent Subclavian Catheters", American Journal of Surgery, Vol. 148, Nov. 1984, pp.633-638.

2 Patel, A, et al "Sheathless Technique of Ash Split Catheter Insertion." J Vasc Interv Radiol 2001; 12:376-378.

3 Zaleski, GX, et al. "Experience with Tunneled Femoral Hemodialysis Catheters." Am J Roentgenol. 1999 Feb; 172(2):493-6.

4 Rogers, P.R. et al "Pocket Radiologist Interventional Top 100 Procedures", Amirsys, 1st Ed., 2003.

5 Mickley, V., "Central venous catheters: many questions: few answers", Nephrol Dial Transplant, (2002) 17:1368-1373.

6 National Kidney Foundation K/DOQI GUIDELINES 2006.

7 Sulek, CA., Blas, ML., Lobato, EB, "A randomized study of left versus right internal jugular vein cannulation in adults." J Clin Anesth. 2000 Mar;12(2):142-5.

8 Tan, P.L., Gibson, M., "Central Venous Catheters: the role of radiology", Clin Rad. 2006, 61:13-22.

9 Octavio, Bella, Colemenares, Garcia, and Flores; "Right Verses Left Internal Vein Catheterization for Hemodialysis: Complications and Impact on Ipsilateral Access Creation"; Artifical Organs; 2004, 28(8):728-733.

10 MacRae JM, Dojcinovic I, Djurdjev O, et al. Citrate 4% versus Heparin and the Reduction of Thrombosis Study (CHARTS). American Society of Nephrology. https://cjasn.asnjournals.org/content/3/2/369. Published March 1, 2008.

Other references available upon request.

An issued or revision 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

BARD

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HemoStar™ / HemoStar™ XK

BARD Access Systems

Long-Term Hemodialysis Catheters

Instructions For Use

For **HemoStar™ and HemoStar™ XK** (Straight and **Alphacurve™** Configuration) Catheters

DESCRIPTION

The HemoStar™ and HemoStar™ XK catheters are made of radiopaque 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.

STERILE EO STERILIZED WITH ETHYLENE OXIDE.

SINGLE PATIENT USE ONLY.

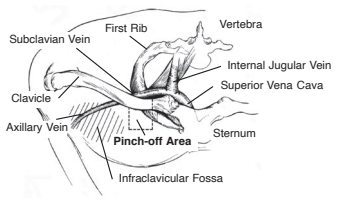
INDICATIONS FOR USE

The HemoStar™ and HemoStar™ XK long-term hemodialysis catheters are indicated for use in attaining short-term or long-term vascular access for hemodialysis, hemoperfusion or apheresis therapy. Access is attained via the internal jugular vein, subclavian vein, or femoral vein. Catheters greater than 40 cm are intended for femoral vein insertion.

CONTRAINDICATION

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

WARNINGS



WARNING: 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 lateral to the thoracic outlet. 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 or fracture and embolization of the catheter.[1] 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.[1]

- Alcohol or alcohol-containing antiseptics (such as chlorhexidine) may be used to clean the skin exit site. When cleaning the exit site, inadvertent contact with the catheter is acceptable, but repeated catheter contact should be avoided. Apply antiseptic per manufacturer's recommendations. Allow to air dry completely before applying dressing. In all cases skin cleaning/disinfection should follow local facility protocols.
- 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.
- 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.
- Follow Universal Precautions when inserting and maintaining this device.
- Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium.
- Close all clamps only in the center of the extension legs. Extensions 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.
- Catheters should be implanted carefully to avoid any sharp or acute angles which could compromise the opening of the catheter lumens.
- To prevent air embolism and/or blood loss, place thumb over the exposed orifice of the sheath introducer.
- To avoid damage to vessels and viscus, infusion pressures should not exceed 25 psi (172 kPa). The use of a 10ml 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 3ml syringe generates pressure in excess of 30 psi (206 kPa) whereas the same three pound (13.3 Newton) force on the plunger of a 10ml syringe generates less than 15 psi (103 kPa) of pressure.
- Accessories and components used in conjunction with this catheter should incorporate luer-lock adapters.
- The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.
- Failure to clamp extensions when not in use may lead to air embolism.
- In the rare event of a leak, the catheter should be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis or infusion procedure.
- The risk of infection is increased with femoral vein insertion.
- Do not resterilize the catheter or components by any method. The manufacturer will not be liable for any damages caused by reuse of the catheter or accessories.
- 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.[7]

CAUTIONS

- Repeated over tightening of blood lines, syringes and caps will reduce connector life and could lead to potential connector failure.
- In case of damage, clamp the catheter between the patient and the damaged area with a smooth-edged, atraumatic clamp.
- Sterile and non-pyrogenic only if packaging is not opened, damaged or broken.
- Read the instructions for use carefully before using this device.
- **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.
- 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 SVC.[5,8]
- Care should be taken NOT to force the dilator sheath introducer assembly into the vessel during insertion as vessel damage including perforation could result.
- Before attempting the insertion of catheters, ensure that you are familiar with the following complications and their emergency treatment should any of them occur.
- These and other complications are well documented in medical literature and should be carefully considered before placing the catheter. Placement and care of hemodialysis catheters should be performed by persons knowledgeable of the risks involved and qualified in the procedures.

CAUTIONS (cont'd)

- For optimal performance, do not insert any portion of the cuff into the vein.
- Do not pull back standard guidewire over needle bevel as this could sever the end of the guidewire. The introducer needle must be removed first.
- Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel as sheath is torn.

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
- Bleeding
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Catheter or Cuff Erosion Through the Skin
- Catheter Embolism
- Catheter Occlusion
- Catheter Occlusion, Damage or Breakage due to Compression Between the Clavicle and First Rib[1]
- Catheter-related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibrin Sheath Formation
- Hematoma
- Hemothorax
- Hydrothorax
- Inflammation, Necrosis or scarring of skin over implant area
- Intolerance Reaction to Implanted Device
- 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 Thrombosis
- Ventricular Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

INSERTION TECHNIQUE (1) Percutaneous Placement Procedure of the HemoStar™ or HemoStar™ XK catheter with cuff using the Bard Access Systems, Inc. split sheath introducer:

For percutaneous placement, the catheter is inserted in either the subclavian vein or internal jugular vein through a split sheath introducer. It has been reported that right side, internal jugular placement is the preferred initial location of consideration for percutaneous insertion.6,9 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: 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.[7]
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.[5,8]

1. Provide a sterile field throughout the procedure. Gloves, masks, gowns, sterile drapes and equipment must be used.
2. Prepare the access site using standard surgical technique and drape the prepped area with sterile towels.
3. (If applicable) Administer local anaesthesia to the insertion site and the path for subcutaneous tunnel.
4. Flush each lumen with heparinized saline prior to insertion and clamp the extension legs.
5. Insert the introducer needle with an attached syringe to the desired location. Aspirate gently as the insertion is made.
6. When the vein has been entered, remove the syringe leaving the needle in place.
7. If using a micropuncture set, insert the flexible end of the microintroducer guidewire into the needle. Advance the microintroducer guidewire as far as appropriate. Verify correct positioning, using fluoroscopy or ultrasound.
   - Gently withdraw and remove the needle, while holding the guidewire in position.
     CAUTION: If the microintroducer guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
   - Advance the small sheath and dilator together as a unit over the microintroducer guidewire, using a slight rotational motion. Advance the unit into the vein as far as appropriate.
   - Withdraw the dilator and microintroducer guidewire, leaving the small sheath in place.
     WARNING: Place a thumb over the orifice of the sheath to minimize blood loss and risk of air aspiration.
8. The standard guidewire can be inserted into the needle hub and passed through the needle. Advance the standard guidewire to the desired location in the vessel. The maximum guidewire size that may be used is 0.038 in. (0.97 mm).
9. If using a microintroducer, gently withdraw and remove the small sheath, while holding the standard guidewire in position.
10. Remove the needle while holding the guidewire in place. Wipe the guidewire clean and secure it in place.
    CAUTION: Do not pull back standard guidewire over needle bevel as this could sever the end of the guidewire. The introducer needle must be removed first.
11. Make a small incision at the insertion site. Make a second incision at the desired exit site of the catheter.
12. B (Common Steps).

B (COMMON STEPS)

1. With a tunneler, create a subcutaneous tunnel from the catheter exit site to emerge at the venous entry site. Attach the catheter to the tunneler so that the catheter's venous tip slides over the barbed connection and rests adjacent to the sheath stop. This allows the catheter to be threaded through the tissue as the tunnel is created. If using the Bard Access Systems, Inc. tunneler, slide the sheath found on the tunneler over the venous tip/tunneler connection and ensure the open end of sheath is covering the arterial tip. This will reduce the drag on the arterial tip in the skin tunnel. (After positioning cuff, tunneler can be removed by sliding sheath away from the catheter and pulling tunneler from venous tip.)
   The catheter should not be forced through the tunnel.
2. Position the white retention cuff approximately midway between the skin exit site and the venous entry site, 3 cm minimum, from the venous entry site. For catheters with depth markings on the catheter shaft, markings may be used to measure the distance (in cm) to the cuff.

C (PERCUTANEOUS PLACEMENT)

1. Fill the catheter lumens with heparinized saline. It is recommended that the venous lumen, as indicated by the blue luer connector, be oriented cephalad. (Should be automatic with the Alphacurve* configuration.)
2. Advance the dilator sheath introducer assembly over the exposed guidewire into the vessel.
   CAUTION: Care should be taken NOT to force the dilator sheath introducer assembly into the vessel during insertion as vessel damage including perforation could result. 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.[5,8]
   WARNING: Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium.

Withdraw the vessel dilator and guidewire, leaving the introducer sheath in place.
CAUTION: Care should be taken not to advance the split sheath too far into vessel as a potential kink would create an impasse to the catheter.
WARNING: To prevent air embolism and/or blood loss, place thumb over the exposed orifice of the sheath introducer.

3. Remove thumb and feed distal section of catheter into the sheath introducer. Advance the catheter tip to the junction of the superior vena cava and right atrium. For catheters with depth markings, markings are in one centimeter increments.
4. With the catheter advanced, peel away the sheath by gripping the "T" handle and breaking it apart with a downward and outward motion to initiate separation and withdrawal of the sheath.
   CAUTION: Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel as sheath is torn.
   CAUTION: For optimal product performance, do not insert any portion of the cuff into the vein.
5. D (Common Steps).

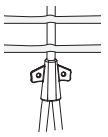
D (COMMON STEPS)

1. To check catheter patency attach a 10ml syringe with sterile normal saline to each lumen of the catheter. Release the catheter clamp and aspirate blood through each lumen. Once flow is satisfactory, flush both lumens with heparinized saline in amounts equal to the priming volume of each lumen. Clamp each lumen immediately.
   WARNING: Failure to clamp can lead to air embolism.
2. For additional security, suture the entry site, or use a StatLock™ stabilization device to anchor the catheter.
3. Manage the exit site per your institution's protocol.
4. Dress the catheter.
   WARNING: Acetone and 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.
5. Verify the catheter and 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 pre-cut gauze and catheter.



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 catheter site through the dressing on the skin so that the slit is over the catheter hub, press one side of dressing into place while holding the other side off the skin.

2c. Partially remove the frame portion of the dressing near the catheter hub which is already secured to the skin.

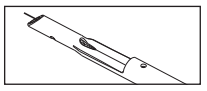
2d. Overlap the unsecured side of the dressing slightly over the secured side to seal dressing under catheter hub. Carefully remove the frame from the dressing while firmly smoothing down the edges. Smooth down the entire dressing.

WARNING: Acetone and 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.

INSERTION TECHNIQUE (2) Sheathless Procedure[2]:

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. It is recommended that the venous lumen, as indicated by the blue luer connector, be oriented cephalad. (It should be automatic with the Alphacurve* configuration.)
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 F 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. The proximal end of the guidewire must be inserted into the venous end hole of the distal-most tip, then brought out the guidewire channel in that same limb, and threaded into the end hole of the arterial tip, passing through the arterial lumen until it extends out the arterial luer connector (red).



7. To minimize the risk of air embolism, clamp the venous extension leg (indicated by the blue luer connector).
8. Advance the catheter over the wire, until the tip reaches the junction of the superior vena cava and right atrium. Note that some resistance may be experienced when passing the catheter through the soft tissues, but this should subside once the catheter tip is intravascular.
   CAUTION: For optimal product performance, do not insert any portion of the cuff into the vein.
9. Remove the guidewire while applying forward pressure on the catheter so it does not withdraw.
10. Go to D (Common Steps).

INSERTION TECHNIQUE (3) Femoral Vein 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[3].

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.[4]
6. Go to C (Percutaneous Placement).

CATHETER REMOVAL

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.

DISPOSAL

After use, the catheter and accessories may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and all applicable laws and regulations.

POST DIALYSIS

1. To maintain patency between treatments a heparin lock must be created in each lumen of the catheter.
2. 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.[10] 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.
   WARNING: The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.
3. This catheter may contain a Heparin solution - aspirate based on the priming volume or as appropriate for each specific catheter.