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 practices 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. Inject 5000 units of heparin per ml of saline (or a concentration approved by your institution) into each lumen in amounts equal to the priming volume of each lumen. To ensure that each lumen is totally filled, inject quickly and clamp extension while under positive pressure. Attach a sterile cap to each clamping extension.

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

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 face masks, 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:

5. Close all clamps only in the center of the extension line. Extensions may develop or leak 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.
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7. Cather should be implanted carefully to avoid any sharp or acute angles which could compromise the opening of the catheter lumen.
8. To prevent air embolism and/or blood loss, place thumb over the exposed orifice of the sheath to introduce.
9. The catheter is contraindicated for patients exhibiting severe, uncontrolled thrombocytopenia or coagulopathy.
10. The heparin solution must be aspirated out of both lumens immediately prior to using the catheter to prevent systemic heparinization of the patient.
11. Failure to clamp extensions when not in use may lead to air embolism.
12. The risk of infection is increased with hemoral venin insertion.
13. Do not reinitialize the catheter or components by any method. The manufacturer will not be liable for any damages caused by reuse of the catheter or accessories.
14. 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.

CATIONS

Kits with Stiffening Wire Only. If using the supplied stiffening wire during placement, do not place it into the arterial lumen because the tip of the wire would prolude from the lumen and may cause vessel trauma. Do not adjust pre-set length of wire. Reference Insertion Technique (3) Step 2.

- Repeated or over tightening of blood lines, syringes and caps will reduce connector life and could lead to potential connector failure.
- The case of damage, clamp the patient and catheter between the damaged area with a smooth-edged, atraumatic clamp.
- Do not pull back standard guide wire over needle bevel as this could sever the end of the guide wire. The introducer needle must be removed first.
- Ensure that the introducer sheath is only tom externally. Catheter may need to be further pushed into the vessel as sheath is tom.

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
- Bruach / Pleural Injury
- Cardiac Arrhythmias
- 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
- Catheter-related Sepsis
- Endocarditis
- Exit Site Infection
- Exit Site Necrosis
- Extravasation
- Fibin Sheath Formation
- Hematoma
- Hydrothorax
- Infammation, Necrosis or scarring of skin over implant area
- Intolience Reaction to Implanted Device
- Laceration of Vessels or Viscus
- Perforation of Vessels or Viscus
- Phalloschere
- Spontaneous Catheter Tip Malposition or Retraction
- Thoracic Duct Injury
- Thromboembolism
- Venous Thrombosis
- Venous Thrombosis
- Vessel Erosion
- Wrisl Native Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

DESCRIPTION

The HemoSplit* and HemoSplit** 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 flow through the use of the a “single needle” system. The catheter comes with a white retention cuff to anchor the catheter.

The HemoSplit* and HemoSplit** XK catheters have two separate free floating tips, separated at a fixed point, and 360° side hole coverage.

STERILE [D] STERLIZED WITH ETHYLENE OXIDE

SINGLE PATENT USE ONLY.

INDICATIONS FOR USE

The Hemospilt* and HemoSplit** 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, external jugular vein, subclavian vein, or femoral vein. Catheters greater than 40 cm are intended for femoral venal insertion.

CONTRAINDICATION

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

WARNINGS

- Alcohol or alcohol-containing antiseptics (such as chlorohexidine) may be used to clean the catheter/skin site; however, care should be taken to avoid prolonged or excessive contact with the solution(s).
- 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.
- Follow Universal Precautions when inserting and maintaining this device.
- Close all clamps only in the center of the extension line. Extensions may develop or leak 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.
- Do not reinitialize 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.

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: December 2010.

* Bard, Alphacurve, HemoSplit, and StatLock are trademarks and/or registered trademarks of C. R. Bard, Inc. All other trademarks are the property of their respective owners.

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Bard Access Systems, Inc.
605 North 5600 West
Salt Lake City, UT 84116 U.S.A.
1-801-522-5000
Customer Service: 800-545-0996
Clinical Information: 800-443-3385
www.bardaccess.com
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.\(^1\)

**A (COMMON STEPS).**

**CATHETERS MUST BE INSERTED UNDER STRICT ASEPTIC CONDITIONS.**

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 anesthesia to the insertion site and the path for subcutaneous tunnel.
4. Flush each lumen with heparinized saline prior to insertion and call the extension lines.
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. WARNING: CATHETERS MUST BE INSERTED UNDER STRICT ASEPTIC CONDITIONS.
8. The standard guidewire can be inserted into the needle hub and passed through the needle. Advance the guidewire to the arterial tip, passing through the arterial lumen until it extends out the arterial luer connector (Should be automatic with the Alphacure\(^\text{®}\) configuration.)
9. Do not clamp the venous lumen if the stiffening wire is in place.
10. The risk of infection is increased with femoral vein insertion.

**CAUTION:**

- The standard guidewire must be withdrawn while the needle is removed, 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.
- To check catheter patency attach a 10 ml syringe with sterile normal saline to each lumen of the catheter. Release the catheter and withdraw slight motion to initiate separation and withdrawal of the sheath.
- Verify the catheter and tip location with x-ray or fluoroscopy.
- CAUTION: 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 4 cm are considered for femoral vein insertion.
- Assess the left and femoral areas for suitability for catheter placement. Ultrasound may be helpful.
- 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.
- Locate the femoral vein, posterior/medial to the femoral artery.

**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 used with the Bard Access Systems, Inc. tunneler, slide the obturator into the sheath introducer over the venous tourniquet connection and ensure the open end of the 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 the tunneler, the catheter over it and the tunneler being pulled out.)
2. The proximal end of the guidewire should be inserted into the venous end hole of the distal-most tip, then brought out the guidewire channel in that same tunnel, and threaded into the hole of the arterial tip, passing through the arterial lumen until it extends out the arterial lumen connector (red).
3. Remove the distal part of the guidewire from the venous system while applying slight compression at the puncture site to maintain hemostasis.
4. Advance the over-the-needle catheter into the arterial lumen following the direction of the guidewire until the prominent arterial cuff can be aligned with the arterial wall. This cuff should be inserted into the artery. After the cuff is in place, the guidewire can be removed and the catheter advanced into the arterial lumen.
5. Withdraw the needle while holding the guidewire in place. The catheter may be inserted into the superior vena cava via the subclavian vein, external jugular vein or the internal jugular vein (standard operating room procedure). For surgical cutdown procedure, the patient should be placed in Trendelenburg position with the head turned to the opposite side of the entry site.
6. Go to C (Percutaneous Placement).

**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 Alphacure\(^\text{®}\) configuration.)
2. Advance the dilator sheath introducer assembly over the exposed guidewire into the vessel. CAUTION: Care should be taken not to advance the split sheath too far into vessel as a potential kink would create an impasse difficulty.
3. WARNING: Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium.
4. 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 into another catheter could create an impasse difficulty.
5. WARNING: To prevent air embolism and/or blood loss, place thumb over the exposed orifice of the sheath introducer.
6. 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. Note that the risk of infection is increased with femoral vein insertion.

**NOTE:**

- For optimal product performance, do not insert any portion of the cuff into the vein.
- The catheter may be inserted into the superior vena cava via the subclavian vein, external jugular vein or the internal jugular vein (standard operating room procedure). For surgical cutdown procedure, the patient should be placed in Trendelenburg position with the head turned to the opposite side of the entry site.

**INSERTION TECHNIQUE (2) Surgical Cutdown Procedure:**

1. Go to A (Common Steps).
2. Loosen the cuff. (Do not use for insertion of the catheter with a small incision. Not: If performing a jugular insertion and external vein is not of adequate size to accommodate the catheter, the internal vein may be used. A purse string suture may be used to secure catheter in the internal vein.
3. Make a small incision at the desired exit site of the catheter, in the area between the nipple and right sternal border. Make the incision just large enough to accommodate the implantable cuff. (Should be automatic with the Alphacure\(^\text{®}\) configuration.)
4. Insert the catheter through a small venotomy in the selected vein. Advance the catheter tip to the junction of the superior vena cava and right atrium. It is recommended that the venous lumen, as indicated by the blue luer connector, be oriented cephalad. (Should be automatic with the Alphacure\(^\text{®}\) configuration.)
5. WARNING: Do not insert any portion of the cuff into the vein.

**INSERTION TECHNIQUE (3) 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. Kits with Stiffening Wire Only. Insert and lock the supplied stiffening wire into the venous lumen if additional stiffness is desired to facilitate placement. Do not adjust pre-length of stiffening wire.
3. Go to B (Common Steps).
4. Remove the guidewire while applying forward pressure on the catheter so it does not withdraw.

**INSERTION TECHNIQUE (4) 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. WARNING: The risk of infection is increased with femoral vein insertion.

**NOTE:**

- Catheters greater than 4 cm are considered for femoral vein insertion.
- Do not remove the guidewire and catheter in the venous system while applying slight compression at the puncture site to maintain hemostasis.
- The proximal end of the guidewire should be inserted into the venous end hole of the distal-most tip, then brought out the guidewire channel in that same tunnel, and threaded into the hole of the arterial tip, passing through the arterial lumen until it extends out the arterial lumen connector (red).
- Remove the stiffening wire, if used, and clamp the venous lumen.
- Remove the guidewire while applying forward pressure on the catheter so it does not withdraw.

**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 an occlusive dressing is used, leave the sheath exposed using sterile scissors. Remove the backing sheet.
3. Partially remove the frame portion of the dressing near the catheter hub which is already secured to the skin.
4. Overlap the unsecured side of the dressing slightly over the secured side to seal dressing under catheter hub. Carefully remove the frame portion of the dressing while firmly smoothing down the hypodermic. Smooth down the entire dressing.

**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., Polysozin\(^\text{®}\) ointment) are the preferred alternative.**

**Recommended In Line Pressure Monitoring**

**Catheter Venous Pressures**

<table>
<thead>
<tr>
<th>Pressure (mmHg)</th>
<th>16 F HemoSplit* XK Catheter</th>
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</thead>
<tbody>
<tr>
<td>300</td>
<td>Venous</td>
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<tr>
<td>350</td>
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<tr>
<td>400</td>
<td>Venous</td>
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<tr>
<td>420</td>
<td>Venous</td>
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**Note:**

- As suggested by in vitro data, using a blood substitute approximating the viscosity of whole blood.

**Acrylic Hemostasis/Irrigation**

**Catheter Venous Pressures**

<table>
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</thead>
<tbody>
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<td>420</td>
<td>Venous</td>
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<td>420</td>
<td>Venous</td>
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</table>

**Note:**

- As suggested by in vitro data, using a blood substitute approximating the viscosity of whole blood.

**Reverse Flow**

**Catheter Venous Pressures**

<table>
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<tbody>
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<td>420</td>
<td>Venous</td>
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<td>Venous</td>
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**Note:**

- As suggested by in vitro data, using a blood substitute approximating the viscosity of whole blood.

**Net Flow/Reverse Flow**

**Catheter Venous Pressures**

<table>
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<tr>
<td>420</td>
<td>Venous</td>
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**Note:**

- As suggested by in vitro data, using a blood substitute approximating the viscosity of whole blood.