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. The heparin lock 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 antisepsics to use.

WARNING: Acetone and PEG-containing ointments can cause failure of this device and should not be used with polyurethane catheters. Chlorhexidine pastes 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 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 contact with 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:


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**HemoStar**

Long-Term Hemodialysis Catheters 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 450 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

STERILIZED WITH ETHYLENE OXIDE.

SINGLE PATENT 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, external 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

- Alcohol or alcohol-containing antiseptics (such as chlorhexidine) 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 pastes or bacitracin zinc ointments (e.g., Polysporin ointment) are the preferred alternative.
- Do not allow Universal Preservatives 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 lugs. Extensions may develop cuts or tears if subjected to excessive pulling or pressure 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 veins and vissous, infusion pressures should not exceed 50 psi (345 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 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.

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.1
- 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 procedure.
- 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 Arrhythmias
- Cardiac Taponndrome
- 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
- Fibro Sheath Formation
- Hematoma
- Hemothorax
- Hydrothorax
- Infarction, 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 Thrombosis
- Venous Thrombosis
- Vessel Erosion
- Risks Normally Associated with Local and General Anesthesia, Surgery, and Post-Operative Recovery

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A (COMMON STEPS). CATHETERS MUST BE INSERTED UNDER STRICT ASEPTIC CONDITIONS.

CAUTION: Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium.

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

5. With the catheter advanced to the desired level, apply slight rotational motion to initiate separation and withdrawal of the sheath.

6. CAUTION: Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel, but should subside once the catheter tip is intravascular.

7. If performing a jugular insertion and external tunneling is preferred, follow the right jugular tunneling procedure. Insert both the needle and wire 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 lumen connector (if used).

8. To minimize the risk of air embolism, clamp the venous extension leg (indicated by the blue luer connector).

9. 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.

10. After removing the dilator, keep the guidewire in the venous system while applying digital compression at the puncture site to prevent air embolism.

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

12. Go to 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 against the sheath stop. This allows the catheter to be threaded through the tissue as the tunneler 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 tunneler.

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 (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 used for blood sampling. If performing a jugular insertion and external tunneling is preferred, follow the right jugular tunneling procedure. Insert both the needle and wire 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 lumen connector (if used).

2. Advance the dilator sheath introducer assembly over the exposed guidewire into the vessel.

3. 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 compared to catheter placement in the right internal jugular vein.

4. Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel, but should subside once the catheter tip is intravascular.

5. CAUTION: Cardiac arrhythmias may result if the guidewire is allowed to pass into the right atrium.

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

7. With the catheter advanced to the desired level, apply slight rotational motion to initiate separation and withdrawal of the sheath.

8. CAUTION: Ensure that the introducer sheath is only torn externally. Catheter may need to be further pushed into the vessel as sheath is torn.

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

10. Go to D (Common Steps).

D (COMMON STEPS)

1. To check catheter patency attach a 10 ml 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.

2. WARNING: Failure to clamp can lead to air embolism.

3. For additional security, suture the entry site, or use a suture anchor.

4. Dress the catheter.

5. 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., Polyson* ointment) are the preferred alternative.

6. 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.

2a. Cut a 2 in. x 2 in. (5 cm x 5 cm) gauze over the pre-cut gauze and catheter.

2b. Apply a cover dressing, leaving the extension legs exposed if using an occlusive or film-style dressing. The following is recommended:

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

2b. Viewing catheter site. Through the dressing on the skin so that the stilt is over the catheter hub. Press one side of dressing into place while holding the other side off the skin.

2c. 14.5 F HemoStar* Catheter Venous Pressures +

19 cm Venous
42 cm Venous
19 cm Arterial
42 cm Arterial

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

HemoStar Catheter Venous Pressures+ with Flow Rate

16 F HemoStar* XX Catheter Venous Pressures +

19 cm Venous
42 cm Venous
19 cm Arterial
42 cm Arterial

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

HemoStar XX Catheter with Flow Rate

Note: Reverse flow will result in higher recirculation.