Do not use acetone, or alcohol-based iodine solutions (tinctures) on any part of the catheter or tubing. Exposing the catheter to these agents may cause catheter damage. Aqueous-based povidone-iodine is recommended for site selection.

• Tissue necrosis must be distal to the tip of the stifferner during catheter insertion.
• Catheter must only be advanced over a guidewire.

General Precautions

• If the patient does not demonstrate any sign of damage (crimped, crushed, cut), do not use.

• Do not use instruments near the extension tubing or catheter shaft.
• Do not use scissors to remove the dressing, as this could possibly cut or damage the patient. Do not cut away anything part of the catheter. If sutures are used to secure the catheter, be sure to use the suture wing. Catheter tubing can tear when subjected to excessive force or rough edges.
• Arterial or venous damage during implantation that may compromise catheter functionality.
• Pressure on the device with sterile, heparinized saline or normal saline solution to help avoid air embolism prior to catheter insertion.
• Excessive force should not be used to flush obstructed lumen. Do not use excess force on the catheter than the catheter can handle.
• To prevent accidents, assure the safety of all caps and bloodline connections prior to and during treatments.
• It is recommended that only luer lock (threaded) accessories and components are used with the UltraStream Chronic Hemodialysis Catheter. Repeated tightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure. Intra-catheter catheter fragments for rights, spiculas, cuts, etc. which could impair its performance.
• Coaxial extension tubes repeatedly in the same spot could weaken the tubing. Change the position of the clamp regularly to prolong the life of the tubing. Avoid clamping near the adapter and hub of the catheter. Do not clamp the shaft of the catheter. Use only the line extension clamp which has been provided with the catheter. Examine tubing for damage any time catheter function is in doubt.

Possible Complications

- Air Embolism
- Bleeding
- Backflow
- Hemodynamic\em

- Pulmonary Edema
- Hypotension
- Intracranial Pressure
- Intracranial Hemorrhage
- Information
- Laceration of Vessel
- Hemorrhage
- Laceration of Vein
- Death
- Flushing
- Sheath Formation

Indications For Use

The UltraStream Chronic Hemodialysis Catheter is designed for chronic hemodialysis and hemofiltration.

Contraindications

The device is contraindicated when:
- The presence of other device-related infection, bacteria, or sepsis is known or suspected.
- Severe chronic stable lung disease exists.
- Post irradiation of prospective insertion site.
- Previous episodes of venous or vascular surgical procedures at the prospective placement site have occurred.
- Local tissue factors will prevent proper device stabilization and/or access.

Warnings

- Be aware of the risk to exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care workers should routinely use universal blood and body-fluid precautions in the care of all patients. Sterile technique must be strictly adhered to during any handling of the device.
- To avoid air embolism, keep the catheter clamped at all times when not attached to syringes or blood lines.

In the event of a catheter or device-related complication, contact your local healthcare practitioner authorized by and under the direction of such physician. Medical techniques and procedures described in these instructions do not represent all medically accepted protocols, nor are they intended as a substitute for a physicians experience and judgment in treating any specific patient.

Directions for Catheter Insertion (Standard Kit with Peel Away Sheath)

The 15.5F UltraStream Chronic Dialysis Catheter should be inserted, maintained, and manipulated only by a qualified, licensed physician or other healthcare practitioner authorized by and under the direction of such physician.

NOTE: If the catheter is not used immediately for treatment, follow standard protocol and keep catheter capped. Do not use forceps and do not clamp the distal portion of the catheter.

NOTE: If excessive resistance to blood aspiration exists, the catheter may have become clogged. It may be necessary to manipulate, and sometimes to sustain adequate blood flow. A pre-existing inflow sheath may also be present.

Note: Insert 0.038” cm marked guidewire through needle and into the vein. Guidewire can be used for control during fluoroscopy, note the depth markings on guidewire when desired tip position is reached.

CAUTION: Length of wire inserted is determined by the size of the patient. Monitor patient for signs of arrhythmia throughout this procedure. Patient may experience some discomfort during this procedure. Catheter should be clamped after removal of the guidewire, re-clamp the extension tubing and remove the syringe. Repeat this step for the other catheter extension.

16) If a 20 M (cc) syringe with sterile, normal or heparinized saline solution, attach to one of the catheter extensions, open clamp, and irrigate the tunnel with hypotonic normal saline solution, keep the device clamp off (right atrium or ventricle). The guidewire should be held securely during this procedure.

17) Attach both injection caps to the catheter luers post placement

18) If the catheter is not used immediately for treatment, follow standard protocol and keep catheter capped. Do not use forceps and do not clamp the distal portion of the catheter.
22) Attach a 20 ml syringe with sterile, normal or heparinized saline solution, attach to one of the catheter extensions, open clamp, and irrigate the lumen. Once the lumen has been irrigated, reclamp the extension tube and remove the syringe. Repeat this step for the other catheter extension.

23) Fill a 20 ml syringe with sterile, normal or heparinized saline solution, attach to one of the catheter extensions, open clamp, and irrigate the lumen. Once the lumen has been irrigated, reclamp the extension tube and remove the syringe. Repeat this step for the other catheter extension.

24) Advise and secure the flexible stifferner into the UltraStream™ luer lock connections. Do not lock the blue venous clamp over the stifferner. The red arterial clamp should be locked prior to advancing over-the-wire.

25) Insert the 0.035/0.038” guidewire into the distal end of the flexible stifferner, until guidewire exits out of the blue venous lumen.

26) Advance the catheter over-the-wire thru the existing tunnel until proper placement. Secure the catheter to the patient according to KDOQI guidelines. It is recommended that arterial lumen, as indicated by the red arterial stifferner, is oriented cephalad. In case of arterial aneurysm, it may be necessary to use a separate and small sheath to prevent perforation of the vessel wall.

CAUTION: Do not advance the catheter and stiffener past the tip of the guidewire as this could cause vessel perforation, and or bleeding.

NOTE: If resistance is felt, it is advisable to dilate tunnel.

NOTE: Polyurethane cuff should be positioned approximately 2.0 cm from the exit site.

11) Once position is confirmed, slowly remove 0.035/0.038” guidewire, flexible stifferner, and attention tag attached to the venous clamp.

12) Attach a 20 ml (cc) syringe to one extension and open clamp. Blood should aspirate easily. Once adequate blood flow has been established, flush the lumen(s) and then re-clamp the extension tube and remove syringe. Repeat this step for the other catheter extension.

CAUTION: Avoid air embolism by keeping the catheter tubing clamped as far as possible when not in use and by filtering the catheter with sterile, normal or heparinized saline solution prior to use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.

CAUTION: Clamp only the extension tubes with the in-line clamps provided with the UltraStream™ catheter. Do not use forceps and do not clamp the distal portion of the catheter.

NOTE: If excessive resistance to blood aspiration exists, the catheter may need to be rotated, flushed or repositioned to sustain adequate blood flow. A pre-existing fibrin sheath may also be present.

27) Suture the tunnel exit site and vein insertion site if necessary. Suture the catheter to the skin using fixed suture wings. Do not suture the catheter tubing.

28) Apply provided dressings per hospital policy.

NOTE: It is particularly important to immobilize cuffed catheters for 7 days to prevent cuff dislodgment. Assess catheter fixation before removing sutures.

NOTE: Before dialysis begins, all connections to the extracorporeal circuit should be checked carefully. During all dialysis procedures, frequent visual inspection should be conducted to detect leaks and prevent blood loss or entry of air into the extracorporeal circuit.

DIRECTIONS FOR EXTRACORPOREAL CATHETERIZATION

The 15.5F UltraStream™ Chronic Dialysis Catheter should be inserted, manipulated, and removed only by a qualified, licensed physician or other healthcare practitioner authorized and trained by the manufacturer in the use of this device. The medical techniques and procedures described in these instructions do not constitute a complete guide for use of this device. The user should consult a physician for a patient’s experience and judgment in treating any specific patient.

CAUTION: Review hospital or departmental protocol, warnings, cautions, guidelines, potential complications and their treatment, prior to catheter removal.

CAUTION: Strict aseptic technique must be used during the insertion, maintenance, and removal procedures.

NOTE: Review existing catheter manufacturer’s instructions for removal and verify if exchange procedure is appropriate.

31) Remove existing catheter by cutting sutures from suture wing, if required.

32) Re-clamp the lumen of the tissue using blunt or sharp dissection as needed (located at exit site)

33) Unlock the venous clamp and advance an 0.035/0.038” guidewire down the venous lumen into the designated position, unless contraindicated.

CAUTION: Confirm proper guidewire placement under fluoroscopy per KDOQI guidelines.

NOTE: Guidewire must be the proper length so the guidewire will extend distal to the tip of the catheter at all time of the placement.

34) While holding the 0.035/0.038” guidewire in place, gently pull the catheter out over the guidewire.

Caution: When removing the catheter, DO NOT use a sharp, jerking motion or undue force; this may tear the catheter.

35) After removing the catheter, apply manual pressure to the puncture site to control bleeding.

36) Remove protective shipping sleeve from the replacement catheter.

37) Prepare the UltraStream™ catheter and flexible stifferner for insertion by gently wiping the exposed distal portion with sterile, normal or heparinized saline solution and irrigating all lumens using 10 ml (cc) syringes filled with normal or heparinized saline solution. Remove the flexible stifferner prior to irrigation. Lock arterial clamp after irrigating.

Site Care

CAUTION: Use caution when cleaning the catheter exit site. Podophyllin, dilute aqueous sodium hypochlorite solution, chlorhexidine gluconate 4%, or chlorhexidine gluconate 2% solution are the recommended antiseptics to be used with this catheter.

Clean the site with an antiseptic. Cover the exit site with two cohesive dressings applied sandwich style around the catheter. Leave the extensions, clamps, adapters and caps exposed for access by the staff. Wound dressings should not be placed over the exit site as it must not swell, shower, or soak dressings while dressing.

CAUTION: If adhesion of dressing is compromised by profuse perspiration or accidental wetting, the dressing must be changed by the medical or nursing staff under sterile conditions.

Management of Lumen Obstruction

Lumen obstruction is usually evident by failure to aspirate blood from the lumen, inadequate blood flow, and resistance pressures during hemodialysis. The causes may include inadequate catheter tip position, catheter kink and clot. If restenosis following the obstruction:

Verify that the clamps are open when trying to aspirate or flush the catheter lumen.

Replace the patient catheter.

Have the patient cough.

CAUTION: There is no resistance, flush the catheter vigorously with sterile normal saline. Never forcibly flush an obstructed lumen. If either lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may consider using a thrombus dissolving solution (i.e. TPA) to dissolve the clot.

Remove the catheter (Note: Do not use a sharp, jerking motion or undue force; this may tear the catheter.)

CAUTION: When removing the catheter, DO NOT use a sharp, jerking motion or undue force; this may tear the catheter.

How Supplied

UltraStream™ Chronic Hemodialysis Catheters are sterilized by ethylene oxide or ethylene oxide/gamma irradiation. They are supplied non-sterile and under sterile conditions.

Do not use catheter if package has been damaged or has been opened.

Storage Store at room controlled temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that catheters are used prior to the expiration date on the package label.

References

• Lebanc, M. BoscJ, Papagiannis, E. Conabu, Central Venous Dialysis Catheter Dysfunction, Advances in Renal Replacement Therapy, 1997; 437-439.
• National Kidney Foundation Dialysis Outcomes Quality Initiative (DOQI).

Priming Volume:

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<th>Tip to Hub Length</th>
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<th>Venous Volume</th>
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