ESCHELON®
LONG-TERM HEMODIALYSIS
CATHETER
INSTRUCTIONS FOR USE

INSTRUCTIONS FOR USE:

- The Eschelon® Catheter is indicated for use in Long-Term access for Hemodialysis and Apheresis.
- It may be inserted percutaneously and is primarily placed in the internal jugular vein.
- Alternate insertion sites include subclavian vein as required.

CONTRAINDICATIONS:

- This catheter is intended for Long-Term use only and should not be used for any purpose other than indicated in the instructions.

- The versatile Eschelon® Catheter offers split distal tips to form internal lumens to help eliminate catheter occlusion by the vessel wall.
- The Eschelon® Catheter is manufactured from soft radiopaque polyurethane material which increases patient comfort and well-being while providing excellent biocompatibility. The catheter lumens may be split no greater than 55% from lumen tip.

INDICATIONS FOR USE:

- Retroperitoneal bleed
- Right Atrial Puncture
- Septicemia
- Subclavian Artery Puncture
- Subcutaneous Hematoma
- Thrombophlebitis
- Tunnel Infection
- Vascular Thrombosis

WARNING:

- In the rare event that a hub or connector is separate from the components during insertion or use, take all necessary steps to prevent blood loss or air embolism and remove catheter.
- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire /stylet forcibly from any component. The wire may break or unravel. If the guidewire becomes damaged, the guidewire is removed and the guidewire inserted needle, Vascu-Shield® intima guard, dilator, or stylet must be removed.
- Federal Law (USA) restricts the device to sale by or on the order of a physician.
- This catheter is for Single Use Only.
- Do not re-sterilize the catheter or accessories by any method.
- Re-use may lead to infection or injury.
- The manufacturer shall not be liable for any damage caused by reuse or re-sterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in vacuum-sealed envelopes. STERILIZED BY ETHYLENE OXIDE GAS.
- Use only Medcomp® Lock Right® Adapters with this catheter.
- Do not use sharp instruments near the extension tubing or catheter hub.
- Do not use air in the catheter.
- Do not use catheter or accessories if they are damaged or impaired.
- Do not use catheter or accessories if the stylet cap is open or damaged.
- Do not use catheter or accessories if any sign of product damage is visible.

CATHETER PRECAUTIONS:

- Use have patient lift his/her head from the head to define the sternomastoid muscle.
- Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three finger breadths above the clavicle. The catheter should be palpatied medially to the point of catheter insertion.
- Subclavian Vein

- Tape injection caps between treatments to prevent accidental removal.
- Do not clamp arterial extension when stylet is in catheter.
- To prevent accidents, assure the security of all caps and blood connections prior to and during treatments.
- Use only Luer Lock® (Hemmed) Connectors with this catheter.
- Repeated use of the subclavian vein may be associated with subclavian vein stenosis.

INTERNAL JUGULAR VEIN

- Note the position of the subclavian vein, which is posterior to the clavicle, superior to the first rib, and anterior to the subclavian artery. (A point just lateral to the angle made by the clavicle and the first rib.)

WARNING:

- Patients requiring ventilator support are at increased risk of pulmonary embolism creating subclavian vein cannulation, which may cause complications.
- Extended use of the subclavian vein may be associated with subclavian vein stenosis.

Tip Placement

- Slide catheter tubing sleeve over the catheter making certain that the sleeve covers the arterial holes of the catheter. Insert into the vein and create a short subcutaneous tunnel. Do not pull all the way through muscle, the catheter should be made with care in order to prevent damage to surrounding tissue.

INSERTION SITE:

- Warning: Physician discretion is strongly advised when inserting this catheter in patients who are unable to take or feel a deep breath.
- The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion site. A small rolled towel may be inserted between the shoulders blazes to facilitate the extension of the chest area.

INSERTION SITE:

- Confirm initial position of catheter with chest x-ray. Routine x-ray should always follow the initial insertion of this catheter to verify tip placement.
- Remove the catheter from the trocar and sleeve.
- Keep trocar straight to prevent damage to catheter tip.
- Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion. Reconfirm the guidewire’s position.
- Do not tunnel out at an angle. Keep trocar straight to prevent damage to catheter tip.

DIRECTIONS FOR SELDIER INSERTION:

- Read instructions carefully before using the Catheter. The Cathether should be used, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.
- The medical techniques and procedures described in these instructions for use do not represent all medically acceptable practices; they are intended as a substitute for the pharmacist’s experience and judgment in treating any specific patient.
- Use standard hospital protocols when applicable.

- 1. Slight asteptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. The Operating Room is the preferred location for catheter placement. Use sterile gloves, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gloves, gown, caps, and mask. Have patient wear mask.
- 2. The length of the proximal catheter length is at the site discretion of the physician. To achieve proper tip placement, proper catheter length selection is important. Routine x-ray should always follow the initial insertion of this catheter to confirm proper placement prior to use.
- 3. Administer sufficient local anesthetic to completely anesthetize the insertion site.
- 4. Make a small incision at the exit site on the skin about a wall paperclip thickness below the clavicle. Make a second incision above the first incision in the same location. Make the incision at the exit site wide enough to accommodate the cuff, approximately 1cm.
- 5. Use blunt dissection to create the subcutaneous tunnel opening. If catheter containing a stylet, unthread stylet cap and slide into tip the arterial lumen until the tip is no longer visible. Attach venous lumen to trocar.
- 6. Lead catheter into the tunnel gently. Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion. Reconfirm the guidewire’s position. Reconfirm the guidewire’s position.
- 7. Push styelt back into lumen and tighten styelt cap onto arterial lumen trocar. The catheter tip is oval into the vessel to Kinking, the guidewire may break or unravel. If the guidewire wire may break or unravel. If the guidewire has become damaged, the guidewire is removed and the guidewire inserted needle, Vascu-Shield® intima guard, dilator, or stylet must be removed.
- 8. Irrigate catheter with saline, then clamp venous extensions and cap stylet to assure that the catheter is not inadvertently drained of saline from lumens. Use clamp and injection cap provided.
- 9. Insert the introducer needle with attached stylet into the target vein. Aspire to insure proper placement.
- 10. Remove the syringe and place thumb over the end of the needle to prevent blood loss or air embolism. Draw flexible end of guidewire back into advance so that only the end of the guidewire is visible. Insert advancement into the vein. Advance guidewire with forward motion into and past the needle hub into the target vein.
- 12. Thread guidrility over guidewire into the vessel (a slight twisting motion may be used). Remove dilator to reduce resistance and sufficiently dilated, leaving guidewire in place.
- 13. Insufficient tissue dilation can cause complications. The catheter must be advanced against the guidewire causing difficulty in the insertion and removal of any purpose other than indicated in the instructions.

CATHETERS:

- Do not leave vessel dilator(s) in place as an indwelling catheter to avoid possible vessel wall perforation.
- Thread the proximal end of the guidewire through the chest wall approximately 8-10cm from the chest. The guidewire should be positioned at the level of the caval atrial junction or into the right atrium to ensure proper placement.
- Once the guidewire exits through the subclavian or the internal jugular site, the catheter is positioned within the catheter. If the guidewire is allowed to pass into the right atrium, there is a potential for kinking. This may result in potential connector complications.
- Do not advance guidewire with catheter into vein. Cardiac arrhythmias may result in serious trauma or fatal complications.
- Remove the guidewire and stylet leaving catheter in place.
- Make any adjustments to catheter under fluorescopy. The venous distal tip should be positioned at the level of the caval atrial junction or into the right atrium to ensure proper placement.
- Attach syringes to both extensions and open clamps. Blood should escape from both lumens and sides. If neither side either side exhibits excessive resistance to blood aspiration, the catheter may need to be removed and repositioned to obtain adequate blood flow.
- Once adequate aspiration has been achieved, the catheter is supplied with saline filled syringes using syringe adapters. Ensure that extensions and catheter are clamped at all times, not in use and by removing the catheter from its container with saline prior to each use. With each catheter cleaning connector, purge air from the catheter and all connecting tubing and caps.
- To maintain patency, a heparin lock must be maintained at both lumens. See your hospital heparinization guidelines.
- Close the extension clamps, remove the syringes, and place an injection cap on each luer lock connector. Avoid air entrapment by keeping extension clamps clamped at all times. Do not use any device to keep the catheter irrigated without saline prior to each use. With each catheter cleaning connector, purge air from the catheter and all connecting tubing and caps.
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CATHETER SECUREMENT AND WOUND MANAGEMENT

3. Attach a syringe containing heparin solution to the female luer of each extension.
4. Open extension clamps.
5. Aspire to ensure that no air will be forced into the patient.
6. Insert heparin into each lumen using quick bulk technique.
   Note: Each lumen should be completely filled with heparin to ensure effectiveness.
7. Close extension clamps.

CATHETER REMOVAL

1. Remove dilator with injection cap from sheath.
2. Insert distal tip of catheter into and through the sheath until catheter tips are correctly positioned in the target vessel.
3. Remove the tear-away sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).
4. Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible toward the sheath exit site.
5. Repeat for second adapter.

CATHETER PERFORMANCE

Warning: Only a physician familiar with the appropriate techniques should attempt the following procedures.

INSERTION WITHOUT STYLET

1. Remove stylet from catheter.
2. Irrigate catheter with saline, then clamp catheter extensions.
3. Insert introducer needle as directed in Insertion Section.
4. Thread Vascu-Sheath® adapter into the collar section of the Lock Right® adapter into the receiving grooves of the StatLock® pad. Repeat for second adapter.
5. Install injection cap over dilator opening of the catheter and extracorporeal circuits should be examined carefully.
6. Insertion Section.

INTESTICE

Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

Sterilely inspect each lumen, including the catheter hub, for air, bubbles, or other debris. Using clamps provided, do not inadvertently drained from the lumens.

If excessive blood loss may lead to patient shock.

Remodelysis should be performed under physician’s instruction.

Catheter removal

1. Place the catheter exit tunnel to locate the catheter exit site.
2. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.
4. Make a 2cm incision over the cuff, parallel to the catheter insertion site.
5. Dissect down to the cuff using blunt and sharp dissection as indicated.
6. When viable, grasp cuff with clamp.
7. Clamp catheter between the cuff and the insertion site.
8. Use by Date* • Do Not Re-use* • Consult Instructions for Use * • Do Not Use if Package is Damaged

SYMBOL TABLE

- © is a registered trademark of C.R. Bard, Inc.
- ™ is a trademark of Medical Components, Inc.
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WARRANTY

Medcomp® warrants that this product was manufactured according to applicable standards and specifications, patient condition, clinical treatment, and product manufacture may affect the performance of this product. Use of this product should be in accordance with the instructions provided and as directed by the prescribing physician.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents without notice.

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