Never forcibly flush a clotted lumen. If either lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may attempt using a thrombolytic agent.

SITE CARE

Warning: DO NOT use iodine or iodine based products on this catheter. Alcohol based solutions are recommended as the antiseptic solution that can be used on this catheter.

Warning: DO NOT use ointments of any kind with this catheter.

Clean the skin around the catheter. Cover each exit site with occlusive dressing and leave the extensions, clamps, adapters and caps exposed for access by the staff.

Wound dressings must be kept dry. Patient must not swim, shower, or soak dressing while bathing. 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.

INSUFFICIENT FLOWS

Excessive force should not be used to flush an obstructed lumen. Insufficient blood flow may be caused by occluded arterial holes resulting from a clot or by side holes contacting the wall of the vein. If reversing arterial and venous lines does not help, then the physician may attempt to dissolve the clot with a thrombolytic agent. Physician discretion is advised.

MANAGEMENT OF ONE-WAY OBSTRUCTION

One way obstructions exist when a lumen can be flushed easily but blood cannot be aspirated. This is usually caused by tip malposition. One of the following adjustments may resolve the obstruction:

-Reposition the patient.

-Have the patient cough.

-***Provided there is no resistance***, flush the catheter vigorously with sterile normal saline to try to move the tip away from the vessel wall.

WARNING:
ONLY A PHYSICIAN FAMILIAR WITH THE APPROPRIATE TECHNIQUE SHOULD ATTEMPT THE FOLLOWING PROCEDURES

-Reverse the bloodlines. If the previous methods fail to resolve a one-way obstruction, the patient may be dialyzed by connecting the arterial bloodline to the venous adaptor and the venous bloodline to the arterial adapter. A significant increase in recirculation may occur.

-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 thrombolytic agent to dissolve the clot.

INFECTION

Due to the risk of 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 the entire procedure.

Clinically recognized infection at the catheter site should be treated with an appropriate antibiotic. If a fever occurs in a patient with a catheter in place, take at least two blood cultures from a site distant from the catheter site. If a blood culture is positive, the catheter should be removed and appropriate antibiotic therapy initiated. Wait 48 hours before inserting another catheter. Insertion should be made only on the side opposite the site which became infected.

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY EFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

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medCOMP®
1499 Delp Drive
Harleysville, PA 19438
Tel:215-256-4201
Fax:215-256-1787
www.medcompnet.com

CE 0434

medCOMP®

Tesio® CATHETER WITH CUFF

INDICATIONS FOR USE

The Medcomp® Tesio® Catheter is designed for long term hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein. Although this catheter may be inserted into the subclavian vein, the internal jugular vein is the preferred site.

CONTRAINDICATIONS

This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels.

To maintain peak performance of the Lock Right® Adapters, it is recommended that the adapters be replaced every 6 months.

POTENTIAL COMPLICATIONS

AIR EMBOLISM
BACTEREMIA
CARDIAC ARRHYTHMIA
CARDIAC TAMPONADE
CENTRAL VENOUS THROMBOSIS
ENDOCARDITIS
EXIT SITE INFECTION
EXSANGUINATION
HEMATOMA
HEMORRHAGE
LACERATION OF THE VESSEL
LUMINAL THROMBOSIS
PERFORATION OF THE VESSEL
PNEUMOTHORAX
RETROPERITONEAL BLEED
RIGHT ATRIAL PUNCTURE
SEPTICEMIA
SUBCLAVIAN ARTERY PUNCTURE
SUBCUTANEOUS HEMATOMA
SUPERIOR VENA CAVA PUNCTURE
THORACIC DUCT LACERATION
TUNNEL INFECTION
VASCULAR THROMBOSIS

Before attempting the insertion, ensure that you are familiar with the above complications and their emergency treatment should any of them occur.

In the rare event that a hub or connector separates from any component during the insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and, if possible, replace extension or remove catheter.

Do not advance the guidewire or catheter if unusual resistance is encountered. Do not insert or withdraw the guidewire forcibly from any component. The wire could break or unravel, in which case both the catheter and guidewire must be removed simultaneously.

WARNINGS

Federal law (USA) restricts the device to sale by or on the order of a physician.

Single use only. Do not resterilize the catheter or accessories by any method. The manufacturer will not be liable for any damages caused by re use or resterilization of the catheter or accessories. Re-Use may lead to infection or illness/injury. SINGLE USE ONLY

Contents sterile and non-pyrogenic in unopened, undamaged package.

Sterilized by Ethylene Oxide. STERILE | EO

Do not use catheter if package is damaged or has been opened. Do not use if catheter or components show signs of damage (crimped, crushed, cut, etc.).

CATHETER PRECAUTIONS

Do not use sharp instruments near the extension lines or tubing. Do not use scissors to remove dressing, as this could possibly cut or damage catheter. Do not suture through any part of the catheter. Catheter tubing can tear when subjected to excessive force or rough edges.

Use only smooth jawed forceps for clamping when not using the clamp supplied with the catheter. We recommend using only line extension clamps which have been provided for clamping. Clamping the catheter 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 adaptor and hub of the catheter. Do not clamp the lumen portion of the catheter. Clamp only the extensions. Examine tubing for damage at the end of each treatment.

To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.

It is recommended that only luer lock (threaded) connections be used with this catheter (including syringes, bloodlines, IV tubing, and injection caps). Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure. Inspect the catheter frequently for nicks, scrapes, cuts, etc. which could impair its performance.

When cutting catheter to desired length, assure that lumen is cut square and that the remaining catheter lumen is not damaged.

EU REPRESENTATIVE: MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels
Germany

INSERTION SITES

IMPLANTATION
This catheter is intended to be left in place for as long as it is clinically required; however, it can be removed at the discretion of the attending physician.

JUGULAR
Have the patient lift his/her head from the bed 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 carotid artery should be palpated medial to the point of catheter insertion.

Confirm final position of catheter with chest x-ray. Routine x-ray should always follow the intial insertion of this catheter to confirm proper placement prior to use.

SUBCLAVIAN
The patient should be in a modified Trendelenberg position, with the upper chest exposed and the head turned slightly to the side opposite that of the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area. Note the position of the subclavian vein which is posterior to the clavicle, superior to the first rib and anterior to the subclavian artery. (At a point just lateral to the angle made by the clavicle and the first rib).

NOTE: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation. Long time use of the subclavian vein may be associated with subclavian vein stenosis.

DIRECTIONS FOR SELDINGER INSERTION:

Read instructions carefully before using this device. The catheter should be inserted, manipulated, and removed only by a qualified, licensed physician or other health care practitioner, authorized by and under the direction of such physician. The medical techniques and procedures described in these instructions do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgement in treating any specific patient. Use standard hospital protocols.

1. Strict aseptic technique must be used during the insertion, maintenance, and catheter removal procedures. Provide a sterile operative field. The operating room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have the patient wear a mask.

2. The selection of the appropriate cannula length is at the sole discretion of the physician. To achieve proper tip positioning, 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. Insert the introducer needle with attached syringe into the selected vein site. Aspirate to insure proper placement.

5. Remove the syringe, placing thumb over the end of the needle to prevent blood loss or air embolism. Insert the flexible end of the guidewire through the needle and into the vein. Insert distal end of guidewire advancer into needle end. Advance guidewire with thumb in a forward movement through the needle and into the vein.

Caution: The length of wire inserted is determined by the size of the patient. Monitor patient for signs of arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmia may result if the guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

Caution: When introducer needle is used, do not withdraw guidewire against needle bevel to avoid possible severing of guidewire.

6. Remove needle, leaving guidewire in the vessel. Enlarge cutaneous puncture site with scalpel.

7. Introduce the second needle and guidewire into the same vein (approximately 3mm adjacent to the first) and remove needle leaving the guidewire in place.

8. Thread Vascu-Sheath® introducer over one guidewire into the vessel (a slight twisting motion may be used). Remove dilator and guidewire, leaving sheath in place. The catheters are irrigated with heparinized saline-filled syringes. The syringes are removed and the extensions are clamped.

Caution: DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted.

Caution: Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.

9. Insert the distal tip of the catheter into and through the sheath and into the vein until the tip is correctly positioned.

10. Remove the tear-away sheath by slowly pulling the sheath out of the vessel and begin to split the sheath by grasping the tabs and pulling them apart.

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 and tear the sheath only a few centimeters at a time. Continue in this manner until the sheath is completely removed from the vessel, and then completely tear apart the sheath and discard.

11. Repeat steps 8-10 for second catheter insertion.

12. Make any adjustments to catheter position under fluoroscopy. The venous distal tip should be positioned at the level of the caval atrial junction or into the right atrium, and approximately 4cm past the arterial catheter.

13. Administer sufficient local anesthetic to completely anesthetize the tunnel site.

NOTE: For ease in dressing the exit site and for patient comfort, locate the subcutaneous tunnel below the vessel entry site. A tunnel with a wide gentle arc lessens the risk of kinking. The tunnel should be short enough to keep the luer adaptor of the catheter from entering the exit site, yet long enough to keep the cuff at least 2cm minimum from the skin opening.

14. Remove tesio plug from lumen proximal end.

15. Attach the threaded trocar to the end of the catheter. Trocar is inserted using a clockwise motion. Insert the trocar into the vein insertion site and create a short subcutaneous tunnel. Do not tunnel through the muscle. The tunnel should be made with care in order to prevent damaging surrounding vessels and/or adjacent catheter. Lead catheter into the tunnel gently, making the tunnel approximately 8-10cm in length. Catheter cuff should lie at the top of the tunnel, under the subcutaneous tissue. Do not pull or tug the catheter tubing. If resistance is encountered, further dissection may facilitate insertion. Remove the catheter from the trocar.

16. If necessary, using aseptic technique, cut catheter squarely (with no points) at one end of the designated priming volume lines, and in such a manner that produces a clean smooth surface.

17. Place adaptors onto catheters (see instructions).

18. Attach syringes on both extensions and open clamps. Blood should aspirate easily from both venous and arterial sides. If either side exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to sustain adequate blood flow. Once adequate blood flow has been established, both lumens are irrigated again with saline-filled syringes. It is necessary to open the extension clamps during the irrigation procedure. Clamp the extensions, remove the syringes, and place an injection cap on each luer lock connector. Avoid air embolism by keeping catheter tubing clamped at all times when not in use and by filling the catheter with saline prior to use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.

CAUTION: DO NOT CLAMP THE LUMEN PORTION OF THE CATHETER. CLAMP ONLY THE CLEAR EXTENSIONS. DO NOT USE SERRATED FORCEPS, USE ONLY THE IN-LINE CLAMP(S) PROVIDED.

19. Immediately after insertion, confirm proper placement of the tip of the catheter with x-ray. The venous distal tip should be positioned at the level of the caval atrial junction or into the right atrium, and approximately 4cm past the arterial catheter.

Caution: Failure to verify catheter placement may result in serious trauma or fatal complications.

Record indwelling catheter length and lot number on patient's chart and check position routinely.

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. In the rare event of a leak, the catheter should be clamped immediately. Necessary remedial action must be taken prior to resuming dialysis procedure. Excess blood leakage may lead to patient shock.

CATHETER REMOVAL

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

Caution: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter removal.

1. Palpate the catheter exit tunnel to locate the cuff.
2. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.
3. Repeat for second catheter.
4. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
5. Make 2cm incision over the cuff, parallel to the catheter.
6. Dissect down to the cuff using blunt and sharp dissection as indicated.
7. When visible, grasp cuff with clamp.
8. Clamp catheter between the cuff and the insertion site.
9. Cut catheter between cuff and exit site. Withdraw internal portion of catheter through the incision in the tunnel.
10. Remove remaining section of catheter (i.e. portion in tunnel) through the exit site.

Caution: Do not pull distal end of catheter through incision as contamination of wound may occur.

11. Apply pressure to proximal tunnel for approximately 10-15 minutes or until bleeding stops.
12. Suture incision and apply dressing in a manner to promote optimal healing.

HEPARINIZATION

If the catheter is not used immediately for treatment, follow the suggested catheter patency guidelines:

- To maintain patency between treatments, a heparin lock must be created in each lumen of the catheter.
- **INJECT A HEPARIN SOLUTION INTO EACH LUMEN OF THE CATHETER. WHEN INJECTING THE HEPARIN, INJECT QUICKLY TO ENSURE THAT THE HEPARIN COMPLETELY FILLS THE LUMEN OF THE CATHETER. THE TOTAL VOLUME OF EACH HEPARIN SOLUTION SHOULD BE EQUAL TO THE INTERNAL VOLUME OF EACH LUMEN. EACH LUMEN MUST BE COMPLETELY FILLED WITH A HEPARIN SOLUTION.**
- Clamp the arterial and venous extension pieces, remove syringe, and attach a sterile injection cap to each luer lock connector. Once the lumina have been heparinized, keep both extensions clamped when not attached to bloodlines or a syringe. If either clamp is opened, blood may enter the distal portion of the catheters, ultimately causing a thrombus.
- In most instances, no further heparin is necessary for 48-72 hours, provided the catheter has not been aspirated or flushed.
- The heparin solution must be removed from each lumen prior to treatment to prevent systemic heparinization of the patient. Aspiration should be based on dialysis unit protocol.

To maintain catheter patency, ensure that a sufficient heparin concentration is used. Since this concentration may vary from institution to institution, please consult your hospital protocol.

Before infusing fresh heparin, aspirate indwelling heparin and flush each lumen with sterile normal saline.