The Medcomp Tri-Flow™ Triple Lumen Hemodialysis Catheters INSTRUCTIONS FOR USE

INDICATIONS FOR USE:
- The Medcomp® Tri-Flow™ Catheter is indicated for use in obtaining Short-Term vascular access for Hemodialysis and Apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternatively insert into the subclavian vein or femoral vein as required. The Tri-Flow™ Catheter is intended to be used in less than 10 days.

CONTRAINDICATIONS:
- This catheter is intended for Short-Term vascular access only and should not be used for any purpose other than indicated in these instructions. Do not insert catheter in thrombosed vessels.

DESCRIPTION:
- The Tri-Flow® Catheter lumen is manufactured from thermoplastic material which provides increased patient comfort while providing excellent biocompatibility.

POTENTIAL COMPLICATIONS:
- Air Embolism
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac tamponade
- Central Venous Thrombosis
- Echocardiogram
- Site Infection
- Necessitating Arterial Bleed
- Femoral Artery Bleed
- Femoral Nerve Damage
- Hemorrhage
- Hemotherax
- Intra-Artic Thrombosis
- Inferior Vena Cava Phlebitis
- Laceration of the Vein
- Lymphedema
- Mediastinal Injury
- Perforation of the Vein
- Pleural Injury
- Pneumothorax
- Venous Thromboembolism
- Right Atrial Septum Puncture
- Septicemia
- Subclavian Artery Puncture
- Subclavian Venous Hematoma
- Superior Vena Cava Phlebitis
- Thrombotic Duct Laceration
- Venous Thrombosis
- Venous Sternosis

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

WARNINGS:
- In the rare event that a hub or connector becomes unsecured or any component becomes unlocked during use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter.

SUBCLAVIAN VEIN:
- Do not advance the guidewire or catheter if you are not familiar with the above complications.
- Do not insert or withdraw the guidewire forcibly from any component. The wire may break with this procedure. If the guidewire becomes damaged, the catheter and guidewire must be removed together.
- 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 resterilize the catheter or accessories by any method.
- Re-use may lead to infection or illness/injury.
- The manufacturer shall not be liable for any damages caused by re-use or re-sterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in solution; use before stated expiration date.

STERILE (EO):
- Do not use catheter or accessories if package is damaged.
- Do not use catheter or accessories if any sign of product damage is visible.

CATHETER PRECAUTIONS:
- Do not use sharp instruments near the extension tubing or catheter lumen.
- Do not use scissors to remove dressing.

Catheter will be damaged if clamps other than the catheter manufacturer-supplied clamps are used.
- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the hars and hub of the catheter.
- Examine catheter lumen and extensions before and after each treatment for damage.
- To prevent accidents, secure the security of all caps and bloodline connections prior to and between treatments.
- Use only Luer Lock (threaded) Connectors with this catheter.
- Repeated over tightening of bloodlines, syringes, and caps will peel-pull the catheter from the insertion site and could lead to potential connector failure.

INSERTION SITES:
- Complete anesthetize the insertion site.
- Have patient lift his/her head from the bed to define the sternomastoid muscle.
- Cannulation will be attempted at the apex of a triangle formed between the two heads of the sternomastoid muscle and the clavicle. The clavicle should be approximately 3 fingers breadth above the clavicle. The clavicle should be palpated medially to the point of catheter insertion.

INTERNAL/JUGULAR VEIN:
- Note the position of the subclavian vein, which is in the axilla, approximately 1 inch from the first rib, and anterior to the subclavian artery. (See illustration made by the clavicle and the first rib.)

Warning: Patients requiring ventilator support are at increased risk of puncturing during subclavian vein cannulation, which may cause complications.

Warning: Extended use of the subclavian vein may be associated with subclavian vein stenosis.

PENCORAL VEIN:
- The patient should lie completely on his/her back. Both femoral arteries should be palpated for site selection and consequence assessment. The knee on the same side if the incision site should be fixed and the abdomen flat. Flat palpation across the anterior iliac crest. This femoral vein is then palpatable posterior to the artery.

Complications of infection may be increased with femoral vein insertion.
- Confirm final position of catheter with chest x-ray. Routine x-ray should always be performed when a guidewire against needle heel to avoid possible severing of guidewire.

CATHETER INSERTION:
- Do not leave vessel dialyzer in place as an occlusion catheter to avoid possible vessel wall perforation.
- Irrigate catheter with saline, then clamp catheter. Catheter extension tubing and vein wall to allow easy passage of catheter into target vein.
- Insufficient tissue dilation can cause compression of the catheter lumen against the chest wall or extremity. Dilation may be determined by the size of the patient. Monitor cardia and check for any unusual resistance.
- Failure to do so may result in air embolism.
- Care must be taken when using sharp objects or needles in close proximity to catheter lumens. Contact from sharp objects may cause catheter failure.
- Cover the insertion site with an occlusive dressing.
- Catheter must be secured/natural for entire duration of implantation.
- Record catheter length and catheter lot number on patient's chart.

HEMODIALYSIS TREATMENT:
- The heparin solution must be removed from each catheter prior to treatment to prevent any type of mechanical or chemical intervention in the catheter.
- Systemic heparinization of the patient.
- Heparin should be based on dialysis unit protocol.
- Before dialysis begins all connections to catheter and extracorporeal circuits should be examined carefully.
- Frequent visual inspection should be conducted regularly to limit to prevent blood loss or air embolism.
- If it is leak, the catheter should be clamped immediately.
- Only clamp catheter in-line clamps provided.
- Necessary remedial action must be taken prior to the continuation of the dialysis treatment.

SITE CARE:
- Clean skin around catheter. Cover the exit site with occlusive dressing and leave extensions, clamps, and dressing exposed for access to arm.
- Wound dressings must be kept clean and dry.
- Patients must not swim, shower, or wear dressing while bathing.
- If parous peritoneal or arterial cannulation, the patient must be monitored closely by medical or nursing staff must change the dressing as needed.

CATHETER PERFORMANCE:
- Always review hospital or unit protocol, potential complications, contraindications, warnings, and precautions prior to undertaking any type of mechanical or chemical intervention in response to patient complications.

WARNING: Only a physician familiar with the specific patient's condition should attempt the following procedures.

INSUFFICIENT FLOWS:
- The following may cause insufficient flows:

- Occluded proximal holes due to clotting or fluid back up.
- Occlusion of the side holes due to contact with vein wall.

- Solutions include:
- Chemical intervention utilizing an anti-thrombolytic agent.

MANAGEMENT OF ONE-WAY OBSTRUCTIONS:
- One-way obstruction exists when a lumen can be flushed easily but blood cannot be aspirated. This is usually caused by tip malposition.

1. Draw heparin into syringes, corresponding to the renal resistance on each extension. Ensure that the syringes are free of air.
2. Remove end caps from the extensions.
3. Attach a syringe containing heparin solution to each lumen of each extension.
4. Open extension clamps.
5. Aseptically to ensure that no air will be forced into the patient.
6. Inject heparin into each lumen using quick injection techniques.

Note: Each lumen should be completely filled with heparin to ensure effectiveness.

7. Close extension clamps.

Extension clamps should only be open for supply of dialysis solutions.
8. Remove syringes.

9. Attach a sterile end cap onto the female luer of the extensions.

10. In most instances, no further heparin is necessary during the treatment, provided the patient's veins have not been aspirated or flushed.

SITE CARE:

16. Close the extension clamps, remove the catheter from the patient, and after each treatment for damage.
12. Make any adjustments to catheter under fluoroscopy. The distal tip should be located just beyond the junction of the superior vena cava and the right atrium.
13. Once proper placement is confirmed, remove any access cannula from the catheter to confirm proper placement prior to use.

Warning: If not in use immediately for treatment, follow the suggested catheter care protocol.

- Hemodialysis should be performed under physician’s instructions.

SITES FOR INSERTION:
- Patients requiring ventilator support are at increased risk of puncturing during subclavian vein cannulation, which may cause complications.
- If profuse perspiration or accidental wetting of the catheter hub or venous tip should be examined carefully.
- Patients requiring ventilator support are at increased risk of puncturing during subclavian vein cannulation, which may cause complications.
- Caution: Failure to verify catheter placement may result in serious trauma or fatal complications.
- If the guidewire is allowed to pass into the right atrium, the guide wire should be retracted into the right atrium.
- Catheter must be secured/natural for entire duration of implantation.
- Record catheter length and catheter lot number on patient's chart.

HEMODIALYSIS TREATMENT:
- The heparin solution must be removed from each catheter prior to treatment to prevent any type of mechanical or chemical intervention in the catheter.
- Systemic heparinization of the patient.
- Heparin should be based on dialysis unit protocol.
- Before dialysis begins all connections to catheter and extracorporeal circuits should be examined carefully.
- Frequent visual inspection should be conducted regularly to limit to prevent blood loss or air embolism.
- If it is leak, the catheter should be clamped immediately.
- Only clamp catheter in-line clamps provided.
- Necessary remedial action must be taken prior to the continuation of the dialysis treatment.

Note: Excessive blood loss may lead to patient shock.
- Hemodialysis should be performed under physician’s instructions.

SEPARATION:
- If the catheter is not to be used immediately for treatment, follow the suggested catheter care protocol.

- To maintain patency between treatments, a heparin lock must be created in each lumen of the catheter.
- Follow hospital protocol for heparin concentration.
One of the following adjustments may resolve the obstruction:

- Reposition catheter.
- Reposition patient.
- Have 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.
- 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 adapter and the venous bloodline to the arterial adapter. A significant increase in recirculation may occur.

INFECTION:

Caution: 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.

- Sterile technique should always be strictly adhered to.
- Clinically recognized infection at a catheter exit site should be treated promptly with the appropriate antibiotic therapy.
- If a fever occurs in a patient with a catheter in place, take a minimum of two blood cultures from a site distant from catheter exit site. If blood culture is positive, the catheter must be removed immediately and the appropriate antibiotic therapy initiated. Wait 48 hours before catheter replacement. Insertion should be made on opposite side of original catheter exit site, if possible.

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.

2. Withdraw catheter through the exit site.
3. Apply pressure to exit site for approximately 10-15 minutes or until bleeding stops.
4. Apply dressing in a manner to promote optimal healing.

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE 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.

Medcomp is a registered trademark of Medical Components, Inc.

Tri-Flow™ is a trademark of Medical Components, Inc.

PN 004050BSI

REV. 2/19 B