medCOMP®

FOR T-3 CATHETER TRIPLE LUMEN HEMODIALYSIS, APHERESIS, AND INFUSION

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The Medcomp® T-3 Catheter is indicated for use in attaining Short-Term central venous access for Hemodialysis, Apheresis, and Infusion. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion site includes subclavian vein as required. The Medcomp® T-3 Catheter is indicated for a duration less than (30) 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.

DESCRIPTION

- The T-3 Catheter lumens are manufactured from radiopaque thermosensititive material which provides increased patient comfort while providing excellent biocompatibility.

POTENTIAL COMPLICATIONS:

- Air Embolus
- Bacteremia
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Central Venous Thrombosis
- Endocarditis
- Exit Site Infection
- Exsanguination
- Hematoma
- Hemorrhage
- Hemothorax
- Laceration of the Vessel
- Lumen Thrombosis
- Mediastinal Injury
- Perforation of the Vessel
- Pleural Injury
- Pneumothorax
- Retroperitoneal Bleed
- Right Atrial Puncture
- Septicemia
- Subclavian Artery Puncture
- Subcutaneous Hematoma
- Superior Vena Cava Puncture
- Thoracic Duct Laceration
- Vascular Thrombosis

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

WARNINGS

- In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the 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 may break or unravel. 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 re-sterilize 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 reuse or re-sterilization of this catheter or accessories.

- Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE

STERILE | EO

- Do not use catheter or accessories if package is opened or 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 what is provided with this kit are used.

- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the luers and hub of the catheter.

- Examine catheter lumen and extensions before and after each treatment for damage.

- To prevent accidents, assure 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 reduce connector life and could lead to potential connector failure.

- Do not infuse incompatible drugs simultaneously through the same lumen; precipitation could occur.

- Do not infuse against a closed clamp or forcibly infuse a blocked catheter.

INSERTION SITES

- The patient should be in a modified Trendelenberg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.

INTERNAL JUGULAR VEIN

- Have 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.

SUBCLAVIAN 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. (At a point just lateral to the angle made by the clavicle and the first rib.)

Warning:

- Patients requiring ventilator support are at an increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.

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

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

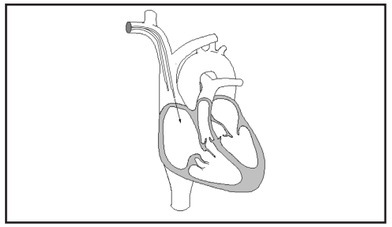
DIRECTIONS FOR SELDINGER INSERTION

- Read instructions carefully before using this device. The catheter should be inserted, 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 protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient. Use standard hospital protocols when applicable.

1. Strict aseptic 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 drapes, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have patient wear mask.

2. The selection of the appropriate catheter length is at the sole 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.

Tip Placement



3. Administer sufficient local anesthetic to completely anesthetize the insertion site.

4. Insert the introducer needle with attached syringe into the target vein. Aspirate to insure proper placement.

Note: If arterial blood is aspirated, remove the needle and apply immediate pressure to the site for at least 15 minutes. Ensure that arterial bleeding has stopped and hematomas have not developed before attempting to cannulate the vein again.

5. 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 advancer so that only the end of the guidewire is visible. Insert advancer's distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.

Caution: The length of the wire inserted is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if 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 the needle, leaving guidewire in the vessel. Enlarge cutaneous puncture site with scalpel to facilitate passage of the dilator and catheter.

7. Thread the dilator over the proximal end of the guidewire. Dilate subcutaneous tissue and vein wall to allow easy passage of catheter into target vein.

Caution: Insufficient tissue dilation can cause compression of the catheter lumen against the guidewire causing difficulty in the insertion and removal of the guidewire from the catheter. This can lead to bending of the guidewire.

8. Remove the dilator leaving the guidewire in place.

Caution: Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.

9. Irrigate catheter with saline, then clamp catheter extensions to assure that saline is not inadvertently drained from catheter. Use clamps provided.

Caution: Do not clamp the lumen portion of the catheter. Clamp only the extensions. Do not use serrated forceps, use only the in-line clamps provided.

10. Open distal extension clamp. Thread the catheter over proximal end of the guidewire.

11. Ease the catheter through the subcutaneous tissue and into the target vein.

Caution: Observe the patient carefully for signs and symptoms of cardiac arrhythmia caused by passage of the catheter into the right atrium. If symptoms appear, pull back the tip of the catheter until they are eliminated.

12. Make any adjustments to catheter under fluoroscopy. The distal tip should be located just before the junction of the superior vena cava and the right atrium.

13. Once proper placement is confirmed, remove guidewire and close slide clamp.

14. Attach syringes to all extensions and open clamps. Blood should aspirate easily from all lumens. If the lumens exhibit excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to obtain adequate blood flows.

15. Once adequate aspiration has been achieved, all lumens should be irrigated with saline filled syringes using quick bolus technique. Assure that extension clamps are open during irrigation procedure.

16. Close the extension clamps, remove the syringes, and place an injection cap on each luer lock connectors. Avoid air embolism by keeping extension tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.

17. To maintain patency, a heparin lock must be created in all lumens. Refer to hospital heparinization guidelines.

Caution: Assure that all air has been aspirated from the catheter and extensions. Failure to do so may result in air embolism.

18. Once the catheter is locked with heparin, close the clamps and install injection caps onto the extensions' female luers. To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.

19. Confirm proper tip placement with fluoroscopy. The distal venous tip should be located just before the junction of the superior vena cava and the right atrium.

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

CATHETER SECUREMENT AND WOUND DRESSING:

20. Suture the catheter to the skin using the suture wing. Do not suture the catheter tubing.

Caution: Care must be taken when using sharp objects or needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.

21. Cover the insertion site with an occlusive dressing leaving extensions, clamps, luers, and caps exposed for access by the staff.

22. Catheter must be secured/sutured for entire duration of implantation.

23. Record catheter length and catheter lot number on patient's chart.

HEMODIALYSIS TREATMENT

- The heparin solution must be removed from arterial and venous lumens prior to treatment to prevent systemic heparinization of the patient. Aspiration 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 to detect leaks to prevent blood loss or air embolism.

- If a leak is found, the catheter should be clamped immediately.

Caution: Only clamp catheter with in-line clamps provided.

- Necessary remedial action must be taken prior to the continuation of the dialysis treatment.

Caution: Excessive blood loss may lead to patient shock.

- Hemodialysis should be performed under physician's instructions.

INFUSION

- The heparin solution must be removed from infusion lumen prior to treatment to prevent systemic heparinization of the patient. Aspiration should be based on dialysis unit protocol.

- Before infusion begins all connections should be examined carefully.

- Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.

- If a leak is found, the catheter should be clamped immediately.

Caution: Only clamp catheter with in-line clamps provided.

- Necessary remedial action must be taken prior to the continuation of the infusion treatment.

Note: Excessive blood loss may lead to patient shock.

- Infusion treatment should be performed under physician's instructions.

HEPARINIZATION

- If the catheter is not to be 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.
- Follow hospital protocol for heparin concentration.

1. Draw heparin into syringes, corresponding to the amount designated on each extension. Assure that the syringes are free of air.
2. Remove injection caps from the extensions.
3. Attach a syringe containing heparin solution to the female luer of each extension.
4. Open extension clamps.
5. Aspirate to insure that no air will be forced into the patient.
6. Inject heparin into each lumen using quick bolus technique.

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

7. Close extension clamps.

Caution: Extension clamps should only be open for aspiration, flushing, and dialysis treatment. If clamp is opened, blood may enter the distal portion of the catheter, ultimately resulting in a thrombus.

8. Remove syringes.
9. Attach a sterile injection cap onto the female luers of the extensions.

- In most instances, no further heparin is necessary for 48-72 hours, provided the lumens have not been aspirated or flushed.

SITE CARE

- Clean skin around catheter. Cover the exit site with occlusive dressing and leave extensions, clamps, and caps exposed for access by staff.
- Wound dressings must be kept clean and dry.

Caution: Patients must not swim, shower, or soak dressing while bathing.

- If profuse perspiration or accidental wetting compromises adhesion of dressing, the medical or nursing staff must change the dressing under sterile conditions.

CATHETER PERFORMANCE

Caution: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to undertaking any type of mechanical or chemical intervention in response to catheter performance problems.

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

INSUFFICIENT FLOWS:

The following may cause insufficient blood flows:

- Occluded proximal holes due to clotting or fibrin sheath.
- Occlusion of the side holes due to contact with vein wall.

Solutions include:

- Chemical intervention utilizing a thrombolytic agent.

MANAGEMENT OF ONE-WAY OBSTRUCTIONS:

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 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.
- Never forcibly flush an obstructed lumen. If any lumen develops a thrombus, first attempt to aspirate the clot with a syringe. If aspiration fails, the physician may consider using appropriate agents or thrombolytic agents to dissolve the clot.

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.

1. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
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.

15.5F x 28cm PRESSURE

	300 ml/MIN	350 ml/MIN	400 ml/MIN
VENOUS	80 mmHg	100 mmHg	120 mmHg
ARTERIAL	-65 mmHg	-75 mmHg	-90 mmHg

FLOW RATE TESTING REPRESENTS OPTIMUM LABORATORY CONDITIONS

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 INACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

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SYMBOL TABLE

5.1.1	Manufacturer *
5.3.4	Keep Dry *
5.4.2	Do Not Re-use *
5.6.3	Non-pyrogenic *
5.3.2	Keep Away from Sunlight *
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide *
5.2.8	Do Not Use if Package is Damaged *
5.1.4	Use-by Date *
5.2.6 NON STERILE	Do Not Resterilize *
5.1.5 LOT	Batch/Lot Number *
5.1.6 REF	Catalogue Number *
5.4.4	Caution, consult Accompanying Documents *
5.4.3	Consult Instructions for Use*
Rx Only	Prescription Use Only ***
5.3.7	Upper and Lower Temperature Limits *

*** This symbol is in accordance with ISO 15223-1.**

***** FDA guidance Use of Symbols in Labeling.**

Note: Temperature symbols : "This symbol only applies to kits with drugs".

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