INDICATIONS FOR USE:
- The Triple Lumen Catheter is indicated for use as an alternate Venous vascular access for Hemodialysis and Apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.
- Alternate insertion into the subclavian, femoral, or carotid vein or femoral vein as required. The Triple Lumen Catheter is intended for Short-Term vascular access only and should not be used in most instances, no further heparin is necessary for treatment, follow the suggested catheter

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 Triple Lumen Catheter lumens are manufactured from thermosensitive material which provides increased patient comfort while providing excellent biocompatibility.

POTENTIAL COMPLICATIONS:
- Air Embolism
- Electrosurgical Injury
- Cardiac Arrhythmia
- Cardiac Perforation
- Central Venous Thrombosis
- Endocarditis
- Septic Vein
- Site Infection
- Evaluating Site
- Femoral Artery Bleed
- Femoral Nerve Damage
- Hematoma
- Hemorrhage
- Hemotherax
- Inferior Vena Cava Puncture
- Laceration of the Vein
- Venous Thrombosis
- Mediastinal Injury
- Perforation of the Vein
- Pleural Injury
- Pneumothorax
- Pulmonary Embolus
- Right Atrial Pleural Effusion
- Septic Site
- Subclavian Artery Puncture
- Subcutaneous Hematoma
- Superior Vena Cava Puncture
- Thrombus Duct Laceration
- Venous Thrombosis
- Venous Sternosis

WARNING:
- In the rare event that a hub or connector separates from any component due to insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter.

SUBLUARY 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. (The subclavian artery is the needle made by the clavicle and the first rib.)

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

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

FEMORAL 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 as the site should be flexed and the thigh abducted. Flat-footed position across the approach. This femoral vein is then palpated/medial to the anterior.

Content sterile and non-pyrogenic in sterilized by ethylene oxide.
- Do not re-stereilize the catheter or accessories by any method.

- Re-use may lead to infection or illness.
- The manufacturer shall not be liable for any damage caused by reuse or re-stereilization of this catheter or accessorize.

- Contents sterile and non-pyrogenic in sterilized by ethylene oxide.
- Do not re-stereilize the catheter or accessories if any sign of product damage is visible.

CATHERTER 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 are used. Handle the catheter carefully and do not manipulate, 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.

- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the hub and between the catheter.
- Examine catheter lumen 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 clamp caps can cause wall puncturing and could lead to potential connector failure.

INSERTION SITES:
- 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 area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the catheter insertion site.

INTERNAL JUGULAR VEIN
- Have patient lift his/her head from the bed to define the sternal mastoid muscle.
- Cannulation will be at the apex of a triangle formed between the two heads of the sternomastoid muscle. The sternum will be approximately two fingers breadth above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.

- Administer sufficient local anesthetic to completely anesthetize the site.
- Insert the introducer needle with attached syringe over the target vein. Aspirate to insure proper placement.

5. Remove the syringe and place through the end of the needle to prevent blood loss or air embolism. Draw flexible end of guidewire back to the hub so that air in the catheter is aspirated. Insert advanced's dial gives up to 2 ml of saline-filled needle into the hub made by the clavicle and the first rib.)

6. Remove the needle, leaving guidewire in the vascular access. Change the needle to an angiocath puncture set with a scalpel.

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

8. Remove the dilator leaving the guidewire in place.

9. Do not leave vessel dilator in place as an occlusive catheter to avoid possible vessel wall perforation.

10. Irrigate catheter with saline, then clamp catheter to prevent back flow. Do not irrigate in the absence of a heparin lock.

11. Thread catheter with saline, then clamp catheter to prevent back flow. Do not irrigate in the absence of a heparin lock.

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

13. Once proper placement is confirmed, remove dilator leaving only the guidewire.

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

15. Once adequate aspiration has been achieved, all lumens should be irrigated with a heparin syringe using quick bone technique. Ensure that all clamps are open during irrigation procedure.

16. Close the extension clamps, remove the syringes, and place an injection site into each luer lock connector. Avoid air embolism by lignifying extension tubing clamping sets using a clamp when net 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.

18. Once the catheter is locked with heparin, close all clamps and insert injection caps onto the extensions’ female lumen.

19. Confirm proper tip placement with fluoroscopy. The catheter tip should be located just past 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 SITE CARE
- 5. Attach a sterile injection cap onto the female luer lock connectors. Avoid air embolism by clotting surface.
- 6. Aspirate to insure that no air will be forced into the patient.
- 7. Irrigate into each lumen using quick bone technique.

10. If each lumen should be completely filled with heparin to ensure effectiveness.
- 12. Remove syringes.
- 13. Attach a sterile injection cap onto the female lumen of the extensions.

SITE CARE
- Clean skin around catheter. Cover the exit site with sterile dressing and leave extension, clamps, or tubes exposed for access at any time.
- Wound dressings must be kept clean and dry.
- Patients must not swim, shower, or use swimming or hair washing.
- If perfusion or arterial and venous complications develop, surgery of drainage, medical or nursing staff must change the dressing or tubing conditions.

CATHETER PERFORMANCE
- Always review hospital or unit protocol, patient-specific complications and warnings, and precautions prior to undertaking any type of medical or clinical intervention in response to catheter performance problems.

WARNING:
- Only a physician familiar with the specific catheter manufacturer’s instructions should attempt the following procedures.

INFUSION PROBLEMS:
- The following may cause insufficient blood flow:
  - Occluded proximal holes due to clotting or fibrin sheath.
  - Occlusion of the side holes due to contact with vein wall.
  - Infiltration of the drug

SOLUTIONS:
- Intravenous infections utilizing an anti-thrombolytic agent.

MANAGEMENT OF ONE-WAY OBSTRUCTIONS:
- One-way obstructions exist when a lumen is patent but blood flow is not permitted or desired. This is usually caused by tip malposition.
- To draw heparin into syringes, corresponding to the minimal resistance on each extension.
- Assure that the syringes are free of air.
- Remove injection caps from the extensions.
- Attach a syringe containing heparin solution into the female lumen of each extension.
- Open extension clamps.
- Aseptically to assure that no air will be forced into the patient.
- Inject heparin into each lumen using quick bone technique.
  - In most instances, no further heparin is necessary beyond 72 hours, provided that lumens have not been aspirated or flushed.

This catheter is for Single Use Only. Do not re-sterilize the catheter or accessories if any sign of product damage is visible.
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 bloodborne 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.

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.

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WARNING

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