The Hemo-Flow® Dialysis Catheter is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis.

- It may be inserted percutaneously and should not be used for any purpose other than indicated in these instructions.

**DESCRIPTION:**

*The Hemo-Flow® Dialysis Catheter is manufactured from soft radiopaque polyurethane material which provides increased patient comfort while providing excellent biocompatibility.*

**INDICATIONS FOR USE:**

- Do not insert or withdraw the guidewire forcibly from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or traverser sleeve should be removed and a new one inserted, keeping the catheter in the vein.
- 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-stereilize 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.
- This catheter is for Single Use Only.

**CONTRAINDICATIONS:**

- Have patient lift his/her head from the bed to define the sternal soft tissue. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscles. The apex should be approximately three fingers breadth above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.
- Subclavian Vein

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

**DIRECTIONS FOR SEDLINGER 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 substitutes for the physician’s experience and judgement in treating any specific patient. It is the responsibility of the physician to evaluate the safety and efficacy of the patient-specific techniques selected.
- Use standard hospital protocols when applicable.

**INSERTION SITES:**

- The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head extended slightly to the side opposite the insertion area. A small roll of gauze should be inserted between the shoulder blades to facilitate the extension of the chest area.

- Internal Jugular Vein

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HEMODIALYSIS TREATMENT

- The heparin solution must be removed from each lumen prior to treatment to prevent systemic heparinization of patient. Aspiration should be based on dialysis unit protocol.
- Before dialysis begins all connections to catheter and extracorporeal circuits must be checked.
- 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.

Note: Excessive blood loss may lead to patient shock.

- Hemodialysis should be performed under physician’s instructions.

REHABILIZATION

- 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 two syringes, corresponding to the amount designated on the arterial and venous extensions. Insure 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.
8. Remove syringes.
9. Attach a sterile injection cap onto the female luer 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. Chlorhexidine gluconate solutions are recommended; however, iodine-based solutions can also be used.
- 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

Note: 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. Insert an .038” guidewire into and through the sheath until it is located in the target vein.
2. Remove the sheath and continue following directions starting at #11.

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

CATHETER REMOVAL

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

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.
4. Make a 2cm incision over the cuff, parallel to the catheter.
5. Dissect down to the cuff using blunt and sharp dissection as indicated.
6. When visible, grasp cuff with clamp.
7. Clamp catheter between the cuff and the insertion site.
8. Cut catheter between cuff and exit site.

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.

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