The Hemo-Flow

The Hemo-Flow catheter is intended for use in attaining Long-Term vascular access for Hemodialysis and Apheresis.

It may be inserted percutaneously and is primarily placed in the internal jugular vein.

Alternate insertion sites include the subclavian vein.

Catheters greater than 40cm are intended for femoral vein insertion.

**CONTRAINDICATIONS:**
- This catheter is intended for Long-Term vascular access only and should not be used for any purpose other than indicated in these instructions.

**DESCRIPTION:**
- The Hemo-Flow® Xf Double Lumen Catheter is manufactured from soft radiopaque polyurethane material which provides increased patient comfort while preserving excellent biocompatibility.

**INDICATIONS FOR USE:**
- The Hemo-Flow® Xf Double Lumen Catheter is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis.
- Federal Law (USA) restricts the device to use by or on the order of a physician.

*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 chest area.*

**STERCILE BY ETHYLENE OXIDE**

**DIRECTIONS FOR SELDINGER INSERTION:**

1. **STERILE**
   - Do not use catheter or accessories if any sign of product damage is visible.
   - End caps are not intended to be punctured.
   - When inserting this catheter in patients who are unable to take or hold a deep breath.

2. **WARNING**
   - Patients requiring ventilator support should be at increased risk of pneumothorax during subclavian vein cannulation, which may cause pneumothorax.
   - Use standard hospital protocols when changing the rate of blood flow but some blood may be associated with subclavian vein stenosis.

3. **CATHERETER PRECAUTIONS:**
   - Do not use sharp instruments near the puncture site or catheter lumen.
   - Do not use scissors to remove dressing.

4. **CATHERETER WILL BE DAMAGED IF CLAMPS OTHER THAN WHAT IS PROVIDED WITH THIS KIT ARE USED.**

5. **WARNING**
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29. **FEMORAL VEIN**
    - The patient should lie completely on his/her back. Both femoral arteries should be palpated for site selection and consequence assessment. The line on the same side of the insertion site should be fixed and the thigh abducted. Place the femoral vein on the opposite leg. The femoral vein is then palpated for the artery.

**Caution:** the incidence of infection may be increased with femoral vein insertion.

30. **CONFOUND**
    - 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.

31. **Femoral catheter tip placement**
    - Is measured at the junction of the iliac vein and the inferior vena cava. 1

32. **DIRECTIONS FOR SELDINGER INSERTION:**

1. **NOTE:**
   - A tunnel with a wide gentle arc lessens the risk of kinking. The tunnel should be short enough to keep the Y-hub of the catheter from entering the exit site, yet long enough to keep the cuff 2cm (minimum) from the skin opening.

2. **Push stylet back into catheter and tighten**
   - until stop is engaged.

3. **Femoral catheter**
   - at least 10 cm above the insertion site.

4. **IRIGATE catheter with saline, then clamp**
   - extension tubing to assure that saline is not inadvertently drained from lumens. Use clamps provided.

5. **Insert the introducer needle with attached**
   - syringe into the vein. Aspirate to confirm placement.

6. **Removal of the syringe and place**
   - tubing over the end of the needle to prevent blood loss or air embolism. Draw flow of guidewire back into introducer so that only the handle of the guidewire is visible. Insert advancement distal end into the needle hub. Advance guidewire forward motion into and past the needle hub into the target vein.

7. **Caution:**
   - The length of the wire is inserted into the skin 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 passed into the right atrium. The guidewire should be held secure during this procedure.

8. **Remove needle, leaving guidewire in the target site.**
   - Create subcutaneous puncture site with scalpel.

9. **Thread dilator(s) over guidewire into the**
   - vessel and enter cannula (venous/muscle) site used. Remove dilator(s) when vessel is sufficiently dilated, leaving guidewire in place.

10. **Caution:**
    - Insufficient tissue dilution can cause compression of the catheter lumen and the guidewire creating difficulties in the insertion and removal of the guidewire from the catheter. This can lead to bending of the guidewire.

11. **Adverse:**
    - The Venous Perivascular Introducer Sheath is designed to reduce blood loss and the risk of air intake but it is not a substitute for the physician's experience.

12. **Adverse:**
    - It is not intended to create a two-way seal and it is intended for arterial use.

13. **Adverse:**
    - The valve will substantially reduce air embolism. At 12 mm Hg vacuum pressure the Venous Perivascular Introducer Sheath may allow up to 4cc/sec of air to pass through the valve.

14. **Adverse:**
    - The valve will substantially reduce the risk of kinking the vein. Do not pull the catheter tubing excessively.

15. **Remove the dilator from the**
    - sheath and slide the valve over the sheath opening. Insert the dilator through the valve and lock in place using the rotating collar.

16. **Adverse:**
    - The distal tip of the catheter may cause damage to the vein wall. Do not pull the catheter tubing excessively.

17. **After the catheter has been positioned,**
    - crack the sheath handle in half.

18. **Peel the non-valved side of**
    - handle away from the sheath opening and use as a standard sheath.

**TRENCHING COLLAR**
Catheter Care: Failure to verify catheter placement may result in serious trauma or fatal complications.

CATHETER SECUREMENT AND WOUND DRESSING

28. Suture insertion site closed. 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.

29. Cover the insertion and exit site with an occlusive dressing.

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

31. Record catheter length and catheter lot number on patient’s chart.

HEMODIALYSIS TREATMENT

- 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.
- Before dialysis begins all connections to catheter and extracorporeal circuits should be examined carefully.
- Frequent visual inspection should be conducted to identify 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 intended for this purpose.

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

Note: Excessive blood loss may lead to patient shock.

- Hemodilution 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 two syringes, corresponding to the amount designated on the arterial and venous extensions. Assure that the syringes are free of air.

2. Remove end 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.

8. Remove syringes.

9. Attach a sterile end 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

- Catheter is compatible with suture material.
- Clean skin around catheter.
- Chlorhexidine gluconate solutions are recommended.
- Close the exit site with occlusive dressing and leaves 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 perpiration 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 unit or 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 arterial holes due to clotting or filter sheath.
  - Occlusion of the arterial 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 lumens can be flushed easily but cannot be aspirated. This is usually caused by tip malposition.

One of the following adjustments may resolve the obstruction:

1. Reposition catheter.

2. Reposition patient.

3. 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.

INFECCTION:

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. Blood cultures in patients who 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.

MICRO PUNCTURE INSERTION METHOD

- Once an 18G guidewire has been introduced into the target vein, the 4F sheath dilator should be threaded over the proximal end of the wire and inserted into the target vein.

- When the 4F sheath dilator is located in the target vein, remove the guidewire and dilator one at a time.

- Insert an 038-Guide wire into and through the sheath until it is located in the target vein.

- Remove the sheath and continue following directions starting at #13.

CATHETER REMOVAL

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

Caution: Always review hospital unit or 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. Cut sutures from a site distant from catheter exit and through the incision in the tunnel.

4. Insert a 038-Guide wire into and through the tunnel until it is located in the target vein.

5. Remove the sheath and continue following directions starting at #13.

6. Clamp catheter between the cuff and the insertion site.

7. Cut catheter between cuff and exit site. Withdraw internal portion of catheter through the incision in the tunnel.

8. Remove remaining section of catheter (i.e. portion in tunnel) through the exit site.

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

10. Apply pressure to proximal tunnel for approximately 10-15 minutes or until bleeding stops.

11. Suture incision and apply dressing in a manner to promote optimal healing.

12. Check catheter integrity for tears and measure catheter when removed. It must be equal to the length of catheter when it was inserted.

*This symbol is in accordance with ISO 19223-1.***

** FDA guidance Use of Symbols in Labeling.