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 may be internally placed in the internal jugular vein of an adult patient.
- Alternate insertion sites include subclavian vein as well as jugular vein.

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

CATHETER PRECAUTIONS:
- Do not use sheath instruments near the needle insertion or catheter lumen.
- Do not use scissors to remove dressing.
- Cather will be damaged if clamps other than what is provided with this kit is used.
- Clamping of the tubing repeatedly in the same location may weaken the tubing and clamping near the lumen 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 capabilities 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 chest area.

WARNING:
- While being certain that you are familiar with the above complications and their emergency treatment any of them should occur.

Do not administer the guidewire or catheter if unusual resistance is encountered.

Do not insert and withdraw the guidewire forcibly from any component which may break or unravel. If the guidewire becomes damaged, the introducer needle or tear-away sheath introducer 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 use sharp instruments near the catheter.

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

Do not advance the guidewire or catheter if unusual resistance is encountered.

• Do not resterilize the catheter or accessories by any method.
• 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.

POTENTIAL COMPLICATIONS:
- Air Embolism
- Cardiac Arrhythmia
- Bacteremia
- Air Embolus
- Central Venous Thrombosis
- Right Atrial Puncture
- Perforation of the Vessel
- Vascular Thrombosis
- Lumen Thrombosis
- Stroke
- Subclavian Thrombosis
- Subclavian Artery Puncture
- Subclavian Artery Thrombosis
- Subclavian Vein Puncture
- Subclavian Vein Thrombosis
- Subclavian Vein Aneurysm
- Subclavian Vein Occlusion
- Thoracic Outlet Syndrome
- Transverse Arch Occlusion

ENCASED VESSEL:
- Assume that all bloodline connections are being monitored.
- Before attempting the insertion, ensure that you are familiar with the above complications and their emergency treatment any of them should occur.

WARNING:
- In the rare event that a hub or connector separates from any component during insertion or use, take all necessary precautions and preps to prevent blood loss or air embolism and remove catheter.
- Do not advance the guidewire or catheter if unusual resistance is encountered.
- Do not insert and withdraw the guidewire forcibly from any component which may break or unravel. If the guidewire becomes damaged, the introducer needle or tear-away sheath introducer 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.

Caution: Do not pull tunneler out at an angle. Keep tunneler straight to prevent damage to catheter tip.

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 from entraining from the skin opening.

1. Insert catheter with saline, then clamp catheter extensions to assure that saline is not inadvertently drained from lumen.
2. Use standard hospital protocols when applicable.
3. Blunt dissection of the subcutaneous tunnel opening. Attach the catheter to the trocar. Avoid any excessive motion which might cause complications.
4. Insert distal tip of catheter into and through the site of catheter insertion.
5. Close the extension clamps, remove the catheter sheath, and aspirate blood from the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein.
6. Use guidewire to direct catheter tip to the actual entry site of the sheath into the lumen of the vein.
7. Confirm final position of catheter with chest x-ray. Routine x-ray should always follow the passage of 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 to substitute for the physician's experience and judgement in treating any specific patient.
- Use standard hospital protocols when applicable.

Caution: Do not pull tunneler out at an angle. Keep tunneler straight to prevent damage to catheter tip.

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 from entraining from the skin opening.

**For alternate sheath method, see Micro Puncture Insertion Method Section.**

Caution: Never leave sheath in place as an indwelling catheter. Damage to the vein may occur.

1. Install injection cap over dialyzer opening to prevent blood loss or air embolism.

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

Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible after the sheath only a few centimeters at a time.

1. Make any adjustments to catheter under fluoroscopy. The venous distal tip should be positioned at the level of the cavat arterial junction or beyond into the right atrium to ensure optimal blood flows.

1. Attach syringes to both extensions and open clamps. Blood should aspirate easily from both arterial and venous sides. If either side exhibits excessive resistance to blood aspiration, the catheter may need to be refilled and confirmed to obtain adequate blood flows.

1. Once adequate aspiration has been achieved, both lumens should be irrigated with 0.9% saline solution to prevent any premature tear. Hold sheath/dilator close to the point of catheter insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the trocar tip at all times and not to be advanced or retracted 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 before re-occluding the circuit.

Caution: Do NOT bend sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the trocar tip at all times and not to be advanced or retracted 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 before re-occluding the circuit.

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

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

1. Once the catheter is locked with heparin, close the clamps and install injection caps.
22. Confirm proper tip placement with fluoroscopy. The distal venous tip should be positioned at the level of the caval atrial junction or into the right atrium to ensure optimal blood flow (as recommended in current NKF DOQI Guidelines).

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

CATHETER SECUREMENT AND WOUND DRESSING
23. 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.

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

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

26. 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 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 systemic heparinization of patient. Extension clamps should only be opened for aspiration, flushing, and dialysis treatment.

• Remove syringes.

• Attach a syringe containing heparin into each lumen using quick bolus technique.

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

• Close extension clamps.

Caution: Extension clamps should only be opened for aspiration, flushing, and dialysis treatment.

3. Remove injection caps from the extensions.

4. Attach a syringe containing heparin solution to the female luer of each extension.

5. Open extension clamps.

6. Aspirate to insure that no air will be forced into the patient.

7. Inject heparin into each lumen using quick bolus technique.

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 wear clothing that may cause friction or irritation to the dressing.

• 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 catheter removal.

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 technique should attempt the following procedure.

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. Withdraw internal portion of catheter through the incision in the tunnel.

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

Caution: Do not pull distal end of catheter through incision as contamination of wound 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.

FLUSH RATE TESTING RECOMMENDS OPTIMUM LABORATORY CONDITIONS
• A 12.5F x 28cm PRESSURE

PN 40287US Rev. 3/17A