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

**INDICATIONS FOR USE:**
- The Hemo-Flow Catheter is indicated for use in attaining Long-Term vascular access only and should not be used for any purpose other than indicated in this instruction.

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

**POSSIBLE COMPLICATIONS:**
- Air Embolism
- Bacteremia
- Bruachal Pneumthony
- Cardiac Arrhythmia
- Deep Venous Thrombosis
- Endocarditis
- Site Infection
- Ennastasion
- Hemorrhage
- Hemoptysis
- Intervenous Cava Puncture
- Laceration of the Vessel
- Lower Thrombosis
- Mediastinal Injury
- Perforation of the Vessel
- Pneumothorax
- Retroperitonal Bleed

**WARNINGS:**
- In the rare event that a hub or connector separates from any component due to the insertion or use, take all necessary steps and precautions 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 or withdraw the guidewire forcibly from any component. The wire may break or unravel. If the guidewire becomes damaged, the introducer needle or Vascul-Shield® introducer and guidewire must be removed together.

**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.

**CATHETER PRECAUTIONS:**
- Do not re-insert the catheter or any accessories if package is opened or damaged.
- Do not use catheter or any accessories if any sign of product damage is visible.

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

**CONTRAINDICATIONS:**
- Federal Law (USA) restricts the device to sale by or on the order of a physician.
- Stenosis.
- Blood flow stenosis.
- Peripheral vasoconstriction.
- Areas of indurated or inflamed skin.
- Areas of subcutaneous infection.
- Areas of active cellulitis or wound infection.
- Areas in which the skin is too thin or too thick.
- Areas with excessive moisture or perspiration.
- Areas with a history of skin ulceration or breakdown.
- Areas of radiation therapy or radiation-induced injury.

**POTENTIAL COMPLICATIONS:**
- 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 this procedure. Perform sterile drapes, instruments, and accessories. Have the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, 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.
- 3. Administer sufficient loca anesthetic to completely anesthetize the insertion site.
- 4. Make a small incision at the exit site on the chest wall approximately 8-10cm below the clavicle. Make a second incision above and parallel to the first, at the insertion site. Make the exit at the site wide enough to accommodate the cuff, approximately 1cm.
- 5. Use blunt dissection to create the subcutaneous tunnel opening. Attach the catheter to the trocar by slight twisting motion may be helpful. Slide catheter tunneling sheath over the catheter making certain that the sheath covers the arterial hole. The trocar should be moved into the exit site into a create a subcutaneous tunnel. Do not tunnel through muscle. The tunnel should be made with care in order to prevent damage to the surrounding vessels.
- 6. 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.
- 7. Irrigate catheter with saline, then clamp catheter extensions to assure that saline is not inadvertently drained from lumens. Use clamps provided.
- 8. Insert the introducer needle with attached syringe, or into the target vein. Aspirate to insure proper placement.
- 9. Remove the syringe, and place thumb over the end of the needle to prevent blood loss or air embolism. Draw flexible end of guide wire back into advance so that only the end of the guidewire is visible. Insert advancement distal end into the needle hub. Advance guidewire with forward motion into and past the needle hub into the target vein. 
- 10. Remove needle, leaving guidewire in the target vein. Enlarge cutaneous puncture site with scalpel.
- 11. Thread Vascul-Shield® introducer over the proximal guidewire, ensuring that Vascul-Shield® introducer is in the target vein, remove the guidewire leaving the sheath and dilator in position.
- **NOTES:**
  - For alternate sheath method, see Micro Puncture Insertion Method Section.
  - Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.
- 12. Install injection cap over dilator 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 inner-line clamps provided.

13. Remove dilator and injection cap from sheath.

14. Insert distal tip of catheter into and through the sheath insertion tract. Confirm that the tip is correctly positioned in the target vein.

15. Remove the tear-away sheath by slowly pulling it out of the vessel while simultaneously splitting the sheath by grasping the tabs and pulling them apart (a slight twisting motion may be helpful).

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 and tease the sheath only a few centimeters at a time.

16. Make any adjustments to catheter under fluoroscopy. The venous distal tip should be clamped at all times when not in use and occlusive dressing.

17. Attach syringes to both extensions and clamp provided.

18. Assure that all air has been removed from each lumen of the catheter.

19. Close the extension clamps, remove the dilator and injection cap from the catheter and extracorporeal circuits. Only clamp catheter with in-line clamps provided.

20. To maintain patency, a heparin lock must be created in both 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.

21. Once the catheter is locked with heparin, close the clamps and assist in caps onto the extensions' female luer.

22. Confirm proper tip placement with fluoroscopy. The distal venous tip should be sutured into the target vein and the inferior venae cava. 

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

CATHETER RECOVERY AND WOUND CARE

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.

HEMORRHAGIC 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 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.

• Excessive blood loss may lead to patient shock.

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

• Hemodialysis should be performed under physician's instructions.

REHAIRURIZATION

• If the catheter is not to be used immediately, refer to 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.

INSUFFICIENT FLOWS

The following may cause insufficient blood flows:

• Occluded arterial holes due to clotting or fibrin sheath.

• Occlusion of the arterial side holes due to cap to 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 or 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.

INSERTION

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 replacing replacement. Insertion should be made on opposite side of original catheter exit site, if possible.

INFECTION:

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 replacement.

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

1. Insert an 0.38” 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.

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. 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 instruments as indicated.

6. When visible, grasp cuff with clamp.

7. Clamp catheter between the cuff and the blood aspiration.

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 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.

Note: All data given is the responsibility of 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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References: