INSTRUCTIONS FOR USE

INDICATIONS FOR USE:
- The Medcomp’s Hemo-Cath™ Silicone Dacron Lumen Catheter is utilized for temporary access for hemodialysis, hemoperfusion, or hemapheresis therapy.
- The cannula may be inserted via the Seldinger technique due to the thin inner stylet, increasing linear strength. The stylet is removed after insertion, leaving the soft silicone cannula in the body. The flexible silicone make-up conforms well to the vessel anatomy, resulting in higher patient tolerance during extended use.

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.

DESCRIPTION:
- The Hemo-Cath™ Catheter is manufactured from soft, high-grade silicone material. Silicones provide increased patient comfort while providing excellent biocompatibility.

POTENTIAL COMPLICATIONS:
- Before attempting the insertion, ensure that you are familiar with the potential complications and their emergency treatment should any of them occur.

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

INSERTION SITES:
- The patient should be in a supine Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small roll may be inserted under the shoulder to facilitate the extension of the chest area.

INTERNAL JUGULAR VEIN:
- The patient should lie completely on his/her back. Both femoral veins should be palpated for the site selection and confirmation consequence assessment. The knee on the same side of the insertion site should be flexed and the thigh abducted. Place the foot across the opposite leg. The femoral vein is then posterior/medial to the artery. Note: For femoral placement, monitor patient closely for thrombosis, infection, and bleeding.

TERLESTED BY ETHYLENE OXID BLE:
- Do not re-sterile the catheter or accessories by any method.
- Re-Use may lead to infection or injury.
- The manufacturer shall not be liable for any costs caused by re-use or re-sterilization of this catheter or accessories.
- Sterilized by ethylene oxide.

STERELE [EO]
- Do not use catheter or accessories if package is opened or damaged.

CATHETER PRECAUTIONS:
- Do not use catheter or accessories if any sign of product damage is visible.
- Do not re-sterile the catheter or accessories by any method.
- Re-Use may lead to infection or injury.
- The manufacturer shall not be liable for any costs caused by re-use or re-sterilization of this catheter or accessories.
- Sterilized by ethylene oxide.

- Contents sterile and non-pyrogenic in unopened, undamaged package.
- Sterilized by ethylene oxide.

DIRECTIONS FOR SELLINGER INSERTION:
- Read instructions carefully before using this device. The catheter should be inserted, manipulated, and removed only by a qualified, licensed physician or other health care practitioner, authorized by and under the direction of such physician.
- The medical techniques and procedures described in these instructions do not represent all medically acceptable protocols; nor are they intended to substitute for the physician's experience and judgment in treating any specific patient.
- Use standard hospital protocols.

1. Strict aseptic technique must be used during the insertion, maintenance, and catheter removal procedures. Provide a sterile operation field. The Operating Room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Share the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have the patient wear a mask.

2. The selection of the appropriate cannula length is at the sole discretion of the physician. To concurrently achieve proper tip positioning, 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 local anesthetic to completely anesthetize the insertion site.

4. Insert the introducer needle with attached syringe into the selected site. 

5. The patient should lie completely on his/her back. Both femoral veins should be palpated for the site selection and confirmation consequence assessment. The knee on the same side of the insertion site should be flexed and the thigh abducted. Place the foot across the opposite leg. The femoral vein is then posterior/medial to the artery. Note: For femoral placement, monitor patient closely for thrombosis, infection, and bleeding.

6. Remove the needle, leaving guidewire in the vessel. Enlarge cutaneous puncture site with scalpel.

7. Thread the dilator over the proximal end of the guidewire. Dilate subcutaneous tissues to allow easy passage into target vein.

8. Iqtrigate catheter with saline, and clamp arterial extension. Use clamps provided. 

9. Use the catheter through the subcutaneous tissue and into the target vein.

10. Use standard hospital protocol.

11. Monitor the patient continuously and for any evidence of complications.

12. Do not clamp vessel in-line unless absolutely necessary.

13. Use only Luor Lock (threaded) connectors with this catheter.

14. Repeated over tensioning of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.

15. Do not clamp vessel in-line unless absolutely necessary.

16. Do not re-sterile the catheter or accessories if any sign of product damage is visible.

17. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have the patient wear a mask.

18. Use the catheter through the subcutaneous tissue and into the target vein.

19. Use standard hospital protocol.

20. Monitor the patient continuously and for any evidence of complications.

ATTACH SYRINGES TO BOTH EXTENSIONS AND OPEN CLAMPS. BLOOD SHOULD ASPIRATE EASILY FROM BOTH ARTERIAL AND VENOUS SIDES. IF EITHER SIDE EXHIBITS signs indicating reduced blood flow or air embolism, the catheter may need to be repositioned to obtain adequate blood flow.

21. Once adequate aspiration has been achieved, both lumens should aspirate with saline filled syringes using quick bolus technique. Assemble extension clamps are open during irrigation procedure.

22. Do not re-sterile the catheter or accessories by any method.

23. Re-Use may lead to infection or injury.

24. The manufacturer shall not be liable for any costs caused by re-use or re-sterilization of this catheter or accessories.


27. Sterilized by ethylene oxide.

28. Do not use catheter or accessories if package is opened or damaged.

29. Do not use catheter or accessories if any sign of product damage is visible.

30. Do not re-sterile the catheter or accessories by any method.

31. Re-Use may lead to infection or injury.

32. The manufacturer shall not be liable for any costs caused by re-use or re-sterilization of this catheter or accessories.

33. Sterilized by ethylene oxide.

34. Do not use sharp instruments near the extension lines or tubing.

35. Do not use scissors to remove dressing.

36. The catheter will be damaged if clamps other than those provided with this kit are used.

37. Do not clamp over guidewire - tubing may become damaged.

38. Examine catheter lumens and extensions before and after each treatment for damage.

39. To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.

40. Use only Luor Lock (threaded) connectors with this catheter.

41. Repeated over tensioning of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.

42. Do not advance the stainless steel guidewire or catheter immediately.

43. Do not clamp over guidewire or stylet - tubing may become damaged.

44. Examine catheter lumens and extensions before and after each treatment for damage.

45. To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.

46. Attach syringes to both extensions and open clamps. Blood should aspirate easily from both arterial and venous sides. If either side exhibits signs indicating reduced blood flow or air embolism, the catheter may need to be repositioned to obtain adequate blood flow.

47. Once adequate aspiration has been achieved, both lumens should aspirate with saline filled syringes using quick bolus technique. Assemble extension clamps are open during irrigation procedure.

48. Clamp the extensions, remove the syringes, and place an injection cap on each luer lock connector. Avoid air embolism by keeping tubing clamped at all times when not in use and by filling the catheter with saline prior to use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.

49. Immediately after insertion, confirm proper placement of the tip of the catheter with fluoroscopy.

50. Failure to verify catheter tip placement may result in serious trauma or fatal complications.

CATHETER SECUREMENT AND WOUND DRESSING:
- Suture the catheter to the skin using the suture wing. Do not suture the catheter tubing.
- Cover the insertion site with an occlusive dressing.
- Catheter must be secured/sutured for entire duration of implantation.
- 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 detect leaks, prevent blood loss or air embolism.
- If a leak is found, the catheter should be clamped immediately.

NOTE:
- Excessive blood loss may lead to patient shock.
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.

SITE CARE

Warning: DO NOT use iodine or iodine based products on this catheter. Failure of catheter will occur. Alcohol based solutions are recommended as the antiseptic solution that can be used on this catheter.

- Clean the skin around catheter. Cover the exit site with occlusive dressing. Leave the extensions, clamps, adapters and caps exposed for access by staff.
- Wound dressings must be kept dry. Patients must not swim, shower, or soak dressings while bathing. If adhesion of dressing is compromised by profuse perspiration or accidental wetting, the dressing must be changed by the medical or nursing staff under sterile conditions.
- Insertion should be made on opposite side of original catheter exit site, if possible.

CATHETER PERFORMANCE

Caution: Always review hospital or unit 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 fibrin 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 lumen can be flushed easily but blood cannot be aspirated. This 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.

INFECT:

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 catheter replacement.

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.

SYMBOL TABLE

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<th>Manufacturer</th>
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Note: Temperature symbols : "This symbol only applies to kits with drugs".

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