

## (TEMPORARY ACCESS) **INSTRUCTIONS FOR USE**

### **INDICATIONS FOR USE:**

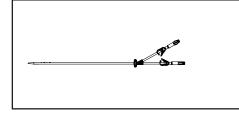
The Medcomp® Hemo-Cath® ST Silicone Double Lumen Catheter can be utilized for temporary access for hemodialysis, hemoperfusion or apheresis therapy. The cannula may be inserted via the Seldinger technique due to the inner Teflon stylet, increasing linear strength. The stylet is removed after insertion, 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:**

The Subclavian Approach is NOT recommended for use with the Medcomp® Hemo-Cath® ST Double Lumen Subclavian-Femoral Catheter in Hemodialysis or Hemoperfusion Procedures used for the management of acute poisoning or other situations in which a ventilator might be used due to risk of traumatic pneumothorax posing a dangerous complication for the patient.

## **DESCRIPTION:**

The Hemo-Cath® Catheter is manufactured from soft radiopaque silicone material. Silicone provides increased patient comfort while providing excellent biocompatibility.



## **POTENTIAL COMPLICATIONS:**

- Air Embolism
- Bacteremia
- Brachial Plexus Injury
- Cardiac Arrrythmia
- Cardiac Tamponade Central Venous Thrombosis
- Endocarditis
- Exit Site Infection
- Exsanguination
- Femoral Artery Bleed
- Femoral Nerve Damage
- Hematoma
- Hemorrhage
- Hemothorax
- Inferior Vena Cava Puncture
- · Laceration of the vessel
- Luminal Thrombosis
- Mediastinal Iniury
- · Perforation of the vesse Pleural Injury
- Pneumothorax
- Retroperitoneal Bleed
- Right Artial Puncture
- Septicemia Subclavian Artery Puncture
- Subcutaneous Hematoma
- Superior Vena Cava Puncture
- Thoracic Duct Laceration
- Vascular Thrombosis
- Venous Stenosis

• 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 steps and precautions to prevent blood loss or air embolism and remove the catheter immediately.
- Do not advance the stainless steel guidewire or catheter if unusual resistance is encountered.
- Do not insert or withdraw the guidewire forcibly from any component. The wire could break or unravel. If the guidewire becomes damaged, the catheter 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 resterilize 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 re-use or resterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in • unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE STERILE EO
- 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.
- End caps are not intended to be punctured with a needle.

## **CATHETER PRECAUTIONS:**

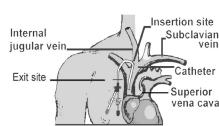
- Do not use sharp instruments near the • extension lines or tubing.
- Do not use scissors to remove dressing.
- Catheter will be damaged if clamps other than what is provided with this kit are used
- Clamping the catheter repeatedly in the same location will weaken tubing. Avoid clamping near the luers and hub of the catheter.
- Do not clamp over guidewire or stylet -• tubing may become damaged.
- Examine catheter lumens 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 overtightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.

## **INSERTION SITES:**

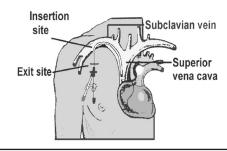
• The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.

Internal Jugular Vein



Have patient lift his/her head from the bed to define the sternomastoid muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternomastoid muscle. The apex should be approximately three finger breadths above the clavicle. The carotid artery should be palpated medial to the point of catheter insertion.

Subclavian Vein



Note the position of the subclavian vein, which is posterior to the clavicle, superior to the first rib, and anterior to the subclavian artery. (At a point just lateral to the angle made by the clavicle and the first rib.)

Warning: Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.

Warning: Extended use of the subclavian vein may be associated with subclavian vein stenosis.



Femoral Vein

The patient should lie completely on

be palpated for site selection and

his/her back. Both femoral veins should

consequence assessment. The knee on

be flexed and the thigh abducted. Place

femoral vein is then posterior/medial to

the foot across the opposite leg. The

patient closely for thrombosis, infection, and

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

DIRECTIONS FOR SELDINGER INSERTION

using this device. The catheter should be

inserted, manipulated, and removed only

by a qualified, licensed physician or other

health care practitioner, authorized by

The medical techniques and procedures

described in these instructions do not

protocols, nor are they intended as a

and judgment in treating any specific

1. Strict aseptic technique must be used

during the insertion, maintenance, and

catheter removal procedures. Provide a

catheter placement. Use sterile drapes,

instruments and accessories. Shave the

skin above and below the insertion site.

Perform surgical scrub. Wear gown, cap,

gloves and mask. Have the patient wear

sterile operative field. The Operating

Room is the preferred location for

substitute for the physician's experience

represent all medically acceptable

Use standard hospital protocols.

Read instructions carefully before

and under the direction of such

Note: For femoral placement, monitor

the artery.

bleeding.

use.

physician.

patient.

a mask

•

the same side of the insertion site should

- 3.
- 4.
- 5. hub into the target vein.

**Caution:** The length of the wire inserted is determined by the size 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 allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

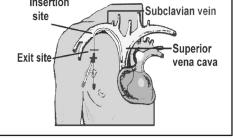
**<u>Caution</u>**: When introducer needle is used, do not withdraw guidewire against needle bevel to avoid possible severing of guidewire.

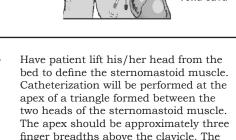
- site with scalpel.
- passage into target vein.

Caution: Do not leave vessel dilator in place as an indwelling catheter to avoid possible vessel wall perforation.

**Caution:** Insufficient tissue dilation can cause compression of the catheter lumen against the guidewire causing difficulty in the insertion and removal of the guidewire from the catheter. This can lead to bending of the guidewire.

- of the guidewire.
- 9. Ease the catheter through the vein.
  - physician.
  - clamp.





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.

Administer sufficient local anesthetic to completely anesthetize the insertion site.

Insert the introducer needle with attached syringe into the selected site. Aspirate to insure proper placement.

Remove the syringe, placing thumb over the end to prevent blood loss or air embolism. Draw flexible end of guidewire back into advancer so that only the end of the guidewire is visible. Insert advancer's distal end into the needle hub. Advance guidewire with forward motion into and past the needle

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

7. Thread the dilator over the proximal end of the guidewire. Dilate subcutaneous tissue and vein wall to allow easy

8. Irrigate catheter with saline, and clamp arterial extension. Use clamps provided. Thread the catheter over proximal end

subcutaneous tissue and into the target

10. Make any adjustments to catheter under fluoroscopy. The distal tip should be located just before the junction of the superior vena cava and the right atrium. Femoral placement to be determined by

11. Once proper placement is confirmed, remove guidewire and stylet and close

- 12. 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 rotated or repositioned to obtain adequate blood flow.
- 13. Once adequate aspiration has been achieved, both lumens should be irrigated with saline filled syringes using quick bolus technique. Assure extension clamps are open during irrigation procedure.
- 14. Clamp the extensions, remove the syringes, and place an end 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.
- 15. Immediately after insertion, confirm proper placement of the tip of the catheter with fluoroscopy.

**<u>Caution</u>**: Failure to verify catheter placement may result in serious trauma or fatal complications.

### CATHETER SECUREMENT AND WOUND DRESSING:

- 16. Suture the catheter to the skin using the suture wing. Do not suture the catheter tubing.
- 17. Cover the insertion site with an occlusive dressing.
- 18. Catheter must be secured/sutured for entire duration of implantation.
- 19. 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 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.

## 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.
- 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.

**<u>Caution</u>**: Extension clamps should only be open for aspiration, flushing, and dialysis treatment.

- 8. Remove syringes.
- 9. Attach a sterile end cap onto the female luers 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

**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 dressing 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.

## CATHETER PERFORMANCE

**<u>Caution</u>:** 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.

#### **INFECTION:**

**<u>Caution</u>:** 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.

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

#### CATHETER REMOVAL

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

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

- 1. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
- 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.

| 14F x 20cm Average Flow vs Pressure |  |
|-------------------------------------|--|
|-------------------------------------|--|

|          | 200 | 300 | 400    | 500    | ml/min |
|----------|-----|-----|--------|--------|--------|
| venous   | 33  | 56  | 81.8   | 113.6  | mmHg   |
| arterial | -49 | -83 | -122.4 | -169.6 | mmHg   |

| 5.3.2               | Keep Away from Sunlight <sup>*</sup>             |
|---------------------|--|
| 5.2.3<br>STERILE EO | Sterilized Using Ethylene Oxide*                 |
| 5.2.8               | Do Not Use if Package is<br>Damaged <sup>*</sup> |
| 5.1.4               | Use-by Date <sup>*</sup>                         |
| 5.2.6               | Do Not Resterilize*                              |
| 5.1.5 LOT           | Batch/Lot Number*                                |
| 5.1.6 REF           | Catalogue Number *                               |
| 5.4.4               | Caution, consult Accompanying Documents*         |
| 5.4.2               | Do Not Re-use *                                  |
| 5.4.3               | Consult Instructions for Use *                   |
| Rx Only             | Prescription Use Only ***                        |
| 5.3.7               | Upper and Lower Temperature<br>Limits *          |

\* This symbol is in accordance with ISO 15223-1. \*\*\* FDA guidance Use of Symbols in Labeling.

Note: Temperature symbols : "This symbol only applies to kits with drugs".



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#### WARRANTY

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Manufacturer

Non-pyrogenic\*

SYMBOL TABLE

Keep Dry