

Hemo-Cath® Silicone **Double Lumen Catheter** (TEMPORARY ACCESS)

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

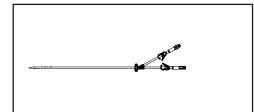
The Hemo-Cath® Silicone Double Lumen Catheter can be utilitized for temporary access for hemodialysis, hemoperfusion, or apheresis therapy. The cannula may be inserted via the Seldinger technique due to the inner stylet, increasing linear strength. The stylet is removed after insertion, leaving the soft 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® Silicone Double Lumen 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 Injury
- Perforation of the vessel
- 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

- Use only Luer Lock (threaded) connectors with this catheter.
 - Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.

INSERTION SITES:

Before attempting the insertion.

potential complications and their

them occur.

immediately.

WARNINGS:

ensure that you are familiar with the

emergency treatment should any of

• 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

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

• This catheter is for Single Use Only.

• Do not re-sterilize the catheter or

accessories by any method.

iniury.

accessories.

sale by or on the order of a physician.

Re-use may lead to infection or illness/

The manufacturer shall not be liable for

Contents sterile and non-pyrogenic in

STERILIZED BY ETHYLENE OXIDE

Do not use catheter or accessories if

• Do not use catheter or accessories if any

Do not use sharp instruments near the

Do not use scissors to remove dressing.

than what is provided with this kit are

Clamping the catheter repeatedly in the

same location will weaken tubing. Avoid

clamping near the luers and hub of the

Do not clamp over guidewire or stylet -

Examine catheter lumens and extensions

To prevent accidents, assure the security

of all caps and bloodline connections

prior to and between treatments.

before and after each treatment for

tubing may become damaged.

Catheter will be damaged if clamps other

sign of product damage is visible.

CATHETER PRECAUTIONS:

catheter.

damage

extension lines or tubing.

any damages caused by re-use or

resterilization of this catheter or

unopened, undamaged package.

STERILE | EO

package is opened or damaged.

air embolism and remove the catheter

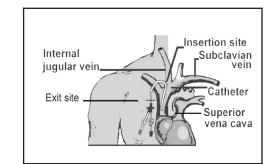
Do not advance the stainless steel

guidewire or catheter if unusual

resistance is encountered.

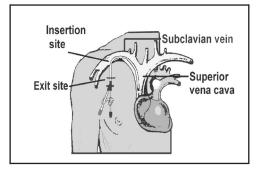
The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest

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

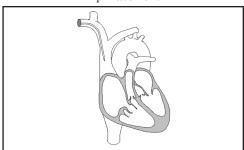


Note the position of the subclavian vein, which is posterior to the clavicle, superior to the first rib, and anterior to the subclavian artery. (At a point just lateral to the angle made by the clavicle and the first rib.)

WARNING:

- Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.
- Extended use of the subclavian vein may be associated with subclavian vein

Tip Placement



Femoral Vein



The patient should lie completely on his/her back. Both femoral veins should be palpated for site selection and 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

Note: For femoral placement, monitor patient closely for thrombosis, infection, and bleeding.

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.

DIRECTIONS FOR SELDINGER 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 as a 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 operative field. The Operating Room is the preferred location for 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 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.
- 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 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.

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

- 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 tissue and vein wall to allow easy 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.

- 8. Irrigate catheter with saline, and clamp arterial extension. Use clamps provided. Thread the catheter over proximal end of the guidewire.
- 9. Ease the catheter through the 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 physician.
- 11. Once proper placement is confirmed, remove guidewire and stylet and close clamp.

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

Caution: 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 injection caps from the extensions.
- 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.

<u>Note:</u> 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 injection 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

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.

INFECTION:

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.

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.

- Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
- 2. Withdraw catheter through the exit
- 3. Apply pressure to exit site for approximately 10-15 minutes or until bleeding stops.
- 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

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