Double Lumen Catheter Set

TEMPORARY HEMODIALYSIS

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

The Double Lumen Catheter Set is indicated for use in establishing Short-Term vascular access for Hemodialysis and Apheresis.

It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient.

Alternate insertion sites include subclavian vein or femoral vein as required.

The curved Double Lumen Catheter Set is intended for internal jugular vein insertions.

This catheter is indicated for a duration less than 30 days. For femoral placement, monitor catheter condition closely.

CONTRAINDICATIONS:

This catheter is contraindicated for Short-Term vascular access only and should not be used for any purpose other than as indicated in these instructions.

DESCRIPTION:

The Double Lumen Catheter set lumens are manufactured from thermosensitive material which provides increased patient comfort while providing excellent biocompatibility.

The patient should lie completely on the back with the head turned to facilitate the extension of the chest area.

Emergency treatment should any of them occur.

WARNING:

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.

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 catheter and guidewire must be removed together.

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

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

Catheter PRECAUTIONS:

Do not use sharp instruments near the extension tubing or catheter lumen.

Do not use scissors to remove dressing.

Catheter will be damaged if clamps other than what is provided with this kit are used.

Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the lures and hub of the catheter.

PERIODICAL EXAMINATION:

Before attempting the insertion, ensure that you are familiar with the potential complications and their emergent treatment should any of them occur.

POTENTIAL COMPLICATIONS:

Flusal Injury
Pneumothorax
Perforation of the Thoracic Duct
Subclavian Artery Puncture
Subcutaneous Hematoma
Superior Vena Cava Puncture
Thrombosis of the Vessel
Vascular Thrombosis

Wound Infection

Inferior Vena Cava Puncture
Laceration of the Vessel
Lumen Thrombosis
Mediastinal Tamponade
Perforation of the Vessel

The following complications are the result of catheter insertion.

Fatal to severe cardiac arrhythmia.

Infectious complications such as Bacteremia and Septicemia.

Air embolism.

Bleeding from the catheter insertion site.

Venous or arterial occlusion.

Perforation of the vessel wall perforation.

False aneurysm formation.

Intravascular thrombosis.

TIMING OF EXAMINATION:

Before attempting the insertion, 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 Luor 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.

Note: Never straighten or twist lumens of LI catheter, as this will kink internal lumen inhibiting flow during treatment.

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 site. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.

Internal Jugular Vein

Femoral Vein

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 complicated with subclavian vein stenosis.

Tip Placement

Use standard hospital protocols when applicable.

1. Strict aseptic technique must be used during insertion, maintenance, and catheter withdrawal. Provide sterile gloves, instruments, and accessories. Shave the skin above and below the insertion site. Perform surgical scrub. Wear gown, cap, gloves, 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 tip placement prior to use.

3. Administer sufficient local anesthetic to completely anesthetize the insertion site.

4. Insert the introducer needle with attached syringe into target vein.

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

6. Open venous extension clamp. Thread guidewire through venous extension to catheter. Clamp only the arterial lumen, do not clamp the dual lumen.

7. Thread the dilator over the proximal end of the guidewire. Dilate subcutaneous tissue site to accommodate the guidewire. Aspirate to confirm proper placement of the guidewire.

8. Remove the needle, leaving guidewire in the vessel. Enlarge cutaneous puncture site and scalpel.

9. Thread the dilator over the proximal end of the guidewire. Dilate subcutaneous tissue and vein wall to allow easy passage of catheter into target vein.

10. Open venous extension clamp. Thread the guidewire over the proximal end of the guidewire

11. Ease the catheter through the subcutaneous tissue and into the target vein.

12. Do not stimulate urine or stool or use a catheter if any of the following occur.

13. Failure to verify catheter placement may result in serious trauma or fatal complications.
The heparin solution must be removed immediately.

**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.

20. Suture the catheter to the skin using the suture wing. Do not suture the catheter tubing.

21. Cover the insertion site with an occlusive dressing.

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

23. 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, legions 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.

1. 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.

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.

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

8. Remove syringes.

9. Attach a sterile injection cap onto the female luer 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**

- Clean skin around catheter.
- Chlorhexidine gluconate solutions are recommended. Iodine solutions may 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 soak dressing while bathing.

- 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 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.

**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.

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