DOUBLE LUMEN CATHETER SET
INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The Double Lumen Catheter is indicated for use in obtaining Long-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 as required.
- Catheters greater than 40cm are intended for femoral vein insertion.

CONTRAINDICATIONS:

- This catheter is intended for Long-Term vascular access and should not be used for any purpose other than indicated in these instructions.

DESCRIPTION:

- The Double Lumen Catheter is manufactured from soft radiopaque polyurethane material which provides increased patient comfort while providing excellent biocompatibility.

POTENTIAL COMPLICATIONS:

- Air Embolism
- Septicemia
- Subclavian Artery Puncture
- Subcutaneous Hematoma
- Superior Vena Cava Puncture
- Thrombotic Laceration
- Tunnel Infection
- Thoracic Venous 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 due to distraction or use, take all necessary steps and precautions to prevent blood 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 unseat. If the guidewire becomes damaged, the introducer needle or Vascul-Sheath™ introducer 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 re-sterilize the catheter or accessories by any method.
- Re-use may lead to infection or injury.
- The manufacturer shall not be liable for any damages caused by reuse or re-sterilization of this catheter or accessories.
- Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE.

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 lars and hubs of the catheter.

- 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 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:

- 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 extension of the chest area.

INFERIOR VENA CAVA

- Have patient lift his/her head from the bed to define the sternommediastinal muscle. Catheterization will be performed at the apex of a triangle formed between the two heads of the sternommediastinal 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.

SUPERIOR VENA CAVA

- The patient should lie completely on his/her back. Routine x-ray should always be performed at the time of this catheter placement to confirm proper tip placement prior to use.

FEMORAL VEIN

- The patient should lie completely on his/her back, and femoral arteries should be palpated for site selection and consequence assessment. The knee on the same side of the insertion should be flexed and the thigh abducted. Place the foot across the opposite leg. The femoral vein is then posterior/medial to the artery.

Mediastinal Injury

- 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 stenosis.

Tip Placement

- Use standard hospital protocols when applicable.

- 1. Strict aseptic technique must be used during insertion, maintenance, and catheter removal procedures. Provide a sterile operating field. The Operating Room is the preferred location for catheter placement. Use sterile drapes, instruments, and accessories. Secure 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 placement prior to use.

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

- 4. Make a small incision at the exit site on the chosen surface of the leg, approximately 8-10cm below the clavicle. Make a second incision above and parallel to the first, at the insertion site. Make the incisions at the exit site wide enough to accommodate the cuff, approximately 1cm.

- 5. Use idant discretion to create the subcutaneous tunnel opening. Attach the catheter to the trocar (a slight twisting motion may be helpful). Slide catheter tunneling sleeve over the catheter making certain the distal flair is positioned a few centimeters above the superior edges of the trocar. Insert the trocar into the exit site and create a short subcutaneous tunnel. Do not tunnel through muscle. The tunnel should be made to promote subcutaneous pooling of blood and avoid damage to surrounding vessels.

- 5a. For Femoral Vein Insertion: Create subcutaneous tunnel with the catheter exit site in the pelvic region. Warning: Do not over-expand subcutaneous tunnel during tunneling. Over-expansion may delay/prevent cuff in-growth.

- 6. Lead catheter into the tunnel gently. Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissection may facilitate insertion. Remove the catheter from the trocar with a slight twisting motion to avoid damage to the catheter.

- 7. 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.

- 8. Femoral catheter tip placement is recommended at the junction of the iliac vein and the inferior vena cava.

DIRECTIONS FOR SELLINGER INSERTION

- Read instructions carefully before using this device. The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician.

- The medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician’s experience and judgement in treating any specific patient.

- Note: A tunnel with a wide profile may increase the risk of kinking. The tunnel should be short enough to keep the Y-hub of the catheter from entering the exit site, yet long enough to keep the cuff 2cm (minimum) from the skin opening.

- 9. Irrigate catheter with saline, then clamp catheter extensions to assure that saline is not inadvertently drained from lumens. Use clamps provided.

- 10. 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 guidewire back into advance so that only the end of the guidewire is visible. Insert advancement’s distal end into the needle hub.

- 11. Thread Vasuc-Sheth™ introducer over the proximal end of the guidewire. Once the Vasuc-Sheth™ introducer is in the target vein, remove the guidewire leaving the sheath and dilator in position.

- Caution: The length of the wire inserted is determined by the size of the patient. Monitor patient for proper wire advancement 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 secure during this procedure.

- 12. Remove needle, leaving guidewire in the target vein. Enlarge cutaneous puncture site with scalpel.

- 13. Thread Vasuc-Sheth™ introducer over the proximal end of the guidewire. Once the Vasuc-Sheth™ introducer is in the target vein, remove the guidewire leaving the sheath and dilator in position.

- Caution: DO NOT bend sheath/dilator during insertion as bending will cause the sheath to prematurely unfold. Hold sheath/dilator close to the tip (approximately 3cm from tip) when initially advancing the sheath and dilator into the skin surface. To progress the sheath/dilator towards the vein, grasp the sheath/dilator a few centimeters (approximately 2cm) above the point of initial skin entry and position the sheath and dilator close to the vein. Repeat procedure until sheath/dilator is fully inserted.

- Note: For alternate sheath method, see Micro Puncture Insertion Method Section.

- Caution: 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 in-line clamps provided.

13. Remove dilator and injection cap from sheath.

14. Insert distal tip of catheter into and through the skin until the distal 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 tear the sheath only a few centimeters at a time.

16. Make any adjustments to catheter under fluoroscopy. The venous distal tip should be positioned at the level of the caval atrial junction or beyond into the right atrium to ensure optimal blood flow.

Note: Femoral catheter tip placement is recommended at the junction of the iliac vein and the inferior vena cava.

17. 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 flows.

18. Once adequate aspiration has been achieved, both lumens should aspirate with salin filled syringes using quick bulbous technique. Assure that extension clamps are open during irrigation procedure.

19. Close the extension clamps, remove the syringes, and place an injection cap on each lumen lock connector. Avoid air embolism by keeping extension tubing clamped at all times when not in use and by aspirating then irrigating the catheter with saline prior to each use. With each change in tubing connections, purge air from the catheter and all connecting tubing and caps.

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 install injection caps onto the extensions’ female luer.

22. Confirm proper tip placement with fluoroscopy. The distal venous tip should be positioned at the level of the caval atrial junction or into the right atrium to ensure optimal blood flow (as recommended in current NKF DOQI Guidelines).

Note: Femoral catheter tip placement is recommended at the junction of the iliac vein and the inferior vena cava.

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 bulbous 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.

Note: 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; however, iodine-based solutions can 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.

Note: Patients must not swim, shower, or soak dressing while bathing.

Warning: Patients must not swim, shower, or soak dressing while bathing.

• If profuse peritonitis or accidental perforation occurs, adhere to standard medical dressings, the medical or nursing staff must change the dressing under aseptic conditions.

CATHETER PERFORMANCE

Caution: Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to catheter placement.

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

MICRO PUNCTURE INSERTION METHOD

Once an .038” guidewire has been introduced into the target vein, the 4F sheath dilator should be threaded over the proximal end of the wire and inserted into the target vein.

When the 4F sheath dilator is located in the target vein, remove the guidewire and dilate one at a time.

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 irrigation utilizing a thrombolytic agent.

MANAGEMENT OF ONE OBSTRUCTION:

One-way obstructions exist when a lumen can be flushed easily but blood cannot be aspirated, which 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 in 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.

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 objects or needles in close proximity to vessel wall.

6. When visible, grasp cuff with clamp.

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

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 or 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 may effect the performance of this product.

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

• 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.

• Clinically recognized infection at a catheter exit site should be treated promptly with the appropriate antibiotic therapy.

• If a fever occurs in a patient in 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.

• Insert an .038” guidewire into and through the sheath until it is located in the target vein.

• Remove the sheath and continue following directions starting at #11.

References:


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