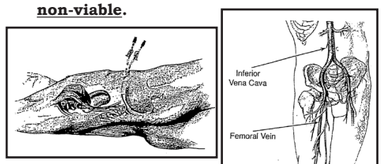
SPLIT CATH® III WITH FAST TRACK PRE-LOADED STYLET TRANSLUMBAR

INSTRUCTIONS FOR USE

WARNING: When using the Vascu-Sheath®, remove pre-loaded stylet from catheter.

INDICATIONS FOR USE:

- The Medcomp® Split Cath® III Catheter is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis in adult patients.
- It may be inserted percutaneously and is primarily placed in the internal jugular vein.
- Alternate insertion sites include the subclavian vein and inferior vena cava as required.
- Catheters greater than 40cm are intended for femoral vein insertion or inferior vena cava insertion. **Translumbar insertion via inferior vena cava is indicated when all other access sites are identified as non-viable.**

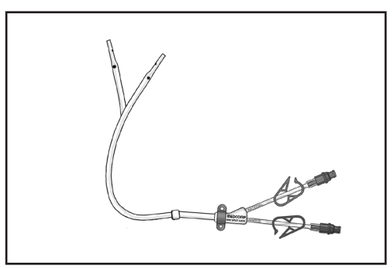


CONTRAINDICATIONS:

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

DESCRIPTION:

- The versatility of the Split Cath® III allows the lumens to be split to form two free floating lumens to help eliminate catheter occlusion by the vessel.
- The Split Cath® III is manufactured from soft radiopaque polyurethane material which provides increased patient comfort while providing excellent biocompatibility.



POTENTIAL COMPLICATIONS:

Complications unique to the translumbar procedure are below in **bold** type; all other complications apply to any catheter insertion.

- Air Embolus
- Bacteremia
- Brachial Plexus Injury
- Cardiac Arrhythmia
- Cardiac Tamponade
- Central Venous Thrombosis
- **Dislodged Catheter**
- Endocarditis
- Exit Site Infection
- Exsanguination
- Femoral Artery Bleed
- Femoral Nerve Damage
- Hematoma (**groin**)
- Hemorrhage
- Hemothorax
- **Illiofemoral Thrombosis**[4]
- Inferior Vena Cava Puncture
- Mediastinal Injury
- **Migration into Retroperitoneum**[3]
- **Migration into Iliac Veins**[3]
- Perforation of the Vessel
- Pleural Injury
- Pneumothorax
- **Reaction to Contrast Media**
- **Renal Artery Bleed**
- **Retroperitoneal Bleed (hematoma)**
- Right Atrial Puncture
- Septicemia
- Subclavian Artery Puncture
- Subcutaneous Hematoma
- Superior Vena Cava Puncture
- Thoracic Duct Laceration
- Tunnel Infection
- **Uretreic Fistuala**[2]
- Vascular Thrombosis
- Venous Stenosis
- Laceration of the Vessel
- Lumen Thrombosis

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

SUGGESTED TREATMENT OF COMPLICATIONS:

- Fibrin sheath or thrombosis - treat with thrombolytic enzyme or replace catheter.
- Infections - possible removal of catheter and antibiotics.
- Dislodged or migration - reposition over guidewire or replace catheter.
- Bleeding - necessary steps for degree of bleed - compression - removal of catheter - blood transfusion.
- Ureteric fistula - noted in one study as possibly due to erosion secondary to chronic extrinsic compression and not to laceration during catheter placement. Fistula healed following stent of the ureter.

Caution: The incidence of infection may be increased with femoral vein insertion and translumbar insertion.[4]

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 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 introducer needle or Vascu-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 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.

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 luers and hub 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.

INSTRUCTIONS FOR TRANSLUMBAR INSERTION:

1. Strict aseptic technique must be used during 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 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. Patient in prone position w/25 degree elevation of the right side.[1]
5. Puncture site chosen 10cm cephalad to the right iliac crest and 10cm lagteral to the spine.[1]
6. Puncture into the IVC is made at 45 degrees from the horizontal and advanced medially and superiorly under fluoroscopic guidance.[1]
7. Entry into the IVC is made below the level of the renal veins. When satisfactory entry is achieved, the guidewire is introduced through the needle and advanced well into the IVC. An inferior vena cavagram can be performed through the dilator to access the upper IVC.[1]
8. At the initial dermatotomy site, a 1cm vertical incision is made through the skin, a second 1cm vertical incision is made approximately 10-15cm lateral to the first incision. The subcutaneous tunnel is created between the two incisions. The catheter is then brought through the subcutaneous tunnel.[1]
9. Use blunt dissection to create the subcutaneous tunnel opening. Unthread stylet cap and slide tip into the arterial lumen until the tip is no longer visible. Attach venous lumen to trocar. Slide catheter tunneling sleeve over the catheter making certain that the sleeve covers the arterial holes of the catheter. Insert the trocar into the exit site and create a short subcutaneous tunnel. Do not tunnel through muscle. The tunnel should be made with care in order to prevent damage to surrounding vessels.

Warning: Do not over-expand subcutaneous tissue during tunneling. Over-expansion may delay/prevent cuff in-growth.

10. Lead catheter into the tunnel gently. Do not pull or tug the catheter tubing. If resistance is encountered, further blunt dissectoin may facilitate insertion. Remove the catheter from the trocar and sleeve.

Caution: Do not pull tunneler out at an angle. Keep tunneler straight to prevent damage to catheter tip.

Note: A tunnel with a wide gentle arc lessens 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.

11. Split the arterial and venous lumens by grasping the distal ends and gently pull apart the lumens to the point printed "**DO NOT SPLIT BEYOND THIS POINT**".

Warning: Splitting the lumens beyond this point may result in excess tunnel bleeding, infection, or damage to the catheter lumens. Also use caution to avoid damaging the stylet when splitting the lumens.

12. Push stylet back into catheter and tighten stylet cap onto arterial catheter luer. Thread stylet tip into proximal hole of venous lumen and out the tip hole to allow the stylet tip to extend beyond the venous tip.
13. Irrigate catheter with saline, then clamp venous extension and cap stylet to assure that saline is not inadvertently drained from lumens. Use clamp and end cap provided.

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.

14. Remove needle, leaving guidewire in the target vein. Enlarge cutaneous puncture site with scalpel.
15. Thread dilator(s) over guidewire into the vessel (a slight twisting motion may be used). Remove dilator(s) when vessel is sufficiently dilated, leaving guidewire in place.

Caution: Insufficent 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.

Caution: Do not leave vessel dilator(s) in place as an indwellig catheter to avoid possible vessel wall perforation.

16. Thread the proximal end of the guidewire through the distal tip of the stylet.
17. Once the guidewire exits through the red luer connector, hold the guidewire securely and advance the catheter over the guidewire and into the target vein, making sure to hold the arterial and venous tips securely to prevent the venous lumen from kinking and the stylet tip from retracting into the catheter during insertion.

Caution: Do not advance guidewire with catheter into vein. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

18. Remove the guidewire and stylet, leaving catheter in place.
19. Make any adjustments to catheter under fluoroscopy.
20. 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.
21. Once adequate aspiration has been achieved, both lumens should be irrigated with saline filled syringes using quick bolus technique. Assure that extension clamps are open during irrigation procedure.
22. Close the extension clamps, remove the syringes, and place an end cap on each luer 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.
23. 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.

24. Once the catheter is locked with heparin, close the clamps and install end caps onto the extensions' female luers.
25. Tip placement is recommended in the IVC at the IVC/right atrial junction, preferably in the right atrium. Confirm proper tip placement with fluoroscopy.

Caution: Failure to verify catheter placement may result in serious trauma or fatal complications.

CATHETER SECUREMENT AND WOUND DRESSING:

26. Suture insertion site closed. Suture the catheter to the skin using the suture wing. Do not suture the catheter tubing.

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.

27. Cover the insertion and exit site with an occlusive dressings.
28. Catheter must be secured/sutured for entire duration of implantation.
29. 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.

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 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.

Caution: 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

- Catheter is compatible with ointments.
- 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.

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.

MICRO PUNCTURE INSERTION METHOD

- Once an .018" 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 dilator one at a time.
- 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 #13.

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.
3. Cut sutures from suture wing. Follow hospital protocol for removal of skin sutures.
4. Make a 2 cm incision over the cuff, parallel to the catheter.
5. Dissect down to the cuff using blunt and sharp dissection as indicated.
6. When visible, grasp cuff with clamp.
7. Clamp catheter between the cuff and the insertion site.
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 must be equal to the length of catheter when it was inserted.

14F x 40cm PRESSURE

	200 ml/MIN	300 ml/MIN	400 ml/MIN
VENOUS	43.0 mmHg	75.8 mmHg	115.8 mmHg
ARTERIAL	-34.2 mmHg	-69.4 mmHg	-113.4 mmHg

14F x 55cm PRESSURE

	200 ml/MIN	300 ml/MIN	400 ml/MIN
VENOUS	48.6 mmHg	85.4 mmHg	127.2 mmHg
ARTERIAL	-44.6 mmHg	-86.4 mmHg	-136.6 mmHg

FLOW RATE TESTING REPRESENTS OPTIMUM LABORATORY CONDITIONS.

References:

1. Beyer, A.J., Malik, N., Waugh, C.A. (10/31/98). Translumbar Placement of Inferior Vena Cava Central Venous Catheters. *MIRS-IR Vol II:7.*
2. Bilbao, J.I., Delgado, C., Elduayen, B., Martinez-Cuesta, A., Pueyo, J.C., Vivas, I. (2000) Central Venous Catheter Placement in the Inferior Vena Cava via the Translumbar Approach. *European Radiology, Vol. 10, pg 450-454.*
3. Lund, G.B., Lieberman, R.P., Haire, W.D., Martin, V.A., Kessinger, a, Armitage, J.O. (1990) Translumbar Inferior Vena Cava Catheters for Long-Term Venous Access. *Radiology, 174:31-35.*
4. Lund, G.B., Scheel, P.J., Trerotola, S.O.: (1995) Percutaneous translumbar inferior vena cava cannulation for hemodialysis. *Am J Kidney Dis 25:732-737.*

WARRANTY

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SYMBOL TABLE

5.1.1	Manufacturer*
5.3.4	Keep Dry*
5.6.3	Non-pyrogenic*
5.3.2	Keep Away from Sunlight*
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide*
5.2.8	Do Not Use if Package is Damaged*
5.1.4	Use-by Date*
5.2.6 2 STERILE	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 *
5.1.2 EC REP	Authorized Representative in the European Community
Rx Only	Prescription Use Only ***

***This symbol is in accordance with ISO 15223-1.**

***** FDA guidance Use of Symbols in Labeling.**

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