medCOMP®

Bio-Flex® Tesio® Catheter with Cuff

LONG-TERM HEMODIALYSIS

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

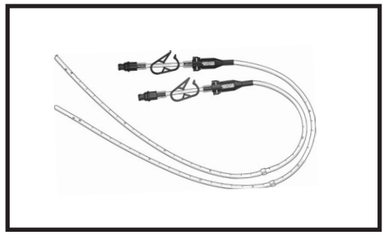
- The Medcomp® Bio-Flex® Catheter is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis.
- It may be inserted percutaneously and is primarily placed in the internal jugular vein of a pediatric patient.
- Alternate insertion sites include subclavian vein as required.

CONTRAINDICATIONS:

- This catheter is intended for Long-Term vascular access only and should not be used for any purpose other than indicated in these directions.
- To maintain peak performance of the Lock Right® Adapters, it is recommended that the adapters be replaced every 6 months.

DESCRIPTION:

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



POTENTIAL COMPLICATIONS:

Air Embolus
Bacteremia
Brachial Plexus Injury
Cardiac Arrhythmia
Cardiac Tamponade
Septicemia
Endocarditis
Exit Site Infection
Exsanguination
Hemorrhage
Hematoma
Hemothorax
Laceration of the Vessel
Lumen Thrombosis
Mediastinal Injury
Perforation of the Vessel
Pleural Injury
Pneumothorax
Retroperitoneal Bleed
Right Atrial Puncture
Central Venous Thrombosis
Subclavian Artery Puncture
Subcutaneous Hematoma
Superior Vena Cava Puncture
Thoracic Duct Laceration
Tunnel Infection
Vascular Thrombosis

- Before attempting the insertion, ensure that you are familiar with the above 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 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 guidewire is damaged, the introducer needle or Vascu-Sheath® introducer and guidewire must be removed together.
- Federal Law (USA) restricts this 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.

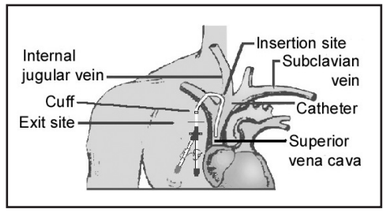
CATHETER PRECAUTIONS:

- Use only Medcomp® Lock Right® Adapters with this catheter.
- Do not use sharp instruments near the adapter 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 adapter or luer of the Lock Right® Adapter.
- Examine catheter lumen and Lock Right® Adapter 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 failure of the Lock Right® Adapter Luer Connector.

INSERTION SITES:

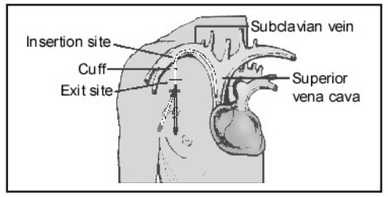
- The patient should be in a modified Trendelenburg position, with the upper chest exposed and the head turned slightly to the side opposite the insertion area. A small rolled towel may be inserted between the shoulder blades to facilitate the extension of the chest area.

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

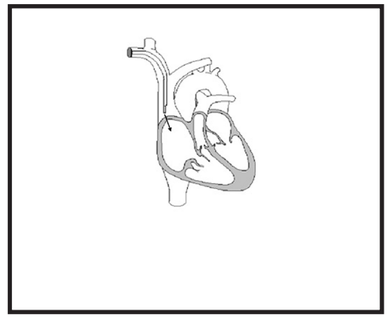


- Note the position of the subclavian vein which is posterior to the clavicle, superior to the first rib, and anterior to the subclavian artery. (At a point just lateral to the angle made by the clavicle and the first rib.)

WARNING:

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

Tip Placement



- 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 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 judgment in treating any specific patient.
- Use standard hospital protocols when applicable.

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, gloves, and mask. Have patient wear mask.
2. The selection of the appropriate cannula 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. Insert the introducer needle with attached syringe, or into the target vein. Aspirate to insure proper placement.
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 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 signs of 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.

6. Remove needle, leaving guidewire in the target vein. Englarge puncture site with scalpel.
7. Introduce the second needle and guidewire into the same target vein approximately 3mm adjacent to the first following method detailed above.
8. Thread Vascu-Sheath® introducer over the proximal end of the guidewire. Once the Vascu-Sheath® introducer is in target vein, remove the guidewire leaving the sheath and dilator in position.

Caution: DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted.

Caution: Never leave sheaths in place as indwelling catheters. Damage to the vein will occur.

9. Install injection cap over dilator openings to prevent blood loss or air embolism.
10. Clamp catheter proximally to prevent air embolism and blood loss. Use clamps provided.
11. Remove dilator and injection cap from sheath.
12. Insert catheter tip into and through the sheath until tip is correctly positioned in the target vein.
13. Remove the tear-away sheath by slowly pulling the sheath out of the vessel while splitting the sheath by grasping the tabs and pulling them apart.
14. Repeat steps 10-13 for second catheter.
15. Make any adjustments to catheter position under fluoroscopy. The venous distal tip should be positioned at the level of the caval atrial junction or into the right atrium, and approximately 4cm past the arterial catheter.

TUNNELIZATION & CUFF PLACEMENT:

16. Position catheter over anticipated tunnel path.
17. Note the desired location at which the cuff will be positioned.
18. Administer sufficient anesthetic to the entire length of tunnel path.
19. Make an incision at the tunnel exit site. Using the trocar tunneler provided, create an 8-10cm tunnel in the direction of the catheter exit site incision.

Caution: Do not tunnel through muscle.

Note: For ease of dressing the exit site and for patient comfort, locate the subcutaneous tunnel below the vein insertion site. A tunnel with a wide gentle arc lessens the risk of kinking, which will result in poor blood flow.

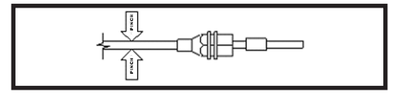
20. When the distal end of the trocar tunneler has passed through the catheter exit site incision, and is visible, remove the clamp from the catheter and connect the proximal end of the catheter onto the proximal end of the trocar tunneler.
21. Carefully pull the catheter through the tunnel feeding the cuff into the tunnel. Palpate the tunnel until proper cuff placement is achieved.
22. Repeat steps 16 through 21 for second catheter.

INSTALLATION OF Lock Right® ADAPTERS:

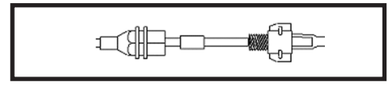
23. Prime the catheter extensions with saline, clamp, and then screw injection caps onto the female luers of the adapters.
24. Make sure white lumen is thoroughly dried before attaching adapter.

Note: Do not soak catheter end or adapter in any antiseptic (i.e. alcohol, PVP, etc.) before or during adapter installation.

25. Pinch catheter lumen to prevent blood loss or air embolism. Install threaded collar and compression ring over catheter lumen.



26. Place the metal cannula of the adapter into the catheter, and push the catheter up the cannula until no metal is visible.



27. Once catheter is installed onto the Lock Right® Adapter, move the compression collar in a proximal direction until it is against the Lock Right® Adapter threads.

28. Completely thread the collar onto the Lock Right® Adapter.

29. Repeat steps 23 through 28 on second catheter.

30. Remove injection caps, attach syringes on both Lock Right® Adapters, and open clamps. Blood should aspirate easily from both catheters. If either catheter exhibits excessive resistance to blood aspiration, the catheter may need to be rotated or repositioned to sustain adequate blood flows.

31. When adequate aspiration has been achieved, both lumens should be irrigated with heparin filled syringes using quick bolus technique. Assure that extension clamps are open for irrigation procedure.

Caution: Assure that all air has been aspirated from catheter and the Lock Right® Adapters. Failure to do so may result in air embolism.

32. Once the catheters are locked with heparin, close the extension clamps, remove the syringes, and install the injection caps onto the the Lock Right® Adapters' female luers.

33. 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, and approximately 4cm past the arterial catheter.

34. Suture insertion site closed.

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

CATHETER SECUREMENT AND WOUND DRESSING:

35. Suture the catheter to the skin using the suture wing. Do not suture 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.

Note: If using **STATLOCK**® for catheter securement, clean the area where the Lock Right® Adapter will lie on the patient with alcohol. Remove the backing of one side of the **STATLOCK**® pad and position on patient. Once positioned, remove the remaining protective backing. Apply slight pressure on the pad to assure adherence. Push the collar section of the Lock Right® Adapter into the receiving grooves of the **STATLOCK**® pad. Repeat for second adapter.

36. Cover the exit site with occlusive dressing.

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

38. Record catheter length and catheter lot number on patient's chart and check catheter position routinely.

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 clamps provided or smooth jawed hemostat.

- 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.

1. Draw heparin in two syringes, corresponding to the amount designated on each catheter lumen. Assure that the syringes are free of air.

2. Remove injection caps from the Lock Right® Adapters.

3. Attach a syringe containing heparin solution to the female luer of each Lock Right® Adapter.

4. Open extension clamps.

5. Aspirate to insure that no air will be forced into the patient.

6. Inject heparin into each catheter 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 luers of the Lock Right® Adapters.

- In most instances, no further heparin is necessary for 48-72 hours, provided the catheters have not been aspirated or flushed.

SITE CARE

- Clean skin around catheter. Cover the exit site with occlusive dressing and leave extensions, clamps, Lock Right® Adapters, and caps exposed for access by staff.

- Wound dressing 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.

1. Administer sufficient local anesthetic to exit site and cuff location to completely anesthetize the area.

2. Apply a firm, steady, downward force on the catheter near the exit site. The catheter should detach from the tunnel and be removed in its entirety.

Warning: Do not use excessive force as this may break the catheter.

If the catheter does not withdraw from the tunnel after moderate force has been applied, or the catheter is removed without the cuff, the following steps may be taken to remove the catheter.

3. Palpate the catheter exit tunnel to locate the cuff.

4. Repeat for second catheter.

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

6. Make 2cm incision over the cuff, parallel to the catheter.

7. Dissect down to the cuff using blunt and sharp dissection as indicated.

8. When visible, grasp cuff with clamp.

9. Clamp catheter between the cuff and the insertion site.

10. Cut catheter between cuff and exit site. Withdraw internal portion of catheter through the incision in the tunnel.

11. 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.

12. Apply pressure to proximal tunnel for approximately 10-15 minutes or until bleeding stops.

13. Suture incision and apply dressing in a manner to promote optimal healing.

MR LABELING BASED ON THE TEST RESULTS

MR Safety Information

MR Information. The Tesio Catheter (polyurethane with embedded stainless steel connector) was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, Pennsylvania, 2005.

Non-Clinical testing demostrated that the Tesio Catheter (polyurethane with embedded stainless steel connector) is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MR-Related Heating
In non-clinical testing, the Tesio Catheter (polyurethane with embedded stainless steel connector) produced the following temperature rise during MR performed for 15-min in the 3-Tesla (3-Tesla/128-MHZ, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR System:

Highest temperature change +1.6°C

Therefore, the MR-related heating experiments for the Tesio Catheter (polyurethane with embedded stainless steel connector) at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9-W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occured in association with these specific conditions was equal to or less than +1.6°C.

Artifact Information
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Tesio Catheter (polyurethane with embedded stainless steel connector). Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	778-mm^2	233-mm^2	1,456-mm^2	1,778-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents without notice.

SYMBOL TABLE

5.1.1	Manufacturer*
5.3.4	Keep Dry*
5.4.2	Do Not Re-use*
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 STERILE R	Do Not Resterilize*
5.1.5 LOT	Batch/Lot Number*
5.1.6 REF	Catalogue Number*
5.4.4	Caution, consult Accompanying Documents*
Rx Only	Prescription Use Only***
5.3.6	Upper Limit of Temperature*
5.1.2 EC REP	Authorized Representative in the European Community*
MR	MR Conditional - 3 Tesla****

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

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

******This Symbol is in accordance with ASTM F 2503-20.**
Note: Temperature symbols :
"This symbol only applies to kits with drugs".

Medical Components, Inc.
1499 Delp

PN 40593BSI REV. 5/21 C