Bio-Flex® Tesio® Catheter with Cuff
LONG-TERM HEMODIALYSIS INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The Medcomp® Bio-Flex® Catheter is intended for Long-Term vascular access for Hemodialysis and Apheresis.
- It may be inserted percutaneously and is primarily placed in the jugular vein of an adult 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.

CATHETER PRECAUTIONS:

- Use only Medcomp® Lock Right® Adapters with this catheter.
- Do not use sharp instruments near the puncture site or catheter hub.
- Do not use scissors to remove dressing.
- Cather will be damaged if clamps other than what is provided with this kit are used.

POSSIBLE COMPLICATIONS:

- Air Embolism
- Bleeding
- Bruised Vein Injury
- Cardiac Tamponade
- Posterior Subclavian
- Posterior Subclavian Septicemia
- Peripheral Nerve Injury
- Pulmonary Embolism
- Right Anterior Puncture
- Central Vein Venous Thrombosis
- Retransfer Artery Perforation
- Retransfer Infections
- Septicemia
- Subclavian Vein Perforation
- Superior Vena Cava Thrombosis
- Tubular Indications
- Hyperthermia
- Pneumothorax
- Subclavian Vein Thrombosis

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

POTENTIAL COMPLICATIONS:

- 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 Vasoc-Shell® 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 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 consequences of re-use or re-sterilization of this catheter or accessories.

- Contents sterile and non-pyrogenic in unopened, unmarked package.

- STERILE EO

- Do not use catheter or accessories if package is opened or damaged.
- Do not use catheter or accessories if any signs of product damage is visible.

- Use only medcomp® Lock Right® Adapters with this catheter.
- Do not use sharp instruments near the puncture site or catheter hub.
- 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 catheter.
- 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 over tightening 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 catheter area.

- Internal Jugular Vein

- Insertion site
- Superficial vein area
- Subclavian vein

- 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 SELLINGER INSERTION

- Re-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.

- 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. Share 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 and dilator/sheath for use is left to the 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 the 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 a wide gentle arc, and direct the needle into the target vein. Aspirate to insure proper placement.
- 5. Remove the syringe and place thumb pressure on the end of the needle to prevent blood loss or air embolism. Draw flexible end of guidewire back into advances so that only the end of the guidewire is visible. Insert advancement 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. Engage puncture site with scalpel.
- 7. Introduce the second needle and push catheter along the guidewire approximately 3mm adjacent to the first following method detailed above.
- 8. Thread Vasoc-Shell® introducer over the proximal end of the guidewire. Once the Vasoc-Shell® introducer is in the target vein, remove any additional needle leaving the sheath and dilator in position.
- Caution: DO NOT bend the sheath/dilator unit. Forceful 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 soft enough to avoid the initial 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 with catheter.
- 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 apart. Do not force the sheath.
- 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.

- 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 tunnel has passed through the catheter exit site incision, and is visible, remove the clamp from the catheter and continue to the proximal end of the catheter onto the proximal end of the trocar tunnel.
- 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® ADAPTER:

- 23. Prime the catheter extensions with saline, clamp, and then screw injection caps into the female luer of the adapters.
- 24. Make sure white lumen is totally drained 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. Punch 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 metal cannula 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 catheter 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 extension clamps. Blood should drain easily from both catheters. If either catheter exhibits excessive resistance to blood flow, the examiner may need to be rotated or repositioned to sustain adequate blood flow.

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

Caution: Ensure that all air has been aspirated from catheter and the Lock Right® Adapter. 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 Lock Right® Adapters' female luer.

33. Confirm proper tip placement with fluoresceo. The tip of each lumen should be positioned at the level of the caval atrial junction or into the right atrium, and 1.5 to 2.0 cm past the arterial catheter.

34. Suture insertion site closed.

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

CATHER REMOVAL

1. Draw heparin in two syringes, and create in each lumen of the catheter.

2. Attach a syringe containing heparin to each catheter lumen. Contact from sharp objects or needles in close proximity to catheter lumen. Caution: Only clinch catheter with clamps provided or smooth jawed hemostat.

3. 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 in a physician's instructions.

HEMODYALYSIS TREATMENT

• The heparin solution must be removed from each lumen prior to treatment to prevent systemic heparinization of the patient. Anticoagulation should be based on dialexis unit protocol.

• Before dialysis begins, all connections to catheter and extracorporeal circuits should be examined carefully.

• 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 treatments, 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 has been aspirated easily but blood cannot be aspirated. This is usually caused by tip malpositioning.

One of the following adjustments may resolve the obstruction:

- Reposition catheter.

- Reposition patient.

- Have patient cough.

Provided or smooth jawed hemostat.

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

SITE CARE

- Clean skin around catheter. Cover the exit site with occlusive dressing, and be removed in its entirety.

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

- 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 treatments, 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:

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

2. Repeat for second catheter.

3. Cut catheter between cuff and exit site. With a sterile stainless steel scalpel enter through the incision in the tunnel.

10. Cut catheter between cuff and exit site. With a sterile stainless steel scalpel enter 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 until bleeding stops.

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

MR LABELING BASED ON THE TEST RESULTS


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