medCOMP®

Arterial and Venous Extension Set for Tesio® Catheters

INSTRUCTIONS FOR USE

INDICATIONS FOR USE:

- The Medcomp® Tesio® Catheter is designed for Long Term Hemodialysis and Apheresis. It may be inserted percutaneously, and is ideally placed in the internal jugular vein. Although this catheter may be inserted into the subclavian vein, the internal jugular vein is the preferred site.

CONTRAINDICATIONS:

- This extension is not intended for any use other than that which is indicated.
- To maintain peak performance of the extension, it is recommended that the extensions be replaced every 6 months.

DESCRIPTION:

- The extension set for Tesio® is manufactured from biocompatible pellathane material and consists of the extension with a clamp that has a metal cannula at one end and a luer at the other end. Also included in the kit is a collar and compression ring as part of the assembly.

POTENTIAL COMPLICATIONS:

Air Embolus
Bacteremia
Exsanguination
Hemorrage
Hematoma

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.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- This device 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

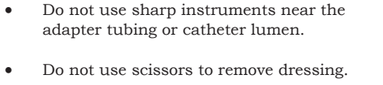
- Do not use if package is opened or damaged.
- Do not use if any sign of product damage is visible.
- The medical techniques and procedures described in these instructions for use do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgement in treating any specific patient.

PRECAUTIONS:

- Do not use sharp instruments near the adapter tubing or catheter lumen.
- Do not use scissors to remove dressing.
- Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near adapter or luer of the extensions.
- Examine catheter lumen and arterial and venous extensions 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.
- Make sure catheter lumen is thoroughly dry before attaching the adapter.
- Repeated over tightening of bloodlines, syringes, and caps will reduce connector life and could lead to failure of the arterial venous extension connector.
- When cutting catheter to desired length, assure the lumen is cut square and that the remaining catheter lumen is not damaged.
- Attach a syringe containing heparin solution to the female luer of extension adapter. Open extension clamps. Aspirate to insure that no air will be forced into the patient. Inject heparin into each catheter using quick bolus technique.

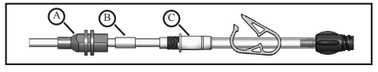
DIRECTIONS FOR ASSEMBLY:

STEP 1



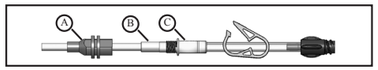
1. Take apart female adapter by twisting parts (A) and (C) apart. The silicone compression ring (B) should be found in part (A).

STEP 2



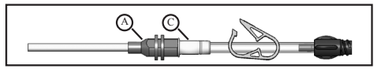
2. Slide adapter part (A) over tubing. Slide compression ring (B) over tubing. Insert metal portion of adapter part (C) into the tubing with a twisting motion, making sure the tubing is fully seated against part (C).

STEP 3



3. Slide compression ring (B) toward end of tubing/adapter assembly.

STEP 4



4. Slide adapter part (A) toward end of tubing/ adapter assembly and twist adapter together firmly until there is no gap between adapter parts (A) and (C). A gentle tug will assure proper assembly.

STEP 5

5. Attach a syringe containing heparin solution to the female luer of extension adapter. Open extension clamps. Aspirate to insure that no air will be forced into the patient. Inject heparin into each catheter using quick bolus technique.

Note: If using StatLock® for catheter securement, clean the area where the adapter will lie on the patient with alcohol. Remove the backing of the 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 adapter into the receiving grooves of the StatLock® pad. Repeat for second adapter.

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 end caps from the arterial venous extension luers.
3. Attach a syringe containing heparin solution to the female luer of each arterial venous extension.
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 end cap onto the female luers of the arterial venous extension.

- 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, arterial and venous extensions, 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.

MR LABELING BASED ON THE TEST RESULTS

MR

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-mm²	233-mm²	1,456-mm²	1,778-mm²
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	Do Not Resterilize *
5.1.5 LOT	Batch/Lot Number *
5.1.6 REF	Catalogue Number *
5.1.2 EC REP	Authorized Representative in the European Community *
5.4.4	Caution, consult Accompanying Documents *
Rx Only	Prescription Use Only***
5.3.6	Upper Limit of Temperature *
5.2.8	Do Not Use if Package is Damaged *
5.4.2	Consult Instructions for Use *
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 F2503-20.**

Note: Temperature symbols : "This symbol only applies to kits with drugs".

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