12F TESIO® SILICONE SINGLE LUMEN CATHETER TWO-PART ADAPTOR INSTRUCTIONS FOR USE

INDICATIONS: 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 subclvian vein, the internal jugular vein of an adult patient is the preferred site.

DEVICE DESCRIPTION: The Two-Part Adaptor is indicated for use on the 12F Tesio® Silicone Single Lumen Catheters only. The Two-Part Adaptor is used to repair an extension tube where a leak or flaw may have developed.

POTENTIAL COMPLICATIONS:

- Infection
- Bleeding

WARNINGS:

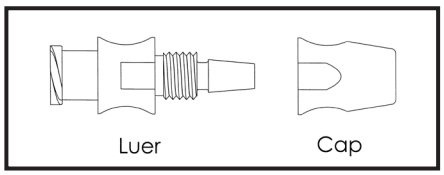
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Product is sterile in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE STERILE EO
- Single use only. DO NOT RE-USE. Re-use may lead to infection or illness/injury.
- Do not use if package or component is damaged.
- Do not resterilize.
- Use caution when assembling to avoid cuts and pinches.

INSTRUCTIONS FOR USE:

WARNING: Do **NOT** soak catheter end or adaptor in any antiseptic (e.g., alcohol, PVP) before or during adaptor installation.

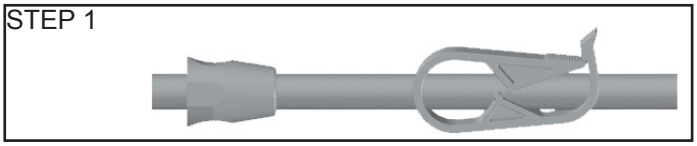
Caution: When cutting catheter to desired length, assure lumen is cut square and that remaining catheter lumen is not damaged.

1. Remove the luer and cap from the package. **Note:** Both components must be utilized to complete installation.

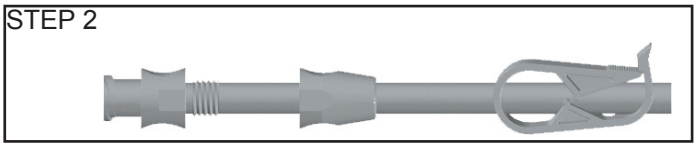


2. Assemble the provided luer to the catheter as follows:

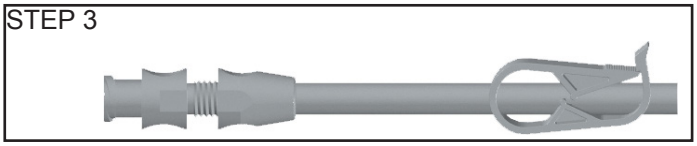
- Slide cap over the catheter tubing such that the taper faces the catheter exit site. (Step 1)



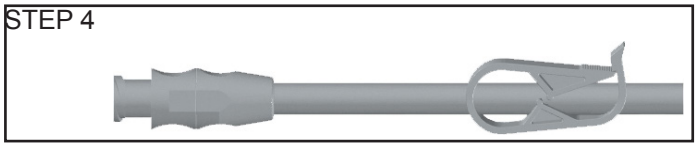
- Push barbed end of the luer into the catheter tubing. Position completely over barbed end of fitting making sure the tubing is **FULLY** seated. (Step 2)



- Gently tug the tubing to ensure snug fit.
- Slide the cap toward the threads on the luer, and rotate it to engage the threads. (Step 3)



- Continue to thread the cap by hand onto the luer until secure. (Step 4)



Caution: Assembly threads **MUST** be fully engaged.

3. Grasping the luer in one hand, and the tubing in the other, gently tug on the joint to test the security of the connector. If the luer pulls out of tubing, repeat the connection procedure. A connection failure may be due to one, or a combination of the following:

   - The luer is not fully inserted into the catheter tubing.

   - The catheter tubing is damaged, preventing a secure connection. If the failure is due to damaged tubing, then the catheter may need to be removed and replaced. **CAUTION:** Be sure to pull on the external tubing and the connector only and not on the catheter *In Situ*.

4. Attach end cap.

5. Use a sterile 10cc luer lock syringe to aspirate any air introduced during the connection procedure.

6. Continue with catheter Instructions for Use.

NOTE: Discard biohazard according to facility protocol.

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY EFFECT 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.

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