



Repair Kit Instructions for Use

- Repairs Medcomp® Catheters: Split Cath®, Hemo-Flow®, Hemo-Flow® XF, Titan HD™





INDICATIONS FOR USE:

- To replace damaged female luer connectors, clamps, or repair extensions where there is a minimum of 4.5cm viable extension tubing.

CONTRAINDICATIONS:

- Do not use to repair catheters other than those specified above.
- Do not replace connector if tubing is swollen or displays signs of degradation.
- This repair kit should not be used for any purpose other than indicated in these instructions.

WARNINGS:

- In the rare event luer connector separates from any component during use, take all necessary steps and precautions to prevent blood loss or air embolism.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.
- This repair kit is for Single Use Only. 
- Do not resterilize the repair kit 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 repair kit.
- Contents sterile and non-pyrogenic in unopened, undamaged package.
STERILIZED BY ETHYLENE OXIDE 
- Do not use repair kit if package is opened or damaged. 
- Do not use repair kit if any sign of product damage is visible.
- The slide clamp is provided for use during the repair procedure only. DO NOT REUSE the slide clamp as it is not permanently attached and could separate from catheter, resulting in excessive bleeding. Dispose of the slide clamp following the repair procedure.
- Failure to clamp could lead to air embolism or blood loss.
- ALL CATHETER REPAIRS ARE DONE AT THE DISCRETION OF THE ATTENDING PHYSICIAN.

PRECAUTIONS:

- For Split Cath®:** Do not use alcohol or acetone based products on this catheter. Failure of catheter will result. Iodine based solutions are recommended as the antiseptic solution that can be used on this catheter.
- 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.
- Examine catheter repair luer 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.

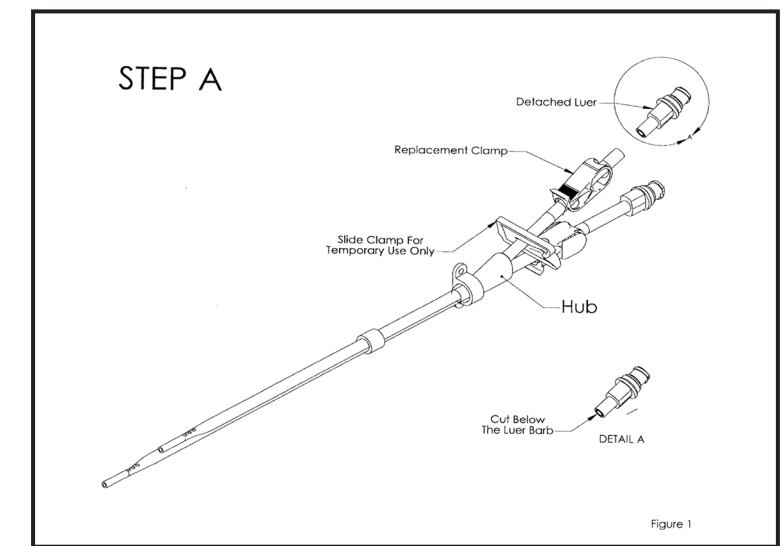
- Repeated overtightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.
- Before dialysis begins all connections to catheter and extracorporeal circuits should be examined carefully.
- Frequent visual inspection should be conducted to detect leaks to prevent blood loss or air embolism.
- If a leak is found, the catheter should be clamped immediately.

Caution: Care must be taken when using sharp objects or needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.

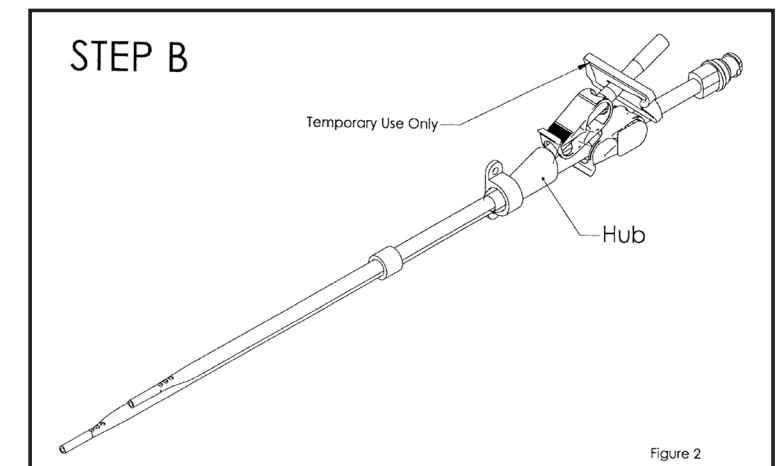
Caution: Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, health care professionals should always use Universal Blood and Body Fluid Precautions in the care of all patients.

DIRECTIONS FOR REPAIR:

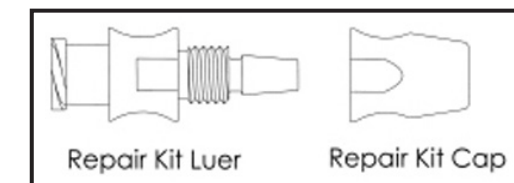
- Read instructions carefully before using this device. The catheter should be repaired by a qualified, licensed physician or other qualified health care professional under the direction of a physician.
 - The medical techniques and procedures described in these instructions for use do not represent 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.
- 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 repair. Use sterile drapes, instruments, and accessories. Perform surgical scrub. Wear gown, cap, gloves, and mask. Have patient wear mask.
 - Examine entire length of extension tubing for damage. If the extension tubing is split, swollen, has other damage, or is shorter than 4.5cm, the catheter should be replaced.
 - Starting at the catheter hub, use the measuring tape provided on the back, right hand side of instructions to measure the length of usable extension tubing that will remain after connector and any damaged tubing are cut off. If the remaining tubing length is over 4.5cm, proceed with repair.
 - Use original clamp to clamp off the catheter between the catheter hub and the damaged portion of the catheter.
 - For clamp repair: Remove damaged clamp and I.D. ring. Use slide clamp provided.
 - Clean the external segment of the catheter extension with iodine based solutions. After drying, place a sterile drape under cleaned segment of catheter.
 - Remove the end cap from the affected extension and aspirate any fluid in the extension tubing, using a 10cc Luer Lock syringe.
 - Apply the slide clamp provided in the kit onto the extension tubing adjacent to the catheter hub.
- Caution:** Do not clamp the dual lumen portion of the catheter. Clamp only the extensions. Do not use serrated forceps; use only the in-line clamps provided.
- Using the scissors included in the kit, cut off the damaged luer/extension tubing at a 90 degree angle. Make the cut as close to the luer as possible.
 - Replace existing clamp and I.D. ring with the appropriate color-coded (blue-venous, red-arterial) clamp provided in the kit, and **close the clamp**. It is important that the clamp is oriented per figure 1. (Step A)



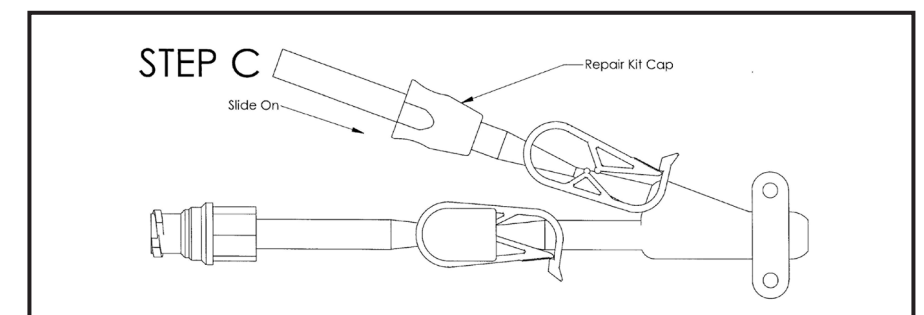
- Remove the slide clamp. Reposition the slide clamp on the extension tubing between the clamp and the cut end of the extension.
- Reposition clamp, sliding clamp partially over hub as shown in figure 2 and close clamp on extension tubing. **WARNING: Failure to clamp could lead to air embolism or blood loss.** (Step B)



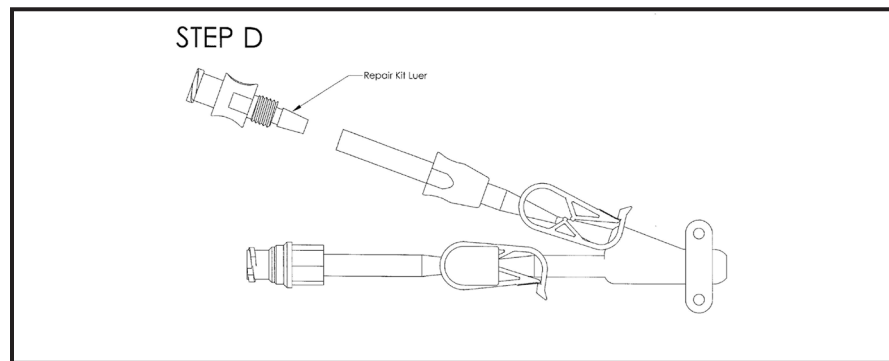
- Remove slide clamp. **WARNING: The slide clamp is provided for use during the repair procedure only. DO NOT RE-USE the slide clamp.** Dispose of the slide clamp following the repair procedure.
- Remove the extension replacement luer and cap from the package. **Note:** Both components must be utilized to complete repairs.



- Assemble the provided luer to the extension as follows:
 - Slide repair kit cap over the extension tubing such that the taper faces the catheter hub. (Step C)



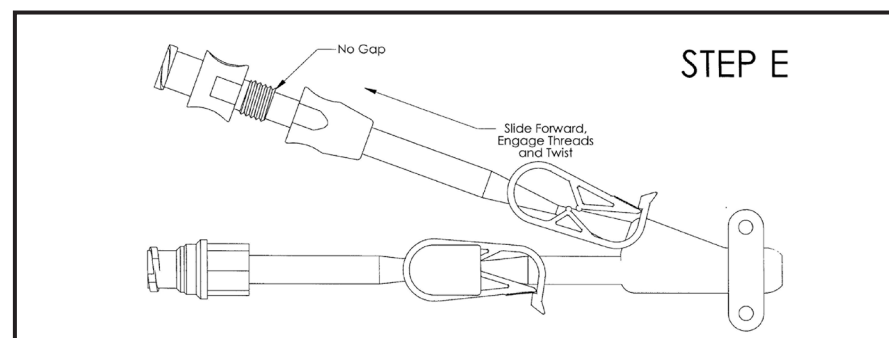
- Push barbed end of the repair kit luer into the extension tubing. Position completely over barbed end of fitting completely against threaded section of luer. (Step D)



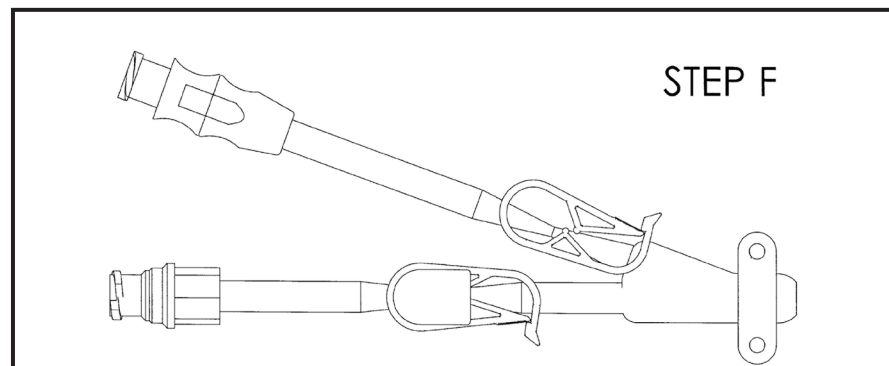
- Gently tug the extension tubing to ensure snug fit.

CAUTION: Be sure to pull on the extension tubing and the connector only and not on the catheter *In Situ*.

- Slide the repair kit cap toward the threads on the repair kit luer, and rotate it to engage the threads. (Step E)



- Continue to thread the cap by hand onto the luer until secure (Step F). A small gap between cap and luer may be present.



15. Grasping the luer in one hand, and the proximal extension 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 repair procedure. A connection failure may be due to one, or a combination of the following:

- The repair kit luer is not fully inserted into the extension tubing.
- Verify 4.5cm - try to retrim extension.
- The extension 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 extension tubing and the connector only and not on the catheter *In Situ*.

16. Attach end cap.

17. Use a sterile 10cc luer lock syringe to aspirate any air introduced during the repair of the extension.

CAUTION: Assure that all air has been aspirated from the extensions. Failure to do so may result in air embolism.

DETERMINING NEW PRIMING VOLUME:

1. Connect saline filled syringe to catheter extension. Assure that extension clamps are open during irrigation procedure.
2. Flush catheter with 1-3cc of saline. Note the volume of saline in syringe after flushing.
3. Aspirate the catheter until first sign of blood flashback.
4. Note the new volume of saline in syringe.
5. Priming volume equals the final volume in syringe minus the initial volume.
6. Record priming volume(s), repair kit lot number, and site care information from ID ring on sticker provided. Place sticker on patient's chart.

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 the lumen(s) of the catheter.
 - Follow hospital protocol for heparin concentration.
7. Draw heparin into syringes, corresponding to the amount previously determined. Assure that the syringes is free of air.
 8. Remove end caps from the extensions.
 9. Attach syringes containing heparin solution on female luers of the extensions.
 10. Open extension clamps.
 11. Aspirate to insure that no air will be forced into the patient.
 12. Inject heparin into each lumen using quick bolus technique.

Note: Each lumen should be completely filled with heparin to ensure effectiveness.

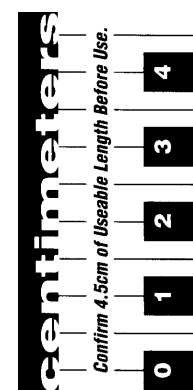
13. Close extension clamps.

Caution: Extension clamps should only be open for aspiration, flushing, and dialysis treatment.

14. Remove syringes.

15. 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 lumen(s) has not been aspirated or flushed.



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.

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SYMBOL TABLE

S.1.1		Manufacturer *
S.3.4		Keep Dry *
S.4.2		Do Not Re-use *
S.6.3		Non-pyrogenic *
S.3.2		Keep Away from Sunlight *
S.3.5		Upper Limit of Temperature *
S.2.3		Sterilized Using Ethylene Oxide *
S.2.8		Do Not Use if Package is Damaged *
S.1.4		Use By Date *
S.2.6		Do Not Resterilize *
S.1.5		Batch/Lot Number *
S.1.6		Catalogue Number *
		Prescription Use Only ***
S.1.2		Authorized Representative in the European Community *
		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 Drive
Harleysville, PA 19438 U.S.A.
Tel:215-256-4201
Fax:215-256-1787
www.medcompnet.com

EC REP
MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels
Germany

CE
2797