Split Stream® Extension Set
Instructions for Use

INDICATIONS FOR USE:

Repairs Medcomp® Split Stream® Catheters

- The Medcomp® Split Stream® 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. Alternate insertion sites include the subclavian vein.
- Catheters greater than 40CM are intended for femoral vein insertion.
- The Split Stream® Repair Kit is intended to repair the Split Stream® Hemodialysis catheter.

CONTRAINDICATIONS:

- This catheter is intended for Long-Term vascular access only and should NOT be used for any purpose other than indicated in these instructions.
- To maintain peak performance of the Split-Stream® extension set, it is recommended that the extension set be replaced every 6 months.

WARNINGS:

- Do **NOT** use to repair catheters other than those specified above.
- Do **NOT** replace extension set if tubing is swollen or displays signs of degradation.
- This extension set should **NOT** be used for any purpose other than indicated in these instructions.
- To maintain peak performance of the extension set, it is recommended that the extension set be replaced every 6 months.
- Do **NOT** resterilize the extension set or accessories by any method.
- Do **NOT** use extension set if package is opened or damaged.
- Do **NOT** use extension set if any sign of product damage is visible.
- Failure to clamp could lead to air embolism or blood loss.
- End caps are not intended to be punctured with a needle.

CAUTIONS:

- 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 extension set is for Single Use Only.
- The manufacturer shall not be liable for any damages caused by re-use or resterilization of the extension sets.
- Re-use may lead to infection or illness/injury.
- Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE STERILE EO
- ALL CATHETER REPAIRS ARE DONE AT THE DISCRETION OF THE ATTENDING PHYSICIAN.
- When cutting catheter to desired length, assure lumen is cut square and that remaining catheter lumen is not damaged.
- Avoid clamping near adapter or luer of the extension set.
- 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 extension set 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.

INSTRUCTIONS FOR USE:

- 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.

Warning: Do **NOT** soak catheter end or adapter in any antiseptic (i.e. alcohol, PVP, etc.) before or during extension set installation.

1. Strict aseptic technique must be used during maintenance and catheter repair 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.

2. Examine entire length of lumen tubing for damage. If the lumen is split, swollen, or has other damage beyond the last printed priming volume mark, the catheter should be replaced.

Caution: Detachable hub should be removed and discarded once catheter is secured by cuff and sutures are removed. Remove by depressing tabs at base of hub.

3. Prime the catheter extensions with saline and clamp the extension sets.

4. Clamp catheter using temporary slide clamps provided to prevent blood loss or air embolism. Clamp closest to catheter bifurcation.

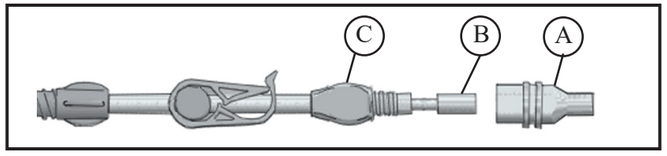
5. Clean the external segment of the catheter with compatible disinfectants. After drying, place a sterile drape under cleaned segment of catheter.

6. Using aseptic technique, cut catheter lumen squarely at the designated priming volume lines, and in such a manner that produces a clean, smooth surface. Cut only at designated priming volume lines.

7. Remove white secondary clamp. Replace with white secondary clamp in kit. Close clamp.

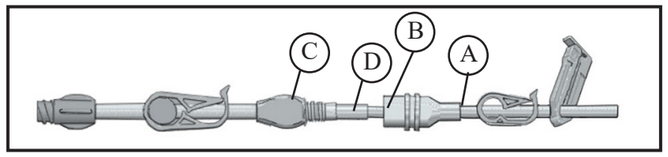
Warning: Do **NOT** soak catheter end or extension set in any antiseptic (i.e. alcohol, PVP, etc.) before or during extension set installation.

Caution: Arterial extension is to be attached to lumen with red printing and the venous extension is to be attached to the lumen with blue printing.

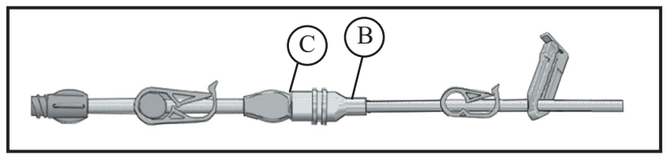


8. Take apart female adapter by twisting parts (A) and (C) apart. The compression ring (B) should be found in part (A).

Warning: Do **NOT** attempt to separate the extension from the adapter. These parts are bonded together.

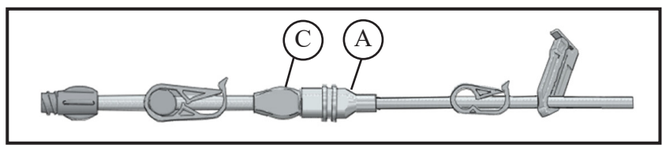


9. Slide adapter part (A) over catheter lumen (D). Slide compression ring (B) over catheter lumen (D). Insert metal cannula of adapter part (C) into the catheter lumen (D) with a twisting motion, making sure the tubing is **FULLY** seated (until no metal is visible).



10. Slide compression ring (B) toward end of catheter lumen/adapter assembly (C) until seated as shown.

Caution: Compression ring **MUST** be fully seated.



11. Slide adapter part (A) toward end of catheter lumen/adapter assembly (C) and twist adapter together firmly. A gentle tug will assure proper assembly.

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

12. Attach syringes on both extension sets, and open clamps. Remove temporary slide clamps. Blood should aspirate easily from both lumens.

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 the lumen(s) of the catheter.
- Follow hospital protocol for heparin concentration.

1. Draw heparin into syringes, corresponding to the priming volume amount indicated on catheter lumen. Assure that the syringe is free of air.

Note: Priming volume values printed on lumen include extension set.

2. Remove end caps from the extension set.
3. Attach syringes containing heparin solution on female luers of the extension set.
4. Open extension clamps and white secondary clamps.
5. Aspirate to insure that no air will be forced into the patient.
6. Inject heparin into each lumen using quick bolus technique.

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

7. Close extension clamps and white secondary clamps.

Caution: 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 extension set.

- 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.

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*
5.4.4	Caution, consult Accompanying Documents*
Rx Only	Prescription Use Only***
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**

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