

LONG TERM HEMODIALYSIS CATHETERS IMPORTANT RISK INFORMATION

PEDIATRIC SPLIT CATH®

Indications for Use: The Medcomp® Pediatric Split Cath® is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis and in pediatric, adolescent, and adult patients as determined by the prescribing physician. It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion sites include the Subclavian and femoral vein.

SPLIT CATH® III

Indications for Use: The Medcomp® Split-Cath® III is indicated for use in attaining chronic (long-term) vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein of an adult patient. Alternate insertion site includes the subclavian vein as required.

SPLIT CATH® III TRANSLUMBAR

Indications for Use: The Medcomp Split Cath® III Catheter is indicated for use in attaining long term vascular access for hemodialysis and apheresis in the adult patient. It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion sites include the subclavian vein and inferior vena cava as required. Catheters greater than 40cm are intended for femoral vein insertion or inferior vena cava insertion. Translumbar insertion via inferior vena cava is indicated when all other access sites are identified as non-viable.

PEDIATRIC SPLIT CATH®, SPLIT CATH® III, SPLIT CATH® III TRANSLUMBAR

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.

SPLIT STREAM®

Indications for Use: The Medcomp® Split-Stream® 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.

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.

SPLIT CATH® RG

Indications for Use: The Medcomp® 14F Split Cath Rg® 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 and femoral vein.

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.

ESCHELON

Indications for Use: The Eschelon 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 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 instructions.

TESIO®

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 is the preferred site.

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, it is recommended that this catheter be replaced after 18 months usage. To maintain peak performance of the Lock right Adapters, it is recommended that the adapters be replaced every 6 months.

TITAN™ HD

Indications for Use: The Medcomp® Titan™ HD is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein of an adult patient. Alternate insertion sites includes the 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 instructions.

HEMO-FLOW®

Indications for Use: The Medcomp® Hemo-Flow® 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.

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.

HEMO-FLOW® XF

Indications for Use: The Medcomp® Hemo-Flow® XF Catheter is indicated for use in attaining Long-Term vascular access for Hemodialysis and Apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein of an adult patient. Alternate insertion site includes the 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 instructions.

HEMO-CATH® LT

Indications for Use: The Medcomp® Hemo-Cath® LT Silicone Double Lumen Catheter can be utilized for long term implantation as well as temporary access for hemodialysis, hemoperfusion, or apheresis therapy. The cannula may be inserted via the Seldinger Technique due to the inner Teflon stylet, increasing linear strength. The stylet is removed after insertion, leaving the soft silicone cannula in the body. The flexible silicone make-up conforms well to the vessel anatomy, resulting in higher patient tolerance during extended use.

Contraindications: The Subclavian Approach is NOT recommended for use with the Medcomp® Double Lumen Subclavian-Femoral Catheter in Hemodialysis or Hemoperfusion Procedures used for the management of acute poisoning or other situations in which a ventilator might be used due to risk of traumatic pneumothorax posing a dangerous complication for the patient.

SYMETREX®/SYMETREX® WITH SIDEHOLE

Indications for Use: The Symetrex® Long Term Hemodialysis Catheter and the Symetrex® Long Term Hemodialysis Catheter with Sideholes are symmetric tip dual lumen catheters designed for chronic hemodialysis and apheresis. They may be inserted percutaneously or by cut down. Catheters with greater than 37 cm implant length are indicated for femoral placement.

Contraindications: Do not use these catheters in thrombosed vessels or for subclavian puncture when ventilator is in use. These devices are contraindicated whenever: Used for any purpose other than indicated in these instructions. The presence of other device related infection, or septicemia is known or suspected. End caps are not intended to be punctured with a needle. Severe chronic obstructive lung disease is present. Tissue factors in the localized area of device placement will prevent proper device stabilization and/or access. Venous thrombosis or vascular surgical procedures have occurred at the prospective placement site. Post irradiation of prospective insertion site.

TESIO® REPAIR KIT

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.

SPLIT STREAM® REPAIR KIT

Indications for Use: Repairs MedComp® Split Stream® Catheters

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.

MEDCOMP® REPAIR KIT

Indications for Use: The Medcomp® Repair Kit is indicated for use in replacing damaged female luer connectors, clamps, or repairing extensions where there is a minimum of 4.5cm viable extension tubing. Repairs Medcomp® Catheters: Split Cath®

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.

Refer to Instructions for Use provided with the product for complete instructions, warnings, precautions, and contraindications. Observe all instructions for use prior to using products. Failure to do so may result in patient complications.



Polyurethane

Material

Split Tip

Tip Design

14F

French Size

Straight

Configuration

Retrograde

Insertion Type



DOUBLE "D" INTERNAL LUMEN DESIGN



BASIC SET		
MR771401	14F X 24CM SPLIT CATH RG® CATHETER	5/BOX
MR771402	14F X 28CM SPLIT CATH RG® CATHETER	5/BOX
MR771403	14F X 32CM SPLIT CATH RG® CATHETER	5/BOX
MR771404	14F X 36CM SPLIT CATH RG® CATHETER	5/BOX
MR771405	14F X 40CM SPLIT CATH RG® CATHETER	5/BOX

BASIC SET CONTENTS:

- (1) Catheter With Stylet
- (1) Extension
- (1) Hub Clamp Assembly
- (1) Lumen Clamp
- (1) Introducer Needle
- (1) Guidewire
- (2) Tunneler
- (2) Dilators
- (1) Valved Peelable Introducer
- (1) Scalpel
- (1) Adhesive Wound Dressing
- (2) End Caps