

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®

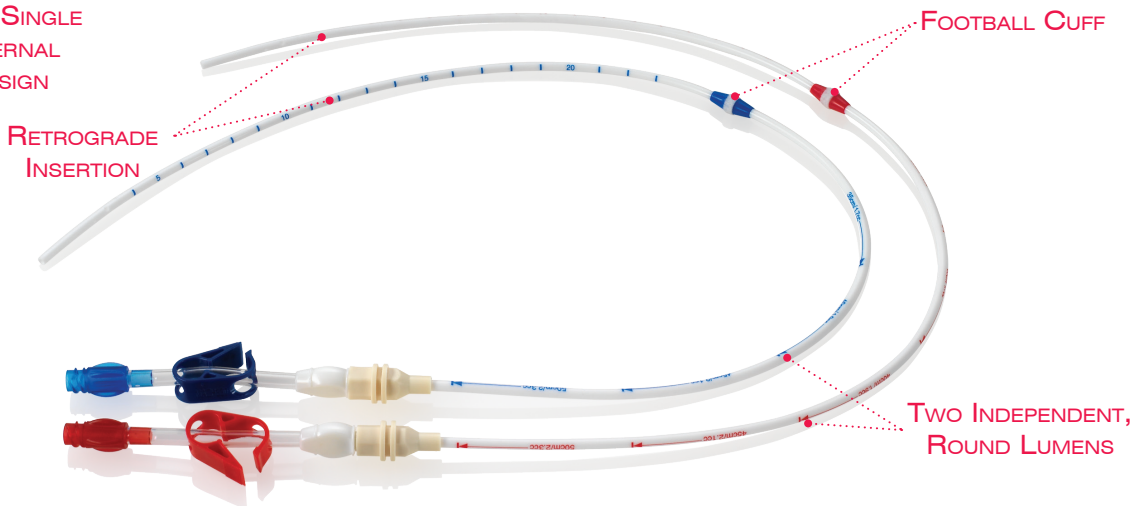
Contraindications: Do not use to repair catheters other than those specified above. Do not replace connector if tubing is swollen or displays signs of degradation. This repair kit should not be used for any purpose other than indicated in these instructions.

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.



INDEPENDENT SINGLE ROUND INTERNAL LUMEN DESIGN

Polyurethane	Single Round	6.5F, 10F	Straight	Retrograde
Material	Tip Design	French Sizes	Configuration	Insertion Type



6.5F BASIC SET		
PBF	6.5F X 29CM TESIO® CATHETER, CUFFS @ 12CM AND 15CM	5/BOX
CATHETER ONLY SET		
DBFS18	10F X 52CM TESIO® CATHETER, CUFF @ 18CM	5/BOX
DBFS21	10F X 52CM TESIO® CATHETER, CUFF @ 21CM	5/BOX
BFR22	10F X 52CM TESIO® CATHETER, CUFF @ 22CM	10/BOX
BFR25	10F X 52CM TESIO® CATHETER, CUFF @ 25CM	10/BOX
10F BASIC SET		
DBFS-6	10F X 52CM TESIO® CATHETERS, CUFFS @ 18CM AND 21CM	5/BOX
DBFR-6	10F X 52CM TESIO® CATHETERS, CUFFS @ 22CM AND 25CM	5/BOX
DBFL-6	10F X 52CM TESIO® CATHETERS, CUFFS @ 27CM AND 30CM	5/BOX
BFRD1070KD-A	10F X 70CM TESIO® CATHETERS, CUFFS @ 46CM AND 50CM	5/BOX
52CM BASIC SET		
DBFR1035KD-A	10F X 52CM TESIO® CATHETERS, CUFFS @ 18CM AND 22CM	5/BOX
BASIC SET WITH STYLET		
DBFS-6S*	10F X 52CM TESIO® CATHETERS, CUFFS @ 18CM AND 21CM	5/BOX
DBFR-6S*	10F X 52CM TESIO® CATHETERS, CUFFS @ 22CM AND 25CM	5/BOX
DBFL-6S*	10F X 52CM TESIO® CATHETERS, CUFFS @ 27CM AND 30CM	5/BOX
BASIC SET WITH CUTTING TROCAR		
DBFS-6CTT	10F X 52CM TESIO® CATHETERS, CUFFS @ 18CM AND 21CM	5/BOX
DBFR-6CTT	10F X 52CM TESIO® CATHETERS, CUFFS @ 22CM AND 25CM	5/BOX
DBFL-6CTT	10F X 52CM TESIO® CATHETERS, CUFFS @ 27CM AND 30CM	5/BOX
SINGLE CATHETER SET		
DBFSS	10F X 52CM TESIO® CATHETER, CUFF @ 21CM	5/BOX
DBFRS	10F X 52CM TESIO® CATHETER, CUFF @ 25CM	5/BOX
DBFLS	10F X 52CM TESIO® CATHETER, CUFF @ 30CM	5/BOX
TESIO® REPAIR KIT		
PBF11A	6.5F TESIO® CATHETER ARTERIAL EXTENSION SET	10/BOX
DBF11A	10F TESIO® CATHETER ARTERIAL EXTENSION SET	10/BOX
PBF11V	6.5F TESIO® CATHETER VENOUS EXTENSION SET	10/BOX
DBF11V	10F TESIO® CATHETER VENOUS EXTENSION SET	10/BOX
DBF11AVS	10F TESIO® VENOUS/ARTERIAL EXTENSION SETS	10/BOX

* Stylet Included

6.5F BASIC SET CONTENTS:

- (2) Catheters
- (2) Introducer Needles
- (2) Guidewires
- (2) Tunneler
- (2) Peelable Introducers
- (1) Arterial Extension Set (Red)
- (1) Venous Extension Set (Blue)
- (2) Clamps
- (2) End Caps
- (1) Patient ID Card

CATHETER ONLY CONTENTS:

- (1) Arterial Catheter
- (1) Patient ID Card

10F BASIC SET CONTENTS:

- (2) Catheters*
- (2) Introducer Needles
- (2) Guidewires
- (2) Tunneler
- (2) Football Tunneler
- (1) Dilator
- (2) Valved Peelable Introducers
- (1) Arterial Extension Set (Red)
- (1) Venous Extension Set (Blue)
- (2) Clamps
- (2) End Caps
- (1) Securement Device
- (1) Patient ID Card

52CM BASIC SET CONTENTS:

- (2) Catheters
- (2) Introducer Needles
- (2) Guidewires
- (2) Tunneler
- (2) Valved Peelable Introducers
- (1) Arterial Extension Set (Red)
- (1) Venous Extension Set (Blue)
- (2) Clamps
- (2) End Caps
- (1) Patient ID Card

10F BASIC SET W/ CUTTING TROCAR CONTENTS:

- (2) Catheters
- (2) Introducer Needles
- (2) Guidewires
- (2) Cutting Tunneler
- (2) Football Tunneler
- (1) Dilator
- (2) Valved Peelable Introducers
- (1) Arterial Extension Set (Red)
- (1) Venous Extension Set (Blue)
- (2) Clamps
- (2) End Caps
- (2) Securement Device
- (1) Patient ID Card

SINGLE SET CONTENTS:

- (1) Venous Catheter
- (1) Introducer Needle
- (1) Guidewire
- (1) Tunneler
- (1) Football Tunneler
- (1) Peelable Introducer
- (1) Venous Extension
- (1) Clamp
- (1) End Cap
- (1) Patient ID Card

TESIO® ARTERIAL EXTENSION SET CONTENTS:

- (1) Arterial Extension Set
- (1) End Cap

TESIO® VENOUS EXTENSION SET CONTENTS:

- (1) Venous Extension Set
- (1) End Cap

TESIO® VENOUS/ARTERIAL EXTENSION SET CONTENTS:

- (1) Arterial Extension Set
- (1) Venous Extension Set
- (2) End Cap

Refer to the Table of Contents for Important Risk Information regarding this device.