

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 SIDHOLES

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

10F, 14F, 16F
French Sizes

Straight,
Pre-Curved
Configurations

Antegrade
Insertion Type



DOUBLE "D" INTERNAL
LUMEN DESIGN



ARTERIOVENOUS STYLET WEAVE



HOLLOW, FAST TRACK STYLET



SPLITTABLE LUMENS



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



10F BASIC SET		
DASPC15P-XL	10F X 15CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC18P-XL	10F X 18CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC24P-XL	10F X 24CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
14F BASIC SET		
DASPC24-3	14F X 24CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC28-3	14F X 28CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC32-3	14F X 32CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC36-3	14F X 36CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC40-3	14F X 40CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC55-3	14F X 55CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC24-3PC	14F X 24CM SPLIT CATH® III CATHETER, PRE-CURVED	5/BOX
DASPC28-3PC	14F X 28CM SPLIT CATH® III CATHETER, PRE-CURVED	5/BOX
DASPC32-3PC	14F X 32CM SPLIT CATH® III CATHETER, PRE-CURVED	5/BOX
DASPC36-3PC	14F X 36CM SPLIT CATH® III CATHETER, PRE-CURVED	5/BOX
16F BASIC SET		
DASPC2416-3	16F X 24CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC2816-3	16F X 28CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC3216-3	16F X 32CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC3616-3	16F X 36CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC4016-3	16F X 40CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC5516-3	16F X 55CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC2416-3PC	16F X 24CM SPLIT CATH® III CATHETER, PRE-CURVED	5/BOX
DASPC2816-3PC	16F X 28CM SPLIT CATH® III CATHETER, PRE-CURVED	5/BOX
DASPC3216-3PC	16F X 32CM SPLIT CATH® III CATHETER, PRE-CURVED	5/BOX
DASPC3616-3PC	16F X 36CM SPLIT CATH® III CATHETER, PRE-CURVED	5/BOX
14F BASIC SET W/ DUAL STYLETS		
DASPC24-3DS	14F X 24CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC28-3DS	14F X 28CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC32-3DS	14F X 32CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC36-3DS	14F X 36CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC40-3DS	14F X 40CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC55-3DS	14F X 55CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
16F BASIC SET WITH DUAL STYLETS		
DASPC2416-3DS	16F X 24CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC2816-3DS	16F X 28CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC3216-3DS	16F X 32CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC3616-3DS	16F X 36CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC4016-3DS	16F X 40CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
DASPC5516-3DS	16F X 55CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
14F TRANSLUMBAR SET		
ASPC40-3	14F X 40CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
ASPC55-3	14F X 55CM SPLIT CATH® III CATHETER, STRAIGHT	5/BOX
ACCESSORIES		
AST	SPLIT CATH® III TUNNELER	5/BOX
ASTSG	SPLIT CATH® III SURE GRIP TUNNELER	5/BOX
RPK-01	MEDCOMP® REPAIR KIT	5/BOX

10F BASIC SET CONTENTS:

- (1) Catheter With Stylet
- (1) Introducer Needle
- (1) Guidewire
- (2) Dilators
- (1) Scalpel
- (1) Tunneler
- (1) Peelable Introducer
- (1) Adhesive Wound Dressing
- (2) End Caps
- (1) Patient ID Card

14F & 16F BASIC SET CONTENTS:

- (1) Catheter With Stylet
- (1) Introducer Needle
- (1) Guidewire
- (2) Dilators
- (1) Scalpel
- (1) Tunneler
- (1) Valved Peelable Introducer
- (1) Adhesive Wound Dressing
- (2) End Caps
- (1) Patient ID Card

14F & 16F BASIC SET WITH DUAL STYLET CONTENTS:

- (1) Catheter
- (2) Stylets
- (1) Introducer Needle
- (1) Guidewire
- (2) Dilators
- (1) Scalpel
- (1) Tunneler
- (1) Valved Peelable Introducer
- (1) Adhesive Wound Dressing
- (2) End Caps
- (1) Patient ID Card

TRANSLUMBAR SET CONTENTS:

- (1) Catheter With Stylet
- (1) Introducer Needle
- (1) Guidewire
- (2) Dilators
- (1) Scalpel
- (1) Tunneler
- (1) Valved Peelable Introducer
- (1) Adhesive Wound Dressing
- (2) End Caps
- (1) Patient ID Card

REPAIR KIT CONTENTS:

- (1) Luer Assembly
- (1) Scissors
- (1) Adhesive Backed Drape
- (3) Clamps
- (2) End Caps