

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	Step Tip Tip Design	15.5F French Size	Straight, Pre-Curved Configurations	Antegrade Insertion Type
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DOUBLE "D" INTERNAL LUMEN DESIGN



15.5F LUMEN

90 DEGREE ARTERIAL TIP

TAPERED, FAST TRACK STYLET

90° Degree

WITH SIDEHOLES CATHETER ONLY		
DTHD155124	15.5F X 24CM TITAN™ HD CATHETER, STRAIGHT	10/BOX
DTHD155128	15.5F X 28CM TITAN™ HD CATHETER, STRAIGHT	10/BOX
DTHD155132	15.5F X 32CM TITAN™ HD CATHETER, STRAIGHT	10/BOX
DTHD155136	15.5F X 36CM TITAN™ HD CATHETER, STRAIGHT	10/BOX
DTHD155140	15.5F X 40CM TITAN™ HD CATHETER, STRAIGHT	10/BOX
DTHD155155	15.5F X 55CM TITAN™ HD CATHETER, STRAIGHT	10/BOX
THD155524	15.5F X 24CM TITAN™ HD CATHETER, PRE-CURVED	10/BOX
THD155528	15.5F X 28CM TITAN™ HD CATHETER, PRE-CURVED	10/BOX
THD155532	15.5F X 32CM TITAN™ HD CATHETER, PRE-CURVED	10/BOX
THD155536	15.5F X 36CM TITAN™ HD CATHETER, PRE-CURVED	10/BOX
BASIC SET		
THD155024	15.5F X 24CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
THD155028	15.5F X 28CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
THD155032	15.5F X 32CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
THD155036	15.5F X 36CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
THD155040	15.5F X 40CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
THD155055	15.5F X 55CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
DTHD155224	15.5F X 24CM TITAN™ HD CATHETER, PRE-CURVED	5/BOX
DTHD155228	15.5F X 28CM TITAN™ HD CATHETER, PRE-CURVED	5/BOX
DTHD155232	15.5F X 32CM TITAN™ HD CATHETER, PRE-CURVED	5/BOX
DTHD155236	15.5F X 36CM TITAN™ HD CATHETER, PRE-CURVED	5/BOX

SPORT PACK		
THD155024CD	15.5F X 24CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
THD155028CD	15.5F X 28CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
THD155032CD	15.5F X 32CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
THD155036CD	15.5F X 36CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
THD155040CD	15.5F X 40CM TITAN™ HD CATHETER, STRAIGHT	5/BOX
THD155055CD	15.5F X 55CM TITAN™ HD CATHETER, STRAIGHT	5/BOX

CATHETER ONLY CONTENTS:

- (1) Catheter
- (2) End Caps

BASIC SET CONTENTS

- WITH SIDEHOLES:**
- (1) Catheter With Stylet
 - (1) Introducer Needle
 - (1) Guidewire
 - (2) Dilators
 - (1) Scalpel
 - (1) Tunneler
 - (1) Adhesive Wound Dressing
 - (1) End Caps

SPORT PACK SET CONTENTS:

- (1) Catheter With Stylet
- (1) Valved Peelable Introducer
- (2) Dilators
- (1) Tunneler
- (2) End Caps

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