

# SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-005

## Split Cath III Catheter Sets Product Family

### IMPORTANT INFORMATION

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

This SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

Applicable Documents	
Document Type	Document Title / Number
DHF	03020, 05026-A1
'MDR Documentation' File Number	MDR-005

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
1	04OCT2021	26535	RS	Implementation of SSCP	<input type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English <input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
2	23JUN2022	27030	RS	Scheduled Update	<input checked="" type="checkbox"/> Yes, this version was

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<b>3</b>	<b>21JUN2023</b>	<b>28223</b>	<b>GM</b>	<b>Periodic Update; Updated in Accordance with CER-005, Revision D</b>	<input checked="" type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English <input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
<b>4</b>	<b>21JUN2024</b>	<b>29453</b>	<b>GM</b>	<b>Periodic Update; Updated in Accordance with CER-005, Revision E</b>	<input type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English <input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device

<b>Revision History</b>					
<b>Revision</b>	<b>Date</b>	<b>CR#</b>	<b>Author</b>	<b>Description of Changes</b>	<b>Validated</b>
<b>5</b>	<b>02SEP2025</b>	<b>25-0148</b>	<b>GM</b>	<b>Periodic Update; Updated in Accordance with CER-005, Revision F</b>	<input type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English <input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device

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**USERS / HEALTHCARE PROFESSIONALS**

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The following information is intended for users/healthcare professionals. Following this information there is a summary intended for patients.

**1. Device identification and general information**

Device trade name(s)	Split Cath® III
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Manufacturer single registration number (SRN)	US-MF-000008230
Basic UDI-DI	00884908248NF
Medical device nomenclature description / text	F900202 – Permanent Hemodialysis Catheter and Kits
Class of device	III
Date first CE certificate was issued for this device	March 2005
Authorized representative name and SRN	European Regulatory Expert Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunfels, Germany SRN: DE-AR-000005009
Notified Body name and single identification number	BSI Netherlands NB2797

The devices in scope of this document are all long-term hemodialysis catheter sets. The device part numbers are organized into variant categories. These devices are distributed as procedure trays, in various configurations inclusive of accessories and adjunctive devices (see section “Accessories intended for use in combination with the Device”).

Variant Devices:

Variant Description	Part Number
14F x 20cm Straight Split Cath III w/ sideholes	10386-820-001
14F x 22cm Straight Split Cath III w/ sideholes	10386-822-001
14F x 24cm Pre-Curved Split Cath III w/ sideholes	10386-824-001C
14F x 24cm Straight Split Cath III w/ sideholes	10386-824-001
14F x 24cm Straight Split Cath III w/o sideholes	10471-824-001
14F x 28cm Pre-Curved Split Cath III w/ sideholes	10386-828-001C

Variant Description	Part Number
14F x 28cm Straight Split Cath III w/ sideholes	10386-828-001
14F x 28cm Straight Split Cath III w/o sideholes	10471-828-001
14F x 32cm Pre-Curved Split Cath III w/ sideholes	10386-832-001C
14F x 32cm Straight Split Cath III w/ sideholes	10386-832-001
14F x 32cm Straight Split Cath III w/o sideholes	10471-832-001
14F x 36cm Pre-Curved Split Cath III w/ sideholes	10386-836-001C
14F x 36cm Straight Split Cath III w/ sideholes	10386-836-001
14F x 36cm Straight Split Cath III w/o sideholes	10471-836-001
14F x 40cm Straight Split Cath III w/ sideholes	10386-840-001
14F x 40cm Straight Split Cath III w/o sideholes	10471-840-001
14F x 55cm Straight Split Cath III w/ sideholes	10386-855-001
16F x 24cm Pre-Curved Split Cath III w/ sideholes	10147-824-001C
16F x 24cm Straight Split Cath III w/ sideholes	10147-824-001
16F x 28cm Pre-Curved Split Cath III w/ sideholes	10147-828-001C
16F x 28cm Straight Split Cath III w/ sideholes	10147-828-001
16F x 32cm Pre-Curved Split Cath III w/ sideholes	10147-832-001C
16F x 32cm Straight Split Cath III w/ sideholes	10147-832-001
16F x 36cm Pre-Curved Split Cath III w/ sideholes	10147-836-001C
16F x 36cm Straight Split Cath III w/ sideholes	10147-836-001
16F x 40cm Straight Split Cath III w/ sideholes	10147-840-001
16F x 55cm Straight Split Cath III w/ sideholes	10147-855-001

Procedure Trays:

Catalog Code	Part Number	Description
ASPC24-3	10386-824-001	14F x 24cm Split Cath® III Catheter w/ Stylet Set (Cuff 19cm From Tip)
ASPC28-3	10386-828-001	14F x 28cm Split Cath® III Catheter w/ Stylet Set (Cuff 23cm From Tip)
ASPC32-3	10386-832-001	14F x 32cm Split Cath® III Catheter w/ Stylet Set (Cuff 27cm From Tip)
ASPC36-3	10386-836-001	14F x 36cm Split Cath® III Catheter w/ Stylet Set (Cuff 31cm From Tip)
ASPC40-3	10386-840-001	14F x 40cm Split Cath® III Catheter w/ Stylet Set (Cuff 35cm From Tip)
ASPC55-3	10386-855-001	14F x 55cm Split Cath® III Catheter w/ Stylet Set (Cuff 50cm From Tip)
ASPC20-3E.	10386-820-001	14F x 20cm Split Cath® III Catheter Set (Cuff 15cm From Tip)
ASPC22-3E.	10386-822-001	14F x 22cm Split Cath® III Catheter Set (Cuff 17cm From Tip)
ASPC24-3E.	10386-824-001	14F x 24cm Split Cath® III Catheter Set (Cuff 19cm From Tip)

Catalog Code	Part Number	Description
ASPC28-3E.	10386-828-001	14F x 28cm Split Cath® III Catheter Set (Cuff 23cm From Tip)
ASPC32-3E.	10386-832-001	14F x 32cm Split Cath® III Catheter Set (Cuff 27cm From Tip)
ASPC36-3E.	10386-836-001	14F x 36cm Split Cath® III Catheter Set (Cuff 31cm From Tip)
ASPC40-3E.	10386-840-001	14F x 40cm Split Cath® III Catheter Set (Cuff 35cm From Tip)
ASPC55-3E.	10386-855-001	14F x 55cm Split Cath® III Catheter Set (Cuff 50cm From Tip)
ASPC24-3PCE.	10386-824-001C	14F x 24cm Pre-Curved Split Cath® III Catheter Set (Cuff 19cm From Tip)
ASPC28-3PCE.	10386-828-001C	14F x 28cm Pre-Curved Split Cath® III Catheter Set (Cuff 23cm From Tip)
ASPC32-3PCE.	10386-832-001C	14F x 32cm Pre-Curved Split Cath® III Catheter Set (Cuff 27cm From Tip)
ASPC36-3PCE.	10386-836-001C	14F x 36cm Pre-Curved Split Cath® III Catheter Set (Cuff 31cm From Tip)
ASPC24-3WOE.	10471-824-001	14F x 24cm Split Cath® III Catheter w/o Sideholes Set (Cuff 19cm From Tip)
ASPC28-3WOE.	10471-828-001	14F x 28cm Split Cath® III Catheter w/o Sideholes Set (Cuff 23cm From Tip)
ASPC32-3WOE.	10471-832-001	14F x 32cm Split Cath® III Catheter w/o Sideholes Set (Cuff 27cm From Tip)
ASPC36-3WOE.	10471-836-001	14F x 36cm Split Cath® III Catheter w/o Sideholes Set (Cuff 31cm From Tip)
ASPC40-3WOE.	10471-840-001	14F x 40cm Split Cath® III Catheter w/o Sideholes Set (Cuff 35cm From Tip)
ASPC40-3TLE.	10386-840-001	14F x 40cm Split Cath® III Catheter Translumbar Set (Cuff 35cm From Tip)
ASPC55-3TLE.	10386-855-001	14F x 55cm Split Cath® III Catheter Translumbar Set (Cuff 50cm From Tip)
ASPC2416-3E.	10147-824-001	16F x 24cm Split Cath® III Catheter Set (Cuff 19cm From Tip)
ASPC2816-3E.	10147-828-001	16F x 28cm Split Cath® III Catheter Set (Cuff 23cm From Tip)
ASPC3216-3E.	10147-832-001	16F x 32cm Split Cath® III Catheter Set (Cuff 27cm From Tip)
ASPC3616-3E.	10147-836-001	16F x 36cm Split Cath® III Catheter Set (Cuff 31cm From Tip)
ASPC4016-3E.	10147-840-001	16F x 40cm Split Cath® III Catheter Set (Cuff 35cm From Tip)
ASPC5516-3E.	10147-855-001	16F x 55cm Split Cath® III Catheter Set (Cuff 50cm From Tip)
ASPC2416-3PCE.	10147-824-001C	16F x 24cm Pre-Curved Split Cath® III Catheter Set (Cuff 19cm From Tip)
ASPC2816-3PCE.	10147-828-001C	16F x 28cm Pre-Curved Split Cath® III Catheter Set (Cuff 23cm From Tip)

Catalog Code	Part Number	Description
ASPC3216-3PCE.	10147-832-001C	16F x 32cm Pre-Curved Split Cath® III Catheter Set (Cuff 27cm From Tip)
ASPC3616-3PCE.	10147-836-001C	16F x 36cm Pre-Curved Split Cath® III Catheter Set (Cuff 31cm From Tip)

Configurations of Procedure Trays:

Configuration Type	Kit Components
Set w/ Stylet	<p>(1) Catheter</p> <p>(1) Stylet: 1.4mm OD 1.05mm ID x 368mm (14F X 24CM) STYLET, 1.4mm OD 1.05mm ID x 406mm (14F X 28CM) STYLET, 1.4mm OD 1.05mm ID x 451mm (14F X 32CM) STYLET, 1.4mm OD 1.05mm ID x 489mm (14F X 36CM) STYLET, 1.4mm OD 1.05mm ID x 527mm (14F X 40CM) STYLET, 1.4mm OD 1.05mm ID x 679mm (14F X 55CM) STYLET</p> <p>(1) 1.3mm OD x 1.0mm ID x 70mm (18GA) INTRODUCER NEEDLE</p> <p>Guidewire: (24, 28cm Sets) (1) 0.97mm x 70cm (.038) GUIDEWIRE J (R 3mm) TIP, (32, 36, 40cm Sets) (2) 0.97mm x 100cm (.038) GUIDEWIRE J (R 3mm) TIP, (55cm Set) (1) 0.97mm x 100cm (.038) GUIDEWIRE J (R 3mm) TIP</p> <p>Advancer: (20, 22, 24, 28, 55cm Sets) (1), (32, 36, 40cm Sets) (2)</p> <p>(1) 3.3mm OD x 17cm 12° BENT TUNNELER</p> <p>(1) Tunneler Sleeve</p> <p>(1) 4.7mm OD x 0.99mm ID x 15cm (14F) DILATOR</p> <p>(1) 5.4mm ID x 19cm (16F) VALVED PEELABLE INTRODUCER</p> <p>(1) Scalpel</p> <p>(2) End Caps</p> <p>(1) Patient ID Card</p> <p>(1) Patient Information Packet</p>
Straight Set	<p>(1) Catheter</p> <p>(1) 1.3mm OD x 1.0mm ID x 70mm (18GA) INTRODUCER NEEDLE</p> <p>(1) Guidewire: (20, 22, 24, 28cm Sets) (1) 0.97mm x 70cm (.038) GUIDEWIRE J (R 3mm) TIP, (32, 36, 40cm Sets) (2) 0.97mm x 100cm (.038) GUIDEWIRE J (R 3mm) TIP, (55cm Sets) (1) 0.97mm x 100cm (.038) GUIDEWIRE J (R 3mm) TIP</p> <p>Advancer: (20, 22, 24, 28, 55cm Sets) (1), (32, 36, 40cm Sets) (2)</p> <p>Tunnelers: (14F and 16F Sets) (1) 3.3mm OD x 17cm 12° BENT TUNNELER, (14F w/o Sideholes Sets) (1) 3.3mm OD x 17cm 12° BENT TUNNELER</p> <p>(1) Tunneler Sleeve</p> <p>(1) Dilator: (14F Sets) 4.7mm OD x 0.99mm ID x 15cm (14F) DILATOR, (16F Sets) 5.4mm OD x 0.99mm ID x 15cm (16F) DILATOR</p> <p>(1) Valved Peelable Introducer: (14F Sets) 5.4mm ID x 19cm (16F) VALVED PEELABLE INTRODUCER, (16F Sets) 5.7mm ID x 19cm (17F) VALVED PEELABLE INTRODUCER</p> <p>(2) End Caps</p> <p>(1) Patient ID Card</p> <p>(1) Patient Information Packet</p>

Configuration Type	Kit Components
Pre-Curved Set	<p>(1) Catheter  (1) 1.3mm OD x 1.0mm ID x 70mm (18GA) INTRODUCER NEEDLE  Guidewire: (24, 28cm Sets) (1) 0.97mm x 70cm (.038) GUIDEWIRE J (R 3mm) TIP, (32, 36cm Sets) (2) 0.97mm x 100cm (.038) GUIDEWIRE J (R 3mm) TIP  Advancer: (24, 28cm Sets) (1), (32, 36cm Sets) (2)  (1) 3.3mm OD x 17cm 12° BENT TUNNELER  (1) Tunneler Sleeve  (1) Dilator: (14F Sets) 4.7mm OD x 0.99mm ID x 15cm (14F) DILATOR, (16F Sets) 5.4mm OD x 0.99mm ID x 15cm (16F) DILATOR  (1) Valved Peelable Introducer: (14F Sets) 5.4mm ID x 19cm (16F) VALVED PEELABLE INTRODUCER, (16F Sets) 5.7mm ID x 19cm (17F) VALVED PEELABLE INTRODUCER  (2) End Caps  (1) Patient ID Card  (1) Patient Information Packet</p>
Translumbar Set	<p>(1) Catheter  (1) Stylet: 1.4mm OD 1.05mm ID x 527mm (14F X 40CM) STYLET, 1.4mm OD 1.05mm ID x 679mm (14F X 55CM) STYLET  (1) 1.3mm OD x 1.0mm ID x 200mm (18GA) INTRODUCER NEEDLE  (2) 0.98mm x 120cm (.038) GUIDEWIRE  (2) Advancer  (1) 3.3mm OD x 17cm 12° BENT TUNNELER  (1) Tunneler Sleeve    (1) 2.2mm OD x 0.99mm ID x 35cm (6F) DILATOR  (1) 6.7mm OD x 0.99mm ID x 20cm (12F) DILATOR  (1) 4.7mm OD x 0.99mm ID x 20cm (14F) DILATOR  (1) 5.5mm ID x 33cm (16F) PEELABLE INTRODUCER  (1) Scalpel  (2) End Caps  (1) Patient ID Card  (1) Patient Information Packet</p>

## 2. Intended use of the device

Intended purpose	<p>Split Cath® III Catheters are intended for use in adult and pediatric patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis and apheresis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is intended to be used under the regular review and assessment of qualified health professionals.</p>
Indication(s)	<p>The Split Cath® III Catheter is indicated for short-term or long-term use where vascular access is required for 14 days or more for the purpose of hemodialysis and apheresis.</p>

Target population(s)	Split Cath® III Catheters are intended for use in adult and pediatric patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis and apheresis is deemed necessary based on the direction of a qualified, licensed physician.
Contraindications and/or limitations	<ul style="list-style-type: none"> <li>• Known or suspected allergies to any of the components of the catheter or the kit.</li> <li>• This device is contraindicated for patients exhibiting severe, uncontrolled coagulopathy or thrombocytopenia.</li> </ul>

**3. Device description**



Figure 1: Split Cath III Catheter (Straight)



Figure 2: Split Cath III Catheter (Pre-Curved)

Description of device	<p>The Split Cath® III Catheter is a long-term double lumen, single access catheter that is used to remove and return blood through two separate passages (lumens). Each lumen is connected through an extension line. The transition between lumen and extension is housed within a molded hub. Each lumen has the priming volume identified by identification rings assembled into the clamps on the extensions. A polyester cuff is placed on the catheter’s lumen for tissue ingrowth to anchor the catheter. The catheter incorporates Barium Sulphate to facilitate visualization under fluoroscopy or Xray. The catheter has been tested at flow rates of up to 500 mL/min. The catheter is available in a variety of sizes to accommodate physician preference and clinical needs.</p>																																
Materials / substances in contact with patient tissue	<p>The percentage ranges in the table below are based on the weights of the 20cm catheter (13.86g) and the 55cm catheter (20.11g).</p> <table border="1" data-bbox="589 751 1292 1087"> <thead> <tr> <th colspan="2">14F Split Cath® III</th> </tr> <tr> <th>Material</th> <th>% Weight (w/w)</th> </tr> </thead> <tbody> <tr> <td>Polyurethane</td> <td>62.03 - 67.62</td> </tr> <tr> <td>Acetal co-polymer</td> <td>11.86 - 17.20</td> </tr> <tr> <td>Silicone</td> <td>5.04 - 7.32</td> </tr> <tr> <td>Barium sulfate</td> <td>5.85 - 10.25</td> </tr> <tr> <td>Acrylonitrile Butadiene Styrene</td> <td>3.55 - 5.15</td> </tr> <tr> <td>Polyethylene terephthalate</td> <td>1.68 - 2.44</td> </tr> </tbody> </table> <p>The percentage ranges in the table below are based on the weights of the 24cm catheter (14.56g) and the 55cm catheter (21.05g).</p> <table border="1" data-bbox="589 1220 1292 1556"> <thead> <tr> <th colspan="2">16F Split Cath® III</th> </tr> <tr> <th>Material</th> <th>% Weight (w/w)</th> </tr> </thead> <tbody> <tr> <td>Polyurethane</td> <td>62.89 - 68.17</td> </tr> <tr> <td>Acetal co-polymer</td> <td>11.33 - 16.38</td> </tr> <tr> <td>Silicone</td> <td>4.82 - 6.97</td> </tr> <tr> <td>Barium sulfate</td> <td>6.53 - 10.69</td> </tr> <tr> <td>Acrylonitrile Butadiene Styrene</td> <td>3.39 - 4.90</td> </tr> <tr> <td>Polyethylene terephthalate</td> <td>1.61 - 2.32</td> </tr> </tbody> </table> <p><b>Note:</b> Per the instructions for use, the device is contraindicated for patients with known or suspected allergies to the above materials.</p> <p><b>Note:</b> Accessories containing stainless steel may contain up to 4% weight of the CMR substance cobalt.</p>	14F Split Cath® III		Material	% Weight (w/w)	Polyurethane	62.03 - 67.62	Acetal co-polymer	11.86 - 17.20	Silicone	5.04 - 7.32	Barium sulfate	5.85 - 10.25	Acrylonitrile Butadiene Styrene	3.55 - 5.15	Polyethylene terephthalate	1.68 - 2.44	16F Split Cath® III		Material	% Weight (w/w)	Polyurethane	62.89 - 68.17	Acetal co-polymer	11.33 - 16.38	Silicone	4.82 - 6.97	Barium sulfate	6.53 - 10.69	Acrylonitrile Butadiene Styrene	3.39 - 4.90	Polyethylene terephthalate	1.61 - 2.32
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Information on medicinal substances in the device	N/A																																

<p>How the device achieves its intended mode of action</p>	<p>Hemodialysis catheters are centrally placed access tubes. A typical hemodialysis catheter uses a thin, flexible tube. The tube has two openings. The tube goes into a large vein. The vein is usually the internal jugular vein. Blood withdraws through one lumen of the catheter. The blood flows to the dialysis machine through a separate tubing set. The blood is then processed and filtered. The blood returns to the patient through the second lumen. This device is used when dialysis must start at once. Patients may not have a functioning AV fistula or graft. Catheter hemodialysis normally happens on a short-term basis. Long-term access may occur in some cases. For example, when there are problems supporting an AV fistula or graft. The catheter may also be used for apheresis. Apheresis can happen in a blood bank facility or hemodialysis center. Like hemodialysis, apheresis treatments withdraw blood from the catheter and then return blood through the catheter. There are different types of apheresis. Where hemodialysis cleans blood, apheresis separates and removes a component of blood.</p>	
<p>Sterilization Information</p>	<p>Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.</p>	
<p>Previous generations / variants</p>	<p>Name of previous generation</p>	<p>Differences from current device</p>
	<p>N/A</p>	<p>N/A</p>
<p>Accessories intended for use in combination with the Split Cath III</p>	<p>Name of Accessory</p>	<p>Description of Accessory</p>
	<p>Guidewire</p>	<p>For general intravascular use to facilitate the selective placement of medical devices in the vessel anatomy.</p>
	<p>Guidewire Advancer</p>	<p>Aid for introduction of guidewire into target vein.</p>
	<p>Stylet</p>	<p>Assist in catheter insertion</p>
	<p>Introducer Needle</p>	<p>Used for the percutaneous introduction of guidewires.</p>
	<p>Scalpel</p>	<p>A cutting device during surgical, pathology and minor medical procedures</p>
	<p>Tunneler</p>	<p>Instrument used to create a subcutaneous tunnel</p>
	<p>Tunneler Sleeve</p>	<p>Sleeve slides down the tunneler and over the catheter tip to secure the catheter to the tunneler.</p>
	<p>Peelable Introducer</p>	<p>Introducers are intended to obtain central venous access to facilitate catheter insertion into the central venous system.</p>
	<p>Dilator</p>	<p>Designed for percutaneous entry into a vessel in order to enlarge the opening of the vessel for the placement of a catheter in a vein.</p>
<p>End Cap</p>	<p>To keep clean and protect catheter luer between treatments.</p>	

	Name of Device or Product	Description of Device or Product
Other devices or products intended for use in combination with the Split Cath III	Tegaderm	Adhesive wound dressing intended to protect the catheter from contamination when not in use
	Syringe	Attached to introducer needle to help capture blood return once introducer needle perforates targeted vein, prevent air embolism

**4. Risks and warnings**

Residual risks and undesirable effects	<p>As per product IFU (IFU 40771BSI), All surgical procedures carry risk. Medcomp has implemented risk management processes to proactively find and mitigate these risks as far as possible without adversely affecting the benefit-risk profile of the device. After mitigation, residual risks and the possibility of adverse events from use of this product remain. Medcomp has determined that all residual risks are acceptable.</p>	
	<b>Residual Harm Type</b>	<b>Possible Adverse Events Associated with Harm</b>
	Bleeding	Bleeding (May be severe) Femoral Artery Bleed Hematoma Retroperitoneal Bleed
	Cardiac Event	Cardiac Arrhythmia Cardiac Tamponade
	Embolism	Air Embolus
	Infection	Bacteremia Endocarditis Exit Site Infection Septicemia Tunnel Infection
	Perforation	Inferior Vena Cava Puncture Laceration of the Vessel Perforation of the Vessel Pneumothorax Right Atrial Puncture Subclavian Artery Puncture Superior Vena Cava Puncture
Thrombosis	Central Venous Thrombosis Fibrin Sheath Formation Lumen Thrombosis Subclavian Vein Thrombosis Vascular Thrombosis	

	<p>Miscellaneous Complications</p>	<p>Brachial Plexus Injury Femoral Nerve Damage Hemothorax Pleural Injury Thoracic Duct Laceration Venous Stenosis</p>																																					
	<table border="1"> <thead> <tr> <th rowspan="4">Patient Residual Harm Category</th> <th colspan="2">Quantification of Residual Risks</th> </tr> <tr> <th>PMS Complaints (01 January 2016 – 31 March 2025)</th> <th>PMCF Events</th> </tr> <tr> <th>Units Sold: 233,659</th> <th>Units Studied: 7,447</th> </tr> <tr> <th>% of Devices</th> <th>% of Devices</th> </tr> </thead> <tbody> <tr> <td>Allergic Reaction</td> <td>Not Reported</td> <td>0.17%</td> </tr> <tr> <td>Bleeding</td> <td>0.0009%</td> <td>11.29%</td> </tr> <tr> <td>Cardiac Event</td> <td>Not Reported</td> <td>1.76%</td> </tr> <tr> <td>Embolism</td> <td>Not Reported</td> <td>15.95%</td> </tr> <tr> <td>Infection</td> <td>0.0004%</td> <td>18.14%</td> </tr> <tr> <td>Perforation</td> <td>Not Reported</td> <td>6.87%</td> </tr> <tr> <td>Stenosis</td> <td>Not Reported</td> <td>1.61%</td> </tr> <tr> <td>Tissue Injury</td> <td>Not Reported</td> <td>Not Reported</td> </tr> <tr> <td>Thrombosis</td> <td>0.0004%</td> <td>22.89%</td> </tr> </tbody> </table>			Patient Residual Harm Category	Quantification of Residual Risks		PMS Complaints (01 January 2016 – 31 March 2025)	PMCF Events	Units Sold: 233,659	Units Studied: 7,447	% of Devices	% of Devices	Allergic Reaction	Not Reported	0.17%	Bleeding	0.0009%	11.29%	Cardiac Event	Not Reported	1.76%	Embolism	Not Reported	15.95%	Infection	0.0004%	18.14%	Perforation	Not Reported	6.87%	Stenosis	Not Reported	1.61%	Tissue Injury	Not Reported	Not Reported	Thrombosis	0.0004%	22.89%
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<p>Warnings and precautions</p>	<p>All warnings have been reviewed against the risk analysis, PMS, and usability testing to validate consistency between the sources of information. As per product IFU (IFU 40771BSI), the Split Cath® III Catheters have the following warnings:</p> <ul style="list-style-type: none"> <li>• Do not insert catheter in thrombosed vessels.</li> <li>• Do not advance the guidewire or catheter if unusual resistance is encountered.</li> <li>• Do not insert or withdraw the guidewire forcibly from any component. If the guidewire becomes damaged, guidewire and any associated componentry must be removed together.</li> <li>• Do not resterilize the catheter or accessories by any method.</li> <li>• Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE</li> <li>• Do not re-use catheter or accessories as there may be a failure to adequately clean and decontaminate the device which may lead to contamination, catheter degradation, device fatigue, or endotoxin reaction.</li> <li>• Do not use catheter or accessories if package is opened or damaged.</li> <li>• Do not use catheter or accessories if any sign of product damage is visible or the use-by date has passed.</li> <li>• Do not use sharp instruments near the extension tubing or catheter lumen.</li> <li>• Do not use scissors to remove dressing.</li> <li>• Do not clamp over guidewire or stylet.</li> </ul>																																						

Precautions listed in the Split Cath® III Catheter IFU are as follows:

- Examine catheter lumen and extensions before and after each treatment for damage.
- To prevent accidents, ensure the security of all caps and bloodline connections prior to and between treatments.
- Use only Luer Lock (threaded) Connectors with this catheter.
- In the rare event that a hub or connector separates from any component during insertion or use, take all necessary steps and precautions to prevent blood loss or air embolism and remove the catheter.
- Before attempting catheter insertion, ensure that you are familiar with the potential complications and their emergency treatment should any of them occur.
- Repeated overtightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure.
- The catheter will be damaged if clamps other than what is provided with this kit are used.
- Avoid clamping near the Luer Lock and hub of the catheter. Clamping of the tubing repeatedly in the same location may weaken tubing.

Additional warnings and cautions listed in the Split Cath® III Catheter IFUs are as follows:

- Physician discretion is strongly advised when inserting this catheter in patients who are unable to take or hold a deep breath.
- Patients requiring ventilator support are at increased risk of pneumothorax during subclavian vein cannulation, which may cause complications.
- Extended use of the subclavian vein may be associated with subclavian vein stenosis.
- The incidence of infection may be increased with femoral vein insertion.
- When using pre-loaded stylet(s), do not use the peelable introducer.
- Do not over-expand subcutaneous tissue during tunneling. Over-expansion may delay/prevent cuff in-growth.
- Do not pull tunneler out at an angle. Keep tunneler straight to prevent damage to catheter tip.
- Splitting the lumens beyond this point may result in excess tunnel bleeding, infection, or damage to the catheter lumens. For kits with pre-loaded stylet(s), use caution to avoid damaging the stylet(s) when splitting the lumens.
- The length of the wire inserted is determined by the size of the patient. Monitor patient for arrhythmia throughout this procedure. The patient should be placed on a cardiac monitor during this procedure. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.

	<ul style="list-style-type: none"> <li>• DO NOT grasp and pull the guidewire prior to releasing the J-Straightener. Damage to the guidewire may occur if it is pulled against the restraint of the J-Straightener.</li> <li>• Insufficient tissue dilation can cause compression of the catheter lumen against the guidewire causing difficulty in the insertion and removal of the guidewire from the catheter. This can lead to bending of the guidewire.</li> <li>• The Valved Peelable Introducer is not designed for use in the arterial system or as a hemostatic device.</li> <li>• DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold the introducer close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the introducer towards the vein, regrasp the introducer a few centimeters above the original grasp location and push down on the introducer. Repeat procedure until introducer is inserted to appropriate depth based on patient anatomy and physician’s discretion.</li> <li>• Never leave sheath in place as an indwelling catheter. Damage to the vein will occur.</li> <li>• Do not advance guidewire with catheter into vein. Cardiac arrhythmias may result if guidewire is allowed to pass into the right atrium. The guidewire should be held securely during this procedure.</li> <li>• Assure that all air has been aspirated from the catheter and extensions. Failure to do so may result in air embolism.</li> <li>• Failure to verify catheter placement may result in serious trauma or fatal complications.</li> <li>• Care must be taken when using sharp objects or needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure.</li> <li>• Only clamp catheter with in-line clamps provided.</li> <li>• Extension clamps should only be open for aspiration, flushing, and dialysis treatment.</li> <li>• Always review hospital or unit protocol, potential complications and their treatment, warnings, and precautions prior to undertaking any type of mechanical or chemical intervention in response to catheter performance problems.</li> <li>• Only a physician familiar with the appropriate techniques should attempt the following procedures.</li> <li>• 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.</li> <li>• Do not pull distal end of catheter through incision as contamination of wound may occur.</li> </ul>
Other relevant aspects of safety (ex. field safety corrective actions, etc.)	For a period of 01 January 2020 to 31 March 2025 there were 102 complaints for 204,298 units sold, giving an overall complaint rate of 0.050%. No events resulted in recalls during the review period.

## 5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

Summary of clinical data related to the subject device				
The below tables display the device insertion case numbers identified and used for clinical performance evaluation in each clinical data source.				
Indication	Clinical Literature	PMCF Data	Total Cases	User Survey Responses
Apheresis	0	45	45	7
Hemodialysis	5,733	7,402	13,135	16
Unknown	0	0	0	0
Total	5,733	7,447	13,180	16
Patient Population	Clinical Literature	PMCF Data	Total Cases	User Survey Responses
Adults	5,456	7,447	12,903	0
Pediatrics	277	0	277	0
Unknown	0	0	0	16
Total	5,733	7,447	13,180	16
Catheter French Size	Clinical Literature	PMCF Data	Total Cases	User Survey Responses
14F	4,383	7,320	11,703	11
16F	227	125	352	7
Unknown	1,123	2	1,125	0
Total	5,733	7,447	13,180	16
Clinical performance was measured using parameters including but not limited to dwell time, catheter insertion outcomes, and adverse event rates. Critical clinical parameters extracted from these studies met standards set forth in the guidelines for the State of the Art. There were no unforeseen adverse events or other high occurrences of adverse events detected in any of the clinical activities.				
Medcomp® catheters are subjected to, and must pass, simulated use testing intended to replicate use 3 times per week for 12 months as part of device development. The Split Cath® III Catheter passed this testing. Although Medcomp® catheters contain no materials which degrade over time, fully functional catheters may be removed for other reasons, such as intractable infection, change of therapy (such as Renal replacement (transplant) or use of an arterio-venous graft/fistula). Published clinical literature does not always focus on the physical lifetime of a catheter for these reasons. In the case of the Split Cath® III Catheter, 5095 catheters had an 87 day [95%CI: 82.9 – 91.1 days] duration of use that has been found in clinical use reported to date. Based on this information, the Split Cath® III Catheter has a 12-month lifetime; however, the decision to remove and/or replace the catheter should be based on clinical performance and need, and not any predetermined point in time.				
Summary of clinical data related to the equivalent device (if applicable)				
Clinical evidence from published literature and PMCF activities has been generated specific to known and unknown variants of the subject device. The equivalency rationale in the updated clinical evaluation report will demonstrate that the clinical evidence available for these variants is representative of the range of device variants in the device family.				

There are no clinical or biological differences between variants within the subject device family, and the potential impact of the technical differences will be rationalized in the updated clinical evaluation report.

Summary of clinical data from pre-market investigations (if applicable)

No pre-market clinical devices were used for the device's clinical evaluation.

Summary of clinical data from other sources:

**Source: Summary of Published Literature**

Clinical evidence literature searches have found thirty eight published literature articles representing 2,315 Split Cath® III device family specific cases and an additional 3,418 mixed cohort cases inclusive of the Split Cath® III device family. The articles include three randomized controlled trials (Richard et al., 2001, Trerotola et al., 2002, O'Dwyer et al., 2005), six prospective studies (Centinkaya et al., 2003, Ash et al., 2002, Ewing et al., 2002, Fry et al., 2008, Gallieni et al., 2002, Mankus et al., 1998), twenty retrospective studies (Aboul Hosn et al., 2017, Aitken et al., 2014, Balamuthusamy et al., 2016, Clark et al., 2009, Clark et al 2015, Conz et al., 2000, Conz et al., 2001, Ekbal et al., 2008, Haas et al., 2010, Kade et al., 2014, Keeling et al., 2007, Lee et al., 2013, Lima et al., 2024, McGarry et al., 2017, Nadolski et al., 2013, Onder et al., 2007, Tapping et al., 2012, Hung et al., 2021, J Les et al., 2021, Zhang et al., 2025), and four case studies (Aljure et al., 2021, Duarte et al., 2021, Jonszta et al., 2021, Maidman et al., 2022).

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#### **Source: Dr Trerotola Data Report\_B**

The dataset was provided by Scott O. Trerotola, MD an Interventional Radiologist at the Hospital of the University of Pennsylvania. Dr. Trerotola is also Stanley Baum Professor of Radiology, Professor of Radiology in Surgery, Vice Chair for Quality, Radiology, Associate Chair and Chief, Interventional Radiology, and Director, Penn HHT Center of Excellence at the Perelman School of Medicine at the University of Pennsylvania. The dataset is consecutive, comprehensive, and includes catheter placements by interventional radiology Attending and Fellowship Physicians, as well as Residents under Attending supervision.

All 5095 Split Cath® III catheters described in the study were 14F Straight Split Cath® III Catheters with sideholes of variable lengths inserted percutaneously. There were 335 catheters of 24cm length, 3,309 catheters of 28cm length, 1,163 catheters of 32cm length, 144 catheters of 36cm length, 82 catheters of 40cm length, and 61 catheters of 55cm length. 45 catheters were indicated for apheresis, and 5,050 catheters were indicated for hemodialysis.

Parameter	Value	Standard Deviation	95% Confidence Interval
Dwell Time (Mean Days)	87	148.2	82.9 – 91.1
Procedural Outcomes (Insertion Success)	99.2%	N/A	99% - 99.4%
Catheter Related Blood Stream Infection (CRBSI) (number per 1,000 catheter days)	2.53	N/A	0 – 2.65
Tunnel Infection Rate (number per 1,000 catheter days)	0.26	N/A	0 – 0.3
Exit Site Infection Rate (number per 1,000 catheter days)	0.02	N/A	0 – 0.04
Catheter Associated Venous Thrombus (CAVT) (number per 1,000 catheter days)	0.04	N/A	0 – 0.05

**Source: LTHD Data Collection Survey Report\_B**

The Long-Term Hemodialysis Catheter Data Collection Survey was intended to gather safety and performance outcome information from sites that purchase Medcomp long-term hemodialysis catheters for use in EU MDR clinical evaluation. Responses were requested to be completed by physicians or other site employees with oversight and direction from a physician. The surveys were distributed globally to existing Medcomp customers. Responses were collected from twenty-one sites, spanning nine countries (Colombia, Croatia, El Salvador, Greece, Italy, Netherlands, Panama, Uruguay, and USA) across North America, South/Latin America, and Europe.

All patients described in this survey listed hemodialysis as the indication for treatment, with an average age of 70.3 years. Patient gender was not recorded in the survey. All 10 catheters described in the study were 14F Split Cath® III. There were 6 catheters of 24 cm length and 4 catheters of 28 cm length.

Parameter	Value	Standard Deviation	95% Confidence Interval
Dwell Time (Mean Days)	316	N/A	N/A

Procedural Outcomes (Insertion Success)	100%	N/A	100% - 100%
Catheter Related Blood Stream Infection (CRBSI) (number per 1,000 catheter days)	0	N/A	N/A
Tunnel Infection Rate (number per 1,000 catheter days)	0	N/A	N/A
Exit Site Infection Rate (number per 1,000 catheter days)	0	N/A	N/A
Catheter Associated Venous Thrombus (CAVT) (number per 1,000 catheter days)	3.16	N/A	N/A

**Source: PMCF\_Medcomp\_211**

The Medcomp User Survey acquired responses from healthcare personnel familiar with any number of Medcomp's product offerings.

28 respondents responded that they or their facility have used Medcomp long-term hemodialysis catheters, with 16 of those respondents using the Split Cath III device, inclusive of variant categories across French size (14F, 16F) and sideholes (with and without sideholes). There were no differences in mean user sentiments within long-term hemodialysis catheters across State of the Art Performance and Safety Outcome Measures or between device types relating to safety or performance.

The following data points were collected from users of Medcomp long-term hemodialysis catheters (n=28):

- (Mean Likert Scale Response) Catheters function as intended – 4.8 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.8 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 4.7 / 5
- Dwell Time (n=26) – 167 days (**95%CI**: 130 – 203)

The following data points were collected from users of Medcomp Split Cath® III catheters (n=16):

- (Mean Likert Scale Response) Catheters function as intended – 4.8 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.8 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 4.8 / 5
- Dwell Time (n=15) – 196 days (**95%CI**: 147.2 – 244.8)

**Source: PMCF\_Infusion\_211**

The Infusion Product Line Data Collection Survey aimed to assess safety and performance outcome information for all variants of Medcomp Infusion Ports, PICCs, Midlines, and CVCs. 70 survey responses were collected from 17 countries representing 471 device cases.

17 Split Cath® III cases, all described as 14F, inclusive of several variant devices across length (28cm, 32cm, 55cm) were collected. The following outcome measures were collected for Medcomp Split Cath® III devices:

- Dwell Time – 132.8 Days (**95%CI:** 76.77 – 188.83)
- Procedural Outcomes – 100%
- Catheter Related Blood Stream Infection – 2.01 per 1,000 catheter days (**95%CI:** 0.04 – 3.98)
- Catheter Associated Venous Thrombus – No Events Reported
- Exit Site Infection – No Events Reported

**Source: PMCF\_LTHD\_242**

The Long-Term Hemodialysis (LTHD) Truveta data analysis assessed safety and performance outcome information for Medcomp® and competitor devices present in Truveta Studio. Truveta data comes from a growing collective of more than 30 health systems that provide 17% of the daily clinical care across all 50 U.S. states from 800 hospitals and 20,000 clinics, representing the full diversity of the United States. The population used for data analysis was derived utilizing Truveta Studio's proprietary coding language (Prose) and unique device identifier (UDI) codes representing all saleable Medcomp® LTHD devices and LTHD devices distributed and/or manufactured by other companies.

2,325 Split-Cath® III cases inclusive of several variant devices were collected. Cases were described as 14F and 16F and Pre-Curved and Straight Cases, configurations (pre-curved, straight), and lengths (24cm, 28cm, 32cm, 36cm, 40cm, 55cm), representation of 24cm, 28cm, 32cm, 36cm, 40cm and 55cm length catheters. The following State of the Art safety and performance outcome measures were observed for Medcomp Split-Cath® III devices:

- Catheter Related Blood Stream Infection – 0.73 per 1,000 catheter days (95%CI: 0.62 – 0.86)
- Catheter Associated Venous Thrombus – 0.09 per 1,000 catheter days (95%CI: 0.05 – 0.14)
- Exit Site Infection – 0.09 per 1,000 catheter days (95%CI: 0.05 – 0.14)
- Tunnel Infection – 0 per 1,000 catheter days (95%CI: 0 – 0.02)
- Dwell Time – 108.2 days (95%CI: 86.82 – 129.58)

The catheter brand logistic regression model did not find that any Medcomp® catheter brands were statistically significantly associated with an increase of the incidence of CRBSI. The brand agnostic logistic regression found that pediatric age group (0–19 years), femoral vein insertion site, catheters that were the fourth or beyond in sequence for a given patient, split-tip designs, and pre-curved configurations were statistically significantly associated with the incidence of CRBSI. The Split Cath® III was associated with a statistically significant decrease in CRBSI incidence in the brand model (OR: 0.46 95%CI: 0.33 - 0.63), and both shorter catheter length (<=24cm) and smaller French size (<14.5F) in the brand agnostic model.

**Overall summary of clinical safety and performance**

Upon review of the Split Cath® III Catheter data across all sources, it is possible to conclude that the benefits of the subject device, which is facilitating hemodialysis and apheresis in patients in whom other therapies or conservative care are not indicated or desirable as determined by the physician, outweigh the overall and individual risks when the device is used as intended by the manufacturer. It is the manufacturer's and clinical expert evaluator's

opinion that activities both complete and ongoing are sufficient to support the safety, efficacy, and acceptable benefit/risk profile of the Split Cath® III catheters.

Outcome	Benefit/Risk Acceptability Criteria	Desired Trend	Clinical Literature (Subject Device)	PMCF Data (Subject Device)
<b>Performance</b>				
Dwell Time	Greater than 40 days	↑	48 days – 302 days (Summary of Published Literature)	316 days (LTHD Data Collection Survey Report_B)  87 days (Dr Trerotola Data Report_B)  196 days (PMCF_Medcomp_211)  Likert Scale Response 4.8 / 5 (PMCF_Medcomp_211)**  132.8 Days (PMCF_Infusion_211)  108.2 Days (PMCF_LTHD_242)
Procedural Outcomes	Greater than 93.3%	↑	94% - 100% (Summary of Published Literature)	100% (LTHD Data Collection Survey Report_B & PMCF_Infusion_211)  99.2% (Dr Trerotola Data Report_B)  Likert Scale Response 4.7 / 5 (PMCF_Medcomp_211)**
<b>Safety</b>				
Catheter Related Blood Stream Infection (CRBSI)	Less than 4.8 incidents of CRBSI per 1,000 catheter days	↓	0.2 – 5.1 per 1,000 catheter days (Summary of Published Literature)	No Events Reported (LTHD Data Collection Survey Report_B)  2.53 per 1,000 catheter days (Dr Trerotola Data Report_B)

				<p>Likert Scale Response 4.6 / 5 <b>(PMCF_Medcomp_211)**</b></p> <p>2.01 per 1,000 catheter days <b>(PMCF_Infusion_211)</b></p> <p>0.73 per 1,000 catheter days <b>(PMCF_LTHD_242)</b></p>
Tunnel Infection Rate	Less than 2.8 incidents of tunnel infection per 1,000 catheter days	↓	ND*	<p>No Events Reported <b>(LTHD Data Collection Survey Report_B)</b></p> <p>0.26 per 1,000 catheter days <b>(Dr Trerotola Data Report_B)</b></p> <p>Likert Scale Response 4.6 / 5 <b>(PMCF_Medcomp_211)**</b></p> <p>0 per 1,000 catheter days <b>(PMCF_LTHD_242)</b></p>
Exit Site Infection Rate	Less than 3.2 incidents of exit site infection per 1,000 catheter days	↓	1.3 per 1,000 catheter days <b>(Summary of Published Literature)</b>	<p>No Events Reported <b>(LTHD Data Collection Survey Report_B)</b></p> <p>0.02 per 1,000 catheter days <b>(Dr Trerotola Data Report_B)</b></p> <p>Likert Scale Response 4.5 / 5 <b>(PMCF_Medcomp_211)**</b></p> <p>0.09 per 1,000 catheter days <b>(PMCF_LTHD_242)</b></p>

Catheter Associated Venous Thrombus (CAVT)	Less than 3.04 incidents of CAVT per 1,000 catheter days	↓	0.4 – 4.8 per 1,000 catheter days (Summary of Published Literature)	3.16 per 1,000 catheter days (LTHD Data Collection Survey Report_B)  0.04 per 1,000 catheter days (Dr Trerotola Data Report_B)  Likert Scale Response 4.6 / 5 (PMCF_Medcomp_211)**  0.09 per 1,000 catheter days (PMCF_LTHD_242)
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\*ND indicates no data on the clinical data parameter

\*\*PMCF\_Medcomp\_211 asked respondents, if they agreed on a scale of 1 -5, that their experience in relation to each outcome was the same or better than the benefit/risk acceptability criteria.

**On-going or planned Post-Market Clinical Follow-up (PMCF)**

Activity	Description	Reference	Timeline
Multi-center Patient-Level Case Series	Collect additional clinical data on the device by acquiring case data healthcare personnel familiar with the device.	PMCF_LTHD_241	Q4 2025
State of the Art Literature Search	Identify risks and trends with use of similar devices by reviewing applicable standards, published literature, conference abstracts, guidance documents and recommendations; information relating to the medical condition managed by the device and medical alternatives available for the same target treated population.	SAP-HD	Q2 2026
Clinical Evidence Literature Search	Identify risks and trends with use of the device by reviewing any	LRP-HD	Q2 2026

	clinical data relevant to the device from published literature.		
Global Trial Database Search	Identify ongoing clinical trials involving Split Cath® III catheters.	N/A	Q2 2026
No emerging risks, complications or unexpected device failures have been detected from PMCF activities.			

## 6. Possible therapeutic alternatives

The Kidney Disease Outcomes Quality Initiative (KDOQI) 2019 clinical practice guidelines have been used to support the below recommendations for treatments.

Alternatives for Hemodialysis:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> <li>Permanent vascular access solution</li> <li>Lower complication rate than hemodialysis via catheter</li> </ul>	<ul style="list-style-type: none"> <li>Requires time to mature</li> <li>Patients must sometimes self-cannulate</li> </ul>	<ul style="list-style-type: none"> <li>Stenosis</li> <li>Thrombosis</li> <li>Aneurysm</li> <li>Pulmonary hypertension</li> <li>Steal Syndrome</li> <li>Septicemia</li> </ul>
Hemodialysis Catheter	<ul style="list-style-type: none"> <li>Useful for quick vascular access without AV Fistula in place</li> <li>Can be used as a bridge dialysis method between other therapies</li> </ul>	<ul style="list-style-type: none"> <li>Not a permanent solution</li> <li>Catheter dysfunction can disrupt regular treatment</li> <li>Benefit is not equal for all patient populations</li> </ul>	<ul style="list-style-type: none"> <li>Post-procedural bleeding</li> <li>Infection</li> <li>Thrombosis</li> <li>Decreased blood flow in dysfunctional catheter</li> <li>Cardiovascular events</li> <li>Fibrin sheath formation around catheter</li> <li>Septicemia</li> </ul>
Peritoneal Dialysis	<ul style="list-style-type: none"> <li>Less restrictive diet than hemodialysis</li> <li>Does not require hospitalization, can be done in any clean place</li> </ul>	<ul style="list-style-type: none"> <li>Clearance of impurities is limited by dialysate flow and peritoneal area</li> </ul>	<ul style="list-style-type: none"> <li>Peritonitis</li> <li>Septicemia</li> <li>Fluid overload</li> </ul>

Therapy	Benefits	Disadvantages	Key Risks
Kidney Transplant	<ul style="list-style-type: none"> <li>Better quality of life compared to HD</li> <li>Lower risk of death compared to HD</li> <li>Fewer dietary restrictions compared to HD</li> </ul>	<ul style="list-style-type: none"> <li>Requires a donor which can take time</li> <li>More risky for certain groups (aged, diabetics, etc.)</li> <li>Patient must take rejection medication for life               <ul style="list-style-type: none"> <li>Rejection medication has side effects</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Thrombosis</li> <li>Hemorrhage</li> <li>Ureteral blockage               <ul style="list-style-type: none"> <li>Infection</li> </ul> </li> <li>Organ rejection               <ul style="list-style-type: none"> <li>Death</li> <li>Myocardial infarction</li> <li>Stroke</li> </ul> </li> </ul>
Comprehensive Conservative Care	<ul style="list-style-type: none"> <li>Less imposed symptom burden than dialysis</li> <li>Preserves life satisfaction</li> </ul>	<ul style="list-style-type: none"> <li>May aggravate clinical condition</li> <li>Not designed to treat, but to minimize adverse events</li> </ul>	<ul style="list-style-type: none"> <li>Treatment may not actually minimize risks associated with CKD</li> </ul>

Alternatives for Apheresis:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> <li>Permanent vascular access solution</li> <li>Lower complication rate than hemodialysis via catheter</li> </ul>	<ul style="list-style-type: none"> <li>Requires time to mature</li> <li>Patients must sometimes self-cannulate</li> </ul>	<ul style="list-style-type: none"> <li>Stenosis</li> <li>Thrombosis</li> <li>Aneurysm</li> <li>Pulmonary hypertension</li> <li>Steal Syndrome</li> <li>Septicemia</li> </ul>
Hemodialysis Catheter	<ul style="list-style-type: none"> <li>Useful for quick vascular access without AV Fistula in place</li> <li>Can be used as a bridge dialysis method between other therapies</li> </ul>	<ul style="list-style-type: none"> <li>Not a permanent solution</li> <li>Catheter dysfunction can disrupt regular treatment</li> <li>Benefit is not equal for all patient populations</li> </ul>	<ul style="list-style-type: none"> <li>Post-procedural bleeding</li> <li>Infection</li> <li>Thrombosis</li> <li>Decreased blood flow in dysfunctional catheter</li> <li>Cardiovascular events</li> <li>Fibrin sheath formation around catheter</li> <li>Septicemia</li> </ul>

Therapy	Benefits	Disadvantages	Key Risks
<p style="text-align: center;">Infusion CVC</p>	<ul style="list-style-type: none"> <li>• Capable of multiple infusions</li> <li>• Ideal for initiation of extracorporeal therapies</li> <li>• Easy access once in place</li> <li>• Minimizes repeated venipuncture</li> <li>• Increased patient mobility during infusion</li> <li>• Easier for outpatient treatment</li> </ul>	<ul style="list-style-type: none"> <li>• Inability to obtain venous access in emergent situations</li> <li>• Requires surgical procedure for placement</li> <li>• Risks associated with surgery: general anesthesia, etc.</li> <li>• Requires maintenance</li> <li>• High risk of infection or thrombotic event</li> </ul>	<ul style="list-style-type: none"> <li>• Active skin or soft tissue infection at the potential site of the central line</li> <li>• Vascular injury proximal or distal to the site of the catheter insertion</li> <li>• Thrombocytopenia</li> <li>• Catheter infection</li> <li>• Occlusion</li> <li>• Malfunction of the CVC</li> <li>• Vascular thrombosis</li> </ul>
<p style="text-align: center;">Implantable Port</p>	<ul style="list-style-type: none"> <li>• Decreases puncture wounds/vein damage compared to traditional injection</li> <li>• Easier to visualize, palpate, and therefore safer form of IV access</li> <li>• Reduces chance for corrosive medications to make skin contact</li> <li>• Only one venipuncture for both treatment and lab draw, as opposed to two for traditional IV</li> <li>• Longer dwelling time compared to IV</li> <li>• Can be permanent, if needed</li> <li>• Flow rates vary by device</li> <li>• Cosmetically, less displeasing than CVCs</li> </ul>	<ul style="list-style-type: none"> <li>• Requires surgical procedure, but IV does not</li> <li>• Risks associated with surgery: general anesthesia, etc.</li> <li>• Requires regular flushing</li> <li>• Sometimes breast tissue in females- makes access painful and difficult</li> </ul>	<ul style="list-style-type: none"> <li>• Drug extravasations</li> <li>• Infection</li> <li>• Thromboembolism</li> <li>• Tissue necrosis of overlying skin / port dehiscence</li> </ul>
<p style="text-align: center;">Peripheral Intravenous Catheters (PIVs)</p>	<ul style="list-style-type: none"> <li>• Does not require surgical procedure</li> </ul>	<ul style="list-style-type: none"> <li>• Higher hemolysis rates</li> </ul>	<ul style="list-style-type: none"> <li>• Thrombosis</li> <li>• Phlebitis</li> </ul>

Therapy	Benefits	Disadvantages	Key Risks
		<p>compared to venipuncture</p> <ul style="list-style-type: none"> <li>• Cannot be used for therapies with blistering agents</li> <li>• Four days maximum use</li> </ul>	<ul style="list-style-type: none"> <li>• Infection</li> </ul>

Alternatives for Pediatrics:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> <li>• Preferred pediatric vascular access route</li> <li>• Better solute clearance</li> <li>• Lower complication rate than hemodialysis with a catheter</li> <li>• Lower risk of infection and thrombosis</li> </ul>	<ul style="list-style-type: none"> <li>• Technical difficulty in fistula/graft creation in children with small vasculature</li> <li>• Not suitable for certain patient size</li> </ul>	<ul style="list-style-type: none"> <li>• High tendency of vasospasm due to small vessels</li> <li>• Primary failure and early access thrombosis</li> </ul>
Hemodialysis Catheter	<ul style="list-style-type: none"> <li>• Great alternative in rapid onset of kidney failure and short period of time until transplantation</li> <li>• Ability to be used in the absence of needle cannulation</li> <li>• Decreased risk of high output cardiac failure</li> </ul>	<ul style="list-style-type: none"> <li>• High infection rates</li> <li>• High failure/replacement rate</li> <li>• Variable blood flow rates leading to potentially poor clearance</li> </ul>	<ul style="list-style-type: none"> <li>• Potential complications with significant morbidity and mortality</li> <li>• Possible Arrhythmia</li> <li>• Permanent damage to central venous system (stenosis/thrombosis) may occur</li> </ul>
Peritoneal Dialysis	<ul style="list-style-type: none"> <li>• Most suitable for children due to its almost universal applicability</li> </ul>	<ul style="list-style-type: none"> <li>• Long-term success is limited by infectious complications and</li> </ul>	<ul style="list-style-type: none"> <li>• Catheter exit site and tunnel infection</li> <li>• Peritonitis</li> </ul>

Therapy	Benefits	Disadvantages	Key Risks
	and superior compatibility with lifestyle over other modalities	gradual ultrafiltration failure	
Kidney Transplant	<ul style="list-style-type: none"> <li>• Enhanced linear growth and potential for remarkable advances in social and intellectual development</li> <li>• Graft survival is about 12-15 years in children.</li> </ul>	<ul style="list-style-type: none"> <li>• Increase in the lifetime risk of cancer for pediatric transplant recipients</li> <li>• Size – newborns and infants may not be large enough to receive a transplant. Patients need to be around 8-10 kg in size generally.</li> </ul>	<ul style="list-style-type: none"> <li>• Infections, post-transplant lymphoproliferative disorders and malignancy</li> <li>• Graft rejection can be difficult to diagnose.</li> </ul>

**7. Suggested profile and training for users**

The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician. In certain circumstances, patients who may be suitable for home hemodialysis may manipulate the external connections of the catheter.

As per guidelines stated from the International Society of Hemodialysis, if home dialysis is recommended, each patient will undergo a thorough training in order to obtain optimal results from home dialysis treatments. The objectives of the training program are to (1) provide the appropriate amount of information to ensure that the patient will be able to dialyze safely at home; (2) enable the patient to monitor and manage other elements of his or her chronic kidney disease, such as obtaining samples for lab work and maintaining appropriate nutrition and diet; and (3) help the patient and his or her care partner(s) cope with barriers and fears associated with home HD. During training, the patient will also receive technical education on the operations and maintenance of the water treatment system.

During training, the ideal nurse trainer-to-patient ratio is typically 1:1. An idealized schedule of training is created, with weekly areas of focus and training objectives. In practice, however, training is individualized to address any identified learning barriers or risks for failure.

## 8. Reference to any harmonized standards and Common Specifications (CS) applied

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
EN ISO 14971	2019+A11:2021	Medical devices. Application of risk management to medical devices	Full
EN ISO 10555-1	2013+A1:2017	Intravascular catheters. Sterile and single-use catheters. General requirements	Full
ISO 10555-3	2013	Intravascular catheters. Sterile and single-use catheters. Central venous catheters	Full
EN ISO 11607-1	2020+A1:2023	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems	Full
EN ISO 11607-2	2020+A1:2023	Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes	Full
MEDDEV 2.7/1	Rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC	Full
MEDDEV 2.12/2	Rev. 2	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES	Full
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	Full
MDCG 2020-6	2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	Full
MDCG 2020-7	2020	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies	Full
MDCG 2020-8	2020	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies	Full
MDCG 2022-9	2022	Summary of safety and clinical performance	Full
MDCG 2022-21	2022	Guidance on Periodic Safety Update Report (PSUR) According to Regulation EU 2017/745 (MDR)	Full
ISO 10993-1	2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Full
ISO 10993-18	2020+A1:2023	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
		materials within a risk management process	
EN ISO 10993-7	2008+ A1:2022	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals— Amendment 1: Applicability of allowable limits for neonates and infants	Full
EN ISO 11135	2014 + A1: 2019	Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices	Full
ISO 14644-1	2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration	Full
ISO 14644-2	2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Full
EN 556-1	2024	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices	Full
EN ISO 11737-1	2018 + A1: 2021	Sterilization of health care products. Microbiological methods. Determination of a population of microorganisms on products	Full
EN 11737-3	2023	Sterilization of health care products. Microbiological methods — Bacterial endotoxin testing	Full
EN ISO 20417	2021	Medical Devices – Information supplied by the manufacturer	Full
EN ISO 15223-1	2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	Full
EN 62366-1	2015 + A1: 2020	Medical devices — Part 1: Application of usability engineering to medical devices	Full
ASTM D4332	2022	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Full
ASTM F2503	2023e1	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Full
EN ISO 11070	2014+A1:2018	Sterile single-use intravascular introducers, dilators and guidewires	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
ISO 594-1	1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements	Full
ISO 594-2	1998	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock Fittings	Full
ASTM D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems	Full
EN ISO 13485	2016 + A11: 2021	Medical Devices – Quality Management system – Requirements for Regulatory Purposes	Full
PD CEN ISO/TR 20416	2020	Medical devices — Post-market surveillance for manufacturers	Full
MDCG 2018-1	Rev. 4	Guidance on BASIC UDI-DI and changes to UDI-DI	Full
EN ISO 11140-1	2014	Sterilization of health care products — Chemical indicators Part 1: General requirements	Full
EN ISO/IEC 17025	2017	General requirements for the competence of testing and calibration laboratories	Full
Regulation (EU) 2017/745	2017	Regulation (EU) 2017/745 of the European Parliament and of the Council	Full
EN 17141	2020	Cleanrooms and associated controlled environments. Biocontamination control	Full
ANSI/AAMI ST72	2019	Bacterial endotoxins-Test methods, routine monitoring, and alternatives to batch testing	Full
EN ISO 80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications — Connectors for intravascular or hypodermic applications	Full

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## PATIENTS

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### SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Revision: SSCP-005 Rev. 5

Date: 02SEP2025

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

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### IMPORTANT INFORMATION

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation.

This SSCP is not intended to replace an Implant Card or the Instructions for Use to provide information on the safe use of the device.

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#### 1. Device identification and general information

Device trade name(s)	Split Cath® III
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908248NF
Date first CE certificate was issued for this device	March 2005

The devices in scope of this document are all long-term hemodialysis catheter sets. The device part numbers are organized into variant categories. These devices are distributed as procedure trays. Procedure trays come in different configurations.

Variant Devices:

Variant Description	Part Number
14F x 20cm Straight Split Cath III w/ sideholes	10386-820-001
14F x 22cm Straight Split Cath III w/ sideholes	10386-822-001
14F x 24cm Pre-Curved Split Cath III w/ sideholes	10386-824-001C
14F x 24cm Straight Split Cath III w/ sideholes	10386-824-001
14F x 24cm Straight Split Cath III w/o sideholes	10471-824-001
14F x 28cm Pre-Curved Split Cath III w/ sideholes	10386-828-001C
14F x 28cm Straight Split Cath III w/ sideholes	10386-828-001
14F x 28cm Straight Split Cath III w/o sideholes	10471-828-001
14F x 32cm Pre-Curved Split Cath III w/ sideholes	10386-832-001C
14F x 32cm Straight Split Cath III w/ sideholes	10386-832-001
14F x 32cm Straight Split Cath III w/o sideholes	10471-832-001
14F x 36cm Pre-Curved Split Cath III w/ sideholes	10386-836-001C
14F x 36cm Straight Split Cath III w/ sideholes	10386-836-001
14F x 36cm Straight Split Cath III w/o sideholes	10471-836-001
14F x 40cm Straight Split Cath III w/ sideholes	10386-840-001
14F x 40cm Straight Split Cath III w/o sideholes	10471-840-001
14F x 55cm Straight Split Cath III w/ sideholes	10386-855-001
16F x 24cm Pre-Curved Split Cath III w/ sideholes	10147-824-001C
16F x 24cm Straight Split Cath III w/ sideholes	10147-824-001
16F x 28cm Pre-Curved Split Cath III w/ sideholes	10147-828-001C
16F x 28cm Straight Split Cath III w/ sideholes	10147-828-001
16F x 32cm Pre-Curved Split Cath III w/ sideholes	10147-832-001C
16F x 32cm Straight Split Cath III w/ sideholes	10147-832-001
16F x 36cm Pre-Curved Split Cath III w/ sideholes	10147-836-001C
16F x 36cm Straight Split Cath III w/ sideholes	10147-836-001
16F x 40cm Straight Split Cath III w/ sideholes	10147-840-001
16F x 55cm Straight Split Cath III w/ sideholes	10147-855-001

Procedure Trays:

Catalog Code	Part Number	Description
ASPC24-3	10386-824-001	14F x 24cm Split Cath® III Catheter w/ Stylet Set (Cuff 19cm From Tip)
ASPC28-3	10386-828-001	14F x 28cm Split Cath® III Catheter w/ Stylet Set (Cuff 23cm From Tip)
ASPC32-3	10386-832-001	14F x 32cm Split Cath® III Catheter w/ Stylet Set (Cuff 27cm From Tip)
ASPC36-3	10386-836-001	14F x 36cm Split Cath® III Catheter w/ Stylet Set (Cuff 31cm From Tip)
ASPC40-3	10386-840-001	14F x 40cm Split Cath® III Catheter w/ Stylet Set (Cuff 35cm From Tip)

Catalog Code	Part Number	Description
ASPC55-3	10386-855-001	14F x 55cm Split Cath® III Catheter w/ Stylet Set (Cuff 50cm From Tip)
ASPC20-3E.	10386-820-001	14F x 20cm Split Cath® III Catheter Set (Cuff 15cm From Tip)
ASPC22-3E.	10386-822-001	14F x 22cm Split Cath® III Catheter Set (Cuff 17cm From Tip)
ASPC24-3E.	10386-824-001	14F x 24cm Split Cath® III Catheter Set (Cuff 19cm From Tip)
ASPC28-3E.	10386-828-001	14F x 28cm Split Cath® III Catheter Set (Cuff 23cm From Tip)
ASPC32-3E.	10386-832-001	14F x 32cm Split Cath® III Catheter Set (Cuff 27cm From Tip)
ASPC36-3E.	10386-836-001	14F x 36cm Split Cath® III Catheter Set (Cuff 31cm From Tip)
ASPC40-3E.	10386-840-001	14F x 40cm Split Cath® III Catheter Set (Cuff 35cm From Tip)
ASPC55-3E.	10386-855-001	14F x 55cm Split Cath® III Catheter Set (Cuff 50cm From Tip)
ASPC24-3PCE.	10386-824-001C	14F x 24cm Pre-Curved Split Cath® III Catheter Set (Cuff 19cm From Tip)
ASPC28-3PCE.	10386-828-001C	14F x 28cm Pre-Curved Split Cath® III Catheter Set (Cuff 23cm From Tip)
ASPC32-3PCE.	10386-832-001C	14F x 32cm Pre-Curved Split Cath® III Catheter Set (Cuff 27cm From Tip)
ASPC36-3PCE.	10386-836-001C	14F x 36cm Pre-Curved Split Cath® III Catheter Set (Cuff 31cm From Tip)
ASPC24-3WOE.	10471-824-001	14F x 24cm Split Cath® III Catheter w/o Sideholes Set (Cuff 19cm From Tip)
ASPC28-3WOE.	10471-828-001	14F x 28cm Split Cath® III Catheter w/o Sideholes Set (Cuff 23cm From Tip)
ASPC32-3WOE.	10471-832-001	14F x 32cm Split Cath® III Catheter w/o Sideholes Set (Cuff 27cm From Tip)
ASPC36-3WOE.	10471-836-001	14F x 36cm Split Cath® III Catheter w/o Sideholes Set (Cuff 31cm From Tip)
ASPC40-3WOE.	10471-840-001	14F x 40cm Split Cath® III Catheter w/o Sideholes Set (Cuff 35cm From Tip)
ASPC40-3TLE.	10386-840-001	14F x 40cm Split Cath® III Catheter Translumbar Set (Cuff 35cm From Tip)
ASPC55-3TLE.	10386-855-001	14F x 55cm Split Cath® III Catheter Translumbar Set (Cuff 50cm From Tip)
ASPC2416-3E.	10147-824-001	16F x 24cm Split Cath® III Catheter Set (Cuff 19cm From Tip)
ASPC2816-3E.	10147-828-001	16F x 28cm Split Cath® III Catheter Set (Cuff 23cm From Tip)
ASPC3216-3E.	10147-832-001	16F x 32cm Split Cath® III Catheter Set (Cuff 27cm From Tip)
ASPC3616-3E.	10147-836-001	16F x 36cm Split Cath® III Catheter Set (Cuff 31cm From Tip)

Catalog Code	Part Number	Description
ASPC4016-3E.	10147-840-001	16F x 40cm Split Cath® III Catheter Set (Cuff 35cm From Tip)
ASPC5516-3E.	10147-855-001	16F x 55cm Split Cath® III Catheter Set (Cuff 50cm From Tip)
ASPC2416-3PCE.	10147-824-001C	16F x 24cm Pre-Curved Split Cath® III Catheter Set (Cuff 19cm From Tip)
ASPC2816-3PCE.	10147-828-001C	16F x 28cm Pre-Curved Split Cath® III Catheter Set (Cuff 23cm From Tip)
ASPC3216-3PCE.	10147-832-001C	16F x 32cm Pre-Curved Split Cath® III Catheter Set (Cuff 27cm From Tip)
ASPC3616-3PCE.	10147-836-001C	16F x 36cm Pre-Curved Split Cath® III Catheter Set (Cuff 31cm From Tip)

Configurations of Procedure Trays:

Configuration Type
Set w/ Stylet
Straight Set
Pre-Curved Set
Translumbar Set

## 2. Intended use of the device

Intended purpose	Split Cath® III Catheters are intended for use in adult and pediatric patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis and apheresis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is intended to be used under the regular review and assessment of qualified health professionals.
Indication(s)	The Split Cath® III Catheter is indicated for short-term or long-term use where vascular access is required for 14 days or more for the purpose of hemodialysis and apheresis.
Intended patient group(s)	Split Cath® III Catheters are intended for use in adult and pediatric patients who do not have functional permanent vascular access or are not candidates for permanent vascular access for whom central venous vascular access for hemodialysis and apheresis is deemed necessary based on the direction of a qualified, licensed physician.
Contraindications	<ul style="list-style-type: none"> <li>Known or suspected allergies to any of the components of the catheter or the kit.</li> <li>This device is contraindicated for patients exhibiting severe, uncontrolled coagulopathy or thrombocytopenia.</li> </ul>

### 3. Device description



**Figure 1: Split Cath III Catheter (Straight)**



**Figure 2: Split Cath III Catheter (Pre-Curved)**

Description of device	<p>The Split Cath® III Catheters are long-term catheters. The catheters are double tubed. The catheters remove and return blood through two separate lines. Each tube connects through an extension line. The transition between lumen and extension is in a central hub. Each tube has the priming volume marked by colored rings on the clamps on the extensions. A polyester cuff on the catheter tubing helps attach the catheter to the patient.</p>																
Materials / substances in contact with patient tissue	<p>The percentage ranges below are based on catheter weights. The 20cm catheter weighs 13.86 grams. The 55cm catheter weighs 20.11 grams.</p> <table border="1" data-bbox="626 1377 1330 1709"> <thead> <tr> <th colspan="2" data-bbox="626 1377 1330 1423">14F Split Cath® III</th> </tr> <tr> <th data-bbox="626 1423 1070 1461">Material</th> <th data-bbox="1070 1423 1330 1461">% Weight (w/w)</th> </tr> </thead> <tbody> <tr> <td data-bbox="626 1461 1070 1503">Polyurethane</td> <td data-bbox="1070 1461 1330 1503">62.03 - 67.62</td> </tr> <tr> <td data-bbox="626 1503 1070 1545">Acetal co-polymer</td> <td data-bbox="1070 1503 1330 1545">11.86 - 17.20</td> </tr> <tr> <td data-bbox="626 1545 1070 1587">Silicone</td> <td data-bbox="1070 1545 1330 1587">5.04 - 7.32</td> </tr> <tr> <td data-bbox="626 1587 1070 1629">Barium sulfate</td> <td data-bbox="1070 1587 1330 1629">5.85 - 10.25</td> </tr> <tr> <td data-bbox="626 1629 1070 1671">Acrylonitrile Butadiene Styrene</td> <td data-bbox="1070 1629 1330 1671">3.55 - 5.15</td> </tr> <tr> <td data-bbox="626 1671 1070 1713">Polyethylene terephthalate</td> <td data-bbox="1070 1671 1330 1713">1.68 - 2.44</td> </tr> </tbody> </table> <p>The percentage ranges below are based on catheter weights. The 24cm catheter weighs 14.56 grams. The 55cm catheter weighs 21.05 grams.</p>	14F Split Cath® III		Material	% Weight (w/w)	Polyurethane	62.03 - 67.62	Acetal co-polymer	11.86 - 17.20	Silicone	5.04 - 7.32	Barium sulfate	5.85 - 10.25	Acrylonitrile Butadiene Styrene	3.55 - 5.15	Polyethylene terephthalate	1.68 - 2.44
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	<b>16F Split Cath® III</b>	
	<b>Material</b>	<b>% Weight (w/w)</b>
	Polyurethane	62.89 - 68.17
	Acetal co-polymer	11.33 - 16.38
	Silicone	4.82 - 6.97
	Barium sulfate	6.53 - 10.69
	Acrylonitrile Butadiene Styrene	3.39 - 4.90
	Polyethylene terephthalate	1.61 - 2.32
	<p><b>Note:</b> The device should not be used if you are allergic to the above materials.</p> <p><b>Note:</b> Accessories containing stainless steel may contain up to 4% weight of the CMR substance cobalt.</p>	
Information on medicinal substances in the device	N/A	
How the device achieves its intended mode of action	<p>Hemodialysis catheters are centrally placed access tubes. A typical hemodialysis catheter uses a thin, flexible tube. The tube has two openings. The tube goes into a large vein. The vein is usually the internal jugular vein. Blood withdraws through one lumen of the catheter. The blood flows to the dialysis machine through a separate tubing set. The blood is then processed and filtered. The blood returns to the patient through the second lumen. This device is used when dialysis must start at once. Patients may not have a functioning AV fistula or graft. Catheter hemodialysis normally happens on a short-term basis. Long-term access may occur in some cases. For example, when there are problems supporting an AV fistula or graft. The catheter may also be used for apheresis. Apheresis can happen in a blood bank facility or hemodialysis center. Like hemodialysis, apheresis treatments withdraw blood from the catheter and then return blood through the catheter. There are different types of apheresis. Where hemodialysis cleans blood, apheresis separates and removes a component of blood.</p>	
Sterilization Information	Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.	
Description of accessories	Name of Accessory	Description of Accessory
	<b>Guidewire</b>	Acts as a path for other components.
	<b>Guidewire Advancer</b>	Helps guidewire introduction.
	<b>Stylet</b>	Assist in catheter insertion.
	<b>Introducer Needle</b>	Placed into the target vein to gain access.
	<b>Tunneler</b>	Creates a pocket in between muscle and skin for catheter.
	<b>Tunneler Sleeve</b>	Helps secure the catheter to the tunneler.

	<b>Peelable Introducer</b>	Used to get central venous access.
	<b>End Cap</b>	To keep the catheter clean between treatments.
	<b>Dilator</b>	Used to make the opening of a vessel larger.
	<b>Scalpel</b>	A cutting device.
	<b>Syringe</b>	Helps get blood return once the needle punctures the vein.
	<b>Tegaderm</b>	Dressing that protects the catheter from contamination.

#### 4. Risks and warnings

Contact your healthcare professional if you believe you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document does not replace a consultation with your healthcare professional.

How potential risks have been controlled or managed	<p>There have been 204,298 devices sold since January 2020. There are side effects and risks associated with the device. These include:</p> <ul style="list-style-type: none"> <li>• Infection</li> <li>• Bleeding</li> <li>• Catheter Removal</li> <li>• Catheter Replacement</li> </ul> <p>These risks are reduced to an acceptable level. The labeling describes the risks. The benefit of the device is access for hemodialysis and apheresis when alternatives are not suitable. These benefits outweigh the risks.</p>
Remaining risks and undesirable effects	<p>The Split Cath® III catheter is associated with risks. These include:</p> <ul style="list-style-type: none"> <li>• Procedural Delays</li> <li>• Thrombosis</li> <li>• Infections</li> <li>• Perforations</li> <li>• Embolism</li> <li>• Cardiac Event</li> <li>• Dissatisfaction</li> </ul> <p>These risks are consistent with risks of other dialysis catheters. They are not unique to the Medcomp product. Some of the most common reactions include infection. Infection may be associated with general surgical procedure and hospitalization. Infection may not always be device-related.</p>

	Patient Residual Harm Category	Quantification of Residual Risks	
		Complaints (01 January 2016 – 31 March 2025)	Post Market Clinical Follow-Up Activity Events
		Units Sold: 233,659	Units Studied: 7,447
		# of Cases Per Event	# of Cases Per Event
	Allergic Reaction	Not Reported.	1 Event in 573 Cases.
	Bleeding	1 Event in 111,000 Cases.	1 Event in 9 Cases.
	Cardiac Event	Not Reported.	1 Event in 57 Cases.
	Embolism	Not Reported.	1 Event in 6 Cases.
	Infection	1 Event in 250,000 Cases.	1 Event in 5 Cases.
	Perforation	Not Reported.	1 Event in 14 Cases.
	Stenosis	Not Reported.	1 Event in 62 Cases.
	Tissue Injury	Not Reported.	Not Reported.
	Thrombosis	1 Event in 250,000 Cases.	1 Event in 4 Cases.
Warnings and precautions	<p>The below are warnings, precautions, or measures to be taken by patient:</p> <ul style="list-style-type: none"> <li>• To reduce the risk of bacteria entering the catheter, wear a mask over your nose and mouth whenever the catheter is accessed.</li> <li>• Keep the catheter dressing clean and dry. The dressing should be changed by a medical professional at each dialysis session.</li> <li>• Avoid letting the catheter or catheter site go under water. Moisture near the catheter site can potentially lead to an infection.</li> <li>• Ask the doctor to explain the signs and symptoms of catheter infection.</li> <li>• Never remove the cap at the end of the catheter. The cap and clamps of the catheter must be kept closed when not being used for dialysis.</li> </ul>		
Summary of any field safety correction action (FSCA)	There were no recalls for the device between 01 April 2024 to 31 March 2025.		

## 5. Summary of clinical evaluation and post-market clinical follow-up

<b>Clinical background of the device</b>
The Split Cath® III catheter has been available since 2005. The CE Mark was received in March 2005. US FDA clearance was in February 2005. All models included are planned for distribution in the European Union.
<b>Clinical evidence for CE-marking</b>
The clinical literature review identified 38 articles relating to the safety and/or performance of the subject device when used as intended. These articles include approximately 5,733 cases. Four patient level data activities received information on 7,447 catheters. 16 user surveys have been received relating to this device.
Findings from the clinical literature and clinical survey support the performance of the subject device. All data on the Split Cath® III catheter has been evaluated. The benefits of the subject device outweigh the risks when the device is used as intended. The benefit of the device is allowing hemodialysis and apheresis in patients in whom other therapies or conservative care are not desirable by the physician.
<b>Safety</b>
There is sufficient data to prove conformity to the applicable requirements. The device is safe and performs as intended and claimed by Medcomp. The device is state of the art for allowing long-term vascular access for hemodialysis and apheresis in adult and pediatric patients.
Medcomp has reviewed:
<ul style="list-style-type: none"> <li>• Post-Market Data</li> <li>• Medcomp Information Materials</li> <li>• Risk Management Documentation</li> </ul>
The risks are appropriately displayed and consistent with the state of the art. The risks associated with the device are acceptable when weighed against the benefits. There were 102 complaints for 204,298 units sold from 01 January 2020 to 31 March 2025. The complaint rate is 0.050%.

## 6. Possible therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can consider your individual situation. The Kidney Disease Outcomes Quality Initiative (KDOQI) 2019 clinical practice guidelines have been used to support the below recommendations for treatments.

Alternatives for Hemodialysis:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> <li>• Permanent solution.</li> <li>• Lower complication rate than catheter.</li> </ul>	<ul style="list-style-type: none"> <li>• Requires time.</li> <li>• Patients must sometimes self-needle stick.</li> </ul>	<ul style="list-style-type: none"> <li>• Stenosis</li> <li>• Thrombosis</li> <li>• Aneurysm</li> </ul>

Therapy	Benefits	Disadvantages	Key Risks
			<ul style="list-style-type: none"> <li>• Pulmonary hypertension</li> <li>• Steal Syndrome</li> <li>• Septicemia</li> </ul>
Hemodialysis Catheter	<ul style="list-style-type: none"> <li>• Useful for quick access.</li> <li>• Can be used as a bridge between therapies.</li> </ul>	<ul style="list-style-type: none"> <li>• Not permanent.</li> <li>• Catheter dysfunction can happen.</li> <li>• Benefit may not be the same for everyone.</li> </ul>	<ul style="list-style-type: none"> <li>• Post-procedural bleeding</li> <li>• Infection</li> <li>• Thrombosis</li> <li>• Decreased blood flow in dysfunctional catheter</li> <li>• Cardiovascular events</li> <li>• Fibrin sheath formation around catheter</li> <li>• Septicemia</li> </ul>
Peritoneal Dialysis	<ul style="list-style-type: none"> <li>• Less restrictive diet than hemodialysis.</li> <li>• Does not require hospitalization.</li> </ul>	<ul style="list-style-type: none"> <li>• Clearance of impurities is limited by flow and space.</li> </ul>	<ul style="list-style-type: none"> <li>• Peritonitis</li> <li>• Septicemia</li> <li>• Fluid overload</li> </ul>
Kidney Transplant	<ul style="list-style-type: none"> <li>• Better quality of life.</li> <li>• Lower risk of death.</li> <li>• Fewer dietary restrictions.</li> </ul>	<ul style="list-style-type: none"> <li>• Requires a donor.</li> <li>• More risky for certain groups.</li> <li>• Patient must take medication for life.</li> <li>• Medication has side effects.</li> </ul>	<ul style="list-style-type: none"> <li>• Thrombosis</li> <li>• Hemorrhage</li> <li>• Ureteral blockage</li> <li>• Infection</li> <li>• Organ rejection</li> <li>• Death</li> <li>• Myocardial infarction</li> <li>• Stroke</li> </ul>
Comprehensive Conservative Care	<ul style="list-style-type: none"> <li>• Less imposed symptom burden.</li> <li>• Preserves life satisfaction.</li> </ul>	<ul style="list-style-type: none"> <li>• May aggravate clinical condition.</li> <li>• Not designed to treat.</li> </ul>	<ul style="list-style-type: none"> <li>• Treatment may not actually minimize risks associated with CKD.</li> </ul>

Alternatives for Apheresis:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> <li>• Permanent solution.</li> <li>• Lower complication rate than catheter.</li> </ul>	<ul style="list-style-type: none"> <li>• Requires time.</li> <li>• Patients must sometimes self-needle stick.</li> </ul>	<ul style="list-style-type: none"> <li>• Stenosis</li> <li>• Thrombosis</li> <li>• Aneurysm</li> <li>• Pulmonary hypertension</li> <li>• Steal Syndrome</li> </ul>

Therapy	Benefits	Disadvantages	Key Risks
Hemodialysis Catheter	<ul style="list-style-type: none"> <li>Useful for quick access.</li> <li>Can be used as a bridge between therapies.</li> </ul>	<ul style="list-style-type: none"> <li>Not permanent.</li> <li>Catheter dysfunction can happen.</li> <li>Benefit may not be the same for everyone.</li> </ul>	<ul style="list-style-type: none"> <li>Septicemia</li> <li>Post-procedural bleeding <ul style="list-style-type: none"> <li>Infection</li> <li>Thrombosis</li> </ul> </li> <li>Decreased blood flow in dysfunctional catheter</li> <li>Cardiovascular events <ul style="list-style-type: none"> <li>Fibrin sheath formation around catheter</li> </ul> </li> <li>Septicemia</li> </ul>
Infusion CVC	<ul style="list-style-type: none"> <li>Capable of multiple infusions.</li> <li>Ideal for initiation of therapy.</li> <li>Easy access.</li> <li>Minimizes repeated needle sticks.</li> <li>Increased patient mobility.</li> <li>Easier for outpatient.</li> </ul>	<ul style="list-style-type: none"> <li>Inability to obtain access in emergent situations.</li> <li>Requires surgery.</li> <li>Risks associated with surgery.</li> <li>Requires maintenance.</li> <li>High risk of infection or thrombosis.</li> </ul>	<ul style="list-style-type: none"> <li>Exit site infection</li> <li>Vascular injury</li> <li>Thrombocytopenia</li> <li>Catheter infection</li> <li>Occlusion</li> <li>Malfunction</li> <li>Thrombosis</li> </ul>
Implantable Port	<ul style="list-style-type: none"> <li>Decreases vein damage.</li> <li>Easier to visualize.</li> <li>Reduces chance for corrosive medications to make skin contact.</li> <li>Only one puncture.</li> <li>Longer dwell time.</li> <li>Can be permanent.</li> <li>Cosmetically, less displeasing.</li> </ul>	<ul style="list-style-type: none"> <li>Requires surgery.</li> <li>Risks associated with surgery.</li> <li>Requires regular flushing.</li> <li>Sometimes breast tissue in females makes access painful and difficult.</li> </ul>	<ul style="list-style-type: none"> <li>Drug extravasations</li> <li>Infection</li> <li>Thromboembolism</li> <li>Tissue necrosis of overlying skin / port dehiscence</li> </ul>
Peripheral Intravenous Catheters (PIVs)	<ul style="list-style-type: none"> <li>Does not require surgery.</li> </ul>	<ul style="list-style-type: none"> <li>Higher hemolysis rates.</li> <li>Cannot be used for therapies</li> </ul>	<ul style="list-style-type: none"> <li>Thrombosis</li> <li>Phlebitis</li> <li>Infection</li> </ul>

Therapy	Benefits	Disadvantages	Key Risks
		<ul style="list-style-type: none"> <li>with blistering agents.</li> <li>• Four days maximum use.</li> </ul>	

Alternatives for Pediatrics:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> <li>• Preferred pediatric vascular access.</li> <li>• Better solute clearance.</li> <li>• Lower complication rate than catheter.</li> <li>• Lower risk of infection and thrombosis.</li> </ul>	<ul style="list-style-type: none"> <li>• Technical difficulty in children with small veins.</li> <li>• Not suitable for certain patient size.</li> </ul>	<ul style="list-style-type: none"> <li>• High tendency of vasospasm due to small vessels.</li> <li>• Primary failure and early access thrombosis.</li> </ul>
Hemodialysis Catheter	<ul style="list-style-type: none"> <li>• Great alternative in rapid onset of kidney failure.</li> <li>• Ability to be used in the absence of needle sticks.</li> <li>• Decreased risk of cardiac failure.</li> </ul>	<ul style="list-style-type: none"> <li>• High infection rates.</li> <li>• High failure/replacement rate.</li> <li>• Potentially poor treatment.</li> </ul>	<ul style="list-style-type: none"> <li>• Potential complications with significant morbidity and mortality.</li> <li>• Possible Arrhythmia</li> <li>• Permanent damage to central venous system.</li> </ul>
Peritoneal Dialysis	<ul style="list-style-type: none"> <li>• Most suitable for children.</li> </ul>	<ul style="list-style-type: none"> <li>• Long-term success is limited by infectious complications and gradual ultrafiltration failure.</li> </ul>	<ul style="list-style-type: none"> <li>• Catheter exit site and tunnel infection</li> <li>• Peritonitis</li> </ul>
Kidney Transplant	<ul style="list-style-type: none"> <li>• Enhanced linear growth and potential for remarkable advances in social and intellectual development.</li> </ul>	<ul style="list-style-type: none"> <li>• Increase in the lifetime risk of cancer.</li> <li>• Newborns and infants may not be large enough to receive a transplant. Patients need to</li> </ul>	<ul style="list-style-type: none"> <li>• Infections, post-transplant lymphoproliferative disorders and malignancy</li> <li>• Graft rejection can be difficult to diagnose.</li> </ul>

Therapy	Benefits	Disadvantages	Key Risks
	<ul style="list-style-type: none"> <li>Graft survival is about 12-15 years in children.</li> </ul>	be around 8-10 kg in size generally.	

## 7. Suggested training for users

The catheter should be inserted, manipulated, and removed by a qualified, licensed physician or other qualified health care professional under the direction of a physician. In certain circumstances, patients who may be suitable for home hemodialysis may manipulate the external connections of the catheter.

Consult International Society of Hemodialysis guidelines. If home dialysis is recommended, you will undergo thorough training. The objectives of the training program are:

- 1) Give you information to dialyze safely at home.
- 2) Enable you to monitor and manage your disease.
- 3) Help you cope with fears and restrictions of home hemodialysis.

The ideal nurse trainer-to-patient ratio is typically 1:1. A training schedule will be created. Training will be individualized to your needs.

Abbreviation	Definition
AV	Arteriovenous
CE	Conformité Européenne (European Conformity)
CKD	Chronic Kidney Disease
cm	centimeter
CMR	Carcinogenic, mutagenic, reprotoxic
CVC	Central Venous Catheter
dba	Doing Business As
F	French (thickness of catheter)
FDA	Food and Drug Administration
FSCA	Field Safety Corrective Action
IV	Intravenous
KDOQI	Kidney Disease Outcomes Quality Initiative
PA	Pennsylvania
PIV	Peripheral Intravenous Catheters

SSCP	Summary of Safety and Clinical Performance
USA	United States of America
w/w	Weight over Weight

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