

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-033

Symetrex® 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	16002-A5
'MDR Documentation' File Number	MDR-033

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
1	15AUG2022	27212	KO	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	10JUL2023	28290	GM	Periodic Update; Updated in Accordance with CER-033, Revision B	<input type="checkbox"/> Yes, this version was validated by the Notified Body in the following language: English

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					<input type="checkbox"/> No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
3	08NOV2023	28592	GM	Correcting date of first CE certificate, list of accessories, and harmonized standardized	<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
4	13DEC2023	28714	GM	Including variants in equivalency rationale	<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
5	01JUL2024	29461	GM	Periodic Update; Updated in Accordance with CER-033, Revision C	<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

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
6	05SEP2025	25-0172	GM	Periodic Update; Updated in Accordance with CER-033, Revision D	<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

USERS / HEALTHCARE PROFESSIONALS

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)	Symetrex®
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	00884908307N6
Medical device nomenclature description / text	F900202 – Permanent Hemodialysis Catheter and Kits
Class of device	III
Date first CE certificate was issued for this device	October 2016
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
15.5F x 19cm Symetrex w/ sideholes	10764-819-201
15.5F x 19cm Symetrex w/o sideholes	10763-819-201
15.5F x 23cm Symetrex w/ sideholes	10764-823-201
15.5F x 23cm Symetrex w/o sideholes	10763-823-201
15.5F x 28cm Symetrex w/ sideholes	10764-828-201
15.5F x 28cm Symetrex w/o sideholes	10763-828-201

Variant Description	Part Number
15.5F x 33cm Symetrex w/ sideholes	10764-833-201
15.5F x 33cm Symetrex w/o sideholes	10763-833-201
15.5F x 37cm Symetrex w/ sideholes	10764-837-201
15.5F x 37cm Symetrex w/o sideholes	10763-837-201
15.5F x 42cm Symetrex w/ sideholes	10764-842-201
15.5F x 42cm Symetrex w/o sideholes	10763-842-201

Procedure Trays:

Catalog Code	Part Number	Description
MBPS019E.	10763-819-201	15.5F X 19CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes w/ Dual Stylet Set
MBPS023E.	10763-823-201	15.5F X 23CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes w/ Dual Stylet Set
MBPS028E.	10763-828-201	15.5F X 28CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes w/ Dual Stylet Set
MBPS033E.	10763-833-201	15.5F X 33CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes w/ Dual Stylet Set
MUPS019E.	10763-819-201	15.5F X 19CM Symetrex® Double Lumen Hemodialysis w/o Sideholes w/ Dual Stylet Catheter Only Set
MUPS023E.	10763-823-201	15.5F X 23CM Symetrex® Double Lumen Hemodialysis w/o Sideholes w/ Dual Stylet Catheter Only Set
MUPS028E.	10763-828-201	15.5F X 28CM Symetrex® Double Lumen Hemodialysis w/o Sideholes w/ Dual Stylet Catheter Only Set
MUPS033E.	10763-833-201	15.5F X 33CM Symetrex® Double Lumen Hemodialysis w/o Sideholes w/ Dual Stylet Catheter Only Set
MBNS037E.	10763-837-201	15.5F X 37CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes Set
MBNS042E.	10763-842-201	15.5F X 42CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes Set
MBPS019SE.	10764-819-201	15.5F X 19CM Symetrex® Double Lumen Hemodialysis Catheter w/ Dual Stylet Set
MBPS023SE.	10764-823-201	15.5F X 23CM Symetrex® Double Lumen Hemodialysis Catheter w/ Dual Stylet Set
MBPS028SE.	10764-828-201	15.5F X 28CM Symetrex® Double Lumen Hemodialysis Catheter w/ Dual Stylet Set
MBPS033SE.	10764-833-201	15.5F X 33CM Symetrex® Double Lumen Hemodialysis Catheter w/ Dual Stylet Set
MUPS019SE.	10764-819-201	15.5F X 19CM Symetrex® Double Lumen Hemodialysis w/ Dual Stylet Catheter Only Set
MUPS023SE.	10764-823-201	15.5F X 23CM Symetrex® Double Lumen Hemodialysis w/ Dual Stylet Catheter Only Set
MUPS028SE.	10764-828-201	15.5F X 28CM Symetrex® Double Lumen Hemodialysis w/ Dual Stylet Catheter Only Set
MUPS033SE.	10764-833-201	15.5F X 33CM Symetrex® Double Lumen Hemodialysis w/ Dual Stylet Catheter Only Set
MBNS037SE.	10764-837-201	15.5F X 37CM Symetrex® Double Lumen Hemodialysis Catheter Set
MBNS042SE.	10764-842-201	15.5F X 42CM Symetrex® Double Lumen Hemodialysis Catheter Set

Configurations of Procedure Trays:

Configuration Type	Kit Components
Catheter Only	(1) Catheter (2) End Cap
Catheter Only with Stylet	(1) Catheter (2) Stylet (2) End Cap
Catheter Set	(1) Catheter (1) Guidewire (1) Guidewire Advancer (1) 18ga Introducer Needles (1) Tunneler (1) 14F Valved Peelable Introducer (1) 12F Dilator (1) 14F Dilator (2) End Cap
Catheter Set with Stylet	(1) Catheter (2) Stylet (1) Guidewire (1) Guidewire Advancer (1) (18GA) Introducer Needle (1) Tunneler (1) 14F Valved Peelable Introducer (1) 12F Dilator (1) 14F Dilator (2) End Cap

2. Intended use of the device

Intended purpose	As per product IFU (IFU 40818-1BSI), Symetrex® Catheters are intended for use in adult 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 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. This catheter is for Single Use Only.
Indication(s)	As per product IFU (IFU 40818-1BSI), the Symetrex® 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.
Target population(s)	Symetrex® Catheters are intended for use in adult 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 is deemed necessary based on the direction of a qualified, licensed physician. The catheter is not intended for use in pediatric patients.
Contraindications and/or limitations	As per product IFU (IFU 40818-1BSI), the Symetrex® Product Family catheters are contraindicated as follows:

- Known or suspected allergies to any of the components of the catheter or the kit.
- This device is contraindicated for patients exhibiting severe, uncontrolled coagulopathy or thrombocytopenia.
- This device is contraindicated for subclavian puncture when ventilator is in use.
- The presence of other device related infection, or septicemia is known or suspected.
- Severe chronic obstructive lung disease is present.
- Tissue factors in the localized area of device placement will prevent proper device stabilization and/or access.
- Post irradiation of prospective insertion site

3. Device description

Figure 1: Symetrex® Catheter without Sideholes



Figure 2: Symetrex® Catheter with Sideholes



Description of device	<p>The Symetrex® Catheter is a 15.5 French, dual lumen, radiopaque catheter made of polyurethane. It has a polyester retention cuff and two female luer adapters. The retention cuff promotes tissue ingrowth to anchor the catheter in the subcutaneous tunnel. The luer adapters are identical in color to indicate the reversibility of this catheter. This catheter features symmetrical side channels with a distal tip configuration designed to separate the intake flow from the output flow in both directions. The catheter has been tested at flow rates of up to 500 mL/min. The catheter is available in a variety of lengths and with or without sideholes 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 15.5F x 19cm catheter without sideholes (11.88g), 15.5F x 19cm catheter with sideholes (11.87g), 15.5F x 42cm catheter without sideholes (15.60g) , and 15.5F x 42cm catheter with sideholes (15.59g).</p> <table border="1" data-bbox="591 695 1294 1031"> <thead> <tr> <th>Material</th> <th>% Weight (w/w)</th> </tr> </thead> <tbody> <tr> <td>Polyurethane</td> <td>35.96 - 46.50</td> </tr> <tr> <td>Acetyl Copolymer</td> <td>15.82 - 20.79</td> </tr> <tr> <td>Isoplast</td> <td>20.94 - 27.53</td> </tr> <tr> <td>Barium Sulfate</td> <td>7.69 - 10.64</td> </tr> <tr> <td>Acrylonitrile butadiene styrene</td> <td>4.26 - 5.60</td> </tr> <tr> <td>Polyester</td> <td>1.85 - 2.43</td> </tr> <tr> <td>Chloroform</td> <td><1</td> </tr> </tbody> </table> <p>Note: Per the instructions for use, the device is contraindicated for patients with known or suspected allergies to the above materials.</p> <p>Note: Accessories containing stainless steel may contain up to 4% weight of the CMR substance cobalt.</p>		Material	% Weight (w/w)	Polyurethane	35.96 - 46.50	Acetyl Copolymer	15.82 - 20.79	Isoplast	20.94 - 27.53	Barium Sulfate	7.69 - 10.64	Acrylonitrile butadiene styrene	4.26 - 5.60	Polyester	1.85 - 2.43	Chloroform	<1
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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.</p>																	
Sterilization Information	Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.																	
Previous generations / variants	Name of previous generation	Differences from current device																
	N/A	N/A																

Accessories intended for use in combination with the Symetrex® Catheter	Name of Accessory	Description of Accessory
	Guidewire	For general intravascular use to facilitate the selective placement of medical devices in the vessel anatomy.
	Guidewire Advancer	Aid for introduction of guidewire into target vein.
	Introducer Needle	Used for the percutaneous introduction of guidewires.
	Stylet	Assists in catheter insertion
	Tunneler	Instrument used to create a subcutaneous tunnel
	Peelable Introducer	Introducers are intended to obtain central venous access to facilitate catheter insertion into the central venous system.
	Dilator	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.
	End Cap	To keep clean and protect catheter luer between treatments.
Other devices or products intended for use in combination with the Symetrex® Catheter	Name of Device or Product	Description of Device or Product
	Syringe	Attached to introducer needle to help capture blood return once introducer needle perforates targeted vein, prevent air embolism
	Scalpel	A cutting device during surgical, pathology and minor medical procedures
	Suture	Used to close the insertion site and exit site
	Adhesive Wound Dressing	Used to protect the catheter from contamination when not in use

4. Risks and warnings

Residual risks and undesirable effects	As per product IFU (IFU 40818-1BSI), 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.
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Residual Harm Type	Possible Adverse Events Associated with Harm
Allergic Reaction	Allergic Reaction Intolerance Reaction to Implanted Device
Bleeding	Bleeding (May be Severe) Femoral Artery Bleed Hematoma Hemomediastinum Retroperitoneal Bleed
Cardiac Event	Cardiac Arrhythmia Cardiac Tamponade
Embolism	Air Embolus
Infection	Bacteremia Endocarditis Exit Site Infection Septicemia Tunnel Infection
Perforation	Arterial Puncture Inferior Vena Cava Puncture Laceration of the Vessel Perforation of the Vessel Pneumothorax Right Atrial Puncture Subclavian Artery Puncture Superior Vena Cava Puncture
Thrombosis	Dissection or Occlusion of the Carotid Artery Central Venous Thrombosis Deep Vein Thrombosis Lumen Thrombosis Subclavian Vein Thrombosis Vascular Thrombosis
Tissue Injury	Brachial Plexus Injury Soft Tissue Injury Exit Site Necrosis
Miscellaneous Complications	Death Femoral Nerve Damage Fibrin Sheath Formation Hemothorax Pleural Injury Thoracic Duct Laceration Venous Stenosis Risks Normally Associated with Local or General Anesthesia, Surgery and Post-Operative Recovery

	Patient Residual Harm Category	Quantification of Residual Risks	
		PMS Complaints (01 January 2019 – 31 March 2025)	PMCF Events
		Units Sold: 31,093	Units Studied: 65
		% of Devices	% of Devices
	Allergic Reaction	Not Reported	Not Reported
	Bleeding	0.02%	Not Reported
	Cardiac Event	Not Reported	Not Reported
	Embolism	Not Reported	Not Reported
	Infection	Not Reported	Not Reported
	Perforation	Not Reported	Not Reported
	Stenosis	Not Reported	Not Reported
	Tissue Injury	Not Reported	Not Reported
	Thrombosis	0.01%	12.3%
Warnings and precautions	<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 40818-1BSI), the Symetrex® Catheters have the following warnings:</p> <ul style="list-style-type: none"> • Do not insert catheter in thrombosed vessels. • Do not advance the guidewire or catheter if unusual resistance is encountered. • 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. • Do not clamp the shaft of the catheter. Use only the line extension clamps which have been provided with the catheter. • Do not insert the valved pull-apart sheath/introducer further than necessary. Depending upon patient size and access site, it may not be necessary to insert the entire length of the introducer into the vessel. • Do not resterilize the catheter or accessories by any method. • Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE • 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. • Do not use catheter or accessories if package is opened or damaged. • Do not use catheter or accessories if any sign of product damage is visible or the use-by date has passed. • Do not use sharp instruments near the extension lines or catheter lumen. • Do not use scissors to remove dressing. 		

- Do not suture through any part of the catheter. There is a danger of tearing the catheter tubing or damaging the suture wing from the bifurcate if excessive force is applied to the catheter.
- Do not use excessive force to flush obstructed lumen.

Precautions listed in the Symetrex® Catheter IFU are as follows:

- Before attempting procedure, ensure that you are familiar with the potential complications and their emergency treatment should any of them occur.
- 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.
- 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 catheter.
- To minimize the risk of air embolism or extravasation, keep the catheter clamps closed at all times when not in use or when attached to a syringe, IV tubing, or bloodlines.
- Before attempting catheter insertion, ensure that you are familiar with the potential complications and their emergency treatment should any of them occur.
- To help avoid air embolism, fill (prime) the device with sterile, anticoagulant lock solution or normal saline solution prior to catheter insertion.
- Avoid sharp or acute angles that could compromise the opening of the catheter lumens.
- 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.
- Health care professionals should always use universal blood and body fluid precautions in the care of all patients to minimize the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens. Sterile technique must be strictly adhered to during any handling of the device.
- Peel-away introducer must only be advanced over a guidewire.
- The valved pull-apart sheath/introducer is designed to reduce blood loss and the risk of air intake.

	<ul style="list-style-type: none"> • The valved pull-apart sheath/introducer is not intended for arterial use. • Discard biohazard according to facility protocol. • Examine the device after it is removed from the patient to ensure no foreign material remains inside the patient.
Other relevant aspects of safety (ex. field safety corrective actions, etc.)	For a period of 01 January 2020 to 31 March 2025 there were 34 complaints for 27,900 units sold, giving an overall complaint rate of 0.122%. There were no death-related events. 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 table displays the device insertion case numbers identified and used for clinical performance evaluation in each clinical data source.			
Clinical Literature	PMCF Data	Total Cases	User Survey Responses
0	65	65	38
<p>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.</p> <p>Medcomp® catheters are subjected to, and must pass, simulated use testing intended to replicate 12 months use as part of device development. The Symetrex® Catheter passed this testing. Although Medcomp® catheters materials contain non-degradable polymers, fully functional catheters may be removed for other reasons, such as intractable infection or change of therapy. Published clinical literature does not always focus on the physical lifetime of a catheter for these reasons. In the case of the Symetrex® Catheter, 46 catheters had a 87 day [95%CI: 61.7 – 112.3 days] duration of use that has been found in clinical use reported to date. Based on this information, the Symetrex® 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.</p>			
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 clinical evaluation report demonstrates that the clinical evidence available for these variants is representative of the range of device variants in the device family.			

Variants Relying on Equivalence:	Variants Contributing Clinical Data:
<ul style="list-style-type: none"> • 15.5F x 33cm Symetrex® without sideholes • 15.5F x 37cm Symetrex® with sideholes • 15.5F x 37cm Symetrex® without sideholes • 15.5F x 42cm Symetrex® with sideholes • 15.5F x 42cm Symetrex® without sideholes 	<ul style="list-style-type: none"> • 15.5F x 19cm Symetrex® without sideholes • 15.5F x 19cm Symetrex® with sideholes • 15.5F x 23cm Symetrex® without sideholes • 15.5F x 23cm Symetrex® with sideholes • 15.5F x 28cm Symetrex® without sideholes • 15.5F x 28cm Symetrex® with sideholes • 15.5F x 33cm Symetrex® with sideholes

There are no clinical or biological differences between variants within the subject device family, and the potential impact of the technical differences is rationalized in the 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: LTHD Data Collection Survey Report

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.

At least partial data was collected on 64 Symetrex® catheter product family cases totalling 4,004 catheter days. Of these 64 cases, 55 described as with sideholes and 13 described as without sideholes. There were 26 catheters of 19cm length, 31 catheters of 23cm length, 6 catheters of 28cm length, and 1 catheters of 33cm. Information was collected on Insertion Success (98.4%, n=64) and dwell time (mean 87 days, 95% CI: 61.7 – 112.3, n=46). There were eight reports of catheter associated venous thrombus (2 per 1,000 catheter days), and no reports of tunnel infection, exit site infection, or catheter related blood stream infection. These outcomes, aside from catheter associated venous thrombus, were concluded to be within State of the Art safety and performance outcome measures from published literature. This is likely attributable to the limited catheter days available for statistical testing, as the sample rate (2 per 1,000 catheter days) is better than the potential acceptance criteria of 3.04 per 1,000 catheter days.

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 2 of those respondents using the Symetrex® device. 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 Symetrex® catheters (n=2):

- (Mean Likert Scale Response) Catheters function as intended – 5 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 5 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 5 / 5
- Dwell Time – 198 days (Range: 1-2 Months – Approximately 1 Year)

Source: Symetrex® Survey Report

The Symetrex® Catheter Survey Report was intended to review and tabulate responses to ensure the device remains safe and effective when used as intended.

Symetrex Survey Protocol was finalized on 08 February 2019. The Symetrex® Catheter Survey was provided electronically to clinicians who use the product worldwide by the product distributors. The survey received responses from 36 clinicians. Symetrex Survey Report was finalized on 30 March 2019. The survey report concluded that the Medcomp® Symetrex® catheter is safe and effective when used as directed, that the features incorporated within the design of the Symetrex® catheter have aided clinicians in its use, and few complications were reported.

Source: PMCF_LTTHD_242

The Long-Term Hemodialysis (LTTHD) 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® LTTHD devices and LTTHD devices distributed and/or manufactured by other companies.

1 Symetrex® case inclusive of several variant devices were collected. The case was described as 15.5F and Straight Case, configurations (straight), and length (42cm), representation of 42cm length catheters. The following State of the Art safety and performance outcome measures were observed for Medcomp Symetrex® devices:

- Catheter Related Blood Stream Infection – 0 per 1,000 catheter days (95%CI: 0 – 40.99)
- Catheter Associated Venous Thrombus – 0 per 1,000 catheter days (95%CI: 0 – 40.99)
- Exit Site Infection – 0 per 1,000 catheter days (95%CI: 0 – 40.99)

- Tunnel Infection – 0 per 1,000 catheter days (95%CI: 0 – 40.99)
- Dwell Time – No Days Reported

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 Symetrex® Catheter data across all sources, it is possible to conclude that the benefits of the subject device, which is facilitating hemodialysis 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 Symetrex® catheters.

Outcome	Benefit/Risk Acceptability Criteria	Desired Trend	Clinical Literature (Subject Device)	PMCF Data (Subject Device)
Performance				
Dwell Time	Greater than 40 days	↑	ND**	87 days (LTHD Data Collection Survey Report) 198 days (PMCF_Medcomp_211) Likert Scale Response 5 / 5 (PMCF_Medcomp_211)*
Procedural Outcomes	Greater than 93.3%	↑	ND**	98.4% (LTHD Data Collection Survey Report) Likert Scale Response 5 / 5 (PMCF_Medcomp_211)*
Safety				
Catheter Related Blood Stream Infection (CRBSI)	Less than 4.8 incidents of CRBSI per 1,000 catheter days	↓	ND**	No Events Reported (LTHD Data Collection Survey Report) Likert Scale Response 5 / 5 (PMCF_Medcomp_211)*

				0 per 1,000 catheter days (PMCF_LTHD_242)
Tunnel Infection Rate	Less than 2.8 incidents of tunnel infection per 1,000 catheter days	↓	ND**	No Events Reported (LTHD Data Collection Survey Report) Likert Scale Response 5 / 5 (PMCF_Medcomp_211)* 0 per 1,000 catheter days (PMCF_LTHD_242)
Exit Site Infection Rate	Less than 3.2 incidents of exit site infection per 1,000 catheter days	↓	ND**	No Events Reported (LTHD Data Collection Survey Report) Likert Scale Response 5 / 5 (PMCF_Medcomp_211)* 0 per 1,000 catheter days (PMCF_LTHD_242)
Catheter Associated Venous Thrombus (CAVT)	Less than 3.04 incidents of CAVT per 1,000 catheter days	↓	ND**	2 per 1,000 catheter days (LTHD Data Collection Survey Report) Likert Scale Response 5 / 5 (PMCF_Medcomp_211)* 0 per 1,000 catheter days (PMCF_LTHD_242)

*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.

**ND = No Data on Parameter

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	SAP-HD	Q2 2026

	managed by the device and medical alternatives available for the same target treated population.		
Clinical Evidence Literature Search	Identify risks and trends with use of the device by reviewing any clinical data relevant to the device from published literature.	LRP-HD	Q2 2026
Global Trial Database Search	Identify ongoing clinical trials involving Symetrex® 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.

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

Therapy	Benefits	Disadvantages	Key Risks
	<ul style="list-style-type: none"> Fewer dietary restrictions compared to HD 	<ul style="list-style-type: none"> Patient must take rejection medication for life <ul style="list-style-type: none"> Rejection medication has side effects 	<ul style="list-style-type: none"> Death Myocardial infarction Stroke
Comprehensive Conservative Care	<ul style="list-style-type: none"> Less imposed symptom burden than dialysis Preserves life satisfaction 	<ul style="list-style-type: none"> May aggravate clinical condition Not designed to treat, but to minimize adverse events 	<ul style="list-style-type: none"> Treatment may not actually minimize risks associated with CKD

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 13485	2016 + A11:2021	Medical Devices – Quality Management system – Requirements for Regulatory Purposes	Full
EN ISO 14971	2019+A11:2021	Medical devices. Application of risk management to medical devices	Full
EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems	Full
EN ISO 11607-2	2020	Packaging for terminally sterilized medical devices. Validation	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
		requirements for forming, sealing and assembly processes	
EN ISO 10555-1	2013+A1:2017	Intravascular catheters. Sterile and single-use catheters. General requirements	Full
EN ISO 10555-3	2013	Intravascular catheters. Sterile and single-use catheters. Central venous catheters	Full
EN ISO 10993-1	2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Full
EN ISO 10993-18	2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	Full
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
EN ISO 14644-1	2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration	Full
EN 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
BS ISO 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	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
		supplied — Part 1: General requirements	
ISO 7000	2019	Graphical symbols for use on equipment. Registered symbols	Partial
EN 62366-1	2015 + A1: 2020	Medical devices — Part 1: Application of usability engineering to medical devices	Full
BS EN ISO 80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications — Connectors for intravascular or hypodermic applications	Full
ASTM D4332	2014	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Full
ASTM D4169	2022	Standard Practice for Performance Testing of Shipping Containers and Systems	Full
ASTM F2503	2023e1	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Full
ASTM F1140/F1140M-13	2020	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages	Full
ASTM F2096-11	2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	Full
ASTM F88/F88M	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials	Full
ASTM F1980	2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices	Full
ASTM F640	2020	Standard Test Methods for determining Radiopacity for Medical Use	Full
EN ISO 11070	2014+A1:2018	Sterile single-use intravascular introducers, dilators and guidewires	Full
PD CEN ISO/TR 20416	2020	Medical devices — post-market surveillance for manufacturers	Full
Regulation (EU) 2017/745	2017	Regulation (EU) 2017/745 of the European Parliament and of the Council	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
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
MDCG 2020-6	2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
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 2019-9	2022	Summary of safety and clinical performance	Full
MDCG 2018-1	Rev. 4	Guidance on BASIC UDI-DI and changes to UDI-DI	Full
EN 17141	2020	Cleanrooms and associated controlled environments. Biocontamination control	Full
EN ISO 11140-1	2014	Sterilization of health care products — Chemical indicators Part 1: General requirements	Full
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	Full

PATIENTS

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Revision: SSCP-033 Rev. 6

Date: 05SEP2025

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.

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.

1. Device identification and general information

Device trade name(s)	Symetrex®
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908307N6
Date first CE certificate was issued for this device	October 2016

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
15.5F x 19cm Symetrex w/ sideholes	10764-819-201
15.5F x 19cm Symetrex w/o sideholes	10763-819-201

Variant Description	Part Number
15.5F x 23cm Symetrex w/ sideholes	10764-823-201
15.5F x 23cm Symetrex w/o sideholes	10763-823-201
15.5F x 28cm Symetrex w/ sideholes	10764-828-201
15.5F x 28cm Symetrex w/o sideholes	10763-828-201
15.5F x 33cm Symetrex w/ sideholes	10764-833-201
15.5F x 33cm Symetrex w/o sideholes	10763-833-201
15.5F x 37cm Symetrex w/ sideholes	10764-837-201
15.5F x 37cm Symetrex w/o sideholes	10763-837-201
15.5F x 42cm Symetrex w/ sideholes	10764-842-201
15.5F x 42cm Symetrex w/o sideholes	10763-842-201

Procedure Trays:

Catalog Code	Part Number	Description
MBPS019E.	10763-819-201	15.5F X 19CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes w/ Dual Stylet Set
MBPS023E.	10763-823-201	15.5F X 23CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes w/ Dual Stylet Set
MBPS028E.	10763-828-201	15.5F X 28CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes w/ Dual Stylet Set
MBPS033E.	10763-833-201	15.5F X 33CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes w/ Dual Stylet Set
MUPS019E.	10763-819-201	15.5F X 19CM Symetrex® Double Lumen Hemodialysis w/o Sideholes w/ Dual Stylet Catheter Only Set
MUPS023E.	10763-823-201	15.5F X 23CM Symetrex® Double Lumen Hemodialysis w/o Sideholes w/ Dual Stylet Catheter Only Set
MUPS028E.	10763-828-201	15.5F X 28CM Symetrex® Double Lumen Hemodialysis w/o Sideholes w/ Dual Stylet Catheter Only Set
MUPS033E.	10763-833-201	15.5F X 33CM Symetrex® Double Lumen Hemodialysis w/o Sideholes w/ Dual Stylet Catheter Only Set
MBNS037E.	10763-837-201	15.5F X 37CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes Set
MBNS042E.	10763-842-201	15.5F X 42CM Symetrex® Double Lumen Hemodialysis Catheter w/o Sideholes Set
MBPS019SE.	10764-819-201	15.5F X 19CM Symetrex® Double Lumen Hemodialysis Catheter w/ Dual Stylet Set
MBPS023SE.	10764-823-201	15.5F X 23CM Symetrex® Double Lumen Hemodialysis Catheter w/ Dual Stylet Set
MBPS028SE.	10764-828-201	15.5F X 28CM Symetrex® Double Lumen Hemodialysis Catheter w/ Dual Stylet Set
MBPS033SE.	10764-833-201	15.5F X 33CM Symetrex® Double Lumen Hemodialysis Catheter w/ Dual Stylet Set
MUPS019SE.	10764-819-201	15.5F X 19CM Symetrex® Double Lumen Hemodialysis w/ Dual Stylet Catheter Only Set
MUPS023SE.	10764-823-201	15.5F X 23CM Symetrex® Double Lumen Hemodialysis w/ Dual Stylet Catheter Only Set
MUPS028SE.	10764-828-201	15.5F X 28CM Symetrex® Double Lumen Hemodialysis w/ Dual Stylet Catheter Only Set

Catalog Code	Part Number	Description
MUPS033SE.	10764-833-201	15.5F X 33CM Symetrex® Double Lumen Hemodialysis w/ Dual Stylet Catheter Only Set
MBNS037SE.	10764-837-201	15.5F X 37CM Symetrex® Double Lumen Hemodialysis Catheter Set
MBNS042SE.	10764-842-201	15.5F X 42CM Symetrex® Double Lumen Hemodialysis Catheter Set

Configurations of Procedure Trays:

Configuration Type	Kit Components
Catheter Only	(1) Catheter (2) End Cap
Catheter Only with Stylet	(1) Catheter (2) Stylet (2) End Cap
Catheter Set	(1) Catheter (1) Guidewire (1) Guidewire Advancer (1) 18ga Introducer Needles (1) Tunneler (1) 14F Valved Peelable Introducer (1) 12F Dilator (1) 14F Dilator (2) End Cap
Catheter Set with Stylet	(1) Catheter (2) Stylet (1) Guidewire (1) Guidewire Advancer (1) (18GA) Introducer Needle (1) Tunneler (1) 14F Valved Peelable Introducer (1) 12F Dilator (1) 14F Dilator (2) End Cap

2. Intended use of the device

Intended purpose	As per product IFU (IFU 40818-1BSI), Symetrex® Catheters are intended for use in adult 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 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. This catheter is for Single Use Only.
Indication(s)	As per product IFU (IFU 40818-1BSI), the Symetrex® 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.
Intended patient group(s)	Symetrex® Catheters are intended for use in adult 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 is deemed necessary based on the direction of a qualified,

	licensed physician. The catheter is not intended for use in pediatric patients.
Contraindications	<p>As per product IFU (IFU 40818-1BSI), the Symetrex® Product Family catheters are contraindicated as follows:</p> <ul style="list-style-type: none"> • Known or suspected allergies to any of the components of the catheter or the kit. • This device is contraindicated for patients exhibiting severe, uncontrolled coagulopathy or thrombocytopenia. • This device is contraindicated for subclavian puncture when ventilator is in use. • The presence of other device related infection, or septicemia is known or suspected. • Severe chronic obstructive lung disease is present. • Tissue factors in the localized area of device placement will prevent proper device stabilization and/or access. • Post irradiation of prospective insertion site.

3. Device description

Figure 1: Symetrex® Catheter without Sideholes



Figure 2: Symetrex® Catheter with Sideholes



Description of device	<p>The Symetrex® 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 15.5F x 19cm catheter without sideholes weighs 11.88 grams. The 15.5F x 19cm catheter with sideholes weighs 11.87 grams. The 15.5F x 42cm catheter without sideholes weighs 15.60 grams. The 15.5F x 42cm catheter with sideholes weighs 15.59 grams.</p> <table border="1" data-bbox="626 632 1328 961"> <thead> <tr> <th>Material</th> <th>% Weight (w/w)</th> </tr> </thead> <tbody> <tr> <td>Polyurethane</td> <td>35.96 - 46.50</td> </tr> <tr> <td>Acetyl Copolymer</td> <td>15.82 - 20.79</td> </tr> <tr> <td>Isoplast</td> <td>20.94 - 27.53</td> </tr> <tr> <td>Barium Sulfate</td> <td>7.69 - 10.64</td> </tr> <tr> <td>Acrylonitrile butadiene styrene</td> <td>4.26 - 5.60</td> </tr> <tr> <td>Polyester</td> <td>1.85 - 2.43</td> </tr> <tr> <td>Chloroform</td> <td><1</td> </tr> </tbody> </table> <p>Note: The device should not be used if you are allergic to the above materials.</p> <p>Note: Accessories containing stainless steel may contain up to 4% weight of the CMR substance cobalt.</p>		Material	% Weight (w/w)	Polyurethane	35.96 - 46.50	Acetyl Copolymer	15.82 - 20.79	Isoplast	20.94 - 27.53	Barium Sulfate	7.69 - 10.64	Acrylonitrile butadiene styrene	4.26 - 5.60	Polyester	1.85 - 2.43	Chloroform	<1
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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.</p>																	
Sterilization Information	Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.																	
Description of accessories	<table border="1"> <thead> <tr> <th>Name of Accessory</th> <th>Description of Accessory</th> </tr> </thead> <tbody> <tr> <td>Guidewire</td> <td>Acts as a path for other components.</td> </tr> <tr> <td>Guidewire Advancer</td> <td>Helps guidewire introduction.</td> </tr> </tbody> </table>	Name of Accessory	Description of Accessory	Guidewire	Acts as a path for other components.	Guidewire Advancer	Helps guidewire introduction.											
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	Introducer Needle	Placed into the target vein to gain access.
	Tunneler	Creates a pocket in between muscle and skin for catheter.
	Stylet	Assists in catheter placement.
	Peelable Introducer	Used to get central venous access.
	End Cap	To keep the catheter clean between treatments.
	Dilator	Used to make the opening of a vessel larger.
	Scalpel	A cutting device.
	Syringe	Helps get blood return once the needle punctures the vein.
	Suture	Used to close the insertion site and exit site
	Adhesive Wound Dressing	Used to protect the catheter from contamination when not in use

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 if needed.

How potential risks have been controlled or managed	<p>There have been 27,900 devices sold since January 2020. There are side effects and risks associated with the device. These include:</p> <ul style="list-style-type: none"> • Infection • Bleeding • Catheter Removal • Catheter Replacement <p>These risks are reduced to an acceptable level. The labeling describes the risks. The benefit of the device is access for hemodialysis when alternatives are not suitable. These benefits outweigh the risks.</p>
Remaining risks and undesirable effects	<p>The Symetrex® catheter is associated with risks. These include:</p> <ul style="list-style-type: none"> • Procedural Delays • Thrombosis • Infections • Perforations • Embolism • Cardiac Event • Dissatisfaction

	<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> <table border="1" data-bbox="558 394 1380 1094"> <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 2019 – 31 March 2025)</th> <th>Post Market Clinical Follow-Up Activity Events</th> </tr> <tr> <th>Units Sold: 31,093</th> <th>Units Studied: 65</th> </tr> <tr> <th># of Cases Per Event</th> <th># of Cases Per Event</th> </tr> </thead> <tbody> <tr> <td>Allergic Reaction</td> <td>Not Reported.</td> <td>Not Reported.</td> </tr> <tr> <td>Bleeding</td> <td>1 Event in 5,000 Cases.</td> <td>Not Reported.</td> </tr> <tr> <td>Cardiac Event</td> <td>Not Reported.</td> <td>Not Reported.</td> </tr> <tr> <td>Embolism</td> <td>Not Reported.</td> <td>Not Reported.</td> </tr> <tr> <td>Infection</td> <td>Not Reported.</td> <td>Not Reported.</td> </tr> <tr> <td>Perforation</td> <td>Not Reported.</td> <td>Not Reported.</td> </tr> <tr> <td>Stenosis</td> <td>Not Reported.</td> <td>Not Reported.</td> </tr> <tr> <td>Tissue Injury</td> <td>Not Reported.</td> <td>Not Reported.</td> </tr> <tr> <td>Thrombosis</td> <td>1 Event in 10,000 Cases.</td> <td>1 Event in 8 Cases.</td> </tr> </tbody> </table>	Patient Residual Harm Category	Quantification of Residual Risks		PMS Complaints (01 January 2019 – 31 March 2025)	Post Market Clinical Follow-Up Activity Events	Units Sold: 31,093	Units Studied: 65	# of Cases Per Event	# of Cases Per Event	Allergic Reaction	Not Reported.	Not Reported.	Bleeding	1 Event in 5,000 Cases.	Not Reported.	Cardiac Event	Not Reported.	Not Reported.	Embolism	Not Reported.	Not Reported.	Infection	Not Reported.	Not Reported.	Perforation	Not Reported.	Not Reported.	Stenosis	Not Reported.	Not Reported.	Tissue Injury	Not Reported.	Not Reported.	Thrombosis	1 Event in 10,000 Cases.	1 Event in 8 Cases.
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<p>Warnings and precautions</p>	<p>The below are warnings, precautions, or measures to be taken by patient:</p> <ul style="list-style-type: none"> • To reduce the risk of bacteria entering the catheter, wear a mask over your nose and mouth whenever the catheter is accessed. • Keep the catheter dressing clean and dry. The dressing should be changed by a medical professional at each dialysis session. • Avoid letting the catheter or catheter site go under water. Moisture near the catheter site can potentially lead to an infection. • Ask the doctor to explain the signs and symptoms of catheter infection. • 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. 																																				
<p>Summary of any field safety correction action (FSCA)</p>	<p>There were no recalls for the device between 01 April 2024 to 31 March 2025.</p>																																				

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

Clinical background of the device
The Symetrex® catheter has been available since 2016. The CE Mark was received in October 2016. US FDA clearance was in August 2017. All models included are planned for distribution in the European Union.
Clinical evidence for CE-marking
The clinical literature review identified 0 articles relating to the safety and/or performance of the subject device when used as intended. Two patient level data activities received information on 65 catheters. 38 user surveys have been received relating to this device.
Findings from the user surveys and data activities support the performance of the subject device. All data on the Symetrex® 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 in patients in whom other therapies or conservative care are not desirable by the physician.
Safety
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 in adult patients.
Medcomp has reviewed:
<ul style="list-style-type: none"> • Post-Market Data • Medcomp Information Materials • Risk Management Documentation
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 34 complaints for 27,900 units sold from 01 January 2020 to 31 March 2025. The complaint rate is 0.122%.

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.

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	<ul style="list-style-type: none"> • Permanent solution. • Lower complication rate than catheter. 	<ul style="list-style-type: none"> • Requires time. • Patients must sometimes self-needle stick. 	<ul style="list-style-type: none"> • Stenosis • Thrombosis • Aneurysm • Pulmonary hypertension • Steal Syndrome • Septicemia
Hemodialysis Catheter	<ul style="list-style-type: none"> • Useful for quick access. 	<ul style="list-style-type: none"> • Not permanent. 	<ul style="list-style-type: none"> • Post-procedural bleeding • Infection

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

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
dba	Doing Business As
F	French (thickness of catheter)
FDA	Food and Drug Administration
FSCA	Field Safety Corrective Action
KDOQI	Kidney Disease Outcomes Quality Initiative
PA	Pennsylvania
SSCP	Summary of Safety and Clinical Performance
USA	United States of America
w/w	Weight over Weight

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