SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-008

Hemo-Cath® LT 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	10013, 10014
'MDR Documentation' File Number	MDR-008

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
1	**04OCT2021**	**26535**	**RS**	**Implementation of SSCP**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device

2	**25JUL2022**	**27030**	**RS**	**Scheduled Update; updated SSCP in accordance with CER-008_C. In addition, the following elements were added throughout: Basic UDI-DI, SRN, Notified Body name and single identification number, EMDN nomenclature, quantification of residual risks, benefits and risks related to alternative therapies, required training for home hemodialysis, and acronym table.**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
3	**19SEP2022**	**27292**	**GM**	**Added additional information to Revision 2 row. Section 8 has been updated to align with the most current harmonized standards and Common Specifications (CS) applied. Quantification of Residual Risks has been updated to align with harm categories in IFU. The total case numbers identified and used for clinical performance evaluation displayed in Section 5 has decreased from 5,506 to 672 on the basis of the exclusion of the following mixed cohort sources of clinical evidence: Onder et al., 2007 (175 Cases), Haas et al., 2010 (3,170 Cases), Granata et al., 2018 (1,489 Cases).**	☒ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
4	**06JUL2023**	**28266**	**GM**	**Periodic Update; Updated in Accordance with CER-008, Revision D**	☐ Yes, this version was validated by the Notified Body in the following language: English

					☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
5	**01JUL2024**	**29151**	**GM**	**Periodic Update; Updated in Accordance with CER-008_E**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
6	**31JUL2025**	**CR# 25-0051**	**GM**	**Periodic Update; Updated in Accordance with CER-008_F**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ 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)	Hemo-Cath® LT
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	00884908106MS
Medical device nomenclature description / text	F900202 – Permanent Hemodialysis Catheter and Kits
Class of device	III
Date first CE certificate was issued for this device	November 1997
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**
12.5F x 15cm Straight Hemo Cath LT	30540-815-100
12.5F x 18cm Straight Hemo Cath LT	30540-818-100
12.5F x 24cm Straight Hemo Cath LT	30540-824-100
12.5F x 28cm Pre-Curved Hemo Cath LT	3293G
12.5F x 28cm Straight Hemo Cath LT	3289G

Variant Description	Part Number
12.5F x 32cm Pre-Curved Hemo Cath LT	3294G
12.5F x 32cm Straight Hemo Cath LT	3306G
8F x 18cm Straight Hemo Cath LT	3189G
8F x 24cm Straight Hemo Cath LT	3190G

Procedure Trays:

Catalog Code	Part Number	Description
SL18P	3189G	8F x 18cm Hemo-Cath® LT Catheter Set (Cuff 15cm From Tip)
SL24P	3190G	8F x 24cm Hemo-Cath® LT Catheter Set (Cuff 21cm From Tip)
MC101241	30540-815-100	12.5F x 15cm Hemo-Cath® LT Catheter Set (Cuff 10cm From Tip)
MC101242	30540-818-100	12.5F x 18cm Hemo-Cath® LT Catheter Set (Cuff 13cm From Tip)
MC101243	30540-824-100	12.5F x 24cm Hemo-Cath® LT Catheter Set (Cuff 19cm From Tip)
SL28E.	3289G	12.5F x 28cm Hemo-Cath® LT Catheter Set (Cuff 23cm From Tip)
SL32E.	3306G	12.5F x 32cm Hemo-Cath® LT Catheter Set (Cuff 27cm From Tip)
SL28PCE.	3293G	12.5F x 28cm Pre-Curved Hemo-Cath® LT Catheter Set (Cuff 23cm From Tip)
SL32PCE.	3294G	12.5F x 32cm Pre-Curved Hemo-Cath® LT Catheter Set (Cuff 27cm From Tip)

Configurations of Procedure Trays:

Configuration Type	Kit Components
8F Set	(1) Catheter (1) 1.3mm OD x 1.0mm ID x 70mm (18GA) INTRODUCER NEEDLE (1) 0.97mm x 70cm (.038) GUIDEWIRE J (R 3mm) TIP (1) Advancer (1) Tunneler (1) 3.4mm ID x 18cm (10F) PEELABLE INTRODUCER (1) Scalpel (1) Hemo-Cath Clip (2) End Caps (1) Patient ID Card (1) Patient Information Packet

Configuration Type	Kit Components
12.5F Set	(1) Catheter (1) 1.3mm OD x 1.0mm ID x 70mm (18GA) INTRODUCER NEEDLE (1) 0.97mm x 70cm (.038) GUIDEWIRE J (R 3mm) TIP (1) Advancer (1) Tunneler (1) Tunneler Sleeve (1) 4.4mm ID x 18cm (13F) PEELABLE INTRODUCER (1) Scalpel (1) Hemo-Cath Clip (2) End Caps (1) Patient ID Card (1) Patient Information Packet
12.5F Pre-Curved Set	(1) Catheter (1) 1.3mm OD x 1.0mm ID x 70mm (18GA) INTRODUCER NEEDLE (1) 0.97mm x 70cm (.038) GUIDEWIRE J (R 3mm) TIP (1) Advancer (1) Tunneler (1) Tunneler Sleeve (1) 4.4mm ID x 18cm (13F) PEELABLE INTRODUCER (1) Scalpel (2) End Caps (1) Patient ID Card (1) Patient Information Packet

2. Intended use of the device

Intended purpose	Hemo-Cath® LT 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. This catheter is for Single Use Only.
Indication(s)	Hemo-Cath® LT Catheters are 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.
Target population(s)	Hemo-Cath® LT 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	• 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.

3. Device description

Figure 1: Hemo-Cath® LT Pre Curved

Figure 2: Hemo-Cath® LT Straight

Description of device	The Hemo-Cath® LT 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 400 mL/min (12.5F) and 250 mL/min (8F). The catheter is available in a variety of sizes to accommodate physician preference and clinical needs.
Materials / substances in contact with patient tissue	The percentage ranges in the table below are based on the weights of the 18cm catheter (11.44g) and the 24cm catheter (11.81g).

8F Hemo-Cath® LT	
Material	**% Weight (w/w)**
Silicone	54.70 - 55.66
Acetal co-polymer	20.19 - 20.85

	Polyurethane	14.99 - 15.48
	Acrylonitrile Butadiene Styrene	6.04 - 6.24
	Barium sulfate	1.75 - 2.17
	Polyethylene terephthalate	0.95 - 0.99

The percentage ranges in the table below are based on the weights of the 15cm catheter (12.08g) and the 32cm catheter (13.89g).

12.5F Hemo-Cath® LT	
Material	**% Weight (w/w)**
Silicone	55.00 - 58.92
Acetal co-polymer	17.16 - 19.74
Polyurethane	13.31 - 15.31
Acrylonitrile Butadiene Styrene	5.20 - 5.98
Barium sulfate	1.91 - 3.62
Polyethylene terephthalate	1.79 - 2.06

Note: Per the instructions for use, the device is contraindicated for patients with known or suspected allergies to the above materials.

Note: Accessories containing stainless steel may contain up to 4% weight of the CMR substance cobalt.

Information on medicinal substances in the device	N/A	
How the device achieves its intended mode of action	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.	
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
	Name of Accessory	Description of Accessory

Accessories intended for use in combination with the Hemo-Cath LT Catheters	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.
	Scalpel	A cutting device during surgical, pathology and minor medical procedures
	Tunneler	Instrument used to create a subcutaneous tunnel
	Hemo-Cath Clip	Anchoring clip curves the extensions
	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 Hemo-Cath LT	Name of Device or Product	Description of Device or Product
	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	As per product IFU (IFU 40767BSI), 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.

Residual Harm Type	**Possible Adverse Events Associated with Harm**
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 Lumen Thrombosis Subclavian Vein Thrombosis Vascular Thrombosis
Miscellaneous Complications	Brachial Plexus Injury Femoral Nerve Damage Hemothorax Pleural Injury Thoracic Duct Laceration Venous Stenosis

Patient Residual Harm Category	**Quantification of Residual Risks**	
	PMS Complaints (01 January 2019 – 30 September 2024)	**PMCF Events**
	Units Sold: 36,417	**Units Studied: 495**
	% of Devices	**% of Devices**
Allergic Reaction	Not Reported	0.2%
Bleeding	0.014%	0.2%
Cardiac Event	0.003%	0.2%
Embolism	Not Reported	Not Reported
Infection	0.003%	9.90%
Perforation	Not Reported	Not Reported
Stenosis	Not Reported	Not Reported
Tissue Injury	Not Reported	Not Reported
Thrombosis	Not Reported	0.2%
Miscellaneous Complications	Not Reported	Not Reported

Warnings and precautions	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 40767BSI), the Hemo-Cath LT Catheters have the following warnings: • 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 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 tubing or catheter lumen. • Do not use scissors to remove dressing. • DO not use iodine or iodine-based disinfectants on this catheter. Failure of catheter will occur. Alcohol based solutions are recommended as the antiseptic solution that can be used on this catheter. Precautions listed in the Hemo-Cath LT Catheter IFUs 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 Hemo-Cath® LT 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. • 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. • 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. • 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. • DO NOT bend the sheath/dilator during insertion as bending will cause the sheath to prematurely tear. Hold sheath/dilator close to the tip (approximately 3cm from tip) when initially inserting through the skin surface. To progress the sheath/dilator towards the vein, regrasp the sheath/dilator a few centimeters (approximately 5cm) above the original grasp location and push down on the sheath/dilator. Repeat procedure until sheath/dilator is fully inserted. • Never leave sheath in place as an indwelling catheter. Damage to the vein will occur. • Do not clamp the dual lumen portion of the catheter. Clamp only the extensions. Do not use serrated forceps, use only the in-line clamps provided. • Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time. • Assure that all air has been aspirated from the catheter and extensions. Failure to do so may result in air embolism. • Failure to verify catheter placement may result in serious trauma or fatal complications. • Care must be taken when using sharp objects or needles in close proximity to catheter lumen. Contact from sharp objects may cause catheter failure. • Only clamp catheter with in-line clamps provided. • Extension clamps should only be open for aspiration, flushing, and dialysis treatment. • 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. • Only a physician familiar with the appropriate techniques should attempt the following procedures. • Do not pull distal end of catheter through incision as contamination of wound may occur.
Other relevant aspects of safety (ex. field safety corrective actions, etc.)	For a period of 01 January 2019 to 30 September 2024 there were 134 complaints for 36,417 units sold, giving an overall complaint rate of 0.368%. There were zero 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 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	399	399	0
Hemodialysis	342	96	438	1
Unknown	0	0	0	0
Total	342	495	837	1

Patient Population	Clinical Literature	PMCF Data	Total Cases	User Survey Responses
Adults	115	468	583	0
Pediatrics	227	27	254	0
Unknown	0	0	0	1
Total	342	495	837	1

Catheter French Size	Clinical Literature	PMCF Data	Total Cases	User Survey Responses
8F	103	19	122	0
12.5F	84	476	560	1
Unknown	155	0	155	0
Total	342	495	837	1

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 Hemo-Cath® LT 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 Hemo-Cath® LT Catheter, 401 catheters had a 49.1 day [95%CI: 40.7 – 57.5 days] duration of use that has been found in clinical use reported to date. Based on this information, the Hemo-Cath® LT 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 eleven published literature articles representing 342 Hemo-Cath® LT device family specific cases and an additional 4,870 mixed cohort cases inclusive of the Hemo-Cath® LT device family.

The articles include two prospective studies (Lucas et al., 2014, Mohamed et al., 2022), nine retrospective studies (Stravropoulos et al., 2003, Onder et al., 2007, Haas et al., 2010, Granata et al., 2018, Silva et al., 2020, Kumar et al., 2021, Novljan et al., 2023, Prakash et al., 2023, Salah et al., 2024), and two case studies (Lin et al., 2013, Lin et al., 2024).

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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 70.9 years. Patient gender was not recorded in the survey. All 57 catheters described in the study were 12.5F Hemo-Cath® LT Catheters of 28cm length.

Parameter	Value	Standard Deviation	95% Confidence Interval
Dwell Time (Mean Days)	104.6	65.7	43.8 – 165.4
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)	1.37	N/A	N/A
Catheter Associated Venous Thrombus (CAVT) (number per 1,000 catheter days)	1.37	N/A	N/A

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 401 Hemo-Cath® LT catheters described in the study were 12.5F Hemo-Cath® LT Catheters of variable lengths inserted percutaneously. There were 324 catheters of 28cm length, 73 catheters of 32cm length, and 4 catheters of unknown length. 399 catheters were indicated for apheresis, and 2 catheters were indicated for hemodialysis. 73 catheters were placed with the Left Internal Jugular, 324 catheters were placed in the Right Internal Jugular, and the insertion site of 1 catheter was unknown.

Parameter	Value	Standard Deviation	95% Confidence Interval
Dwell Time (Mean Days)	49.1	86	40.7 – 57.5
Procedural Outcomes (Insertion Success)	99.3%	N/A	98.5% - 100%
Catheter Related Blood Stream Infection (CRBSI) (number per 1,000 catheter days)	1.83	N/A	N/A
Tunnel Infection Rate (number per 1,000 catheter days)	0.36	N/A	N/A
Exit Site Infection Rate (number per 1,000 catheter days)	0.05	N/A	N/A
Catheter Associated Venous Thrombus (CAVT) (number per 1,000 catheter days)	0	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 3 of those respondents using the Hemo-Cath LT 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 Hemo-Cath® LT catheters (n=3):

- (Mean Likert Scale Response) Catheters function as intended – 4.6 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.3 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 4.3 / 5
- Dwell Time (n=3) – 161.3 days (95%CI: 0 – 466.7)

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.

2 Hemo-Cath® LT cases, inclusive of several variant categories across French size (8F, 12.5F) and length (18cm, 24cm) were collected. The following outcome measures were collected for the Medcomp Hemo-Cath® LT device:

- Dwell Time – 30 days
- Procedural Outcomes – 100%
- Catheter Related Blood Stream Infection – No Events Reported
- 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.

35 Hemo-Cath® LT cases inclusive of several variant devices were collected. All cases were described as 8F and 12.5F and Straight and Pre-Curved Cases, configurations (straight, pre-curved), and lengths (18cm, 24cm, 28cm, 32cm), representation of 18cm, 24cm, 28cm and 32cm length catheters. The following State of the Art safety and performance outcome measures were observed for Medcomp Hemo-Cath® LT devices:

- Catheter Related Blood Stream Infection – 2.2 per 1,000 catheter days (95%CI: 0.89 – 4.58)
- Catheter Associated Venous Thrombus – 0 per 1,000 catheter days (95%CI: 0 – 1.17)
- Exit Site Infection – 0.32 per 1,000 catheter days (95%CI: 0.01 – 1.77)
- Tunnel Infection – 0 per 1,000 catheter days (95%CI: 0 – 1.17)

- Dwell Time – 16 days (95%CI: 0 – 45.59)

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 Hemo-Cath® LT 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 Hemo-Cath® LT catheters.

Outcome	Benefit/Risk Acceptability Criteria	Desired Trend	Clinical Literature (Subject Device)	PMCF Data (Subject Device)
Performance				
Dwell Time	Greater than 40 days	↑	110 days – 281 days **(Summary of Published Literature)**	104.6 days **(LTHD Data Collection Survey Report)** 49.1 days **(Dr. Trerotola Data Report)** 161.3 days **(PMCF_Medcomp_211)** Likert Scale Response 4.3 / 5 **(PMCF_Medcomp_211)**** 30 Days **(PMCF_Infusion_211)** **16 Days (PMCF_LTHD_242)**
Procedural Outcomes	Greater than 93.3%	↑	100% **(Summary of Published Literature)**	100% **(LTHD Data Collection Survey**

				Report & Section 6.5.8) 99.3% **(Dr. Trerotola Data Report)** Likert Scale Response 4.6 / 5 **(PMCF_Medcomp_211)****
Safety				
Catheter Related Blood Stream Infection (CRBSI)	Less than 4.8 incidents of CRBSI per 1,000 catheter days	↓	1.72 – 10.1*** per 1,000 catheter days **(Summary of Published Literature)**	No Events Reported **(LTHD Data Collection Survey Report & PMCF_Infusion_211)** 1.83 per 1,000 catheter days **(Dr. Trerotola Data Report)** Likert Scale Response 4.3 / 5 **(PMCF_Medcomp_211)**** **2.2 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 & PMCF_Infusion_211)** 0.36 per 1,000 catheter days **(Dr. Trerotola Data Report)** Likert Scale Response 4.6 / 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*	1.37 per 1,000 catheter days **(LTHD Data Collection Survey Report)** 0.05 per 1,000 catheter days **(Dr. Trerotola Data Report)** Likert Scale Response 4 / 5 **(PMCF_Medcomp_211)**** **0.32 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	↓	0.79 – 2.4 per 1,000 catheter days **(Summary of Published Literature)**	1.37 per 1,000 catheter days **(LTHD Data Collection Survey Report)** No Events Reported **(Dr. Trerotola Data Report)** Likert Scale Response 3.6 / 5 **(PMCF_Medcomp_211)**** **0 per 1,000 catheter days (PMCF_LTHD_242)**

*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.
*** Salah et al, 2024 report cuffed CVCs were utilized in young children (weighing less than 9 kg) with veins too small for fistula needles, as well as in individuals with previously unsuccessful arteriovenous fistulas (AVFs) and those with vascular complications (such as previously failed or thrombosed AVFs).

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	PMCF_LTHD_241	Q4 2025

	personnel familiar with the device.		
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 clinical data relevant to the device from published literature.	LRP-HD	Q2 2026
Global Trial Database Search	Identify ongoing clinical trials involving Hemo-Cath® LT 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	• Permanent vascular access solution • Lower complication rate than hemodialysis via catheter	• Requires time to mature • Patients must sometimes self-cannulate	• Stenosis • Thrombosis • Aneurysm • Pulmonary hypertension • Steal Syndrome • Septicemia

Therapy	Benefits	Disadvantages	Key Risks
Hemodialysis Catheter	• Useful for quick vascular access without AV Fistula in place • Can be used as a bridge dialysis method between other therapies	• Not a permanent solution • Catheter dysfunction can disrupt regular treatment • Benefit is not equal for all patient populations	• Post-procedural bleeding • Infection • Thrombosis • Decreased blood flow in dysfunctional catheter • Cardiovascular events • Fibrin sheath formation around catheter • Septicemia
Peritoneal Dialysis	• Less restrictive diet than hemodialysis • Does not require hospitalization, can be done in any clean place	• Clearance of impurities is limited by dialysate flow and peritoneal area	• Peritonitis • Septicemia • Fluid overload
Kidney Transplant	• Better quality of life compared to HD • Lower risk of death compared to HD • Fewer dietary restrictions compared to HD	• Requires a donor which can take time • More risky for certain groups (aged, diabetics, etc.) • Patient must take rejection medication for life • Rejection medication has side effects	• Thrombosis • Hemorrhage • Ureteral blockage • Infection • Organ rejection • Death • Myocardial infarction • Stroke
Comprehensive Conservative Care	• Less imposed symptom burden than dialysis • Preserves life satisfaction	• May aggravate clinical condition • Not designed to treat, but to minimize adverse events	• Treatment may not actually minimize risks associated with CKD

Alternatives for Apheresis:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	• Permanent vascular access solution	• Requires time to mature	• Stenosis • Thrombosis • Aneurysm

Therapy	Benefits	Disadvantages	Key Risks
	• Lower complication rate than hemodialysis via catheter	• Patients must sometimes self-cannulate	• Pulmonary hypertension • Steal Syndrome • Septicemia
Hemodialysis Catheter	• Useful for quick vascular access without AV Fistula in place • Can be used as a bridge dialysis method between other therapies	• Not a permanent solution • Catheter dysfunction can disrupt regular treatment • Benefit is not equal for all patient populations	• Post-procedural bleeding • Infection • Thrombosis • Decreased blood flow in dysfunctional catheter • Cardiovascular events • Fibrin sheath formation around catheter • Septicemia
Infusion CVC	• Capable of multiple infusions • Ideal for initiation of extracorporeal therapies • Easy access once in place • Minimizes repeated venipuncture • Increased patient mobility during infusion • Easier for outpatient treatment	• Inability to obtain venous access in emergent situations • Requires surgical procedure for placement • Risks associated with surgery: general anesthesia, etc. • Requires maintenance • High risk of infection or thrombotic event	• Active skin or soft tissue infection at the potential site of the central line • Vascular injury proximal or distal to the site of the catheter insertion • Thrombocytopenia • Catheter infection • Occlusion • Malfunction of the CVC • Vascular thrombosis
Implantable Port	• Decreases puncture wounds/vein damage compared to traditional injection • Easier to visualize, palpate, and therefore safer form of IV access	• Requires surgical procedure, but IV does not • Risks associated with surgery: general anesthesia, etc. • Requires regular flushing	• Drug extravasations • Infection • Thromboembolism • Tissue necrosis of overlying skin / port dehiscence

Therapy	Benefits	Disadvantages	Key Risks
	• Reduces chance for corrosive medications to make skin contact • Only one venipuncture for both treatment and lab draw, as opposed to two for traditional IV • Longer dwelling time compared to IV • Can be permanent, if needed • Flow rates vary by device • Cosmetically, less displeasing than CVCs	• Sometimes breast tissue in females- makes access painful and difficult	
Peripheral Intravenous Catheters (PIVs)	• Does not require surgical procedure	• Higher hemolysis rates compared to venipuncture • Cannot be used for therapies with blistering agents • Four days maximum use	• Thrombosis • Phlebitis • Infection

Alternatives for Pediatrics:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	• Preferred pediatric vascular access route • Better solute clearance • Lower complication rate than	• Technical difficulty in fistula/graft creation in children with small vasculature • Not suitable for certain patient size	• High tendency of vasospasm due to small vessels • Primary failure and early access thrombosis

Therapy	Benefits	Disadvantages	Key Risks
	hemodialysis with a catheter • Lower risk of infection and thrombosis		
Hemodialysis Catheter	• Great alternative in rapid onset of kidney failure and short period of time until transplantation • Ability to be used in the absence of needle cannulation • Decreased risk of high output cardiac failure	• High infection rates • High failure/replacement rate • Variable blood flow rates leading to potentially poor clearance	• Potential complications with significant morbidity and mortality • Possible Arrhythmia • Permanent damage to central venous system (stenosis/thrombosis) may occur
Peritoneal Dialysis	• Most suitable for children due to its almost universal applicability and superior compatibility with lifestyle over other modalities	• Long-term success is limited by infectious complications and gradual ultrafiltration failure	• Catheter exit site and tunnel infection • Peritonitis
Kidney Transplant	• Enhanced linear growth and potential for remarkable advances in social and intellectual development • Graft survival is about 12-15 years in children.	• Increase in the lifetime risk of cancer for pediatric transplant recipients • Size – newborns and infants may not be large enough to receive a transplant. Patients need to be around 8-10 kg in size generally.	• Infections, post-transplant lymphoproliferative disorders and malignancy • Graft rejection can be difficult to diagnose.

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	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
EN ISO 10555-3	2013	Intravascular catheters. Sterile and single-use catheters. Central venous catheters	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 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
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	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
		materials within a risk management process	
EN ISO 10993-7	2008+ A1:2019	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	2001	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 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 ISO 80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors for intravascular or hypodermic applications	Full
EN 62366-1	2015 + A1: 2020	Medical devices — Part 1: Application of usability engineering to medical devices	Full
ASTM D4332-14	2014	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Full
ASTM D4169-16	2016	Standard Practice for Performance Testing of Shipping Containers and Systems	Full
ASTM F2503-20	2020	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
EN ISO 11070	2014+A1:2018	Sterile single-use intravascular introducers, dilators and guidewires	Full
EN ISO 13485	2016 + A11: 2021	Medical Devices – Quality Management system – Requirements for Regulatory Purposes	Full
ISO/TR 20416	2020	Medical devices — Post-market surveillance for manufacturers	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
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-2020-6	2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	Full
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	Full
MDCG 2018-1	Rev. 4	Guidance on BASIC UDI-DI and changes to UDI-DI	Full
EN ISO 11138-1	2017	Sterilization of health care products — Biological indicators Part 1: General requirements	Full
ISO 11138-2	2017	Sterilization of health care products—Biological indicators—Part 2: Biological indicators for ethylene oxide sterilization processes	Full
ISO 11138-7	2019	Sterilization of health care products. Biological indicators - Guidance for the selection, use and interpretation of results	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

PATIENTS

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE
Revision: SSCP-008 Rev. 6
Date: 31JUL2025

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)	Hemo-Cath® LT
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908106MS
Date first CE certificate was issued for this device	November 1997

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
12.5F x 15cm Straight Hemo Cath LT	30540-815-100
12.5F x 18cm Straight Hemo Cath LT	30540-818-100

Variant Description	Part Number
12.5F x 24cm Straight Hemo Cath LT	30540-824-100
12.5F x 28cm Pre-Curved Hemo Cath LT	3293G
12.5F x 28cm Straight Hemo Cath LT	3289G
12.5F x 32cm Pre-Curved Hemo Cath LT	3294G
12.5F x 32cm Straight Hemo Cath LT	3306G
8F x 18cm Straight Hemo Cath LT	3189G
8F x 24cm Straight Hemo Cath LT	3190G

Procedure Trays:

Catalog Code	Part Number	Description
SL18P	3189G	8F x 18cm Hemo-Cath® LT Catheter Set (Cuff 15cm From Tip)
SL24P	3190G	8F x 24cm Hemo-Cath® LT Catheter Set (Cuff 21cm From Tip)
MC101241	30540-815-100	12.5F x 15cm Hemo-Cath® LT Catheter Set (Cuff 10cm From Tip)
MC101242	30540-818-100	12.5F x 18cm Hemo-Cath® LT Catheter Set (Cuff 13cm From Tip)
MC101243	30540-824-100	12.5F x 24cm Hemo-Cath® LT Catheter Set (Cuff 19cm From Tip)
SL28E.	3289G	12.5F x 28cm Hemo-Cath® LT Catheter Set (Cuff 23cm From Tip)
SL32E.	3306G	12.5F x 32cm Hemo-Cath® LT Catheter Set (Cuff 27cm From Tip)
SL28PCE.	3293G	12.5F x 28cm Pre-Curved Hemo-Cath® LT Catheter Set (Cuff 23cm From Tip)
SL32PCE.	3294G	12.5F x 32cm Pre-Curved Hemo-Cath® LT Catheter Set (Cuff 27cm From Tip)

Configurations of Procedure Trays:

Configuration Type
8F Set
12.5F Set
12.5F Pre-Curved Set

2. Intended use of the device

Intended purpose	Hemo-Cath® LT 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. This catheter is for Single Use Only.
Indication(s)	Hemo-Cath® LT Catheters are 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)	Hemo-Cath® LT 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	• 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.

3. Device description

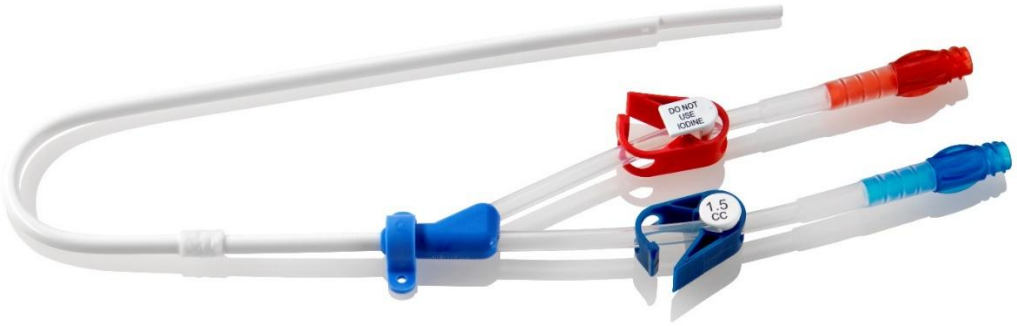

Figure 1: Hemo-Cath® LT Pre Curved

Figure 2: Hemo-Cath® LT Straight

Description of device	The Hemo-Cath® LT 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.

<table>
<tr><td>Materials / substances in contact with patient tissue</td><td>
The percentage ranges below are based on catheter weights. The 18cm catheter weighs 11.44 grams. The 24cm catheter weighs 11.81 grams.
<table>
<tr><th colspan="2">8F Hemo-Cath® LT</th></tr>
<tr><th>Material</th><th>% Weight (w/w)</th></tr>
<tr><td>Silicone</td><td>54.70 - 55.66</td></tr>
<tr><td>Acetal co-polymer</td><td>20.19 - 20.85</td></tr>
<tr><td>Polyurethane</td><td>14.99 - 15.48</td></tr>
<tr><td>Acrylonitrile Butadiene Styrene</td><td>6.04 - 6.24</td></tr>
<tr><td>Barium sulfate</td><td>1.75 - 2.17</td></tr>
<tr><td>Polyethylene terephthalate</td><td>0.95 - 0.99</td></tr>
</table>
The percentage ranges below are based on catheter weights. The 15cm catheter weighs 12.08 grams. The 32cm catheter weighs 13.89 grams.
<table>
<tr><th colspan="2">12.5F Hemo-Cath® LT</th></tr>
<tr><th>Material</th><th>% Weight (w/w)</th></tr>
<tr><td>Silicone</td><td>55.00 - 58.92</td></tr>
<tr><td>Acetal co-polymer</td><td>17.16 - 19.74</td></tr>
<tr><td>Polyurethane</td><td>13.31 - 15.31</td></tr>
<tr><td>Acrylonitrile Butadiene Styrene</td><td>5.20 - 5.98</td></tr>
<tr><td>Barium sulfate</td><td>1.91 - 3.62</td></tr>
<tr><td>Polyethylene terephthalate</td><td>1.79 - 2.06</td></tr>
</table>
<u>Note:</u> The device should not be used if you are allergic to the above materials.

<u>Note:</u> Accessories containing stainless steel may contain up to 4% weight of the CMR substance cobalt.
</td></tr>
<tr><td>Information on medicinal substances in the device</td><td>N/A</td></tr>
<tr><td>How the device achieves its intended mode of action</td><td>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,</td></tr>
</table>

	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.	
Sterilization Information	Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.	
Description of accessories	Name of Accessory	Description of Accessory
	Guidewire	Acts as a path for other components.
	Guidewire Advancer	Helps guidewire introduction.
	Introducer Needle	Placed into the target vein to gain access.
	Tunneler	Creates a pocket in between muscle and skin for catheter.
	Hemo-Cath Clip	Anchors extensions.
	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.
	Tegaderm	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 if needed.

How potential risks have been controlled or managed	There have been 36,417 devices sold since January 2019. There are side effects and risks associated with the device. These include: • Infection • Bleeding • Catheter Removal • Catheter Replacement 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.
Remaining risks and undesirable effects	The Hemo-Cath® LT catheter is associated with risks. These include: • Procedural Delays

- Thrombosis
- Infections
- Perforations
- Embolism
- Cardiac Event
- Dissatisfaction

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.

Patient Residual Harm Category	Quantification of Residual Risks	
	Complaints (01 January 2019 – 30 September 2024)	Post Market Clinical Follow-Up Activity Events
	Units Sold: 36,417	Units Studied: 495
	# of Cases Per Event	# of Cases Per Event
Allergic Reaction	Not Reported.	1 Event in 500 Cases.
Bleeding	1 Event in 7,000 Cases.	1 Event in 500 Cases.
Cardiac Event	1 Event in 30,000 Cases.	1 Event in 500 Cases.
Embolism	1 Event in 30,000 Cases.	Not Reported.
Infection	Not Reported.	1 Event in 10 Cases.
Perforation	Not Reported.	Not Reported.
Stenosis	Not Reported.	Not Reported.
Tissue Injury	Not Reported.	Not Reported.
Thrombosis	Not Reported.	1 Event in 500 Cases.
Miscellaneous Complications	Not Reported.	Not Reported.

Warnings and precautions

The below are warnings, precautions, or measures to be taken by patient:

• 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.
Summary of any field safety correction action (FSCA)	There were no recalls for the device between 01 October 2023 to 30 September 2024.

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

Clinical background of the device
The Hemo-Cath® LT catheter has been available since 1989. The CE Mark was received in November 1997. US FDA clearance was in May 1989. All models included are planned for distribution in the European Union.
Clinical evidence for CE-marking
The clinical literature review identified 13 articles relating to the safety and/or performance of the subject device when used as intended. These articles include approximately 342 cases. Four patient level data activities received information on 495 catheters. 3 user surveys have been received relating to this device. Findings from the clinical literature and clinical data support the performance of the subject device. All data on the Hemo-Cath® LT 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.
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 and apheresis in adult and pediatric patients. Medcomp has reviewed: • 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 134 complaints for 36,417 units sold from 01 January 2019 to 30 September 2024. The complaint rate is 0.368%.

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	• Permanent solution. • Lower complication rate than catheter.	• Requires time. • Patients must sometimes self-needle stick.	• Stenosis • Thrombosis • Aneurysm • Pulmonary hypertension • Steal Syndrome • Septicemia
Hemodialysis Catheter	• Useful for quick access. • Can be used as a bridge between therapies.	• Not permanent. • Catheter dysfunction can happen. • Benefit may not be the same for everyone.	• Post-procedural bleeding • Infection • Thrombosis • Decreased blood flow in dysfunctional catheter • Cardiovascular events • Fibrin sheath formation around catheter • Septicemia
Peritoneal Dialysis	• Less restrictive diet than hemodialysis. • Does not require hospitalization.	• Clearance of impurities is limited by flow and space.	• Peritonitis • Septicemia • Fluid overload
Kidney Transplant	• Better quality of life. • Lower risk of death. • Fewer dietary restrictions.	• Requires a donor. • More risky for certain groups. • Patient must take medication for life. • Medication has side effects.	• Thrombosis • Hemorrhage • Ureteral blockage • Infection • Organ rejection • Death • Myocardial infarction • Stroke
Comprehensive Conservative Care	• Less imposed symptom burden. • Preserves life satisfaction.	• May aggravate clinical condition. • Not designed to treat.	• Treatment may not actually minimize risks associated with CKD.

Alternatives for Apheresis:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	• Permanent solution. • Lower complication rate than catheter.	• Requires time. • Patients must sometimes self-needle stick.	• Stenosis • Thrombosis • Aneurysm • Pulmonary hypertension • Steal Syndrome • Septicemia
Hemodialysis Catheter	• Useful for quick access. • Can be used as a bridge between therapies.	• Not permanent. • Catheter dysfunction can happen. • Benefit may not be the same for everyone.	• Post-procedural bleeding • Infection • Thrombosis • Decreased blood flow in dysfunctional catheter • Cardiovascular events • Fibrin sheath formation around catheter • Septicemia
Infusion CVC	• Capable of multiple infusions. • Ideal for initiation of therapy. • Easy access. • Minimizes repeated needle sticks. • Increased patient mobility. • Easier for outpatient.	• Inability to obtain access in emergent situations. • Requires surgery. • Risks associated with surgery. • Requires maintenance. • High risk of infection or thrombosis.	• Exit site infection • Vascular injury • Thrombocytopenia • Catheter infection • Occlusion • Malfunction • Thrombosis
Implantable Port	• Decreases vein damage. • Easier to visualize. • Reduces chance for corrosive medications to make skin contact. • Only one puncture.	• Requires surgery. • Risks associated with surgery. • Requires regular flushing. • Sometimes breast tissue in females makes	• Drug extravasations • Infection • Thromboembolism • Tissue necrosis of overlying skin / port dehiscence

Therapy	Benefits	Disadvantages	Key Risks
	• Longer dwell time. • Can be permanent. • Cosmetically, less displeasing.	access painful and difficult.	
Peripheral Intravenous Catheters (PIVs)	• Does not require surgery.	• Higher hemolysis rates. • Cannot be used for therapies with blistering agents. • Four days maximum use.	• Thrombosis • Phlebitis • Infection

Alternatives for Pediatrics:

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	• Preferred pediatric vascular access. • Better solute clearance. • Lower complication rate than catheter. • Lower risk of infection and thrombosis.	• Technical difficulty in children with small veins. • Not suitable for certain patient size.	• High tendency of vasospasm due to small vessels. • Primary failure and early access thrombosis.
Hemodialysis Catheter	• Great alternative in rapid onset of kidney failure. • Ability to be used in the absence of needle sticks. • Decreased risk of cardiac failure.	• High infection rates. • High failure/replacement rate. • Potentially poor treatment.	• Potential complications with significant morbidity and mortality. • Possible Arrhythmia • Permanent damage to central venous system.
Peritoneal Dialysis	• Most suitable for children.	• Long-term success is limited by infectious complications and	• Catheter exit site and tunnel infection • Peritonitis

Therapy	Benefits	Disadvantages	Key Risks
		gradual ultrafiltration failure.	
Kidney Transplant	• Enhanced linear growth and potential for remarkable advances in social and intellectual development. • Graft survival is about 12-15 years in children.	• Increase in the lifetime risk of cancer. • Newborns and infants may not be large enough to receive a transplant. Patients need to be around 8-10 kg in size generally.	• Infections, post-transplant lymphoproliferative disorders and malignancy • Graft rejection can be difficult to diagnose.

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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