SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-036

I-Series and V-Series Peritoneal Dialysis Catheters

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	04019, 11026, 96101
'MDR Documentation' File Number	MDR-034

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
1	**01MAR2023**	**27836**	**KO**	**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	**19JUN2023**	**28215**	**KO**	**Update in accordance**	☐ Yes, this version was validated by the Notified

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
				with CER-036 Revision B	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	**27JUN2023**	**28325**	**GM**	**Including accessory descriptions; adding planned PMCF activity "Truveta Data Queries and Retrospective Analysis"**	☐ 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	**11SEP2023**	**28443**	**GM**	**Updating Intended Use, Indications for Use, and Patient Population to Include the Indirect Clinical Condition (CKD or AKI); Including Suture in Accessories Section**	☒ 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	**14OCT2024**	**29471**	**GM**	**Update in accordance with CER-036 Rev. C**	☐ 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)	Medcomp® / Jet / Nipro I-Series Peritoneal Dialysis Catheters Medcomp® / Jet V-Series Peritoneal Dialysis Catheters
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	00884908308N8
Medical device nomenclature description / text	F900101 – Peritoneal Dialysis Catheters and Kits
Class of device	IIb
Date first CE certificate was issued for this device	I-Series: February 2003 V-Series: May 2006
Authorized representative name and SRN	Gerhard Frömel 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 Group The Netherlands B.V. NB2797

The devices in scope of this document are all peritoneal dialysis 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:

I-Series Variants in Scope of Clinical Evaluation

Variant Description	Part Number(s)	Explanation of Multiple Part Numbers
32.25cm I-Series Straight w/ 2 Cuffs	003305	N/A
42cm I-Series Straight w/ 2 Cuffs	003303	N/A
31cm I-Series Straight w/ 2 Cuffs	003306	N/A
37cm I-Series Straight w/ 2 Cuffs	003304	N/A
47cm I-Series Straight w/ 2 Cuffs	003302	N/A
57.5cm I-Series Coiled w/ 2 Cuffs	003308	N/A
63cm I-Series Coiled w/ 2 Cuffs	003307	N/A
41cm I-Series Straight w/ 1 Cuff	003310	N/A
46cm I-Series Straight w/ 1 Cuff	003309 003314	No significant clinical, biological, or technical difference (only difference is cuff position)
60cm I-Series Coiled w/ 1 Cuff	003311	N/A
40.25cm I-Series Coiled w/ 1 Cuff	30685	N/A
57.5cm I-Series Coiled w/ 1 Cuff	003313	N/A
31cm I-Series Straight w/ 1 Cuff	003317	N/A
37cm I-Series Straight w/ 1 Cuff	003316	N/A
42cm I-Series Straight w/ 1 Cuff	003315	N/A
18cm I-Series Straight w/ 1 Cuff	30501-04-18	N/A

V-Series Variants in Scope of Clinical Evaluation

Variant Description	Part Number(s)	Explanation of Multiple Part Numbers
63cm V-Series Coiled	30339-625-1 30339-625-2	No significant clinical, biological, or technical difference (only difference in positing on radiopaque stripe for visualization)
43cm V-Series Straight	30339-430-1 30339-430-2	No significant clinical, biological, or technical difference (only difference in positing on radiopaque stripe for visualization)
39cm V-Series Straight	30686	N/A

Procedure Trays:

I-Series Procedure Trays in Scope of Clinical Evaluation

Catalog Code	Part Number	Description
JDC31S	003306	15F X 31Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC32S	003305	15F X 32.25Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC37S	003304	15F X 37Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC42S	003303	15F X 42Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC47S	003302	15F X 47Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set

Catalog Code	Part Number	Description
JDC57C	003308	15F X 57.5Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC63C	003307	15F X 63Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JET-141	003310	15F X 41Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
JET-146	003309	15F X 46Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
JET-146S	003314	15F X 46Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
JET-160	003311	15F X 60Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
JET-242	003303	15F X 42Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
JET-257	003308	15F X 57.5Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
JET-263	003307	15F X 63Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
JPP40C	30685	15F X 40.25Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
JPP41S	003310	15F X 41Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
JPP57C	003313	15F X 57.5Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
JPP60C	003311	15F X 60Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
JSC31S	003317	15F X 31Cm Jet I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
JSC37S	003316	15F X 37Cm Jet I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
JSC42S	003315	15F X 42Cm Jet I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
JSC46S	003314	15F X 46Cm Jet I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
MDC31S	003306	15F X 31Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC32S	003305	15F X 32.25Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC37S	003304	15F X 37Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC42S	003303	15F X 42Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC47S	003302	15F X 47Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC57C	003308	15F X 57.5Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC63C	003307	15F X 63Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MPD-118	30501-04-18	15F X 18Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
MPD-141	003310	15F X 41Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
MPD-146	003309	15F X 46Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
MPD-146S	003314	15F X 46Cm I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Basic Set
MPD-160	003311	15F X 60Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
MPD-237	003304	15F X 37Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
MPD-242	003303	15F X 42Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
MPD-257	003308	15F X 57.5Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
MPD-263	003307	15F X 63Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set

Catalog Code	Part Number	Description
MPP40C	30685	15F X 40.25Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
MPP41S	003310	15F X 41Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
MPP57C	003313	15F X 57.5Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
MPP60C	003311	15F X 60Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
MSC31S	003317	15F X 31Cm I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
MSC37S	003316	15F X 37Cm I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
MSC42S	003315	15F X 42Cm I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
MSC46S	003314	15F X 46Cm I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
NIPD31S	003306	15F X 31Cm Nipro I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
NIPD32S	003305	15F X 32.5Cm Nipro I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
NIPD37S	003304	15F X 37Cm Nipro I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
NIPD57C	003308	15F X 57.5Cm Nipro I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
NIPD63C	003307	15F X 63Cm Nipro I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
NIPDS31S	003317	15F X 31Cm Nipro I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set

V-Series Procedure Trays in Scope of Clinical Evaluation

Catalog Code	Part Number	Description
JS200101	30339-430-1	15F X 43Cm Jet V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Only Set
JS200102	30339-430-2	15F X 43Cm Jet V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Only Set
JS200201	30339-625-1	15F X 63Cm Jet V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Only Set
JS200202	30339-625-2	15F X 63Cm Jet V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Only Set
JS200301	30339-430-1	15F X 43Cm Jet V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Basic Set
JS200302	30339-430-2	15F X 43Cm Jet V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Basic Set
JS200401	30339-625-1	15F X 63Cm Jet V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Basic Set
JS200402	30339-625-2	15F X 63Cm Jet V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Basic Set
MC200101	30339-430-1	15F X 43Cm V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Basic Set
MC200102	30339-430-2	15F X 43Cm V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Basic Set
MC200201	30339-625-1	15F X 63Cm V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Basic Set
MC200202	30339-625-2	15F X 63Cm V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Basic Set
MC200301	30339-430-1	15F X 43Cm V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Only Set
MC200302	30339-430-2	15F X 43Cm V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Only Set
MC200303	30686	15F X 39Cm V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Only Set
MC200401	30339-625-1	15F X 63Cm V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Only Set

Catalog Code	Part Number	Description
MC200402	30339-625-2	15F X 63Cm V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Only Set

Configurations of Procedure Trays:

Configuration Type	Kit Components
I-Series / V-Series Catheter Only Set	(1) Catheter (1) Clamp (1) Luer Lock Adaptor (1) End Cap (1) Patient ID Card (1) Patient Information Packet
I-Series / V-Series Basic Set	(1) Catheter (1) Guidewire w/ Advancer (1) Introducer Needle (1) Scalpel (6) Gauze (1) Syringe (1) Tunneler w/ Sleeve (1) 17F Valved Peelable Introducer (1) Clamp (1) Luer Lock Adaptor (1) End Cap (1) Patient ID Card (1) Patient Information Packet

2. Intended use of the device

Intended purpose	I-Series / V-Series Peritoneal Dialysis Catheters are intended for use in adult patients with Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD) for whom peritoneal access for peritoneal dialysis is deemed necessary based on the direction of a qualified, licensed physician. The device is intended to be used under the regular review and assessment of qualified health professionals. This catheter is for Single Use Only.
Indication(s)	The I-Series / V-Series Peritoneal Dialysis Catheter is indicated for short-term or long-term use where peritoneal access is required for the purpose of peritoneal dialysis for Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD).
Target population(s)	I-Series / V-Series Peritoneal Dialysis Catheters are intended for use in adult patients with Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD) for whom peritoneal access for peritoneal dialysis 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	• The catheter is not intended for the Tenckhoff trocar method of insertion.
	• The catheter is contraindicated for patients with:
	  ○ Infected anterior abdominal wall.
	  ○ Active peritonitis.
	  ○ Known or suspected allergies to any of the components of the catheter or the kit.

3. Device description

Figure 1: Representative Image of I-Series Peritoneal Dialysis Catheter

Figure 2: Representative Image of V-Series Peritoneal Dialysis Catheter

Description of device	**Medcomp® / Jet / Nipro I-Series Peritoneal Dialysis Catheters** The I-Series Peritoneal Dialysis Catheter is used to remove and return dialysate fluid through single lumen tubing. The lumen inner diameter is of circular design. The distal tip is available in two versions: straight or coiled.

<table>
<tr><td></td><td>The catheters are available with one or two polyester cuffs. The polyester cuffs provide material for tissue in-growth to stabilize the catheter. A wide radiopaque stripe extends throughout the entire length of the catheter. A nylon luer adaptor is used to attach the catheter to the external PD system. The catheter is available in a variety of lengths to accommodate patient anthropometrics, physician preference and clinical needs.

Medcomp® / Jet V-Series Peritoneal Dialysis Catheters
The V-Series Peritoneal Dialysis Catheter is used to remove and return dialysate fluid through single lumen tubing. The lumen inner diameter is of circular design. The distal tip is available in two versions: straight or coiled. The polyester cuffs provide material for tissue in-growth to stabilize the catheter. A wide radiopaque stripe extends throughout the entire length of the catheter. The catheters are available with different positioning of the radiopaque stripe to facilitate visualization for left or right side placement. A nylon luer adaptor is used to attach the catheter to the external PD system. The catheter is available in a variety of lengths to accommodate patient anthropometrics, physician preference and clinical needs.</td></tr>
<tr><td>Materials / substances in contact with patient tissue</td><td>The percentage ranges in the table below are based on the weights of the 18cm catheter (4.34g) and the 63cm catheter (12.40g).

I-Series Peritoneal Dialysis Catheters
<table>
<tr><th>Material</th><th>% Weight (w/w)</th></tr>
<tr><td>Silicone</td><td>56.65 - 78.20</td></tr>
<tr><td>Barium Sulfate</td><td>11.28 - 13.80</td></tr>
<tr><td>Nylon</td><td>7.33 - 20.94</td></tr>
<tr><td>Polyester</td><td>0.35 - 11.13</td></tr>
</table>
The percentage ranges in the table below are based on the weights of the 39cm catheter (8.37g) and the 63cm catheters (12.91g).

V-Series Peritoneal Dialysis Catheters
<table>
<tr><th>Material</th><th>% Weight (w/w)</th></tr>
<tr><td>Silicone</td><td>70.53 - 73.86</td></tr>
<tr><td>Barium Sulfate</td><td>17.63 - 18.46</td></tr>
<tr><td>Nylon</td><td>7.04 - 10.85</td></tr>
<tr><td>Polyester</td><td>0.64 - 0.99</td></tr>
</table>
<u>Note:</u> Accessories containing stainless steel may contain up to 0.4% weight of the CMR substance cobalt.</td></tr>
</table>

	Note: Per the instructions for use, the device is contraindicated for patients with known or suspected allergies to the above materials.	
Information on medicinal substances in the device	N/A	
How the device achieves its intended mode of action	The subject device can be inserted using an open surgical, laparoscopic, or percutaneous technique. Catheter insertion is to be performed using aseptic techniques in a sterile field, preferably in an operating room. Peritoneal dialysis uses the barrier lining of the peritoneum and a cleaning solution (dialysate) to remove soluble waste materials from the blood. The two most common types of peritoneal dialysis are continuous ambulatory peritoneal dialysis (CAPD) and continuous cycler-assisted peritoneal dialysis (CCPD). CAPD is a manual cycling of dialysate in and out of the abdomen for a prescribed number of exchanges per day. The filling and draining is accomplished via gravity. The final filling of the abdomen usually occurs just before bedtime. CCPD is usually performed at night when the patient sleeps. An automated fluid cycler fills the abdomen with dialysate and drains it after the prescribed dwell time to refill it again afterward. This cycling takes place up to several times per night, and the final cycle before morning is not drained.	
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 device	Name of Accessory	Description of Accessory
	Guidewire*	Facilitates the selective placement of the medical device
	Guidewire Advancer*	Aids the introduction of the guidewire
	Introducer Needle*	Used for the percutaneous introduction of the guidewire
	Scalpel**	A cutting device during surgical, pathology and minor medical procedures
	Gauze*	Absorbs excess fluid during device insertion
	Syringe**	Used to assess catheter function
	Tunneler*	Creates a pocket in between muscle and skin for catheter
	Peelable Introducer*	Used to insert the device
	Subclavian Clip	Used to clamp catheter

	Barbed Luer Lock Adaptor	Attaches to the end of catheter to allow for connections to transfer sets.
	Suture***	Used to secure the device.
	End Cap	To keep clean and protect catheter luer between treatments

**Not included in catheter only configurations*

***Not included in catheter only configurations but necessary for use*

****Not included in all configurations but necessary for use*

4. Risks and warnings

Residual risks and undesirable effects

As per product IFUs, 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 when considered with respect to the expected clinical benefits of the Medcomp® / Jet / Nipro I-Series and Medcomp® / Jet V-Series Peritoneal Dialysis Catheters and the benefits of other similar devices. Regardless, informed consent should be obtained from the patient or substitute decision maker, prior to proceeding.

Residual Harm Type	**Possible Adverse Events Associated with Harm**
Allergic Reaction	Allergic Reaction Intolerance Reaction to Implanted Device
Bleeding	Bleeding Subcutaneous Hematoma
Ileus	Ileus
Infection	Exit Site Infection Peritonitis Tunnel Infection Sepsis
Obstruction	Obstruction (One- or Two- Way) Obstruction by Omentum
Perforation	Viscus Perforation
Tissue Injury	Genital Edema Hernia Organ Erosion Soft Tissue Injury
Miscellaneous Complications	Abdominal Pain Cuff Extrusion Dialysate Leak (Peri-Catheter, Pleural, Port Site, Scrotal) Death Drain Pressure or Pain

	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 August 2024)	PMCF Events
	Units Sold: 194,364	Units Studied: 242
	% of Devices	% of Devices
Allergic Reaction	Not Reported	Not Reported
Bleeding	Not Reported	0.83%
Ileus	Not Reported	Not Reported
Infection	0.004%	21.07%
Obstruction	Not Reported	2.48%
Perforation	Not Reported	Not Reported
Tissue Injury	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. The devices in scope of this clinical evaluation have the following warnings in the IFUs:

- 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 excessive force when inserting the catheter and other components of the Kit. Carefully confirm correct tip placement before beginning the subcutaneous tunnel.
- 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 catheter lumen.

Precautions listed in the IFUs 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.

	• The medical techniques and procedures described in these instructions do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient. • The catheter should be inserted and removed only by a qualified, licensed physician or other health care practitioner authorized by and under the direction of such physician. • Observe sterile technique at all times when handling catheter or insertion components. • Caution is necessary to avoid injuring the abdominal viscera and bladder, particularly when using the sharp introducer needle. [1] • Use the guidewire straightener to insert the "J" end of the guidewire into the introducer needle. • Overtightening catheter connections can crack some adapters. • Clamping the catheter repeatedly in the same spot could weaken the tubing: change the position of the clamp regularly to prolong the life of the tubing. Avoid clamping near the adapter. • Use only smooth-jawed forceps for clamping when not using the clamp supplied with the catheter. • Exercise caution when using sharp instruments near the catheter. • Catheter tubing can tear when subjected to excessive force or rough edges. • Inspect the catheter frequently for nicks, scrapes, cuts, etc., which could impair its performance. • Record catheter model and catheter lot number on patient's chart. This information will allow for the identification of patients at risk in the event of a recall or alert from the manufacturer. • The CMR substance Cobalt is a naturally occurring component of stainless steel. Based on biocompatibility evaluation it was determined that the main hazards of stainless steels are related to the processing of the material, especially welding, thus not applicable to the intended use of the device. Stainless steels used in these devices are unlikely to reach exposure levels that will elicit carcinogenicity, mutagenicity or reproductive toxicity.
Other relevant aspects of safety (ex. field safety corrective actions, etc.)	For a period of 01 January 2019 to 31 August 2024 there were 95 complaints for 194,364 units sold, giving an overall complaint rate of 0.049%. 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

Product Family	Clinical Literature	PMCF Data	Total	User Survey Responses
I-Series	88	142	230	5
V-Series	0	100	100	4

Clinical performance was measured using parameters including but not limited to catheter survival, 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.

Survivability of a given implant is a multi-factorial event that depends on numerous factors, including: the limits of the implant, surgical technique, difficulty level of the surgical procedure, patient health, patient activity level, patient medical history, and other factors. In the case of the I-Series Peritoneal Dialysis Catheter, 131 catheters had a 20.71 month [95%CI: 17.76-23.66 months] duration of use that has been found in clinical use reported to date. In the case of the V-Series Peritoneal Dialysis Catheter, 100 catheters had a 403 day [Median: 371 days; Standard Deviation: 297 days] duration of use that has been found in clinical use reported to date. Based on this information, the I-Series and V-Series Peritoneal Dialysis 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. An equivalency rationale within the manufacturer's technical documentation demonstrates 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 has been rationalized.

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

No pre-market clinical investigations 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 three published literature article representing 88 I-Series cases. The articles include three retrospective studies (Chen et al., 2022; Huang et al., 2022; Singh et al., 2023).

Bibliography:

Chen, K.K., Yeo, G.P., Tham, Z.D., Ching, C.H., Asmee, M.F., Wong, C.M., Ku Md Razi, K.R., Chan, Z.Y. (2022) POS-677 COMPARISON BETWEEN SINGLE AND DOUBLE CUFFED TENCKHOFF CATHETER IN EARLY ONSET EXIT SITE INFECTION AND PERITONITIS - SINGLE CENTER EXPERIENCE. *Kidney International Reports.*

Singh, V., Mishra, S. C., Singh, P., & Rout, B. B. (2023). The Influence of Peritoneal Dialysis Catheter Tip Design on Technique Survival: A Retrospective Observational Study. *Indian Journal of Nephrology*, *33*(2), 119.

Huang, J., Bao, S., Bao, L., Zhang, A., Gu, L., Dai, L., & Bian, X. (2022). The efficacy and safety of an improved percutaneous peritoneal dialysis catheter placement technique in urgent-start peritoneal dialysis patients: a retrospective cohort study. *Annals of Palliative Medicine*, *11*(11), 3455-3463.

Source: PMCF_PD_202

The PD Data Collection Survey aimed to acquire responses from healthcare personnel familiar with use and/or care of the I-Series, V-Series, and X-Series peritoneal dialysis catheter product families. The surveys were distributed globally to existing Medcomp customers and responses were collected from 25 November 2020 to 26 March 2021. At least partial data was collected on 134 catheter insertion cases from five respondents, spanning three countries (Greece, Portugal, and Sweden).

134 I-Series with 2 cuffs cases inclusive of several variant categories across lengths (37cm, 42cm, 47cm, 57cm, 63cm) and tip configuration (straight, coiled) were collected. The following outcome measures were confirmed to be within State of the Art safety and performance outcome measures from published literature for Medcomp I-Series catheters:

- Peritonitis Rate – 0.04 episodes/patient year
- Tunnel Infection Rate – 0.01 episodes/patient year
- Exit Site Infection Rate – 0.03 episodes/patient year
- Procedural Outcomes – 98.5% (**95%CI:** 96.4%– 100%)
- Catheter Survival – 78% (**95%CI:** 69.9% –86.1%)
- Dwell Time (n=131) – 20.71 months (**95%CI:** 17.76 – 23.66)

Source: Practical Peritoneal Dialysis Study

The Vanderbilt University Practical Peritoneal Dialysis Study was a retrospective observational study with the primary objective to collect clinical data on the safety and efficacy of the Medcomp V-Series Peritoneal Dialysis Catheter Kits. The sample is from 100 sequential peritoneal dialysis catheter placements in adults at the Vanderbilt University Medical Center (VUMC) June 2018 – March 2021. The Vanderbilt peritoneal dialysis program uses exclusively Medcomp catheters, specifically Model MC20VC63LS. Data was abstracted from the EPIC electronic medical record system.

100 V-Series cases all described as 63cm in length, with a coiled tip were collected. The following outcome measures were confirmed to be within State of the Art safety and performance outcome measures from published literature for Medcomp V-Series catheters:

- Peritonitis Rate – 0.16 episodes/patient-year
- Tunnel Infection Rate – 0.03 episodes/patient year
- Exit Site Infection Rate – 0.12 episodes/patient year
- Procedural Outcomes – 98%
- Catheter Survival – 81% at one year
- Dwell Time – 403 days [median 371 days, SD 297 days]

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.

8 I-Series catheters cases, all described as 15F, inclusive of several variant devices across length (32.25cm, 37cm, 40.25cm, 57.5cm), tip configuration (straight, coiled), and number of cuffs (1,2) were collected. The following outcome measures were collected for Medcomp Peritoneal Dialysis devices:

- Procedural Outcomes – 100%

Source: PMCF_Medcomp_211

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

8 respondents responded that they or their facility have used Medcomp Peritoneal Dialysis catheters, with 5 of those respondents using the I-Series device and 4 of those respondents using V-Series device. There were no differences in mean user sentiments within peritoneal dialysis 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 Peritoneal Dialysis catheters (n=8):

- (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 (n=8) – 361 days (**95%CI:** 103 – 619)

The following data points were collected from users of I-Series Peritoneal Dialysis catheters (n=5):

- (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 (n=5) – 468 days (**95%CI:** 23 – 913)

The following data points were collected from users of V-Series Peritoneal Dialysis catheters (n=4):

- (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 (n=4) – 182.6 days (**95%CI:** 176.1 – 188.8)

Overall summary of clinical safety and performance

Upon review of the data across all sources, it is possible to conclude that the benefits of the subject device, which is facilitating peritoneal dialysis 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 subject devices.

I-Series Outcome Parameters Across Data Sources

Outcome	Benefit/Risk Acceptability Criteria	Desired Trend	Clinical Literature (Subject Device)	PMCF Data (Subject Device)
Performance				
Dwell Time	Greater than 17.4 months	↑	20.9 Months **(Summary of Published Literature)**	20.71 months **(PMCF_PD_202)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Procedural Outcomes	Greater than 95%	↑	96.4% - 100% **(Summary of Published Literature)**	98.5% **(PMCF_PD_202)** 100% **(PMCF_Infusion_211)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Catheter Survival	Greater than 74.29% at 1-year	↑	92.8% **(Summary of Published Literature)**	78% **(PMCF_PD_202)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Safety				
Peritonitis Rate	Less than 0.48 incidents per patient-year	↓	0.14 – 0.24 incidents per patient-year **(Summary of Published Literature)** 15% Early Onset Incidence **(Summary of Published Literature)**	0.04 incidents per patient-year **(PMCF_PD_202)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Tunnel Infection Rate	Less than 0.34 incidents per patient-year	↓	0 incidents per patient-year **(Summary of Published Literature)**	0.01 incidents per patient-year **(PMCF_PD_202)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Exit Site Infection Rate	Less than 0.34 incidents per patient-year	↓	0 incidents per patient-year **(Summary of**	0.03 incidents per patient-year **(PMCF_PD_202)**

			Published Literature) 8% Early Onset Incidence **(Summary of Published Literature)**	Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****

*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.

V-Series Outcome Parameters Across Data Sources

Outcome	Benefit/Risk Acceptability Criteria	Desired Trend	Clinical Literature (Subject Device)	PMCF Data (Subject Device)
Performance				
Dwell Time	Greater than 17.4 months	↑	ND*	13.4 months*** **(Practical Peritoneal Dialysis Study)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Procedural Outcomes	Greater than 95%	↑	ND*	98% **(Practical Peritoneal Dialysis Study)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Catheter Survival	Greater than 74.29% at 1-year	↑	ND*	81% **(Practical Peritoneal Dialysis Study)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Safety				
Peritonitis Rate	Less than 0.48 incidents per patient-year	↓	ND*	0.16 incidents per patient-year **(Practical Peritoneal Dialysis Study)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Tunnel Infection Rate	Less than 0.34 incidents per patient-year	↓	ND*	0.03 incidents per patient-year **(Practical Peritoneal Dialysis Study)** Likert Scale Response 5 / 5

				(PMCF_Medcomp_211)**
Exit Site Infection Rate	Less than 0.34 incidents per patient-year	↓	ND*	0.12 incidents per patient-year **(Practical Peritoneal Dialysis Study)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****

*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.
***The Practical Peritoneal Dialysis Study does not censor dwell time for reasons that would not be indicative of catheter performance, or include complete dwell time for catheters that remained implanted at the time of data collection. For these reasons, Medcomp does not believe this number is not aligned with the benefit/risk acceptability criteria.

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

Activity	Description	Reference	Timeline
Multicenter Patient-Level Case Series	Collect additional clinical data on the device to measure safety and performance.	PMCF_PD_231	Q4 2025
State of the Art Literature Search	Identify risks and trends with use of similar devices by reviewing applicable standards, published literature, conference abstracts, guidance documents and recommendations; information relating to the medical condition managed by the device and medical alternatives available for the same target treated population.	SAP-PD	Q3 2025
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-PD	Q3 2025
Global Trial Database	Identify ongoing clinical trials involving the subject devices.	N/A	Q3 2025
Truveta Data Queries and Retrospective Analysis	Collect additional clinical data on the device and comparators	TBD	Q4 2025

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 and various International Society for Peritoneal Dialysis (ISPD) guidelines have been used to support the below recommendations for treatments.

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
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

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. Appropriately trained healthcare professionals, patients, care givers and support workers can access the catheter for clinical use as appropriate.

As per 2016 International Society for Peritoneal Dialysis (ISPD) guidelines for teaching peritoneal dialysis to patients and caregivers, training programs should recognize physical and

psychological stability, as well as cognitive ability, motivation, and support. The training for these patients should be comprehensive, including both theoretical and practical components, with regular retraining as needed. The training should cover topics such as infection prevention, catheter care, and communication with healthcare providers, and should be tailored to the individual patient's needs. The effectiveness of this training should be evaluated through patient and healthcare provider satisfaction, as well as infection rates and longevity of PD as a treatment.

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

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
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 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 20697	2018	Sterile drainage catheters and accessory device for single use	Full
EN ISO 10993-1	2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Full
EN ISO 10993-7	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 10993-18	2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	Full
EN ISO 11070	2014+A1:2018	Sterile single-use intravascular introducers, dilators and guidewires	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 11138-1	2017	Sterilization of health care products — Biological indicators Part 1: General requirements	Full
EN ISO 11138-2	2017	Sterilization of health care products—Biological indicators—Part 2: Biological indicators for ethylene oxide sterilization processes	Full
EN 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

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
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
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 13485	2016 + A11: 2021	Medical Devices – Quality Management system – Requirements for Regulatory Purposes	Full
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	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 ISO 14971	2019+A11:2021	Medical devices. Application of risk management to medical devices	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/IEC 17025	2017	General requirements for the competence of testing and calibration laboratories	Full
PD CEN ISO/TR 20416	2020	Medical devices — post-market surveillance for manufacturers	Full
EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer.	Full
EN 62366-1	2015 + A1: 2020	Medical devices — Part 1: Application of usability engineering to medical devices	Full
ISO 7000	2019	Graphical symbols for use on equipment. Registered symbols	Partial
ISO 594-1	1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements	Full
ISO 594-2	1998	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock Fittings	Full
MEDDEV 2.7.1	Rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC	Full
MEDDEV 2.12/2	Rev. 2	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES	Full
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 2018-1	Rev. 4	Guidance on BASIC UDI-DI and changes to UDI-DI	Full
MDCG 2019-9	2022	Summary of safety and clinical performance	Full
ASTM D 4169-22	2022	Standard Practices for Performance Testing of Shipping Containers and Systems.	Full
ASTM F2096-11	2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	Full
ASTM F2503-20	2020	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Full
ASTM F640-20	2020	Standard Test Methods for determining Radiopacity for Medical Use	Full
ASTM D4332-14	2014	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	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-036 Rev. 5
Date: 14OCT2024

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)	Medcomp® / Jet / Nipro I-Series Peritoneal Dialysis Catheters Medcomp® / Jet V-Series Peritoneal Dialysis Catheters
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908308N8
Date first CE certificate was issued for this device	I-Series: February 2003 V-Series: May 2006

This document talks about hemodialysis tubes [catheter] sets. These tubes are used for a short time and come in different sets. These devices are distributed as procedure trays. Procedure trays come in different configurations.

Variant Devices:

I-Series Variants in Scope of Clinical Evaluation

Variant Description	Part Number(s)
32.25cm I-Series Straight w/ 2 Cuffs	003305
42cm I-Series Straight w/ 2 Cuffs	003303
31cm I-Series Straight w/ 2 Cuffs	003306
37cm I-Series Straight w/ 2 Cuffs	003304
47cm I-Series Straight w/ 2 Cuffs	003302
57.5cm I-Series Coiled w/ 2 Cuffs	003308
63cm I-Series Coiled w/ 2 Cuffs	003307
41cm I-Series Straight w/ 1 Cuff	003310
46cm I-Series Straight w/ 1 Cuff	003309 003314
60cm I-Series Coiled w/ 1 Cuff	003311
40.25cm I-Series Coiled w/ 1 Cuff	30685
57.5cm I-Series Coiled w/ 1 Cuff	003313
31cm I-Series Straight w/ 1 Cuff	003317
37cm I-Series Straight w/ 1 Cuff	003316
42cm I-Series Straight w/ 1 Cuff	003315
18cm I-Series Straight w/ 1 Cuff	30501-04-18

V-Series Variants in Scope of Clinical Evaluation

Variant Description	Part Number(s)
63cm V-Series Coiled	30339-625-1 30339-625-2
43cm V-Series Straight	30339-430-1 30339-430-2
39cm V-Series Straight	30686

Procedure Trays:

I-Series Procedure Trays in Scope of Clinical Evaluation

Catalog Code	Part Number	Description
JDC31S	003306	15F X 31Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC32S	003305	15F X 32.25Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC37S	003304	15F X 37Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC42S	003303	15F X 42Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC47S	003302	15F X 47Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC57C	003308	15F X 57.5Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JDC63C	003307	15F X 63Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
JET-141	003310	15F X 41Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set

Catalog Code	Part Number	Description
JET-146	003309	15F X 46Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
JET-146S	003314	15F X 46Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
JET-160	003311	15F X 60Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
JET-242	003303	15F X 42Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
JET-257	003308	15F X 57.5Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
JET-263	003307	15F X 63Cm Jet I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
JPP40C	30685	15F X 40.25Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
JPP41S	003310	15F X 41Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
JPP57C	003313	15F X 57.5Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
JPP60C	003311	15F X 60Cm Jet I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
JSC31S	003317	15F X 31Cm Jet I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
JSC37S	003316	15F X 37Cm Jet I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
JSC42S	003315	15F X 42Cm Jet I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
JSC46S	003314	15F X 46Cm Jet I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
MDC31S	003306	15F X 31Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC32S	003305	15F X 32.25Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC37S	003304	15F X 37Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC42S	003303	15F X 42Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC47S	003302	15F X 47Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC57C	003308	15F X 57.5Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MDC63C	003307	15F X 63Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
MPD-118	30501-04-18	15F X 18Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
MPD-141	003310	15F X 41Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
MPD-146	003309	15F X 46Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
MPD-146S	003314	15F X 46Cm I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Basic Set
MPD-160	003311	15F X 60Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Basic Set
MPD-237	003304	15F X 37Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
MPD-242	003303	15F X 42Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
MPD-257	003308	15F X 57.5Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
MPD-263	003307	15F X 63Cm I-Series Dual Cuff Peritoneal Dialysis Catheter Basic Set
MPP40C	30685	15F X 40.25Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
MPP41S	003310	15F X 41Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
MPP57C	003313	15F X 57.5Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set

Catalog Code	Part Number	Description
MPP60C	003311	15F X 60Cm I-Series Single Preperitoneal Cuff Peritoneal Dialysis Catheter Only Set
MSC31S	003317	15F X 31Cm I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
MSC37S	003316	15F X 37Cm I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
MSC42S	003315	15F X 42Cm I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
MSC46S	003314	15F X 46Cm I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set
NIPD31S	003306	15F X 31Cm Nipro I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
NIPD32S	003305	15F X 32.5Cm Nipro I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
NIPD37S	003304	15F X 37Cm Nipro I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
NIPD57C	003308	15F X 57.5Cm Nipro I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
NIPD63C	003307	15F X 63Cm Nipro I-Series Dual Cuff Peritoneal Dialysis Catheter Only Set
NIPDS31S	003317	15F X 31Cm Nipro I-Series Single Subcutaneous Cuff Peritoneal Dialysis Catheter Only Set

V-Series Procedure Trays in Scope of Clinical Evaluation

Catalog Code	Part Number	Description
JS200101	30339-430-1	15F X 43Cm Jet V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Only Set
JS200102	30339-430-2	15F X 43Cm Jet V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Only Set
JS200201	30339-625-1	15F X 63Cm Jet V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Only Set
JS200202	30339-625-2	15F X 63Cm Jet V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Only Set
JS200301	30339-430-1	15F X 43Cm Jet V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Basic Set
JS200302	30339-430-2	15F X 43Cm Jet V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Basic Set
JS200401	30339-625-1	15F X 63Cm Jet V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Basic Set
JS200402	30339-625-2	15F X 63Cm Jet V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Basic Set
MC200101	30339-430-1	15F X 43Cm V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Basic Set
MC200102	30339-430-2	15F X 43Cm V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Basic Set
MC200201	30339-625-1	15F X 63Cm V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Basic Set
MC200202	30339-625-2	15F X 63Cm V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Basic Set
MC200301	30339-430-1	15F X 43Cm V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Only Set
MC200302	30339-430-2	15F X 43Cm V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Only Set
MC200303	30686	15F X 39Cm V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Only Set
MC200401	30339-625-1	15F X 63Cm V-Series Dual Cuff Left Side Peritoneal Dialysis Catheter Only Set
MC200402	30339-625-2	15F X 63Cm V-Series Dual Cuff Right Side Peritoneal Dialysis Catheter Only Set

Configurations of Procedure Trays:

Configuration Type
I-Series / V-Series Catheter Only Set
I-Series / V-Series Basic Set

2. Intended use of the device

Intended purpose	I-Series / V-Series Peritoneal Dialysis Catheters are intended for use in adult patients with Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD) for whom peritoneal access for peritoneal dialysis is deemed necessary based on the direction of a qualified, licensed physician. The device is intended to be used under the regular review and assessment of qualified health professionals. This catheter is for Single Use Only.
Indication(s)	The I-Series / V-Series Peritoneal Dialysis Catheter is indicated for short-term or long-term use where peritoneal access is required for the purpose of peritoneal dialysis for Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD).
Intended patient group(s)	I-Series / V-Series Peritoneal Dialysis Catheters are intended for use in adult patients with Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD) for whom peritoneal access for peritoneal dialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is not intended for use in pediatric patients.

Contraindications	• The catheter is not intended for the Tenckhoff trocar method of insertion.
	• The catheter is contraindicated for patients with:
	  ○ Infected anterior abdominal wall.
	  ○ Active peritonitis.
	  ○ Known or suspected allergies to any of the components of the catheter or the kit.

3. Device description

Figure 1: Representative Image of I-Series Peritoneal Dialysis Catheter

Figure 2: Representative Image of V-Series Peritoneal Dialysis Catheter

<table>
<tr><td>Description of device</td><td>The Peritoneal Dialysis tube (Catheter) is a tool that helps remove and return fluid during treatment. There are two types of catheters, the I-Series and the V-Series. Both have a round shape inside and come in different lengths to fit the patient. The end of the catheter can be straight or curled and has a special material to keep it in place. Doctors can see where the catheter is using an x-ray because it has a special stripe on it. An adaptor can connect the catheter to an outside system.</td></tr>
<tr><td>Materials / substances in contact with patient tissue</td><td>The numbers in the table below show the percentage for the 18cm catheter (4.34g) and the 63cm catheter (12.40g).

I-Series Peritoneal Dialysis Catheters
<table><tr><th>Material</th><th>% Weight (w/w)</th></tr><tr><td>Silicone</td><td>56.65 - 78.20</td></tr><tr><td>Barium Sulfate</td><td>11.28 - 13.80</td></tr><tr><td>Nylon</td><td>7.33 - 20.94</td></tr><tr><td>Polyester</td><td>0.35 - 11.13</td></tr></table>
The percentage ranges in the table below are based on the weights of the 39cm catheter (8.37g) and the 63cm catheters (12.91g).</td></tr>
</table>

<table>
<tr><td></td><td>
V-Series Peritoneal Dialysis Catheters
<table>
<tr><th>Material</th><th>% Weight (w/w)</th></tr>
<tr><td>Silicone</td><td>70.53 - 73.86</td></tr>
<tr><td>Barium Sulfate</td><td>17.63 - 18.46</td></tr>
<tr><td>Nylon</td><td>7.04 - 10.85</td></tr>
<tr><td>Polyester</td><td>0.64 - 0.99</td></tr>
</table>

<u>Note:</u> Accessories containing stainless steel may contain up to 0.4% weight of the CMR substance cobalt.

<u>Note:</u> The device should not be used if you are allergic to the above materials.
</td></tr>
<tr><td>Information on medicinal substances in the device</td><td>N/A</td></tr>
<tr><td>How the device works</td><td>There are three ways to put the catheter inside your body: through open surgery, laparoscopic surgery, or percutaneous needle stick technique. The procedure should be done in a very clean and sterile place, like an operating room.

Peritoneal dialysis is a way to clean waste materials from the blood using a lining in your belly called the peritoneum and a cleaning solution. There are two common types of peritoneal dialysis. One is called continuous ambulatory peritoneal dialysis (CAPD). This way uses gravity to put in and take out the cleaning solution many times a day, including right before bedtime.

The other way is called continuous cycler-assisted peritoneal dialysis (CCPD). This way is usually done at night when you're asleep. A special machine puts the cleaning solution in and takes it out after a certain amount of time. This process can happen several times.</td></tr>
<tr><td>Cleaning (Sterilization) Information</td><td>Contents are clean and will not cause fever in unopened, undamaged package. Sterilized by Ethylene Oxide.</td></tr>
<tr><td>Description of accessories</td><td colspan="2">
<table>
<tr><th>Name of Accessory</th><th>Description of Accessory</th></tr>
<tr><td>Guidewire</td><td>Acts as a path for other components.</td></tr>
<tr><td>Introducer Needle</td><td>Placed into the body to gain access.</td></tr>
<tr><td>Peelable Introducer</td><td>Used to insert the device.</td></tr>
<tr><td>Scalpel</td><td>A cutting device.</td></tr>
<tr><td>Tunneler</td><td>Creates a pocket in between muscle and skin for catheter.</td></tr>
<tr><td>Guidewire Advancer</td><td>Helps guidewire introduction.</td></tr>
<tr><td>Gauze</td><td>Used to absorb fluid during insertion.</td></tr>
<tr><td>Subclavian Clip</td><td>Used to clamp catheter.</td></tr>
</table>
</td></tr>
</table>

	Barbed Luer Lock Adaptor	Attaches to end of catheter.
	End Cap	Used to cover catheter luer.
	Suture	Used to secure the device.
	Syringe	Used to assess catheter function.

4. Risks and warnings

If you think something is wrong with how you feel after using the device or you're worried about any problems, talk to your healthcare professional. Remember, this information is not meant to take the place of talking to your doctor if you need to.

<table>
<tr><td>How potential risks have been controlled or managed</td><td>There have been 194,364 devices sold since January 2019. There are side effects and risks that you should be aware of associated with the device. These include:

• Infection
• Bleeding
• Tube Removal
• Tube Replacement

These risks are reduced to an acceptable level. The labeling describes the risks. The benefit of the device is peritoneal access when alternatives are not suitable. These benefits outweigh the risks.</td></tr>
<tr><td>Remaining risks and undesirable effects</td><td>The catheters are associated with risks. These include:

• Procedural Delays
• Blockage
• Infections
• Perforations
• feeling unhappy with the procedure (Dissatisfaction)

The risks of using the Medcomp device are similar to other dialysis tubes. The most common problem is getting an infection. Infections can happen when someone has surgery or stays in the hospital. Infections are not always caused by use of the device

<table>
<tr><th rowspan="3">Patient Residual Harm Category</th><th colspan="2">Quantification of Residual Risks</th></tr>
<tr><th>Complaints (01 January 2019 – 31 August 2024)</th><th>Post Market Clinical Follow-Up Activity Events</th></tr>
<tr><th>Units Sold: 194,364</th><th>Units Studied: 242</th></tr>
<tr><th># of Cases Per Event</th><th># of Cases Per Event</th></tr>
<tr><td>Allergic Reaction</td><td>Not Reported.</td><td>Not Reported.</td></tr>
<tr><td>Bleeding</td><td>Not Reported.</td><td>1 Event in 120 Cases.</td></tr>
<tr><td>Ileus</td><td>Not Reported.</td><td>Not Reported.</td></tr>
</table>
</td></tr>
</table>

	Infection	1 Event in 20,000 Cases.	1 Event in 4 Cases.
	Obstruction	Not Reported.	1 Event in 40 Cases.
	Perforation	Not Reported.	Not Reported.
	Tissue Injury	Not Reported.	Not Reported.
Warnings and precautions	The below are warnings, precautions, or measures to be taken by patient: • To lower the risk of bacterial contamination of catheter, wear a mask over your nose and mouth and wash your hands before touching your catheter. Observe proper sterile technique. • Never put anything on your exit site without direction from a healthcare professional. • Ask the doctor to explain the signs and symptoms of infection. • Call a healthcare professional immediately if you think you have signs of an infection including: redness, swelling, pain or tenderness, drainage.		
Summary of any field safety correction action (FSCA)	There were no recalls for the device since 01 December 2023.		

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

Clinical background of the device
These devices have been around since 2003 and are approved for use in the European Union
Clinical evidence for CE-marking
The clinical literature review identified 3 articles relating to the safety and/or performance of the subject devices when used as intended. These articles included approximately 88 cases. Three patient level data activities received information on 242 devices. 8 user surveys have been received relating to this device. The subject device works well according to studies and data analysis. Experts have evaluated all data on the I-Series and V-Series catheters. When used as intended, the benefits of the device are greater than the risks. The device helps patients who can't use other treatments as determined by their doctor.
Safety
There is sufficient data to prove conformity to the applicable requirements. The device is safe and performs as intended. The device is state of the art. 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 194,364 devices sold from January 1st 2019, to August 31st 2024. Also, during this period there were 95 complaints received resulting in a 0.049% complaint frequency for the product family.

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 and various International Society for Peritoneal Dialysis (ISPD) guidelines have been used to support the below recommendations for treatments.

Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	• Permanent solution. • Lower complication rate than catheter.	• Requires time. • Patients must sometimes self-needle stick.	• Narrowing of a vein (Stenosis) • Thrombosis • Bulge in a blood vessel (Aneurysm) • High blood pressure in the lungs (Pulmonary hypertension) • Lack of blood flow to an area (Steal Syndrome) • Blood infection (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.	• Infection of the abdomen (Peritonitis) • Septicemia • Fluid overload
Kidney Transplant	• Better quality of life. • Lower risk of death.	• Requires a donor.	• Thrombosis

Therapy	Benefits	Disadvantages	Key Risks
	• Fewer food restrictions.	• More risky for certain groups. • Patient must take medication for life. • Medication has side effects.	• Severe bleeding (Hemorrhage) • Blockage of the tubes that carry urine (Ureteral blockage) • Infection • Organ rejection • Death • Heart problem (Myocardial infarction) • Blocked blood flow to brain (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.

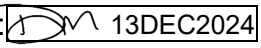
7. Suggested training for users

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. Appropriately trained healthcare professionals, patients, care givers and support workers can access the catheter for clinical use as appropriate.

A special doctor or nurse should put in, move, and take out the tube for peritoneal dialysis. Trained healthcare workers, patients, and caregivers can use the tube if they are allowed. People who want to learn how to do peritoneal dialysis need to be healthy, smart, want to do it, and have support. The training should teach them everything they need to know about avoiding germs, taking care of the tube, and talking to doctors. The training should be different for everyone and should be taught again as needed. To see if the training is good, doctors will ask patients and healthcare workers how they liked it and will see how often people get sick and how long the peritoneal dialysis works.

Abbreviation	Definition
AV	Arteriovenous
CE	Conformité Européenne (European Conformity)
CKD	Chronic Kidney Disease
cm	centimeter
CMR	Carcinogenic, mutagenic, reprotoxic
F	French (thickness of catheter)
FDA	Food and Drug Administration

FSCA	Field Safety Corrective Action
ISPD	International Society for Peritoneal Dialysis
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

Add copy to ‘MDR Documentation’ (Initial & Date):  13DEC2024