SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-027

Duo-Flow® Soft-Line® Catheter

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	10016, 17007, 17008
'MDR Documentation' File Number	TD-027

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
1	**07NOV2022**	**27445**	**KO**	**Initial Implementation of SSCP**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					not validated by the Notified Body as this is a Class IIa or IIb implantable device
2	**06JUN2023**	**28181**	**KO**	**Addition of planned PMCF activity PMCF_STHD_241; updated language throughout the patient section to enhance readability**	☒ 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	**15APR2024**	**29025**	**GM**	**Update SSCP to include the addition of planned PMCF activity Truveta Data Queries and Retrospective Analysis and updated post market surveillance information**	☐ 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	**16SEP2024**	**29468**	**GM**	**Update in accordance with CER-020 Revision D**	☐ Yes, this version was validated by the Notified Body in the

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					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)	Duo-Flow® Soft-Line® Catheter
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	00884908301MS
Medical device nomenclature description / text	F900201 – Temporary Hemodialysis Catheters and Kits
Class of device	III
Date first CE certificate was issued for this device	March 2001
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 short-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(s)
11.5F x 12cm Straight Duo-Flow Soft-Line	1348G
11.5F x 15cm Pre-Curved Duo-Flow Soft-Line	1388G
11.5F x 15cm Straight Duo-Flow Soft-Line	1346G
11.5F x 20cm Pre-Curved Duo-Flow Soft-Line	1389G

Variant Description	Part Number(s)
11.5F x 20cm Straight Duo-Flow Soft-Line	1347G
11.5F x 24cm Straight Duo-Flow Soft-Line	1364G
7F x 10cm Straight Duo-Flow Soft-Line	1352G-10
7F x 7cm Straight Duo-Flow Soft-Line	1352G-7
9F x 12cm Straight Duo-Flow Soft-Line	1349
9F x 15cm Straight Duo-Flow Soft-Line	1350
9F x 20cm Straight Duo-Flow Soft-Line	1351

Procedure Trays:

Catalog Code	Part Number	Description
DJST710	1352G-10	7F X 10cm Duo-Jet® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
DL7/10	1352G-10	7F X 10cm Nikkiso Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T114ME	1348G	11.5F X 12cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T116IJS-2E.	1388G	11.5F X 15cm Duo-Flow® Soft-Line® Double Lumen Pre-Curved Hemodialysis Catheter W/ Dual Suture Wing Basic Set
T116ME	1346G	11.5F X 15cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T118IJS-2E.	1389G	11.5F X 20cm Duo-Flow® Soft-Line® Double Lumen Pre-Curved Hemodialysis Catheter W/ Dual Suture Wing Basic Set
T118ME	1347G	11.5F X 20cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T119M	1364G	11.5F X 24cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T73M	1352G-7	7F X 7cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T74M	1352G-10	7F X 10cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T94M	1349	9F X 12cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T96M	1350	9F X 15cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T98M	1351	9F X 20cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set

Configurations of Procedure Trays:

Configuration Type	Kit Components
Duo-Flow® Soft-Line® Basic Set	(1) Catheter (1) Guidewire (1) Guidewire Advancer (1) Needle (1) Scalpel (1) Dilator (2) End Cap

2. Intended use of the device

Intended purpose	The Duo-Flow® Soft-Line® Catheters are intended for use in adult patients with Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD) for whom immediate central venous vascular access for short-term hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is intended to be used under the regular review and assessment of qualified health professionals. This catheter is for Single Use Only.
Indication(s)	The Duo-Flow® Soft-Line® Catheter is indicated for short-term use where vascular access is required for less than 14 days for the purpose of hemodialysis.
Target population(s)	Duo-Flow® Soft-Line® catheters are intended for use in adult patients with Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD) for whom immediate central venous vascular access for short-term hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is not intended for use in pediatric patients.
Contraindications and/or limitations	• 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 – Duo-Flow® Soft-Line® Catheter (Straight)

Figure 2 – Duo-Flow® Soft-Line® Catheter (Pre-Curved)

<table>
<tr><td>Description of device</td><td><u>Duo-Flow® Soft-Line®</u>

The Duo-Flow® Soft-Line® Catheter removes and returns blood through two segregated lumen passages. Each lumen is connected to an extension line with color-coded female luer connectors. The transition between lumen and extension is housed within a molded hub. Both arterial and venous lumens contain side-holes. The catheter incorporates Barium Sulphate to facilitate visualization under fluoroscopy or Xray. The catheter is available with a straight or pre-curved lumen in a variety of French sizes and lengths to accommodate physician preference and clinical needs.

<u>Duo-Jet® Soft-Line®</u>

The Duo-Jet® Soft-Line® Catheter removes and returns blood through two segregated lumen passages. Each lumen is connected to an extension line with color-coded female luer connectors. The transition between lumen and extension is housed within a molded hub. Both arterial and venous lumens contain side-holes. The catheter incorporates Barium Sulphate to facilitate visualization under fluoroscopy or Xray.

<u>Nikkiso Soft-Line®</u>

The Nikkiso Soft-Line® Catheter removes and returns blood through two segregated lumen passages. Each lumen is connected to an extension line with color-coded female luer connectors. The transition between lumen and extension is housed within a molded hub. Both arterial and venous lumens contain side-holes. The catheter incorporates Barium Sulphate to facilitate visualization under fluoroscopy or Xray.</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 7F x 7cm catheter (7.48g) and the 11.5F x 20cm catheter (9.94g).

<table><tr><th>Material</th><th>% Weight (w/w)</th></tr><tr><td>Polyurethane</td><td>37.75 - 46.38</td></tr><tr><td>Acetal co-polymer</td><td>19.28 – 25.63</td></tr><tr><td>Polyvinyl chloride</td><td>19.23 – 25.56</td></tr><tr><td>Acrylonitrile Butadiene Styrene</td><td>7.81 - 10.38</td></tr><tr><td>Barium sulfate</td><td>0.68 - 5.01</td></tr><tr><td>Vythene</td><td>0 - 2.28</td></tr></table>
<u>Note:</u> Per the instructions for use, the device is contraindicated for patients with known or suspected allergies to the above materials.</td></tr>
<tr><td>Information on medicinal</td><td>N/A</td></tr>
</table>

substances in the device		
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.	
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	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
	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 device	Name of Device or Product	Description of Device or Product
	Syringe	Attached to introducer needle to help capture blood return once introducer needle perforates targeted vein, prevent air embolism

4. Risks and warnings

Residual risks and undesirable effects	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 Duo-Flow® Soft-Line® Catheter and the benefits of other similar hemodialysis devices.

Residual Harm Type	Possible Adverse Events Associated with Harm
Allergic Reaction	Allergic Reaction Intolerance Reaction to Implanted Device
Bleeding	Bleeding (May be severe) Exsanguination Femoral Artery Bleed Hematoma Hemorrhage Retroperitoneal Bleed
Cardiac Event	Cardiac Arrhythmia Cardiac Tamponade
Embolism	Air Embolus
Infection	Bacteremia Endocarditis Exit Site Infection Septicemia
Perforation	Inferior Vena Cava Puncture Laceration of the Vessel Perforation of the Vessel Pneumothorax Right Atrial Puncture Subclavian Artery Puncture Superior Vena Cava Puncture
Stenosis	Venous Stenosis
Tissue Injury	Brachial Plexus Injury Exit Site Necrosis Mediastinal Injury Pleural Injury
Thrombosis	Central Venous Thrombosis Lumen Thrombosis Subclavian Vein Thrombosis Vascular Thrombosis
Miscellaneous Complications	Catheter Dysfunction Femoral Nerve Damage Hemothorax Malposition Thoracic Duct Laceration

	Patient Residual Harm Category	**Quantification of Residual Risks**	
		PMS Complaints (01 January 2018 – 31 December 2023)	**PMCF Events**
		Units Sold: 28,628	**Units Studied: 0**
		% of Devices	**% of Devices**
	Allergic Reaction	Not Reported	Not Reported
	Bleeding	0.003%	Not Reported
	Cardiac Event	Not Reported	Not Reported
	Embolism	Not Reported	Not Reported
	Infection	Not Reported	Not Reported
	Perforation	Not Reported	Not Reported
	Stenosis	Not Reported	Not Reported
	Tissue Injury	Not Reported	Not Reported
	Thrombosis	Not Reported	Not Reported

Warnings and precautions

Warnings listed for the Duo-Flow® Soft-Line® Catheter are as follows:

- 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.

Precautions listed for Duo-Flow® Soft-Line® Catheter 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.
Other relevant aspects of safety (ex. field safety corrective actions, etc.)	For a period of 01 January 2019 to 31 December 2023 there were 12 complaints for 24,408 units sold, giving an overall complaint rate of 0.049%. There were no death-related events. No events resulted in recalls during the review period.

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

Summary of clinical data related to the subject device

Clinical Literature	PMCF Data	Total Cases	User Survey Responses
70 (& 88 Mixed Cohort Cases)	0	70 (& 88 Mixed Cohort Cases)	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® STHD catheters are subjected to, and must pass, simulated use testing intended to replicate 30 days use as part of device development. The Duo-Flow® Soft-Line® Catheter passed this testing. Clinical guidelines recommend to limit the use of temporary, noncuffed, nontunneled dialysis catheters to a maximum of 2 weeks (KDOQI 2019), however, duration of use of these catheters has varied in available clinical evidence identified by the manufacturer to date. Although Medcomp® catheters materials contain non-degradable polymers, fully functional catheters may be removed for other reasons, such as intractable infection or change of therapy. Published clinical literature does not always focus on the physical lifetime of a catheter for these reasons. In the case of the Duo-Flow® Soft-Line® Catheter, 69 catheters had a mean dwell time of 36.4 days [95% CI: 0 – 73.6 days] duration of use that has been found in clinical use reported to date. Based on this information, the Duo-Flow® Soft-Line® catheters have a 30 day 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.

Variants Relying on Equivalence:	Variants Contributing Clinical Data:
• Specific Duo-Flow® Soft-Line® Variants	• Duo-Flow® Soft-Line® (Unknown Variant)

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 three published literature articles representing 70 Duo-Flow® Soft-Line® device family specific cases, and an additional 88 mixed cohort cases inclusive of Duo-Flow® Soft-Line® devices.

The articles included two retrospective studies (Amira et al. and Park et al.) and one case report (Fuentes et al.).

Bibliography:

Amira CO, Bello BT, Braimoh RW. A study of outcome and complications associated with temporary hemodialysis catheters in a Nigerian dialysis unit. Saudi journal of kidney diseases and transplantation: an official publication of the Saudi Center for Organ Transplantation, Saudi Arabia. 2016;27(3):569-75.

Fuentes, A. D., Rubio, G. T., Acuña, C. A., Rubio, F. D., Milic, F. B., & Troncoso, P. C. (2023). Near-fatal cocaine intoxication in an infant with thrombotic microangiopathy associated with multiple organ failure. *Revista Paulista de Pediatria*, *42*, e2022159.

Park HS, Choi J, Kim HW et al. Exchange over the guidewire from non-tunneled to tunneled hemodialysis catheters can be performed without patency loss. The Journal of Vascular Access. 2018;19(3):252-7.

Source: PMCF_Medcomp_211

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

20 respondents responded that they or their facility have used Medcomp short-term hemodialysis catheters, with 1 of those respondents using the Duo-Flow® Soft-Line® device. There were no differences in mean user sentiments within short-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 short-term hemodialysis catheters (n=20):

- (Mean Likert Scale Response) Catheters function as intended – 4.8 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.9 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 4.7 / 5
- Dwell Time (n=19) – 15.74 days (**95%CI:** 6.3 – 25.1)

The following data points were collected from users of Medcomp Duo-Flow® Soft-Line® catheters (n=1):

- (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=1) – 14 days

Overall summary of clinical safety and performance

Upon review of the Duo-Flow® Soft-Line® catheter data across all sources, it is possible to conclude that the benefits of the subject device 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.

Outcome	**Published Guideline (State of Art)**	**Desired Trend**	**Clinical Literature (Subject Device)**	**PMCF Data (Subject Device)**
Performance				
Dwell Time	Greater than 8 days	↑	36.4 days **(Summary of Published Literature)**	14 days **(PMCF_Medcomp_211)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Procedural Outcomes	Greater than 95%	↑	No insertion complications reported. **(Summary of Published Literature)**	Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Safety				
Catheter Related Blood Stream Infection (CRBSI)	Less than 7.8 incidents of CRBSI per 1,000 catheter days	↓	0.25 – 1.73 per 1,000 catheter days **(Summary of Published Literature)**	Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Exit Site Infection Rate	Less than 3.5 incidents of exit site infection per 1,000 catheter days	↓	ND*	Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Catheter Associated Venous Thrombus (CAVT)	Less than 11.4 incidents of CAVT per 1,000 catheter days	↓	9.88 per 1,000 catheter days **(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.

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

Description	Objective	Reference	Timeline
Multicenter Patient-Level Case Series	Collect additional clinical data on the device	PMCF_STHD_241	Q4 2025
State of the Art Literature Search	Identify risks and trends with use of dialysis catheters	SAP-HD	Q1 2025
Clinical Evidence Literature Search	Identify risks and trends with use of the device	LRP-STHD	Q3 2025
Global Trial Database Search	Identify ongoing clinical trials involving Medcomp® catheters	N/A	Q3 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 have been used to support the below recommendations for treatments.

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
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	• Clearance of impurities is limited by dialysate flow and peritoneal area	• Peritonitis • Septicemia • Fluid overload

Therapy	Benefits	Disadvantages	Key Risks
	be done in any clean place		
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.

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 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	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
		medical device materials within a risk management process	
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
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

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
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
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

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
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-027 Rev. 4
Date: 16 September 2024

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)	Duo-Flow® Soft-Line® Catheter
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908301MS
Date first CE certificate was issued for this device	March 2001

This document talks about hemodialysis tube [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:

Variant Description	Part Number(s)
11.5F x 12cm Straight Duo-Flow Soft-Line	1348G
11.5F x 15cm Pre-Curved Duo-Flow Soft-Line	1388G
11.5F x 15cm Straight Duo-Flow Soft-Line	1346G
11.5F x 20cm Pre-Curved Duo-Flow Soft-Line	1389G
11.5F x 20cm Straight Duo-Flow Soft-Line	1347G
11.5F x 24cm Straight Duo-Flow Soft-Line	1364G
7F x 10cm Straight Duo-Flow Soft-Line	1352G-10
7F x 7cm Straight Duo-Flow Soft-Line	1352G-7
9F x 12cm Straight Duo-Flow Soft-Line	1349
9F x 15cm Straight Duo-Flow Soft-Line	1350
9F x 20cm Straight Duo-Flow Soft-Line	1351

Procedure Trays:

Catalog Code	Part Number	Description
DJST710	1352G-10	7F X 10cm Duo-Jet® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
DL7/10	1352G-10	7F X 10cm Nikkiso Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T114ME	1348G	11.5F X 12cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T116IJS-2E.	1388G	11.5F X 15cm Duo-Flow® Soft-Line® Double Lumen Pre-Curved Hemodialysis Catheter W/ Dual Suture Wing Basic Set
T116ME	1346G	11.5F X 15cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T118IJS-2E.	1389G	11.5F X 20cm Duo-Flow® Soft-Line® Double Lumen Pre-Curved Hemodialysis Catheter W/ Dual Suture Wing Basic Set
T118ME	1347G	11.5F X 20cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T119M	1364G	11.5F X 24cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T73M	1352G-7	7F X 7cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T74M	1352G-10	7F X 10cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T94M	1349	9F X 12cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T96M	1350	9F X 15cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set
T98M	1351	9F X 20cm Duo-Flow® Soft-Line® Double Lumen Hemodialysis Catheter Basic Set

Configurations of Procedure Trays:

Configuration Type
Duo-Flow® Soft-Line® Basic Set

2. Intended use of the device

Intended purpose	The Duo-Flow® Soft-Line® Catheters are intended for use in adult patients with Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD) for whom immediate central venous vascular access for short-term hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is intended to be used under the regular review and assessment of qualified health professionals. This catheter is for Single Use Only.
Indication(s)	The Duo-Flow® Soft-Line® Catheter is indicated for short-term use where vascular access is required for less than 14 days for the purpose of hemodialysis.
Intended patient group(s)	Duo-Flow® Soft-Line® catheters are intended for use in adult patients with Acute Kidney Injury (AKI) or Chronic Kidney Disease (CKD) for whom immediate central venous vascular access for short-term hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is not intended for use in pediatric patients.
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 – Duo-Flow® Soft-Line® Catheter (Straight)

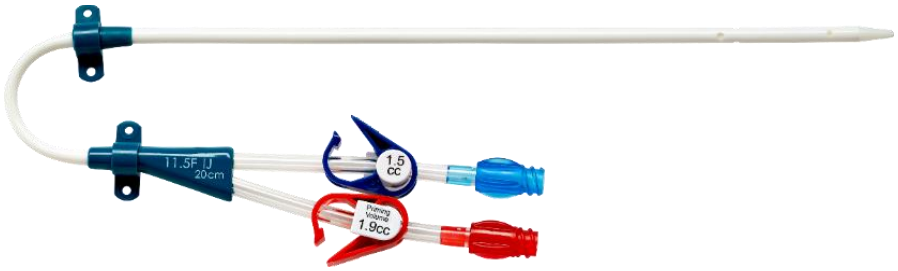

Figure 2 – Duo-Flow® Soft-Line® Catheter (Pre-Curved)

<table>
<tr><td>Description of device</td><td><u>Duo-Flow® Soft-Line®</u>

The Duo-Flow® Soft-Line® Catheter has two separate paths to move blood in and out of the body. Each path has a different colored tube. The tubes connect to a part that is shaped like a hub. Both paths have small holes to help the blood flow. The device contains a substance called Barium Sulphate to make it easier to see with X-rays. It comes in various sizes and shapes to fit the needs of the patient as determined by the doctor.

<u>Duo-Jet® Soft-Line®</u>

The Duo-Jet® Soft-Line® Catheter has two separate paths to move blood in and out of the body. Each path has a different colored tube. The tubes connect to a part that is shaped like a hub. Both paths have small holes to help the blood flow. The device contains a substance called Barium Sulphate to make it easier to see with X-rays.

<u>Nikkiso Soft-Line®</u>

The Nikkiso Soft-Line® Catheter has two separate paths to move blood in and out of the body. Each path has a different colored tube. The tubes connect to a part that is shaped like a hub. Both paths have small holes to help the blood flow. The device contains a substance called Barium Sulphate to make it easier to see with X-rays.</td></tr>
<tr><td>Materials / substances in contact with patient tissue</td><td>The percentage ranges below are based on catheter weights. The 7F x 7cm catheter weighs 7.48 grams. The 11.5F x 20cm catheter weighs 9.94 grams.

<table><tr><th>Material</th><th>% Weight (w/w)</th></tr><tr><td>Polyurethane</td><td>37.75 - 46.38</td></tr><tr><td>Acetal co-polymer</td><td>19.28 – 25.63</td></tr><tr><td>Polyvinyl chloride</td><td>19.23 – 25.56</td></tr><tr><td>Acrylonitrile Butadiene Styrene</td><td>7.81 - 10.38</td></tr><tr><td>Barium sulfate</td><td>0.68 - 5.01</td></tr><tr><td>Vythene</td><td>0 - 2.28</td></tr></table>
<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>
</table>

How the device works	Hemodialysis tubes provide access through the vein or artery. The tube is thin and flexible and goes into a big vein near the center of the body. There are two openings in the tube. One opening takes out the blood and sends it to a machine that cleans it. The other opening puts the clean blood back into the body. This tube is used when someone needs to have their blood cleaned right away, and they can't use a different kind of tube. This tube is only used for a short time.	
Cleaning (Sterilization) Information	Contents are clean and will not cause fever 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.
	Scalpel	A cutting device.
	Dilator	Used to make the opening of a vessel larger.
	End Cap	To keep the catheter clean between treatments.
	Syringe	Helps get blood return once the needle punctures the vein.

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.

How potential risks have been controlled or managed	There have been 24,408 devices sold since January 2019. There are side effects and risks 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 access for hemodialysis when alternatives are not suitable. These benefits outweigh the risks.
Remaining risks and undesirable effects	The Duo-Flow® Soft-Line® catheter is associated with risks. These include: • Procedural Delays • Blood clots in veins (Thrombosis) • Infections • Punctures in organs (Perforations) • Air bubbles in veins (Embolism) • Heart problems (Cardiac Event)

<table>
<tr><td></td><td>
• 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>PMS Complaints (01 January 2018 – 31 December 2023)</th><th>Post Market Clinical Follow-Up Events</th></tr>
<tr><th>Units Sold: 28,628</th><th>Units Studied: 0</th></tr>
<tr><th></th><th>% of Devices</th><th>% of Devices</th></tr>
<tr><td>Allergic Reaction</td><td>Not Reported</td><td>Not Reported</td></tr>
<tr><td>Bleeding</td><td>1 Event in 28,000 Cases.</td><td>Not Reported</td></tr>
<tr><td>Cardiac Event</td><td>Not Reported</td><td>Not Reported</td></tr>
<tr><td>Embolism</td><td>Not Reported</td><td>Not Reported</td></tr>
<tr><td>Infection</td><td>Not Reported</td><td>Not Reported</td></tr>
<tr><td>Perforation</td><td>Not Reported</td><td>Not Reported</td></tr>
<tr><td>Stenosis</td><td>Not Reported</td><td>Not Reported</td></tr>
<tr><td>Tissue Injury</td><td>Not Reported</td><td>Not Reported</td></tr>
<tr><td>Thrombosis</td><td>Not Reported</td><td>Not Reported</td></tr>
</table>
</td></tr>
<tr><td>Warnings and precautions</td><td>
The below are warnings, precautions, or measures to be taken by patient:

• To keep germs away from the catheter, wear a mask over your nose and mouth every time the catheter is used.
• Keep the catheter dressing clean and dry. The dressing should be changed by a medical professional at each dialysis session.
• Avoid getting the catheter or catheter site wet. Moisture near the catheter site can cause 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.
</td></tr>
<tr><td>Summary of any field safety correction action (FSCA)</td><td>There were no recalls for the device between 01 January 2019 to 31 December 2023.</td></tr>
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5. Summary of clinical evaluation and post-market clinical follow-up

Clinical background of the device
The Duo-Flow® Soft-Line® catheter has been available since 1999. The CE Mark was received in March 2001. US FDA clearance was in June 1999. All models included are planned for distribution 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 device when used as intended. These articles included approximately 158 cases. 1 user survey have been received relating to this device. Findings from the clinical literature and data activities support the performance of the subject device. All data on the Duo-flow® Soft-Line® catheter has been evaluated. When you use the device as intended, the good things it does are more than the bad things it might cause. This device helps people who have kidney problems get hemodialysis when other treatments are not right for them.
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 short-term vascular access for hemodialysis in adult patients. Medcomp has reviewed: • Post-Market Data • Medcomp Information Materials • Risk Management Documentation The device's risks are displayed clearly and are acceptable for this type of product. Compared to the good things the device does, the risks are okay. There were 12 complaints for 24,408 units sold from 01 January 2019 to 31 December 2023. The complaint rate is 0.049%.

6. Possible therapeutic alternatives

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

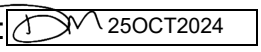
Therapy	Benefits	Disadvantages	Key Risks
AV Fistula	• Permanent solution. • Lower complication rate than catheter.	• Requires time. • Patients must sometimes self-needle stick.	• Narrowing of a vein (Stenosis) • Thrombosis • Bulge in a blood vessel (Aneurysm) • High blood pressure in the

Therapy	Benefits	Disadvantages	Key Risks
			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. • Fewer food restrictions.	• Requires a donor. • More risky for certain groups. • Patient must take medication for life. • Medication has side effects.	• Thrombosis • 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.

Abbreviation	Definition
AKI	Acute Kidney Injury
AV	Arteriovenous
CE	Conformité Européenne (European Conformity)
CKD	Chronic Kidney Disease
cm	centimeter
CMR	Carcinogenic, mutagenic, reprotoxic
CVC	Central Venous Catheter
EU	European Union
F	French (thickness of catheter)
FDA	Food and Drug Administration
FSCA	Field Safety Corrective Action
HD	Hemodialysis
KDOQI	Kidney Disease Outcomes Quality Initiative
PA	Pennsylvania
PMCF	Post Market clinical follow-up
PMS	Post Market Surveillance
SSCP	Summary of Safety and Clinical Performance
STHD	Short-term Hemodialysis
USA	United States of America
w/w	Weight over Weight

Add copy to 'MDR Documentation' (Initial & Date):  25OCT2024