SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-020

Duo-Flow® 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	17006, 11027
'MDR Documentation' File Number	TD-020

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	**27JUL2023**	**28323**	**GM**	**Update in accordance with CER-020 Revision 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
3	**18OCT2023**	**28540**	**GM**	**Correct Variant Description for 1072, 1074, 10541, and 1880-815-405 to "Raulerson IJ"**	☒ 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

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					implantable device
4	**16SEP2024**	**29466**	**GM**	**Update in accordance with CER-020 Revision D**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device

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® 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	00884908294NN
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 Netherlands 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)	Explanation of Multiple Part Numbers
11.5F x 12cm Raulerson IJ Duo-Flow	1072	
11.5F x 12cm Pre-Curved Duo-Flow w/ 2 Suture Wings	1365	

Variant Description	Part Number(s)	Explanation of Multiple Part Numbers
11.5F x 12cm Straight Duo-Flow	1020	
11.5F x 13.5cm Raulerson IJ Duo-Flow	10541	
11.5F x 15cm Pre-Curved Duo-Flow	1316	
11.5F x 15cm Pre-Curved Duo-Flow w/ 2 Suture Wings	1362	
11.5F x 15cm Raulerson IJ Duo-Flow	1073 1880-815-405	No significant clinical, biological, or technical difference (only difference is branding)
11.5F x 15cm Straight Duo-Flow	1021 1879-815-405	No significant clinical, biological, or technical difference (only difference is branding)
11.5F x 20cm Raulerson IJ Duo-Flow	1074 1880-820-405	No significant clinical, biological, or technical difference (only difference is branding)
11.5F x 20cm Pre-Curved Duo-Flow w/ 2 Suture Wings	1363	
11.5F x 20cm Straight Duo-Flow	1022 1879-820-405	No significant clinical, biological, or technical difference (only difference is branding)
11.5F x 24cm Straight Duo-Flow	1023 1879-824-405	No significant clinical, biological, or technical difference (only difference is branding)
9F x 12cm Pre-Curved Duo-Flow	1336	
9F x 12cm Straight Duo-Flow	1064 1358	No significant clinical, biological, or technical difference (only difference is branding)
9F x 15cm Pre-Curved Duo-Flow	1337	
9F x 15cm Straight Duo-Flow	1065 1353	No significant clinical, biological, or technical difference (only difference is branding)
9F x 20cm Pre-Curved Duo-Flow	1338	
9F x 20cm Straight Duo-Flow	1066 1357	No significant clinical, biological, or technical difference (only difference is branding)

Procedure Trays:

Catalog Code	Part Number	Description
XTP114CT	1020	11.5F X 12cm Duo-Flow® Double Lumen Hemodialysis Catheter Only Set
XTP114IJC	1072	11.5F X 12cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Only Set
XTP116CT	1021	11.5F X 15cm Duo-Flow® Double Lumen Hemodialysis Catheter Only Set
XTP116IJC	1073	11.5F X 15cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Only Set
XTP118CT	1022	11.5F X 20cm Duo-Flow® Double Lumen Hemodialysis Catheter Only Set
XTP118IJC	1074	11.5F X 20cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Only Set

Catalog Code	Part Number	Description
XTP119CT	1023	11.5F X 24cm Duo-Flow® Double Lumen Hemodialysis Catheter Only Set
DJIJ116	1880-815-405	11.5F X 15cm Duo-Jet® Double Lumen IJ Hemodialysis Catheter Basic Set
DJIJ118	1880-820-405	11.5F X 20cm Duo-Jet® Double Lumen IJ Hemodialysis Catheter Basic Set
DJST116	1879-815-405	11.5F X 15cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DJST118	1879-820-405	11.5F X 20cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DJST119	1879-824-405	11.5F X 24cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DJST912	1358	9F X 12cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DJST915	1353	9F X 15cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DJST920	1357	9F X 20cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DL11/24	1023	11.5Fx24cm Nikkiso Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP114IJS-2	1365	11.5F X 12cm Duo-Flow® Double Lumen Pre-Curved Hemodialysis Catheter W/Dual Suture Wing Basic Set
XTP114IJSE	1072	11.5F X 12cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP114MTE	1020	11.5F X 12cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP115IJSE	10541	11.5 X 13.5cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP116IJS-1	1316	11.5F X 15cm Duo-Flow® Double Lumen Pre-Curved Hemodialysis Catheter Basic Set
XTP116IJS-2	1362	11.5F X 15cm Duo-Flow® Double Lumen Pre-Curved Hemodialysis Catheter W/Dual Suture Wing Basic Set
XTP116IJSE	1073	11.5F X 15cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP116MTE	1021	11.5F X 15cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP118IJS-2	1363	11.5F X 20cm Duo-Flow® Double Lumen Pre-Curved Hemodialysis Catheter W/Dual Suture Wing Basic Set
XTP118IJSE	1074	11.5F X 20cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP118MTE	1022	11.5F X 20cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP119MTE	1023	11.5F X 24cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP94IJS	1336	9F X 12cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP94MT	1064	9F X 12cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP96IJS	1337	9F X 15cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP96MT	1065	9F X 15cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set

Catalog Code	Part Number	Description
XTP98IJS	1338	9F X 20cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP98MT	1066	9F X 20cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set

Configurations of Procedure Trays:

Configuration Type	Kit Components
Duo-Flow® Catheter Only Set	(1) Catheter (1) Dilator (2) End Cap
Duo-Flow® 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® 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® 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® 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

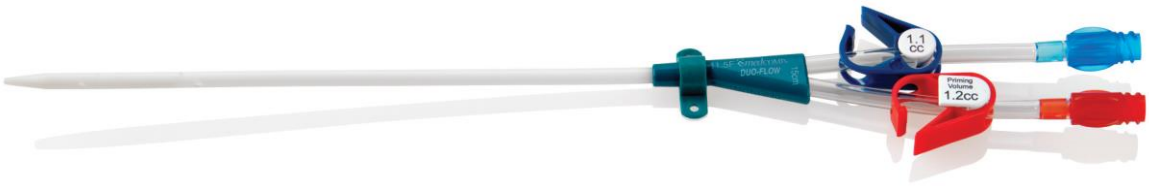

Figure 1 – Duo-Flow® Catheter

Description of device	**Duo-Flow® Catheter** The Duo-Flow® 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 has been tested at flow rates of up to 400 mL/min (9F Straight), 300ml/min (9F & 11F IJ), 450ml/min (11.5F Straight). 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. The pre-curved devices are not suitable for femoral insertion. **Duo-Jet® Catheter** The Duo-Jet® 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 has been tested at flow rates of up to 300ml/min (11.5F Straight) and 400 mL/min (9F Straight & 11.5F IJ). 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. The pre-curved devices are not suitable for femoral insertion. **Nikkiso Duo-Flow® Catheter** The Nikkiso Duo-Flow® 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 has been tested at flow rates of up to 400 mL/min.
Materials / substances in	The percentage ranges in the table below are based on the weight of the 11.5F X 12cm (10.21g) and 11.5F X 24cm (11.75g) Duo-Flow catheters.

<table>
<tr><td>contact with patient tissue</td><td>
<table>
<tr><th colspan="2">11.5F Duo-Flow</th></tr>
<tr><th>Material</th><th>% Weight (w/w)</th></tr>
<tr><td>Polyurethane</td><td>42.96 – 47.81</td></tr>
<tr><td>Acetal co-polymer</td><td>20.40 – 23.47</td></tr>
<tr><td>PVC</td><td>15.83 – 18.22</td></tr>
<tr><td>ABS</td><td>6.25 – 7.20</td></tr>
<tr><td>Vythene</td><td>5.04 – 5.80</td></tr>
<tr><td>Barium sulfate</td><td>2.35 – 4.66</td></tr>
</table>

The percentage ranges in the table below are based on the weight of the 9F X 12cm (9.81g) and 9F X 20cm (10.41g) Duo-Flow catheters.

<table>
<tr><th colspan="2">9F Duo-Flow</th></tr>
<tr><th>Material</th><th>% Weight (w/w)</th></tr>
<tr><td>Polyurethane</td><td>41.56 – 43.79</td></tr>
<tr><td>Acetal co-polymer</td><td>23.02 – 24.43</td></tr>
<tr><td>PVC</td><td>17.86 – 18.96</td></tr>
<tr><td>ABS</td><td>7.06 – 7.49</td></tr>
<tr><td>Vythene</td><td>5.69 – 6.04</td></tr>
<tr><td>Barium sulfate</td><td>1.51 – 2.59</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 substances in the device</td><td>N/A</td></tr>
<tr><td>How the device achieves its intended mode of action</td><td>Hemodialysis catheters are centrally placed access tubes. A typical hemodialysis catheter uses a thin, flexible tube. The tube has two openings. The tube goes into a large vein. The vein is usually the internal jugular vein. Blood withdraws through one lumen of the catheter. The blood flows to the dialysis machine through a separate tubing set. The blood is then processed and filtered. The blood returns to the patient through the second lumen. This device is used when dialysis must start at once. Patients may not have a functioning AV fistula or graft. Catheter hemodialysis normally happens on a short-term basis.</td></tr>
<tr><td>Sterilization Information</td><td>Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.</td></tr>
<tr><td rowspan="2">Previous generations / variants</td><td>Name of previous generation</td><td>Differences from current device</td></tr>
<tr><td>N/A</td><td>N/A</td></tr>
<tr><td rowspan="3">Accessories intended for use in combination with the device</td><td>Name of Accessory</td><td>Description of Accessory</td></tr>
<tr><td>Guidewire</td><td>For general intravascular use to facilitate the selective placement of medical devices in the vessel anatomy.</td></tr>
<tr><td>Guidewire Advancer</td><td>Aid for introduction of guidewire into target vein.</td></tr>
</table>

	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® 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

The occurrence of patient harm includes events at the time of insertion or removal and over the entirety of the duration of use of the device.

Patient Residual Harm Category	Quantification of Residual Risks	
	PMS Complaints (01 January 2017 – 31 December 2023)*	**PMCF Events**
	Units Sold: 245,146	**Units Studied: 29**
	% of Devices	**% of Devices**
Allergic Reaction	Not Reported	Not Reported
Bleeding	0.0004%	Not Reported
Cardiac Event	Not Reported	Not Reported
Embolism	Not Reported	Not Reported
Infection	Not Reported	20.69%
Perforation	Not Reported	Not Reported
Stenosis	Not Reported	Not Reported
Tissue Injury	Not Reported	Not Reported
Thrombosis	Not Reported	10.34%

**Complaint data may be associated with significant under-reporting*

Warnings and precautions	Warnings listed for the Duo-Flow® 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 the Duo-Flow® 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. • 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 December 2023 there were 94 complaints for 208,951 units sold, giving an overall complaint rate of 0.045%. There were no death-related events. No events resulted in recalls during the review period.

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

Summary of clinical data related to the subject device

The below table displays the device insertion case numbers identified and used for clinical performance evaluation in each clinical data source.

Clinical Literature	PMCF Data	Total Cases	User Survey Responses
460 (& 45 Mixed Cohort Cases)	29	489 (& 45 Mixed Cohort Cases)	0

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® 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® Catheter, post market clinical follow-up activities and published literature have found mean durations of use ranging from 2 days to 4.53 months reported to date. Based on this information, the Duo-Flow® 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:**
• 11.5F x 12cm and 24cm Straight Duo-Flow® Catheters • 11.5F x 12cm and 13.5cm Pre-Curved Duo-Flow® Catheters • 11.5F x 12cm, 15cm, and 20cm Pre-Curved Duo-Flow® Catheters w/ 2 Suture Wings • 9F x 15cm and 20cm Straight Duo-Flow® Catheters • 9F x 12cm, 15cm, and 20cm Pre-Curved Duo-Flow® Catheters	• Duo-Flow® (Unknown Variant) • 11.5F x 15cm and 20cm Straight Duo-Flow® Catheters • 11.5F x 15cm and 20cm Pre-Curved Duo-Flow® Catheters • 11.5F x 15cm Raulerson IJ Duo-Flow® Catheter • 9F x 12cm Straight Duo-Flow® Catheter

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

Thirteen published literature articles representing 460 device family specific cases and 45 mixed cohort cases inclusive of the Duo-Flow® device family have been sourced by the manufacturer to date.

The articles include five randomized controlled trials (Weijmer et al., 2008, Weijmer et. al., 2005, and Kukavica et al., 2009, Masolitin et al., 2022, Ratanarat et al., 2023), four prospective studies (Bingol et al., 2007, Elaldi et. al., 2001, Sramek et al., 2002, Baird et al., 2010), three retrospective studies (Demirkilic et. al., 2004, Haller et. al., 2009, Novak et. al., 1997), and one case study (Ekinci et al., 2018).

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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 0 of those respondents using the Duo-Flow® 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)

Source: PMCF_STHD_211 (Retrospective Patient-Level Usage Data Survey)

The Short-Term Hemodialysis (STHD) Product Line Data Collection Survey aimed to assess safety and performance outcome information for all variants of Medcomp STHD catheters. 19 survey responses were collected from 10 countries representing 381 device cases.

15 Duo-Flow® cases inclusive of several variant devices were collected. All cases were described as 11.5F and Pre-Curved, with representation of 15cm and 20cm length catheters. The following outcome measures were confirmed to be within State of the Art safety and performance outcome measures from published literature for Medcomp Duo-Flow® devices:

- Dwell Time – 53.53 Days (**95%CI:** 40.27 – 66.80)
- Procedural Outcomes – 100%
- Catheter Related Blood Stream Infection – 1.24 per 1,000 catheter days (**95%CI:** 0 – 3.69)
- Catheter Associated Venous Thrombus – 1.24 per 1,000 catheter days (**95%CI:** 0 – 3.69)
- Exit Site Infection – 1.24 per 1,000 catheter days (**95%CI:** 0 – 3.69)

Source: PMCF_DLOCK_211 (Retrospective Database Analysis)

The Netherlands 2021A data report is intended to assess safety and performance outcome information from collected data on Medcomp Long-Term Hemodialysis Catheters, Short-Term Hemodialysis Catheters, and 30.0% Duralock-C Locking Solution for use in EU MDR clinical evaluation. These outcome measures include dwell time, reasons for removal, exit site infection rates, catheter related blood stream infection (CRBSI) rates, and catheter associated venous

thrombosis (CAVT) rates. Product family identification information was also included in the collected data.

The dataset was provided by Marcel C. Weijmer, MD, PhD the head of the Department of Internal Medicine and Nephrology at OLVG located in Amsterdam, Netherlands. The dataset is comprised of consecutive cases from January 2010 to October 2019. The dataset was obtained 26 February 2021 and copied into a password protected un-editable format per QA-CL-400.

4 Duo-Flow® cases, described as 11.5F and Pre-Curved, were collected. The following outcome measures were collected for Medcomp Duo-Flow® devices:

- Dwell Time – 28 days (Range: 6 – 64 days)
- Catheter Related Blood Stream Infection – 2 Events Reported
- Catheter Associated Venous Thrombus – 4 Events Reported
- Exit Site Infection – No Events Reported

Source: PMCF_Infusion_211 (Retrospective Patient-Level Usage Data Survey)

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.

4 Duo-Flow® cases inclusive of several variant devices across French size (9F, 11.5F) and length (12cm, 15cm, 20cm) were collected. The following outcome measures were collected for Medcomp Duo-Flow® devices:

- Dwell Time – 28 days (Range: 6 – 64 days)
- Procedural Outcomes – 100%
- Catheter Related Blood Stream Infection – No Events Reported
- Catheter Associated Venous Thrombus – No Events Reported
- Exit Site Infection – No Events Reported

Source: PMCF_STHD_242 (Short-Term Hemodialysis Truveta Data Analysis)

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

6 Duo-Flow® cases inclusive of several variant devices were collected. Cases were described as 11.5F and Pre-Curved Cases included multiple French sizes (9F, 11.5F), configurations (straight, pre-curved), and lengths (12cm, 15cm, 20cm). The following State of the Art safety and performance outcome measures were observed for Medcomp Duo-Flow® devices:

- Catheter Related Blood Stream Infection – 23.81 per 1,000 catheter days (95%CI: 2.88 – 86.01)

- Catheter Associated Venous Thrombus – 0 per 1,000 catheter days (95%CI: 0 – 43.92)
- Exit Site Infection – 0 per 1,000 catheter days (95%CI: 0 – 43.92)

The catheter brand logistic regression model did not find that any Medcomp® catheter brands were statistically significantly associated with the incidence of CRBSI. The brand agnostic logistic regression found that Triple Lumen catheters **OR:** 1.63 (95%CI: 1.17 – 2.28) (as compared to the reference category of Double Lumen catheters) and Pre-Curved catheters **OR:** 7.26 (95%CI: 1.32 – 32.69) (as compared to the reference category of straight catheters) were statistically significantly associated with the incidence of CRBSI.

Overall summary of clinical safety and performance

Upon review of the Duo-Flow® 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	↑	2 days – 4.53 months **(Summary of Published Literature)**	53.53 days **(PMCF_STHD_211)** 28 days **(PMCF_DLOCK_211)**
Procedural Outcomes	Greater than 95%	↑	100% **(Summary of Published Literature)**	100% **(PMCF_STHD_211, PMCF_Infusion_211)**
Safety				
Catheter Related Blood Stream Infection (CRBSI)	Less than 7.8 incidents of CRBSI per 1,000 catheter days	↓	0 – 3.9 per 1,000 catheter days **(Summary of Published Literature)**	1.24 per 1,000 catheter days **(PMCF_STHD_211)** No Events Reported **(PMCF_Infusion_211)** 2 Events Reported **(PMCF_DLOCK_211)** 2 Events Reported **(PMCF_STHD_242)**
Exit Site Infection Rate	Less than 3.5 incidents of exit site infection per 1,000 catheter days	↓	0 – 5.3 per 1,000 catheter days **(Summary of Published Literature)**	1.24 per 1,000 catheter days **(PMCF_STHD_211)** No Events Reported **(PMCF_Infusion_211**

				& PMCF_DLOCK_211 & PMCF_STHD_242)
Catheter Associated Venous Thrombus (CAVT)	Less than 11.4 incidents of CAVT per 1,000 catheter days	↓	4.3 – 7.2 per 1,000 catheter days **(Summary of Published Literature)**	1.24 per 1,000 catheter days **(PMCF_STHD_211)** No Events Reported **(PMCF_Infusion_211 & PMCF_STHD_242)** 4 Events Reported **(PMCF_DLOCK_211)**

*ND indicates no data on the clinical data parameter

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 the devices	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	• Post-procedural bleeding • Infection • Thrombosis • Decreased blood flow in dysfunctional catheter

Therapy	Benefits	Disadvantages	Key Risks
		• Benefit is not equal for all patient populations	• 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.

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

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
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
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	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
		performance related to air cleanliness by particle concentration	
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
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

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
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-020 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® Catheter
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908294NN
Date first CE certificate was issued for this device	March 2001

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:

Variant Description	Part Number(s)
11.5F x 12cm Raulerson IJ Duo-Flow	1072
11.5F x 12cm Pre-Curved Duo-Flow w/ 2 Suture Wings	1365
11.5F x 12cm Straight Duo-Flow	1020
11.5F x 13.5cm Raulerson IJ Duo-Flow	10541
11.5F x 15cm Pre-Curved Duo-Flow	1316
11.5F x 15cm Pre-Curved Duo-Flow w/ 2 Suture Wings	1362
11.5F x 15cm Raulerson IJ Duo-Flow	1073 1880-815-405
11.5F x 15cm Straight Duo-Flow	1021 1879-815-405
11.5F x 20cm Raulerson IJ Duo-Flow	1074 1880-820-405
11.5F x 20cm Pre-Curved Duo-Flow w/ 2 Suture Wings	1363
11.5F x 20cm Straight Duo-Flow	1022 1879-820-405
11.5F x 24cm Straight Duo-Flow	1023 1879-824-405
9F x 12cm Pre-Curved Duo-Flow	1336
9F x 12cm Straight Duo-Flow	1064 1358
9F x 15cm Pre-Curved Duo-Flow	1337
9F x 15cm Straight Duo-Flow	1065 1353
9F x 20cm Pre-Curved Duo-Flow	1338
9F x 20cm Straight Duo-Flow	1066 1357

Procedure Trays:

Catalog Code	Part Number	Description
XTP114CT	1020	11.5F X 12cm Duo-Flow® Double Lumen Hemodialysis Catheter Only Set
XTP114IJC	1072	11.5F X 12cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Only Set
XTP116CT	1021	11.5F X 15cm Duo-Flow® Double Lumen Hemodialysis Catheter Only Set
XTP116IJC	1073	11.5F X 15cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Only Set
XTP118CT	1022	11.5F X 20cm Duo-Flow® Double Lumen Hemodialysis Catheter Only Set
XTP118IJC	1074	11.5F X 20cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Only Set
XTP119CT	1023	11.5F X 24cm Duo-Flow® Double Lumen Hemodialysis Catheter Only Set
DJIJ116	1880-815-405	11.5F X 15cm Duo-Jet® Double Lumen IJ Hemodialysis Catheter Basic Set
DJIJ118	1880-820-405	11.5F X 20cm Duo-Jet® Double Lumen IJ Hemodialysis Catheter Basic Set
DJST116	1879-815-405	11.5F X 15cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DJST118	1879-820-405	11.5F X 20cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DJST119	1879-824-405	11.5F X 24cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DJST912	1358	9F X 12cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DJST915	1353	9F X 15cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set

Catalog Code	Part Number	Description
DJST920	1357	9F X 20cm Duo-Jet® Double Lumen Hemodialysis Catheter Basic Set
DL11/24	1023	11.5Fx24cm Nikkiso Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP114IJS-2	1365	11.5F X 12cm Duo-Flow® Double Lumen Pre-Curved Hemodialysis Catheter W/Dual Suture Wing Basic Set
XTP114IJSE	1072	11.5F X 12cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP114MTE	1020	11.5F X 12cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP115IJSE	10541	11.5 X 13.5cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP116IJS-1	1316	11.5F X 15cm Duo-Flow® Double Lumen Pre-Curved Hemodialysis Catheter Basic Set
XTP116IJS-2	1362	11.5F X 15cm Duo-Flow® Double Lumen Pre-Curved Hemodialysis Catheter W/Dual Suture Wing Basic Set
XTP116IJSE	1073	11.5F X 15cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP116MTE	1021	11.5F X 15cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP118IJS-2	1363	11.5F X 20cm Duo-Flow® Double Lumen Pre-Curved Hemodialysis Catheter W/Dual Suture Wing Basic Set
XTP118IJSE	1074	11.5F X 20cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP118MTE	1022	11.5F X 20cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP119MTE	1023	11.5F X 24cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP94IJS	1336	9F X 12cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP94MT	1064	9F X 12cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP96IJS	1337	9F X 15cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP96MT	1065	9F X 15cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set
XTP98IJS	1338	9F X 20cm Duo-Flow® Double Lumen IJ Hemodialysis Catheter Basic Set
XTP98MT	1066	9F X 20cm Duo-Flow® Double Lumen Hemodialysis Catheter Basic Set

Configurations of Procedure Trays:

Configuration Type
Duo-Flow® Catheter Only Set
Duo-Flow® Basic Set

2. Intended use of the device

Intended purpose	The Duo-Flow® 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® 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® 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

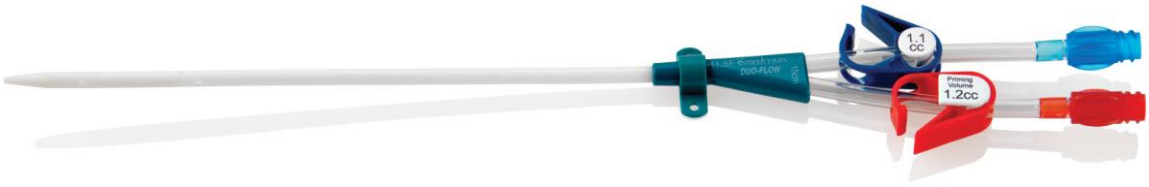

Figure 1 – Duo-Flow® Catheter

Description of device	**Duo-Flow® Catheter** The Duo-Flow® 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. **Duo-Jet® Catheter** The Duo-Jet® 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. **Nikkiso Duo-Flow® Catheter** The Nikkiso Duo-Flow® 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.
Materials / substances in contact with patient tissue	The percentage ranges below are based on catheter weights. The 11.5F x 12cm catheter weighs 10.21 grams. The 11.5F x 24cm catheter weighs 11.75 grams. **11.5F Duo-Flow** **Material** | **% Weight (w/w)**

	Polyurethane	42.96 – 47.81
	Acetal co-polymer	20.40 – 23.47
	PVC	15.83 – 18.22
	ABS	6.25 – 7.20
	Vythene	5.04 – 5.80
	Barium sulfate	2.35 – 4.66

The percentage ranges below are based on catheter weights. The 9F x 12cm catheter weighs 9.81 grams. The 9F x 20cm catheter weighs 10.41 grams.

9F Duo-Flow	
Material	**% Weight (w/w)**
Polyurethane	41.56 – 43.79
Acetal co-polymer	23.02 – 24.43
PVC	17.86 – 18.96
ABS	7.06 – 7.49
Vythene	5.69 – 6.04
Barium sulfate	1.51 – 2.59

Note: The device should not be used if you are allergic to the above materials.

Information on medicinal substances in the device	N/A
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.

<table>
<tr><td>How potential risks have been controlled or managed</td><td>There have been 208,951 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.</td></tr>
<tr><td>Remaining risks and undesirable effects</td><td>The Duo-Flow® 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)
• 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. The below tables includes events that can happen when the tube is put in, used, or taken out. Not all device problems are reported.

<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 2017 – 31 December 2023)</th><th>Post Market Clinical Follow-Up Events</th></tr>
<tr><th>Units Sold: 245,146</th><th>Units Studied: 29</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>1 Event in 245,000 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>1 Event in 5 Cases.</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>
</table>
</td></tr>
</table>

	Tissue Injury	Not Reported.	Not Reported.
	Thrombosis	Not Reported.	1 Event in 9 Cases.
Warnings and precautions	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.		
Summary of any field safety correction action (FSCA)	There were no recalls for the device between 01 January 2023 to 31 December 2023.		

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

Clinical background of the device
The Duo-Flow® catheter has been available since 1984. The CE Mark was received in March 2001. US FDA clearance was in July 1984. All models included are planned for distribution in the European Union.
Clinical evidence for CE-marking
The clinical literature review identified 13 articles relating to the safety and/or performance of the subject device when used as intended. These articles included approximately 505 cases. Three patient level data activities received information on 29 catheters. Findings from the clinical literature and data activities support the performance of the subject device. All data on the Duo-flow® 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 risks are appropriately displayed and consistent with the state of the art. The risks associated with the device product family are acceptable when weighed against the benefits. There were 94 complaints for 208,951 units sold from 01 January 2019 to 31 December 2023. The complaint rate is 0.045%.

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 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.	• Thrombosis • Severe bleeding (Hemorrhage) • Blockage of the tubes that carry

Therapy	Benefits	Disadvantages	Key Risks
		• Medication has side effects.	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

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