SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-017

Pro-Line® Power Injectable Central Venous 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	05028, 11013-A1, 11013, 11014-A1, 11014-A2, 11014, 11015
'MDR Documentation' File Number	MDR-017

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
1	**26APR2022**	**26921**	**RS**	**Implementation of SSCP**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
2	**17JUN2022**	**27027**	**RS**	**Scheduled Update**	☐ 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	**23NOV2022**	**27509**	**GM**	**Scheduled Update; updated SSCP in accordance with CER-017_C and QA-CL-200-1 Version 3.00 Template. Acronym table was added in Section 7 of the Patient Section.**	☒ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
4	**03APR2023**	**28001**	**GM**	**Clean Copy of SSCP after Clinical Q&A; Addition of Planned PMCF Activity PMCF_CVC_231**	☒ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device
5	**20OCT2023**	**28545**	**GM**	**Updated in accordance with CER-017_D**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					by the Notified Body as this is a Class IIa or IIb implantable device
6	**22OCT2024**	**29484**	**GM**	**Updated in accordance with CER-017_E**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the Notified Body as this is a Class IIa or IIb implantable device

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)	Pro-Line® Power Injectable Central Venous Catheters
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Manufacturer single registration number (SRN)	US-MF-000008230
Basic UDI-DI	00884908290NE
Medical device nomenclature description / text	C010203 – Central Venous Catheters, Partially Tunneled
Class of device	III
Date first CE certificate was issued for this device	Pro-Line® - October 2008
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 central venous catheter (CVC) sets. The catheter 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
5F x 55cm Double Lumen Pro-Line	10667-955-801 10669-955-801	No significant clinical, biological, or technical difference (only difference is relative position of cuff)
5F x 60cm Single Lumen Pro-Line	10570-960-801 10606-960-801	No significant clinical, biological, or technical difference (only difference is relative position of cuff)
6F x 60cm Double Lumen Pro-Line	10573-960-801 10608-960-801	No significant clinical, biological, or technical difference (only difference is relative position of cuff)
6F x 60cm Single Lumen Pro-Line	10571-960-801 10607-960-801	No significant clinical, biological, or technical difference (only difference is relative position of cuff)
6F x 60cm Triple Lumen Pro-Line	10575-960-801	N/A
7F x 60cm Double Lumen Pro-Line	10290-860-801	N/A
7F x 60cm Single Lumen Pro-Line	10289-860-801	N/A

Procedure Trays:

Catalog Code	Part Number	Description
MR28035201	10667-955-801	5F X 55CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER DUAL LUMEN BASIC SET
MR28035221	10669-955-801	5F X 55CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER DUAL LUMEN BASIC SET
MR28036201	10573-960-801	6F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER DUAL LUMEN BASIC SET
MR28036221	10608-960-801	6F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER DUAL LUMEN BASIC SET
MR28037201	10290-860-801	7F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER DUAL LUMEN BASIC SET
MR28035101	10570-960-801	5F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER SINGLE LUMEN BASIC SET
MR28035121	10606-960-801	5F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER SINGLE LUMEN BASIC SET
MR28036101	10571-960-801	6F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER SINGLE LUMEN BASIC SET

Catalog Code	Part Number	Description
MR28036121	10607-960-801	6F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER SINGLE LUMEN BASIC SET
MR28037101	10289-860-801	7F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER SINGLE LUMEN BASIC SET
MR28036301	10575-960-801	6F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER TRIPLE LUMEN BASIC SET

Configurations of Procedure Trays:

Configuration Type	Kit Components
Basic Set	(1) Catheter w/ Stylet, (1) Peelable Introducer: (5F Sets) 1.8mm ID x 10cm (5.5F) Peelable Introducer, (6F Single Lumen Sets) 1.9mm ID x 10cm (6F) Peelable Introducer, (6F Dual, Triple Lumen Sets) 2.0mm ID x 10cm (6.5F) Peelable Introducer, (7F Sets) 2.2mm ID x 10cm (7F) Peelable Introducer, (1/2/3) Needleless Connector(s), (1) 0.76mm (0.030") I.D. Adaptor w/Sideport, (1) 0.9mm OD x 0.5mm ID x 70mm (21GA) Needle w/Echo Tip, (1) 10CC Syringe, (1) 0.47mm x 70cm (.018) Coated Guidewire Floppy Straight Tip, (1) Securement Device, (1) Scalpel, (1) Tape Measure, (2) Tunnelers, (1) Patient Information Packet, (1) Patient ID Card

2. Intended use of the device

Intended purpose	The Pro-Line® Power Injectable Central Venous Catheters are intended for use in adult patients requiring frequent needlesticks for whom short-term or long-term access to the central venous system without requiring frequent needlesticks is deemed necessary based on the direction of a qualified, licensed physician. The device is intended to be used under the regular review and assessment of qualified health professionals. This catheter is for Single Use Only.
Indication(s)	The Pro-Line® Power Injectable Central Venous Catheter is indicated for short-term or long-term access to the central venous system for intravenous administration of fluids or medications and power injection of contrast media.
Target population(s)	Pro-Line® Power Injectable Central Venous Catheters are intended for use in adult patients requiring frequent needlesticks for whom short-term or long-term access to the central venous system without requiring frequent needlesticks is deemed necessary based on the direction of a qualified, licensed physician. The device is not intended for use in pediatric patients.
Contraindications and/or limitations	• The presence of device related infection, bacteremia or septicemia is known or suspected.

	• This catheter is intended for short- or long-term vascular access and should not be used for any purpose other than indicated in these instructions. • The patient is known or is suspected to be allergic to materials contained in the device.

3. Device description

Figure 1: Representative Image of Pro-Line® device

<table>
<tr><td>Description of device</td><td>The Pro-Line® Power Injectable Central Venous Catheters are made from specially formulated biocompatible medical grade materials and are available in a variety of lumen configurations and sizes to accommodate clinical needs. They are packaged in a tray with accessories necessary for percutaneous insertion using a microintroducer (Modified Seldinger or Seldinger technique). The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the Pro-Line® Power Injectable CVC may not exceed 300psi.</td></tr>
<tr><td>Materials / substances in contact with patient tissue</td><td>The percentage ranges in the table below are based on the weight of the 5F Single Lumen (3.64g) and 6F Triple Lumen (7.76g) Pro-Line® devices.

<table>
<tr><th>Material</th><th>% Weight (w/w)</th></tr>
<tr><td>Polyurethane</td><td>29.24 - 63.56</td></tr>
<tr><td>Polyvinyl Chloride</td><td>0 - 30.44</td></tr>
<tr><td>Acetal Co-polymer</td><td>15.55 - 23.44</td></tr>
<tr><td>Barium Sulfate</td><td>5.96 - 12.56</td></tr>
<tr><td>Acrylonitrile Butadiene Styrene</td><td>6.73 - 10.15</td></tr>
<tr><td>Polyethylene Terephthalate</td><td>0.43 - 2.47</td></tr>
</table>

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

<table>
<tr><td></td><td><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>The subject device can be inserted using a standard or modified Seldinger percutaneous surgical technique. Catheter insertion is to be done using aseptic techniques in a sterile field, preferably in an operating room.

Once in place, the CVC can be connected to a gravity-feed intravenous (IV) bag, or connected to a pump, for administration of fluids and medications. Catheter care includes use of a locking solution to maintain catheter function. Catheter removal is a surgical procedure intended to be performed by a physician familiar with the appropriate techniques.</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>Previous generations / variants</td><td>
<table>
<tr><th>Name of previous generation</th><th>Differences from current device</th></tr>
<tr><td>N/A</td><td>N/A</td></tr>
</table>
</td></tr>
<tr><td>Accessories intended for use in combination with the device</td><td>
<table>
<tr><th>Name of Accessory</th><th>Description of Accessory</th></tr>
<tr><td colspan="2">
<table>
<tr><th>Part Number</th><th>Description</th></tr>
<tr><td>30415-018-070</td><td>0.47mm x 70cm (.018) Coated Guidewire Floppy Straight Tip</td></tr>
<tr><td>10129</td><td>0.76mm (0.030”) I.D. Adaptor w/Sideport</td></tr>
<tr><td>30205-210</td><td>0.9mm OD x 0.5mm ID x 70mm (21GA) Needle W/Echo Tip</td></tr>
<tr><td>30824</td><td>Securement Device</td></tr>
<tr><td>30479</td><td>Scalpel</td></tr>
<tr><td>5663</td><td>Tunneler</td></tr>
<tr><td>5663-1</td><td>Tunneler</td></tr>
<tr><td>5690</td><td>Tunneler</td></tr>
<tr><td>5690-1</td><td>Tunneler</td></tr>
<tr><td>5659</td><td>Tunneler</td></tr>
<tr><td>5659-1</td><td>Tunneler</td></tr>
<tr><td>30198-075</td><td>Stylet</td></tr>
<tr><td>10700-10-055</td><td>1.8mm ID x 10cm (5.5F) Peelable Introducer</td></tr>
<tr><td>10590-10-060</td><td>1.9mm ID x 10cm (6F) Peelable Introducer</td></tr>
<tr><td>10590-10-065</td><td>2.0mm ID x 10cm (6.5F) Peelable Introducer</td></tr>
<tr><td>10590-10-070</td><td>2.2mm ID x 10cm (7F) Peelable Introducer</td></tr>
<tr><td>3035</td><td>Syringe</td></tr>
<tr><td>3418</td><td>Tape Measure</td></tr>
<tr><td>30823</td><td>Needleless Connector</td></tr>
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4. Risks and warnings

Residual risks and undesirable effects

As per product IFUs, All surgical procedures carry risk. Medcomp has implemented risk management processes to proactively find and mitigate these risks as far as possible without adversely affecting the benefit-risk profile of the device. After mitigation, residual risks and the possibility of adverse events from use of this product remain. Medcomp has determined that all residual risks are acceptable.

Residual Harm Type	**Possible Adverse Events Associated with Harm**
Allergic Reaction	Allergic Reaction Intolerance Reaction to Implanted Device
Bleeding	Bleeding Hematoma
Cardiac Event	Cardiac Arrythmia Cardiac Tamponade Myocardial Erosion
Embolism	Air Embolism Thromboembolism Catheter Embolism Catheter Occlusion
Infection	Catheter Related Sepsis Endocarditis Exit Site Infection Phlebitis
Perforation	Perforation of Vessels or Viscus Vessel Erosion Laceration of the Vessels
Stenosis	Venous Stenosis
Tissue Injury	Brachial Plexus Injury Exit Site Necrosis Soft Tissue Injury
Thrombosis	Venous Thrombosis Ventricular Thrombosis Fibrin Sheath Formation
Miscellaneous complications	Catheter Erosion Through Skin Spontaneous Catheter Tip Malposition or Retraction Risks Normally Associated with Local or General Anesthesia, Surgery and Post-Operative Recovery

	Patient Residual Harm Category	**Quantification of Residual Risks**	
		PMS Complaints (01 January 2019 – 31 August 2024)	**PMCF Events**
		Units Sold: 80,809	**Units Studied: 749**
		% of Devices	**% of Devices**
	Allergic Reaction	Not Reported	Not Reported
	Bleeding	Not Reported	Not Reported
	Cardiac Event	Not Reported	Not Reported
	Embolism	Not Reported	Not Reported
	Infection	0.0012%	12.82%
	Perforation	Not Reported	Not Reported
	Stenosis	Not Reported	Not Reported
	Tissue Injury	Not Reported	Not Reported
	Thrombosis	Not Reported	0.67%

Warnings and precautions

All warnings have been reviewed against the risk analysis, PMS, and usability testing to validate consistency between the sources of information. The devices in scope of this clinical evaluation have the following warnings in the IFUs:

- Do not 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 pull tunneler off of catheter. Use scalpel to sever catheter from tunneler.
- Do not resterilize the catheter or accessories by any method.
- Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE
- Do not re-use catheter or accessories as there may be a failure to adequately clean and decontaminate the device which may lead to contamination, catheter degradation, device fatigue, or endotoxin reaction.
- Do not use catheter or accessories if package is opened or damaged.
- Do not use catheter or accessories if any sign of product damage is visible or the use-by date has passed.
- Do not use sharp instruments near the extension lines or catheter lumen.
- Do not use scissors to remove dressing.

Precautions listed in the IFUs are as follows:

- Syringes smaller than ten (10) ml will generate excessive pressure and may damage the catheter. Ten (10) ml or larger syringes are recommended.

	• Hydrate guidewire prior to use. • Always flush catheter prior to removing stylet. • Catheter will be damaged if clamps other than what is provided with this kit are used. • Clamping of the tubing repeatedly in the same location may weaken tubing. Avoid clamping near the luer(s) and hub of the catheter. • Examine catheter lumen and extension(s) before and after each infusion for damage. • To prevent accidents, assure the security of all caps and connections prior to and between uses. • 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. • Repeated overtightening of bloodlines, syringes, and caps will reduce connector life and could lead to potential connector failure. • Confirm catheter tip position by x-ray prior to use. Monitor tip placement routinely per institution policy. • Discard biohazard according to facility protocol. • This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardia erosion, or cardiac tamponade. • Refer to standards of practice and institutional policies for compatible infusion agents for central venous access. • Follow all contraindications, warnings, precautions, and instructions for all infusates as specified by their manufacturer.
Other relevant aspects of safety (ex. field safety corrective actions, etc.)	For a period of 01 January 2019 to 31 August 2024 there were 47 complaints for 80,809 units sold, giving an overall complaint rate of 0.058%. 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	User Survey Responses
54	751	805	14

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.

Survivability of a given implant is a multi-factorial event that depends on numerous factors, including: the limits of the implant, surgical technique, difficulty level of the surgical procedure, patient health, patient activity level, patient medical history, and other factors. In the case of the Pro-Line® Power Injectable Central Venous Catheter, 738 catheters had a 95.42 day [95%CI: 83.66 – 107.18 days] duration of use that has been found in clinical use reported to date. Based on this information, the Pro-Line® Power Injectable Central Venous Catheter has a 12 month lifetime; however, the decision to remove and/or replace the catheter should be based on clinical performance and need, and not any predetermined point in time.

Summary of clinical data related to the equivalent device (if applicable)

Clinical evidence from published literature and PMCF activities has been generated specific to known and unknown variants of the subject device. The equivalency rationale in the updated clinical evaluation report will demonstrate that the clinical evidence available for these variants is representative of the range of device variants in the device family.

There are no clinical or biological differences between variants within the subject device family, and the potential impact of the technical differences will be rationalized in the updated clinical evaluation report.

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

No pre-market clinical investigations were used for the device's clinical evaluation.

Summary of clinical data from other sources:

Source: Summary of Published Literature

Clinical evidence literature searches have found three published literature articles representing 54 cases specific to the Pro-Line® device family. The articles included one randomized controlled trial (Yong et al.), one prospective study (Kehagias et al.), and a case study (Highnell et al.).

Bibliography:

Hignell, E. R., & Phelps, J. (2020). Recurrent central venous catheter migration in a patient with brittle asthma. *The journal of vascular access, 21*(4), 533-535.

Kehagias, E., & Tsetis, D. (2019). The "Arm-to-Chest Tunneling" technique: A modified technique for arm placement of implantable ports or central catheters. *The journal of vascular access, 20*(6), 771-777.

Sze Yong T, Vijayanathan AA, Chung E, Ng WL, Yaakup NA, Sulaiman N. Comparing catheter related bloodstream infection rate between cuffed tunnelled and non-cuffed tunnelled peripherally inserted central catheter. *J Vasc Access*. 2022;23(2):225-31.

Source: PMCF_Infusion_201

The CVAD Registry was acquired from CVAD Resources, LLC on 23 August 2020. All data received was de-identified, but otherwise represented exactly what was entered by clinicians on a consecutive basis. Medcomp received only data pertaining to devices with the manufacturer listed as "Medcomp" and all case information was sourced from two US hospitals. Hospital ID 121 is described as a "Vascular Access team in a Not-for-Profit Community Based Hospital", and Hospital ID 123 is described as a "PICC (peripherally inserted central catheter) team in an Academic Medical Center". Insertion of device dates range from 06 August 2012 through 21 April 2015. Removal of device dates from 09 August 2012 through 07 May 2015.

2 Pro-Line® cases, described as 5F and double lumen, were collected. The following outcome measure was confirmed to be within State of the Art safety and performance outcome measures from published literature for Medcomp Pro-Line® devices:

- Procedural Outcomes – 100%

Source: PMCF_Infusion_211

The Infusion Product Line Data Collection Survey aimed to assess safety and performance outcome information for all variants of Medcomp Infusion Ports, PICCs, Midlines, and CVCs. 70 survey responses were collected from 17 countries representing 471 device cases.

8 Pro-Line® cases inclusive of several variant devices across French size (5F and 7F) and lumen configuration (single and dual) were collected. The following outcome measures were confirmed to be within State of the Art safety and performance outcome measures from published literature for Medcomp Pro-Line® devices:

- Dwell Time – 247.6 Days (95%CI: 236.07 – 259.13)
- Procedural Outcomes – 100%
- Catheter Associated Venous Thrombus – No Events Reported
- Catheter Related Blood Stream Infection – No Events Reported
- Power Injection Related Complications – No Events Reported

The variants included in the dataset are displayed below.

Variant	n	French Size(s)	Length(s)
Single Lumen Pro-Line	5	5F	60cm
Dual Lumen Pro-Line	3	7F	60cm

Source: Duration of Use Customer Survey

An email questionnaire was distributed globally to users of Medcomp PICCs and CVCs from 10 October 2019 to 16 October 2019. The questionnaire asked respondents to identify, from their own experience, the number of products used yearly, the average dwell time, and the longest dwell time for each applicable device family.

Across the five device families, a total of 69 responses were collected from 14 countries. Means and ranges of responses for each device family were compiled on 16 October 2019.

7 responses were acquired relating to the Pro-Line® device family. Across an estimated 580 products used yearly, the mean average dwell time was 126.4 days (Range: 45 – 240 days), and the mean longest dwell time was 405 days (Range: 235 – 547.5 days).

Source: PMCF_Infusion_222

The University of Pittsburgh Medical Center (UPMC) Database assessed safety and performance outcome information for Pro-Line® and Vascu-Line® SL (referred to in the data set as “LT Silicone CVC”) Medcomp Infusion CVCs. 825 of 1,028 cases (80.25%) are directly from the University of Pittsburgh Medical Center Presbyterian which the investigator notes may be a population prone to infection and chronic illness. The remainder of the cases are from other hospitals in the UPMC system which the investigator notes may have a patient population more similar to a community hospital. The multi-center approach aimed to be representative of the broad spectrum of users within the user population.

739 Pro-Line® cases inclusive of several variant devices across French size (5F and 6F) and lumen configuration (single, double, and triple) were collected. The following outcome measures were confirmed to be within State of the Art safety and performance outcome measures from published literature for Medcomp Pro-Line® devices:

- Dwell Time – 95.42 Days (**95%CI:** 83.66 – 107.18)
- Procedural Outcomes – 100%
- Catheter Associated Venous Thrombus – 0.07 per 1,000 catheter days (**95%CI:** 0.02 – 0.15)
- Catheter Related Blood Stream Infection – 1.36 per 1,000 catheter days (**95%CI:** 1.1 – 1.6)
- Power Injection Related Complications – No Events Reported

Source: PMCF_Infusion_231

The King Faisal Specialist Hospital & Research Center dataset was finalized 22 March 2023. The full King Faisal Specialist Hospital & Research Center dataset was acquired on 23 February 2023. The country of origin of the data set is Saudi Arabia. The full dataset included information on 92 Vascu-Line®, 2 Pro-Line®, and 1 Vascu-Line® SL cases with dates of insertion ranging from 22 December 2021 to 11 January 2023 and dates of removal (or last known follow-up) ranging from 09 May 2022 to 23 February 2023.

Real-world performance data on the use of two Medcomp Pro-Line® catheters was collected.

- Dwell Time (94 days 95%CI: 0 – 1072.4 days)
- Procedural Outcomes (100% 95%CI: 100% - 100%)
- Catheter Related Blood Stream Infection (CRBSI) Rate (0 per 1,000 catheter days 95%CI: 0 – 19.6)
- Catheter Associated Venous Thrombus (CAVT) Rate (0 per 1,000 catheter days 95%CI: 0 – 19.6)

Source: PMCF_Medcomp_211

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

11 respondents responded that they or their facility have used Medcomp CVCs, with 7 of those respondents using the Pro-Line® device. There were no differences in mean user sentiments within CVCs 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 CVCs (n=11):

- (Mean Likert Scale Response) Catheters function as intended – 4.6 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.6 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 4.7 / 5 *(n=10)*
- Dwell Time (n=6) – 20.33 days (**95%CI:** 4.27 – 36.4)

The following data points were collected from users of Medcomp Pro-Line® CVCs (n=7):

- (Mean Likert Scale Response) Catheters function as intended – 4.5 / 5

- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.5 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 4.6 / 5 *(n=6)*
- Dwell Time (n=4) – 21.5 days (**95%CI:** 0 – 49.26)

The following complications were reported for Pro-Line® devices:

- No Blood Return (3 out of 200 Cases)
- Infection (No Comments on Frequency)

Overall summary of clinical safety and performance

Upon review of the data across all sources, it is possible to conclude that the benefits of the subject device, which is facilitating delivery of fluids and medications for treatments including chemotherapy and power injection of contrast media for CT examinations in patients in whom short-term or long-term access to the central venous system without requiring frequent needlesticks is deemed necessary based on the direction of a qualified, licensed physician, outweigh the overall and individual risks when the device is used as intended by the manufacturer. It is the manufacturer's and clinical expert evaluator's opinion that activities both complete and ongoing are sufficient to support the safety, efficacy, and acceptable benefit/risk profile of the subject devices.

Outcome	Benefit/Risk Acceptability Criteria	Desired Trend	Clinical Literature (Subject Device)	PMCF Data (Subject Device)
Performance				
Dwell Time	Greater than 55 days	↑	37.28 days **(Summary of Published Literature)**	247.6 days **(PMCF_Infusion_211)** 126.4 days **(Duration of Use Customer Survey)** 95.42 Days **(PMCF_Infusion_222)** 94 Days **(PMCF_Infusion_231)** 21.5 Days **(PMCF_Medcomp_211)** Likert Scale Response 4.6 / 5 **(PMCF_Medcomp_211)****
Procedural Outcomes	Greater than 92.0%	↑	ND*	100% **(PMCF_Infusion_211)** 100% **(PMCF_Infusion_201)** 100% **(PMCF_Infusion_222)**

				100% **(PMCF_Infusion_231)** Likert Scale Response 4.6 / 5 **(PMCF_Medcomp_211)****
Safety				
Catheter Associated Venous Thrombus (CAVT)	Less than 0.3 incidents of CAVT per 1,000 catheter days	↓	1.1 per 1,000 catheter days **(Summary of Published Literature)**	None Reported **(PMCF_Infusion_211)** 0.07 per 1,000 catheter days **(PMCF_Infusion_222)** None Reported **(PMCF_Infusion_231)** Likert Scale Response 4.6 / 5 **(PMCF_Medcomp_211)****
Central Line Associated Blood Stream Infection (CLABSI) / Catheter Related Blood Stream Infection (CRBSI)	Less than 5.0 incidents of CLABSI/CRBSI per 1,000 catheter days	↓	2.7 per 1,000 catheter days **(Summary of Published Literature)**	None Reported **(PMCF_Infusion_211)** 1.36 per 1,000 catheter days **(PMCF_Infusion_222)** None Reported **(PMCF_Infusion_231)** Likert Scale Response 4.6 / 5 **(PMCF_Medcomp_211)****
Power Injection Related Complications	Less than 1.8% catheters with reported incidents of rupture due to contrast injection Less than 15.4% catheters with reported incidents of displacement due to contrast injection	↓	ND*	None Reported **(PMCF_Infusion_211)** None Reported **(PMCF_Infusion_222)** None Reported **(PMCF_Infusion_231)** Likert Scale Response 4.6 / 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)

Activity	Description	Reference	Timeline
Multicenter Patient-Level Case Series	Collect additional clinical data on the device	PMCF_CVC_231	Q4 2025

State of the Art Literature Search	Identify risks and trends with use of similar devices	SAP-Infusion	Q2 2025
Clinical Evidence Literature Search	Identify risks and trends with use of the device	LRP-Infusion	Q2 2025
Global Trial Database Search	Identify ongoing clinical trials involving Medcomp® catheters	N/A	Q3 2025
Truveta Data Queries and Retrospective Analysis	Collect additional clinical data on the device and comparators	TBD	Q4 2025

No emerging risks, complications or unexpected device failures have been detected from PMCF activities.

6. Possible therapeutic alternatives

The Infusion Nurses Society (INS) Standards 2021 clinical practice guidelines have been used to support the below recommendations for treatments.

Therapy	Benefits	Disadvantages	Key Risks
Central Venous Catheters (CVCs)	• Easy access once in place • Minimizes repeated venipuncture • Increased patient mobility during infusion • Easier for outpatient treatment	• Requires surgical procedure for placement • Risks associated with surgery: general anesthesia, etc. • Requires maintenance • High risk of infection or thrombotic event	• Catheter infection • Occlusion • Malfunction of the CVC • Vascular thrombosis
Implantable Ports	• Decreases puncture wounds/vein damage compared to traditional injection • Easier to visualize, palpate, and therefore safer form of IV access • Reduces chance for corrosive medications to make skin contact • Only one venipuncture for both treatment and lab draws, as	• Requires surgical procedure, but IV does not • Risks associated with surgery: general anesthesia, etc. • Requires regular flushing	• Drug extravasations • Infection • Thromboembolism • Tissue necrosis of overlying skin / port dehiscence

Therapy	Benefits	Disadvantages	Key Risks
	opposed to two for traditional IV • Longer dwelling time compared to IV • Can be permanent, if needed		
Midline Catheters	• Patient comfort – fewer restarts than IVs • Longer dwell time than IVs • Lower risk of infection compared to IVs • No X-ray required before use • Decreased chance of extravasation of infusate	• Data on clear disadvantages compared to other modalities is not available • Not suitable for continuous injections of most vesicants or irritants	• Insertion-related phlebitis
Peripherally Inserted Central Catheters (PICCs)	• Decreased risk of catheter occlusion compared to CVC • Fewer venous punctures compared to traditional PIV	• Increased risk of deep vein thrombosis compared to CVC • Pain/Discomfort over time • Need for adaptation in daily life	• Deep vein thrombosis (DVT) • Pulmonary embolism • Venous thromboembolism (VTE) • Post thrombotic syndrome
Peripheral Intravenous Catheters (PIVs)	• Does not require surgical procedure	• Higher hemolysis rates compared to venipuncture • Infection • Hematoma/thrombosis • Cannot be used for therapies with blistering agents • Four days maximum use	• Infection • Phlebitis

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 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 Excludes Section 7	2020	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems	Partial; (Transition Plan)
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

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
EN ISO 13485	2016 + A11: 2021	Medical Devices – Quality Management system – Requirements for Regulatory Purposes	Full
EN ISO 14155	2020	Clinical investigation of medical devices for human subjects — Good clinical practice	Full
EN ISO 14644-1	2015	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration	Full
EN ISO 14644-2	2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Full
EN ISO 14971	2019+A11:2021	Medical devices. Application of risk management to medical devices	Full
EN ISO 15223-1	2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	Full
EN ISO/IEC 17025	2017	General requirements for the competence of testing and calibration laboratories	Full
PD CEN ISO/TR 20416	2020	Medical devices — post-market surveillance for manufacturers	Full
EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer.	Full
EN 62366-1	2015 + A1: 2020	Medical devices — Part 1: Application of usability engineering to medical devices	Full
ISO 7000	2019	Graphical symbols for use on equipment. Registered symbols	Partial
ISO 594-1	1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements	Full
ISO 594-2	1998	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock Fittings	Full
MEDDEV 2.7.1	Rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC	Full
MEDDEV 2.12/2	Rev. 2	GUIDELINES ON MEDICAL DEVICES POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES	Full
MDCG 2020-6	2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC	Full
MDCG 2020-7	2020	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
MDCG 2020-8	2020	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies	Full
MDCG 2019-9	2022	Summary of safety and clinical performance	Full
MDCG 2018-1	Rev. 4	Guidance on BASIC UDI-DI and changes to UDI-DI	Full
ASTM D 4169-16	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

PATIENTS

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

Revision: SSCP-017 Rev. 6
Date: 22OCT2024

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)	Pro-Line® Power Injectable Central Venous Catheters
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908290NE
Date first CE certificate was issued for this device	Pro-Line® - October 2008

The devices in scope of this document are all central venous catheter (CVC) sets. The catheter part numbers are organized into variant categories. These devices are distributed as procedure trays. Procedure trays come in different configurations.

Variant Devices:

Variant Description	Part Number(s)
5F x 55cm Double Lumen Pro-Line	10667-955-801 10669-955-801
5F x 60cm Single Lumen Pro-Line	10570-960-801 10606-960-801
6F x 60cm Double Lumen Pro-Line	10573-960-801 10608-960-801
6F x 60cm Single Lumen Pro-Line	10571-960-801 10607-960-801
6F x 60cm Triple Lumen Pro-Line	10575-960-801
7F x 60cm Double Lumen Pro-Line	10290-860-801
7F x 60cm Single Lumen Pro-Line	10289-860-801

Procedure Trays:

Catalog Code	Part Number	Description
MR28035201	10667-955-801	5F X 55CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER DUAL LUMEN BASIC SET
MR28035221	10669-955-801	5F X 55CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER DUAL LUMEN BASIC SET
MR28036201	10573-960-801	6F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER DUAL LUMEN BASIC SET
MR28036221	10608-960-801	6F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER DUAL LUMEN BASIC SET
MR28037201	10290-860-801	7F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER DUAL LUMEN BASIC SET
MR28035101	10570-960-801	5F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER SINGLE LUMEN BASIC SET
MR28035121	10606-960-801	5F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER SINGLE LUMEN BASIC SET
MR28036101	10571-960-801	6F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER SINGLE LUMEN BASIC SET
MR28036121	10607-960-801	6F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER SINGLE LUMEN BASIC SET
MR28037101	10289-860-801	7F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER SINGLE LUMEN BASIC SET

Catalog Code	Part Number	Description
MR28036301	10575-960-801	6F X 60CM PRO-LINE® POWER INJECTABLE CENTRAL VENOUS CATHETER TRIPLE LUMEN BASIC SET

Configurations of Procedure Trays:

Configuration Type
Basic Set

2. Intended use of the device

Intended purpose	The Pro-Line® Power Injectable Central Venous Catheters are for use in adult patients requiring frequent needlesticks for whom short-term or long-term access to the central venous system without requiring many needlesticks is deemed necessary based on the direction of a qualified, licensed physician. The device is intended to be used under the regular review and assessment of qualified health professionals. This catheter is for Single Use Only.
Indication(s)	The Pro-Line® Power Injectable Central Venous Catheter is for short-term or long-term access to the central venous system for intravenous administration of fluids or medications and power injection of contrast media.
Intended patient group(s)	Pro-Line® Power Injectable Central Venous Catheters are intended for use in adult patients requiring many needlesticks for whom short-term or long-term access to the central venous system without the need for many needlesticks is deemed necessary based on the direction of a qualified, licensed physician. The device is not intended for use in pediatric patients.
Contraindications	• The presence of device related infection is known or suspected. • This catheter is intended for short- or long-term vascular access and should not be used for any purpose other than indicated in these instructions. • The patient is known or is suspected to be allergic to materials contained in the device.

3. Device description

*

Figure 1: Representative Image of Pro-Line® device

<table>
<tr><td>Description of device</td><td>The Pro-Line® Power Injectable Central Venous Catheters are made from specially formulated biocompatible medical grade materials and are available in a variety of lumen shapes and sizes to accommodate clinical needs. They are packaged in a tray with accessories necessary for percutaneous insertion using a microintroducer (Modified Seldinger or Seldinger technique). The highest recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the Pro-Line® Power Injectable CVC may not exceed 300psi.</td></tr>
<tr><td>Materials / substances in contact with patient tissue</td><td>The percentage ranges in the table below are based on the weight of the 5F Single Lumen (3.64g) and 6F Triple Lumen (7.76g) Pro-Line® devices.

<table><tr><th>Material</th><th>% Weight (w/w)</th></tr><tr><td>Polyurethane</td><td>29.24 - 63.56</td></tr><tr><td>Polyvinyl Chloride</td><td>0 - 30.44</td></tr><tr><td>Acetal Co-polymer</td><td>15.55 - 23.44</td></tr><tr><td>Barium Sulfate</td><td>5.96 - 12.56</td></tr><tr><td>Acrylonitrile Butadiene Styrene</td><td>6.73 - 10.15</td></tr><tr><td>Polyethylene Terephthalate</td><td>0.43 - 2.47</td></tr></table>
<u>Note:</u> Accessories containing stainless steel may contain up to 0.4% weight of the CMR substance cobalt.

<u>Note:</u> The device should not be used if you are allergic to the above materials.</td></tr>
<tr><td>Information on medicinal substances in the device</td><td>N/A</td></tr>
<tr><td>How the device achieves its intended mode of action</td><td>The subject device can be inserted using a standard or modified Seldinger percutaneous surgical technique. Catheter insertion is to be done using aseptic techniques in a sterile field, preferably in an operating room.

Once in place, the CVC can be connected to a gravity-feed intravenous (IV) bag, or connected to a pump, for administration of fluids and medications. Catheter care includes use of a locking solution to maintain catheter function. Catheter removal is a surgical procedure intended to be performed by a physician familiar with the appropriate techniques.</td></tr>
<tr><td>Sterilization Information</td><td>Contents sterile and non-pyrogenic in unopened, undamaged package. Sterilized by Ethylene Oxide.</td></tr>
</table>

	Name of Accessory	Description of Accessory
Description of accessories	**Guidewire**	Acts as a path for other components.
	Introducer Needle	Placed into the target vein to gain access.
	Stylet	Assists in catheter placement.
	Peelable Introducer	Used to get central venous access.
	Scalpel	A cutting device.
	Tunneler	Instrument used to create a subcutaneous tunnel.
	Syringe	Helps get blood return once the needle punctures the vein.

4. Risks and warnings

Contact your healthcare professional if you believe you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

How potential risks have been controlled or managed	There have been 80,809 devices sold since January 2019. There are side effects and risks associated with the device. These include: • Infection • Bleeding • Device Removal • Device Replacement These risks are reduced to an acceptable level. The labeling describes the risks. The benefit of the device is central venous access when alternatives are not suitable. These benefits outweigh the risks.
Remaining risks and undesirable effects	The Power Injectable Central Venous Catheters are associated with risks. These include: • Procedural Delays • Thrombosis • Infections • Perforations • Embolism • Cardiac Event • Dissatisfaction These risks are consistent with risks of other catheters. They are not unique to the Medcomp product. Some of the most common reactions include infection. Infection may be associated with general surgical procedure and hospitalization. Infection may not always be device-related.

<table>
<tr><td></td><td>
<table>
<tr><th rowspan="3">Patient Residual Harm Category</th><th colspan="2">Quantification of Residual Risks</th></tr>
<tr><th>Complaints (01 January 2019 – 31 August 2024)</th><th>Post Market Clinical Follow-Up Activity Events</th></tr>
<tr><th>Units Sold: 80,809</th><th>Units Studied: 749</th></tr>
<tr><th># of Cases Per Event</th><th># of Cases Per Event</th></tr>
<tr><td>Allergic Reaction</td><td>Not Reported.</td><td>Not Reported.</td></tr>
<tr><td>Bleeding</td><td>Not Reported.</td><td>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>1 Event in 80,000 Cases.</td><td>1 Event in 8 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>
<tr><td>Tissue Injury</td><td>Not Reported.</td><td>Not Reported.</td></tr>
<tr><td>Thrombosis</td><td>Not Reported.</td><td>1 Event in 150 Cases.</td></tr>
</table>
</td></tr>
<tr><td>Warnings and precautions</td><td>The below are warnings, precautions, or measures to be taken by patient:

• Keep catheter dressing clean and dry. Ask your doctor for specific instructions on how to care for your catheter.
• Avoid letting the catheter or catheter site go under water. Moisture near the catheter site can potentially lead to an infection. Patients must not swim, shower or soak dressing while bathing.
• Contact your doctor right away if you notice any signs or symptoms of your catheter complications, such as

o The area around your line is increasingly red, swollen, bruised or warm to the touch.

o Drainage from your catheter site.

o The length of the catheter that sticks out of your insertion site gets longer.

o Difficulty flushing your line because it seems to be blocked.
• Avoid lifting heavy objects.
• Do not have blood pressure readings taken on arm where the catheter is placed</td></tr>
<tr><td>Summary of any field safety correction action (FSCA)</td><td>There were no recalls for the device between 01 December 2023 to 31 August 2024.</td></tr>
</table>

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

Clinical background of the device

The subject devices have been available since 2008. The CE Mark was received in October 2008. US FDA clearance was in November 2009. 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 54 cases. Three patient level data activities received information on 751 catheters. 14 user surveys 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 Pro-Line® catheter has been evaluated. The benefits of the subject device outweigh the risks when the device is used as intended. The benefit of the device is facilitating delivery of fluids and medications for treatments including chemotherapy and power injection of contrast media for CT examinations. These benefits are for patients in whom short-term or long-term access to the central venous system without requiring frequent needlesticks is deemed necessary based on the direction of a qualified, licensed physician.

Safety

There is sufficient data to prove conformity to the applicable requirements. The device is safe and performs as intended. The device is state of the art.

Medcomp has reviewed:

- Post-Market Data
- Medcomp Information Materials
- Risk Management Documentation

The risks are appropriately displayed and consistent with the state of the art. The risks associated with the device are acceptable when weighed against the benefits.

There were 80,809 devices sold from January 1st 2019, to August 31st, 2024. Also, during this period there were 47 complaints received resulting in a 0.058% complaint frequency for the product family.

6. Possible therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can consider your individual situation. The Infusion Nurses Society (INS) Standards 2021 clinical practice guidelines have been used to support the below recommendations for treatments.

Therapy	Benefits	Disadvantages	Key Risks
Central Venous Catheters (CVCs)	• Easy access. • Minimizes repeat puncture.	• Requires surgery. • Surgery risks. • Requires maintenance.	• Infection • Occlusion • Malfunction

Therapy	Benefits	Disadvantages	Key Risks
	• Increased patient mobility. • Easier for outpatients.	• High risk of infection or thrombosis.	• Thrombosis
Implantable Ports	• Less Vein Damage. • Easier to See and Access. • Reduces chance for corrosive medications to make skin contact • One puncture location. • Longer Dwell Time. • Can be permanent.	• Requires surgery. • Surgery Risks. • Requires maintenance.	• Infection • Embolism • Necrosis
Midline Catheters	• Patient comfort. • Longer dwell time than PIVs. • Lower risk of infection compared to IVs • No X-ray required. • Decreased chance of extravasation.	• Not suitable for continuous injections of most vesicants or irritants	• Phlebitis
Peripherally Inserted Central Catheters (PICCs)	• Decreased risk of catheter occlusion compared to CVC • Fewer punctures compared to PIV	• Increased risk of deep vein thrombosis compared to CVC • Pain/Discomfort over time • Daily Life Adaption	• Deep vein thrombosis (DVT) • Pulmonary embolism • Venous thromboembolism (VTE) • Post thrombotic syndrome

Therapy	Benefits	Disadvantages	Key Risks
Peripheral Intravenous Catheters (PIVs)	• No Surgery.	• Infection • Bleeding • Thrombosis • Cannot be used for therapies with blistering agents • Four days maximum use.	• Infection • Phlebitis

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
CE	Conformité Européenne (European Conformity)
cm	centimeter
CMR	Carcinogenic, mutagenic, reprotoxic
CT	Computerized Tomography (CAT Scan)
CVC	Central Venous Catheter
dba	Doing Business As
F	French (thickness of catheter)
FDA	Food and Drug Administration
FSCA	Field Safety Corrective Action
INS	Infusion Nurses Society
IV	Intravenous
N/A	Not Applicable
PA	Pennsylvania
PICC	Peripherally Inserted Central Catheter
PIV	Peripheral Intravenous Catheters
SSCP	Summary of Safety and Clinical Performance
USA	United States of America
w/w	Weight over Weight

Add copy to 'MDR Documentation' (Initial & Date): 24OCT2024