SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-016

1.9F & 2.6F Vascu-PICC® Peripherally Inserted Central Catheter

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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	11004-A1, 11005
'MDR Documentation' File Number	MDR-016

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-016_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	**20OCT2023**	**28545**	**GM**	**Update in accordance with CER-016_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
5	**22OCT2024**	**29485**	**GM**	**Update in accordance with CER-016_E**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by

Revision History					
Revision	Date	CR#	Author	Description of Changes	Validated
					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)	1.9F & 2.6F Vascu-PICC® Peripherally Inserted Central 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	00884908289NV
Medical device nomenclature description / text	C010201 – Central I.V. Catheters, Peripheral Access
Class of device	III
Date first CE certificate was issued for this device	1.9F & 2.6F Vascu-PICC® - October 2008 1.9F & 2.6F Jet-PICC - 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 peripherally inserted central catheter (PICC) 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
1.9F x 20cm Single Lumen Pediatric PICC	10533-820-001
1.9F x 50cm Single Lumen Pediatric PICC	10533-850-001
2.6F x 20cm Double Lumen Pediatric PICC	10539-820-001
2.6F x 50cm Double Lumen Pediatric PICC	10539-850-001
2.6F x 50cm Double Lumen Pediatric PICC w/ Cuff	10552-950-001

Procedure Trays:

Catalog Code	Part Number	Description
MR17012600	10539-850-001	2.6F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN CATHETER SET
MR17012601	10539-850-001	2.6F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC SET
MR170126024S	10539-850-001	2.6F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC MST SET
MR17012608	10552-950-001	2.6F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN WITH CUFF BASIC SET
MR17012621	10539-820-001	2.6F X 20CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC SET
MR170126224S	10539-820-001	2.6F X 20CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC MST SET
JSAP2.620	10539-820-001	2.6F X 20CM JET-PICC PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC SET
JSAP2.650	10539-850-001	2.6F X 50CM JET-PICC PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC SET
JSAP1.920	10533-820-001	1.9F X 20CM JET-PICC PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET
JSAP1.950	10533-850-001	1.9F X 50CM JET-PICC PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET
MR17011100	10533-850-001	1.9F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN CATHETER SET
MR17011101	10533-850-001	1.9F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET
MR170111024S	10533-850-001	1.9F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC MST SET

Catalog Code	Part Number	Description
MR17011121	10533-820-001	1.9F X 20CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET
MR170111224S	10533-820-001	1.9F X 20CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC MST SET
VP1.9S20-NS	10533-820-001	1.9F X 20CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET WITHOUT STYLET
VP1.9S50-NS	10533-850-001	1.9F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET WITHOUT STYLET

Configurations of Procedure Trays:

Configuration Type	Kit Components
Vascu-PICC® Catheter Set	(1) Catheter w/ Stylet, (1) 0.76mm (0.030”) I.D. Adaptor w/Sideport, (1|2) Needleless Connector(s), (1) Securement Device, (1) Patient Information Packet, (1) Patient ID Card
Vascu-PICC® Basic Set	(1) Catheter w/ Stylet, (1) 0.76mm (0.030”) I.D. Adaptor w/Sideport, (1) OTN Tearaway Introducer: (1.9F Sets) 1.2mm OD x 0.7mm ID x 2.2cm (2F) OTN Tearaway Introducer, (2.6F Sets) 1.6mm OD x 1.1mm ID x 3.2cm (3F) OTN Tearaway Introducer, (1|2) Needleless Connectors, (10) 2" X 2" Gauze, (1) 10cc Syringe, (1) Tourniquet, (1) Tape Measure, (1) Securement Device, (1) Patient Information Packet, (1) Patient ID Card
Vascu-PICC® Basic MST Set	(1) Catheter w/ Stylet, (1) 0.27mm x 20cm (.010) Guidewire Nitinol Straight Tip, (1) 0.76mm (0.030”) I.D. Adaptor w/Sideport, (1) Peelable Introducer: (1.9F Sets) 0.7mm ID x 2.2cm (2F) Peelable Introducer, (2.6F Sets) 1.0mm ID x 3.2cm (3F) Peelable Introducer, (1|2) Needleless Connector(s), (1) 24GA IV Catheter, (10) 2" X 2" Gauze, (1) 10cc Syringe, (1) Tourniquet, (1) Tape Measure, (1) Securement Device, (1) Patient Information Packet, (1) Patient ID Card
Vascu-PICC® Basic Set without Stylet	(1) Catheter, (1) 1.2mm OD x 0.7mm ID x 2.2cm (2F) OTN Tearaway Introducer, (1) Needleless Connector, (10) 2" X 2" Gauze, (1) 10cc Syringe, (1) Tourniquet, (1) Tape Measure, (1) Securement Device, (1) Patient Information Packet, (1) Patient ID Card
Vascu-PICC® Basic Set with Cuff	(1) Catheter w/Cuff and Stylet, (1) 0.76mm (0.030”) I.D. Adaptor w/ Sideport, (1) 1.6mm OD x 1.1mm ID x 3.2cm (3F) OTN Tearaway Introducer, (10) 2 x 2 Gauze, (1) 10CC Syringe, (2) Needless Connectors, (1) Tourniquet, (1) Tape Measure, (1) Securement Device, (1) Patient Information Packet, (1) Patient ID Card
Jet-PICC 1.9F Basic Set	(1) Catheter w/ Stylet, (1) 0.76mm (0.030”) I.D. Adaptor w/Sideport, (1) 1.2mm OD x 0.7mm ID x 2.2cm (2F) OTN Tearaway Introducer, (1) Securement Device, (1) Needleless Connector, (10) 2" X 2" Gauze, (1) 10cc Syringe, (1) Tourniquet,

Configuration Type	Kit Components
	(1) Tape Measure, (1) Patient Information Packet, (1) Patient ID Card
Jet-PICC 2.6F Basic Set	(1) Catheter w/ Stylet, (1) 0.76mm (0.030”) I.D. Adaptor w/Sideport, (1) 1.6mm OD x 1.1mm ID x 3.2cm (3F) OTN Tearaway Introducer, (1) Securement Device, (2) Needleless Connectors, (10) 2" X 2" Gauze, (1) 10cc Syringe, (1) Tourniquet, (1) Tape Measure, (1) Patient Information Packet, (1) Patient ID Card

2. Intended use of the device

Intended purpose	The 1.9F and 2.6F Vascu-PICC®/Jet-PICC Peripherally Inserted Central Catheters are intended for use in pediatric and neonate patients requiring frequent needlesticks for whom short-term or long-term peripheral 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 1.9F and 2.6F Vascu-PICC®/Jet-PICC Peripherally Inserted Central Catheter is indicated for short-term or long-term peripheral access to the central venous system for the intravenous administration of fluids or medications.
Target population(s)	1.9F and 2.6F Vascu-PICC®/Jet-PICC Peripherally Inserted Central Catheters are intended for use in pediatric and neonate patients requiring frequent needlesticks for whom short-term or long-term peripheral access to the central venous system without requiring frequent needlesticks is deemed necessary based on the direction of a qualified, licensed physician.
Contraindications and/or limitations	• This catheter is not intended for any use other than that which is indicated. Do not implant catheter in thrombosed vessels. • The presence of skin related problems around the insertion site (infection, phlebitis, scars, etc.) • The presence of device related bacteremia or septicemia. • Previous history of venous/subclavian thrombosis or vascular surgical procedures at insertion site. • Fever of unknown origin. • The patient's body size is insufficient to accommodate the size of the implanted device. • The patient is known or is suspected to be allergic to materials contained in the device. • Past irradiation of prospective insertion site. • Local tissue factors will prevent proper device stabilization and/or access. • Known tape or Zinc Oxide adhesive allergies. • This catheter is not suitable for insertion through non-superficial veins.

3. Device description

Figure 1: Representative Image of 1.9F & 2.6F Vascu-PICC® device

<table>
<tr><td>Description of device</td><td>The 1.9F and 2.6F Vascu-PICC® Peripherally Inserted Central Catheter is used for short- or long-term central venous access, via peripheral insertion, during the administration of fluids, medication and nutritional therapy for neonates, infants and children. The lumen ID and OD are continuous throughout the entire length of the lumen tubing. Each catheter lumen terminates through an extension to a female luer-lock connector. Each extension has an in-line clamp to control fluid flow and is marked with the lumen gauge size. The transition between the lumen and extension is housed within a molded hub. The hub is marked with the catheter French size. The lumen is marked with depth markers every centimeter.</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 1.9F x 20cm Single Lumen (2.85g) and 2.6F x 50cm Double Lumen w/ Cuff (4.16g) Vascu-PICC® devices.

<table><tr><th>Material</th><th>% Weight (w/w)</th></tr><tr><td>Polyurethane</td><td>56.04 - 68.86</td></tr><tr><td>Acetal Co-polymer</td><td>20.66 - 30.32</td></tr><tr><td>Acrylonitrile Butadiene Styrene</td><td>8.95 - 13.13</td></tr><tr><td>Barium Sulfate</td><td>0.51 - 1.53</td></tr><tr><td>Polyethylene Terephthalate</td><td>0 - 0.33</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> 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>
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<table>
<tr><td>How the device achieves its intended mode of action</td><td colspan="2">The subject devices utilize a Seldinger or Modified Seldinger technique to obtain access. The main difference is one technique utilizes an Introduction Sheath and one does not. The Seldinger techniques for venous access are well-known surgical techniques used for inserting PICC devices. The instructions for use of each catheter are detailed in the IFUs. Catheters are to be inserted, manipulated and removed by a qualified, licensed physician or other qualified health care professional utilizing strict aseptic technique.

Once in place, fluids are delivered or blood is withdrawn via the PICC catheter most commonly with a disposable tubing set or syringe. Catheter care includes use of a locking solution to maintain catheter patency. Catheter removal is normally done by gently pulling on the catheter, but removal may require that a surgical procedure be performed by a physician familiar with the appropriate techniques in some circumstances.</td></tr>
<tr><td>Sterilization Information</td><td colspan="2">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="2">Accessories intended for use in combination with the device</td><td>Name of Accessory</td><td>Description of Accessory</td></tr>
<tr><td colspan="2"><table>
<tr><th>Part Number</th><th>Description</th></tr>
<tr><td>1258</td><td>1.6mm OD x 1.1mm ID x 3.2cm (3F) OTN Tearaway Introducer</td></tr>
<tr><td>3015</td><td>Gauze</td></tr>
<tr><td>3035</td><td>Syringe</td></tr>
<tr><td>3418</td><td>Tape Measure</td></tr>
<tr><td>5731</td><td>Securement Device</td></tr>
<tr><td>5732</td><td>Securement Device</td></tr>
<tr><td>10129</td><td>0.76mm (0.030”) I.D. Adaptor w/Sideport</td></tr>
<tr><td>30306</td><td>1.2mm OD x 0.7mm ID x 2.2cm (2F) OTN Tearaway Introducer</td></tr>
<tr><td>30656</td><td>Tourniquet</td></tr>
<tr><td>30823</td><td>Needleless Connector</td></tr>
<tr><td>10348-02</td><td>0.7mm ID x 2.2cm (2F) Peelable Introducer</td></tr>
<tr><td>10348-03</td><td>1.0mm ID x 3.2cm (3F) Peelable Introducer</td></tr>
<tr><td>30353-030</td><td>Stylet</td></tr>
<tr><td>30353-060</td><td>Stylet</td></tr>
<tr><td>30754-010-020</td><td>0.27mm x 20cm (.010) Guidewire Nitinol Straight Tip</td></tr>
<tr><td>5620-1</td><td>IV Catheter</td></tr>
</table></td></tr>
</table>

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: 222,776	Units Studied: 11
	% of Devices	% of Devices
Allergic Reaction	0.00045%	Not Reported
Bleeding	0.00045%	Not Reported
Cardiac Event	0.00045%	Not Reported
Embolism	Not Reported	Not Reported
Infection	0.00090%	Not Reported
Perforation	0.00045%	Not Reported
Stenosis	Not Reported	Not Reported

<table>
<tr><td></td><td>
<table>
<tr><td>Tissue Injury</td><td>0.00045%</td><td>Not Reported</td></tr>
<tr><td>Thrombosis</td><td>Not Reported</td><td>Not Reported</td></tr>
</table>
</td></tr>
<tr><td>Warnings and precautions</td><td>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 use infusion equipment which can exceed the working pressure of 1.0bar max/750mmHg (14.5 psi).
• Do not use high-pressure injectors for contrast medium studies. Excessive pressures may damage catheter.
• Do not use the securement device where loss of adherence could occur, such as with a confused patient or nonadherent skin.
• 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 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.
• Bolus injections should be slow and must not exceed the maximum bolus pressure of 1.2bar/900mmHg (17.4 psi).
• 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.</td></tr>
</table>

	• Examine catheter lumen and extension(s) before and after each infusion for damage. • To prevent accidents, assure the security of all caps and connectors 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. • 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. • Observe universal blood and body fluid precautions and infection control procedures, during application and removal of the securement device. • Avoid securement device contact with alcohol or acetone. Both can weaken bonding of components and the securement device pad adherence. • Minimize catheter/tube manipulation during application and removal of the securement device. • Remove oil and moisturizer from targeted skin area prior to placing the securement device. • The securement device should be monitored daily and replaced when clinically indicated, at least every 7 days. • Confirm catheter tip position by x-ray prior to use. Monitor tip placement routinely per institution policy. • Discard biohazard according to facility protocol. • 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. • The CMR substance Cobalt is a naturally occurring component of stainless steel. Based on biocompatibility evaluation it was determined that the main hazards of stainless steels are related to the processing of the material, especially welding, thus not applicable to the intended use of the device. Stainless steels used in these devices are unlikely to reach exposure levels that will elicit carcinogenicity, mutagenicity, or reproductive toxicity.
Other relevant aspects of safety (ex. field safety corrective actions, etc.)	For a period of 01 January 2019 to 31 August 2024 there were 132 complaints for 222,776 units sold, giving an overall complaint rate of 0.059%. 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
844	11	855	2

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 1.9F and 2.6F Vascu-PICC® Peripherally Inserted Central Catheter, 57 catheters had a 14 day [Range: 1-70 days] median duration of use that has been found in clinical use reported to date. Based on this information, the 1.9F and 2.6F Vascu-PICC®/Jet-PICC Peripherally Inserted Central 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 nine published literature articles representing 844 cases specific to the 1.9F & 2.6F Vascu-PICC® device family. The articles included two prospective studies (Yang et al., Zhou et al.), five retrospective studies (Luo et al., Richter et al., Uygun et al., Wang et al., Yanping et al.), and two case reports (Chen et al., Chen et al.).

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Chen Q, Hu Y, Su S, Huang X, Li Y. "AFGP" bundles for an extremely preterm infant who underwent difficult removal of a peripherally inserted central catheter: A case report. *WJCC*. 2021;9(17):4253-61.

Chen Q, Hu Y, Li Y, Huang X. Peripherally inserted central catheter placement in neonates with persistent left superior vena cava: Report of eight cases. *WJCC*. 2021;9(26):7944-53.
Luo, F., Cheng, X., Lou, X., Wang, Q., Fan, X., & Chen, S. (2020). Insertion of a 1.9F central venous catheter via the internal jugular vein in neonates. *J Int Med Res, 48*(6). doi:10.1177/0300060520925380
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Yang, L., Bing, X., Song, L., Na, C., Minghong, D., & Annuo, L. (2019). Intracavitary electrocardiogram guidance for placement of peripherally inserted central catheters in premature infants. *Medicine (Baltimore), 98*(50). doi:10.1097/md.0000000000018368
Richter, R. P., Law, M. A., Borasino, S., Surd, J. A., & Alten, J. A. (2016). Distal superficial femoral vein cannulation for peripherally inserted central catheter placement in infants with cardiac disease. *Congenital heart disease, 11*(6), 733-740.
Wang Y, Chen S, Yan W, et al. Congenital Short-Bowel Syndrome: Clinical and Genetic Presentation in China. *Journal of Parenteral and Enteral Nutrition*. 2021;45(5):1009-15.
Zhou, L., Xua, H., Xu, M., Hu, Y., & Lou, X. F. (2017). An Accuracy Study of the Intracavitary Electrocardiogram (IC-ECG) Guided Peripherally Inserted Central Catheter Tip Placement among Neonates. *Open Med (Wars), 12*, 125-130. doi:10.1515/med-2017-0019

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.

1 1.9F & 2.6F Vascu-PICC® case, described as 1.9F and Single Lumen, was collected. The following outcome measure was confirmed to be within State of the Art safety and performance outcome measures from published literature for Medcomp Vascu-PICC® 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.

10 1.9F & 2.6F Vascu-PICC® cases inclusive of several variant devices across French size (1.9F and 2.6F) 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 1.9F & 2.6F Vascu-PICC® devices:

- Dwell Time – 7.4 Days (95%CI: 0.68 – 14.12)
- Procedural Outcomes – 100%
- Phlebitis – No Events Reported
- Infiltration/Extravasation – No Events Reported
- Catheter Associated Venous Thrombus – No Events Reported
- Catheter Related Blood Stream Infection – No Events Reported

The variants included in the dataset are displayed below.

Variant	n	French Size(s)	Length(s)
1.9F Vascu-PICC	3	1.9F	50cm
2.6F Vascu-PICC	7	2.6F	20cm, 50cm

Source: PMCF_Medcomp_211

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

13 respondents responded that they or their facility have used Medcomp PICCs, with 2 of those respondents using the 1.9F & 2.6F Vascu-PICC device. There were no differences in mean user sentiments within PICCs 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 PICCs (n=13):

- (Mean Likert Scale Response) Catheters function as intended – 4.7 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.9 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 4.6 / 5
- Dwell Time (n=11) – 58.1 days (**95%CI:** 15.5 – 100.8)

The following data points were collected from users of Medcomp 1.9F & 2.6F Vascu-PICC (n=2):

- (Mean Likert Scale Response) Catheters function as intended – 5 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 5 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 5 / 5
- Dwell Time (n=2) – 45 days (**95%CI:** 0 – 235.6)

No information on complications was collected from users of Medcomp 1.9F & 2.6F Vascu-PICC devices.

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 in patients with small blood vessels, including neonates, in whom short-term or long-term peripheral 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 6.27 days	↑	10.3 - 18 days **(Summary of Published Literature)**	7.4 days **(PMCF_Infusion_211)** 45 days **(PMCF_Medcomp_211)** Likert Scale Response 4.5 / 5 **(PMCF_Medcomp_211)***
Procedural Outcomes	Greater than 43% (Bedside) / 90% (Interventional Radiology)	↑	88% - 100% **(Summary of Published Literature)**	100% **(PMCF_Infusion_211 & PMCF_Infusion_201)** Likert Scale Response 4 / 5 **(PMCF_Medcomp_211)***
Safety				
Phlebitis	Less than 2.4% catheters with reported incidents of phlebitis	↓	1.6% - 3.3% **(Summary of Published Literature)**	None Reported **(PMCF_Infusion_211)** Likert Scale Response 4.5 / 5 **(PMCF_Medcomp_211)***
Infiltration/Extravasation	Less than 7% catheters with reported incidents of infiltration or extravasation	↓	1.6% - 3.3% **(Summary of Published Literature)**	None Reported **(PMCF_Infusion_211)** Likert Scale Response 4.5 / 5 **(PMCF_Medcomp_211)***
Catheter Associated Venous Thrombus (CAVT)	Less than 5.4 incidents of CAVT per 1,000 catheter days	↓	4 of 34 PICCs (11.8%) were associated with deep venous thrombosis **(Summary of Published Literature)**	None Reported **(PMCF_Infusion_211)** Likert Scale Response 4.5 / 5 **(PMCF_Medcomp_211)***
Central Line Associated Blood Stream Infection (CLABSI) / Catheter Related Blood Stream Infection (CRBSI)	Less than 5.7 incidents of CLABSI/CRBSI per 1,000 catheter days	↓	0 - 5.6** per 1,000 catheter days **(Summary of Published Literature)**	None Reported **(PMCF_Infusion_211)** Likert Scale Response 4 / 5 **(PMCF_Medcomp_211)***

*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.
**Yanping et al., 2022 found the incidence of CLABSI to be 5.6 per 1,000 catheter days, but the incidence of CRBSI to be 1.46 per 1,000 catheter days. This wide variation suggests there may be reporting variation between these two definitions (where many data sources use them interchangeably).

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_PICC_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	• Requires surgical procedure, but IV does not • Risks associated with surgery: general anesthesia, etc. • Requires regular flushing	• Drug extravasations • Infection • Thromboembolism • Tissue necrosis of overlying skin / port dehiscence

Therapy	Benefits	Disadvantages	Key Risks
	• Reduces chance for corrosive medications to make skin contact • Only one venipuncture for both treatment and lab draws, as 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

Therapy	Benefits	Disadvantages	Key Risks
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	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
		indicators for ethylene oxide sterilization processes	
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
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

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
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 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-016 Rev. 5
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)	1.9F & 2.6F Vascu-PICC® Peripherally Inserted Central Catheter
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908289NV
Date first CE certificate was issued for this device	1.9F & 2.6F Vascu-PICC®- October 2008 1.9F & 2.6F Jet-PICC- October 2008

The devices in scope of this document are all peripherally inserted central catheter (PICC) 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
1.9F x 20cm Single Lumen Pediatric PICC	10533-820-001
1.9F x 50cm Single Lumen Pediatric PICC	10533-850-001
2.6F x 20cm Double Lumen Pediatric PICC	10539-820-001
2.6F x 50cm Double Lumen Pediatric PICC	10539-850-001
2.6F x 50cm Double Lumen Pediatric PICC w/ Cuff	10552-950-001

Procedure Trays:

Catalog Code	Part Number	Description
MR17012600	10539-850-001	2.6F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN CATHETER SET
MR17012601	10539-850-001	2.6F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC SET
MR170126024S	10539-850-001	2.6F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC MST SET
MR17012608	10552-950-001	2.6F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN WITH CUFF BASIC SET
MR17012621	10539-820-001	2.6F X 20CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC SET
MR170126224S	10539-820-001	2.6F X 20CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC MST SET
JSAP2.620	10539-820-001	2.6F X 20CM JET-PICC PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC SET
JSAP2.650	10539-850-001	2.6F X 50CM JET-PICC PERIPHERALLY INSERTED CENTRAL CATHETER DUAL LUMEN BASIC SET
JSAP1.920	10533-820-001	1.9F X 20CM JET-PICC PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET
JSAP1.950	10533-850-001	1.9F X 50CM JET-PICC PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET
MR17011100	10533-850-001	1.9F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN CATHETER SET
MR17011101	10533-850-001	1.9F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET
MR170111024S	10533-850-001	1.9F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC MST SET

Catalog Code	Part Number	Description
MR17011121	10533-820-001	1.9F X 20CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET
MR170111224S	10533-820-001	1.9F X 20CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC MST SET
VP1.9S20-NS	10533-820-001	1.9F X 20CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET WITHOUT STYLET
VP1.9S50-NS	10533-850-001	1.9F X 50CM VASCU-PICC® PERIPHERALLY INSERTED CENTRAL CATHETER SINGLE LUMEN BASIC SET WITHOUT STYLET

Configurations of Procedure Trays:

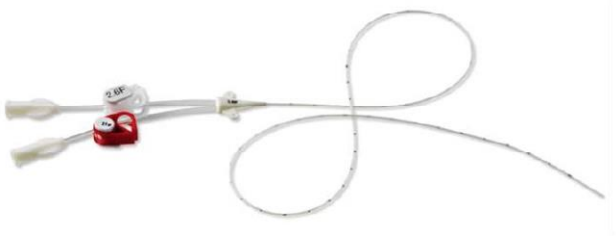
Configuration Type
Vascu-PICC® Catheter Set
Vascu-PICC® Basic Set
Vascu-PICC® Basic MST Set
Vascu-PICC® Basic Set without Stylet
Vascu-PICC® Basic Set with Cuff
Jet-PICC 1.9F Basic Set
Jet-PICC 2.6F Basic Set

2. Intended use of the device

Intended purpose	The 1.9F and 2.6F Vascu-PICC®/Jet-PICC Peripherally Inserted Central Catheters are intended for use in pediatric and neonate patients requiring frequent needlesticks for whom short-term or long-term peripheral 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 1.9F and 2.6F Vascu-PICC®/Jet-PICC Peripherally Inserted Central Catheter is indicated for short-term or long-term peripheral access to the central venous system for the intravenous administration of fluids or medications.
Intended patient group(s)	1.9F and 2.6F Vascu-PICC®/Jet-PICC Peripherally Inserted Central Catheters are for use in pediatric and neonate patients requiring frequent needlesticks for whom short-term or long-term peripheral access to the central venous system without requiring frequent needlesticks is deemed necessary based on the direction of a qualified, licensed physician.
Contraindications	• This catheter is not for any use other than that which is indicated. Do not implant catheter in thrombosed vessels. • The presence of skin related problems around the insertion site (infection, phlebitis, scars, etc.)

	• The presence of device related infection. • Previous history of venous/subclavian blood clots or vascular surgeries at insertion site. • Fever of unknown origin. • The patient's body size is too small to accommodate the size of the implanted device. • The patient is known or is suspected to be allergic to materials contained in the device. • Past irradiation of prospective insertion site. • Local tissue factors will prevent proper device security and/or access. • Known tape or Zinc Oxide adhesive allergies. • This catheter is not suitable for insertion through non-superficial veins.

3. Device description



*

Figure 1: Representative Image of 1.9F & 2.6F Vascu-PICC® device

Description of device	The 1.9F and 2.6F Jet-PICC Peripherally Inserted Central Catheter is used for short- or long-term central venous access, via peripheral insertion, during the administration of fluids, medication and nutritional therapy for neonates, infants and children. The lumen inner and outer sizes are the same throughout the entire length of the lumen tubing. Each catheter lumen terminates through an extension to a female connector. Each extension has an in-line clamp to control fluid flow and is marked with the lumen gauge size. The transition between the lumen and extension is housed within a molded hub. The hub is marked with the catheter French size. The lumen is marked with depth markers every centimeter.
Materials / substances in contact with patient tissue	The percentage ranges in the table below are based on the weight of the 1.9F x 20cm Single Lumen (2.85g) and 2.6F x 50cm Double Lumen w/ Cuff (4.16g) Vascu-PICC® devices.

Material	% Weight (w/w)
Polyurethane	56.04 - 68.86
Acetal Co-polymer	20.66 - 30.32

<table>
<tr><td></td><td>
<table>
<tr><td>Acrylonitrile Butadiene Styrene</td><td>8.95 - 13.13</td></tr>
<tr><td>Barium Sulfate</td><td>0.51 - 1.53</td></tr>
<tr><td>Polyethylene Terephthalate</td><td>0 - 0.33</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 devices utilize a Seldinger or Modified Seldinger technique to obtain access. The main difference is one technique utilizes an Introduction Sheath and one does not. The Seldinger techniques for venous access are well-known surgical techniques used for inserting PICC devices. The instructions for use of each catheter are detailed in the IFUs. Catheters are to be inserted, manipulated and removed by a qualified, licensed physician or other qualified health care professional utilizing strict aseptic technique.

Once in place, fluids are delivered or blood is withdrawn via the PICC catheter most commonly with a disposable tubing set or syringe. Catheter care includes use of a locking solution to maintain catheter patency. Catheter removal is normally done by gently pulling on the catheter, but removal may require that a surgical procedure be performed by a physician familiar with the appropriate techniques in some circumstances.</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>Description of accessories</td><td>
<table>
<tr><th>Name of Accessory</th><th>Description of Accessory</th></tr>
<tr><td>Guidewire</td><td>Acts as a path for other components.</td></tr>
<tr><td>Introducer Needle</td><td>Placed into the target vein to gain access.</td></tr>
<tr><td>Stylet</td><td>Assists in catheter placement.</td></tr>
<tr><td>Peelable Introducer</td><td>Used to get central venous access.</td></tr>
<tr><td>Scalpel</td><td>A cutting device.</td></tr>
<tr><td>Syringe</td><td>Helps get blood return once the needle punctures the vein.</td></tr>
<tr><td>Gauze</td><td>Used to clean blood.</td></tr>
<tr><td>Securement Device</td><td>Stabilization device.</td></tr>
<tr><td>Tourniquet</td><td>Stops the flow of blood.</td></tr>
</table>
</td></tr>
</table>

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.

<table>
<tr><td>How potential risks have been controlled or managed</td><td>There have been 222,776 devices sold since January 2019.

There are side effects and risks associated with the device. These include:

• Infection
• Bleeding
• Catheter Removal
• Catheter Replacement

These risks are reduced to an acceptable level. The labeling describes the risks. The benefit of the device is facilitating peripheral access when alternatives are not suitable. These benefits outweigh the risks.</td></tr>
<tr><td>Remaining risks and undesirable effects</td><td>The 1.9F & 2.6F Vascu-PICC® Peripherally Inserted Central Catheter is associated with risks. These include:

• Procedural Delays
• Thrombosis
• Infections
• Perforations
• Embolism
• Cardiac Event
• Dissatisfaction

These risks are consistent with risks of other peripherally inserted central 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><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: 222,776</th><th>Units Studied: 11</th></tr>
<tr><th># of Cases Per Event</th><th># of Cases Per Event</th></tr>
<tr><td>Allergic Reaction</td><td>1 Event in 200,000 Cases.</td><td>Not Reported.</td></tr>
<tr><td>Bleeding</td><td>1 Event in 200,000 Cases.</td><td>Not Reported.</td></tr>
<tr><td>Cardiac Event</td><td>1 Event in 200,000 Cases.</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 100,000 Cases.</td><td>Not Reported.</td></tr>
<tr><td>Perforation</td><td>1 Event in 200,000 Cases.</td><td>Not Reported.</td></tr>
</table>
</td></tr>
</table>

	Stenosis	Not Reported.	Not Reported.
	Tissue Injury	1 Event in 200,000 Cases.	Not Reported.
	Thrombosis	Not Reported.	Not Reported.
Warnings and precautions	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 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 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 the arm where the catheter is placed.		
Summary of any field safety correction action (FSCA)	There were no recalls for the device between 01 December 2023 to 31 August 2024.		

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 June 2009. All models included are planned for distribution in the European Union.
Clinical evidence for CE-marking
The clinical literature review identified 9 articles relating to the safety and/or performance of the subject device when used as intended. These articles included approximately 844 cases. Two patient level data activities received information on 11 catheters. 2 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 1.9F & 2.6F Vascu-PICC® 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 in patients with small blood vessels, including neonates. These benefits are for patients in whom short-term or long-term peripheral 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 222,776 devices sold from January 1st 2019, to August 31st, 2024. Also, during this period there were 132 complaints received resulting in a 0.059% 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. • Increased patient mobility. • Easier for outpatients.	• Requires surgery. • Surgery risks. • Requires maintenance. • High risk of infection or thrombosis.	• Infection • Occlusion • Malfunction • 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.	• Not suitable for continuous injections of most vesicants or irritants	• Phlebitis

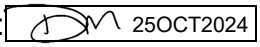
Therapy	Benefits	Disadvantages	Key Risks
	• Lower risk of infection compared to IVs • No X-ray required. • Decreased chance of extravasation.		
Peripherally Inserted Central Catheters (PICCs)	• Decreased risk of catheter occlusion compared to CVC • Fewer punctures compared to PIV	• Increased risk of 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
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
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):  25OCT2024