SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP-014

Dignity® and Pro-Fuse® Power Injectable Ports

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	12004
'MDR Documentation' File Number	MDR-014

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

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	**07NOV2022**	**27433**	**GM**	**Scheduled Update; updated SSCP in accordance with CER-014_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	**20JAN2023**	**27662**	**GM**	**Information related to product recalls has been added to Section 4 of the Users/Healthcare Professional Section and Section 4 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
5	**20OCT2023**	**28545**	**GM**	**Update in accordance with CER-014_D**	☐ Yes, this version was validated by the Notified Body in the following language: English ☐ No, this version was not validated by the

					Notified Body as this is a Class IIa or IIb implantable device

USERS / HEALTHCARE PROFESSIONALS

The following information is intended for users/healthcare professionals. Following this information there is a summary intended for patients.

1. Device identification and general information

Device trade name(s)	Dignity®, Jet Port, Pro-Fuse®, Jet-Fuse Power Injectable Ports
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	00884908287NR
Medical device nomenclature description / text	C01020499 – Subcutaneous Implantable Venous Access Port Systems - Other
Class of device	III
Date first CE certificate was issued for this device	Dignity® - May 2009 Jet Port – September 2008 Pro-Fuse® - January 2008 Jet-Fuse – January 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 implantable port sets. The device part numbers are organized into variant categories. These devices are distributed as procedure trays, in various configurations inclusive of accessories and adjunctive devices (see section “Accessories intended for use in combination with the Device”).

Variant Devices:

Dignity® / Jet Port Variant Devices

Variant Description	Part Number(s)	Explanation of Multiple Part Numbers
5F Dignity® Low Profile	30625-850CT	N/A
5F Dignity® Low Profile w/ Silicone Filled Suture Holes	30625-850SF	N/A
5F Dignity® Mid-Sized	30624-850CT	N/A
5F Dignity® / Jet Port Mini	30626-850CT 30626-950CT	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
5F Dignity® / Jet Port Mini w/ Silicone Filled Suture Holes	30626-850SF 30626-950SF	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
6.6F Dignity® / Jet Port Low Profile	30625-866CT 30625-966CT	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
6.6F Dignity® / Jet Port Low Profile w/ Silicone Filled Suture Holes	30625-866SF 30625-966SF	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
6.6F Dignity® / Jet Port Mid-Sized	30624-866CT 30624-966CT	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
6.6F Dignity® / Jet Port Mid-Sized w/ Silicone Filled Suture Holes	30624-866SF	N/A
6.6F Dignity® / Jet Port Mini	30626-866CT	N/A
6.6F Dignity® / Jet Port Mini w/ Silicone Filled Suture Holes	30626-866SF 30626-966SF	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
8F Dignity® / Jet Port Low Profile	30625-880CT 30625-980CT	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
8F Dignity® / Jet Port Low Profile w/ Silicone Filled Suture Holes	30625-880SF 30625-980SF	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
8F Dignity® / Jet Port Mid-Sized	30624-880CT 30624-980CT	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)

Variant Description	Part Number(s)	Explanation of Multiple Part Numbers
8F Dignity® / Jet Port Mid-Sized w/ Silicone Filled Suture Holes	30624-880SF 30624-980SF	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
8F Dignity® / Jet Port Mini	30626-880CT	N/A
8F Dignity Mini w/ Silicone Filled Suture Holes	30626-880SF 30626-980SF	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
9.6F Dignity® / Jet Port Mid-Sized	30624-896CT 30624-996CT	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
9.6F Dignity® / Jet Port Mid-Sized w/ Silicone Filled Suture Holes	30624-896SF	N/A

Pro-Fuse® / Jet-Fuse Variant Devices

Variant Description	Part Number(s)	Explanation of Multiple Part Numbers
6.6F Pro-Fuse® / Jet-Fuse Low Profile	30623-866CT 30623-966CT	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
6.6F Pro-Fuse® / Jet-Fuse Low Profile w/ Silicone Filled Suture Holes	30623-866SF	N/A
8F Pro-Fuse® / Jet-Fuse Low Profile	30623-880CT	N/A
8F Pro-Fuse® / Jet-Fuse Standard	30622-880CT 30622-980CT	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)
9.6F Pro-Fuse® / Jet-Fuse Standard	30622-896CT 30622-996CT	No significant clinical, biological, or technical difference (only difference is whether catheter is pre-assembled)

Procedure Trays:

Dignity® Procedure Trays

Catalog Code	Part Number	Description
MICTI5004S	30625-850SF	5F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI5004SM	30626-850SF	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI50041M	30626-850CT	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET

Catalog Code	Part Number	Description
MRCTI50001	30624-850CT	5F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI5004SM	30626-850SF	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI50041	30625-850CT	5F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI50041DMP	30625-850CT	5F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI50041M	30626-850CT	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI50041MDMP	30626-850CT	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI5084SM	30626-950SF	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI50841M	30626-950CT	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MICTI6600S	30624-866SF	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH 5F MICRO-STICK® SET
MICTI66001	30624-866CT	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH 5F MICRO-STICK® SET
MICTI6604S	30625-866SF	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI6604SM	30626-866SF	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI66041	30625-866CT	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI66041M	30626-866CT	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI66841	30625-966CT	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MRCTI6600S	30624-866SF	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI66001	30624-866CT	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI66001DMP	30624-866CT	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH DIRECT MICROPUNCTURE SET
MRCTI6604S	30625-866SF	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI6604SM	30626-866SF	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI66041	30625-866CT	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI66041DMP	30625-866CT	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI66041M	30626-866CT	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI66041MDMP	30626-866CT	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI66801	30624-966CT	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET

Catalog Code	Part Number	Description
MRCTI66801DMP	30624-966CT	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH DIRECT MICROPUNCTURE SET
MRCTI6684S	30625-966SF	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI6684SM	30626-966SF	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI66841	30625-966CT	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MICTI8000S	30624-880SF	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH 5F MICRO-STICK® SET
MICTI80001	30624-880CT	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH 5F MICRO-STICK® SET
MICTI8004S	30625-880SF	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI8004SM	30626-880SF	8F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI80041	30625-880CT	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI80041M	30626-880CT	8F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI8084SM	30626-980SF	8F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI80841	30625-980CT	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MRCTI8000S	30624-880SF	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI80001	30624-880CT	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI80001DMP	30624-880CT	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH DIRECT MICROPUNCTURE SET
MRCTI8004S	30625-880SF	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI80041	30625-880CT	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI80041DMP	30625-880CT	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI80041M	30626-880CT	8F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI80041MDMP	30626-880CT	8F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI8080S	30624-980SF	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI80801	30624-980CT	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI8084S	30625-980SF	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI80841	30625-980CT	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI9600S	30624-896SF	9.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET

Catalog Code	Part Number	Description
MRCTI96001	30624-896CT	9.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI96801	30624-996CT	9.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET

Jet Port Procedure Trays

Catalog Code	Part Number	Description
JSACTI5004SM	30626-850SF	5F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI50041M	30626-850CT	5F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI5084SM	30626-950SF	5F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI50841M	30626-950CT	5F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI6600S	30624-866SF	6.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI66001	30624-866CT	6.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI6604S	30625-866SF	6.6F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI6604SM	30626-866SF	6.6F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI66041	30625-866CT	6.6F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI66041M	30626-866CT	6.6F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI66801	30624-966CT	6.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI6684S	30625-966SF	6.6F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI6684SM	30626-966SF	6.6F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI66841	30625-966CT	6.6F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI8000S	30624-880SF	8F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI80001	30624-880CT	8F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI8004S	30625-880SF	8F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI80041	30625-880CT	8F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI80041M	30626-880CT	8F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI8080S	30624-980SF	8F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI80801	30624-980CT	8F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI8084S	30625-980SF	8F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI80841	30625-980CT	8F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI9600S	30624-896SF	9.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI96001	30624-896CT	9.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI96801	30624-996CT	9.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET

Pro-Fuse® Procedure Trays

Catalog Code	Part Number	Description
MRCTT6604S	30623-866SF	6.6F PRO-FUSE® POWER INJECTABLE LOW PROFILE PORT SET
MRCTT66041	30623-866CT	6.6F PRO-FUSE® POWER INJECTABLE LOW PROFILE PORT SET
MRCTT66841	30623-966CT	6.6F PRO-FUSE® POWER INJECTABLE LOW PROFILE PORT SET
MRCTT80001	30622-880CT	8F PRO-FUSE® POWER INJECTABLE PORT SET
MRCTT80001DMP	30622-880CT	8F PRO-FUSE® POWER INJECTABLE PORT WITH DIRECT MICROPUNCTURE SET
MRCTT80041	30623-880CT	8F PRO-FUSE® POWER INJECTABLE LOW PROFILE PORT SET
MRCTT80041DMP	30623-880CT	8F PRO-FUSE® POWER INJECTABLE LOW PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTT80801	30622-980CT	8F PRO-FUSE® POWER INJECTABLE PORT SET
MRCTT96001	30622-896CT	9.6F PRO-FUSE® POWER INJECTABLE PORT SET
MRCTT96801	30622-996CT	9.6F PRO-FUSE® POWER INJECTABLE PORT SET

Jet-Fuse Procedure Trays in Scope of Clinical Evaluation

Catalog Code	Part Number	Description
JSACTT6604S	30623-866SF	6.6F JET-FUSE POWER INJECTABLE LOW PROFILE PORT SET
JSACTT66041	30623-866CT	6.6F JET-FUSE POWER INJECTABLE LOW PROFILE PORT SET
JSACTT66841	30623-966CT	6.6F JET-FUSE POWER INJECTABLE LOW PROFILE PORT SET
JSACTT80001	30622-880CT	8F JET-FUSE POWER INJECTABLE PORT SET
JSACTT80041	30623-880CT	8F JET-FUSE POWER INJECTABLE LOW PROFILE PORT SET
JSACTT80801	30622-980CT	8F JET-FUSE POWER INJECTABLE PORT SET
JSACTT96001	30622-896CT	9.6F JET-FUSE POWER INJECTABLE PORT SET
JSACTT96801	30622-996CT	9.6F JET-FUSE POWER INJECTABLE PORT SET

Configurations of Procedure Trays:

Configuration Type	Kit Components
Dignity® Set	(1) Dignity® Power Injectable Port, (1) Catheter, (2) Catheter Locks, (1) Safety Scalpel, (1) 1.3mm OD x 1.0mm ID x 70mm (18GA) Needle w/ Echo Tip, (1) 0.90mm x 70cm (.035) Guidewire J (R 3mm) Tip, (1) 10cc Syringe, (1) Peelable Introducer: (5F Sets) 1.7mm ID x 10cm (5.5F) Peelable Introducer, (6.6F Sets) 2.3mm ID x 14cm (7F) Valved Peelable Introducer, (8F Sets) 3.0mm ID x 14cm (9F) Valved Peelable Introducer, (9.6F Sets) 3.3mm ID x 14cm (10F) Valved Peelable Introducer, (1) Tunneler, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Straight, (1) 0.72mm x 25mm

Configuration Type	Kit Components
	RW (22GA) Huber Needle- Right-Angle, (1) Blunt Tip Needle, (1) Vein Pick, (1) Patient Information Pack, (1) Patient ID Card
Dignity® Set with Micro-Stick®	(1) Dignity® Power Injectable Port, (1) Catheter, (2) Catheter Locks, (1) Safety Scalpel, (1) 0.90mm x 70cm (.035) Guidewire J (R 3mm) Tip, (1) 10cc Syringe, (1) Peelable Introducer: (5F Sets) 1.7mm ID x 10cm (5.5F) Peelable Introducer, (6.6F Sets) 2.3mm ID x 14cm (7F) Valved Peelable Introducer, (8F Sets) 3.0mm ID x 14cm (9F) Valved Peelable Introducer, (1) Tunneler, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Straight, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Right-Angle, (1) Blunt Tip Needle, (1) Vein Pick, (1) Patient Information Pack, (1) Patient ID Card, (1) 1.0mm ID x 9.4cm (5F) (OD) Coaxial Dilator Assembly, (1) 0.47mm x 45cm (.018) Guidewire Straight Tip, (1) 0.9mm OD x 0.5mm ID x 70mm (21GA) Needle w/ Echo Tip
Dignity® Set with Direct Micropuncture	(1) Dignity® Power Injectable Port, (1) Catheter, (2) Catheter Locks, (1) Safety Scalpel, (1) 0.9mm OD x 0.5mm ID x 70mm (21GA) Needle w/Echo Tip, (1) 0.47mm x 45cm (.018) Guidewire Straight Tip, (1) 10cc Syringe, (1) Peelable Introducer: (5F Sets) 1.8mm ID x 10cm (5.5F) Peelable Introducer, (6.6F Sets) 2.3mm ID x 14cm (7F) Valved Peelable Introducer, (8F Sets) 3.0mm ID x 14cm (9F) Valved Peelable Introducer, (1) Tunneler, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Right-Angle, (1) Blunt Tip Needle, (1) Patient Information Pack, (1) Patient ID Card
Jet Port Set	(1) Jet Power Injectable Port, (1) Catheter, (2) Catheter Locks, (1) Safety Scalpel, (1) 1.3mm OD x 1.0mm ID x 70mm (18GA) Needle w/ Echo Tip, (1) 0.90mm x 70cm (.035) Guidewire J (R 3mm) Tip, (1) 10cc Syringe, (1) Peelable Introducer: (5F Sets) 1.7mm ID x 10cm (5.5F) Peelable Introducer, (6.6F Sets) 2.3mm ID x 14cm (7F) Valved Peelable Introducer, (8F Sets) 3.0mm ID x 14cm (9F) Valved Peelable Introducer, (9.6F Sets) 3.3mm ID x 14cm (10F) Valved Peelable Introducer, (1) Tunneler, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Straight, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Right-Angle, (1) Blunt Tip Needle, (1) Vein Pick, (1) Patient Information Pack, (1) Patient ID Card
Pro-Fuse® Set	(1) Pro-Fuse® Power Injectable Port, (1) Catheter, (2) Catheter Locks, (1) Safety Scalpel, (1) 1.3mm OD x 1.0mm ID x 70mm (18GA) Needle w/ Echo Tip, (1) 0.90mm x 70cm (.035) Guidewire J (R 3mm) Tip, (1) 10cc Syringe, (1) Peelable Introducer: (6.6F Sets) 2.3mm ID x 14cm (7F) Valved Peelable Introducer, (8F Sets) 3.0mm ID x 14cm (9F) Valved Peelable Introducer, (9.6F Sets) 3.3mm ID x 14cm (10F) Valved Peelable Introducer, (1) Tunneler, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Straight, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Right-Angle, (1) Blunt Tip Needle, (1) Vein Pick, (1) Patient Information Pack, (1) Patient ID Card
Pro-Fuse® Set with Direct Micropuncture	(1) Pro-Fuse® Power Injectable Port, (1) Catheter, (2) Catheter Locks, (1) Safety Scalpel, (1) 0.9mm OD x 0.5mm ID x 70mm (21GA) Needle w/ Echo Tip, (1) 0.47mm x 45cm (.018) Guidewire Floppy Straight Tip, (1) 10cc Syringe, (1) 3.0mm ID x 14cm (9F) Valved Peelable Introducer, (1) Tunneler, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Right-Angle, (1) Blunt Tip Needle, (1) Patient Information Pack, (1) Patient ID Card

Configuration Type	Kit Components
Jet-Fuse Set	(1) Jet-Fuse Power Injectable Port, (1) Catheter, (2) Catheter Locks, (1) Safety Scalpel, (1) 1.3mm OD x 1.0mm ID x 70mm (18GA) Needle w/ Echo Tip, (1) 0.90mm x 70cm (.035) Guidewire J (R 3mm) Tip, (1) 10cc Syringe, (1) Peelable Introducer: (6.6F Sets) 2.3mm ID x 14cm (7F) Valved Peelable Introducer, (8F Sets) 3.0mm ID x 14cm (9F) Valved Peelable Introducer, (9.6F Sets) 3.3mm ID x 14cm (10F) Valved Peelable Introducer, (1) Tunneler, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Straight, (1) 0.72mm x 25mm RW (22GA) Huber Needle- Right-Angle, (1) Blunt Tip Needle, (1) Vein Pick, (1) Patient Information Pack, (1) Patient ID Card

2. Intended use of the device

Intended purpose	The Dignity®/Pro-Fuse®/Jet Port/Jet-Fuse Power Injectable Ports are intended for use in adult patients requiring frequent needlesticks for whom 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.
Indication(s)	The Dignity®/Pro-Fuse®/Jet Port/Jet-Fuse Power Injectable Port is indicated for long-term access to the central venous system for intravenous administration of fluids or medications, power injection of contrast media, and withdrawal of blood samples.
Target population(s)	The Dignity®/Pro-Fuse®/Jet Port/Jet-Fuse Power Injectable Ports are intended for use in adult patients requiring frequent needlesticks for whom 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.
Contraindications and/or limitations	This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off. The device is also contraindicated: • When the presence of device related infection, bacteremia, or septicemia is known or suspected. • When the patient's body size is insufficient for the size of the implanted device. • When the patient is known or is suspected to be allergic to materials contained in the device. • If severe chronic obstructive lung disease exists. • If the prospective insertion site has been previously irradiated. • If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures. • If local tissue factors will prevent proper device stabilization and/or access.

3. Device description

Figure 1: Representative Image of Dignity®/Jet Port Mini

Figure 2: Representative Image of Dignity®/Jet Port Low Profile

Figure 3: Representative Image of Dignity®/Jet Port Mid-Sized

Figure 4: Representative Image of Pro-Fuse®/Jet-Fuse Low Profile

Figure 5: Representative Image of Pro-Fuse®/Jet-Fuse Standard

Description of device	**Dignity®** The Dignity® Power Injectable Ports are an implantable venous access device. Port access is performed by percutaneous needle insertion using a non-coring needle. The Dignity® Power Injectable Port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Dignity® Power Injectable Ports can be identified subcutaneously by feeling the top of the septum and the top rim of the port housing. Dignity® Power Injectable Ports can be identified by the letters “CT” under radiographic imaging. Sizes include Dignity® Mini Profile, Dignity® Mid-Sized and Dignity® Low Profile. Power injection is performed using a power injectable needle only. For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19- or 20-gauge non-coring power injectable needle. The maximum recommended infusion rate is 2ml/s with a 22-gauge non-coring power injectable needle. **Pro-Fuse®** The Pro-Fuse® Power Injectable Ports are an implantable venous access device. Port access is performed by percutaneous needle insertion using a non-coring needle. The Pro-Fuse® Power Injectable Port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Pro-Fuse® Power Injectable Ports can be identified subcutaneously by feeling the top of the septum and the top rim of the port housing. Pro-Fuse® Power Injectable Ports can be identified by the letters “CT” under radiographic imaging. Sizes include Pro-Fuse® & Pro-Fuse® Low Profile. Power injection is performed using a power injectable needle only. For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19- or 20-gauge non-coring power injectable needle. The maximum recommended infusion rate is 2ml/s with a 22-gauge non-coring power injectable needle. **Jet Port** The Jet Port Power Injectable Ports are an implantable venous access device. Port access is performed by percutaneous needle insertion using a non-coring needle. The Jet Port Power Injectable Port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Jet Port Power Injectable Ports can be identified subcutaneously by feeling the top of the septum and the top rim of the port housing. Jet Port Power Injectable Ports can be identified by the letters “CT” under radiographic imaging. Sizes include Jet Port Mini Profile, Jet Port Mid-Sized and Jet Port Low Profile. Power injection is performed using a power injectable needle only. For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19- or 20-gauge non-coring power injectable needle. The maximum recommended infusion rate is 2ml/s with a 22-gauge non-coring power injectable needle.

<table>
<tr><td></td><td>Jet-Fuse
The Jet-Fuse Power Injectable Ports are an implantable venous access device. Port access is performed by percutaneous needle insertion using a non-coring needle.
The Jet-Fuse Power Injectable Port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Jet-Fuse Power Injectable Ports can be identified subcutaneously by feeling the top of the septum and the top rim of the port housing. Jet-Fuse Power Injectable Ports can be identified by the letters “CT” under radiographic imaging. Sizes include Jet-Fuse & Jet-Fuse Low Profile. Power injection is performed using a power injectable needle only.
For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19- or 20-gauge non-coring power injectable needle. The maximum recommended infusion rate is 2ml/s with a 22-gauge non-coring power injectable needle.</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 assembled 5F (5.52g) and 9.6F (6.44g) Power Injectable Dignity Ports.

Dignity® Ports
<table><tr><th>Material</th><th>% Weight (w/w)</th></tr><tr><td>Polysulfone</td><td>30.17 – 53.18</td></tr><tr><td>Silicone</td><td>10.39 – 59.21</td></tr><tr><td>Polyurethane</td><td>0.75 – 41.32</td></tr><tr><td>Barium Sulfate</td><td>6.42 – 11.72</td></tr><tr><td>Titanium</td><td>1.76 – 2.98</td></tr><tr><td>Polycarbonate</td><td>0.04 – 1.96</td></tr></table>
The percentage ranges in the table below are based on the weight of the assembled 5F (5.32g) and 9.6F (14.22g) Pro-Fuse Power Injectable Ports.

Pro-Fuse® Ports
<table><tr><th>Material</th><th>% Weight (w/w)</th></tr><tr><td>Polysulfone</td><td>28.16 - 39.92</td></tr><tr><td>Silicone</td><td>11.1 - 65.05</td></tr><tr><td>Polyurethane</td><td>0.02 - 40.7</td></tr><tr><td>Barium Sulfate</td><td>5.5 - 11.48</td></tr><tr><td>Titanium</td><td>1.51 - 2.54</td></tr><tr><td>Polycarbonate</td><td>0.76 - 2.03</td></tr></table></td></tr>
</table>

<table>
<tr><td></td><td><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>
<tr><td>How the device achieves its intended mode of action</td><td>The subject device can be inserted using a percutaneous or cutdown surgical technique. Catheter insertion is to be performed using aseptic techniques in a sterile field, preferably in an operating room.

Once the port placement site is healed sufficiently following implantation, port access is done by percutaneous needle insertion using a non-coring needle. Power injection is performed using a power injectable needle only. Subject devices consist of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Implanted ports can be identified subcutaneously by feeling the top of the septum and the top rim of the port housing. Power injectable ports can be identified by the letters “CT” under radiographic imaging.</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></table><table><tr><th>Part Number</th><th>Description</th></tr><tr><td>30330-018</td><td>0.47mm x 45cm (.018) Guidewire Floppy Straight Tip</td></tr><tr><td>30718</td><td>0.72mm x 25mm RW (22GA) Huber Needle- Right-Angle</td></tr><tr><td>30717</td><td>0.72mm x 25mm RW (22GA) Huber Needle- Straight</td></tr><tr><td>3086M</td><td>0.90mm x 70cm (.035) Guidewire Floppy J (R 3mm) Tip</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>10472-050</td><td>1.0mm ID X 9.4cm (5F) (OD) Coaxial Dilator Assembly</td></tr><tr><td>30394-018</td><td>1.24mm x 19mm TW (18GA) Blunt Tip Needle</td></tr><tr><td>30205-180</td><td>1.3mm OD x 1.0mm ID x 70mm (18GA) Needle W/Echo Tip</td></tr><tr><td>30394-017</td><td>1.47mm x 19mm TW (17GA) Blunt Tip Needle</td></tr><tr><td>10526-10-055</td><td>1.7mm ID x 10cm (5.5F) Peelable Introducer</td></tr><tr><td>30394-015</td><td>1.80mm x 19mm TW (15GA) Blunt Tip Needle</td></tr><tr><td>10700-10-055</td><td>1.8mm ID x 10cm (5.5F) Peelable Introducer</td></tr><tr><td>10680-070-15-2</td><td>2.3mm ID x 14cm (7F) Valved Peelable Introducer</td></tr><tr><td>10694-070-15-2</td><td>2.3mm ID x 14cm (7F) Valved Peelable Introducer</td></tr><tr><td>10680-090-15-2</td><td>3.0mm ID x 14cm (9F) Valved Peelable Introducer</td></tr></table></td></tr>
</table>

	10694-090-15-2	3.0mm ID x 14cm (9F) Valved Peelable Introducer
	10680-100-15-2	3.3mm ID x 14cm (10F) Valved Peelable Introducer
	5104	Advancer
	30479	Scalpel
	3073	Syringe
	30409-6	Tunneler
	30375	Tunneler
	30579-800	Tunneler
	30391	Vein Pick

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 Inflammation, Necrosis, or Scarring of Skin Over Implant Area Soft Tissue Injury Thoracic Duct Injury
Thrombosis	Venous Thrombosis Ventricular Thrombosis

	Fibrin Sheath Formation
Miscellaneous complications	Catheter or Port Erosion Through Skin Device Rotation or Extrusion 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 2016 – 30 June 2021)	PMCF Events
	Units Sold: 358,615	Units Studied: 195
	% of Devices	% of Devices
Allergic Reaction	Not Reported	Not Reported
Bleeding	Not Reported	Not Reported
Cardiac Event	0.0003%	Not Reported
Embolism	0.0011%	Not Reported
Infection	0.0006%	7.69%
Perforation	Not Reported	Not Reported
Stenosis	Not Reported	Not Reported
Tissue Injury	0.0008%	Not Reported
Thrombosis	0.0014%	1.54%

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:

During Placement:

- 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 bend catheter at sharp angles during implantation. This can compromise catheter patency.
- Do not allow accidental device contact with sharp instruments. Mechanical damage may occur. Use only smooth edged, atraumatic clamps or forceps.
- Do not suture catheter to port. Any damage or constriction of catheter may compromise power injection performance.
- Do not power inject through a port system that exhibits signs of clavicle-first rib compression or pinch-off as it may result in port system failure.
- Do not use sutures to secure catheter to the port stem as it could collapse or damage the catheter.
- Do not resterilize the port or accessories by any method.

	• Contents sterile and non-pyrogenic in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE
	• Do not re-use port 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 port or accessories if package is opened or damaged.
	• Do not use port or accessories if any sign of product damage is visible or the use-by date has passed.
	
	During Port Access:
	• Do not use a syringe smaller than 10ml. Prolonged infusion pressure greater than 25 psi may cause damage to a patient's vessels or viscus.
	• Failure to warm contrast media to body temperature prior to power injection may result in port system failure.
	• Failure to ensure patency of the catheter prior to power injection studies may result in port system failure.
	• Power injector machine pressure limiting feature may not prevent over pressurization of an occluded catheter.
	• Exceeding the maximum flow rate may result in port system failure and/or catheter tip displacement.
	• Power Injectable Implantable Infusion Port device indication for power injection of contrast media implies the Port's ability to withstand the procedure but does not imply appropriateness of the procedure for a particular patient nor for a particular infusion set. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure and for evaluating the suitability of any infusion set used to access the port.
	• Do not exceed a 325 psi pressure limit setting, or the maximum flow rate setting on the power injection machine, if power injecting through the Power Injectable Implantable Infusion Port device.
	• Medical procedures on a patient's arm in which the system is implanted should be restricted as follows:
	  ○ Do not withdraw blood from or infuse medication into any area of the arm where the system is located unless you are using the port.
	  ○ Do not measure the patient's blood pressure on this arm.
	
	Precautions listed in the IFUs are as follows:
	
	• Carefully read and follow all instructions prior to use.
	• 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.
	• Only qualified healthcare practitioners should insert, manipulate, and remove these devices.
	• Use only non-coring needles with the port.

	• Prior to advancing the catheter lock, ensure that the catheter is properly positioned. A catheter not advanced to the proper region may not seat securely and lead to dislodgment and extravasation. The catheter must be straight with no sign of kinking. A slight pull on the catheter is sufficient to straighten it. Advancing the catheter lock over a kinked catheter may damage the catheter. • Follow Universal Precautions when inserting and maintaining the catheter. • Follow all contraindications, warnings, precautions, and instructions for all infusates as specified by their manufacturers. • Precautions are intended to help avoid catheter damage and/or patient injury. • When utilizing the port for arm placement, the port should not be placed in the axillary cavity. • Discard biohazard according to facility protocol. • Power Injectable Implantable Infusion Ports are only power injectable when accessed with a power injectable needle. • 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. Additional Precautions Prior to Placement: • Inspect kit for presence of all components. • Check patient's records, and ask patient, whether they have any known allergies to chemicals or materials that will be used during the placement procedure. • Fill (prime) the device with sterile heparinized saline or normal saline solution to help avoid air embolism. Remember that some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their port primed with heparinized saline. • When using an introducer kit, verify that the catheter fits easily through the introducer sheath. Additional Precautions During Placement: • Avoid inadvertent puncture of the skin or fascia with the tip of the tunneler. • Avoid vessel perforation. • Take care not to perforate, tear, or fracture the catheter during placement. After assembling catheter to port, check assembly for leaks or damage. • During placement through a sheath, hold thumb over exposed opening of sheath to prevent air aspiration. The risk of air

<table>
<tr><td></td><td>aspiration is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver.
• 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.
• Carefully follow the connection technique given in these instructions to ensure proper catheter connection and to avoid catheter damage.
• When using peel-apart introducers:
o Carefully insert the introducer and catheter to avoid inadvertent penetration to vital structures in the thorax.
o Avoid blood vessel damage by maintaining a catheter or dilator as internal support when using a peel-apart introducer.
o Avoid sheath damage by simultaneously advancing the sheath and dilator as a single unit using a rotational motion.</td></tr>
<tr><td>Other relevant aspects of safety
(ex. field safety corrective actions, etc.)</td><td>For a period of 01 January 2016 to 31 September 2022 there were 83 complaints for 339,352 units sold, giving an overall complaint rate of 0.024%. For a period from 01 July 2021 to 31 September 2022, there were 1 FDA Medical Device Reporting (FDA MDR) reportable complaints and 1 Medical Device Vigilance (MDV) complaints reportable to the applicable European Competent Authority. There were no death-related events. Four events resulted in recalls, as shown in the below table.
<table>
<tr><th>Event Number</th><th>Recall Initiation Date</th><th>Event summary</th><th>Status</th></tr>
<tr><td>Z-1271-2017 (FDA)</td><td>22 NOV 2017</td><td>8F Dignity Port packaged with incorrect guidewire.</td><td>Closed 11 JUL 2018, all 24 units accounted for 21 products were used (no additional complaints reported) and 3 products returned</td></tr>
<tr><td>Z-1536-2017 (FDA)</td><td>23 FEB 2017</td><td>9.6F Dignity Port packaged with incorrect sized valved peelable introducer.</td><td>Closed 21 FEB 2018, all 71 units accounted for 25 products were used (no additional complaints reported) and 46 products returned.</td></tr>
<tr><td>Z-0533-2018 (FDA)</td><td>01 JUN 2017</td><td>6.6F Dignity Port packaged with incorrect sized introducer needle.</td><td>Closed 04 SEP 2018 all 65 units accounted for 50 products were used (no additional complaints reported) and 15 products returned.</td></tr>
<tr><td>Z-1184-2021 (FDA)</td><td>25 JAN 2021</td><td>5F Dignity CT Port kits were packaged with</td><td>As of 22 MAY 2022, Medcomp received recall responses from 63% of</td></tr>
</table></td></tr>
</table>

			the incorrect size port.	recipients of device. Thirteen units were returned and scrapped. No additional complaints reported.

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

Summary of clinical data related to the subject device

Product Family	Clinical Literature	PMCF Data	Total	User Survey Responses
Dignity®	444 (& 4,781 Mixed Cohort Cases)	141	585 (& 4,781 Mixed Cohort Cases)	22
Pro-Fuse®	209	54	263	5

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 Dignity® Power Injectable Port, 33 devices had a 140.42 day [95%CI: 106.62-174.23 days] duration of use that has been found in clinical use reported to date. In the case of the Pro-Fuse® Power Injectable Port, 18 devices had a 135.28 day [95%CI: 83.34-187.22 days] duration of use that has been found in clinical use reported to date. Based on this information, the Dignity®/Jet Port/Pro-Fuse®/Jet-Fuse Power Injectable Port 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 fifteen published literature articles representing 209 Pro-Fuse® device family specific cases, 444 Dignity® device family specific

cases, and an additional 4,781 mixed cohort cases inclusive of the Dignity® device family. The articles included a randomized controlled trial (Chen et al., 2022), prospective studies (Fonseca et al., 2016, Son et al., 2020), retrospective studies (Annetta et al., 2021, Bertoglio et al., 2022, Chou et al., 2019, Li et al., 2022, Pike et al., 2021, Salawu et al., 2022, Tumay et al., 2021, Yang et al., 2018, Yun et al., 2021, Zhang et al., 2018), a technical study (Wu et al.), and a procedure explanation (Kim et al.).

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Source: Dr Trerotola Data Report

The dataset was provided by Scott O. Trerotola, MD an Interventional Radiologist at the Hospital of the University of Pennsylvania. Dr. Trerotola is also Stanley Baum Professor of Radiology, Professor of Radiology in Surgery, Vice Chair for Quality, Radiology, Associate Chair and Chief, Interventional Radiology, and Director, Penn HHT Center of Excellence at the Perelman School of Medicine at the University of Pennsylvania. The dataset is consecutive, comprehensive, and includes catheter placements by interventional radiology Attending and Fellowship Physicians, as well as Residents under Attending supervision.

100 Dignity Port® cases, all identified as 8F Dignity® Mid-Sized ports, 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 Dignity® devices:

- Dwell Time – 380.2 Days (**95%CI:** 308 – 452.4)
- Procedural Outcomes – 100%
- Port/Catheter Separation – 1% (**95%CI:** 0% - 3%)
- Catheter Associated Venous Thrombus – 0.03 per 1,000 Catheter Days
- Catheter Related Blood Stream Infection – 0.39 per 1,000 Catheter Days
- Power Injection Related Complications – No Events Reported

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.

41 Dignity® Port and 54 Pro-Fuse® cases inclusive of several variant devices across French size (5F, 6.6F, 8F, and 9.6F) and port configuration (Dignity® Mini, Dignity® Low Profile, Dignity® Mid-Sized, Pro-Fuse® Standard) 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 Port devices:

Dignity® Port:

- Dwell Time – 140.42 Days (**95%CI:** 106.62 – 174.23)
- Procedural Outcomes – 100%
- Port/Catheter Separation – No Events Reported
- Catheter Associated Venous Thrombus – 0.43 per 1,000 Catheter Days (**95%CI:** 0 – 1.03)
- Catheter Related Blood Stream Infection – No Events Reported
- Power Injection Related Complications – No Events Reported

Pro-Fuse® Port:

- Dwell Time – 135.28 Days (**95%CI:** 83.34 – 187.22)
- Procedural Outcomes – 100%
- Port/Catheter Separation – No Events Reported
- 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)
Dignity Port Mini	9	5F, 6.6F, 8F
Dignity Port Low Profile	25	6.6F, 8F
Dignity Port Mid-Sized	7	8F, 9.6F
Pro-Fuse Port Standard	54	8F, 9.6F

Source: PMCF_Medcomp_211

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

24 respondents responded that they or their facility have used Medcomp implantable ports, with 22 of those respondents using the Dignity® device and 5 of those respondents using the Pro-Fuse® device. There were no differences in mean user sentiments within short-term hemodialysis catheters across State of the Art Performance and Safety Outcome Measures or between device types relating to safety or performance.

The following data points were collected from users of Medcomp implantable ports (n=24):

- (Mean Likert Scale Response) Catheters function as intended – 4.7 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.7 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 4.8 / 5 *(n=23)*
- Dwell Time (n=22) – 543 days (**95%CI:** 199 – 887)

The following data points were collected from users of Medcomp Dignity® Ports (n=22):

- (Mean Likert Scale Response) Catheters function as intended – 4.7 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 4.7 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 4.8 / 5 *(n=21)*
- Dwell Time (n=20) – 578 days (**95%CI:** 201 – 954)

The following data points were collected from users of Medcomp Pro-Fuse® Ports (n=5):

- (Mean Likert Scale Response) Catheters function as intended – 5 / 5
- (Mean Likert Scale Response) Packaging allows for aseptic presentation – 5 / 5
- (Mean Likert Scale Response) Benefit outweighs the risk – 5 / 5
- Dwell Time (n=5) – 224.1 days (**95%CI:** 46.5 – 401.7)

The following complications were reported for Dignity® and Pro-Fuse® Ports:

- Infection (1 out of 100 Cases)
- Site Infection (1 out of 100 Cases)
- Fibrin Sheath (1 out of 100 Cases)
- Malposition (No Comments on Frequency)
- Port Flipped (No Comments on Frequency)
- Detached Catheter (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 access to the central venous system in patients in whom other therapies are not indicated or desirable as determined by the physician, outweigh the overall and individual risks when the device is used as intended by the manufacturer. It is the manufacturer's and clinical expert evaluator's opinion that activities both complete and ongoing are sufficient to support the safety, efficacy, and acceptable benefit/risk profile of the subject devices.

Dignity® Outcome Parameters Across Data Sources

Outcome	Benefit/Risk Acceptability Criteria	Desired Trend	Clinical Literature (Subject Device)	PMCF Data (Subject Device)
Performance				
Dwell Time	Greater than 169 days	↑	272 - 420 days **(Summary of Published Literature)**	Uncensored: 140.42 days (**95%CI**: 106.62 – 174.23 days) / Censored: 192.76 days (**95%CI**: 156.91 – 228.62 days **(PMCF_Infusion_211)** 380.2 days (**95%CI**: 308 – 452.4 days) **(Dr Trerotola Data Report)** 578 days (**95%CI**: 201 – 954 days) **(PMCF_Medcomp_211)** Likert Scale Response 4.8 / 5 **(PMCF_Medcomp_211)****
Procedural Outcomes	Greater than 90%	↑	98% - 100% **(Summary of Published Literature)**	100% **(PMCF_Infusion_211)** 100% **(Dr Trerotola Data Report)** Likert Scale Response 4.6 / 5 **(PMCF_Medcomp_211)****
Safety				
Port/Catheter Separation	Less than 0.5% catheters with reported incidents	↓	No Events Reported **(Summary of**	No Events Reported **(PMCF_Infusion_211)**

	of port/catheter separation		**Published Literature)**	1% (**95%CI**: 0% – 3%) **(Dr Trerotola Data Report)** Likert Scale Response 4.7 / 5 **(PMCF_Medcomp_211)****
Catheter Associated Venous Thrombus (CAVT)	Less than 0.35 incidents of CAVT per 1,000 catheter days	↓	0 – 0.45 per 1,000 catheter days **(Summary of Published Literature)**	0.43 per 1,000 catheter days (**95%CI**: 0 – 1.03) **(PMCF_Infusion_211)** 0.03 per 1,000 catheter days **(Dr Trerotola Data Report)** Likert Scale Response 4.6 / 5 **(PMCF_Medcomp_211)****
Central Line Associated Blood Stream Infection (CLABSI) / Catheter Related Blood Stream Infection (CRBSI)	Less than 2.35 incidents of CLABSI/CRBSI per 1,000 catheter days	↓	0 – 0.07 per 1,000 catheter days **(Summary of Published Literature)**	No Events Reported **(PMCF_Infusion_211)** 0.39 per 1,000 catheter days **(Dr Trerotola Data Report)** Likert Scale Response 4.7 / 5 **(PMCF_Medcomp_211)****
Power Injection Related Complications	Less than 1.8% reported incidents of rupture and/or less than 15.4% reported incidents of displacement	↓	No Events Reported **(Summary of Published Literature)**	No Events Reported **(PMCF_Infusion_211)** No Events Reported **(Dr Trerotola Data Report)** Likert Scale Response 4.4 / 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.

Pro-Fuse® Outcome Parameters Across Data Sources

Outcome	Benefit/Risk Acceptability Criteria	Desired Trend	Clinical Literature (Subject Device)	PMCF Data (Subject Device)
Performance				
Dwell Time	Greater than 169 days	↑	30 - 43.2 months **(Summary of Published Literature)**	Uncensored: 135.28 days (**95%CI**: 83.34 – 187.22 days) / Censored: 216.11 days (**95%CI**: 148.37 – 283.85 days) **(PMCF_Infusion_211)** 224.1 days (**95%CI**: 46.5 – 401.7 days)

				(PMCF_Medcomp_211) Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Procedural Outcomes	Greater than 90%	↑	100% **(Summary of Published Literature)**	100% **(PMCF_Infusion_211)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Safety				
Port/Catheter Separation	Less than 0.5% catheters with reported incidents of port/catheter separation	↓	ND*	No Events Reported **(PMCF_Infusion_211)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Catheter Associated Venous Thrombus (CAVT)	Less than 0.35 incidents of CAVT per 1,000 catheter days	↓	0.043 per 1,000 catheter days **(Summary of Published Literature)**	No Events Reported **(PMCF_Infusion_211)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Central Line Associated Blood Stream Infection (CLABSI) / Catheter Related Blood Stream Infection (CRBSI)	Less than 2.35 incidents of CLABSI/CRBSI per 1,000 catheter days	↓	0.043 per 1,000 catheter days **(Summary of Published Literature)** 9% of catheters removed due to infection **(Summary of Published Literature)**	No Events Reported **(PMCF_Infusion_211)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****
Power Injection Related Complications	Less than 1.8% reported incidents of rupture and/or less than 15.4% reported incidents of displacement	↓	ND*	No Events Reported **(PMCF_Infusion_211)** Likert Scale Response 5 / 5 **(PMCF_Medcomp_211)****

*ND indicates no data on the clinical data parameter

**PMCF_Medcomp_211 asked respondents, if they agreed on a scale of 1 -5, that their experience in relation to each outcome was the same or better than the benefit/risk acceptability criteria.

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

Activity	Description	Reference	Timeline
Multicenter Patient-Level Case Series	Collect additional clinical data on the device	PMCF_Port_231	Q4 2025
State of the Art Literature Search	Identify risks and trends with use of similar devices	SAP-Infusion	Q2 2023
Clinical Evidence Literature Search	Identify risks and trends with use of the device	LRP-Infusion	Q2 2023

Global Trial Database Search	Identify ongoing clinical trials involving Medcomp® catheters	N/A	Q2 2024
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 opposed to two for traditional IV • Longer dwelling time compared to IV	• 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
	• 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	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
		designated "STERILE". Requirements for terminally sterilized medical devices	
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
EN ISO 13485	2016 + A11: 2021	Medical Devices – Quality Management system – Requirements for Regulatory Purposes	Full

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
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
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

Harmonized Standard or CS	Revision	Title or Description	Level of Compliance
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-014 Rev. 5
Date: 20OCT2023

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)	Dignity®, Jet Port, Pro-Fuse®, Jet-Fuse Power Injectable Ports
Manufacturer name and address	Medical Components, Inc. 1499 Delp Drive Harleysville, PA 19438 USA
Basic UDI-DI	00884908287NR
Date first CE certificate was issued for this device	Dignity® - May 2009 Jet Port – September 2008 Pro-Fuse® - January 2008 Jet-Fuse – January 2008

The devices in scope of this document are all implantable port sets. The device part numbers are organized into variant categories. These devices are distributed as procedure trays. Procedure trays come in different configurations.

Variant Devices:

Dignity® / Jet Port Variant Devices

Variant Description	Part Number(s)
5F Dignity® Low Profile	30625-850CT
5F Dignity® Low Profile w/ Silicone Filled Suture Holes	30625-850SF
5F Dignity® Mid-Sized	30624-850CT
5F Dignity® / Jet Port Mini	30626-850CT 30626-950CT
5F Dignity® / Jet Port Mini w/ Silicone Filled Suture Holes	30626-850SF 30626-950SF
6.6F Dignity® / Jet Port Low Profile	30625-866CT 30625-966CT
6.6F Dignity® / Jet Port Low Profile w/ Silicone Filled Suture Holes	30625-866SF 30625-966SF
6.6F Dignity® / Jet Port Mid-Sized	30624-866CT 30624-966CT
6.6F Dignity® / Jet Port Mid-Sized w/ Silicone Filled Suture Holes	30624-866SF
6.6F Dignity® / Jet Port Mini	30626-866CT
6.6F Dignity® / Jet Port Mini w/ Silicone Filled Suture Holes	30626-866SF 30626-966SF
8F Dignity® / Jet Port Low Profile	30625-880CT 30625-980CT
8F Dignity® / Jet Port Low Profile w/ Silicone Filled Suture Holes	30625-880SF 30625-980SF
8F Dignity® / Jet Port Mid-Sized	30624-880CT 30624-980CT
8F Dignity® / Jet Port Mid-Sized w/ Silicone Filled Suture Holes	30624-880SF 30624-980SF
8F Dignity® / Jet Port Mini	30626-880CT
8F Dignity Mini w/ Silicone Filled Suture Holes	30626-880SF 30626-980SF

Variant Description	Part Number(s)
9.6F Dignity® / Jet Port Mid-Sized	30624-896CT 30624-996CT
9.6F Dignity® / Jet Port Mid-Sized w/ Silicone Filled Suture Holes	30624-896SF

Pro-Fuse® / Jet-Fuse Variant Devices

Variant Description	Part Number(s)
6.6F Pro-Fuse® / Jet-Fuse Low Profile	30623-866CT 30623-966CT
6.6F Pro-Fuse® / Jet-Fuse Low Profile w/ Silicone Filled Suture Holes	30623-866SF
8F Pro-Fuse® / Jet-Fuse Low Profile	30623-880CT
8F Pro-Fuse® / Jet-Fuse Standard	30622-880CT 30622-980CT
9.6F Pro-Fuse® / Jet-Fuse Standard	30622-896CT 30622-996CT

Procedure Trays:

Dignity® Procedure Trays

Catalog Code	Part Number	Description
MICTI5004S	30625-850SF	5F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI5004SM	30626-850SF	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI50041M	30626-850CT	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MRCTI50001	30624-850CT	5F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI5004SM	30626-850SF	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI50041	30625-850CT	5F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI50041DMP	30625-850CT	5F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI50041M	30626-850CT	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI50041MDMP	30626-850CT	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH DIRECT MICROPUNCTURE SET

Catalog Code	Part Number	Description
MRCTI5084SM	30626-950SF	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI50841M	30626-950CT	5F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MICTI6600S	30624-866SF	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH 5F MICRO-STICK® SET
MICTI66001	30624-866CT	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH 5F MICRO-STICK® SET
MICTI6604S	30625-866SF	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI6604SM	30626-866SF	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI66041	30625-866CT	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI66041M	30626-866CT	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI66841	30625-966CT	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MRCTI6600S	30624-866SF	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI66001	30624-866CT	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI66001DMP	30624-866CT	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH DIRECT MICROPUNCTURE SET
MRCTI6604S	30625-866SF	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI6604SM	30626-866SF	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI66041	30625-866CT	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI66041DMP	30625-866CT	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI66041M	30626-866CT	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI66041MDMP	30626-866CT	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI66801	30624-966CT	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI66801DMP	30624-966CT	6.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH DIRECT MICROPUNCTURE SET
MRCTI6684S	30625-966SF	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI6684SM	30626-966SF	6.6F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI66841	30625-966CT	6.6F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MICTI8000S	30624-880SF	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH 5F MICRO-STICK® SET

Catalog Code	Part Number	Description
MICTI80001	30624-880CT	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH 5F MICRO-STICK® SET
MICTI8004S	30625-880SF	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI8004SM	30626-880SF	8F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI80041	30625-880CT	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI80041M	30626-880CT	8F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI8084SM	30626-980SF	8F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH 5F MICRO-STICK® SET
MICTI80841	30625-980CT	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH 5F MICRO-STICK® SET
MRCTI8000S	30624-880SF	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI80001	30624-880CT	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI80001DMP	30624-880CT	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT WITH DIRECT MICROPUNCTURE SET
MRCTI8004S	30625-880SF	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI80041	30625-880CT	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI80041DMP	30625-880CT	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI80041M	30626-880CT	8F DIGNITY® POWER INJECTABLE MINI PROFILE PORT SET
MRCTI80041MDMP	30626-880CT	8F DIGNITY® POWER INJECTABLE MINI PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTI8080S	30624-980SF	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI80801	30624-980CT	8F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI8084S	30625-980SF	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI80841	30625-980CT	8F DIGNITY® POWER INJECTABLE LOW PROFILE PORT SET
MRCTI9600S	30624-896SF	9.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI96001	30624-896CT	9.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET
MRCTI96801	30624-996CT	9.6F DIGNITY® POWER INJECTABLE MID-SIZED PORT SET

Jet Port Procedure Trays

Catalog Code	Part Number	Description
JSACTI5004SM	30626-850SF	5F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI50041M	30626-850CT	5F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI5084SM	30626-950SF	5F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI50841M	30626-950CT	5F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI6600S	30624-866SF	6.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI66001	30624-866CT	6.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI6604S	30625-866SF	6.6F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI6604SM	30626-866SF	6.6F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI66041	30625-866CT	6.6F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI66041M	30626-866CT	6.6F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI66801	30624-966CT	6.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI6684S	30625-966SF	6.6F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI6684SM	30626-966SF	6.6F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI66841	30625-966CT	6.6F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI8000S	30624-880SF	8F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI80001	30624-880CT	8F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI8004S	30625-880SF	8F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI80041	30625-880CT	8F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI80041M	30626-880CT	8F JET PORT POWER INJECTABLE MINI PROFILE PORT SET
JSACTI8080S	30624-980SF	8F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI80801	30624-980CT	8F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI8084S	30625-980SF	8F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI80841	30625-980CT	8F JET PORT POWER INJECTABLE LOW PROFILE PORT SET
JSACTI9600S	30624-896SF	9.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI96001	30624-896CT	9.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET
JSACTI96801	30624-996CT	9.6F JET PORT POWER INJECTABLE MID-SIZED PORT SET

Pro-Fuse® Procedure Trays

Catalog Code	Part Number	Description
MRCTT6604S	30623-866SF	6.6F PRO-FUSE® POWER INJECTABLE LOW PROFILE PORT SET
MRCTT66041	30623-866CT	6.6F PRO-FUSE® POWER INJECTABLE LOW PROFILE PORT SET
MRCTT66841	30623-966CT	6.6F PRO-FUSE® POWER INJECTABLE LOW PROFILE PORT SET
MRCTT80001	30622-880CT	8F PRO-FUSE® POWER INJECTABLE PORT SET
MRCTT80001DMP	30622-880CT	8F PRO-FUSE® POWER INJECTABLE PORT WITH DIRECT MICROPUNCTURE SET
MRCTT80041	30623-880CT	8F PRO-FUSE® POWER INJECTABLE LOW PROFILE PORT SET
MRCTT80041DMP	30623-880CT	8F PRO-FUSE® POWER INJECTABLE LOW PROFILE PORT WITH DIRECT MICROPUNCTURE SET
MRCTT80801	30622-980CT	8F PRO-FUSE® POWER INJECTABLE PORT SET
MRCTT96001	30622-896CT	9.6F PRO-FUSE® POWER INJECTABLE PORT SET
MRCTT96801	30622-996CT	9.6F PRO-FUSE® POWER INJECTABLE PORT SET

Jet-Fuse Procedure Trays in Scope of Clinical Evaluation

Catalog Code	Part Number	Description
JSACTT6604S	30623-866SF	6.6F JET-FUSE POWER INJECTABLE LOW PROFILE PORT SET
JSACTT66041	30623-866CT	6.6F JET-FUSE POWER INJECTABLE LOW PROFILE PORT SET
JSACTT66841	30623-966CT	6.6F JET-FUSE POWER INJECTABLE LOW PROFILE PORT SET
JSACTT80001	30622-880CT	8F JET-FUSE POWER INJECTABLE PORT SET
JSACTT80041	30623-880CT	8F JET-FUSE POWER INJECTABLE LOW PROFILE PORT SET
JSACTT80801	30622-980CT	8F JET-FUSE POWER INJECTABLE PORT SET
JSACTT96001	30622-896CT	9.6F JET-FUSE POWER INJECTABLE PORT SET
JSACTT96801	30622-996CT	9.6F JET-FUSE POWER INJECTABLE PORT SET

Configurations of Procedure Trays:

Configuration Type
Dignity® Set
Dignity® Set with Micro-Stick®
Dignity® Set with Direct Micropuncture
Jet Port Set

Configuration Type
Pro-Fuse® Set
Pro-Fuse® Set with Direct Micropuncture
Jet-Fuse Set

2. Intended use of the device

Intended purpose	The Dignity®/Pro-Fuse®/Jet Port/Jet-Fuse Power Injectable Ports are intended for use in adult patients requiring frequent needlesticks for whom 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.
Indication(s)	The Dignity®/Pro-Fuse®/Jet Port/Jet-Fuse Power Injectable Port is indicated for long-term access to the central venous system for intravenous administration of fluids or medications, power injection of contrast media, and withdrawal of blood samples.
Intended patient group(s)	The Dignity®/Pro-Fuse®/Jet Port/Jet-Fuse Power Injectable Ports are intended for use in adult patients requiring frequent needlesticks for whom 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.
Contraindications	This device is contraindicated for catheter insertion in the subclavian vein medial to the border of the first rib, an area which is associated with higher rates of pinch-off. The device is also contraindicated: • When the presence of device related infection, bacteremia, or septicemia is known or suspected. • When the patient's body size is insufficient for the size of the implanted device. • When the patient is known or is suspected to be allergic to materials contained in the device. • If severe chronic obstructive lung disease exists. • If the prospective insertion site has been previously irradiated. • If the prospective placement site has previously suffered episodes of venous thrombosis or vascular surgical procedures. • If local tissue factors will prevent proper device stabilization and/or access.

3. Device description

Figure 1: Representative Image of Dignity®/Jet Port Mini

Figure 2: Representative Image of Dignity®/Jet Port Low Profile

Figure 3: Representative Image of Dignity®/Jet Port Mid-Sized

Figure 4: Representative Image of Pro-Fuse®/Jet-Fuse Low Profile

Figure 5: Representative Image of Pro-Fuse®/Jet-Fuse Standard

Description of device	**Dignity®** The Dignity® Power Injectable Ports are an implantable venous access device. Port access is performed by percutaneous needle insertion using a non-coring needle. The Dignity® Power Injectable Port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Dignity® Power Injectable Ports can be identified under the skin by feeling the top of the septum and the top rim of the port housing. Dignity® Power Injectable Ports can be identified by the letters “CT” under radiographic imaging. Sizes include Dignity® Mini

	Profile, Dignity® Mid-Sized and Dignity® Low Profile. Power injection is performed using a power injectable needle only. For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19- or 20-gauge non-coring power injectable needle. The maximum recommended infusion rate is 2ml/s with a 22-gauge non-coring power injectable needle. **Pro-Fuse®** The Pro-Fuse® Power Injectable Ports are an implantable venous access device. Port access is performed by percutaneous needle insertion using a non-coring needle. The Pro-Fuse® Power Injectable Port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Pro-Fuse® Power Injectable Ports can be identified under the skin by feeling the top of the septum and the top rim of the port housing. Pro-Fuse® Power Injectable Ports can be identified by the letters “CT” under radiographic imaging. Sizes include Pro-Fuse® & Pro-Fuse® Low Profile. Power injection is performed using a power injectable needle only. For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19- or 20-gauge non-coring power injectable needle. The maximum recommended infusion rate is 2ml/s with a 22-gauge non-coring power injectable needle. **Jet Port** The Jet Port Power Injectable Ports are an implantable venous access device. Port access is performed by percutaneous needle insertion using a non-coring needle. The Jet Port Power Injectable Port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Jet Port Power Injectable Ports can be identified under the skin by feeling the top of the septum and the top rim of the port housing. Jet Port Power Injectable Ports can be identified by the letters “CT” under radiographic imaging. Sizes include Jet Port Mini Profile, Jet Port Mid-Sized and Jet Port Low Profile. Power injection is performed using a power injectable needle only. For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19- or 20-gauge non-coring power injectable needle. The maximum recommended infusion rate is 2ml/s with a 22-gauge non-coring power injectable needle. **Jet-Fuse** The Jet-Fuse Power Injectable Ports are an implantable venous access device. Port access is performed by percutaneous needle insertion using a non-coring needle. The Jet-Fuse Power Injectable Port consists of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Jet-Fuse Power Injectable Ports can be identified under the skin by feeling the top of the septum and the top rim of the

<table>
<tr><td></td><td>port housing. Jet-Fuse Power Injectable Ports can be identified by the letters “CT” under radiographic imaging. Sizes include Jet-Fuse & Jet-Fuse Low Profile. Power injection is performed using a power injectable needle only.
For power injection of contrast media, the maximum recommended infusion rate is 5ml/s with a 19- or 20-gauge non-coring power injectable needle. The maximum recommended infusion rate is 2ml/s with a 22-gauge non-coring power injectable needle</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 assembled 5F (5.52g) and 9.6F (6.44g) Power Injectable Dignity Ports.

Dignity® Ports
<table><tr><th>Material</th><th>% Weight (w/w)</th></tr><tr><td>Polysulfone</td><td>30.17 – 53.18</td></tr><tr><td>Silicone</td><td>10.39 – 59.21</td></tr><tr><td>Polyurethane</td><td>0.75 – 41.32</td></tr><tr><td>Barium Sulfate</td><td>6.42 – 11.72</td></tr><tr><td>Titanium</td><td>1.76 – 2.98</td></tr><tr><td>Polycarbonate</td><td>0.04 – 1.96</td></tr></table>
The percentage ranges in the table below are based on the weight of the assembled 5F (5.32g) and 9.6F (14.22g) Pro-Fuse Power Injectable Ports.

Pro-Fuse® Ports
<table><tr><th>Material</th><th>% Weight (w/w)</th></tr><tr><td>Polysulfone</td><td>28.16 - 39.92</td></tr><tr><td>Silicone</td><td>11.1 - 65.05</td></tr><tr><td>Polyurethane</td><td>0.02 - 40.7</td></tr><tr><td>Barium Sulfate</td><td>5.5 - 11.48</td></tr><tr><td>Titanium</td><td>1.51 - 2.54</td></tr><tr><td>Polycarbonate</td><td>0.76 - 2.03</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 colspan="2"><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 colspan="2">N/A</td></tr>
<tr><td>How the device achieves its intended mode of action</td><td colspan="2">The subject device can be inserted using a percutaneous or cutdown surgical technique. Catheter insertion is to be performed using aseptic techniques in a sterile field, preferably in an operating room.

Once the port placement site is healed sufficiently following implantation, port access is done by percutaneous needle insertion using a non-coring needle. Power injection is performed using a power injectable needle only. Subject devices consist of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. Implanted ports can be identified subcutaneously by feeling the top of the septum and the top rim of the port housing. Power injectable ports can be identified by the letters “CT” under radiographic imaging.</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="9">Description of accessories</td><td>Name of Accessory</td><td>Description of Accessory</td></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>Peelable Introducer</td><td>Used to get central venous access.</td></tr>
<tr><td>Scalpel</td><td>A cutting device.</td></tr>
<tr><td>Tunneler</td><td>Creates a pocket in between muscle and skin for catheter.</td></tr>
<tr><td>Guidewire Advancer</td><td>Helps guidewire introduction.</td></tr>
<tr><td>Vein Pick</td><td>Allows for cut down procedure.</td></tr>
<tr><td>Syringe</td><td>Helps get blood return once the needle punctures the vein.</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.

How potential risks have been controlled or managed	There have been 339,352 devices sold since January 2016. 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

<table>
<tr><td></td><td>access when alternatives are not suitable. These benefits outweigh the risks.</td></tr>
<tr><td>Remaining risks and undesirable effects</td><td>The Ports are associated with risks. These include:

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

These risks are consistent with risks of other implantable ports. 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 2016 – 30 June 2021)</th><th>Post Market Clinical Follow-Up Activity Events</th></tr>
<tr><th>Units Sold: 358,615</th><th>Units Studied: 195</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>1 Event in 350,000 Cases.</td><td>Not Reported.</td></tr>
<tr><td>Embolism</td><td>1 Event in 85,000 Cases.</td><td>Not Reported.</td></tr>
<tr><td>Infection</td><td>1 Event in 175,000 Cases.</td><td>1 Event in 13 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>1 Event in 115,000 Cases.</td><td>Not Reported.</td></tr>
<tr><td>Thrombosis</td><td>1 Event in 70,000 Cases.</td><td>1 Event in 64 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:

Explain the insertion procedure, signs and symptoms of complications and general maintenance to the patient. Ensure all information is presented with respect to patient’s level of understanding, culture, and language.</td></tr>
</table>

	For the first few days following insertion, avoid heavy exertion and follow your healthcare provider's instructions. Once the small incision has healed, you may resume normal activities. Inform your healthcare provider if you notice any redness or swelling after the incision has healed.
Summary of any field safety correction action (FSCA)	There were four recalls for the device since 01 January 2017. All recalls were related to incorrect componentry included during packaging.

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

Clinical background of the device
The subject devices have been available since 2007. The CE Mark was received in January 2008. US FDA clearance was in May 2007. All models included are planned for distribution in the European Union.
Clinical evidence for CE-marking
The clinical literature review identified 15 articles relating to the safety and/or performance of the subject devices when used as intended. These articles included approximately 5,434 cases. Two patient level data activities received information on 195 devices. 24 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 Dignity® and Pro-Fuse® ports 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 access to the central venous system in patients in whom other therapies are not indicated or desirable as determined by the 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 339,352 devices sold from January 1st 2016, to September 31st, 2022. Also, during this period there were 83 complaints received resulting in a 0.024% complaint frequency for the Ports 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. • 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): AC 20OCT2023