Jet Medical SA

Jet-Fuse Power Injectable Ports
Patient Information Packet

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PIP Statement:

This patient information packet is intended to provide general information regarding this device and should not replace the Information for Use.

Information for Users/Healthcare Professionals:

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

Indications for Use:

The 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.

Device Lifetime:

Medcomp® devices are subjected to, and must pass, simulated use testing intended to replicate 12 months use as part of device development. The Jet-Fuse Power Injectable Port passed this testing. Although Medcomp® device materials contain non-degradable polymers, fully functional catheters may be removed for other reasons, such as intractable infection or change of therapy. Published clinical literature does not always focus on the physical lifetime of a device for these reasons. In the case of the Jet-Fuse Power Injectable Port, 18 Medcomp® branded Pro-Fuse® 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[1].

Based on this information, the 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.

MRI Safety Information:

MR Conditional - 3 Tesla (artifacts may present imaging problems if MRI area is on or near area where device is located)

Report Conclusion: MRI Information
MR Conditional
The Implantable Vascular Access Port was determined to be MR-conditional.

Non-clinical testing demonstrated that the Implantable Vascular Access Port is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720-Gauss/ cm or less

MRI-Related Heating
In non-clinical testing, the Implantable Vascular Access Port produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.7˚C

Therefore, the MRI-related heating experiments for the Implantable Vascular Access Port at 3-Tesla using a transmit/ receive RF body coil at an MR system

reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.7˚C.

Artifact Information
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Implantable Vascular Access Port. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 45-mm^2 (for worst case scenario) relative to the size and shape of this device during MR imaging (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, transmit/receive RF body coil, General Electric Healthcare, Milwaukee, WI). Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void	1,443-mm^2	1,235-mm^2	2,414-mm^2	2,320-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Warnings, Precautions, or Measures to be Taken by Healthcare Professional:

- 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.
- Jet-Fuse Power Injectable Implantable Infusion Ports are only power injectable when accessed with a power injectable needle.
- Use only non-coring needles with the port.
- 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.
- Due to the risk of exposure to HIV (Human Immunodeficiency Virus) or other blood borne pathogens, healthcare professionals should always use Universal Blood and Body Fluid precautions in the care of all patients.To prevent accidents, assure the security of all caps and bloodline connections prior to and between treatments.
- Call 215-256-4201 or visit http://www.medcomp.net for any information to ensure safe use of the device, warnings, precautions or measures to be taken by the patient or a healthcare professional.

How To Fill Out Patient ID Card:

Instructions for Completion of Patient ID Card:

1. Name of the patient or patient ID. To be filled by the healthcare institution/ provider.
2. Date of implantation. To be filled by the healthcare institution/provider.
3. Name and address of the healthcare institution/provider. To be filled by the healthcare institution/provider.

Patient Information:

The information presented below is intended for patients or lay persons. A more extensive summary of this device prepared for healthcare professionals is found in the first part of this document.

Contact your healthcare professional if you believe that 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.

Device Lifetime:

The Jet-Fuse Power Injectable Port device has a 12-month lifetime. However, duration of use varies between patients. Your healthcare professional should decide when to remove and/or replace the device.

Warnings, Precautions, or Measures to be Taken by Patient:

- 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.

Patient Information Website Symbol and URL:

www.medcomp.net/patientinformation

Materials or Substances the Patient May be Exposed to:

The percentage ranges in the table below are based on the weight of the assembled 5F (5.52g) and 9.6F (6.44g) Jet-Fuse Power Injectable Ports.

Material	% Weight (w/w)
Polysulfone	28.16 - 39.92
Silicone	11.10 – 65.05
Polyurethane	0.02 – 40.07
Barium sulfate	5.50 – 11.48
Titanium	1.51 - 2.54
Polycarbonate	0.76 - 2.03

NOTE: Accessories containing stainless steel may contain up to 0.4% weight of the CMR substance cobalt.

Reference:

1. Medcomp. PMCF_Infusion_211_ Report_A. 17 December 2021.

Medcomp® is a trademark of Medical Components, Inc. registered in the United States.

SYMBOL TABLE

5.1.1 	Manufacturer *
5.1.7 	Serial Number *
5.1.5 	Batch Code *
5.1.2 	Authorized Representative in the European Community/European Union *
5.7.7 	Medical Device *
5.7.10 	Unique Device Identifier *
	MR Conditional - 1.5, 3.0 Tesla ****
5.7.4 	Patient Information Website *
5.7.6 	Date *
5.7.5 	Healthcare Center or Doctor *
5.7.3 	Patient Identification *
	United Kingdom Responsible Person **
5.4.10 	Contains Hazardous Substances *
	Contains the CMR Substance, Cobalt ***
	Contains the CMR Substance, Lead ***

***This symbol is in accordance with ISO 15223-1.**

****Not a recognized symbol.**

***** FDA guidance Use of Symbols in Labeling.**

******This symbol is in accordance with ASTM F2503.**

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