IMPEDE® - FX Embolization Plug

Instructions for Use

■ English

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Part: PRT1196-01 Rev. A DCO1625 (June 2019)

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DEVICE DESCRIPTION

The IMPEDE-FX Embolization Plug is a pushable embolization device (see Figure 1) comprised of a self-expanding porous Shape Memory Polymer (SMP) Plug and a proximal platinum/iridium markerband. The IMPEDE-FX device may only be used in conjunction with the IMPEDE Embolization Plug to further enhance vessel occlusion or increase the length of occlusion within the target vessel.

The device is supplied pre-loaded in an Introducer with the SMP Plug in a crimped state. It is designed to be delivered to the target vessel using a guidewire through a standard catheter/sheath (See Table 1). Upon deployment in the target vessel and exposure to an aqueous environment and body temperature, the SMP Plug will self-expand to embolize the target vessel.

The IMPEDE-FX Embolization Plug System is packaged as a single unit and is provided sterile, non-pyrogenic, and is intended for single use only.

SMP undergoes slow degradation, with the majority (>90%) of the polymer remaining at 30 days in a swine intravascular model. Near complete degradation was observed *in vivo* in rat subcutaneous and rabbit intramuscular implants at 180 days.

CAUTION: Carefully read all instructions prior to use. Failure to observe all warnings and precautions may result in complications.

INTENDED USE

The IMPEDE-FX Embolization Plug is indicated for use with the IMPEDE Embolization Plug to obstruct or reduce the rate of blood flow in the peripheral vasculature.

The IMPEDE-FX Embolization Plug System is intended for use by physicians trained and experienced in embolization techniques, angiographic techniques, and interventional procedures. Standard techniques for placement of vascular access sheaths, catheter/sheath and guidewires should be employed.

Table 1 - Recommended Catheter and Guidewire

REF	IMP-FX Crimped OD	IMP-FX Expanded OD	Minimum Recommended Catheter ID	Minimum Guidewire OD	Compatible IMPEDE	Compatible IMPEDE Expanded OD
IMP-FX-06	0.8 mm	6 mm	0.038"	0.032"	IMP-05	6 mm
IMP-FX-08	1.2 mm	8 mm	0.055"	0.035"	IMP-05	6 mm
					IMP-07	8 mm
IMP-FX-12	1.7 mm	12 mm	0.070"	0.035"	IMP-05	6 mm
					IMP-07	8 mm
					IMP-10	12 mm

Figure 1a - IMPEDE-FX Embolization Plug Device (Crimped)

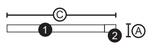

Figure 1b - IMPEDE-FX Embolization Plug Device (Expanded)

1. Crimped SMP Plug
2. Proximal Markerband
3. Expanded SMP Plug

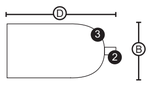

Figure 2 - IMPEDE-FX Introducer

Table 2 - IMPEDE-FX Embolization Plug Device Dimensions

REF	A	B	C	D	E
IMP-FX-06	0.032"	6 mm	10 mm	10 mm	0.055"
IMP-FX-08	0.046"	8 mm	10 mm	10 mm	0.068"
IMP-FX-12	0.065"	12 mm	15 mm	15 mm	0.080"

WARNINGS

- The safety and effectiveness of the IMPEDE-FX Embolization Plug has not been established for cardiac uses (e.g., cardiac septal occlusion, patent ductus arteriosus, paravalvular leak closure) or neurologic uses.
- Inspect the package and system prior to use. Do not use if the sterile package is open or damaged or if the system is damaged.
- Device is intended for single-use only. Do not attempt to re-process, re-sterilize, clean, or re-use the device. Improper sterilization and re-use can cause malfunction to the device and injury to the patient.
- Do not use a power injection syringe to inject contrast solution through the device.
- Do not use after the "Use-by" date specified on the package.
- Only physicians who have received appropriate training and who are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with embolization and interventional procedures should use this device.
- Please note care in specific populations: pregnancy - care should be taken to minimize radiation exposure to the mother and fetus, and nursing mothers - there has been no quantitative assessment of the presence of leachables in breast milk.

PRECAUTIONS

- Physicians should exercise clinical judgement in situations that involve use of anticoagulants or antiplatelet drugs before, during, and/or after use of the device.
- Physicians should exercise clinical judgement when using the IMPEDE-FX Embolization Plug in anatomy that may lead to unintended device placement and/or movement (i.e. high flow vasculature, large luminal vessel diameter).
- The IMPEDE-FX Embolization Plug is intended to self-expand *in vivo*. Placement in vessels too small to accept the selected device may cause injury.
- Verify IMPEDE-FX Embolization Plug compatibility when using other ancillary devices in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.
- It is recommended to deploy the IMPEDE-FX Embolization Plug to the target vessel within one (1) minute of entering the catheter/sheath (*working time*). A working time greater than one (1) minute (i.e. exposure within an aqueous environment) may result in increased delivery friction or the device may not be able to exit the catheter into the target vessel.
- Excessive use of contrast solution injections immediately following deployment to target vessel and prior to full expansion of IMPEDE-FX Embolization Plug may inhibit full expansion and performance of IMPEDE-FX Embolization Plug.
- Verify temperature indicator label on front of pouch has not exceeded 40°C (100°F). If temperature indicator label shows temperature has been exceeded, do not use device as SMP Plug may have expanded impacting delivery performance.
- It is not recommended to wet the IMPEDE-FX Embolization Plug prior to use. Exposure to an aqueous environment will impact the device working time.
- If difficulties occur when deploying the IMPEDE-FX Embolization Plug and the SMP Plug has not exited the catheter/sheath within the recommended working time, wait a minimum of five (5) minutes to allow the SMP Plug to expand within the catheter/sheath. Withdraw and remove the guidewire; using a syringe to apply light suction, remove the device and catheter/sheath simultaneously as one unit.
- Catheter/sheath and guidewire selection, by the physician, must be selected to minimize gaps that may allow the guidewire tip to inadvertently wedge between the device and catheter lumen. Refer to Table 1 and Table 2 for device and accessory selection guidance.
- Refer to product label for device dimensions to determine vessel diameter compatibility.

POTENTIAL ADVERSE EVENTS

Potential adverse events that may occur during or after a procedure include, but are not limited to:

- Air embolus
- Allergic reaction/toxic effects
- Bleeding
- Death
- Device migration
- Fever
- Foreign material embolic event
- Hematoma
- Hemolysis
- Infection
- Occlusion of unintended vessel
- Peripheral embolism
- Pulmonary embolism
- Recanalization
- Residual flow
- Stroke/TIA
- Surgical intervention
- Unintended thrombosis
- Vascular access site complication
- Vessel trauma/perforation

CONTRAINDICATIONS

None known.

MR CONDITIONAL

MRI Safety Information

Non-clinical testing and MRI simulations were performed to evaluate all of the IMPEDE Embolization Plug Devices. Non-clinical testing demonstrated that all versions of the IMPEDE Embolization Plug Device (see Table 1) are MR Conditional. A patient with any version of the IMPEDE Embolization Plug Device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the IMPEDE Embolization Plug Device is expected to produce a maximum temperature rise of 4°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the IMPEDE Embolization Plug Device extends approximately 5-mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

MATERIALS REQUIRED

- Rotating Hemostasis Valve (RHV)
- Catheter/sheath (See Table 1)
- Guidewire (See Table 1)

DIRECTIONS FOR USE

1. Before use of the IMPEDE-FX Embolization Plug, be sure that an IMPEDE Embolization Plug is first deployed in the desired location in accordance with the IMPEDE Embolization Plug IFU.
2. Allow at least 5 minutes for the IMPEDE device to expand within the target vessel.
3. Select an appropriate size of the IMPEDE-FX Embolization Plug, referring to the device compatibility table (See Table 1).
4. Verify the target vessel is long enough to accommodate the device without obstructing unintended vessels. Refer to Table 2 for device dimensions in the fully-compressed state and the fully-expanded state.
5. Select compatible catheter/sheath and guidewire and prepare according to the manufacturer's instructions for use. (See Table 1)
6. Position the catheter/guidewire to the target vessel.
7. Remove the guidewire.
8. Remove IMPEDE-FX Embolization Plug System from package.
9. Inspect the IMPEDE-FX Embolization Plug System for any damage. If damage exists, replace with a new system.
10. Insert Introducer through RHV and into the hub of the catheter/sheath until Introducer is firmly seated. Tighten the RHV to prevent back flow of blood.
    CAUTION: Do not overtighten to avoid damaging the Introducer and/or device.
11. Insert guidewire through hub of Introducer to push the IMPEDE-FX Embolization Plug out from Introducer into the catheter/sheath. Once transferred, continue to push device through the catheter.
    CAUTION: It is recommended to deploy the IMPEDE-FX Embolization Plug to the target vessel within one (1) minute of entering the catheter/sheath (working time). A working time greater than one (1) minute (i.e. exposure within an aqueous environment) may result in increased delivery friction or the device may not be able to exit the catheter into the target vessel.
12. Using the guidewire, advance the IMPEDE-FX Embolization Plug to the distal tip of the catheter/sheath.
    CAUTION: The Crimped SMP Plug IS NOT radiopaque and may not be visible under angiography. It is recommended to refer to Table 2 to consider the device length and the location of the radiopaque proximal markerband that is visible under angiography for optimal device placement.
13. Once positioned at the distal tip of the catheter/sheath, hold the guidewire in place and carefully unsheath the device by slowly retracting the delivery catheter/sheath to deploy the device into the target site.
14. After deployment, remove the guidewire and Introducer from the RHV and lock the RHV.
15. Wait a minimum of five (5) minutes after device deployment to verify embolization and device expansion has occurred via angiography.
    CAUTION: Contrast injections prior to five (5) minutes and excessive contrast injections before device expansion, may impact the device performance and ability to fully expand to embolize the vessel.
16. If embolization is not observed, wait another five (5) minutes to verify embolization.
    NOTE: SMP Plug under *in vivo* conditions, is expected to expand to its final diameter within ten (10) minutes.

PRODUCT DISPOSAL INFORMATION

After the device usage, the IMPEDE-FX Embolization Plug System should be disposed of according to normal hospital practices (e.g., biohazardous materials should be properly handled and disposed of in appropriate containers). Infected medical devices are not regulated under the WEEE Directive but rather must be disposed of as medical waste.

WARRANTY

Shape Memory Medical Inc. warrants to buyer that, for a period equal to the validated shelf life of the product, this product shall meet the product specifications established by the manufacturer when used in accordance with the manufacturer's instructions for use and shall be free from defects in materials and workmanship. Shape Memory Medical Inc.'s obligation under this warranty is limited to replacing or repairing at its option, this product if returned within the warranty period to Shape Memory Medical Inc. and after confirmed to be defective by the manufacturer.

Except as expressly provided in this warranty, Shape Memory Medical Inc. disclaims any representation or warranty of any kind, express or implied, including any warranty as to merchantability or fitness for a particular purpose.

See the Terms and Conditions of Sale for further information.

SYMBOLS

The following symbols are used within product labeling:

CE	European Conformity		Do Not Resterilize
	Refer to Instructions for Use		Caution
	Manufacturer		MR Conditional
	Use-by Date		Keep Dry
	Do not use if package is damaged		Storage, Temperature
LOT	Lot Number		Storage, Humidity
REF	Catalog Number		Non-Pyrogenic
STERILE R	Sterilized by Radiation (Electron Beam)	EC REP	Authorized European Representative
	Single Use Only. Do not Re-use		
Rx Only	Federal law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).		