IMPEDE Product Family Patient Information Leaflet

This leaflet has information about your implant(s). It does not contain all the information and if you have any questions, talk to your healthcare team. All implants have risks and benefits. Follow your healthcare team's advice even if it differs from what is in this leaflet. Please read this leaflet carefully and keep it in a safe place in case you need to refer to it in the future.

The name and number of your IMPEDE Embolization Plug, IMPEDE-FX Embolization Plug or IMPEDE-FX RapidFill implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.

Device Description

The IMPEDE Embolization Plug is a pushable embolization device comprised of a self-expanding, polyurethane Shape Memory Polymer (SMP) foam plug, a platinum-iridium and nickel-titanium anchor coil, and a platinum-iridium alloy markerband. It is supplied pre-loaded in an introducer sheath (i.e., packaging cartridge). The IMPEDE-FX Embolization Plug uses the same foam plug and markerband as the IMPEDE device however it does not contain an anchor coil. Finally, the IMPEDE-FX RapidFill comprises of multiple IMPEDE-FX devices loaded in one cartridge.

Device Description	Device Model Number	Plug Material	Markerband Material	Anchor Coil Material
IMPEDE Embolization Plug, 5mm	IMP-05	Polyurethane Foam	Platinum-Iridium	Platinum-iridium, Nickel*, Titanium
IMPEDE Embolization Plug, 7mm	IMP-07			
IMPEDE Embolization Plug, 10mm	IMP-10			
IMPEDE-FX Embolization Plug, 6mm	IMP-FX-06			N/A
IMPEDE-FX Embolization Plug, 8mm	IMP-FX-08			
IMPEDE-FX Embolization Plug, 12mm	IMP-FX-12			
IMPEDE-FX RapidFill	IMP-FX-12X5			N/A

* Although the nickel-titanium alloy is generally considered safe, patients who are allergic to nickel may have an allergic reaction, especially those with a history of metal allergies.

The IMPEDE, IMPEDE-FX, and IMPEDE-FX RapidFill are indicated to obstruct or reduce the rate of blood flow in the blood vessels, not including those in the brain, chest, or abdomen. Embolization plugs are used by surgeons to treat blood vessel abnormalities in the body. When a blood vessel abnormality is filled with embolization plugs, the blood saturates the plugs and forms clots in and around them. The clot then blocks blood from entering the vessel, which reduces the chance of bleeding.

Peripheral vessels requiring embolization represent a wide variety of medical diagnoses, diseases, syndromes, and clinical circumstances. Among those that potentially would require endovascular intervention and that fall within the recommended vessel sizes itemized in the IMPEDE system's IFU include, but are not limited to:

- Aneurysms
- AVMs, VM, and fistulae

- Congenital large vessel defects
- Endoleaks
- Lymphatic malformations
- Peripheral vessel embolization during central vessel repair
- Pseudoaneurysm
- Therapeutic tissue death, such as tumors and malignancies
- Vascular congestion syndromes of arterial, venous, or solid-organ origins
- Vascular trauma

Expected Implant Lifetime

Embolization plugs are intended to be permanently implanted. The polyurethane foam undergoes slow degradation, with the majority of the polyurethane plug remaining at 30 days in a porcine intravascular model. Near complete degradation was observed *in vivo* in rat subcutaneous and rabbit intramuscular implants at 180 days. The metallic components of the device will permanently remain in your body. Your physician may schedule follow-up appointments to monitor the performance of the implant(s).

Possible Side Effects / Risks

Your physician will provide information about the side effects of your operation. All operations carry risks; the risk of serious issue after the IMPEDE, IMPEDE-FX, or IMPEDE-FX RapidFill is implanted is low. However, there is a risk that you may require additional operations or treatments for several reasons. While many possible reactions may occur these include, but are not limited to:

- Allergic reaction/toxic effects
- Device migration
- Embolism (blocked artery caused by a foreign body)
- Fever
- Hematoma (bruising, caused by blood collecting and pooling under the skin)
- Infection
- Occlusion (blockage) of unintended vessel
- Recanalization (the embolized blood vessel reopens to blood flow)
- Residual flow
- Surgical intervention
- Unintended thrombosis (blood clots or foreign materials block blood vessels)

Information for Safe Use

Make sure you follow your physician's advice after surgery. Not following your physician's advice may result in complications and the need for additional operations.

A Magnetic Resonance Imaging (MRI) scan is a test used to diagnose certain diseases and can be used during medical procedures.

The IMPEDE, IMPEDE-FX, and IMPEDE-FX RapidFill is MR Conditional. If you are asked to go for an MRI scan, please show your implant card to the physician and MRI technician. The MRI scan may

interact with your implant and cause issues if your technician is unaware of your implant. This will allow them to manage your MRI scan safely.

Implant information and MRI testing use information is available on request from Shape Memory Medical.

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.

Patient Information Portal
Any updated information will be provided on our website www.shapemem.com/patients. Information specific to your implant, including the serial number, unique device identifier, etc., are included on the implant card as well as in the patient records kept by your healthcare provider.

Reporting Adverse Effects
If you wish to report any adverse effects you believe are a result of your surgery, please speak with your medical team or report the information to the Shape Memory Medical Product Safety Department at complaints@shapemem.com or the Therapeutic Goods Administration at https://www.tga.gov.au.

For electronic access to this leaflet, please visit www.shapemem.com/patients.

Sponsor
Diverse Devices Pty Ltd
98 Riley Street, Darlinghurst, Sydney NSW 2010
Tel: +61 2 9976 2710