shape memory medical

Original Investigational Device Exemption (IDE)

IMPEDE-FX RapidFill

Pivotal Trial

VOL 016

Appendix 17, Attachment 17-2

Instructions for Use

1. DEVICE DESCRIPTION

The IMPEDE®-FX RapidFill is intended to be used for infrarenal abdominal aortic aneurysm (AAA) sac treatment during endovascular aneurysm repair (EVAR) with an endograft. The excluded aneurysm sac outside of the endograft (target flow lumen) is treated with IMPEDE-FX RapidFill Shape Memory Polymer (SMP) devices, which facilitate thrombus formation and a biological response that is intended to promote AAA sac regression.

The IMPEDE-FX RapidFill (**Figure 3**) is comprised of five (5) self-expanding porous SMP implants pre-loaded linearly in a rigid PEEK cartridge with the SMP in a crimped state (**Figure 1**). Upon exposure to an aqueous environment and body temperature, the SMP will self-expand (**Figure 2**). Each SMP implant has a proximal platinum/iridium (Pt/Ir) markerband for radiopacity.

The SMP implants are pushed from the cartridge through an off the shelf guiding sheath into the target flow lumen using an off the shelf guidewire after the endograft has been fully deployed.

The unrestrained, fully-expanded SMP material in a single SMP implant occupies approximately 1.25mL (each IMPEDE-FX RapidFill cartridge containing 5 implants occupies approximately 6.25mL). The fully-expanded SMP material is porous: approximately 98% open space and 2% solid material. Multiple IMPEDE-FX RapidFills are intended to be used sequentially to fill and treat the AAA sac outside of the endograft.

The IMPEDE-FX RapidFill 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.

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

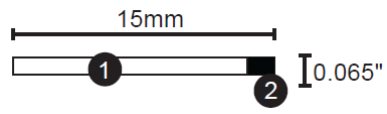

Figure 1: Crimped SMP

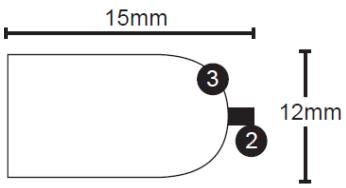

Figure 2: Expanded SMP

1. Crimped SMP Implant
2. Proximal Markerband
3. Expanded SMP Implant
4. Cartridge

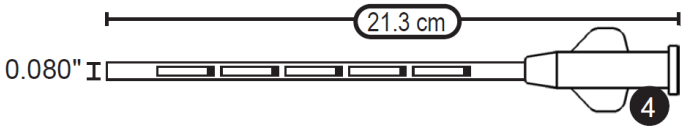

Figure 3: IMPEDE-FX RapidFill

2. INTENDED USE

IMPEDE-FX RapidFill is intended to be used as an adjunct to EVAR with commercially available endografts in the treatment of patients with an infrarenal abdominal aortic aneurysm to promote aneurysm sac regression.

3. CONTRAINDICATIONS

None known.

4. WARNINGS AND PRECAUTIONS

Consult the endograft manufacturer's IFU for all warnings and precautions applicable to the endograft.

Warnings

- 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.
- The 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 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 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

- If complications occur during the endograft implantation procedure that may affect successful exclusion of the aneurysm sac (e.g., endograft puncture, improper placement, limb interference), it is not recommended to proceed with the IMPEDE-FX RapidFill use to avoid SMP implant migration outside of the target flow lumen.
- If any resistance is felt when accessing the target flow lumen using the IMPEDE-FX RapidFIll accessory devices, or if disruption of the endograft contralateral limb is observed, stop and carefully remove the guiding sheath and do not proceed with the IMPEDE-FX RapidFill use. Instead, proceed with deployment of the endograft per the manufacturer's IFU.
- Care must be taken when treating patients with calcification and/or plaque in the common iliac vessels and abdominal aortic aneurysm (AAA). Significant calcification, as determined by the treating physician, may preclude safe insertion of the guiding sheath, EVAR limbs, and/or IMPEDE-FX RapidFill.
- Exercise care in handling and delivery technique to prevent vessel damage (e.g., perforation). It is recommended to use a flexible guiding sheath for initial positioning

within the target flow lumen to prevent aneurysm damage or rupture. If a steerable guiding sheath is used, observe the location of the guiding sheath tip angiographically when positioning/re-positioning to ensure safe placement within the target flow lumen, and avoid implant deployment directly towards the aneurysm wall.

- Appropriate accessory device size selection is important to minimize gaps to prevent the guidewire from traversing past the proximal end of the IMPEDE-FX RapidFill SMP implants and becoming lodged between the SMP implants and guiding sheath inner wall. Use of tapered guidewires is not recommended. During SMP implant deployment, observe the radiopaque marker on the implant as well as the guidewire tip location and ensure an appropriate interface is maintained while pushing the SMP implants. If resistance is encountered, pull back the guidewire to relieve any interference and then re-engage forward movement. A guiding sheath dilator may also be used to reduce the lumen gap. Refer to **Section 8** for guidance.
- It is recommended to deploy the IMPEDE-FX RapidFill SMP implants to the target flow lumen within one (1) minute of entering the guiding sheath (working time). A working time greater than one (1) minute (i.e., exposure to an aqueous environment and body temperature) may result in increased delivery friction or the SMP implants may not be able to exit the guiding sheath into the target flow lumen.
- It is not recommended to wet the IMPEDE-FX RapidFill prior to use. Exposure to an aqueous environment will impact the working time.
- Due to the low delivery resistance of the crimped SMP implants, it is recommended to use fluoroscopic visualization to verify the presence of the SMP implants and their Pt/Ir markerbands prior to exiting the guiding sheath to verify location.
- Excessive use of contrast solution injections immediately following deployment and prior to full expansion of the SMP may inhibit full expansion and performance of the IMPEDE-FX RapidFill.
- Verify the temperature indicator label on the packaging has not exceeded 40°C (105°F). If the temperature indicator label turns black, the temperature has been exceeded. Do not use the device as the SMP may have expanded, impacting delivery performance.
- Verify the SMP implants have completely exited the guiding sheath. While in the crimped shape prior to expansion the SMP implant may re-enter the distal tip of the guiding sheath if not fully deployed.
- If difficulties occur when delivering the IMPEDE-FX RapidFill and the SMP implants have not exited the guiding sheath within the recommended working time, wait a minimum of five (5) minutes to allow the SMP to expand within the guiding sheath. Withdraw and remove the guidewire. Using a syringe to apply light suction, remove the SMP implants and guiding sheath simultaneously as one unit.
- If a SMP implant becomes stuck in the guiding sheath and needs to be withdrawn, the aneurysm sac may be re-accessed by temporarily leaving the guiding sheath in place and easing a guidewire alongside the guiding sheath and between the iliac wall and endograft into the aneurysm under fluoroscopic guidance. The guiding sheath may then be removed and a new guiding sheath/dilator may be placed over the guidewire using care not to disrupt the endograft. If any risk of limb disruption is observed, it is not recommended to proceed with the IMPEDE-FX RapidFill procedure.

- Each SMP implant occupies up to approximately 1.25mL. This is an estimate and based on maximum SMP expansion. The low radial force of the SMP when interfacing with surrounding devices and treatment site boundaries (i.e., other SMP implants, the aneurysm wall, or endograft wall) may decrease the extent of SMP expansion and this volume estimate. Since each IMPEDE-FX RapidFIll device is comprised of five (5) SMP implants pre-loaded in a cartridge, each device contains approximately 6.25mL of implantable material.
- The number of IMPEDE-FX RapidFill devices required for treatment will be provided to you as a range prior to the procedure by a Shape Memory Medical clinical specialist (refer to Section 9.1). The maximum number determined pre-procedurally should not be exceeded to prevent potential damage to the endograft or aneurysm perforation.

5. MR CONDITIONAL

Non-clinical testing and MRI simulations demonstrated that the IMPEDE-FX RapidFill is MR Conditional. Refer to **Table 1** for the MRI Safety Information**.**

Table 1: IMPEDE-FX RapidFill MRI Safety Information

MRI Safety Information

Non-clinical testing and MRI simulations were performed to evaluate the IMPEDE-FX RapidFill device. These results demonstrate that the IMPEDE-FX RapidFill device is MR Conditional. A patient with the IMPEDE-FX RapidFill device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient. If information about a specific parameter is not included, there are no conditions associated with that parameter.

MR Conditional

Parameter	***Condition of Use/Information***
Nominal Values of Static Magnetic Field (T)	1.5-Tesla or 3.0-Tesla
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., Quadrature-Transmission)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 15 minutes of continuous RF exposure (i.e., per

	pulse sequence or back-to-back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

6. 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
- Allergic reaction and/or anaphylactoid response (e.g., to x-ray contrast dye, antiplatelet therapy, device materials)
- Amputation
- Anaphylaxis
- Anesthesia complications and subsequent attendant problems (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm injury/perforation/dissection/rupture and death
- Aortic damage, including perforation/dissection/bleeding/rupture and death
- Arterial or venous thrombosis and/or pseudoaneurysm
- Arteriovenous fistula
- Bleeding, hematoma or coagulopathy
- Blood loss
- Bowel complications (e.g., ileus, ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, atrial fibrillation, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Complications associated with EVAR
- Inflammation
- Investigational product explantation, partial or total
- Investigational product damage, fracture, fragmentation, failure to expand, partially or totally
- Lymphatic complications and subsequent attendant problems (e.g., lymph fistula)
- Necrosis
- Neurologic local or systemic complications and subsequent attendant problems (e.g., confusion, stroke, transient ischemic attack, paraplegia, paraparesis, paralysis, plexopathy)
- New aneurysm formation
- Occlusion of stent graft
- Occlusion of unintended vessel
- Pain
- Peripheral embolism
- Post-implant syndrome
- Pulmonary embolism
- Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Radiation injury, late malignancy
- Recanalization
- Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)

- Complications associated with use of stent graft outside its IFU
- Death
- Device migration
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Fever and localized inflammation
- Foreign material embolic event
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, femoral-femoral artery thrombosis, fistula, incontinence, hematuria, infection)
- Hematoma
- Hemolysis
- Hepatic failure
- Impotence
- Infection of the aneurysm and/or device access sites, including abscess formation, transient fever and pain
- Residual flow
- Stent graft complications per its IFU
- Stent graft thrombosis/occlusion, damage, migration/shift, explantation and/or repair, modification/extension
- Stroke/transient ischemic attack
- Surgical intervention
- Surgical conversion to open repair
- Systemic complications
- Unintended ischemia/occlusion/thrombosis
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula, dissection
- Vascular spasm or vascular trauma (e.g., iliofemoral vessel dissection, bleeding, rupture, death)
- Vessel injury/perforation/dissection/rupture
- Wound complications and subsequent attendant problems (e.g., dehiscence, infection, hematoma, seroma, cellulitis)

7. PACKAGING AND STORAGE

The IMPEDE-FX RapidFill is provided sterile, in a desiccated pouch and inside a protective plastic tube.

- 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.
- It is intended for SINGLE PATIENT 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 after the “Use-by” date specified on the package.
- DO NOT use if labeling is incomplete or illegible.
- DO NOT use if the temperature indicator label on the packaging has turned black and exceeded 40°C (105°F).

Store in an ambient environment and away from direct sunlight, not to exceed 40°C.

8. MATERIALS RECOMMENDED

Materials/devices listed are required for IMPEDE-FX RapidFill use during EVAR with an endograft. Standard materials required for EVAR with an endograft are not listed here. However, the introducer sheath used for endograft contralateral leg access **must be 2F larger** than that specified in the endograft manufacturer's IFU for IMPEDE-FX RapidFill access using the contralateral leg. Refer to the endograft manufacturer's Instructions for Use (IFU) for the remainder of materials required for endograft use, and the list below for IMPEDE-FX RapidFill use.

- 0.035" hydrophilic-coated guidewire
- 4F angiographic/diagnostic catheter
- 0.035" J-tip guidewire (buddy wire)
- 5F or 6F flexible guiding sheath and dilator (0.070" to 0.090" inner diameter, or guiding catheter with equivalent inner diameter specifications)
- Introducer sheath for endograft contralateral leg and buddy wire access (must be 2F larger than that specified in the endograft manufacturer's IFU for the contralateral leg) or introducer sheath for endograft ipsilateral leg and buddy wire access (no upsizing required). Refer to **Section 9.2**.
- Steerable guiding sheath with an 0.070" or 0.090" inner diameter (optional)

9. DIRECTIONS FOR USE

9.1. Preoperative Planning

In order to determine the number of IMPEDE-FX RapidFill devices that may be required for treatment, and to ensure a sufficient number of devices are available for the procedure, flow lumen volume estimates from preoperative CTA imaging as well endograft model and size selection is needed to determine the residual space (target flow lumen) available for IMPEDE-FX RapidFill deployment. Consult a Shape Memory Medical clinical specialist to determine proper number of devices for use based on patient anatomy and pre-selected endograft. A minimum, target, and maximum number of implants will be identified during pre-case planning.

9.2. General EVAR Procedure and Access Requirements Information

IMPEDE-FX RapidFill use requires a guidewire (buddy wire) to be jailed in the AAA sac during endograft deployment. IMPEDE-FX RapidFill may utilize one of the bilateral femoral artery access sites for the endograft but IMPEDE-FX RapidFill access via the ipsilateral (endograft main body access site) or contralateral (limb body access site) approach has different requirements, which should be taken into consideration prior to starting the EVAR procedure with the endograft. Refer to **Figure 4** and **Figure 5** for a visual representation of each approach.

- IMPEDE-FX RapidFill access via the **contralateral** side (start at Section 9.3)
    - Contralateral access should be used if the ipsilateral limb of the endograft main body extends into and covers the ipsilateral common iliac artery.

- An introducer sheath for the contralateral limb that is 2F greater in size than stated in the endograft IFU is required to accommodate both the 0.035" buddy wire and the endograft contralateral limb.

- IMPEDE-FX RapidFill access via the **ipsilateral** side (start at Section 9.4)
  - Ipsilateral access should be used if the endograft ipsilateral limb and contralateral limb of the main body lands above the aortic bifurcation.
  - In this case, no deviation from the endograft IFU for introducer sheath sizing is required for either side.

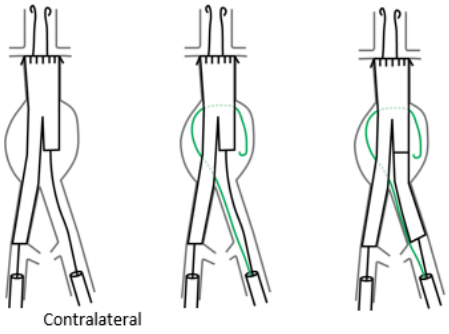

Figure 4: Contralateral Access Option

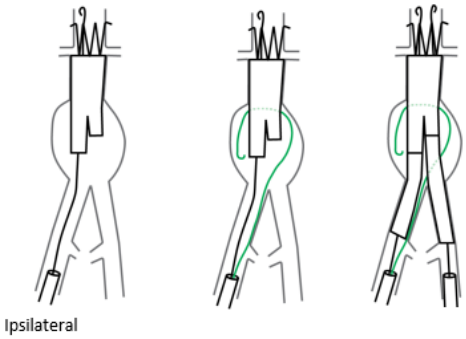

Figure 5: Ipsilateral Access Option

9.3. Contralateral Access

If using ipsilateral access, skip to Section 9.4

9.3.1. During preparation for arterial access for the endograft procedure, review the introducer sheath requirements for the contralateral limb of the endograft. Select an introducer sheath that is at least 2F greater than required for the endograft contralateral limb.

NOTE: The 2F increase of in size is intended to accommodate the buddy wire that will be jailed in the AAA sac during endograft deployment.

9.3.2. Proceed with arterial access via percutaneous or surgical methods and insert the introducer sheath in the contralateral vessel.

9.3.3. Proceed with arterial access for the ipsilateral limb per the endograft manufacturer's IFU.

9.3.4. Deploy the endograft main body and ipsilateral limb per manufacturer's IFU.

9.3.5. Cannulate the endograft contralateral limb gate per the manufacturer's IFU but do not deploy it.

9.3.6. Insert a 0.035" hydrophilic guidewire and 4F angiographic catheter and position them within the target flow lumen.

9.4. Ipsilateral Access Approach

If accessed already obtained through contralateral side, skip to Section 9.5

9.4.1. Proceed with arterial access via percutaneous or surgical methods and insert the introducer sheath in the ipsilateral vessel and contralateral vessel.

9.4.2. Deploy the endograft main body and ipsilateral limb per the manufacturer's IFU.

CAUTION: The ipsilateral leg of the main body after initial main body deployment should terminate within the aneurysm sac, above the aortic bifurcation. The ipsilateral leg should not extend into the common iliac artery. Do not introduce the ipsilateral limb extension until the buddy wire has been placed in the aneurysm sac.

9.4.3. Deploy the contralateral limb of the endograft per the manufacturer's IFU.

9.4.4. Once the EVAR stent graft main body and the contralateral limb have been deployed and the ipsilateral gate has been cannulated, insert a 0.035" hydrophilic guidewire and 4F angiographic catheter and position within the target flow lumen.

9.5. IMPEDE-FX RapidFill Accessory Device Placement

9.5.1. Remove the hydrophilic guidewire from the catheter and replace it with a 0.035" J-tip guidewire (buddy wire).

CAUTION: If using a stiff-tipped buddy wire, use caution as it maneuvers around within the target flow lumen and around the endograft to avoid risk of aneurysm puncture or rupture, or damage to the endograft.

9.5.2. With the buddy wire in position, remove the 4F angiographic catheter and then complete deployment of the endograft limb(s), thereby jailing the buddy wire in target flow lumen.

9.5.3. Perform balloon molding to seal the endograft per the endograft manufacturer's IFU.

CAUTION: Do not perform balloon molding of the limb at this step adjacent to the buddy wire. Excessive balloon molding/sealing of the limb may disrupt placement of the guiding sheath and/or cause migration of the endograft limb.

9.5.4. Perform an angiogram at the suprarenal position to verify proper placement of the endograft and absence of proximal/distal endoleak at the ipsilateral seal zones.

9.5.5. Pass a 5F or 6F flexible guiding sheath over the buddy wire positioned within the target flow lumen and then remove the buddy wire.

CAUTION: During transfer of the guiding sheath over the buddy wire, if any resistance is felt or disruption of the endograft contralateral limb is observed, stop and carefully remove the guiding sheath and do not proceed with the IMPEDE-FX RapidFill use. Instead, proceed with deployment of the endograft per the manufacturer's IFU.

9.5.6. Perform a sacogram through the guiding sheath to verify seals and to visualize the target flow lumen.

CAUTION: If a proximal or distal endoleak is observed, perform balloon molding as necessary to ensure adequate seal of the endograft and to reduce the risk of SMP implant migration.

9.6. IMPEDE-FX RapidFill Device Preparation

9.6.1. Remove the IMPEDE-FX RapidFill from its package and inspect it for any damage (including confirming that the temperature indicator label has not changed to black; refer to Section 7). If damage exists, replace it with a new device.

CAUTION: Use sterile, dry gloves when preparing IMPEDE-FX RapidFill. Do not wet or flush the IMPEDE-FX RapidFill as the SMP will begin to expand upon exposure to fluid.

9.7. IMPEDE-FX RapidFill Deployment

9.7.1. Position the guiding sheath tip in the desired location of the target flow lumen.

NOTE: Position the guiding sheath tip at a location such that it is furthest from the aneurysm access point (i.e., past the endograft limb). If possible, depending on patient anatomy and user preference, advance the guiding sheath around the contour of the sac (see Figures 4 and 5).

CAUTION: The guiding sheath tip should be positioned to minimize catheter movement that leads to loss of access to the aneurysm sac during SMP implant deployment. It is also recommended to consider the starting location of the guiding sheath tip in order to optimize aneurysm filling by selectively deploying the SMP implants in groups starting furthest from the aneurysm access point and continuing throughout the target flow lumen by slowly retracting the guiding sheath.

9.7.2. Insert the IMPEDE-FX RapidFill cartridge into the guiding sheath until it is firmly seated at the guiding sheath hub.

CAUTION: If a rotating hemostatic valve is attached to the guiding sheath hub, do not overtighten to avoid damaging the cartridge and/or implants.

9.7.3. Insert the 0.035” J-tip guidewire (buddy wire) through the hub of the IMPEDE-FX RapidFill cartridge to push and transfer the SMP implants from the cartridge and into the guiding sheath. Once transferred, under fluoroscopic guidance, continue to push the SMP implants to the target flow lumen.

CAUTION: It is recommended to deploy the IMPEDE-FX RapidFill implants into the target flow lumen within one (1) minute of entering the guiding 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 guiding sheath into the target flow lumen.

CAUTION: After the guidewire enters the cartridge, do not remove it until the implants are fully transferred into the guiding sheath. Premature withdrawal of the guidewire may cause the implants to move backwards through the cartridge towards the hub upon sudden changes in pressure.

CAUTION: Verify the SMP devices have completely exited the guiding sheath. While in the crimped shape and prior to expansion the SMP implant may re-enter the distal tip of the guiding sheath if not fully deployed.

9.7.4. Repeat IMPEDE-FX RapidFill deployment/implantation in each accessed area, slowly retracting/repositioning the guiding sheath as areas are filled to allow for placement of implants throughout the target flow lumen. Implant between the minimum and maximum number of implants recommended during pre-case planning.

CAUTION: Use caution during guiding sheath retraction to minimize disruption to the endograft.

9.7.5. Perform sacograms as needed to monitor filling of the target flow lumen. An absence of contrast filling indicates the occupation of the space by the SMP implants and initiation of thrombosis.

NOTE: The porous expanded SMP may retain contrast when expanded.

NOTE: The SMP takes approximately 5-10 minutes to fully expand. Prior to this time, the crimped SMP implant may move around within the target flow lumen.

9.7.6. Perform a confirmatory sacogram. If contrast filling is observed in any specific region within the target flow lumen, additional IMPEDE-FX RapidFills may be used, provided the region can be safely accessed.

CAUTION: Do not exceed the maximum number of implants recommended during pre-case planning.

CAUTION: A different guiding sheath (i.e., steerable guiding sheath) may be needed to deploy additional SMP devices. To exchange sheaths, reinsert the buddy wire through the existing guiding sheath to maintain access to the target flow lumen. Remove the existing guiding sheath over the buddy wire while maintaining the buddy wire position in the target flow lumen. Re-access the target flow lumen with the new guiding sheath over the buddy wire.

CAUTION: When transferring the guiding sheath over the buddy wire, if any resistance is felt or disruption of the limb is observed, stop and carefully remove the guiding sheath.

9.7.7. After completion of the procedure and prior to removal of the guiding sheath, perform a final sacogram.

9.7.8. Remove guiding sheath.

9.7.9. Perform balloon molding to seal the endograft main body and limbs per the endograft manufacturer's IFU.

9.7.10. Perform a final angiogram of the aorta to verify aneurysm exclusion and absence of type I/III endoleak.

9.7.11. Complete the EVAR procedure per the endograft manufacturer's IFU.

10. Product Disposal Information

After the device usage, the IMPEDE-FX RapidFill 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.

11. Symbols

The following symbols are used within product labeling:

	Single Use Only. Do not Re-use		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)		
Rx Only	Restricts this device to sale by or on the order of a physician (or properly licensed practitioner).		