1. Device Description

The False Lumen Embolization System is comprised of the Implant and the Pusher (see **Figures 1, 2 and 3**).

The Implant consists of 1, 3, or 5 segments of proprietary self-expanding, porous, biodegradable polyurethane-based shape memory polymer (SMP). Each Implant includes a proximal platinum/iridium marker band with detachment collar. Multi-segment Implants (3-segment and 5-segment configurations) include a central wire and distal marker band, both made of platinum/iridium.

The Pusher consists of a polyether block amide (PEBAX) outer shaft, an outer polyethylene (PE) transfer tube, an inner stainless steel (SS) pull-wire, a distal SS implant attachment mechanism, and a proximal molded polymer pusher hub. The pusher hub includes a release knob which is used to mechanically detach the Implant from the Pusher.

The Implant is supplied in a crimped state, pre-loaded into a PE peel-away retainer sleeve. It is designed to be delivered to the false lumen of an aortic dissection through an introducer sheath (not supplied), see **Table 1**. Upon deployment into the false lumen and exposure to an aqueous environment and body temperature, the SMP will self-expand to facilitate thrombus formation and embolization of the false lumen.

The False Lumen Embolization System is packaged as a single unit and is provided sterile and non-pyrogenic. The False Lumen Embolization System is intended for single use only.

Figure 1:
Schematic Diagram of False Lumen Embolization System (Components)

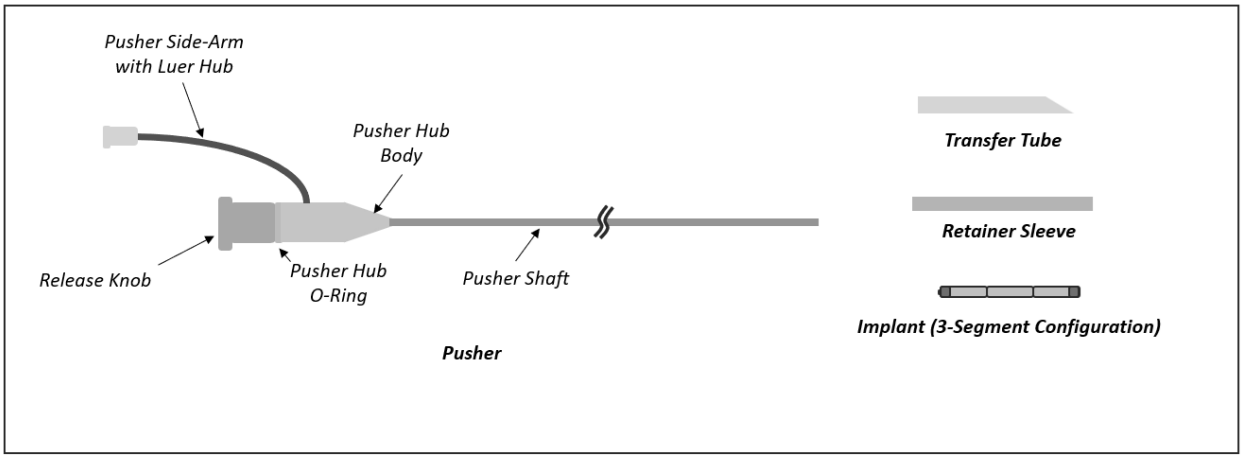


Figure 2:
Schematic Diagram of False Lumen Embolization System (Final Assembly)

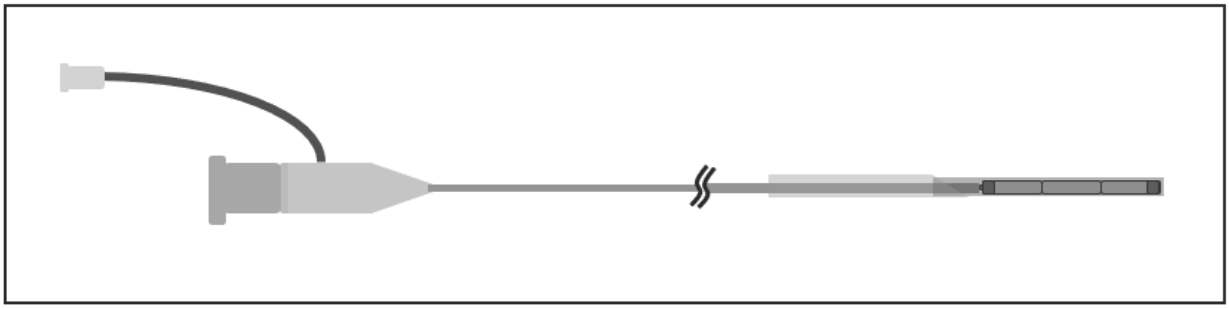


Figure 3a: 1-Segment Implant

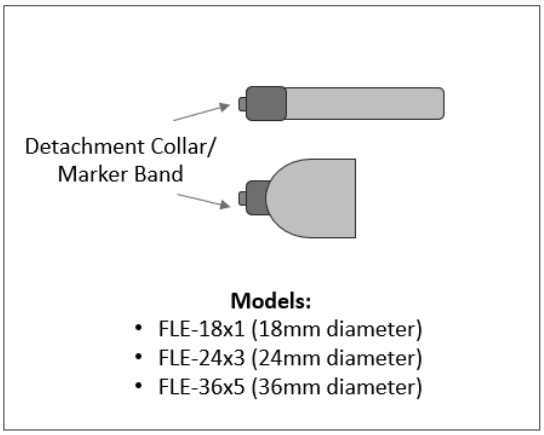


Figure 3b: 3-Segment Implant

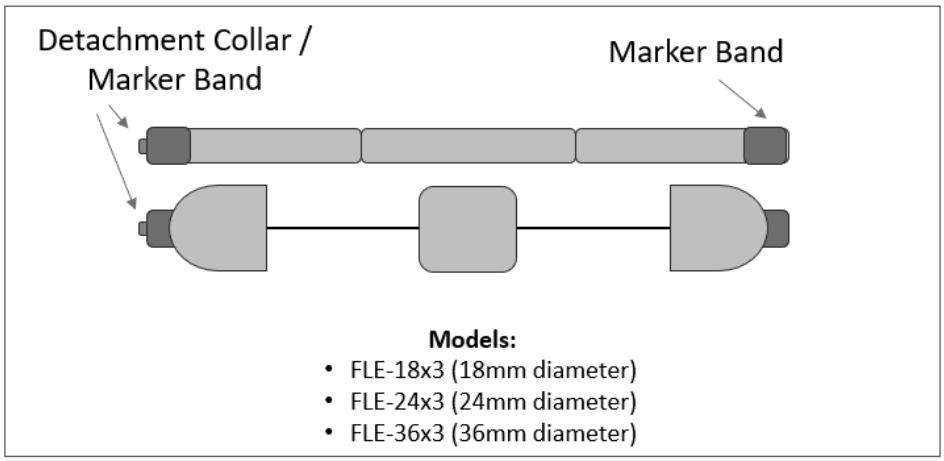
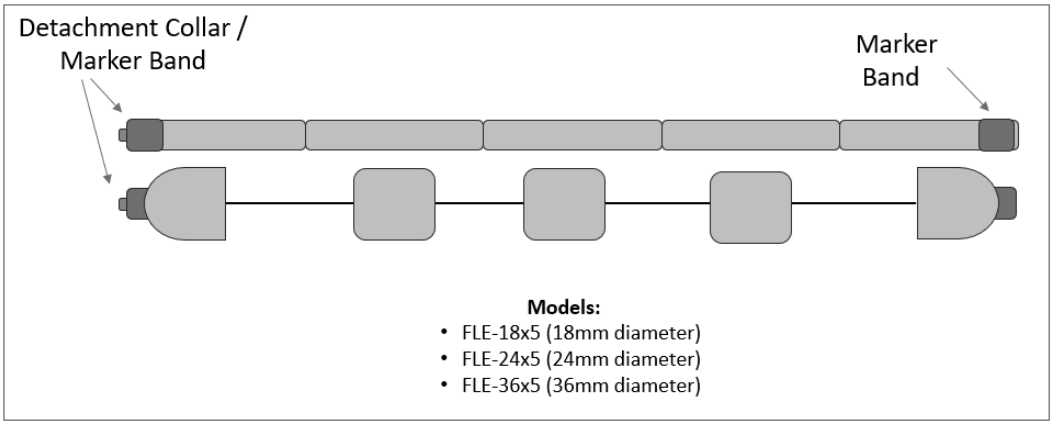


Figure 3c: 5-Segment Implant



2. Intended Use

The False Lumen Embolization System is indicated for use in patients with subacute or chronic aortic dissection. After or during the primary entry tear repair procedure, the False Lumen Embolization System is intended to obstruct or reduce the rate of blood flow in the false lumen.

The False Lumen Embolization System is intended for use by physicians trained and experienced in endovascular management of aortic dissection, embolization techniques, angiographic techniques, and interventional procedures. Standard techniques for placement of vascular access sheaths, introducer sheaths, and guidewires should be employed.

3. Contraindications

The False Lumen Embolization System is contraindicated in patients with known sensitivities or allergies to platinum, iridium, or polyurethane.

4. Warnings

- The safety and effectiveness of the False Lumen Embolization System 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.
- System is intended for single-use only. Do not attempt to re-process, re-sterilize, clean, or re-use the system. Improper sterilization and re-use can cause malfunction to the system and injury to the patient.
- Do not use a power injection syringe to inject contrast solution through the Pusher.
- Do not use after the “Use-By” Date printed on the label.
- Only physicians who have received appropriate training and who are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with endovascular procedures involving the management of aortic dissection and vascular embolization techniques 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.

5. Precautions

- Verify False Lumen Embolization System compatibility when using other ancillary devices in endovascular procedures. The operator must be familiar with percutaneous, endovascular techniques and possible complications associated with the procedure.
- When using the system with adjunctive devices or procedures, it is not recommended to proceed with False Lumen Embolization System use if complications occur during the primary or adjunctive procedure that may lead to further complications.

- Exercise care in handling and delivery technique to prevent vascular damage (e.g., perforation or rupture). It is recommended to observe the location of the introducer sheath tip fluoroscopically when positioning/re-positioning to ensure safe placement within the false lumen. Avoid Implant deployment directly towards the vascular wall.
- Physicians should exercise clinical judgment in situations that involve use of anticoagulants or antiplatelets before, during, and/or after use of the system.
- Refer to **Table 1** and the product label for device dimensions to guide device selection.
- Keep the system dry prior to use. Exposure to fluids prior to use will impact the working time of the system.
- Remove the retainer tube from the implant prior to inserting the system into introducer sheath. Failure to do so may result in the system becoming lodged in the introducer sheath, or complications during endovascular delivery of the system into the false lumen leading to the need for surgical conversion.
- If the transfer tube does not advance over the Implant, discard the system as the Implant may have expanded prematurely.
- Saline preparation of the Pusher should be performed immediately before advancement of the system into the introducer sheath.
- Failure to seat the transfer tube in the proximal hub of the introducer sheath may result in damage to the implant as it is being advanced into the introducer sheath.
- Do not overtighten the hemostasis valve as this may pinch down on the transfer tube and Implant, inhibiting the ability to advance the Implant into the introducer sheath.
- Under tightening the hemostasis valve may result in excessive bleeding.
- The Implant should be deployed into the false lumen within 30 seconds of advancement into the introducer sheath (working time). Allowing the Implant to dwell in the introducer sheath for more than 30 seconds may result in increased delivery friction or may result in the inability to fully advance the Implant out of the introducer sheath.
- If significant resistance is felt or difficulties occur when advancing the Implant through the introducer sheath and no part of the Implant has exited the introducer sheath, carefully withdraw the system and introducer sheath simultaneously as one unit. If one or more segments of the Implant have exited the introducer sheath, take care when withdrawing the introducer sheath to avoid damaging the Implant or vessel during withdrawal.
- The entire Implant must be fully deployed into the false lumen all at once, without pausing between segments or prior to full deployment to prevent the implant from becoming partially lodged in the introducer sheath.
- Do not attempt to retract the Implant into the introducer sheath. Attempting to do so may result in damage to the Implant or unintentional detachment of the Implant.

- When deploying the implant into the false lumen, do not advance the Implant out of the introducer sheath. Instead, maintain the position of the Implant while slowly retracting the introducer sheath. Advancing the Implant out of the introducer sheath may result in rupture or dissection of the false lumen.
- If using multiple implants or other adjunctive embolization devices, use caution to minimize damage or disruption to the devices.
- Excessive manipulation of the Implant within the false lumen may lead to damage, fracture or fragmentation of the implant or dissection, perforation or rupture of the false lumen
- If, after deployment into the false lumen, the Implant prematurely or unintentionally detaches from the Pusher, assess the position of the Implant using fluoroscopy, injecting radiopaque contrast as necessary. If appropriate, assess whether additional Implants should be deployed into the false lumen to achieve the desired result.
- Confirm implant position within the false lumen prior to release. Failure to do so may result in device migration, embolization leading to stroke, paraplegia or paralysis.
- Failure to withdraw the release knob a minimum of 3cm during the implant release step may result in a failure to release the Implant
- Attempting to withdraw the Pusher prior to Implant release may result in damage to the Implant leading to unintended migration, transient or permanent ischemia, or stroke.
- Aggressive power injection into the false lumen following release of the Implant may result in Implant migration, embolization and transient or permanent ischemia or stroke.
- If the introducer sheath must be withdrawn prior to conclusion of the procedure, use caution when re-accessing the false lumen. Use fluoroscopic guidance and take care to avoid damage to the vascular space or damage/disruption of any ancillary, adjunctive, or previously placed devices.
- Verify temperature indicator label on the packaging has not exceeded 40°C (105°F). If temperature indicator label shows temperature has been exceeded (indicator dot color is black), do not use device as SMP Plug may have expanded impacting delivery performance.

6. Potential Adverse Events

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

- Access, delivery, and deployment events (e.g. access failure, deployment difficulties/failures, failure to deliver the device, misplacement, and insertion or removal difficulty)
- Adjunctive device damage, thrombosis, or occlusion
- Allergic reaction and/or anaphylactoid response (e.g., to x-ray contrast dye, antiplatelet therapy, device materials), hypersensitivity
- Amputation

- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Angina
- Aortic branch vessel occlusion or obstruction
- Aortic expansion (e.g., aneurysm, false lumen, landing zone, lesion) including new dissection or aneurysm formation and effect on abdominal or thoracic diameter
- Aortic valve damage
- Aortic vessel or aneurysm rupture
- Arterial or venous thrombosis and/or pseudoaneurysm
- Atelectasis / pneumonia
- Bleeding, hemorrhage, hematoma, hemolysis, or coagulopathy
- Blindness
- Blood loss
- Bowel complications (e.g., ileus, adynamic ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, tamponade, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Change in mental status
- Claudication (e.g., buttock, lower limb)
- Contrast toxicity
- Death
- Device damage, fracture, fragmentation, failure to expand, partially or totally
- Device explantation, partial or total
- Device migration
- Dissection, perforation, or rupture of the aortic vessel & surrounding vasculature
- Edema
- Embolization (unintended, micro and macro) with transient or permanent ischemia or infarction, including air embolism
- Endoleak (entry flow)
- Erectile dysfunction, impotence
- Excessive or inappropriate radiation exposure
- Extrusion/erosion
- Fever and localized inflammation
- Fistula (e.g., aortoeneteric, arteriovenous, aortoesophogeal, aortobronchial)
- Gastrointestinal bleeding/complications
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, urinary incontinence, hematuria, infection)
- Hepatic failure
- Infarction
- Infection of the aneurysm, device or access site, including abscess formation, transient fever, and pain
- Lymphatic complications and subsequent attendant problems (e.g., lymph fistula, lymphocele)

- Nerve injury
- Neurologic complications (local or systemic) and subsequent attendant problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, spinal cord shock, paralysis)
- Neuropathy, femoral neuropathy
- Occlusion, stenosis (including restenosis), or thrombosis – venous or arterial
- Pain
- Paresthesia
- Peripheral malperfusion or ischemia and subsequent attendant problems (e.g., spinal cord ischemia, visceral vessel ischemia, limb ischemia)
- Persistent perfusion of the false lumen (and/or incomplete thrombosis)
- Post implantation syndrome
- Pulmonary embolism
- Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- Reoperation
- Sepsis
- Seroma
- Shock
- Surgical conversion
- Tissue necrosis
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula
- Vascular spasm or vascular trauma or damage (e.g., iliofemoral vessel dissection, bleeding, rupture)
- Wound complications and subsequent problems (e.g., dehiscence, infection)

Should a serious device-related event occur, immediately notify Shape Memory Medical of the incident and the applicable competent authority or regulatory body.

7. MR Conditional

Non-clinical testing and MRI simulations were performed to evaluate the Implant in its worst-case (largest) configuration. Non-clinical testing demonstrated that the Implant is MR Conditional. A patient implanted with one or more Implants may be scanned safely in an MR system under the following conditions:

- Static, horizontal, magnetic field of 1.5-Tesla or 3-Tesla, only
- Maximum spatial gradient magnetic field of 10,000-gauss/cm (100-T/m)
- Maximum whole body averaged (WBA) specific absorption rate (SAR) in Normal Operating Mode

  - 1.5-Tesla/64-MHz, WBA SAR, 1-W/kg
  - 3-Tesla/128MHz, WBA SAR, 2-W/kg
- Scan Duration and Wait Time
  - 1.5-Tesla/64-MHz, WBA SAR, 1-W/kg: 10 minutes continuous RF exposure, followed by 20 minute wait period, repeated twice in 60 minutes. Alternatively, the patient may undergo 15 minutes continuous RF exposure, followed by a 45 minute wait period (once per 60 minutes).
  - 3-Tesla/128-MHz, WBA SAR, 2-W/kg: 60 minutes continuous RF exposure (i.e., per pulse sequence or back-to-back sequences/series without breaks).

Under the scan conditions defined, the Implant is expected to produce a temperature rise of less than or equal to 6°C.

In non-clinical testing, the image artifact caused by the Implant extends approximately 4 mm from the device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

8. Packaging and Storage

- The False Lumen Embolization System is provided sterile, in a desiccated pouch and mounted on a polyethylene packaging card.
- The system is intended for single use only.
- Inspect the system and packaging to verify that no damage has occurred as a result of shipping. Do not use this system if damage has occurred, if the sterilization barrier has been damaged or broken, or if the vacuum seal of the desiccated pouch has been broken. If damage has occurred, do not use the product and return to Shape Memory Medical.
- The Implant is pre-loaded into a Retainer Sleeve to prevent premature SMP expansion. Remove the retainer sleeve only when prepared to deliver and deploy the Implant.
- Do not use after the “Use-By” Date printed on the label.
- Store in a cool, ambient environment and away from direct sunlight, not to exceed 40°C.

9. Required Accessory Materials

a. Syringe (3 cc or 5 cc)

b. 2-way or 3-way stopcock

c. Guidewire: 0.035”

d. Introducer sheath and dilator (see **Table 1**)

10. Pre-False Lumen Embolization Planning and Accessory Device Selection

a. Preoperative planning of the target region (aortic dissection true lumen and false lumen, and branch vessels) should be performed by computed tomography angiography or fluoroscopic imaging.

b. Access the target region with guidewire and vascular access sheath with dilator. Determine the length, diameter, and morphology of the target region through fluoroscopic imaging.

   a. Verify that the length of the target embolization site in the false lumen is sufficient to accommodate the crimped Implant for delivery. Refer to **Table 1** for Implant dimensions in the crimped state.

   b. Verify that the length and diameter of the target embolization site in the false lumen are sufficient to accommodate the expanded Implant. Refer to **Table 1** for Implant dimensions in the expanded state.

   NOTE: While oversizing the SMP by 2x has been shown to result in minimal outward radial force, completely filling the target region with SMP is not considered necessary

c. Select the appropriate introducer sheath and guidewire for delivery of the False Lumen Embolization System (see **Table 1**); prepare the ancillary devices according to the manufacturer's instructions for use.

Table 1
False Lumen Embolization System:
Introducer Sheath Compatibility & Implant Dimensions

REF	Introducer Sheath Compatibility	Implant, Crimped		Implant, Expanded	
		Diameter (mm)	Length (mm)	Diameter (mm)	Length* (mm)
FLE-18x1	10F ID x 65cm Length	2.2	33	18	20
FLE-18x3			97		60
FLE-18x5			157		100
FLE-24x1	12F ID x 65cm Length	2.7	33	24	20
FLE-24x3			97		60
FLE-24x5			157		100
FLE-36x1	16F ID x 65cm Length	3.9	33	36	20
FLE-36x3			97		60
FLE-36x5			157		100

** Aggregate length of segments*

11. Directions for Use

1. Advance the guidewire and introducer sheath with dilator into the false lumen using the appropriate endovascular technique. Carefully advance the introducer sheath so that the sheath tip is positioned at the most proximal (most cephalad) target embolization site within the false lumen.

CAUTION: If using a stiff-tipped wire, use caution when manipulating the wire within the false lumen to avoid vessel damage, puncture or rupture, or damage to adjunctive devices.

2. Withdraw the guidewire and dilator.
3. Carefully inspect the False Lumen Embolization System package for damage and confirm that a vacuum seal has been maintained. If damage to the package is noted, discard the system and replace it with a new system.
4. Remove False Lumen Embolization System from the package.
5. Inspect the False Lumen Embolization System for any damage. If damage exists, discard the system and replace it with a new system.
6. Remove the False Lumen Embolization System from the packaging card.
7. Separate the transfer tube from the retainer sleeve, exposing the two proximal tabs on the retainer sleeve.
8. To remove the retainer sleeve, grip the two tabs and pull apart (perpendicular to the axis of the Pusher Shaft). See **Figures 4a and 4b**:

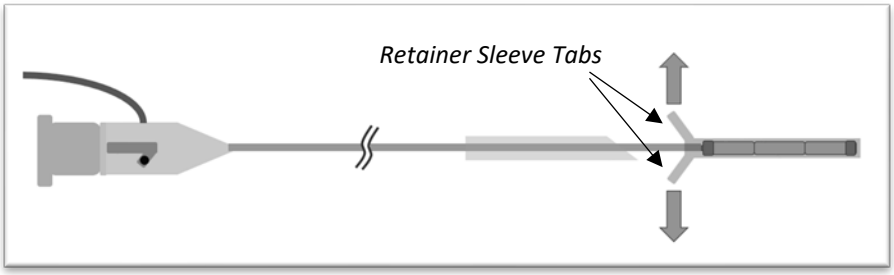


Figure 4a:
Grip the tabs of retainer tube and pull apart to release the Implant

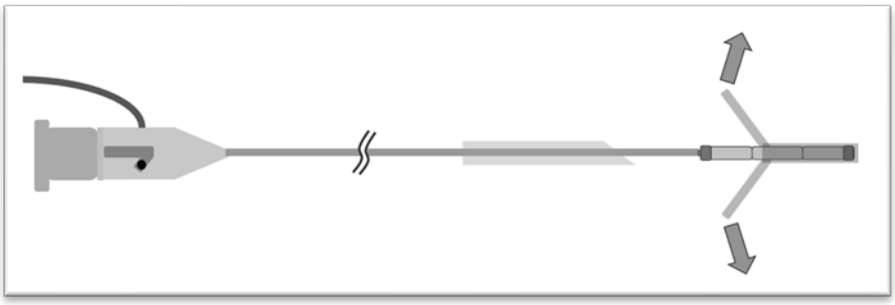


Figure 4b:
Continue pulling retainer tube tabs apart until the retainer tube is fully released from the Implant

9. Carefully advance the transfer tube over the Implant.

CAUTION: If the transfer tube does not advance over the Implant, discard the system as the Implant may have expanded prematurely.

10. Attach a stopcock to the side-arm port of the pusher hub.
11. Using a 3-5 cc syringe, gently inject room temperature sterile saline through the lumen of the pusher shaft to displace air. Close the stopcock.
12. Immediately insert the transfer tube approximately 1-2 cm into the proximal hub of the introducer sheath. Quickly advance the Pusher and Implant into the introducer sheath. Withdraw the transfer tube from the hemostasis valve. Under fluoroscopic guidance, advance the Pusher until the Implant is positioned near the tip of the introducer sheath.

    CAUTION: Failure to seat the transfer tube in the proximal hub of the introducer sheath may result in damage to the implant as it is being advanced into the introducer sheath.

    CAUTION: Do not overtighten the hemostasis valve as this may pinch down on the Implant, inhibiting the ability to transfer the Implant into the introducer sheath.

    CAUTION: Undertightening the hemostasis valve may result in excessive bleeding.

13. Maintaining a stable position of the Pusher, slowly retract the introducer sheath to unsheathe the Implant to deploy the Implant into the false lumen.

    CAUTION: When deploying the implant into the false lumen, do not advance the Implant out of the introducer sheath. Instead, maintain the position of the implant while slowly retracting the introducer sheath. Advancing the Implant out of the introducer sheath may result in rupture or dissection of the false lumen.

    CAUTION: It is recommended to deploy the Implant to the false lumen within **30 seconds** of entering the introducer sheath. Allowing the Implant to dwell in the introducer sheath for greater than 30 seconds may result in increased delivery friction or the inability to fully advance the Implant out of the introducer sheath.

    CAUTION: The entire Implant must be fully deployed into the false lumen all at once, without pausing between segments or prior to full deployment to prevent the implant from becoming partially lodged in the introducer sheath. Do not attempt to retract the Implant into the introducer sheath. Attempting to do so may result in damage to the Implant or unintentional detachment of the Implant.

    CAUTION: If using multiple implants or other adjunctive embolization devices, use caution to minimize damage or disruption to the devices.

    CAUTION: Excessive manipulation of the Implant within the false lumen may lead to damage, fracture or fragmentation of the implant or dissection, perforation or rupture of the false lumen

14. After deployment, perform angiograms as needed to monitor the Implant position and expansion of the SMP. An absence of contrast filling indicates the occupation of the space by the SMP and initiation of thrombosis.

    NOTE: The porous SMP may retain contrast when expanded.
    NOTE: The SMP takes approximately 10 minutes (up to 30 minutes) to fully expand.

15. Once the SMP has expanded satisfactorily, reconfirm Implant position via fluoroscopy, then release the Implant (see **Figures 5a-5c**).
    a. Rotate the proximal release knob 1/8 turn in the counter-clockwise direction.
    b. Withdraw the release knob 3 cm to release the Implant from the Pusher.
    c. Withdraw and remove the Pusher from the introducer sheath, taking care maintain access to the false lumen with the introducer sheath.
    d. Confirm detachment of the Implant in the false lumen using fluoroscopy.

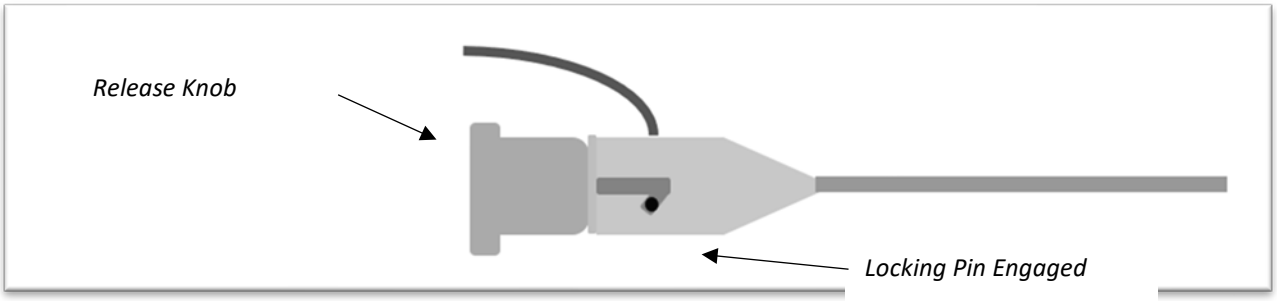


Figure 5a: Pusher hub, release knob in LOCKED position

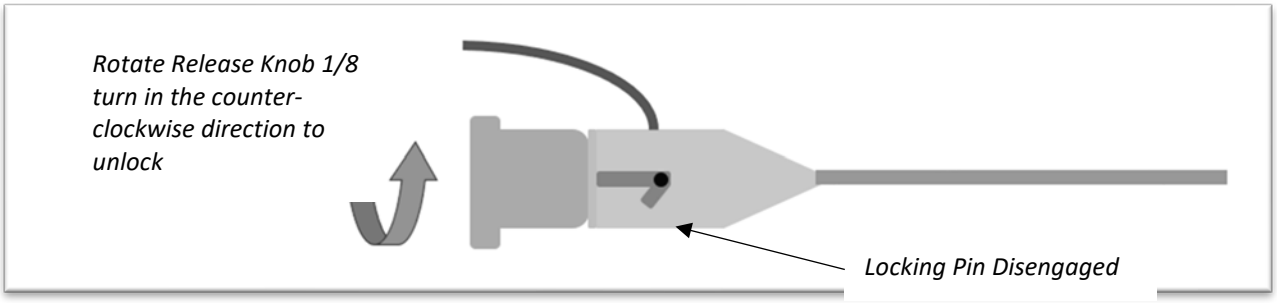


Figure 5b: Pusher hub, release knob in UNLOCKED position

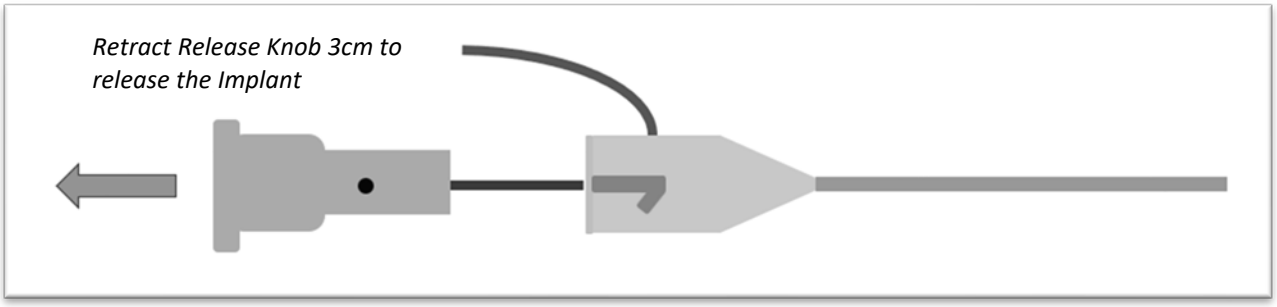


Figure 5c: Pusher hub, release knob RETRACTED, Implant released

CAUTION: Confirm implant position within the false lumen prior to release. Failure to do so may result in device migration, embolization leading to stroke, paraplegia or paralysis.

CAUTION: Failure to withdraw the release knob a minimum of 3cm during the Implant release step may result in a failure to release the Implant.

CAUTION: Attempting to withdraw the Pusher prior to Implant release may result in damage to the Implant leading to embolization, transient or permanent ischemia, or stroke.

NOTE: If the Implant fails to detach from the Pusher following activation of the release knob, gently withdraw the distal end of the Pusher several millimeters into the introducer sheath while observing under fluoroscopy. If the Implant still fails to detach, carefully withdraw the system and introducer sheath simultaneously as one unit, taking care to avoid damaging the Implant or vessel during withdrawal.

16. Additional Implants may be deployed, provided the additional target embolization site can be safely accessed. If implanting more than one Implant, repeat deployment/implantation until the desired number of Implants have been delivered.

17. Upon completion of the Implant deployment and prior to removal of the introducer sheath, perform a final angiogram.

    CAUTION: Aggressive power injection into the false lumen following release of the Implant may result in Implant migration, embolization and transient or permanent ischemia or stroke.

18. Withdraw and remove the introducer sheath.

12. Product Disposal Information

After the device usage, the False Lumen Embolization 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.

13. Potential Risks and Benefits

Embolization of the false lumen of an aortic dissection with the False Lumen Embolization System is designed to reduce perfusion into the false lumen, which may prevent disease progression and consequent aortic rupture (by stabilization/regression of the false lumen diameter and stabilization of the true lumen diameter). Embolization of the false lumen may also contribute to reduced dissection-related reinterventions and reduced mortality. However, the benefits of the False Lumen Embolization System for the treatment aortic dissections are not fully established at this time.

Adverse events potentially associated with the False Lumen Embolization System are listed in **Section 6**. The associated hazards can be categorized as device-related (e.g., lack of sterility, toxicity, biodegradation of the Implant), deployment-related (e.g., failure to reach the target site, misdeployment, further dissection), and performance-related (e.g., unintended ischemia, malperfusion, lack of thrombosis, failure to stabilize the false lumen). The consequent risks to the patient depend on the incidence and effects of each hazard, which have been evaluated through preclinical testing. There are no alternative devices with the same intended use as the False Lumen Embolization System and therefore the risks must be weighed against the risks associated with no treatment or other aortic dissection management techniques such as open surgical repair. Implantation of the False Lumen Embolization System is a minimally invasive alternative to open surgical repair. Therefore, potential clinical benefits to patients treated with the False Lumen Embolization System may include a suitable dissection repair with less risk and fewer complications than those treated with open surgical repair, or reduced occurrence of continued false lumen perfusion after endovascular repair.

15. Symbols

The following symbols are used within product labeling:

	Refer to Instructions for Use		Do not use if package is damaged
	Manufacturer		Caution
	Use-by Date		Do Not Resterilize
	Lot Number		Keep Dry
	Catalog Number		MR Conditional
	Single Use Only. Do not Re-use		Non-Pyrogenic
	Sterilized by Radiation (Electron Beam)		Storage, Temperature
	Single sterile barrier system with protective packaging outside		Storage, Humidity
	Medical Device		Date of Manufacture
	Restricts this device to sale by or on the order of a physician (or properly licensed practitioner)		

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