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**MULTILAYER FLOW MODULATOR (MFM®)
FOR PERIPHERAL ANEURYSMS TREATMENT
(LOWER LIMBS, VISCERALS AND SUBCLAVIAN)
WITH ITS ANGIOGRAPHIC CONTROL DELIVERY SYSTEM**

INSTRUCTIONS FOR USE (I.F.U.)

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Before the handling of this product, please read carefully these Indications, Contra-indications, Warnings and Precautions, Clinical Use information, Directions for Use and Sizing Recommendations.

These Instructions for Use are transversal to all Cardiatis Multilayer Flow Modulator (MFM®) devices designed to treat Peripheral Aneurysm: of the Lower Limbs Arteries (iliac, femoral and popliteal), Visceral Arteries (celiac, superior mesenteric, inferior mesenteric, hepatic, splenic, renal) and subclavian artery.

All the Specifications for each product (device nominal length, nominal diameter, respective delivery system) are summarized in the table in the end pages.

1. DEVICE DESCRIPTION

The multilayer flow modulator (MFM®) is a radiopaque tubular self-expandable implant (see Figure 1). It consists of multilayer braided wires mesh made of a cobalt alloy.

The radiopaque delivery system consists of a guiding catheter (braided sheath with a softtip). The delivery system - size from 6 to 8 F is compatible with a 0.025" guidewire. The delivery system size from 9 to 12 F - is compatible with a 0.035" guidewire.

The sheath is connected to the pusher by a Y hemostasis valve. When it is tightened, the sheath is locked to the holder. This lock is necessary to prevent premature deployment of the multilayer flow modulator.

The multilayer flow modulator is preloaded into its delivery system. Both are introduced percutaneously or by cut down through the access artery (preferentially the femoral artery) and advanced endoluminally under angiographic visualization to the desired lesion site.

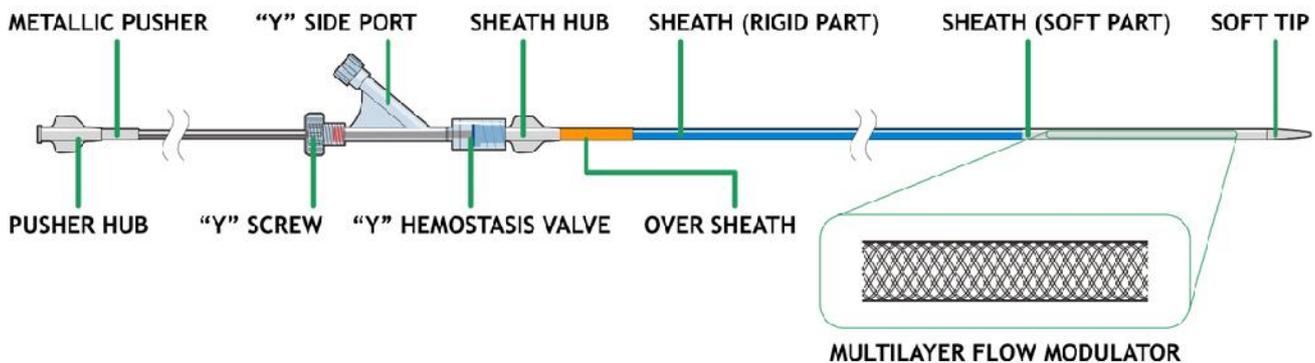


Figure 1.

The delivery system is compatible to available introducer's sheath, the appropriate size is indicated in table 1 and on the label of the device.

2. INDICATIONS

The multilayer flow modulator (MFM®) within its delivery system is indicated for endovascular treatment of patients with peripheral arterial aneurysms with morphology suitable for endovascular repair, including:

- ✓ Adequate iliac/femoral arteries access compatible with the required delivery system,
- ✓ Healthy arterial proximal and distal segments (neck) for good sealing with MFM® diameter compatible with the compression rate as defined in the table 2.
- ✓ Non aneurysmal artery segment (neck) with proximal and distal landing zones of at least 10 mm.

3. CONTRAINDICATIONS

All usual contraindications applicable to angioplasty of arterial lesions and stenting:

- ✓ Inadequate Arterial Access (due to tortuosity, calcifications, occlusion);
- ✓ Inadequate distal flow
- ✓ Absence of Healthy Landing Zone;
- ✓ Ruptured Aneurysm;
- ✓ Not to be combined with previously implanted Stent-Graft;
- ✓ Presence/ Suspicion of Infection (ex: Mycotic Aneurysm);
- ✓ Presence/ Suspicion of Connective Tissue Disorders;
- ✓ Patient undergoing Chemotherapy treatment;
- ✓ History of Coagulation Problems;
- ✓ Takayasu's Arteritis;
- ✓ Patients who cannot tolerate contrast agents;
- ✓ Arterio-venous fistula;
- ✓ Pregnant or breastfeeding woman;
- ✓ People aged less than 18 years old.

4. RECOMMENDATIONS

It is recommended to size the diameter of the flow modulator to the diameter of the target vessel according to the characteristics given in Tables 1 & 2.

5. WARNINGS & PRECAUTIONS

5.1 GENERAL

- J Read all instructions and sizing recommendations carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.
- J Implantation of the device requires experience with standard interventional procedures. Some national legislation may restrain the authorization to practice this kind of intervention to certain medical professions.
- J Do not attempt to use the MFM® in patients unable to undergo the necessary pre-operative, peri-operative and postoperative imaging.
- J Radiographic equipment providing high quality images is required to accurately control the implant procedure.
- J The device is furnished STERILE and FOR SINGLE USE ONLY. Discard the delivery system after one procedure only. The integrity of the device is not guaranteed for any reuse. In case of reuse, there is a contamination risk. If the device is not deployed, the entire device must be discarded.
- J It should be used before the "Use by" (expiration) date printed on the label.
- J Store at room temperature in dry place.

5.2 WARNINGS

- J When branches or collaterals need to be covered by the MFM®, please verify if there is any stenosis, calcifications or thrombus during the pre-implant CT scan and the angiography prior to the procedure. Should any of these events be identified, proceed to angioplasty/stenting of the branch prior implantation.
- J When overlapping several different diameters, please ensure that the larger diameter is placed into the smaller diameter.
- J The contrast agent must be used with precautions when patient with renal insufficiency, allergies and/or creatinaemia > 200 micromol/l before injection of contrast agent.
- J For the treatment of the splenic aneurysm, the access might be difficult. In the case of severe tortuosity, please, do not force and remove the device.
- J In case of popliteal aneurysm treatment, the overlapping is not recommended.

5.3 IMPLANT PROCEDURE

- J Please follow the sizing table as recommended, otherwise inaccurate placement, inadequate fixation and/or incomplete sealing of the MFM® within the vessel may result in increased risk of peri-implant leak (endoleak type I) or migration of the flow modulator.
- J Systemic Anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol (recommended medication, see §9). If heparin is contraindicated, an alternative anticoagulant should be considered.
- J Minimize handling of the device during preparation and insertion to lower the risk of contamination and infection.
- J Maintain guidewire position during the procedure.
- J Do not bend or kink the delivery system. Doing so, may cause damage to the delivery system and the multilayer flow modulator.
- J Do not rotate the delivery system during access and deployment to avoid any twisting.
- J When the delivery system is inserted in the human body, it should be manipulated under fluoroscopy.
- J Do not exercise extra force during deployment.
- J The use of the MFM® requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure post-operatively. Care should be taken to limit the amount of contrast media used during the procedure.
- J Do not continue advancing any portion of the delivery system if resistance is felt as it might produce arterial wall and/or catheter damage. Stop and assess the cause of resistance. Exercise particular care in areas of stenosis, intravascular thrombus or in calcified or tortuous vessels. In this case, use classical interventional techniques to straighten out the passage. If the access is impossible, choose a different one.
- J Carefully manipulate the catheters, guidewires and sheaths within an aneurysm. Significant disturbances may dislodge fragments of thrombus, which can cause distal embolization.
- J Carefully manipulate the catheters, guidewires and sheaths within the vasculature. Iatrogenic dissection may occur.
- J Care should be taken not to damage or disturb the MFM® after placement when retrieving the delivery system and/or using other instrumentations.

5.4 MRI SAFETY AND COMPATIBILITY

Non-clinical testing has demonstrated that the MFM® is MR conditional as defined in ASTM F2503. For placement in artery, it can be scanned safely any time after implantation under the following conditions:

- J Static magnetic field of 1.5 Tesla or 3.0 Tesla
- J Spatial gradient field of 2500 Gauss/cm or less
- J Maximum whole body average specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning for

patient landmarks above umbilicus.

- J For information, maximum WB-SAR of 1W/kg for 15 minutes of scanning for patient landmarks below umbilicus.
- J Transmit body coil should be used in normal operating mode, as defined in IEC 60601-2-33. The effect on heating of local transmit coils is not known.

6. ANTICIPATED ADVERSE EVENTS

Implantation of a MFM[®] device in the artery may lead to Adverse Events such as:

- J Bleeding during or after the procedure;
- J Problems with Blood Coagulation;
- J Haematoma;
- J Development of a false aneurysm on or around the implanted artery, or new Stenosis of an Artery;
- J Cardiac Complications;
- J Thrombosis;
- J Intestinal Complications;
- J Impaired Sexual Function, either impotence or retrograde ejaculation for men;
- J The need for an emergency operation;
- J Inability to implant the MFM[®] device in the intended position, or incorrect placement;
- J Rupture of part of the device;
- J Migration of the device within the artery;
- J Change in the shape or size of the arteries;
- J Pulmonary Complications;
- J Pseudoaneurysm;
- J Sustained Hypotension or Hypertension;
- J Syncope/ Vasovagal Response;
- J Problems in gut;
- J Obstruction of the Blood Flow;
- J Bleeding or a collection of blood from the artery used to implant the device;
- J Complications affecting the nervous system;
- J Stroke;
- J Insufficient Blood irrigation in the spine or lesion of certain Spinal Nerves;
- J Loss of ability to move and/or feel certain parts of the body;
- J Infection;
- J Fever;
- J Medical and/or surgical reintervention;
- J Embolism;
- J Wall perforation requiring reintervention;
- J Bruising or hemorrhage at the access site.

7. CLINICAL USE INFORMATION

The MFM[®] should only be used by a skilled multi-disciplinary team trained and skilled in standard vascular interventional techniques.

7.1 EQUIPMENT AND MATERIALS REQUIRED

- J Fluoroscope with digital angiography capabilities (C-arm or fixed unit)
- J Contrast media
- J Heparinized saline solution

7.2 RECOMMENDED ACCESSORIES

The following products are recommended:

- J The delivery system - size from 6 to 8 F - is compatible with a 0.025" guidewire. (please refer to table 1)
- J The delivery system - size from 9 to 12 F is compatible with a 0.035" guidewire. (please refer to table 1)
- J Appropriate Introducer Sheath, if used
- J Sizing instruments
- J Angiographic radiopaque tip catheter
- J Puncture needle
- J Stopcock and connecting tubing

8. DIRECTIONS FOR USE (SEE §5 (WARNINGS & PRECAUTIONS))

The following instructions are basic guidelines for flow modulator placement.

8.1 PREPARATION & INSPECTION PRIOR TO USE

1. The MFM[®] preloaded into its delivery system is supplied sterile in peel-open packaging.
2. Prior to use, verify the size of the device.
3. Puncture the selected entry artery using standard techniques (percutaneous or cut down approach). Upon vessel access, insert the right 0.025" or 0.035" guidewire and appropriate size sheath 6-8F and 9-12F, respectively.
4. Perform an angiography to localize the site of deployment, to measure the artery lumen diameters and the

lesion length to treat. Verify the measurements (see Tables 1 and 2, for guidelines).

CAUTION: Care should be taken to verify if any of the branches to be covered by the MFM[®] are calcified, stenosed or occluded. In this case, first proceed to the angioplasty/stenting of the branch prior to the procedure.

5. Before use, inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the device and return it to Cardiatis S.A.
6. Open the sterile packaging and transfer the contents to the sterile field.
7. Flush the delivery system with heparinized saline solution through the side port of the Y hemostasis valve until fluid emerges between the sheath distal end and the tip (see Figure 2). Continue to inject flushing solution through the device. Discontinue injection and close the Y side port (stopcock on connecting tube and/or male luer lock cap).
8. Flush the delivery system with heparinized saline solution through the hub on the metallic pusher until fluid emerges at the tip (see Figure 3). Continue to inject flushing solution through the device.
9. Check that there is no gap between the tip and the catheter. If so, pull back the pusher to ensure a smooth transition.
10. Check that the Y hemostasis valve is screwed onto the pusher to avoid premature MFM[®] deployment.

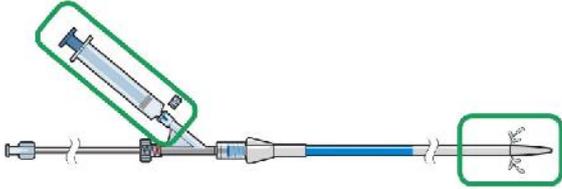


Figure 2.



Figure 3.

8.2 INSERTION AND ACCESS

1. To minimize any distal embolization and risk of blood clotting: use systemic heparinization.
2. Insert the 0.025" or 0.035" guidewire into the arteriotomy and advance through catheter and up to the artery (proximal to the lesion). Remove flush catheter and sheath while maintaining guide wire position.
3. The delivery system - size from 6 to 8 F - is compatible with a 0.025" guidewire.
The delivery system - size from 9 to 12 F - is compatible with a 0.035" guidewire.
4. Use the adequate size for the introducer sheath if necessary. (cfr table 1)
5. Introduce the delivery system onto the guidewire in place.
6. Advance the whole system until the radiopaque marker at the delivery system tip (which indicates the upper limit of the MFM[®]) is placed above the target lesion site, at least 10 mm upstream (see Figure 4).

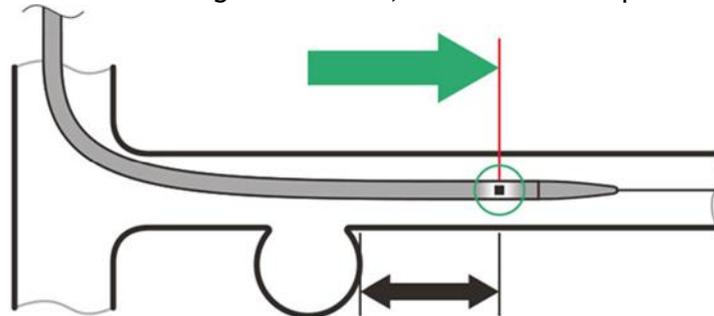


Figure 4.

CAUTION: Maintain guidewire position during the procedure.

8.3 DEPLOYMENT

1. Verify position of guide wire in the artery upstream to the tip.
2. Repeat the angiogram to verify the position.
3. To deploy the MFM[®], unscrew the Y hemostasis valve (Figure 5, Step 1) and slowly withdraw the delivery system to the target lesion site by gently and progressively pulling the sheath towards the fixed position of the pusher (Figure 5, Step 2). The MFM[®] begins to release.

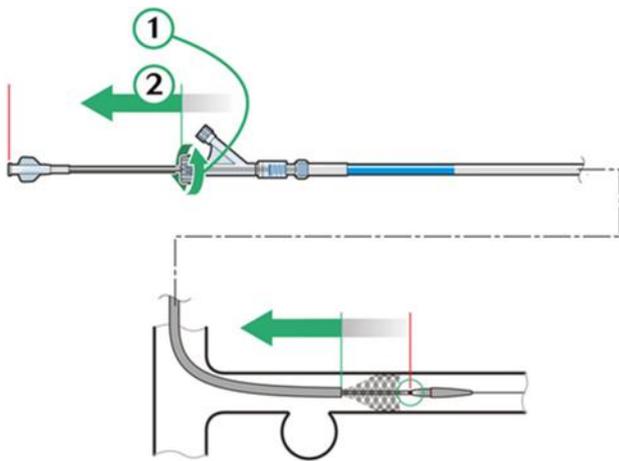


Figure 5. Start Deployment

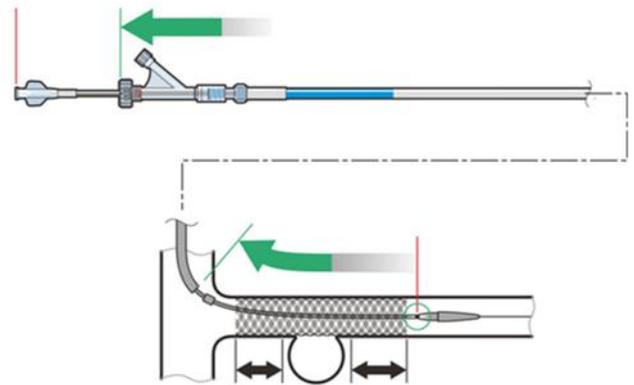


Figure 6. Full deployment

CAUTION: To ease self-fixation of the MFM®, release gently step by step under fluoroscopy and if necessary “push-pull”. See full deployment (Figure 6).

8.4 WITHDRAWAL

1. When fully deployed, safely retrieve, under fluoroscopic control, the pusher in its initial position in order to bring the tip in front of the sheath (see Figure 7 and Figure 8, Step 1) and lock the Y hemostasis valve (see Figure 8, Step 2).

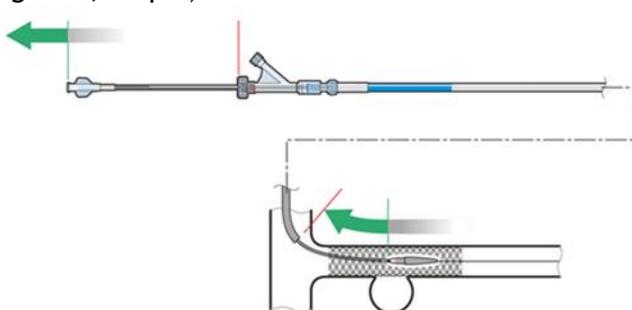


Figure 7. Retrieval of the tip

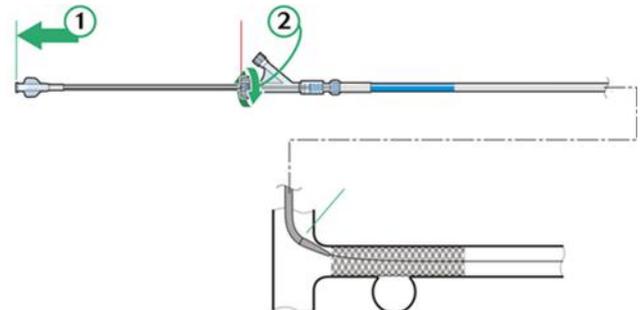


Figure 8. Tip back in its original position

2. The delivery system can be withdrawn and discarded.

3. Position angiographic catheter above the treated lesion. Perform angiography to verify position of the flow modulator with respect to the aneurysm and to check branch patency.

4. If more than one MFM® is needed to cover the lesion, an additional device can be used. Repeat the same procedure (Starting 8.1 Step 4).

NOTE: When overlapping, please ensure a minimum of 20 mm overlap and that the bigger diameter is placed in the smaller diameter as shown in Figure 9 and Figure 10.

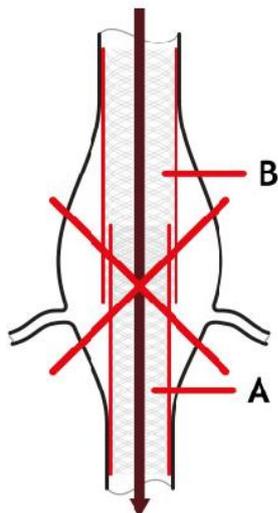


Figure 9. Wrong procedure

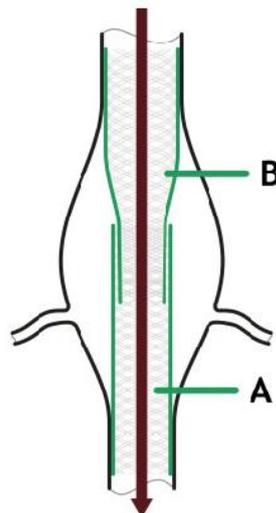


Figure 10. Correct procedure

Diameter A < diameter B

5. When the procedure is complete, remove the sheaths, wires and catheters.

6. Close the arteriotomy using applicable standard techniques.

9. RECOMMENDED MEDICATION

Antithrombotic medications are those that are used as current practice in the hospital institution. The following guidelines are given for information and not with the aim of dictating medical practice.

Before the procedure:

ASA 75-162mg per day for 3 days

During the procedure:

-) Standard intravenous bolus of 2500 U.I. Heparin. ACT (Activated Clotting Time) must be greater than 200 seconds throughout the procedure.

After the procedure:

-) Dual antiplatelet therapy.
-) Clopidogrel 75 mg daily in addition to ASA 75-162mg daily at least 1 month after MFM® implantation. Followed by ASA 75-162 mg daily for life.

10. WARRANTY

CARDIATIS warrants only that:

-) The device has been designed and manufactured to provide the highest possible reliability with regards to the actual knowledge of today.
-) The device has been inspected and found free of defects at the time of the packaging for shipment.
-) The device has been given to the carrier in a sterile state.
-) Factors such as shipping, storage and handling, patient selection and skills in the use of the device can affect the product performance. Cardiatis cannot control these factors and therefore will not be liable for any damage, loss, or expense, consequential or incidental.
-) No person has the authority from Cardiatis to make any warranty or assume any liability other than the above.

SYMBOLS AND DEFINITIONS

	Reference or Catalog Number (symbol followed by the reference number)
	Serial number (symbol followed by the serial number)
	Date of Manufacture (symbol followed by a date)
	Use by (Expiration) Date (symbol followed by a date)
	Content (1 unit)
	Do not reuse / Single use only
	Pyrogen Free
	Do not resterilize
	Keep away from sunlight
	Keep dry
	Consult instructions for use
	Manufacturer (accompanied by the name, address and contact information)
	CE Mark (followed by the Certification Notify Body Code Number)
	Sterilized using ethylene oxide. In the label, symbol followed by the sterilization lot number.
	MR Conditional. This means MFM® has been demonstrated to not present any known hazards in a specified MRI environment with specified conditions of use.
	Caution. Safety symbol used to highlight that there are specific warnings or precautions associated with the device. Read carefully the instructions for use.
	Do not use if package is damaged. Do not use if the product sterilization barrier or its packaging is compromised.