CGUARD® PRIME

Carotid Embolic Prevention System

Instructions for Use

INSPIREMD

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INSPIREMD

1 DEVICE DESCRIPTION

The InspireMD CGuard® Prime Carotid Embolic Prevention System (EPS) is designed to deliver a self-expanding stent to the carotid arteries using a rapid exchange (Rx) delivery system. The self-expanding stent is constructed of a nickel titanium alloy (Nitinol) and is covered by a permanent protective micromesh (MicroNet™). The stent is loaded into the Rx delivery system. The delivery system is placed at the intended lesion site and then the stent is expanded by retraction of a protective sheath. The stent and micromesh remain as a permanent vessel scaffolding implant. Upon deployment, the stent imparts an outward radial force on the arterial wall to establish lumen patency. The stents are available in the below size matrix.

Vessel Diameter (mm)	Length (mm)				
	Diameter (mm)	20	30	40	60
4.8 – 5.7	6.0	CND0620	CND0630	CND0640	CND0660
5.6 – 6.5	7.0	CND0720	CND0730	CND0740	CND0760
6.4 – 7.3	8.0	CND0820	CND0830	CND0840	CND0860
7.2 – 8.1	9.0	CND0920	CND0930	CND0940	CND0960
8.0 – 9.0	10.0	CND1020	CND1030	CND1040	CND1060

Table 1- CGuard® Prime Carotid EPS Size Matrix

Figure 1 CGuard® Prime Carotid stent

The Rapid Exchange (RX) CGuard® Prime delivery system is designed with two deployment steps mechanism: pre-release mechanism (step 1), and stent deployment (step 2), to improve the system operation and allow easy and accurate deployment. This delivery system is suitable for all sizes of CGuard® Prime stents. It is comprised of an outer shaft and an inner assembly. A pictorial representation of the delivery system is presented in Figure 2.

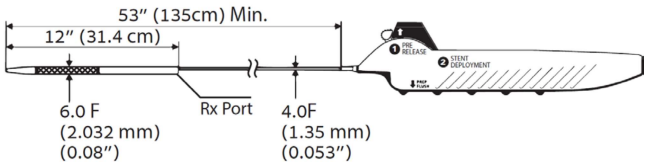

Figure 2. Rx Delivery system of 135 cm working length

The following accessories are compatible with the 135 cm delivery system:

1. 8F Guiding catheters (Inner Diameter ≥2.20 mm, or >0.086").
2. Vascular sheath 6F (Inner Diameter ≥2.20 mm, or >0.086").
3. 0.014" (0.36 mm) guiding wire, with at least 190 cm long.
4. Proximal protective device Inner Diameter ≥2.12mm or ≥0.083" (for example 9F Mo.Ma™ ultra by Medtronic), or comparable.
5. Distal protection device Emboshield NAV6™ by Abbot Cardiovascular, or comparable.
6. 3 cc or 5 cc luer lock syringe for flushing.

2 HOW SUPPLIED

This device is supplied sterile after sterilization with ETO. Non-pyrogenic. Intended for single use only.

Contents: One (1) CGuard® Prime Self-Expanding Carotid Stent with one Rx Delivery System.

The system is placed inside a hoop and secured to the tray for support.

The CGuard® Prime Self-Expanding Carotid Stent with Rx Delivery System is designed for single use only; do not reuse the device.

Reuse may cause device failure or procedural complications including device damage, compromised device biocompatibility, and device contamination which may lead to patient harm.

3 STORAGE & HANDLING

- Store in a dry place. Avoid exposing the package or device to extreme hot or cold temperatures.
- Do not use the CGuard® Prime self-expanding carotid stent with the Rx delivery system if the packaging is compromised or if the device is damaged.
- Handle and dispose of the device and packaging in accordance with acceptable medical practice and with applicable local, state, and federal laws and regulations.

4 INDICATIONS, INTENDED USE AND PATIENT TARGET GROUP

The CGuard® Prime EPS is indicated for:

Improving carotid luminal diameter in patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet both criteria outlined below:

- Patients with neurological symptoms and >50% stenosis of the common or internal carotid artery by either ultrasound or angiogram or patients without neurological symptoms and > 80% stenosis of the common or internal carotid artery by either ultrasound or angiogram.
- Patients having a vessel with reference diameters between 4.8 mm and 9.0 mm at the target lesion.

5 CLINICAL BENEFITS

Benefits associated with the use of the CGuard® Prime System compared to surgical carotid endarterectomy may include, but are not limited to:

- Less invasive treatment of carotid artery stenosis
- Reduced pain and discomfort
- The percutaneous approach may lead to a shorter overall procedure time and a reduction in scaring

6 CONTRAINDICATIONS

The CGuard® Prime EPS is contraindicated for use in:

- Patients in whom anti-coagulant and/or antiplatelet therapy is contraindicated
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction positioning, support or proper performance of a guide catheter, sheath, or stent system to allow the effective implant
- Patients with known hypersensitivity to nickel-titanium
- Patients with uncorrected bleeding disorders
- Lesions in the ostium of the common carotid artery

7 WARNINGS

- Only physicians familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid stent placement should use this device.
- This device is intended for single-use only.
- DO NOT use the product after the 'Use By' date noted on the packaging
- If overlapped stents are required, stent materials should be of similar composition.
- *Do not use contrast material while performing flush preparation to the CGuard® Prime EPS delivery system.*
- Perform all device exchanges slowly in order to prevent air being introduced to the system, or trauma to the artery.
- Pre-dilating the lesion without embolic protection may increase the risk of an adverse outcome.
- Implanting a stent may lead to distal and/or proximal dissection and may cause acute closure of the vessel, requiring additional intervention (carotid endarterectomy, further dilatation, or placement of additional stents).
- The stent systems may cause thrombus migration from the site of implant down the arterial lumen and may produce distal embolization.
- In the event of thrombosis of the expanded stent, thrombectomy or thrombolysis should be considered, and surgical removal of the stent may be required.
- In the event of complications such as infection, pseudo-aneurysm, or fistulization, surgical removal of the stent may be required.
- If a distal protection filter (embolic protection system) is used, maintain an adequate distance between CGuard® Prime EPS and the filter, to avoid potential engagement or entanglement. If filter engagement and/or filter detachment occurs, additional catheter-based intervention or surgical conversion may be required.
- If a distal protection filter (embolic protection device) is used, choose a system with at least 190 cm length (for CGuard® Prime 135 cm working length).
- Package contains one self-expanding carotid stent system compressed in an Rx delivery system. Store at room temperature.
- DO NOT re-use. DO NOT re-sterilize, as this can compromise device performance and may increase the risk of cross-contamination due to inappropriate reprocessing.
- The delivery system is not designed for use with power injection. The use of power injection may adversely affect device performance.
- Ensure optimal positioning of the stent prior to deployment. Position correction might be performed after pre-deployment step. Once deployment is initiated the stent cannot be repositioned or recaptured. Stent retrieval methods as snares, and/or forceps may result in additional trauma to the carotid vessel or the vascular access site. Complications may result in bleeding, haemathoma, pseudoaneurysm, stroke or death.
- Continuously observe the CGuard® Prime Stent under fluoroscopy during stent deployment.
- Safety and effectiveness of CGuard® Prime have not yet been established in pregnant patients or patients under the age of 18.

8 PRECAUTIONS

CAUTION: *Venous access should be available during carotid stenting to manage possible bradycardia and/or hypotension by either pharmaceutical intervention or placement of a temporary pacemaker, if needed.*

- The use of embolic protection devices is recommended when using CGuard® Prime EPS (refer to the list of compatible accessories above).
- Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.
- The stent and the delivery system are designed to perform as an integrated system and to be used only as designed.
- Do not expose the delivery system to organic solvents as structural integrity and/ or device function may be impaired.

9 UNDESIRABLE SIDE-EFFECTS

Based on the literature and on clinical and commercial experience with carotid stents and embolic protection systems, the following list includes possible adverse events associated with these devices:

- Abrupt closure
- Acute myocardial infarction
- Allergic reaction (contrast medium; drug; stent or filter material)
- Amaurosis fugax
- Aneurysm or pseudoaneurysm in the vessel or at the vascular access site
- Angina Coronary ischemia
- Arrhythmia (including premature beats, bradycardia, atrial and/or ventricular tachycardia, atrial and/or ventricular fibrillation [VF])
- Asystole or bradycardia requiring placement of a temporary pacemaker
- Arteriovenous fistula
- Bleeding complications from anticoagulant or antiplatelet medication requiring transfusion or surgical intervention
- Cerebral edema
- Cerebral haemorrhage
- Cerebral ischemia
- Congestive heart failure (CHF)
- Death
- Detachment and/or implantation of a component of the system
- Dissection of blood vessel
- Distal embolic protection device thrombosis and or occlusion
- Emboli (air, tissue, plaque, thrombotic material, stent)
- Emergent or urgent surgery (Carotid Endarterectomy [CEA])
- Emergent surgery to remove stent or distal embolic protection device
- Fever
- Haematoma at vascular access site, with or without surgical repair
- Haemorrhagic event, with or without transfusion
- Hyperperfusion syndrome
- Hypotension/Hypertension
- Infection, local or systemic including bacteremia or septicemia
- Ischemia/ infarction of tissue organ
- Pain (head/neck)/ severe unilateral headache
- Pain at catheter insertion site
- Renal failure/insufficiency secondary to contrast medium
- Restenosis of vessel in stented segment
- Seizure
- Stent distal embolic protection device entanglement/ damage
- Stent distal embolic protection device collapse or fracture
- Stent malposition/migration
- Stent thrombosis occlusion
- Stroke / cerebrovascular accident (CVA) / transient ischemic attack (TIA)
- Total occlusion of the carotid artery
- Vascular thrombosis/occlusion at puncture site, treatment site, or remote site
- Vessel dissection, perforation or rupture
- Vessel spasm or recoil

10 MR SAFETY INFORMATION

No clinical testing was performed on MR (Magnetic Resonance) to evaluate the CGuard® Prime Carotid Stent compatibility concluding CGuard® Prime Carotid Stent is MR Conditional. A patient with a CGuard® Prime implant can be safely submitted to MR under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 1,900-gauss/cm (19-T/m)
- Maximum MR system reported a 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 CGuard® Prime Carotid Stent is expected to produce a maximum temperature rise of 2.7˚C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the CGuard® Prime Carotid Stent extends approximately 15-mm from this device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MR system. The lumen of the CGuard® Prime Carotid Stent cannot be visualized on the gradient echo or T1-weighted spin echo pulse sequences.

11 STENT SIZE DETERMINATION

CAUTION: *stent sizing is important for successful stenting. A stent shall provide a minimum of 0.5mm -1mm over-size between the vessel and the stent, depending on the stent size. This is recommended in order to achieve optimum sizing and stent expansion of the self-expanding stent (see table 1 for reference).*

- The stent will expand to accommodate the varying sizes of the internal carotid artery, bifurcation, and common carotid artery. Thus, the stent sizing should be determined usually by the common carotid artery diameter.
- For example, select a 6.0 mm stent to treat a 4.8 – 5.7 mm diameter vessel. Select a 7.0 mm stent to treat a 5.6 – 6.5 mm diameter vessel.
- The mean percentage of foreshortening for all stent sizes is less than 6%. The shortest stent length consistent with total lesion coverage plus the safety margins is the optimal length size. Should adequate coverage by one stent not be possible, the use of a second stent is at physician's discretion. In that case, implant the distal stent first.

WARNING: *The CGuard® Prime Stent is contraindicated for use with lesions in the ostium of the common carotid and aortic artery.*

WARNING: *Appropriate sizing of the stent to the vessel is required to reduce the possibility of stent migration.*

12 MATERIAL REQUIRED

- 6F Vascular sheath or 8F guiding catheter/ sheath length should not interfere with stent Rx delivery system requirements
- Optional pre-dilatation balloon catheter/post-dilatation balloon catheter
- A carotid distal EPD with at least 190 cm length or a proximal protection system
- A 0.014" guidewire
- One 3 cc or 5 cc luer lock syringe for delivery system preparation
- 500 cc heparinized saline solution (sterile)

13 PRE-PROCEDURE

Patient preparation and sterile precautions should be the same as for any angioplasty procedure. The placement of the carotid stent in a stenotic or obstructed carotid artery must be done in a procedure room with angiography capabilities. Angiography should be performed to map out the extent of the lesion and the collateral flow. Access vessels must be sufficiently patent to proceed with further intervention.

CAUTION: *Do not use if the package is damaged, unintentionally opened or exposed to environmental conditions outside of those specified on the label before use.*

14 INSPECTIONS PRIOR TO USE

- Inspect the CGuard® Prime protective packaging (pouch). Ensure that the pouch is sealed and in an undamaged/non-deformed state.

CAUTION: *Do not use the system if the protective packaging is found to be damaged.*

- System unpackaging: The operating assistant (non-sterile assistant) should open the protective packaging, and the sterile operator should take the system tray out of the protective packaging (pouch).
- All the following steps as described below, should be performed by the physician (an sterile operator);
- Carefully remove the CGuard® Prime EPS Self-Expanding Stent with Rx Delivery System from the hoop and out of its tray. Lay the device flat. Take care not to kink the shaft of the Rx delivery catheter system.
- Inspect the delivery system handle for any damage (see Figure 3)

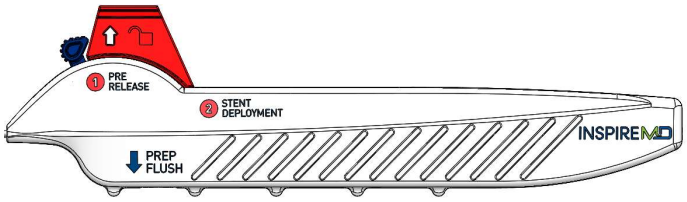

Figure 3 Delivery System handle

- Inspect the Rx delivery system distal shaft and tip to verify that it has not been damaged during shipment.

CAUTION: *Carefully inspect the CGuard® Prime EPS to verify that the device has not been damaged in shipment. Do not use damaged equipment.*

CAUTION: *The Rx delivery system has an internal shaft. Take care to avoid unnecessary handling which may kink or damage the delivery system. Keep the Rx delivery system as straight as possible and the delivery handle stationary during deployment. Do not use if the device is kinked.*

- Ensure that the stent is fully covered by the delivery system shaft.

CAUTION: *Special care must be taken not to handle or in any way disrupt the stent on the delivery system. This is especially important during delivery system removal from packaging, placement over the distal embolic protection device wire and advancement through a haemostatic valve and guiding catheter hub.*

CAUTION: *The stent on the Rx delivery system is intended to perform as a system. Do not remove the stent from the delivery system as removal may damage the stent. If removed, the stent cannot be placed back on the Rx delivery system.*

15 DELIVERY SYSTEM PREPARATION

CAUTION: *Do not expose the CGuard® Prime EPS to organic solvents as structural integrity and/or function may be impaired.*

- For device flushing, connect a 3cc or 5 cc luer lock syringe to the "PREP FLUSH" port (see Figure 4) filled with heparinized saline solution (DO NOT USE CONTRAST), maintain positive pressure until saline fluid drops are observed exiting the CGuard® Prime EPS at the distal end. This process may take up to 30 seconds. Ensure saline is observed at the distal end as well as at the RX guide wire port.

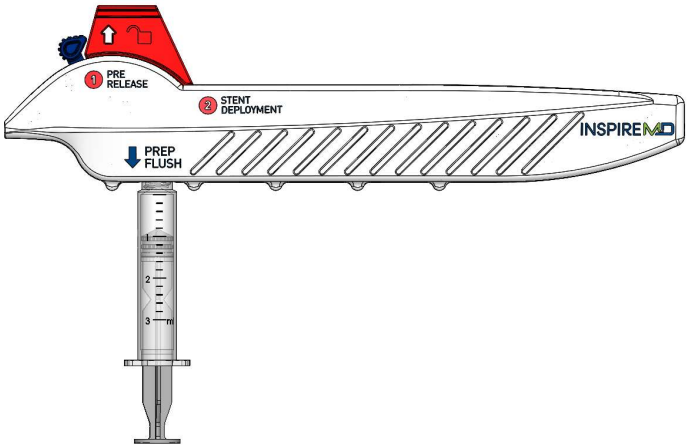

Figure 4 Example of 3cc luer lock syringe connected to the CGuard® Prime for flushing

- At the end of the flushing process, remove the syringe.
- The system is flushed.

CAUTION: *Make sure to flush the system with at least 2cc of saline.*

CAUTION: *Ensure correct flushing is performed in order to remove all air from the delivery system and eliminate the chance of friction within the sheath.*

CAUTION: *Ensure that CGuard® Prime EPS is fully flushed with heparinized saline prior to use. Do not use the CGuard® Prime EPS if flushing is not visible exiting at the distal end of the catheter.*

CAUTION: *Do not use contrast material while flushing.*

- Keep the device straight and flat to avoid kinking the shaft.
- Special care must be taken not to handle or in any way disrupt the stent on the delivery system. This is most important during catheter removal from packaging, placement over the guidewire and advancement through the haemostasis valve and guiding catheter or vascular sheath.
- Do not attempt to deploy the stent from its delivery system while the system is not located in target lesion. If deployed, the stent cannot be retrieved back into the delivery system and the stent may become damaged.

16 LESION PREPARATION

- Maintain the patient's Activated Clotting Time (ACT) at > 250 seconds throughout system usage.

WARNING: *Administer heparin dose sufficient to maintain an ACT of > 250 secs to prevent thrombus formation on the devices.*

CAUTION: *Venous access should be available during carotid stenting to manage bradycardia and or hypotension by a pacemaker placement or pharmaceutical intervention, if needed.*

CAUTION: *The CGuard® Prime EPS must be used with a guiding catheter or vascular sheath to maintain adequate support of the 0.014" guidewire or embolic protection device throughout the procedure.*

CAUTION: *The system is not compatible with guidewires or embolic protection devices larger than 0.014" wire (0.36 mm).*

CAUTION: *Use of automatic bleedback control haemostatic valves is not recommended.*

CAUTION: *When the catheter is in the body, it should be manipulated only under fluoroscopy. Radiographic equipment that provides high-quality images is needed.*

WARNING: *Perform all catheter exchanges slowly in order to prevent air embolism or trauma to the artery.*

- It is recommended to use a proximal or distal embolic protection device.
- If required, pre-dilate the lesion with an appropriate size balloon dilatation catheter to a minimum of 3.0 mm after the distal protection device is in place beyond the lesion.
- Note: If no pre-dilatation balloon is utilized, there must be a minimum luminal opening of 3.0 mm to enable retrieval of the tip of the CGuard® Prime delivery system.
- Maintain the embolic protection device stationary while withdrawing the balloon catheter.

17 PROCEDURE

- If lesion pre-dilatation has been performed, remove the balloon catheter and load the delivery system onto the 0.014" (0.36 mm) guide wire.

CAUTION: *Using a proximal protection device (Mo.Ma™ with minimum internal diameter of 2.12 mm or 0,083") along with a power injector for lesion visualization is not recommended, CGuard® Prime 135 cm working length delivery system may move distally from its position during injection.*

- Keep the device flat to avoid kinking the shaft.
- Insert the Rx delivery system through the haemostatic valve adapter. Ensure that the haemostatic valve of the guiding sheath/ guiding catheter is open to allow freedom of movement of the delivery system outer sheath during deployment.

CAUTION: *If resistance is encountered during Rx delivery system introduction, the system should be withdrawn and a new system used.*

- Advance the stent and Rx delivery system forward under fluoroscopic guidance to the lesion site.

CAUTION: *Avoid any tension in the Rx delivery system prior to deployment.*

18 STENT DEPLOYMENT

The deployment mechanism contains two steps;

Step 1 – Stent Pre-deployment – In this step, the stent is pushed toward the end of the catheter,

Step 2 – Stent Deployment – In this step, the catheter is retracted and the stent is deployed.

CAUTION: *Ensure that the haemostatic valve of the guiding sheath/ guiding catheter is open before the pre-deployment step and during deployment, to allow delivery system outer sheath free movement.*

Catheter positioning at target lesion:

- Ensure optimal positioning of the stent prior to deployment. Once deployment is initiated, the stent cannot be repositioned or recaptured. Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the carotid vasculature and/or vascular

access site. Complications may include death, stroke, bleeding, haematoma, or pseudoaneurysm.
- Confirm the stent position angiographically prior to deployment. Adjust position, if necessary, after pre-deployment step.

Step 1 – Stent Pre-deployment

When the target location is achieved, squeeze the safety tab with your fingers to release the tab and remove the safety tab. Discard the tab. See figures 5.1 and 5.2 below for a visual demonstration of the start and end positions of the safety tab removal step.

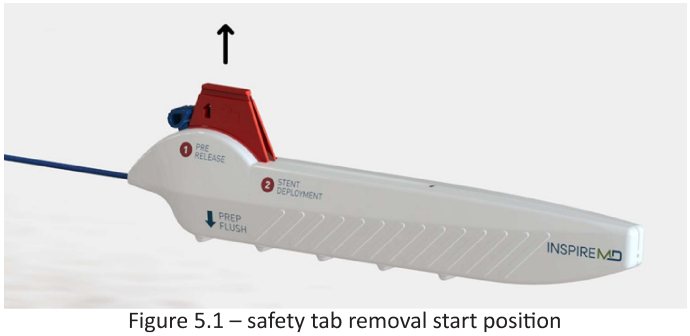

Figure 5.1 – safety tab removal start position

Figure 5.2 – safety tab removal end position

Note: *Ensure that the Rx delivery system is straight and not coiled. Keep the Rx delivery system stationary during deployment. Do not restrain the main shaft of the Rx delivery catheter during deployment. It must be free to move.*

Now the system is ready for deployment.

Carefully retract the lever along the top arc. This is the pre deployment step. See figure 6.1 below for a visual demonstration of the pre-deployment step.

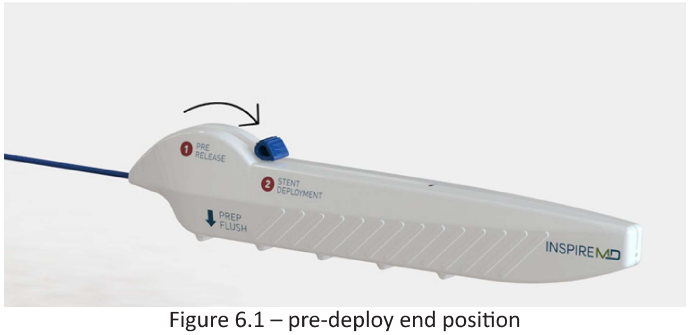

Figure 6.1 – pre-deploy end position

Following pre-deployment, check stent positioning and if required, immediately perform a location adjustment.

CAUTION: *stent location cannot be adjusted once step 2- stent deployment has begun.*

Step 2 – Stent deployment

Carefully retract the lever along the top plane of the handle until the lever reaches the end of its stroke. This is the stent deployment step. See figures 7.1 and 7.2 below for a visual demonstration of the start and end positions of the stent deployment step.

Note: *Before the beginning of the deployment step, ensure that the previous step, pre-deployment, was completed. i.e., the blue lever is located on the lowest point of the arc, ready to be pulled back along the straight plane.*

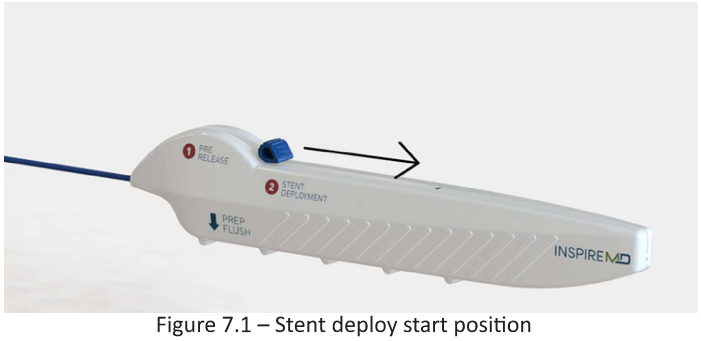

Figure 7.1 – Stent deploy start position

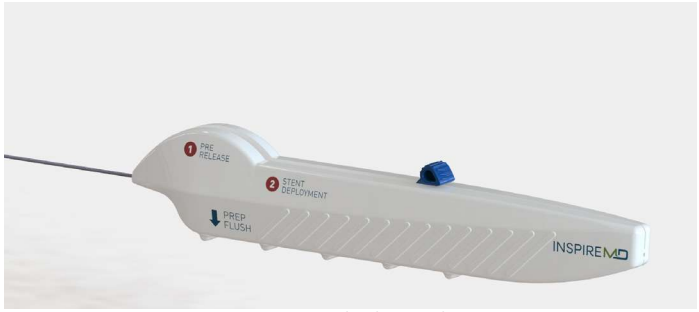

Figure 7.2 – Stent deploy end position

Note: *If significant resistance is encountered during lever retraction for deployment and before stent release is initiated, stop this action and remove the system. Once stent deployment is initiated, the stent cannot be recovered back to the sheath.*

CAUTION: *Once stent placement has been initiated, do not attempt to pull a partially expanded stent back through the guiding catheter or vascular sheath as dislodgement of the stent from the Rx delivery system may occur.*

CAUTION: *In the event of partial deployment of the stent as the result of the inability to fully deploy the stent, remove the entire Rx delivery system from the patient by pulling it gently backward. This may result in damage to the vessel wall and may require surgical intervention.*

CAUTION: *Do not return the deployment lever back to its home position once the deployment step has begun or completed.*

- Under fluoroscopy, confirm that the stent has been deployed at the target lesion.

19 POST STENT PLACEMENT

After stent deployment, carefully withdraw the white distal tip of the Rx delivery system, through the stent. Then, carefully withdraw the delivery system out of the patient body.

CAUTION: *Ensure that the Rx delivery system was entirely taken out of the patient. Once the Rx delivery system is out of the patient, you should be able to entirely remove it from the guiding wire.*

- If additional stent-to-wall apposition is desired or to facilitate the use of other interventional devices, the stent can be post-dilated with a balloon dilatation catheter. Do not expand the stent beyond its unconstrained maximum diameter as stated on the label and in Table 1. Post-dilate as needed in accordance with the compliance chart accompanying the selected balloon catheter.

CAUTION: *When more than one stent is required to cover the*

lesion or if there are multiple lesions, the distal lesion should be stented first followed by stenting of the proximal lesion. Stenting in this order will avoid the need to cross the proximal stent in order to place the distal stent and reduce the chance of dislodging stents that have already been placed.

CAUTION: *Care must be exercised when crossing a newly deployed stent with other interventional devices to avoid disrupting the stent geometry and placement of the stent.*

WARNING: *Overstretching of the artery may result in artery rupture and life-threatening bleeding.*

- Following stent placement, an angiogram should be performed to document the stent final result and vessel patency.
- Upon completion of the angiogram, the embolic protection device should be removed in accordance with the instructions for use with that device.
- Patients should be put on an appropriate regimen of anticoagulants / antiplatelets.

20 INFORMATION ON THE MATERIALS TO WHICH PATIENTS CAN BE EXPOSED

The implant, self- expanding stent is constructed of a nickel titanium alloy (Nitinol) and is covered by a permanent protective micromesh made of polyethylene terephthalate (PET). The delivery system, in which the patient is exposed for a short time is constructed of Stainless steel, Pebax, Polyimide, Polyethylene terephthalate (PET), Polyolefin & Polytetrefluoroethylene (PTFE).

21 WARRANTY/LIABILITY

The product and each component of its system have been designed, manufactured, tested, and packaged with all reasonable care. The warnings contained in InspireMD instructions for use are expressly considered an integral part of this provision. InspireMD warrants the product until the expiration date indicated on its packaging. The warranty is valid provided that the use of the product was consistent with the instructions for use. InspireMD disclaims any warranty of merchantability or fitness for a particular purpose of the product. InspireMD is not liable for any direct, indirect, incidental, or consequential damages caused by the product. Except in the case of fraud or grave fault on InspireMD's part, compensation for any damage to the buyer will not, in any event, be greater than the invoice price of the disputed products. The guarantee contained in this provision incorporates and substitutes the legal guarantees for defects and compliance, and excludes any other possible liability of InspireMD, however originating, from its product supplied.

These limitations of liability and warranty are not intended to contravene any mandatory provisions of law applicable. If any clause of the disclaimer is considered by a competent court to be invalid or to be in conflict with the applicable law, the remaining part of it shall not be affected and remain in full force and effect. The invalid clause shall be substituted by a valid clause that best reflects InspireMD legitimate interest in limiting its liability or warranty. No person has any authority to bind InspireMD to any warranty or liability regarding the product.

22 REPORTING OF ADVERSE EVENT AND SERIOUS INCIDENT

Contact the Customer Service Center with any feedback via the website **https://www.inspiremd.com** or email **complaints@inspiremd.com**. Report any serious incident to the competent authority of the Member State to report any serious incident that has occurred during usage of this device

23 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The SSCP (Summary of Safety and Clinical Rerformance) is available on the InspireMD website:

https://www.inspiremd.com/en/sscp-summary-of-safety-clinical-performance/

and on the European database on medical devices (Eudamed) :

https://ec.europa.eu/tools/eudamed

Basic UDI- DI: 7290018054CGuardPrime01QW