

CGUARD™

Carotid Embolic Prevention System

Instruction for Use

Australia



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2 HOW SUPPLIED

This device is supplied sterile after sterilization with ETO. Non-pyrogenic. Intended for single use only.
Contents: One (1) CGuard™ Self-Expanding Carotid Stent with Rx Delivery System. The system is placed inside a hoop and secured to the tray for support.
Storage: Store in a dry, dark, cool place.

1 DEVICE DESCRIPTION

The InspireMD CGuard™ 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 mesh (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 mesh 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
4.8 – 5.7	6.0	CRX0620	CRX0630	CRX0640
5.6 – 6.5	7.0	CRX0720	CRX0730	CRX0740
6.4 – 7.3	8.0	CRX0820	CRX0830	CRX0840
7.2 – 8.1	9.0	CRX0920	CRX0930	CRX0940
8.0 – 9.0	10.0	CRX1020	CRX1030	CRX1040

Table 1- CGuard™ Carotid EPS Size Matrix

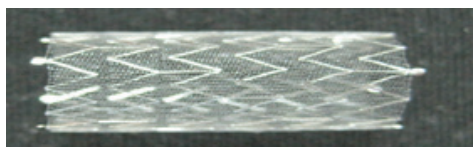


Figure 1 CGuard™ Carotid stent

The stent delivery system is a Rapid Exchange (Rx) system. The delivery system is comprised of an outer shaft and inner assembly. The Rx system is a pin-pull platform available in one size for CGuard™ stents. A pictorial representation of the delivery system is presented in Figure 2. The delivery system has a 135 cm working length and is compatible with the following accessories:

- 0.014" guiding wire Hi-Torque Balance Middle Weight by Abbott Vascular or its comparable, with at least 190 cm long, and 0.014" Distal Protective Devices.
- 8F (ID>2.20) Guiding catheter e.g. Mach 1™ by Boston scientific or Cordis Vista Brite tip MPA 1 or its comparable, or
- Vascular sheath 6F (ID> 2.20) as Neuron Max Vascular Long Sheath by Penumbra, or Destination™ from Terumo, or Flexor® Shuttle® from Cook or its comparable.
- Distal protection device such as Filter EZ™ by Boston Scientific, Spider FX™ by EV3, Abbott Emboshield™ or their comparable.
- Proximal protective device such as a 9F (ID 2.12mm) MoMa ultra by Medtronic or its comparable.

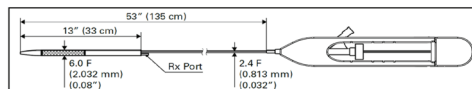


Figure 2 Rx Delivery system.

3 INDICATIONS

The CGuard™ 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.

4 CONTRAINDICATIONS

The CGuard™ EPS is contraindicated for use in:

- Patients in whom anti-coagulant and/or anti-platelet therapy is contraindicated.
- Patients with severe vascular tortuosity or anatomy that would preclude the safe introduction of a guide catheter, sheath or stent system.
- Patients with known hypersensitivity to nickel-titanium.
- Patients with uncorrected bleeding disorders.
- Patients with lesions in the ostium of the common carotid artery.
- Patients with pre- jaw claudication.
- Patients with chronic total occlusion of the index carotid artery.
- Patients with severe circular calcification of the target lesion.

5 WARNINGS

- Only physicians who have received appropriate training and are 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.
- Do not use the product if the temperature indicator on inner pouch is black.
- If overlapped stents are required, stent materials should be of similar composition.
- Do not use contrast material while performing flush preparation to the CGuard™ 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, thrombolysis should be attempted, and surgical removal of the stent may be required.
- In the event of complications such as infection, pseudoaneurysm or fistulization, surgical removal of the stent may be required.
- If a distal protection filter (embolic protection system) is used, maintain adequate distance between CGuard™ EPS and the

filter, to avoid potential engagement or entanglement. If filter engagement and/or entanglement or filter detachment occurs, additional catheter based intervention may be required or surgical conversion.

- If a distal protection filter (embolic protection system) is used, choose a system with at least 190 cm 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. Use of power injection may adversely affect device performance.
- Ensure optimal positioning of the stent prior to deployment. 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™ Stent under fluoroscopy during stent deployment.

6 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 or distal protection device is recommended when using CGuard™ EPS.
- 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.
- In case of a pre-existing stent that extended into the aortic arch, intubate the aortic access with caution.
- Safety and effectiveness has not been established for the following populations:
 1. Stage III renal insufficiency
 2. Acute stroke within 30 days
 3. Myocardial infarct within 72 hours
 4. Atrial fibrillation or any other known reason for stroke different than carotid stenosis
 5. pre-existing stent that extended into the aortic arch

7 POTENTIAL ADVERSE EVENTS

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 vessel or at 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 occlusion
- Emboli, distal (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 malapposition/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

8 MRI Safety Information



Non-clinical testing and MRI simulations were performed to evaluate the entire family of the CGuard™ Carotid Stent. Non-clinical testing demonstrated that the entire family of the CGuard™ Carotid Stent is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
 - Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
 - Maximum MR system reported, 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™ Carotid Stent is expected to produce a maximum temperature rise of 5.0°C after 15-minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artifact caused by the CGuard™ Carotid Stent extends approximately 5-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system. The lumen of the CGuard™ Carotid Stent cannot be visualized on the gradient echo or T1-weighted spin echo pulse sequences.

9 STENT SIZE DETERMINATION

Caution: stent sizing is important to successful stenting. A minimum “interference” fit of approx. 0.5 mm between the vessel and the stent, depending on the stent size, is recommended in order to achieve optimum sizing and stent expansion of the self-expanding stent (see table 1 for reference).

- 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 is optimal. Should adequate coverage by one stent not be possible, the use of a second stent is per physician discretion.

WARNING: The CGuard™ Stent is contraindicated for use with lesions in the ostium of the common carotid artery.

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

10 MATERIAL REQUIRED

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

11 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.

12 INSPECTION PRIOR TO USE

- Remove the CGuard™ EPS Self-Expanding Stent with Rx Delivery System from its protective packaging. Lay the device flat. Take care not to kink the shaft of the Rx delivery catheter system.
- Inspect the Rx delivery system sheath to verify that it has not been damaged during shipment.

CAUTION: Carefully inspect the CGuard™ 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 device is kinked.

- Ensure that the stent is fully covered by the sheath.

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 put back on the Rx delivery system.

13 DELIVERY SYSTEM PREPARATION

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

- For device flushing use a 3 cc luer lock syringe filled with heparinized saline solution (DO NOT USE CONTRAST), maintain positive pressure until saline fluid drops are observed exiting the CGuard™ 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.

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™ EPS is fully flushed with heparinized saline prior to use. Do not use the CGuard™ EPS if flush 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.
- Ensure the haemostatic valve of the introducing sheath is open to ensure freedom of movement of the delivery systems outer sheath, during deployment.
- 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.

14 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™ 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 an embolic protection device or distal protective device.
- If require, 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 predilatation balloon is utilized, there must be a minimum luminal opening of 3.0 mm to enable retrieval of the tip of the CGuard™ delivery system.
- Maintain the embolic protection device stationary while withdrawing the balloon catheter.

15 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 (MoMa™ with minimum ID of 2.12 mm) along with a power injector for lesion visualization is not recommended, CGuard™ 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.

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.

16 STENT DEPLOYMENT

- 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.
- Whilst holding the handle stationary, rotate the locking nut of the haemostatic valve within the handle slot anti-clockwise until it rotates freely with no resistance. Ensure the locking nut does not disengage from the thread; if this occurs rescrew at least one full turn.

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

- Deploy the stent by holding the haemostatic valve body and slowly pull it back within the handle slot, do not pull using the locking nut. Continue to pull back until the haemostatic valve has reached the end of its travel, within the handle slot and the stent is fully deployed.

Note: If significant resistance is encountered during retraction of the outer sheath and before stent release is initiated, re-lock valve and remove the system. Once deployment is initiated, the stent cannot be recovered by 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 delivery 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.

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

17 POST STENT PLACEMENT

Following stent deployment, carefully withdraw the distal tip of the Rx delivery system, through the stent, by moving the haemostatic valve forward and rotate the valve nut to the locked position, to ensure safe retrieval of the tip into the guiding catheter /vascular sheath or the proximal protection device working channel. Then, carefully withdraw the delivery system out of the patient body.

CAUTION: When using a proximal protective device (MoMa) it is required to re-sheath the tip to ensure safe system retrieval into the proximal protective device working channel.

- 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 reduces 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 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.







18 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 as an integral part of this provision. InspireMD warrants the product until the expiration date indicated on the same. 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 part, compensation of 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 which 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.

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	CAUTION
	KEEP AWAY FROM SUNLIGHT
	CATALOGUE NUMBER
	KEEP DRY
	SERIAL NUMBER
	TEMPERATURE LIMITATION

	USE BY
	STERILIZED WITH ETHYLENE OXIDE GAS
	DO NOT REUSE
	DO NOT RESTERILIZE
	DO NOT USE IF PACKAGE IS DAMAGED
	CONSULT INSTRUCTIONS FOR USE

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