CGUARD™

Carotid Embolic Prevention System

Summary of Safety and Clinical Performance (SSCP) Report

Document reference number: REP-9278
Document revision: 05
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INSPIREMD

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1. DEVICE IDENTIFICATION AND GENERAL INFORMATION

DEVICE TRADE NAME:

CGuard Carotid Embolic Prevention System

MANUFACTURER NAME AND ADDRESS:

InspireMD Ltd. 4 Menorat Hamaor St., 6744832 Tel Aviv, Israel

BASIC UNIQUE DEVICE IDENTIFICATION OF THE DEVICE (UDI-DI):

7290018054CGuard01KH

YEAR WHEN THE FIRST CERTIFICATE (CE) WAS ISSUED COVERING THE DEVICE

2014

2. INTENDED USE OF THE DEVICE

INTENDED PURPOSE

Improving carotid luminal diameter in patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization.

INDICATION(S) AND PATIENT GROUPS

The CGuard™ EPS is indicated for: improving carotid luminal diameter in the target population of 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.

CONTRAINDICATIONS

The CGuard™ EPS implantation is contraindicated in:

- Patients in whom anticoagulant and/or antiplatelet 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
- Lesions in the ostium of the common carotid artery

3. DEVICE DESCRIPTION

3.1. DEVICE DESCRIPTION AND MATERIAL/SUBSTANCES IN CONTACT WITH PATIENT TISSUES

The CGuard Carotid Stent System (CGuard or CGuard System) is a sterile, single-use, permanent implant consisting of a mesh (MicroNet) covered self-expanding carotid stent that is loaded into a transfemoral rapid exchange (Rx) delivery system. The components of the CGuard Carotid Stent System, including the delivery system with stent, are sterilized.

CGuard MicroNet™ covered stent has been designed to contain plaque prolapse and consequently, to prevent micro-embolization.

3.2. INFORMATION ABOUT MEDICINAL SUBSTANCES IN THE DEVICE

Not applicable

3.3. DESCRIPTION OF HOW THE DEVICE IS ACHIEVING ITS INTENDED MODE OF ACTION

The CGuard Carotid Stent is implanted in the patient during the stenting procedure. The stenting involves the percutaneous delivery of a catheter and stent through the vascular system (access by vessel puncture or incision) to the site of carotid artery stenosis/blockage.

The delivery system is placed at the intended lesion site, and the stent is expanded by retraction of a protective sheath. Upon deployment, the stent imparts an outward radial force on the arterial wall to establish lumen patency.

3.4. DESCRIPTION OF ACCESSORIES

The CGuard Carotid Stent is implanted in the patient by using the following accessories:

- Guiding wire with specific characteristics
- Guiding catheter or Vascular sheath with specific characteristics
- Distal protection devices with specific characteristics

4. RISKS AND WARNINGS

Contact your healthcare professional if you believe that you are experiencing side- effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1. HOW POTENTIAL RISKS HAVE BEEN CONTROLLED OR MANAGED

It is important to take the medication your physician indicated. In case any side effects or unexpected symptoms occur, contact your physician immediately and follow their instructions. This document is not intended to replace a consultation with your healthcare professional if needed. It is important to keep up with regular check-ups with your physician.

4.2. REMAINING RISKS AND UNDESIRABLE EFFECTS

Carotid artery stenting is a medical procedure requiring specialized equipment and appropriately trained interventional specialists (https://intersocietal.org/wp-content/uploads/2023/07/IACCarotidStentingStandards2022B.pdf). The residual risk claimed by the manufacturer identified the clinical risks of carotid stenting complications (Instruction For Use, PAC-9020 CG IFU MDR). These adverse clinical events may happen during an angiography, angioplasty, and placement of any other stent/carotid stent or stent-graft. This is consistent with the labelling.

4.3. WARNINGS AND PRECAUTIONS

For all current warnings and precautions, see the current version of Instruction for Use (PAC-9020 CG IFU MDR).

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 the CGuard EPS device.
- The safety and effectiveness of CGuard™ have not yet been established in pregnant patients or patients under the age of 18.

Precautions:

- No specific precautions for users

SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION, (FSCA INCLUDING FSN) IF APPLICABLE

NA

5. SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

The clinical evidence archived with CGuard™ in the PARADIGM Study demonstrated safety and effectiveness. As published in peer-reviewed journals, both in independent investigator-initiated studies or in sponsored studies by the device manufacturer, CGuard meets General Safety and Performance requirements compared with other therapeutic options, provides Clinical Benefits, and achieves a positive and acceptable Benefit-Risk Ratio.

Additionally, a post-market clinical follow-up study PARADIGM EXTEND remains screening CGuard™ results uninterruptedly. The PARADIGM EXTEND independent monitored results analysis supports the claims that in the current indications, CGuard can be used safely, is effective, and his benefit sustained.

5.1. CLINICAL BACKGROUND OF THE DEVICE

In total, 3 studies had been consecutively implemented: CARENET, PARADIGM, and PARADIGM EXTEND. In addition, randomized control trials, multiple peer-reviewed independent studies and several meta-analysis confirmed the CGuard results.

5.2. THE CLINICAL EVIDENCE FOR THE CE-MARKING

Since his CE mark obtention and commercialization in 2014, PARADIGM constitutes the Pivotal evidence, and PARADIGM EXTEND is maintained on-going as Post Marketing Clinical Follow-up. The Studies achieve ISO 14155:2020 compliance.

5.3. SAFETY

According to the Benefit-Risk Analysis and clinical data presented, CGuard provides low-risk sustained carotid revascularization treatment.

6. POSSIBLE DIAGNOSTIC OR THERAPEUTIC

ALTERNATIVES

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

6.1. GENERAL DESCRIPTION OF THERAPEUTIC ALTERNATIVES

A carotid stenting procedure is an alternative treatment to surgery in patients with predetermined high surgical risks. However, decisions are not based on the absolute advantage of one of the treatment methods, as endovascular revascularization indication remains the sole responsibility of the treating physician, who considers all factors affecting individual patients risks and benefits.

A comprehensive evaluation of patient status, medical history, and co-morbidities evaluated by his specialists (neurologist, vascular surgeon, cardiologist, vascular interventionalist) will provide to the patient with the best and most reasonable therapeutic options.

7. SUGGESTED TRAINING FOR USERS

No training needed for users. The product has been tested and is proven to be safe and effective for carotid artery treatment.