CGUARD® PRIME

Summary of Safety and Clinical Performance (SSCP) Report

Document reference number: REP-9383
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INSPIRE MD

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1. DEVICE IDENTIFICATION AND GENERAL INFORMATION

1.1 DEVICE TRADE NAME:

CGuard Prime Carotid Embolic Prevention System

1.2 MANUFACTURER NAME AND ADDRESS:

InspireMD Ltd. 4 Menorat Hamaor Tel Aviv, Israel

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

7290018054CGuardPrime01QW

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

2025

2. INTENDED USE OF THE DEVICE

2.1 INTENDED PURPOSE

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

2.2 INDICATION(S) AND PATIENT GROUPS

The CGuard Prime 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

2.3 CONTRAINDICATIONS

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

CGuard Prime 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 Prime 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 Prime 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
- 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-9017 CGuard Prime 135cm IFU -EU and PAC-5018 CGuard Prime 80 cm IFU -EU). 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-9017 CGuard Prime 135cm IFU -EU and PAC-5018 CGuard Prime 80 cm IFU -EU).

4.3.1 WARNINGS:

• Only physicians familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid stent placement should use this device.

• The safety and effectiveness of CGuard Prime have not yet been established in pregnant patients or patients under the age of 18.

4.3.2 PRECAUTIONS:

• No specific precautions for users

4.4 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 independent academic 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 continues 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-analyses confirmed the CGuard results, as consequence CGuard Prime.

5.2 THE CLINICAL EVIDENCE FOR THE CE-MARKING

Since his CE mark obtention and commercialization in 2014, PARADIGM independent academic study constitutes the Pivotal evidence, and PARADIGM EXTEND independent academic study 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 Prime 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 is needed for users. The product has been tested and is proven to be safe and effective for carotid artery treatment.