Patient Information Leaflet

COPY-CORDIS-25030 REV.1

Cordis PRECISE PRO RX™ Nitinol Stent System

Device Name and Model

Cordis PRECISE PRO RX™ Nitinol Stent System

Device Description

The Cordis PRECISE PRO RX Nitinol Stent System consists of a nitinol self-expanding stent preloaded on a sheathed delivery system.

The self-expanding PRECISE stent is constrained within the space between the inner shaft and the distal outer sheath, located between distal and proximal stent markers on the inner shaft. The stent expands to its unconstrained diameter when released from the deployment catheter into the vessel. Upon deployment, the stent forms an open lattice and pushes outward on the luminal surface, helping to maintain the patency of the vessel. Due to the self-expanding behavior of nitinol, the stents are indicated for placement into vessels that are 1–2 mm smaller in diameter than the unconstrained diameter of the stent.

Intended Purpose

The Cordis PRECISE PRO RX Nitinol Stent System is a single-use device consisting of an endovascular stent and sheath delivery system, intended to deliver a self-expanding endovascular stent to the carotid artery(ies).
The stent component imparts an outward radial force on the luminal surface of the vessel wall restoring vascular patency.

Patient Target Group

The patient target group includes individuals with stenotic lesions of the carotid artery(ies). The patient target group of this device is based on the patient's anatomy and compatibility with the device.

Operating Instructions

This device is intended to be implanted by trained healthcare professionals in a hospital or clinical setting. It is not operated or adjusted by the patient.

After the procedure, follow all instructions provided by your doctor regarding recovery, medications, and follow-up visits. Attend all scheduled check-ups so your doctor can monitor the device and ensure it is functioning correctly. Immediately contact your healthcare provider if you experience any new or unusual symptoms, such as pain, swelling, changes in sensation, or any symptoms your doctor has advised you to watch for. Always carry your patient implant card and show it to healthcare professionals when receiving medical care.

Residual Risks

Persons with allergic reaction to nickel titanium (Nitinol) may suffer an allergic response to this implant.

Warnings and Precautions

This stent contains nickel and cobalt. These metals may cause allergic reactions in some people. Tell your doctor if you have any known allergies to metals. The stent is for single use only. It must not be reused or re-sterilised, as this could make it unsafe or ineffective.

This stent may not be suitable for people who are pregnant, have severe kidney problems, have bleeding disorders, cannot take blood-thinning medication, or have certain blood vessel conditions. Your doctor will decide if it is safe for you.

Tell your doctor if you take antacids or stomach acid–reducing medicines, as these can interfere with the absorption of other medicines you may need after the procedure (such as aspirin).

Potential Complications

Adverse Events (in alphabetical order) that may be associated with the use of the Cordis PRECISE Nitinol Stent System when used in conjunction with the ANGIOGUARD XP Emboli Capture Guidewire include, but may not be limited to:

- Air embolism
- Allergic/anaphylactoid reaction
- Aneurysm
- Angina/coronary ischemia
- Arrhythmia (including bradycardia, possibly requiring need for a temporary or permanent pacemaker)

- Arterial occlusion/restenosis of the treated vessel
- Arterial occlusion/thrombus, at puncture site
- Arterial occlusion/thrombus, remote from puncture site
- Arteriovenous fistula
- Bacteremia or septicemia
- Cerebral edema
- Damage to emboli capture device
- Death
- Embolization, arterial
- Embolization, stent
- Emergent repeat hospital intervention
- Fever
- GI bleeding from anticoagulation/antiplatelet medication
- Hematoma bleed, puncture site
- Hematoma bleed, remote site
- Hemorrhage
- Hyperperfusion syndrome
- Hypotension/hypertension
- Infection
- Intimal injury/dissection
- Ischemia/infarction of tissue/organ
- Local infection and pain at insertion site
- Malposition (failure to deliver the stent to the intended site)
- Myocardial infarction
- Pain
- Pseudoaneurysm
- Renal failure
- Restenosis of the vessel (> 50% obstruction)
- Seizure
- Severe unilateral headache
- Stent migration
- Stent thrombosis
- Stroke
- Transient ischemic attack
- Vasospasm
- Venous occlusion/thrombosis, at puncture site
- Venous occlusion/thrombosis, remote from puncture site
- Vessel rupture, dissection, perforation

Lifetime of the Device

This device is a permanent implant device.

Materials and substances included in the device

Maximum Stent Composition: Nickel 57.0% weight/weight, Titanium 45.5% weight/weight

Device Interaction and MRI Information

A patient with the PRECISE stent may be safely scanned under the limited conditions.

If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have a stent implant. The Cordis PRECISE PRO RX stent has been shown to be MRI conditional.

Adverse Event Report

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration (TGA).

TGA:
http://www.tga.gov.au/reporting-problems (website)

Sponsor:
Cordis Australia Pty Ltd.
Level 14/3 Parramatta Square
153 Macquarie Street, Parramatta, NSW, 2150
Email: anz-product-complaints@cordis.com

Manufacturer

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Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, suggested procedure, warnings and precautions. Please contact your Cordis representative for additional product information.