Patient Information Leaflet

COPY-CORDIS-25031 REV.1

Cordis S.M.A.R.T. CONTROL™ Nitinol Stent System

Device Name and Model

Cordis S.M.A.R.T. CONTROL™ Nitinol Stent System

Device Description

The Cordis S.M.A.R.T. CONTROL Nitinol Stent System is designed to deliver a self-expanding stent to the peripheral vasculature via a sheathed delivery system.

The self-expanding stent is a flexible, fine mesh tubular prosthesis made from a nickel-titanium alloy (nitinol) with 12 tantalum radiopaque marker bands (6 at each end). It expands upon deployment to conform to the vessel wall, exerting an outward radial force to maintain vessel patency. The maximum stent mass is 502 mg, comprising up to 280 mg (58%) nickel and up to 230 mg (45.5%) titanium, with no intentional alloy additions beyond nickel and titanium.

Intended Purpose

The Cordis S.M.A.R.T. CONTROL Nitinol Stent System is intended to deliver a self-expanding endovascular stent to the iliac and/or superficial femoral arteries via a sheathed delivery system. 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 requiring treatment for atherosclerotic lesions of iliac and/or superficial femoral arteries. 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 reactions to nickel may suffer an allergic response to this device.

Warnings and Precautions

This stent contains nickel, which may cause an allergic reaction in people who are sensitive to nickel. The stent is for single use only. It must not be reused or re-sterilised, as this could make it unsafe or ineffective.

People who are pregnant, have severe kidney problems, bleeding disorders, or certain blood vessel conditions may not be suitable for this stent. Your doctor will decide if it is safe for you.

Tell your doctor if you have any allergies, if you are taking medicines that affect blood clotting, or if you take antacids or stomach acid-reducing medicines, as these may affect other medicines you need after the procedure.

Potential Complications

Complications may occur at any time during or after the procedure. Potential complications may include, but are not limited to:

- Additional surgical intervention
- Amputation
- Aneurysm and pseudoaneurysm formation
- Arrhythmia
- Arteriovenous fistula
- Blue toe syndrome
- Coronary ischemia
- Death
- Disseminated intravascular coagulation
- Drug reactions, allergic reaction to contrast medium or to the implanted device
- Embolism
- Emergency artery bypass graft surgery
- Hematoma

- Hemorrhage
- Hemorrhagic or embolic stroke/ TIA
- Intimal tear/dissection
- Renal failure
- Sepsis/infection
- Stent fracture
- Stent migration/embolization
- Stent misplacement
- Thrombosis
- Tissue necrosis
- Vascular injury, including perforation, rupture and dissection
- Vessel occlusion, restenosis
- Vessel Spasm

Lifetime of the Device

This device is a permanent implant device.

Materials and substances included in the device

The maximum stent mass does not exceed 502 mg. The alloy composition contains maximum 280 mg (58%) nickel. Titanium as the other primary element at
maximum 230 mg (45.5%). No intentional alloy additions beyond nickel and titanium are allowed. A total of 12 (6 at each end) tantalum radiopaque markers are located on the ends of the stent.

Device Interaction and MRI Information

A patient with the S.M.A.R.T. 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 S.M.A.R.T. 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.