Patient Information Leaflet

COPY-CORDIS-25031 REV.1

Cordis S.M.A.R.T. ™ Flex Vascular Stent System

Device Name and Model

The Cordis S.M.A.R.T. ™ Flex Vascular Stent is a self-expanding stent made from superelastic nitinol tubing which provides its great flexibility.

Device Description

The S.M.A.R.T. Flex Vascular Stent System is a self-expanding stent made of nickel-titanium alloy (nitinol) with tantalum marker bands, pre-mounted on an over-the-wire delivery system with a retractable sheath.

Constructed from super-elastic nitinol tubing, integrating helically wound struts with flexible helical coils for both radial stiffness and expansion capability.
Nearly fully connected structure, designed to self-expand inside the vessel to provide support.

Intended Purpose

The S.M.A.R.T. Flex Stent is a single-use device consisting of an endovascular stent and sheath delivery system, intended to deliver a self-expanding endovascular stent to the superficial femoral artery. 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 superficial femoral artery lesions and proximal popliteal lesions. 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

Tell your doctor if you have any metal allergies, especially to nickel. You may need to take blood-thinning medication before and after the procedure; follow your doctor's instructions carefully. Always tell healthcare providers, including dentists and radiology staff, that you have a stent. If you have had reactions to contrast dye used in X-ray or CT scans, tell your doctor before the procedure. If you are pregnant, planning to become pregnant, breastfeeding, or under 18 years old, tell your doctor, as this device may not be suitable.

Potential Complications

Potential hazards and side effects include, but are not limited to:

- Abrupt stent closure
- Allergic reaction to nitinol
- Angina/coronary ischemia
- Aneurysm or Pseudoaneurysm in vessel or vessel access site
- Arrhythmia
- Atheroembolization (Blue Toe Syndrome)
- AV Fistula formation
- Death
- Embolization (air, plaque, thrombus, device or other)
- Fever
- Hematoma/Hemorrhage
- Hypotension/hypertension
- Infection and/or pain at the access site
- Infection secondary to contamination of the stent may lead to sepsis and hemodynamic instability
- Intimal injury/dissection

- Ischemia requiring intervention (bypass or amputation of toe, foot or leg)
- Limb loss
- Myocardial infarction (MI)
- Overstretching the artery may result in rupture
- Renal insufficiency or failure
- Restenosis of the stented segment
- Septicemia/bacteremia
- Stent malapposition/migration
- Stent structure fracture
- Stroke
- Thrombosis/thrombus
- Tissue necrosis
- Vasospasm
- Vessel perforation or rupture
- Worsened claudication/rest pain

Lifetime of the Device

This device is a permanent implant device.

Materials and substances included in the device

Materials & Composition: Maximum mass 502 mg, containing up to 280 mg (58%) nickel and up to 230 mg (45.5%) titanium, with no other alloying elements. Nine tantalum radiopaque markers (total 1 mg, 0.03%) are located at the stent ends.

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. Flex 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

Cordis Cashel
Cashel Road
Cashel, Co Tipperary
Ireland

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.