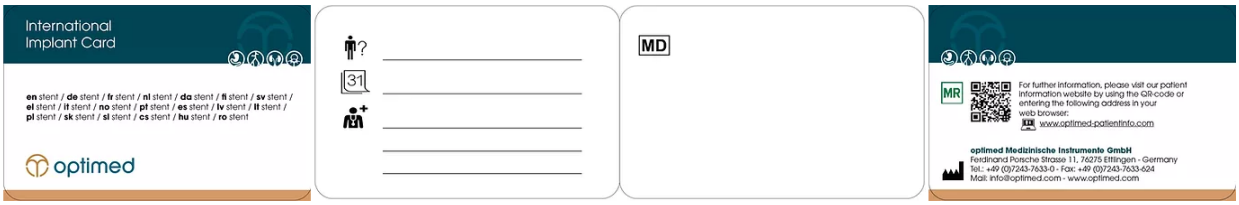
optimed GmbH · Postfach 100 665 · 76260 Ettlingen · Germany

Dear patient,

You have received an implant from optimed. Please read this patient information carefully since it contains important information about the implant.

Your doctor has given you an **International Implant Card**. First of all, we would like to explain the symbols used on this card to you:



List of symbols recommended for use on the International Implant Card:

- Patient Name or Patient ID
- Date of implantation
- Name and Address of the implanting healthcare institution/ provider
- Device Name (The doctor has to peel the identification label from the product and place it to the corresponding field on the PIC.)
- Magnetic resonance
- Information website for patients
- Name and Address of the manufacturer

Regular Follow-Up Visits
It's important to go to all follow-up appointments with your healthcare team, even if you're feeling well. During these visits, your doctor will monitor your progress, evaluate your medications, check the status of your disease and determine how the stent is working for you.

Stent Implant Card
Whether you're running a quick errand or going on vacation, it's important to carry your stent implant card with you at all times. If you receive dental or medical care or report to an emergency room, show your stent implant card. You will be given an implant card at the time of your procedure. Your implant card contains your name, your doctor's name and phone number, and information about your implanted stent(s).

The implant may have an impact on medical investigations, especially on magnetic resonance imaging (MRI). Your stent is one of the items that may create a health hazard or other problem during an MRI examination. Therefore, you need to present your implant card to the MRI technologist or radiologist, that he can find, via the QR code or web address, this website. In some unusual cases the examination may be cancelled because of concern related to a particular implant or device.

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Below we have summarized for each stent some information regarding MRI Compatibility, Possible Complications, Intended Use and some additional important information.

If you have questions or need further information on the optimed stents, please contact our Customer Service department in Germany by phone toll-free at 0800-7628000 (for calls within Germany) or send an email to info@optimed.com. For calls from abroad, you can reach us by phone at +49 7243 7633-0.

Please choose from the list below the stent implanted into your body. You can find the name of your stent on the label on the inside of the implant card.

We wish you good health!

Your optimed team

sinus-XL Flex

MR Compatibility:
Non-clinical trials (1) have shown that the sinus-XL Flex stent is MR Conditional for lengths (single or overlapped stents) of up to 160 mm in accordance with the guidelines set forth in the American Society for Testing Materials ASTM F2503-13 (Standard Practice Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment).
A patient with this stent can safely be scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla or 3 Tesla
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reports whole body averaged specific absorption rate (SAR) of up to 2 W/kg

Note: The effect of heating in the MRI environment for overlapping stents longer than 160 is not known. Under the scan conditions defined above (positioned at isocentre), a stent of worst-case length (including two overlapping stents) is expected to produce a maximum temperature rise of up to 4.0 °C after 15 minutes of continuous scanning. The actual in vivo rise is expected to be less than these values as the calculations did not include the cooling effects due to blood flow in the lumen of the stent and blood perfusion in the tissue outside the stent.
In non-clinical testing, the image artefact caused by the device extends approximately 5 mm from the stent when imaged with a gradient echo pulse sequence and a 3.0 Tesla MR system. The artefact may obscure the stent lumen.
(1) ASTM F2503-13, "Standard Practice Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"

kind of patient on whom the device is intended to be used:
Adults (fully grown)

intended performance of the device:
The sinus-XL Flex stent system is used to introduce a self-expanding nitinol stent into the central vascular system using the application device. The stent itself has the purpose of increasing the lumen diameter of the target vessel and improving blood flow.

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possible complications:

- Stent collapse/inadequate anchorage/dislocation due to insufficient diameter of the stent
- Stent fails to expand evenly/to the specified diameter, stent kinking
- (In-stent) Restenosis
- Stent embolisation
- Stent migration
- Stent fracture
- Haemorrhage/haematoma in insertion area
- Haemorrhage, general
- Acute thrombosis in cases of lack of perfusion (e.g. spasms or other occlusions) of the runoff vessels and insufficient anticoagulation
- Blood pressure dysregulation
- Cardiac dysrhythmia up to complete cardiac arrest, myocardial infraction, pericardial tamponade and death
- Allergic/hypersensitive reaction to contrast medium or nickel
- Respiratory complaints and pulmonary failure up to complete respiratory arrest and death
- Infection
- Sepsis
- Inflammation
- Fever
- Necrosis
- Embolism (peripheral and pulmonary)
- Damage to vessels (dissection, perforation, rupture, haematoma, lesion, pseudoaneurysm, arteriovenous fistula, distention of target area)
- Vascular spasm
- Ischaemia
- Intimal hyperplasia
- Pain
- Organ failure, e.g. renal failure
- Cerebrovascular dysfunction up to stroke and death

the expected device lifetime:
The product is an implant that normally remains in the body for life.

the materials and substances included in the device:
Stent: Nitinol/Tantal
Introducer sheath: Pebax

a notice that any serious incident that occurs in relation to the device should be reported to the manufacturer and to the TGA:
Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the TGA.

the address of the Therapeutic Goods Administration's website:
https://www.tga.gov.au

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