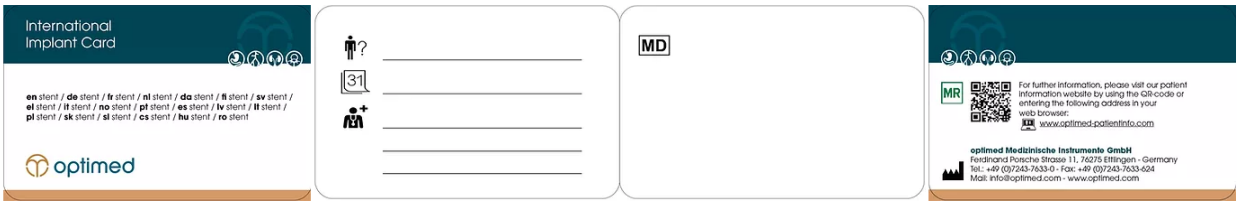
optimed GmbH · Postfach 100 665 · 76260 Ettlingen · Germany

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-SuperFlex-635

MR Compatibility:
The implant / device was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-13. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

MRI-Related Displacement Force and Torque
A scientific investigation (1, 2) demonstrated that implant / device made out of nitinol and/or tantalum are MR Conditional. A patient with this implant / device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3.0-Tesla or less

MRI-Related Heating
In non-clinical testing, the implant / device produced the following temperature rises when MRI was performed for 3 min at 1.5 Tesla (Intera, Philips Medical Systems (PMS), Software 12.6.1.4) and performed for 15 min. at 3 Tesla (Signa Hdxt, General Electric (GE) Medical Systems, Software 15.0_M4_0910.a) and at an average whole-body SAR of 3 W/kg registered by the MRI system.

Highest temperature change MRI Condition:
- Less than or equal to 4.0 degrees C at 1.5-Tesla
- Less than or equal to 4.0 degrees C at 3.0-Tesla

Remark: The effect of heating in the MRI environment for overlapping stents is not known.

MRI-Related Artifacts
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the implant / device. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant/device may be necessary.

(1) ASTM F2503-13, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment"
(2) Shellock FG, "Biomedical Implants and Devices: Assessment of Magnetic Field Interactions With a 3.0-Tesla MR System. Journal of Magnetic Resonance Imaging, 2002"

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

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intended performance of the device:
The sinus-SuperFlex-635 Stent System is used to introduce a self-expanding nitinol stent into the arterial vascular system of the pelvis/lower extremities using the application device. The stent itself has the purpose of increasing the lumen diameter of the target vessel and improving blood flow.

possible complications:
Only doctors familiar with the possible complications may apply this product. Complications may occur at any time during or following the procedure. Possible complications include:

- Malimplantation of the stent
- Inadequate anchorage / dislocation due to insufficient diameter of the stent
- Stent migration
- Lesion / perforation of vascular wall
- Vascular spasms
- Haemorrhage / haematoma in insertion area
- Stent fracture
- Acute thrombosis in cases of lack of perfusion (e.g. spasms or other occlusions) of the passage vessels and insufficient anticoagulation
- Peripheral embolisation
- Blood pressure dysregulation
- Cardiac dysrhythmia up to complete cardiac arrest
- Allergic reaction to contrast media
- Respiratory complaints up to complete respiratory arrest
- Haemorrhage
- Infection / sepsis
- Dissection
- 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

last update: 24th November 2021, revision 1