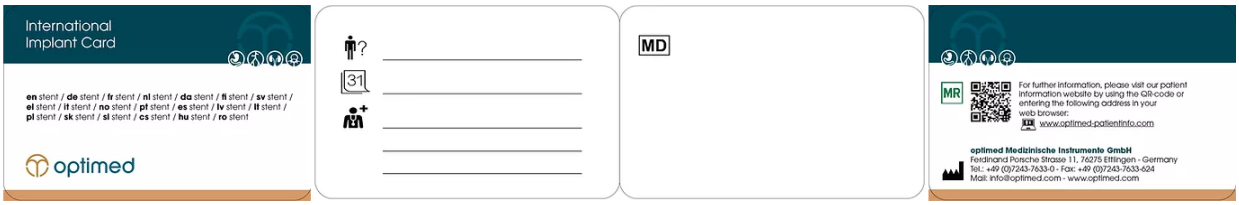
optimed GmbH · Postfach 100 665 · 76260 Ettlingen · Germany

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-Obliquus

MR Compatibility:
The implant / device was determined to be MRI-conditional according to the guidelines of the American Society for Testing 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 implants / devices made out of nitinol and / or tantalum are MRI-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 13 min at 1.5 Tesla (MIPS 1.5, Medical Implant Test System, Software MIPS-DUALBAND 1.2.5.2) and 3 Tesla (Signa Hdxt, General Electric (GE) Medical Systems, Software 15.0_M4_0910.a) MRI-systems and at an average whole-body SAR of 2.5 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
MRI-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, optimisation 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)

intended performance of the device:
The sinus-Obliquus stent system is used to introduce a self-expanding nitinol stent into the peripheral 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.

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:

- Failure of the stent or stent application system
- Allergic reactions
- Erroneous implantation of the stent
- Inadequate anchorage
- Stent migration or stent embolisation
- Dislocation due to insufficient stent diameters
- Bleeding
- Pain
- Haematoma
- Renal failure
- Fracture of the stent
- Acute thrombosis in cases of lack of perfusion (e.g. spasms or other occlusions) of the passage vessels and insufficient anticoagulation
- Stroke
- Stent closure
- Vascular damage including dissection and rupture
- Haemorrhage
- Infection
- Formation of arteriovenous fistula
- Tissue necrosis
- Pyrexia
- Hypertension or hypotension
- Ischaemia
- Perfusion limitations in lateral branches of arteries or veins or distal vessels
- Reperfusion damage including cardiac or pulmonary dysfunction caused by abrupt change to haemodynamics, including cardiac arrest and pulmonary failure or pulmonary embolism
- Cerebrovascular dysfunction
- Organ failure
- Complications at vascular entrance such as pseudo aneurysms or haematoma
- Restenosis
- Hypersensitive reactions
- Cardiac and cardiovascular dysfunction, e.g. myocardial infarction
- 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
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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