

 **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.

optimed

Medizinische Instrumente GmbH
Ferdinand-Porsche Strasse 11
76275 Ettlingen · Germany

Tel. +49 (0) 7243 / 7633-0

Fax +49 (0) 7243 / 7633-624
info@optimed.com
www.optimed.com

Geschäftsführer
Jürgen Kiesel
HRB 361913 AG Mannheim

HypoVereinsbank AG Karlsruhe
BIC HYVEDEMM475
IBAN DE53 660202860002330628

Volksbank Ettlingn eG
BIC GENODE61ETT
IBAN DE96 66091200000884405

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

Ureteral Stents:

MR Compatibility:

The ureteral stents (except "Ex-stent" tumor stent) are made of plastic material; therefore, they are MR Safe according to

ASTM F 2503-2020. The materials are electrically nonconductive, nonmetallic and nonmagnetic.

The Ex-stent tumor ureteral stents contain two small marker bands made of platinum-iridium, these marker bands are very small and nonmagnetic. Since we have not performed any MR tests on the parts, we cannot make any statement about safety in the MR environment, including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields according to ASTM F 2503-2020.

kind of patient on whom the device is intended to be used:

Adults

Children

Neonates

intended performance of the device:

Ureteral stents are used to ensure the patency of a ureter, which may be compromised, for example, by a kidney stone or a procedure.

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:

- Encrustation / Occlusion of the ureteral stent
- Migration of the ureteral stent
- Iatrogenically caused infections / Sepsis
- Organ perforation / Dissection
- Haemorrhage / Haematoma

Note: Products whose drainage effect is impaired must be changed. The statutory hygiene regulations must be adhered to.

the expected device lifetime:

The maximum indwelling time is 1 year.

anything that could shorten or lengthen the device lifetime:

Please discuss dietary measures and fluid supply with your doctor.

 **optimed** GmbH · Postfach 100 665 · 76260 Ettlingen · Germany

other circumstances in which the patient should contact a health professional in relation to the operation of the device:

Please contact your doctor if you experience sudden or severe pain.

the materials and substances included in the device:

Polyurethane

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