I-125 Seed - Prostate

en

Patient Information Leaflet

Dear Patient,

As part of your prostate cancer treatment, you were implanted with a low-level radioactive I-125 implant (IsoSeed®/IsoCord®/IsoStrand® - in the following referred to as I-125 Seeds). During patient education you have received the Implant Card and the present Patient Information Leaflet. Please read the information and follow the instructions on how to behave with the implant.

Your Implant

The I-125 Seeds are permanent implants that remain in your prostate for life. The radioactive material of the I-125 Seeds is enclosed in a sealed titanium capsule so that the radioactivity cannot leak into your blood, urine, or other body fluids.

Implant Properties

Most of the radiation emitted by the I-125 Seeds is absorbed by your body. The measurable radioactive radiation decreases rapidly with increasing distance. At a distance of 1 m from your body for example, no relevant radiation values can be measured. The radioactive material of the I-125 Seeds loses 50 % of its power every 2 months.

Moreover, there is no interaction of your implant with a pacemaker or, for example, a microwave oven.

After the Surgery

In rare cases a I-125 Seed is excreted in the urine. We recommend that you check your urine during the first 8 weeks after surgery. If you find an I-125 Seed in your urine, do not touch it! Pick up the

I-125 Seed with a spoon or tweezers and place it in a closable container (preferably a screw-top jar). Immediately inform your treating physician so that a safe disposal of the I-125 Seed can be arranged.

In rare cases a I-125 Seed may be excreted during ejaculation. The same precautions apply as when an I-125 Seed is excreted in the urine.

Everyday Life

Please refrain from sexual intercourse for the first 8 weeks after your surgery!

If a woman in your home environment is pregnant, you must inform your attending physician so that he can order appropriate precautions. For example, possible precautions could include sleeping with a pillow to provide separation or sleeping in separate beds until the baby is born.

You cannot harm a person by shaking their hand in greeting, giving them a brief hug, or staying in the same room.

We strongly recommend ensuring distance from your pelvic area for up to 8 weeks after surgery. For example, you should not have a person sit on your lap or sit close to a person for an extended period.

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Inform your Partner / Relatives

In the event you die in the first 12 months after the surgery, cremation of your body may be hazardous due to the risk of contamination and possible residual radioactivity in the cremated ashes. In this case, the attending physician must be consulted to determine the potential level of risk.

Inform Future Attending Physicians

Before you want to have a magnetic resonance imaging scan (MRI), please inform your attending physician about the implant.

Non-clinical testing has demonstrated that a patient implanted with I-125 Seeds can be safely scanned in an MRI system that meets the following conditions [1]:

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial gradient magnetic field of 3.000 Gauss/cm (30 T/m)
- Maximum whole body averaged specific absorption rate (SAR) of 2.1 W/kg
- MRI systems that display fractional (whole body or head) SAR values
- MRI scan with the patient in dorsal position only

If further surgery on your prostate or in the pelvic area, is required, even several years after I-125 Seed implantation, you must inform the attending physician about the implant. All relevant information is given on your implantation card.

Sensitive safety devices can detect the low radiation your body emits in the first few months after implantation - your Implant Card is important evidence for you.

[1] Validation was performed with a Philips MRI system (Intera).

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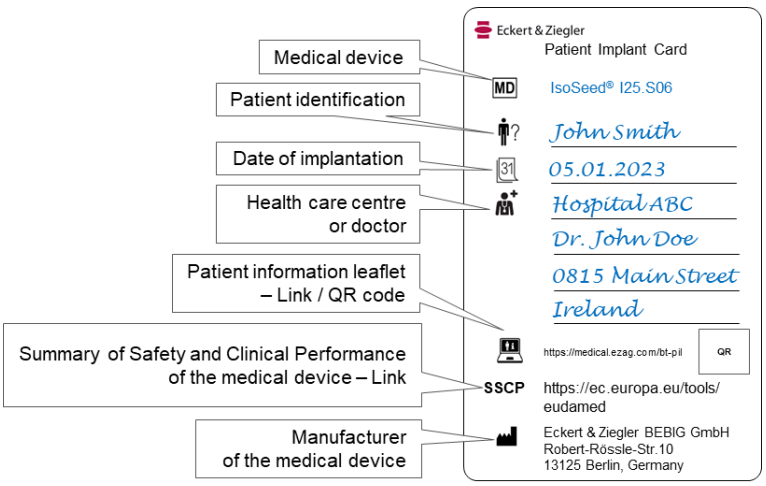
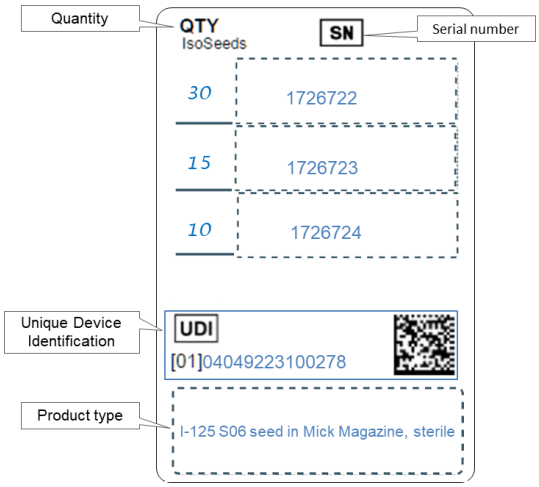
Your Patient Implant Card – Content Information



Front view



Back view

Note The layout of the back view and all information displayed in blue may differ for the medical device applied to you.

An up-to-date version of this patient information leaflet is available in different languages on the website of the manufacturer.

https://medical.ezag.com/bt-pil QR-Code

Please compare the document number of this patient information leaflet with the one on the website of the manufacturer. A higher revision number indicates a more up-to-date version of the patient information leaflet.

Note the information below: IFU-08-### [2]_## [3]

SSCP The Summary of Safety and Clinical Performance with information specific for patients is available in the European Database for Medical Devices (EUDAMED) [4]:

https://ec.europa.eu/tools/eudamed

The medical device applied to you is specified on the patient implant card under the positions **MD** and **UDI**.

The manufacturer has the **SRN** (Single Registration Number): **DE-MF-000005760**.

[2] Document number
[3] Document version
[4] Depending on functional status of EUDAMED.

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