# I-125 Seed - Brain

en

## Patient Information Leaflet

### Dear Patient,

As part of your brain tumor treatment, you were implanted with a low-level radioactive I-125 implant (IsoSeed® I25.S17plus - 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

Depending on the treatment required, the I-125 Seeds were applied in your brain as temporary or permanent implants. The radioactive material of the I-125 Seeds is enclosed in a sealed titanium capsule so that the radioactivity cannot leak into your brain or any 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.

### Everyday Life

After surgery, you must follow certain precautions to protect people in your immediate environment.

Your attending physician will inform you about the method and duration of the precautionary measures.

If a woman in your home environment is pregnant, you must inform your attending physician so that he can order appropriate precautions.

You cannot harm a person by shaking their hand in greeting, giving them a brief hug, or staying in the same room. Until 8 weeks after surgery, we strongly recommend avoiding close and prolonged contact with people.

### 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.

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## Inform Future Attending Physicians

Before you want to have a magnetic resonance imaging scan (MRI), please inform your treating 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 brain 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 Implant 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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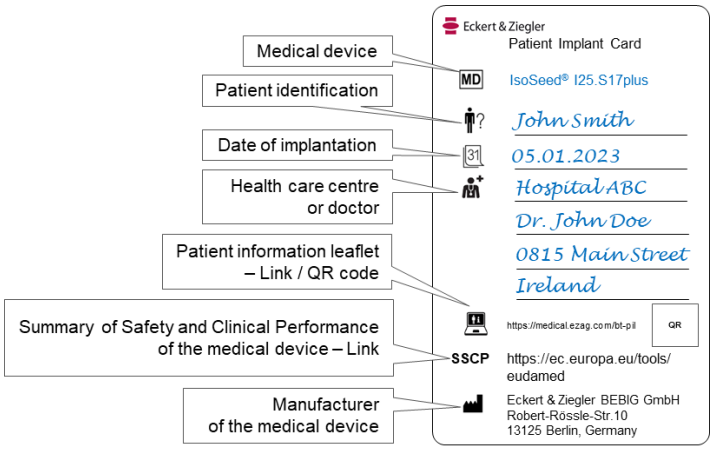
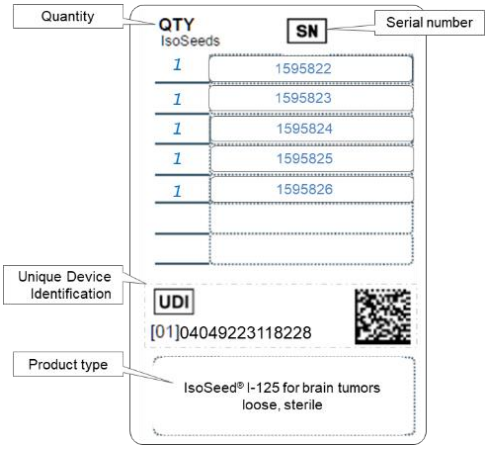
### Your Patient Implant Card – Content Information




*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 **S**ummary of **S**afety and **C**linical **P**erformance 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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