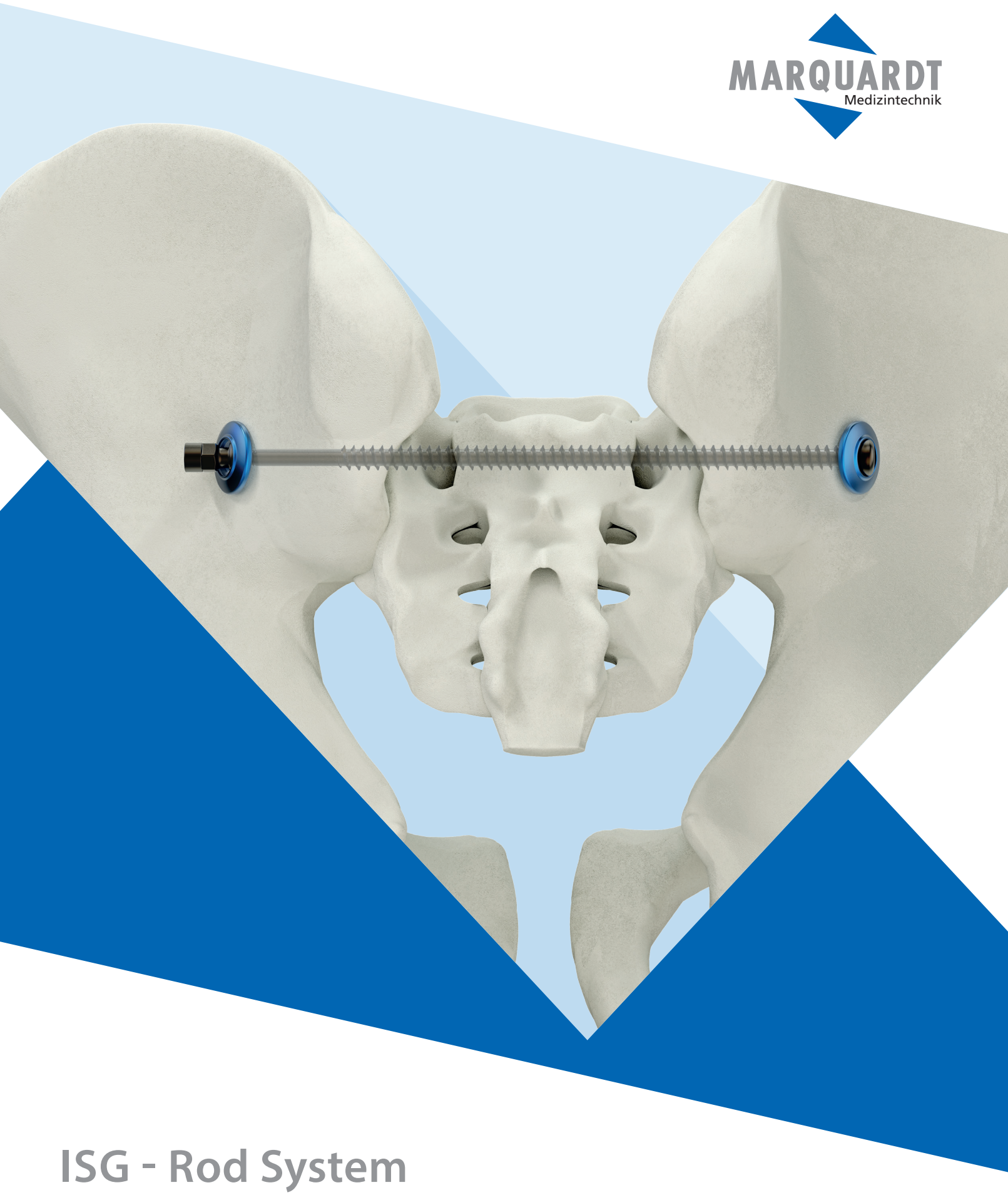
MARQUARDT
Medizintechnik



# ISG - Rod System

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**Note:**

The surgical technique outlined below reflect the surgical procedure usually chosen by the clinical advisor. However, each surgeon must decide which surgical method and which approach is the most successful for his patient.

# ISG - Rod

## Introduction

### Product Specification

- The ***ISG - Rod*** as well as the compression nut have movably mounted washers, which ensure an even distribution of load on the bone.
- Length gradation in 5mm steps allows selection of the appropriate length, no intraoperative shortening of the implant necessary.
- Minimally invasive procedure using cannulated implants and instruments as well as appropriate length gradations of the rod.
- The rod has a cortical thread in the head section and a metric thread at the tip.

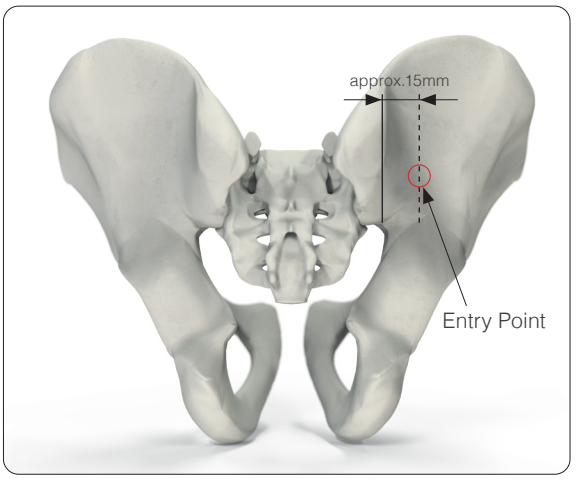

### Indication

- Fractures of the sacrum
- Dislocations of the sacroiliac joint with fixation of the posterior pelvis

## Surgical technique

### Access

- Access is through a stab incision above the planned rod entry point at S1.
- This should be located in the middle of the parallels - offset by approx. 15mm - to the linea glutea posterior.



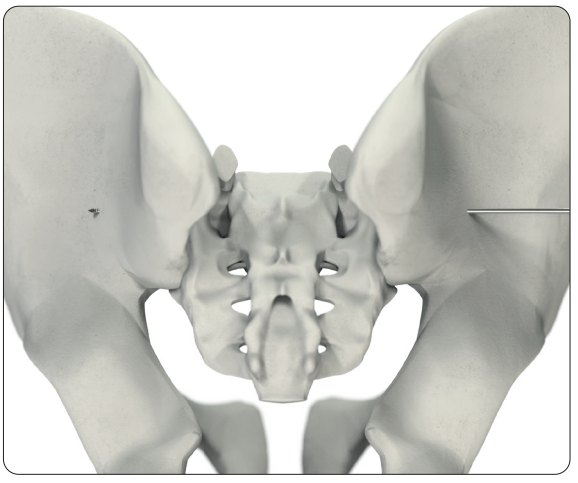

### Insertion of the Kirschner wire

**Instruments**

| | |
|---|---|
| *REF 11.90228.300* | *Kirschner Wire Ø 2.8mm, L 300mm, threaded tip* |

Optional:

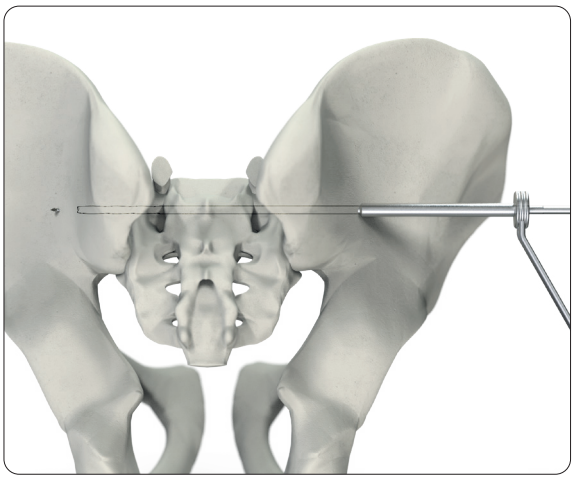
| | |
|---|---|
| *REF 11.92028.300* | *Kirschner Wire Ø 2.8mm, L 300mm, drill tip* |



- The first sacral vertebral body S1 is localized by help of an image converter.
- The Kirschner wire is inserted in the lateral beam path according to the anatomical conditions up to the opposite cortex.
- This is followed by inlet- and outlet images and if necessary a correction of the target wire position.
- The correct position of the Kirschner wire is verified by 3D scan.

**Note:**

- The Kirschner wire should run at an angle of approximately 90° to the fracture gap.
- Alternatively the Kirschner wire can be inserted under 3D navigation.

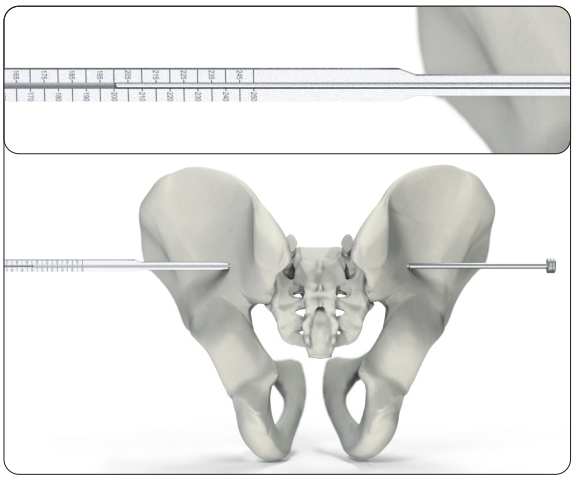


### Drilling and replacing the Kirschner wire

**Instruments**

| | |
|---|---|
| *REF 08.20010.155* | *Drill Bit Ø 5.5mm* |
| *REF 08.20120.075* | *Drill Sleeve Ø 5.5mm* |
| *REF 08.20120.520* | *Guide Wire Ø 2.8mm, L 520mm* |

- Using the cannulated drill bit, the cortex is drilled over the Kirschner wire through the drill sleeve.
- The Kirschner wire must be completely overdrilled.
- The overdrilled Kirschner wire is then removed.
- The guide wire (length 520 mm) is now pushed through the cannulated drill bit that has remained in the body.

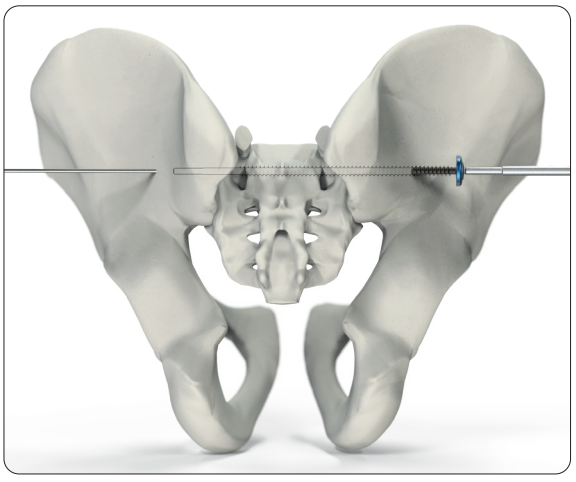


### Determination of the ISG - Rod length

**Instrumentes**

| | |
|---|---|
| *REF 08.20100.075* | *Length Determination Instrument for ISG - Rod* |
| *REF 08.20100.076* | *Stop for REF 08.20100.075* |

- The stop is advanced over the guide wire up to the cortex.
- The end of the guide wire must be forced to the end of the stop and held.
- The length determination instrument is then inserted over the guide wire to the opposite cortex.
- The required rod length can be read directly on the scale of the length determination instrument (end of the guide wire).
- If the rod length lies between two scale values, the longer rod length should be selected. If compression is performed, the shorter length should be selected.



### Insertion of the ISG - Rod

**Instruments**

| | |
|---|---|
| *REF 08.20040.173* | *Screwdriver* |

- The ISG - Rod is inserted over the guide wire with the cannulated screwdriver.

**Note:**

- The ISG - Rod must be screwed in until the washer is in contact with the bone.

**Compression**

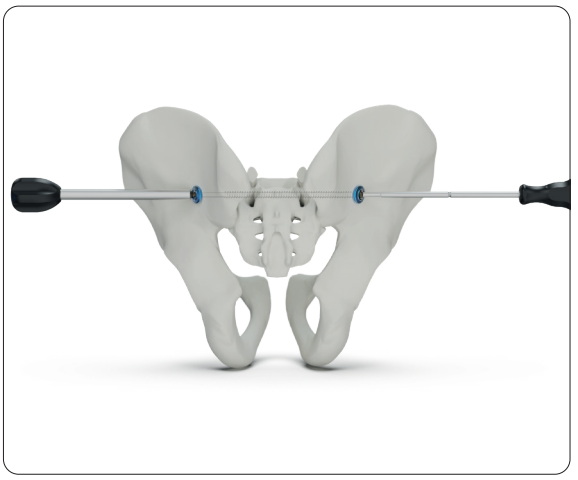
**Instruments**

*REF 08.20040.205* *ISG Wrench for Compression Nut*
*REF 08.20040.173* *Screwdriver*

- With the ISG wrench for compression nut the compression nut with washer is screwed over the guide wire on the ISG - Rod and the desired compression is adjusted.

**Note:**

- The ISG - Rod must be held in place with the screwdriver when setting the compression.

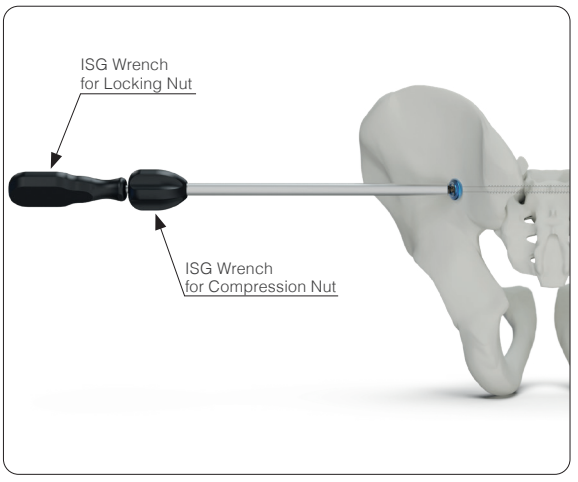


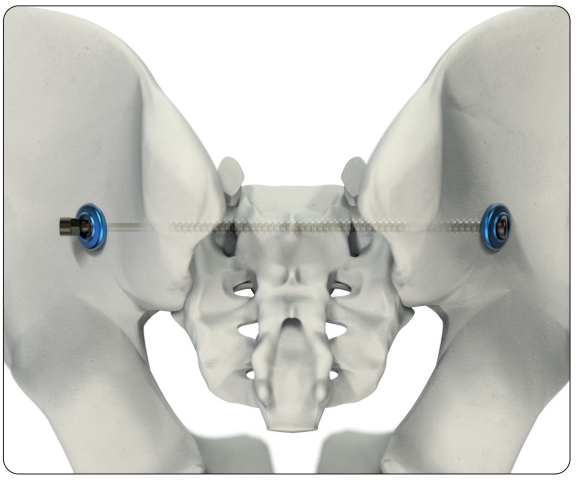
**Locking**

**Instruments**

*REF 08.20040.210* *ISG Wrench for Locking Nut*

- Finally, the ISG wrench for locking nut is used to insert the locking nut through the ISG wrench for compression nut.
- Locking is accomplished by holding the ISG wrench for compression nut in position and hand-tightening the locking nut.



# ISG - Rod

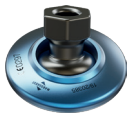
## Product information

**Implants**

### ISG - Rod Ø 7.5mm

- Thread diameter: Ø 7.5mm / M 5.5
- Hexagon socket: SW 4.0mm
- Material: Ti6Al4V

| Article Number | Length | Article Number | Length |
|---|---|---|---|
| 08.03914.120S | 120mm | 08.03914.190S | 190mm |
| 08.03914.125S | 125mm | 08.03914.195S | 195mm |
| 08.03914.130S | 130mm | 08.03914.200S | 200mm |
| 08.03914.135S | 135mm | 08.03914.205S | 205mm |
| 08.03914.140S | 140mm | 08.03914.210S | 210mm |
| 08.03914.145S | 145mm | 08.03914.215S | 215mm |
| 08.03914.150S | 150mm | 08.03914.220S | 220mm |
| 08.03914.155S | 155mm | 08.03914.225S | 225mm |
| 08.03914.160S | 160mm | 08.03914.230S | 230mm |
| 08.03914.165S | 165mm | 08.03914.235S | 235mm |
| 08.03914.170S | 170mm | 08.03914.240S | 240mm |
| 08.03914.175S | 175mm | 08.03914.245S | 245mm |
| 08.03914.180S | 180mm | 08.03914.250S | 250mm |
| 08.03914.185S | 185mm | | |



### Compression Nut for ISG - Rod

- Thread diameter: M 5.5
- Hexagonal: SW 9.0mm
- Material: Ti6Al4V

| Article Number |
|---|
| 08.03914.005S |

### Locking Nut for ISG - Rod

- Thread diameter: M 5.5
- Material: Ti6Al4V

| Article Number |
|---|
| 08.03914.010S |

## Instruments

11.90228.300 Kirschner Wire Ø 2.8mm, threaded tip, L 300mm, stainless steel



08.20120.520 Guide Wire Ø 2.8mm, L 520mm, stainless steel

08.20010.155 Drill Bit Ø 5.5/2.8mm, cannulated, Jacobs Chuck, L 395/375mm



08.20100.075 Length Determination Instrument for ISG - Rod

08.20100.076 Stop for REF 08.20100.075

08.20120.400 Cleaning Wire Ø 2.8mm, L 400mm

08.20120.075 Drill Sleeve Ø 5.5

08.20040.173 Screwdriver, hex 4.0mm, cannulated, L 295/185mm

08.20040.205 ISG Wrench for Compression Nut

08.20040.210 ISG Wrench for Locking Nut

## Optional

11.92028.300 Kirschner Wire Ø 2.8mm, drill tip, L 300mm, stainless steel

## MRI Safety Information

Non-clinical testing has demonstrated that the screw range from Marquardt Medizintechnik is MR Conditional in accordance with the ASTM F2503 standard definitions. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Cylindrical-bore
- Horizontal magnetic field ($B_0$)
- Spatial field gradient lower than or equal to
  - **1.5 T:** 23.45 T/m (2345 G/cm)
  - **3.0 T:** 11.75 T/m (1175 G/cm)
- Radiofrequency (RF) field exposure:
  - RF excitation: Circularly Polarized (CP)
  - RF transmit coil: whole-body transmit coil
  - RF receive coil type: whole-body receive coil
  - Maximum permitted whole-body averaged specific absorption rate (SAR): Normal Operating Mode, 2 W/kg.
  - Scan duration and wait time:

    **1.5 T:** 2 W/kg whole-body average SAR for **10min and 55s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **10min and 55s** if this limit is reached.

    **3.0 T:** 2 W/kg whole-body average SAR for **7min and 54s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **7min and 54s** if this limit is reached.
- The screws are expected to produce a maximum temperature rise of 6.2 °C at 1.5 T and 6.5 °C at 3 T both after the scanning periods presented above.
- The presence of this implant may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. In non-clinical testing, the image artifact caused by the device extends approximately 83 mm from the device edge when imaged with a spin echo pulse sequence and 65 mm with a gradient echo, both at 1.5 T.
- Patients with uncompromised thermoregulation and under uncontrolled conditions or patients with compromised thermoregulation (all persons with impaired systemic or reduced local thermoregulation) and under controlled conditions (a medical doctor or a dedicated trained person can respond instantly to heat induced physiological stress).

**Note:**

Undergoing an MRI scan, there is a potential risk for patients with a metallic implant. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, or other undesirable effects.

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