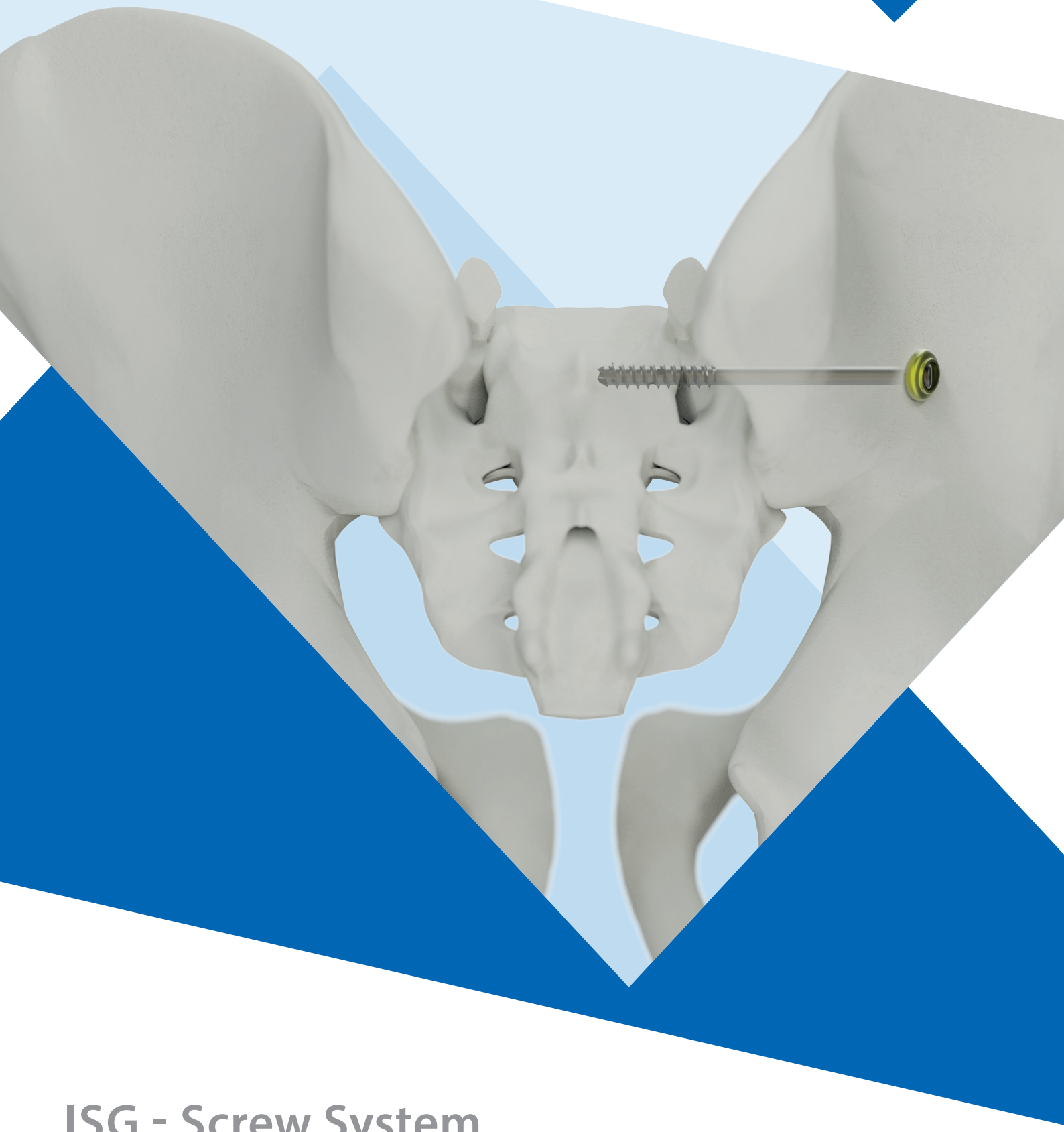
MARQUARDT
Medizintechnik



ISG - Screw System

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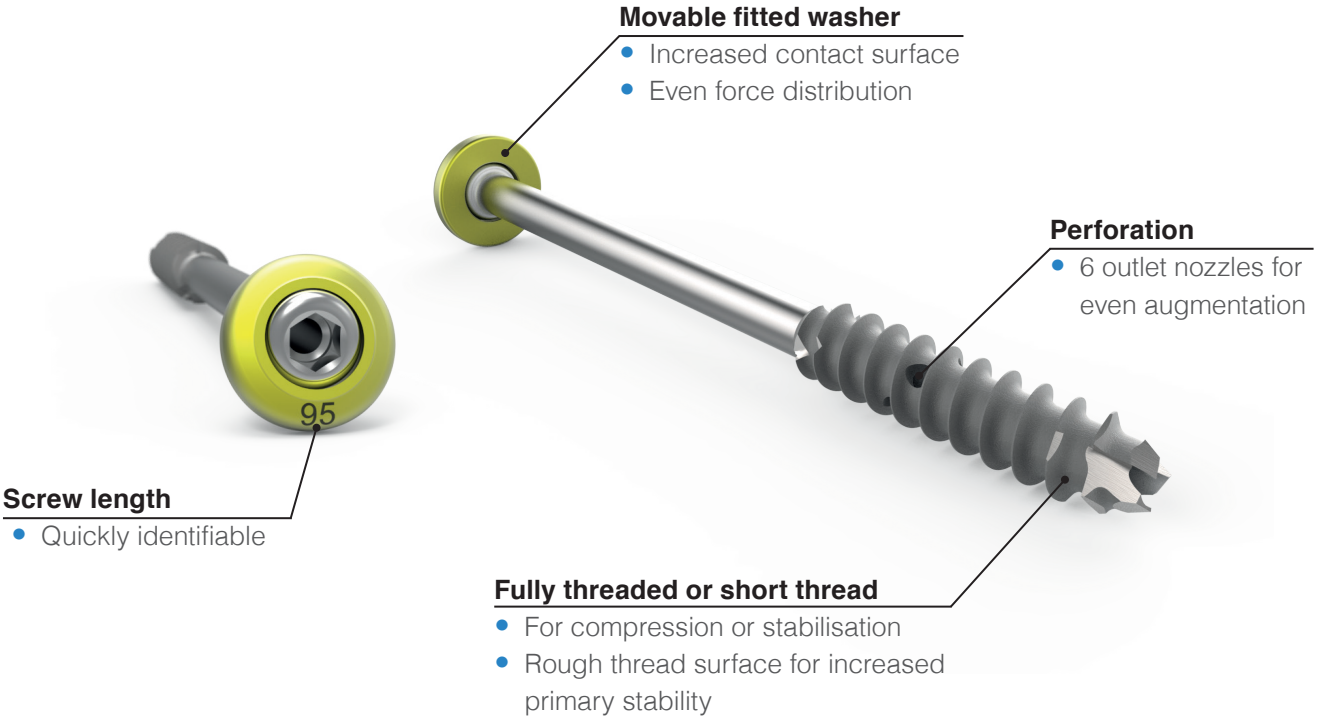
Note:

The surgical technique outlined below reflects 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.

Introduction

System Characteristics

- The ***ISG - Screw System*** can be used for iliosacral screw fixation.
- The screws are fitted with a movable washer and are optionally available fully threaded or with a short thread.
- The washers fitted ensure an even distribution of force on the bone.
- The osteosynthesis stability of the ISG screw can be increased with the use of bone cement, as necessary.



Indication

- Fixation of osteoporotic and non-osteoporotic fractures of the pelvis.
- Arthrosis or dislocation in the sacroiliac joint.

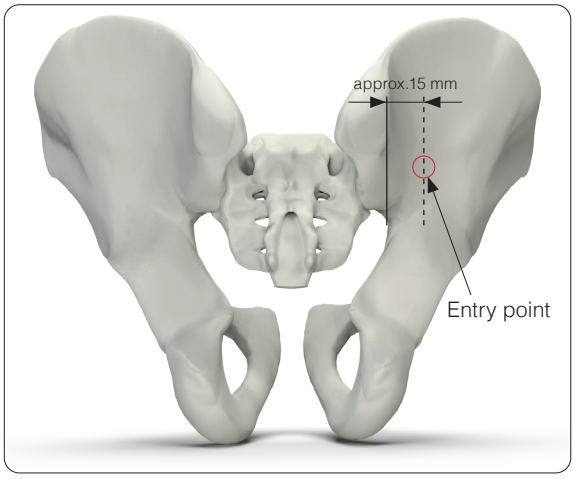
Surgical Technique

1. Positioning

- The operation is performed in the supine position on an X-ray permeable operating table.
- The C-arm should be positioned such that anteroposterior, inlet and outlet X-rays can be taken.
- With medial padding of the pelvis, the guide wire can be correctly placed in the dorsoventral/lateromedial direction.
- Movable covering of the leg on the side to be operated.

2. Access

- Access is obtained with a stab incision above the planned screw insertion point on S1.
- This should be located in the middle of the parallel - to the linea glutea posterior - offset by approx. 15 mm.

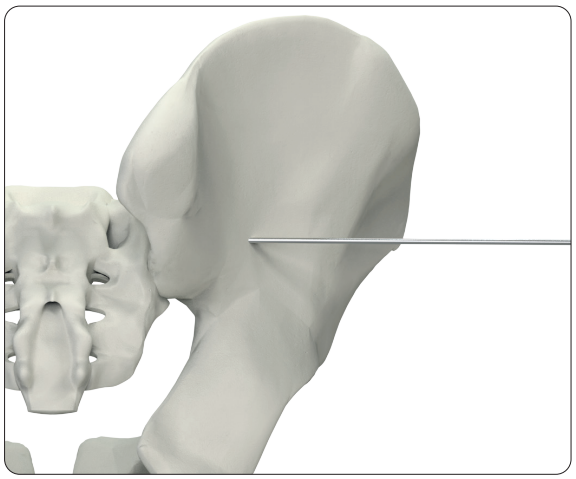


3. Insertion of the Guide Wire

Instruments

REF 11.90228.300 *Kirschner Wire Ø 2.8 mm*

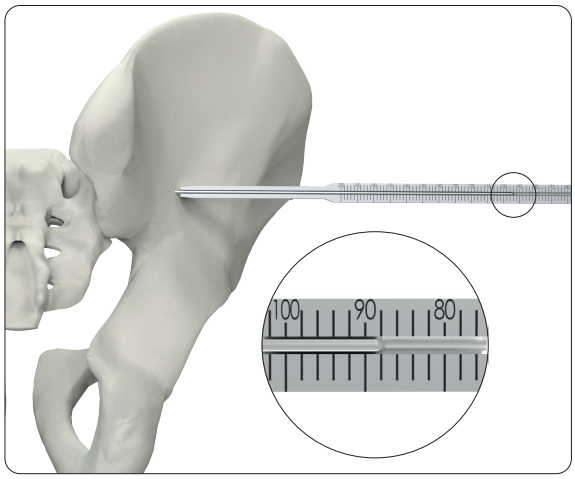
Optional:
REF 08.20120.430 *Kirschner Wire Ø 2.8 mm, L 430 mm*



- The first sacral vertebral body S1 is localised with the help of an image converter.
- The K-wire is inserted along the lateral beam path according to the anatomical conditions through to the ilium cortex.
- Inlet and outlet X-rays are taken and the K-wire position is corrected, as necessary.
- Given the correct positioning, the K-wire is placed through the S1 corridor in the vertebral body.
- The correct position of the K-wire is verified by means of a 3D scan.

Please note:

- The K-wire should run at an angle of approx. 90° to the fracture gap.
- The ventral and dorsal cortical bone of the sacrum should not be injured.
- Alternatively, the K-wire can be inserted under 3D navigation.

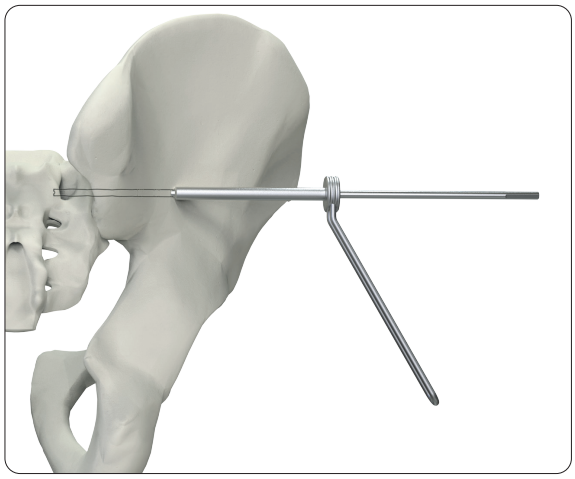


3. Determination of the Screw Length

Instruments

REF 08.20100.073 *Length Determination Instrument, for Kirschner Wires*

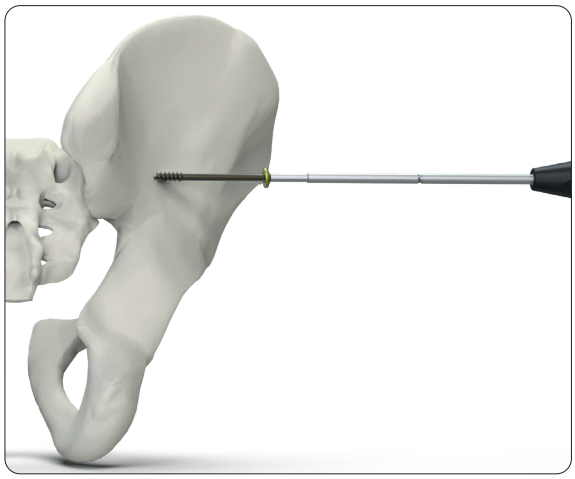
- The length determination instrument is pushed over the K-wire through to the bone.
- The screw length is read off at the end of the K-wire.
- Using the optional Kirschner wire (REF 08.20120.430), the screw length is determined by its laser marking.



Instruments

REF 08.20010.150 *Drill Bit Ø 5.0 mm*
REF 08.20120.075 *Drill Sleeve 5.5*

- Using the cannulated drill bit Ø 5.0 mm, the cortical bone is drilled above the K-wire, through the drill sleeve.
- Ensure under image intensification that the drill bit is not advanced further than the tip of the K-wire to prevent loosening of the K-wire.



4. Insertion of the Screw

Instruments

REF 08.20040.173 *Screwdriver*

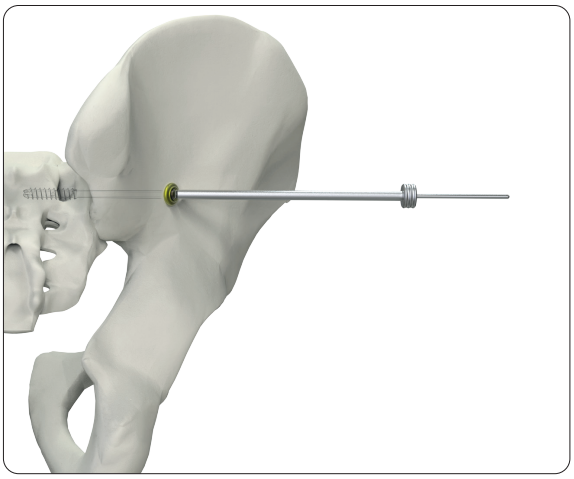
- The screw is inserted over the K-wire using the cannulated screwdriver.

Please note:

- The screw must be tightened until the washer rests on the bone.

Optional

Given reduced bone quality, the implant anchoring may optionally be improved by cement augmentation.



5. Preparation for Cement Application

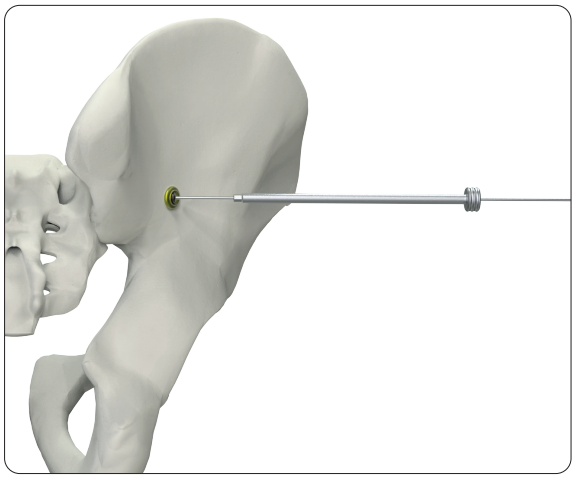
Instruments

REF 08.20120.422 *Exchange Tube Ø 2.8 mm*

- Removing the screwdriver, the K-wire Ø 2.8 mm should not come out of the screw head.
- Next, the exchange tube is advanced over the Ø 2.8 mm K-wire into the screw head.

Instrumente

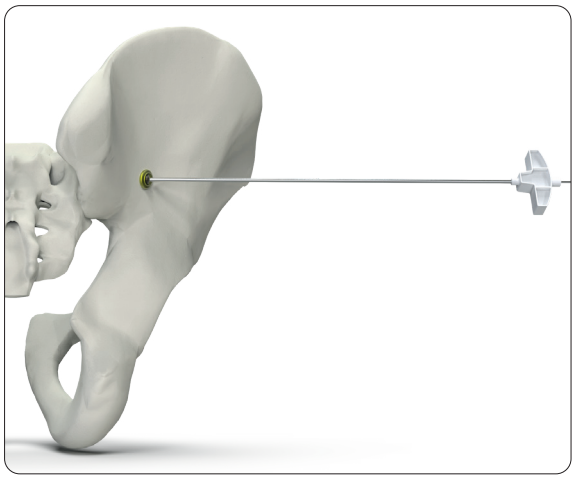
REF 08.20120.421 *Guide Wire Ø 1.6 mm*



- The Ø 2.8 mm Kirschner wire is pulled out of the exchange tube.
- Then advance the Ø 1.6 mm guide wire through the exchange tube and the screw.
- Removing the exchange tube, the Ø 1.6 mm guide wire should not be pulled out of the screw.

Instruments

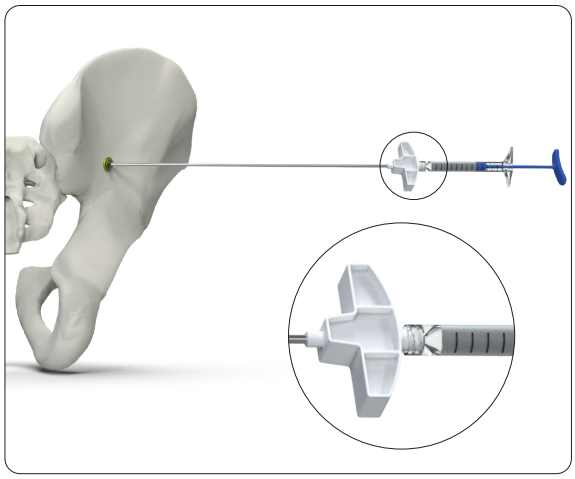
REF SF112601D *Cement Cannula*



- The cement cannula is advanced over the guide wire into the screw head.

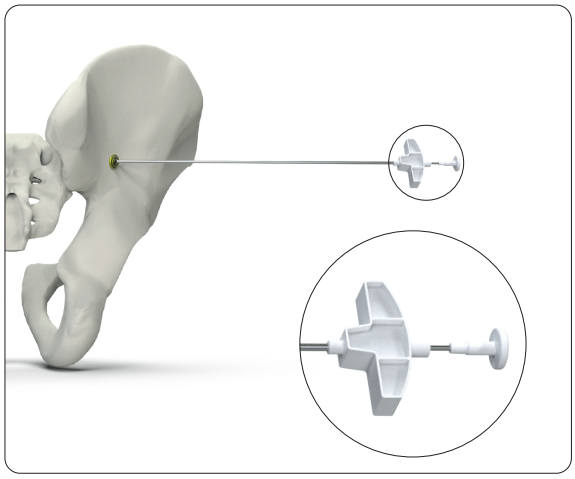
Please note:

- The information from the respective manufacturer must be observed in the preparation and use of the bone cement.



6. Cement Application

- Prior to augmentation, a contrast agent is applied through the cement cannula while monitoring with the image converter and the distribution in the bone and the outflow via presacral veins is verified.
- If the contrast agent test is inconspicuous, augmentation can be performed via the Luer port of the cement cannula.
- The filling volume of the cement cannula is 1.0 ml.
- A volume of approx. 2-3 ml is usually sufficient to enclose the screw tip with a cloud shape.
- During augmentation, the distribution of the bone cement should be monitored with the image converter.



Instruments

REF SF112601D *Plunger for Cement Cannula*

- Using the pusher, the bone cement can be completely expelled from the cannula into the screw.
- After the application, the cement cannula and the plunger will be removed and disposed of.
- Finally there is X-ray control from anteroposterior and lateral.

Product Informations

Implants

Article Number	Length	Article Number	Length
08.03910.050S	50 mm	08.03910.110S	110 mm
08.03910.055S	55 mm	08.03910.115S	115 mm
08.03910.060S	60 mm	08.03910.120S	120 mm
08.03910.065S	65 mm	08.03910.125S	125 mm
08.03910.070S	70 mm	08.03910.130S	130 mm
08.03910.075S	75 mm	08.03910.135S	135 mm
08.03910.080S	80 mm	08.03910.140S	140 mm
08.03910.085S	85 mm	08.03910.145S	145 mm
08.03910.090S	90 mm	08.03910.150S	150 mm
08.03910.095S	95 mm	08.03910.155S	155 mm
08.03910.100S	100 mm	08.03910.160S	160 mm
08.03910.105S	105 mm	08.03910.165S	165 mm

ISG - Screw Ø 7.5 mm, Fully threaded

- Thread diameter:: Ø 7.5 mm
- Hexagon socket: SW 4.0 mm
- Washer diameter: Ø 14.0 mm
- Material: Ti6Al4V

Article Number	Length	Article Number	Length
08.03912.050S	50 mm	08.03912.110S	110 mm
08.03912.055S	55 mm	08.03912.115S	115 mm
08.03912.060S	60 mm	08.03912.120S	120 mm
08.03912.065S	65 mm	08.03912.125S	125 mm
08.03912.070S	70 mm	08.03912.130S	130 mm
08.03912.075S	75 mm	08.03912.135S	135 mm
08.03912.080S	80 mm	08.03912.140S	140 mm
08.03912.085S	85 mm	08.03912.145S	145 mm
08.03912.090S	90 mm	08.03912.150S	150 mm
08.03912.095S	95 mm	08.03912.155S	155 mm
08.03912.100S	100 mm	08.03912.160S	160 mm
08.03912.105S	105 mm	08.03912.165S	165 mm

ISG - Screw Ø 7.5 mm, Short thread

- Thread diameter: Ø 7.5 mm
- Hexagone socket: SW 4.0 mm
- Washer diamter: Ø 14.0 mm
- Material: Ti6Al4V

Instruments

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

08.20120.421 Guide Wire Ø 1.6 mm, L 350 mm, stainless steel

08.20010.150 Drill Bit Ø 5.0/2.9 mm, cannulated, scaled, Jacobs Chuck, L 295/265 mm

08.20100.073 Length Determination Instrument for Kirschner Wires Ø 2.8 mm x 300 mm

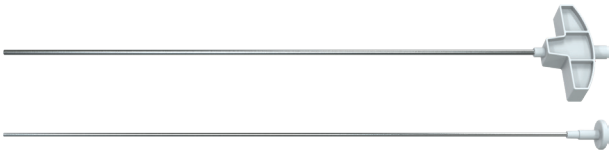
08.20120.400 Cleaning Wire Ø 2.8 mm, L 400 mm

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

08.20120.422 Exchange Tube Ø 2.8 mm, hex 4.0 mm

08.20120.075 Drill Sleeve 5.5

SF112601D Canule injection ciment



Optional

08.20120.430 Kirschner Wire Ø 2.8 mm, threaded tip, L 430 mm, 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.

Release date: 11.07.2024 • 08.99100.302 • Rev.: 009/00

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