

PEDUS-R Rearfoot Plating 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.

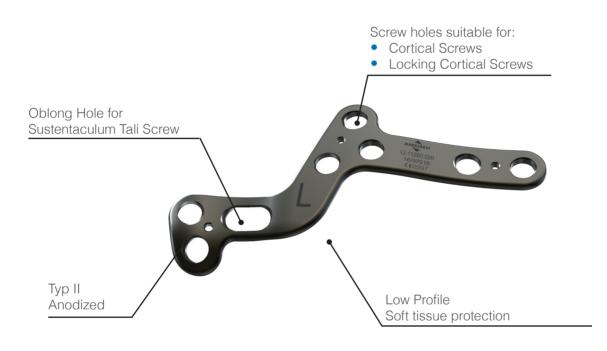


Surgical Technique PEDUS-R MIS WS Calcaneus Plate

PEDUS-R MIS WS Calcaneus Plate

Product Specifications:

- Plate size: short and long
- Side-specific anatomical shape for the right and left foot



Indication

• Fixation of calcaneal fractures





1. Access and Resection

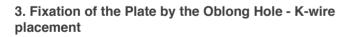
- Access is obtained via an approx. 5 to 8 cm skin incision above the sinus tarsi. Starting from the fibula head, work over the anterior part of the calcaneus, the peroneal tendons and up to the calcaneocuboid joint.
- The sural nerve and the peroneal tendon sheath remain undamaged in the process.

2. Implant Selection and Positioning

Instruments

REF 11.90012.070 Kirschner Wire Ø 1.2 mm, L 70 mm

- The posterior plate end is inserted through the skin incision until the plate lies in the required position above the calcaneus.
- The position of the plate can then be determined with the image intensifier.
- Afterwards the plate is temporarily fixed K-wires.



Screw selection:

• The plate can be fastened in the oblong hole with a cannulated screw Ø 4.0 mm. Alternatively, a cortical screw Ø 3.5 mm can be used.

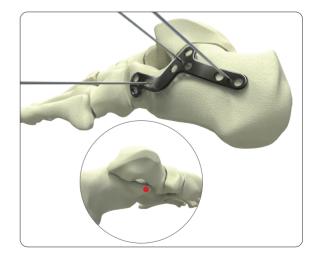
Instruments

REF 11.90212.150 Kirschner Wire Ø 1.2 mm, L 150 mm

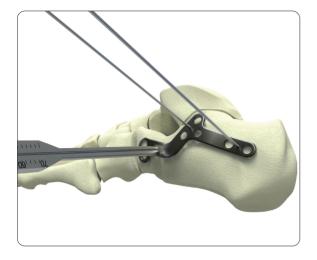
Use of a Ø 4.0 mm cannulated screw

- First, the screw position is determined with the aid of the K-wire.
- The entry point of the K-wire is in the middle of the oblong hole and should end in the sustentaculum tali.
- With the aid of a C-arm, the correct position of the K-wire is then checked.









Fixation of the Plate by the Oblong Hole - Measuring Instruments

REF 08.20100.035

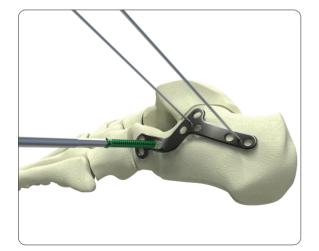
Length Determination Instrument, for K-Wire \emptyset 1.2 mm x 150 mm

- The required screw length is determined using the length determination instrument via the inserted K-wire.
- The screw length is calculated as follows: add 2 mm to the value read off at the end of the K-wire (as the length determination instrument sits directly on the bone and not on the plate surface).

Fixation of the Plate by the Oblong Hole - Drilling Instruments

REF 08.20010.027(S) Drill Bit Ø 2.7 mm

• The cannulated drill bit is then pushed forward over the K-wire until it reaches the bone, and then the screw hole is drilled.



Fixation of the Plate by the Oblong Hole - Screwing Instruments

REF 08.20040.025

Screwdriver, hex 2.5 mm

- The corresponding screw is then inserted via the K-wire with the cannulated screwdriver.
- Final tightening of the cannulated screw should not be performed until after correction and final positioning of the plate.
- Take an X-ray image to check the length and position of the screw in both planes.



Fixation of the Plate by the Oblong Hole - Using a \varnothing 3.5 mm Cortical Screw

Instruments

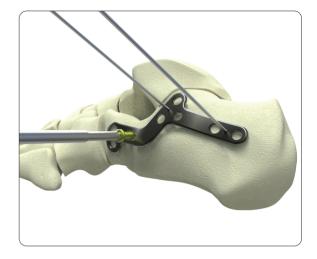
REF 03.20010.425 REF 03.20060.025 REF 03.20040.025 REF 03.20100.060

Drill Bit Ø 2.5 mm Double Drill Giude 3.5 / 2.5 Screwdriver, hex 2.5 mm Length Determination Instrument, for Screw up to 60 mm

- The screw hole is pre-drilled bicortically via the double drill guide using the drill bit.
- The length is measured bicortically using the length determination instrument.
- Afterwards the corresponding cortical screw is inserted with the screwdriver.
- Final tightening of the screw should not be performed until after correction and final positioning of the plate.

Fixation of the Plate by the Oblong Hole - Plate positioning

- If necessary, the position of the plate can be corrected via the length of the oblong hole.
- When the plate is exactly aligned on the bone, final tightening of the cannulated screw is performed.
- Afterwards the plate position and the screw length are checked with the aid of an X-ray.





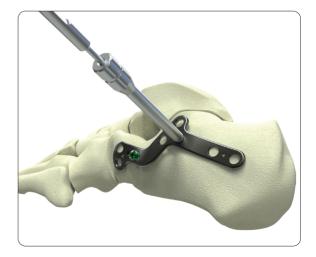
4. Fixation of the Plate with Locking Screws - Drilling

Instruments

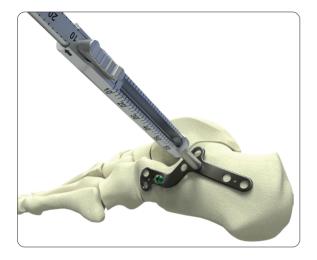
| REF 10.20010.020 |
|-------------------|
| (REF 03.20010.425 |
| REF 03.20060.015 |
| (REF 03.20060.020 |

Drill Bit Ø 2.0 mm Drill Bit Ø 2.5 mm) Drill Guide 2.0 Drill Guide 2.5)

• For Ø 3.0 mm (Ø 3.5 mm) locking screws the drill guide Ø 2.0 mm (drill guide Ø 2.5 mm) is screwed into the screw hole that is to be used.







Fixation of the Plate with Locking Screws - Measuring

Instruments

REF 03.20100.060

Length Determination Instrument, for Screw up to 60 mm

- To determine the required screw length the length determination instrument must be used.
- The length determination instrument is placed directly on the plate and after hooking onto the opposite cortical bone the value can be read off.

Fixation of the Plate with Locking Screws - Screwing

Instruments

REF 03.20040.025

Screwdriver, hex 2.5 mm

- After determination of the required screw lengths, the corresponding locking screw is inserted with the screwdriver.



- Afterwards, all locking screw holes on the plate are filled.
- Here, the procedure for inserting the screws described in point 4 is followed.
- Finally, a radiological check is performed in both planes.





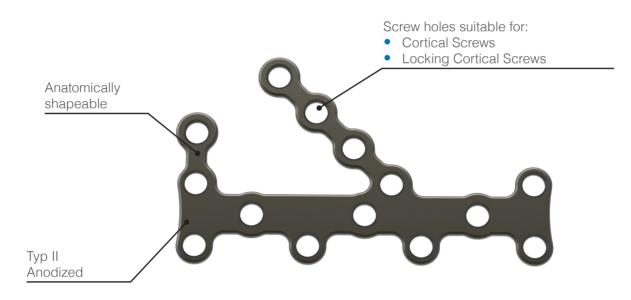


Surgical Technique PEDUS-R WS Calcaneus Plate

PEDUS-R WS Calcaneus Plate

Product Specifications

- 3 different plate sizes
- Symmetrical plate geometry suitable for the right and left foot



Indication

• Fixation of fractures and osteotomies of the calcaneus





1. Access and Resection

- Perform a right-angled, lateral skin incision.
- The vertical part of the skin incision should run close to the Achilles tendon and extend to the plantar and lateral areas of the skin.
- The calcaneocuboid joint can be reached by extending the skin incision in the distal direction.
- Continue the skin incision at the same angle down towards the bone, so that afterwards a single, complete flap can be lifted off the periosteal surface.

2. Implant Selection and Positioning

Instruments

REF 11.90012.070 Kirschner Wire Ø 1.2 mm, L 70 mm

- The plate is placed in the required position on the calcaneus.
- Here, the plate can be anatomically adapted to the bone.
- Afterwards the plate is temporarily fixed with K-wires.
- The position of the plate can then be determined with the image intensifier.

3. Fixation of the Plate

- The plate is secured with locking screws.
- The steps for drilling, measuring the screw length and fixing are the same as step 4 in the PEDUS-R MIS surgical technique (see above)



PEDUS-R WS Universal Plate

Indication: Fixation of fractures, osteotomies and joint fusions at the midfoot and rearfoot

- The locking universal plate is also secured with locking screws.
- The steps for drilling, measuring the screw length and fixing are the same as step 4 in the PEDUS-R MIS surgical technique (see above).





Product Information

Implants



PEDUS-R MIS WS Calcaneus Plate

- Plate thickness: 1.6 mm
- Material: Ti6Al4V

| Article Number * | Size | Orientation |
|------------------|------|-------------|
| 12.11260.010 | S | right |
| 12.11260.110 | S | left |
| 12.11260.020 | L | right |
| 12.11260.120 | L | left |
| | | |



PEDUS-R WS Calcaneus Plate

- Plate thickness: 1.5 mm
- Material: Titanium

| Article Number * | Length |
|------------------|--------|
| 12.11241.160 | 60 mm |
| 12.11241.170 | 70 mm |
| 12.11241.180 | 80 mm |
| | |



PEDUS-R WS Universal Plate

- Plate thickness: 1.6 mm
- Material: Titanium

| Article Number * | Hole | Length |
|------------------|------|---------|
| 12.11123.024 | 4 | 23.5 mm |
| 12.11123.045 | 6 | 45.0 mm |
| 12.11123.055 | 8 | 55.0 mm |
| 12.11123.076 | 12 | 76.0 mm |

* All implants are also available in sterile. Therefor, add suffix "S" to article number.



| Article Number Ø 2.7 mm | Article Number Ø 3.5 mm | Length (mm) |
|----------------------------|----------------------------|----------------|
| 03.03527.010 | 03.03612.010 | 10 |
| 03.03527.012 | 03.03612.012 | 12 |
| 03.03527.014 | 03.03612.014 | 14 |
| 03.03527.016 | 03.03612.016 | 16 |
| 03.03527.018 | 03.03612.018 | 18 |
| 03.03527.020 | 03.03612.020 | 20 |
| 03.03527.022 | 03.03612.022 | 22 |
| 03.03527.024 | 03.03612.024 | 24 |
| 03.03527.026 | 03.03612.026 | 26 |
| 03.03527.028 | 03.03612.028 | 28 |
| 03.03527.030 | 03.03612.030 | 30 |
| 03.03527.032 | 03.03612.032 | 32 |
| 03.03527.034 | 03.03612.034 | 34 |
| 03.03527.036 | 03.03612.036 | 36 |
| 03.03527.038 | 03.03612.038 | 38 |
| 03.03527.040 | 03.03612.040 | 40 |
| 03.03527.045 | 03.03612.045 | 45 |
| 03.03527.050 | 03.03612.050 | 50 |

| Article Number Ø 3.0 mm | Article Number Ø 3.5 mm | Length (mm) |
|----------------------------|----------------------------|----------------|
| 10.03530.010 | 03.05612.010 | 10 |
| 10.03530.012 | 03.05612.012 | 12 |
| 10.03530.014 | 03.05612.014 | 14 |
| 10.03530.016 | 03.05612.016 | 16 |
| 10.03530.018 | 03.05612.018 | 18 |
| 10.03530.020 | 03.05612.020 | 20 |
| 10.03530.022 | 03.05612.022 | 22 |
| 10.03530.024 | 03.05612.024 | 24 |
| 10.03530.026 | 03.05612.026 | 26 |
| 10.03530.028 | 03.05612.028 | 28 |
| 10.03530.030 | 03.05612.030 | 30 |
| 10.03530.032 | 03.05612.032 | 32 |
| 10.03530.034 | 03.05612.034 | 34 |
| 10.03530.036 | 03.05612.036 | 36 |
| 10.03530.038 | 03.05612.038 | 38 |
| 10.03530.040 | 03.05612.040 | 40 |
| | 03.05612.042 | 42 |
| | 03.05612.044 | 44 |
| 10.03530.045 | | 45 |
| | 03.05612.046 | 46 |
| | 03.05612.048 | 48 |
| 10.03530.050 | 03.05612.050 | 50 |

Cortical Screw, self-tapping

| Thread diameter: | 2.7 mm | 3. |
|------------------|--------|----|
| Core diameter: | 1.9 mm | 2. |
| Head diameter: | 5.0 mm | 6. |
| Hexagon socket: | 2.5 mm | 2. |
| | | |

• Material:

Ø 2.7 mmØ 3.5 mm2.7 mm3.5 mm1.9 mm2.4 mm5.0 mm6.0 mm2.5 mm2.5 mmTi6Al4VTi6Al4V

Locking Cortical Screw, self-tapping

| | Ø 3.0 mm | Ø 3.5 mm | |
|------------------|----------|----------|--|
| Thread diameter: | 3.0 mm | 3.5 mm | |
| Core diameter: | 1.9 mm | 2.4 mm | |
| Head diameter: | 4.75 mm | 4.75 mm | |
| Hexagon Socket: | 2.5 mm | 2.5 mm | |
| Material: | Ti6Al4V | Ti6Al4V | |





Cannulated Screws Ø 4.0 mm, short thread, self-drilling

| Thread diameter: | 4.0 mm |
|--------------------------------------|---------|
| Core diameter: | 2.6 mm |
| Head diameter: | 5.0 mm |
| Hexagon socket: | 2.5 mm |
| • Material: | Ti6Al4V |

| Length |
|--------|
| 20 mm |
| 22 mm |
| 24 mm |
| 26 mm |
| 28 mm |
| 30 mm |
| 32 mm |
| 34 mm |
| 36 mm |
| 38 mm |
| 40 mm |
| 42 mm |
| 44 mm |
| 46 mm |
| 48 mm |
| 50 mm |
| |



Cannulated Screws Ø 4.0 mm, fully thread, self-drilling

| • | Thread diameter: | 4.0 mm |
|---|------------------|---------|
| • | Core diameter: | 2.6 mm |
| • | Head diameter: | 5.0 mm |
| • | Hexagon socket: | 2.5 mm |
| • | Material: | Ti6Al4V |

| Article Number | Length |
|----------------|--------|
| 08.03640.020 | 20 mm |
| 08.03640.022 | 22 mm |
| 08.03640.024 | 24 mm |
| 08.03640.026 | 26 mm |
| 08.03640.028 | 28 mm |
| 08.03640.030 | 30 mm |
| 08.03640.032 | 32 mm |
| 08.03640.034 | 34 mm |
| 08.03640.036 | 36 mm |
| 08.03640.038 | 38 mm |
| 08.03640.040 | 40 mm |
| 08.03640.042 | 42 mm |
| 08.03640.044 | 44 mm |
| 08.03640.046 | 46 mm |
| 08.03640.048 | 48 mm |
| 08.03640.050 | 50 mm |
| | |





Instruments

| 11.90012.070 | Kirschner Wire Ø 1.2 mm, trocar tip, L 70 mm, stainless steel | 08.20120.135 | Cleaning Wire Ø 1.2 mm, L 200 mm |
|----------------|---|---------------|--|
| 11.90012.150 | Kirschner Wire Ø 1.2 mm, trocar tip, L 150 mm, stainless steel | | |
| 11.90212.150 | Kirschner Wire Ø 1.2 mm, threaded tip, L 150 mm, stainless steel | 08.20100.035 | Length Determination Instrument for Kirschner Wire Ø 1.2 mm x 150 |
| 0.20010.020 | Drill Bit Ø 2.0 mm, AO Coupling, L 112 / 84 mm | 03.20100.060 | Length Determination Instrument for Screws up tp 60 mm |
| 03.20010.425 | Drill Bit Ø 2.5, scaled, AO Coupling, | | |
| 270 | L 160 / 130 mm | 03.20040.125 | Screwdriver Shaft, hex 2.5 mm, AO Coupling, L 100 / 70 mm |
| 8.20010.027(S) | Drill Bit Ø 2.7 / 1.35 mm, cannulated, AO Coupling, L 160 / 130 mm | | * 1.000 (0.00) |
| 3.20060.015 | Drill Guide 2.0 for WS Plates | 03.20040.025 | Screwdriver, hex 2.5 mm, L 200/85 mm |
| 3.20060.020 | Drill Guide 2.5 für WS Plates | 08.20040.025 | Screwdriver, hex 2.5 mm, cannulated, L 199 / 89 mm |
| 2.20060.017 | Double Drill Guide 2.0 / 1.7 | | |
| 0002.0 | RAEURADI 21/13754 €€0297 Ø1.7 € | 02 200 40 020 | Helding Closure for Coroure (2.2.7.4.0 pr |
| 3.20060.025 | Double Drill Guide 3.5 / 2.5 | 03.20040.026 | Holding Sleeve for Screws Ø 2.7 - 4.0 mr |
| Ø @ Ø 3.5 | 03.20060.025 19/20385 CE0297 Ø 2,5 - | 02.20120.015 | Screw Forceps, self-holding |

Templates



PEDUS-R MIS WS Calcaneus Plate

| Article Number | Size | Orientation |
|----------------|------|-------------|
| 12.21260.010 | S | right |
| 12.21260.110 | S | left |
| 12.21260.020 | L | right |
| 12.21260.120 | L | left |





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MRI Safety Information

Non-clinical testing has demonstrated that the plates 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 (B₀)
 - 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 **8min and 15s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **8min and 15s** if this limit is reached.

3.0 T: 2 W/kg whole-body average SAR for **6min and 19s** of continuous RF (a sequence or back-to-back series/scan without breaks) followed by a wait time of **6min and 19s** if this limit is reached.

- The plates are expected to produce a maximum temperature rise of 8.5 °C at 1.5 T and 6.9 °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.





Dieter Marquardt Medizintechnik GmbH

Robert-Bosch-Straße 1 • 78549 Spaichingen, Germany Telefon +49 7424 9581-0 • Telefax +49 7424 501441 info@marquardt-medizintechnik.de • www.marquardt-medizintechnik.de

C € 0297