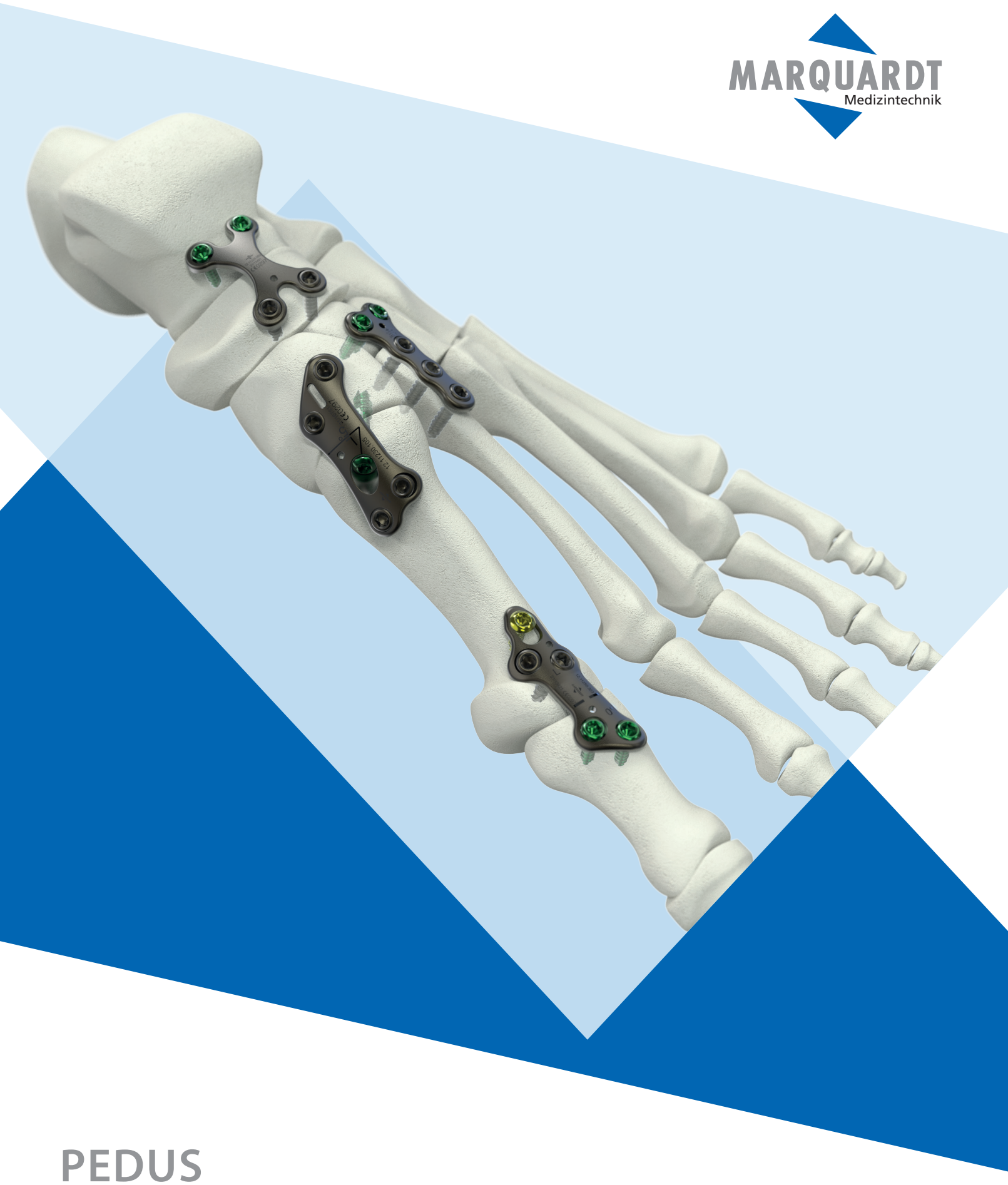
MARQUARDT
Medizintechnik



PEDUS
Fore- and Midfoot System

Clinical consultant

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Table of Contents

Note:

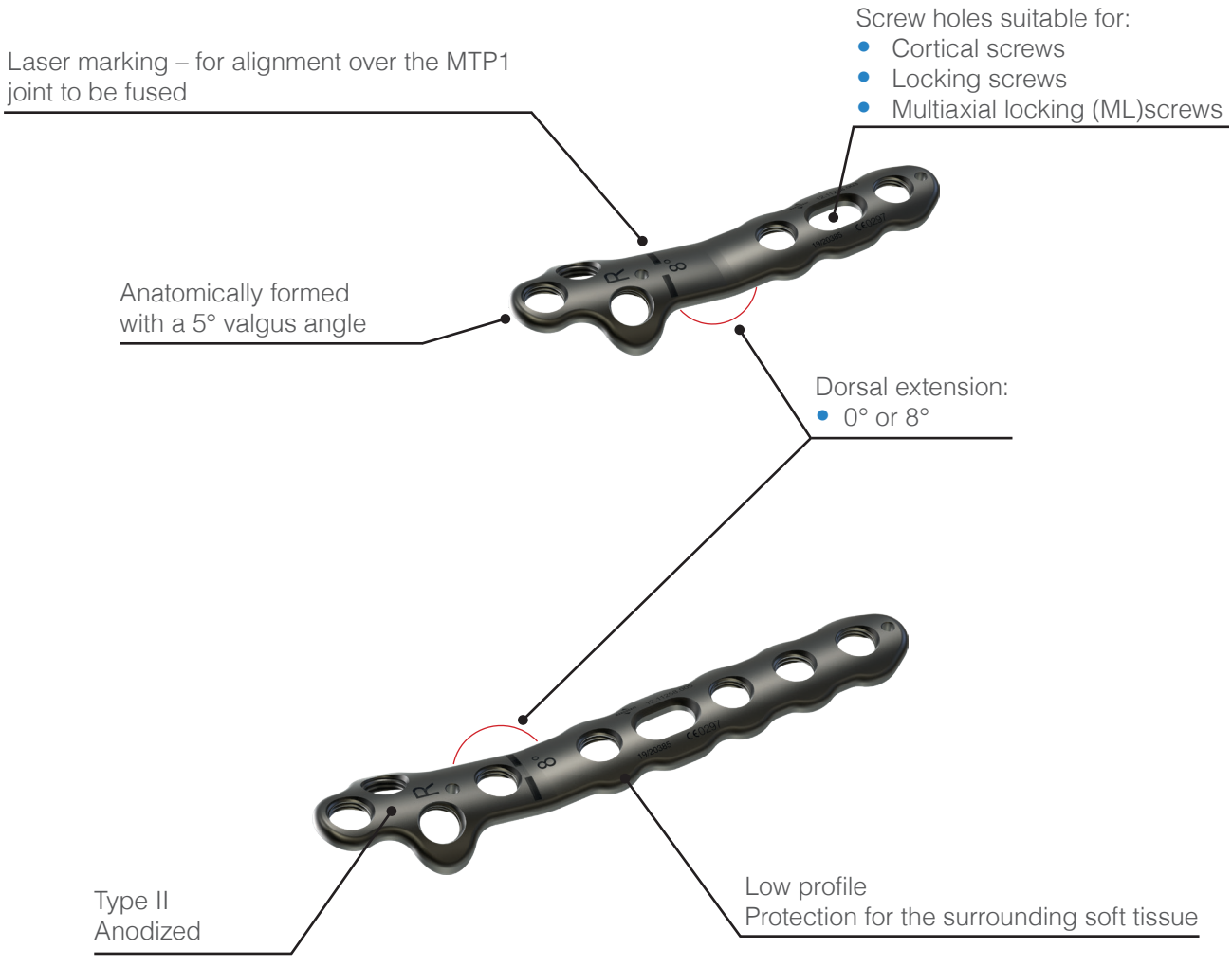
The surgery instructions outlined below reflect the surgery procedure usually chosen by the clinical consultant. However, each surgeon must decide individually which course of action offers the best chance of success in the individual case.

Surgical technique PEDUS-MTP1 Plate

PEDUS-MTP1 Plate

Product Specification

- 3 different plate lengths
- Separate versions for the left / right foot
- 2 different adjustments of the dorsal extension (0° and 8°)



Indication

- PEDUS-MTP1 Arthrodesis Plates are indicated for fixation of fractures, osteotomies and joint fusions at the fore- and midfoot, especially at the first metatarsophalangeal joint with Hallux Rigidus.

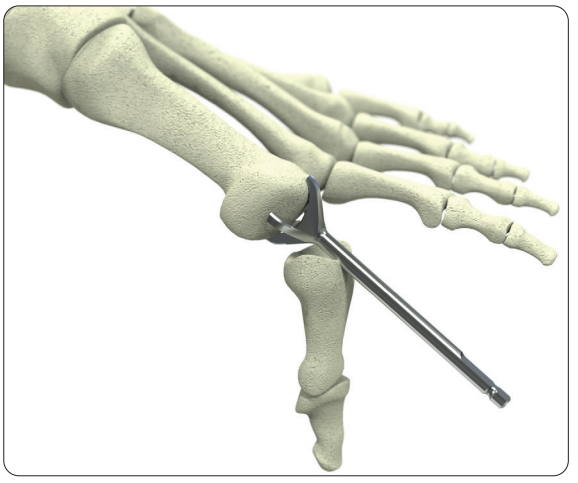
1. Access and Resection

- Dorsal longitudinal cut over the metatarsophalangeal joint of the hallux, approx. 4–5 cm.
- The tendon of the extensor hallucis longus muscle is retracted laterally.
- Separation of the joint capsule and presentation of the metatarsal head and the basis of the proximal phalanx.
- The joint capsule is preserved where possible and sutured during wound closure as a sliding layer between plate and extensor tendon.

2. Preparation of the Metatarsophalangeal Joint: MT1

Instruments

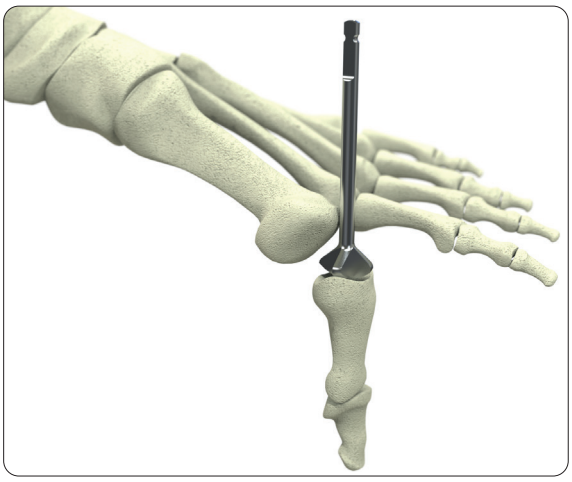
REF 12.20032.075	*Reamer for arthrodesis, concave, small*
REF 12.20032.085	*Reamer for arthrodesis, concave, medium*
REF 12.20033.075	*Reamer for arthrodesis, concave, large*
REF 11.90016.150	*Kirschner wire, Ø 1.6 mm, L 150 mm*



- Osteophyte removal
- The K-wire is inserted under plantar flexion of the phalanx into the metatarsal head and comes to rest centrally in the metatarsal I.
- A concave reamer is used to ream the joint surface of the metatarsal I until subchondral bone becomes visible.

Note:

- If you are unsure about which size of reamer to use, start with a large reamer and then reduce the size if required.
- Only minor resection may be required for certain revision surgery. Reaming progress should be constantly monitored to prevent excessive shortening of the metatarsal I.



3. Preparation of the Metatarsophalangeal Joint of the Hallux: Phalanx

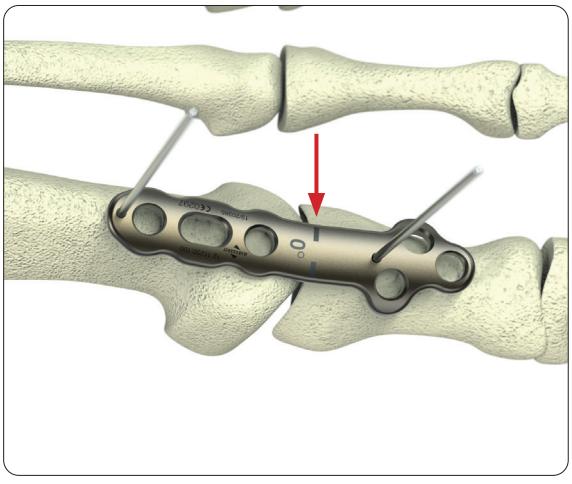
Instruments

REF 12.20030.075	*Reamer for arthrodesis, convex, small*
REF 12.20030.085	*Reamer for arthrodesis, convex, medium*
REF 12.20031.075	*Reamer for arthrodesis, convex, large*
REF 11.90016.150	*Kirschner wire, Ø 1.6 mm, L 150 mm*

- The plantar flexion is preserved, and the K-wire is inserted in the proximal phalanx.
- The K-wire comes to rest centrally in the proximal phalanx.
- The joint surface of the phalanx is removed with a convex reamer.
- In order to obtain congruent surfaces, the same size of reamer should be used for this process as in point 2.

Note:

- The K-wire should not extend distally into the interphalangeal joint.
- During the reaming process, care must be taken to ensure that the metatarsal head is not damaged with the convex reamer.



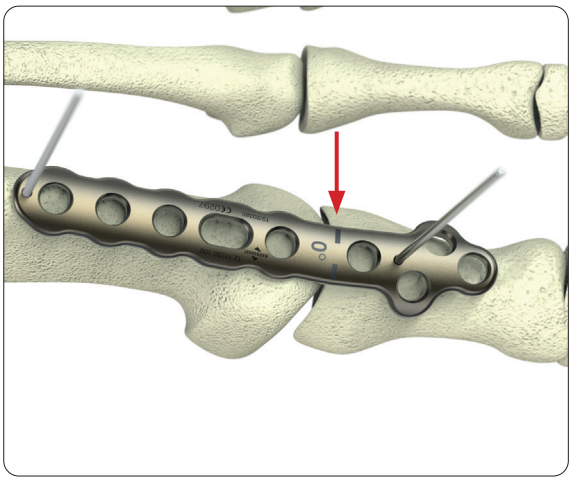
4. Implant Selection and Positioning

Instruments

REF 11.90012.070	*Kirschner wire, Ø 1.2 mm, L 70 mm*

- The PEDUS-MTP1 plate is applied dorsally, as a result of which the position of the toe is predetermined.
- The plates are preformed with a valgus angle of 5° and are available in angles of 0° and 8° depending on the required dorsal extension.
- The laser marking is provided for guide purposes and should be positioned level with the resected metatarsophalangeal joint of the hallux.
- The plate is temporarily fixed on the bone with K-wires. At this stage the position of the plate can be checked very well with the image intensifier.
- It is possible to additionally stabilize the arthrodesis temporarily with a K-wire.

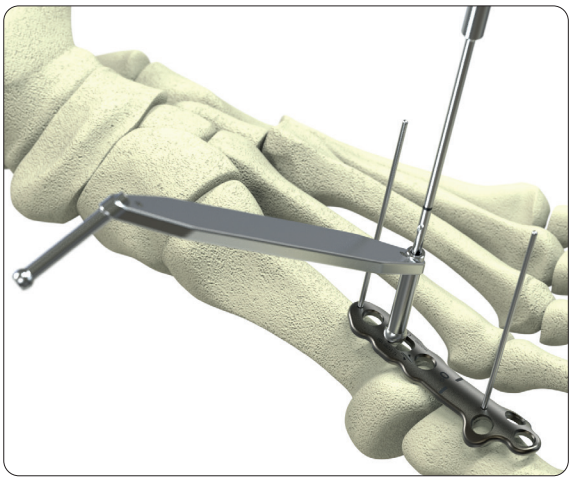
- In the event of bone defects or revision surgery it may be expedient to insert bone transplants. Plates with a correspondingly longer proximal design are available for this indication.



5. Fixation of the Plate

Instruments

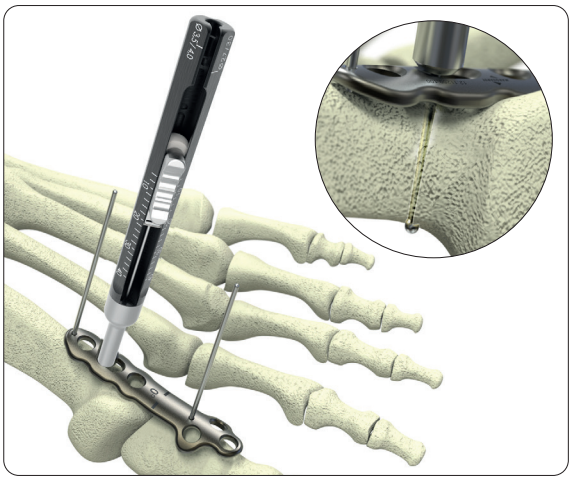
REF 10.20010.020 *Drill bit Ø 2.0 mm*
REF 12.20060.017 *Double Drill Guide 2.0 / 1.7*



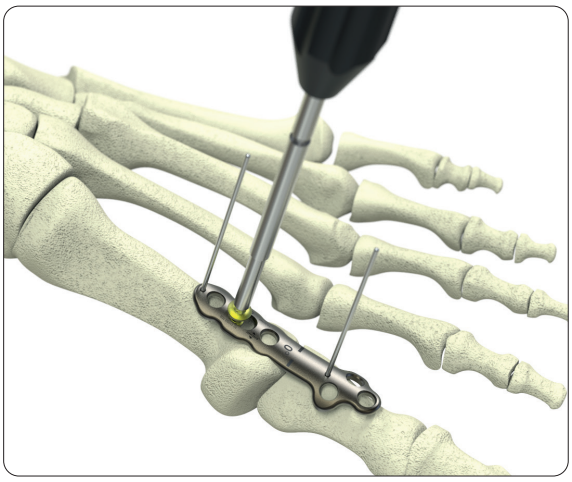
- The proximal oval hole is filled with a non-locking Ø 2.7 mm screw.
- The screw hole is pre-drilled using the drill bit via the guide wire, through the double drill guide.

Instruments

REF 03.20100.040 *Length Determination Instrument, for screws up to 40 mm*



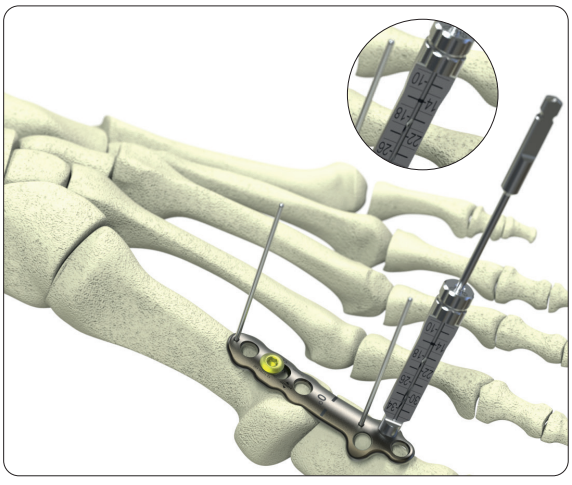
- Afterwards the length determination instrument, is used to determine the required screw length.



Instruments

REF 03.20040.030 *Screwdriver, hex 2.5 mm*

- Once the required screw length has been determined, the corresponding screw will be inserted with the screwdriver.
- Final tightening of the non-locking screw should not be performed until the proximal phalanx has been screwed in and after the tension screw has been inserted.

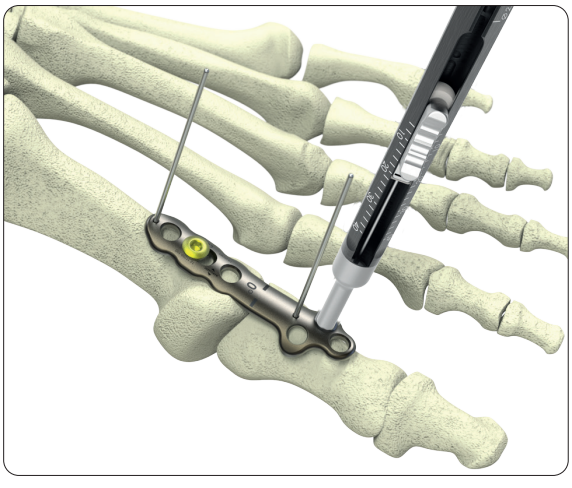


6. Drilling the Locking Screws at the Proximal Phalanx

Instruments

REF 10.20010.020 *Drill bit Ø 2.0 mm*
REF 10.20060.047 *Drill Guide 2.0*

- For the Ø 3.0 mm locking screws the scaled drill guide is screwed into the screw hole that is to be used.
- With the aid of the drill bit the required screw length can be read off directly via the scaling of the drill guide.



7. Length Determination via Depth Gauge

Instruments

REF 03.20100.040 *Length Determination Instrument, for screws up to 40 mm*

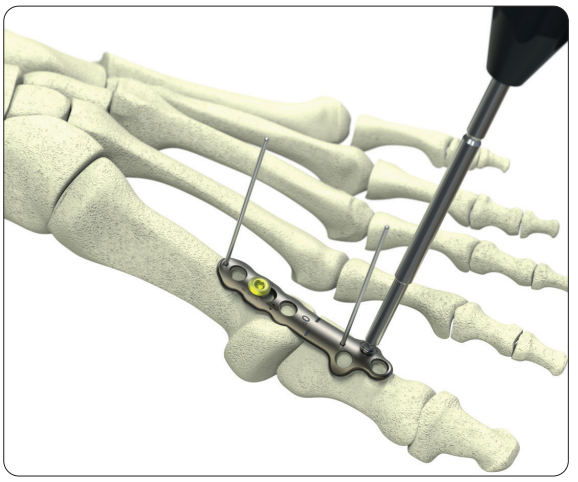
- Alternatively, it is also possible to use a length determination instrument to determine the required screw length.
- The length determination instrument is placed directly on the plate here, and after hooking onto the opposite cortical bone the value can be read off.

8. Insertion of Screws into the Proximal Phalanx

Instruments

REF 03.20040.030 *Screwdriver, hex 2.5 mm*

- After determination of the required screw lengths, the screws are inserted with the screwdriver.
- Non-locking screws should be inserted before the locking screws are inserted.
- The bores for the locking screws should not be made until the non-locking screws have been fully tightened. Otherwise the position of the plate can change slightly in relation to the bone, as a result of which the drilled axes will no longer line up exactly.

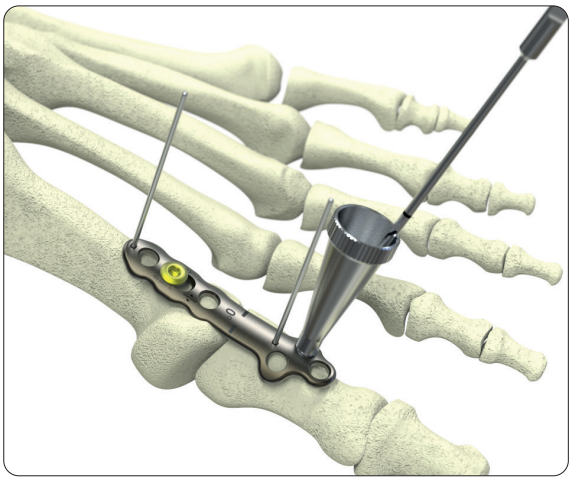


9. Insertion of ML Screws

Instruments

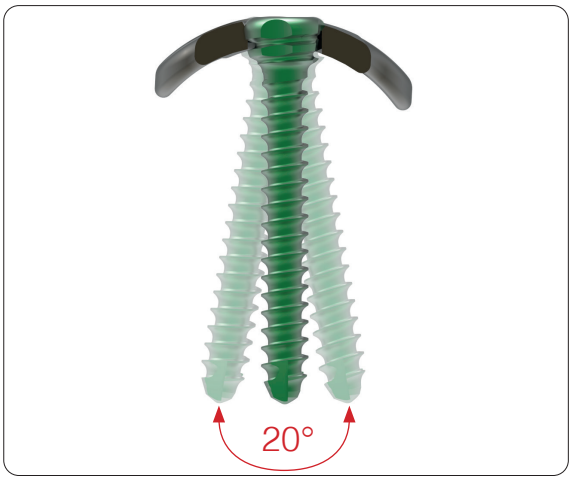
REF 03.20100.040 *Length Determination Instrument, for screws up to 40 mm*
REF 10.20010.020 *Drill bit Ø 2.0 mm*
REF 10.20050.025 *ML Drill Guide 2.0*

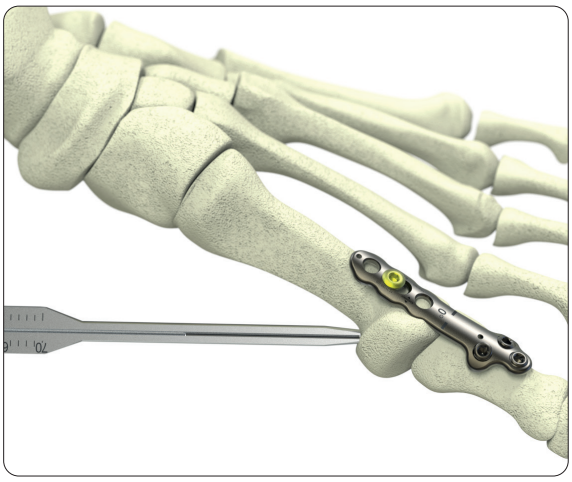
- The ML drill guide is used for Ø 2.7 mm ML screws. The funnel-shaped sleeve is screwed into the hole and then enables continuous multiaxial drilling in a 20° cone.
- The measurement of the screw length is performed as described in point 7, and the screw is inserted as described in point 8.



Note:

- The range of 20° must not be exceeded, as otherwise correct blocking between screw and plate will not be ensured.



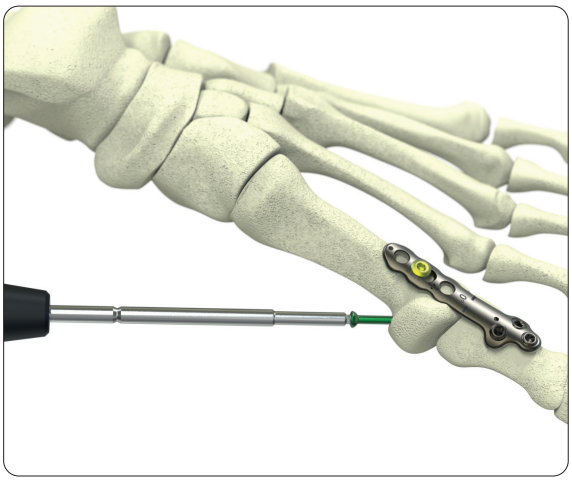


10. Insertion of the Lag Screw

Instruments

REF 08.20100.035	*Length Determination Instrument, for K-wires*
REF 12.20010.027	*Drill Bit Ø 2.7 mm, cannulated*

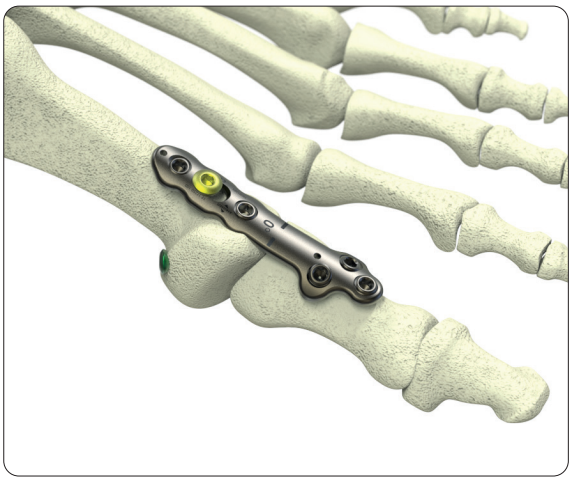
- The compression of the arthrodesis is performed via a lag screw, which is inserted via a K-wire obliquely from medial to lateral through the metatarsophalangeal joint of the hallux.
- The screw is normally inserted from proximal to distal.
- The required screw length is determined using the length determination instrument over the inserted K-wire.
- The end of the K-wire indicates the length of the required screw.
- Subsequently, bicortical advancement is made via the K-wire with the cannulated drill bit.
- Check the length and position of the screw under radiological control in both planes.



Note:

- Alternatively it is also possible to use compression screws with similar dimensions following similar mechanical principles.

11. Fixation of the Proximal Screw Holes



- After insertion of the lag screw and compression of the metatarsophalangeal joint of the hallux, further compression is performed by tightening the non-locking screw in the oval hole. Afterwards the proximal locking screw holes of the plate are filled.
- Here, the procedure for inserting the screws corresponds to the procedure described in points 6, 7, 8 and 9.
- Once all of the screw holes have been filled, a final radiological check is performed.

12. Postoperative Protocol

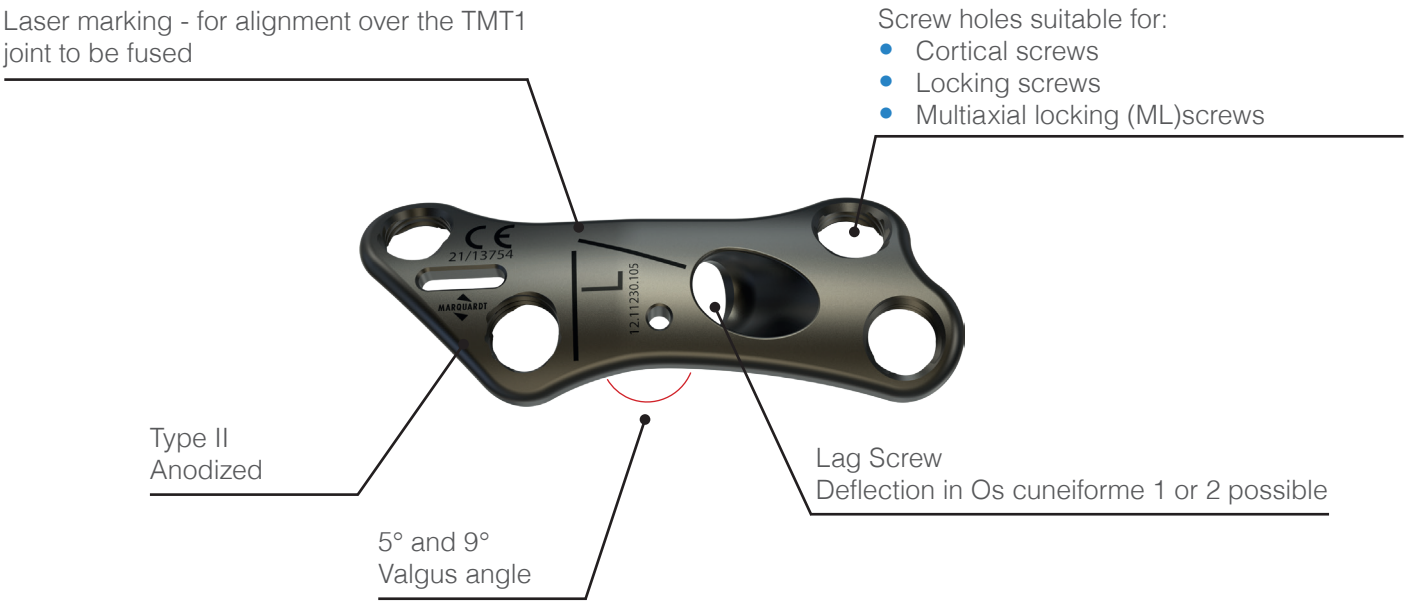
- The postoperative protocol is performed using a surgical shoe with a stiff sole or a special post-operative shoe with forefoot support until bony consolidation has taken place.
- Normally the arthrodesis has been fused with bone growth after six weeks. However, as a result of individual patient factors, such as bone quality or medication that inhibits the formation of new bone, significant deviations from this value are possible.
- The transition to normal shoes can be facilitated with a stiff insert (rigidus spring plate) or with the aid of a shoe modification with a midfoot roll.

Surgical Technique PEDUS-Lx Compression Plate

PEDUS-Lx Compression Plate

Product Specification

- Separate versions for the left / right foot
- 2 different valgus angle: 5° and 9°



Indication

- PEDUS-Lx Compression Plates are indicated for fixation of fractures, osteotomies and joint fusions at the midfoot, especially at the first tarsometatarsal joint. The Plates may be used for correction of deformities, especially hallux valgus.

1. Access and Resection

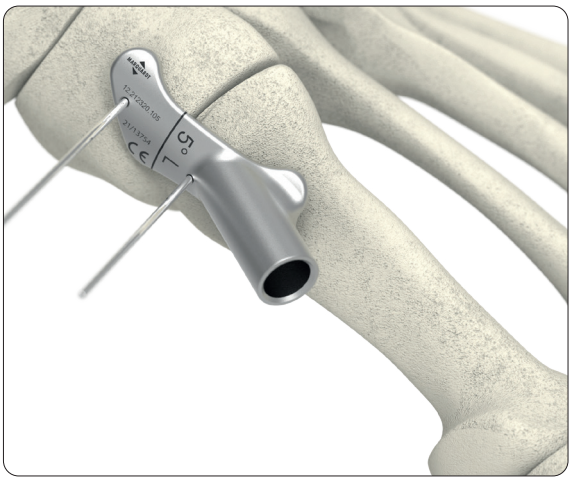
- A dorsomedial incision is made over the first tarsometatarsal (TMT1) joint from the medial cuneiform to the mid of the MTP1. The incision is placed medial to the extensor hallucis longus.
- The TMT1 joint is identified, the cartilage is removed and the joint surfaces are prepared for fusion. The resected wedge determines the direction of correction.

2. Determination of the Implant Size and Position

Instruments

REF 11.90012.070 *K-wire Ø 1.2mm, L = 70mm*
REF 12.21230.xxx *Milling Guide for PEDUS-Lx Plates*

- The milling guide, which also works as a trial implant, is used to determine the implant angle and the implant position..
- The milling guide is temporarily fixed with K-wires.

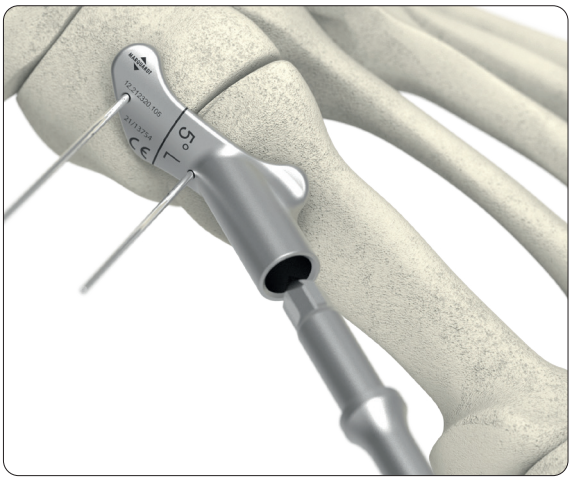


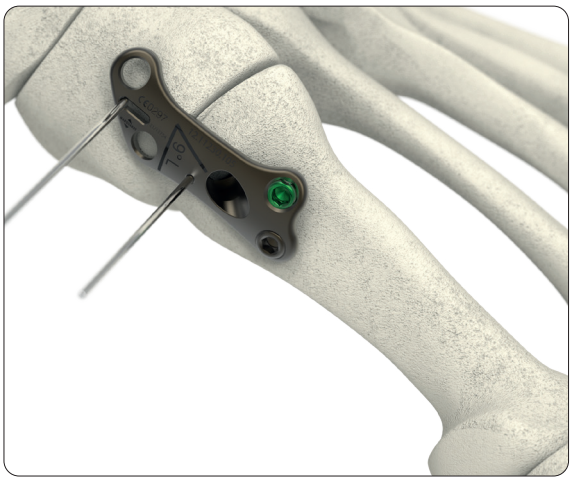
3. Reaming

Instruments

REF 12.20030.040 *Reamer for PEDUS-Lx Plates*

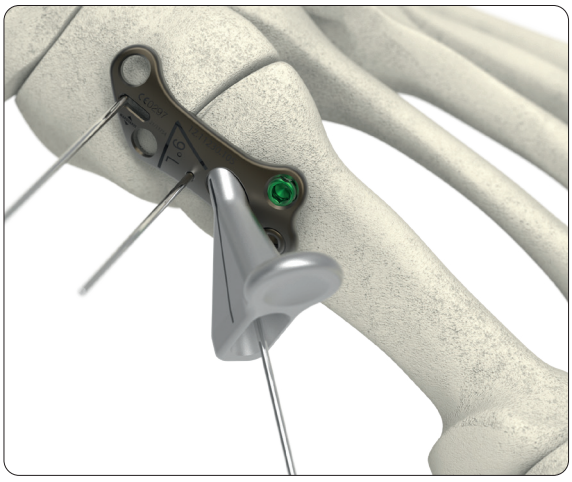
- The reamer is used to prepare the placement of the implant via the milling guide.
- The stop of the reamer must be advanced to the milling guide.





4. Positioning of the Implant

- The milling guide is removed and the K-wires remain in the bone.
- The corresponding PEDUS-Lx plate is then placed over the K-wires.
- The distal screw holes of the plate are filled with locking or ML screws.
- Drilling and measuring the screw length as well as fixation correspond to steps 6, 7, 8 and 9 of the MTP surgical technique (see pages 6, 7 and 8).

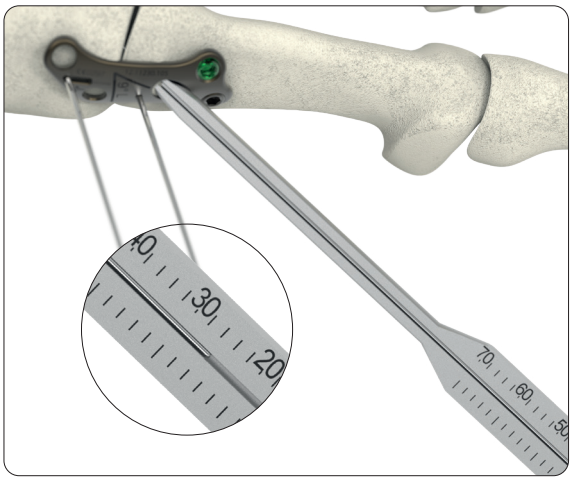


5. Insertion of the K-wire for the Lag Screw

Instruments

REF 11.90012.150	*K-wire Ø 1.2mm, L = 150mm*
REF 12.20060.040	*Guide Sleeve for K-wires Ø 1.2mm*

- The guide sleeve is inserted into the lag screw hole.
- The marking of the guide sleeve must be axially aligned with the marking of the implant.
- Insert the K-wire through the guide sleeve.
- The position of the K-wire is checked in both planes under radiological control.



6. Determination of the Lag Screw Length

Instruments

REF 08.20100.035	*Length Determination Instrument for K-wires Ø 1.2mm*

- The length determination instrument is then inserted over the K-wire as far as it will go.
- The required screw length can be read directly from the scale of the length determination instrument (end of the K-wire).

Note:

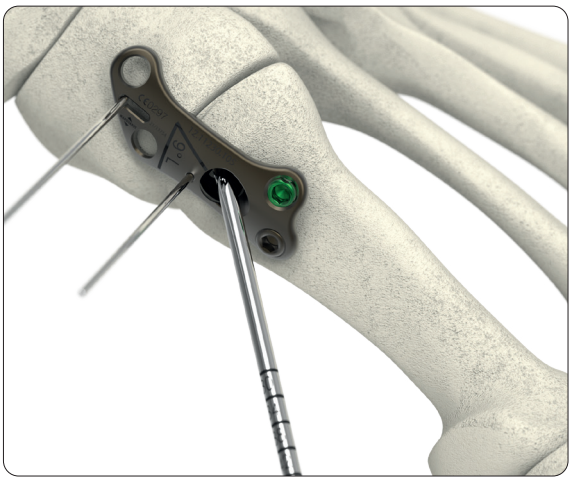
- The screw length must be selected to ensure a secure screw connection in Cuneiforme I or II.

7. Drilling

Instruments

REF 12.20010.027 *Drill Bit Ø 2.7mm*

- Pre-drill over the K-wire with the cannulated drill bit.
- The K-wire should not be completely over-drilled.

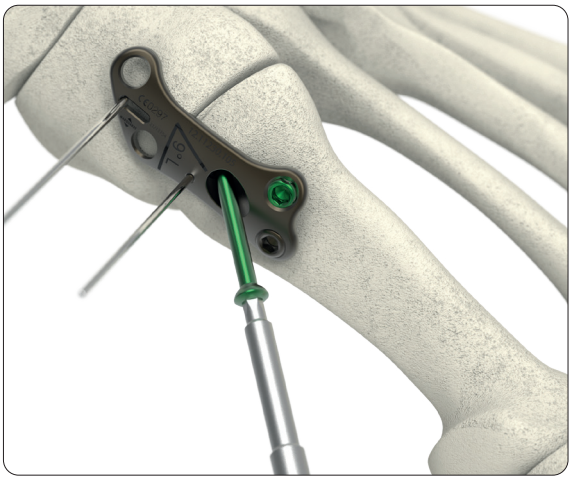


8. Screw Insertion

Instruments

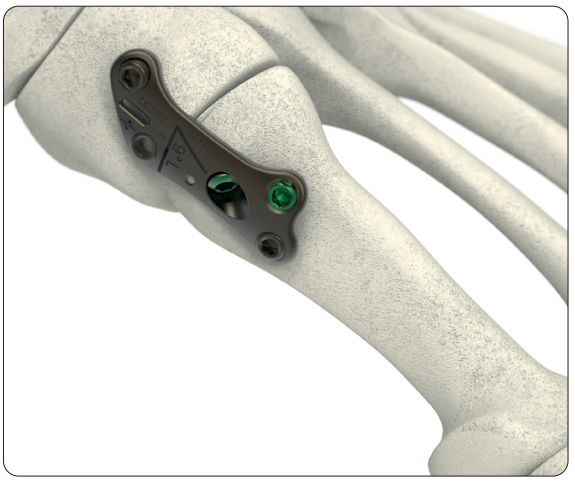
REF 08.20040.025 *Screwdriver, hex 2.5mm*

- The corresponding length of cannulated screws is inserted over the K-wire with the cannulated screwdriver.
- After inserting the lag screw and adjusting the compression, all K-wires are removed.



9. Fixation of the Proximal Screw Holes

- The proximal screw holes of the plate are filled with locking or ML screws.
- Drilling and measuring the screw length as well as fixation correspond to steps 6, 7, 8 and 9 of the MTP surgical technique (see pages 6, 7 and 8).
- After all screw holes have been filled, a final radiological check is performed.

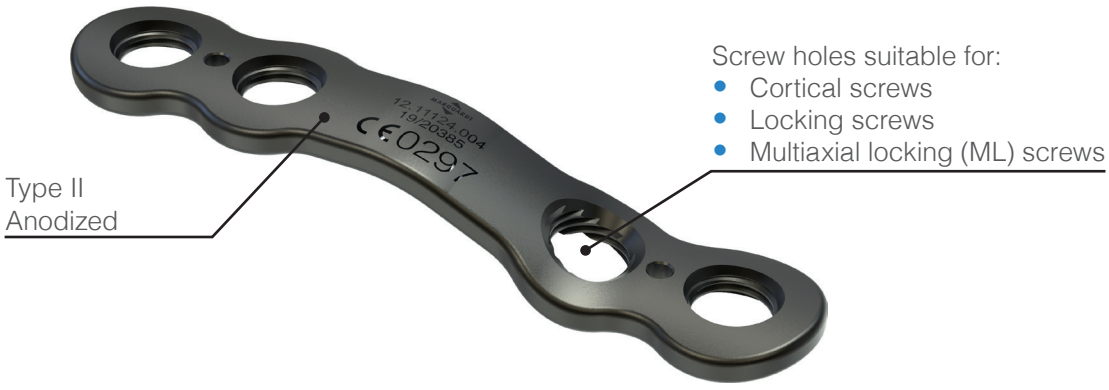


Surgical technique PEDUS-L Plantar Lapidus Plate

PEDUS-L Plantar Lapidus Plate

Product specification

- The plantar contact of the plate generates a tension band mechanism, which causes a compression of the arthrodesis under load.
- In addition, the plate is completely covered by the abductor hallucis muscle, which reduces postoperative tissue repair problems and makes the removal of metal unnecessary in most cases.



Indication

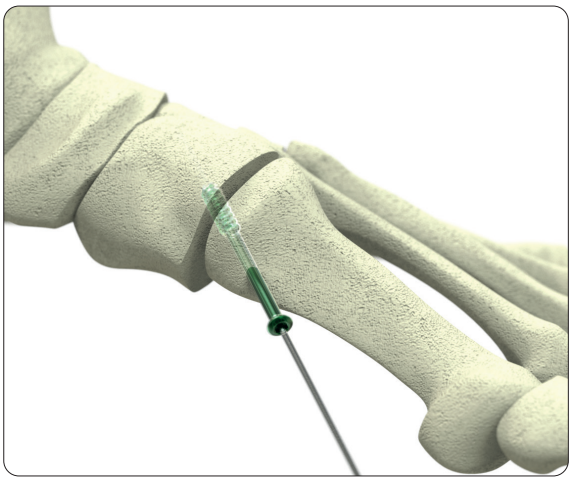
- PEDUS-L Plantar Lapidus Plates are indicated for fixation of fractures, osteotomies and joint fusions at the midfoot, especially at the first tarsometatarsal joint. The Plates may be used for correction of deformities, especially hallux valgus.

1. Access and Resection

- The incision is made medioplantar over the first tarsometatarsal (TMT1) joint along the metatarsal up to the MTP1 joint.
- The joint surfaces are removed and the joint is repositioned.
- Alternatively, a medioplantar incision is made above the TMT1 joint and a second incision is made from the medial side above the MTP1 joint. Afterwards the medial Os cuneiform I and the basis of the metatarsal are exposed.

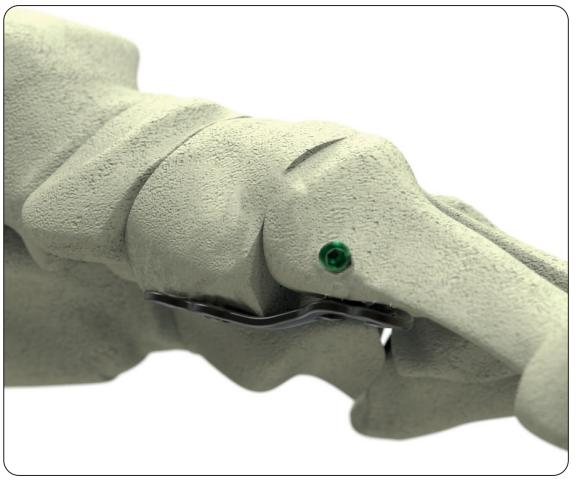
2. Insertion of the Lag Screw

- The TMT1 joint is fixed in the required position with a K-wire, Ø 1.2 mm, using the double drill guide.
- A cannulated lag screw Ø 4.0 mm is inserted from plantar medial to dorsal lateral into the second Os cuneiform.
- The insertion of the cannulated screw Ø 4.0 mm is done as described in step 10 in the MTP surgical technique.



3. Positioning and Fixation of the Plate

- The plate is positioned and can be temporarily fixed with a K-wire.
- The plate can be fixed with locking or multiaxial locking screws.
- The steps for drilling, measuring the screw length and fixation are the same as steps 6, 7, 8 and 9 in the MTP surgical technique (see above).

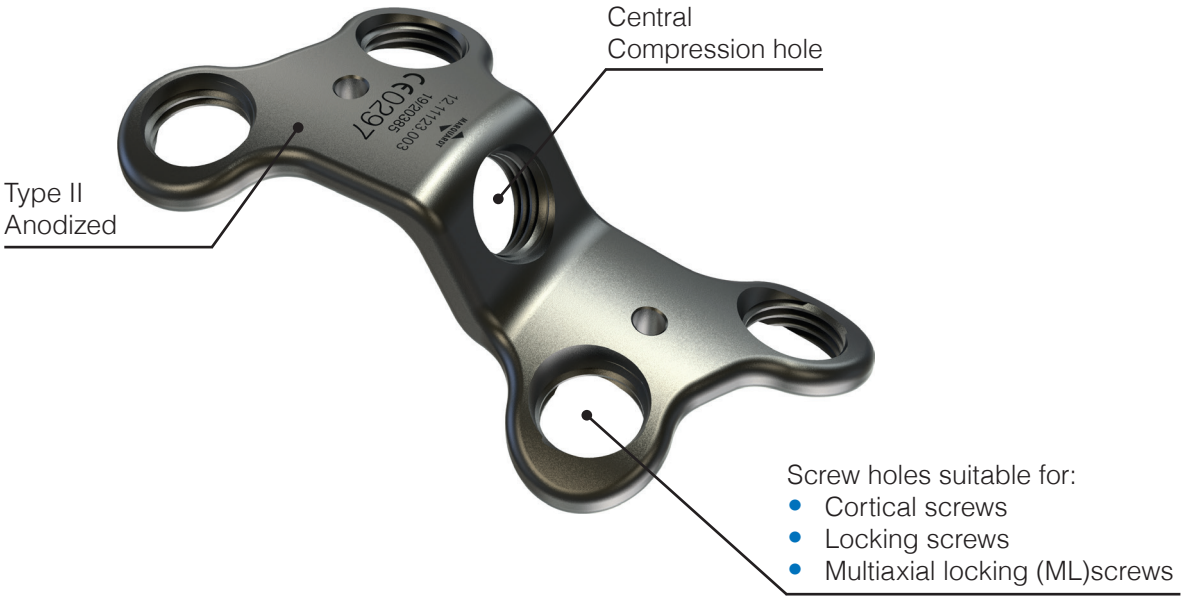


Surgical technique PEDUS-L

PEDUS-L

Product specification

- 5 different step heights: 0, 2, 3, 4 and 5 mm
- The plate design allows the insertion of a cortical screw, which can be used to exert compression on the arthrodesis surfaces.



Indication

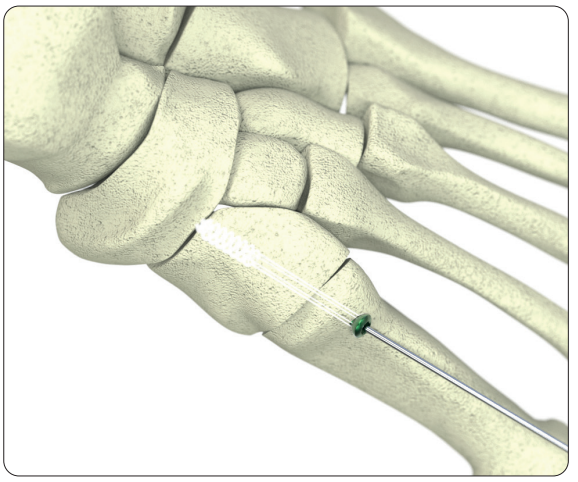
- PEDUS-L Lapidus Plates are indicated for fixation of fractures, osteotomies and joint fusions at the midfoot, especially at the first tarsometatarsal joint. The Plates may be used for correction of deformities, especially hallux valgus.

1. Access and Resection

- A dorsomedial incision is made over the first tarsometatarsal (TMT1) joint from the medial cuneiform to the mid of the MTP1. The incision is placed medial to the extensor hallucis longus.
- The TMT1 joint is identified, the cartilage is removed and the joint surfaces are prepared for fusion. The resected wedge determines the direction of correction.

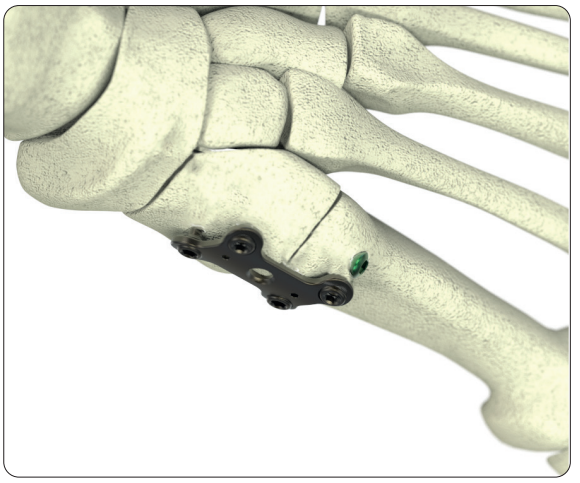
2. Insertion of the Lag Screw

- The TMT1 joint is fixed in the required position with a K-wire Ø 1.2 mm, using the double drill guide.
- A cannulated lag screw is inserted from dorsal to plantar into the first Os cuneiform.
- The insertion of the cannulated screw Ø 4.0 mm is done as described in step 10 in the MTP surgical technique (see above).



3. Positioning and Fixation of the Plate

- The plate is positioned and can be temporarily fixed with a K-wire.
- The plate can be fixed with locking or multiaxial locking screws.
- The steps for drilling, measuring the screw length and fixation are the same as steps 6, 7, 8 and 9 in the MTP surgical technique (see above).

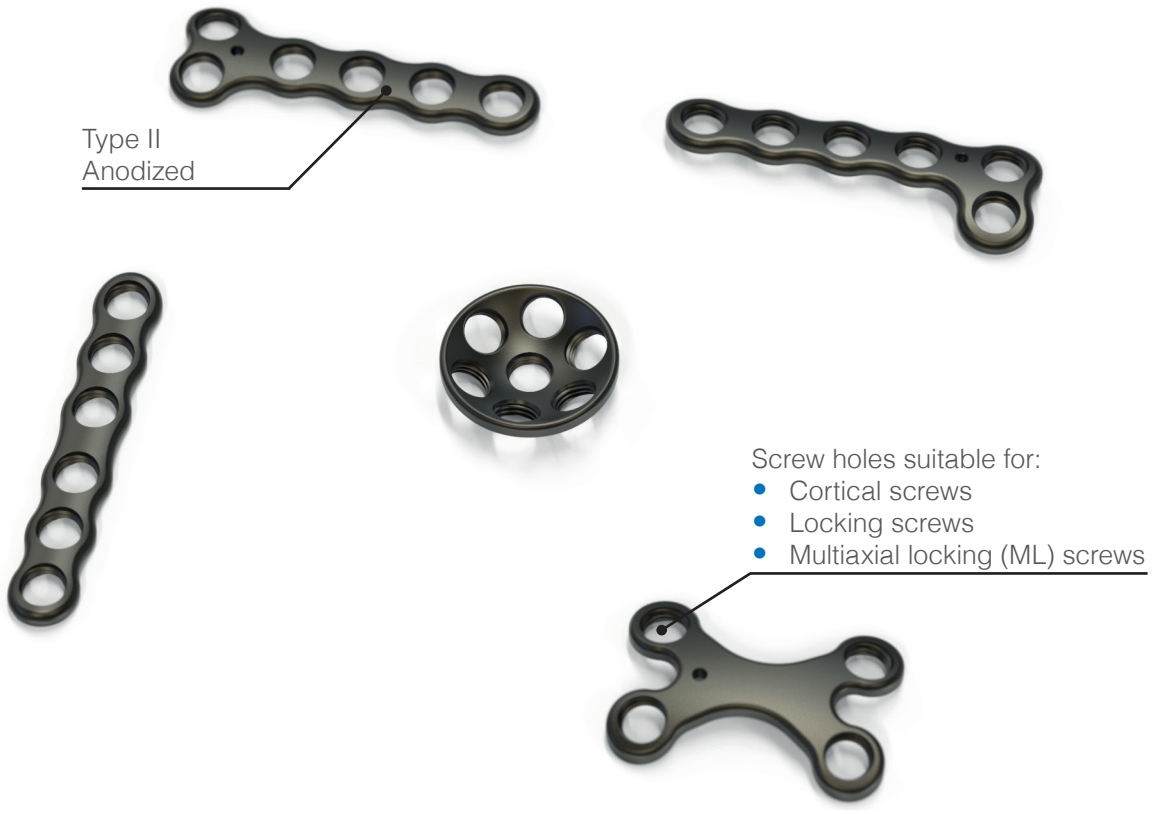


Surgical technique

PEDUS Locking Plate System

Product specification

- The PEDUS Locking Plate System includes 5 different plate geometries:
  - PEDUS Locking Plate, straight
  - PEDUS Locking T-Plate
  - PEDUS Locking L-Plate
  - PEDUS Locking X-Plate
  - PEDUS Locking Multifix Plate
- Combination holes enable the use of locking and non locking screws.



Indication

- PEDUS Locking Plates are indicated for fixation of fractures, osteotomies and joint fusions at the fore and midfoot.

1. PEDUS Multifix Plate – Access and Resection

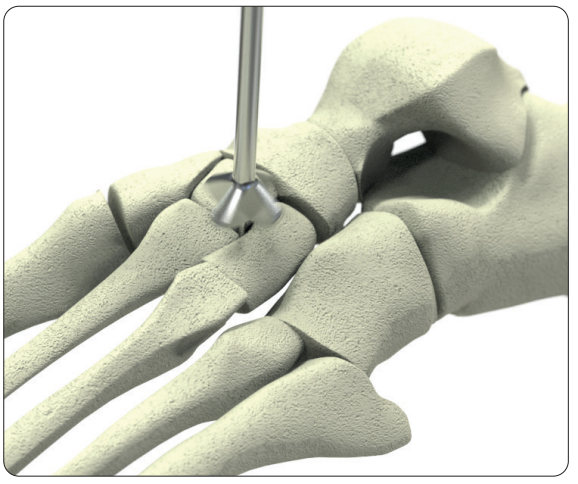
- Incision starting above the third metatarsal, extending over the scaphoid bone up to the middle of the metatarsal shaft.
- Expose the dorsalis pedis artery and the medial dorsal cutaneous nerve, slide to one side and expose the bone.

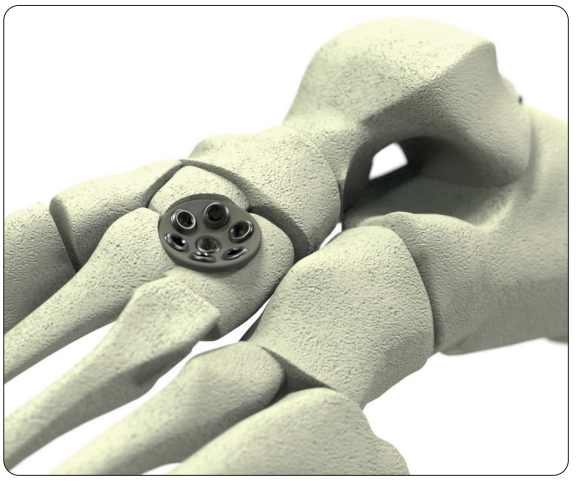
2. Positioning and Fixation of the Plate

Instruments

REF 12.20030.085	*Reamer for arthrodesis, convex, medium*
REF 11.90016.150	*Kirschner wire, Ø 1.6 mm, L 150 mm*
REF 10.20010.020	*Drill bit Ø 2.0 mm*
REF 08.20060.027	*Double Drill Guide 2.7 / 1.25*
REF 08.20100.035	*Direct Measuring Device*
REF 08.20040.025	*Screwdriver, hex 2.5 mm*

- A K-wire is inserted centrally into the joint surface.
- The convex reamer is inserted over the K-wire and the joint surface is removed.
- The plate is positioned and can be fixed with locking or multiaxial locking screws.
- The steps for drilling, measuring the screw length and fixation are the same as steps 6, 7, 8 and 9 in the MTP surgical technique (see above).





Product Information

Implants

PEDUS-MTP1, short

- 2 distal holes
- 3 shaft holes
- 0° und 8° dorsal extension
- 5° valgus angle
- Material: Ti6Al4V

Article number *	Flexion	Orientation
12.11250.203	0°	right
12.11250.303	0°	left
12.11258.203	8°	right
12.11258.303	8°	left

PEDUS-MTP1, 3 holes

- 3 distal holes
- 3 shaft holes
- 0° and 8° dorsal extension
- 5° valgus angle
- Material: Ti6Al4V

Articel number *	Flexion	Orientation
12.11250.003	0°	right
12.11250.103	0°	left
12.11258.003	8°	right
12.11258.103	8°	left

PEDUS-MTP1, 5 holes

- 4 distal holes
- 5 shaft holes
- 0° and 8° dorsal extension
- 5° valgus angle
- Material: Ti6Al4V

Article number *	Flexion	Orientation
12.11250.005	0°	right
12.11250.105	0°	left
12.11258.005	8°	right
12.11258.105	8°	left

PEDUS-Lx Compression Plate

- 5° and 9° valgus angle
- Material: Ti6Al4V

Article number *	Valgus angle	Orientation
12.11230.005	5°	right
12.11230.105	5°	left
12.11230.009	9°	right
12.11230.109	9°	left

PEDUS-L

- Steps: 0, 2, 3, 4 and 5 mm

Article number *	Step	Material
12.11123.000	0 mm	Titanium
12.11123.002	2 mm	Ti6Al4V
12.11123.003	3 mm	Ti6Al4V
12.11123.004	4 mm	Ti6Al4V
12.11123.005	5 mm	Ti6Al4V

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

Article number *	Holes	Length
12.11124.003	4	39 mm
12.11124.004	4	44 mm

PEDUS-L Plantar Lapidus Plate

- 4 shaft holes
- Length: 39 and 44 mm
- Material: Ti6Al4V

Article number *	Holes
12.11211.004	4
12.11211.006	6
12.11211.008	8

PEDUS Locking Plate, straight

- Material: Ti6Al4V

Article number *	Holes
12.11210.003	3
12.11210.004	4
12.11210.006	6

PEDUS Locking T-Plate

- Material: Ti6Al4V

Article number *	Holes	Orientation
12.11212.003	3	90°, right
12.11212.004	4	90°, right
12.11212.006	6	90°, right
12.11212.103	3	90°, left
12.11212.104	4	90°, left
12.11212.106	6	90°, left

PEDUS Locking L-Plate

- Material: Ti6Al4V

Article number *	Size
12.11220.002	small
12.11220.003	large

PEDUS Locking X-Plate

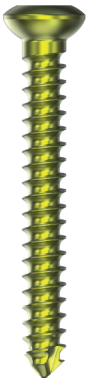
- Material: Ti6Al4V

Article number *	Holes	Diameter
12.11018.007	7	18 mm

PEDUS Locking Multifix Plate

- Material: Ti6Al4V

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



Cortical Screw Ø 2.7 mm, self-tapping

- Thread diameter: 2.7 mm
- Core diameter: 1.9 mm
- Head diameter: 5.0 mm
- Hexagone socket: 2.5 mm
- Material: Ti6Al4V

Article number *	Length
03.03527.008	8 mm
03.03527.010	10 mm
03.03527.012	12 mm
03.03527.014	14 mm
03.03527.016	16 mm
03.03527.018	18 mm
03.03527.020	20 mm
03.03527.022	22 mm
03.03527.024	24 mm
03.03527.026	26 mm
03.03527.028	28 mm
03.03527.030	30 mm
03.03527.032	32 mm
03.03527.034	34 mm
03.03527.036	36 mm
03.03527.038	38 mm
03.03527.040	40 mm

Locking Screw, Ø 3.0 mm

- Thread diameter: 3.0 mm
- Core diameter: 1.9 mm
- Head diameter: 4.75 mm
- Hexagone socket: 2.5 mm
- Material: Ti6Al4V

Article number *	Length
10.03530.008	8 mm
10.03530.010	10 mm
10.03530.012	12 mm
10.03530.014	14 mm
10.03530.016	16 mm
10.03530.018	18 mm
10.03530.020	20 mm
10.03530.022	22 mm
10.03530.024	24 mm
10.03530.026	26 mm
10.03530.028	28 mm
10.03530.030	30 mm
10.03530.032	32 mm
10.03530.034	34 mm
10.03530.036	36 mm
10.03530.038	38 mm
10.03530.040	40 mm

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

Article number *	Length
03.03540.008	8 mm
03.03540.010	10 mm
03.03540.012	12 mm
03.03540.014	14 mm
03.03540.016	16 mm
03.03540.018	18 mm
03.03540.020	20 mm
03.03540.022	22 mm
03.03540.024	24 mm
03.03540.026	26 mm
03.03540.028	28 mm
03.03540.030	30 mm
03.03540.032	32 mm
03.03540.034	34 mm
03.03540.036	36 mm

Multiaxial Locking Screw, Ø 2.7 mm, self-tapping

- Thread diameter: 2.7 mm
- Core diameter: 1.9 mm
- Head diameter: 4.75 mm
- Hexagone socket: 2.5 mm
- Material: Ti6Al4V

Article number	Length
08.03644.020	20 mm
08.03644.022	22 mm
08.03644.024	24 mm
08.03644.026	26 mm
08.03644.028	28 mm
08.03644.030	30 mm
08.03644.032	32 mm
08.03644.034	34 mm
08.03644.036	36 mm
08.03644.038	38 mm
08.03644.040	40 mm
08.03644.042	42 mm
08.03644.044	44 mm
08.03644.046	46 mm
08.03644.048	48 mm
08.03644.050	50 mm

Cannulated Screw, Ø 4.0 mm, partial thread, self-tapping

- Thread diameter: 4.0 mm
- Core diameter: 2.6 mm
- Head diameter: 5.0 mm
- Hexagone socket: 2.5 mm
- Material: Ti6Al4V

Article number
03.91000.070

Washer Ø 7.0 mm, for screw diameters Ø 2.7 to 4.0 mm

- External diameter: 7.0 mm
- Material: Ti6Al4V

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

Instruments

11.90012.070 Kirschner wire, Ø 1.2 mm, trocar tip, L 70 mm, steel

11.90212.150 Kirschner wire, Ø 1.2 mm, threaded tip, L 150 mm, steel

11.90016.150 Kirschner wire, Ø 1.6 mm, trocar tip, L 150 mm, steel

08.20120.135 Cleaning wire, Ø 1.2 mm, L 200 mm

10.20010.020 Drill bit Ø 2.0 mm, 2-flute, AO coupling, L 112 / 82 mm

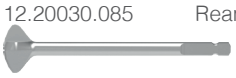
12.20010.027 Drill bit, Ø 2.7 / 1.35 mm, 4-flute, cannulated, scaled, AO Coupling, L 160 / 130 mm

08.20030.035 Countersink, cannulated, for cannulated screws, Ø 3.5 / 4.0 mm, AO Coupling

12.20030.040 Reamer for PEDUS-Lx Plates

12.20030.075 Reamer for arthrodesis, convex, small

12.20030.085 Reamer for arthrodesis, convex, medium

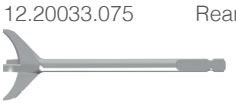


12.20031.075 Reamer for arthrodesis, convex, large

12.20032.075 Reamer for arthrodesis, concave, small

12.20032.085 Reamer for arthrodesis, concave, medium

12.20033.075 Reamer for arthrodesis, concave, large



02.20120.015 Screw forceps, self-holding

03.20040.026 Holding sleeve for screws, Ø 2.7 - 4.0 mm

03.20100.040 Length Determination Instrument, for Screws up to 40 mm

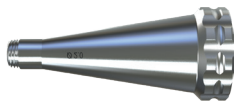
08.20100.035 Length Determination Instrument for Kirschner Wires Ø 1.2 mm x 150 mm

08.20060.027 Double Drill Guide 2.7 / 1.25

12.20060.017 Double Drill Guide 2.0 / 1.7

10.20060.047 Drill Guide 2.0, scaled for Locking Plates

10.20050.025 ML Drill Guide 2.0



03.20040.030 Screwdriver, hex 2.5 mm, ball handle, L 200 / 85 mm

08.20040.025 Screwdriver, hex 2.5 mm, cannulated, L 199 / 89 mm

12.21230.005/105 Milling Guide for PEDUS-Lx Plates 5°, right/left
12.21230.009/109 Milling Guide for PEDUS-Lx Plates 9°, right/left

12.20060.040 Guide Sleeve for Kirschner Wires Ø 1.2mm

Templates

PEDUS-MTP1, short

Article number	Flexion	Orientation
12.21250.203	0°	right
12.21250.303	0°	left
12.21258.203	8°	right
12.21258.303	8°	left

PEDUS-MTP1, 3 / 5 holes

Article number	Flexion	Orientation
12.21250.003	0°	right
12.21250.005	0°	right
12.21250.103	0°	left
12.21250.105	0°	left
12.21258.003	8°	right
12.21258.005	8°	right
12.21258.103	8°	left
12.21258.105	8°	left

PEDUS-L, Plantar Lapidus Plate

Article number	Holes	Length
12.21124.003	4	39 mm
12.21124.004	4	44 mm

PEDUS WS Plate, straight

Article number	Holes
12.21211.004	4

PEDUS WS T-Plate

Article number	Holes
12.21210.003	3

PEDUS WS L-Plate

Article number	Holes	Orientation
12.21212.003	3	90°, right
12.21212.103	3	90°, left

PEDUS WS X-Plate

Article number	Size
12.21220.002	small
12.21220.003	large

PEDUS WS Multifix Plate

Article number	Holes	Diameter
12.21018.007	7	18 mm

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 (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 **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.

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