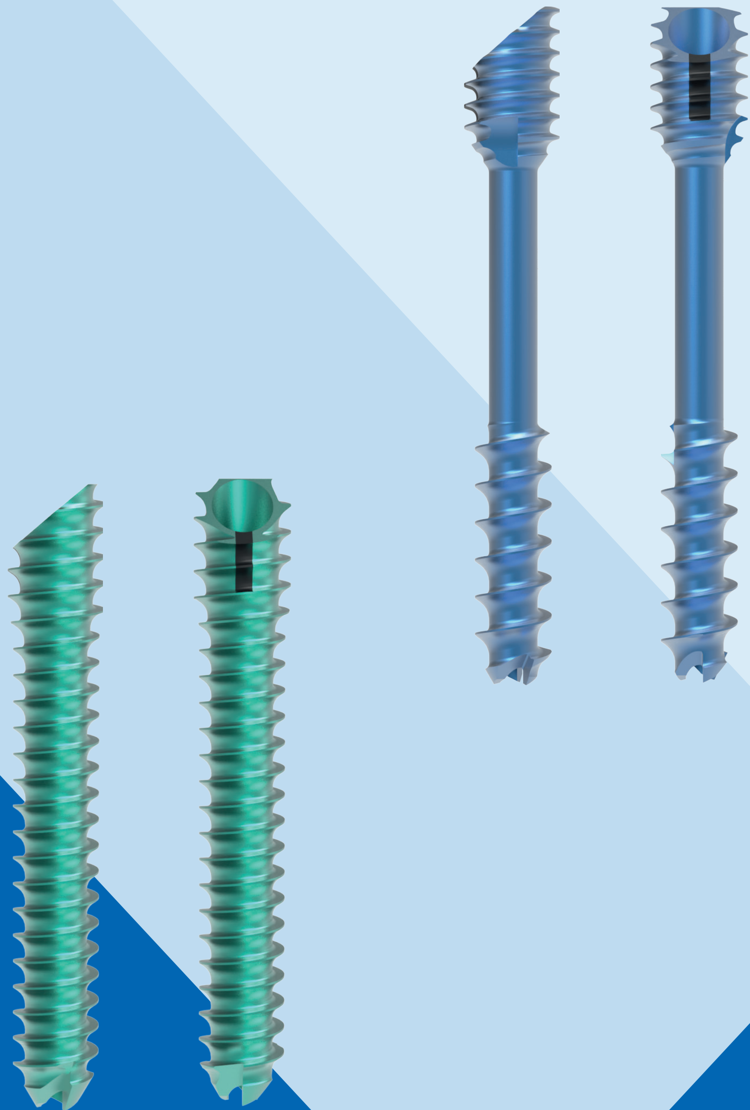

TWIN MIS & MIS
Screw System

Clinical Advisor

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Table of Contents

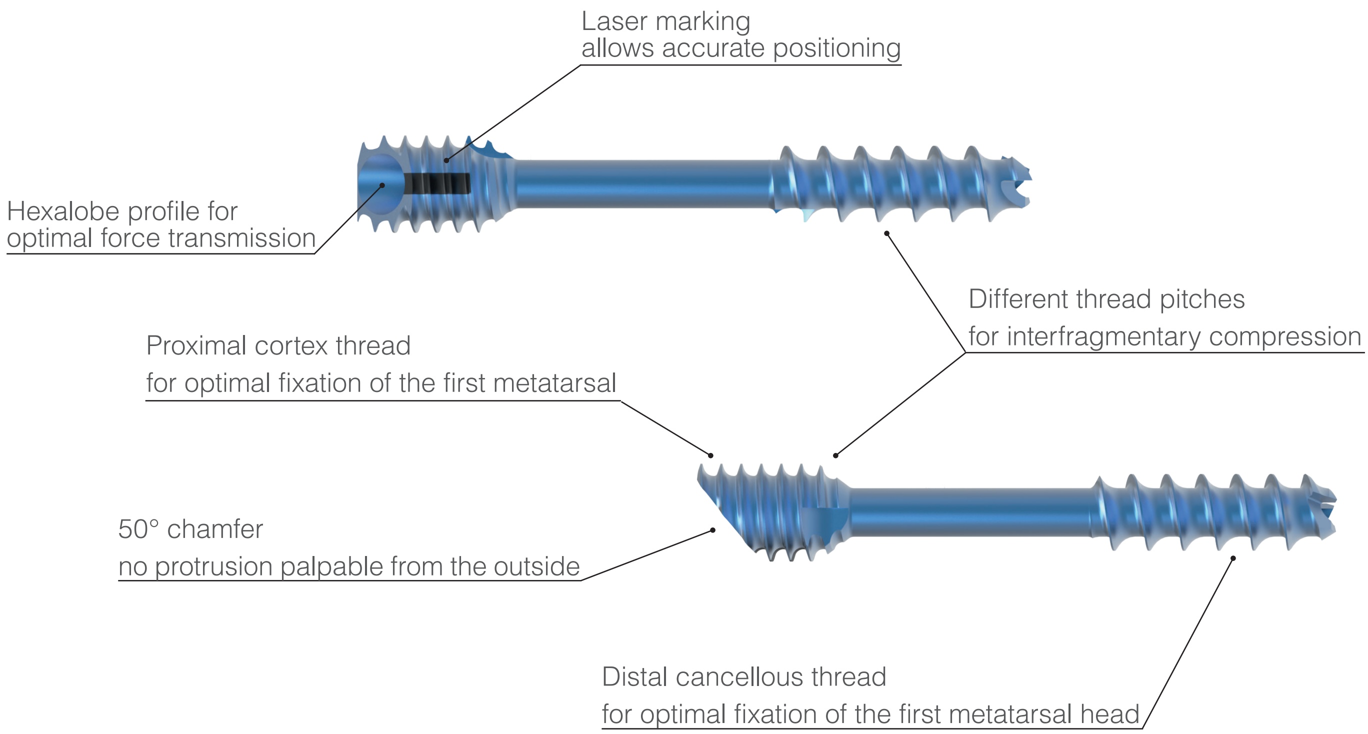
Note:

The surgical instructions outlined below reflect the surgical procedure usually chosen by the Clinical Advisor. However, each surgeon must decide individually which course of action offers the best prospect of success in the individual case.

Introduction - TWIN MIS

System Characteristics

- The design of the ***TWIN MIS Screw*** allows stable anchoring in the cortical bone, without any protrusion remaining that can be felt from outside.
- The screw has different thread pitches, as a result of which interfragmentary compression is produced during screw insertion.
- The hexalobe profile provides very good force transmission.



Indications

- Fixation of fractures, osteotomies and arthrodeses in the fore- and midfoot.
- In particular for hallux valgus correction osteotomies at the first metatarsal.

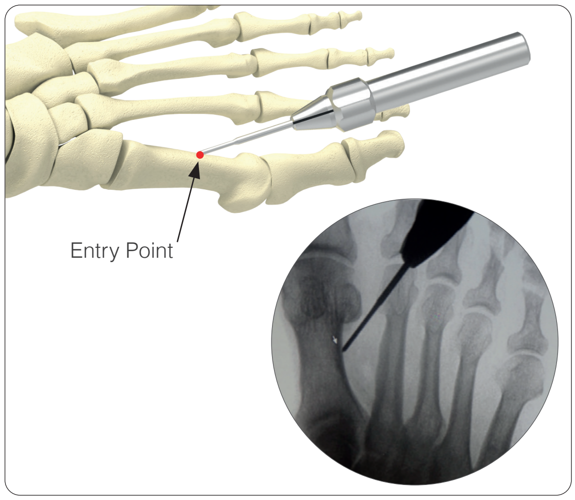
Surgical Technique - TWIN MIS

1. Access for Basal Closed Wedge Osteotomy

Instruments

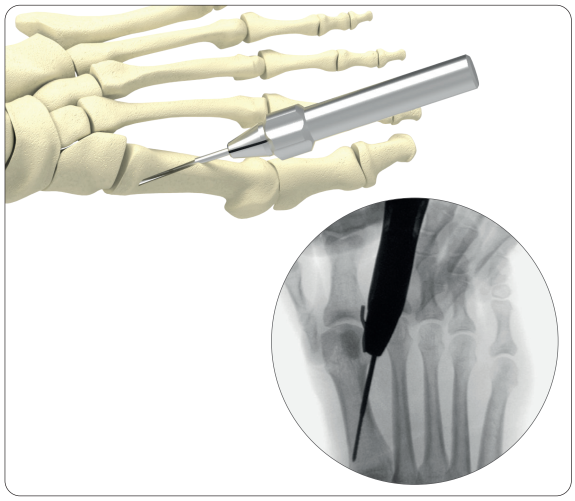
REF 12.20038.050S Shannon Reamer Recta Ø 2.0

- In the middle of the shaft in the first metatarsal space, make a small stab incision at the level of the sesamoid bones parallel to the course of the vessels and nerves.
- The reamer perforates the lateral metatarsal bone I in the middle region.
- Now place the first drill hole with a Shannon reamer. Here, the reamer is aimed at the medial base of the first metatarsal (Os metatarsale I). The medial cortex itself must not be weakened in the process.
- The position of the reamer is checked with the image intensifier.



2. Closed Wedge Osteotomy

- In dorsal osteotomy, care must be taken to ensure that no leverage forces are applied.
- The osteotomy is checked with the image intensifier.
- Performance of plantar osteotomy while monitoring with the image intensifier.
- Osteotomy takes place at an angle of approx. 10 degrees from dorsal lateral to plantar medial.
- This cutting geometry achieves plantarization of the metatarsal I head by approx. 2 mm.

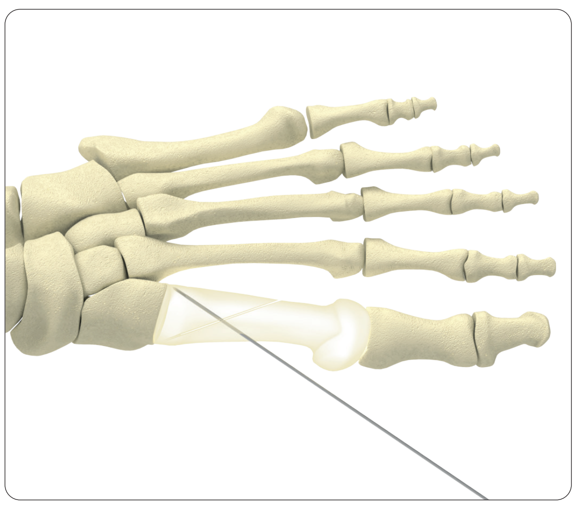


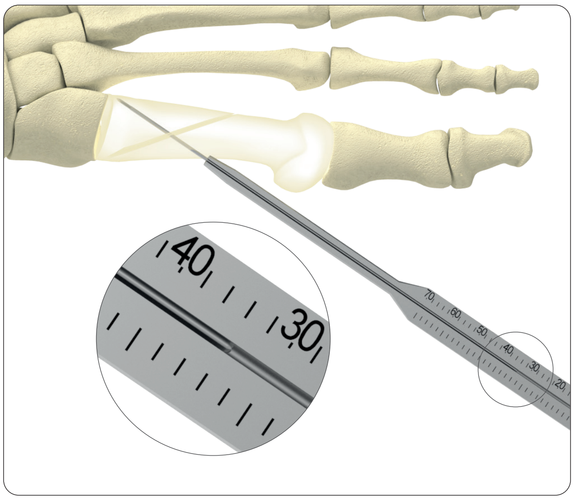
3. Setting the Kirschner Wire

Instruments

REF 11.90212.150 Kirschner Wire Ø 1.2 mm

- As the first step, the medial cortex is perforated at the desired entry point of the screw using the Shannon reamer roughly in the direction of the planned screw trajectory.
- The Kirschner wire is inserted through the drill hole, so that the wire tip is positioned towards the lateral base of the first metatarsal (Os metatarsale I).
- The quality of bone is high in the region of the lateral, plantar base of the first metatarsal, which improves the stability of the screws.

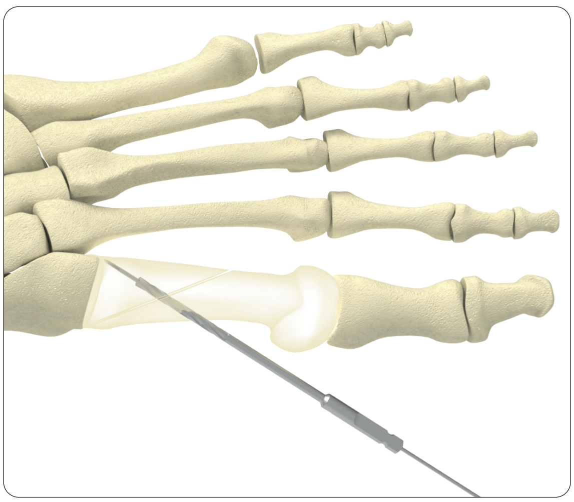




Instruments

REF 12.20100.070 *Length Determination Device for Kirschner Wires*

- The required screw length is determined using the length determination device for K-wires.
- The end of the K-wire indicates the length of the required screw.
- If the measured value is between two available screw lengths, the shorter option should be selected to avoid protrusion of the screw into the metatarsophalangeal joint or beyond the level of the medial cortex of the proximal metatarsal bone.
- Check the length and position of the screw under radiological control and make corrections if necessary.



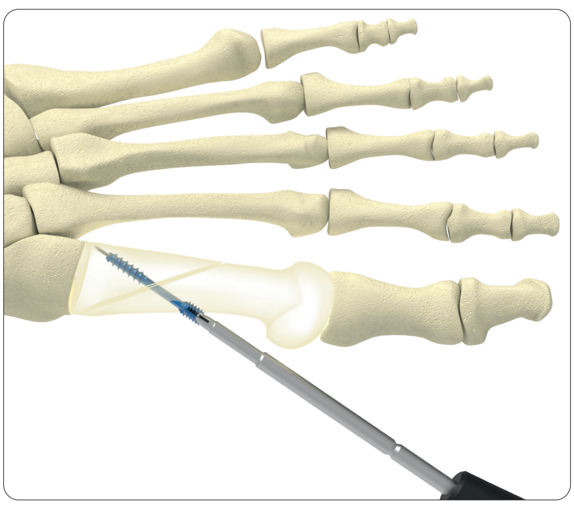
Instruments

REF 08.20010.027(S) *Drill Bit Ø 2.7 mm*

- The medial cortical bone is drilled through using the drill bit via the K-wire.

Note:

The self-drilling and self-tapping screw allows stable anchoring of the Os metatarsal I without drilling the lateral cortical bone.



4. Insertion of the Screws

Instruments

REF 08.20040.011 *Screwdriver T10*

- The screw is placed onto the cannulated, self-retaining hexalobe T10 screwdriver (as previously described).
- The screw is screwed in via the kirschner wire, while the forefoot is compressed to close the osteotomy.
- The position of the screw is checked using the image intensifier; attention should also be paid here to the position of the head and to ensure level countersinking at bone level.

Note:

A second screw can be used to improve osteosynthesis and to increase rotational stability.

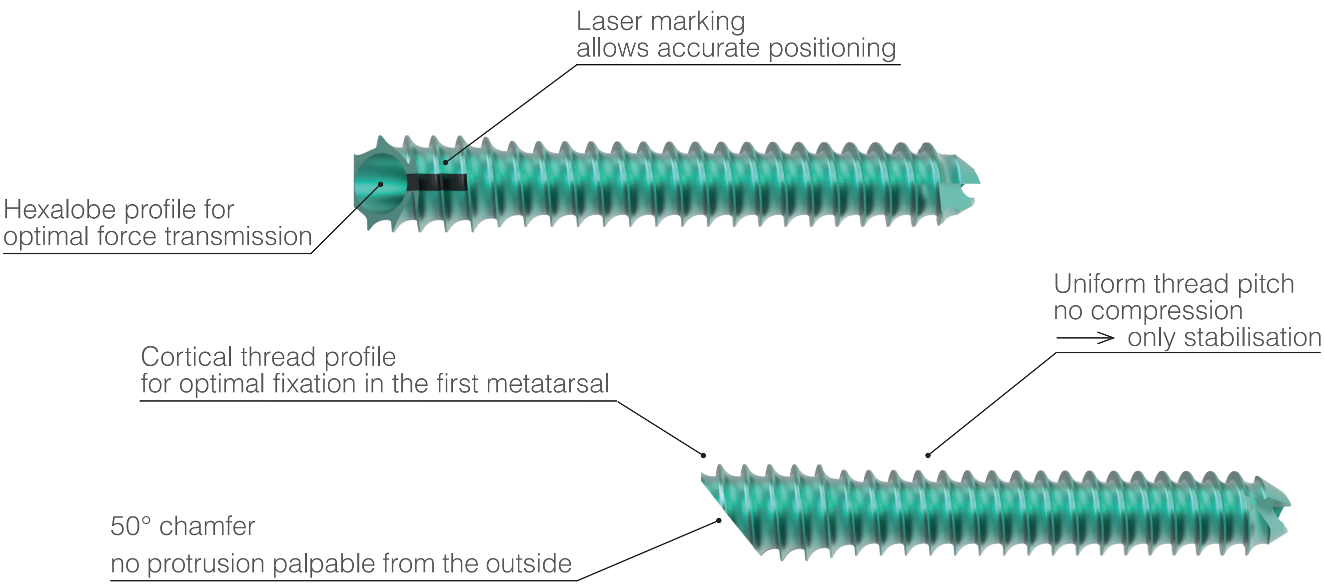
Introduction - MIS

Basics of the MIS Screw

- By shifting of the first metatarsal head by almost 100% of the shaft width of the first metatarsal, minimally invasive Chevron osteotomy allows correction of significantly higher intermetatarsal angles than traditional open chevron osteotomy does. (Redfern and Perera, 2014)
- In minimally invasive Chevron osteotomy, via a stab incision at the proximal end of the pseudoexostosis an extra-articular V osteotomy of the first metatarsal is performed, and subsequently the osteotomy is stabilised by means of a percutaneous screw. (Redfern et al., 2015)

System Characteristics

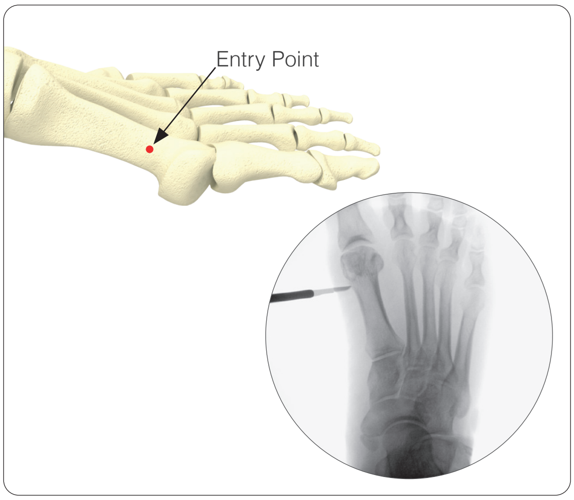
- The design of the ***MIS Screw*** allows stable anchoring in the cortical bone, without any protrusion remaining that can be felt from outside.
- The screw has a uniform thread pitch, whereby upon insertion no interfragmentary compression, but exclusive stabilisation is produced.
- The hexalobe profile provides very good force transmission.



Indications

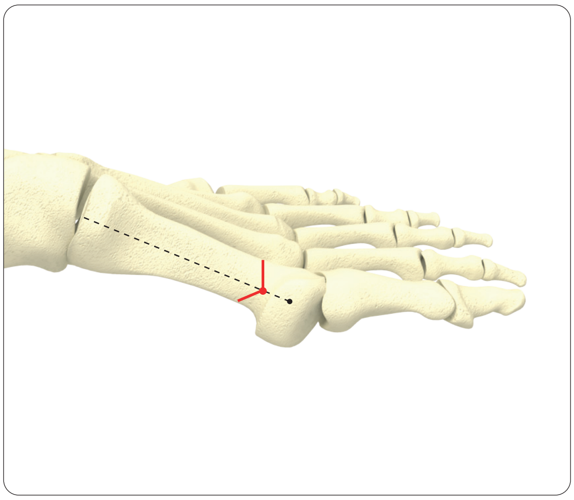
- Fixation of fractures, osteotomies and arthrodeses in the fore- and midfoot.
- In particular for hallux valgus correction osteotomies at the first metatarsal.

Surgical Technique - MIS



1. Access for Chevron Osteotomy

- The entry point for the Chevron osteotomy is located on the metaphyseal-diaphyseal junction, proximally to the exostosis.
- Using the beaver knife, a 3 mm incision is made in the course of the metatarsal axis.
- The incision is located at the transition from the middle to the dorsal third of the shaft.
- The dorsal periosteum is pushed off with a mini-elevator.
- As the collateral ligaments are required during the course of the surgery for control of the metatarsal head, primarily **no** lateral release is performed.



2. Chevron Osteotomy

Instruments

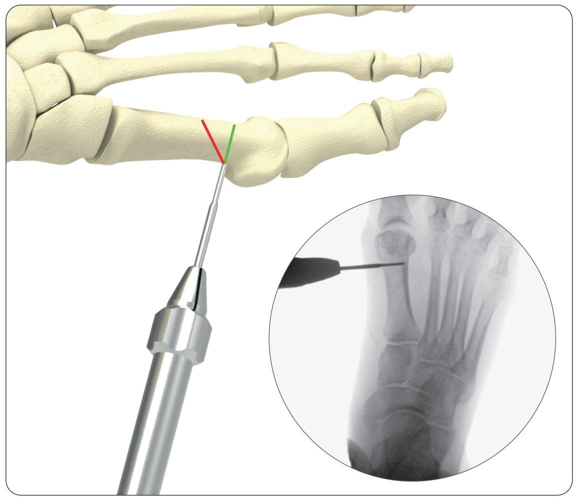
REF 12.20038.050S Shannon Reamer Recta Ø 2.0

- The entry point of the reamer is located, as described above, on the metatarsal axis proximally of the exostosis, and is checked with the image intensifier.
- The osteotomy is performed extracapsularly.
- The soft tissue is pushed off with a small periosteal elevator.
- The reamer is advanced into the bone with continuous cooling.
- By slight oscillating movements the reamer can be prevented from getting stuck in the bone.
- First, the dorsal leg of the Chevron osteotomy is reamed.
- The reaming is carried out by wrist action, and here the pivot point of the reamer is the skin portal.
- Subsequently, the plantar leg of the Chevron osteotomy is reamed.
- The reamer is first brought back to the starting position.
- The pivot point of the reamer is in the plane of the portal.
- For the tricortical osteosynthesis, an intact lateral cortex of the metatarsal is necessary.
- A short plantar leg is necessary, since a long leg might result in the area for the possible screw passage point being too small, rendering, under certain circumstances, stable osteosynthesis impossible.

Note:
To prevent tissue damage, no soft tissue should be pressed against the reamer while it is running.

3. Choosing the Osteotomy Plane

- The osteotomy plane determines whether the metatarsal will be extended (green line), shortened (red line), shifted plantar or shifted dorsal.
- The Shannon reamer leads to a bone loss of approximately 2.0 mm.
- By orientation of the reamer by 10° plantar and 10° distal, the bone loss from the translation of the metatarsal head can be compensated.
- If extension is desired, tilting of more than 10° distal relative to the shaft axis is necessary.
- If the metatarsal head is to shifted plantar, the reamer must be tilted plantar by more than 10° in the transverse plane.
- A long plantar leg should be avoided.

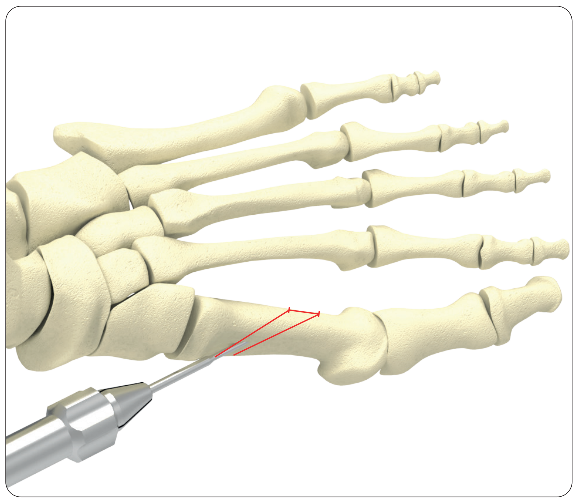


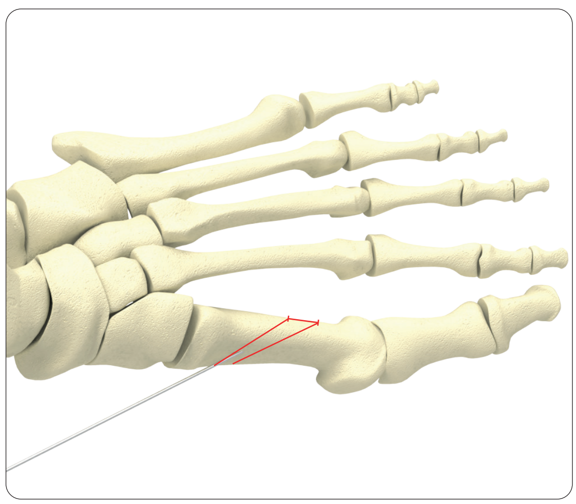
4. Setting the First Kirschner Wire

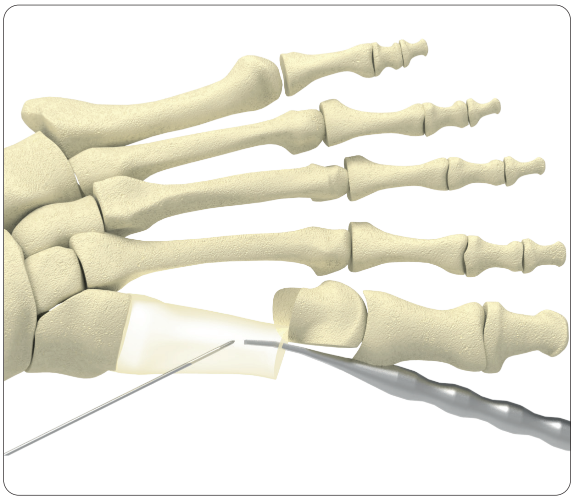
Instruments

REF 11.90212.150 *Kirschner Wire Ø 1.2 mm*
REF 12.20038.050S *Shannon Reamer Recta Ø 2.0*

- Using the Shannon reamer, the medial cortical bone is perforated at the desired entry point of the screw (about 1 cm distally of the tarsometatarsal joint) approximately in the direction of the planned course of the K-wire.
- Through the 2.0 mm hole, the K-wire can be accurately positioned under image intensifier control in both planes.
- In lateral view, the K-wire must run along the shaft axis of the first metatarsal.
- The exit point of the K-wire from the lateral cortical bone should be located about 5 mm proximally from the osteotomy to avoid breaking out of the screw from the lateral cortex.







5. Displacement of the Metatarsal Head

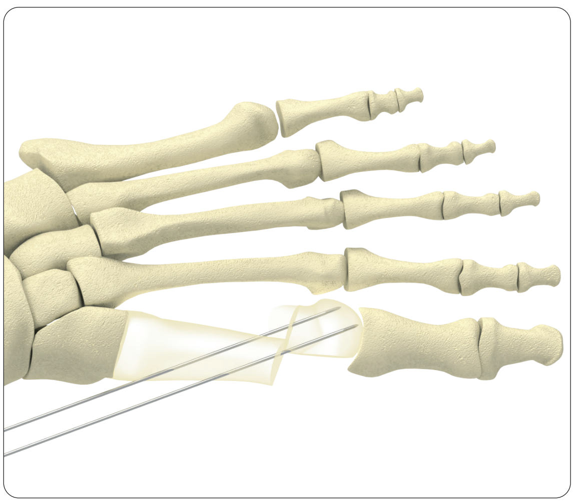
Instruments

REF 12.20080.010 MIS Chisel, straight

- With a chisel inserted by stab incision into the proximal metatarsal, the metatarsal head can be leveraged lateral.
- Alternatively, a Hohmann retractor or K-wire can be used.
- The varus or valgus tilting of the metatarsal head is controlled via the proximal phalanx. If the lateral ligaments are intact, the articular surface angle can be adjusted precisely by varus stress of the hallux.

Note:

When shifting lateral, attention must be paid to the precise plane. Avoid shifting dorsal and excessively plantar.



6. Fixation of the Metatarsal

Instruments

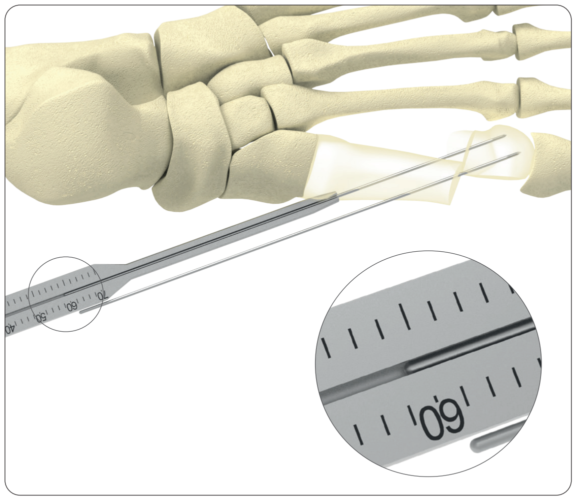
REF 11.90212.150 Kirschner Wire Ø 1.2 mm

- After achieving the desired correction, the metatarsal head is fixed by advancing the K-wire (see illustration above).
- In case of displacement of the metatarsal head by more than 50%, the proximal screw should be inserted bicortically.
- The articular surface angle can be controlled via the position of the big toe. If the articular surface angle is tilted laterally, the metatarsal head can be tilted to a physiological position by varying the size of the big toe.
- Bicortical fixation in the proximal metatarsal allows very high primary stability even in case of strong displacement.
- Subsequently, about 1 cm distally, parallel to the first K-wire, the second K-wire is inserted (see illustration below).
- Check position of the two K-wires in two planes with the image intensifier.

MARQUARDT Medizintechnik

Instruments

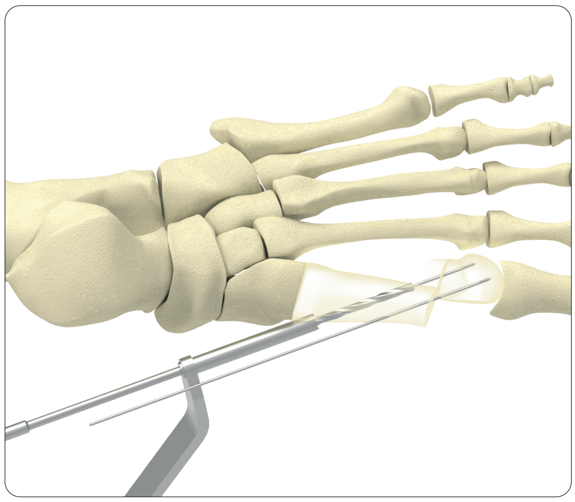
REF 12.20100.070 Length Determination *Device for Kirschner Wires*



- The required screw length is determined using the length determination device for the K-wire.
- The end of the K-wire indicates the length of the required screw.
- If the measured value is between two available screw lengths, the shorter option should be selected to avoid protrusion of the screw into the metatarsophalangeal joint or beyond the level of the medial cortex of the proximal metatarsal bone.
- Check the length and position of the screw under radiological control and make corrections if necessary.

Instruments

REF 08.20010.032(S) *Drill Bit Ø 3.2 mm*
REF 08.20060.132 *Double Drill Guide 3.2 / 1.2*



- The screw hole is pre-drilled using the drill bit via the K-wire, through the double drill guide.

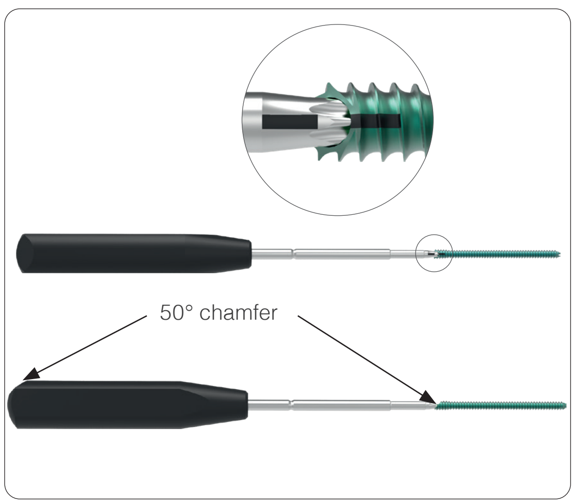
Note:

- It is recommended to restrict the drilling to the cortical portions of the proximal fragment only.
- This method avoids loosening of the K-wire during drilling.
- The self-drilling and self-tapping screw tip ensures very stable anchoring of the thread in the cancellous bone upon entry into the metatarsal head.

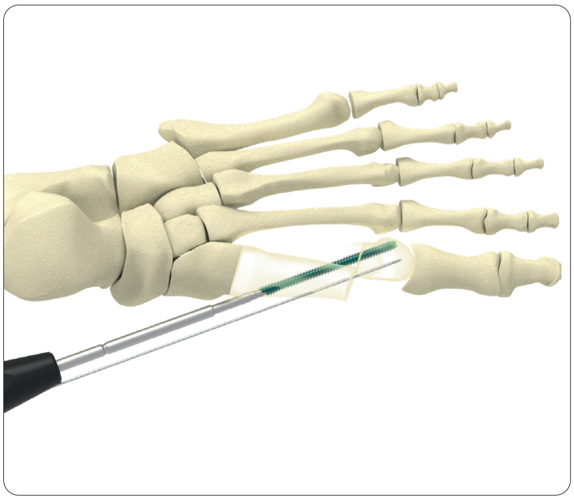
7. Insertion of the Screws

Instruments

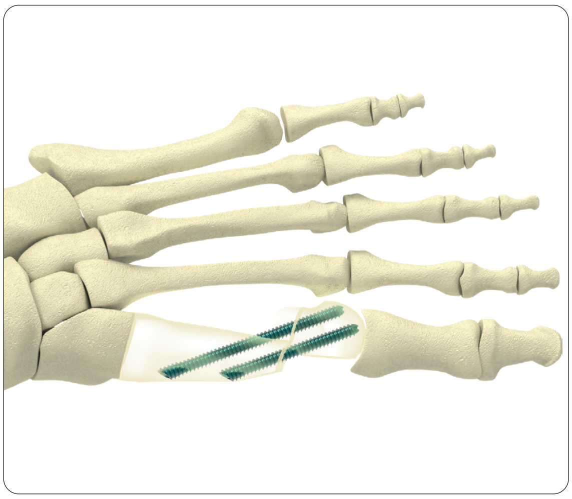
REF 08.20040.011 *Screwdriver T10*



- The screw is placed onto the cannulated, self-retaining hexalobe T10 screwdriver.
- Make sure that the laser markings of the screwdriver tip and the screw match.
- Then the bevel of the screw head matches the handle surface of the screwdriver, and later it is possible to position the screw head so that the bevel is precisely flush with the medial cortical bone.



- The screw is screwed in via the K-wire; due to the slightly larger diameter of the screw head, the screw achieves high strength during the screwing in of the last thread pitches.
- The position of the screw is checked using the image converter; here attention should be paid to the position of the head and a flat countersinking at the bone level as well.
- In case of strong lateral displacement, the proximal, lateral screw extends through the medial and lateral cortex of the metatarsal before engaging in the metatarsal head.
- This bicortical anchoring in the proximal metatarsal bone results in very stable fixation of the screw.
- With a shift of more than 50% shaft width, the rotation stability is secured by a second screw.



8. Lateral Release

- Check for tension-free abduction of the hallux. If tension-free abduction is already possible, no additional lateral release is necessary.
- If the hallux cannot be positioned in 20° abduction, the knife is introduced through a stab incision laterally of the extensor hallucis longus tendon into the joint space under image intensification.
- Subsequently, using the inside-out technique the metatarsosesamoidal ligament, the insertion of the M. adductor hallucis obliquus et transversus and the lateral capsule can be notched or transected.
- In very contracted situations, additionally weakening of the lateral head of the m. flexor hallucis brevis is possible.
- Complete transection of this tendon insertion should be avoided.
- In the case of a strong displacement, the medial protrusion of the proximal Os metatarsal is removed with the reamer. This can be done in inside-out technique. Approx 3 mm distal to the distal screws, a reamer is drilled into the bone and the protrution is milled off. In most cases, it is sufficient to press the mobile bone fragment to the osteotomy, so that no disturbing edge is palpable. Alternatively, disruptive bone fragments can be recovered with a clamp.
- Finally, a radiological assessment is to be performed.

Note:
The procedure can be combined with a minimally invasive Akin osteotomy, as required.

Postoperative Protocol

- Radiographic controls (forefoot in two planes) postoperatively and possibly after two weeks, in both cases without loading.
- Bandage shoe (with pain-adapted heel loading) and restorative dressing for 6 weeks.
- Postoperative elevation and decongestant measures for the first two weeks after surgery.
- Full loading (walking) in comfortable off-the-shelf shoe after the sixth postoperative week.
- Due to the strong displacement, after six weeks the osseous remodelling is still ongoing. Radiography usually shows constant findings after six months.
- Postoperative treatment depends on individual factors such as bone quality, age and compliance of the patient. Due to these factors, the healing process may deviate from the times mentioned above, which serve only for preliminary guidance.

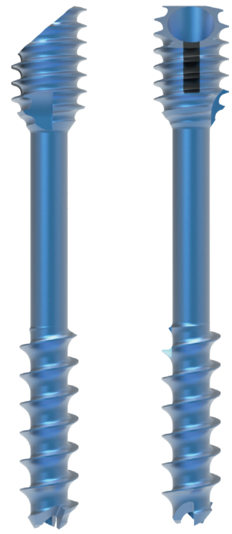
Product Informations

Implants

TWIN MIS Ø 3.5 / 4.5 mm

- Thread diameter: 3.5 / 4.5 mm
- Pitch: 1.75 / 1.0 mm
- Cannulation: 1.3 mm
- Hexalobe: T10
- Drill bit: Ø 2.7 mm
- Material: Ti6Al4V

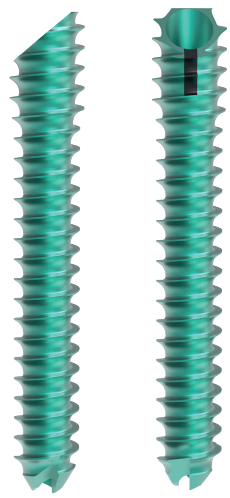
Article Number	Length
12.03835.026S	26 mm
12.03835.028S	28 mm
12.03835.030S	30 mm
12.03835.032S	32 mm
12.03835.034S	34 mm
12.03835.036S	36 mm
12.03835.038S	38 mm
12.03835.040S	40 mm
12.03835.042S	42 mm
12.03835.044S	44 mm
12.03835.046S	46 mm



MIS Screw Ø 4.0 mm

- Thread diameter: 4.0 mm
- Cannulation: 1.4 mm
- Hexalobe: T10
- Drill bit: Ø 3.2 mm
- Material: Ti6Al4V

Article Number	Length
08.03700.026S	26 mm
08.03700.028S	28 mm
08.03700.030S	30 mm
08.03700.032S	32 mm
08.03700.034S	34 mm
08.03700.036S	36 mm
08.03700.038S	38 mm
08.03700.040S	40 mm
08.03700.042S	42 mm
08.03700.044S	44 mm
08.03700.046S	46 mm
08.03700.048S	48 mm
08.03700.050S	50 mm
08.03700.052S	52 mm
08.03700.054S	54 mm
08.03700.056S	56 mm
08.03700.058S	58 mm
08.03700.060S	60 mm
08.03700.062S	62 mm
08.03700.064S	64 mm



TWIN MIS & MIS Screw

Instruments

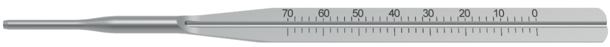
11.90212.150 Kirschner Wire Ø 1.2 mm,
threaded tip, L 150 mm, stainless steel

08.20010.032(S) Drill Bit Ø 3.2 mm/1.85 mm, 4-flute,
cannulated, AO Coupling, L 170/140 mm

08.20010.027(S) Drill Bit Ø 2.7 mm/1.35 mm, 4-flute,
cannulated, AO Coupling, L 160/130 mm

08.20120.135 Cleaning Wire Ø 1.2 mm, L 200 mm

12.20100.070 Length Determination Device for Kirschner
Wires Ø 1.2 / 1.6 mm x 150 mm



08.20040.011 Screwdriver, T10, cannulated, L 199/89 mm

08.20060.132 Double Drill Guide 3.2/1.2

12.20080.010 MIS Chisel, straight, width 3 mm

12.20080.015 MIS Chisel, curved, width 3 mm

12.20080.020 Periosteal Elevator, straight, width 3/5 mm

12.20080.025 Periosteal Elevator, curved, width 4/4 mm

12.20080.030 Handle for Scalpel

12.20038.030S Wedge Reamer Ø 2.9 mm,
L 13 mm, sterile
Gesamtlänge: 65 mm

12.20038.040S Wedge Reamer Ø 4.3 mm,
L 13 mm, sterile
Gesamtlänge: 65 mm

12.20038.050S Shannon Reamer Recta Ø 2.0 mm,
L 13 mm, sterile
Gesamtlänge: 65 mm

12.20038.060S Shannon Reamer Recta Larga Ø 2.2 mm,
L 22 mm, sterile
Gesamtlänge: 75 mm

12.20038.070S Shannon Reamer Corta Ø 2.0 mm,
L 8 mm, sterile
Gesamtlänge: 65 mm

12.20038.080S Shannon Reamer Corta Ø 2.0 mm,
L 8 mm, sterile
Gesamtlänge: 65 mm

12.20038.090S Shannon Reamer Recta Larga Ø 3.1 mm,
L 20 mm, sterile
Gesamtlänge: 70 mm

12.20038.100S Shannon Reamer Recta X-Larga Ø 3.0 mm,
L 30 mm, sterile
Gesamtlänge: 100 mm

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: 10.06.2024 • 12.99100.502 • Rev.: 012/00

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