SURGICAL TECHNIQUE GUIDE

EN

AGO MED

FOREFOOT & REARFOOT SYSTEMS

Made in Germany

INNOVATIVE MEDICAL TECHNOLOGY

EN *Working with AGOMED means working with a company committed to excellence. Our products are German engineered, biocompatible, and cutting-edge. Our team members collectively bring decades of medical technology experience to the table.*

We're reliable. We're flexible. We're inventive.

AGOMED collaborates with distributors, hospitals, and doctors worldwide to create and develop exacting, state-of-the-art solutions. We work closely with specialists to insure that our implants for trauma and extremities improve the patient's quality of life.

Patient safety is always our number one priority.

DE *Mit AGOMED zu arbeiten, bedeutet mit einem Unternehmen zu arbeiten, dass sich zur Exzellenz und Hochleistung verpflichtet.*

Unsere Produkte werden von deutschen Ingenieuren entwickelt, sind biokompatibel, innovativ und auf dem neuesten Stand der Technik. Unser Team hat jahrzehntelange Erfahrung im Bereich der Medizintechnik.

Wir sind zuverlässig. Wir sind flexibel. Wir sind innovativ.

AGOMED arbeitet weltweit mit Unternehmen, Krankenhäusern und Ärzten zusammen, um anspruchsvolle, hochmoderne Lösungen zu entwickeln. Wir arbeiten eng mit Spezialisten zusammen, um sicherzustellen, dass unsere Implantate für Traumatologie und Extremitäten die Lebensqualität der Patienten verbessern.

Die Sicherheit der Patienten steht bei uns immer an erster Stelle.

ES *Trabajar con AGOMED significa trabajar con una empresa comprometida con la excelencia. Nuestros productos son diseñados en Alemania, biocompatibles y de vanguardia. Los miembros de nuestro equipo aportan, de manera colectiva, décadas de experiencia en tecnología médica.*

Somos fiables. Somos flexibles. Somos innovadores.

AGOMED colabora con distribuidores, hospitales y doctores a nivel mundial con el objetivo de crear y desarrollar soluciones rigurosas y con lo último de la tecnología. Cooperamos estrechamente con especialistas para garantizar que nuestros implantes para trauma y extremidades mejoren la calidad de vida de los pacientes.

La seguridad de los pacientes siempre es nuestra prioridad.

QUALITY IS PART OF OUR DNA

DIN EN ISO 13485

CE CERTIFICATE

EN AGOMED MEANS QUALITY. WE EXCEED ISO 13485 STANDARDS AND HAVE CE CERTIFICATION.

DE AGOMED BEDEUTET QUALITÄT. WIR SIND ZERTIFIZIERT NACH ISO 13485 UND HABEN DIE CE ZERTIFIZIERUNG

ES *AGOMED ES SINÓNIMO DE CALIDAD. SUPERAMOS LOS ESTÁNDARES ISO 13485 Y CONTAMOS CON CERTIFICACIÓN CE.*

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FOREFOOT 2.7 SYSTEM

METATARSOPHALANGEAL FUSION SURGICAL PROCEDURE

The Metatarsophalangeal (MTP) Plate is indicated for hallux valgus associated with osteoarthritis. Fusion can be beneficial for bunion patients with rheumatoid arthritis. The MTP plates are available in both left and right sides of four sizes and are anatomically contoured with an integrated 8° of valgus correction and configured for challenging forefoot procedures. The plates feature an internal dynamic screw position for use with the Compression Distraction Device and accept 2.7 locking and non locking screws. The low profiled, soft tissue friendly design of the plates allows for placement of a 3.5 mm cannulated compression screw across the resection site ensuring good compression.

SAMPLE INDICATION:

- *1st MTP Arthrodesis*

The same procedure is done for the Universal plate

SAMPLE INDICATIONS:

- *Open-Wedge and Crescentic*
- *Revisions of non-unions*
- *Base osteotomies*
- *Lisfranc fusions*
- *Closed-Wedge*
- *MTPJ fusion*

EXPOSURE AND JOINT PREPARATION

- *Access to the 1st MTP joint and to the osteotomy site is typically through a dorsal longitudinal or dorso-medial approach, according to surgeon preference. The incision is started and deepened medial to the EHL tendon (retracted laterally) and the joint capsule collateral ligaments released to expose the base of the proximal phalanx and metatarsal head.*

METATARSAL PREPARATION

- *The phalanx is displaced plantarly to expose the metatarsal head.Using a powered drill insert a 1.6mm K-Wire centrally through the metatarsal head and into the diaphysis.*
- *Run the Metatarsal concave reamer over the guide wire and employ a Cup and Cone device, clearing bone debris frequently, and until bleeding subchondral bone becomes visible on the joint surface.*

Tip: *Run the drill at low RPM, clearing debris frequently and with irrigation to prevent thermal necrosis.*

Tip: *Start with the largest concave reamer and if necessary, move progressively down through the reamer sizes until the correct radius removes the entire surface of articular cartilage, and take note of the final reamer size used.*

- *The phalanx is prepared in a similar fashion by plantar-flexing the phalanx and inserting a 1.6mm K-Wire into the centre of the articular cartilage and driving through in the diaphysis.*

Tip: *Start with the smallest convex reamer and move progressively up through the reamer sizes until the corresponding size used on the metatarsal is reached. The metatarsal and phalangeal sides of the joint will then be fully conforming. Proceed with caution, taking care to protect the metatarsal head.*

PLATE SELECTION AND POSITIONING

- *The valgus transition and resection indication line on the MTP plate can be used to identify the valgus transition point and ideal joint resection and should be used as a tool in establishing the ideal plate position.*

- *The matching surface of the joint should be aligned in the desired position. Rotate the position as necessary and match the valgus angle.*

Tip: *Proper positioning can be evaluated with the placing of support against the plantar surface of the foot.*

COMPRESSION & DISTRACTION

- *Perform drilling according to the selected preferred screw size in the most proximal dynamic standard screw position.*

PROXIMAL SCREW INSERTION

Tip: *Plate benders can be used to bend the plate if determined necessary.*

PLATES SHOULD ONLY BE BENT IN ONE DIRECTION AND NEVER RE-BENT.

Tip: *Using the appropriate drill, penetrate the near cortex and continue drilling until the far cortex is reached. Take care to stop drilling immediately the far cortex is breached.*

- *After determining length with the depth gauge, insert the appropriate screw. Inserting the non locking screw first will help to seat the plate flush on the bone surface.*
- *Advance the screw flush to the plate but do not lock the screw down. The non locking screw in the dynamic slot allows for movement of the plate during final compression.*

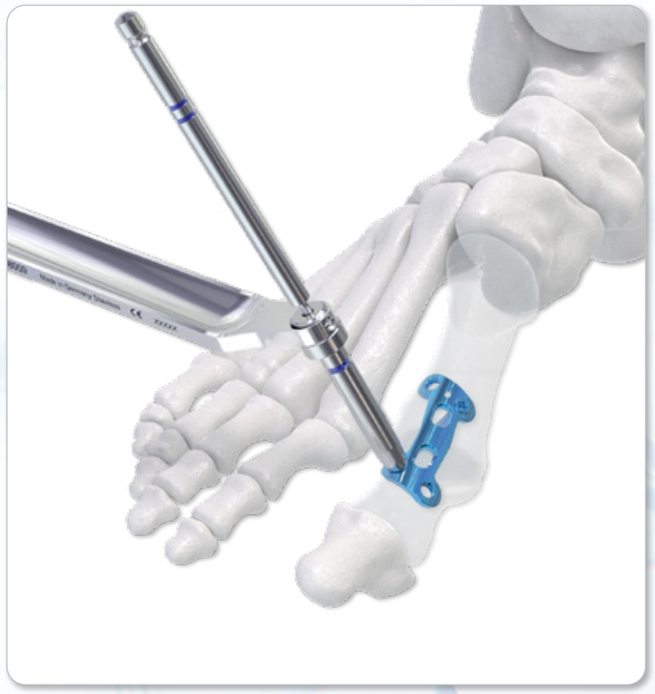
Tip: *All plate screw holes accept 2.7 (blue) locking or non locking screws.*

DISTAL SCREW INSERTION

- *Perform drilling of the proximal screw holes through the appropriate drill guide for the screws selected.*

Tip: *Using the appropriate drill, penetrate the near cortex and continue drilling until the far cortex is reached. Take care to stop drilling immediately the far cortex is breached.*

- *The drill guide will have ensured the correct trajectory of the screw drill hole, and the screw should be advanced to a position where the head is flush with the plate and locked.*



- *With the distal screw locked down, ensure adequate compression is applied through the CDD and lock down the non locking screw.*

Tip: *When completing final screw positions, all screws used on axis (locking screws) should sit with the head flush to the outer plate profile.*

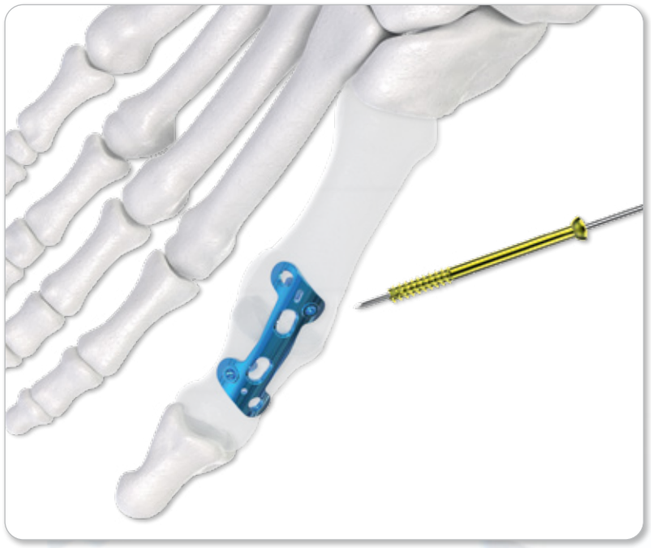
STABILISING THE FUSION CONSTRUCT

- *To stabilise the fusion construct, remove the Compression Distraction Device and temporary fixation pins and use the technique previously described to place locking and / or non locking screws through all remaining screw positions within the plate. 2.7mm screws are generally recommended for fixation of the MTP plate.*

Tip: *When completing final screw positions, all screws used on axis (locking screws) should sit with the head flush to the outer plate profile.*

ACROSS JOINT COMPRESSION

- *The Forefoot Plating System includes a 3.5mm cannulated compression screw which can be used to provide additional, across joint, mechanical compression and stabilisation.*
- *Screw trajectory is determined by inserting a K-Wire, medially mid height of the metatarsal head, distally out of the lateral side of the phalanx.*



- *The required length of the 3.5mm cannulated compression screw is established using the depth gauge provided. Advance the screw so the head is flush and taking care not to fracture the cortex. The construct provides the stability of plate fixation and screw compression across the joint with a lag effect.*

TITANIUM MP-JOINT FUSION PLATE

1.6 mm

4001080
5 - holes 28 mm,
small size

4001081
6 - holes 35 mm,
10° valgus angle,
medium size

4001082
6 - holes 45 mm,
10° valgus angle,
large size

TITANIUM UNIVERSAL PLATE

1.3 mm

4001016
10 mm

4001017
12 mm

4001018
14 mm

4001019
16 mm

4001020
18 mm

4001021
20 mm

4001022
22 mm

4001023
24 mm

4001024
30 mm

TITANIUM SCREWS 2.7

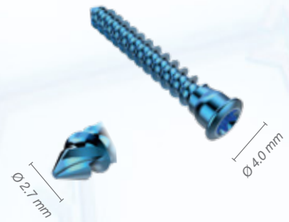
Length

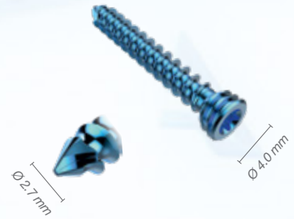
Standard, TX 8

Threaded head, TX 8

L	*∅ 2.7 mm*	*∅ 2.7 mm*	*Pack*
8 mm	***5001108***	***5001008***	***5***
10 mm	***5001110***	***5001010***	***5***
12 mm	***5001112***	***5001012***	***5***
14 mm	***5001114***	***5001014***	***5***
16 mm	***5001116***	***5001016***	***5***
18 mm	***5001118***	***5001018***	***5***
20 mm	***5001120***	***5001020***	***5***
22 mm	***5001122***	***5001022***	***5***
24 mm	***5001124***	***5001024***	***5***
26 mm	***5001126***	***5001026***	***5***
28 mm	***5001128***	***5001028***	***5***
30 mm	***5001130***	***5001030***	***5***

Drill-ø 2.0 mm





PLANTAR LAPIDUS PLATE SURGICAL PROCEDURE

SAMPLE INDICATIONS:

- *Long metatarsal I /elevation due to Hallux valgus or Hallux limitus*
- *Arthrosis in the metatarso cuneiform I joint*
- *Substep of the correction of Pes adductus*
- *Diabetic foot with instable medial column*
- *Correction of relapsed Hallux valgus*
- *HALLUX VALGUS correction*
- *Lapidus arthrodesis*
- *Rheumatoid foot*

RECOMMENDED USE

- *Hallux valgus correction in combination with*
  - *Hypermobility of the first ray to the forefoot flat*
  - *Subluxation in the metatarso cuneiform I joint*
- *Arthrosis in the metatarso cuneiform I joint*
- *Long metatarsal I*
- *Correction of relapsed Hallux valgus*
- *Rheumatoid foot*
- *Diabetic foot with instable medial column*
- *Substep of the correction of Pes adductus*
- *Elevation due to Hallux valgus or Hallux limitus*

Patient Positioning

- *Patient positioning per surgeon's technique and preference.*

Osteotomies / Bone Tissue Preparation

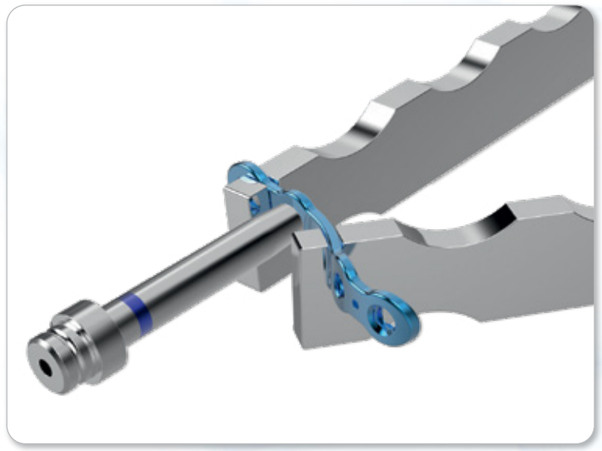
- *Joint preparation: Decorticate involved joint surfaces completely by means of appropriate burrs, curettes and osteotomes (e.g. AGOMED Charcot chisel or special osteotomes for joint surface preparation) until the subchondral bone surface is fully exposed on each side.*
- *Only use appropriate saw blades designed for small bone surgery.*

HANDLING OF INSTRUMENTS / IMPLANTS

Handling of Implants

1002527

- *Use the provided forceps as to remove plates and screws from the tray.*
- *Implants that have been removed from the tray intraoperatively, but were not used in situ, need to be cleaned separately with a validated procedure before being put back into the tray. Afterwards they can be sterilized.*



Modelling of Locking Plates

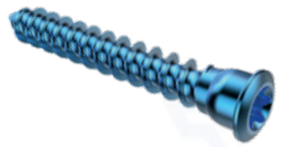
- *Bending: If considered necessary, the bending instruments provided (e.g. plate bending forceps or pliers) may be used to accomplish necessary plate adjustments in order to fit the specific patient anatomy. The plate shaft can be bent up to an angle of 8°.*
- **Warning:** *The dedicated thread function of the screw holes may suffer functional reduction or may become inoperative, if located in the bended area(s).*

Tip for maintaining the thread function of screw holes: *Prior to bending a near locking thread, it is important to mount the drill guide for protection of the locking threads within the plate.*

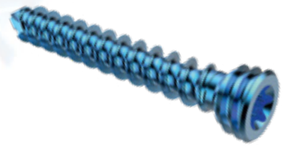
Selection of Screws

- *There are different screw options for the plate fixation:*

Threaded screw holes:

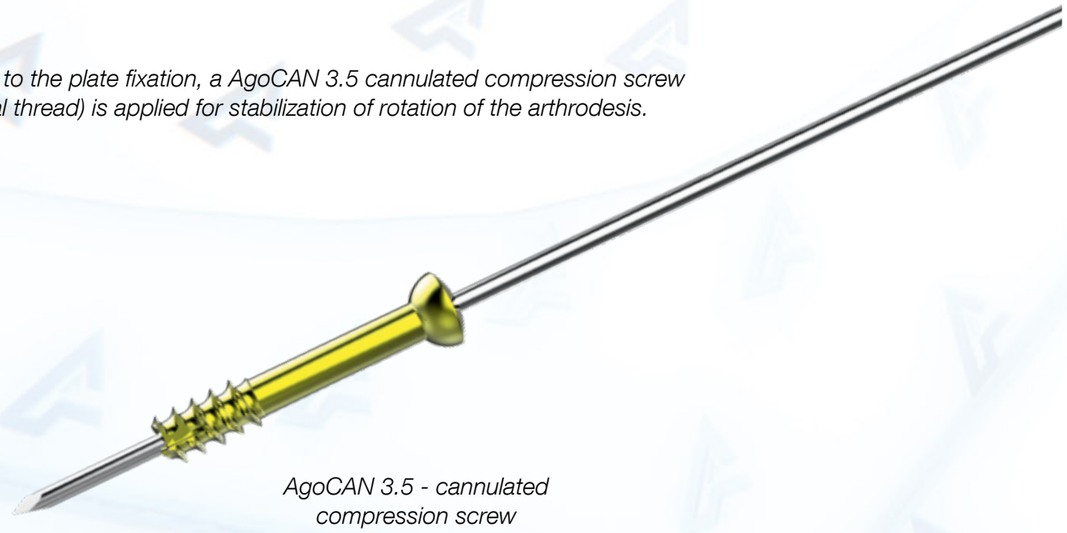


Standard screw 2.7



Locking screw 2.7

- *In addition to the plate fixation, a AgoCAN 3.5 cannulated compression screw (with partial thread) is applied for stabilization of rotation of the arthrodesis.*



AgoCAN 3.5 - cannulated compression screw

Tip: *Cannulated screws should always be inserted over K-Wire (0.9 mm)! We recommend to predrill over K-Wire with a cannulated drill (2.5 mm).*

Drilling

- **Locking Screw Technique:** *During drilling the threaded screw holes must not be damaged! The drill guides, part of the system, must be used to avoid damages of the threads and to ensure the correct drill direction for locking screws. The drill bit is to be led through the drill guide's canal.*
- **Standard Screw Technique:** *The drill bit may be led through the threaded screw holes without a drill guide. However, the drill bit may suffer high wear during the procedure. Also the threads of the plate may suffer.*
- **ATTENTION:** *Avoid thermal necrosis using appropriate irrigation.*

Tip: *The drill guides can be used as tissue protectors to a certain degree.*

Tip: *When drilling through plates and drill guides ensure correct guiding (along longitudinal axis) of the drill and the drilling machine! Even slight canting causes premature wear and may result in metal abrasion.*

Depth Measurement

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- *To measure the length of the screw use the depth gauge which should be positioned on the plate hole.*
- *Its probe is to be forwarded into the pre-drilled intramedullary canal.*
- *If the drill hole reaches through the cortical bone on the opposite site, pull back the measuring gauge until the tip of the gauge catches the bone crest.*
- *Determine the appropriate screw length directly from the scale on the gauge. The reading on the scale is to be understood as the length of the whole screw.*

Warning: *If the drill hole does not reach trough the cortical bone on the opposite site, 1 mm is to be deducted from the read result.*

Screw Application

1001022

1001008

1004036

- *Only the appropriate instruments must be used to manipulate and handle the screws. AO system screw-drivers as well as screwdriver handles are provided.Manipulating the screws with inappropriate instruments may result in damage of the threads. The screws may become unusable. Damaged screws must no longer be used and be replaced.*

- *Attach the screwdriver blade to the handle by pulling the coupling piece backwards while introducing the blade into the shaft. Once the blade reaches the end of the shaft, release the coupling piece to lock the blade in the handle. Ensure the proper mounting of all components prior to passing the instrument to the surgeon.*

- **Warning:** *The screwdriver blade has to be removed from the screwdriver handle before the instruments are passed on to sterilization.*

Tip: *For removing the screws from the tray, the screwdriver blade needs to be pushed firmly in vertical direction into the screw head in order to achieve a good grip of the screw.*

Wound Closure and Dressing; Post-op positioning

- *The incision is closed per the surgeon's preferred technique. Sterile wound dressing and post-op positioning are carried out according to the surgeon's instruction.*

PLANTAR LAPIDUS TITANIUM PLATE

4001056
3 mm

4001057
5 mm

4001058
8 mm

TITANIUM SCREWS

Length | Standard, TX 8 | Threaded head, TX 8

L	∅ 2.7 mm	∅ 2.7 mm	Pack
8 mm	*5001108*	*5001008*	*5*
10 mm	*5001110*	*5001010*	*5*
12 mm	*5001112*	*5001012*	*5*
14 mm	*5001114*	*5001014*	*5*
16 mm	*5001116*	*5001016*	*5*
18 mm	*5001118*	*5001018*	*5*
20 mm	*5001120*	*5001020*	*5*
22 mm	*5001122*	*5001022*	*5*
24 mm	*5001124*	*5001024*	*5*
26 mm	*5001126*	*5001026*	*5*
28 mm	*5001128*	*5001028*	*5*
30 mm	*5001130*	*5001030*	*5*

Length | Partial thread /

L	∅ 3.5 mm	Pack
28 mm	*5008028*	*1*
30 mm	*5008030*	*1*
32 mm	*5008032*	*1*
34 mm	*5008034*	*1*
36 mm	*5008036*	*1*
38 mm	*5008038*	*1*
40 mm	*5008040*	*1*

REARFOOT 3.5 SYSTEM

ARROW PLATING SYSTEM SURGICAL PROCEDURE

Agomed recognizes that proper surgical procedures and techniquesare responsibilities of medical professionals.

The following guidelines are provided for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on their medical training, experience and condition ofthe patient. Before using the system, the surgeon must consult the operating instructions for additional warnings, precautions, indications, contraindications and adverse effects.

SAMPLE INDICATIONS:

- *Opening wedge osteotomy Os cuneiforme (Cotton osteotomy)*
- *Revision of pseudo arthrosis with splinter / wedge plastic*
- *Charcot stabilization from Metatarso I to Os naviculare*
- *Revision of the base osteotomy of the Metatarsal I*
- *Charcot reconstruction of the medial column*
- *Stabilization of the lateral column*
- *Revision of the Lapidus arthrodesis*
- *Stabilization of the medial column*
- *Arthrodesis of the medial column*
- *Multiple arthrodesis*
- *Lapidus arthrodesis*
- *Lisfranc stabilizatio*
- *Lapidus revision*
- *Charcot foot*

Locking Plate System, anatomical to the medial arch of the foot, developed for rearfoot surgery

- *Anatomical plate system to the medial arch of the foot, with Offset screw holes that allows maximum stability and earlier load bearing.*
- *Arrow Plate System can be associated to the 3.5 mm Cannulated Screw, Fully Threaded.*
- *Thickness 1.5mm and 2.0mm.*

- *After choosing the appropriate plate, it can be moulded better fit patient's anatomy.*

Note: *Avoid excessive modeling of the plate as this can compromise its locking mechanisms. When using plate benders, holes adjacent to the bender can lose the ability to lock. If this occurs, a Cortical Screw must be used.*

- *Properly place the Threaded Drill Guide (1008036) by turning it into the threaded hole, then proceed with drilling using the Drill Bit.*
- *The reading of the screw measure can be acquired by using the Depth Gauge.*

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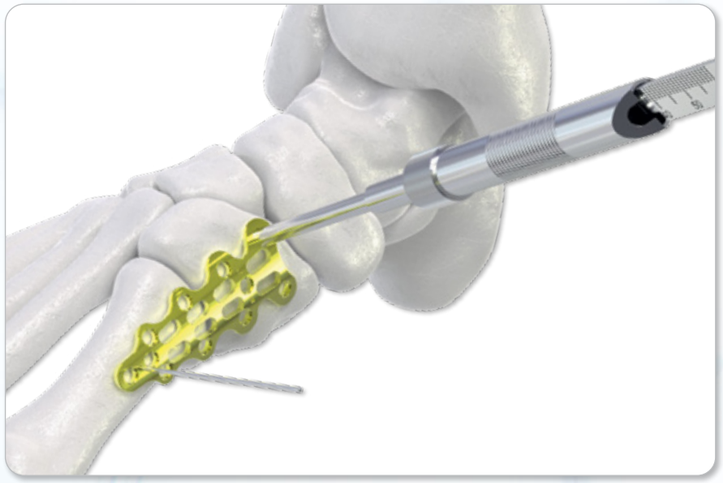
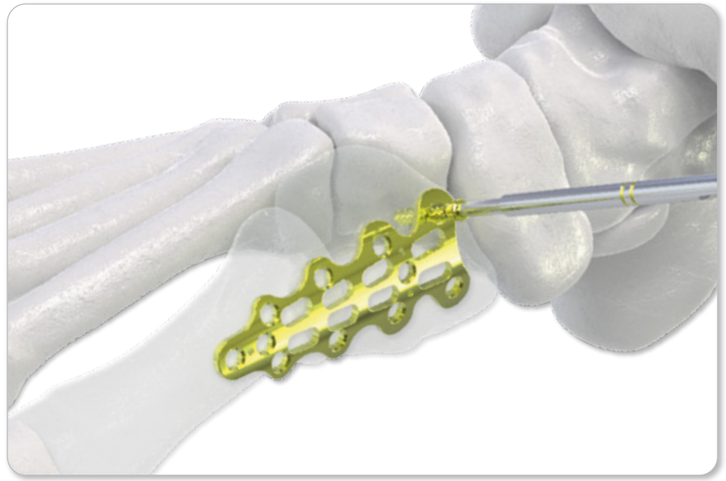
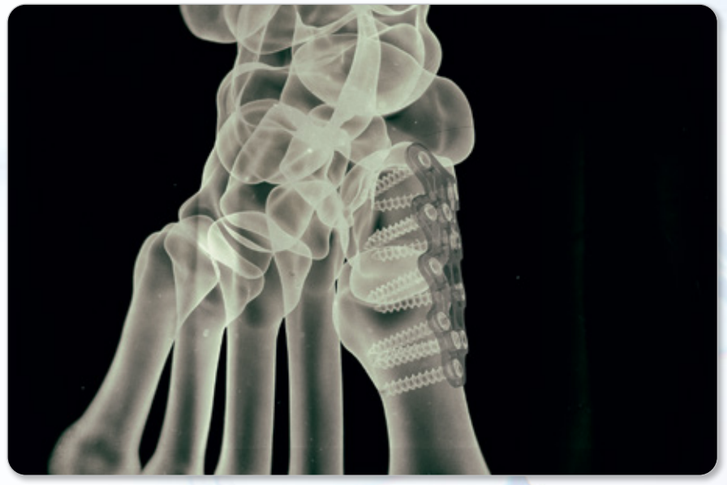


- *Use the Handle and Shaft Screwdriver to position the screws.*



- *The placement of the screws procedure is repeated as many times as necessary, for optimal fixation of the plate.*
- *Check the final position of the screws through the image intensifier.*
- *Remove and dispose of the Kirschner Wire.*

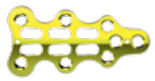
- *Proceed with X-ray to check if final position is according to initial intention.*



ARROW TITANIUM PLATE

1.5 mm

4001106
1,5 mm, size XS,
pack/1



4001107
1,5 mm, size S,
pack/1

2.0 mm

4001108
2,0 mm, size M,
pack/1

4001109
2,0 mm, size L,
pack/1

LEFT 2.0 mm

4001110
2,0 mm, size L,
pack/1

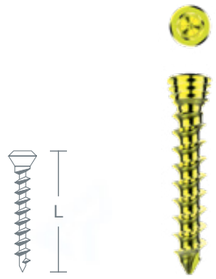
4001112
2,0 mm, size XL,
pack/1

RIGHT 2.0 mm

4001111
2,0 mm, size L,
pack/1

4001113
2.0 mm, size XL,
pack/1

TITANIUM SCREWS

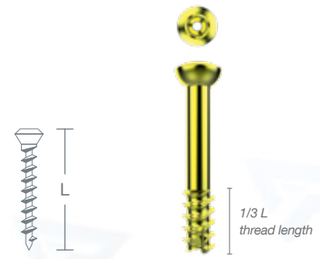


Length

Threaded head

Standard

L	*∅ 3.5 mm*	*∅ 3.5 mm*	*Pack*
8 mm	***5002008***	***5002108***	***5***
10 mm	***5002010***	***5002110***	***5***
12 mm	***5002012***	***5002112***	***5***
14 mm	***5002014***	***5002114***	***5***
16 mm	***5002016***	***5002116***	***5***
18 mm	***5002018***	***5002118***	***5***
20 mm	***5002020***	***5002120***	***5***
22 mm	***5002022***	***5002122***	***5***
24 mm	***5002024***	***5002124***	***5***
26 mm	***5002026***	***5002126***	***5***
28 mm	***5002028***	***5002128***	***5***
30 mm	***5002030***	***5002130***	***5***
32 mm	***5002032***	***5002132***	***5***
34 mm	***5002034***	***5002134***	***5***
35 mm	***5002035***	***5002135***	***5***
36 mm	***5002036***	***5002136***	***5***
38 mm	***5002038***	***5002138***	***5***
40 mm	***5002040***	***5002140***	***5***



Length

Partial thread /

L	*∅ 3.5 mm*	*Pack*
34 mm	***5008034***	***1***
36 mm	***5008036***	***1***
38 mm	***5008038***	***1***
40 mm	***5008040***	***1***
45 mm	***5008045***	***1***
50 mm	***5008050***	***1***

MALLEOLAR PLATING SYSTEM SURGICAL PROCEDURE

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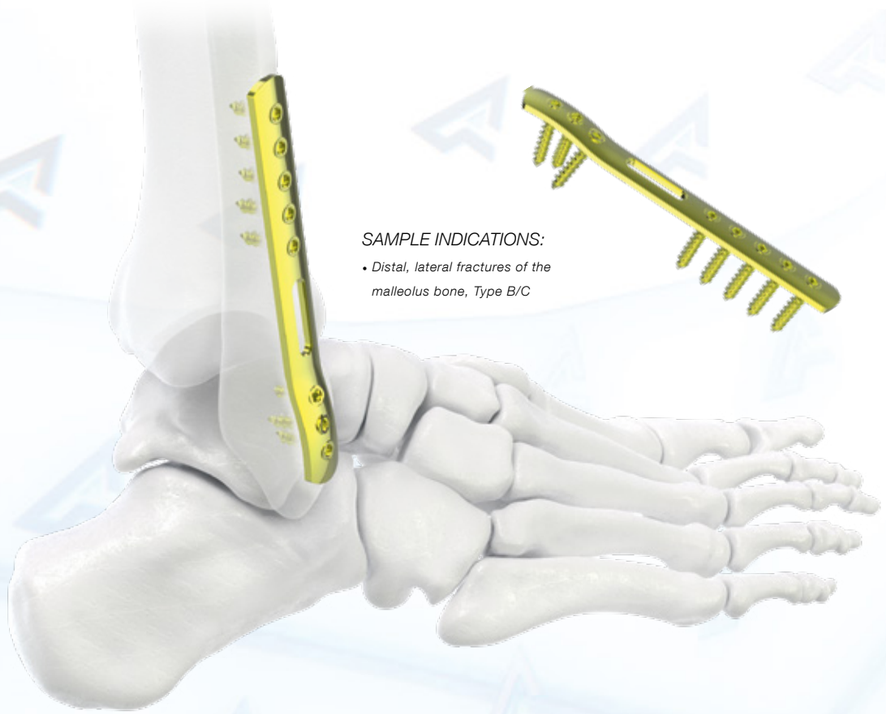

SAMPLE INDICATIONS:

- *Distal, lateral fractures of the malleolus bone, Type B/C*

- *Malleolus Plate System consists in distal / lateral plates with 5, 6, 8 and 10 holes, which can be fixed by Locking Screws and / or Cortical Screws.*
- *Malleolus Plate System is recommended for distal and lateral fractures of malleolus bone and can be associated to the Ø 3.5mm Cannulated Screws, Partly and Fully Threaded.*

- *After choosing the appropriate plate, position it cover the fracture and fix provisionally with a Cortical Screw, using the appropriated Drill Bit for drilling.*

- *The screw measure can be obtained by reading on the Depth Gauge.*

- *Use the Handle and Shaft Screwdriver to position the screws.*

LOCKING SCREWS POSITIONING

- *Properly place the Threaded Drill Guide (1008036) by turning into the threaded hole, then proceed with drilling using the Drill Bit.*

- *The reading of the screw measure can be acquired by using the Depth Gauge.*

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- *Use the Handle and Shaft Screwdriver to position the screws.*

- *The placement of the screws procedure is repeated as many times as necessary, for optimal fixation of the plate.*
- ***Fixed angle technique (Locking Screws):** During the drilling process, the hole in the plates cannot be damaged. This drilling process must be perpendicular to the plate by using the appropriate Drill Guide. The Drill Bit must be conducted through the drilling guide canal.*
- ***Variable angle technique (Cotical Screws):** The Drill Bit must be conducted through the holes of the plates without a drill guide.*
- *Proceed with X-ray to check if final position is according to initial intention.*

MALLEOLAR TITANIUM PLATE

1.9 mm

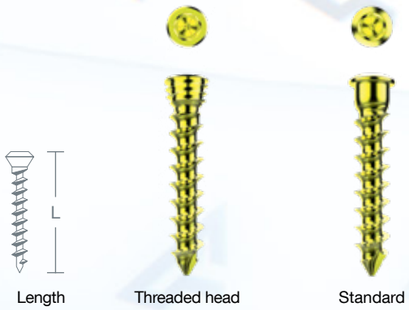
4001171
5-holes

4001172
6-holes

4001173
8-holes

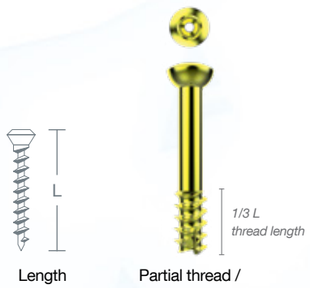
4001174
10-holes

TITANIUM SCREWS



Length | Threaded head | Standard

L	∅ 3.5 mm	∅ 3.5 mm	Pack
8 mm	***5002008***	***5002108***	***5***
10 mm	***5002010***	***5002110***	***5***
12 mm	***5002012***	***5002112***	***5***
14 mm	***5002014***	***5002114***	***5***
16 mm	***5002016***	***5002116***	***5***
18 mm	***5002018***	***5002118***	***5***
20 mm	***5002020***	***5002120***	***5***



Length | Partial thread /

L	∅ 3.5 mm	Pack
18 mm	***5008018***	***1***
20 mm	***5008020***	***1***
22 mm	***5008022***	***1***
24 mm	***5008024***	***1***
36 mm	***5008036***	***1***
40 mm	***5008040***	***1***

NOTES

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