merete®

MetaFix™ PlantarMAX™

Locking Plantar Lapidus
Surgical Technique and Ordering Information

This surgical technique applies only to the U.S.

FootFamily
Merete® Foot & Ankle Solutions

merete®

Caution
Federal law restricts this device to sale by or on the order of a physician.

Caution
The following product descriptions contain detailed information on the recommended procedure (and associated surgical techniques) for Merete® implants and instruments. Training in the correct handling of implants and instruments is only to be executed by an authorized Merete representative.

Table of Contents

1. Description

Merete GmbH has designed a special Plantar/Medial Lapidus plate to take advantage of the tension side of the TMT (Tarsometatarsal) joint during a Lapidus Hallux Valgus correction procedure. The tension side of the joint offers the most biomechanically superior fixation as cited in the literature. The MetaFix™ PlantarMAX™ Lapidus Plate is designed with 2 plantar locking screws, an interfragmentary screw placed through the plate and 2 medial locking or non locking screws for additional fixation. There are specially designed bending locations in the plate to allow the plate to be formed to meet the specific anatomy. The goal of the lapidus procedure is to correct and stabilize the first metatarsal at the apex of the hallux valgus deformity.

1.1. Intended Purpose / Use

***Warning:* Use of implants contrary to intended purpose. Risk of injury due to implant failure! Implants must only be used in accordance with intended purpose.**

The Merete Locking Bone Plate System III can be used for adult and pediatric patients. Indications for use include fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, and toes.

1.3. Contraindications

- Osteoarthritis
- Primary chronical Polyarthritis
- Osteoporotic bone

1.4. MRI Safety Information

The Merete® Locking Bone Plate Systems, MetaFix™ LS Locking Screws, Merete® Cannulated PCS, Merete® CS Cortical Screws, Merete® Cannulated HCS, TwistCut™ Snap-Off and Mecron® Cannulated Screws have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the plates and screws in the MR environment is unknown. Scanning a patient who has these plates/screws may result in patient injury.

Warning: Examination of patient using MRI

Risk of injury due to alternating magnetic fields! Merete Technologies, Inc. does not authorize the use of MRI examinations in conjunction with the components described in these user instructions. Always perform an individual risk-benefit analysis. Check whether other imaging procedures can be used to achieve the desired diagnostic goal.

2. General Information

Warning: **Use of damaged or defective instruments/ implants. Risk of injury due to premature implant failure! Instruments/ implants with identifiable damage may not be used. Avoid notches, scratches or bending of the instrument/ implant in order to preserve its stability.**

Warning: **Use of implant/instrument contrary to intended purpose. Damage to/destruction of instrument/ implant and injury to patient! Ensure correct handling of implant/instrument. Do not misuse.**

Warning: **Use of implants which have been previously used. Risk of injury due to premature implant fracture! Risk of Sepsis! Implants are only approved for single use, not reuse use.**

Warning: **Risk of infection due to non-sterile implants! Do not use implants whose packaging is damaged. Do not use implants beyond their expiration date.**

Warning: **Use of contaminated implants. Risk of Sepsis! Use only implants without visible contamination. Handle implants only with sterile surgical gloves.**

Warning: **Resterilization of implants. Risk of injury due to premature implant fracture caused by adverse material changes! Implants delivered sterile by Merete Technologies, Inc. must not be resterilized and/or repackaged. Products whose expiry date has passed may be returned to Merete Technologies, Inc.**

Warning: **Combination with products from other manufacturers. Risk of injury due to implant failure! Implants may not be combined with components from other manufacturers.**

Warning: **Use of instruments with electrical energy. Risk of injury due to implant failure! Do not damage the surfaces of the implants under any circumstances.**

Warning: **Use of contaminated instruments. Risk of Sepsis! Use only instruments without visible contamination. Handle instruments only with sterile surgical gloves.**

Warning: **Bending to adjust. Risk of injury due to implant failure! Do not overbend the implant. Do not bend implants repeatedly as it weakens the implant material. Do not bend above the threaded holes. Unsing unsuitable instruments can lead to implant failure.**

Warning: **Foreign bodies (e.g., tissue, bones) between implant components. Risk of injury due to implant failure! Thoroughly clean any foreign bodies from implant components.**

Warning: **Combination of implant components of different sizes. Damage to implant components! Combine only components of the same size.**

Warning: **Improper use of an implant/instrument. Damage to/destruction of instrument/implant and injury to patient! Ensure correct implant/instrument handling. Do not misuse. Ensure to use the instruments belonging to the implant.**

NOTE
Sterilization of instruments/implants supplied non-sterile. If Merete products are sterilized by the user, this must be noted in the surgical report. All relevant labels and user instructions must be retained. Observe the standard preparation instructions provided.

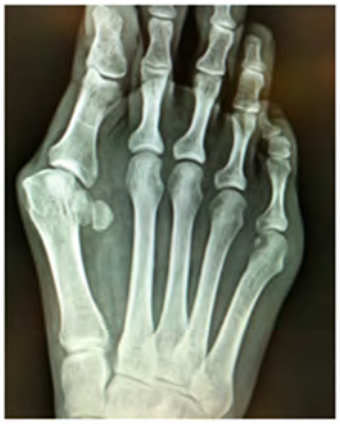
NOTE
Non-sterile screws, whose color cannot be clearly identified must not be used.

NOTE
Observe symbol on packaging: "Do not reuse".

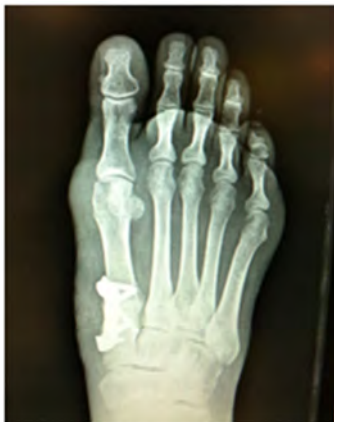
3. Surgical Technique

3. Surgical Technique

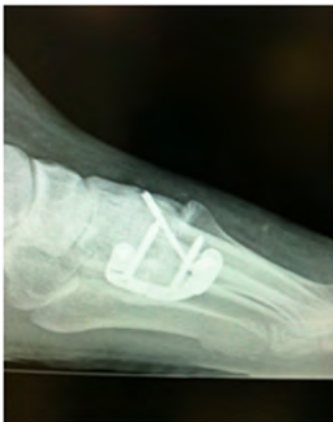
The surgical technique presented here only serves as an example to illustrate the basic procedure during implantation. Merete the manufacturer of these medical products, does not stipulate that this or any other treatment method is to be used for any specific patient. Selecting appropriate operational techniques for a particular patient is the responsibility of the operating physician. Merete is not responsible for any decisions regarding which operational technique should be used on an individual patient. Use only the tools included when implanting the MetaFix™ PlantarMAX plate. MetaFix™ implants are single-use products and may not be reused.



1) Extreme deformity sesamoid bones far lateral



2) After correction, view from dorsal



3) View from Medial

3.1. Joint Exposure and Preparation

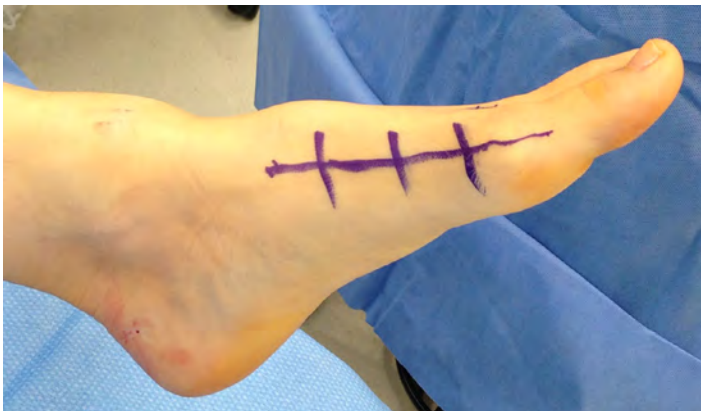


Figure 1: Surgical approach / Medial incision

A longitudinal medial approach is performed and required, centered slightly plantar to midline over the medial aspect of the 1st tarsometatarsal (TMT) joint (Figure 1). Extend this incision ~3 cm proximal to the 1st TMT joint. Soft tissue dissection protects branches of the superficial peroneal nerve. This incision will allow for plantar plate and screw placement as well as excellent exposure of the 1st TMT joint.

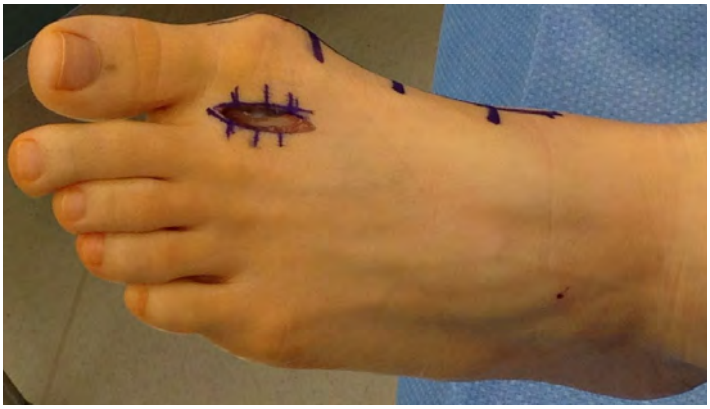


Figure 2: Surgical approach / Lateral release incision

This medial incision may be extended distally to the 1st MTP joint to allow for resection of the medial exostosis. A second incision between the 1st and the 2nd ray may be indicated to allow for a lateral release of the sesamoids.

NOTE

Next, the deep fascia covering the anterior tibial tendon is identified. A longitudinal incision through this thin layer will expose the anterior tibial tendon and capsule of the 1st TMT joint. **Do not dissect or in any way weaken the insertion of the anterior tibial tendon.** This plate is designed to lay on the plantar surface of the broad insertion of this tendon. Gentle dissection with your thumb on the plantar side of the tendon insertion creates additional space for placement of the PlantarMAX™ plate. Next, expose the 1st TMT joint through a longitudinal capsular incision dorsal to the anterior tibial tendon. You may gently retract the anterior tibial tendon plantarly with a small rake to facilitate exposure of the 1st TMT joint. The insertion of the anterior tibial tendon remains completely intact with this technique (Figure 3).

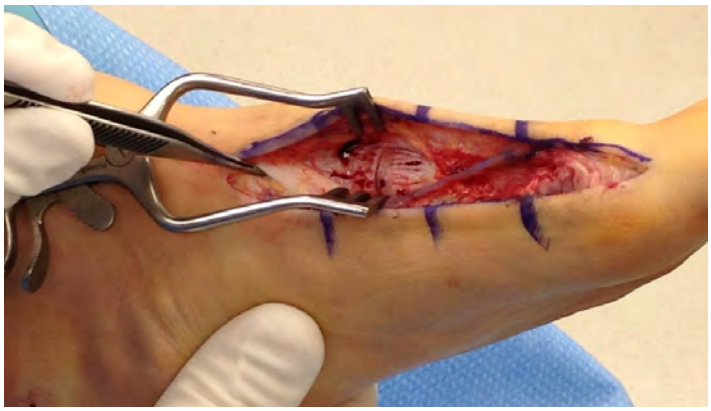


Figure 3: 1st TMT joint exposure and Anterior Tibial Tendon identification

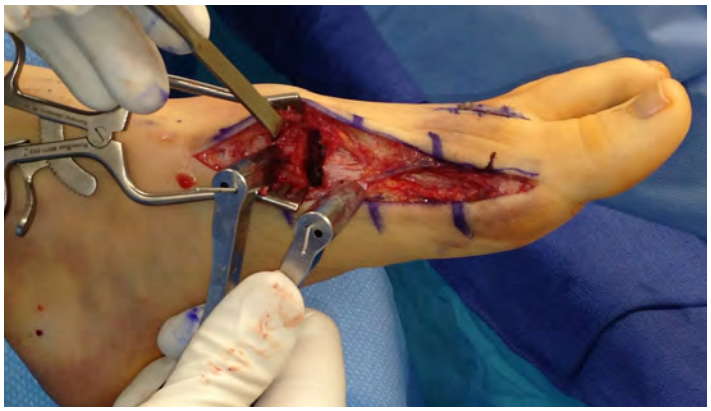


Figure 4: Distraction and preparartion of 1st TMT joint

As this time, use a pin-type distractor to open up the 1st TMT joint (Figure 4). This should allow excellent visualization of the entire 1st TMT joint. Preparation of the joint surface should proceed by hand with curettes. We avoid the use of power equipment (flat cuts with a saw or use of a power burr) to avoid shortening the 1st ray. Curettes remove the articular cartilage; small drills penetrate the subchondral bone and flexible chisels or small osteotomes „feather" or „rose-petal" the first TMT joint. This technique minimizes bone removal/resection. The goal is to expose healthy, bleeding cancellous bone on both sides of the fusion. It is important to ensure complete preparation of the plantar and lateral aspects of the joint. Preparation of the 1-2 interspace is typically not necessary but if chosen, this area can be exposed either through the joint (by the use of a distractor) or by extending the capsular dissection dorsally and laterally.

The 1st metatarsal is then adducted and plantarflexed as needed to obtain an acceptable position. Optimal positioning includes the sesamoids reduced under the 1st Metatarsal head, Intermetatarsal Angle of 0-9 degrees, and a congruent 1st MTP joint. Sagittal plane alignment should reveal that the 1st Metatarsal is parallel to the lesser metatarsals.

A number of intra-operative techniques may be used to maintain optimal positioning during plate implantation. We prefer the use of a bone reduction tenaculum applied between the 1st and 2nd metatarsal heads (Figure 5). When compressing the clamp and correcting the IM angle, maintain proper sagittal plane alignment and avoid excessive plantar or dorsiflexion of the 1st metatarsal. Alternatively, the surgeon may use manual pressure applied to the 1st metatarsal head to reduce the deformity.

While manipulating the 1st metatarsal, avoid translating the 1st TMT joint plantarly or medially as this reduces the surface area available for fusion and will prevent proper plate positioning. When alignment has been achieved, a guide pin (1.4 mm x 70 mm) placed across the joint will provide temporary fixation (Figure 5).

3.2. Plate Placement and Compression Screw Fixation

Place the MetaFix™ PlantarMAX™ plate along the plantar surface of the 1st TMT joint, overlying the insertion of the anterior tibial and peroneus longus tendons. Care is taken to avoid excessive dissection of either tendon. The plate was anatomically designed to match the contour of the plantar surface of the 1st TMT joint and does not routinely require bending. If indicated, the MetaFix™ PlantarMAX™ plate may be molded and bent with the available bending instruments to ensure a contoured fit. The placement of the plate on the plantar (tension) side of the joint provides a biomechanically superior construct for fusion.

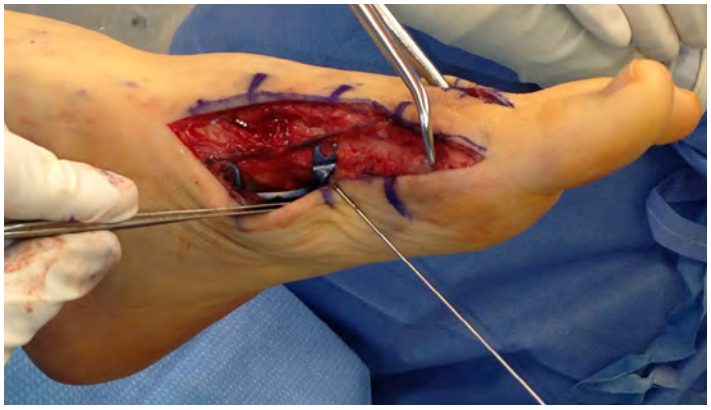


Figure 5: Plantar position of the PlantarMAX and interfragmentary K-wire screw placement

NOTES

- Do not bend the plate near or on the distal screw holes as this will damage the screw holes. This may prevent the locking scews from threading and locking into the plate.
- The plate has to fit exactly to the bone. If not, the osteotomy may lose its desired correction.

NOTES

- Bending back or using inappropriate instruments can cause the plate to break under load.
- Do not bend over the threaded holes, otherwise the threaded holes will lose their function.
- Depending on the plate, bend with the drill sleeve in place; this ensures the integrity of the thread.

Use your thumb to hold the plate in a optimal position on the plantar surface of the 1st TMT joint.

Once proper placement of the plate is achieved, a temporary K-wire (1.4 mm x 70 mm) is placed through the plate in the slotted K-wire hole located on the cuneiform side of the joint. The temporary 1.4 mm x 70 mm K-wire is placed in the most proximal portion of the slotted K-wire hole, to allow for compression of the joint when placing the interfragmentary screw.

Next, the guide wire for the interfragmentary compression screw (1.0 mm x 150 mm) is placed from distal to proximal, through the interfragmentary screw hole, going from the metatarsal to the cuneiform. This guide wire may be inserted with the available Tissue Protector / K-wire Guide positioned in the interfragmentary screw hole prior to insertion to assist in guiding the K-wire into the appropriate position.

Fluoroscopy confirms proper positioning and length of the guide wire as well as the overall reduction of the pre-operative deformity. The sesamoids should be reduced under the 1st Metatarsal head, the Intermetatarsal Angle reduced to 0-9 degrees, and the 1st MTP joint should be congruent. The white cannulated length gauge is passed over the guide wire to determine the appropriate length. To ensure bicortical fixation of the screw, add 2 mm to account for plate thickness.

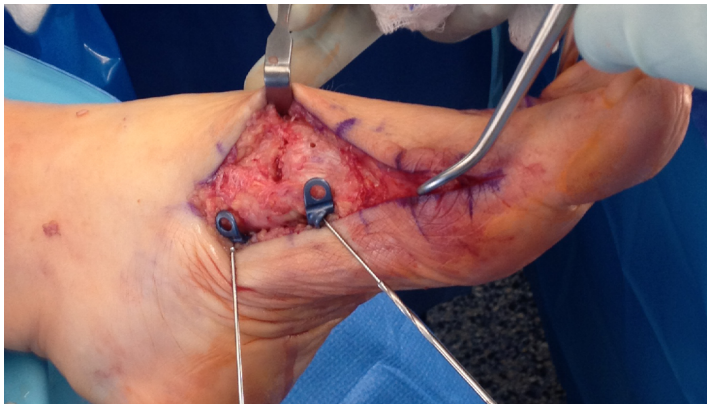
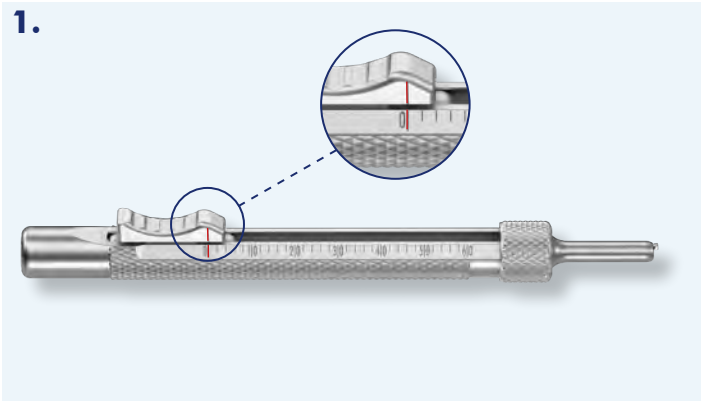


Figure 6: Proximal temporary K-wire fixation and over drilling for interfragmentary Compression Screw

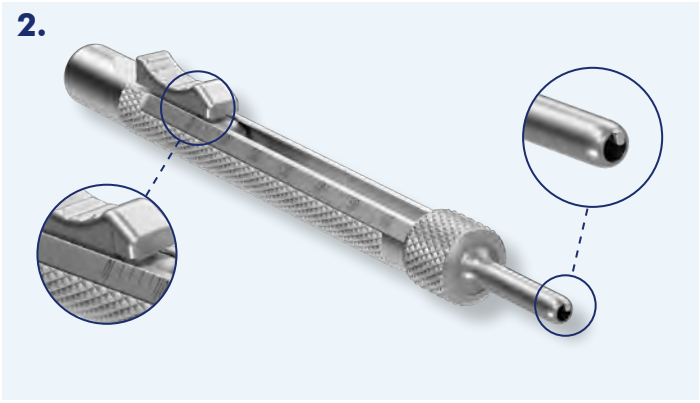
Pre-drill over the guide wire with the 2.0 mm cannulated drill bit, drilling all 4 cortices.

Place the Merete® 3.0 mm Cannulated compression screw over the guide wire to fixate and compress the TMT joint. Fluoroscan imaging confirms acceptable plate placement and anatomic osseous alignment. Proper screw length is critical as to avoid injury to the dorsal soft tissues.

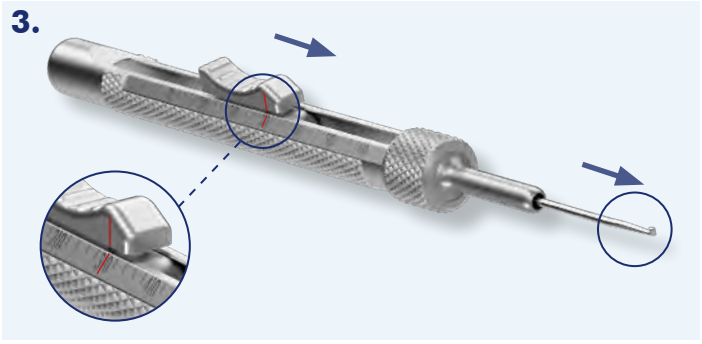
Application description of the depth gauge



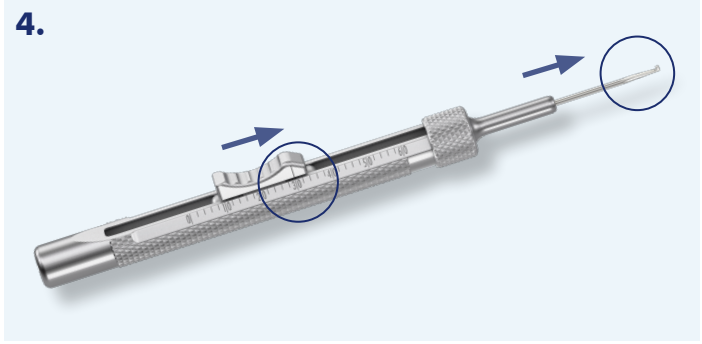
Note the line marking on the slide for the depth gauge (illustration in zero position).



To check the zero position, hook the test needle into the opening tip of the depth gauge.



The test needle with hook is extended using the slide



The length shown indicates the distance from the extended test needle to the hook.

NOTE
If the determined screw size falls between two line markings, the surgeon is responsible for deciding whether to select the shorter or longer screw length.

3.3. Plantar Locking Screw Placement

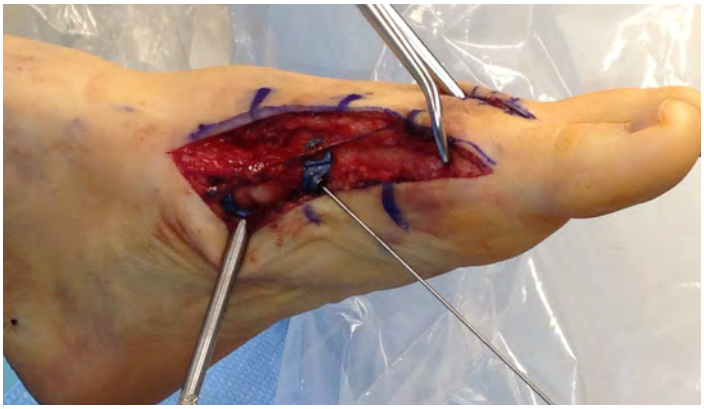


Figure 7: Placement of drill guides for plantar Locking Scews

Next, the plantar screws are inserted. Place threaded drill guide into the plantar holes of the plate. It is recommended to thread one 2.5 mm Drill Guide into the metatarsal/distal screw hole plantarly and one 2.5 mm Drill Guide into the cuneiform/ proximal screw hole.

Pre-drill the Metatarsal plantar side first with the 2.5 solid drill bit. Determine the appropriate length of the 3.5 mm (green) locking screw with the silver sliding depth gauge.

Pre-drill the Cuneiform plantar side next with the 2.5 mm solid drill bit. Determine and place a 3.5 mm (green) locking screw.

3.4. Medial Locking Screw Placement

Finally, the medial screws are placed. The medial holes on the MetaFix™ PlantarMAX™ plate allow for locking or non-locking screws. For most applications, locking screws are recommended. If the surgeon chooses to fuse the 1-2 interspace or the inter-cuneiform joint, compression screws may be utilized.

Pre-drill the medial Metatarsal side first with the 2.0 mm solid drill bit, using the threaded drill guide if locking screws are chosen. Use the silver sliding depth gauge to determine length of the screw. Insert a 3.0 mm locking screw (blue) for medial/distal fixation.

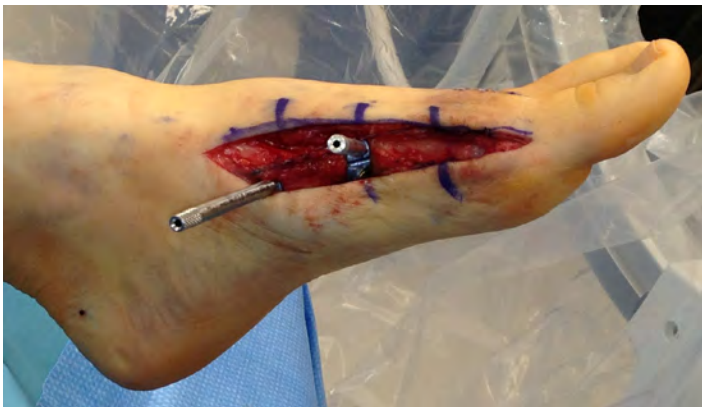


Figure 8: Placement of drill guides for medial Locking Scews

Pre-drill the medial Cuneiform side next with the 2.0 mm solid drill bit placed through the threaded guide. Use the silver sliding depth gauge to determine length of the screw. Insert a 3.0 mm locking screw (blue) into the medial/proximal screw location for final fixation.

NOTES

- Ensure that the drill sleeve axis is linear to the plate threaded hole axis when screwing it into the plate.
- Ensure that the screw axis and the plate threaded hole axis are linear when screwing in.

NOTE

Placement of Locking Screws

- The screw and the screwdriver should be exactly aligned with the axis of the screw hole. The screw should easily thread and lock into the plate.
- Do not use much force when tightening the screws. If resistance is met, slightly back out screw, realign screw and screw driver and turn the screw in again. The screw head should end up flush to the plate.
- For determined screw lengths with odd numbers, round up to the next even number to ensure bi-cortical placement of the locking screw.

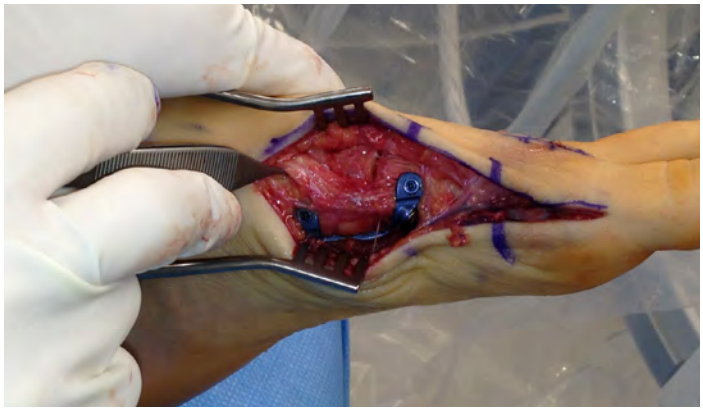


Figure 9: Final fixation of PlantarMAX™ plate

NOTE
If a screw cannot be screwed into the plate, it is helpful to loosen previously tightened screws by one turn so that the screw can then be inserted without tension.

3.5. Wound Closure

Final fluoroscan imaging confirms proper bone alignment and hardware placement. Proper screw length is critical as to avoid injury to the dorsal soft tissues.

Wounds are closed in layers in standard fashion. Bulky sterile dressing is applied.

Post-operative protocol will vary based on a number of factors including the overall health of the patient and quality of the soft tissues and ultimately will be based on surgeon judgment.

3.6. Explantation

The osteosynthesis implants can usually be removed after the osteotomy successfully has consolidated. The surgeon should careful weigh risks and benefits when deciding whether to remove the implant or not. Implants must be explanted carefully to avoid new bone fractures.

NOTE
Non-cannulated solid profile screwdrivers are required for safe explantation of screws. Cannulated screwdrivers are NOT to be used.

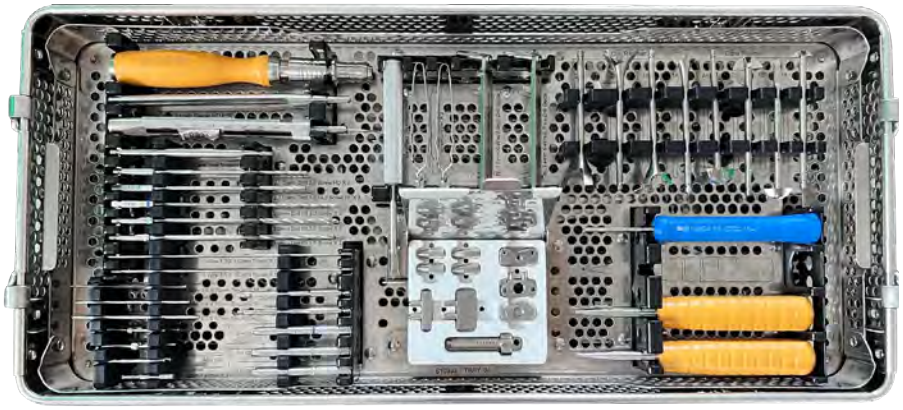
- For explantation of T8 screws: Ref. AI14332 Screwdriver with handle, T8, non-sterile.
- For explantation of T10 screws: Ref. AI14333 Screwdriver with handle, T10, non-sterile
- For explantation of Hex 2.5 screws: Ref. AI14338 Screwdriver SW2.5, AO connection, without handle, Ref. FH90003 Handle with ratchet and AO coupling small

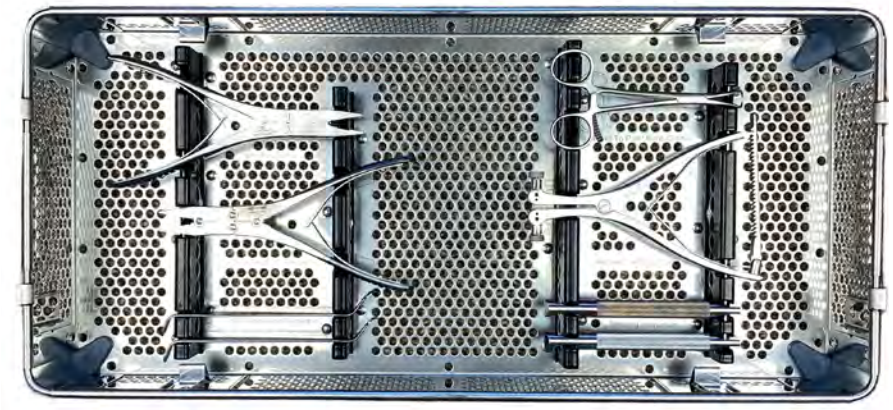
For explantation of screws, use a non-cannulated screwdriver of the appropriate size for the screw drive connection. To ensure that the screwdriver grips optimally, any ingrown tissue material must be removed from the screw drive connection.

4. Ordering Information

4.1. Instrument Tray

Description	Ref.
Instrument Tray	FH95501





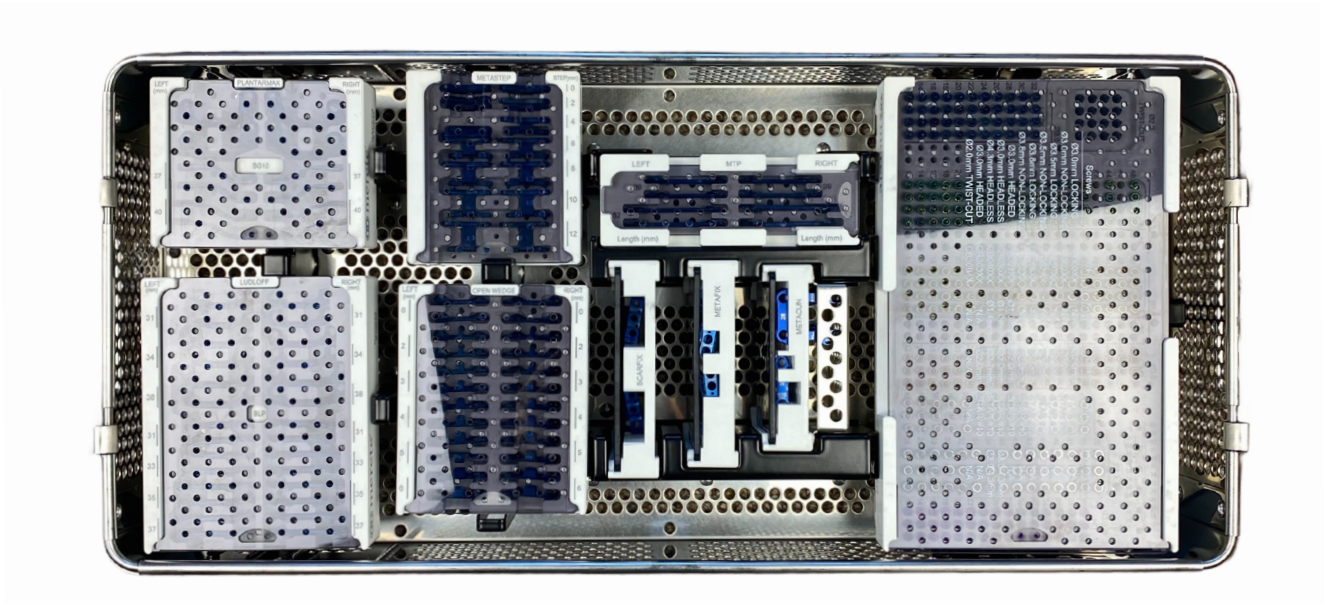
Instrument Base Tray Insert		
Qty.	**Description**	**Ref.**
4	Olive K-wire	AI14104
4	Olive K-wire, threaded	AI14105
4	Step K-wire	AI14106
2	2.0 Drill Bit 140 mm	FH10003
2	2.5 Drill Bit 140 mm	FH10004
2	2.9 Drill Bit 140 mm	FH10009
2	2.0 Cannulated Drill Bit 120 mm	FH11020
2	2.7 Drill Bit 120 mm	FH15027
2	Starter Screw	CK00025

Qty.	Description	Ref.
10	1.0 K-wire (70 mm)	CK10207
10	1.0 K-wire (150 mm)	CK10215
10	1.4 K-wire (70 mm)	CK14207
10	1.4 K-wire (150 mm)	CK14215
1	Screw Driver TwistCut	CB22010
1	Double Drill Guide	AC10020
1	Double Drill Guide	AC14027
1	Length Gauge	AI14001
1	Sliding Depth Gauge 0-60 mm	AI00301
1	2.5 Cannulated Hex Screw Driver	AI14225
1	2.5 Hex Screw Driver	AI14326
2	2.0 Drill Guide (Driver Compatible)	FH10045
2	2.5 Drill Guide (Driver Compatible)	FH10046
2	2.0 Short Drill Guide (Driver Compatible)	FH10047
2	2.5 Short Drill Guide (Driver Compatible)	FH10048
2	Drill Guide for 2.9 mm drill for locking screws	FH10049
1	Countersink	FH15043
1	Cup Reamer 14	FH20014
1	Cup Reamer 18	FH20018
1	Cup Reamer 20	FH20020
1	Cup Reamer 24	FH20024
1	Cone Reamer 14	FH21014
1	Cone Reamer 18	FH21018
1	Cone Reamer 20	FH21020
1	Cone Reamer 24	FH21024
1	Ratcheting Handle	FH90003
1	MetaStep Saw Template	FH14100
1	MetaStep Displacement Device	FH14101
1	MetaStep Stamp	FH14102
1	Screwdriver Hex 2.5, non-sterile	FH10025

Qty.	Description	Ref.
1	MetaStep Positioning Screw	FH14103
1	MetaStep Saw Template 10°	FH14104
1	MetaStep Saw Template 20°	FH14105
1	MetaStep Steinmann Nail	FH14106
1	Screw Forceps - 1.7-2.7 mm	gs 86.6108
1	Screw Forceps - 3.5-6.5 mm	gs 86.6110
Instrument Base Tray (FH95511)		
Qty.	**Description**	**Ref.**
2	Bending Instrument II	FH10902
1	Bending Pliers	FH10905
1	Bending Plier with Transverse Groove	FH10906
1	Lewin Small Bone Clamp - 5"(Point to Point Bone Clamp)	4685
1	Hintermann Retractor	4215-SS
2	Mini Hohmann Retractor .6 mm Blade/17 mm Drop	1665-01

4.2. Implant Tray

Description	Ref.
Foot & Ankle Screw and Plate Tray	FH95500



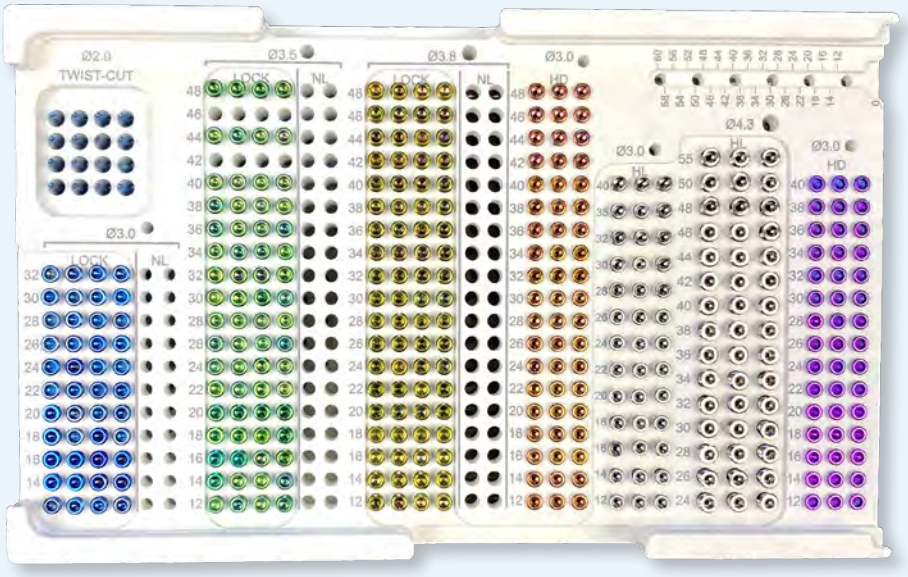
4.3. MetaFix™Plantar BG10 Plates and Screws

MetaFix™ Plantar BG10 and MetaFix™ PlantarMax Caddy (FH95518)		
Qty.	**Description**	**Ref.**
2	MetaFix™ PlantarMAX, **left**	FH02110
2	MetaFix™ PlantarMAX, **right**	FH02115

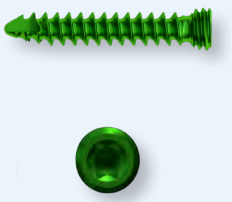
Plates

Screw Caddy
non-sterile

Description	Ref.
Screw Caddy with Screws	FH95521



Screws

			
Length	**MetaFix™ LS Locking Screw dia. 3.0 mm**	**MetaFix™ LS Locking Screw dia. 3.5 mm**	**Merete® Cannulated PCS dia. 3.0 mm**
12 mm	FH30012	FH35012	FH30112
14 mm	FH30014	FH35014	FH30114
16 mm	FH30016	FH35016	FH30116
18 mm	FH30018	FH35018	FH30118
20 mm	FH30020	FH35020	FH30120
22 mm	FH30022	FH35022	FH30122
24 mm	FH30024	FH35024	FH30124
26 mm	FH30026	FH35026	FH30126
28 mm	FH30028	FH35028	FH30128
30 mm	FH30030	FH35030	FH30130
32 mm	FH30032	FH35032	FH30132
34 mm	-	FH35034	FH30134
36 mm	-	FH35036	FH30136
38 mm	-	FH35038	FH30138
40 mm	-	FH35040	FH30140
42 mm		-	FH30142
44 mm		FH35044	FH30144
46 mm		-	FH30146
48 mm		FH35048	FH30148

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