



MetaFix[®] I

Low Profile Locking Bone Plate System
Surgical Technique and Ordering Information

This surgical technique applies only to the U.S.



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.

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1. Description

The Merete MetaFix® I Low Profile Locking Bone Plate System was developed in collaboration with D. W. Haesen, M.D.; Medical Director of Foot and Joint Surgery, Clinic Fleetinsel Hamburg/Germany.

The system is made of titanium alloy Ti-6Al-4V ELI and consists of straight, oblique-T or small-T profile plates in various sizes (26, 28, 30, 32 and 36 mm) for the left and the right foot. The plates incorporate MetaFix® LS locking screws in a screw-to-plate locking feature which creates a fixed angle construction to hold fractures or osteotomies. Two 1.4 mm holes allow temporary fixation of the plate to the bone with K-wires.



Figure 1: MetaFix® I Plate



Figure 2: MetaFix® LS locking screws dia. 3.0 mm (blue), dia. 3.5 mm (green)

Characteristics

The MetaFix® I Plate

- Adjusts to the natural curvature of the first proximal metatarsal
- Transmits forces safely due to its construction.
- Is made of titanium alloy (Ti6Al4V ELI)
- Is available in different sizes
- Is operated with the MetaFix® instruments
- Is fixed with MetaFix® locking screws. The MetaFix® locking screws have a length of 12 – 32 mm in 2 mm steps and are made of titanium alloy (Ti6Al4V ELI) thus providing an excellent fixation

The heads of the locking screws have conical threads and lock themselves unidirectionally, angle fixed into the threaded holes of the Plate. The MetaFix® LS locking screws can be screwed flat into the plate with little effort and if intended, effort may be increased to sink the screws further into the plate.

As soon as the screw head is concise with the plate surface, the required screwing depth has been reached (Figure 3). If the plate is to be brought closer to the bone, the screw can be screwed deeper into the plate (Figure 4). The distance "A" can measure up to half a plate thickness. The emerging circumferential tension in the plate gives the screw a secure fit.



Figure 3: screw head flat with plate surface

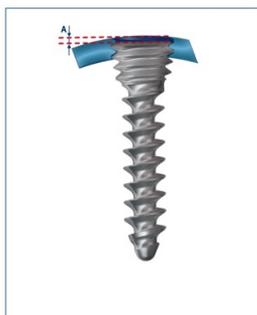
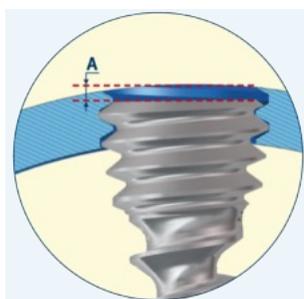


Figure 4: flat-mounted screw by the measure A



1.1. Intended Use / Purpose

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 system is used for adult or pediatric patients as indicated for small bone fracture fixation. Indications for use include fixation of fractures, osteotomies, non unions of the clavicle, scapula, olecranon, radius, ulna, fibula, metacarpals, metatarsals, middle hand and middle foot bones, particular in osteopenic bones.

1.2. Contraindication

- Osteoarthritis
- Primary chronicl Polyarthritis
- Osteoporotic bone

1.3. 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. Using 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

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3. Surgical Technique

The surgical technique presented here (please see chapter 3.1 and chapter 3.2 below) 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™ I plate. MetaFix™ implants are single-use products and may not be reused.

The operating surgeon is solely responsible for the individual choice of the appropriate surgical technique for a patient. Merete Medical GmbH is not liable for the choice of the surgical technique being used for each patient.

3.1. Closing Base Wedge Osteotomy (Juvara)

1. Medial/longitudinal incision across the first proximal metatarsal where the osteotomy will take place.
2. Careful preparation and soft tissue dissection to achieve desired exposure of metatarsal surgical site. Ensure that preparation allows exposure to the proximal/plantar screw location on MetaFix® I plate.



Figure 7: Trial placement

3. Prior to making the osteotomy cut, place the plate on the bone and select the appropriate plate length (Figure 7).



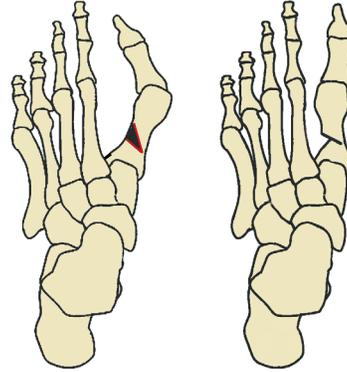
Figure 8: Marking of plate position

4. Mark both the distal and the proximal point of the selected plate and the location of the distal screw holes with a marking pen on the bone to indicate the desired position of the plate (Figure 8).

5. Perform an oblique osteotomy cut according to the marks to obtain the correction desired. The resected bone is taken out which is not shown in the following pictures. Hold the osteotomy close and fix this position with 1.4 mm K-wires, length 150 mm (Ref. CK14015). This will hold the correction in position for placement/fixation of the MetaFix™ I plate (Figure 9). Check the selected plate with a trial positioning.



Figure 9: Oblique osteotomy cut



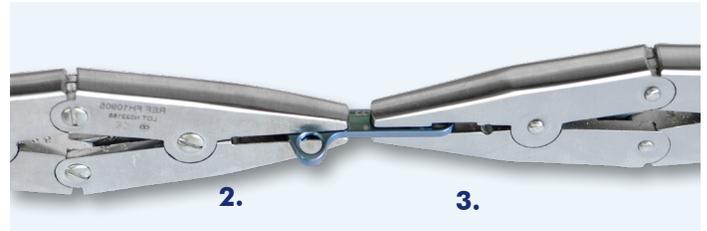
Instead of K-wires you may use a scarf osteotomy clamp to clamp the plate to the bone while holding the osteotomy site closed tightly in position.

6. If bending of the plate is required, use the bending instruments to achieve exact plate alignment of plate and bone. For this, insert the proximal side of the plate into the bending instrument II (Ref. FH10902) and slide the ring over the plate.

1.



Pass bending instrument II (Ref. FH10902) with its T-side over the distal side of the plate. If both bending instruments are aligned, the plate can be bent.



Instruments	Ref.
1. Bending instrument II	FH10902
2. Bending pliers	FH10905
3. Bending pliers with transverse groove	FH10906

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.

If it is necessary to twist the plate, the I-side of bending instrument II is used by holding it in a right angle to the bending instrument I.

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 screws 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.

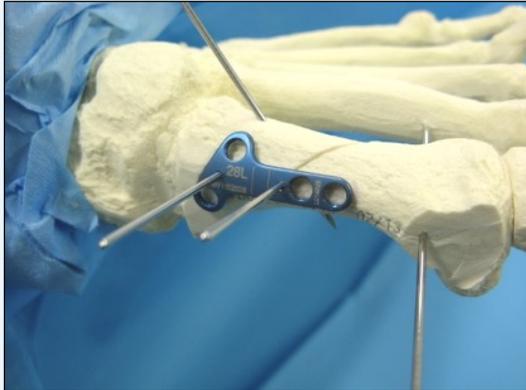


Figure 10: Temporary fixation of MetaFix™ I plate

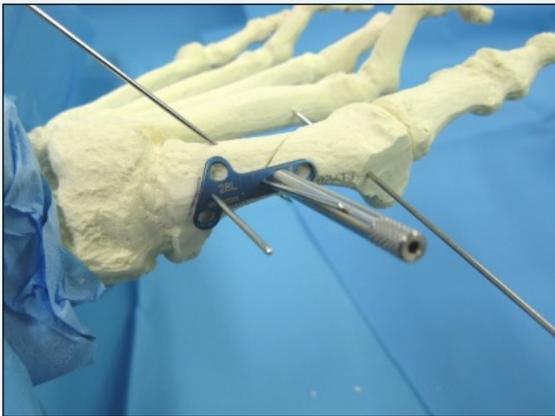


Figure 11: Use of drill guide

- 7.** Temporary fixation of the MetaFix™ I plate:
Place the plate onto the bone and insert a K-wire 1.4 mm, length 70 mm (Ref. CK14007), through each of the distal and the proximal K-wire holes into the bone (Figure 10).

- 8.** Thread the 2.0 mm drill guide (Ref. FH10045) into the inner distal screw hole (Figure 11).

NOTE

The short drill guide (Ref. FH10048) serves not only as a drill guide but to assist with manual stabilization and orientation of the plate (Figure 7).

It is easier to place the MetaFix™ I plate if the short drill sleeve dia. 2.5 mm (Ref. FH10048) is placed in the proximal plantar hole.

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.

- 9.** Using the 2.0 mm drill bit (Ref. FH10003), drill through the drill guide into the metatarsal bone making sure to also perforate the opposite cortex. In case of very hard bone use the 2.5 mm drill bit (Ref. FH10004) with the 2.5 mm drill guide (Ref. FH10046) instead.

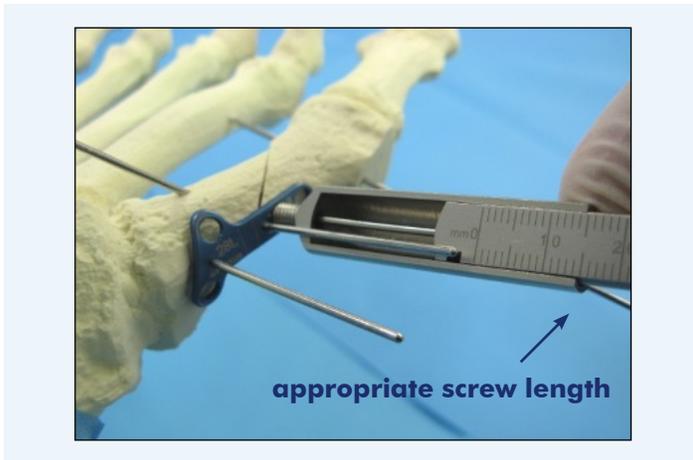


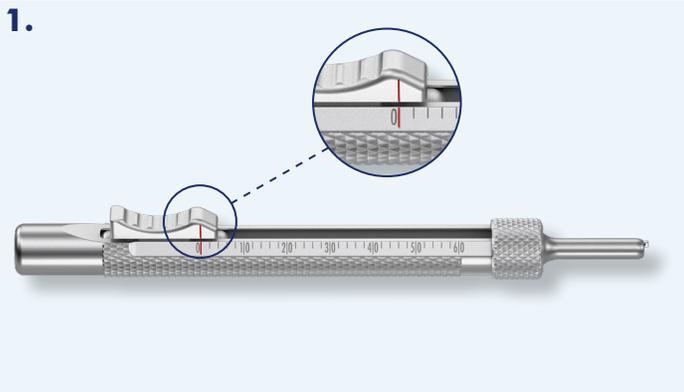
Figure 12: Use of sliding depth gauge

- Remove the drill guide and use the sliding depth gauge (Ref. AC00007) to determine the appropriate screw length by passing the measuring rod through the bone and hooking onto the outside of the opposite cortex. The appropriate screw length can be read off the scale at the end of the outer mantle of the depth gauge (Figure 12).

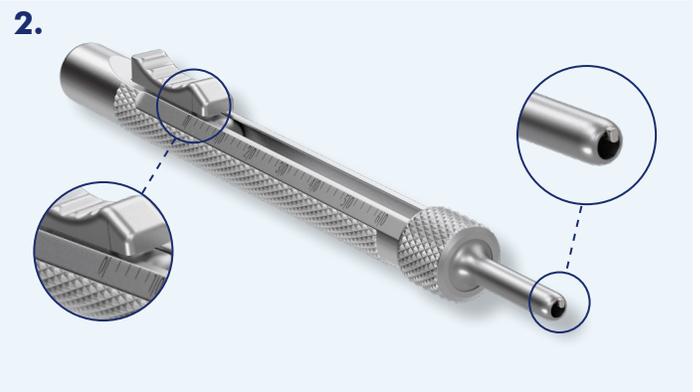
NOTE

Remove the protection sleeve from the sliding depth gauge before use! The protection sleeve prevents the measuring rod from damage and bending. Replace the protection sleeve onto the sliding depth gauge after use.

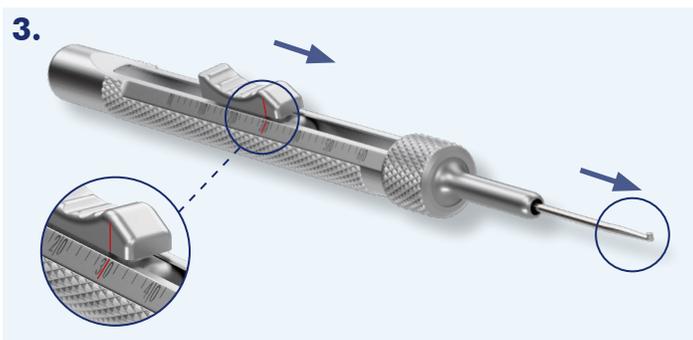
Application description of the depth gauge



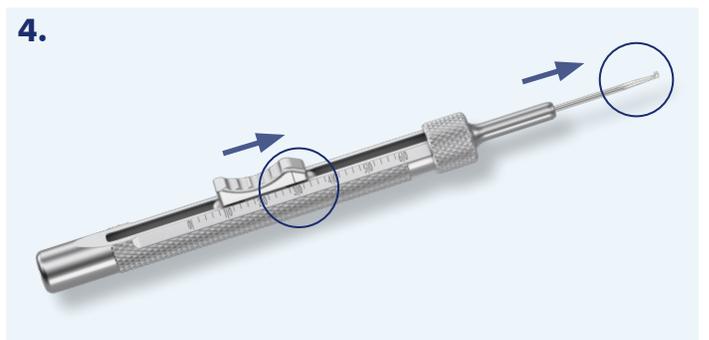
Note the line marking on the slide for the depth gauge (illustration in zero position).



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

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 screw length measurements indicated with odd numbers, round up to the next even number to ensure bi-cortical placement of the locking screw.



Figure 13: Tightening of first distal screw

- 11.** Select appropriate screw length and screw it into plate and bone with the screw driver (Ref. FH10025) (Figure 13). The axis of the screw driver should be exactly aligned with the axis of the screw and screw hole. The screw should easily thread and lock into the 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.



Figure 14: Drilling through drill guide and placing the first proximal screw

- 12.** Repeat steps 9-11 for placement of proximal screw into plate (Figure 14).

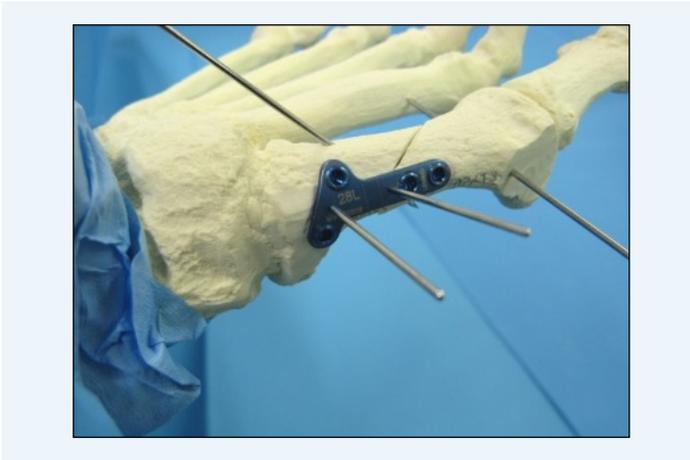


Figure 15: All screws tightened

- 13.** Repeat steps 9-12 to insert the second proximal screw and finally the second distal screw into the plate (Figure 15).



Figure 16: Temporary K-wires removed; osteotomy fixed

- 14.** Remove temporary K-wires from plate and bone (Figure 16).

- 15.** Close incision.

3.2. Opening Base Wedge Osteotomy

1. Medial/longitudinal incision across the first proximal metatarsal where osteotomy will take place.
2. Careful preparation and soft tissue dissection to achieve desired exposure of metatarsal surgical site. Ensure that preparation allows exposure to the proximal/plantar screw location on the MetaFix™ I plate.
3. Prior to making the osteotomy cut, place the plate on the bone and select the appropriate plate length (Figure 17).



Figure 17: Trial placement

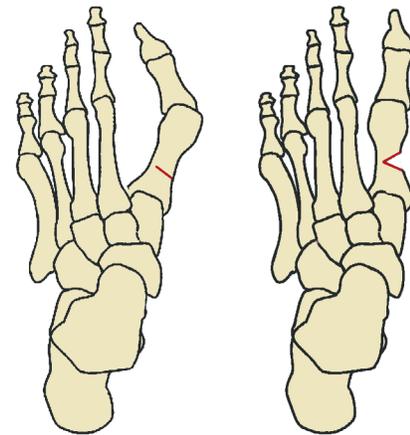


Figure 18: Marking of plate position

4. Mark both the distal and the proximal point of the selected plate and mark a center line between the two laser mark lines on the plate with a marking pen on the bone. This indicates the desired position of the plate and the osteotomy (Figure 18).

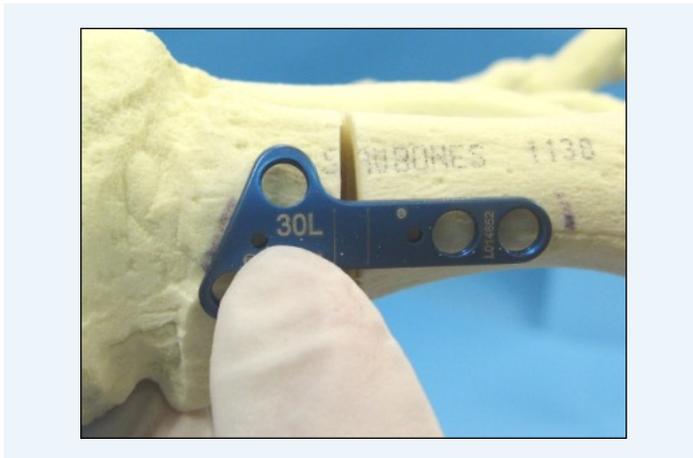


Figure 19: Osteotomy gap in the area of the laser marking lines



Figure 20: Fixation of the osteotomy with two diagonally K-wires

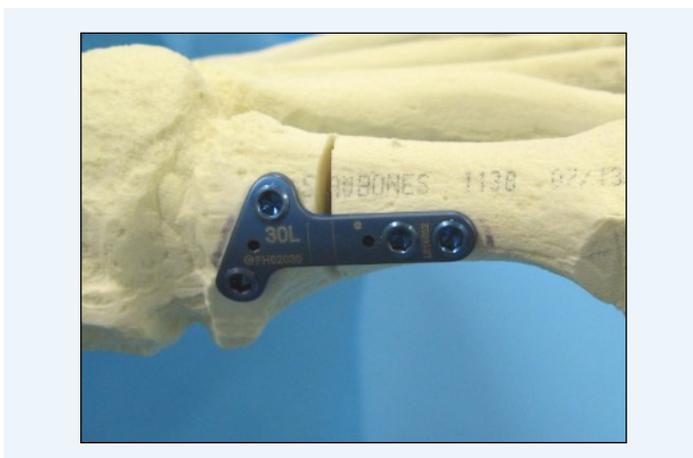


Figure 21: Osteotomy fixed

5. Perform the osteotomy cut and open up medially to the calculated extent. Finally fill up the gap with cortical-spongy filler material. Check the selected plate with a trial positioning.

NOTE

The gap of the osteotomy should not be greater than the distance of the two laser mark lines on the plate to assure that both proximal and distal screws are off the osteotomy site (Figure 19).

6. Once the correct position is achieved, fix the opened osteotomy by drilling two Ø 1.4 mm K-wires, length 150 mm (Ref. CK14015), crosswise through the osteotomy. This will hold the correction and the opening wedge in position temporarily for placement/fixation of the MetaFix™ I plate (Figure 20).

You may also fix the osteotomy with a K-wire distal to the osteotomy and plate position: Advance the K-wire from the medial side into the 1st Metatarsal bone and stop at the distal cortex. Obtain correction manually and advance the K-wire through the 2nd Metatarsal bone to hold the correction in position.

7. If the plate is required to be bent, use the bending instruments to achieve exact plate alignment of plate and bone. Use the bending instruments according to the described procedure on page 4.
8. Temporary fixation of the MetaFix™ I plate: Fix the plate to the bone by drilling a 1.4 mm K-wire length 70 mm (Ref. CK14007), through both the distal and the proximal k-wire holes into the bone.
9. The further steps correspond with the steps as described in step 8 (page 10) of the closing base wedge (Juvara) technique.

Also the MetaFix I can be used for the following surgical procedures:

- Opening Base Wedge Osteotomy* see chapters above
- Closing Base Wedge Osteotomy* see chapters above
- Proximal Chevron Osteotomy
- Oblique Base Wedge Osteotomy
- Crescentic- Osteotomie
- MTP I Arthrodesis
- TMT I Arthrodesis (Lapidus)

3.3. Postoperative Care

- Wound closure in layers
- Optional Redon drainage
- Compression foot and ankle bandage
- Walking is possible immediately, in flat post operative shoe and under consideration of all influencing factors
- X-ray check intra operatively as well as after the sixth post-surgical week

3.4. K-wire removal

Remove the K-wires.

3.5. Wound closure

Subcutaneous and skin suture are applied to seal the wound. Good results may be achieved applying redression bandages after wound closure.

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. A114332 Screwdriver with handle, T8, non-sterile.
- For explantation of T10 screws: Ref. A114333 Screwdriver with handle, T10, non-sterile
- For explantation of Hex 2.5 screws: Ref. A114338 Screwdriver SW2.5, AO connection, without handle, Ref. FH90003 Handle with ratchet and AO coupling small

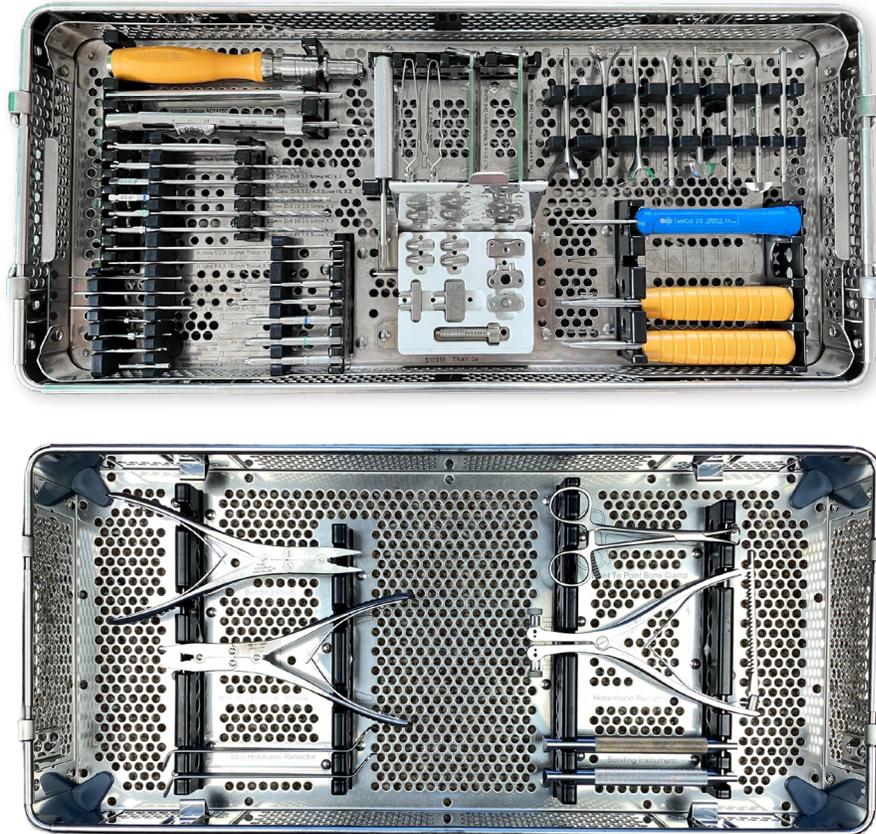
For explantation of screws, use a non-cannulated screwdriver of the appropriate size for the screw drive connection. To ensure that the screwdriver grips optimally, any ingrown tissue material must be removed from the screw drive connection.

4. Ordering Information

- 4.1. Instrument Tray 22
- 4.2. Implant Tray 24
- 4.3. MetaFix™ I Plates and Screws 25

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 Cann 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 w/ 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™ I and Screws

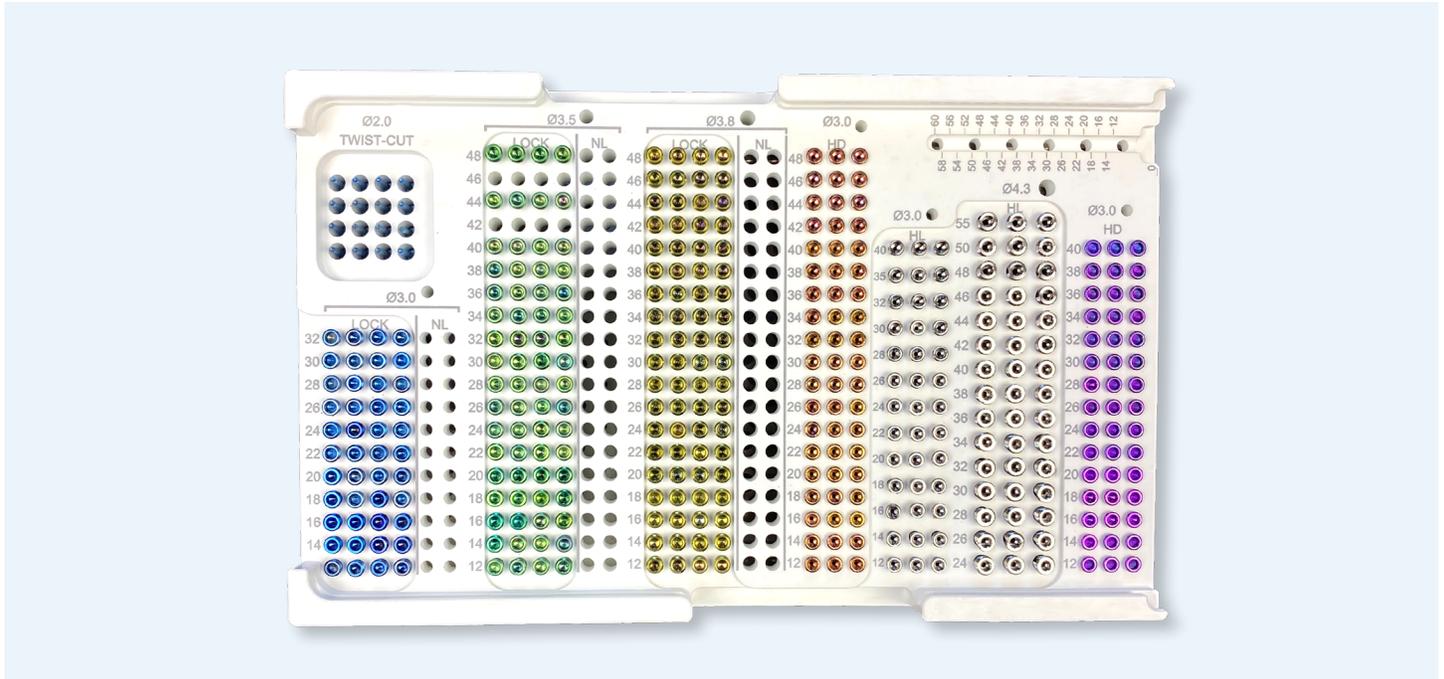
MetaFix™ I Caddy (FH95516)		
Qty.	Description	Ref.
2	MetaFix™ I Length 26 mm, left	FH02026
2	MetaFix™ I Length 26 mm, right	FH01026
2	MetaFix™ I Length 28 mm, left	FH02028
2	MetaFix™ I Length 28 mm, right	FH01028
2	MetaFix™ I Length 30 mm, left	FH02030
2	MetaFix™ I Length 30 mm, right	FH01030
2	MetaFix™ I Length 32 mm, left	FH02032
2	MetaFix™ I Length 32 mm, right	FH01032
2	MetaFix™ I Length 36 mm, left	FH02036
2	MetaFix™ I Length 36 mm, right	FH01036

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
12 mm	FH30012	FH35012
14 mm	FH30014	FH35014
16 mm	FH30016	FH35016
18 mm	FH30018	FH35018
20 mm	FH30020	FH35020
22 mm	FH30022	FH35022
24 mm	FH30024	FH35024
26 mm	FH30026	FH35026
28 mm	FH30028	FH35028
30 mm	FH30030	FH35030
32 mm	FH30032	FH35032
34 mm	-	FH35034
36 mm	-	FH35036
38 mm	-	FH35038
40 mm	-	FH35040
42 mm		-
44 mm		FH35044
46 mm		-
48 mm		FH35048

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