

Merete
MetaFix® BLP

Low Profile Locking Bone Plate System



Surgical Technique
and
Ordering Information

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CAUTION

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

DESCRIPTION

The Merete BLP™ Low Profile Locking Bone Plate System has been developed in collaboration with James K. DeOrio, M.D.; Duke University Medical Center, North Carolina.

The system is made of titanium alloy Ti-6Al-4V ELI and consists of anatomically shaped U-oblique plates which adapt the natural curvature of the first proximal metatarsal. The plates are available in three lengths (33, 35 and 37 mm) right and left. The plates incorporate 3.0 mm locking screws in a screw-to-plate locking feature which creates a fixed angle construction to hold fractures or osteotomies. Two holes, 1.4 mm each, allow the temporary fixation of the plate to the bone with two K-wires.

The plate has especially been designed for the fixation of the proximal Chevron Osteotomy (V-Type) for Hallux-Valgus correction. However, other bunion osteotomies can also be fixed with the plate.

**INTENDED USE**

The Merete MetaFix® BLP Low Profile Locking Bone Plate System is used for adult and pediatric patients. Indications for use include fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones.

CONTRAINDICATIONS

Not for use in

- Acute infections
- Osteoarthritis
- Primary chronic Poliarthritis
- Ostopereatic bone

WARNINGS AND PRECAUTIONS

- This product is provided non-sterile and is for single use only. An internal fixation device must never be re-used
- The device must be properly cleaned and sterilized before use
- Prior to use examine device and check for proper functioning
- The device is designed for use by surgeons experienced in the appropriate specialized procedures. It is the responsibility of the surgeon to become familiar with the proper techniques
- Additional precautions include those applicable to any surgical procedure. In general, careful attention must be paid to asepsis and avoidance of anatomical hazards
- For use in pediatric patients this product should not be placed across the growth plate
- For the implantation of the Merete Locking Bone Plate System use only the original Merete Locking Bone Plate System Instruments
- This product has not been evaluated for safety and compatibility in the MR environment and it has not been tested for heating or migration in the MR environment

ADVERSE EFFECTS

The adverse effects associated with this device are the same as with any metallic internal fixation device. These include but not limited to the following:

- Delayed or non-union which may lead to breakage of the implant
- Bending or fracture of the implant
- Metal sensitivity, or allergic reaction to a foreign body
- Pain, discomfort, or abnormal sensation due to the presence of the device

PLEASE NOTE

For the implantation of the Merete MetaFix® BLP™ Plate only the provided Merete MetaFix® instruments and MetaFix® LS locking screws should be used and the surgical instructions below followed. Merete BLP™ is a single-use product only and should not be reused.

SURGICAL TECHNIQUE

The surgical technique presented here is used to demonstrate the fundamental procedure. Merete GmbH, as the manufacturer of these devices, does not practice medicine and does not recommend these or any other surgical techniques for use on a particular patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting a prosthesis in each individual patient. Merete GmbH is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

PROXIMAL CHEVRON OSTEOTOMY (V-TYPE)

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 the BLP™ plate.



Figure 1: Trial placement

3. Prior to making the osteotomy cut, place the plate at the bone and select the appropriate plate length (Figure 1).



Figure 2: 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 at the bone to indicate the desired position of the plate (Figure 2).



Figure 3: Markings of plate position and osteotomy position



Figure 4: Osteotomy cut



Figure 5: Correction fixed with K-wires



Figure 6: Insertion of BLP™ plate into bending instrument I

5. Make a line on the bone between the two laser markings on the plate. This indicates where the osteotomy should take place (Figure 3).

6. Perform the osteotomy cut according to the marks (Figure 4) and perform the desired correction.

7. Use 1.4 mm K-wires, length 150 mm (Ref. CK14215) to hold the osteotomy in its position (Figure 5). Cut off the overlapping bone at the medial side. This bone piece can be used to fill the plantar gap of the osteotomy created when the distal metatarsal is translated plantarly. Check the selected plate with a trial positioning.

8. If bending of the plate is required, use the bending instruments to achieve exact plate alignment of plate to bone. Therefore, insert the proximal side of the plate into the bending instrument I (Ref. FH10901) and slide the ring over the plate (Figure 6).

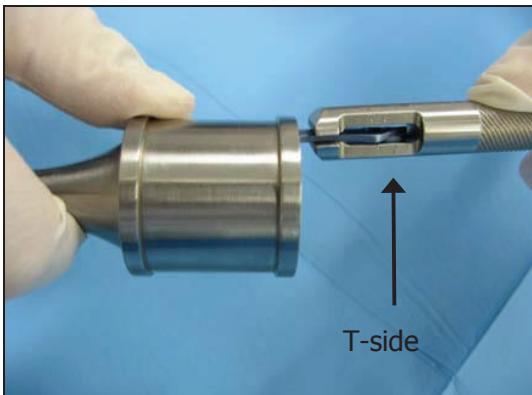


Figure 7: Bending of BLP™ plate

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 (Figure 7).

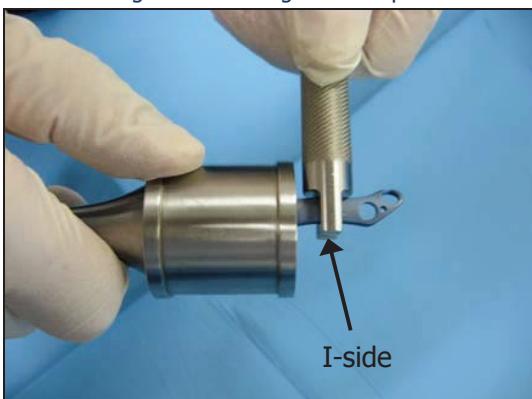


Figure 8: Twisting of BLP™ plate

If it is necessary to twist the plate, the I-side of bending instrument II is used by holding it in right angle to bending instrument I (Figure 8).



Figure 9: Temporary fixation of BLP™ plate

9. **Temporary fixation of the BLP™ plate:**
Place the plate to the bone and drill the bone with K-wires 1.4 mm, length 70 mm (Ref. CK14207), through both the distal and the proximal K-wire hole locations in the plate (Figure 9).



Figure 10: Use of drill guide

10. Thread the 2.0 mm drill guide into the (inner) distal screw hole (Figure 10).

11. Drill the metatarsal bone through the screw hole completely with the 2.0 mm drill bit (Ref. FH10003) through the 2.0 mm drill guide (Ref. FH10045). Use the 2.5 mm drill bit (Ref. FH10004) with the 2.5 mm drill guide (Ref. FH10046) if the bone is very hard.

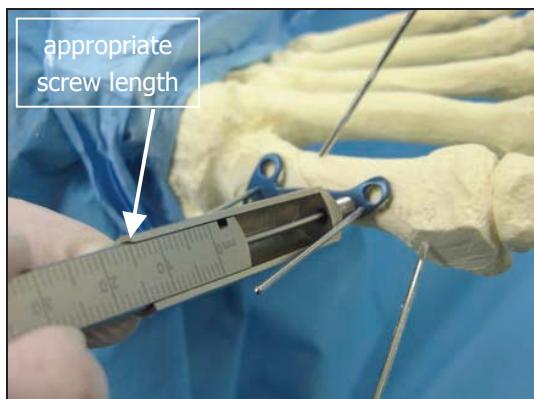


Figure 11: Use of sliding depth gauge

12. Remove the drill guide and use the sliding depth gauge (Ref. AC00007) to measure the appropriate screw length by hooking the opposite cortex. The appropriate screw length can be read off the scale at the end of the outer mantle of the sliding depth gauge (Figure 11).

Please note:

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



Figure 12: Tightening of first distal screw

13. Select appropriate screw length and screw it into plate and bone with the screw driver (Ref. FH10025) (Figure 12). The screw driver axis should be exactly aligned with the axis of screw and screw hole. The screw should easily thread and lock into the plate.

Please note:

- Do **not** use too much force when tightening the screw. If resistance is met, slightly back out screw, realign both screw and screw driver and turn the screw in again. The screw head should end up flat to the plate.
- The screws should also penetrate the opposite cortex to achieve bicortical fixation.

14. Repeat steps 9-11 for placement of proximal screw into plate (Figure 13 and 14).



Figure 13: Drilling through drill guide



Figure 14: Tightening of first proximal screw



Figure 15: All screws tightened

15. Repeat steps 8-12 for placement of the second proximal screw into plate and finally for placement of the second distal screw into plate (Figure 15).



Figure 16: Temporary K-wires removed; osteotomy fixed

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

17. Close incision.

POSTOPERATIVE CARE

- Wound closure in layers
- Optional Redon drainage
- Compression foot and ankle bandage
- Walking is possible immediately, in the 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

ORDERING INFORMATION

MetaFix® BLP plates, non-sterile

Length [mm]	Ref. right	Ref. left
33	FH01033	FH02033
35	FH01035	FH02035
37	FH01037	FH02037



MetaFix® BLP
locking plate

MetaFix® LS locking Screws, non-sterile

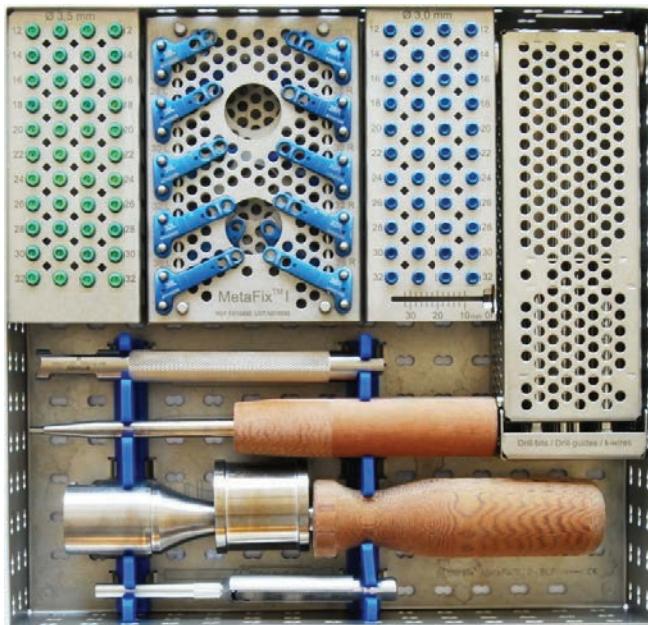
Length [mm]	3.0 mm Ref.	3.5 mm Ref.
12	FH30012	FH35012
14	FH30014	FH35014
16	FH30016	FH35016
18	FH30018	FH35018
20	FH30020	FH35020
22	FH30022	FH35022
24	FH30024	FH35024
26	FH30026	FH35026
28	FH30028	FH35028
30	FH30030	FH35030
32	FH30032	FH35032



MetaFix® LS
locking screw
3.0 mm (blue)
3.5 mm (green)

MetaFix® Sterilizing Container

Configuration MetaFix Sterilizing Container	REF
- 1 complete set of instruments - 2 MetaFix™ I plates each length (20 plates) - 2 BLP™ plates each length (12 plates) - 4 screws 3.0 mm each length (44 screws) - 4 screws 3.5 mm each length (44 screws)	FH10550
- 1 complete set of instruments without implants	FH10500


Instruments

Qty	Description	Ref.	
2	2.0 mm drill bit, L=150 mm, AO connector small	FH10003	
2	2.5 mm drill bit, L=150 mm, AO connector small	FH10004	
1	Bending instrument 1	FH10901	
1	Bending instrument 2	FH10902	
2	2.0 mm drill sleeve for locking screws	FH10045	
2	2.5 mm drill sleeve for locking screws	FH10046	
4	1.4 mm K-wire, L=150 mm, Trokar angle tip, round end	CK14015*	
4	1.4 mm K-wire, L=70 mm, Trokar angle tip, round end	CK14007*	
1	2.5 mm hex screwdriver L=175mm	FH10025	
1	Depth gauge 0-40 mm	AC00007	

*package with 10 pcs

FURTHER MERETE FOOT SURGERY PRODUCTS

MetaFix® I

Low Profile Locking Plate System for the fixation of the proximal Chevron Osteotomy (V-Type) for Hallux-Valgus correction.



MetaCun™, DuoMetaCun™

Low Profile Locking Plate System for the fixation of midfoot arthrodesis



MetaFix® MTP

Low Profile Locking Plate System for the fixation of arthrodesis of great toe TMT1 joint



MetaFix® Ludloff

Low Profile Locking Plate System for the fixation of the Ludloff Osteotomy for Hallux-Valgus correction.



DuoThread™

Cannulated Bone Screws, 3.0 mm

The DuoThread™ Bone Screw is a fully or partially threaded cannulated fixation screw with a threaded head. The screw is made of titanium alloy (Ti-6Al-4V ELI) in 3.0 mm and in lengths 10 to 34 mm.



TwistCut™

Snap-Off Bone Screws (self-drilling, self-tapping), made of titanium alloy (Ti-6Al-4V ELI), consists of a screw with a flat thin head which is integrated with a short round shaft. The shaft is fixed on a standard surgical power equipment and separates from the screw when the head meets cortical bone. The screw is 2.0 mm in diameter and 11 to 14 mm in length. Removable with a screwdriver



ProToe® - Endosorb®

Bioresorbable hammertoe pin, made from PLGA, reabsorbed latest after 24 month



ABOUT THE COMPANY

Merete GmbH is a medical technology company specializing in the manufacture of implants and instruments for endoprosthetics and osteosynthesis. With its name and qualified employees, Merete GmbH stands for many years of experience and innovative research and development, as well as for state-of-the-art manufacturing technology.

Merete GmbH's activities are focused on the needs of patients, physicians and specialized personnel of clinics and out-patient surgical centers. A trained team of medical product consultants assists the clinics in the successful application of our products.

Our extensive array of products ranges from tailor-made implants and instruments for orthopedic surgery and traumatology to sterile surgical disposables and post-surgical products, such as splints and bandages.

We are always available to answer questions about our products and to respond to your individual wishes.

The core competence of the company is the development and the production of implants and instruments for orthopedics and surgery, made of both metallic materials and modern synthetic materials. Due to our staff's specialized know-how in this field and our close collaboration with medical consultants and specialized medical product consultants, we can provide users with the necessary implants or biomaterials made either of metal, resorbable and non-resorbable plastic, as well as transplants of biological derivation.

For further information for this or other products, please contact our customer service.

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