



Merete
MetaToe™ EndoSorb™
Bioresorbable Hammer Toe Pin



**Surgical Technique
and
Ordering Information**

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1. Description

The MetaToe™ EndoSorb™ Hammer Toe Pin is made of the absorbable poly(L-lactide-co-glycolide) material (PLGA). PLGA degrades and absorbs in vivo by hydrolysis to lactic and glycolic acids, which are then metabolized by the body. During the healing process, the affected bone segments gain strength, while the absorbable MetaToe™ EndoSorb™ Hammer Toe Pin gradually loses its strength. The MetaToe™ EndoSorb™ Hammer Toe Pin maintains its mechanical strength for at least 8 weeks and adsorbs completely in approximately 12-24 months thus eliminating the need for implant removal surgery.

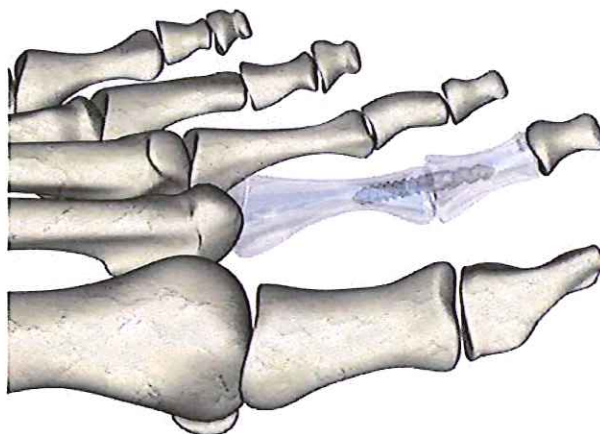
The MetaToe™ EndoSorb™ Hammer Toe Pin provides a screw with a diameter of 2.7 mm and is designed with two different pitched threads proximally and distally. The central portion of the screw provides a diameter of 2.7 mm. The Pin is available in the length 22 mm.



REF	Length	Ø
FP30022	22 mm	2.7 mm

2. Indications

The MetaToe™ EndoSorb™ Hammer Toe Pin is indicated for the interphalangeal (PIP) joint arthrodesis.



3. Contraindications

- Active infection,
- Obesity,
- Insufficient quantity or quality of bone stock, blood supply limitations or latent infection,
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions,
- Do not use in spine or load bearing procedures.

WARNINGS:

The MetaToe™ EndoSorb™ Hammer Toe Pin is used for the alignment and stabilization in reconstructive surgical application. In general these implants are successful in attaining the named goals. However, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly on the presence of nonunion, delayed union, or incomplete healing. The size of the implant depends on the size and shape of bones and soft tissue. Absorbable Pins may eventually break, if there is delayed union or nonunion of bone in the presence of weight bearing, or load bearing. Therefore it is important that immobilization (use of external support, walking aids, braces, etc.) of the fracture site be maintained until firm bone union (confirmed by clinical and radiographic examination) is established. Surgical implants are subject to repeated stresses in use, which can result in fatigue fracture. Factors such as patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of its material properties

1. Correct selection of the implant is extremely important. Size and strength of an implant is limited due to size and form of the human bone. To minimize risks, the selection of a proper implant should result from consideration of the physical condition of the patient. Absorbable Pins are not designed to withstand the unsupported stress of full weight bearing, load bearing, or excessive activity.
2. Selection, placement, positioning and fixation of the Pins are important for a successful surgical intervention. Failure of the Pins or surgical intervention may occur due to false estimation. The surgeon has to be familiar with the instruments and devices, the method of application and the surgical procedure prior to performing the surgery. The surgeon must select a type or types of internal fixation devices appropriate for treatment.
3. The Pins do not provide a permanent fixation. The Pin is absorbable and therewith unsuitable for surgical applications which require a permanent implant.
4. Heating or deformation of the Pin is not allowed and may lead to failure of the implant.
5. Follow exactly the specified procedures in the surgical technique of the absorbable Pin. Do not modify or bend the Pin except intraoperative shortening (as described below and displayed in Figure 9). It may not show any notches or scratches. Notches or scratches which arise during the surgery may lead to failure of the implants. If excessive force (torque) is applied while seating, intraoperative fracturing of the Pin can occur.
6. Excessive activity or trauma may contribute to breakage or damage of the screws. Damaged implants can fail and require additional surgery and device removal.
7. Do not use but discard implants from previously opened or damaged containers. Damaged implants out of unopened or undamaged containers are not to be used and must be discarded as well.
8. The implants are intended for single use only. Discard absorbable Pins if there is loss of sterility. Resterilization of implants is not permitted.
9. These absorbable Pins are not intended to replace normal healthy bone or withstand stress of load bearing. They are designed for temporary fixation only.
10. Patients are to be warned that injury at or near the implant site can lead to failure of the screws and/or treatment.

11. Adequate instructions for the patient and their postoperative care are very important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. Patients who are unwilling to follow those instructions are at higher risk of implant failure. This risk exists especially for patients with senility, mental illness, alcoholism, drug abuse or patients who ignore activity restrictions. The patient has to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. Ensure that the patient is fully aware and warned that the device does not replace normal healthy bone and that the implant may break, bend or be damaged as a result of stress, activity, load bearing or weight bearing.
12. If postoperative instructions are not followed, the implant can fail, which could require additional surgery and implant removal.
13. Inadequate fixation of the implant during surgery can increase the risk of loosening and migration of the Pin or tissue supported by the device. For a successful outcome an adequate fixation is required. At the time of surgery the bone quality must be assessed. Poor bone quality, e.g. patients with osteoporotic bone, increases the risk of device loosening and procedure failure.
14. These absorbable Pins are not intended to be used for application at the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

PRECAUTIONS:

- Combination of the MetaToe™ EndoSorb™ Hammer Toe Pins with absorbable implants made by other manufacturers is not permitted due to the probability of incompatible fits, size and rate of absorption.
- Use only the original Merete Instruments. Surgical Instruments are subject to wear with normal usage and may break intraoperatively. Instruments, which have experienced extensive use or excessive force, are susceptible to breakage. All instruments are to be regularly inspected for wear and disfigurement and when indicated to be discarded. The instruments are only to be used for their intended purpose.
- The patient is made to be aware of surgical risks and possible adverse effects prior to surgery. Furthermore he must be warned about the resulting consequences in noncompliance with postoperative care instructions.

POSSIBLE ADVERSE EFFECTS:

- Foreign material may cause inflammatory response or allergic reaction
- Surgical interventions may result in neurovascular injuries
- Pain, discomfort, or abnormal sensation due to the presence of the implant
- Infection can lead to a decreased success or to failure of the procedure
- Excessive physical activity, load bearing or trauma can cause bending, breakage, loosening, rubbing and migration of the implant
- Due to incomplete healing the implant may break or the procedure may fail
- Disfigurement can occur due to improper alignment of bone fragments
- Necrosis of bone
- Temporarily liquid accumulation
- Inadequate healing

4. Combination with other Products

Combination of Merete MetaToe™ EndoSorb™ Hammer Toe Pin with absorbable implants made by other manufactures is not permitted due to the probability of incompatible fits, size and rate of degradation.

Use only the original Merete instruments for implantation.

5. Sterility and Storage

The MetaToe™ EndoSorb™ Hammer Toe Pins are sterilized by gamma radiation.

Do not resterilize.

Do not use past expiration date. Store at or below room temperature.

Do not expose to direct insolation.

The color of the sensitive temperature indicator (yellow adhesive label with a circle dot) has to be pale gray.

Do not use the implant if the color of the circle dot changed to black.

6. Surgical Technique

MetaToe™ EndoSorb™ Hammer Toe Pin

All instruments have AO-chuck coupling and are to be used with the handle.

Open and prepare both parts of proximal interphalangeal joint (Figure 1). Perform a perpendicular straight cut of the proximal and intermediate phalanx (Figure 2).

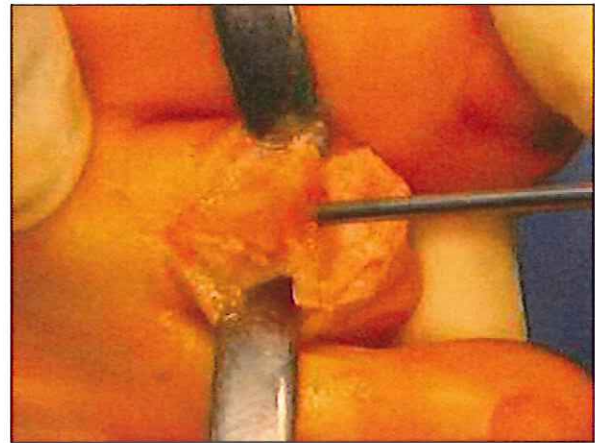


Fig. 1

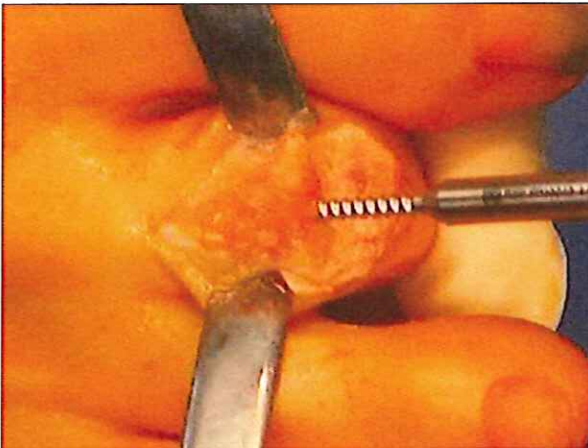


Fig. 2

Drill both the proximal and intermediate phalanx, using the drill bit Ø 2.0 mm (FP90008) (Figures 3 and 4).

**Fig. 3****Fig. 4**

Tap the drilled hole of the proximal phalanx, using the tap \varnothing 2.5 mm (FP90013) (Figure 5).

**Fig. 5****Fig. 6**

Join the grooved end of the hammer toe pin with the socket wrench (FP90020). The two grooves of the hammer toe pin act as guidance and have to correspond with the tongues of the socket wrench for proper positioning (Figure 6).

Note: Moisten the MetaToe™ EndoSorb™ Hammer Toe Pin with sterile solution before insertion.



Fig. 7



Fig. 8

Torque the threaded end of the of the hammer toe pin into the tapped hole in the proximal phalanx (Figure 7 and 8).

Note:

If the hammer toe pin is used on the 3rd or 4th toes, surgeon should further screw in the implant proximally by bringing back the socket wrench approx 2-3mm on the hammer toe pin. This will allow for the implant to be screwed in deeper into the proximal bone for easier distraction/press fit implantation distally. Care is to be taken not to screw the implant in with force.

Alternatively to this method the distal end of the implant can be trimmed with a side cutter (Figure 9), if the phalanx is short and remove the detached part using forceps.

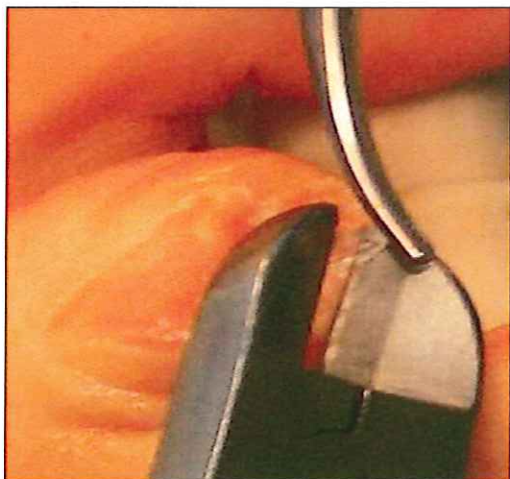


Fig. 9

Distract and plantar flex the intermediate phalanx. Hold the implant with forceps and press-fit the distal portion of the pin into the drilled hole in the intermediate phalanx until contact of both bone parts is met (Figure 10 and 11).

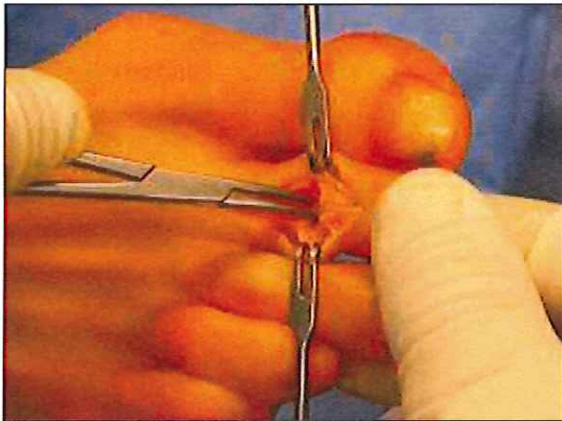


Fig. 10



Fig. 11

7. Postoperative recommendation

Bandage and Protection:

Generally, a surgical bandage (e.g. Hohmann redressing) is applied immediately postoperative for about 14 days

Treatment with a stiffed soled post-op shoe for about 4 weeks

Rest and elevation:

Rest particularly in the first 48 hours

Elevate the foot above hip level

Radiographs:

immediately postoperative and 4 weeks postoperative

Medication:

give painkillers if necessary

Postoperative visits:

Subsequent visits are recommended to control postoperative healing

In the absence of complications, the patient should initially be seen within the first week following the procedure(s)

8. Ordering Information






Implants

MetaToe™ EndoSorb™ Hammer Toe Pin



REF	Length	Ø
FP30022	22 mm	2.7 mm

Instruments

No.	Description	REF
1	Handle 	FP90018
2	Socket wrench 	FP90020
3	Tap Ø 2.5 mm 	FP90013
4	Drill bit Ø 2.0 mm 	FP90008
5	OneStep Drill Bit 	FP 90023