



DuaFit[®]

PROXIMAL INTERPHALANGEAL IMPLANT



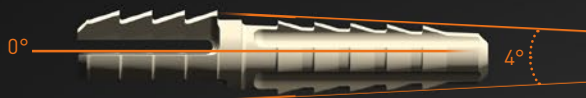


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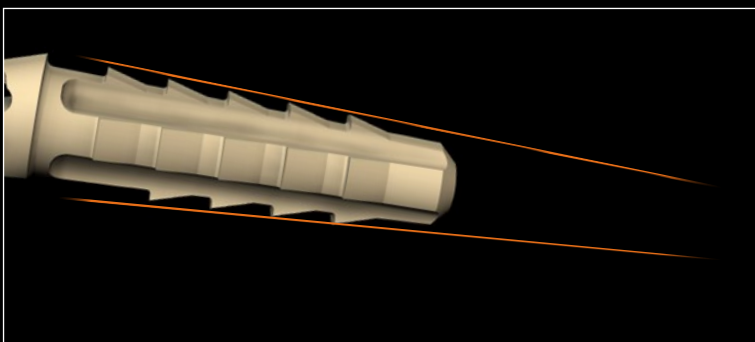
- ▶ The DuaFit® system is a set of implants and instruments for the arthrodesis of interphalangeal joint, as treatment for deformities of the lesser toes, such as claw, hammer and mallet toe.
- ▶ The intramedullary implants have features to securely hold adjacent phalanges. These design features are a combination of a long barbed segment in the proximal phalanx and three distal blades for enhanced stabilization.
- ▶ The implants come in 4 sizes and 3 angles 17°, 10° and 0° to accommodate the size variation of the phalanges across the patient population and the interphalangeal angles.
- ▶ The implants 0° are cannulated, which provides the surgeon the option to temporarily pin the corrected phalanx to the metatarsal with a guide wire in order to minimize the MTP subluxation upon healing.
- ▶ The surgeon also has the option to utilize the implant without the guide wire in order not to disturb a distal joint or to prevent complications from a percutaneous pin.





RADIO TRANSPARENT

- ▶ PEEK-OPTIMA® is radio transparent. This enables control of bone consolidation.



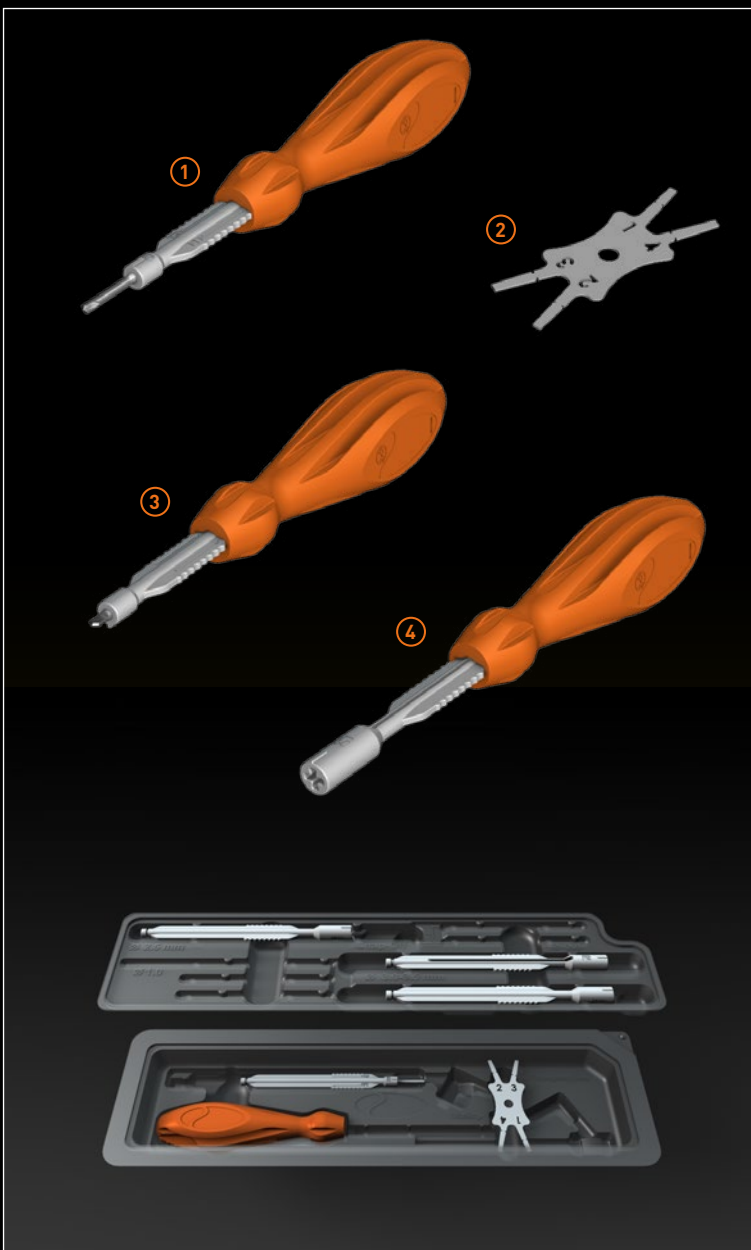
PROXIMAL DESIGN

- ▶ The conical shape of the implant guarantees a cortical fixation at the level of the isthmus of the phalanx (P1). The implant section is equal for all 4 sizes, only the length varies from size to size.



DISTAL DESIGN

- ▶ Three blades on the distal aspect of the implant (P2) guarantee the primary fixation while respecting the osseous stock.



INSTRUMENTS

- ▶ **P1 CANAL SHAPER ①**
The P1 canal shaper allows to prepare the medullary canal and to center the implant in P1.
- ▶ **SIZER ②**
The DuaFit sizer is used for implant sizing in P1.
- ▶ **P2 CANAL SHAPER ③**
The P2 canal shaper allows to prepare the DuaFit print in P2 without jeopardizing the bone stock.
- ▶ **HOLDER ④**
The holder, specific to each angle of implant, enables to engage and impact the DuaFit axially.

INDICATIONS

- ▶ The DUAFIT® implant is intended for fixation of proximal interphalangeal joint arthrodesis of the lesser toes.

Examples include:

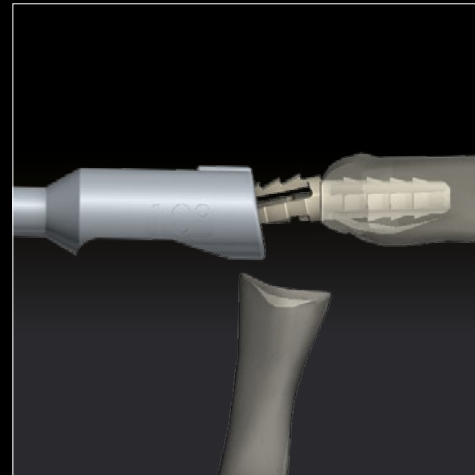
- ▶ rigid or semi-rigid hammertoe deformity,
- ▶ revision of failed arthroplasty or arthrodesis,
- ▶ 2nd toe shortening.

CONTRAINDICATIONS

- ▶ The implant should not be used in a patient who has currently, or who has history of:
 - ▶ acute or chronic systemic inflammations,
 - ▶ active infections,
 - ▶ sensitivity/allergies to the implant materials.

SURGICAL TECHNIQUE #1

WITHOUT GUIDE WIRE (DUAFIT® 0° · 10° · 17°)

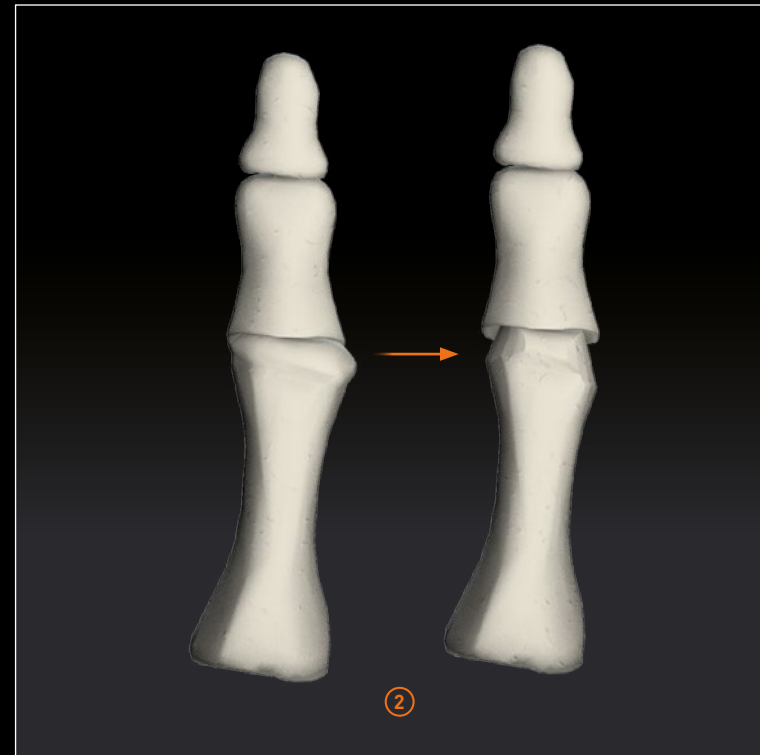


In2Bones® as the manufacturer of this device, does not practice medicine. The surgeon who performs any implant procedure is responsible for determining and using the appropriate surgical techniques for implanting the device in each patient. This Surgical Technique Manual is furnished for information purposes, as an aid to use properly the device and its dedicated instruments.

1 - INCISION



- ▶ Make incision on the dorsal surface of PIP joint in the flexion folds. ①
- ▶ Excision of corn is made at this stage.
- ▶ Perform skin and extensors sections at the same time.
 - ▶ Dissect lateral ligaments insertions on P1 condyles in such a way that the head of P1 can be exposed.



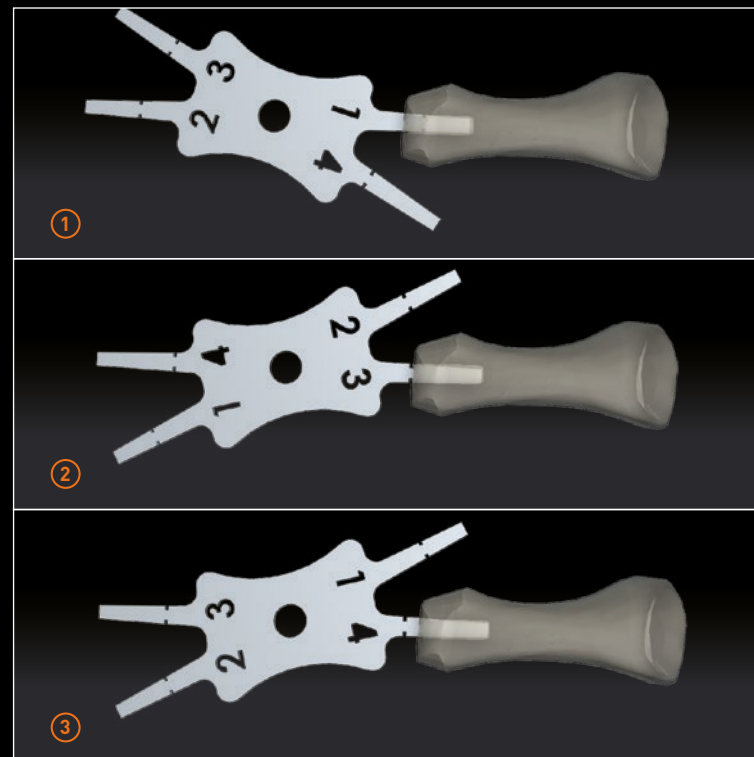
- ▶ Remove the phalangeal head right under the condyles.
- ▶ Shape P1 in arrow with a rongeur. ②
- ▶ Resect soft tissue around P2 while protecting the flexor tendon and pedicles.
- ▶ Remove cartilage and subchondral bone to expose the spongy bone.

2 - PROXIMAL PHALANX PREPARATION



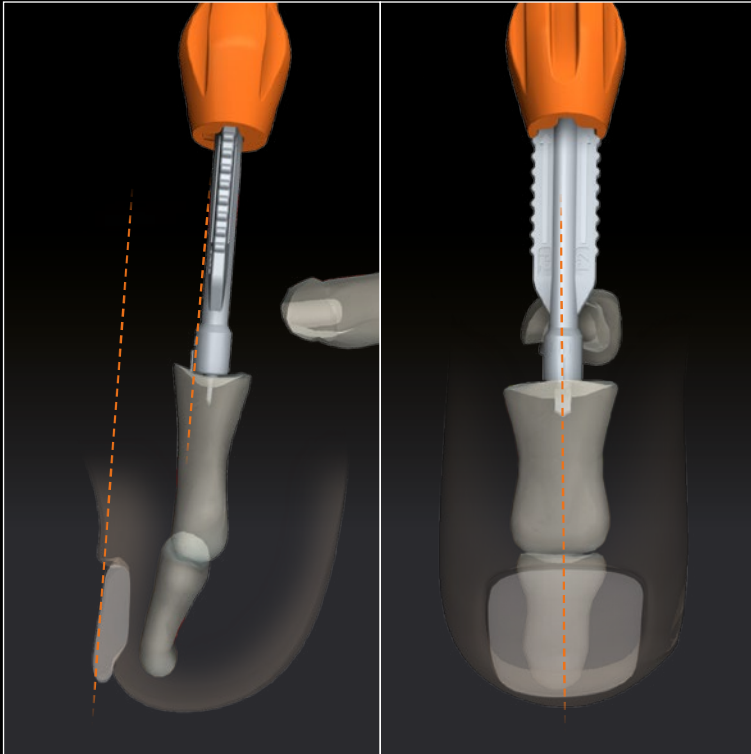
- ▶ Create a pilot hole in the intramedullary canals of the proximal phalanx with the DuaFit® proximal shaper.
- ▶ In case of a narrow intramedullary canal, extra reaming might be necessary. In that case use a straight burr at low speed (5/7000 RPM).
- ▶ At this stage, size of the implant can be defined.

3 - IMPLANT SIZE



- ▶ Introduce the different sizers in the proximal phalanx in order to determine the implant size. Start with size 1. The distal tip of the sizer must be in contact with the isthmus.
- ▶ If the laser mark does not appear, try a bigger size. ①
- ▶ If the laser mark can be seen, choose the corresponding size. ②
- ▶ In case where P1 would be in between 2 sizes, prefer the smaller size. ③

4 - MIDDLE PHALANX PREPARATION

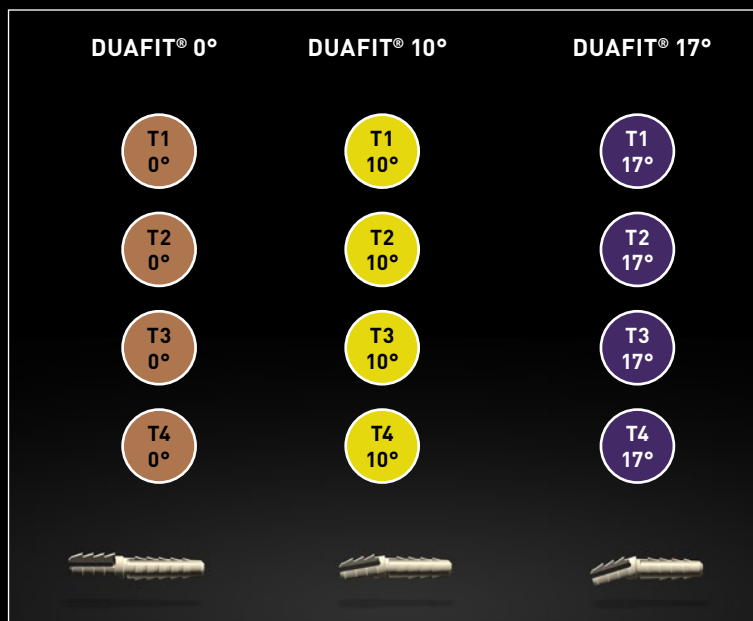


- ▶ While maintaining P2, insert the distal shaper to create one slot in spongy bone.
- ▶ In order to avoid any adverse rotating effect, the slot must be performed in the same plan as the nail.



- ▶ The distal shaper has been designed to prepare the slot in a soft bone, hence ensuring satisfactory stability.
- ▶ In a hard bone, it is necessary to repeat introduction of the shaper several times, slightly changing its position between one insertion and another, to create a larger slot.
- ▶ Should the implantation be difficult despite this bone preparation, it is then possible to create a second slot with the shaper, centered and perpendicular to the first slot, to allow an easier insertion of the dorsal stem. ①
- ▶ One should also check that resection at the base of P2 is adequate, with no subchondral bone left.

5 - IMPLANT CHOICE



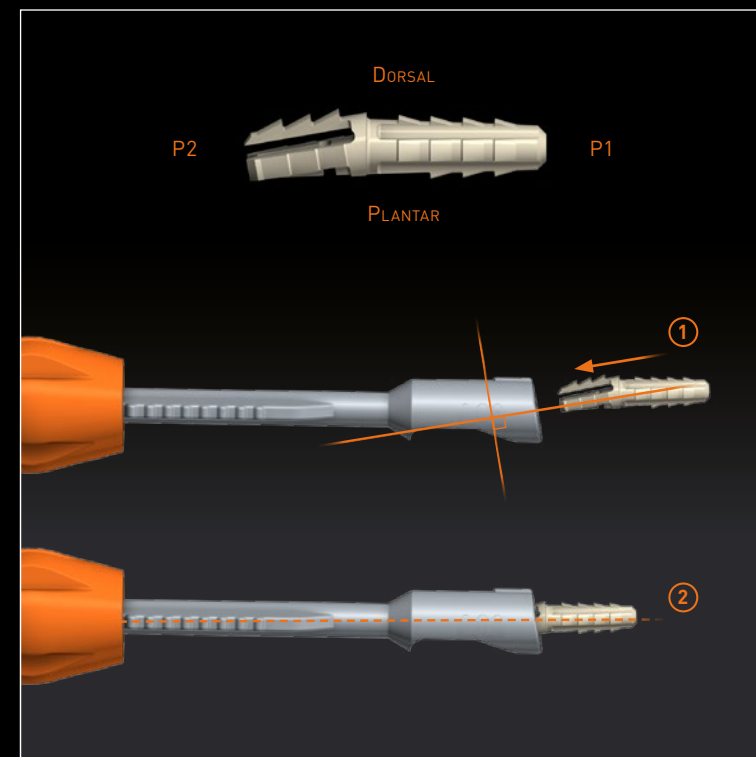
- ▶ Select appropriate implant angulation and size.
- ▶ Remove outer sleeve, open outside tube and hold out the inner tube to the scrub nurse.

6 - INSERTION STRATEGY

- ▶ Once P1 is prepared, depending upon the angle of the implant chosen and the use (or not) of a guide wire, the surgeon may choose two different surgical options.
- ▶ For DuaFit® 0, 10, 17° without the use of the K Wire guide, the implant may be positioned in P1 first.
- ▶ For DuaFit® 0° with the use of K-wire guide, it is required to insert the distal part of the implant in P2 first, then introduce the proximal part in P1.

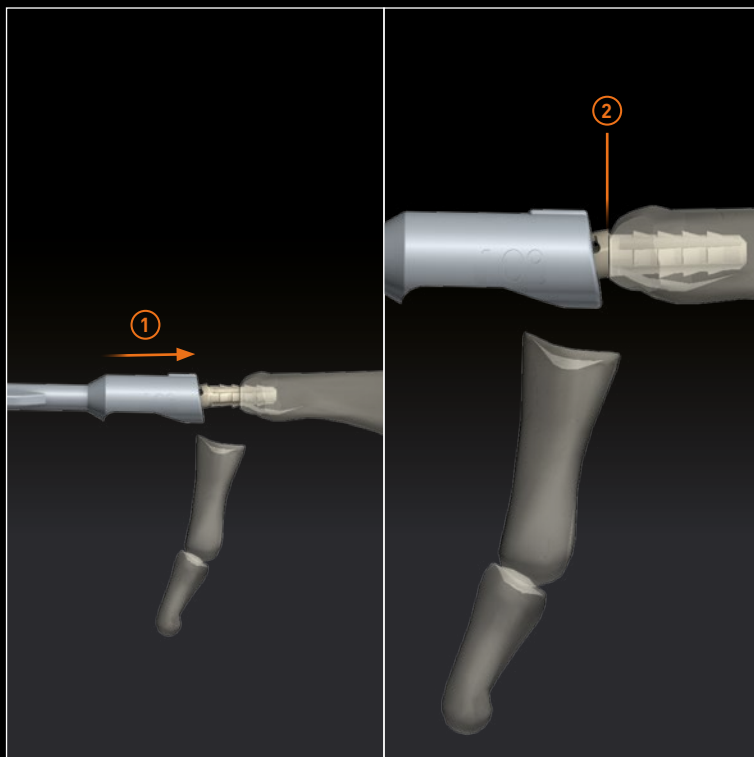
For surgical procedure adapted to the introduction of a DuaFit 0° with a K-wire guide, read pages starting p14 ▶

7 - ASSEMBLY OF THE IMPLANT WITH THE HOLDER

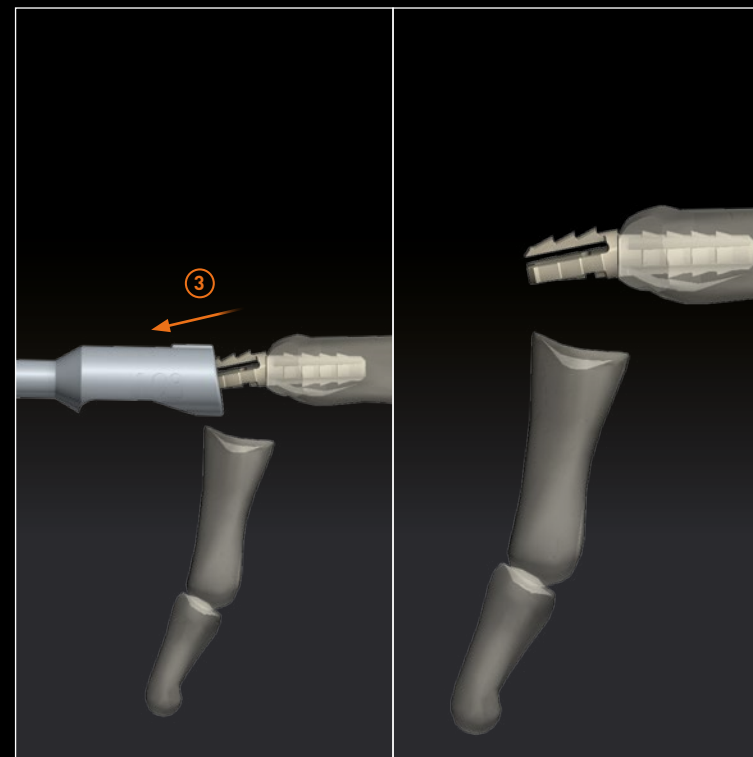


- ▶ Insert the distal portion (P2) of the implant in the holder.
- ▶ The holder shows a mark "up" indicating the dorsal aspect of the phalanx.
- ▶ The dorsal portion of P2 should be presented perpendicular to the surface of the holder. ①
- ▶ The implant is slid inside the holder.
- ▶ Once inserted, the proximal portion of the implant is in the axis of the holder. ②

8 - INSERT THE IMPLANT IN THE PROXIMAL PHALANX



- ▶ Present the implant so that the indication “Up” on the holder is aligned with the dorsal face of P1. ①
- ▶ Introduce the implant ② up to the ring (junction between proximal and distal parts of the implant) and remove the holder. The holder should be removed from the implant axially. ③
- ▶ It is not necessary to impact the implant.
- ▶ In the case where the implant remains prominent, it is recommended to remove it. Then using a straight percutaneous burr diameter 2.0mm, ream slightly the isthmus. The implant can be represented.



- ▶ In order to insert the implant without difficulty in P1, it is recommended not to perform any surgical act on the metatarsal head (such as DMMO, Weil, or resection of the heads).
- ▶ The presence of an intact metatarsal head ensures a good wall support on the phalanx at the impaction.

9 - INTRODUCTION OF THE IMPLANT IN THE MIDDLE PHALANX



- ▶ The middle phalanx is then presented axially on the implant and pressed until the two phalanges are in contact .
- ▶ It is possible, if P1 has been shaped in an arrow shape to impact P1 into P2.

10 - CLOSURE

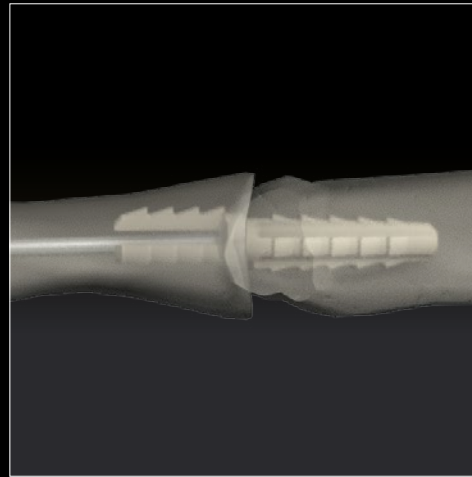
- ▶ The closure is done by total points including the skin and the extensor.

11 - REMOVAL

- ▶ Should removal of the implant be required :
- ▶ Expose the proximal interphalangeal joint. Distract the joint space until the distal blades of the Duafit implant are exposed.
- ▶ Using surgical Forceps, grasp the distal side of the implant to remove it from the middle phalanx.
- ▶ Then, back implant out of the proximal phalanx using surgical forceps.

SURGICAL TECHNIQUE #2

WITH GUIDE WIRE (DUAFIT® 0°)

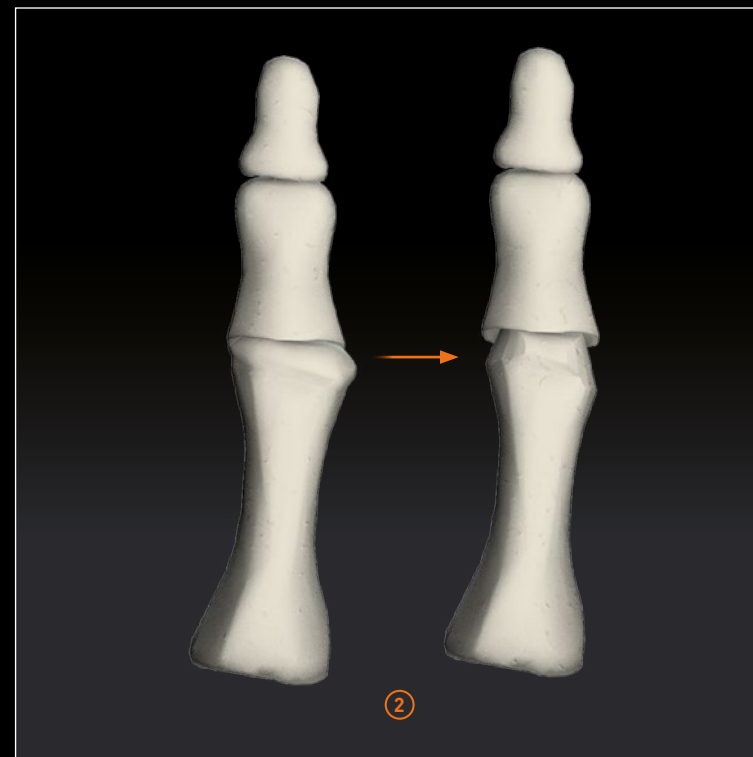


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 - ▶ Dissect lateral ligaments insertions on P1 condyles in such a way that the head of P1 can be exposed.



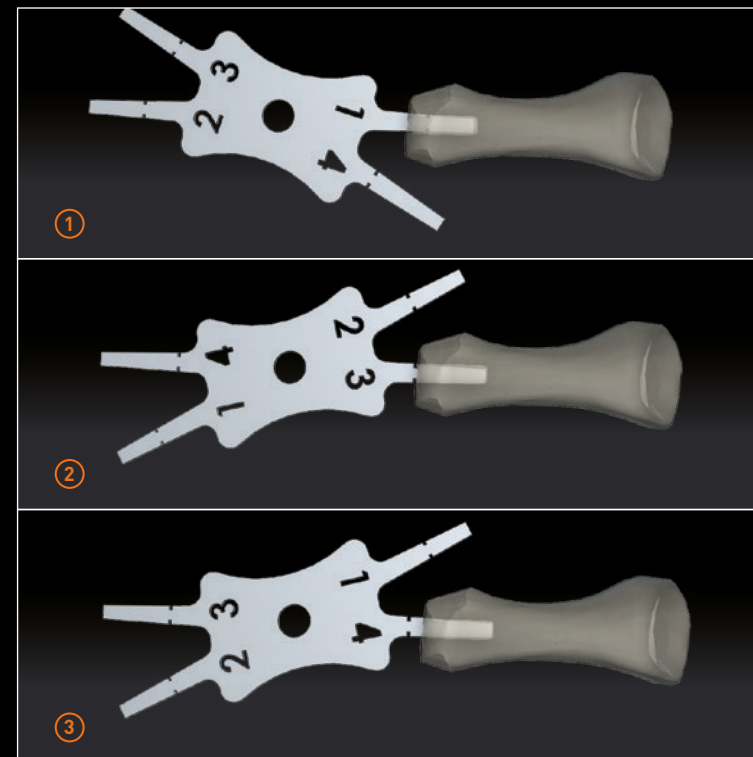
- ▶ Remove the phalangeal head right under the condyles.
- ▶ Shape P1 in arrow with a rongeur. ②
- ▶ Resect soft tissue around P2 while protecting the flexor tendon and pedicles.
- ▶ Remove cartilage and subchondral bone to expose the spongy bone.

2 - PROXIMAL PHALANX PREPARATION



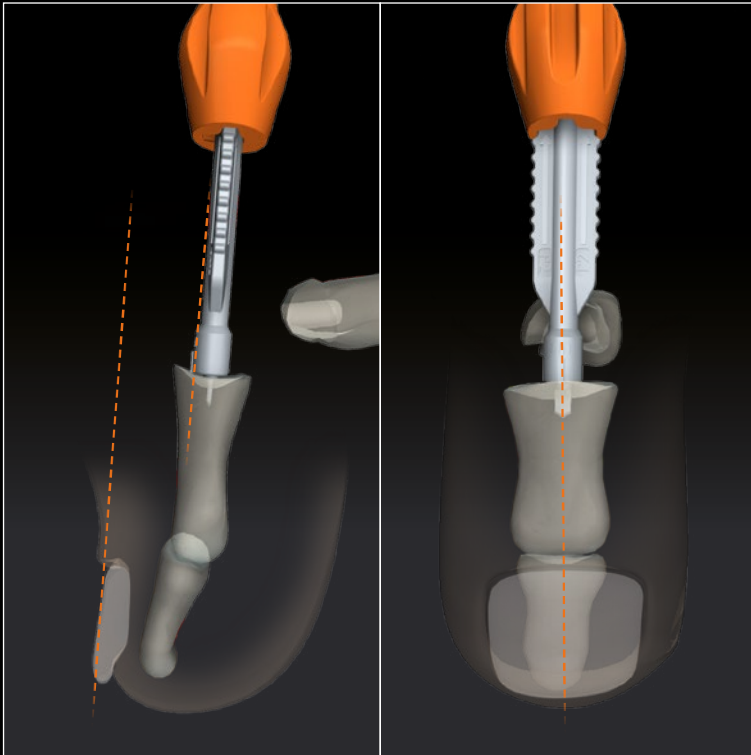
- ▶ Create a pilot hole in the intramedullary canals of the proximal phalanx with the DuaFit® proximal shaper.
- ▶ In case of a narrow intramedullary canal, extra reaming might be necessary. In that case use a straight burr at low speed (5/7000 RPM).
- ▶ At this stage, size of the implant can be defined.

3 - IMPLANT SIZE

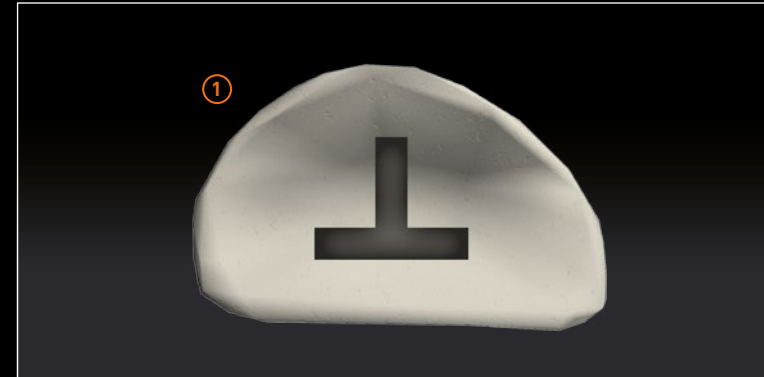


- ▶ Introduce the different sizers in the proximal phalanx in order to determine the implant size. Start with size 1. The distal tip of the sizer must be in contact with the isthmus.
- ▶ If the laser mark does not appear, try a bigger size. ①
- ▶ If the laser mark can be seen, choose the corresponding size. ②
- ▶ In case where P1 would be in between 2 sizes, prefer the smaller size. ③

4 - MIDDLE PHALANX PREPARATION (1/2)

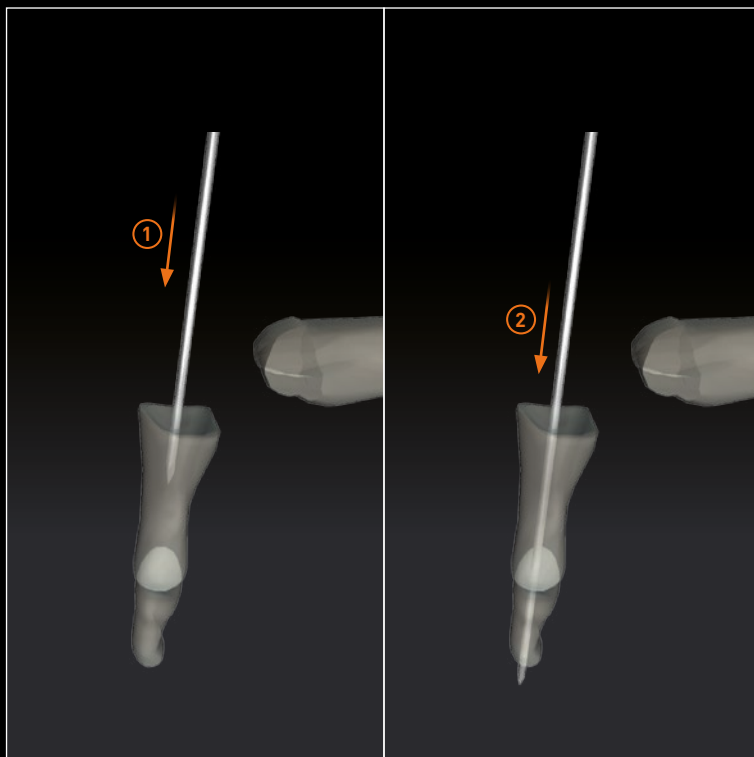


- ▶ While maintaining P2, insert the distal shaper to create one slot in spongy bone.
- ▶ In order to avoid any adverse rotating effect, the slot must be performed in the same plan as the nail.

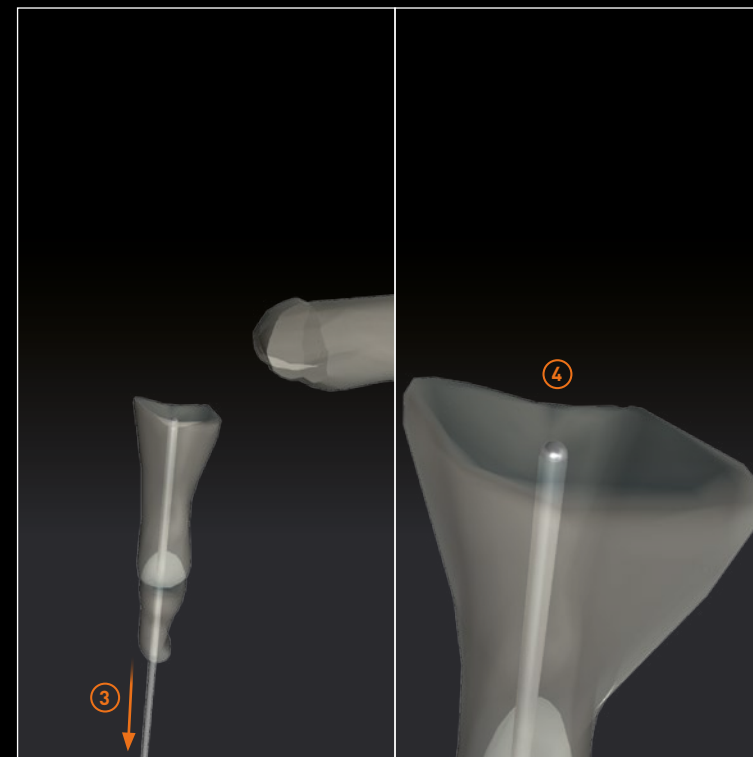


- ▶ The distal shaper has been designed to prepare the slot in a soft bone, hence ensuring satisfactory stability.
- ▶ In a hard bone, it is necessary to repeat introduction of the shaper several times, slightly changing its position between one insertion and another, to create a larger slot.
- ▶ Should the implantation be difficult despite this bone preparation, it is then possible to create a second slot with the shaper, centered and perpendicular to the first slot, to allow an easier insertion of the dorsal stem. ①
- ▶ One should also check that resection at the base of P2 is adequate, with no subchondral bone left.

4 - MIDDLE PHALANX PREPARATION (2/2)

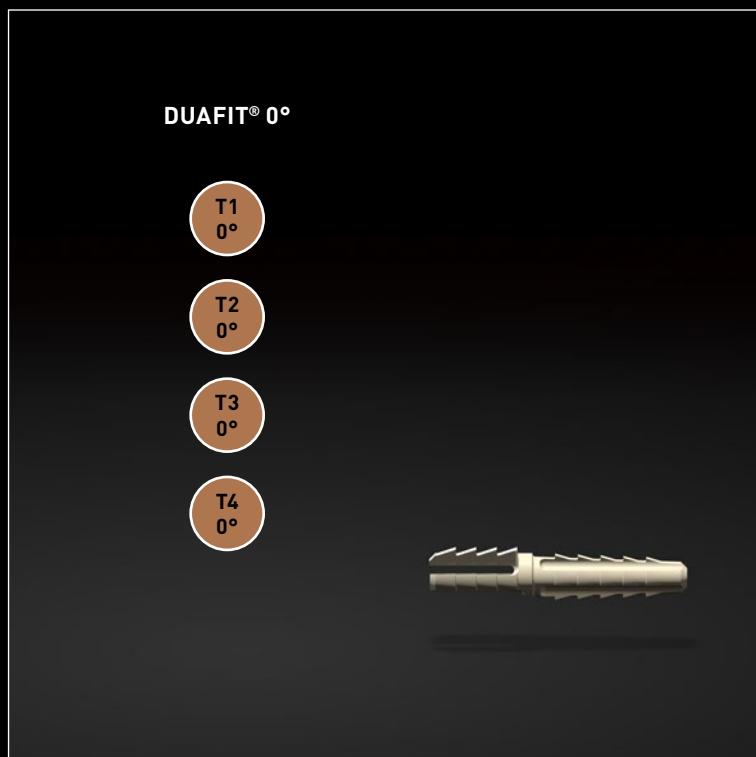


- ▶ Insert the extremity of the guide wire into the middle phalanx along its central axis ①. Verify the correct position of the guide wire with dorsal-plantar and medial-lateral fluoroscopy views. After the position has been verified, continue to drive the guide wire distally through both middle and distal phalanges until it exits the toe ②.



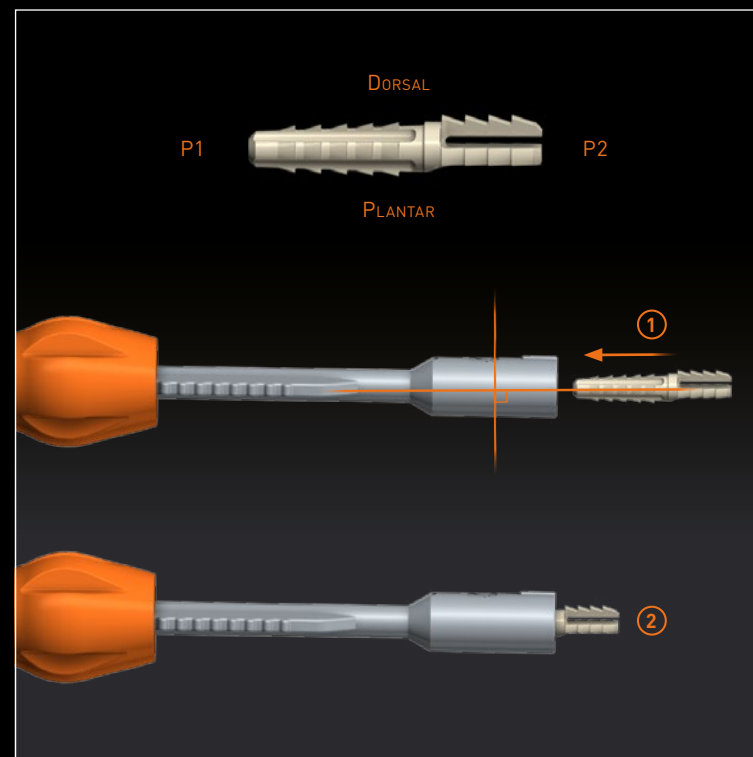
- ▶ Continue to drive the guide wire distally ③ (by engaging the wire driver's collet on the distal end of the guide wire and pulling) until the tip end of the wire just contacts the cut surface of the middle phalanx ④.

5 - IMPLANT CHOICE



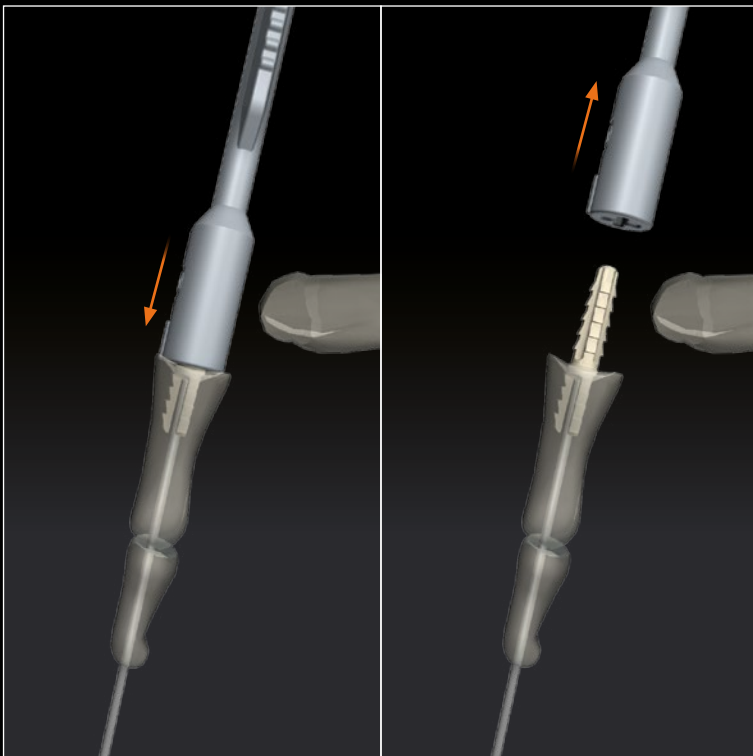
- ▶ Select appropriate implant angulation and size.
- ▶ Remove outer sleeve, open outside tube and hold out the inner tube to the scrub nurse.

6 - ASSEMBLY OF THE IMPLANT WITH THE HOLDER



- ▶ Insert the proximal portion (P1) of the implant in the holder.
 - ▶ The holder shows a mark "up" indicating the dorsal aspect of the phalanx.
 - ▶ The implant is slid inside the holder ①.
- ▶ Once the proximal portion of the implant is inserted in the holder, the distal portion is ready for insertion in the middle phalanx ②.

7 - INSERT THE IMPLANT IN THE MIDDLE PHALANX



- ▶ Present the implant with the holder on the extremity of the guide wire, reading the indication "Up" on the holder aligned with the dorsal face of P2
- ▶ The K-Wire will help to guide the implant in the middle phalanx P2.
- ▶ Introduce the implant up to the ring (junction between proximal and distal parts of the implant).

8 - INTRODUCTION OF THE IMPLANT IN THE PROXIMAL PHALANX



- ▶ The middle phalanx and Duafit implant are then presented axially on the first phalanx, so that the proximal part of the implant is inserted in the intramedullary canal. The toe is pressed until the two phalanges are in contact .
- ▶ It is possible, if P1 has been shaped in an arrow shape to impact P1 into P2.

9 - GUIDE WIRE POSITIONNING



- ▶ Drive the conical tip of the guide wire proximally through the implant and back into the proximal phalanx.
- ▶ **Optional** : Based on the surgeon's discretion, the guide wire may be driven back to the metatarsal to stabilize the MTP joint. The guide wire fixation of the toe to the metatarsal can be left in place for the initial recovery period to allow the soft tissues to heal and prevent MTP joint subluxation. Optimal fixation is obtained by leaving the wire in the implant.

10 - CLOSURE

- ▶ The closure is done by total points including the skin and the extensor.

11 - REMOVAL

- ▶ Should removal of the implant be required :
- ▶ Expose the proximal interphalangeal joint. Distract the joint space until the distal blades of the Duafit implant are exposed.
- ▶ Using surgical Forceps, grasp the distal side of the implant to remove it from the middle phalanx.
- ▶ Then, back implant out of the proximal phalanx using surgical forceps.

IMPLANTS

► DuaFit® PIP 0°

A60 SP001	DUAFIT® PIP 0° PEEK - Sterile	Size 1
A60 SP002	DUAFIT® PIP 0° PEEK - Sterile	Size 2
A60 SP003	DUAFIT® PIP 0° PEEK - Sterile	Size 3
A60 SP004	DUAFIT® PIP 0° PEEK - Sterile	Size 4

► DuaFit® PIP 10°

A60 SP101	DUAFIT® PIP 10° PEEK - Sterile	Size 1
A60 SP102	DUAFIT® PIP 10° PEEK - Sterile	Size 2
A60 SP103	DUAFIT® PIP 10° PEEK - Sterile	Size 3
A60 SP104	DUAFIT® PIP 10° PEEK - Sterile	Size 4

► DuaFit® PIP 17°

A60 SP171	DUAFIT® PIP 17° PEEK - Sterile	Size 1
A60 SP172	DUAFIT® PIP 17° PEEK - Sterile	Size 2
A60 SP173	DUAFIT® PIP 17° PEEK - Sterile	Size 3
A60 SP174	DUAFIT® PIP 17° PEEK - Sterile	Size 4

INSTRUMENTS

A06 10401	DUAFIT® 17° / 10° / 0° - SINGLE USE INSTRUMENTS SET
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RECOMMANDATION

- ▶ It is recommended to carefully read the instructions for use available in the package insert.


DEVICES

- ▶ Implants :
 - ▶ DuaFit® Implant: CE Class IIb - CE0499
- ▶ Instruments :
 - ▶ Single use instruments kits - CE class IIa

REIMBURSEMENT

- ▶ Reimbursement may vary from country to country. Check with local authorities.

MANUFACTURER

- ▶  In2Bones SAS
28, chemin du Petit Bois
69130 Ecully – FRANCE

Tél : +33 (0)4 72 29 26 26

Fax : +33 (0)4 72 29 26 29

DOCUMENT

- ▶ Reference : ST-DuaFit PIP-En-122014
- ▶ Revision date: 12/2014
- ▶ Version 02



Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

Always refer to the appropriate instructions for use for complete clinical instructions.

Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

WARNING: Applicable laws restrict these products to sale by or on the order of a physician.

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