DuaFit[®]

PROXIMAL INTERPHALANGEAL IMPLANT





A GLOBAL EXTREMITY COMPANY

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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.

Contra-Indications

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.

DuaFit® PRODUCT DESCRIPTION

- 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.







Proximal design

Radio transparent

- PEEK-OPTIMA® is radio transparent.

This enables control of bone consolidation.

 The conical shape of the implant is designed to provide 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.

Single use instruments

- PROXIMAL SHAPER 1 is used to prepare the medullary canal and to center the implant in the proximal phalanx P1. It is conical to respect the shape of the canal. The laser marks are used to define the implant size.
- DISTAL SHAPER ② allows to prepare the DuaFit print in the middle phalanx P2 without adversely affecting the bone stock. The reverse «T» shape reproduces the design of the implant.
- HOLDER ③ The holder, specific to each angle of implant, enables to engage and impact the DuaFit axially.
- K-WIRE ④ Ø1.0mm Lg100mm, Kwire double trochar.
- HANDLE (5)









DuaFit[®] 0°/ 10°/ 17° SURGICAL TECHNIQUE #1 WITHOUT GUIDE WIRE

In2Bones[®] as the manufacturer of this device, does not practice medicine. The surgeon who performs any implants 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.

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.

Resect soft tissue around P2 while protecting the flexor tendon and pedicules.

Remove cartilage and subchondral bone to expose the spongious 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.

3 - Implant size



At this stage, size of the implant can be defined. Insert the shaper until the the distal tip gets in contact with the isthmus.

Read the size of the implant directly on the shaper.



DuaFit[®] 0°/ 10°/ 17° SURGICAL TECHNIQUE #1 WITHOUT GUIDE WIRE

4 - Middle Phalanx preparation



While maintaining P2, insert the distal shaper (with the «UP» mark oriented dorsally) to create one slot in spongious bone.

In order to avoid any adverse rotating effect, the slot must be performed in the same plan as the nail.



The shaper, correctly orientated with the «UP» mark dorsally, reproduces the implant reverse « T » shape to allow a better fitting of the implant in P2.

The distal shaper has been designed to prepare the slot in a soft bone, hence ensuring satisfactory stability.

In a hard bone, it might be necessary to repeat introduction of the shaper several times.

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.

Size	Total Length	<mark>D</mark> Distal Length	P Proximal Length
01	11.0 mm	4.5 mm	6.5 mm
02	14.0 mm	5.5 mm	8.5 mm
03	17.0 mm	7.0 mm	10.0 mm
04	20.0 mm	8.0 mm	12.0 mm
1L	13.5 mm	7.0 mm	6.5 mm
2L	15.5 mm	7.0 mm	8.5 mm



RECOMMENDATION FOR SIZE SELECTION

During bone preparation:

- In case of hard and dense bone select a standard size.

- In case of soft bone select size 1L or 2L instead of size 1 or 2.



6 - Insertion

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 surgical procedure adapted to the introduction of a DUAFIT 0° WITH A K-WIRE GUIDE, read pages starting p12 →

7 - Assembly of the implant with the holder





With the Holder tab up, insert the shorter, (P2) distal end of the Implant into Holder up to the transition ring (junction between proximal and distal aspects).

The Holder has a **RAISED TAB** corresponding to the dorsal aspect of the Implant and phalanx.

Position the implant in such way that the shorter (P2) distal end is perpendicular to the holder face.

When properly placed in the holder for the angled Duafit[®], the [P1] proximal end of the Implant is aligned with the holder ready for insertion.



8 - Implant insertion in proximal phalanx

For clear access, position the dorsal surface of the distal phalanx (P2) perpendicular to the holder. With the Implant /Holder tab up, insert the Implant ⁽¹⁾ to the transition ring ⁽²⁾ and remove the Holder directly on axis with implant ⁽³⁾.

Secure insertion should NOT require impacting the Implant / Holder. If the Implant remains prominent, remove and ream the insertion point with a 2.0mm drill. The Implant can then be reinserted.

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 - Implant insertion in middle phalanx



Manually reduce middle phalanx over the distal aspect of the Implant and compress until the two phalanges are in flush contact and implant is fully seated.

10 - 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.

DuaFit® 0° SURGICAL TECHNIQUE #1 WITH GUIDE WIRE

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1 - Incision



Make incision on the dorsal surface of PIP joint in the flexion folds.

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.

Resect soft tissue around P2 while protecting the flexor tendon and pedicules.

Remove cartilage and subchondral bone to expose the spongious 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.

3 - Implant size



At this stage, size of the implant can be defined. Insert the shaper until the the distal tip gets in contact with the isthmus.

Read the size of the implant directly on the shaper.



4 - Middle phalanx preparation







While maintaining P2, insert the distal shaper (with the «UP» mark oriented dorsally) to create one slot in spongious bone.

In order to avoid any adverse rotating effect, the slot must be performed in the same plan as the nail.

The shaper, correctly orientated with the «UP» mark dorsally, reproduces the implant reverse « T » shape to allow a better fitting of the implant in P2.

The distal shaper has been designed to prepare the slot in a soft bone, hence ensuring satisfactory stability.

In a hard bone, it might be necessary to repeat introduction of the shaper several times.

One should also check that resection at the base of P2 is adequate, with no subchondral bone left.

Drive the K-wire into the center of the P2. Verify the correct position with dorsal-plantar and mediallateral fluoroscopy. With the position verified, continue to drive the K-wire distally through P2 and P3, the middle AND distal phalanx, until it exits the P3 by 4-5mm ^①. Release the driver and re-engage on the distal K-wire, pulling it thru until the proximal end protrudes 4-5mm from prepared proximal surface of the P2 2. Release the Driver.



5 - Implant choice



Select appropriate implant size.

Size	Total Length	D Distal Length	P Proximal Length
01	11.0 mm	4.5 mm	6.5 mm
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03	17.0 mm	7.0 mm	10.0 mm
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2L	15.5 mm	7.0 mm	8.5 mm



RECOMMENDATION FOR SIZE SELECTION

During bone preparation:

- In case of hard and dense bone select a standard size.
- In case of soft bone select size 1L or 2L instead of size 1 or 2.

6 - Assembly of the implant with the holder

Insert the proximal portion (P1) of the implant in the holder.

- The Holder has a RAISED TAB corresponding to the dorsal aspect of the Implant and phalanx.
- The implant is slid inside the holder \bigcirc .

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 into P2 middle phalanx



For clear access, position the dorsal surface of P2 perpendicular to proximal phalanx. With the Implant /Holder tab facing the dorsal aspect of P2, insert the Implant OVER the end of the K-wire protruding from the proximal end of the middle phalanx using the K-wire to guide insertion. Insert up to the transition ring.

8 - Insertion into P1 proximal phalanx



Grasping the middle phalanx / DuaFit combined, manually reduce the proximal aspect of the DuaFit into the proximal phalanx intramedullary canal and compress until the two phalanges are in flush contact and the Implant is fully seated.

9 - K-wire positioning



Re-engage the driver on the distal K-wire and drive back into the proximal phalanx through the implant.

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 - 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.

DuaFit® ORDERING INFORMATIONS

IMPLANTS

Color	Designation	Size	Ref
	DUAFIT® PIP 0° PEEK - sterile	1	A60 SP001
	DUAFIT® PIP 0° PEEK - sterile	2	A60 SP002
	DUAFIT® PIP 0° PEEK - sterile	3	A60 SP003
	DUAFIT® PIP 0° PEEK - sterile	4	A60 SP004
	DUAFIT® PIP 0° PEEK - sterile	1L	A60 SP005
	DUAFIT® PIP 0° PEEK - sterile	2L	A60 SP006

Color	Designation	Size	Ref
	DUAFIT® PIP 10° PEEK - sterile	1	A60 SP101
	DUAFIT® PIP 10° PEEK - sterile	2	A60 SP102
	DUAFIT® PIP 10° PEEK - sterile	3	A60 SP103
	DUAFIT® PIP 10° PEEK - sterile	4	A60 SP104
	DUAFIT® PIP 10° PEEK - sterile	1L	A60 SP105
	DUAFIT® PIP 10° PEEK - sterile	2L	A60 SP106

Color	Designation	Size	Ref
	DUAFIT® PIP 17° PEEK - sterile	1	A60 SP171
	DUAFIT® PIP 17° PEEK - sterile	2	A60 SP172
	DUAFIT® PIP 17° PEEK - sterile	3	A60 SP173
	DUAFIT® PIP 17° PEEK - sterile	4	A60 SP174
	DUAFIT® PIP 17° PEEK - sterile	1L	A60 SP175
	DUAFIT [®] PIP 17° PEEK - sterile	2L	A60 SP176







INSTRUMENTS

Designation	Ref
DUAFIT 0° / 10° / 17°	A06 10401
SINGLE USE INSTRUMENT SET*	

*This set contains the following instruments: Proximal shaper / Distal shaper / Holders (one for each graduation : 0°, 10° and 17°) / K-wire / Handle





DuaFit[®] REGULATORY INFORMATIONS

RECOMMANDATION

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

DEVICES

CE Classification (Directive MDD 93/42/EC)

- Implants: CE Class Ilb CE2797
- Single use instruments set : Class IIa CE2797

REIMBURSEMENT

Reimbursement may vary from countries to countries. Check with local authorities.

MANUFACTURER

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DOCUMENT

Reference : ST-DIG-DUAFIT-EN-092020

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.

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