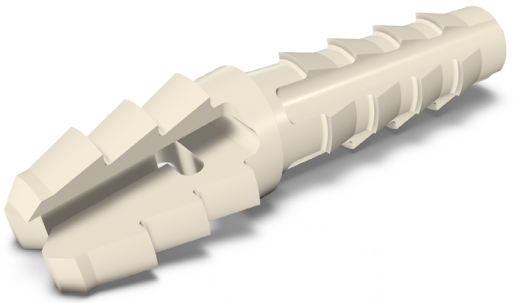
DuaFit®

PROXIMAL INTERPHALANGEAL IMPLANT



Legal manufacturer

In2Bones SAS
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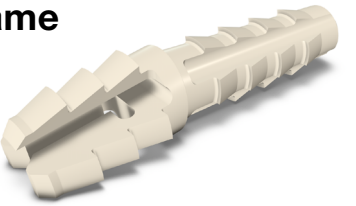
Single Registration Number is: FR-MF-000005246

Device trade name

DUAFIT®
Proximal
interphalangeal
implant



Description of the device

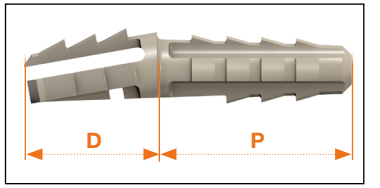
The DUAFIT® implant is an intramedullary implant designed to act as a bone fastener for proximal interphalangeal arthrodesis of the lesser toes.

The implant is used to get a joint immobilization between your first (proximal) and second (intermediate) phalanges of the toes.

Such outcome can be expected for the treatments of lesser toe deformities *(see further details in paragraph "Indications and intended patient population")*.

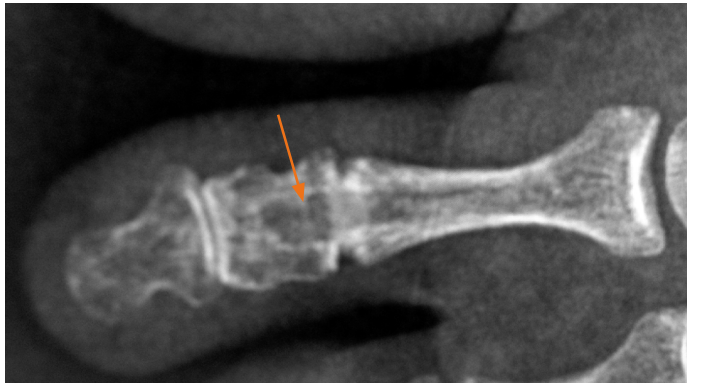
The main features of the DUAFIT® implant are as follows:

- A proximal taper **P** with barbs, intended to be implanted in your proximal phalanx,
- A distal blade **D**, intended to be implanted in your middle phalanx.



The DUAFIT® implant is available in several sizes, with different lengths and angles so your surgeon can choose the best implant considering your anatomy and your bony quality.

The DUAFIT® implant is made of PEEK-OPTIMA®, polymer from Invibio® recognized for its mechanical and radiolucent properties. The implant is not visible under radiological examination: it allows bone fusion post-operative follow-up with X-rays.



Materials / Substances

The DUAFIT® implant is made of PEEK according to standard ASTM F2026.

The DUAFIT® implant is an implant in permanent contact (i.e. greater than 30 days) with bone. Appropriate biological safety evaluation was performed in compliance with relevant standards in force, ensuring biocompatibility of these implants. However, sensitivity / allergic reactions cannot be anticipated and are patient specific. The implant should not be used if you currently have or have an history of sensitivity / allergies to the implant materials listed above.

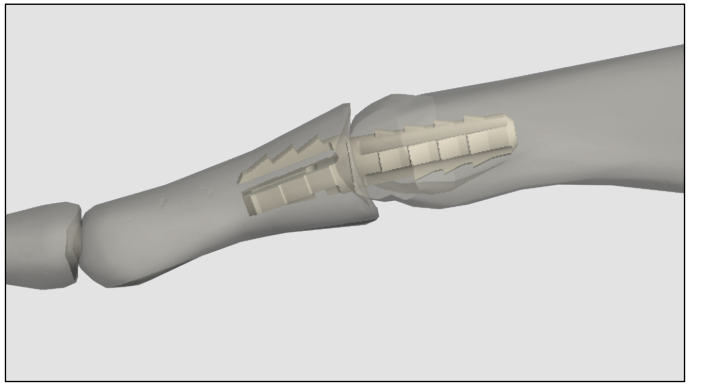
The devices do not contain any CMR (carcinogenic, mutagenic or toxic for reproduction) or endocrine-disrupting substances referred to in Section 10.4.1 of Regulation (UE) 2017/745 Annex I.

Indications and intended patient population

The DUAFIT® implant is intended to be used in adult patients in conditions such as:

- rigid or semi-rigid deformities of the first interphalangeal joint (claw, hammer or mallet toe),
- revision of failed arthroplasty or arthrodesis,
- second toe shortening.

The DUAFIT® implant is intended to be used for fixation of proximal interphalangeal joint arthrodesis of the lesser toes and treat the above-mentioned conditions. It maintains the two bone fragments during the time necessary to obtain fusion between the two phalanges. More simply said, this is an implant that your surgeon may want to use to block the problematic joint and fuse the first two phalanges in order to realign or shorten the toe. The surgery with the DUAFIT® implant allows elimination of painful pressure points and improved foot function and foot alignment once in place.



Contraindications and/or limitations

The DUAFIT® implant should not be used in a patient who currently ha, or who has history of:

- acute or chronic inflammations, whether local or systemic,
- active infections,
- sensitivity/allergies to the implant materials (PEEK).

Warnings and precautions

Before implantation, your physician shall determine if the device is appropriate for you if you have any of the following conditions:

- Lack of good general physical condition,
- Bone pathologies that may compromise the rigidity of the implant fixation (examples include: osteoporosis, acute cystic developments, acute osteopenia, bone tumor, etc…),
- Use of steroid derivatives, chemotherapy,... etc,
- Drug and/or alcohol and/or smoke addiction and/or abuse,
- Obesity,
- Compromised wound healing,
- Vascular disorder,
- If you are unwilling or unable to comply with postoperative instructions.

Detailed instructions on the use and limitations of the device should be given to you by your surgeon.

If partial weight-bearing is recommended or required, you must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident.

You are encouraged to report to your surgeon any unusual changes of the operated extremity. If evidence suggests loosening of the implant (particular pain and progressive changes in the radiographs), your surgeon may advise an intensified schedule of check-ups and give you new warning and instructions regarding further activity restrictions.

You are encouraged to receive prompt medical attention for any infection that could occur, whether at your operated-member level or elsewhere in the body.

MRI safety information

Before any medical examination, you shall systematically mention that you are implanted with a surgical orthopaedic implant.

Non-clinical testing and electromagnetic simulations were performed to evaluate the orthopedic implants from In2Bones® under MRI conditions. The tests demonstrated that the DUAFIT® implant is MR safe and poses no known hazards in all MR environments.

Removal of the implant

The implant is intended to be permanent once in place, but your surgeon can decide to remove it if it is deemed necessary.

Remaining risks and undesirable effects

Contact your surgeon if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your surgeon if needed.

The possible side-effects that can be encountered with the device after the surgery are the followings:

- Pain, discomfort or abnormal sensations due to presence of the implant,
- Bending, loosening and/or breakage,
- Migration of the implant position,
- Bone loss due to stress shielding,
- Deformation recurrence, loss of correction,
- Delayed union or pseudarthrosis,
- Tissue irritation (tendon, nerve, soft tissue),
- Infections, hematoma, allergy, thrombosis.

The full list of remaining risks and undesirable side effects can be found in the Summary of Safety and Clinical Performance at: https://ec.europa.eu/tools/eudamed.

Every serious incident that you may experience in relation to the device should be reported without any delay to the manufacturer and, depending on your location, to the:

- European Union: Competent authority of your country https://ec.europa.eu/
- Australia: Therapeutic Goods Administration https://www.tga.gov.au

In2Bones