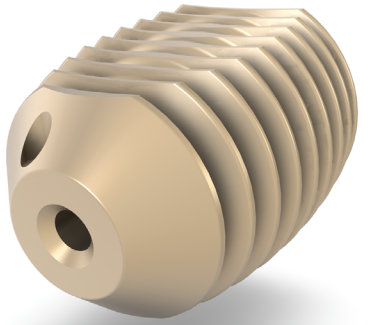
In2Bones

PIT'Stop®

FLAT FOOT ENDORTHESIS



Legal manufacturer

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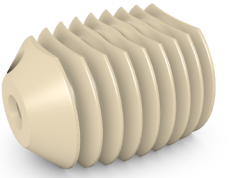
Single Registration Number is: FR-MF-000005246

Device trade name

PIT'Stop system
Endorthesis
Subtalar implant

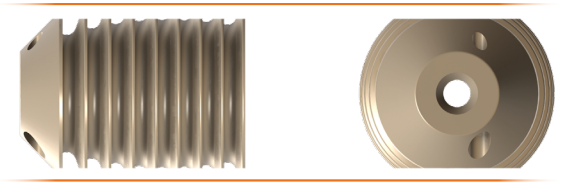


Description of the device

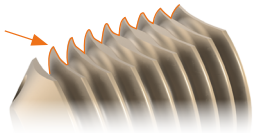
The PIT'Stop® implant is a device used in the treatment of Flat Foot. It is involved in a minimally invasive surgical procedure (called "subtalar arthroereisis") where the implant is positioned in the sinus tarsi, a cylindrical cavity between the talus (heel bone) and calcaneus (ankle bone) on the lateral aspect of the foot.

Its main features are as follows:

- Anatomical flats designed to improve load bearing distribution that may decrease incidence of reactive synovitis (joint lining inflammation) and improve patient tolerance;



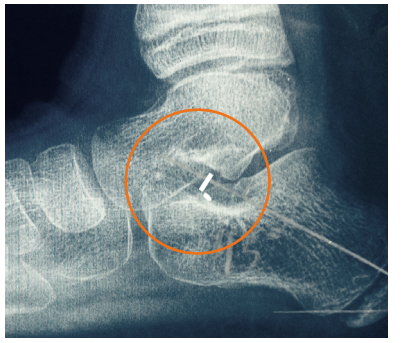
- Flat design for a more balanced weight-bearing forces distribution over the bones;
- Flanges designed to resist expulsion forces so the device can stay in place once implanted.



The PIT'Stop® implant is designed in 7 sizes, from 10mm to 17mm.

The PIT'Stop® implant is made of PEEK-OPTIMA®, polymer from Invibio® recognized for its mechanical and radiolucent properties

Two radiopaque markers are inserted in the PIT'Stop® implant to allow postoperative positioning checking with x-rays.



Materials / Substances

The PIT'Stop® implant is made of PEEK according to standard ASTM F2026 and includes markers made of tantalum according to ASTM F560.

The PIT'Stop® 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 PIT'Stop® implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. Hyperpronation is observed when your talus (ankle bone) slips from its stable position on the calcaneus (heel bone). Most times, hyperpronation is associated with a lower-than-normal arch.

More simply said, PIT'Stop® is a temporary implant that your surgeon may want to use to treat your flatfoot deformity by recreating a normal foot arch.

As per PIT'Stop® Instructions for use, this implant is intended to be used for children, adolescents or adult patients having none of its contraindications and at least one of the following indications:

- Flat foot treatment in children and adolescents
- Congenital flat foot
- Non-successful long term orthopaedic treatment (shoes, insoles…)
- Tarsal coalitions (=abnormal connection of two or more bones in the foot)
- Painfully flat foot
- Supple deformity in posterior tibial tendon dysfunction (=a non rigid flatfoot deformity occurring as a consequence of a dysfunction of a tendon called the posterior tibial tendon)
- Paralytic flat foot
- Subtalar instability (=an instability between the talus (ankle bone) and the calcaneus (heel bone))

Contraindications and/or limitations

The PIT'Stop® implant should not be used in a patient who has currently, or who has history of:

- acute or chronic inflammations, whether local or systemic,
- active infections,
- stiff or fixed deformity of the flat foot,
- flat foot with a forefoot abductus (when the front part of the foot turns inward),
- chronic rupture of the posterior tibial tendon,
- symptomatic arthritis,
- neurological affections (paraplegia…),
- sensitivity/allergies to the implant materials (PEEK and Tantalum).

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,
- 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 warnings 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 PIT'Stop® implants are "MR Conditional": it means that you can be scanned safely in an MR system under specific conditions.

Before an MRI scan involving your foot in which a PIT'Stop® implant is in place, you shall communicate to your healthcare provider that the following conditions should be used:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

Removal of the implant

The PIT'Stop® device is not intended to remain implanted. In the long run, its main role is to limit the hindfoot movements and maintain a proper foot position until the surrounding tendons and ligaments strengthen and adapt so these structures can ensure their stability role and maintain of the plantar arch even after the removal of the implant. Therefore, a second more minor procedure for the removal is necessary. Depending on your case, the PIT'Stop® device should be removed:

- at the end of the growth when used in pediatric patients or
- by 12 months when used in adult patients or
- if pain occurs earlier.

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. Complications may necessitate re-operation, revision or removal surgery.

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:

Possible side-effect reported in the device IFU	Occurrence reported on PIT'Stop study	Occurrence reported for similar devices	Relation in time
Pain, discomfort or abnormal sensations due to presence of the implant	Occasional (5 to 10%)	Frequent (> to 10%)	Early complication – Expected to happen before 6 months post-operatively
Bending, loosening and/or breakage	Almost never (inferior to 0.01%)	Unlikely (1 to 5%)	Late complication – Expected to happen after 6 months post-operatively
Migration of the implant position	Almost never (inferior to 0.01%)	Occasional (5 to 10%)	Early or late complication
Deformation recurrence, inadequate correction	Unlikely (1 to 5%)	Frequent (> to 10%)	Early or late complication
Infections, hematoma, allergy, thrombosis	Almost never (inferior to 0.01%)	Unlikely (1 to 5%)	Early complication
Peroneal and Achilles tendon contracture	Unlikely (1 to 5%)	Unlikely (1 to 5%)	Early complication

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