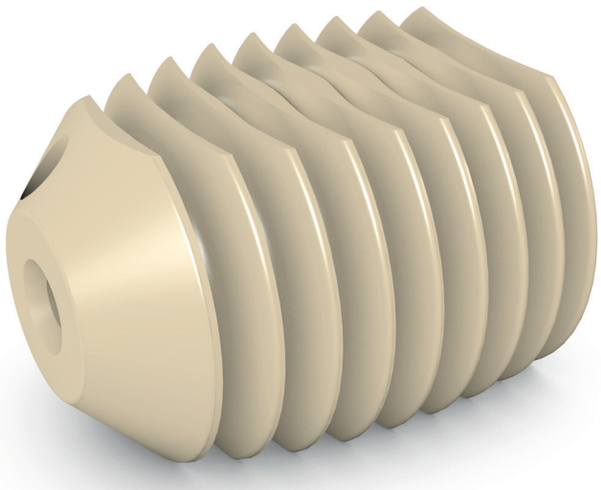
PIT'stop®

FLAT FOOT ENDORTHESIS



The PIT'stop implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint

Made of PEEK-Optima®.
This biocompatible and inert polymer is flexible (radiolucence invisible on X-ray)

The anatomical design with the two symmetrical and flattened sides are to reduce the compressive constraints and to improve distribution of stress

In2Bones

A GLOBAL EXTREMITY COMPANY

BR-DIG-PITSTOP-EN-012022

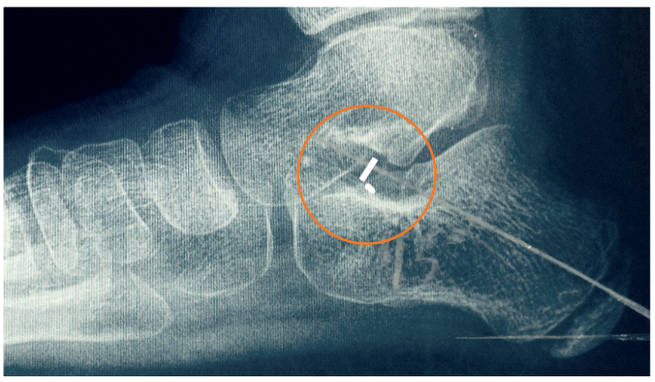
PIT’stop®
FLAT FOOT ENDORTHESIS - PRODUCT DESCRIPTION

Complete range

– A complete range which includes multiple size to adapt all anatomy.

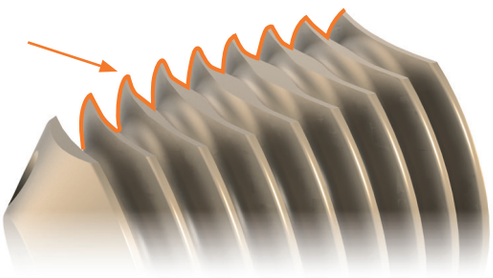
X-Ray markers

Two X-Ray markers made of tantalum, placed at each extremities of the implant to control the position of the implant, per and post operatively.



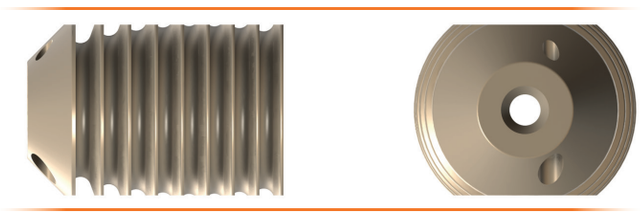
Anti-return flanges

Anti-return flanges, (small blades) are designed to provide primary stability in the Sinus Tarsi.



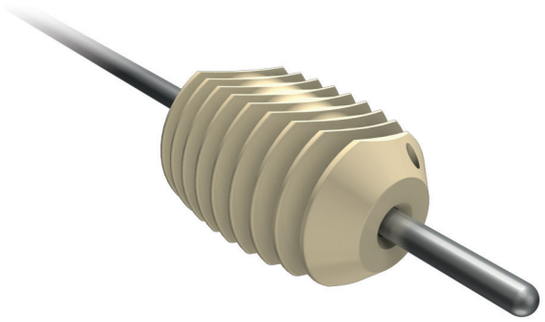
Anatomical shape

The anatomical design with the two symmetrical and flattened sides are to reduce the compressive constraints and to improve distribution of stress. This may help to decrease incidence of reactive synovitis and improve patient tolerance.



Cannulated implant

The PIT’stop® is cannulated to facilitate and secure accurate positioning of the implant over a positionning guide.



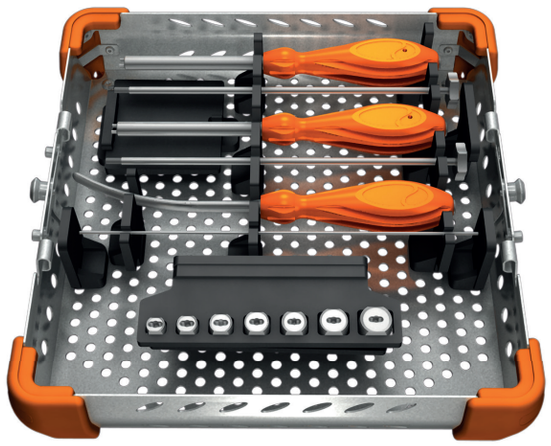
Implant-instrument assembly

The specific bayonet imprint allows a tight assembly between the implant and the instrument. This secure cooperation between implant and instruments provides a good implant drive during final adjustment in surgery.

INSTRUMENTATION

In2bones provides a complete and simple instrumentation set :

- Internal Holder
- External Holder
- Trial implants
- PitStop positioning guide Diam 1.6mm Lg.150mm
- Viladot's lever (optional)



PIT'stop®

FLAT FOOT ENDORTHESIS - ORDERING INFORMATIONS

IMPLANTS

PIT'stop®
Flat Foot Endorthesis

Size	Ref
10 mm	M20 SP010
11 mm	M20 SP011
12 mm	M20 SP012
13 mm	M20 SP013
14 mm	M20 SP014
15 mm	M20 SP015
17 mm	M20 SP017

INSTRUMENTS

Designation	Ref
PIT'stop trial implant - Size 10mm	M02 00011
PIT'stop trial implant - Size 11mm	M02 00021
PIT'stop trial implant - Size 12mm	M02 00031
PIT'stop trial implant - Size 13mm	M02 00041
PIT'stop trial implant - Size 14mm	M02 00051
PIT'stop trial implant - Size 15mm	M02 00061
PIT'stop trial implant - Size 17mm	M02 00071
Viladot's lever	M02 00081
External holder	M02 00091
Internal holder	M02 00101
PitStop positioning guide - Diam. 1.6mm Lg. 150mm	K20 NS150

DESCRIPTION OF THE MEDICAL DEVICE

PIT'stop implants existing in different lengths and diameters.
They are made out of PEEK (Poly Ether Ether Ketone) according to standard ASTM F2026. The PEEK implants include radiopaque markers made out of Tantalum according to ASTM F560 for radiological evaluation.
These medical devices are sold sterile.
Elements sterilized using irradiation have been exposed to a minimum of 25kGy of gamma irradiation.
These devices do not contain phtalates unless this is indicated on the label.
These devices are intended to be removed 12 months after implantation, at the end of the growth when used in pediatric patients or earlier if pain occurs.

INDICATIONS

The PIT'stop implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

- Flat foot treatment in children and adolescents
- Congenital flat foot
- Non successful long term orthopaedic treatment (shoes, insoles…)
- Tarsal coalitions
- Painfully flat foot
- Supple deformity in posterior tibial tendon dysfunction
- Paralytic flat foot
- Subtalar instability

CONTRA-INDICATIONS

The 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,
- chronic rupture of the posterior tibial tendon,
- symptomatic arthritis,
- neurological affections (paraplegia…),
- sensitivity/allergies to the implant materials.

RECOMMANDATION

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

REIMBURSEMENT

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

CE MARKED MEDICAL DEVICE

CE Classification (Directive MDD 93/42/EC)

- Implants : Class CE IIb - CE2797
- Trial implants : CE Class IIa - CE2797

CE Classification (EC Regulation 2017/745/EC)

- Invasive reusable surgical instruments: Class Ir - CE2797

MANUFACTURER

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

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

DOCUMENT

Reference : BR-DIG-PITSTOP-EN-012022

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.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

Peek-Optima® is a polymer produced by INVIBIO®.
Peek- Optima® is a registered brand of INVIBIO®.

International Office
In2Bones SAS • 28, chemin du Petit Bois • 69130 Ecully • FRANCE
+33 (0)4 72 29 26 26 • contact@in2bones.com

Corporate Headquarters
In2Bones Global, Inc. • In2Bones USA • Memphis, TN • USA
+1 844. 602. 6637 • Info@i2b-USA.com