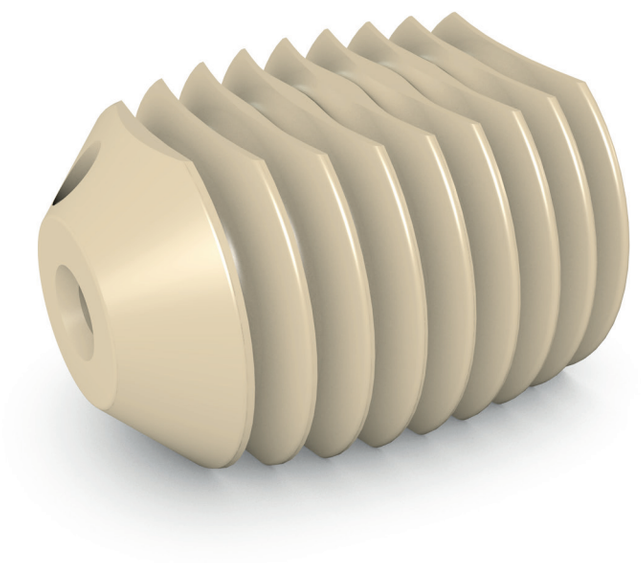
PIT'stop®

FLAT FOOT ENDORTHESIS



In2Bones

A GLOBAL EXTREMITY COMPANY

ST-DIG-PITSTOP-EN-012022

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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.

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PRODUCT DESCRIPTION

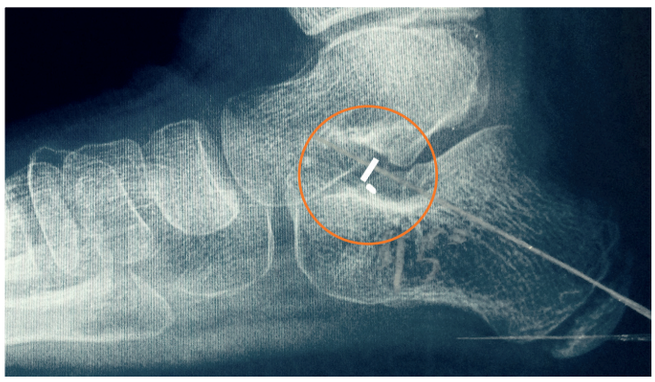
Flat foot endorthesis

– The implant is made of PEEK-Optima®*. This biocompatible and inert polymer is flexible, which allows a filling of the Sinus Tarsi with better load distribution on bone surfaces versus stiffer materials such as Titanium, Stainless steel …etc

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

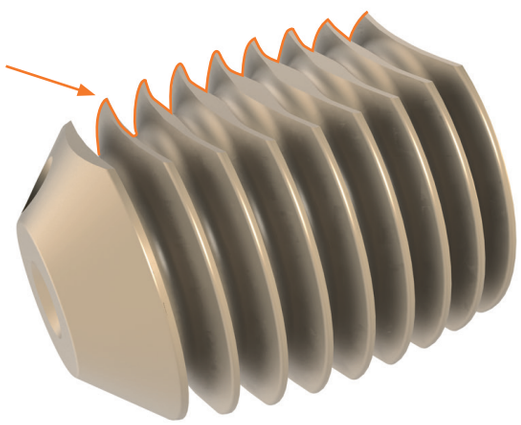
X-Ray markers

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

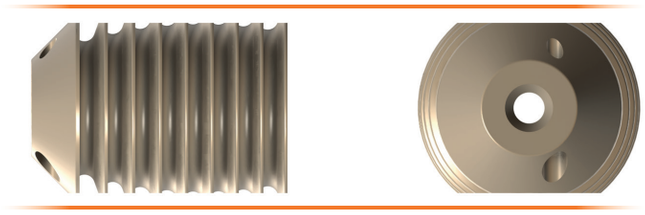
Anti-return flanges, (small blades) are designed to provide primary stability in the Sinus Tarsi.



** PEEK-Optima® is a registered trademark of Invibio®*

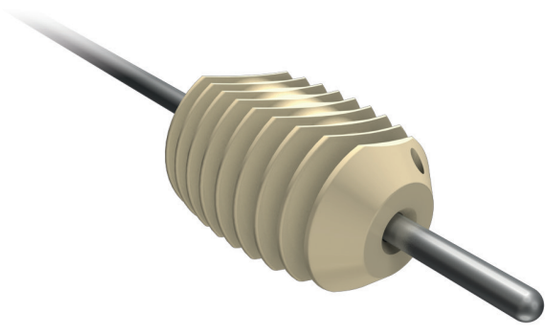
Anatomical shape

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 positioning guide.



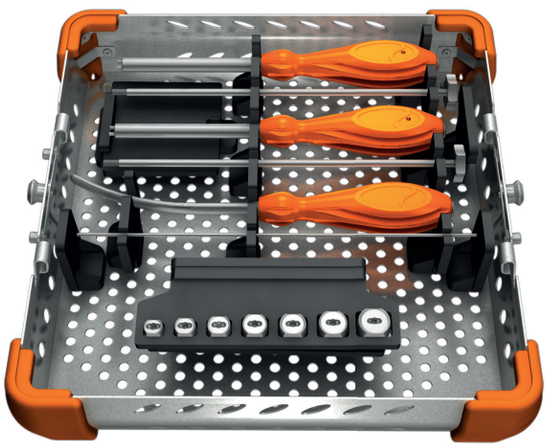
Implant-instrument assembly

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
- PIT'stop® positioning guide
  Diam 1.6mm Lg.150mm
- Viladot's lever (optional)



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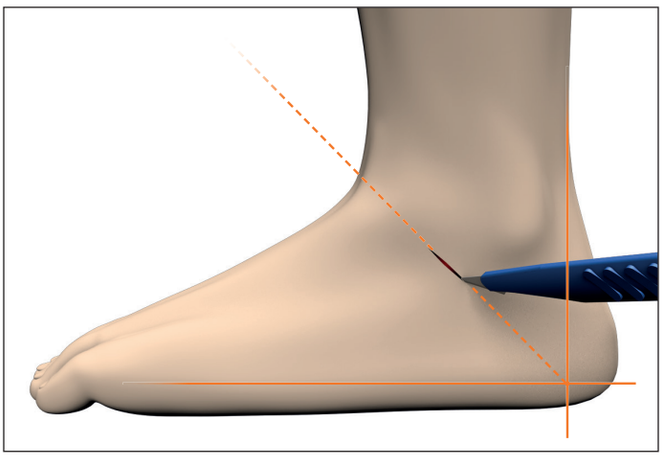
SURGICAL TECHNIQUE

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.

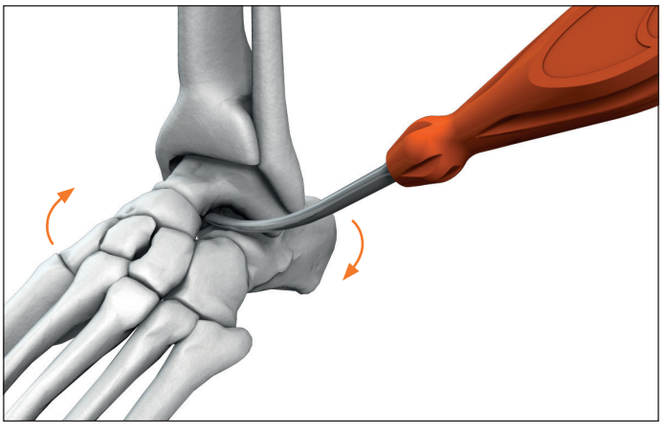
1 - Incision



A 1-3cm incision is made on the lateral foot in the skin overlying the sinus tarsi.

The incision can be made straight or in S shape provided the sural nerve is protected

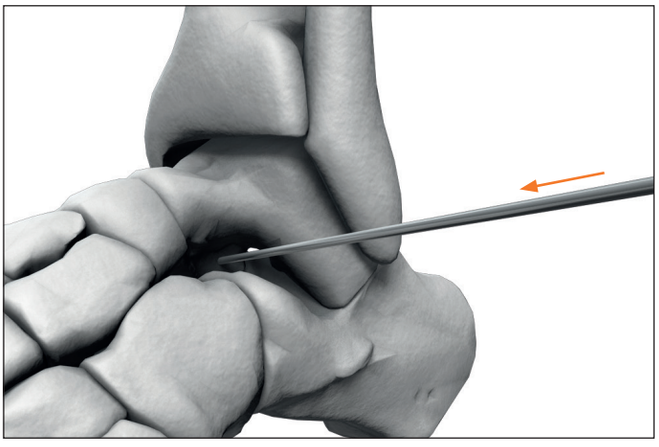
2 - Use of Viladot's lever



The Viladot's Lever is introduced in the sinus tarsi.

The lever helps to achieve the reduction : the hindfoot is deviated in varus, at the same time the forefoot is in pronation position thanks to the help of the assistant.

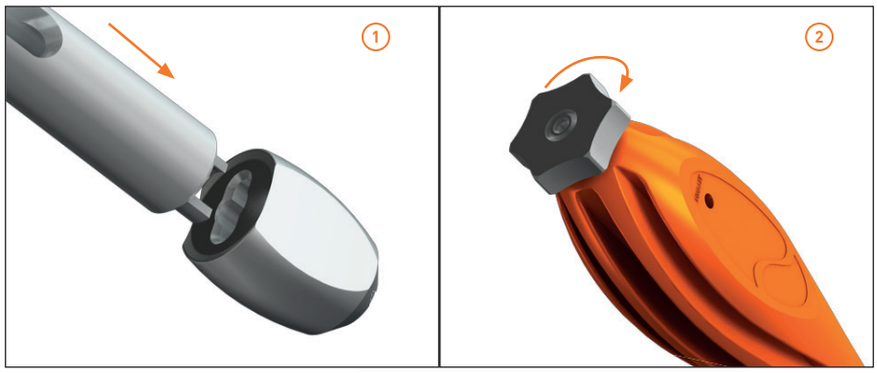
3 - Positionning guide introduction



Once the talus is positioned on the calcaneus, the 1.6mm positioning guide is introduced into the axis of the sinus tarsi until the guide is felt on the medial aspect of the hindfoot.

Accurate placement may be confirmed with fluoroscopy.

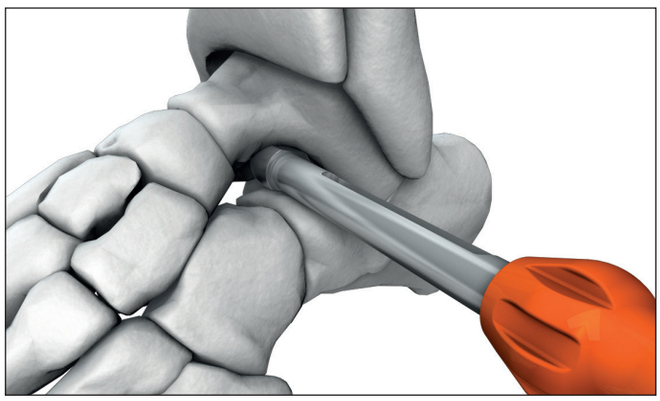
4 - Holder Preparation for Trials



Position the trial implant to the extremity of the external holder. The pins must be introduced in the holes of the trial implant ①. The flattened sides of the trial implant and the handle of the external holder are aligned.

The internal holder, passing through the external holder, is screwed to the trial implant ②.

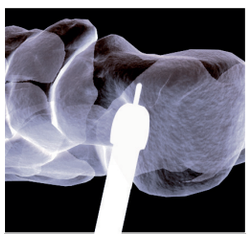
5 - Trial Sizer

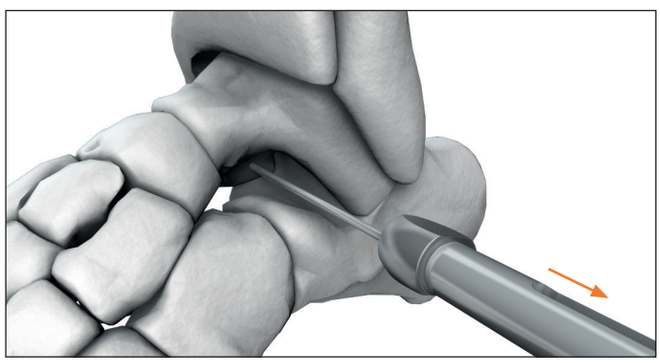


The trial implant of the estimated required size is placed over the positionning guide until seated in the sinus tarsi.

Hindfoot mobility is assessed and the size may be adjusted accordingly.

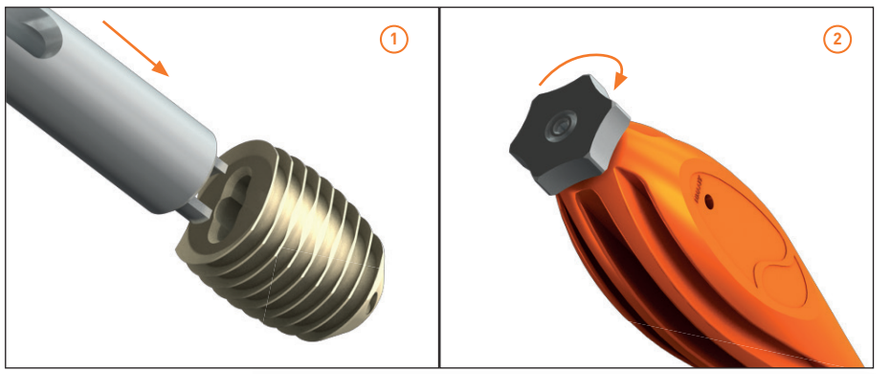
Correct position of the trial implant may be verified by fluoroscopy. It is recommended to advance the leading edge of the trial implant close to but not past the talonavicular bisection on the AP view.



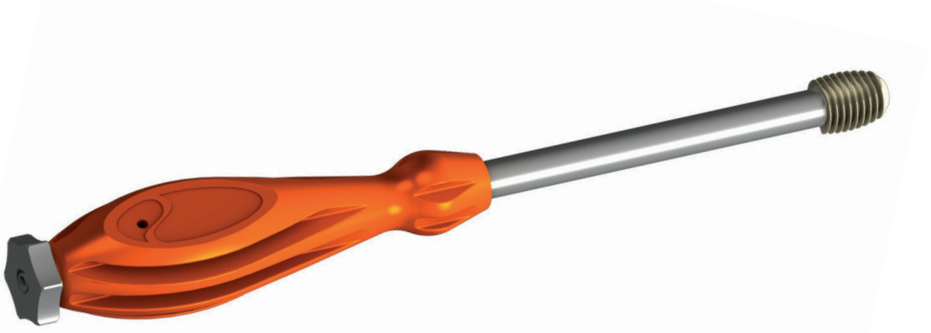


The trial implant is removed leaving the positioning guide in place.

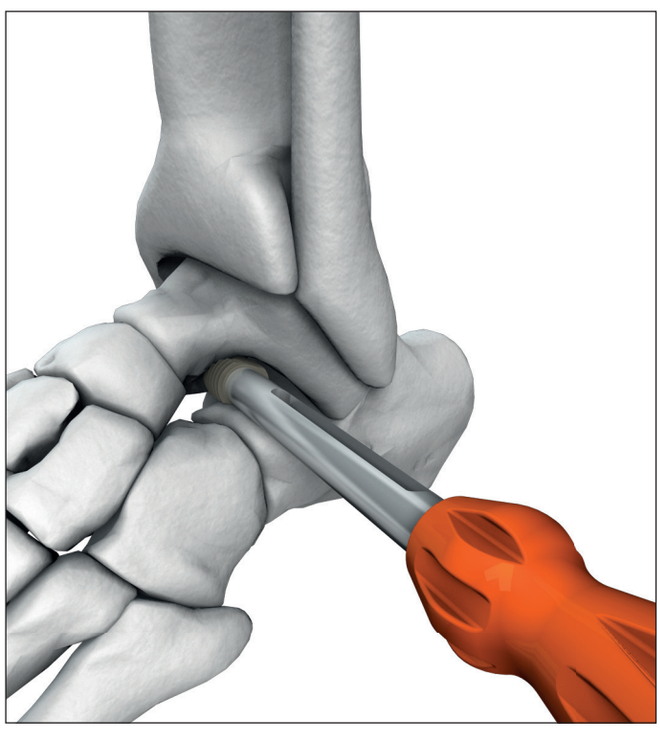
6 - Holder Preparation for Implant



As with the trial, the implant is fixed on the external holder ①, then tightened with the locker of the internal holder ②.



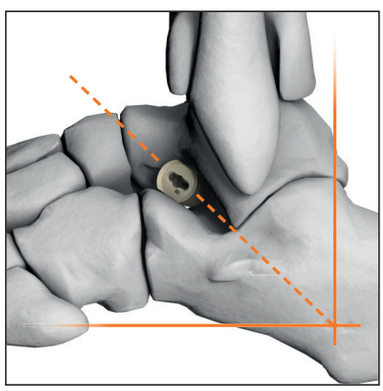
7 - Cannulated Insertion

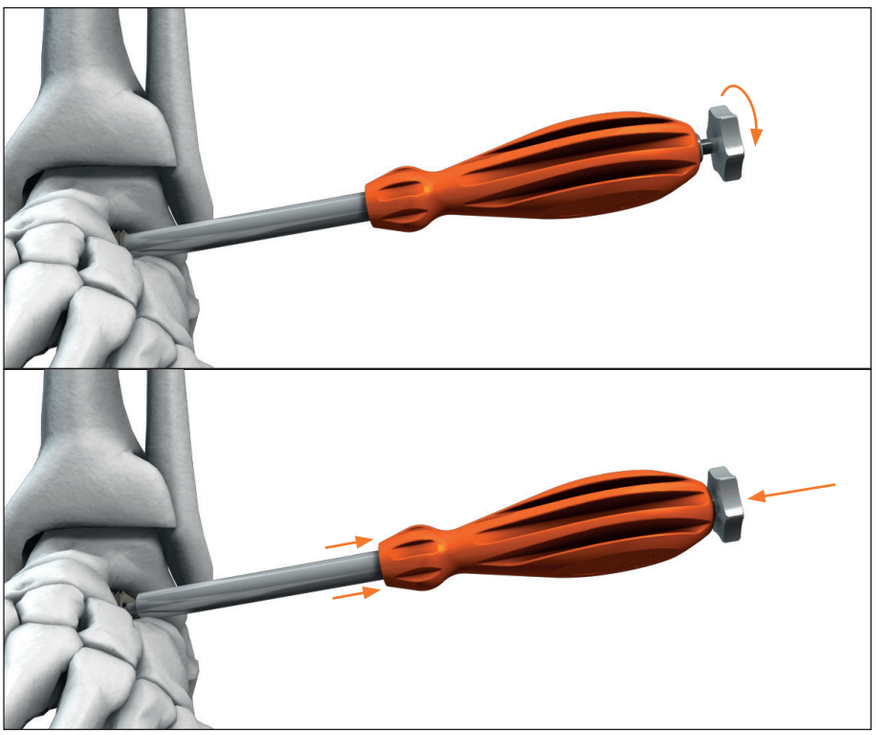


The inserter is used to place the implant in the correct position .

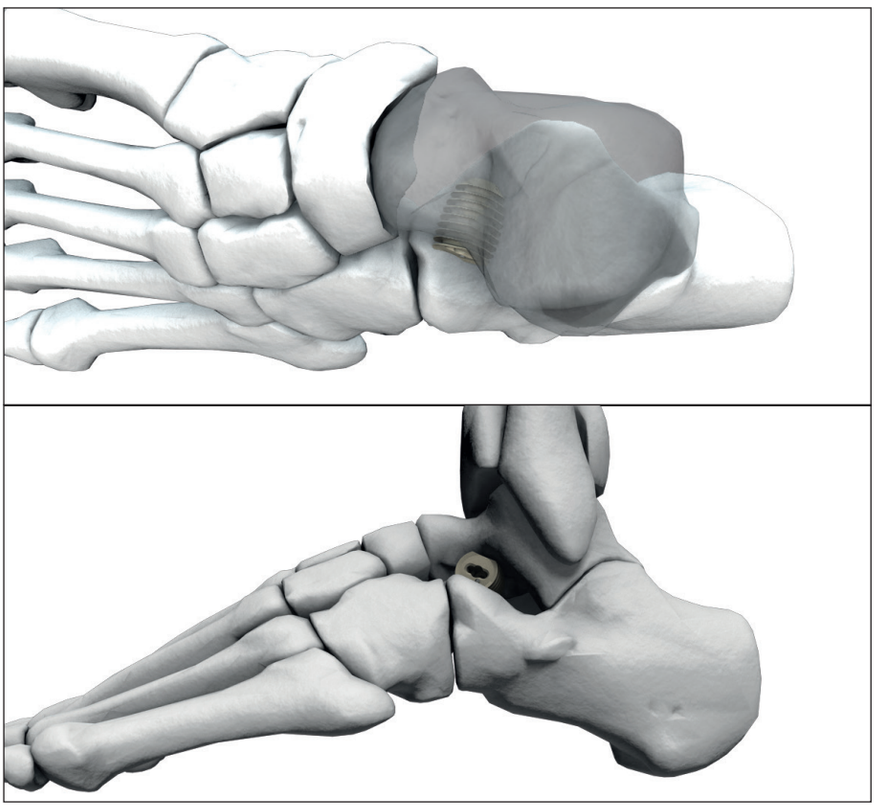
Two markers in the implant help to control its position in the 3 dimensions by fluoroscopy.

The flat surface is parallel to the lateral talar process which is approximately a 45° angle to the fibula and the plantar aspect of the foot.





Unscrew the locker, and push with the finger for removing the holder from the implant.



A final control of Hindfoot mobility is assessed to verify adequate correction.

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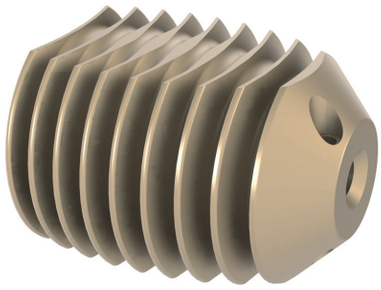
ORDERING INFORMATIONS

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
PIT’stop positioning guide Diam. 1.6mm - Lg. 150mm	K20 NS150

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

CE Classification (EC Regulation 2017/745/EC)

- Invasive reusable surgical instruments : Class Ir - CE2797

REIMBURSEMENT

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

MANUFACTURER

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DOCUMENT

Reference : ST-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®.

A GLOBAL EXTREMITY COMPANY

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