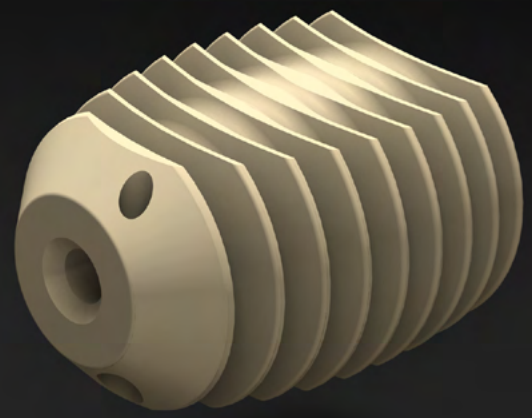
In2Bones®

PIT'stop®

Flat foot endorthesis



ST-PITSTOP-EN-022016 - Version 01

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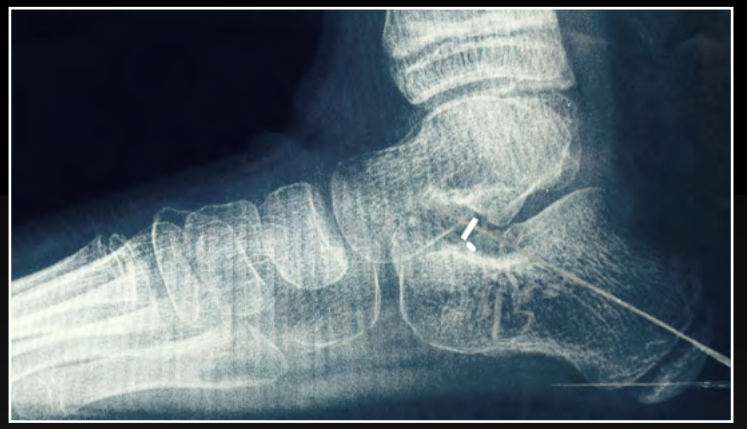
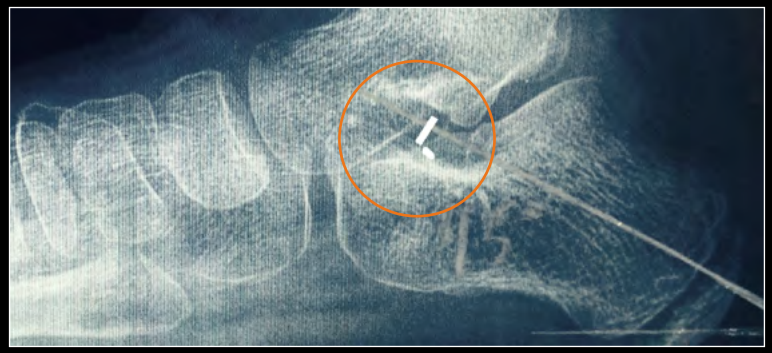
PIT'STOP® - FLAT FOOT ENDORTHESIS

- The PIT'Stop® implant is intended for treatment of flat foot for children and adults.
- 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

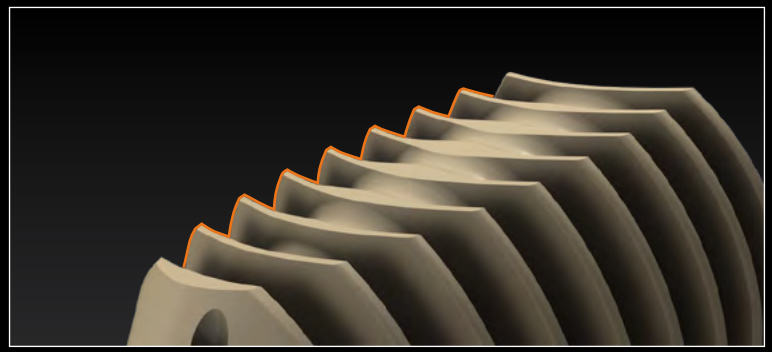


** PEEK-Optima® is a registered trademark of Invibio®*



X-RAY MARKERS

- Two X-Ray markers made of tantalum, placed at each extremities of the implant, help control the positioning of the implant per and post operative.

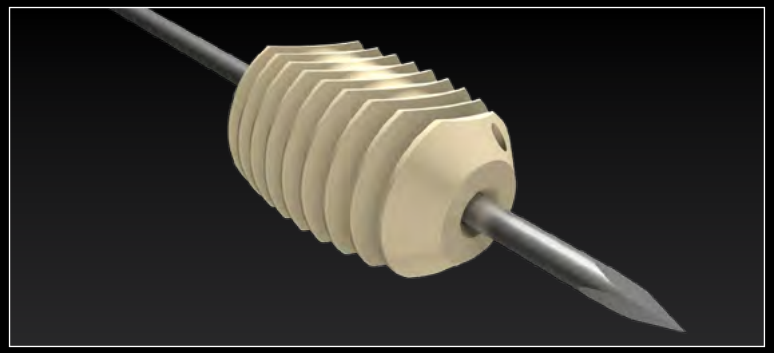


ANTI-RETURN FLANGES

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

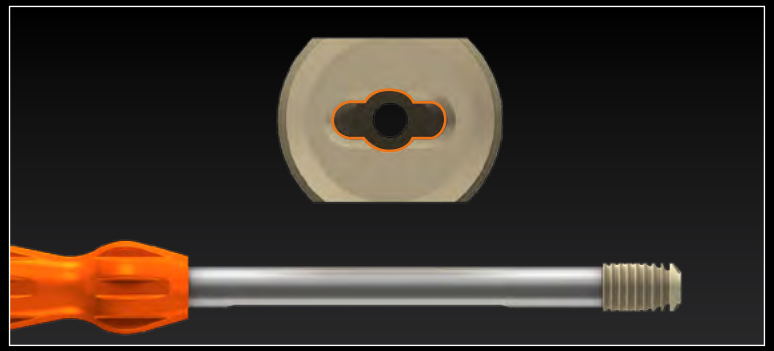
ANATOMICAL SHAPE

- 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 guide wire.



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
  - 1.6mm Diam guide-wire
  - Viladot's lever (optional)

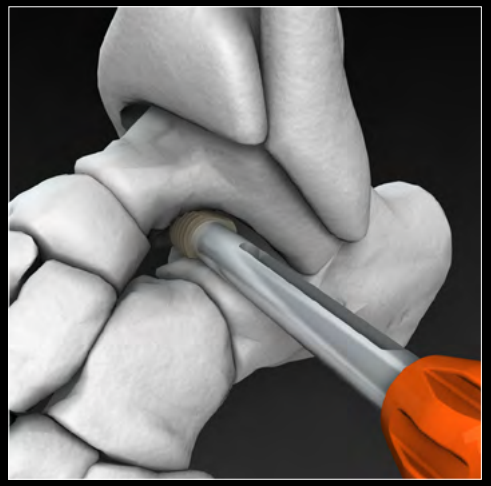
INDICATIONS

- 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

CONTRAINDICATIONS

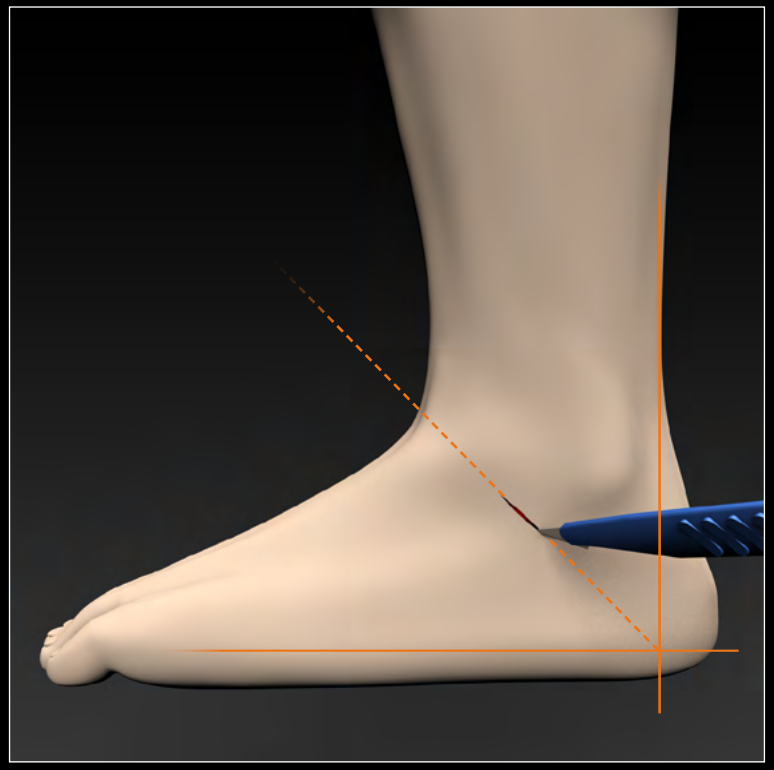
- The implant should not be used in a patient who has currently, or who has history of:
  - acute or chronic systemic inflammations,
  - active infections,
  - stiff or fixed deformity of the flat foot,
  - flat foot with a forefoot abductus,
  - chronic rupture of the posterior tibial tendon,
  - symptomatic arthritis,
  - neurological affections (paraplegia...),
  - sensitivity/allergies to the implant materials.

SURGICAL TECHNIQUE



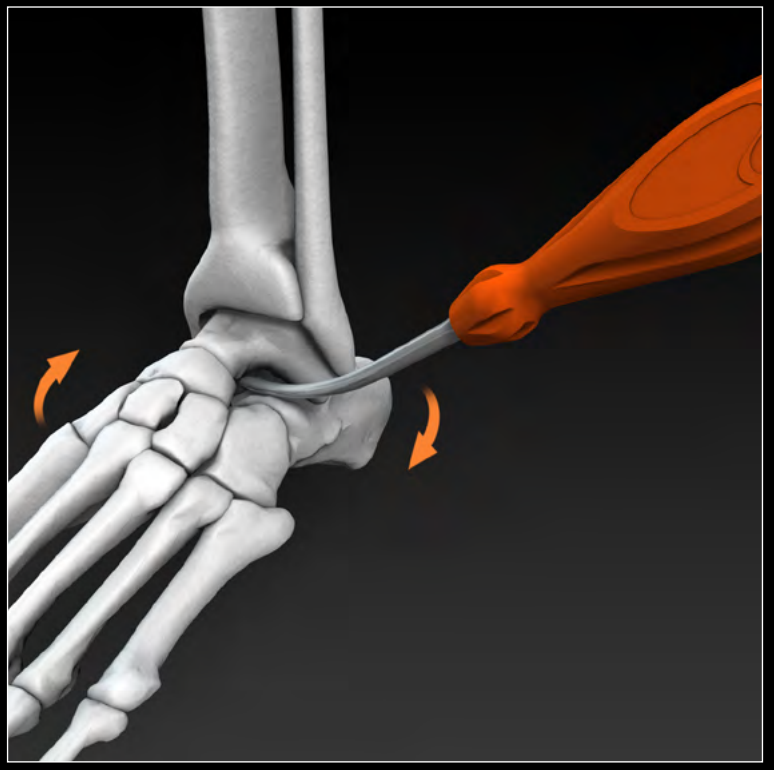
In2Bones® as the manufacturer of this device, does not practice medicine.
The surgeon who performs any implant procedure is responsible for determining
and using the appropriate surgical techniques for implanting the device in each patient.
This Surgical Technique Manual is furnished for information purposes,
as an aid to use properly the device and its dedicated instruments.

1 - INCISION



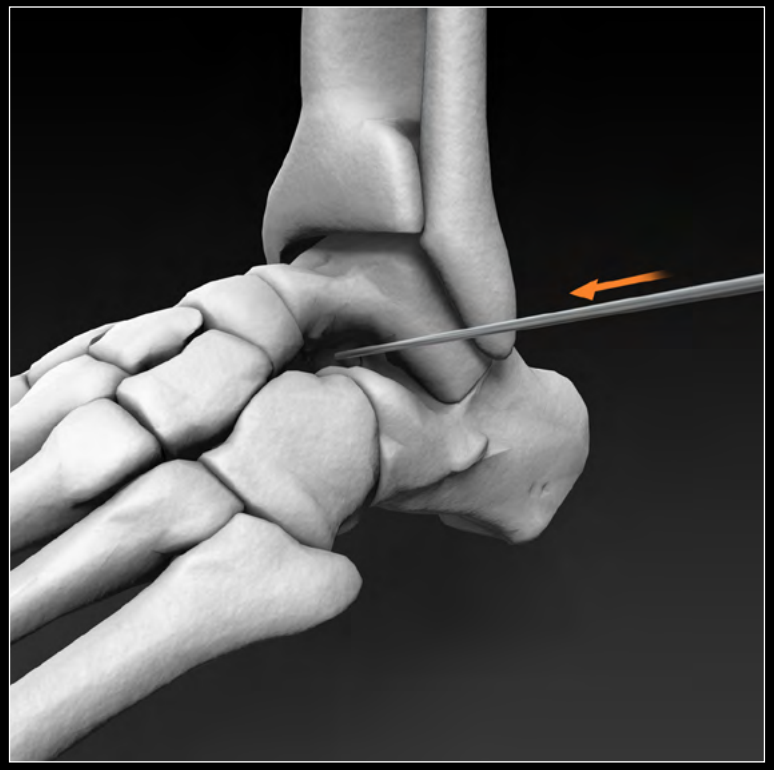
- A 1-3cm incision is made on the lateral foot in the skin overlying the sinus tarsi.
- The incision can be made straight or in S shape provided the sural nerve is protected

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 - GUIDE-WIRE INTRODUCTION



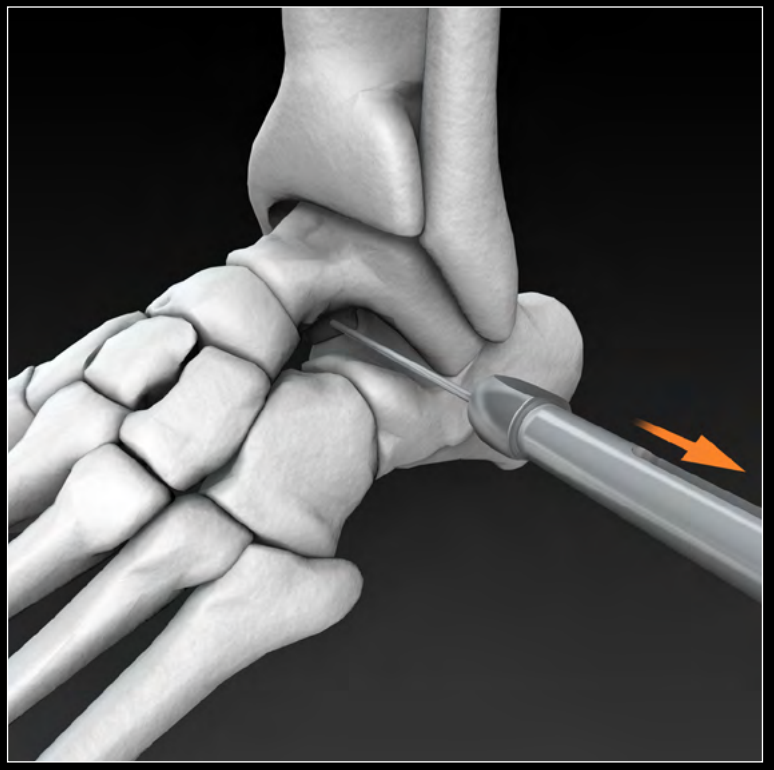
- Once the talus is positioned on the calcaneus, the 1.6mm guide-wire is introduced into the axis of the sinus tarsi until the wire is felt on the medial aspect of the hindfoot.
- Accurate placement may be confirmed with fluoroscopy.

4 - HOLDER PREPARATION FOR TRIALS

- Positioning 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 guide-wire 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.

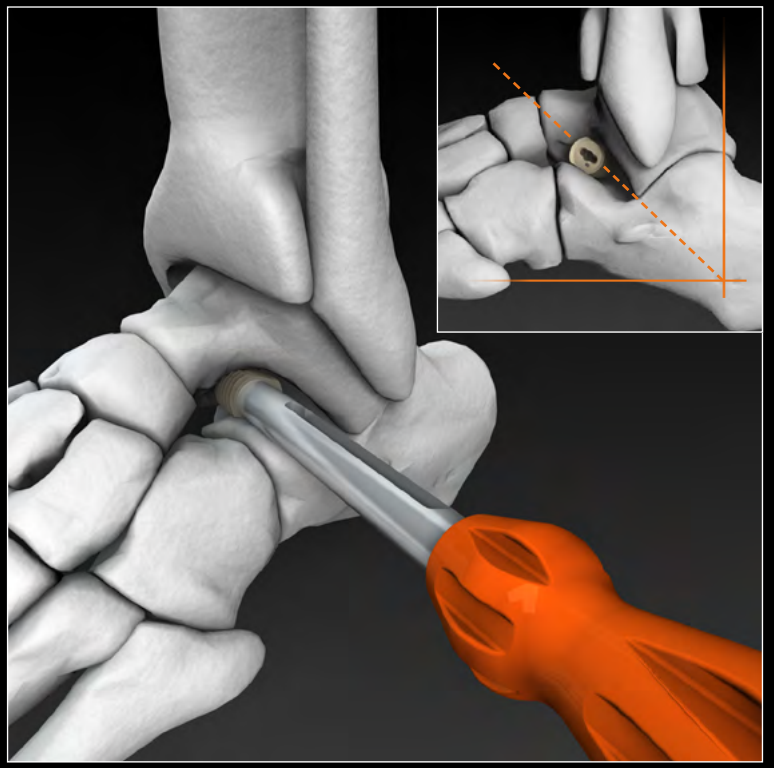


- The trial implant is removed leaving the guide-wire in place.

6 - HOLDER PREPARATION FOR IMPLANT

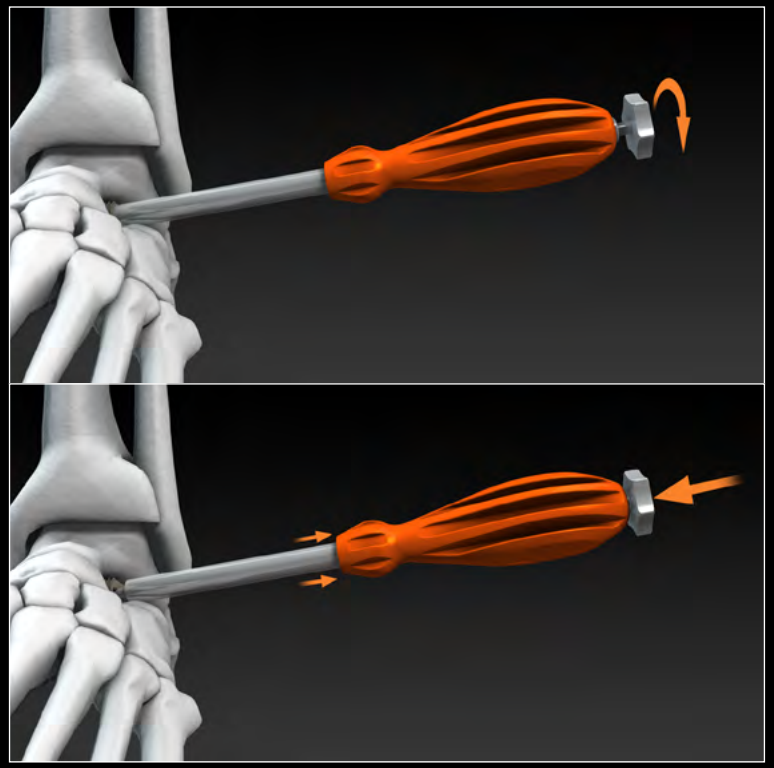
- As with the trial, the implant is fixed on the external holder ①, then tightened with the locker of the internal holder ②.

7 - CANNULATED INSERTION (1/2)

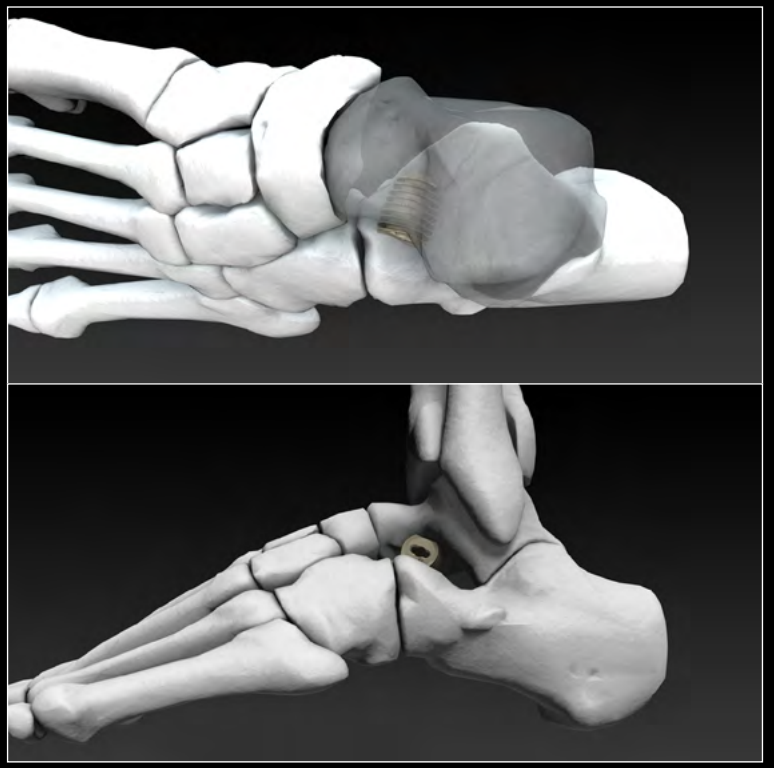


- The inserter is used to place the implant in the correct position .
- Two markers in the implant help to achieve the adequate position in the 3 dimensions by fluoroscopy.
- The flat surface is parallel to the lateral talar process which is approximately a 45° angle to the fibula and the plantar aspect of the foot.

7 - CANNULATED INSERTION (2/2)



- 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.

IMPLANTS

PIT'Stop® - Subtalar Implant - PEEK - Stérile

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

INSTRUMENTS

Reference	Description
M02 00011	PIT'Stop trial implant - Size 10mm
M02 00021	PIT'Stop trial implant - Size 11mm
M02 00031	PIT'Stop trial implant - Size 12mm
M02 00041	PIT'Stop trial implant - Size 13mm
M02 00051	PIT'Stop trial implant - Size 14mm
M02 00061	PIT'Stop trial implant - Size 15mm
M02 00071	PIT'Stop trial implant - Size 17mm
M02 00081	Viladot's lever
M02 00091	External holder
M02 00101	Internal holder
K10 NS150	Guide wire Diam. 1.6mm - Lg. 150mm

RECOMMANDATION

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

DEVICES

- Implants :
  - Implants : CE Class IIb - CE0086
- Instruments :
  - Trial implants : CE Class IIa - CE0086
  - Other instruments : CE Class I

REIMBURSEMENT

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

MANUFACTURER

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DOCUMENT

- Reference : ST-PITSTOP-EN-022016
- Revision date : 02/2016
- Version 01

www.in2bones.com/ifu

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.

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