

I.B.S.[®]

SNAP-OFF SCREW



A GLOBAL EXTREMITY COMPANY

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1. Description of the medical device

The I.B.S.® S screws are:

- Osteosynthesis bone screws, existing in different diameters and lengths
- The Implants are manufactured in: titanium alloy in accordance with the standard NF ISO 5832-3 and ASTM F136
- 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.

2. Indications

The I.B.S.® Snap-off screw is intended for use in foot surgery, as a fixation of metatarsal osteotomies. Examples include:

- Weil osteotomy,
- Modified Distal Horizontal Metatarsal Osteotomy,
- Dorsal Closing Wedge Osteotomy.

3. Contraindications

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

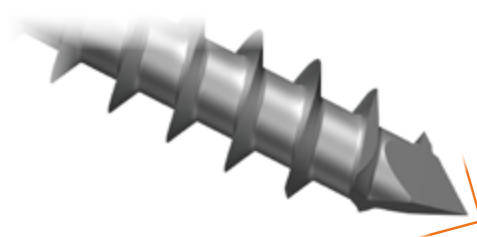
- systemic, acute or chronic inflammations, ,
- active infections,
- sensitivity/allergies to the implant materials (cf paragraph 1).

- The I.B.S.® snap-off screw by In2Bones is designed for monocortical fixation.
- The I.B.S.® snap-off is made of Titanium alloy TA6V and is available in 2.2mm and 2.7mm.
- The I.B.S.® snap-off design optimizes self-drilling performance, reduces risk of breakage below the screw head and thus improves comfort of use.

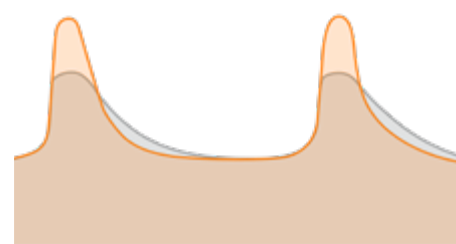


Threads design optimization

- The tip of the I.B.S.® screw is designed as a trocar so it can penetrate easily the cortical wall.



- Screw thread profile has also been designed for an optimized fixation and an easy insertion.



— I.B.S.® screw thread design
— Regular screw thread design

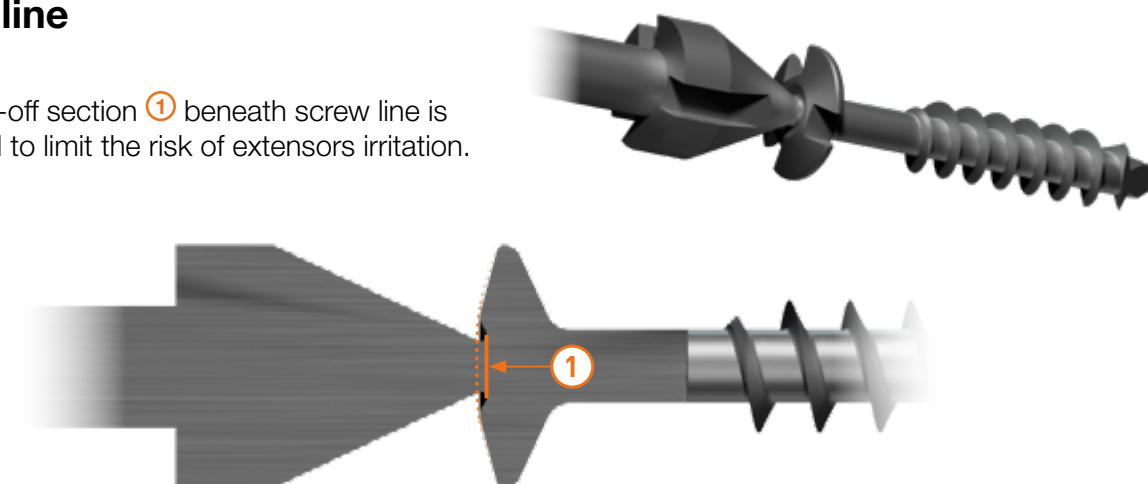
Barrel length

- The 25mm barrel allows the snap-off screw to be inserted with a power system.



Snap-off line

- The snap-off section ① beneath screw line is optimized to limit the risk of extensors irritation.



Single Use Instruments range Neosys®

The Neosys single use instrument sets range is specially designed to implant:

- 2,2 and 2,7mm snap-off screw
- 2.0, 3.0 and 3.5mm compression screw
- 2.5, 3.0 and 3.5mm neutralization screw

For further information about the Neosys single use instrument sets, please refer to the dedicated brochure.

In2Bones® Single use instruments are in recyclable polymer.

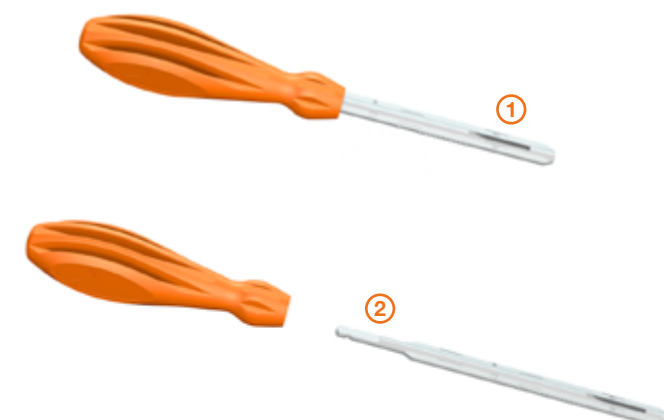
It has been specially designed to be single use while guaranteeing efficiency and optimal comfort for the practitioner.

The design of instruments guarantees precision and resistance to torsional stresses.

Screwdrivers axis have an open window to ease barrel extraction after snap-off. ①

Screw driver axis can be used either with the handle or with a power drill equipped with an AO attachment. ②

Screwdriver axis is secured inside the handle with a locking mechanism. The T shape of the handle guarantees that the axis is properly positioned with the locking mechanism.



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 - Setting Up And Assembly



In the Neosys single use instrument set range select the appropriate set configuration according to the procedure. *For further information about the Neosys single use instrument sets, please refer to the dedicated brochure.*

Single use instruments that haven't been used during surgery can be placed in a container and processed per Hospital procedures.

For each surgery, based on the type of screw and technic chosen by the surgeon, following instruments will be needed :

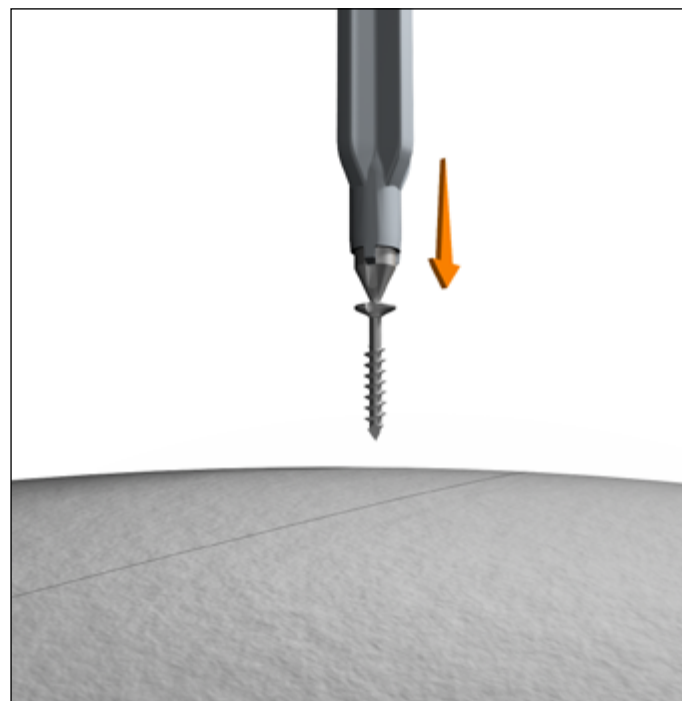
- Screwdriver handle ①
- Snap-off screwdriver axis ②

Screw driver axis can be used either with the handle or with a power driver equipped with an AO attachment.

When screwdriver axis is used with a handle, verify that it has been properly positioned up to the locking position. To free the axis, one just needs to push the unlock button.

I.B.S.® snap-off screws can also be inserted directly with a kwire driver.

2 - Snap-off screw insertion

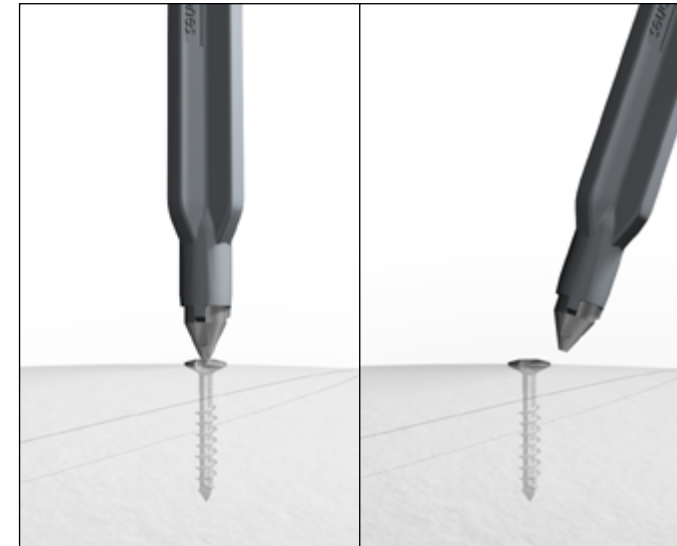


The snap-off screw is self-drilling and self-tapping.

In some cases, it can be necessary to drill the cortical. Use a 1mm kwire.

The snap-off screw is inserted either with the screwdriver or directly with a kwire driver.

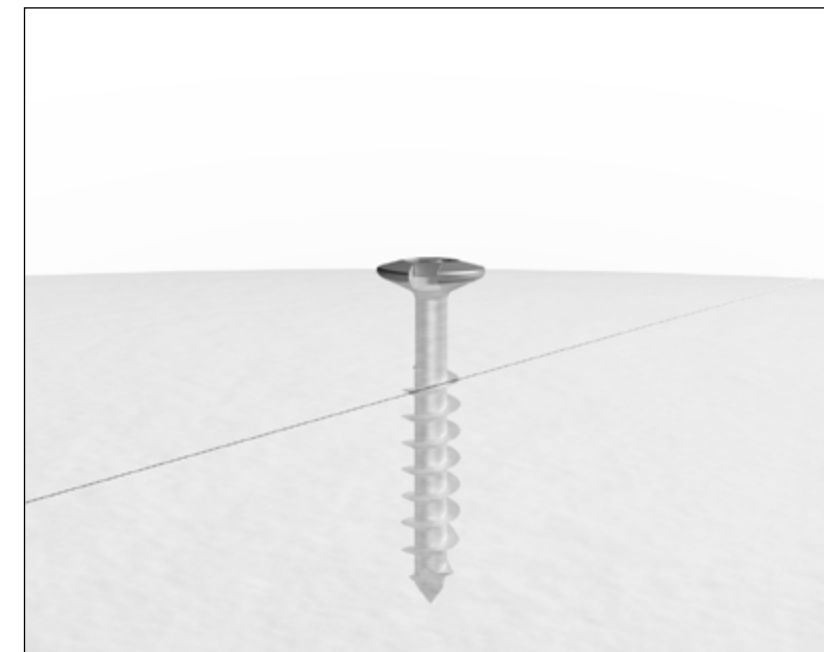
3 - Barrel snap-off



As soon as the screw head gets in contact with the cortical bone, the barrel breaks.

CAUTION:

In osteoporotic bone, it may be necessary to provoke release of the barrel prior screw head reaches the cortical bone to protect screw fixation. Therefore gentle forward motion of the handle or use of a forceps is recommended to achieve snap-off effect. Careful screwdriver use will then allow final fixation



INSTRUMENTS

The Neosys Single Use Instrument Set is available in different configuration according to surgeon’s technics and preferences.

For further information about the Neosys single use instrument sets, please refer to the dedicated brochure.

G01 00432	Neosys [®] reusable - Screw driver
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IMPLANTS

Innovative Bone Synthesis[®] 2.2-S Snap-off screw

S22 ST009	IBS [®] 2.2-S - Snap-off Screw Titanium Sterile - Diam 2.2mm	Lg 09mm
S22 ST010	IBS [®] 2.2-S - Snap-off Screw Titanium Sterile - Diam 2.2mm	Lg 10mm
S22 ST011	IBS [®] 2.2-S - Snap-off Screw Titanium Sterile - Diam 2.2mm	Lg 11mm
S22 ST012	IBS [®] 2.2-S - Snap-off Screw Titanium Sterile - Diam 2.2mm	Lg 12mm
S22 ST013	IBS [®] 2.2-S - Snap-off Screw Titanium Sterile - Diam 2.2mm	Lg 13mm
S22 ST014	IBS [®] 2.2-S - Snap-off Screw Titanium Sterile - Diam 2.2mm	Lg 14mm

Innovative Bone Synthesis[®] 2.7-S Snap-off screw

S27 ST011	IBS [®] 2.7-S - Snap-off Screw Titanium Sterile - Diam 2.7mm	Lg 11mm
S27 ST012	IBS [®] 2.7-S - Snap-off Screw Titanium Sterile - Diam 2.7mm	Lg 12mm
S27 ST013	IBS [®] 2.7-S - Snap-off Screw Titanium Sterile - Diam 2.7mm	Lg 13mm
S27 ST014	IBS [®] 2.7-S - Snap-off Screw Titanium Sterile - Diam 2.7mm	Lg 14mm
S27 ST016	IBS [®] 2.7-S - Snap-off Screw Titanium Sterile - Diam 2.7mm	Lg 16mm
S27 ST018	IBS [®] 2.7-S - Snap-off Screw Titanium Sterile - Diam 2.7mm	Lg 18mm
S27 ST020	IBS [®] 2.7-S - Snap-off Screw Titanium Sterile - Diam 2.7mm	Lg 20mm

RECOMMENDATION

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

DEVICES

EC Classification (EC Directive MDD 93/42/CE):

- Implant: CE Class IIb - CE2797
- Single Use Instruments: Class IIa - CE2797
- Other Instrument : class I - CE

REIMBURSEMENT

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

MANUFACTURER

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DOCUMENT

Reference : ST-DIG-IBSS-EN-012021

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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