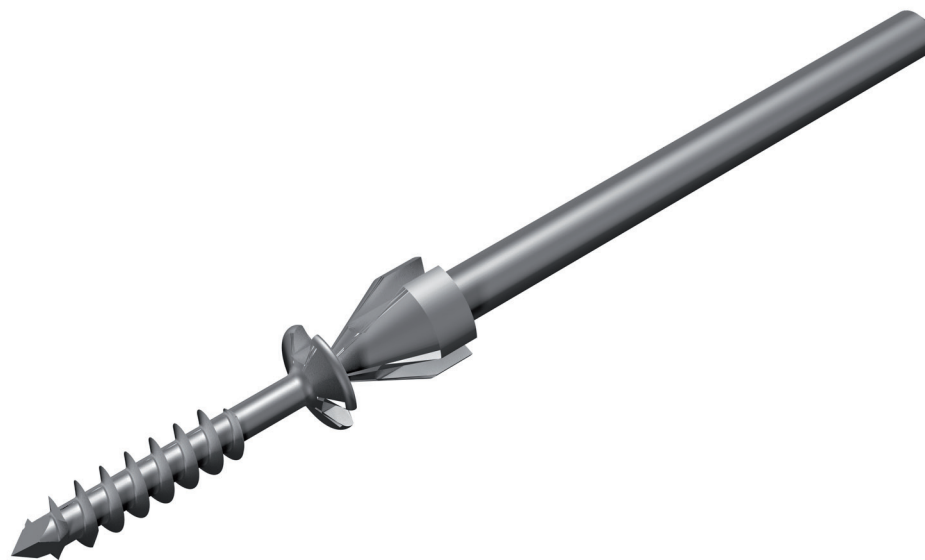




I.B.S.[®]

INNOVATIVE BONE SYNTHESIS

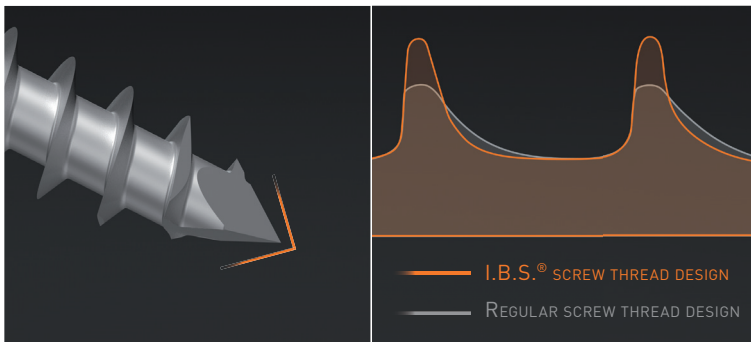
SNAP-OFF SCREW



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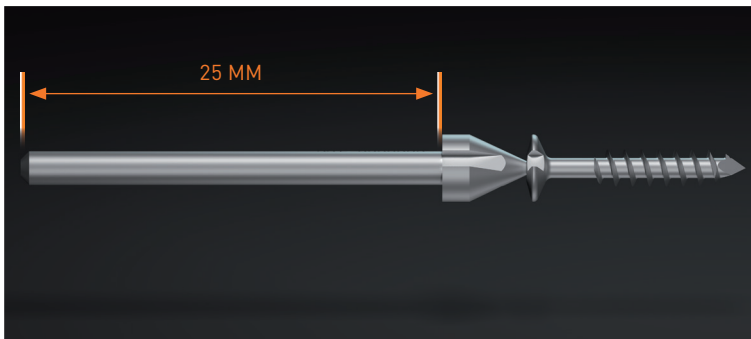
- ▶ The I.B.S.[®] snap-off screw by In2Bones is designed for monocortical fixation.
- ▶ The I.B.S.[®] snap-off is made of Titanium alloy TA6V and is available in 2.2mm and 2.7mm. It is packaged in sterile tube.
- ▶ The I.B.S.[®] snap-off design optimizes self-drilling performance, reduces risk of breakage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





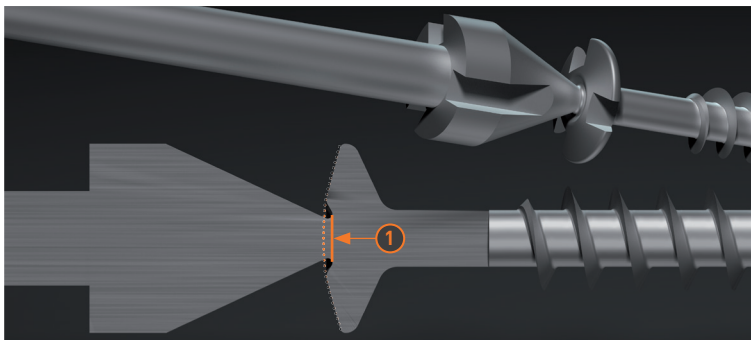
THREADS DESIGN OPTIMIZATION

- ▶ The tip of the I.B.S.[®] screw is designed as a trocart so it can penetrate easily the cortical wall.
- ▶ Screw thread profile has also been designed for an optimized fixation and an easy insertion.



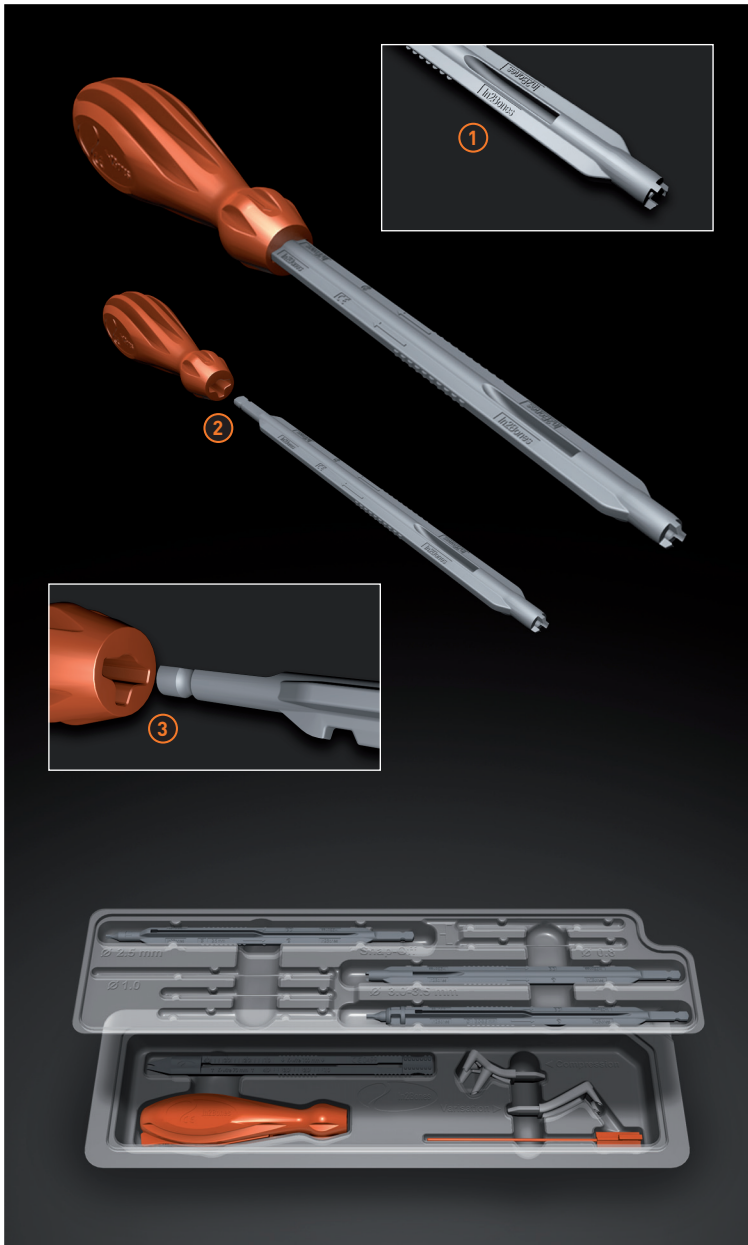
BARREL LENGTH

- ▶ 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 INSTRUMENT - NEOSYS®

- ▶ The blister pack contains all the necessary instruments to implant:
 - ▶ 2,2 and 2,7mm snap-off screw
 - ▶ 2.5, 3.0 and 3.5mm compression screw
 - ▶ 2.5, 3.0 and 3.5mm neutralization screw
 - ▶ Static and compression staples.
- ▶ 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.
- ▶ Screw drivers axis are canulated with 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. ③



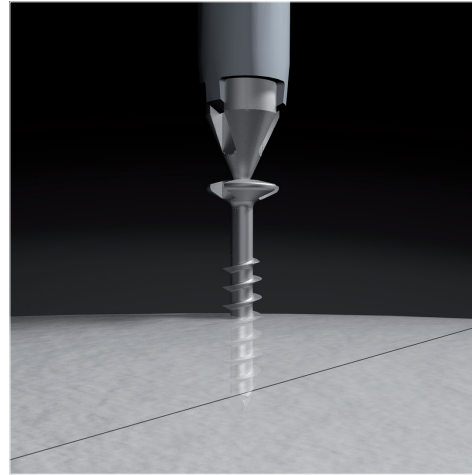
INDICATIONS

- ▶ The In2Bones I.B.S.[®] snap-off screw is indicated for bone reconstruction, osteotomy and fracture fixation of bones appropriate for the size of the device.
- ▶ Examples include :
 - ▶ Fixation of small bone fragments
 - ▶ Weil osteotomy
 - ▶ Osteotomies and fractures fixation in the foot and hand.
- ▶ Implant size is based on indication.

CONTRAINDICATIONS

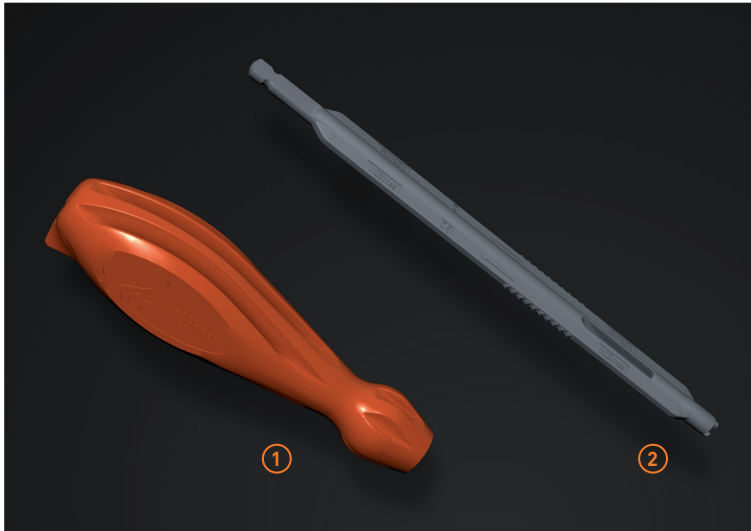
- ▶ The implant should not be implanted in patients who currently have or have had :
 - ▶ acute or chronic inflammations, whether local or systemic,
 - ▶ active infections,
 - ▶ an allergy or intolerance to metals, whether suspected or known,
 - ▶ vascularization disorders; a pathological condition of the soft tissues to be sutured to the bone, liable to undermine the rigidity of the fixation by the structure,
 - ▶ bone deviation, severe osteoporosis, loss of bone mass,
 - ▶ bone pathologies such as acute cystic developments or acute osteopenia that risk preventing proper drilling of a clean hole or compromising the rigidity of the fixation of the implant,
 - ▶ anchorage systems are not intended for use for the fixation of artificial ligaments or other implants,
 - ▶ the use of steroid derivatives, chemotherapy, ... etc.

SURGICAL TECHNIQUE



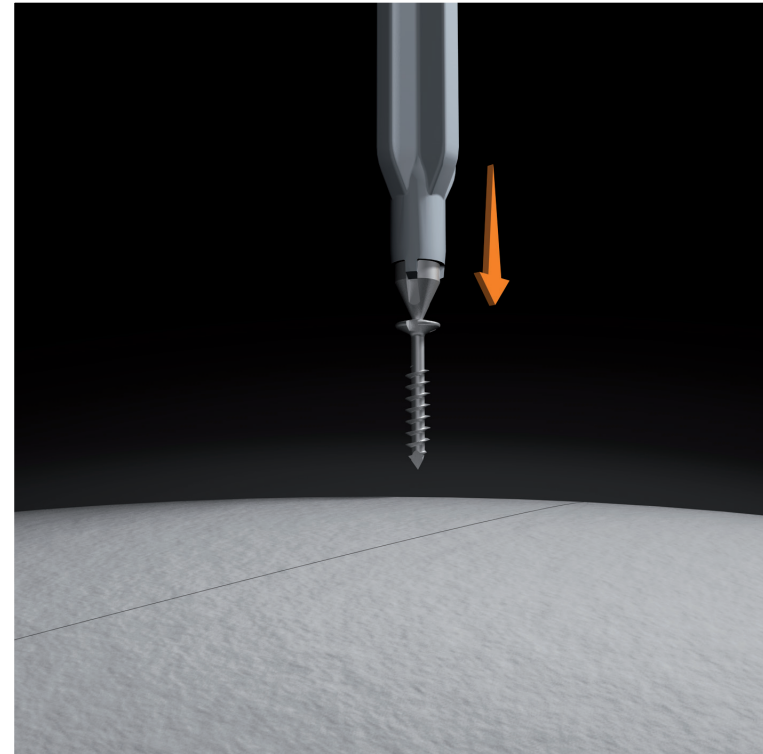
In2Bones® as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

1 - SETTING UP AND ASSEMBLY



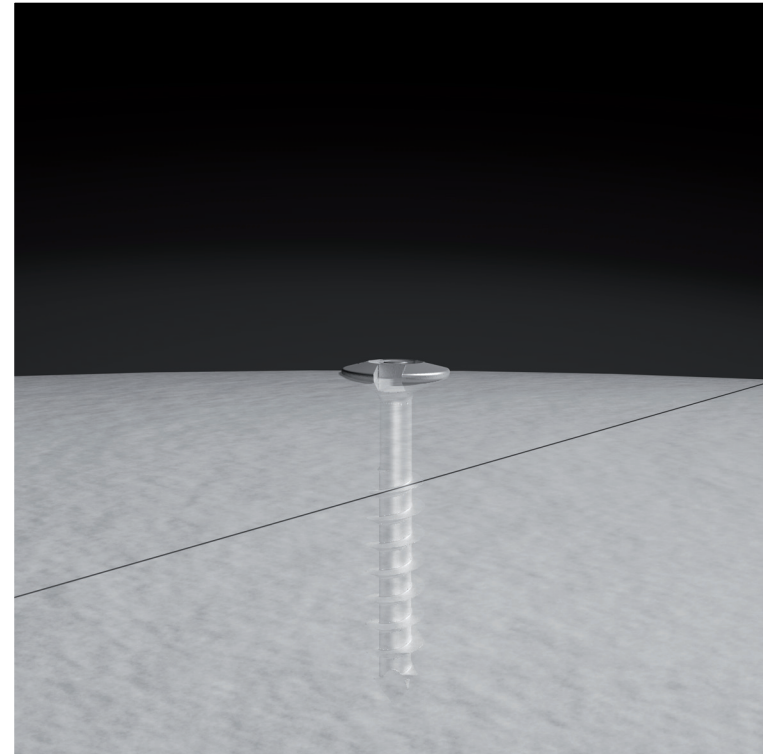
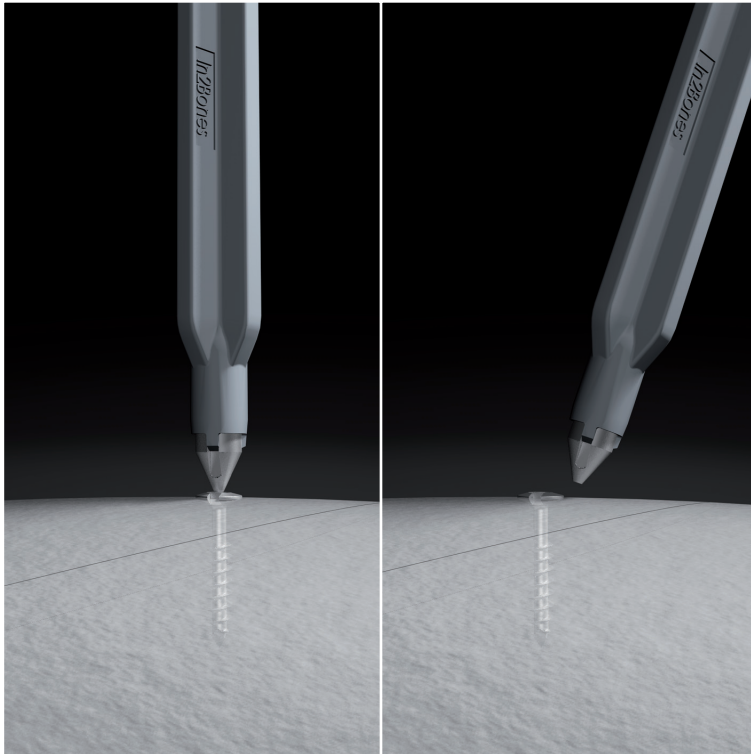
- ▶ In the Neosys[®] single use instrument set (ref G02 10001) select necessary instruments and put aside non required instruments for the procedure. They will be placed in recycle containers and processed per Hospital procedures.
- ▶ For each surgery, based on the type of screw and technic chosen by the surgeon, following instruments will be needed :
 - ▶ Screwdriver handle ①
 - ▶ 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

IMPLANTS

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

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 Cheville Sécable

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

INSTRUMENTS

G02 10001 Neosys[®] kit - Osteosynthesis single use instruments

RECOMMANDATION

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


DEVICES

- ▶ Implants :
 - ▶ Snap-off screws : Class IIb - CE0499
- ▶ Instruments :
 - ▶ Single Use Instruments: Class IIa - CE0499

REIMBURSEMENT

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

MANUFACTURER

- ▶  In2Bones SAS
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DOCUMENT

- ▶ Référence : ST-Snap-off screws-Eng-032013
- ▶ Revision Date : 03/2013
- ▶ Version 01



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.

WARNING: Applicable laws restrict these products to sale by or on the order of a physician.

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