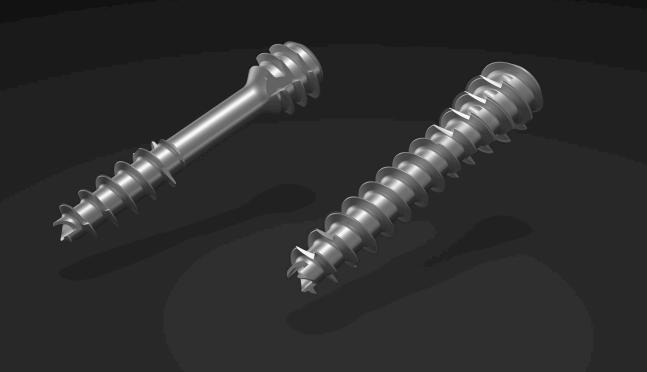


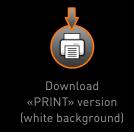


# Compression screw Neutralization screw





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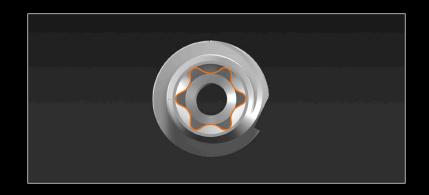




- ▶ The design of the I.B.S.® screw by In2Bones® is optimized to distribute the compression effort, maximize and facilitate the osteosynthesis.
- ▶ As from 2.5mm, a neutralization version fully threaded of the I.B.S.® screw is also available.
- ▶ The I.B.S.® screw is available in 2.5mm, 3.0mm, 3.5mm. The I.B.S.® compression and neutralization screw are cannulated, self-drilling and self-tapping.
- ▶ Made in titanium TAV6, all the screws are delivered in sterile tubes.
- ▶ The I.B.S.® screws are proposed with the single use instruments Neosys®. (G02 10001)

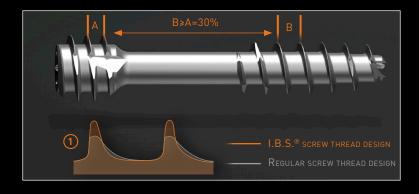






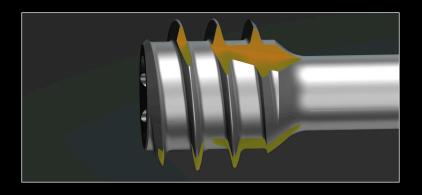
## TORX IMPRINT

- ▶ The range of compression and neutralization I.B.S.® screws has a Torx imprint.
  - ▶ The « star » shape supports a higher torque without degradation of the imprint.



## DISTAL THREAD

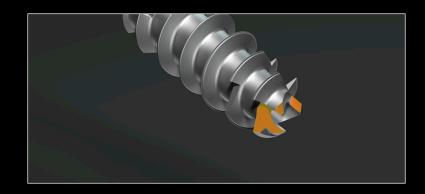
- ▶ The number of distal threads is optimized to allow an optimal placement of the screw in the osteotomy site.
- ▶ The shape of threads ① allows optimal penetration in cortical bones and a better grip.
- ▶ A minimal ratio of 30% between distal and proximal threads guarantees an optimal compression.



## PROXIMAL THREAD

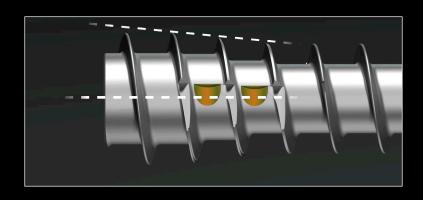
- ▶ The I.B.S.® compression screw head is self-drilling and self-tapping.
- ▶ The conic shape of the self-drilling part improves comfort of use.
- ▶ Thinner threads guarantee an increased stability of the screw in the bone.





## SELF-DRILLING

▶ Distal teeth angle guarantees self drilling performance.



## PROXIMAL THREAD FOR NEUTRALIZATION SCREW

- ▶ The I.B.S.® neutralization screw head is conical allowing a better sensation at the end of race.
- ▶ Self-drilling performance of screw head is reinforced by inter-thread gorges which reduce the risk of re-splits during the final tightening

Product name	Screw diameter	Color code	Screw type	Screw imprint	<b>Length</b> 2mm incremental	Kwire diameter	Drill diameter (Optional)
I.B.S. <sup>®</sup> 2.5	2.5mm		Compression screw (C) Neutralisation screw (N)	Torx 7	12 > 28mm	0.8mm	1.6mm
I.B.S. <sup>®</sup> 3.0	3.0mm		Compression screw (C) Neutralisation screw (N)	Torx 8	12 > 34mm	1.0mm	2.0mm
I.B.S. <sup>®</sup> 3.5	3.5mm		Compression screw (C) Neutralisation screw (N)	Torx 8	18 > 40mm	1.0mm	2.2mm





## SINGLE USE INSTRUMENT - NEOSYS®

- ▶ The blister pack contains all the necessary instruments to implant:
  - ▶ 2.5, 3.0 and 3.5mm compression screw,
  - ▶ 2.5, 3.0 and 3.5mm neutralization screw,
  - ▶ 2,2 and 2,7mm snap-off screw,
  - ▶ Static and compression staples.
- ▶ Kwires are provided in the set (0.8mm/70mm; 1.0mm/70 & 100mm).
- ▶ Drills are available upon request.
- ▶ 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. Connection tips with implants are in stainless steel ① grade 1 to insure on one hand the appropriate torque and on the other hand implants grip.
- Screw drivers axes are canulated ② with an open window to allow kwire extraction.
- ▶ Screw diameter is indicated directly on the axis. ③
- ▶ Screw driver axis can be used either with the handle or with a power drill equipped with an AO attachment. <
- Screwdriver axis is secured inside the handle with a locking mechanism, which T shape garantees proper positioning.
- ▶ Implant can be measured either on kwire or with the depth gauge. ⑤



#### INDICATIONS

- ▶ IB.S.® screws are indicated for:
  - ▶ The fixation of arthrodeses, osteotomies or fractures of long or short bones of the upper and lower limbs,
  - ▶ Osteosyntheses requiring a mono or bicortical compression.
- 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,
  - ▶ the use of steroid derivatives, chemotherapy, ... etc.



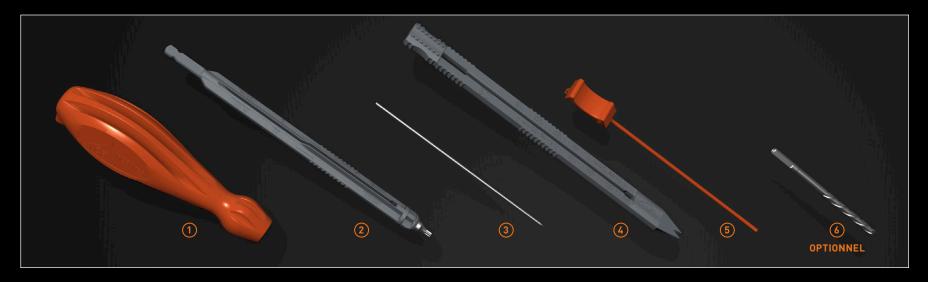
## Surgical Technique



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



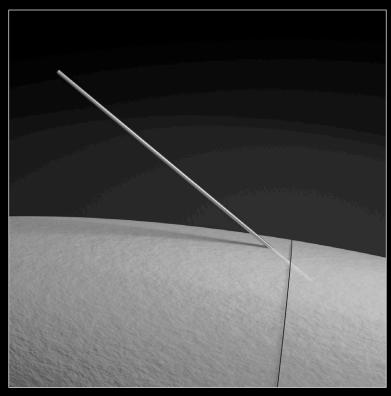
- ▶ In the Neosys® single use instrument set (ref G02 10001) select necessary instruments and put aside non required instruments for the procedure. They will be placed in recycle containers and process per Hospital procedures.
- ▶ For each surgery, based on the type of screw and technic chosen by the surgeon, following instruments will be needed:
  - ▶ screwdriver handle ①
  - ▶ screwdriver axis ②
  - · Torx T7 for 2.5mm screw
  - · Torx T8 for 3.0mm and 3.5mm
  - ▶ Kwire: <sup>3</sup>
  - · 0.8mm/70mm for 2.5mm screw
  - · 1.0mm/70mm or 100mm for 3.0 and 3.5mm screws
  - ▶ measurer 4 or assembled depth gauge 5
- ▶ A drill **6** can be necessary based on bone quality.

Screwdriver handle can be assembled to screwdriver axis but also to staples drilling guides. 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.



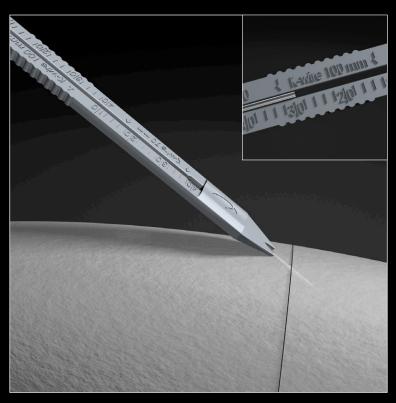


## 2 - OSTEOSYNTHESIS REDUCTION

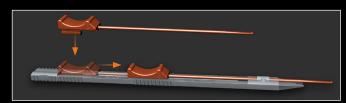


- ▶ Bony fragments are immobilized with a Kwire adapted to the diameter of the chosen screw. It will serve as a guide for the screw.
- ▶ Position of bones can be checked by fluoroscopy.
- It is possible to remove and replace the kwire until proper positioning of the bones.

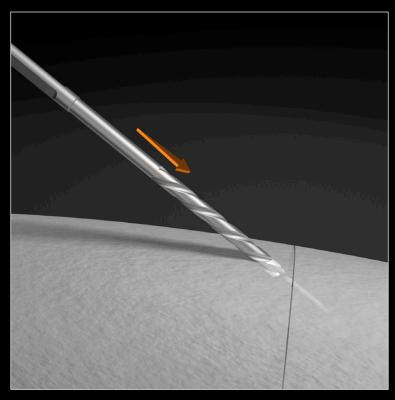
## 3 - MEASURE



- ▶ Slide measurer (flat side) directly on Kwire between the 2 teeth.
- ▶ Read directly the implant length on side measurer.
- ▶ Measure can also be made with the depth gauge. In that case assemble the orange gauge on the measurer (tunnel side).

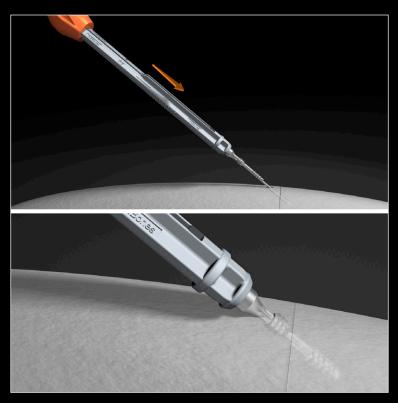


## 4 - DRILLING



- ▶ The I.B.S.® screw is self-drilling and self-tapping.
- ▶ In some cases, it might be necessary to drill the first cortical bone. In that case, use the appropriate size drill.

## 5 - SCREW INSERTION



- ▶ The screw is inserted with the canulated screwdriver axis. It can be either inserted manually or with a power driver.
- ▶ In case of a I.B.S.® Compression screw, screw head must be fully embedded into the cortical bone in order to obtain the optimized compression
- ▶ Kwire is removed after screw insertion.



#### COMPRESSION SCREW

#### ► Innovative Bone Synthesis® - 2.5-C Compression screw

```
S25 ST012 · · · · I.B.S.® 2.5-C Compression screw Titanium Sterile - Diam. 2.5mm · Lg 12mm S25 ST014 · · · · I.B.S.® 2.5-C Compression screw Titanium Sterile - Diam. 2.5mm · Lg 14mm S25 ST016 · · · · I.B.S.® 2.5-C Compression screw Titanium Sterile - Diam. 2.5mm · Lg 16mm S25 ST018 · · · · I.B.S.® 2.5-C Compression screw Titanium Sterile - Diam. 2.5mm · Lg 18mm S25 ST020 · · · · I.B.S.® 2.5-C Compression screw Titanium Sterile - Diam. 2.5mm · Lg 20mm S25 ST022 · · · · I.B.S.® 2.5-C Compression screw Titanium Sterile - Diam. 2.5mm · Lg 22mm S25 ST024 · · · · I.B.S.® 2.5-C Compression screw Titanium Sterile - Diam. 2.5mm · Lg 24mm S25 ST026 · · · · I.B.S.® 2.5-C Compression screw Titanium Sterile - Diam. 2.5mm · Lg 26mm S25 ST028 · · · · I.B.S.® 2.5-C Compression screw Titanium Sterile - Diam. 2.5mm · Lg 28mm
```

#### ▶ Innovative Bone Synthesis® - 3.0-C Compression screw

```
$30 ST112 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 12mm} $30 ST114 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 14mm} $30 ST116 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 18mm} $30 ST118 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 18mm} $30 ST120 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 22mm} $30 ST122 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 24mm} $30 ST124 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 28mm} $30 ST128 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 28mm} $30 ST130 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 30mm} $30 ST132 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 32mm} $30 ST134 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 32mm} $30 ST134 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 34mm} $30 ST134 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 34mm} $30 ST134 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 34mm} $30 ST134 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 34mm} $30 ST134 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 34mm} $30 ST134 \cdots \cdots \text{I.B.S.} \@ 3.0-C Compression screw Titanium Sterile - Diam. 3.0mm \cdots \text{Lg 34mm} $30 ST134 \cdots \cdots \text{Lg 34mm} $
```

#### ► Innovative Bone Synthesis® - 3.5-C Compression screw

```
$35 $T118 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 18mm} $35 $T120 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 22mm} $35 $T122 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 24mm} $35 $T124 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 24mm} $35 $T126 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 28mm} $35 $T128 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 30mm} $35 $T130 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 32mm} $35 $T134 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 34mm} $35 $T136 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 36mm} $35 $T138 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 38mm} $35 $T138 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdot \text{Lg 38mm} $35 $T138 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 38mm} $35 $T138 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 40mm} $15 $T140 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 40mm} $15 $T140 \cdots \cdots \text{I.B.S.} \@ 3.5-C Compression screw Titanium Sterile - Diam. 3.5mm \cdots \text{Lg 40mm} $15 $T140 \cdots \cdots \text{Lg 40mm} $15
```



#### NEUTRALIZATION SCREW

#### ► Innovative Bone Synthesis® - 2.5-N Neutralization screw

```
S25 ST212 · · · · I.B.S.® 2.5-N Neutralization screw Titanium Sterile - Diam. 2.5mm· Lg 12mm S25 ST214 · · · · I.B.S.® 2.5-N Neutralization screw Titanium Sterile - Diam. 2.5mm· Lg 14mm S25 ST216 · · · · I.B.S.® 2.5-N Neutralization screw Titanium Sterile - Diam. 2.5mm· Lg 16mm S25 ST218 · · · · I.B.S.® 2.5-N Neutralization screw Titanium Sterile - Diam. 2.5mm· Lg 18mm S25 ST220 · · · · I.B.S.® 2.5-N Neutralization screw Titanium Sterile - Diam. 2.5mm· Lg 20mm S25 ST222 · · · · I.B.S.® 2.5-N Neutralization screw Titanium Sterile - Diam. 2.5mm· Lg 22mm S25 ST224 · · · · I.B.S.® 2.5-N Neutralization screw Titanium Sterile - Diam. 2.5mm· Lg 24mm S25 ST226 · · · · I.B.S.® 2.5-N Neutralization screw Titanium Sterile - Diam. 2.5mm· Lg 26mm S25 ST228 · · · · I.B.S.® 2.5-N Neutralization screw Titanium Sterile - Diam. 2.5mm· Lg 28mm
```

#### ▶ Innovative Bone Synthesis® - 3.0-N Neutralization screw

```
$30 $T212 \cdots \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 12mm} $30 $T214 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 14mm} $30 $T216 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 16mm} $30 $T218 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 18mm} $30 $T220 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 22mm} $30 $T222 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 22mm} $30 $T226 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 26mm} $30 $T228 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 28mm} $30 $T230 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 30mm} $30 $T232 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 32mm} $30 $T232 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 32mm} $30 $T232 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 32mm} $30 $T234 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 32mm} $30 $T234 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 32mm} $30 $T234 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 32mm} $30 $T234 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 34mm} $30 $T234 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile - Diam. 3.0mm} \text{Lg 34mm} $30 $T234 \cdots \text{I.B.S.} \@ 3.0-N \text{ Neutralization screw Titanium Sterile
```

#### ► Innovative Bone Synthesis® - 3.5-N Neutralization screw

```
S35 ST218 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 18mm S35 ST220 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 20mm S35 ST222 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 22mm S35 ST224 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 24mm S35 ST226 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 26mm S35 ST228 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 28mm S35 ST230 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 30mm S35 ST232 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 32mm S35 ST234 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 34mm S35 ST236 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 36mm S35 ST238 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 38mm S35 ST238 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 38mm S35 ST240 ··· I.B.S.® 3.5-N Neutralization screw Titanium Sterile - Diam. 3.5mm· Lg 40mm
```



## INSTRUMENTS

G02 10001 · · · · · Neosys® kit - Osteosynthesis single use instruments

## Drill - Lg 75 mm :

G01 00041	Diam. 1.6mm	Canulated	Non Sterile
G01 00061	Diam. 1.6mm	Non Canulated	Non Sterile
G01 00071	Diam. 2.0mm	Canulated	Non Sterile
G01 00081	Diam. 2.0mm	: Non Canulated	Non Sterile



#### RECOMMANDATION

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

#### **DEVICES**

▶ Implants :

▶ Screws : Class IIb - CE0499

Instruments:

▶ Single use instruments and drills: Class IIa - CE0499

#### REIMBURSEMENT

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

#### MANUFACTURER

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

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

#### DOCUMENT

▶ Référence : ST-Screws 2.5&3&3.5mm-Eng-032013

▶ Date de révision: 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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