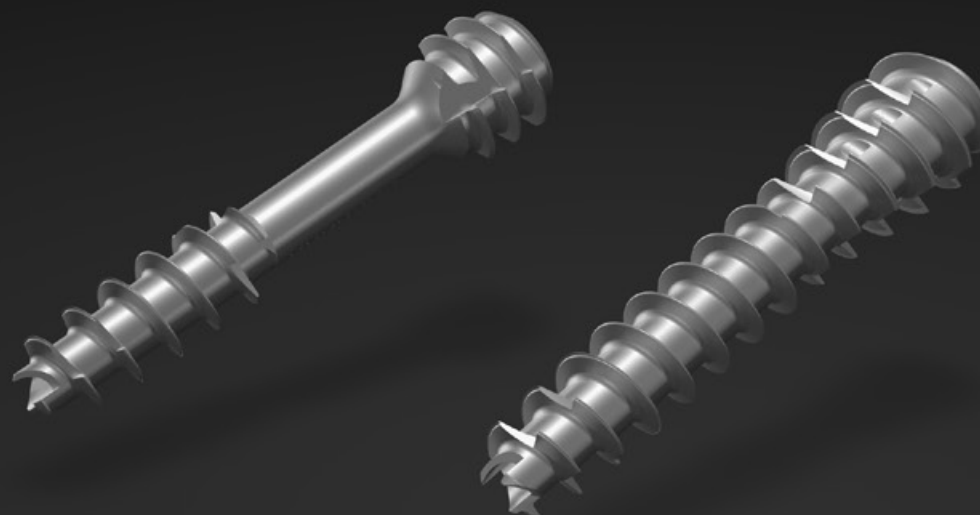




I.B.S.[®]

INNOVATIVE BONE SYNTHESIS

COMPRESSION SCREW
NEUTRALIZATION SCREW



▶ PRODUCT DESCRIPTION	3
▶ INDICATIONS	7
▶ SURGICAL TECHNIQUE	8
1 - SETTING UP AND ASSEMBLY	9
2 - OSTEOSYNTHESIS REDUCTION	10
3 - MEASURE	10
4 - SCREW HEAD PREPARATION	11
5 - DRILLING	11
6 - SCREW INSERTION	12
▶ REFERENCES	13
IMPLANTS	13
INSTRUMENTS	15

I.B.S.® - COMPRESSION SCREW / NEUTRALIZATION SCREW

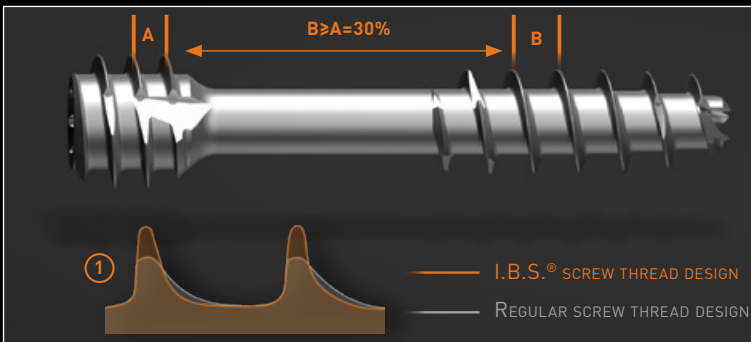
- ▶ The design of the I.B.S.® screw by In2Bones® is optimized to distribute the compression effort, maximize and facilitate the osteosynthesis.
- ▶ The I.B.S.® compression and neutralization screw are cannulated, self-drilling and self-tapping.
- ▶ The I.B.S.® screw is available in 2.0 - 2.5 - 3.0 - 3.5 - 4.5 - 6.5 - 8.0mm.
Length : 10 to 120mm, dependent on models and diameters.
- ▶ As from 2.5mm, a neutralization version fully threaded of the I.B.S.® screw is also available.
- ▶ The I.B.S.® screws are proposed with the single use instruments Neosys®.





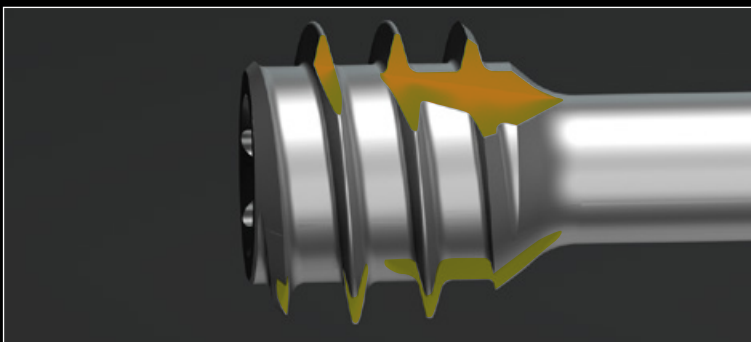
TORX IMPRINT

- ▶ 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.



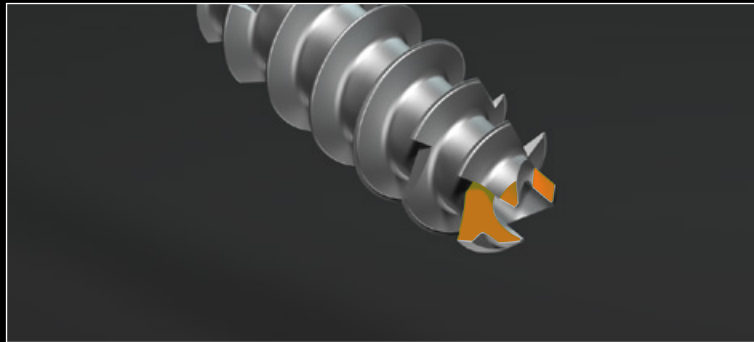
DISTAL THREAD

- ▶ 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 optimized penetration and fixation in cortical bone.
- ▶ A minimal ratio of 30% between distal and proximal threads guarantees an optimal compression.



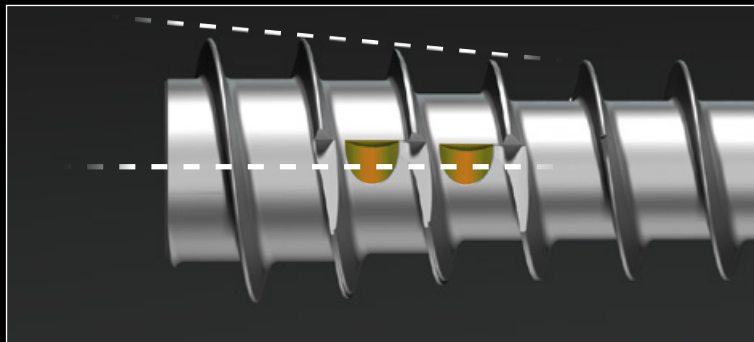
PROXIMAL THREAD

- ▶ 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

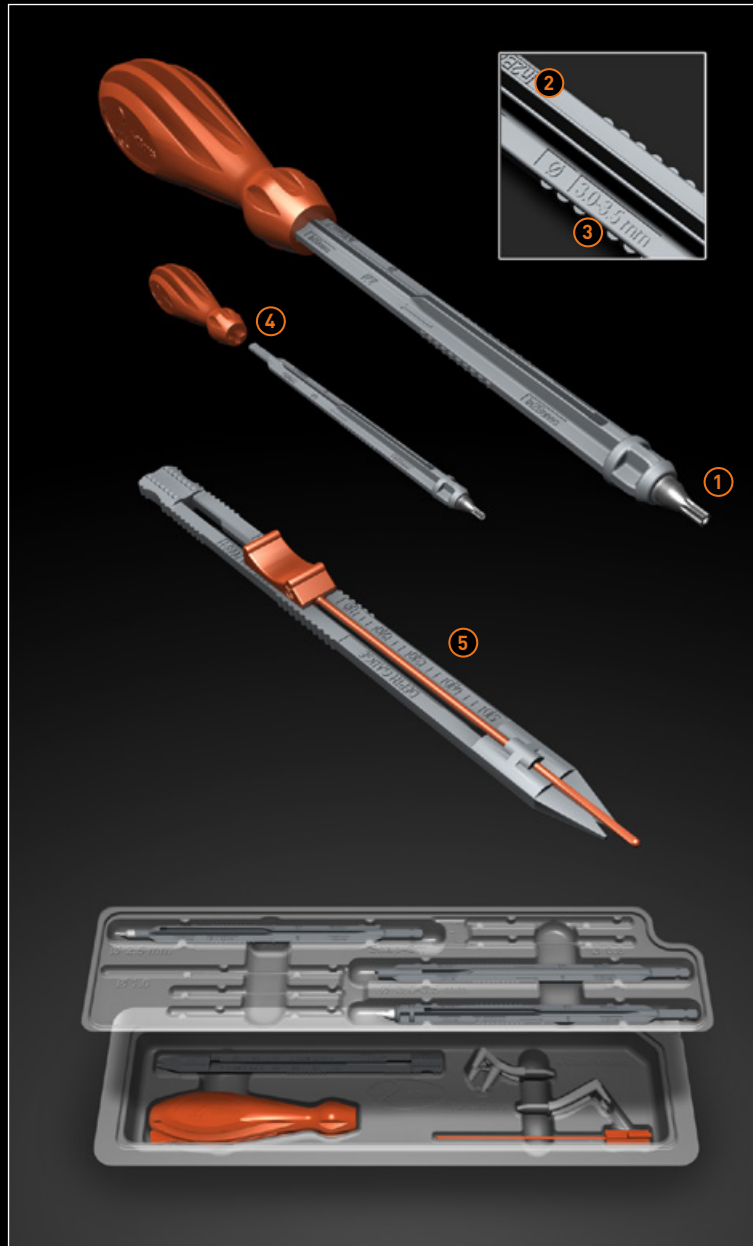
- ▶ Distal teeth angle guarantees self drilling performance.



PROXIMAL THREAD FOR NEUTRALIZATION SCREW

- ▶ The I.B.S.® neutralization screw conical head profile allows to feel tightening at the end of the 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	Length 2mm incremental	Kwire diameter	Drill diameter (Optional)
I.B.S.® 2.0	2.0mm		Compression screw (C)	Torx 7	10 > 30mm	0.8mm	1.6mm
I.B.S.® 2.5	2.5mm		Compression screw (C) Neutralization screw (N)	Torx 7	12 > 28mm	0.8mm	1.6mm
I.B.S.® 3.0	3.0mm		Compression screw (C) Neutralization screw (N)	Torx 8	12 > 34mm	1.0mm	2.0mm
I.B.S.® 3.5	3.5mm		Compression screw (C) Neutralization screw (N)	Torx 8	18 > 40mm	1.0mm	2.2mm



SINGLE USE INSTRUMENT - NEOSYS®

- ▶ The blister pack contains all the necessary instruments to implant:
 - › 2.0, 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. ④
- ▶ Screwdriver axis is secured inside the handle with a locking mechanism, which T shape guarantees proper positioning.
- ▶ Implant can be measured either on kwire or with the depth gauge. ⑤



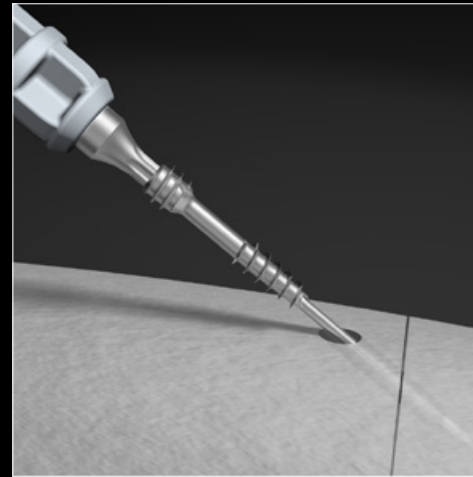
INDICATIONS

- ▶ IB.S.® screws are intended 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.
- ▶ The size of the chosen screw should be adapted to the specific indications.

CONTRAINDICATIONS

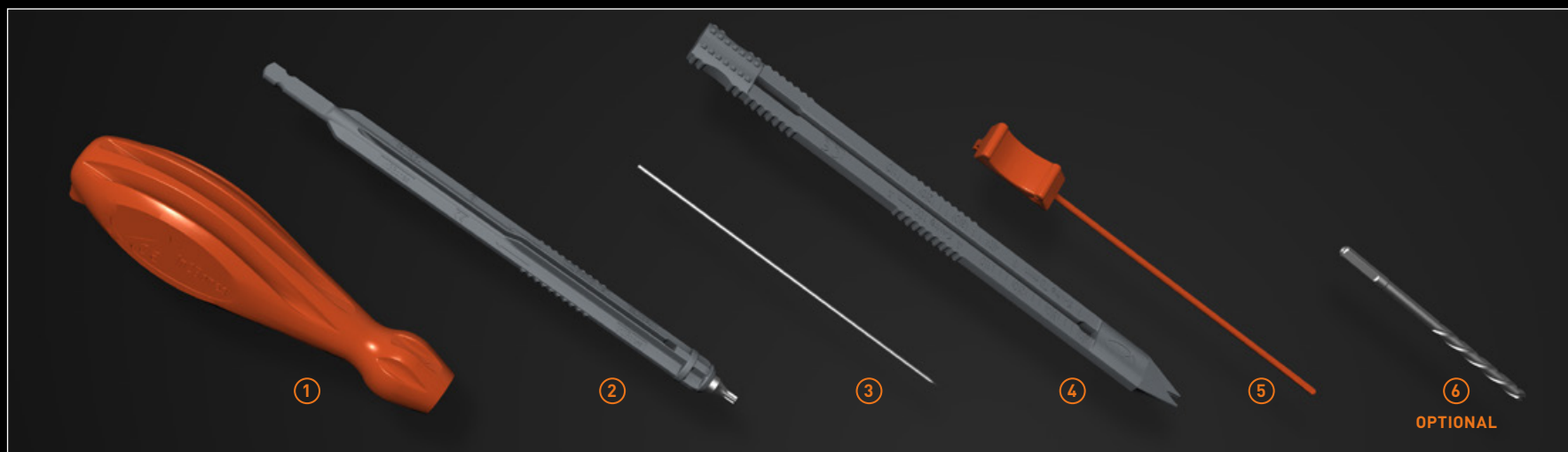
- ▶ The implant should not be used in a patient who has currently, or who has history of:
 - › acute or chronic systemic inflammations,
 - › active infections,
 - › sensitivity/allergies to the implant materials.

SURGICAL TECHNIQUE



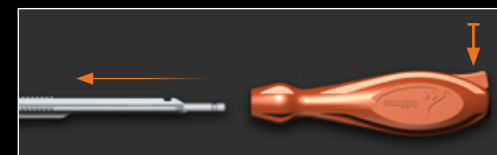
In2Bones® as the manufacturer of this device,
does not practice medicine and does not recommend
this or any other surgical technique for use on a specific patient.
The surgeon who performs any implant procedure is responsible
for determining and using the appropriate techniques for implanting
the device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

1 - SETTING UP AND ASSEMBLY

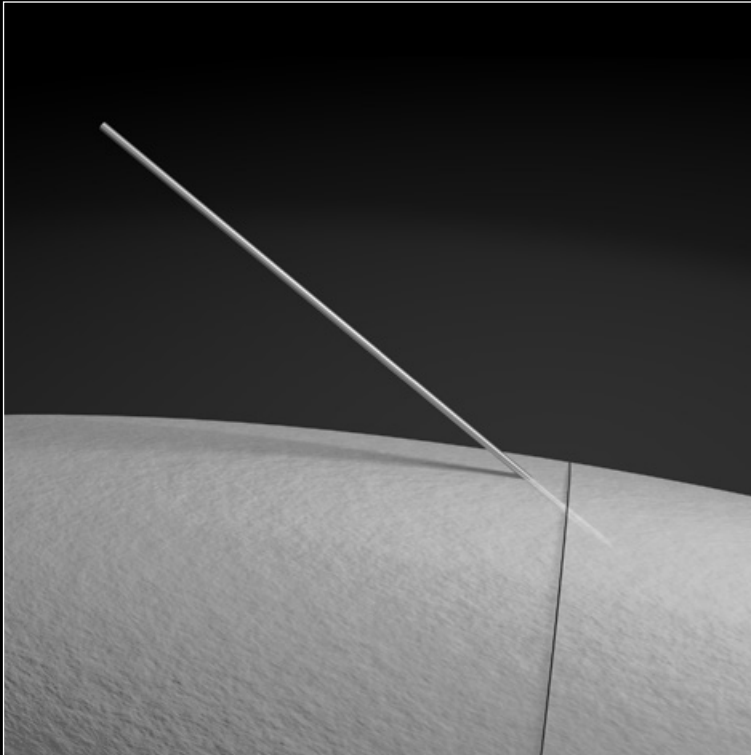


- ▶ In the Neosys® single use instrument set (ref G02 10001) select necessary instruments and put aside non required instruments for the procedure. They can be placed in recycling bins according to recycling procedure in force in the health care facility.
- ▶ For each surgery, based on the type of screw and technic chosen by the surgeon, following instruments will be needed:
 - › screwdriver handle ①
 - › screwdriver axis ②
 - Torx T7 for 2.0 and 2.5 mm screws
 - Torx T8 for 3.0mm and 3.5mm
 - › Kwire: ③
 - 0,8/70mm for 2.0 and 2.5 mm screws
 - 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.

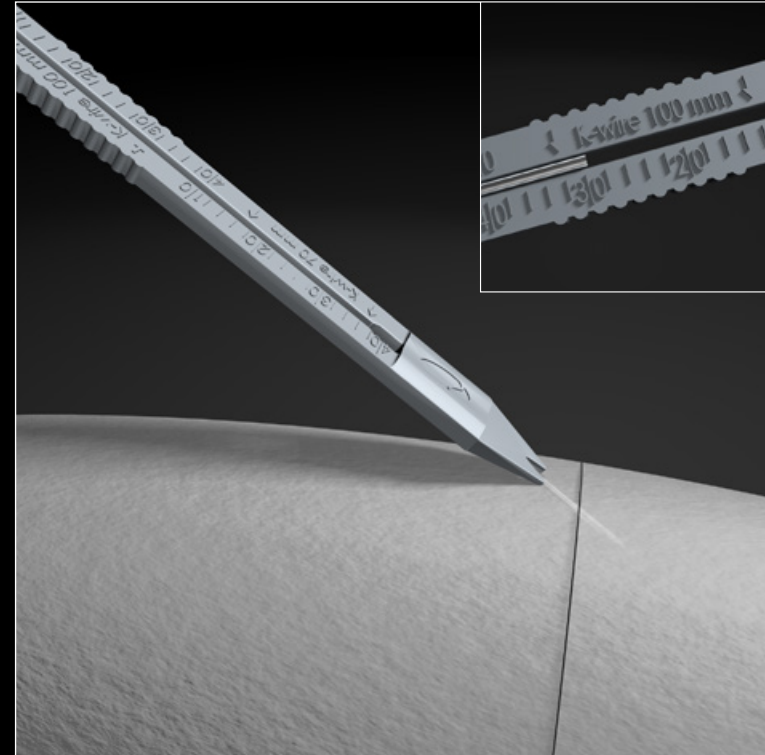


2 - OSTEOSYNTHESIS REDUCTION

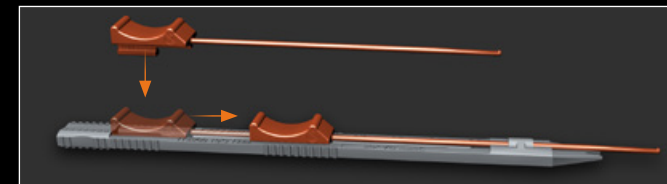


- ▶ Bony fragments are immobilized with a Kwire adapted to the diameter of the chosen screw. It will serve as a guide for the screw.
- ▶ Position of bones can be checked by fluoroscopy.
- ▶ It is possible to remove and replace the kwire until proper positioning of the bones.

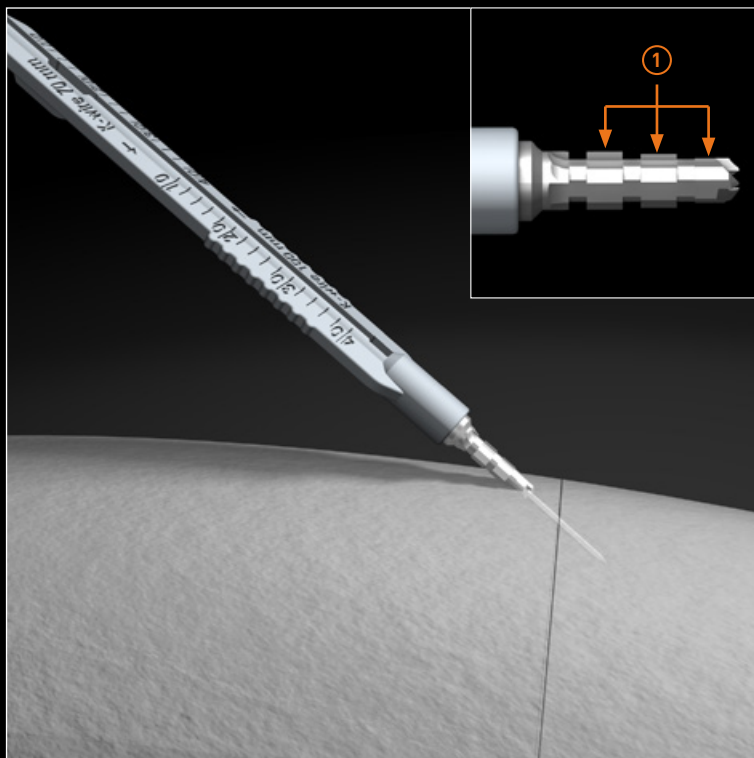
3 - MEASURE



- ▶ 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).

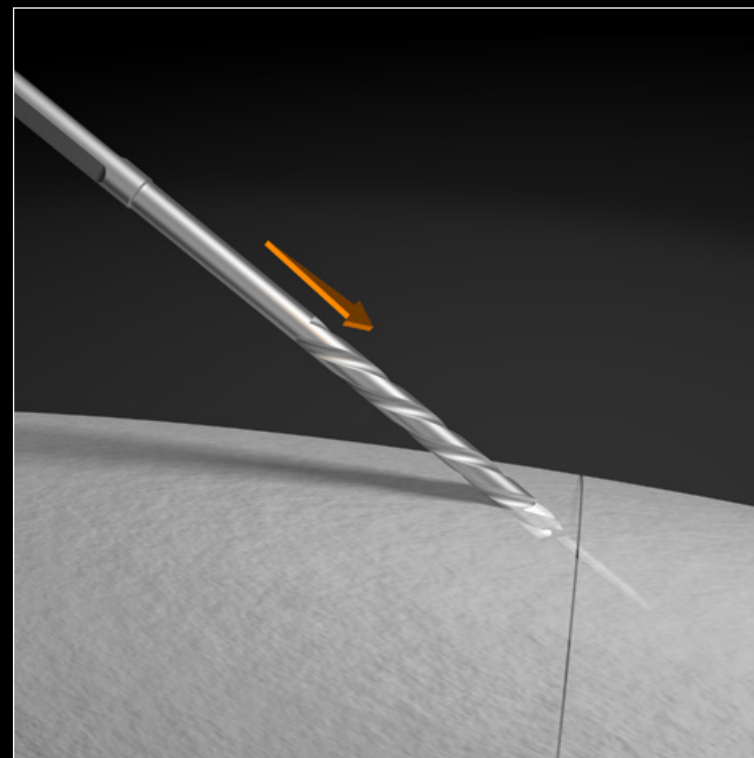


4 - SCREW HEAD PREPARATION



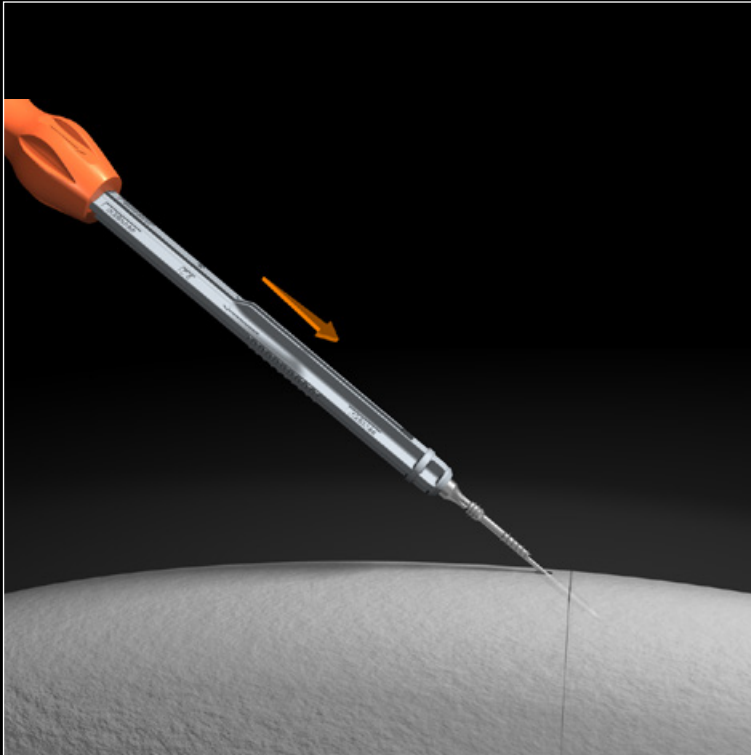
- ▶ Prepare head near cortex entry using the stepped-Starter drill.
- ▶ The stepped-Starter drill can be used on the universal handle or directly connected to the power equipment. It is recommended though to initiate first drilling using power equipment.
- ▶ The Starter drill has 3 marks ① corresponding to the different screw diameter depth : (2.0/2,5) – 3.0 and 3.5mm.

5 - DRILLING

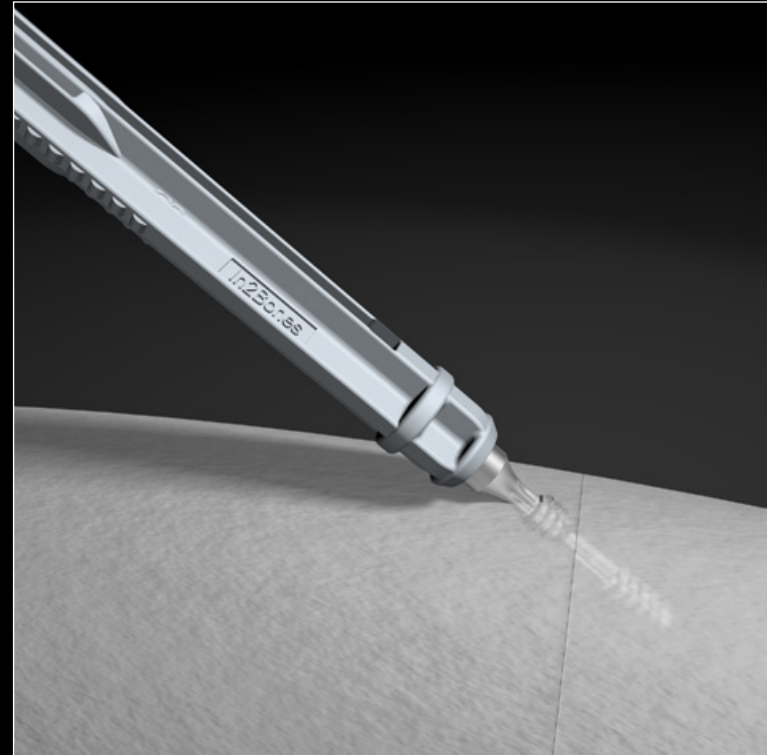


- ▶ The I.B.S.® screw is self-drilling and self-tapping.
- ▶ In some cases, it might be necessary to drill the first cortical bone. In that case, use the appropriate size drill.

6 - 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.

IMPLANTS

Innovative Bone Synthesis® - Screw diam. 2.0mm - Titanium Sterile

I.B.S.® 2.0-C Compression screw	Length
S20 ST010	10mm
S20 ST012	12mm
S20 ST014	14mm
S20 ST016	16mm
S20 ST018	18mm
S20 ST020	20mm
S20 ST022	22mm
S20 ST024	24mm
S20 ST026	26mm
S20 ST028	28mm
S20 ST030	30mm

Innovative Bone Synthesis® - Screw diam. 2.5mm -Titanium Sterile

I.B.S.® 2.5-C Compression screw	Length	I.B.S.® 2.5-N Neutralization screw
S25 ST012	12mm	S25 ST212
S25 ST014	14mm	S25 ST214
S25 ST016	16mm	S25 ST216
S25 ST018	18mm	S25 ST218
S25 ST020	20mm	S25 ST220
S25 ST022	22mm	S25 ST222
S25 ST024	24mm	S25 ST224
S25 ST026	26mm	S25 ST226
S25 ST028	28mm	S25 ST228

IMPLANTS

Innovative Bone Synthesis® - Screw diam. 3.0mm - Titanium Sterile

I.B.S.® 3.0-C Compression screw	Length	I.B.S.® 3.0-N Neutralization screw
S30 ST112	12mm	S30 ST212
S30 ST114	14mm	S30 ST214
S30 ST116	16mm	S30 ST216
S30 ST118	18mm	S30 ST218
S30 ST120	20mm	S30 ST220
S30 ST122	22mm	S30 ST222
S30 ST124	24mm	S30 ST224
S30 ST126	26mm	S30 ST226
S30 ST128	28mm	S30 ST228
S30 ST130	30mm	S30 ST230
S30 ST132	32mm	S30 ST232
S30 ST134	34mm	S30 ST234

Innovative Bone Synthesis® - Screw diam. 3.5mm - Titanium Sterile

I.B.S.® 3.5-C Compression screw	Length	I.B.S.® 3.5-N Neutralization screw
S35 ST116	16mm	S35 ST216
S35 ST118	18mm	S35 ST218
S35 ST120	20mm	S35 ST220
S35 ST122	22mm	S35 ST222
S35 ST124	24mm	S35 ST224
S35 ST126	26mm	S35 ST226
S35 ST128	28mm	S35 ST228
S35 ST130	30mm	S35 ST230
S35 ST132	32mm	S35 ST232
S35 ST134	34mm	S35 ST234
S35 ST136	36mm	S35 ST236
S35 ST138	38mm	S35 ST238
S35 ST140	40mm	S35 ST240

INSTRUMENTS

G02 10001Neosys® kit - Osteosynthesis single use instruments

2in1 Drill - Total length 65mm - AO connexion

G01 00721	Diam. 2.2mm / Lg 18mm	Canulated	Sterile
G01 00731	Diam. 2.2mm / Lg 28mm	Canulated	Sterile
G01 00781	Diam. 2.2mm / Lg 18mm	Not Canulated	Sterile
G01 00801	Diam. 2.2mm / Lg 28mm	Not Canulated	Sterile

G01 01351	Diam. 1.6mm / Lg 18mm	Canulated	Sterile
G01 01361	Diam. 1.6mm / Lg 28mm	Canulated	Sterile
G01 01371	Diam. 1.6mm / Lg 18mm	Not Canulated	Sterile
G01 01381	Diam. 1.6mm / Lg 28mm	Not Canulated	Sterile

RECOMMENDATION

- ▶ 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

- ▶ Reference : ST-SCREWS-EN-052015
- ▶ Revision date : 05/2015
- ▶ Version 03

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.

I.B.S., In2Bones and the In2Bones logo are trademarks or registered trademarks of In2Bones or its subsidiaries

