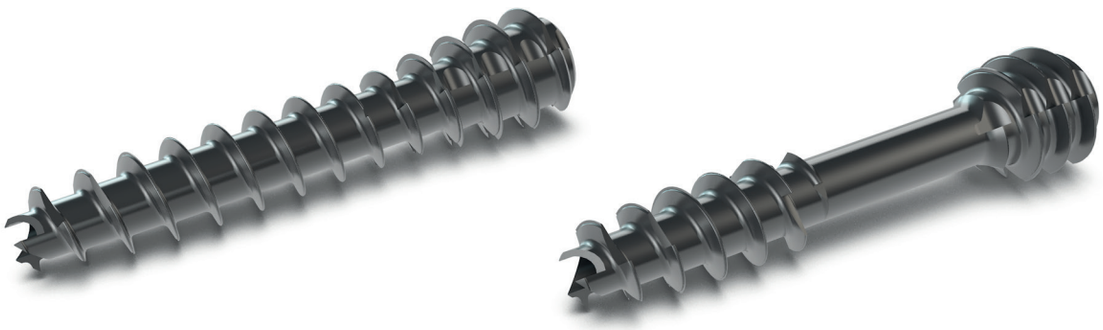
I.B.S.®

COMPRESSION SCREW / NEUTRALIZATION SCREW
DIAMETER: 2.0 - 2.5 - 3.0 - 3.5 MM



In2Bones

A GLOBAL EXTREMITY COMPANY

ST-DIG-IBSCN-EN-012021

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1. Description of the medical device

The I.B.S.® screws are:

- Osteosynthesis bone screws, existing in different models, 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.® compression and neutralization osteosynthesis screws are intended for:

- The fixation of arthrodesis, osteotomies or fractures of long or short bones of the upper and lower limbs
- Osteosynthesis requiring a mono or bicortical compression

The size of the chosen screw should be adapted to the specific indications.

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).

I.B.S.®
PRODUCT DESCRIPTION

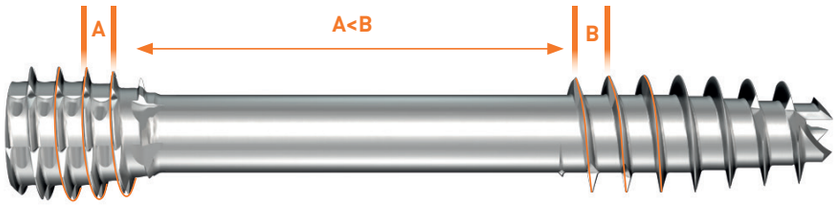
- The design of the I.B.S.® compression screw by In2Bones® is optimized to distribute the compression effort, maximize and facilitate the osteosynthesis.
- The I.B.S.® compression and neutralization screws are cannulated, self-drilling and self-tapping.
- Made of Titanium alloy Ti6Al4V The I.B.S.® Compression screw is available in 2.0 - 2.5 - 3.0 and 3.5 mm (for diameters 4.5 - 6.5 and 8.0 mm, see the Large I.B.S.® brochure).
- 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®.
- The I.B.S.® screws are delivered sterile.

Torx imprint

- The I.B.S.® screw range is designed with a Torx imprint.
- The « star » shape supports a higher torque without degradation of the imprint.
- Self-retaining I.B.S.® Compression and Neutralization screw are fail-safe.

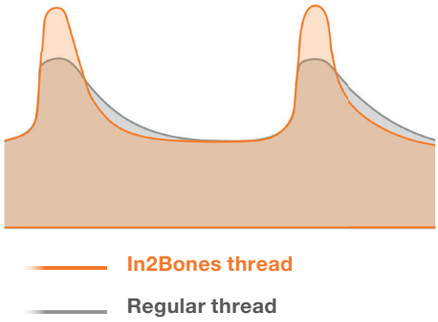
Compression

– Differential pitch of head and shaft threads.



Thread

– I.B.S.® threads design
  - offers approximatively 40% more contact area than standard threads.
  - allows optimal penetration in cortical bones and a enhanced grip.



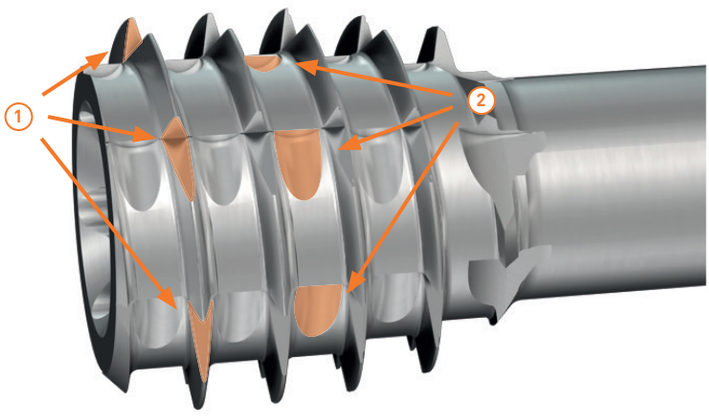
I.B.S.® compression and neutralization screw range is headless

– The head of the screw is countersunk into cortical bone to increase compression and reduce soft-tissue impingement

Head is self-tapping and self-drilling

– Self-drilling and self-tapping cutting flutes ① facilitate countersink of the screw head.

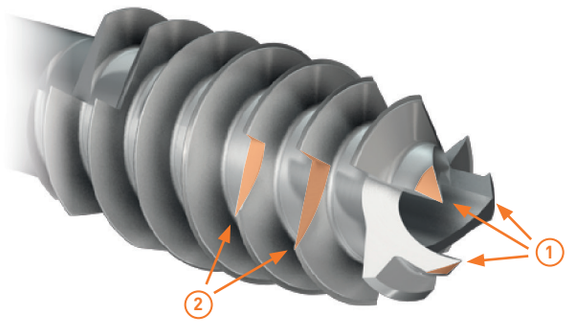
– Inter-thread notches ② in the screw head reduce the risk of stress fracture during the final insertion phase (Patented).



I.B.S.®
PRODUCT DESCRIPTION

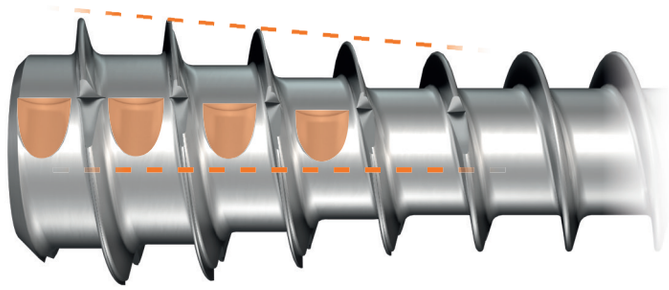
Self-drilling

- Compression and Neutralization screws are self-drilling and self-tapping.
- 3 cutting edges with specific angulation to guarantee self drilling performance ①
- Distal cutting flutes facilitate the screw insertion ②



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	Kwire diam.	*Drill diam.* *(Optional)*
I.B.S.® 2.0	2.0mm		Compression screw (C)	Torx 7	10 > 30mm* *1mm incremental*	0.8mm	*1.6mm*
I.B.S.® 2.5	2.5mm		Compression screw (C) Neutralization screw (N)	Torx 7	12 > 28mm *2mm incremental*	0.8mm	*1.6mm*
I.B.S.® 3.0	3.0mm		Compression screw (C) Neutralization screw (N)	Torx 8	12 > 34mm *2mm incremental*	1.0mm	*2.2mm*
I.B.S.® 3.5	3.5mm		Compression screw (C) Neutralization screw (N)	Torx 8	16 > 40mm *2mm incremental*	1.0mm	*2.2mm*

* Odd length are only available in some countries

Single use instruments range - Neosys®

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

- 2.0, 2.5, 3.0 and 3.5mm compression screws,
- 2.5, 3.0 and 3.5mm neutralization screws,
- 2.2 and 2.7mm snap-off screws,

Kwire and drills are available in the Neosys® single use instrument range.

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.

Screwdriver axes are cannulated ② with an open window to allow kwire extraction.

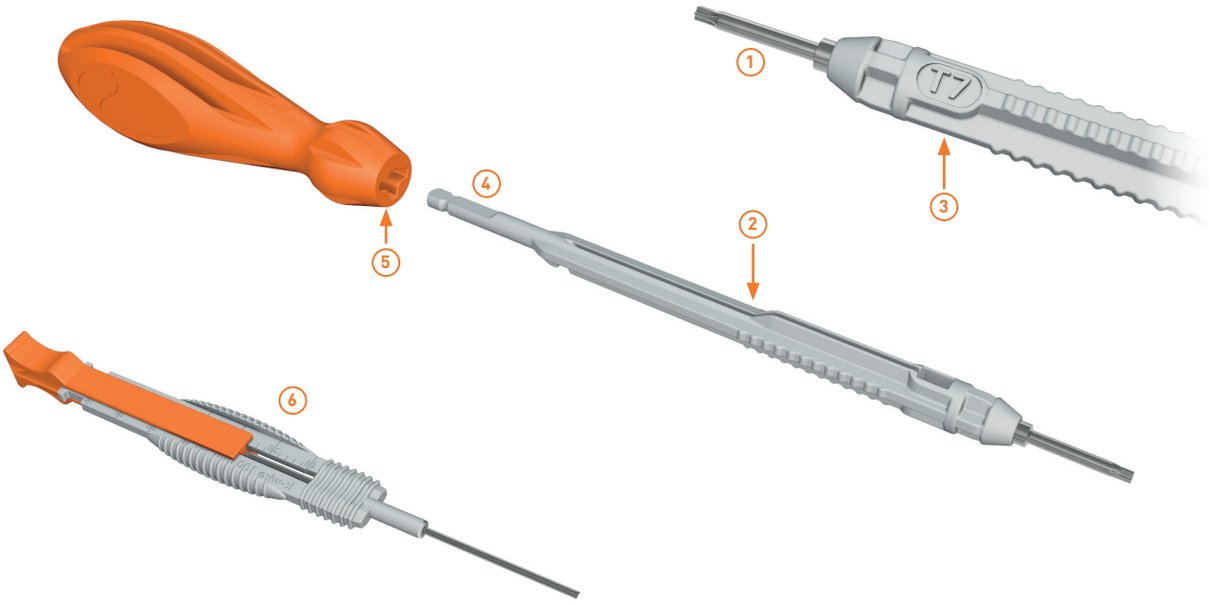
Torx imprint is indicated directly on the axis. ③

Screwdriver 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 garantees proper positioning. ⑤

Implant can be measured either on k-wire or with the depth gauge. ⑥ The use of a depth gauge is optional.

For a complete description of all available Neosys single use instrument sets, please refer to Neosys dedicated brochure.

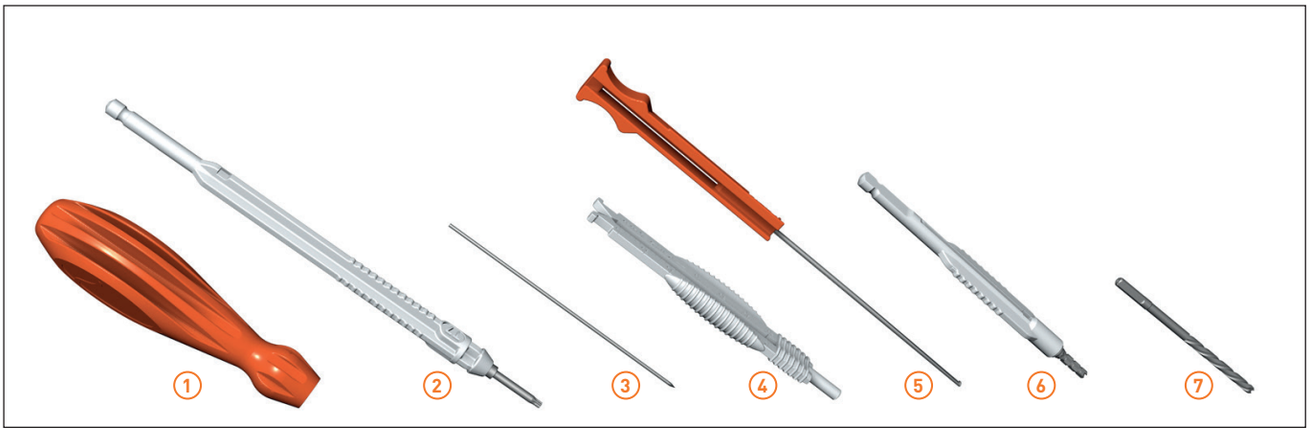


I.B.S.®
SURGICAL TECHNIQUE

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.

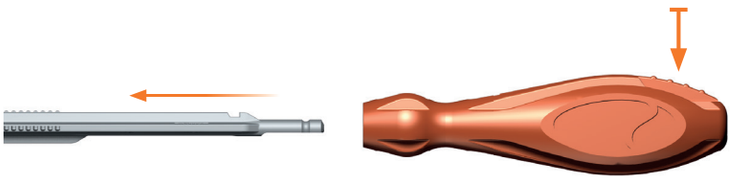
1 - Setting up and assembly

In the Neosys® single use instrument set range select the appropriate set configuration according to the procedure.



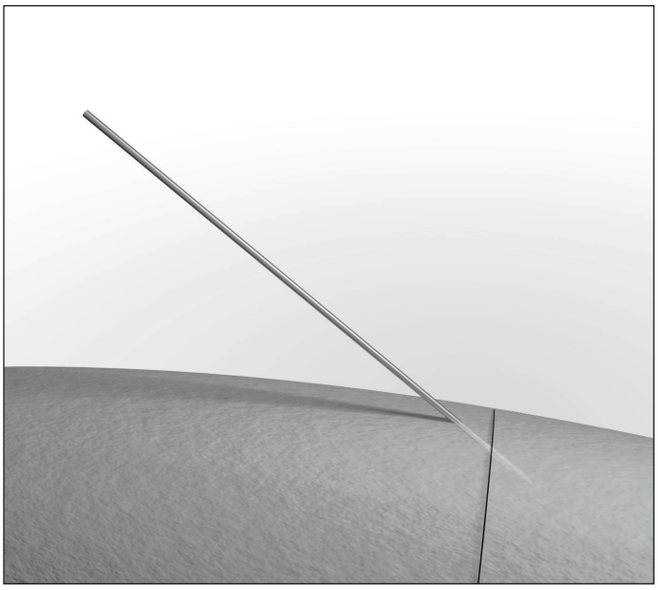
For each surgery, based on the type of screw and technic chosen by the surgeon, following instruments will be needed:

- Screwdriver handle ①
- Screwdriver axis ②
  · Torx T7 for 2.0 and 2.5 mm screws
  · Torx T8 for 3.0mm and 3.5mm
- K-wire: 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
- Starter ⑥ : it allows to prepare the first cortical bone for the insertion of the screw head.
- A drill ⑦ can be necessary based on bone quality or surgeon's preference.



Screwdriver handle can be assembled to screwdriver axis. 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

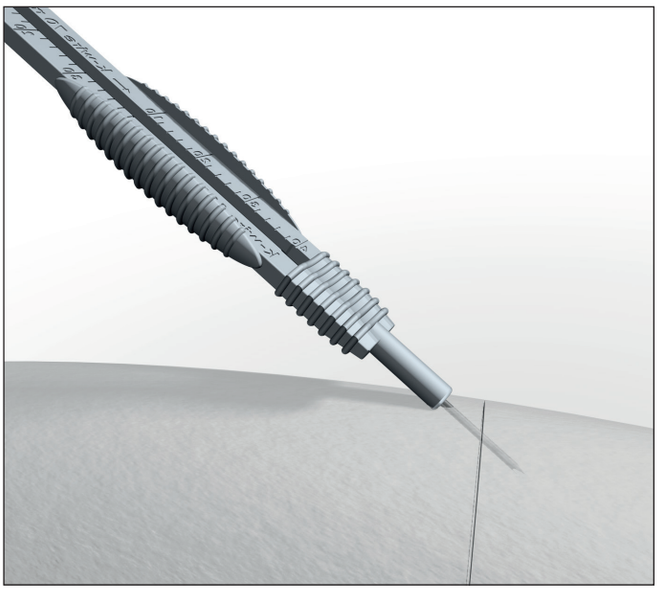


Bony fragments are immobilized with a K-wire adapted to the diameter of the chosen screw. It will serve as a guide for the screw.

Position of bones can be checked by fluoroscopy.

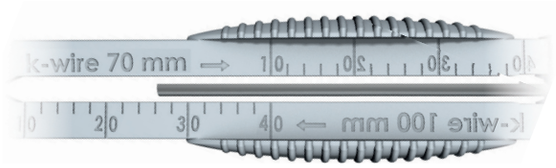
It is possible to remove and replace the K-wire until proper positioning of the bones.

3 - Measure

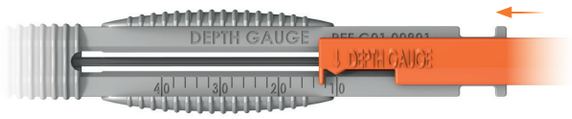


Measure of the screw length:

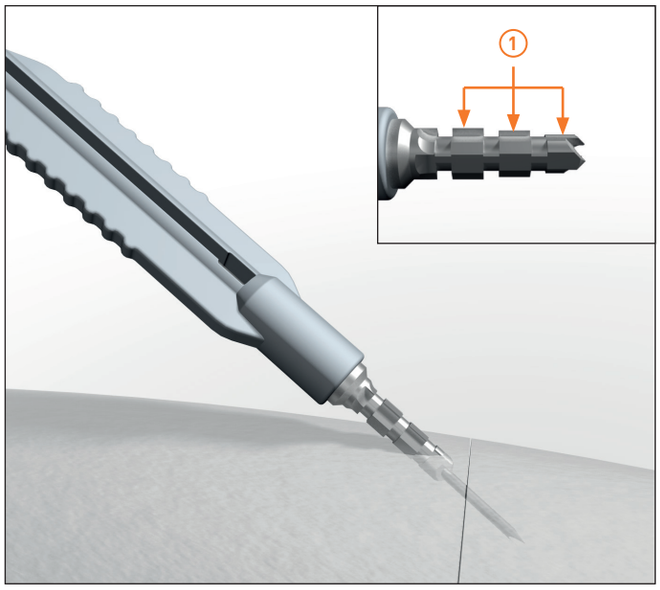
- Slide the measurer on the K-wire and read directly the length on side measurer (side «K-wire 70 mm» or «K-wire 100 mm»)



- Measure can also be made with the depth gauge. In that case insert the gauge on the measurer (tunnel side).



4 – Screw head preparation



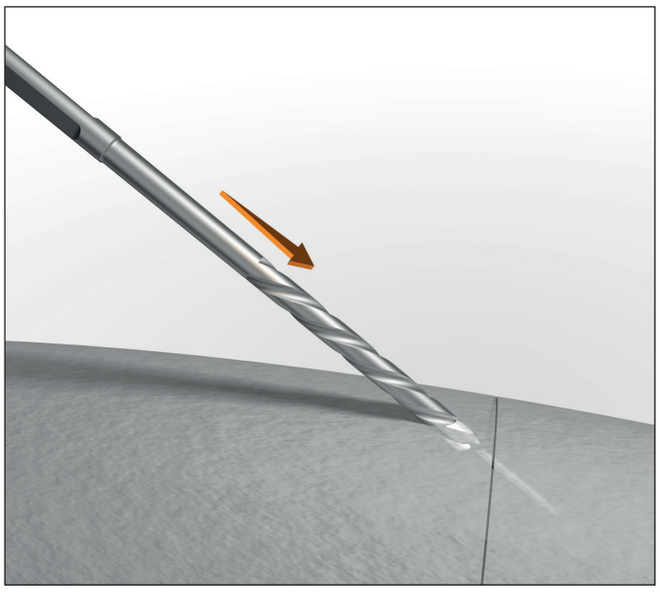
Prepare head near cortex entry using the stepped-Starter drill.

The stepped-Starter drill is directly connected to the power equipment.

For smaller diameter (2.0/2.5mm) the stepped starter can be assembled to the universal handle. Attention must be taken as the shaft is not secured in the handle.

The Starter drill has 3 marks ① corresponding to the different screw diameter depth : (2.0/2.5) – 3.0 and 3.5mm. It also has a measuring function.

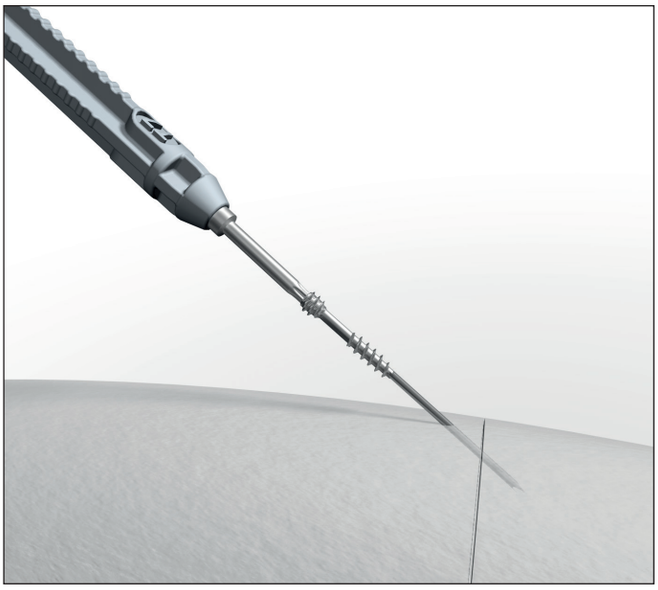
5 - Drilling (optional)



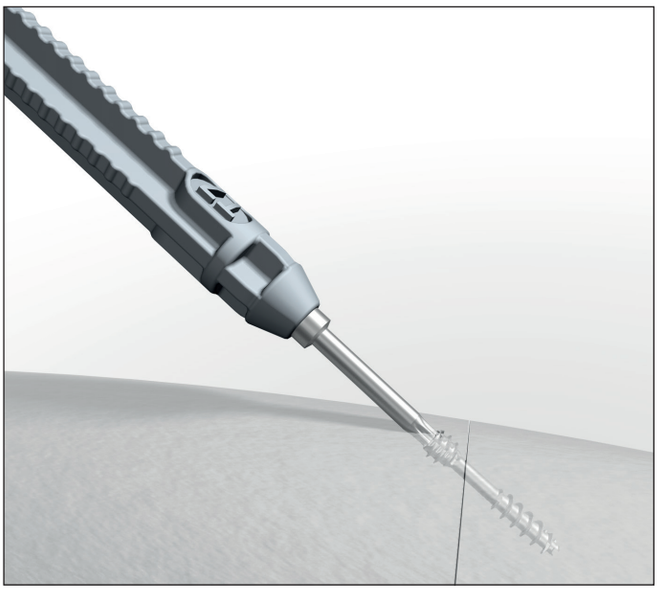
The I.B.S.® screw is self-drilling and self-tapping.

In some cases, it might be necessary to drill. In that case, use the appropriate size drill.

6 - Screw insertion



The screw is inserted with the cannulated screwdriver axis. It can be either inserted manually or with a power driver.



In case of an I.B.S.® Compression screw, screw head must be fully embedded into the cortical bone in order to obtain the optimized compression

K-wire is removed after screw insertion.

I.B.S.®
ORDERING INFORMATIONS

IMPLANTS

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

I.B.S.® 2.0-C Compression screw	Length
S20 ST010	10mm
S20 ST011	11mm
S20 ST012	12mm
S20 ST013	13mm
S20 ST014	14mm
S20 ST015	15mm
S20 ST016	16mm

I.B.S.® 2.0-C Compression screw	Length
S20 ST017	17mm
S20 ST018	18mm
S20 ST019	19mm
S20 ST020	20mm
S20 ST021	21mm
S20 ST022	22mm
S20 ST023	23mm

I.B.S.® 2.0-C Compression screw	Length
S20 ST024	24mm
S20 ST025	25mm
S20 ST026	26mm
S20 ST027	27mm
S20 ST028	28mm
S20 ST029	29mm
S20 ST030	30mm

Odd lengths are only available in some countries

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

I.B.S.® 2.5-C Compression screw	Length	I.B.S.® 2.5-N Neutralization screw
S25 ST010	10mm	-
S25 ST011	11mm	-
S25 ST012	12mm	S25 ST212
S25 ST014	14mm	S25 ST214
S25 ST016	16mm	S25 ST216
S25 ST018	18mm	S25 ST218

I.B.S.® 2.5-C Compression screw	Length	I.B.S.® 2.5-N Neutralization screw
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

Innovative Bone Synthesis® - Screw diam. 3.0 mm - 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

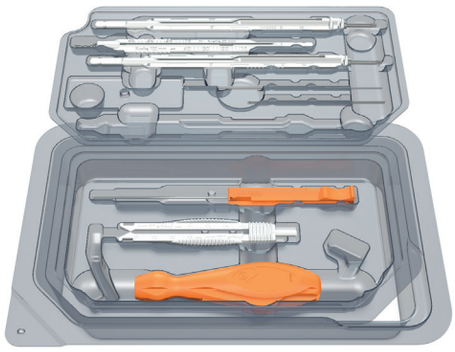
I.B.S.® 3.0-C Compression screw	Length	I.B.S.® 3.0-N Neutralization screw
S30 ST124	24mm	S30 ST224
S30 ST126	26mm	S30 ST226
S30 ST128	28mm	S30 ST228
S30 ST130	30mm	S30 ST230
S30 ST132	32mm	S30 ST232
S30 ST134	34mm	S30 ST234

Innovative Bone Synthesis® - Screw diam. 3.5 mm - 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

I.B.S.® 3.5-C Compression screw	Length	I.B.S.® 3.5-N Neutralization screw
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



NEOSYS - Single use instrument set range

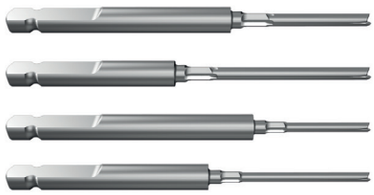
The Neosys Single Use Instrument Set is available in different configuration according to surgeon's technics and preferences.
Please refer to the dedicated brochure for more information.

2in1 drills

2in1 drills are available individually packed or directly inside some of the Neosys Single Use instrument set configurations.
Please refer to the dedicated brochure for more information.

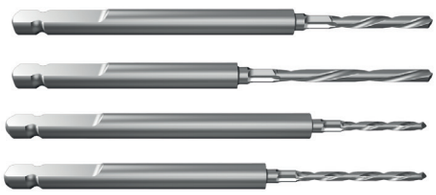
2in1 Drill - Total length 65mm - AO connexion

G01 00721	Diam. 2.2mm / Lg 22mm	Cannulated	Sterile
G01 00731	Diam. 2.2mm / Lg 32mm	Cannulated	Sterile
G01 01351	Diam. 1.6mm / Lg 18mm	Cannulated	Sterile
G01 01361	Diam. 1.6mm / Lg 26mm	Cannulated	Sterile



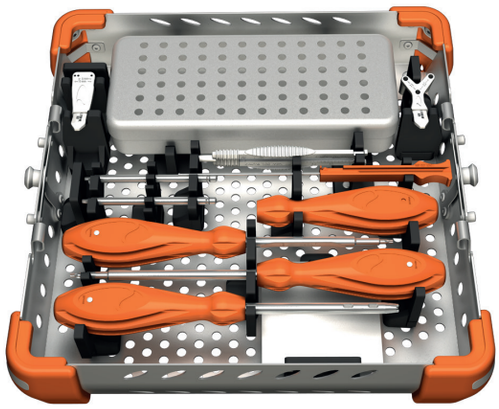
2in1 Drill - Total length 75mm - AO connexion

G01 00781	Diam. 2.2mm / Lg 22mm	Not Cannulated	Sterile
G01 00801	Diam. 2.2mm / Lg 32mm	Not Cannulated	Sterile
G01 01371	Diam. 1.6mm / Lg 18mm	Not Cannulated	Sterile
G01 01381	Diam. 1.6mm / Lg 26mm	Not Cannulated	Sterile



NEOSYS - Reusable instrument set

G01 00881	Orange Modular Handle Small Size
G01 00901	Forefoot Depth Gauge
G01 00852	Torx T7 graduated screwdriver
G01 00862	Torx T8 graduated screwdriver
G01 00891	Injected Ruler For K-wire 70 & 100mm
G01 00201	Cannulated Torx 7 attachment screwdriver
G01 00241	Cannulated Torx 8 attachment screwdriver
G01 00921	K-wire Holder 70 and 100mm Diam 0.8mm - 1.0mm - 2.5mm
K10 NS070	Kirschner wire non sterile Diam 0.8mm length 70mm 1 sharp end
K10 NS071	Kirschner wire non sterile Diam 1.0mm length 70mm 1 sharp end
K10 NS100	Kirschner wire non sterile Diam 1.0mm length 100mm 1 sharp end
G01 01341	Pilot Hole Starter Drill



I.B.S.®
REGULATORY INFORMATIONS

RECOMMANDATION

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

DEVICES

CE Classification (Directive MDD 93/42/EC)

- Implants : Class CE IIb - CE2797
- Single use instruments and instruments connected to a power driver: Class CE IIa - CE2797
- Instruments with measuring function: Class Im - CE2797
- Other instruments: Class I - CE

REIMBURSEMENT

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

MANUFACTURER

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DOCUMENT

Reference : ST-DIG-IBSCN-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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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. In2bones and the In2bones logo are trademarks or registered trademarks of In2bones or its subsidiaries.
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