

I.B.S.TM

COMPRESSION SCREW / NEUTRALIZATION SCREW
DIAMETER: 4.5 - 6.5 - 6.5C+ - 8.0 MM

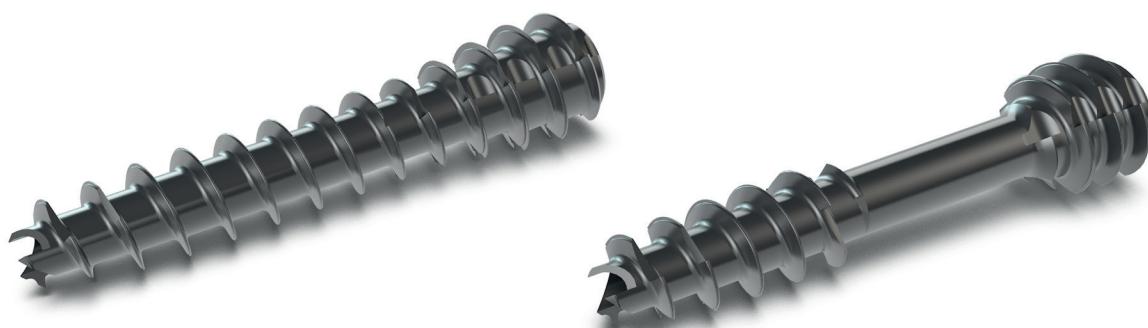


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1. Description of the medical device

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 phthalates 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:

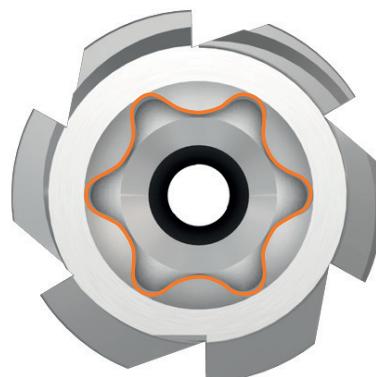
- systemic, acute or chronic inflammations, ,
- active infections,
- sensitivity/allergies to the implant materials (cf paragraph 1).

- 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 and Neutralization screw is available in 4.5 - 6.5 and 8.0 mm.
- The I.B.S.™ 6.5mm compression screws are available in two versions : 15mm distal thread (C) and 30mm distal thread (C+)
- The I.B.S.™ Mid and Hindfoot screws are available in compressive version and in neutralization version fully threaded
- The I.B.S.™ screws are delivered sterile.



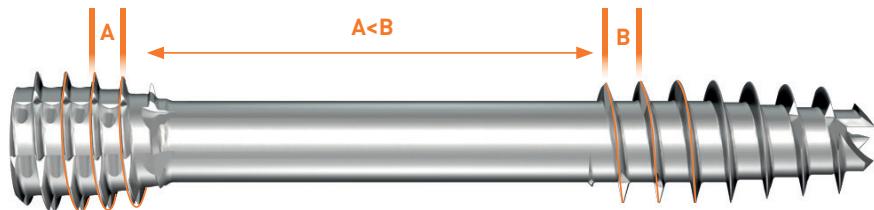
Torx imprint

- 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.



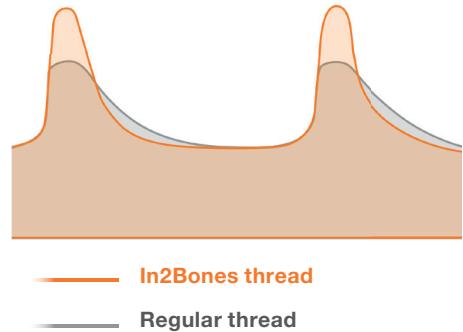
Compression

- 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.

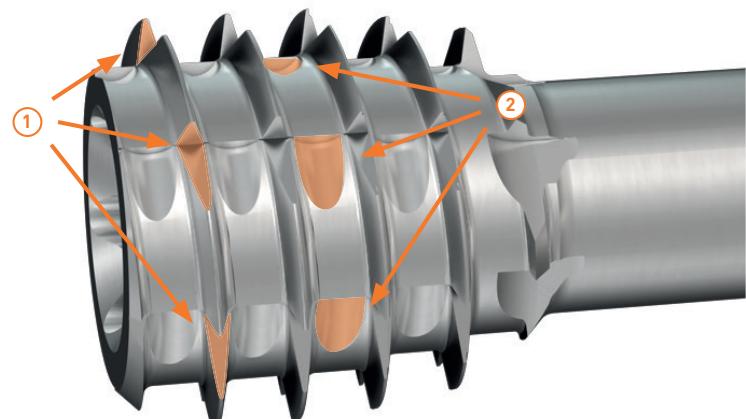


I.B.S.™ compression and neutralization screw range is headless

- 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).

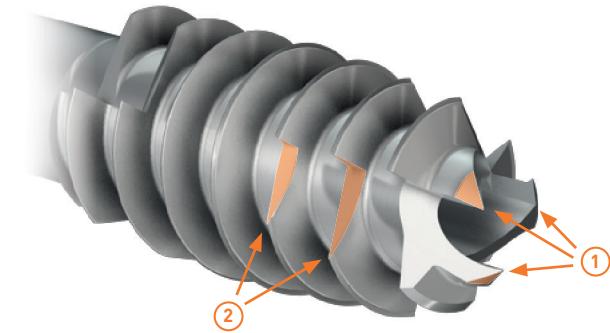


I.B.S.™

PRODUCT DESCRIPTION

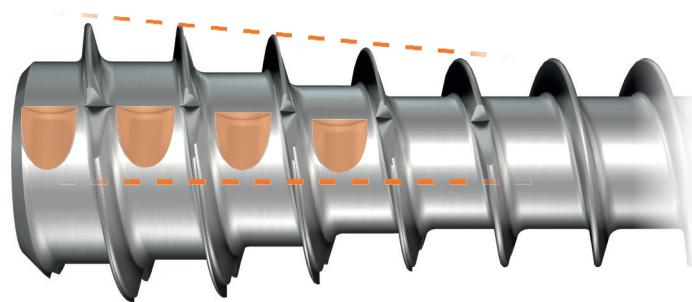
Self-drilling

- 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.

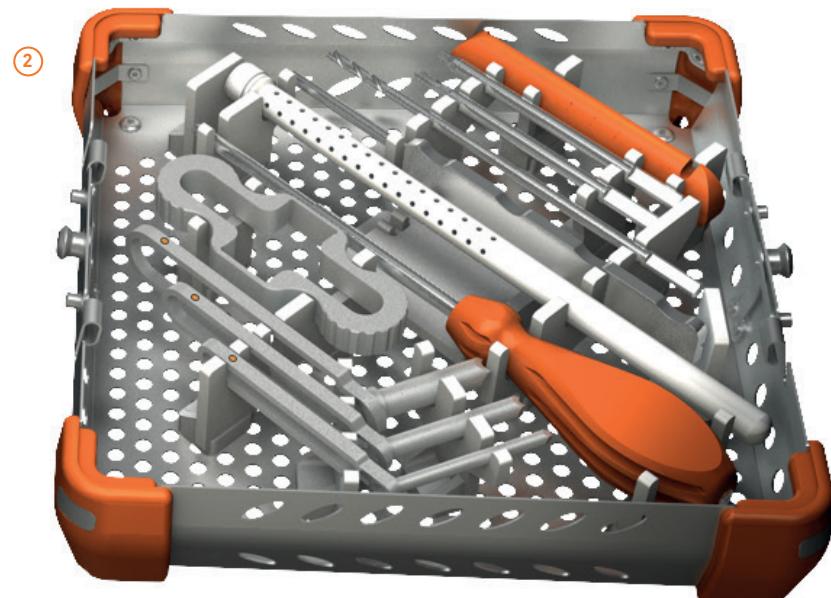
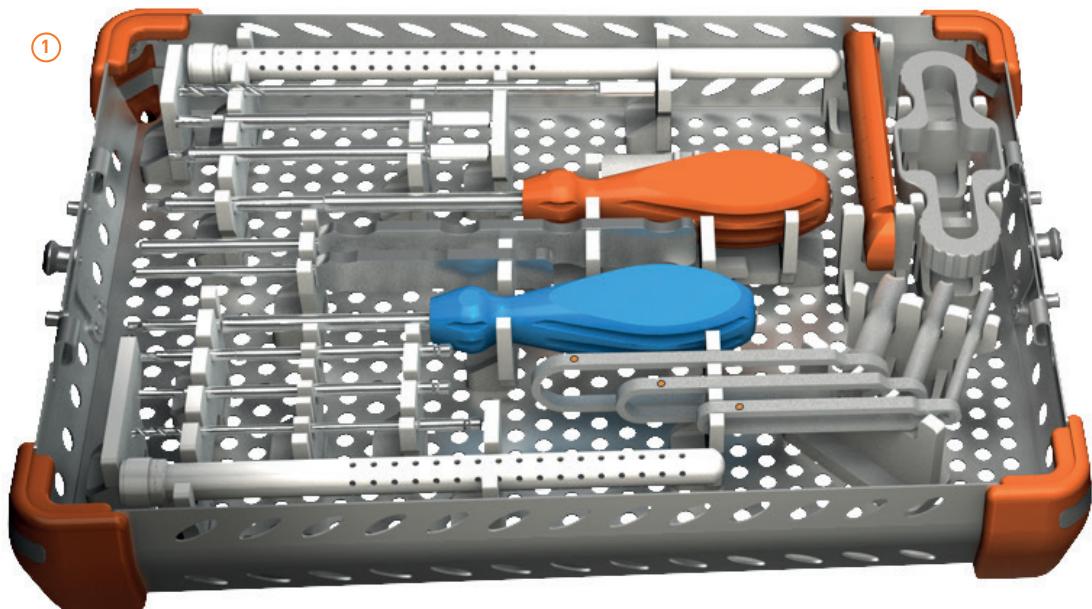


Product name	Screw diameter	Color code	Screw type	Screw imprint	Length	Kwire diam.	Drill diam.
I.B.S.™ 4.5	4.5mm		Compression screw (C) Neutralization screw (N)	Torx 15	20 < 70mm 2mm incremental	1.6mm	3.0mm
I.B.S.™ 6.5	6.5mm		Compression screw (C) Neutralization screw (N)	Torx 25	20 < 115mm 5mm incremental	2.0mm	4.3mm
I.B.S.™ 6.5C+	6.5mm		Compression screw (C)	Torx 25	60 < 115mm 5mm incremental	2.0mm	4.3mm
I.B.S.™ 8.0	8.0mm		Compression screw (C) Neutralization screw (N)	Torx 30	40 < 115mm 5mm incremental	2.5mm	5.5mm

Instrumentation

The following instruments sets are available:

- diam. 4.5mm instruments
- diam. 4.5 & 6.5mm COMBO instruments ①
- diam. 6.5mm instruments ②
- diam. 8.0mm instruments
- diam. 6.5 & 8.0mm COMBO instruments

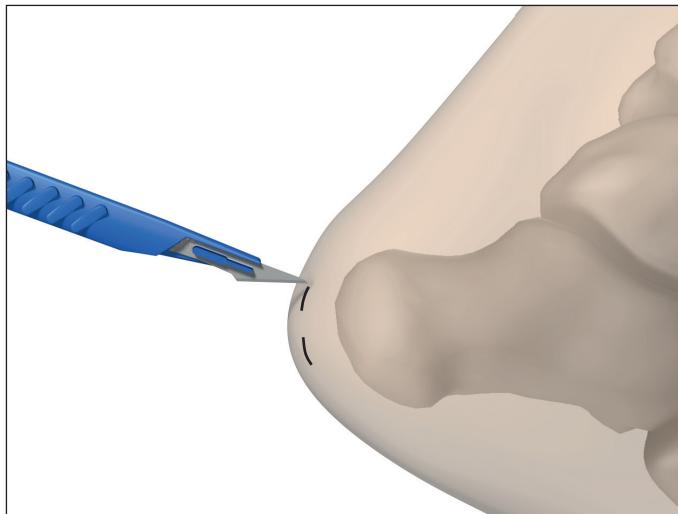


I.B.S.™

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 - Preparation



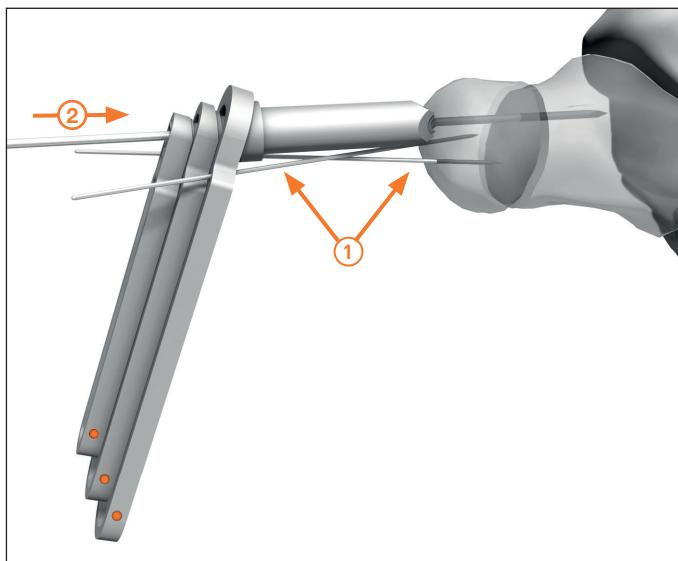
For a calcaneal realignment osteotomy, two incisions are made to allow the use of the drilling guide and the protecting guide

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.

2 - Drilling guide and protecting sleeve

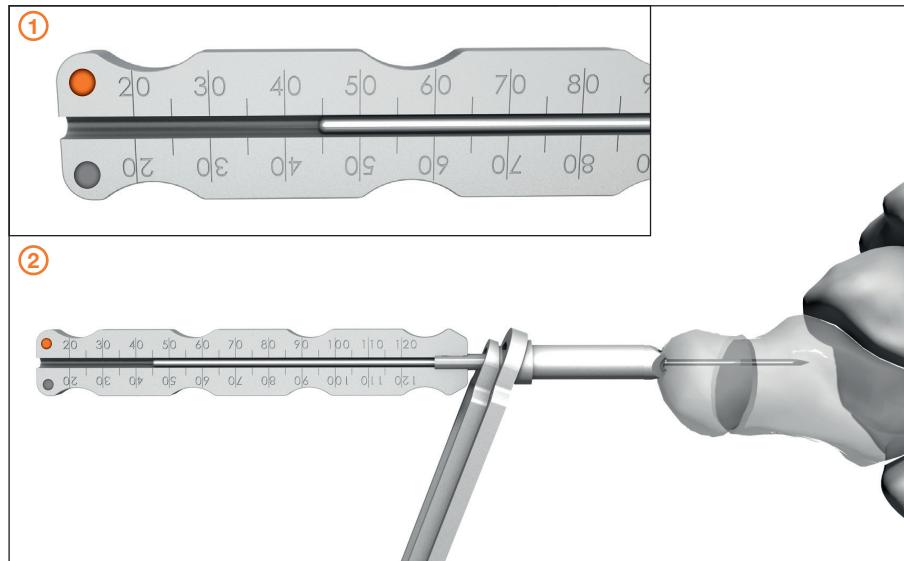


Secure soft tissues with the use of protectors (for 6.5 and 8.0 mm screws only), stabilized with an optional 1.0mm kwire ①.

The K-wire is guided by the internal drilling guide ②. Its diameter depends upon the screws to be implanted. The depth of the K-wire insertion relies upon the surgeon's desire to achieve a mono or bicortical fixation.

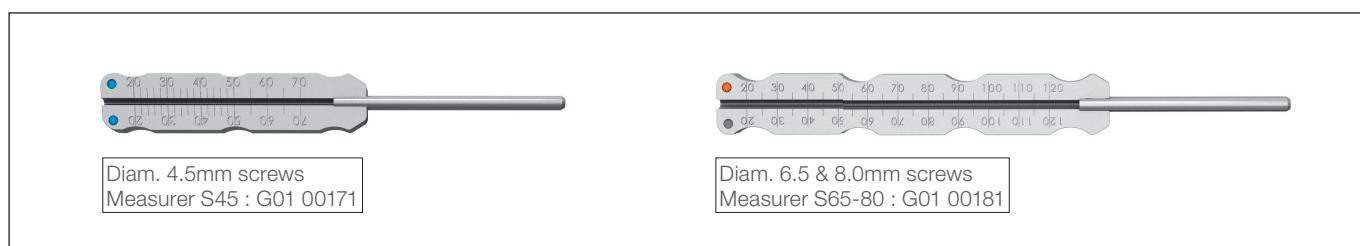
	Diam. 4.5mm	Diam. 6.5mm	Diam. 8.0mm
K-Wire	1.6 mm	2.0 mm	2.5 mm
K-wire guide	-	• G01 01251 •	• G01 01291 •
Drill guide	-	• G01 01261 •	• G01 01301 •
Protecting sleeve	-	• G01 01271 •	• G01 01311 •

3 - Screw length assessment



Slide the narrow end of the measurer, whether directly applied on the kwire for a 4.5 mm ①, or inserted through the protecting guide for a 6.5 or a 8.0 mm ②.

Graduated in milimeters, the measurer is intended to provide the most suitable length of the screw.



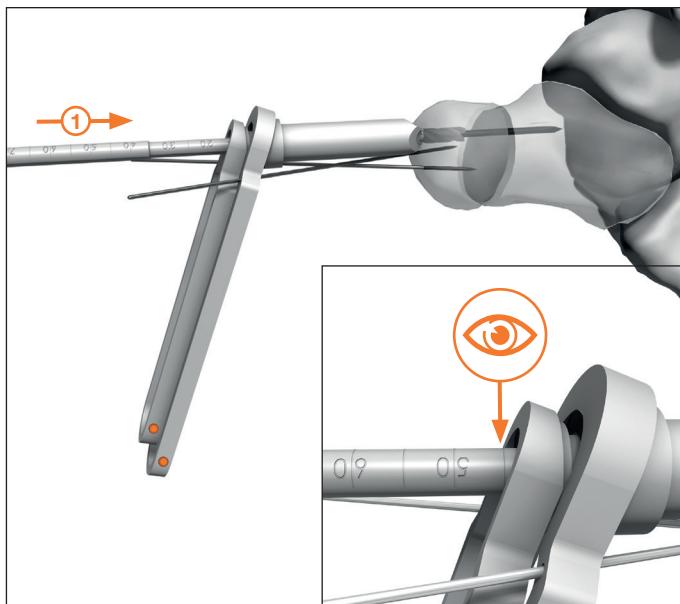
The appropriate screw length is then determined directly from the measurer.

WARNING

The measurement taken from the measurer/K-wire is directly linked to the positioning of the K-wire and therefore, cannot be considered optimal unless the K-wire is correctly positioned.

The positioning of the K-wire can be validated by means of peroperative X-ray or fluoroscopy.

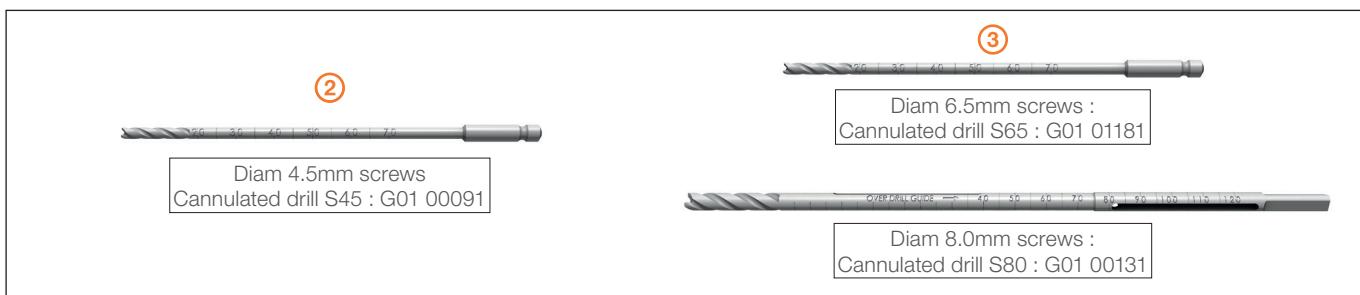
4 – Use of the drills



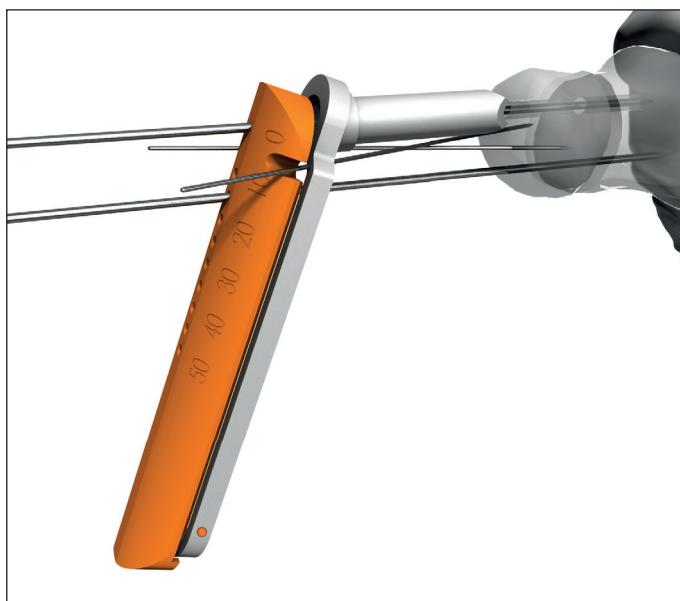
During this step the screw shaft is prepared with a cannulated drill. ①

- For 4.5mm screws the drill ② is used with no protecting sleeve and depth length is directly checked on the drill.
- For 6.5mm and 8.0mm screws, the drill ③ is used through a protecting sleeve and guided over the guide pin. Measurement of the length is read on the top end of the guide over the drill, above the mention : « OVER DRILL GUIDE ».

Should the surgeon not wish to use the drill guides, measure of the length is made directly on the drill on the side opposite to that marked «over drill guide».



Tip : optional parallel drilling



Available option for diam. 6.5mm and diam. 8.0mm screws only:

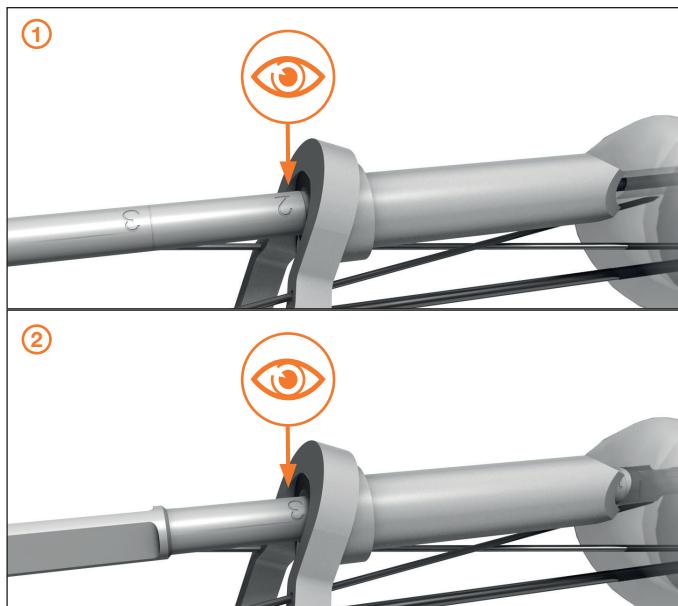
A second guide wire, parallel to the first one, may be used thanks to the « drilling matrix ».

The later is inserted over the first guide pin and locked into the protecting sleeve handle. Once stable, it offers a selection of positioning holes aligned with the first guide wire.

The matrix offers a range of holes away from the base pin of 10mm to a maximum 50mm by 5 mm increments.

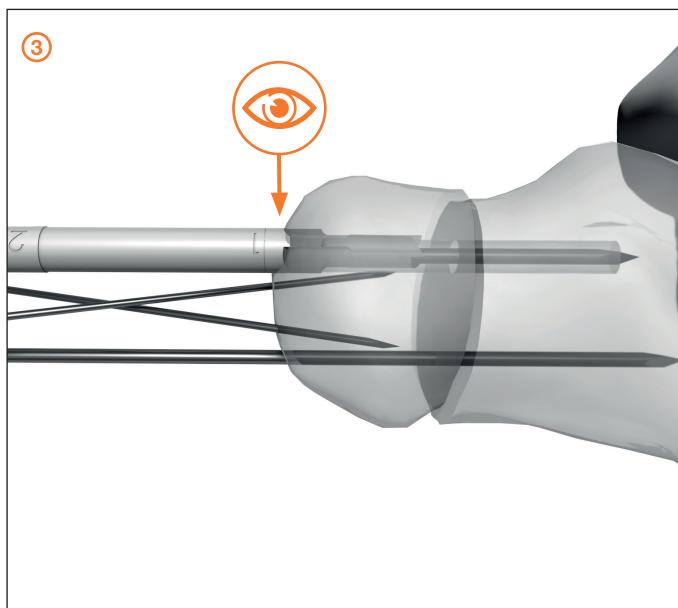
	Diam. 6.5mm	Diam. 8.0mm
Guide wire matrix	• G01 01281 •	• G01 01321 •

5 - Screw head preparation



When a compression screw is implanted, screw head is prepared with the short cannulated drill.

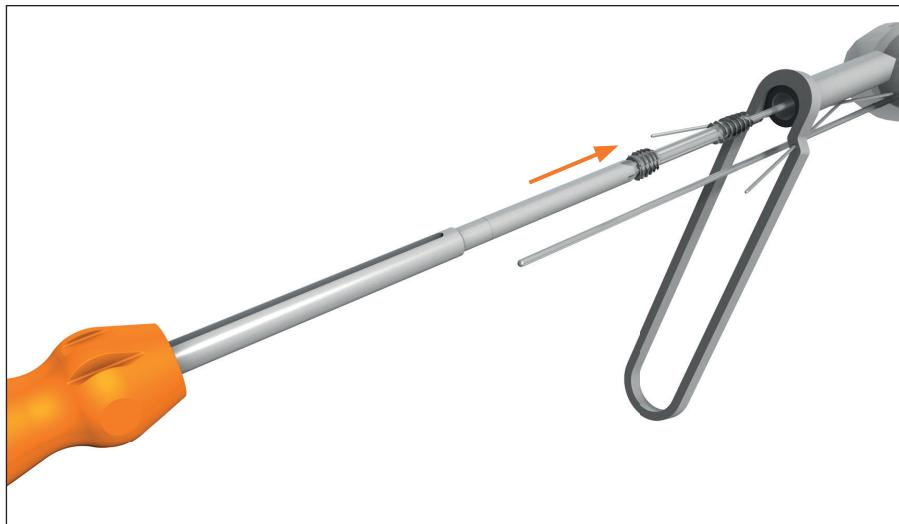
- For the 4.5mm screws, the drill is guided on the guide pin. Position 1 indicates the length for which the head is totally embedded.
- For the 6.5mm and 8.0mm, if the surgeon is using the protection guides, two markings are used:
 - Position 2 indicates that the drill through the protecting guide is against the bone. ①
 - Position 3 indicates that the screw head is totally embedded. ②



If not using the protection guides, one can read the position of the drill with position 1 that indicates that the screw head is totally embedded. ③

	Diam. 4.5mm	Diam. 6.5mm	Diam. 8.0mm
Cannulated step drill	G01 00531	G01 00031	G01 00141

6 – Screw insertion



The screw is then inserted over the guide pin.

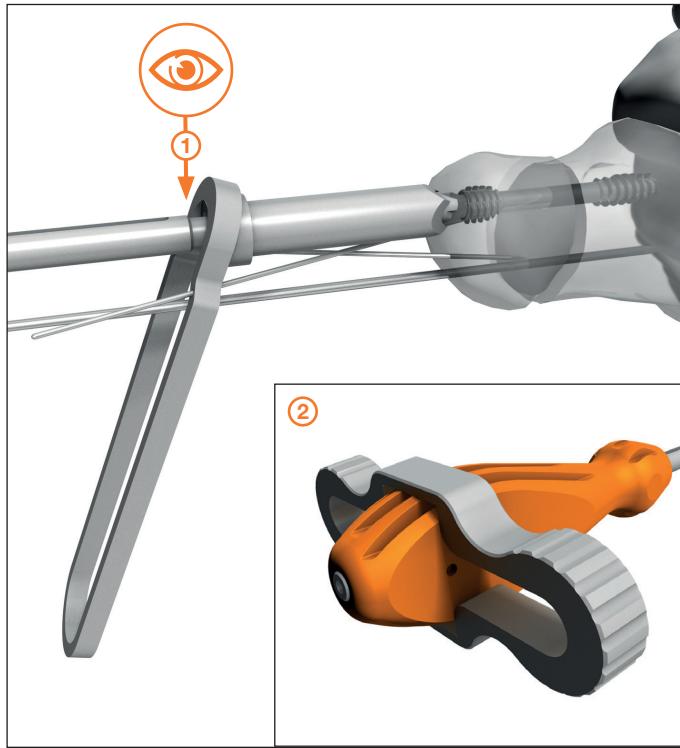
It can be screwed manually with the cannulated screwdriver.

	Diam. 4.5mm	Diam. 6.5mm	Diam. 8.0mm
Cannulated screwdriver	T15 : G01 00331	T25 : G01 00411	T30 : G01 00421



Alternatively it can be screwed using a cannulated screwdriver tip attached to the power driver.

	Diam. 4.5mm	Diam. 6.5mm	Diam. 8.0mm
Screwdriver tip	T15 : G01 00361	T25 : G01 00381	T30 : G01 00371

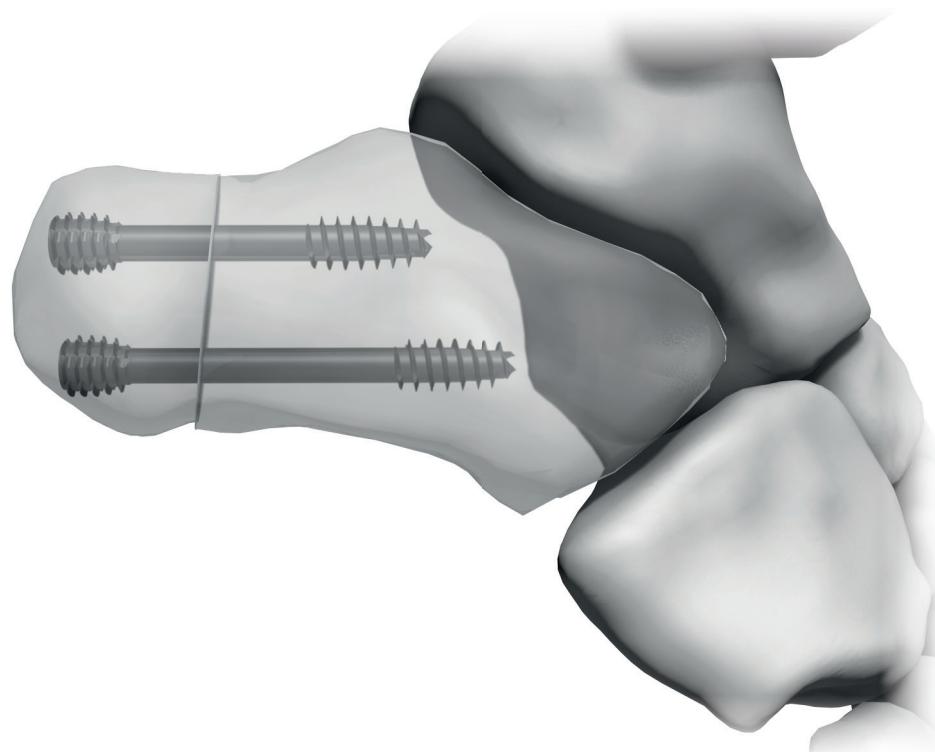


For 6.5mm and 8.0mm screws, when the surgeon uses the protecting guides, a marking on the screwdriver shaft ① indicates the position where the screw head is totally embedded in the cortical bone.

A special adaptor allows, if necessary, to transform the handle in a « T handle » ② allowing to tighten the screw when high torque transmission is necessary.

It can be used as well to extract the screws.

	Diam. 6.5mm	Diam. 8.0mm
Handle	T25	T30
Transformer	G01 01391	G01 01401



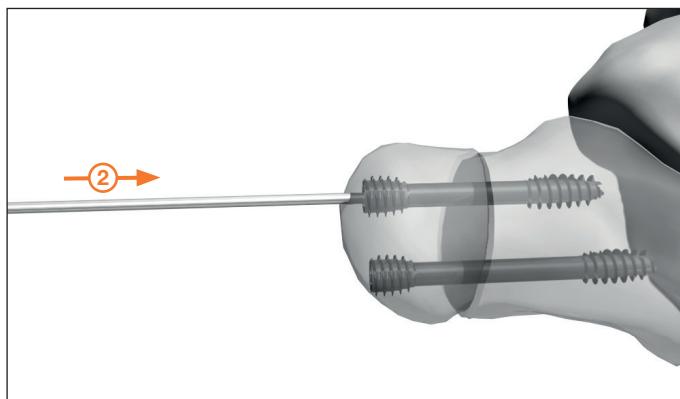
I.B.S.™

SURGICAL TECHNIQUE

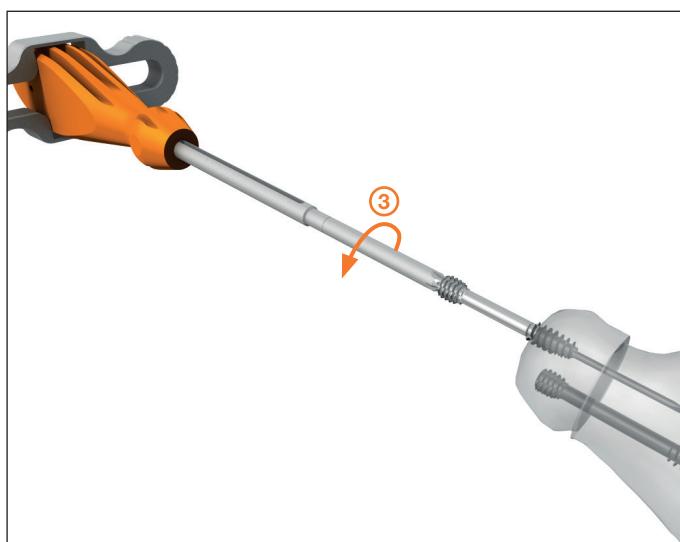
7 – Screw removal



Each screw has on its distal end threads reverse cutting notches easing the implants removal. ①



A corresponding size k-wire must be introduced through the cannula of the screw - use of the screwdriver on the k-wire secures a precise fit in the head imprint. ②



Initial unscrewing turns are performed manually. ③

TIP: A light hammer use will allow to remove soft tissues from the head imprint

IMPLANTS**Innovative Bone Synthesis™ - Screw diam. 4.5 mm - Titanium Sterile**

I.B.S.™ 4.5-C Compression screw	Length	I.B.S.™ 4.5-N Neutralization screw	I.B.S.™ 4.5-C Compression screw	Length	I.B.S.™ 4.5-N Neutralization screw
S45 ST120	20mm	S45 ST220	S45 ST140	40mm	S45 ST240
S45 ST122	22mm	S45 ST222	S45 ST142	42mm	S45 ST242
S45 ST124	24mm	S45 ST224	S45 ST144	44mm	S45 ST244
S45 ST125	25mm	S45 ST225	S45 ST145	45mm	S45 ST245
S45 ST126	26mm	S45 ST226	S45 ST146	46mm	S45 ST246
S45 ST128	28mm	S45 ST228	S45 ST148	48mm	S45 ST248
S45 ST130	30mm	S45 ST230	S45 ST150	50mm	S45 ST250
S45 ST132	32mm	S45 ST232	S45 ST155	55mm	S45 ST255
S45 ST134	34mm	S45 ST234	S45 ST160	60mm	S45 ST260
S45 ST135	35mm	S45 ST235	S45 ST165	65mm	S45 ST265
S45 ST136	36mm	S45 ST236	S45 ST170	70mm	S45 ST270
S45 ST138	38mm	S45 ST238			

Innovative Bone Synthesis™ - Screw diam. 6.5 mm - Titanium Sterile

I.B.S.™ 6.5-C Compression screw	Length	I.B.S.™ 6.5-N Neutralization screw	I.B.S.™ 6.5-C Compression screw	Length	I.B.S.™ 6.5-N Neutralization screw
S65 ST120	20mm	S65 ST220	S65 ST165	65mm	S65 ST265
S65 ST125	25mm	S65 ST225	S65 ST170	70mm	S65 ST270
S65 ST130	30mm	S65 ST230	S65 ST175	75mm	S65 ST275
S65 ST135	35mm	S65 ST235	S65 ST180	80mm	S65 ST280
S65 ST140	40mm	S65 ST240	S65 ST185	85mm	S65 ST285
S65 ST145	45mm	S65 ST245	S65 ST190	90mm	S65 ST290
S65 ST150	50mm	S65 ST250	S65 ST195	95mm	S65 ST295
S65 ST155	55mm	S65 ST255	S65 ST300	100mm	S65 ST400
S65 ST160	60mm	S65 ST260			

Innovative Bone Synthesis™ - Screw PLUS diam. 6.5 mm - Titanium Sterile

I.B.S.™ 6.5-C+ Compression screw	Length	I.B.S.™ 6.5-C+ Compression screw	Length	I.B.S.™ 6.5-C+ Compression screw	Length
S65 ST560	60mm	S65 ST575	75mm	S65 ST590	90mm
S65 ST565	65mm	S65 ST580	80mm	S65 ST595	95mm
S65 ST570	70mm	S65 ST585	85mm	S65 ST600	100mm

Innovative Bone Synthesis™ - Screw diam. 8.0 mm - Titanium Sterile

I.B.S.™ 8.0-C Compression screw	Length	I.B.S.™ 8.0-N Neutralization screw	I.B.S.™ 8.0-C Compression screw	Length	I.B.S.™ 8.0-N Neutralization screw
S80 ST140	40mm	S80 ST240	S80 ST175	75mm	S80 ST275
S80 ST145	45mm	S80 ST245	S80 ST180	80mm	S80 ST280
S80 ST150	50mm	S80 ST250	S80 ST185	85mm	S80 ST285
S80 ST155	55mm	S80 ST255	S80 ST190	90mm	S80 ST290
S80 ST160	60mm	S80 ST260	S80 ST195	95mm	S80 ST295
S80 ST165	65mm	S80 ST265	S80 ST300	100mm	S80 ST400
S80 ST170	70mm	S80 ST270	S65 ST300	100mm	S65 ST400

INSTRUMENTS

Reusable instrument set - Diam. 4.5 mm

Ref	Designation
G01 00531	Cannulated step drill S45
G01 00091	Cannulated drill S45
G01 00171	Measurer S45
G01 00361	Screwdriver Tip T15 - AO Quick coupling
G01 00331	Cannulated screwdriver T15
G01 01391	Medium T Handle
G01 70011	Stainless steel container S45
K10 NS150	K-Wire Diam 1,6mm Length 150mm 1 Sharp Tip

Reusable instrument set - Diam. 6.5 mm

Ref	Designation
G01 00031	Cannulated step drill S65
G01 01181	Cannulated drill S65
G01 00181	Measurer S65-80
G01 00381	Screwdriver tip T25 - AO Quick coupling
G01 00411	Cannulated screwdriver T25
G01 01391	Handle transformer T25
G01 01251	K-wire-guide S65
G01 01261	Drill guide S65
G01 01271	Protection sleeve S65
G01 01281	Guide wire matrix S65
G01 80011	Stainless steel container S65
K10 NS220	K-Wire Diam 2,0mm Length 200mm 1 Sharp tip

Reusable instrument set - Diam. 8.0 mm

Ref	Designation
G01 00141	Cannulated step drill S80
G01 00131	Cannulated drill S80
G01 00181	Measurer S65-80
G01 00371	Screwdriver tip T30 - Quick coupling
G01 00421	Screwdriver T30
G01 01401	Handle transformer T30
G01 01291	K-wire-guide S80
G01 01301	Drill Guide S80
G01 01311	Protection sleeve S80
G01 01321	Guide wire matrix S80
G01 90011	Stainless steel container S80
K10 NS200	K-Wire Diam 2,5mm Length 200mm 1 Sharp Tip

Reusable instrument set Combo Diam. 4.5 mm & 6.5 mm

Ref	Designation
G01 00031	Cannulated step drill S65
G01 01181	Cannulated drill S65
G01 00181	Measurer S65-80
G01 00381	Screwdriver tip T25 - AO Quick coupling
G01 00411	Cannulated screwdriver T25
G01 01391	Handle transformer T25
G01 01251	K-wire-guide S65
G01 01261	Drill guide S65
G01 01271	Protection sleeve S65
G01 00531	Cannulated step drill S45
G01 00091	Cannulated drill S45
G01 00171	Measurer S45
G01 00361	Screwdriver Tip T15 - AO Quick coupling
G01 00331	Cannulated screwdriver T15
G01 85011	Stainless steel container S45 -S65

Reusable instrument set Combo Diam. 6.5 mm & 8 mm

Ref	Designation
G01 00141	Cannulated step drill S80
G01 00131	Cannulated drill S80
G01 00181	Measurer S65-80
G01 00371	Screwdriver tip T30 - Quick coupling
G01 00421	Screwdriver T30
G01 01401	Handle transformer T30
G01 01291	K-wire-guide S80
G01 01301	Drill Guide S80
G01 01311	Protection sleeve S80
G01 01321	Guide wire matrix S80
K10 NS200	K-Wire Diam 2,5mm Length 200mm 1 Sharp Tip
G01 00031	Cannulated step drill S65
G01 01181	Measurer S65-80
G01 00381	Screwdriver tip T25 - AO Quick coupling
G01 00411	Cannulated screwdriver T25
G01 01391	Handle transformer T25
G01 01251	K-wire-guide S65
G01 01261	Drill guide S65
G01 01271	Protection sleeve S65
G01 01281	Guide wire matrix S65
K10 NS220	K-Wire Diam 2,0mm Length 200mm 1 Sharp tip
G01 95011	Stainless steel container S65-S80

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

EC Regulation 2017/745/EC:

- Invasive reusable surgical instruments: Class I_r - CE2797
- Instrument with measuring function: Class I_m - 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-IBSLARGE-EN-072022

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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