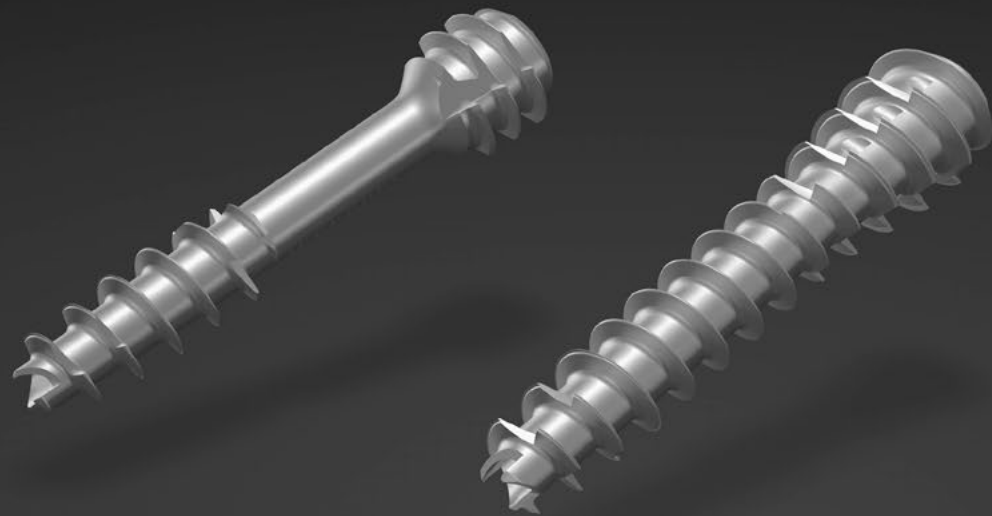




I.B.S.<sup>TM</sup>  
INNOVATIVE BONE SYNTHESIS<sup>TM</sup>

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MID & HINDFOOT SCREW SYSTEM  
COMPRESSION SCREW  
NEUTRALIZATION SCREW



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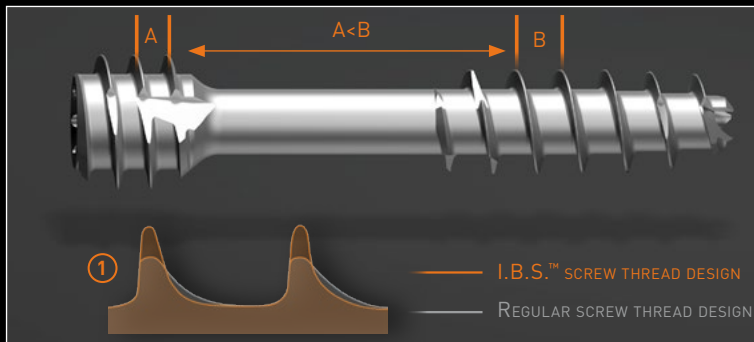
- ▶ The design of the I.B.S.™ screw by In2Bones® is optimized to distribute the compression effort, maximize and facilitate the osteosynthesis.
- ▶ A neutralization version fully threaded of the I.B.S.™ screw is also available.
- ▶ The I.B.S.™ screw is available in 4.5mm, 6.5mm, 8.0mm. The I.B.S.® compression and neutralization screws are cannulated, self-drilling and self-tapping.
- ▶ Made in titanium Ti6Al4V, all the screws are delivered in sterile tubes.





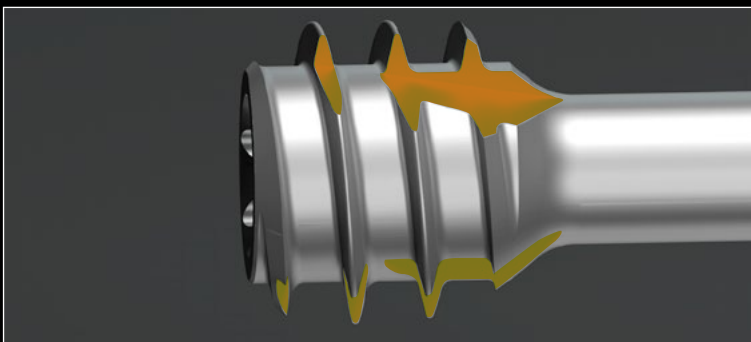
## TORX IMPRINT

- ▶ The range of compression and neutralization I.B.S.<sup>™</sup> screws has a Torx imprint.
- ▶ The « star » shape delivers a higher torque without degradation of the imprint.



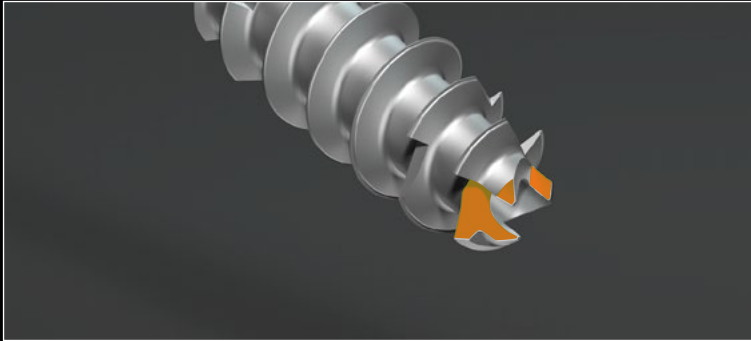
## DISTAL THREAD

- ▶ The number of distal threads is optimized to allow an accurate placement of the screw in the osteotomy site.
- ▶ The shape of threads ① improves penetration and bone purchase of the screw.
- ▶ A ratio between distal and proximal threads guarantees bone fragments compression.



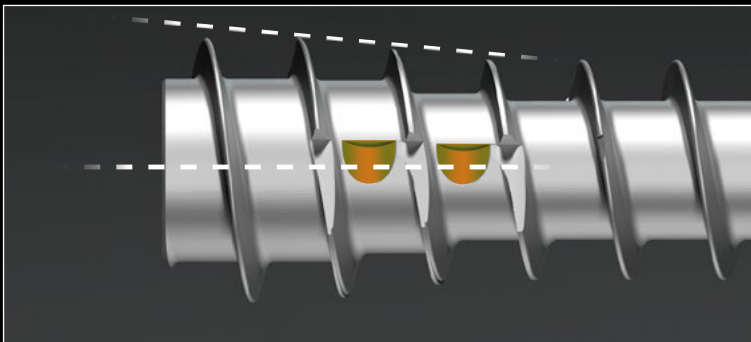
## PROXIMAL THREAD

- ▶ The I.B.S.<sup>™</sup> 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.



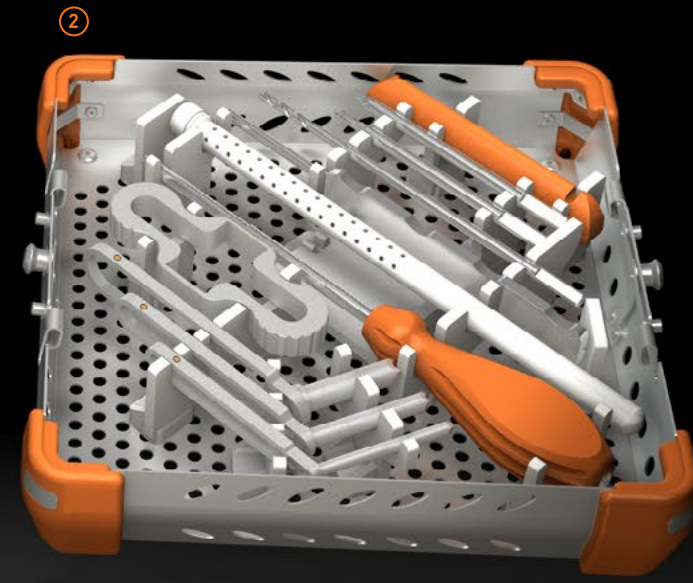
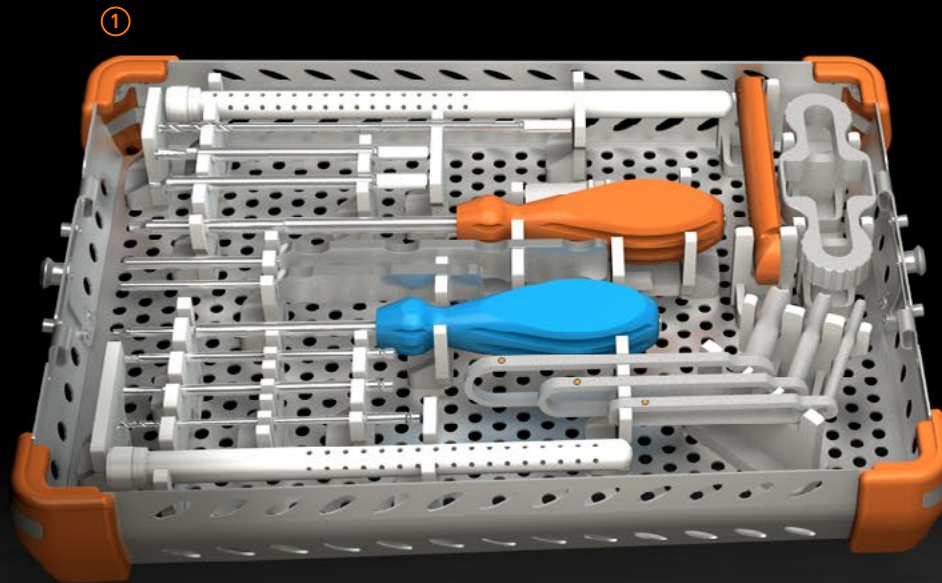
## PROXIMAL THREAD FOR NEUTRALIZATION SCREW

- ▶ 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	Length	Kwire diameter	Drill diameter
I.B.S.™ 4.5	4.5mm		Compression screw (C) Neutralisation screw (N)	Torx 15	20 > 70mm	1.6mm	3.0mm
I.B.S.™ 6.5	6.5mm		Compression screw (C) Neutralisation screw (N)	Torx 25	20 > 80mm	2.0mm	4.3mm
I.B.S.™ 8.0	8.0mm		Compression screw (C) Neutralisation screw (N)	Torx 30	40 > 160mm	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



## INDICATIONS

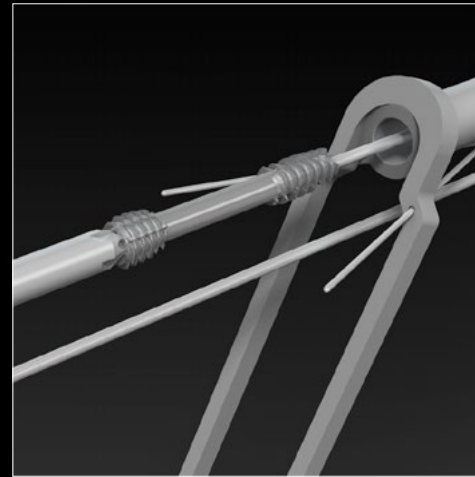
- ▶ I.B.S.<sup>TM</sup> screws are intended for:
  - ▶ The fixation of arthrodeses, osteotomies or fractures of long or short bones of the upper and lower limbs,
  - ▶ Osteosyntheses requiring a mono or bicortical compression.
- ▶ The size of the chosen screw should be adapted to the specific indications.

## CONTRAINDICATIONS

- ▶ The implant should not be 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

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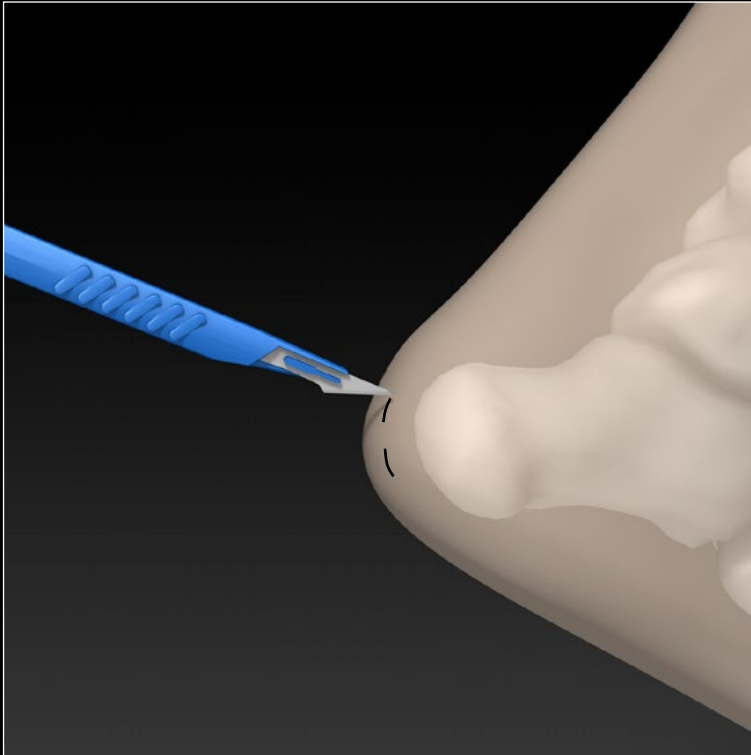


In2Bones® as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device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

THIS TECHNIQUE WAS DEVELOPED IN COLLABORATION  
WITH M. JOEL VERNONIS, AMIENS - FRANCE

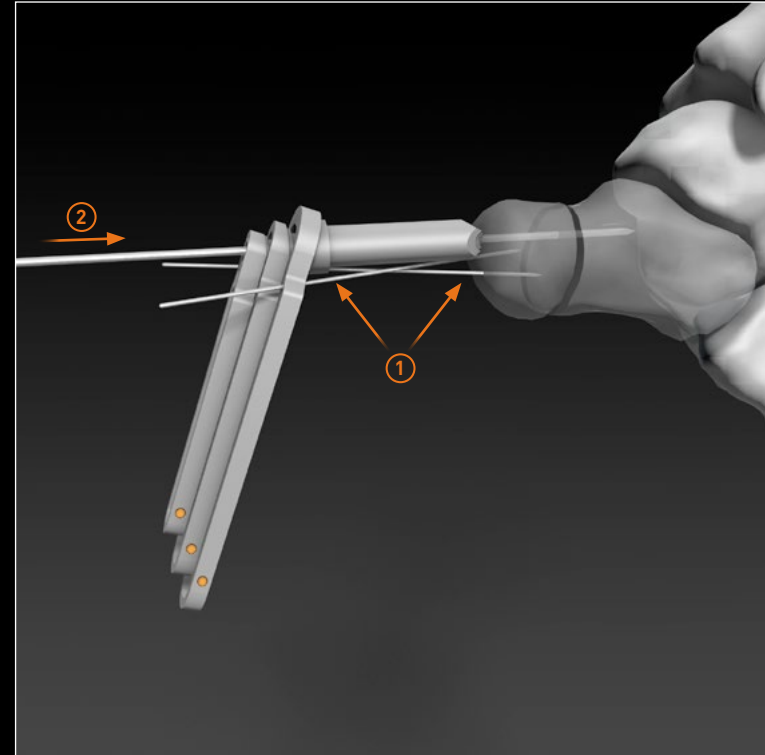


## 1 - PREPARATION



- Incisions : for a calcaneal realignment osteotomy, two incisions are made to allow the use of the drilling guide and the protecting guide.

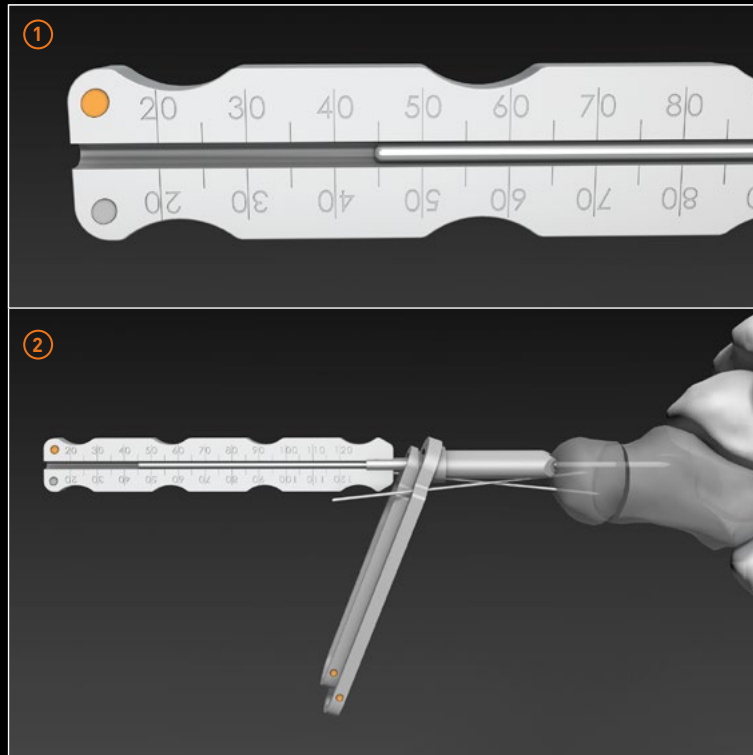
## 2 - DRILLING GUIDE AND PROTECTING SLEEVE



- For the 6.5mm and 8.0mm screws only, soft tissues protectors are used, they might be fixed to the bone using optional 1.0mm K-wire 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 bi-cortical fixation.

	Diam. 4.5	Diam. 6.5	Diam. 8.0
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



- ▶ The appropriate screw length is determined by use of the measurer. ①
- ▶ For 4.5mm diameter screws, the measurer is used directly on the K-wire.
- ▶ For 6.5mm and 8.0mm diameter screws, the measurer is used into the protecting guide using the k-wire guiding. ②

> Diam. 4.5mm screws - Measurer S45 : G01 00171



> Diam. 6.5 & 8.0mm screws - Measurer S65-80 : G01 00181



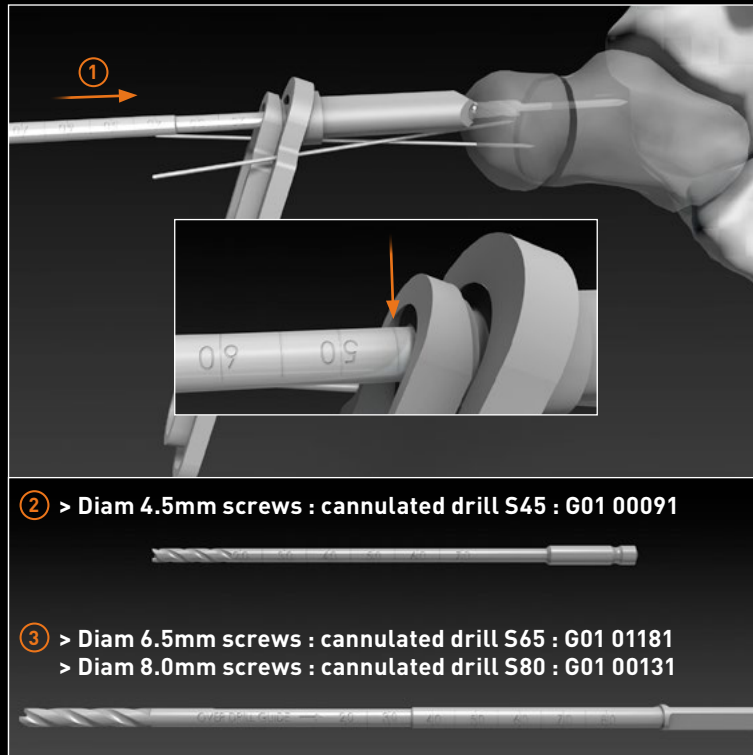
- ▶ Measurer can also be used directly over the k-wire should the protection sleeve not be used.
- ▶ The appropriate screw length is then determined directly from the measurer.

#### 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.

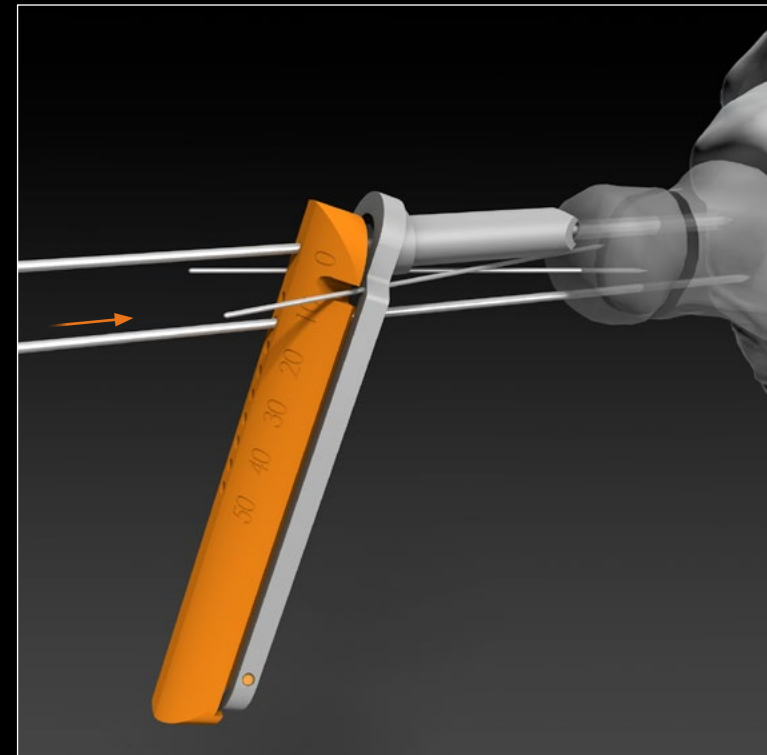
The positioning of the K-wire can be validated by means of peroperative X-ray or fluoroscopy.

## 4 - USE OF THE DRILLS



- ▶ During this step the screw shaft is prepared with a cannulated drill. ①
- ▶ For 4.5mm screws the drill is used with no protecting sleeve and depth length is directly checked on the drill. ②
- ▶ For 6.5mm and 8.0mm screws, the drill 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 ». ③
- ▶ 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

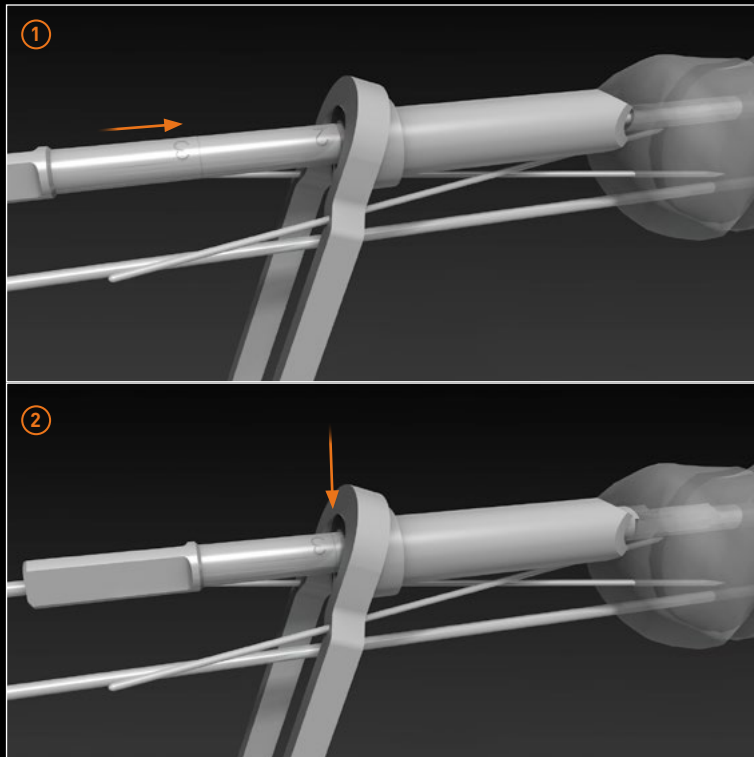


Available option for diam. 6.5mm and diam. 8.0mm screws only:

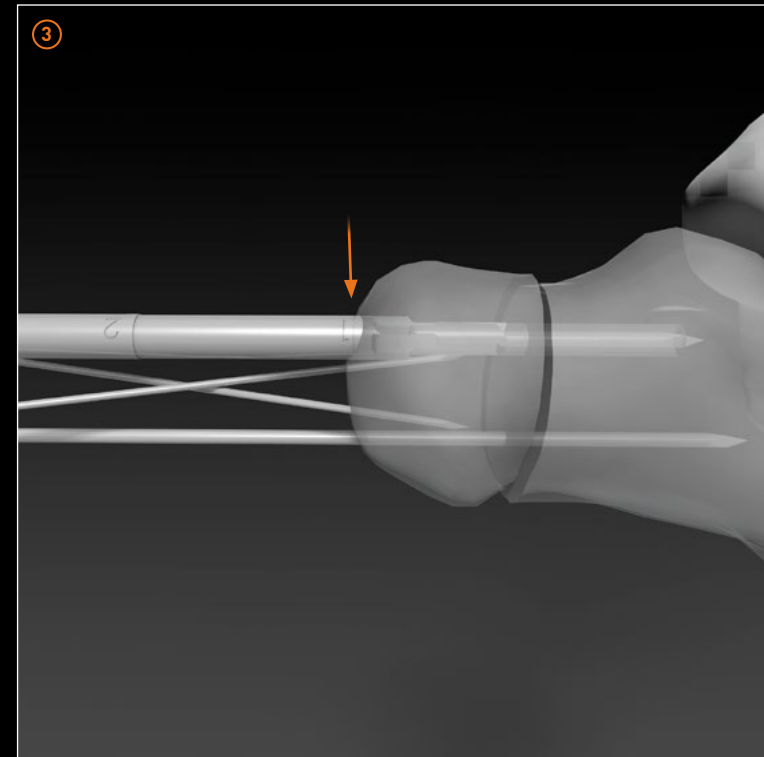
- ▶ A second guide wire, parallel to the first one, may be used thanks to the « drilling matrix ».
- ▶ The later is inserted over the first guide pin and locked into the protecting sleeve handle. Once stable, it offers a selection of positioning holes aligned with the first guide wire.
- ▶ The matrix offers a range of holes away from the base pin of 10mm to a maximum 50mm by 5 mm increments.

	Diam. 6.5	Diam. 8.0
Guide wire matrix	• G01 1281 •	• G01 1321 •

## 5 - SCREW HEAD PREPARATION



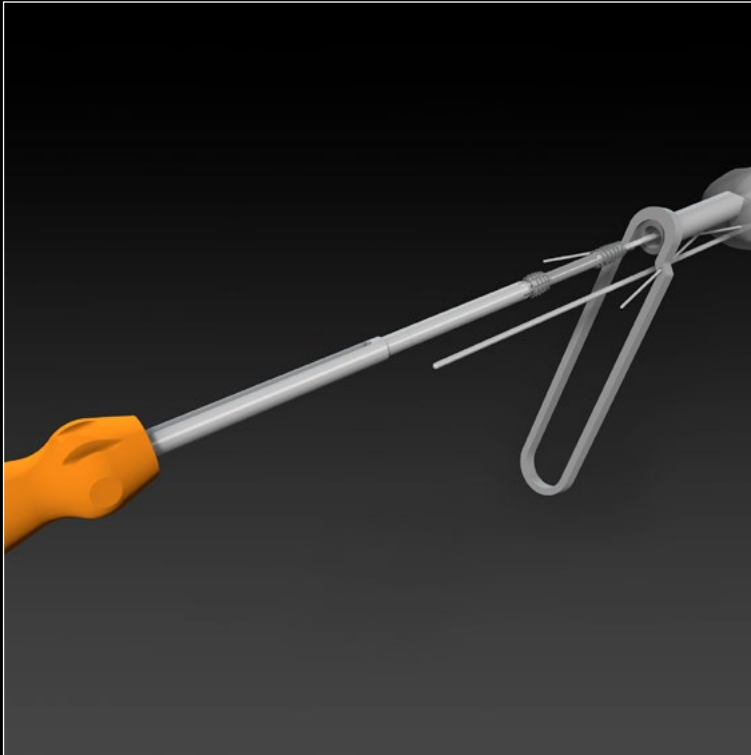
- ▶ When a compression screw is implanted, screw head is prepared with the short cannulated drill.
- ▶ For the 4.5mm screws, the drill is guided on the guide pin. Position 1 indicates the length for which the head is totally embedded.
- ▶ For the 6.5mm and 8.0mm, if the surgeon is using the protection 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

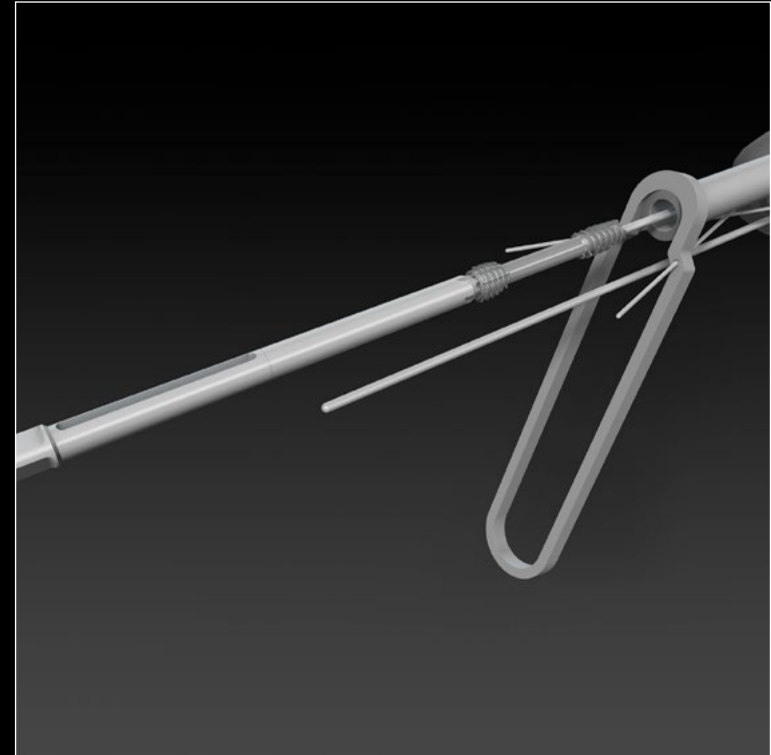
	Diam. 4.5	Diam. 6.5	Diam. 8.0
Cannulated step drill	G01 00531	G01 00031	G01 00141

## 6 - SCREW INSERTION (1/2)



- ▶ The screw is then inserted over the guide pin.
- ▶ It can be screwed manually with the cannulated screwdriver.

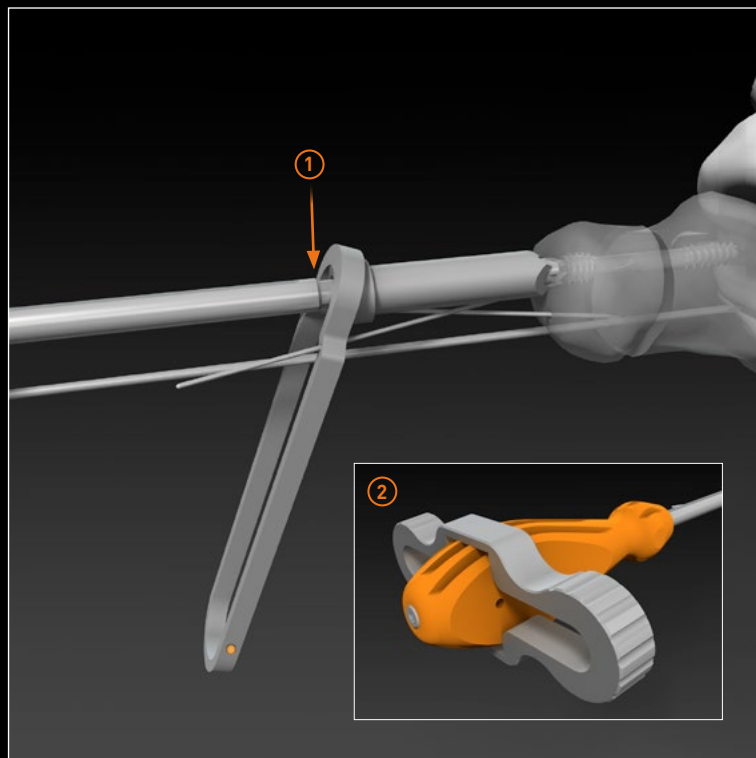
	Diam. 4.5	Diam. 6.5	Diam. 8.0
Cannulated screwdriver	T15 G01 00331	T25 G01 00411	T30 G01 00421



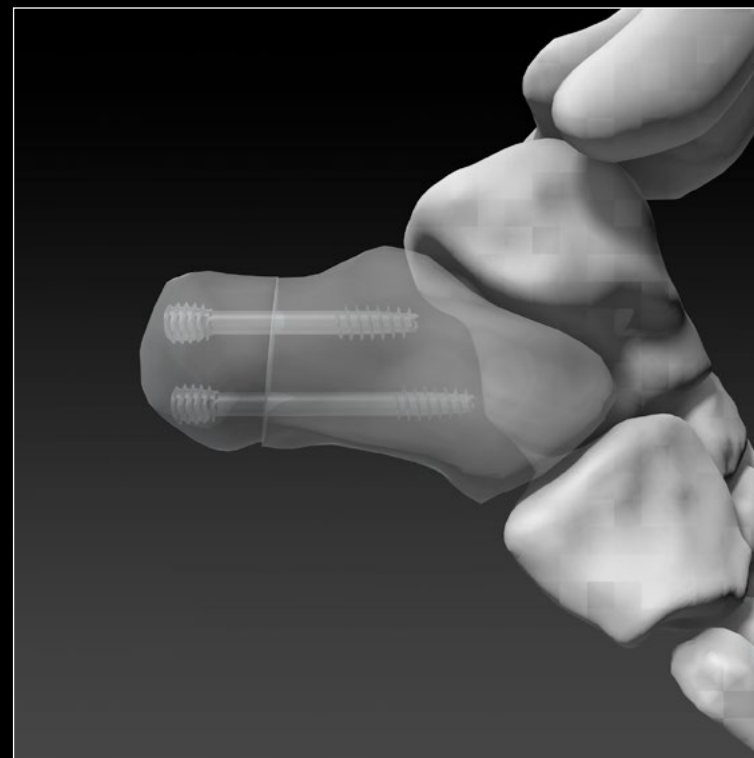
- ▶ Alternatively it can be screwed using a cannulated screwdriver tip attached to the power driver.

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

## 6 - SCREW INSERTION (2/2)

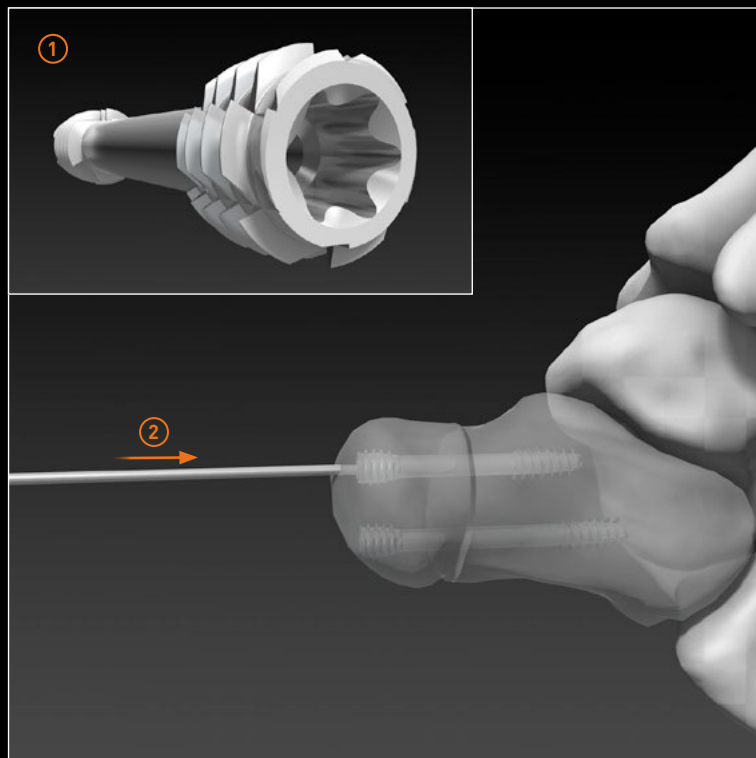


- ▶ For 6.5mm and 8.0mm screws, when the surgeon uses the protecting guides, a marking on the screwdriver shaft ① indicates the position where the screw head is totally embedded in the cortical bone.
- ▶ A special adaptor allows, if necessary, to transform the handle in a « T handle » ② allowing to tighten the screw when high torque transmission is necessary. It can be used as well to extract the screws.

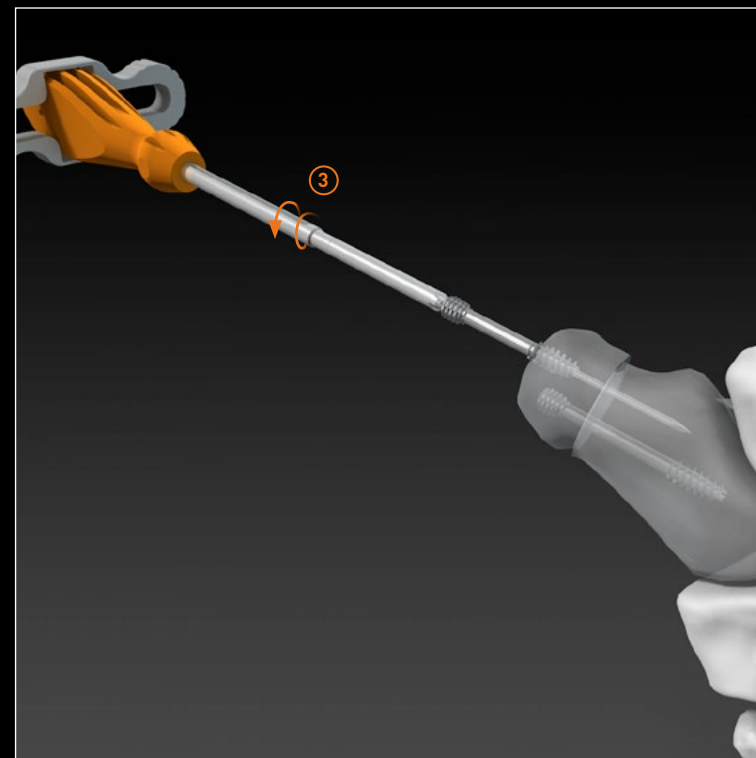


	Diam. 6.5	Diam. 8.0
Handle	T25	T30
Transformer	G01 01391	G01 01401

## 7 - SCREWS REMOVAL



- ▶ Each screw has on its distal end threads reverse cutting notches easing the implants removal. ①
- ▶ The following steps must be followed:
  - ▶ 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

## SCREWS

## ► Innovative Bone Synthesis® - 4.5 mm Screws - Titanium Sterile

<b>I.B.S.™ 4.5-C Compression screw</b>	<b>Length</b>	<b>I.B.S.™ 4.5-N Neutralization screw</b>
S45 ST120	20mm	S45 ST220
S45 ST122	22mm	S45 ST222
S45 ST124	24mm	S45 ST224
S45 ST126	26mm	S45 ST226
S45 ST128	28mm	S45 ST228
S45 ST130	30mm	S45 ST230
S45 ST132	32mm	S45 ST232
S45 ST134	34mm	S45 ST234
S45 ST136	36mm	S45 ST236
S45 ST138	38mm	S45 ST238
S45 ST140	40mm	S45 ST240
S45 ST142	42mm	S45 ST242
S45 ST144	44mm	S45 ST244
S45 ST146	46mm	S45 ST246
S45 ST148	48mm	S45 ST248
S45 ST150	50mm	S45 ST250
S45 ST155	55mm	S45 ST255
S45 ST160	60mm	S45 ST260

## ► Innovative Bone Synthesis® - 6.5 mm Screws - Titanium Sterile

<b>I.B.S.™ 6.5-C Compression screw</b>	<b>Length</b>	<b>I.B.S.™ 6.5-N Neutralization screw</b>
S65 ST120	20mm	S65 ST220
S65 ST125	25mm	S65 ST225
S65 ST130	30mm	S65 ST230
S65 ST135	35mm	S65 ST235
S65 ST140	40mm	S65 ST240
S65 ST145	45mm	S65 ST245
S65 ST150	50mm	S65 ST250
S65 ST155	55mm	S65 ST255
S65 ST160	60mm	S65 ST260
S65 ST165	65mm	S65 ST265
S65 ST170	70mm	S65 ST270
S65 ST175	75mm	S65 ST275
S65 ST180	80mm	S65 ST280



## SCREWS

## ► Innovative Bone Synthesis® - 8.0 mm Screws - Titanium Sterile

<b>I.B.S.™ 8.0-C Compression screw</b>	<b>Length</b>	<b>I.B.S.™ 8.0-N Neutralization screw</b>
S80 ST140	40mm	S80 ST240
S80 ST145	45mm	S80 ST245
S80 ST150	50mm	S80 ST250
S80 ST155	55mm	S80 ST255
S80 ST160	60mm	S80 ST260
S80 ST165	65mm	S80 ST265
S80 ST170	70mm	S80 ST270
S80 ST175	75mm	S80 ST275
S80 ST180	80mm	S80 ST280
S80 ST185	85mm	S80 ST285
S80 ST190	90mm	S80 ST290
S80 ST195	95mm	S80 ST295
S80 ST300	100mm	S80 ST400
S80 ST305	105mm	S80 ST405
S80 ST310	110mm	S80 ST410
S80 ST315	115mm	S80 ST415
S80 ST320	120mm	S80 ST420

## SCREWS : OPTIONAL - ON ORDER

## ► Innovative Bone Synthesis® - 8.0 mm Screws - Titanium Sterile

<b>I.B.S.™ 8.0-C Compression screw</b>	<b>Length</b>	<b>I.B.S.™ 8.0-N Neutralization screw</b>
S80 ST325	125mm	S80 ST425
S80 ST330	130mm	S80 ST430
S80 ST335	135mm	S80 ST435
S80 ST340	140mm	S80 ST440
S80 ST345	145mm	S80 ST445
S80 ST350	150mm	S80 ST450
S80 ST355	155mm	S80 ST455
S80 ST360	160mm	S80 ST460

## INSTRUMENTS

## ► Diam. 4.5 mm - C &amp; N Instruments

Ref / SKU	Description
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 70011	Stainless steel container S45
K10 NS150	K-Wire Diam 1,6mm Length 150mm 1 Sharp Tip

## ► Diam. 6.5 mm - C &amp; N Instruments

Ref / SKU	Description
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

## ► Diam. 8.0 mm - C &amp; N Instruments

Ref / SKU	Description
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

## RECOMMANDATION

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


## DEVICES

- ▶ Implants :
  - ▶ Screws : EC Class IIb - CE0499
- ▶ Instruments :
  - ▶ Instruments connected to a power driver : EC class IIa - CE0499
  - ▶ Instruments with a measuring function : EC class Im - CE0499
  - ▶ Other instruments : EC class I - 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-MHFScrews-EN-042014
- ▶ Revision date: 04/2014
- ▶ Version 02



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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