ENG

Integra®

BOLD® 2.5 mm - 3.0 mm - 3.7 mm
Compression screw

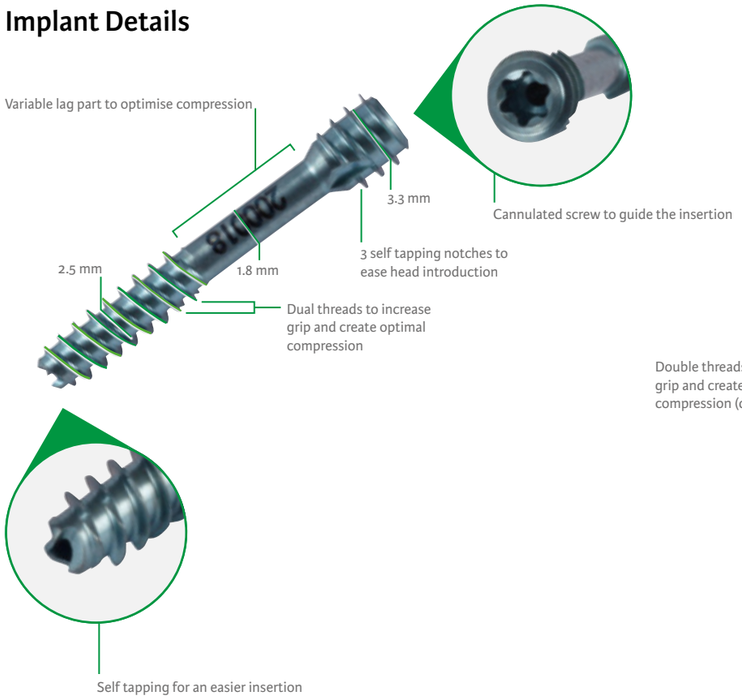
QWIX® 3.0 mm
Fixation screw

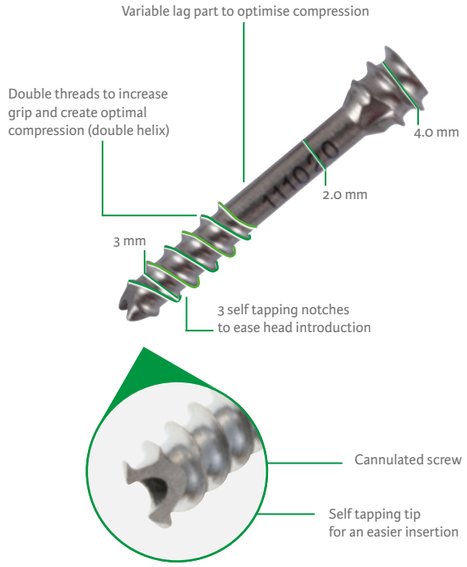
SURGICAL TECHNIQUE

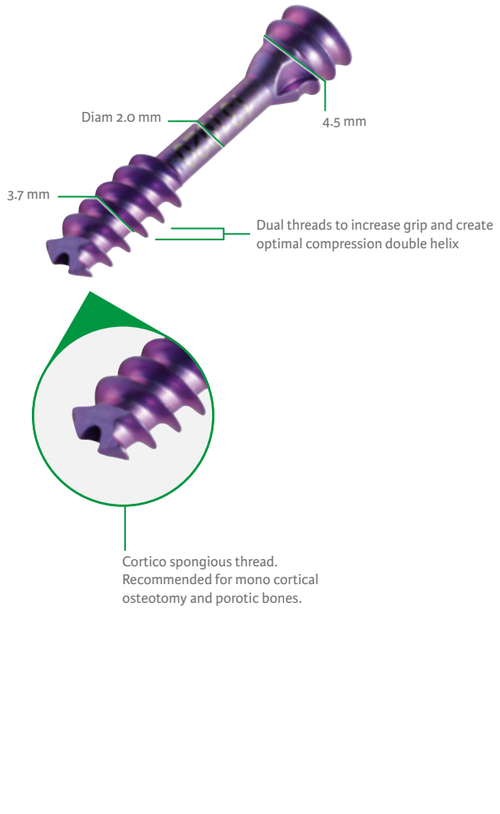
INTEGRA®
LIMIT UNCERTAINTY

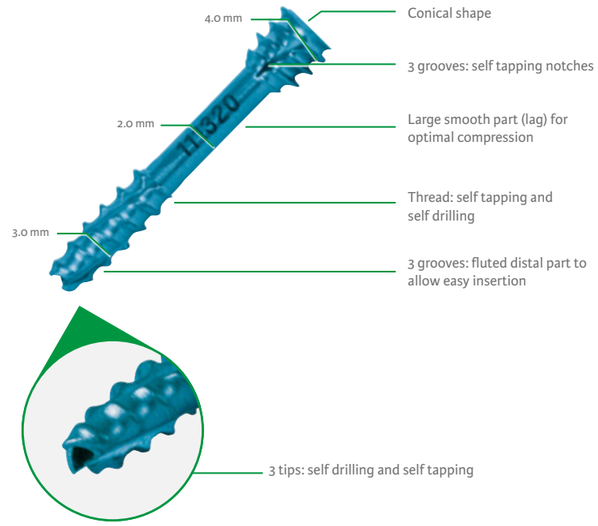
Table of Contents

Implant Details









Bold® 2.5 mm

- Material: Titanium alloy, TiAi6V4 ISO 5832-3 ASTM F136.
- Sterile and non sterile implants.
- Compression screws.
- Range of sizes: 10 mm to 30 mm (by 2.0 mm).
- Laser marked for tractability.
- Cannulated screw.
- Dual threads.
- 3 self-tapping notches.
- Variable lag part.
- 3 tips.

Bold® 3.0 mm

- Material: Titanium alloy, TiAi6V4 ISO 5832-3 ASTM F136.
- Sterile and non sterile implants.
- Compression screws.
- Range of sizes: 10 mm to 34 mm (by 2.0 mm).
- Laser marked for tractability.
- Cannulated screw.
- Dual threads.
- 3 self-tapping notches.

Bold® 3.7 mm

- Material: Titanium alloy, TiAi6V4 ISO 5832-3 ASTM F136.
- Sterile and non sterile implants.
- Compression screws.
- Range of sizes: 14 mm to 34 mm (by 2.0 mm).
- Cannulated screw.
- Laser marked for tractability.
- Dual threads.
- 3 self-tapping notches.
- Variable lag part.

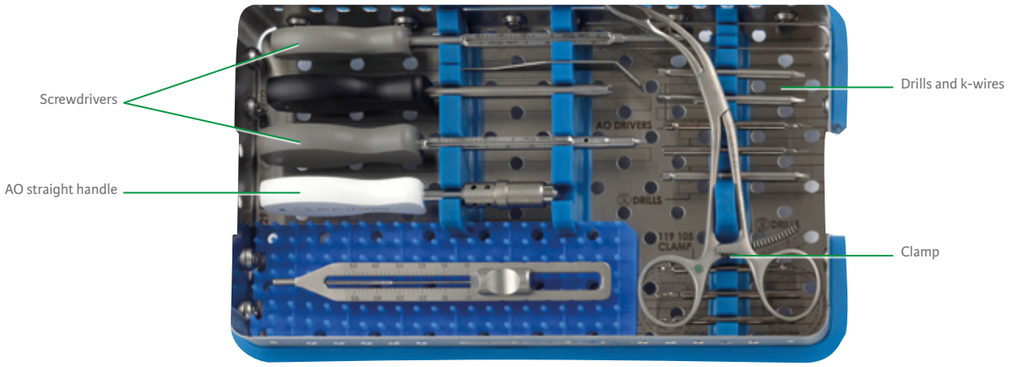
Qwix® 3.0 mm

- Material: Titanium alloy: Ti-6Al-4V, ISO 5832-3 ASTM F136.
- Sterile and non sterile implants.
- Stabilization screw.
- Range of sizes: 12 mm to 32 mm (by 2.0 mm).
- Cannulated screw.
- Hexagonal screw head.
- Totally bone embedded.
- Fluted distal part.
- 6 conical heads.
- Blue color code for the screws and instruments.

Indications

- For fixation of bone fractures or for bone reconstruction.
- Examples include:
  - Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.).
  - Mono or Bi-cortical osteotomies in the foot or hand.
  - Distal or proximal metatarsal or metacarpal osteotomies.
  - Arthrodesis in hand or foot surgery.
  - Fixation of small bone fragments, in long bones or small bones fractures.

Instruments Details



Thank you to refer to the table in order to choose the right screwdriver.

	Bold® 2.5 mm	**Bold® 3.0 mm Bold® 3.7 mm Qwix® 3.0 mm**
Screwdrivers	T7 star Monobloc: 229003 AO: 229004	Hexa 2.0 Monobloc: 229002 AO: 229005
Head design	Torx drive 	Hexagonal drive 

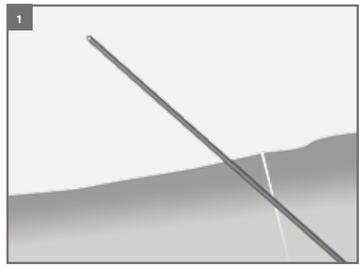
NEWDEAL as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device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

Surgical Technique

1 K-wire Insertion

Secure the bone fragments with a K-wire (fig. 1). The position should be checked under fluoroscopy.

This K-wire guides the screw. Due to the traumatic aspects of the K-wire, it can be withdrawn and replaced until the desired position is achieved.



Thank you to refer to the table in order to choose the right kwire.

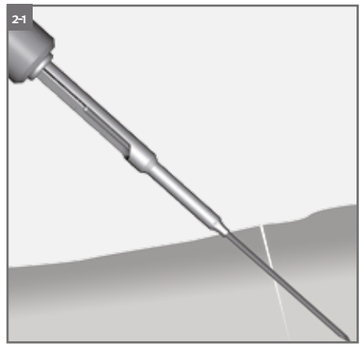
	K-wire		
Screw	**Reference**	**Diameter**	**Length**
Bold® 2.5 mm	115008S	0.8 mm	70 mm
Bold® 3.0 mm	115070(S) and/or 115100(S)	1.0 mm	70 and/or 100 mm
Bold® 3.7 mm			
Qwix® 3.0 mm			

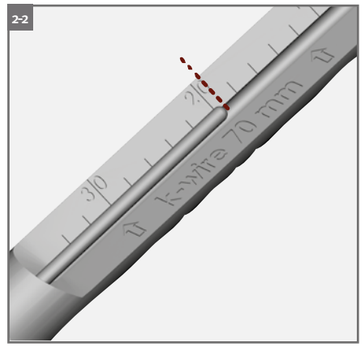
*(s): delivered sterile and non sterile.

2 Measurement

Insert the appropriate cannulated screwdriver on the K-wire (fig. 2-1), and read the screw length to be used directly on the scale (fig. 2-2).

Note
If the surgeon wishes a monocortical fixation, subtract 1.5 mm to determine the appropriate screw length.





Refer to the table in order to choose the right screw, regarding the desired fixation.

	Bold® 2.5 mm Bold® 3.0 mm Qwix® 3.0 mm	**Bold® 3.7 mm**
Compression	Bicortical compression	Monocortical compression

Thank you to refer to the table in order to choose the right screwdriver.

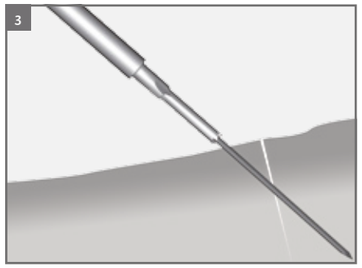
	Bold® 2.5 mm	**Bold® 3.0 mm Bold® 3.7 mm Qwix® 3.0 mm**
Screwdrivers	T7 star Monobloc: 229003 AO: 229004	Hexa 2.0 Monobloc: 229002 AO: 229005
Head design	Torx drive 	Hexagonal drive 

229 xxxS / 119 xxx(S)
159 xxx(S)
Cannulated drill

229 003 / 229 004
229 002 / 229 005
Cannulated screwdriver
Hexa 2.0
T7 - Diam 0.9 mm

3 Drilling

Prepare the cortex by power or manually with dedicated forefoot drill (fig. 3).



Note
For Qwix® fixation screw 3.0, this step is optional. Although the Qwix® screw is self-drilling and self-tapping in most bone, it may be necessary to drill the cortex in certain cases.

Thank you to refer to the table in order to choose the right drill.

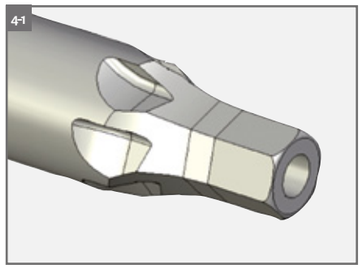
	"2 in 1" Short drill L12 mm Screw length 10 mm to 16 mm	"2 in 1" Medium drill L22 mm Screw length 18 mm to 24 mm	"2 in 1" Long drill L32 mm Screw length 26 mm to 34 mm
Cannulated	119 027(S): Dia 2.2 mm 229 227S: Dia 1.9 mm	119 025(S): Dia 2.2 mm 229237S: Dia 1.9 mm	119 023(S): Dia 2.2 mm
Non Cannulated	119 227(S): Dia 2.2 mm 229228S: Dia 1.9 mm	119 225(S): Dia 2.2 mm 229238S: Dia 1.9 mm	119 223(S): Dia 2.2 mm
AO Cannulated	159 027(S): Dia 2.2 mm 229027S: Dia 1.9 mm	159 025(S): Dia 2.2 mm 229037S: Dia 1.9 mm	159 023(S): Dia 2.2 mm
AO Non Cannulated	159 227(S): Dia 2.2 mm 229028S: Dia 1.9 mm	159 225(S): Dia 2.2 mm 229038S: Dia 1.9 mm	159 223(S): Dia 2.2 mm

Green: for the Bold® 3.0mm Bold® 3.7 mm, Qwix® 3.0 mm screws
Black: For the Bold® 2.5 mm screws.

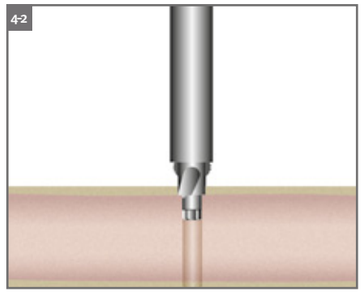
4 Chamfren Recommended for Bold® 3.7 mm Screws

Caution
Be careful to not use the chamfren when you insert the Bold® 2.5, Bold® 3.0 and Qwix® 3.0 screws.

Bold® 3.7 mm



Screwdriver



Caution
Development of a dedicated screwdriver (229 002) which allows to break the cortical with the chamfren. In order to properly insert the screw head without any micro fractures, it is mandatory to use this chamfren each time.

115 070S
115 100S
or 115 008S
K-wire
Dia 1.0 mm or
Dia 0.8 mm

229 003 / 229 004
229 002 / 229 005
Cannulated screwdriver
Hexa 2.0
T7 - Diam 0.9 mm

5 Screw Insertion

The screw is inserted with the appropriate cannulated screwdriver (cf table).

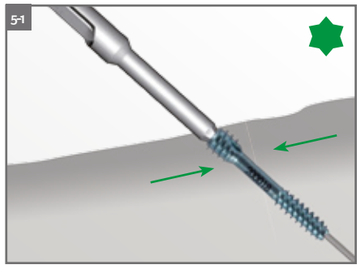
Thank you to refer to the table in order to choose the right screwdriver.

	Bold® 2.5 mm	**Bold® 3.0 mm Bold® 3.7 mm Qwix® 3.0 mm**
Screwdrivers	T7 star Monobloc: 229003 AO: 229004	Hexa 2.0 Monobloc: 229002 AO: 229005
Head design	Torx drive 	Hexagonal drive 

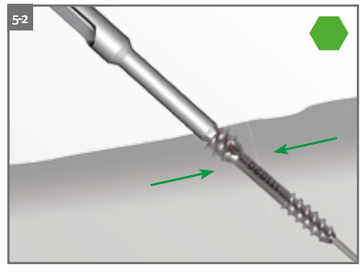
The compression screws can be inserted totally under power then completed by hand. The head of the screw must be completely embedded in the cortex to obtain optimal compression (fig. 5-1). Complete insertion is also recommended to prevent soft tissue irritation particularly on the dorsal aspect of the foot.

Thank you to refer to the table in order to choose the right screw, regarding the desired fixation.

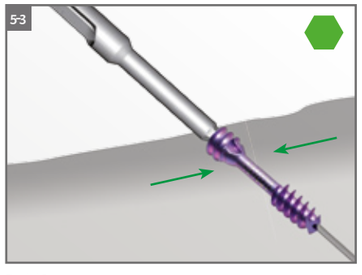
	Bold® 2.5 mm Bold® 3.0 mm Qwix® 3.0 mm	**Bold® 3.7 mm**
Compression	Bicortical compression	Monocortical compression



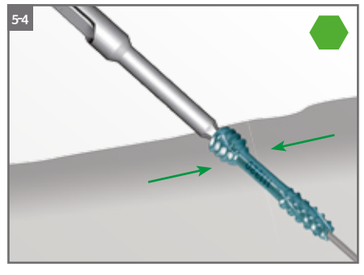
Bold® 2.5 mm



Bold® 3.0 mm

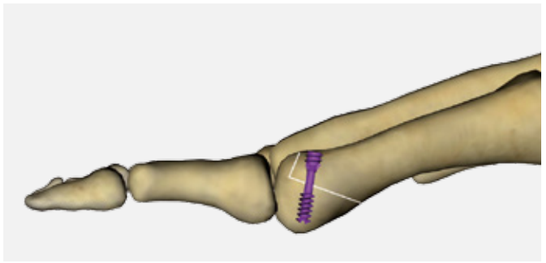


Bold® 3.7 mm

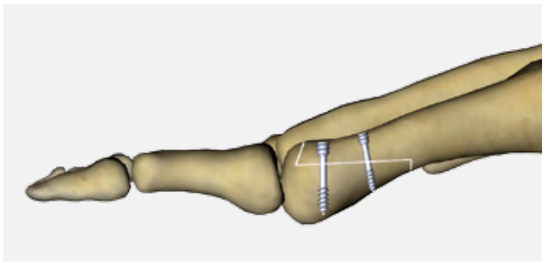


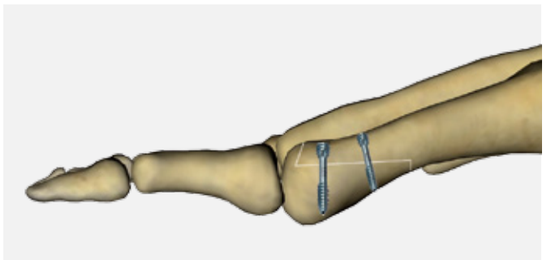
Qwix® 3.0 mm

Chevron Osteotomy: Monocortical Osteotomy with the Bold® 3.7 Compression Screw

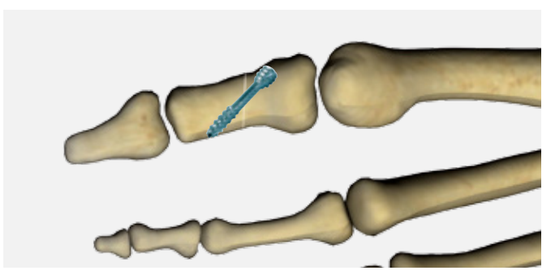


Scarf Osteotomy: Bicortical Osteotomy with the Bold® 3.0 or Bold® 2.5 Compression Screw





Akin Osteotomy: Bicortical Osteotomy with the Qwix® 3.0 Compression Screw



References

Bold® 2.5 mm: Compression Screw

Reference	Description
200 010(S)	Dia 2.5 mm - Length 10 mm
200 012(S)	Dia2.5 mm - Length 12 mm
200 014(S)	Dia 2.5 mm - Length 14 mm
200 016(S)	Dia 2.5 mm - Length 16 mm
200 018(S)	Dia 2.5 mm - Length 18 mm
200 020(S)	Dia 2.5 mm - Length 20 mm
200 022(S)	Dia 2.5 mm - Length 22 mm
200 024(S)	Dia 2.5 mm - Length 24 mm
200 026(S)	Dia 2.5 mm - Length 26 mm
200 028(S)	Dia 2.5 mm - Length 28 mm
200 030(S)	Dia 2.5 mm - Length 30 mm

*(S): delivered sterile and non sterile.

Bold® 3.0 mm: Compression Screw

Reference	Description
111 010(S)	Dia 3.0 mm - Length 10 mm
111 012(S)	Dia 3.0 mm - Length 12 mm
111 014(S)	Dia 3.0 mm - Length 14 mm
111 016(S)	Dia 3.0 mm - Length 16 mm
111 018(S)	Dia 3.0 mm - Length 18 mm
111 020(S)	Dia 3.0 mm - Length 20 mm
111 022(S)	Dia 3.0 mm - Length 22 mm
111 024(S)	Dia 3.0 mm - Length 24 mm
111 026(S)	Dia 3.0 mm - Length 26 mm
111 028(S)	Dia 3.0 mm - Length 28 mm
111 030(S)	Dia 3.0 mm - Length 30 mm
111 032(S)	Dia 3.0 mm - Length 32 mm
111 034(S)	Dia 3.0 mm - Length 34 mm

*(S): delivered sterile and non sterile.

Bold® 3.7 mm: Compression Screw

Reference	Description
131 014(S)	Dia 3.7 mm - Length 14 mm
131 016(S)	Dia 3.7 mm - Length 16 mm
131 018(S)	Dia 3.7 mm - Length 18 mm
131 020(S)	Dia 3.7 mm - Length 20 mm
131 022(S)	Dia 3.7 mm - Length 22 mm
131 024(S)	Dia 3.7 mm - Length 24 mm
131 026(S)	Dia 3.7 mm - Length 26 mm
131 028(S)	Dia 3.7 mm - Length 28 mm
131 030(S)	Dia 3.7 mm - Length 30 mm
131 032(S)	Dia 3.7 mm - Length 32 mm
131 034(S)	Dia 3.7 mm - Length 34 mm

*(S): delivered sterile and non sterile.

Qwix® 3.0 mm: Fixation Screw

Reference	Description
111 312(S)	Dia 3.0mm - Length 12 mm
111 314(S)	Dia 3.0mm - Length 14 mm
111 316(S)	Dia 3.0mm - Length 14 mm
111 318(S)	Dia 3.0mm - Length 18 mm
111 320(S)	Dia 3.0mm - Length 20 mm
111 322(S)	Dia 3.0mm - Length 22 mm
111 324(S)	Dia 3.0mm - Length 24 mm
111 326(S)	Dia 3.0 mm - Length 26 mm
111 328(S)	Dia 3.0mm - Length 28 mm
111 330(S)	Dia 3.0mm - Length 30 mm
111 332(S)	Dia 3.0mm - Length 32 mm
111 334(S)	Dia 3.0mm - Length 34 mm

*(S): delivered sterile and non sterile.

Drills and K-wires

	#	Reference	Description
Bold® 3.0 mm - Bold® 3.7 mm - Qwix® 3.0 mm	3	119 027(S)	"2 in 1" Drill - L 12 mm – cannulated
	3	119 025(S)	"2 in 1" Drill - L 22 mm – cannulated
	3	119 023(S)	"2 in 1" Drill - L 32 mm – cannulated
	3	159 027(S)	"2 in 1" Drill - L 12 mm – AO – cannulated
	3	159 025(S)	"2 in 1" Drill - L 22 mm – AO – cannulated
	3	159 023(S)	"2 in 1" Drill - L 32 mm – AO – cannulated
	3	119 227(S)	"2 in 1" Drill - L 12 mm – non cannulated
	3	119 225(S)	"2 in 1" Drill - L 22 mm – non cannulated
	3	119 223(S)	"2 in 1" Drill - L 32 mm – non cannulated
	3	159 227(S)	"2 in 1" Drill - L12 mm – AO – non cannulated
	3	159 225(S)	"2 in 1" Drill - L 22 mm – AO – non cannulated
	3	159 223(S)	"2 in 1" Drill - L 32 mm – AO – non cannulated
	3	115 070(S)	K-wire - Dia 1.0 x L 70 mm - 1 sharp – 1 soft
	3	115 100(S)	K-wire - Dia 1.0 x L 100 mm - 2 sharps
Bold® 2.5 mm	3	229 227S	2.5 mm "2 in 1" Drill - L 12 mm - cannulated
	3	229 237S	2.5 mm "2 in 1" Drill - L 22 mm - cannulated
	11	229 027S	2.5 mm "2 in 1" Drill - L 12 mm - AO - cannulated
	11	229 037S	2.5 mm "2 in 1" Drill - L 22 mm - AO - cannulated
	11	229 028S	2.5 mm "2 in 1" Drill - L 12 mm - AO - non cannulated
	3	229 038S	2.5 mm "2 in 1" Drill - L 22 mm - AO - non cannulated
	3	229 228S	2.5 mm "2 in 1" Drill - L 12 mm - non cannulated
	3	229 238S	2.5 mm "2 in 1" Drill - L 22 mm - non cannulated
	3	115 008S	K-wire - dia 0.8 x L 70 mm - 1 sharp - 1 soft

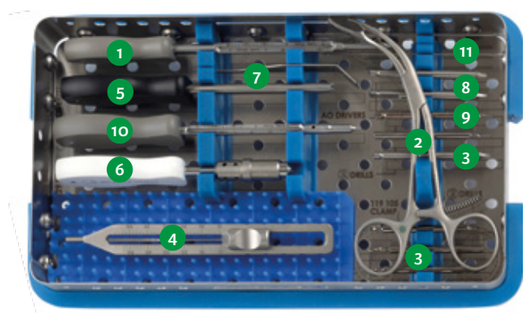
*S: delivered sterile and non sterile.

Associated Instruments

#	Reference	Description
2	119 105	Bold® clamp
1	229 002	Screwdriver - HEXA 2.0
9	229 005	AO Screwdriver - HEXA 2.0 - AO attachment
10	229 003	Screwdriver - T7 STAR - Dia 0.9 cannulated
8	229 004	AO Screwdriver - T7 STAR - Dia 0.9 cannulated
5	229 301	Screwdriver Spin®
6	997 311	AO Straight handle
7	229 101	Ruler
	229 011	Longitudinal cutting guide (optional)
	229 012	Transversal cutting guide (optional)
4	997 301	Depth gauge - Dia 2.0 mm - L10 mm - 60 mm (optional)

Container

Reference	Description
229 951	Forefoot II: set - screws instrumentation
229 961	Forefoot II: base - screws instrumentation
229 970	Lid
229 971	Forefoot II: mat - screws instrumentation



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QWIX® 3.0 mm Fixation screw

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