SINGLE USE KIT STERILE R

NEWCLIP-TECHNICS

INITIAL™

Screws for foot

Ready
when you are!

With a non sterile
standard kit

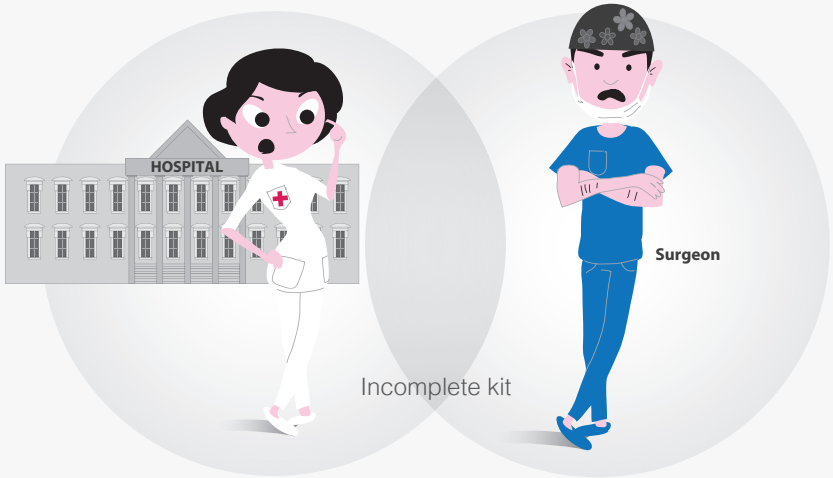
Calling on medical staff

Constraints → Complex traceability + Contracted out sterilization + Suppliers' deadline

High costs

- $ Stocks
- $ Control
- $ Cleaning
- $ Decontamination
- $ Sterilization

Bulky storage



Complex process

1 Delivery
2 Storage
3 Unpacking
4 Control
5 Deconta-mination
6 Cleaning
7 Drying
8 Control
9 Packaging of the kit
10 Sterilization
11 Surgery
12 Deconta-mination
13 Cleaning
14 Drying
15 Control
16 Traceability
17 Restocking
18 Packaging of the kit
19 Sterilization
20 Storage

Prevents an effective solution & a quick response

URGENT SURGICAL CASES COMPROMISED

Defective sterilization + Incomplete kit + Damaged instrumentation = **INCREASED RISKS** / **NON OPTIMAL surgery**

With the INITIAL™ kits

Safety > **TRACEABILITY 100%** + STERILE R SINGLE USE KIT + Always NEW + **Risk of contamination**

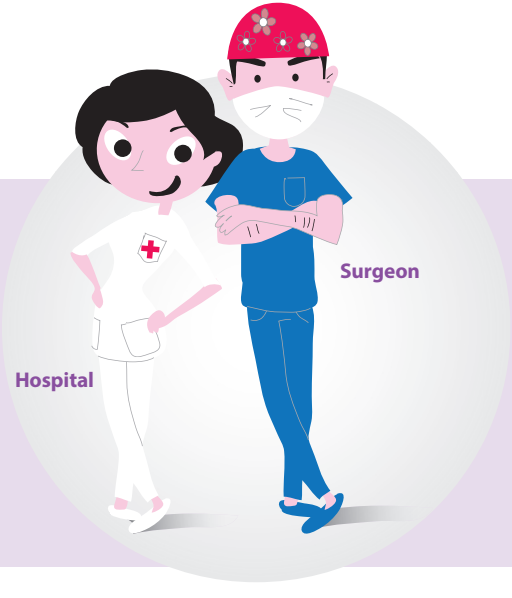
Cost efficiency

Controlled stocks
Simplified control

- 0 Cleaning
- 0 Decontamination
- 0 Sterilization

Sundry expenses

Optimized storage



Efficiency

1 Delivery
2 Storage
3 Surgery

An effective solution & a quick response

Available when needed

READY-TO-USE FOR SURGERY

Optimized handling of URGENT SURGICAL CASES

STERILE R SINGLE USE KIT
with state-of-the-art implants

Ready when you are!

Safety:

The Initial S™ kit is fully traceable and has a shelf life of 5 years.
Its instrumentation and implants are "always new" and have never been opened or used before.

Available when needed:

The Initial S™ kit comes pre-sterilized and ready to use.
The combination of sterile implants and single use instrumentation kits makes Initial S™ ideal for use in urgent surgical cases.

INITIAL S™ innovation

Storage:

Initial S™ kit can be easily stored in the operating room because of its small size.

Costs:

Initial S™ is a cost-effective solution.
The additional costs including cleaning, decontamination, sterilization of kits are cancelled.

Contamination:

The combination of sterile implants and sterile single-use instrumentation kits minimizes contamination risks.

Buying procedure:

Initial S™ facilitates buying procedures: restocking and orders are simplified, stock management is optimized.

Initial S™ kits - Foot

Indications

The implants of the Inital S™ range are intended for the fixation of bone fractures and osteotomies and for arthrodeses of foot and hand in adults.

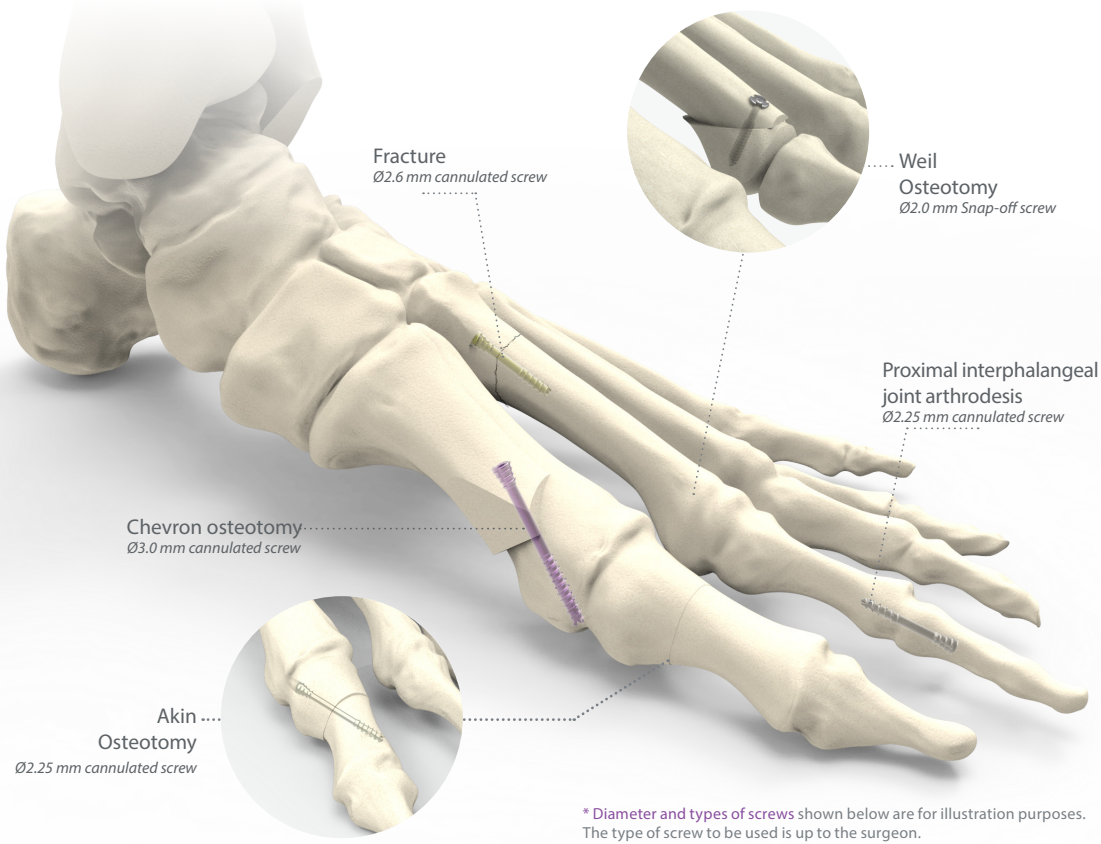
Contra-indications

- Serious vascular deterioration, bone devitalization,
- Pregnancy.
- Acute or chronic, local or systemic infections.
- Lack of musculo-cutaneous cover, severe vascular deficiency affecting the concerned area.
- Insufficient bone quality preventing a good fixation of the implants into the bone.
- Muscular deficit, neurological deficiency or behavioral disorders, which could submit the implant to abnormal mechanical strains.
- Allergy to one of the materials used or sensitivity to foreign bodies.
- Serious problems of non-compliance, mental or neurological disorders, failure to follow post-operative care recommendations.
- Unstable physical and/or mental condition.

Disposable instrumentation kits for use with Footmotion sterile **cannulated screws**:
Ø2.25 mm, Ø2.6 mm and Ø3.0 mm

Disposable instrumentation kits for use with Footmotion sterile **snap-off screws**:
Ø2.0 mm

Applications*



* Diameter and types of screws shown below are for illustration purposes.
The type of screw to be used is up to the surgeon.

Initial S™ kits - Foot

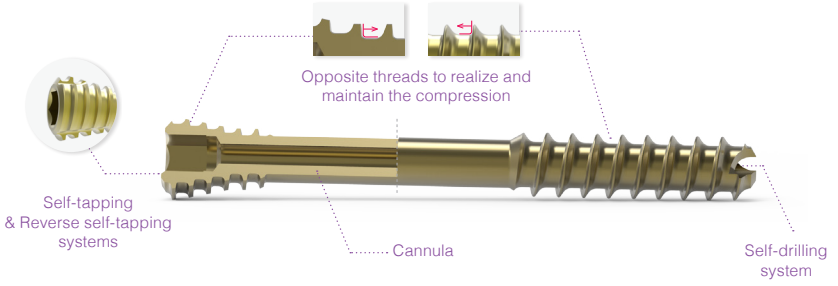
Comprehensive range

Cannulated screws

Technical features

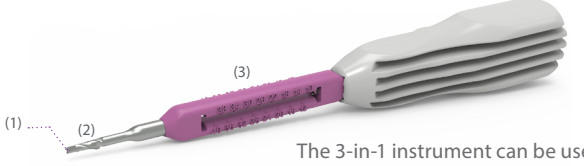
• 3 diameters

Cannulated screws Ø2.25 mm Pin: Ø 0.8 mm	Cannulated screws Ø2.6 mm Pin: Ø1.0 mm	Cannulated screws Ø3.0 mm Pin: Ø1.0 mm



Dedicated ergonomic instruments

The 3-in-1 instrument combines **three tools**:
- Screwdriver (1),
- Countersink (2),
- Depth gauge (3).

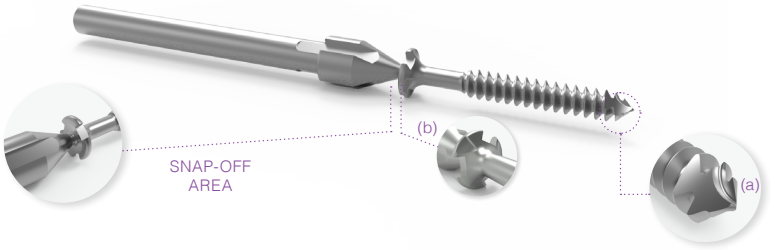


The 3-in-1 instrument can be used with the handle and the power tool. In the latter case, it is recommended to finalize the screwing by hand.

Snap-off screws (for weil osteotomy)

Technical features

Ø2.0 mm snap-off screw dedicated to Weil osteotomy.



- **Self-drilling** and **self-tapping** extremity ensuring an easy penetration in cortical bone (a),
- **Self-drilling of the screw head** allowing a partial burying to limit soft tissues irritations (b),
- **Section area in a recess** of the screw head

Dedicated ergonomic instrument

Screwdriver allowing:
- Separation between the shank and the screw,
- Finalization of the compression after separation,
- Implant removal performance.

Initial S™ kits - Foot

Surgical technique - Cannulated screws

Example: surgical technique with a Ø2.6 mm cannulated screw (KIT-SC2.6F)

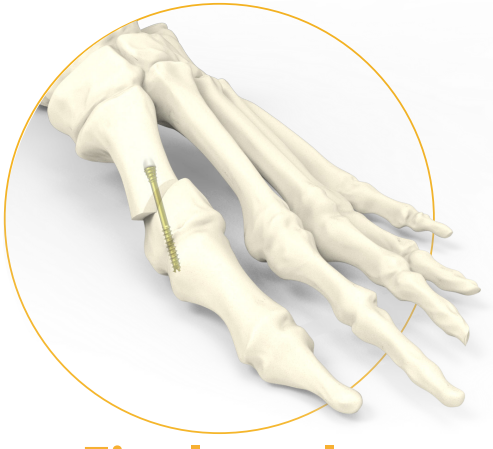
1. Insert the Ø1.0 mm pin until the opposite cortex is reached.

2. Slide the 3-in-1 instrument along the Ø1.0 mm pin to the bone. Read directly the length of the screw on the measuring gauge part of the 3-in-1 instrument at the rear of the pin. At this stage the pin can be inserted deeper in order to prevent its removal during the drilling step.

3. To make the screw insertion easier, widen in the first cortex using the countersink part of 3-in-1 instrument.

4. Insert the screw through the pin using the 3-in-1 instrument* until the desired reduction and compression are reached.

NB: *In case of a hard cortical bone or several cortex, it is recommended to drill before the screw insertion (c).*

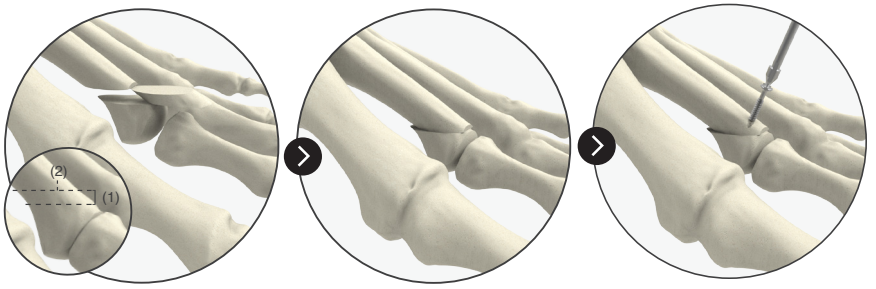


Final result

Initial S™ kits - Foot

Surgical technique - Snap-off screws

Example: surgical technique with a Ø2.0 mm snap-off screw (KIT-SC2.0)



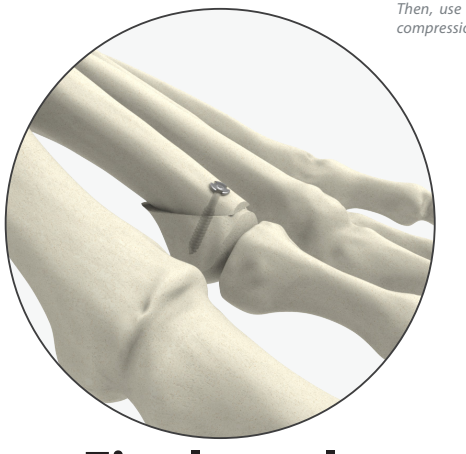
1. Perform a first horizontal cut using the oscillating saw starting at the junction of the dorsal cartilage (1).
Then perform the second dorsal cut parallel with the first cut and then remove the bone fragment (2).

2. The reduction is made manually by flexing the toe.

3. Insert the screw with the power tool. As soon as the compression is finished, the screw snaps off.

NB: *In case of a hard cortical bone it is recommended to prepare the screw insertion using a Ø1.0 mm pin (33.0210.080).*

Caution: *In osteoporotic bone, it may be necessary to provoke release of the shank prior to the screw head reaching the cortical bone to avoid excessive screwing. Then, use the screwdriver to realize the compression.*



Final result

Initial S™ kits - Foot

References

Instrumentation kit for Ø2.25 mm cannulated screws

INITIAL S™ - INSTRUMENTATION KIT CONTENT			
Ref.	Description	Content	Qty
KIT-SC2.25F	Kit for Ø2.25 mm cannulated screws - Foot	Ø1.7 mm quick coupling drill bit – cannula Ø0.9 mm - L75 mm	1
		3 in 1 instrument for Ø2.25 mm screws	1
		5.8 mm single use handle	1
		Pin Ø0.8 L80 mm	3

Instrumentation kit for Ø2.6 mm cannulated screws

INITIAL S™ - INSTRUMENTATION KIT CONTENT			
Ref.	Description	Content	Qty
KIT-SC2.6F	Kit for Ø2.6 mm cannulated screws - Foot	Ø2.0 mm quick coupling drill bit – cannula Ø1.1 mm - L75 mm	1
		3 in 1 instrument for Ø2.6 mm screws	1
		5.8 mm single use handle	1
		Pin Ø1.0 L80 mm	3

Ø2.25 mm sterile cannulated screws*

Ø2.25 MM CANNULATED SCREW REFERENCES	
Ref.	Description
H0.9HFT2.25L10 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 10 mm - STERILE
H0.9HFT2.25L12 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 12 mm - STERILE
H0.9HFT2.25L14 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 14 mm - STERILE
H0.9HFT2.25L16 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 16 mm - STERILE
H0.9HFT2.25L18 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 18 mm - STERILE
H0.9HFT2.25L20 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 20 mm - STERILE
H0.9HFT2.25L22 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 22 mm - STERILE
H0.9HFT2.25L24 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 24 mm - STERILE
H0.9HFT2.25L26 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 26 mm - STERILE
H0.9HFT2.25L28 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 28 mm - STERILE
H0.9HFT2.25L30 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 30 mm - STERILE
H0.9HFT2.25L32 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 32 mm - STERILE
H0.9HFT2.25L34 - ST	Self-drilling self-compressive screw - Ø2.25 mm -cannulated Ø0.9 mm - L 34 mm - STERILE

Ø2.6 mm sterile cannulated screws*

Ø2.6 MM CANNULATED SCREW REFERENCES	
Ref.	Description
H1.1HFT2.6L10 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 10 mm - STERILE
H1.1HFT2.6L12 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 12 mm - STERILE
H1.1HFT2.6L14 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 14 mm - STERILE
H1.1HFT2.6L16 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 16 mm - STERILE
H1.1HFT2.6L18 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 18 mm - STERILE
H1.1HFT2.6L20 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 20 mm - STERILE
H1.1HFT2.6L22 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 22 mm - STERILE
H1.1HFT2.6L24 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 24 mm - STERILE
H1.1HFT2.6L26 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 26 mm - STERILE
H1.1HFT2.6L28 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 28 mm - STERILE
H1.1HFT2.6L30 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 30 mm - STERILE
H1.1HFT2.6L32 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 32 mm - STERILE
H1.1HFT2.6L34 - ST	Self-drilling self-compressive screw - Ø2.6 mm -cannulated Ø1.1 mm - L 34 mm - STERILE

Initial S™ kits - Foot
References

Instrumentation kit for Ø3.0 mm cannulated screws

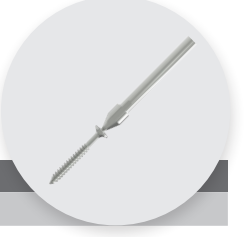
INITIAL S™ KITS - INSTRUMENTATION CONTENT			
Ref.	Description	Content	Qty
KIT-SC3.0F	Kit for Ø3.0 mm cannulated screws - Foot	Ø2.2 mm quick coupling drill bit – cannula Ø1.1 mm - L80 mm	1
		3 in 1 instrument for Ø3.0 mm screws	1
		5.8 mm single use handle	1
		Pin Ø1.0 L80 mm	3

Ø3.0 mm sterile cannulated screws*

Ø3.0 MM CANNULATED SCREW REFERENCES	
Ref.	Description
H1.1HFT3.0L10 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 10 mm - STERILE
H1.1HFT3.0L12 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 12 mm - STERILE
H1.1HFT3.0L14 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 14 mm - STERILE
H1.1HFT3.0L16 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 16 mm - STERILE
H1.1HFT3.0L18 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 18 mm - STERILE
H1.1HFT3.0L20 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 20 mm - STERILE
H1.1HFT3.0L22 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 22 mm - STERILE
H1.1HFT3.0L24 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 24 mm - STERILE
H1.1HFT3.0L26 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 26 mm - STERILE
H1.1HFT3.0L28 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 28 mm - STERILE
H1.1HFT3.0L30 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 30 mm - STERILE
H1.1HFT3.0L32 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 32 mm - STERILE
H1.1HFT3.0L34 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 34 mm - STERILE
H1.1HFT3.0L36 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 36 mm - STERILE
H1.1HFT3.0L38 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 38 mm - STERILE
H1.1HFT3.0L40 - ST	Self-drilling self-compressive screw - Ø3.0 mm -cannulated Ø1.1 mm - L 40 mm - STERILE

Instrumentation kit for Ø2.0 mm snap-off screws

INITIAL S™ KITS - INSTRUMENTATION CONTENT			
Ref.	Description	Content	Qty
KIT-SC2.0	Kit for Ø2.0 mm snap off screw	Screwdriver for Ø2.0 mm Snap-off screws	1



Ø2.0 mm sterile snap-off screws*

Ø2.0 MM SNAP OFF SCREWS	
Ref.	Description
WST2.0L11 - ST	Snap-Off Weil screw - Ø2.0 mm - L 11 mm - STERILE
WST2.0L12 - ST	Snap-Off Weil screw - Ø2.0 mm - L 12 mm - STERILE
WST2.0L13 - ST	Snap-Off Weil screw - Ø2.0 mm - L 13 mm - STERILE
WST2.0L14 - ST	Snap-Off Weil screw - Ø2.0 mm - L 14 mm - STERILE
WST2.0L15 - ST	Snap-Off Weil screw - Ø2.0 mm - L 15 mm - STERILE

*Available separately in «Sterile screw caddy»

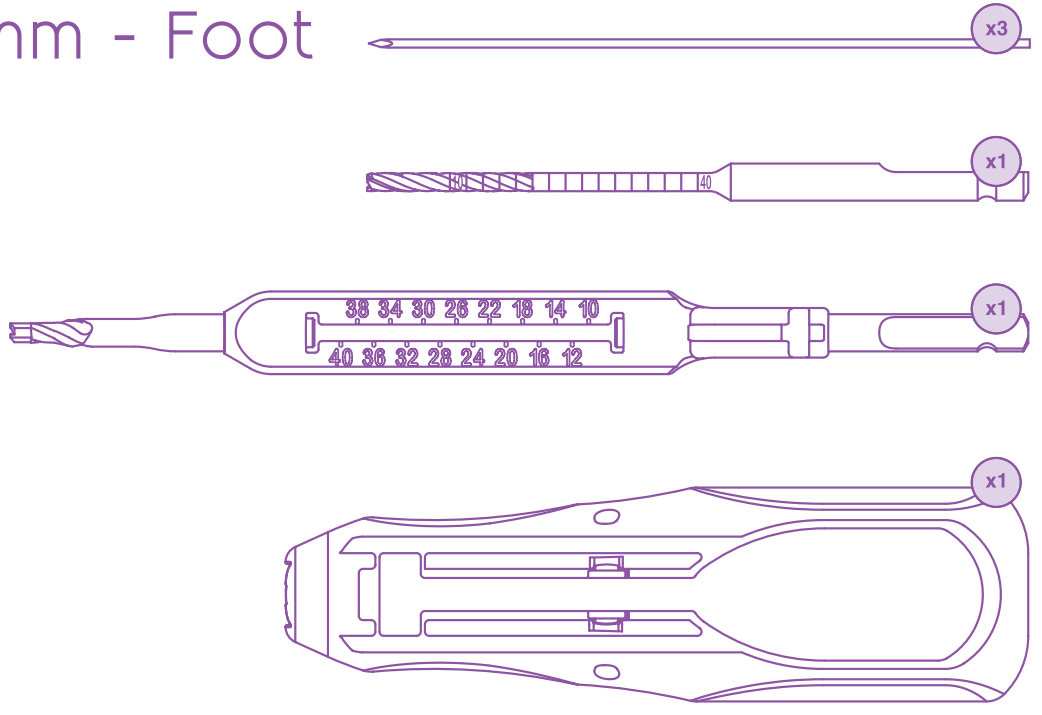
The information presented in this brochure is intended to demonstrate a Newclip Technics product. Always refer to the package insert, product label and/or user instructions before using any Newclip Technics product. Surgeons must always rely on their own clinical judgment when deciding which products and techniques to use with their patients. Products may not be available in all markets. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Newclip Technics representative if you have questions about the availability of Newclip Technics products in your area.

Example of kit content.

KIT-SC3.0F

Instrumentation for Cannulated screws

Ø3.0 mm - Foot



INITIAL S™

Degree of accuracy for devices with a measuring function: ± 0.8 mm

SINGLE USE KIT STERILE R CE 0120 Rx only

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Non contractual pictures

Brochure EN - Initial-S - Foot - Ed.2 - 07/2017 - Medical device - class IIb - US Class: II - Read labeling and instructions before use.