

SINGLE USE KIT

STERILE R

NEWCLIP-TECHNICS



INITIAL LAPIDUS



With a non sterile standard kit



Calling on medical staff

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

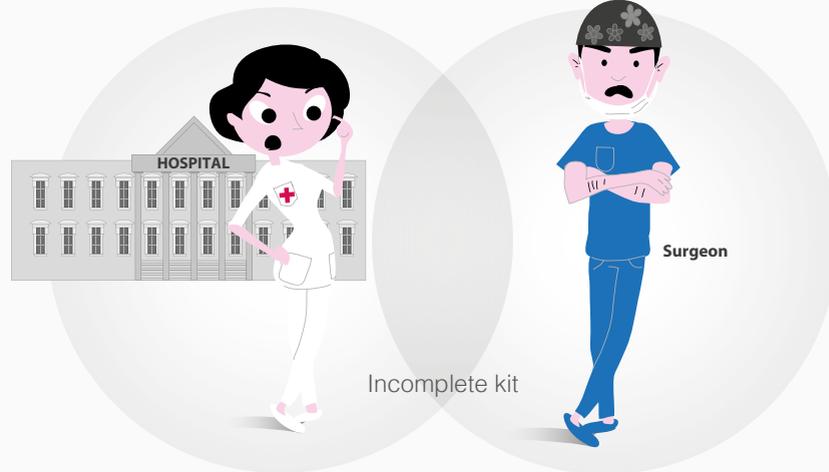
High costs



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



Bulky storage



Complex process



Prevents an effective solution & a quick response



Defective sterilization



Incomplete kit



Damaged instrumentation



INCREASED RISKS

NON OPTIMAL surgery



URGENT SURGICAL CASES COMPROMISED

With the kit



Safety >



Risk of contamination

Cost efficiency

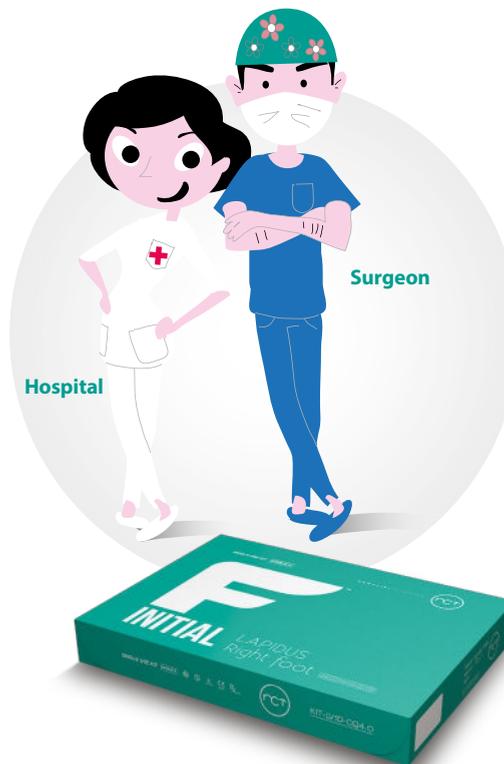
Controlled stocks
Simplified control

- 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!



Available when needed:

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



Costs:

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



Safety:

The Initial F™ Lapidus 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.

F
INITIAL Lapidus **innovation**



Storage:

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



Contamination:

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



Buying procedure:

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

Initial F™ - Lapidus kit

Kit content

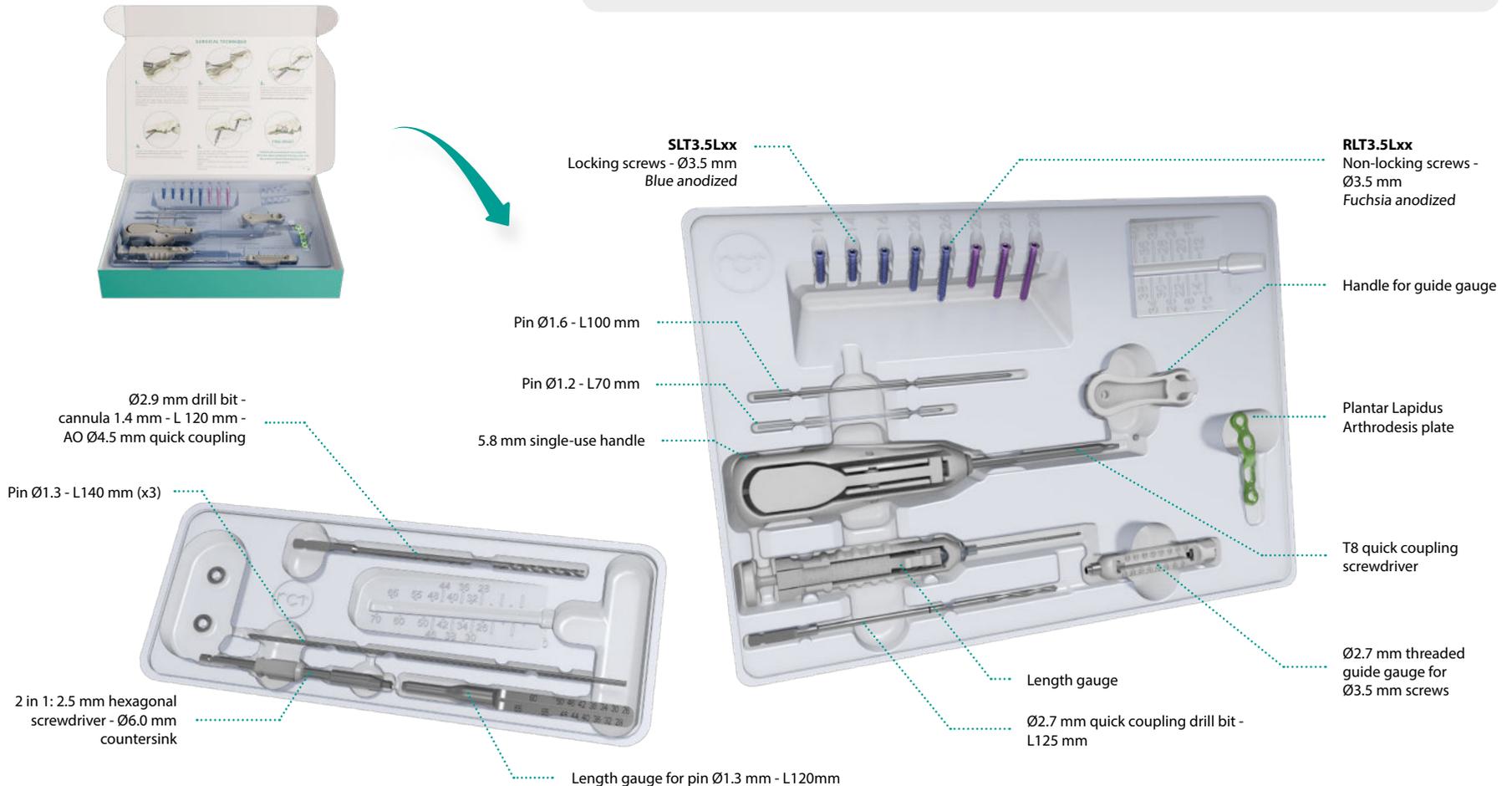
Example : Kit LV1D - CQ4.0

> Intended purpose

The implants of the Initial F™ range are intended for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.

> Contraindications

- Pregnancy
- Acute or chronic, local or systemic infections.
- Allergy to one of the materials used or sensitivity to foreign bodies.



Initial F™ - Lapidus Kit

Technical features

> Plates for the plantar Lapidus arthrodesis

Examples of applications: osteoarthritis, functional deformities.

Compression screw

The stand-alone screw is inserted through the joint providing compression of the joint. The Ø4.0 mm cannulated headed screws (H1.4QT4.0Lxx-ST) are available separately on request in sterile version. The available range is from 26 mm to 48 mm with an incremental of 2 mm.

Plantar positioning of the plate

The plantar positioning of the plate offers a strong mechanical assembly allowing immediate weight-bearing.

Anatomical plate

The design of the implant is the result of a proprietary state-of-the-art mapping technology to establish maximum congruence between the plate and the bone.

Bending properties

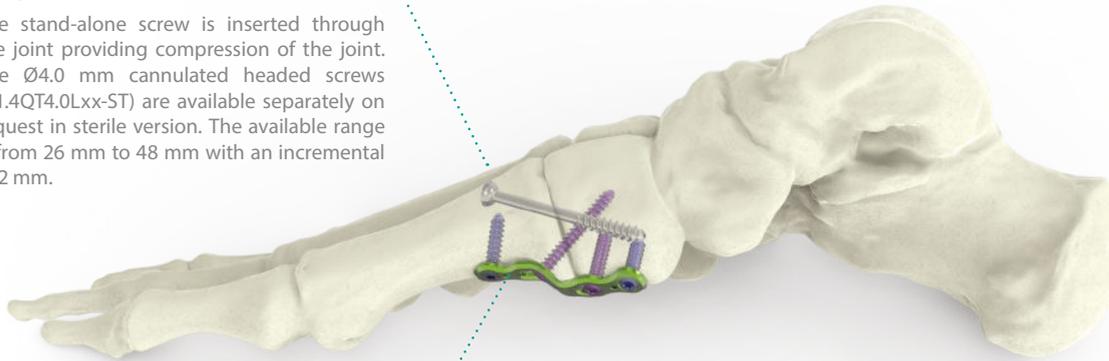
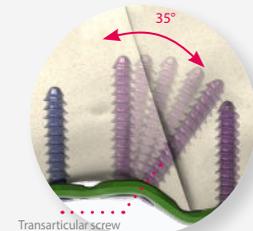
The plate is made of Grade 2 Titanium, for an adaptation to the first tarsometatarsal (TMT1) joint anatomies when using the guide gauge.

3 sizes of plates

The right (green plates) and left (blue plates) sides offering comprehensive solutions.



➤ Screw angulation up to 35°

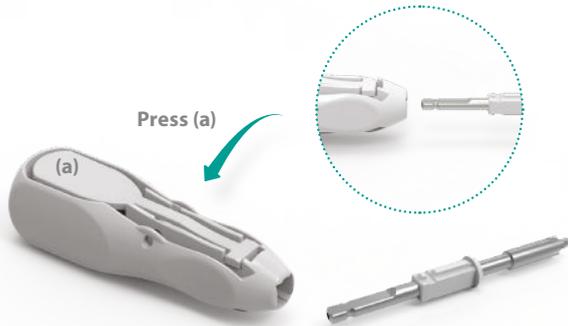


Initial F™ - Lapidus kit

Instrumentation - Technical features

> 2-in-1 instrument: screwdriver and countersink

> T8 quick coupling screwdriver



The 2-in-1 instrument and the T8 quick coupling screwdriver can be used with the handle and the power tool. In the latter case, it is recommended to finalize the screwing by hand.

To release the 2-in-1 instrument or the T8 quick coupling screwdriver from the handle, press the button (a).

> Handle for guide gauge

Before performing the drilling into the oblong hole, snap the handle for guide gauge on the Ø2.7 mm threaded guide gauge.



Handle for guide gauge

> Template

The Initial F™ - Lapidus template is available separately and allows to quickly and simply determine the appropriate kit prior its opening. The template is bendable to fit the anatomy and select the desired plate size.



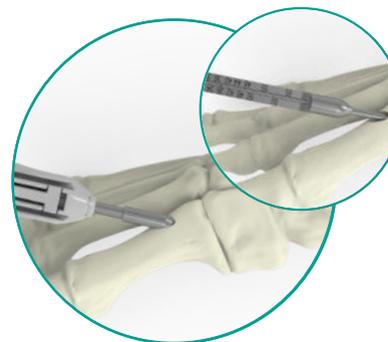
Initial F™ - Lapidus kits

Surgical technique

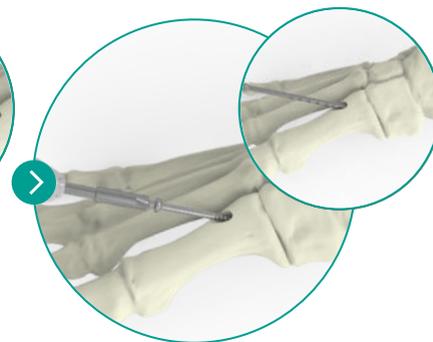
Example: surgical technique with a size 1 plate (KIT-LV1D-CQ4.0).



1. Select the correct kit according to the template.



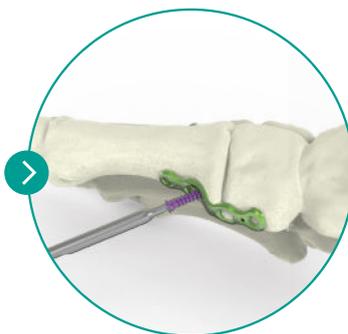
2. Insert the $\text{\O}1.3$ mm pin transversally from the 1st metatarsal to the first cuneiform. Connect the handle to the 2-in-1 instrument and slide it along the $\text{\O}1.3$ mm pin and widen the surface of insertion using the countersink part of the 2-in-1 instrument. Then, slide the length gauge along the $\text{\O}1.3$ mm pin to determine the length of the screw using the marking on the $\text{\O}1.3$ mm pin.



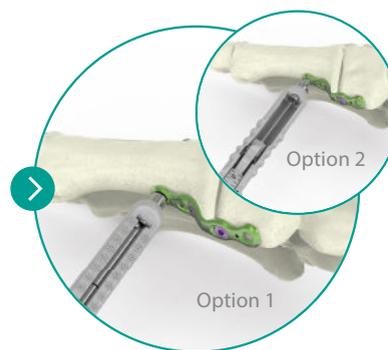
3. Drill to prepare the screw insertion. The drilling depth can be checked using the marking on the drill bit. Select the appropriate screw length and insert the screw (H1.4QT4.0Lxx) along the $\text{\O}1.3$ mm pin using the screwdriver part of the 2-in-1 instrument until the desired reduction and compression are achieved. Then remove the pin. NB: The $\text{\O}1.3$ mm pin can be inserted deeper in drilling in order to prevent its removal during drilling.



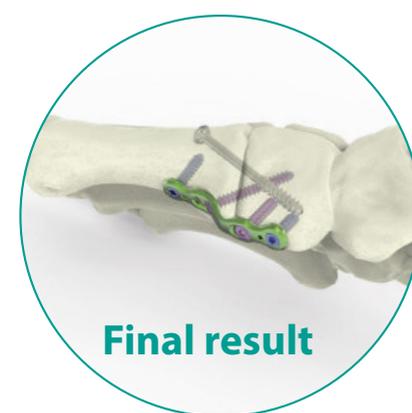
4. Position the plate plantarly over the TMT1 joint and stabilize it temporarily by inserting a $\text{\O}1.2$ mm pin. Snap the handle for guide gauge and perform the drilling using the assembly into the distal oblong hole. **Determine the screw length using the length gauge (a).**



5. Connect the handle to the screwdriver and insert a $\text{\O}3.5$ mm pink anodized non-locking screw using the screwdriver. Repeat the same procedure for the proximal oblong hole.



6. Lock the $\text{\O}2.7$ mm threaded guide gauge into the most distal hole and perform the drilling. **Option 1 :** Determine the screw length using the drill bit and guide gauge. **Option 2 :** Determine the screw length using the length gauge. Insert a $\text{\O}3.5$ mm blue anodized locking screw using the screwdriver.



Final result

Finalize the assembly by inserting the $\text{\O}3.5$ mm blue anodized locking screw into the proximal hole following the same procedure.

Initial F™ - Lapidus kits

References



INITIAL F™ - LAPIDUS KITS - INSTRUMENTATION CONTENT STERILE INSTRUMENTATION FOR PLANTAR LAPIDUS PLATE

Description	Qty
Ø2.7 mm quick coupling drill bit - L 125 mm	1
Ø2.7 mm threaded guide gauge for Ø3.5 mm screws	1
Length gauge for Ø2.8 and 3.5 mm screws - L8-40 mm	1
T8 quick coupling screwdriver	1
Handle for guide gauge	1
5.8 mm single use handle	1
Pin Ø1.6 - L100 mm	1
Pin Ø1.2 - L70 mm	2

STERILE INSTRUMENTATION FOR Ø4.0 MM CANNULATED SCREWS *

Description	Qty
Length gauge for pin Ø1.3 mm - 120 mm	1
2 in 1: 2.5 mm hexagonal screwdriver - Ø6.0 mm countersink	1
Ø2.9 mm drill bit - cannula 1.4 mm - L120 mm - AO Ø4.5 mm quick coupling	1
Pin Ø1.3 - L140 mm	3

* The Ø4.0 mm cannulated headed screws (H1.4QT4.0Lxx-ST) are available separately on request in sterile version. The available range is from 26 mm to 48 mm with an increment of 2 mm.

INITIAL F™ - LAPIDUS KITS

Ref.	Description
KIT-LV0D-CQ4.0	Foot kit - Lapidus Arthrodesis - Plantar - Size 0 - Right + for Ø4.0 mm screws
KIT-LV0G-CQ4.0	Foot kit - Lapidus Arthrodesis - Plantar - Size 0 - Left + for Ø4.0 mm screws
KIT-LV1D-CQ4.0	Foot kit - Lapidus Arthrodesis - Plantar - Size 1 - Right + for Ø4.0 mm screws
KIT-LV1G-CQ4.0	Foot kit - Lapidus Arthrodesis - Plantar - Size 1 - Left + for Ø4.0 mm screws
KIT-LV2D-CQ4.0	Foot kit - Lapidus Arthrodesis - Plantar - Size 2 - Right + for Ø4.0 mm screws
KIT-LV2G-CQ4.0	Foot kit - Lapidus Arthrodesis - Plantar - Size 2 - Left + for Ø4.0 mm screws

INITIAL F™ - LAPIDUS KITS - IMPLANTS CONTENT

	Ref.	Description	KIT-LV0D-CQ4.0	KIT-LV0G-CQ4.0	KIT-LV1D-CQ4.0	KIT-LV1G-CQ4.0	KIT-LV2D-CQ4.0	KIT-LV2G-CQ4.0
PLATES	FLTDV0	Plantar Lapidus arthrodesis plate - Narrow - Right - Size 0 (length 37.0mm)	1	-	-	-	-	-
	FLTGV0	Plantar Lapidus arthrodesis plate - Narrow - Left - Size 0 (length 37.0mm)	-	1	-	-	-	-
	FLTDV1	Plantar Lapidus arthrodesis plate - Narrow - Right - Size 1 (length 41.8mm)	-	-	1	-	-	-
	FLTGV1	Plantar Lapidus arthrodesis plate - Narrow - Left - Size 1 (length 41.8mm)	-	-	-	1	-	-
	FLTDV2	Plantar Lapidus arthrodesis plate - Narrow - Right - Size 2 (length 49.8mm)	-	-	-	-	1	-
	FLTGV2	Plantar Lapidus arthrodesis plate - Narrow - Left - Size 2 (length 49.8mm)	-	-	-	-	-	1
LOCKING SCREWS Ø3.5 MM	SLT3.5L14	Ø3.5 mm locking screw - L14 mm	1	1	1	1	2	2
	SLT3.5L16	Ø3.5 mm locking screw - L16 mm	1	1	1	1	1	1
	SLT3.5L20	Ø3.5 mm locking screw - L20 mm	1	1	1	1	1	1
	SLT3.5L26	Ø3.5 mm locking screw - L26 mm	1	1	1	1	1	1
NON LOCKING SCREWS Ø3.5 MM	RLT3.5L20	Ø3.5 mm non-locking screw - L20 mm	1	1	1	1	1	1
	RLT3.5L26	Ø3.5 mm non-locking screw - L26 mm	1	1	1	1	1	1
	RLT3.5L28	Ø3.5 mm non-locking screw - L28 mm	1	1	1	1	1	1

Initial F™ - Lapidus kits

References

Additional implants

Sterile screws packaged in the supplemental sterile screw caddy



NON LOCKING SCREWS - Ø3.5 mm*			
Ref.	Description		Qty
RLT3.5L10-ST	Ø3.5 mm non-locking screw - L10 mm - STERILE		1
RLT3.5L12-ST	Ø3.5 mm non-locking screw - L12 mm - STERILE		1
RLT3.5L14-ST	Ø3.5 mm non-locking screw - L14 mm - STERILE		1
RLT3.5L16-ST	Ø3.5 mm non-locking screw - L16 mm - STERILE		1
RLT3.5L18-ST	Ø3.5 mm non-locking screw - L18 mm - STERILE		1
RLT3.5L20-ST	Ø3.5 mm non-locking screw - L20 mm - STERILE		1
RLT3.5L22-ST	Ø3.5 mm non-locking screw - L22 mm - STERILE		1
RLT3.5L24-ST	Ø3.5 mm non-locking screw - L24 mm - STERILE		1
RLT3.5L26-ST	Ø3.5 mm non-locking screw - L26mm - STERILE		2
RLT3.5L28-ST	Ø3.5 mm non-locking screw - L28 mm - STERILE		2
RLT3.5L30-ST	Ø3.5 mm non-locking screw - L30 mm - STERILE		1
RLT3.5L32-ST	Ø3.5 mm non-locking screw - L32 mm - STERILE		1
RLT3.5L34-ST	Ø3.5 mm non-locking screw - L34 mm - STERILE		1
RLT3.5L36-ST	Ø3.5 mm non-locking screw - L36 mm - STERILE		1
RLT3.5L38-ST	Ø3.5 mm non-locking screw - L38 mm - STERILE		1
RLT3.5L40-ST	Ø3.5 mm non-locking screw - L40 mm - STERILE		1



LOCKING SCREWS - Ø3.5 mm*			
Ref.	Description		Qty
SLT3.5L10-ST	Ø3.5 mm locking screw - L10 mm - STERILE		1
SLT3.5L12-ST	Ø3.5 mm locking screw - L12 mm - STERILE		1
SLT3.5L14-ST	Ø3.5 mm locking screw - L14 mm - STERILE		2
SLT3.5L16-ST	Ø3.5 mm locking screw - L16 mm - STERILE		2
SLT3.5L18-ST	Ø3.5 mm locking screw - L18 mm - STERILE		1
SLT3.5L20-ST	Ø3.5 mm locking screw - L20 mm - STERILE		2
SLT3.5L22-ST	Ø3.5 mm locking screw - L22 mm - STERILE		1
SLT3.5L24-ST	Ø3.5 mm locking screw - L24 mm - STERILE		1
SLT3.5L26-ST	Ø3.5 mm locking screw - L26 mm - STERILE		2
SLT3.5L28-ST	Ø3.5 mm locking screw - L28 mm - STERILE		1
SLT3.5L30-ST	Ø3.5 mm locking screw - L30 mm - STERILE		1
SLT3.5L32-ST	Ø3.5 mm locking screw - L32 mm - STERILE		1
SLT3.5L34-ST	Ø3.5 mm locking screw - L34 mm - STERILE		1

* Blue anodized

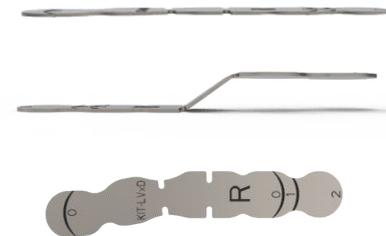


CANNULATED SCREWS - Ø4.0 mm	
Ref.	Description
H1.4QT4.0Lxx-ST	Ø4.0 mm compressive screw - cannula Ø1.4 - short thread - L26-48 mm - STERILE

Template

Sterile template

INITIAL F™ - LAPIDUS TEMPLATE	
Ref.	Description
ANC958	Template for foot kit - Lapidus Arthrodesis - Plantar - Sizes 0-1-2 - Left & Right (KIT-LVxx)



* Fuchsia anodized

Removal and rescue kits

Sterile instruments

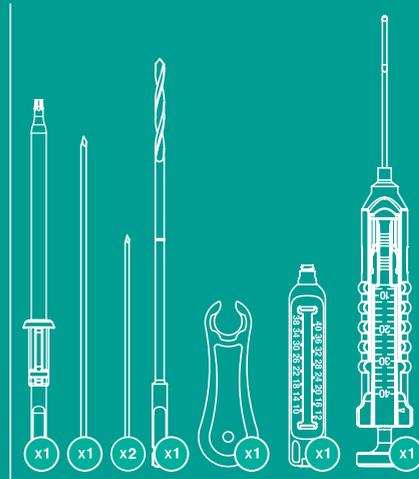
REMOVAL AND RESCUE KITS - STERILE PACKAGING		
Ref.	Description	Content
KIT-REMOVE-2	Removal kit for T8 hexalobe	- 1x T8 Prehensor Screwdriver
KIT-REMOVE-A	Removal kit for hexagonal stamp 2.5 mm	- 1x 2in1 2.5 mm Prehensor Screwdriver & Ø3.5 mm countersink
KIT-RESCUE-6	Rescue kit for Initial F Lapidus	- 1x Ø2.7 mm threaded guide gauge for Ø3.5 mm screws - 1x Ø2.7 mm quick coupling drill bit - L125 mm - 1x Handle for guide gauge - 1x Length gauge - 1x Pin Ø1.6 L100 mm - 2x Pin Ø1.2 L70 mm



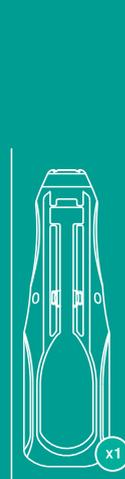
Ready
when you are!

KIT-LVOG-CQ4.0

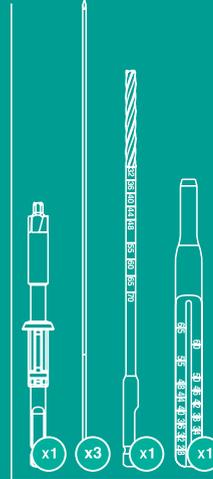
Left Foot Lapidus Arthrodesis Plantar - Size 0



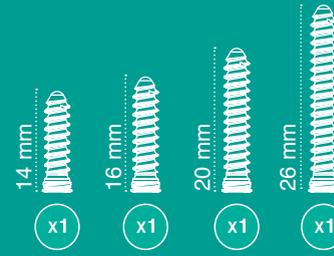
For Lapidus plate



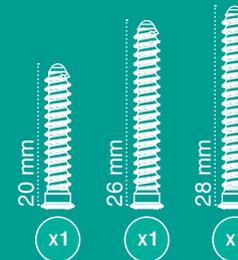
For both



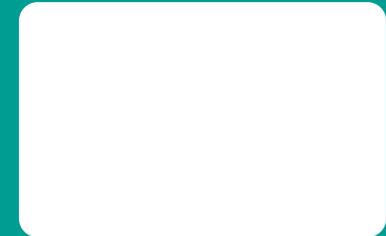
For Ø4.0 mm screws*



Locking screws $\varnothing 3.5$ mm



Non Locking screws $\varnothing 3.5$ mm



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Implant material: Titanium TA6V - ISO 5832-3 / ASTM F136 - CP Titanium - ISO 5832-2 / ASTM F67
Degree of accuracy for devices with a measuring function: ± 1.0 mm
* $\varnothing 4.0$ mm screws are available separately in sterile screw caddy.

Manufacturer : Newclip Technics - Brochure EN+US - Initial F LAPIDUS - ED4 - 0725 - Medical device EC- class IIb - CE1639 SGS BE - US Class: II
Read labelling and instructions before the use of Newclip Technics medical devices. These products must be handled and/or implanted by trained and qualified staff who have read the instructions before use. | Non contractual pictures.

Non contractual pictures.