

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

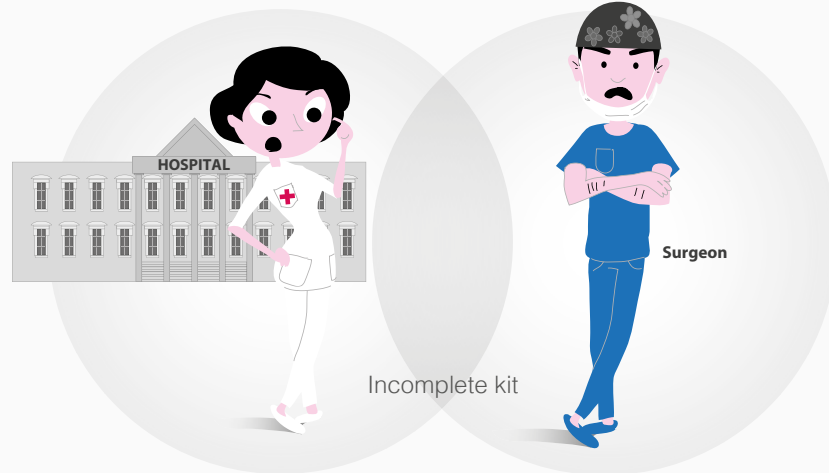
### High costs



- \$ 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

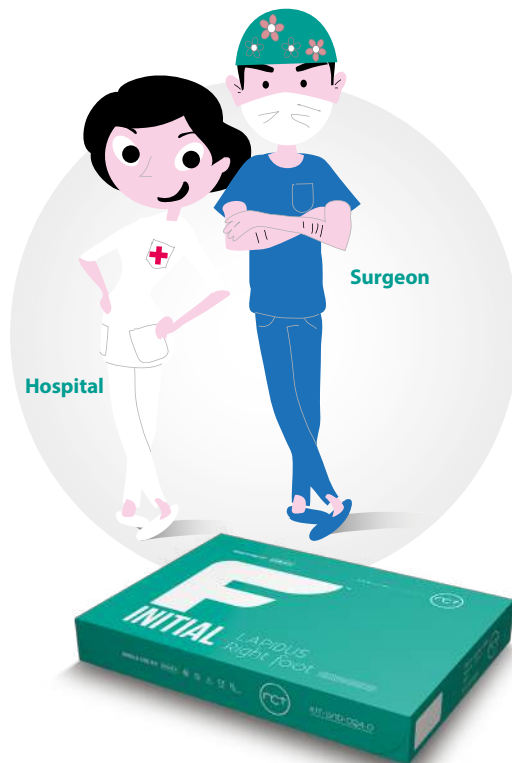
- 0 Cleaning
- 0 Decontamination
- 0 Sterilization



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!



### TRACEABILITY:

- Easiest traceability with detailed label sheets.
- Easy inventory management.
- Streamlining of logistic monitoring for nurses and pharmacists.



### RESPONSIBILITY:

- External packaging in recyclable cardboard.
- Dematerialized instructions for use.
- Less CO2 emissions during manufacture and use than a reusable kit<sup>(6)</sup>.



### PRACTICALITY:

- Immediate identification and intuitive use.
- Ergonomic format for gears.
- Simplified orderings.



### AVAILABILITY:

- Equipment availability: no restocking and waiting time.
- Shorter and easiest process<sup>(5)</sup>.
- Full range of latest-generation implants in sterile format.
- No interruption of preoperative flow<sup>(3)</sup>.



### EFFICIENCY:

- Less transportation costs.
- No sterilization costs for hospitals.
- Reduced operative costs<sup>(3)</sup>.
- Reduced perioperative time<sup>(4)</sup>.
- Reduced receiving and handling costs.
- Increased turnover in the OR<sup>(4)</sup>.



### SAFETY:

- Reduced risk of contamination<sup>(1)</sup>.
- Reduced risk of a bacterial biofilm formation<sup>(2)</sup>.
- New instruments for each surgery.

<sup>(1)</sup> Mont et al. Single-use instrumentation, cutting blocks, and trials decrease contamination during total knee arthroplasty: a prospective comparison of navigated and nonnavigated cases. J Knee Surg. 2013;26(4):285-290. - <sup>(2)</sup> Costa D de M, Lopes LK de O, Tipple AFV, Johani K, Hu H, Deva AK, et al. Evaluation of stainless-steel surgical instruments subjected to multiple use/processing. Infect Dis Heal. 2018;23(1):3-9. - <sup>(3)</sup> Shippert RD. A Study of Time-Dependent Operating Room Fees and How to save \$100,000 by Using Time-Saving Products. Am J Cosmet Surg. 2005;22(1):25-34. - <sup>(4)</sup> Siegel GW et al. Cost Analysis and Surgical Site Infection Rates in Total Knee Arthroplasty Comparing Traditional vs. Single-Use Instrumentation. J Arthroplasty. 2015;30(12):2271-4. - <sup>(5)</sup> Matron P. Etude comparative économique et pratique de plaques d'ostéosynthèse de l'extrémité distale du radius présentées individuellement et en kit stérile "tout en un" dans un établissement de santé privé, 2016, 1-21. - <sup>(6)</sup> "Empreinte carbone comparée de deux dispositifs médicaux implantables" - Etude Carbon 4.

# Initial F™ - Lapidus kit

## Kit content

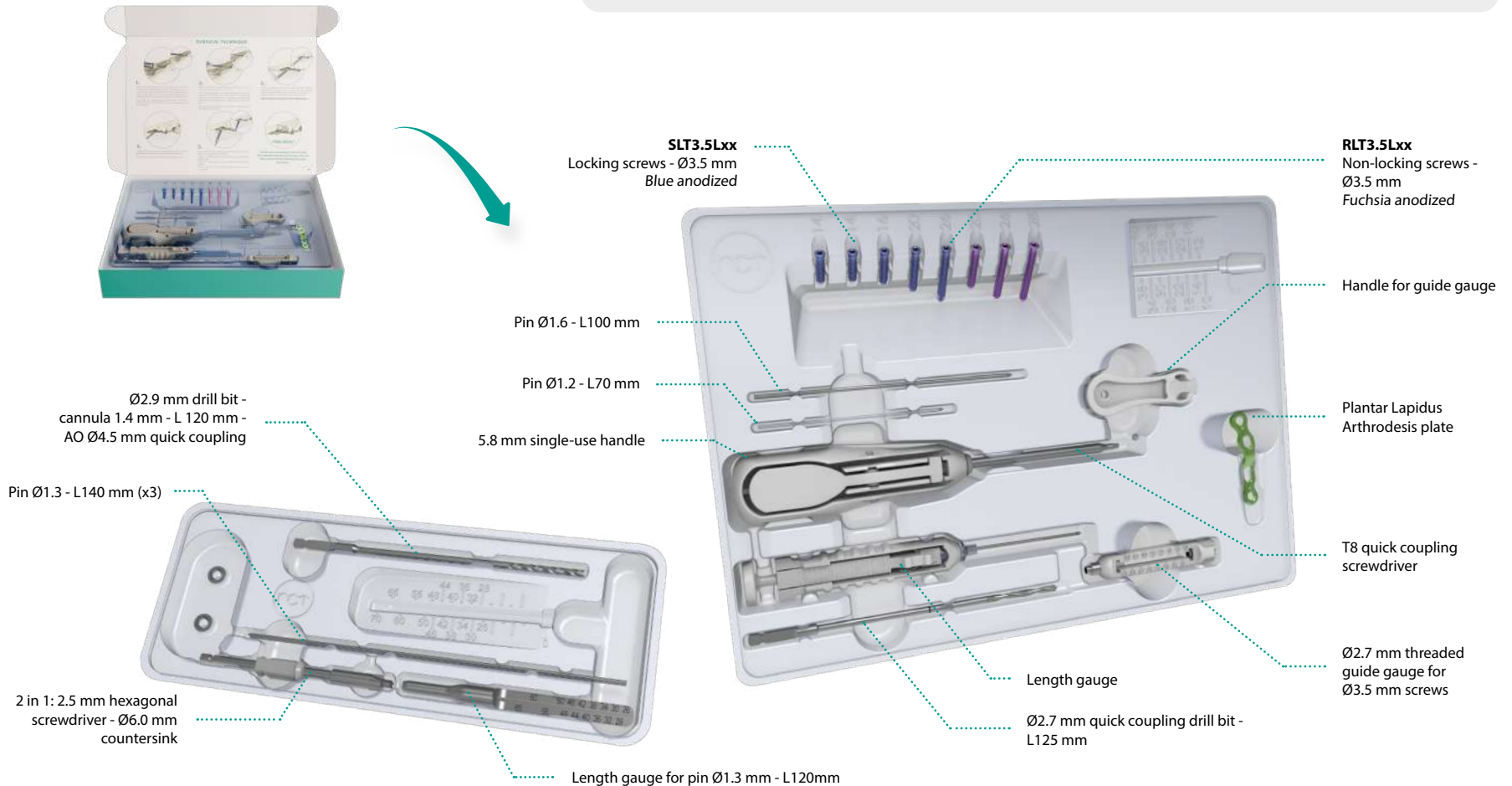
Example : Kit LV1D - CQ4.0

### > 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

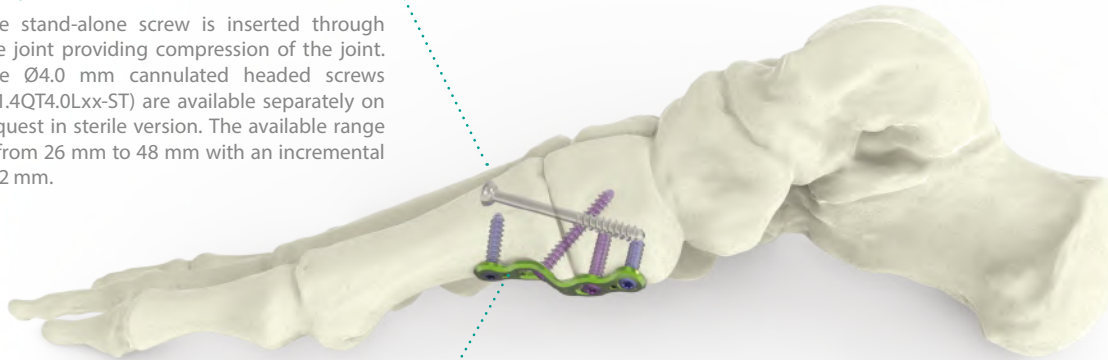
## Technical features

### > 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

Plantar positioning of the plate allows 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

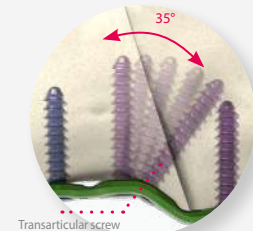
The plate is made of Grade 2 Titanium, for an adaptation to the first tarsometatarsal (TMT1) joint anatomies when using bending pliers.

#### 3 sizes of plates

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



#### Transarticular screw angulation up to 35°

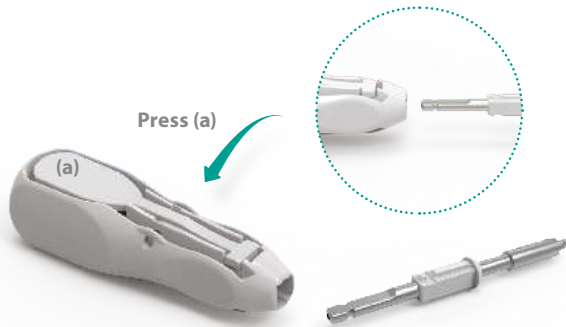


# Initial F™ - Lapidus kit

## 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).

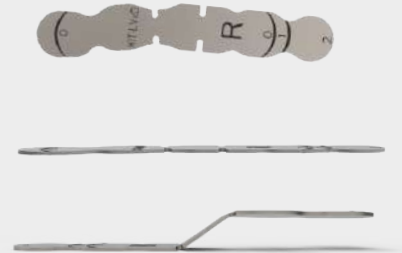
### > Handle for guide gauge

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



### > 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.



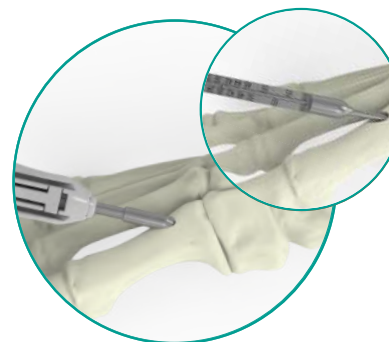
# Initial F™ - Lapidus kits

## Surgical technique

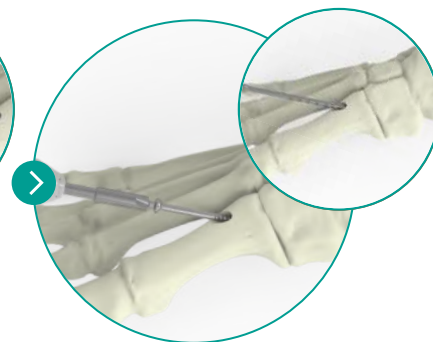
Example: surgical technique with a size 1 plate (KIT-LV1D-CQ4.0).



1. Select the correct kit according to the template.



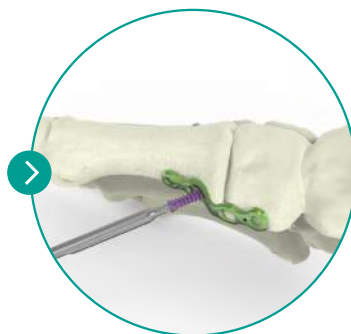
2. Insert the  $\text{\O}1.3$  mm pin transversally from the 1st metatarsal to the first cuneiform. Connect the handle to the 2-in-1 instrument and slide it along the  $\text{\O}1.3$  mm pin and widen the surface of insertion using the countersink part of the 2-in-1 instrument. Then, slide the length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



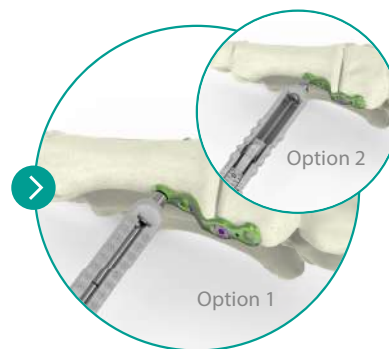
3. Drill to prepare the screw insertion. The drilling depth can be checked using the marking on the drill bit. Select the appropriate screw length and insert the screw (H1.4QT4.0Lxx) along the  $\text{\O}1.3$  mm pin using the screwdriver part of the 2-in-1 instrument until the desired reduction and 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  $\text{\O}0.35$  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  $\text{\O}0.35$  mm blue anodized locking screw using the screwdriver.



**Finalize the assembly by inserting the  $\text{\O}0.35$  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

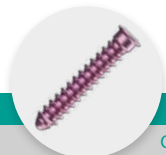
	Ref.	Description	KIT-LV0D-CQ4.0	KIT-LV0G-CQ4.0	KIT-LV1D-CQ4.0	KIT-LV1G-CQ4.0	KIT-LV2D-CQ4.0	KIT-LV2G-CQ4.0
PLATES	FLTDV0	Plantar Lapidus arthrodesis plate - Narrow - Right - Size 0 (length 37.0mm)	1	-	-	-	-	-
	FLTGV0	Plantar Lapidus arthrodesis plate - Narrow - Left - Size 0 (length 37.0mm)	-	1	-	-	-	-
	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

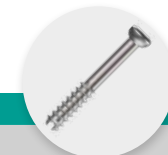


NON LOCKING SCREWS - Ø3.5 mm*			
Ref.	Description		Qty
RLT3.5L10-ST	Ø3.5 mm non-locking screw - L10 mm - STERILE		1
RLT3.5L12-ST	Ø3.5 mm non-locking screw - L12 mm - STERILE		1
RLT3.5L14-ST	Ø3.5 mm non-locking screw - L14 mm - STERILE		1
RLT3.5L16-ST	Ø3.5 mm non-locking screw - L16 mm - STERILE		1
RLT3.5L18-ST	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



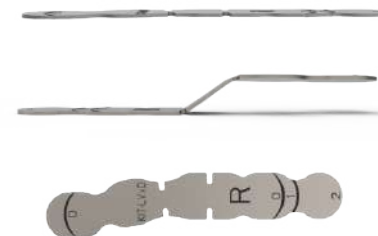
CANNULATED SCREWS - Ø4.0 mm	
Ref.	Description
H1.4QT4.0Lxx-ST	Ø4.0 mm compressive screw - cannula Ø1.4 - short thread - L26-48 mm - STERILE

### 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

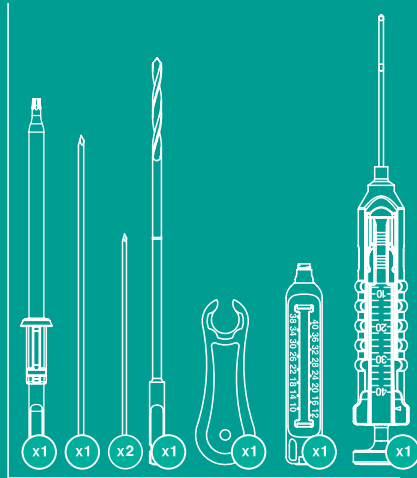
REMOVAL AND RESCUE KITS - STERILE PACKAGING		
Ref.	Description	Content
KIT-REMOVE-2	Removal kit for T8 hexalobe	- 1x T8 Prehensor Screwdriver
KIT-REMOVE-A	Removal kit for hexagonal stamp 2.5 mm	- 1x 2in1 2.5 mm Prehensor Screwdriver & Ø3.5 mm countersink
KIT-RESCUE-6	Rescue kit for Initial F Lapidus	- 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



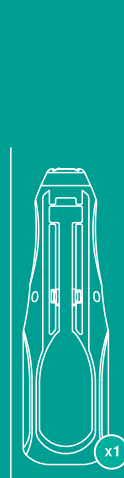
Ready  
when you are!

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  
 \* Ø4.0 mm screws are available separately in sterile screw caddy.

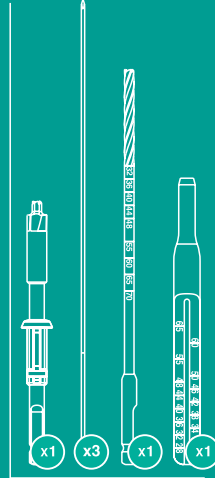
**F**<sup>TM</sup>  
**INITIAL LAPIDUS**



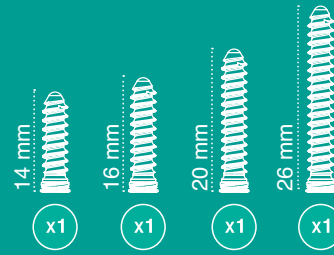
For Lapidus plate



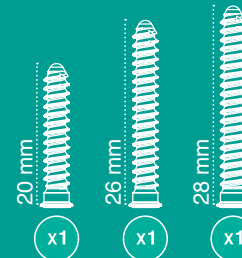
For both



For Ø4.0 mm screws\*



Locking screws Ø3.5 mm



Non Locking screws Ø3.5 mm



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