

SINGLE USE KIT

STERILE R

NEWCLIP-TECHNICS



**INITIAL** LAPIDUS



With a non sterile standard kit



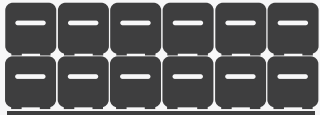
Calling on medical staff

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

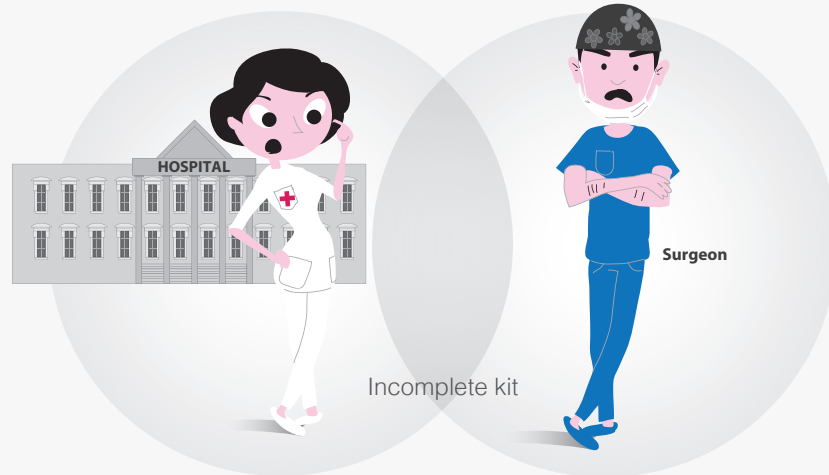
### High costs



- \$ 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

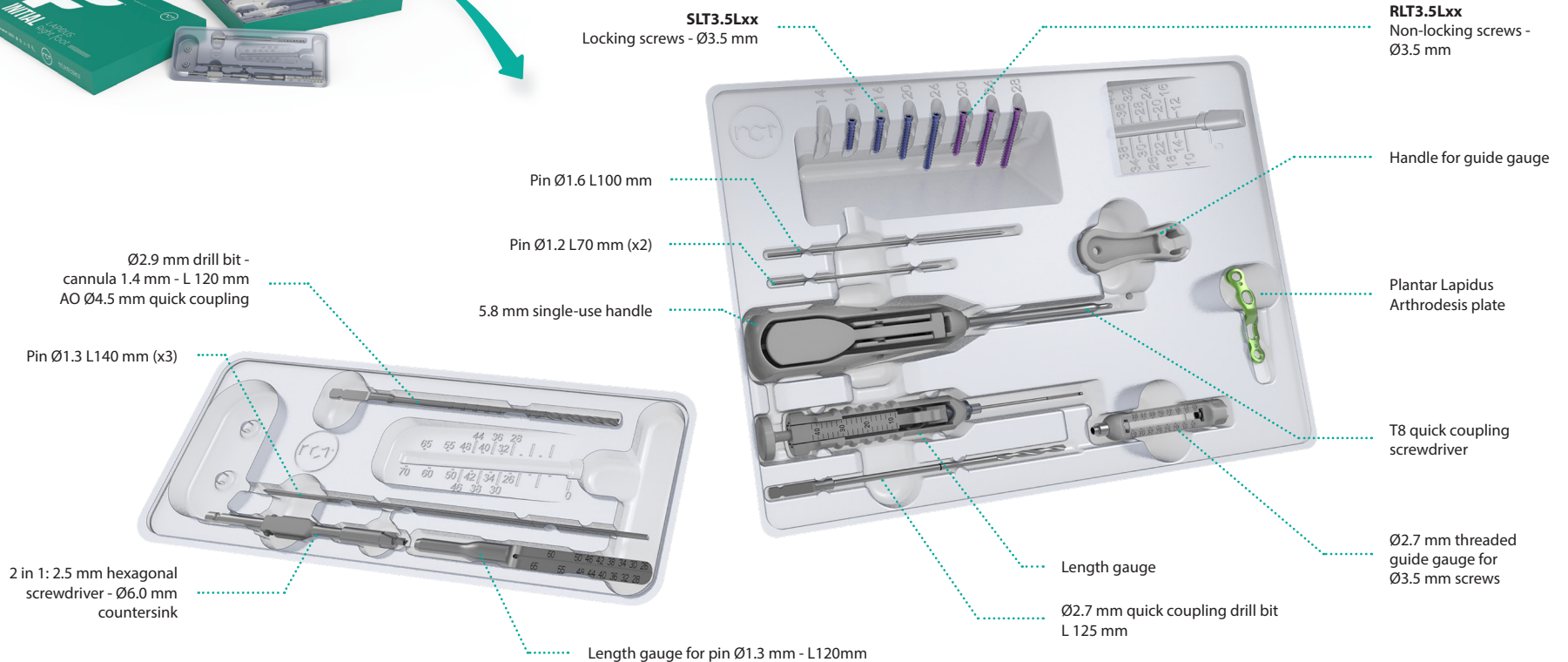


### > Indications

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

### > Contraindications

- 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.



# Initial F™ - Lapidus Kit

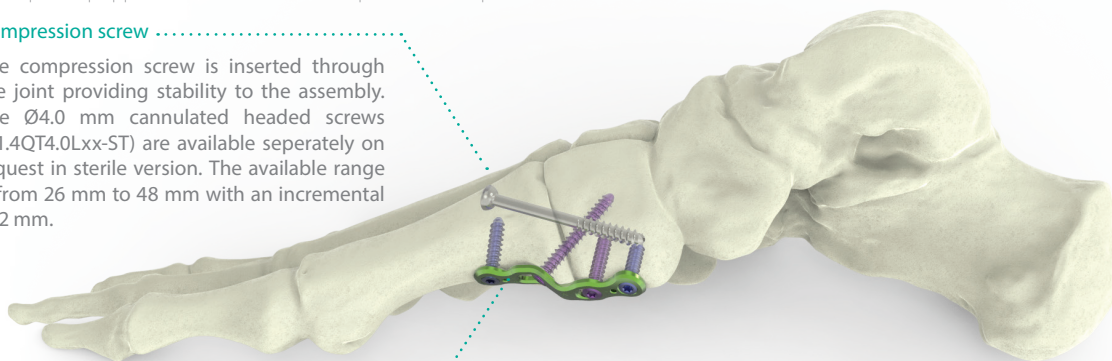
## Technical features

### > Plate for the plantar Lapidus arthrodesis

Examples of applications: osteoarthritis, functional deformities.

#### Compression screw

The compression screw is inserted through the joint providing stability to the assembly. 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 positioning minimizes conflicts with the extensor hallucis longus and tibialis anterior tendons. Offers stable assembly and generates dynamic compression congruence between the plate and the bone.

#### 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

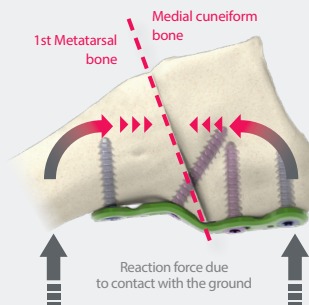
The plate is made of Grade 2 Titanium, for an easier adaptation to the first tarsometatarsal (TMT1) joint anatomies when using the guide gauge.

#### 3 sizes of plates

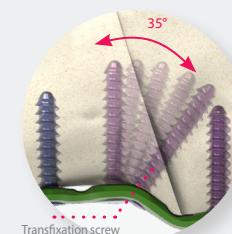
The right (green plates) and left (blue plates) sides offering versatile solutions.



#### Dynamic compression



#### Screw angulation up to 35°

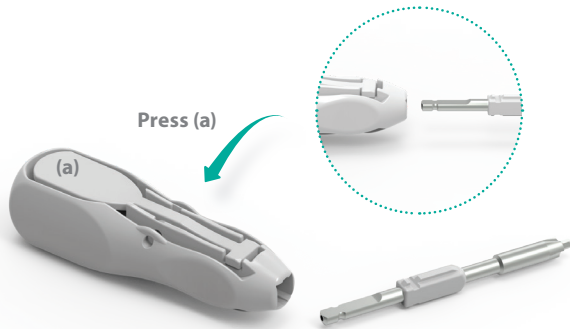


# Initial F™ - Lapidus kit

## Instrumentation - Technical features

### > 2-in-1 instrument: screwdriver and countersink

### > T8 quick coupling screwdriver

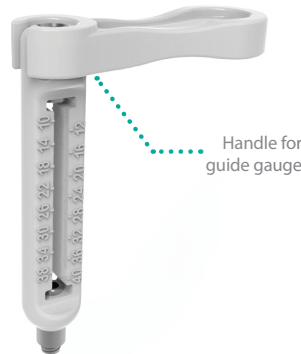
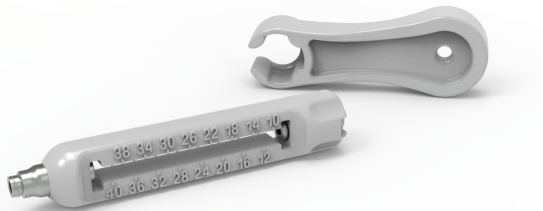


The 2-in-1 instrument and the T8 quick coupling screwdriver can be used with the handle and the power tool. In the latter case, it is recommended to finalize the screwing by hand.

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

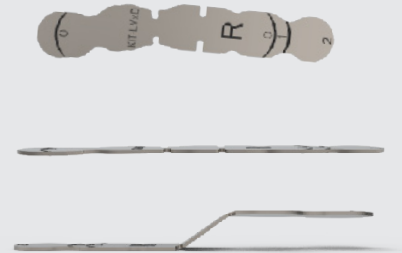
### > Handle for guide gauge

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.





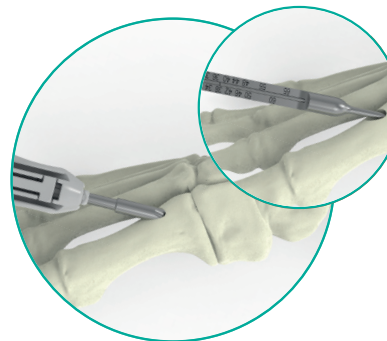
# Initial F™ - Lapidus kits

## Surgical technique

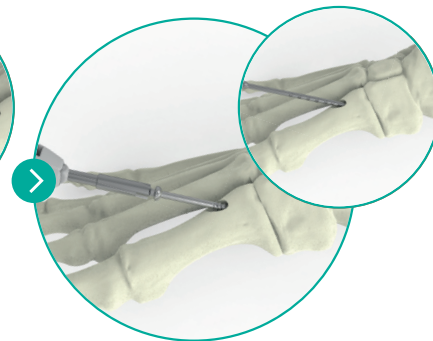
Example: surgical technique with a size 1 plate (KIT-LV1D-CQ4.0).



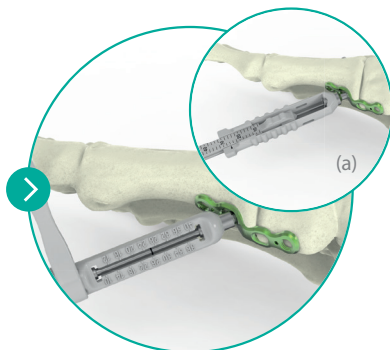
1. Select the correct kit according to the template.



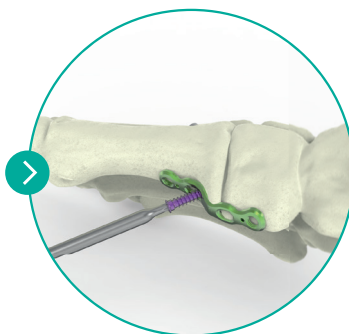
2. Insert the  $\text{\O}1.3$  mm pin transversally from the 1st metatarsal to the first cuneiform. Connect the handle to the 2-in-1 instrument and slide it along the  $\text{\O}1.3$  mm pin and widen the surface of insertion using the countersink part of the 2-in-1 instrument. Then, slide the length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



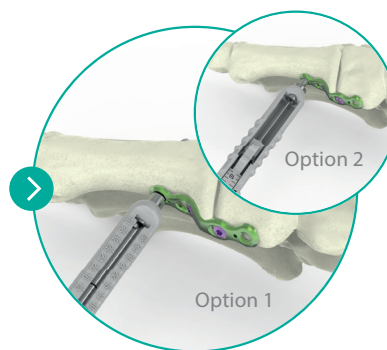
3. Drill to prepare the screw insertion. The drilling depth can be checked using the marking on the drill bit. Select the appropriate screw length and insert the screw (H1.4QT4.0Lxx) along the  $\text{\O}1.3$  mm pin using the screwdriver part of the 2-in-1 instrument until the desired reduction and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



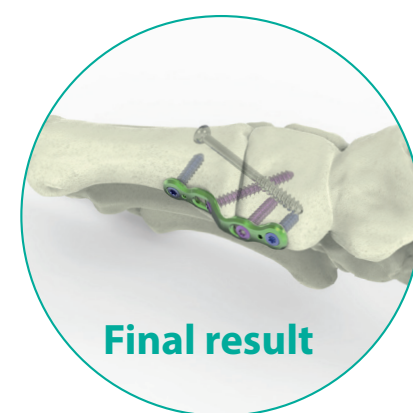
4. Position the plate plantarly over the TMT1 joint and stabilize it temporarily by inserting a  $\text{\O}1.2$  mm pin. Snap the handle for guide gauge and perform the drilling using the assembly into the distal oblong hole.  
**Determine the screw length using the length gauge (a).**



5. Connect the handle to the screwdriver and insert a  $\text{\O}3.5$  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 - L 120 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	Lapidus Arthrodesis kit - Plantar plate - Right - Size 0 - for Ø4.0 mm headed cannulated screws
KIT-LV0G-CQ4.0	Lapidus Arthrodesis kit - Plantar plate - Left - Size 0 - for Ø4.0 mm headed cannulated screws
KIT-LV1D-CQ4.0	Lapidus Arthrodesis kit - Plantar plate - Right - Size 1 - for Ø4.0 mm headed cannulated screws
KIT-LV1G-CQ4.0	Lapidus Arthrodesis kit - Plantar plate - Left - Size 1 - for Ø4.0 mm headed cannulated screws
KIT-LV2D-CQ4.0	Lapidus Arthrodesis kit - Plantar plate - Right - Size 2 - for Ø4.0 mm headed cannulated screws
KIT-LV2G-CQ4.0	Lapidus Arthrodesis kit - Plantar plate - Left - Size 2 - for Ø4.0 mm headed cannulated 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 - Size 0 - Right	1	-	-	-	-	-
	FLTGV0	Plantar Lapidus Arthrodesis plate - Size 0 - Left	-	1	-	-	-	-
	FLTDV1	Plantar Lapidus Arthrodesis plate - Size 1 - Right	-	-	1	-	-	-
	FLTGV1	Plantar Lapidus Arthrodesis plate - Size 1 - Left	-	-	-	1	-	-
	FLTDV2	Plantar Lapidus Arthrodesis plate - Size 2 - Right	-	-	-	-	1	-
	FLTGV2	Plantar Lapidus Arthrodesis plate - Size 2 - Left	-	-	-	-	-	1
LOCKING SCREWS Ø3.5 MM	SLT3.5L14	Locking screw Ø3.5 mm - L 14 mm	1	1	1	1	2	2
	SLT3.5L16	Locking screw Ø3.5 mm - L 16 mm	1	1	1	1	1	1
	SLT3.5L20	Locking screw Ø3.5 mm - L 20 mm	1	1	1	1	1	1
	SLT3.5L26	Locking screw Ø3.5 mm - L 26 mm	1	1	1	1	1	1
NON LOCKING SCREWS Ø3.5 MM	RLT3.5L20	Non locking screw - Ø3.5 mm - L 20 mm	1	1	1	1	1	1
	RLT3.5L26	Non locking screw - Ø3.5 mm - L 26 mm	1	1	1	1	1	1
	RLT3.5L28	Non locking screw - Ø3.5 mm - L 28 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	Non locking screw - Ø3.5mm - L 10 mm - STERILE	1
RLT3.5L12-ST	Non locking screw - Ø3.5mm - L 12 mm - STERILE	1
RLT3.5L14-ST	Non locking screw - Ø3.5mm - L 14 mm - STERILE	1
RLT3.5L16-ST	Non locking screw - Ø3.5mm - L 16 mm - STERILE	1
RLT3.5L18-ST	Non locking screw - Ø3.5mm - L 18 mm - STERILE	1
RLT3.5L20-ST	Non locking screw - Ø3.5mm - L 20 mm - STERILE	1
RLT3.5L22-ST	Non locking screw - Ø3.5mm - L 22 mm - STERILE	1
RLT3.5L24-ST	Non locking screw - Ø3.5mm - L 24 mm - STERILE	1
RLT3.5L26-ST	Non locking screw - Ø3.5mm - L 26 mm - STERILE	2
RLT3.5L28-ST	Non locking screw - Ø3.5mm - L 28 mm - STERILE	2
RLT3.5L30-ST	Non locking screw - Ø3.5mm - L 30 mm - STERILE	1
RLT3.5L32-ST	Non locking screw - Ø3.5mm - L 32 mm - STERILE	1
RLT3.5L34-ST	Non locking screw - Ø3.5mm - L 34 mm - STERILE	1
RLT3.5L36-ST	Non locking screw - Ø3.5mm - L 36 mm - STERILE	1
RLT3.5L38-ST	Non locking screw - Ø3.5mm - L 38 mm - STERILE	1
RLT3.5L40-ST	Non locking screw - Ø3.5mm - L 40 mm - STERILE	1

\* Pink anodized

LOCKING SCREWS - Ø3.5 mm*		
Ref.	Description	Qty
SLT3.5L10-ST	Locking screw - Ø3.5mm - L 10 mm - STERILE	1
SLT3.5L12-ST	Locking screw - Ø3.5mm - L 12 mm - STERILE	1
SLT3.5L14-ST	Locking screw - Ø3.5mm - L 14 mm - STERILE	2
SLT3.5L16-ST	Locking screw - Ø3.5mm - L 16 mm - STERILE	2
SLT3.5L18-ST	Locking screw - Ø3.5mm - L 18 mm - STERILE	1
SLT3.5L20-ST	Locking screw - Ø3.5mm - L 20 mm - STERILE	2
SLT3.5L22-ST	Locking screw - Ø3.5mm - L 22 mm - STERILE	1
SLT3.5L24-ST	Locking screw - Ø3.5mm - L 24 mm - STERILE	1
SLT3.5L26-ST	Locking screw - Ø3.5mm - L 26 mm - STERILE	2
SLT3.5L28-ST	Locking screw - Ø3.5mm - L 28 mm - STERILE	1
SLT3.5L30-ST	Locking screw - Ø3.5mm - L 30 mm - STERILE	1
SLT3.5L32-ST	Locking screw - Ø3.5mm - L 32 mm - STERILE	1
SLT3.5L34-ST	Locking screw - Ø3.5mm - L 34 mm - STERILE	1

\* Blue 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 2.5	- 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 - L 125 mm - 1x Handle for guide gauge - 1x Length gauge - 1x Pin Ø1.6 L100 mm - 2x Pin Ø1.2 L70 mm

### Template

Sterile template

INITIAL F™ - LAPIDUS TEMPLATE	
Ref.	Description
ANC958	FLTDVx and FLTGVx template



Ready  
when you are!

# KIT-LV1G-CQ4.0

Implants material: (Screws) Titanium T46V - ISO 5832-3 / ASTM F136. (Plates) Grade 2 Titanium - ISO 5832-2 / ASTM F67  
 Degree of accuracy for devices with a measuring function: ± 0.8 mm



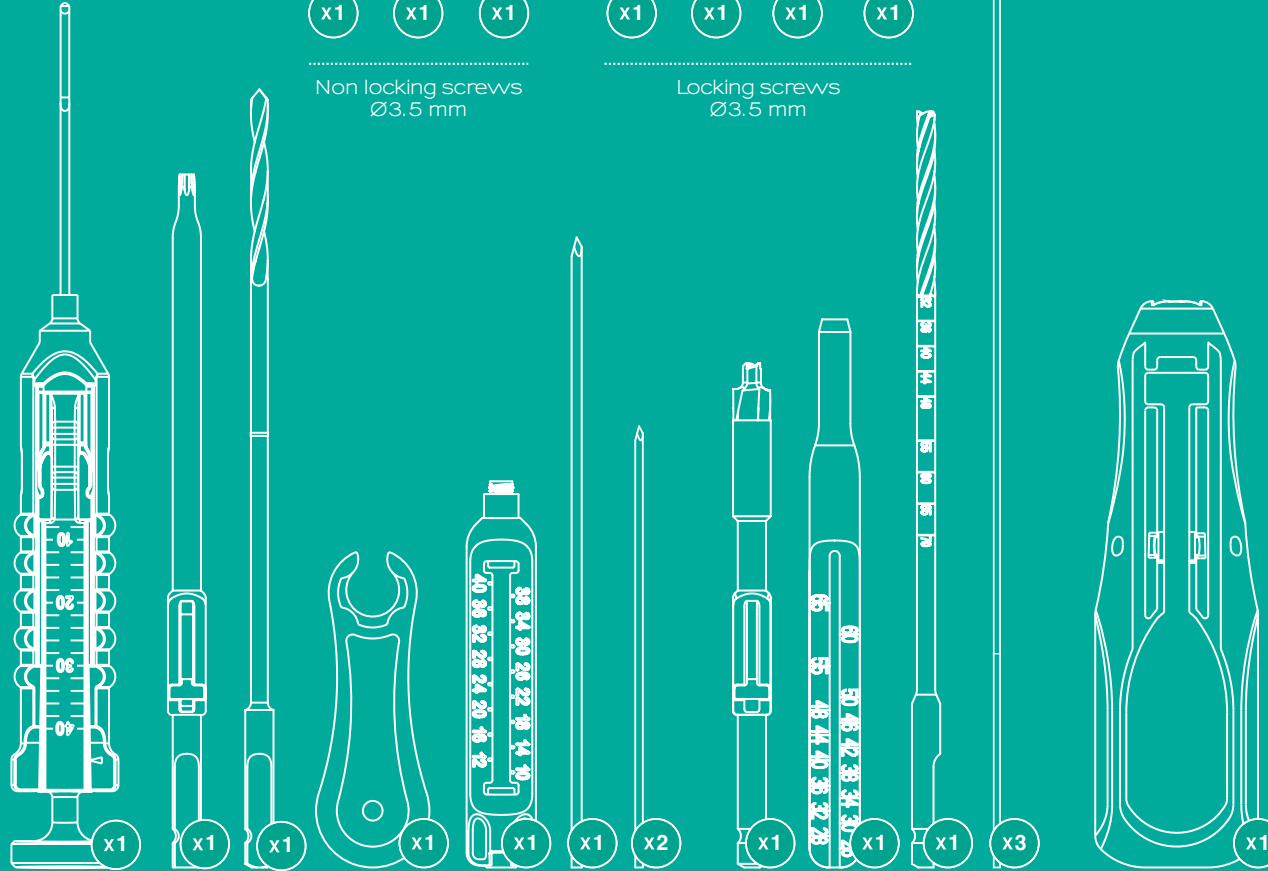
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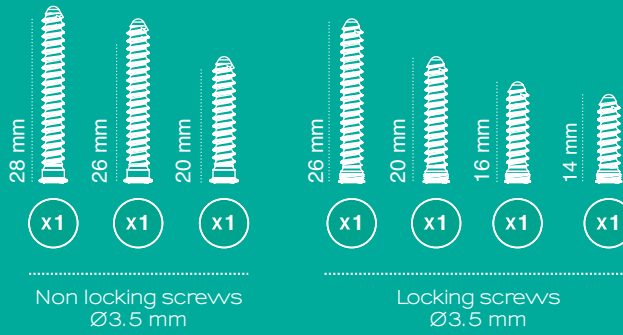
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Instruments for Lapidus plate

Instruments for cannulated screws\*

Handle for both



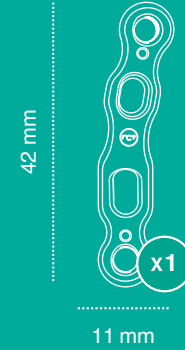
Non locking screws  
 Ø3.5 mm

Locking screws  
 Ø3.5 mm

SINGLE USE KIT



Left foot  
 Lapidus arthrodesis  
 Plantar - Narrow - Size 1



Brochure EN - Initial-F™ - Lapidus - Ed.3 - 05/2020 - Medical devices: class IIb - CE 1639 SGS BE - Read labeling and instructions before use.

Non contractual pictures.