

SINGLE USE KIT

STERILE R

NEWCLIP-TECHNICS



INITIAL MTP



Ready
when you are!

With a non sterile
standard kit



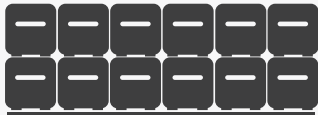
Calling on medical staff

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

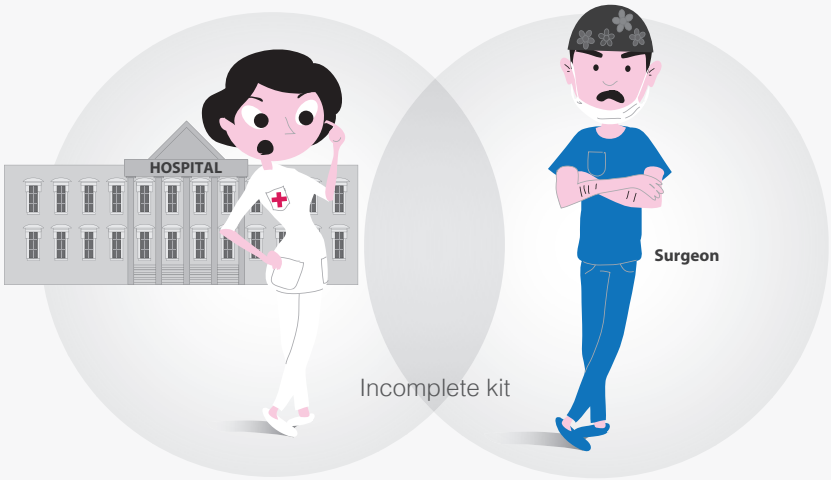
High costs



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



Bulky storage



Complex process



- | | | | |
|---------------------------|----------------------------|---------------------|-----------------------|
| 1
Delivery | 2
Storage | 3
Unpacking | 4
Control |
| 5
Decontamination | 6
Cleaning | 7
Drying | 8
Control |
| 9
Packaging of the kit | 10
Sterilization | 11
Surgery | 12
Decontamination |
| 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



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

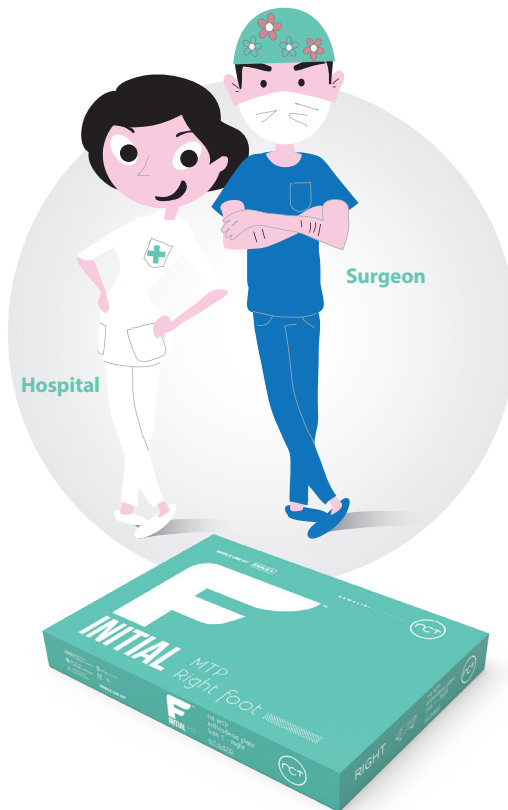
- 0 Cleaning
- 0 Decontamination
- 0 Sterilization



Sundry
expenses



Optimized storage



STERILE R SINGLE USE KIT

with state-of-the-art implants

Efficiency



An effective
solution &
a quick response



Available when
needed



READY-TO-USE FOR
SURGERY



Optimized handling of
URGENT SURGICAL CASES

Ready
when you are!



Available when needed:

The Initial F™ - MTP kit comes pre-sterilized and ready to use.

The combination of sterile implants and single use instrumentation in a single packaging makes Initial F™ - MTP ideal for use in urgent surgical cases.



Safety:

The Initial F™ - MTP 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.



Storage:

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



Costs:

Initial F™ - MTP 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 minimizes contamination risks.



Buying procedure:

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

Initial F™ - MTP kits

Technical features

> Plate for the first metatarso-phalangeal (MTP) joint arthrodesis

Examples of applications: hallux rigidus, severe hallux valgus, polyarthritis

> Indications

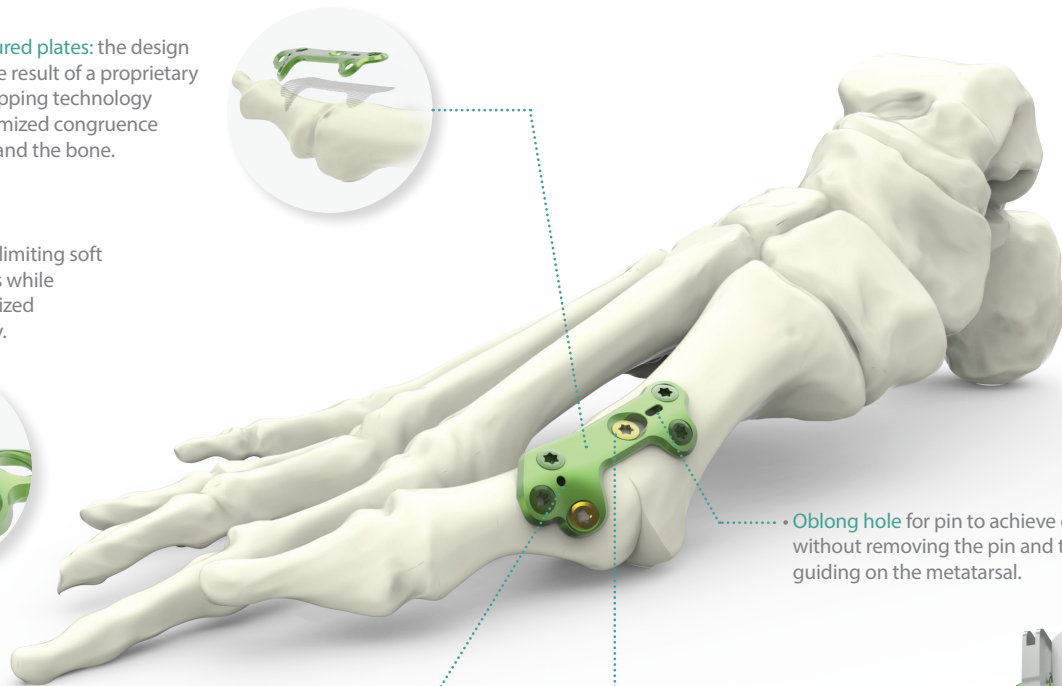
The implants of the Initial F™ - MTP range are intended for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.

> 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.

- **Range of precontoured plates:** the design of this implant is the result of a proprietary state-of-the-art mapping technology to establish an optimized congruence between the plate and the bone.

- **Low profile plate:**
1,7 mm thick, thus limiting soft tissue irritation risks while providing an optimized mechanical stability.



- **Hole for pin** to temporarily stabilize the plate.

- **Ramp oblong hole**

- **Oblong hole** for pin to achieve compression without removing the pin and to ensure the guiding on the metatarsal.

- **3 standards sizes and 1 narrow size of plates** for the right (green plates) and left (blue plates) sides offering versatile solutions.

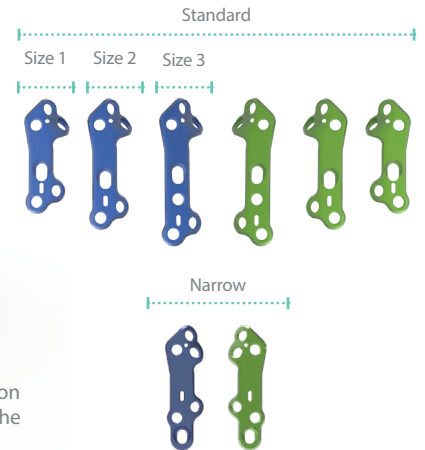


PLATE BENDING

Bending is only possible in the areas intended for this purpose. A bendable area must be bent only once, in one direction and not be performed excessively. The holes must be protected to avoid damaging the fixation.

Initial F™ - MTP kits

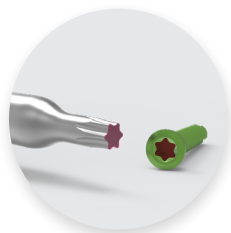
Implants - Technical features

> Fixations and screws

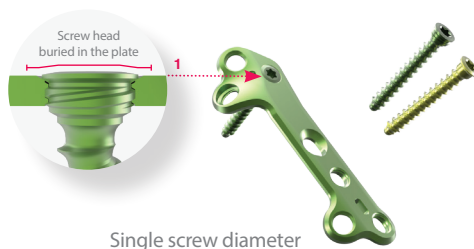
- **A single screw diameter:** Ø2.8 mm.
Both locking (SLT2.8Lxx) and non locking screws (RLT2.8Lxx) are available.

- **Screw head is buried in the plate** (1) to limit the risk of soft tissue irritation.

- **The hexalobular screw stamp.**

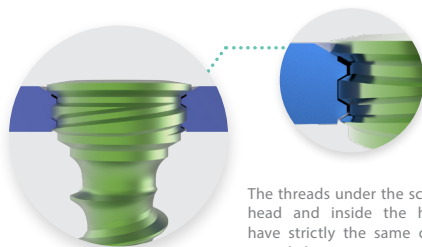


Hexalobular stamp



Single screw diameter

> Efficient locking



The threads under the screw head and inside the hole have strictly the same characteristics.

Features :

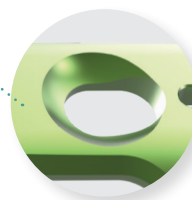
- The screw head is stopped in the hole by its cap, ensuring the locking,
- The screw head is buried in the plate,
- Plate and screws are all made of titanium alloy.

Coaptation of both profiles during locking, limiting a cold welding risk and improving the removal properties.

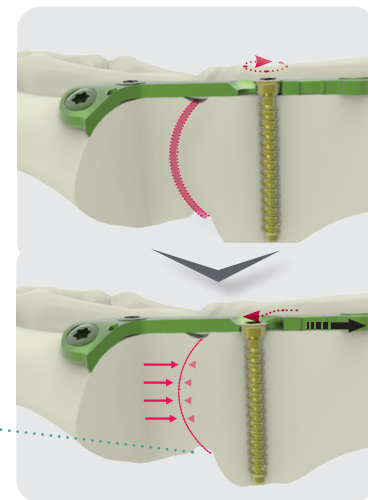
> Specific fixations for stable assembly

Ramp oblong hole

The ramp oblong hole enables a simple and controlled compression by its screw-plate interface.

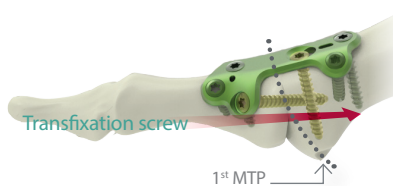


Compression of the joint up to 1.5 mm

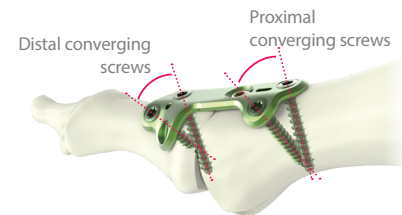


Hole for transfixation screw

The transfixation screw available on standard plates goes through the 1st MTP joint providing stability to the assembly.



Holes for converging screws in the distal and proximal areas

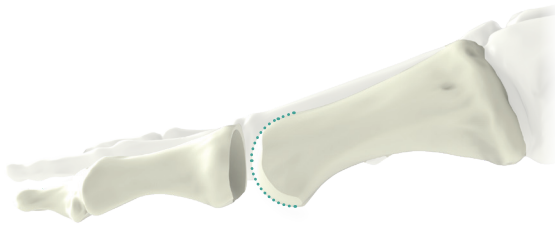


Initial F™ - MTP kits

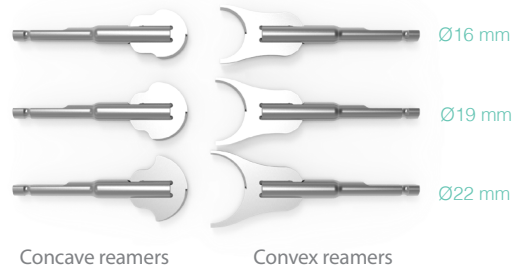
Instrumentation - Technical features

> Convex and concave reamers

Convex and concave reamers are used respectively to prepare the surfaces of the head of the first metatarsal and the base of the phalanx, ensuring congruity of the joint.

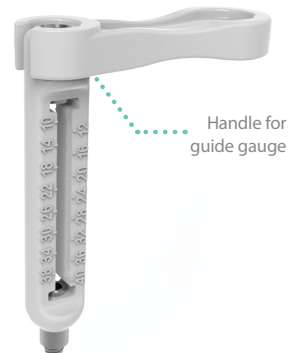


Reamers are available in 3 sizes :



> Handle for guide gauge

Before performing the drilling into the oblong hole, snap the handle for guide gauge on the Ø2.0 mm threaded guide gauge.



Handle for guide gauge

> Templates

The Initial F™ - MTP templates are available separately and allow to quickly and simply determine the appropriate kit.

• REAMER TEMPLATE

The template for **Initial F™ - MTP - Reamers kits** allows to determine the appropriate reamer diameter (Ø16 mm, Ø19mm or Ø22mm) to be used for joint preparation.



• IMPLANT TEMPLATE

The template for **Initial F™ - MTP kits** allows to determine the desired plate size prior opening a kit.



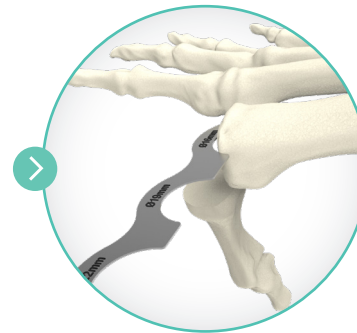
Initial F™ - MTP kits

Surgical technique - Joint surfaces preparation

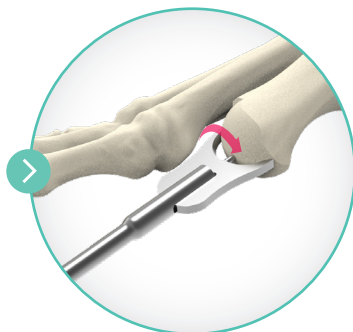
Example: surgical technique
with a Ø16 mm reamers kit
(KIT-MI16).



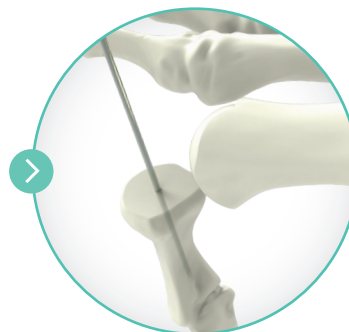
1. Dislocate the joint so as to expose the head of the first metatarsal and the proximal base of the first phalanx.



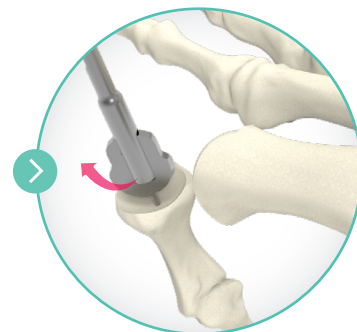
2. Use the reamers template to determine the appropriate reamers kit for joint preparation.



3. Insert the Ø1.6 mm pin through the head of the first metatarsal into the medullary cavity. With the chosen convex reamer, progressively remove the cartilage surface. Then, remove the reamer and the pin.



4. Expose the base of the phalanx and insert the Ø1.6 mm pin so as to achieve the proper alignment with the diaphysis.



5. Take a concave reamer with **the same diameter** as the convex reamer (determined at step 2). Insert it along the pin and perform the reaming until the cartilage surface has been removed. Then, remove the reamer and the pin.

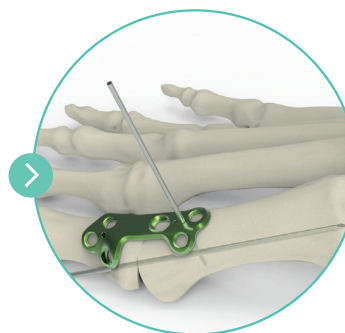
Initial F™ - MTP kits

Surgical technique

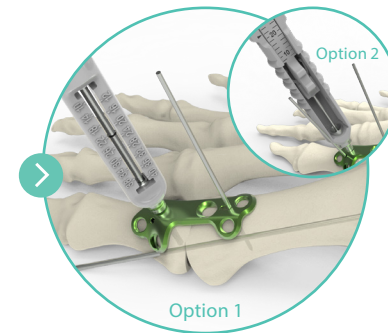
Example: surgical technique with a standard plate, size 1 (KIT-MD1D)



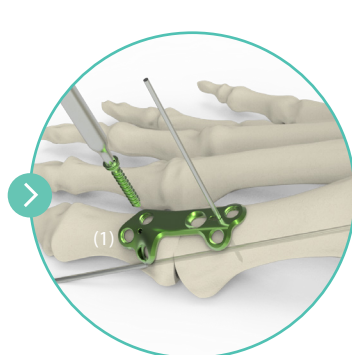
1. Select the correct kit according to the template.



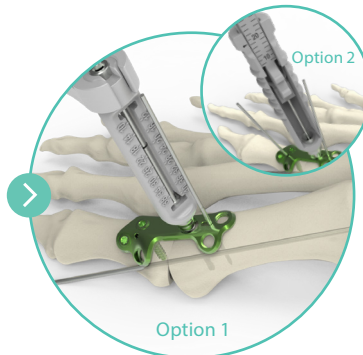
2. Position the joint in the desired direction and stabilize it using a Ø1.6 mm pin. Then, position the plate and stabilize it temporarily by inserting a Ø1.2 mm pin into the proximal part of the oblong hole for pin.



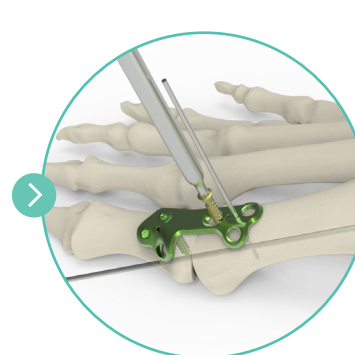
3. Lock the Ø2.0 mm threaded guide gauge into the distal lateral hole and perform the drilling.
Option 1 - Determine the screw length using the gauge.
Option 2 - Determine the screw length using the length gauge.



4. Insert the Ø2.8 mm green locking screw with the screwdriver. Repeat the same procedure for the most distal hole (1).



5. Snap the handle for guide gauge and perform the drilling using the assembly into the proximal part of the ramp oblong hole.
Option 1 - Determine the screw length using the gauge.
Option 2 - Determine the screw length using the length gauge.



6. In the ramp oblong hole, insert a Ø2.8 mm yellow non locking screw and perform the compression using the screwdriver. Insert the Ø2.8 mm green locking screws into the 2 proximal holes following the steps 2 & 3, then remove the pins.



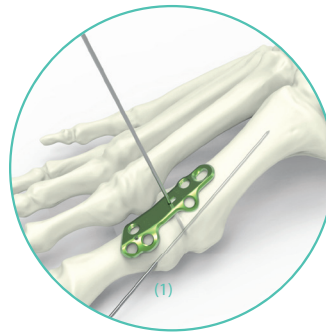
Final result
Drill through the distal hole dedicated for the transfixation screw (2). Finalized the osteosynthesis by inserting a Ø2.8 mm yellow non-locking screw using the screwdriver.

Initial F™ - MTP kits

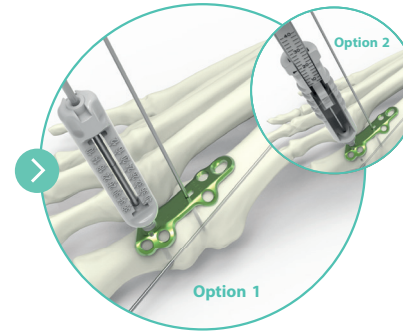
Surgical technique

Example: surgical technique with a narrow plate, size 1 (KIT-MDN1D)

The narrow plates are designed to be combined with the use of a stand-alone screw, cannulated or solid based on the surgeon's preference, to fix the joint using the technique of her/his choice.



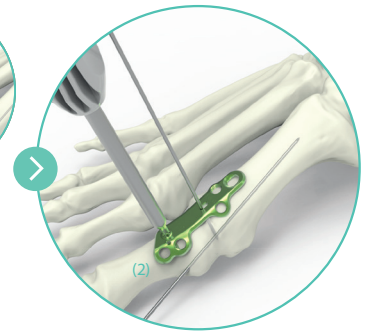
1. Secure the joint temporarily using a Ø1.6 mm pin (1), then position the plate and stabilize it temporarily by inserting a Ø1.2 mm pin into the proximal part of the oblong hole for pin.



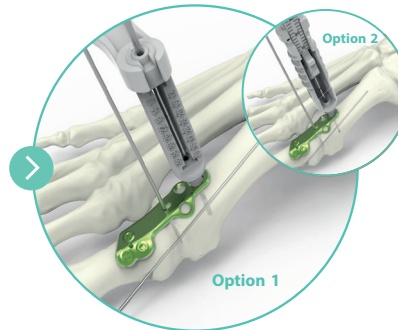
2. Lock the Ø2.0 mm threaded guide gauge into the distal lateral hole and perform the drilling.

Option 1 - Determine the screw length using the gauge.

Option 2 - Alternatively determine the screw length using the length gauge.



3. Insert the Ø2.8 mm green locking screw with the screwdriver. Repeat the same procedure for all the distal holes (2).



4. Snap the handle for guide gauge and perform the drilling using the assembly into the proximal part of the ramp oblong hole.

Option 1 - Determine the screw length using the gauge.

Option 2 - Determine the screw length using the length gauge.



5. In the oblong hole, insert a Ø2.8 mm yellow non locking screw, then perform the compression using the screwdriver.

Insert the Ø2.8 mm green locking screws into the 2 proximal holes following the steps 2 & 3. Then remove the pins.



FINAL RESULT

Initial F™ - MTP kits

References



INITIAL F™ - MTP KITS

Ref.	Description
KIT-MD1D	1 st MTP Arthrodesis kit - Right - Size 1
KIT-MD1G	1 st MTP Arthrodesis kit - Left - Size 1
KIT-MD2D	1 st MTP Arthrodesis kit - Right - Size 2
KIT-MD2G	1 st MTP Arthrodesis kit - Left - Size 2
KIT-MD3D	1 st MTP Arthrodesis kit - Right - Size 3
KIT-MD3G	1 st MTP Arthrodesis kit - Left - Size 3
KIT-MDN1D	1 st MTP Arthrodesis kit - Right - Narrow - Size 1
KIT-MDN1G	1 st MTP Arthrodesis kit - Left - Narrow - Size 1

INITIAL F™ - MTP KITS - INSTRUMENTATION CONTENT

Description	
Ø2.0 mm quick coupling drill bit - L 125 mm	1
Ø2.0 mm threaded guide gauge for Ø2.8 mm screws	1
Length gauge for Ø2.8 and Ø3.5 mm screws - L 8-40 mm	1
T8 prehensor screwdriver	1
Handle for guide gauge	1
Pin Ø1.2 L70 mm	2
Pin Ø1.6 L100 mm	1

NB : Supplemental screws are available in sterile package (cf. : Initial F - MTP™ additional kits, additional implants)

INITIAL F™ - MTP KITS - IMPLANTS CONTENT			QUANTITY PER KIT							
	Ref.	Description	KIT-MD1D	KIT-MD1G	KIT-MD2D	KIT-MD2G	KIT-MD3D	KIT-MD3G	KIT-MDN1D	KIT-MDN1G
STANDARD PLATES	FMTDD1	1 st MTP arthrodesis plate - Size 1 - Right	1	-	-	-	-	-	-	-
	FMTGD1	1 st MTP arthrodesis plate - Size 1 - Left	-	1	-	-	-	-	-	-
	FMTDD2	1 st MTP arthrodesis plate - Size 2 - Right	-	-	1	-	-	-	-	-
	FMTGD2	1 st MTP arthrodesis plate - Size 2 - Left	-	-	-	1	-	-	-	-
	FMTDD3	1 st MTP arthrodesis plate - Size 3 - Right	-	-	-	-	1	-	-	-
	FMTGD3	1 st MTP arthrodesis plate - Size 3 - Left	-	-	-	-	-	1	-	-
NARROW PLATES	FMTDDN1	1 st MTP arthrodesis plate - Narrow - Size 1 - Right	-	-	-	-	-	-	1	-
	FMTGDN1	1 st MTP arthrodesis plate - Narrow - Size 1 - Left	-	-	-	-	-	-	-	1
LOCKING SCREWS Ø2.8 MM	SLT2.8L12	Locking screw Ø2.8 mm - L 12 mm	-	-	-	-	-	-	1	1
	SLT2.8L14	Locking screw Ø2.8 mm - L 14 mm	1	1	1	1	1	1	2	2
	SLT2.8L16	Locking screw Ø2.8 mm - L 16 mm	2	2	2	2	2	2	2	2
	SLT2.8L18	Locking screw Ø2.8 mm - L 18 mm	2	2	2	2	2	2	1	1
	SLT2.8L20	Locking screw Ø2.8 mm - L 20 mm	1	1	1	1	1	1	-	-
NON LOCKING SCREWS Ø2.8 MM	RLT2.8L14	Non locking screw - Ø2.8 mm - L 14 mm	-	-	-	-	-	-	1	1
	RLT2.8L16	Non locking screw - Ø2.8 mm - L 16 mm	1	1	1	1	1	1	1	1
	RLT2.8L18	Non locking screw - Ø2.8 mm - L 18 mm	1	1	1	1	1	1	-	-
	RLT2.8L22	Non locking screw - Ø2.8 mm - L 22 mm	1	1	1	1	1	1	-	-
	RLT2.8L26	Non locking screw - Ø2.8 mm - L 26 mm	1	1	1	1	1	1	-	-

Initial F™ - MTP - Additional sterile implants and kits

References

Additional implants

Sterile screws packaged in the Supplemental sterile screw caddy

NON LOCKING SCREWS - Ø2.8 mm*			LOCKING SCREWS - Ø2.8 mm*		
Ref.	Description	Qty	Ref.	Description	Qty
RLT2.8L10-ST	Non locking screw - Ø2.8 mm - L 10 mm - STERILE	1	SLT2.8L10-ST	Locking screw - Ø2.8 mm - L 10 mm - STERILE	1
RLT2.8L12-ST	Non locking screw - Ø2.8 mm - L 12 mm - STERILE	1	SLT2.8L12-ST	Locking screw - Ø2.8 mm - L 12 mm - STERILE	2
RLT2.8L14-ST	Non locking screw - Ø2.8 mm - L 14 mm - STERILE	1	SLT2.8L14-ST	Locking screw - Ø2.8 mm - L 14 mm - STERILE	3
RLT2.8L16-ST	Non locking screw - Ø2.8 mm - L 16 mm - STERILE	1	SLT2.8L16-ST	Locking screw - Ø2.8 mm - L 16 mm - STERILE	3
RLT2.8L18-ST	Non locking screw - Ø2.8 mm - L 18 mm - STERILE	1	SLT2.8L18-ST	Locking screw - Ø2.8 mm - L 18 mm - STERILE	3
RLT2.8L20-ST	Non locking screw - Ø2.8 mm - L 20 mm - STERILE	1	SLT2.8L20-ST	Locking screw - Ø2.8 mm - L 20 mm - STERILE	2
RLT2.8L22-ST	Non locking screw - Ø2.8 mm - L 22 mm - STERILE	1	SLT2.8L22-ST	Locking screw - Ø2.8 mm - L 22 mm - STERILE	2
RLT2.8L24-ST	Non locking screw - Ø2.8 mm - L 24 mm - STERILE	1	SLT2.8L24-ST	Locking screw - Ø2.8 mm - L 24 mm - STERILE	1
RLT2.8L26-ST	Non locking screw - Ø2.8 mm - L 26 mm - STERILE	1	SLT2.8L26-ST	Locking screw - Ø2.8 mm - L 26 mm - STERILE	1
RLT2.8L28-ST	Non locking screw - Ø2.8 mm - L 28 mm - STERILE	1	SLT2.8L28-ST	Locking screw - Ø2.8 mm - L 28 mm - STERILE	1
RLT2.8L30-ST	Non locking screw - Ø2.8 mm - L30 mm - STERILE	1	SLT2.8L30-ST	Locking screw - Ø2.8 mm - L30 mm - STERILE	1
RLT2.8L32-ST	Non locking screw - Ø2.8 mm - L32 mm - STERILE	1	SLT2.8L32-ST	Locking screw - Ø2.8 mm - L32 mm - STERILE	1
RLT2.8L34-ST	Non locking screw - Ø2.8 mm - L34 mm - STERILE	1	SLT2.8L34-ST	Locking screw - Ø2.8 mm - L34 mm - STERILE	1

* Yellow anodized

* Green anodized

Removal and rescue kits

Sterile instruments

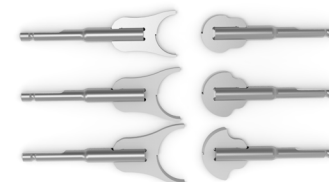
REMOVAL AND RESCUE KITS		
Ref.	Description	Content
KIT-REMOVE-2	Removal kit for T8 hexalobe	- 1 x T8 Prehensor Screwdriver
KIT-RESCUE-4	Rescue kit for Initial MTP	- 1x Ø2.0 mm threaded guide gauge for Ø2.8 mm screws - 1x Ø2.0 mm quick coupling drill bit – L125 mm - 1 x length gauge for Ø2.8 and Ø3.5 mm screws - L 8-40 mm - 1 x handle for guide gauge - 2 x pin Ø1.2 L70 mm - 1 x pin Ø1.6 L100 mm

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.

Additional instrumentation kits

Convex & Concave reamers

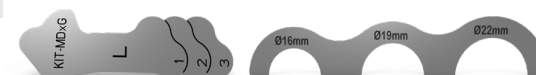
SINGLE USE CONVEX AND CONCAVE REAMERS - STERILE PACKAGING		
Ref.	Description	Qty
KIT-MI16	Ø16 mm reamers kit for 1 st MTP arthrodesis	- Ø16 mm Initial convex reamer - Ø16 mm Initial concave reamer - Pin Ø1.6 L100 mm x 2
KIT-MI19	Ø19 mm reamers kit for 1 st MTP arthrodesis	- Ø19 mm Initial convex reamer - Ø19 mm Initial concave reamer - Pin Ø1.6 L100 mm x 2
KIT-MI22	Ø22 mm reamers kit for 1 st MTP arthrodesis	- Ø22 mm Initial convex reamer - Ø22 mm Initial concave reamer - Pin Ø1.6 L100 mm x 2



Templates

Sterile templates

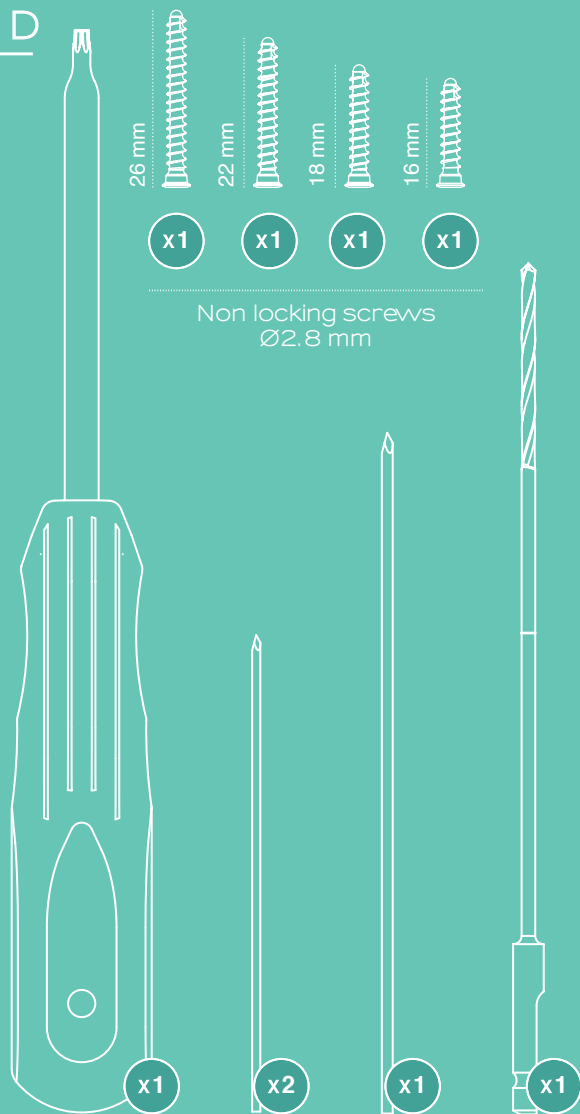
INITIAL F™ - MTP TEMPLATES	
Ref.	Description
ANC808	1 st MTP arthrodesis plates template
ANC846	1 st MTP arthrodesis reamers template



KIT-MD1D

Example of kit content.

Implants material: Titanium TA6V - ISO 5832-3 / ASTM F136
Degree of accuracy for devices with a measuring function: ± 0.8 mm

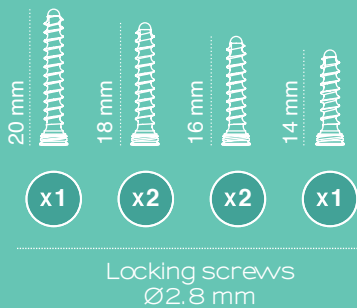


SINGLE USE KIT

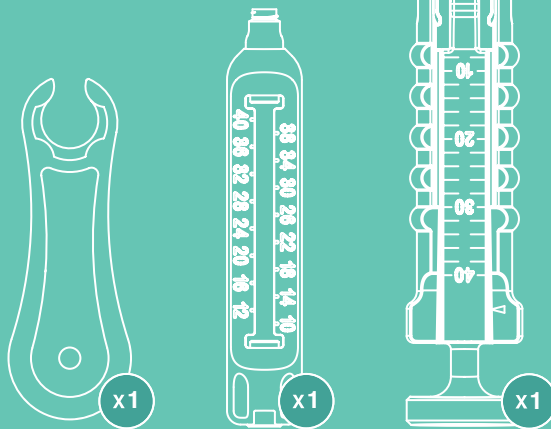
STERILE R



R_x only



Right foot
1st MTP Arthrodesis
Size 1



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