SINGLE USE KIT STERILE R

NEWCLIP TECHNICS

INITIAL™ MTP

Ready
when you are!

With a non sterile
standard kit

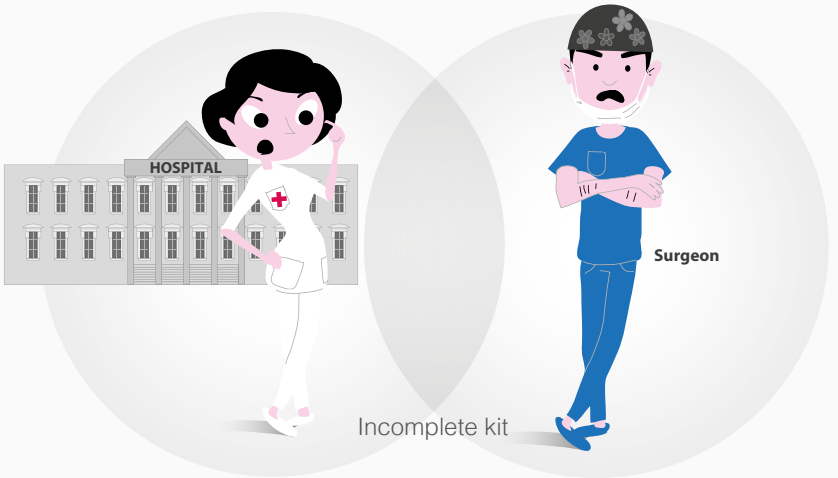
Calling on medical staff

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 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 kit

INITIAL MTP™

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

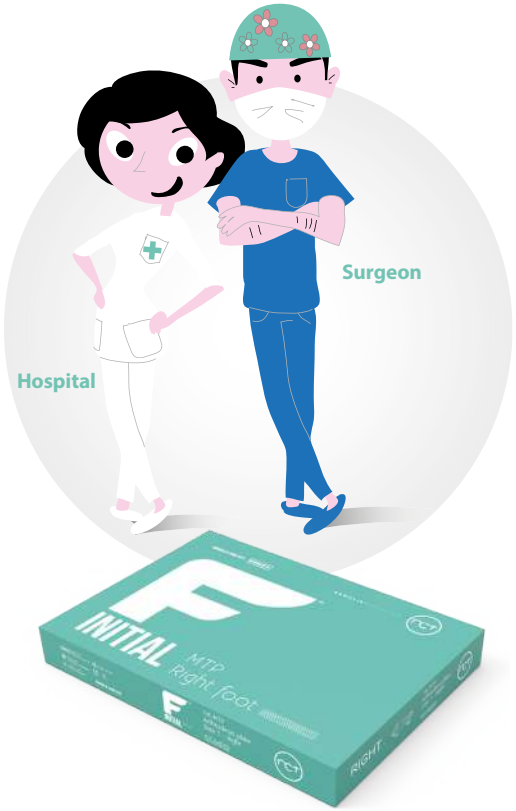
Cost efficiency

Controlled stocks
Simplified control

- 0 Cleaning
- 0 Decontamination
- 0 Sterilization

Sundry expenses

Optimized storage



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

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

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[6].

PRACTICALITY:

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

AVAILABILITY:

- Equipment availability: no restocking and waiting time.
- Shorter and easiest process[5].
- Full range of latest-generation implants in sterile format.
- No interruption of preoperative flow[3].

SAFETY:

- Reduced risk of contamination[1].
- Reduced risk of a bacterian biofilm formation[2].
- New instruments for each surgery.

EFFICIENCY:

- Less transportation costs.
- No sterilization costs for hospitals.
- Reduced operative costs[3].
- Reduced perioperative time[4].
- Reduced receiving and handling costs.
- Increased turnover in the OR[4].

(1) 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. - (2) 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. - (3) 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. - (4) 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. - (5) 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. - (6) "Empreinte carbone comparée de deux dispositifs médicaux implantables" - Etude Carbon 4.

Kits content

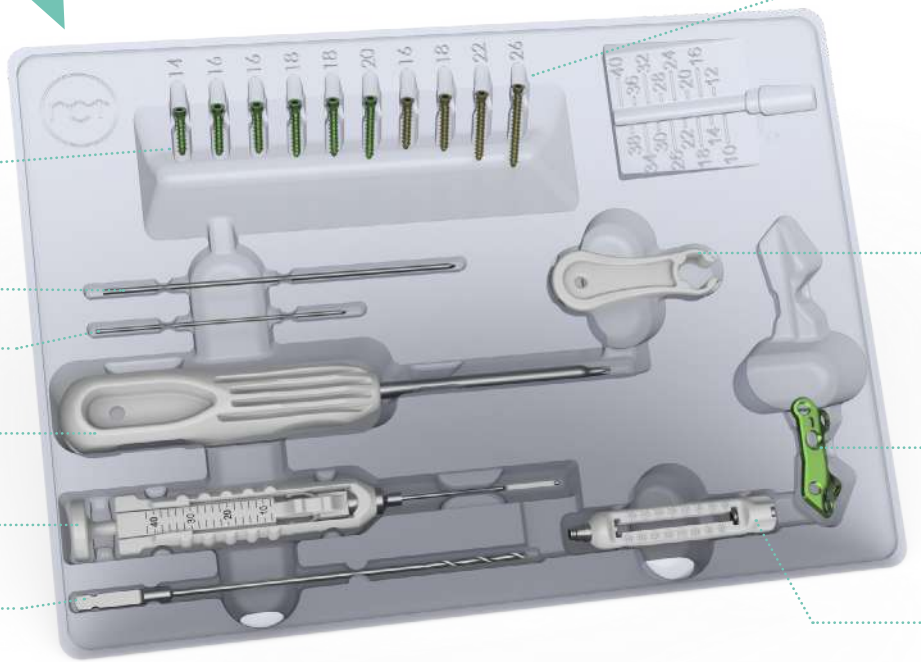
Intented purpose

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.

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



SLT2.8Lxx
Ø2.8 mm locking screws
Green anodized

Pin - Ø1.6 L100 mm

Pins - Ø1.2 L70 mm (x2)

T8 prehensor screwdriver

Length gauge for Ø2.8 and Ø3.5 mm screws - L 8-40 mm

Ø2.0 mm quick coupling drill bit - L125 mm

RLT2.8Lxx
Ø2.8 mm non locking screws
Yellow anodized

Handle for guide gauge

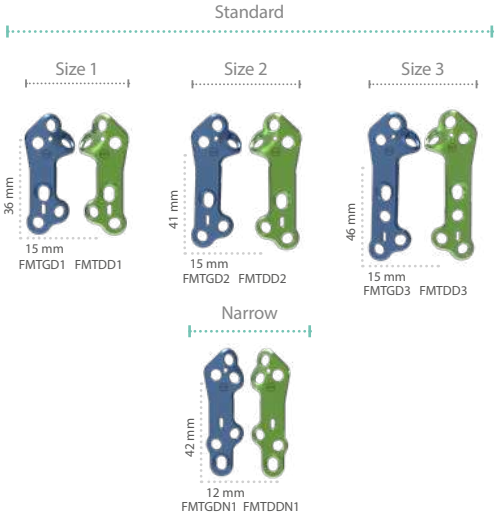
MTP plate

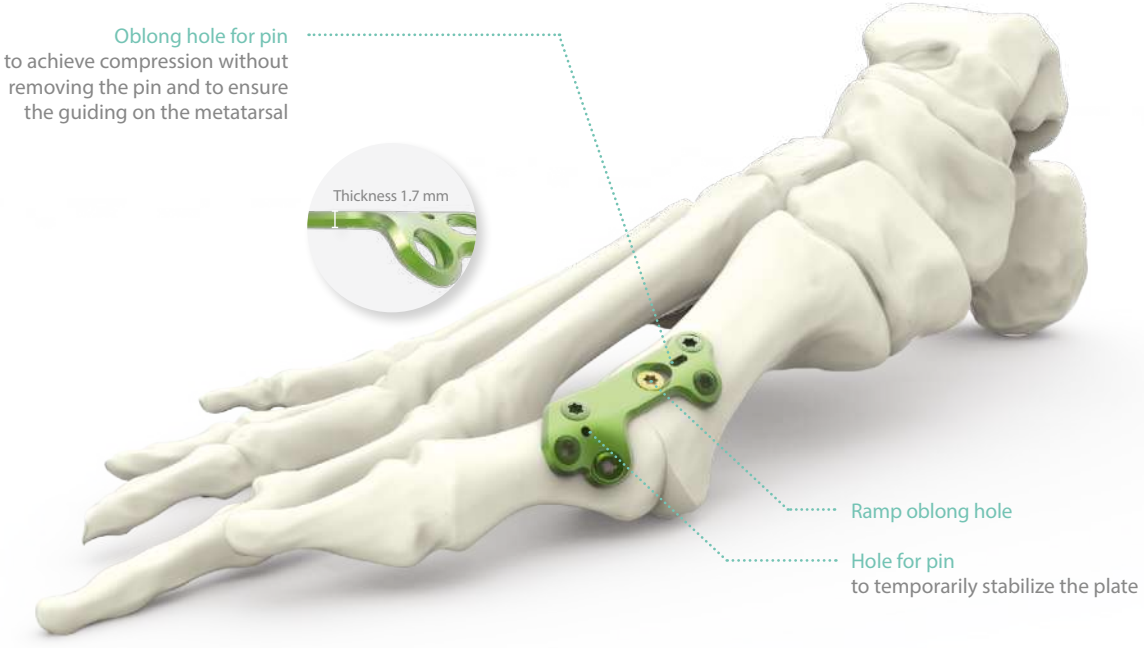
Ø2.0 mm threaded guide gauge for Ø2.8 mm screws

Plate features

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

3 standard sizes and 1 narrow size of plates for the right (green plates) and left (blue plates) sides, offering comprehensive solutions.





Range of precontoured plates for an anatomical fit

PLATE BENDING

All the Initial F™ MTP plates can be bent with the appropriate bending pliers (ANC578). These are available in a non-sterile version and on demand.

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.

Screw and fixation features

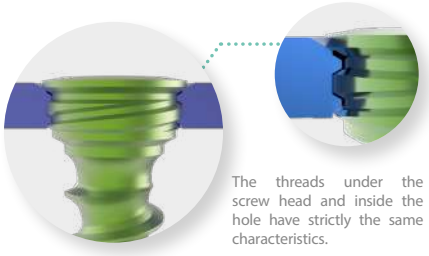
Fixations and screws

- **A single screw diameter: Ø2.8 mm**
  Both locking (SLT2.8Lxx) and non locking screws (RLT2.8Lxx) are available.
- **Hexalobular screw recess (T8).**

Hexalobular stamp

Single screw diameter

Locking screw



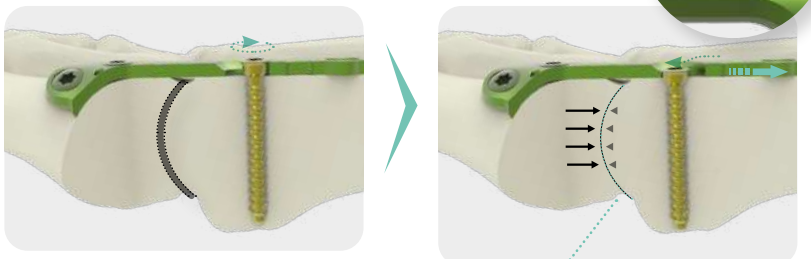
The threads under the screw head and inside the hole have strictly the same characteristics.

FEATURES:

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

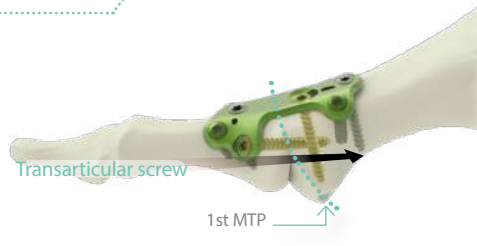
Specific fixations for stable assembly

- **Ramp oblong hole:**
  The ramp oblong hole allows compression by the screw/plate interface.

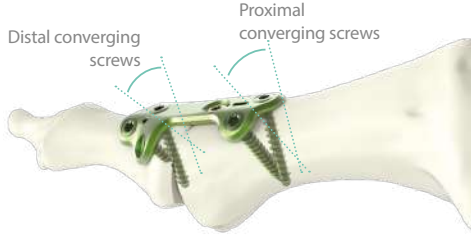


Compression of the joint up to 1.5 mm

- **Hole for transarticular screw:**
  The transarticular screw available on standard plates goes through the 1st MTP joint.



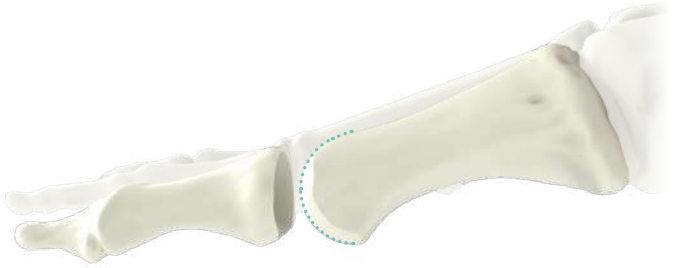
- **Holes for converging screws in the distal and proximal areas.**



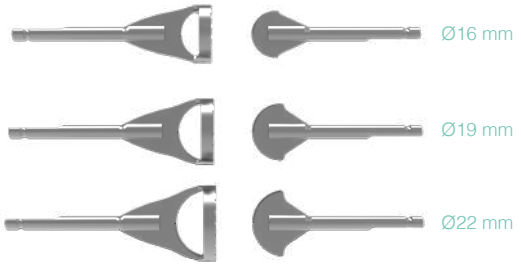
Instrumentation features

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.



3 SIZES AVAILABLE



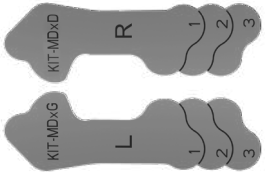
Convex reamers Concave reamers

Templates

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

- **Reamer template**
  The template for Intial F™ - MTP - Reamers kit allows to determine the appropriate reamer diameter (Ø16 mm, Ø19 mm or Ø22 mm) to be used for joint preparation.

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



Handle for guide gauge :

To improve the ergonomics of the Ø2.0 mm threaded guide gauge when positioning it in the oblong hole, a handle can be used and clipped directly onto the gauge.

Surgical technique

Joint surface preparation

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

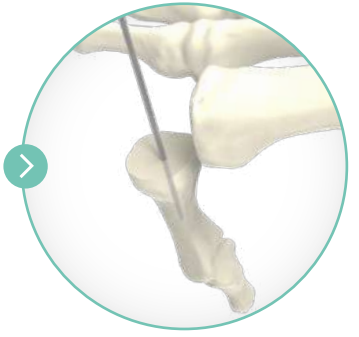
1. Dislocate the joint to expose the head of the first metatarsal and the proximal base of the first phalanx.

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.

Surgical technique

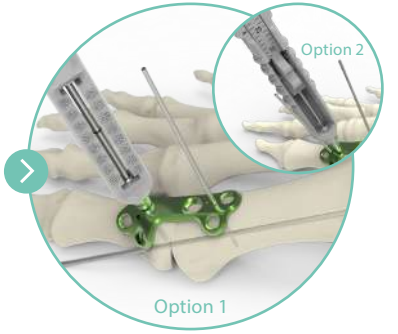
Standard plate

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

(Same technique for all the standard plates)

1. Determine the plate size thanks to the template, then choose the suitable kit.

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.

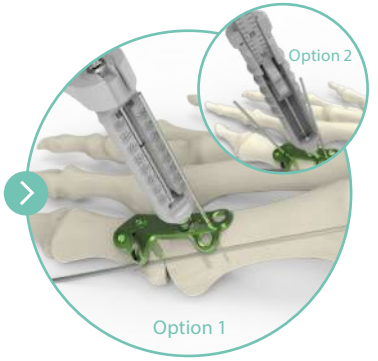


3. Lock the Ø2.0 mm threaded guide gauge into the distal lateral hole and perform the drilling.

Option 1 - Determine the screw length using drill bit and guide 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. Clip the handle for guide gauge on the Ø2.0 mm threaded guide gauge and perform the drilling using the guide gauge in the proximal part of the ramp oblong hole.

Option 1 - Determine the screw length using the drill bit and guide 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 two proximal holes following the steps 2 & 3, then remove the pins.

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

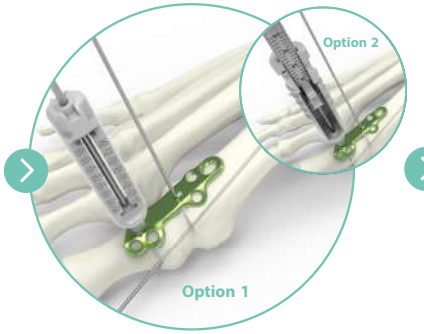
Surgical technique

Narrow plate

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

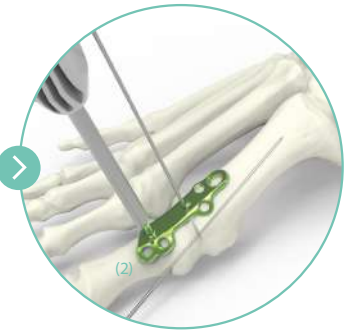
The narrow plates are designed to be combined with the use of a stand-alone screw, cannulated or solid based on the surgeon's preference, to fix the joint using the technique of his/her choice.

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.

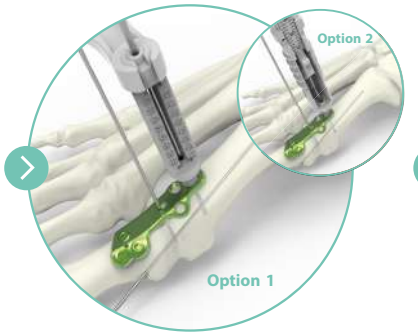


2. Lock the Ø2.0 mm threaded guide gauge into the distal lateral hole and perform the drilling.

   Option 1 - Determine the screw length using the gauge.
   Option 2 - 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. Clip 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 two proximal holes following the steps 2 & 3.

   Then remove the pins.

References

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

INITIAL F™ - MTP KITS - INSTRUMENTATION CONTENT	
Description	
Ø2.0 mm quick coupling drill bit - L125 mm	1
Ø2.0 mm threaded guide gauge for Ø2.8 mm screws	1
Length gauge for Ø2.8 and Ø3.5 mm screws - L8-40 mm	1
T8 prehensor screwdriver	1
Handle for guige 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	1st MTP arthrodesis plate - Standard - Right - Size 1 (length 36.5mm)	1	-	-	-	-	-	-	-
	FMTGD1	1st MTP arthrodesis plate - Standard - Left - Size 1 (length 36.5mm)	-	1	-	-	-	-	-	-
	FMTDD2	1st MTP arthrodesis plate - Standard - Right - Size 2 (length 41.5mm)	-	-	1	-	-	-	-	-
	FMTGD2	1st MTP arthrodesis plate - Standard - Left - Size 2 (length 41.5mm)	-	-	-	1	-	-	-	-
	FMTDD3	1st MTP arthrodesis plate - Standard - Right - Size 3 (length 46.5mm)	-	-	-	-	1	-	-	-
	FMTGD3	1st MTP arthrodesis plate - Standard - Left - Size 3 (length 46.5mm)					-	1	-	-
NARROW PLATES	FMTDDN1	1st MTP arthrodesis plate - Narrow - Right - Size 1 (length 41.6mm)	-	-	-	-	-	-	1	-
	FMTGDN1	1st MTP arthrodesis plate - Narrow - Left - Size 1 (length 41.6mm)	-	-	-	-	-	-	-	1
LOCKING SCREWS Ø2.8 MM	SLT2.8L12	Ø2.8 mm locking screw - L12 mm	-	-	-	-	-	-	1	1
	SLT2.8L14	Ø2.8 mm locking screw - L14 mm	1	1	1	1	1	1	2	2
	SLT2.8L16	Ø2.8 mm locking screw - L16 mm	2	2	2	2	2	2	2	2
	SLT2.8L18	Ø2.8 mm locking screw - L18 mm	2	2	2	2	2	2	1	1
	SLT2.8L20	Ø2.8 mm locking screw - L20 mm	1	1	1	1	1	1	-	-
NON LOCKING SCREWS Ø2.8 MM	RLT2.8L14	Ø2.8 mm non-locking screw - L14 mm	-	-	-	-	-	-	1	1
	RLT2.8L16	Ø2.8 mm non-locking screw - L16 mm	1	1	1	1	1	1	1	1
	RLT2.8L18	Ø2.8 mm non-locking screw - L18 mm	1	1	1	1	1	1	-	-
	RLT2.8L22	Ø2.8 mm non-locking screw - L22mm	1	1	1	1	1	1	-	-
	RLT2.8L26	Ø2.8 mm non-locking screw - L26 mm	1	1	1	1	1	1	-	-

References

Additional implants

Sterile screws packaged in the supplemental sterile screw caddy

NON LOCKING SCREWS - Ø2.8 mm*

Ref.	Description	Qty
RLT2.8L10-ST	Ø2.8 mm non-locking screw - L10 mm - STERILE	1
RLT2.8L12-ST	Ø2.8 mm non-locking screw - L12 mm - STERILE	1
RLT2.8L14-ST	Ø2.8 mm non-locking screw - L14 mm - STERILE	1
RLT2.8L16-ST	Ø2.8 mm non-locking screw - L16 mm - STERILE	1
RLT2.8L18-ST	Ø2.8 mm non-locking screw - L18 mm - STERILE	1
RLT2.8L20-ST	Ø2.8 mm non-locking screw - L20 mm - STERILE	1
RLT2.8L22-ST	Ø2.8 mm non-locking screw - L22 mm - STERILE	1
RLT2.8L24-ST	Ø2.8 mm non-locking screw - L24 mm - STERILE	1
RLT2.8L26-ST	Ø2.8 mm non-locking screw - L26 mm - STERILE	1
RLT2.8L28-ST	Ø2.8 mm non-locking screw - L28 mm - STERILE	1
RLT2.8L30-ST	Ø2.8 mm non-locking screw - L30 mm - STERILE	1
RLT2.8L32-ST	Ø2.8 mm non-locking screw - L32 mm - STERILE	1
RLT2.8L34-ST	Ø2.8 mm non-locking screw - L34 mm - STERILE	1

* Yellow anodized

LOCKING SCREWS - Ø2.8 mm*

Ref.	Description	Qty
SLT2.8L10-ST	Ø2.8 mm locking screw - L10 mm - STERILE	1
SLT2.8L12-ST	Ø2.8 mm locking screw - L12 mm - STERILE	2
SLT2.8L14-ST	Ø2.8 mm locking screw - L14 mm - STERILE	3
SLT2.8L16-ST	Ø2.8 mm locking screw - L16 mm - STERILE	3
SLT2.8L18-ST	Ø2.8 mm locking screw - L18 mm - STERILE	3
SLT2.8L20-ST	Ø2.8 mm locking screw - L20 mm - STERILE	2
SLT2.8L22-ST	Ø2.8 mm locking screw - L22 mm - STERILE	2
SLT2.8L24-ST	Ø2.8 mm locking screw - L24 mm - STERILE	1
SLT2.8L26-ST	Ø2.8 mm locking screw - L26 mm - STERILE	1
SLT2.8L28-ST	Ø2.8 mm locking screw - L28 mm - STERILE	1
SLT2.8L30-ST	Ø2.8 mm locking screw - L30 mm - STERILE	1
SLT2.8L32-ST	Ø2.8 mm locking screw - L32 mm - STERILE	1
SLT2.8L34-ST	Locking screw - Ø2.8 mm - L34 mm - STERILE	1

* Green anodized

Additional instrumentation kits

Convex & Concave reamers

SINGLE USE CONVEX AND CONCAVE REAMERS - STERILE PACKAGING

Ref.	Description	Content
KIT-MI16	Foot kit - 1st MTP Arthrodesis - Ø16 mm reamers	- Ø16 mm Initial convex reamer - Ø16 mm Initial concave reamer - Pin Ø1.6 L100 mm x2
KIT-MI19	Foot kit - 1st MTP Arthrodesis - Ø19 mm reamers	- Ø19 mm Initial convex reamer - Ø19 mm Initial concave reamer - Pin Ø1.6 L100 mm x2
KIT- MI22	Foot kit - 1st MTP Arthrodesis - Ø22 mm reamers	- Ø22 mm Initial convex reamer - Ø22 mm Initial concave reamer - Pin Ø1.6 L100 mm x2

Removal and rescue kits

Sterile instruments

REMOVAL AND RESCUE KITS

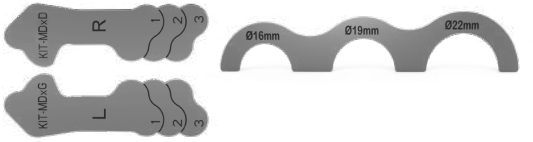
Ref.	Description	Content
KIT-REMOVE-2	Removal kit for T8 hexalobe	- 1 x T8 Prehensor Screwdriver
KIT-RESCUE-4	Rescue kit for Initial MTP	- 1x Ø2.0 mm threaded guide gauge for Ø2.8 mm screws - 1x Ø2.0 mm quick coupling drill bit – L125 mm - 1 x length gauge for Ø2.8 and Ø3.5 mm screws - L8-40 mm - 1 x handle for guide gauge - 2 x pin Ø1.2 L70 mm - 1 x pin Ø1.6 L100 mm

Templates

Sterile templates

INITIAL F™ - MTP TEMPLATES

Ref.	Description
ANC808	Template for foot kit - 1st MTP Arthrodesis - Standard - Sizes 1-2-3 - Left & Right (KIT-MDxx)
ANC846	Template for foot kit - 1st MTP Arthrodesis - Ø16 / Ø19 / Ø22 mm reamers (KIT-MIxx)



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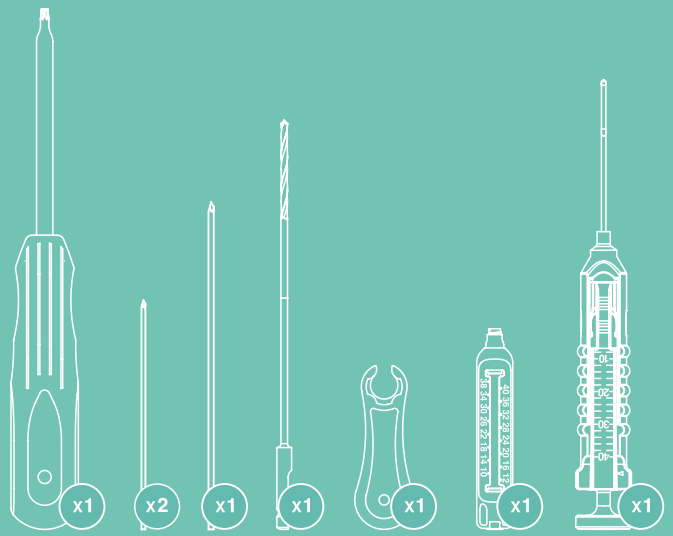
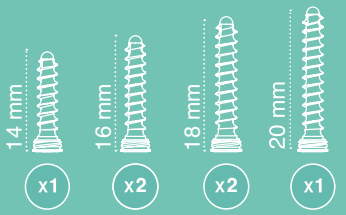
NEWCLIP-TECHNICS

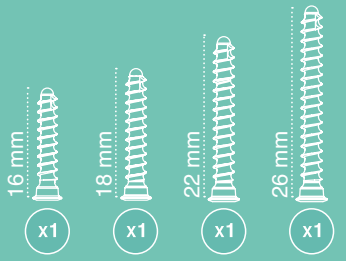
INITIAL MTP™



Implant material: Titanium TA6V - ISO 5832-3 / ASTM F136
Degree of accuracy for devices with a measuring function: ±1.0 mm



Locking screws ø2.8 mm



Non Locking screws ø2.8 mm

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Manufacturer : Newclip Technics – Brochure EN – Initial F MTP – ED6 - 04/26 - 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.