

SINGLE USE KIT

STERILE R

NEWCLIP-TECHNICS



INITIAL

Ankle

Ready
when you are!

With a non sterile standard kit



Calling on medical staff

Constraints



Complex traceability



Contracted out sterilization

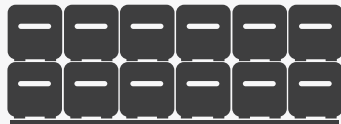


Suppliers' deadline

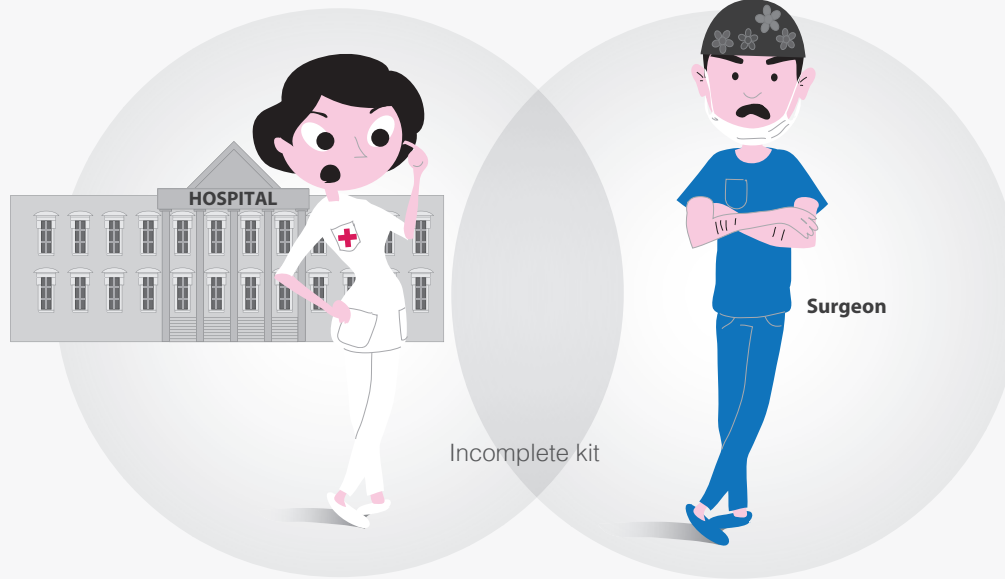
High costs



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



Bulky storage



Complex process



Prevents an effective solution & a quick response



Defective sterilization



Incomplete kit



Damaged instrumentation



INCREASED RISKS

NON OPTIMIZED surgery

URGENT SURGICAL CASES COMPROMISED

With the



kit

Safety >

TRACEABILITY
100%

STERILE R
SINGLE USE KIT

Always
NEW



Risk
of contamination

Cost efficiency

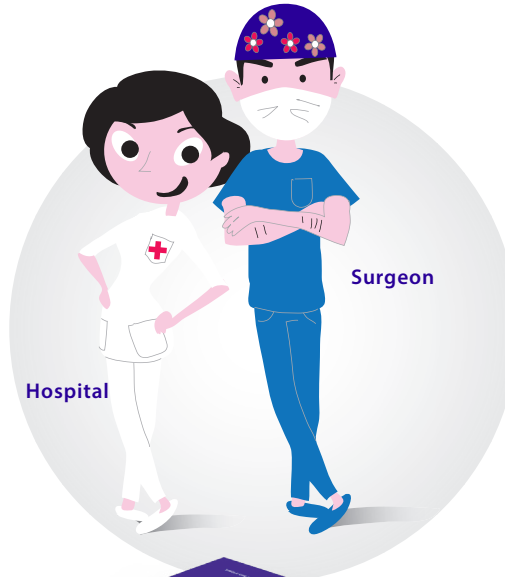
Controlled stocks
Simplified control

- 0 Cleaning
- 0 Decontamination
- 0 Sterilization

Sundry expenses



Optimized storage



Hospital

Surgeon



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!



Safety:

The Initial A™ kits are fully traceable and have a shelf life of 5 years. Its instrumentation and implants are “always new” and have never been opened or used before.



Available when needed:

The Initial A™ kits (Initial A™ - Fibula and Initial A™- Syndesmosis) come pre-sterilized and ready to use. The combination of sterile implants and single use instrumentation in a single packaging makes Initial A™ ideal for use in urgent surgical cases.



Storage:

Initial A™ kits can be easily stored in the operating room because of its small size.



Costs:

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

Initial A™ - Fibula kits

Technical features

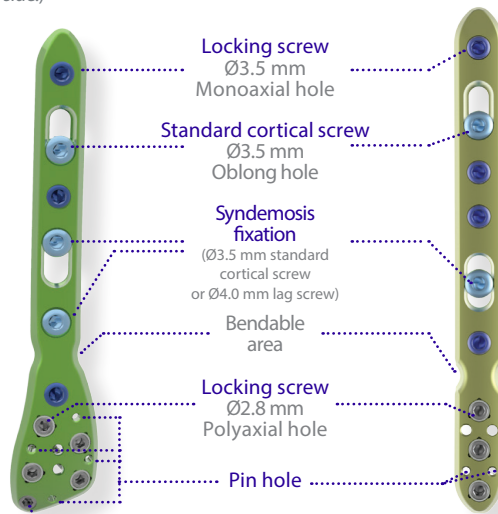


Standard plate

Fixation of osteoporotic bones and complex fractures with or without syndesmosis injuries (green anodized plate for right side, blue anodized plate for left side.)

Narrow plate

Fixation of simple fractures with or without syndesmosis injuries (same plate for both sides).



Locking screw - Ø3.5 mm
Ref. SOT3.5Lxx

Standard cortical screw - Ø3.5 mm
Ref. CT3.5Lxx

Locking screw - Ø2.8 mm
Ref. SDT2.8Lxx

Lag screw - Ø4.0 mm
Ref. QT4.0Lxx

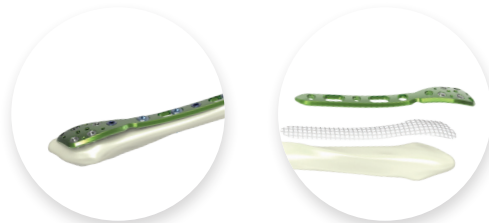
> Indications

The implants of the Initial A™ are intended for the fixation of fractures, osteotomies and pseudarthroses of the distal fibula, and for syndesmosis repair in adults.

> Contra-indications

- Serious vascular deterioration, bone devitalization.
- Pregnancy.
- Acute or chronic, local or systemic infections.
- Lack of musculo-cutaneous cover, severe vascular deficiency touching the focus.
- Insufficient bone quality preventing a good fixation of the implant into the bone.
- Muscular deficit, neurological deficiency or behavioural disorders which could submit the osteosynthesis to abnormal mechanical strains.
- Foreign body sensitivity or allergy to one of the materials used.
- Patients with mental or neurological conditions who are unwilling or incapable of following post-operative care instructions.
- Patients with poor physical condition and/or mental instability.

> Precontoured implant



Optimized anatomical congruence

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.

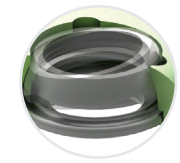
▶ PLATE BENDING

The implant also offers bendable areas which allow an optimal adjusting of the plate on the diaphyseal part and on the junction of the diaphysis and epiphysis parts thanks to the bending pliers. **They are available separately, on demand, in non sterile version.**

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 so as to avoid damaging the fixation.

> Angular range: +/- 10° polyaxial locking fixation

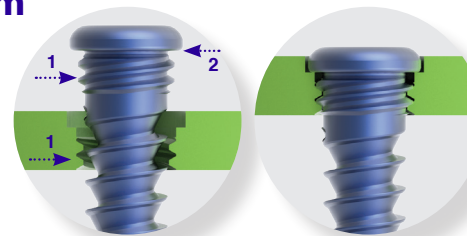
Initial A™ plates combine both polyaxial and locking technologies to create a fixed-angle construct particularly useful for poor bone quality and/or multifragmentary fractures.



Dualtec System® II
Technology
Clip + nut

> Monoaxial locking system

- The threaded sections under the screw head and inside the hole have strictly the same characteristics (1),
- Screw head cap (2),
- Implants material: titanium alloy.

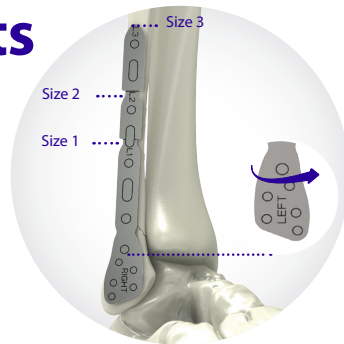


- Construct limiting cold welding risks for improved removal properties.

Initial A™ - Fibula kits

Surgical technique

Example: surgical technique with a right standard plate, size 2 (KIT-AL2D).



1. Using the template (ANC607), define the suitable plate size, then determine the appropriate kit. N.B.: The templates can be used both for the right side and for the left side and are available sterile separately.



2. Drill using the Ø2.7 mm drill bit.



3. When a lag effect is necessary, use the countersink part of the blue 2-in-1 instrument to widen the first cortex previously drilled.

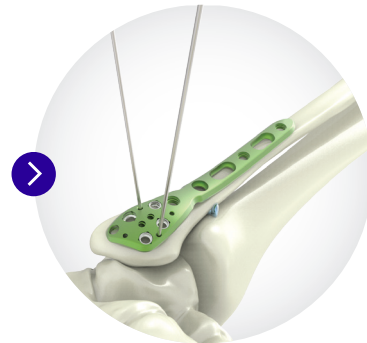


4. Insert the interfragmentary non-locking Ø3.5 mm light blue cortical screw using the screwdriver part of the 2-in-1 instrument.

2-in-1 instrument

The 2-en-1 instrument includes the 2 following functions:

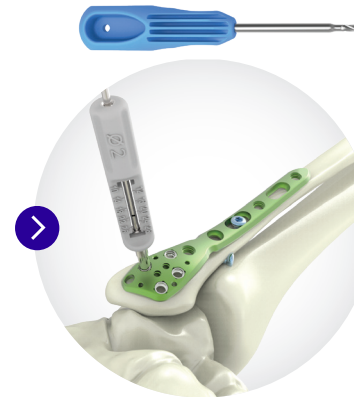
- **Screwdriver** for Ø3.5 mm and Ø4.0 mm screws,
- **Countersink** to widen the drilling made in the first cortex before screw insertion.



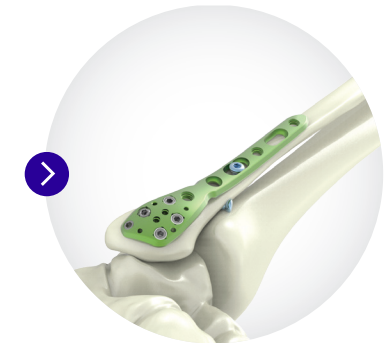
5. Hold the plate with two pins inserted through the distal holes.



6. The plate is securely placed using a non-locking Ø3.5 mm light blue cortical screw in the most distal oblong hole.



7. Using the Ø2.0 mm threaded guide gauge (grey), choose the angle of the Ø2.8 mm non anodized screws in the polyaxial holes then drill (Ø2.0 mm) and measure the screw length directly on the gauge.



8. Using the grey screwdriver to insert and lock the Ø2.8 mm non anodized screws.



9. Option1: Using the Ø2.7 mm threaded guide gauge (blue), drill (Ø2.7 mm) and measure the screw length directly on the gauge.

Or



9. Option 2: Alternatively, the drilling depth can be measured by inserting the length gauge through the guide gauge.



10. Using the countersink part of the blue 2-in-1 instrument, widen the first cortex previously drilled. Insert a Ø3.5 mm blue screw using the screwdriver part of the blue 2-in-1 instrument and lock it.

Final Result

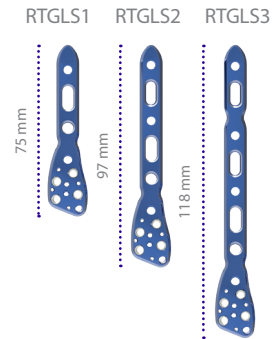


Repeat previous steps to insert the remaining Ø3.5 mm screws in the plate.

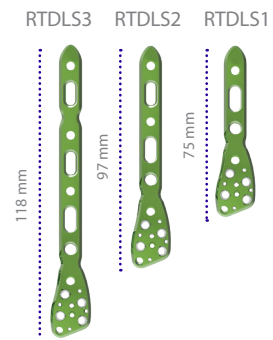
Initial A™ - Fibula kits

References

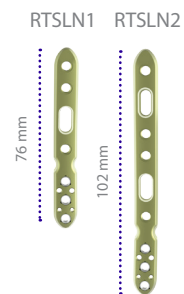
Standard plates - Left side



Standard plates - Right side



Narrow plates



INITIAL A™ - FIBULA KITS

Ref.	Description
KIT-AL1D	Distal fibula kit - Standard - Right - Size 1
KIT-AL1G	Distal fibula kit - Standard - Left - Size 1
KIT-AL2D	Distal fibula kit - Standard - Right - Size 2
KIT-AL2G	Distal fibula kit - Standard - Left - Size 2
KIT-AL3D	Distal fibula kit - Standard - Right - Size 3
KIT-AL3G	Distal fibula kit - Standard - Left - Size 3
KIT-AL1S	Distal fibula kit - Narrow symmetrical - Size 1
KIT-AL2S	Distal fibula kit - Narrow symmetrical - Size 2

INITIAL A™ - FIBULA KIT - INSTRUMENTATION CONTENT

Description
Ø2.0 mm threaded guide gauge for Ø2.8 mm screws
Ø2.0 mm quick coupling drill bit - L 125 mm
Ø2.7 mm quick coupling drill bit - L 125 mm
2 in 1: 2.5 mm hexagonal prehensor screwdriver - Ø3.5 mm countersink
Ø2.7 mm threaded guide gauge for Ø3.5 mm screws
Length gauge for Ø3.5 mm screws
2.0 mm hexagonal prehensor screwdriver
Pin - Ø1.4 L120 mm (x2)

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

INITIAL A™ - FIBULA KITS - IMPLANTS CONTENT

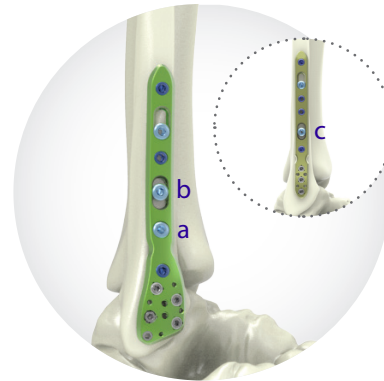
	Ref.	Description	QUANTITY PER KIT				
			KIT-AL1D or KIT-AL1G	KIT-AL2D or KIT-AL2G	KIT-AL3D or KIT-AL3G	KIT-AL1S	KIT-AL2S
STANDARD PLATES	RTDLS1 or RTGLS1	Lateral plate for distal fibula - Standard Right or left - Size 1	1	-	-	-	-
	RTDLS2 or RTGLS2	Lateral plate for distal fibula - Standard Right or left - Size 2	-	1	-	-	-
	RTDLS3 or RTGLS3	Lateral plate for distal fibula - Standard Right or left - Size 3	-	-	1	-	-
NARROW PLATES	RTSLN1	Lateral plate for distal fibula - Narrow symmetrical - Size 1	-	-	-	1	-
	RTSLN2	Lateral plate for distal fibula - Narrow symmetrical - Size 2	-	-	-	-	1
LOCKING SCREWS Ø2.8 MM	SDT2.8L10	Locking screw - Ø2.8 mm - L 10 mm	1	1	1	-	-
	SDT2.8L12	Locking screw - Ø2.8 mm - L 12 mm	1	1	1	1	1
	SDT2.8L14	Locking screw - Ø2.8 mm - L 14 mm	2	2	2	1	1
	SDT2.8L16	Locking screw - Ø2.8 mm - L 16 mm	2	2	2	1	1
	SDT2.8L18	Locking screw - Ø2.8 mm - L 18 mm	2	2	2	1	1
LOCKING SCREWS Ø3.5 MM	SOT3.5L12	Locking screw - Ø3.5 mm - L 12 mm	1	2	3	2	2
	SOT3.5L14	Locking screw - Ø3.5 mm - L 14 mm	2	2	3	2	2
	SOT3.5L16	Locking screw - Ø3.5 mm - L 16 mm	1	1	1	1	2
STANDARD CORTICAL SCREWS Ø3.5 MM	CT3.5L12	Standard cortical screw - Ø3.5 mm - L 12 mm	1	1	1	-	1
	CT3.5L14	Standard cortical screw - Ø3.5 mm - L 14 mm	1	1	2	1	1
	CT3.5L16	Standard cortical screw - Ø3.5 mm - L 16 mm	-	1	1	1	1
	CT3.5L18	Standard cortical screw - Ø3.5 mm - L 18 mm	1	1	1	-	-
	CT3.5L20	Standard cortical screw - Ø3.5 mm - L 20 mm	1	1	1	1	1

Initial A™ - Syndesmosis kit

Surgical technique

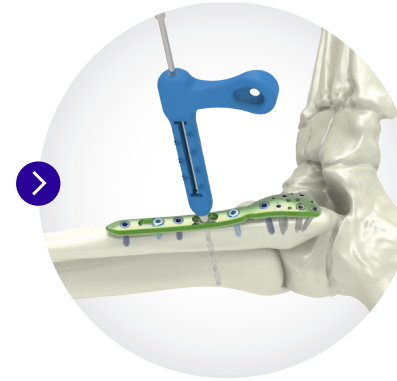
Example: surgical technique with a right standard plate, size 2 (KIT-AL2D + KIT-AMS)

Initial A™ - Syndesmosis kit is intended for the syndesmosis repair in adults.



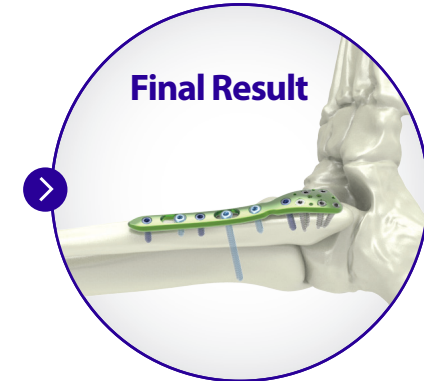
1. The syndesmosic screw can be inserted in the following holes:

- For the standard plates:
 - a. The most distal diaphyseal hole,
 - b. The most distal oblong hole,
- For the narrow plates:
 - c. The most distal oblong hole.



2. Drill using the non threaded bent long guide gauge for syndesmosic screws. The drilling length can be directly measured on the guide gauge.

⚠ It is compulsory to use this guide.



Insert the syndesmosic screw and finalize the tightening with the screwdriver part of the blue 2-in-1 instrument from the Initial A™ - Fibula kit.

NB: The syndesmosic screw must be removed using the removal kit for Ø3.5 mm screws (ref: KIT-REMOVE-A) once the syndesmosis has healed, usually after six to eight weeks.

References



INITIAL A™ - SYNDESMOSIS KIT

Ref.	Description
KIT-AMS	Syndesmosis kit

INITIAL A™ - SYNDESMOSIS KIT CONTENT

Description	Qty
Ø2.7 mm quick coupling drill bit - L 180 mm	1
Ø2.7 mm non threaded bent long guide gauge for Ø3.5 and Ø4.0 mm screws	1
2.5 mm quick coupling hexagonal screwdriver	1
Washer	2

STERILE SCREWS FOR INITIAL A™ - AVAILABLE SEPARATELY - SYNDESMOSIS KIT*

Ref.	Description	Qty
CT3.5L40-ST	Standard cortical screw - Ø3.5 mm - L 40 mm - STERILE	2
CT3.5L45-ST	Standard cortical screw - Ø3.5 mm - L 45 mm - STERILE	3
CT3.5L50-ST	Standard cortical screw - Ø3.5 mm - L 50 mm - STERILE	3
CT3.5L55-ST	Standard cortical screw - Ø3.5 mm - L 55 mm - STERILE	3
CT3.5L60-ST	Standard cortical screw - Ø3.5 mm - L 60 mm - STERILE	2
CT3.5L65-ST	Standard cortical screw - Ø3.5 mm - L 65 mm - STERILE	2
QT4.0L40-ST	Lag screw - Ø4.0 mm - L 40 mm - STERILE	3
QT4.0L45-ST	Lag screw - Ø4.0 mm - L 45 mm - STERILE	3
QT4.0L50-ST	Lag screw - Ø4.0 mm - L 50 mm - STERILE	3
QT4.0L55-ST	Lag screw - Ø4.0 mm - L 55 mm - STERILE	3
QT4.0L60-ST	Lag screw - Ø4.0 mm - L 60 mm - STERILE	3
QT4.0L65-ST	Lag screw - Ø4.0 mm - L 65 mm - STERILE	3

*CT3.5Lxx: Light blue anodized.
QT4.0Lxx: Non anodized.

Initial A™ kits - Additional kits

References

Additional implants

Sterile screws

LOCKING SCREWS - Ø2.8 mm*			LOCKING SCREWS - Ø3.5 mm*			STANDARD CORTICAL SCREWS - Ø3.5 mm*		
Ref.	Description	Qty	Ref.	Description	Qty	Ref.	Description	Qty
SDT2.8L10-STI	Locking screw - Ø2.8 mm - L 10 mm - STERILE	1	SOT3.5L10-ST	Locking screw - Ø3.5 mm - L 10 mm - STERILE	2	CT3.5L10-ST	Standard cortical screw - Ø3.5 mm - L 10 mm - STERILE	2
SDT2.8L12-STI	Locking screw - Ø2.8 mm - L 12 mm - STERILE	1	SOT3.5L12-ST	Locking screw - Ø3.5 mm - L 12 mm - STERILE	1	CT3.5L12-ST	Standard cortical screw - Ø3.5 mm - L 12 mm - STERILE	1
SDT2.8L14-STI	Locking screw - Ø2.8 mm - L 14 mm - STERILE	1	SOT3.5L14-ST	Locking screw - Ø3.5 mm - L 14 mm - STERILE	1	CT3.5L14-ST	Standard cortical screw - Ø3.5 mm - L 14 mm - STERILE	1
SDT2.8L16-STI	Locking screw - Ø2.8 mm - L 16 mm - STERILE	1	SOT3.5L16-ST	Locking screw - Ø3.5 mm - L 16 mm - STERILE	1	CT3.5L16-ST	Standard cortical screw - Ø3.5 mm - L 16 mm - STERILE	1
SDT2.8L18-STI	Locking screw - Ø2.8 mm - L 18 mm - STERILE	1	SOT3.5L18-ST	Locking screw - Ø3.5 mm - L 18 mm - STERILE	2	CT3.5L18-ST	Standard cortical screw - Ø3.5 mm - L 18 mm - STERILE	1
SDT2.8L20-STI	Locking screw - Ø2.8 mm - L 20 mm - STERILE	2	SOT3.5L20-ST	Locking screw - Ø3.5 mm - L 20 mm - STERILE	2	CT3.5L20-ST	Standard cortical screw - Ø3.5 mm - L 20 mm - STERILE	2
SDT2.8L22-STI	Locking screw - Ø2.8 mm - L 22 mm - STERILE	2	SOT3.5L22-ST	Locking screw - Ø3.5 mm - L 22 mm - STERILE	2	CT3.5L22-ST	Standard cortical screw - Ø3.5 mm - L 22 mm - STERILE	2
SDT2.8L24-STI	Locking screw - Ø2.8 mm - L 24 mm - STERILE	1	SOT3.5L24-ST	Locking screw - Ø3.5 mm - L 24 mm - STERILE	2	CT3.5L24-ST	Standard cortical screw - Ø3.5 mm - L 24 mm - STERILE	2

*Non anodized.

*Blue anodized.

*Light blue anodized.

Removal and rescue kits

Sterile instruments

REMOVAL KITS		
Ref.	Description	Content
KIT-REMOVE-R	Removal kit for Ø2.8 mm screws	• 1x 2.0 mm hexagonal prehensor screwdriver
KIT-REMOVE-A	Removal kit for Ø3.5 mm screws	• 1x 2 in 1: 2.5 mm hexagonal prehensor screwdriver - Ø3.5 mm countersink

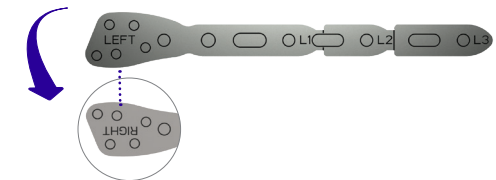
RESCUE KITS		
Ref.	Description	Content
KIT-RESCUE-R	Rescue kit for Ø2.8 mm screws	• 1x Ø2.0 mm quick coupling drill bit - L 125 mm • 1x Length gauge for Ø2.8 mm screws • 1x Ø2.0 mm threaded guide gauge for Ø2.8 mm screws • 2x Pins - Ø1.4 L120 mm
KIT-RESCUE-A	Rescue kit for Ø3.5 mm screws	• 1x Ø2.7 mm quick coupling drill bit - L 125 mm • 1x Ø2.7 mm threaded guide gauge for Ø3.5 mm screws • 1x Length gauge for Ø3.5 mm screws

Templates

Sterile templates

INITIAL A™ TEMPLATES		
Ref.	Description	Qty

ANC607	Standard lateral fibula template plate - Sizes 1/2/3 - Right side and left side	5
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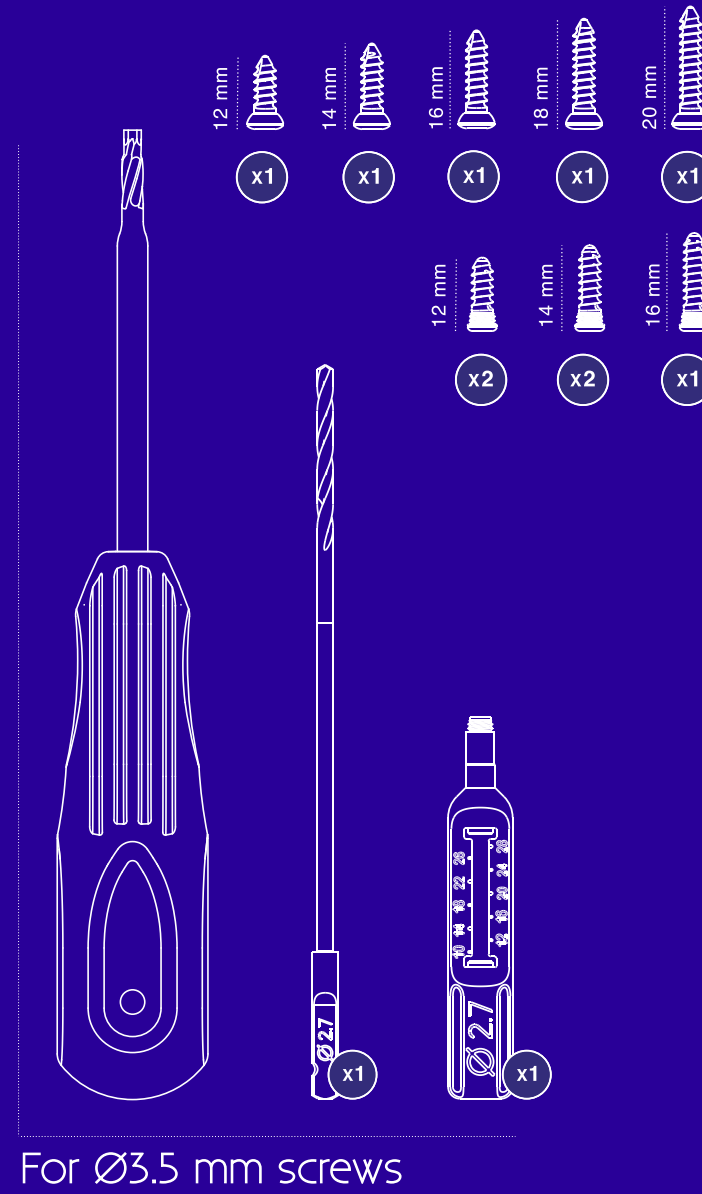
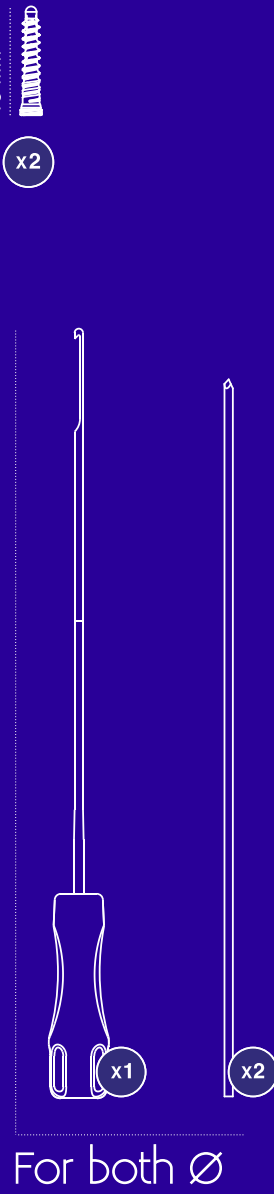
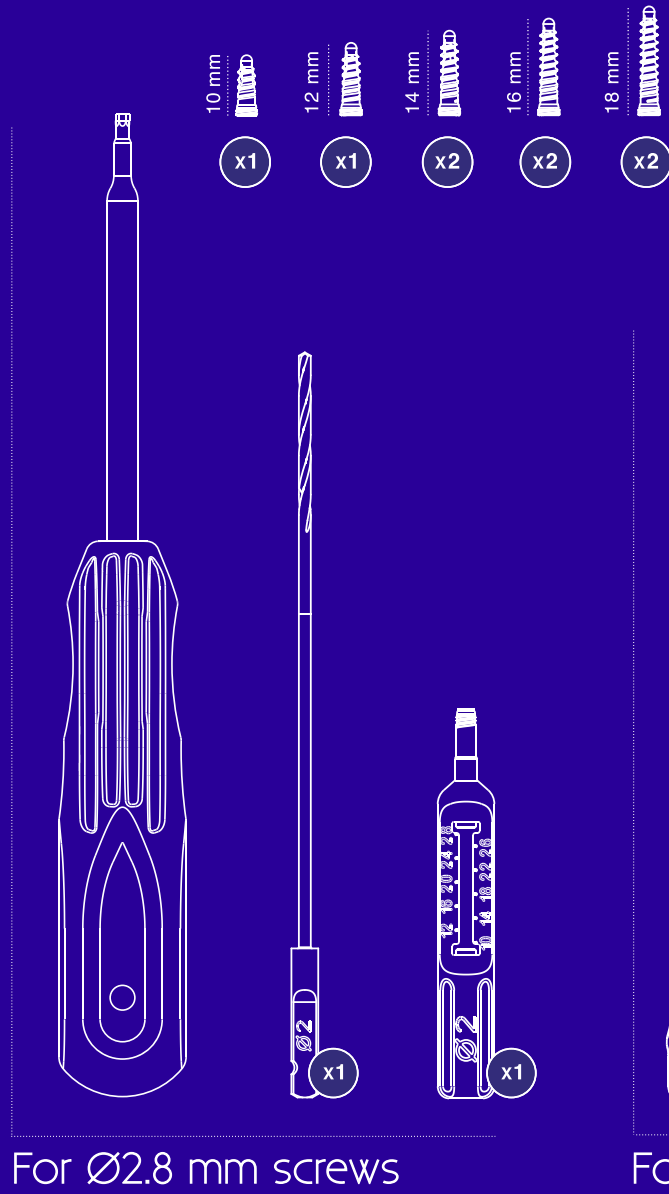
ANC659	Narrow lateral fibula template plate - Sizes 1/2	5
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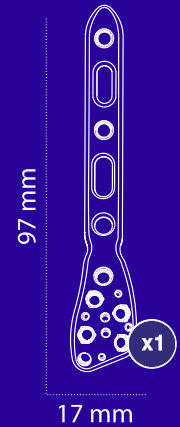
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KIT-AL2D

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



Right Fibula Lateral Standard Size 2



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