

SINGLE USE KIT

STERILE R



TM

NEWCLIP
TECHNICS



Ankle

With a non sterile standard kit



Calling on medical staff

Constraints



Complex traceability



Contracted out sterilization

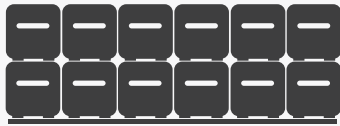


Suppliers' deadline

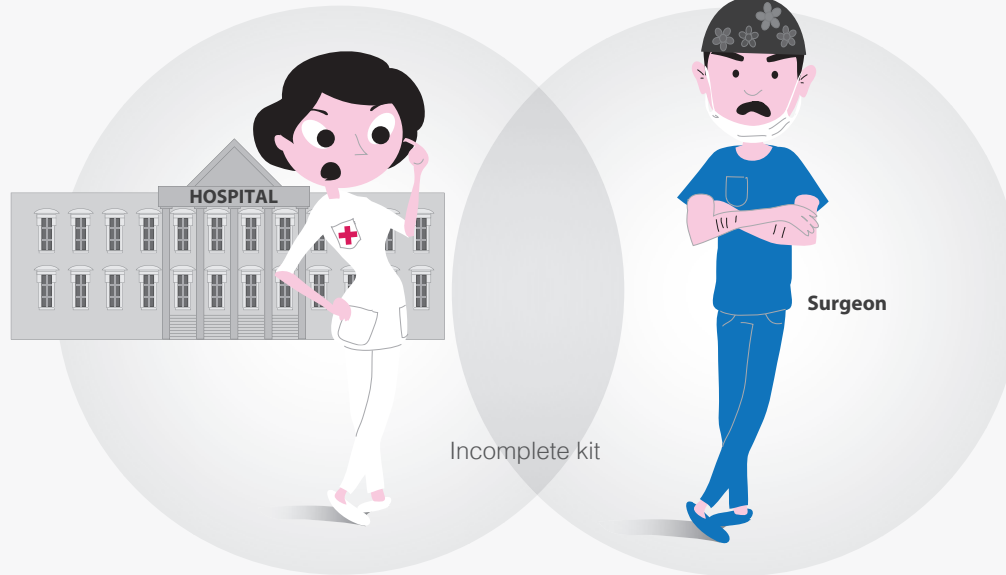
High costs



- \$ 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



Risk of contamination

Cost efficiency

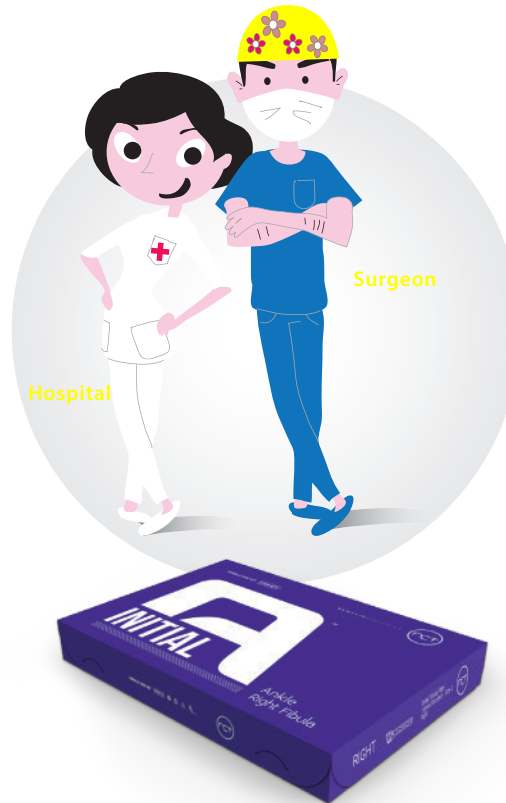
Controlled stocks
Simplified control

- 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!



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.

Kit Content



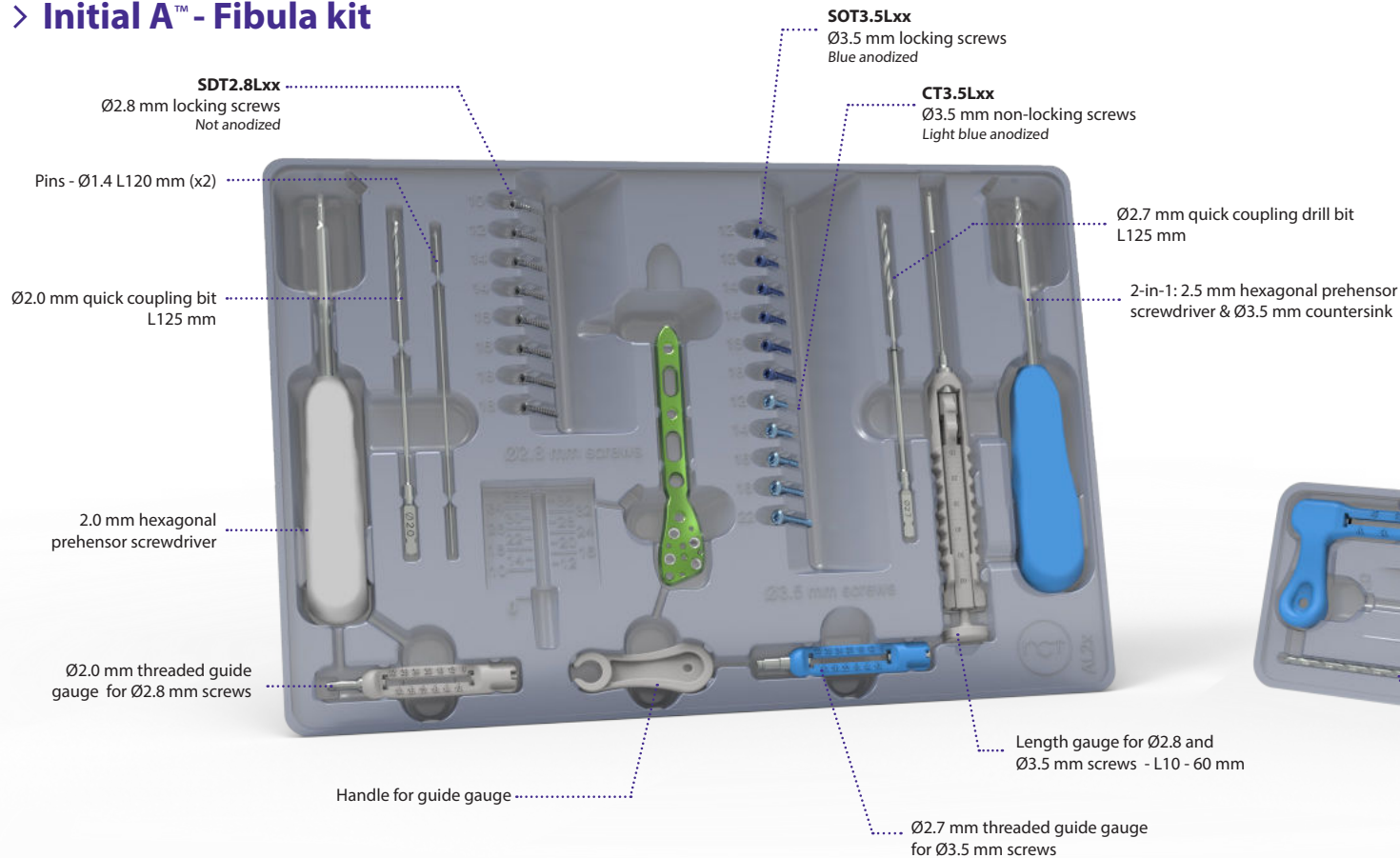
> Indications for use

Initial A is part of the Activ Ankle range. The Activ Ankle range is intended for the fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, for the fixation of fractures of the medial malleolus and for the syndesmotic repair in adults.

> Contraindications

- Pregnancy.
- Acute or chronic, local or systemic infections.
- Allergy to one of the materials used or sensitivity to foreign bodies.

> Initial A™ - Fibula kit



> Initial A™ - Syndesmosis kit

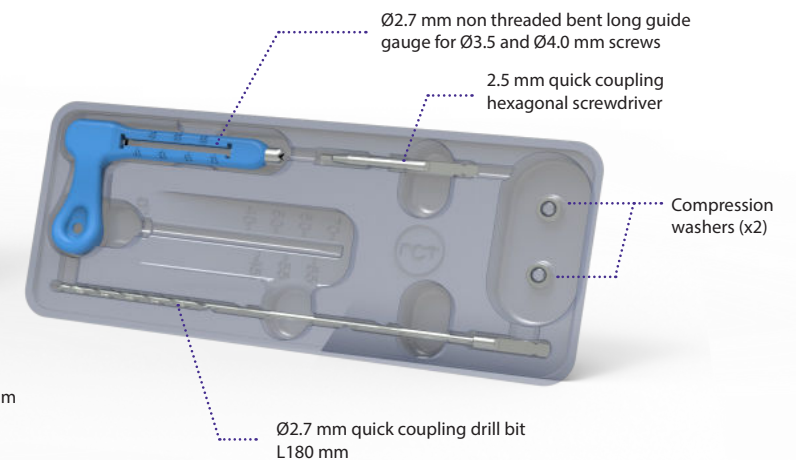


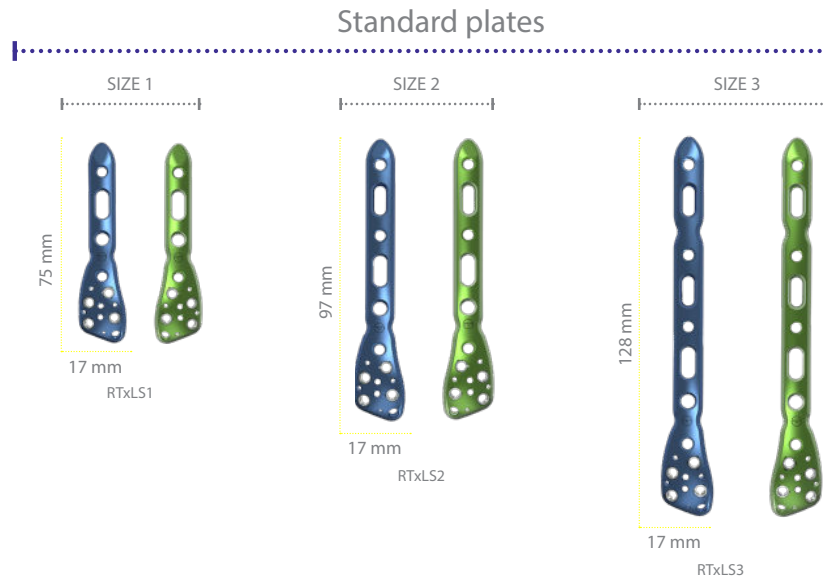
Plate features

> A comprehensive range of plates



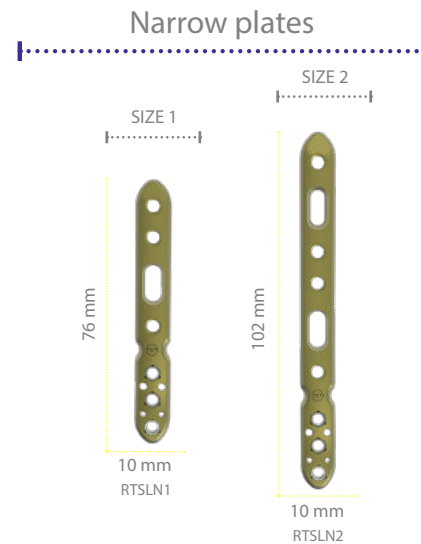
Standard plates

Available in 3 sizes (green anodized plates for the right side, blue anodized plates for the left side).

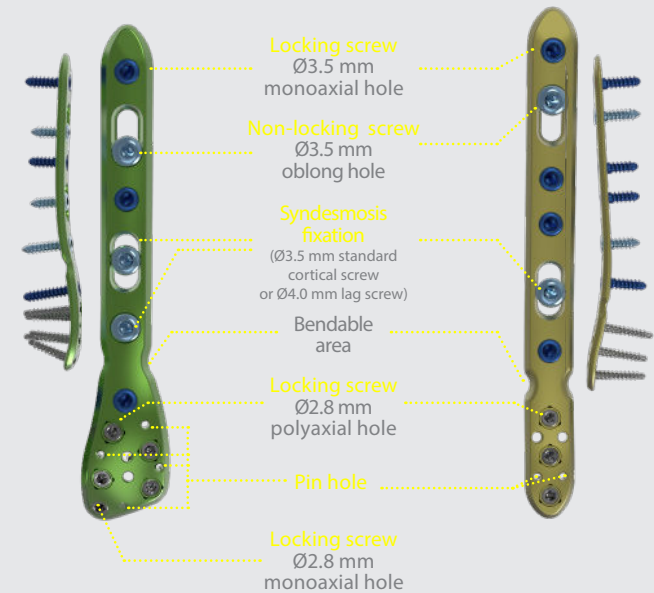


Narrow plates

Available in 2 sizes (same plate for both sides).



> Fixation system



Locking screw - $\varnothing 3.5$ mm
Ref. SOT3.5Lxx



Non-locking screw - $\varnothing 3.5$ mm
Ref. CT3.5Lxx



Locking screw - $\varnothing 2.8$ mm
Ref. SDT2.8Lxx

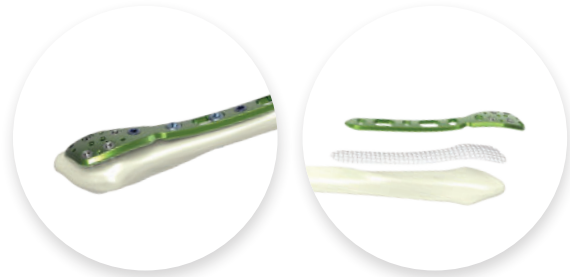


Lag screw - $\varnothing 4.0$ mm
Ref. QT4.0Lxx

Technical features: Initial A - Fibula kits

> Precontoured implant

The design of this implant is the result of a proprietary state-of-the-art mapping technology to establish a congruence between the plate and the bone.



► PLATE BENDING

The implant also offers bendable areas which allows 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.



Handle for guide gauge: before performing the drilling into the oblong hole, clip the handle for guide gauge on the Ø2.7 mm threaded guide gauge.



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

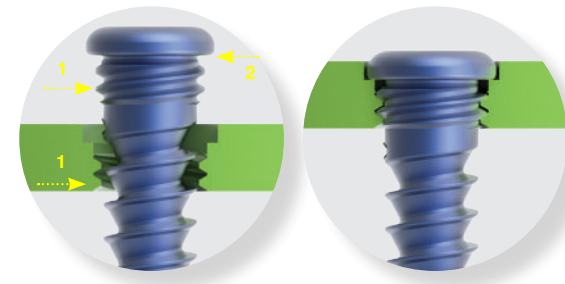
Initial A™ plates combine both polyaxial and locking technologies to create a fixed-angle construct particularly useful for poor bone quality and/or multifragmentary fractures.



Dualtec System® II
Technology
Clip + nut

> Monoaxial locking system

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



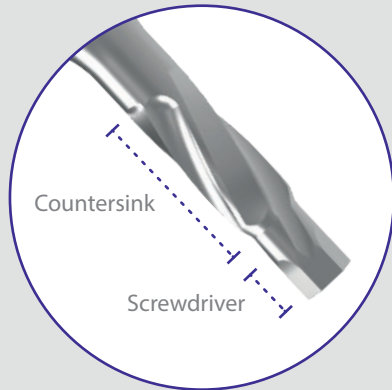
Surgical technique: Initial A - Fibula kits

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

(Same technique for all standard and narrow plates)

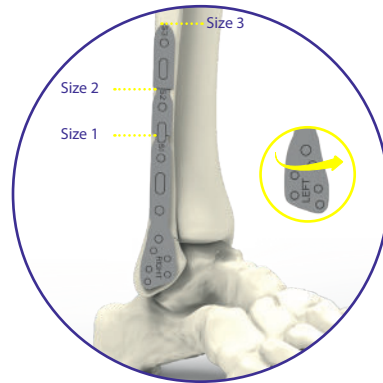
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2-IN-1 INSTRUMENT (ANC543)



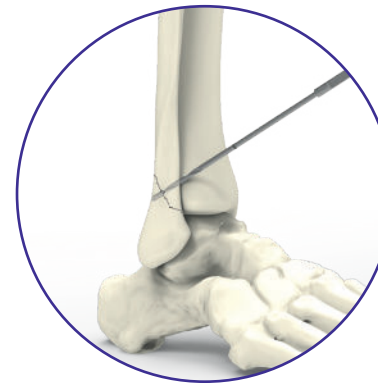
The 2-in-1 instrument includes the 2 following functions:

- **Screwdriver** for $\varnothing 3.5$ mm and $\varnothing 4.0$ mm screws,
- **Countersink** to widen the drilling made in the first cortex before screw insertion.



1. Using the template (ANC607 or ANC659), define the suitable plate size, then determine the appropriate kit.

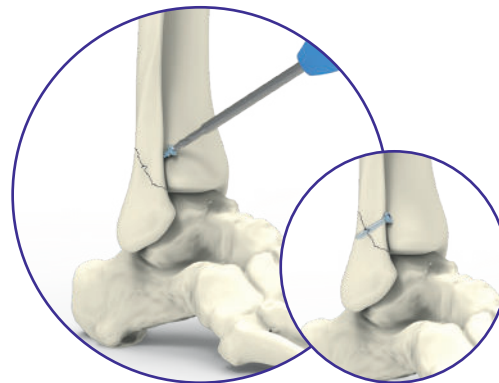
N.B.: The templates can be used both for the right side and for the left side and are available separately in a sterile version.



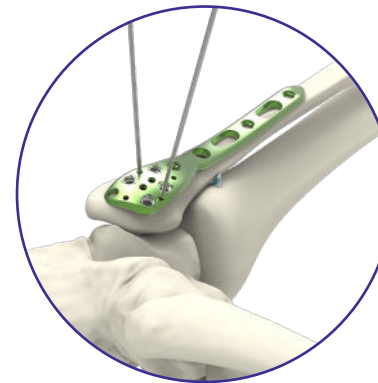
2. To insert an interfragmentary screw, drill using the $\varnothing 2.7$ mm drill bit.



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.

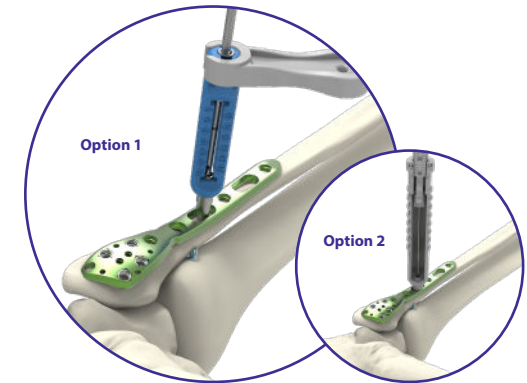


4. Insert the interfragmentary light blue $\varnothing 3.5$ mm non-locking screws using the screwdriver part of the blue 2-in-1 instrument.



5. Hold the plate by inserting pins through the dedicated distal holes.

The pins can be removed once the plate is stabilized.



6. Clip the handle for guide gauge on the blue $\varnothing 2.7$ mm threaded guide gauge and perform the drilling using the assembly in the most distal 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.

Surgical technique: Initial A - Fibula kits

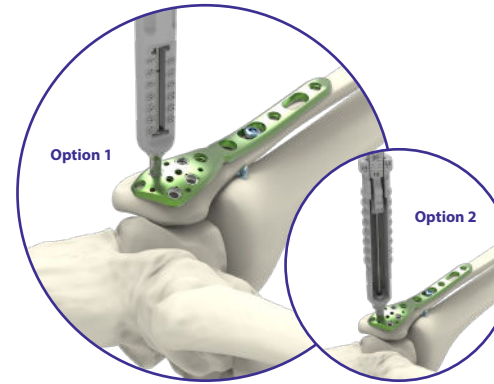
Example: surgical technique with a standard size 2 right (KIT-AL2D).

(Same technique for all standard and narrow plates)

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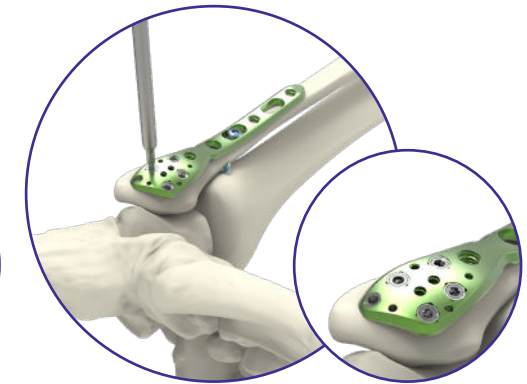
7. Screw a light blue Ø3.5 mm non-locking screws in the oblong hole using the screwdriver part of the blue 2-in-1 instrument to secure the plate in place.



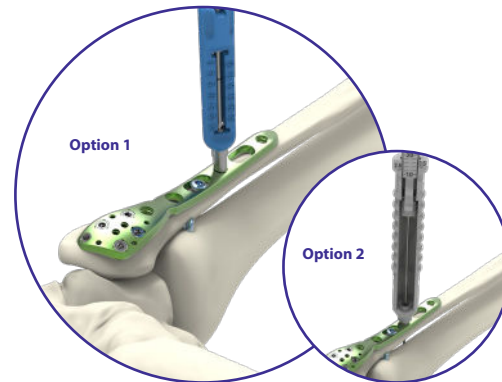
8. Using the grey Ø2.0 mm threaded guide gauge, choose the angle of the non-anodized Ø2.8 mm locking screws in the polyaxial holes then drill (Ø2.0 mm).

Option 1 - Determine the screw length using the drill bit and guide gauge.

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



9. Using the grey screwdriver, insert and lock the non-anodized Ø2.8 mm locking screws.



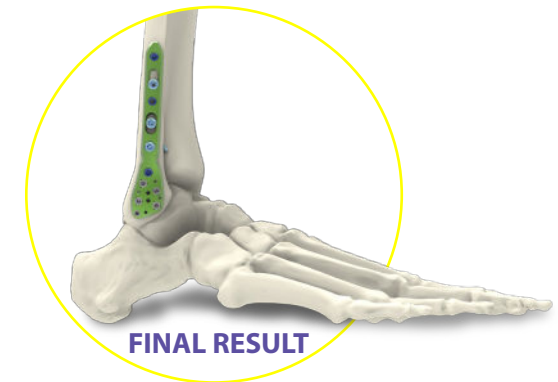
10. Using the blue Ø2.7 mm threaded guide gauge, drill (Ø2.7 mm).

Option 1 - Determine the screw length using the drill bit and guide gauge.

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



11. Using the countersink part of the blue 2-in-1 instrument, widen the first cortex previously drilled. Insert a blue Ø3.5 mm locking 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.

⚠ The final tightening of the screws must be performed by hand.

References: Initial A - Fibula kits



INITIAL A™ - FIBULA KITS

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

INITIAL A™ - FIBULA KIT - INSTRUMENTATION CONTENT

Description
Ø2.0 mm quick coupling drill bit - L 125 mm
Ø2.7 mm quick coupling drill bit - L 125 mm
Ø2.0 mm threaded guide gauge for Ø2.8 mm screws
Ø2.7 mm threaded guide gauge for Ø3.5 mm screws
Handle for guide gauge
Length gauge for Ø2.8 and Ø3.5 mm screws - L 10-60 mm
2.0 mm hexagonal prehensor screwdriver
2 in 1 : 2.5 mm hexagonal prehensor screwdriver - Ø3.5 mm countersink
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

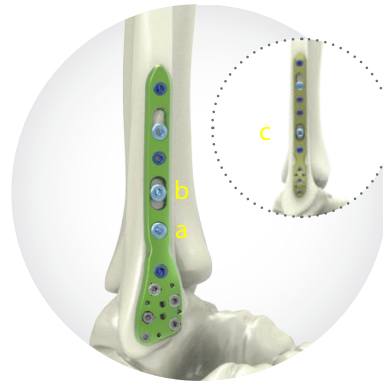
	Ref.	Description	QUANTITY PER KIT				
			KIT-AL1D or KIT-AL1G	KIT-AL2D or KIT-AL2G	KIT-AL3D or KIT-AL3G	KIT-AL1S	KIT-AL2S
STANDARD PLATES	RTDLS1 or RTGLS1	Lateral plate - Distal fibula - Standard - Right or left - Size 1	1	-	-	-	-
	RTDLS2 or RTGLS2	Lateral plate - Distal fibula - Standard - Right or left - Size 2	-	1	-	-	-
	RTDLS3 or RTGLS3	Lateral plate - Distal fibula - Standard - Right or left - Size 3	-	-	1	-	-
NARROW PLATES	RTSLN1	Lateral plate - Distal fibula - Narrow - Symmetrical - Size 1	-	-	-	1	-
	RTSLN2	Lateral plate - Distal fibula - Narrow - Symmetrical - Size 2	-	-	-	-	1
LOCKING SCREWS Ø2.8 MM	SDT2.8L10	Ø2.8 mm locking screw - L10 mm	1	1	1	-	-
	SDT2.8L12	Ø2.8 mm locking screw - L12 mm	1	1	1	-	-
	SDT2.8L14	Ø2.8 mm locking screw - L14 mm	2	2	2	1	1
	SDT2.8L16	Ø2.8 mm locking screw - L16 mm	2	2	2	2	2
	SDT2.8L18	Ø2.8 mm locking screw - L18 mm	2	2	2	1	1
LOCKING SCREWS Ø3.5 MM	SOT3.5L12	Ø3.5 mm locking screw - L12 mm	1	2	3	2	2
	SOT3.5L14	Ø3.5 mm locking screw - L14 mm	1	2	2	2	2
	SOT3.5L16	Ø3.5 mm locking screw - L16 mm	1	1	1	1	2
	SOT3.5L18	Ø3.5 mm locking screw - L18 mm	1	1	1	-	-
NON-LOCKING SCREWS Ø3.5 MM	CT3.5L12	Ø3.5 mm non-locking screw - L12 mm	-	1	1	-	1
	CT3.5L14	Ø3.5 mm non-locking screw - L14 mm	1	1	2	1	1
	CT3.5L16	Ø3.5 mm non-locking screw - L16 mm	1	1	1	1	1
	CT3.5L18	Ø3.5 mm non-locking screw - L18 mm	-	1	1	-	-
	CT3.5L20	Ø3.5 mm non-locking screw - L20 mm	1	-	-	-	-
	CT3.5L22	Ø3.5 mm non-locking screw - L22 mm	-	1	1	1	1
	CT3.5L24	Ø3.5 mm non-locking screw - L24 mm	1	-	-	-	-

Surgical technique: Initial A - Syndesmosis kit

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

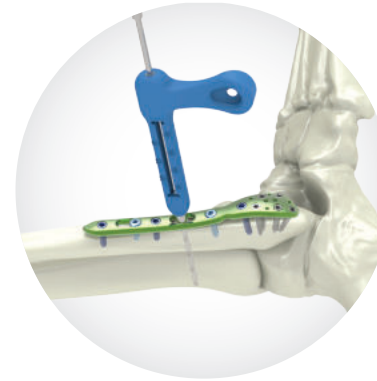
(Same technique for all standard and narrow plates)

 The final tightening of the screws must be performed by hand.



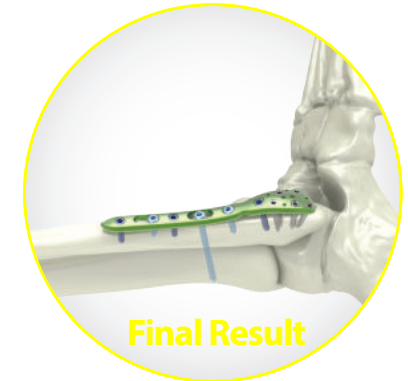
1. The syndesmosic screw can be inserted in the following holes:

- 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



INITIAL A™ - SYNDESMOSIS KIT

Ref.	Description
KIT-AMS	Instrumentation kit for syndesmosis & Ø4.0 mm lag screws + washers

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*

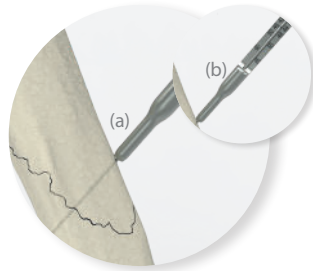
Ref.	Description	Qty
CT3.5L40-ST	Ø3.5 mm non-locking screw - L40 mm - STERILE	2
CT3.5L45-ST	Ø3.5 mm non-locking screw - L45 mm - STERILE	3
CT3.5L50-ST	Ø3.5 mm non-locking screw - L50 mm - STERILE	3
CT3.5L55-ST	Ø3.5 mm non-locking screw - L55 mm - STERILE	3
CT3.5L60-ST	Ø3.5 mm non-locking screw - L60 mm - STERILE	2
CT3.5L65-ST	Ø3.5 mm non-locking screw - L65 mm - STERILE	2
QT4.0L40-ST	Ø4.0 mm lag screw - L40 mm - STERILE	3
QT4.0L45-ST	Ø4.0 mm lag screw - L45 mm - STERILE	3
QT4.0L50-ST	Ø4.0 mm lag screw - L50 mm - STERILE	3
QT4.0L55-ST	Ø4.0 mm lag screw - L55 mm - STERILE	3
QT4.0L60-ST	Ø4.0 mm lag screw - L60 mm - STERILE	3
QT4.0L65-ST	Ø4.0 mm lag screw - L65 mm - STERILE	3

CT3.5Lxx-ST: Light blue anodized.
QT4.0Lxx-ST: Non anodized.

Surgical technique Initial S™ - 4.0 cannulated screw for medial malleolus fractures



1. Insert the Ø1.3 mm pin to stabilize the two fragments.

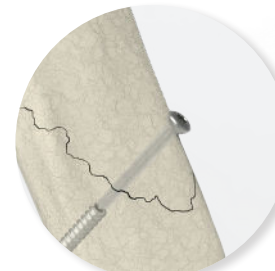


2. Slide the length gauge along the Ø1.3 mm pin until the cortex is reached (a). Determine the insertion depth using the marking on the pin (b).

NB: The pin can then be inserted deeper in order to prevent its removal during drilling.



3. Select the appropriate screw length and insert the screw along the pin using the screwdriver part of the 2-in-1 instrument until the desired reduction and compression are achieved. Then remove the pin.



FINAL RESULT



Compression washer

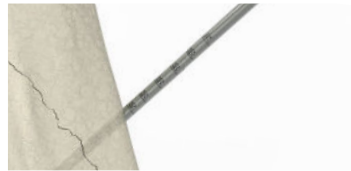


NB: In case of osteoporotic bone, it is possible to add a compression washer under the screw head before step 3.

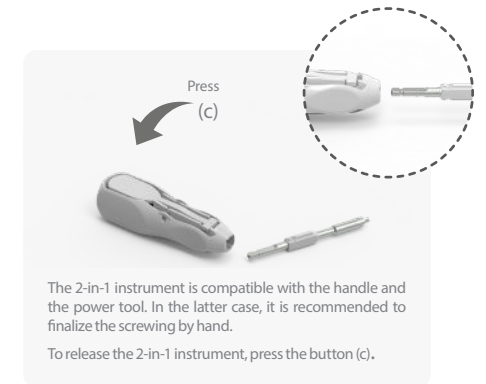
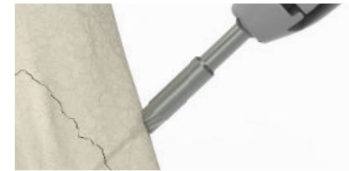
Optional steps:

These steps can be done before screwing.

1- In case of a hard bone density or several cortices, it is recommended to drill before the screw insertion. The drilling depth can be checked using the marking on the drill bit.



2- If reaming is required, widen the surface of the insertion using the countersink part of the 2-in-1 instrument.



References

STERILE INSTRUMENTATION FOR Ø4.0 MM CANNULATED SCREWS			
Kit	Description	Content	Qty
KIT-SCQ4.0	Kit for Ø4.0 mm cannulated headed screws	Length gauge for pin Ø1.3 mm - L120 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
		Washer	2
		Pin Ø1.3 L140 mm	3
		5.8 mm single use handle	1

CANNULATED HEADED SCREWS Ø4.0 MM*	
Réf.	Description
H1.4QT4.0L26-ST to H1.4QT4.0L50-ST	Ø4.0 mm compressive screw - cannulated Ø1.4 mm - short thread - Lxx mm (from 26 to 50) - 2 mm increment - STERILE
H1.4QT4.0L50-ST to H1.4QT4.0L70-ST	Ø4.0 mm compressive screw - cannulated Ø1.4 mm - short thread - Lxx mm (from 50 to 70) - 5 mm increment - STERILE

*Available separately in sterile version.

To order, use the code H1.4QT4.0Lxx-ST and replace "xx" by the desired length. Example: "H1.4QT4.0L26-ST"

References: Additional kits

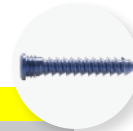
> Additional implants

Sterile screws



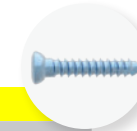
LOCKING SCREWS - Ø2.8 mm*			
Ref.	Description	Qty	
SDT2.8L10-STI	Ø2.8 mm locking screw - L10 mm - STERILE	1	
SDT2.8L12-STI	Ø2.8 mm locking screw - L12 mm - STERILE	1	
SDT2.8L14-STI	Ø2.8 mm locking screw - L14 mm - STERILE	1	
SDT2.8L16-STI	Ø2.8 mm locking screw - L16 mm - STERILE	1	
SDT2.8L18-STI	Ø2.8 mm locking screw - L18 mm - STERILE	1	
SDT2.8L20-STI	Ø2.8 mm locking screw - L20 mm - STERILE	2	
SDT2.8L22-STI	Ø2.8 mm locking screw - L22 mm - STERILE	2	
SDT2.8L24-STI	Ø2.8 mm locking screw - L24 mm - STERILE	1	

Not anodized.



LOCKING SCREWS - Ø3.5 mm*			
Ref.	Description	Qty	
SOT3.5L10-ST	Ø3.5 mm locking screw - L10 mm - STERILE	2	
SOT3.5L12-ST	Ø3.5 mm locking screw - L12 mm - STERILE	1	
SOT3.5L14-ST	Ø3.5 mm locking screw - L14 mm - STERILE	1	
SOT3.5L16-ST	Ø3.5 mm locking screw - L16 mm - STERILE	1	
SOT3.5L18-ST	Ø3.5 mm locking screw - L18 mm - STERILE	2	
SOT3.5L20-ST	Ø3.5 mm locking screw - L20 mm - STERILE	2	
SOT3.5L22-ST	Ø3.5 mm locking screw - L22 mm - STERILE	2	
SOT3.5L24-ST	Ø3.5 mm locking screw - L24 mm - STERILE	2	

Blue anodized.



NON-LOCKING SCREWS - Ø3.5 mm*			
Ref.	Description	Qty	
CT3.5L10-ST	Ø3.5 mm non-locking screw - L10 mm - STERILE	2	
CT3.5L12-ST	Ø3.5 mm non-locking screw - L12 mm - STERILE	1	
CT3.5L14-ST	Ø3.5 mm non-locking screw - L14 mm - STERILE	1	
CT3.5L16-ST	Ø3.5 mm non-locking screw - L16 mm - STERILE	1	
CT3.5L18-ST	Ø3.5 mm non-locking screw - L18 mm - STERILE	1	
CT3.5L20-ST	Ø3.5 mm non-locking screw - L20 mm - STERILE	2	
CT3.5L22-ST	Ø3.5 mm non-locking screw - L22 mm - STERILE	2	
CT3.5L24-ST	Ø3.5 mm non-locking screw - L24 mm - STERILE	2	

Light blue anodized.



Also available on demand

Longer non-locking screws (26 to 38 mm long) are available on demand.

To order, use the code CT3.5Lxx-ST and replace "xx" by the desired length. Example: "CT3.5L30-ST"

> Removal and rescue kits

Sterile instruments

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

RESCUE KITS		
Ref.	Description	Content
KIT-RESCUE-2*	Rescue kit for Ø2.8 mm screws - Initial C & Initial A	• 1x Ø2.0 mm quick coupling drill bit - L 125 mm • 1x Ø2.0 mm threaded guide gauge for Ø2.8 mm screws
KIT-RESCUE-7	Rescue kit for Ø3.5 mm screws - Initial A	• 1x Ø2.7 mm quick coupling drill bit - L 125 mm • 1x Ø2.7 mm threaded guide gauge for Ø3.5 mm screws • 1x Handle for guide gauge • 1x Length gauge for Ø2.8 and Ø3.5 mm screws - L 10-60 mm • 2x Pins - Ø1.4 L120 mm

*WARNING: When using a drill or locking guide gauge from a rescue kit, only use it in combination with the instruments of the same rescue kit to guarantee an accurate measure.

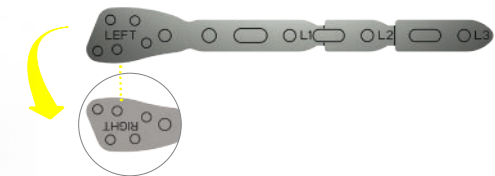


Supplemental instrumentation kits

> Templates

Sterile templates

INITIAL A™ TEMPLATES			
Ref.	Description	Qty	
ANC607	Template for distal fibula kit - Lateral Standard - Left & Right - Sizes 1-2-3 (KIT-ALxG/ALxD)	1	
ANC659	Template for distal fibula kit - Lateral Narrow - Symmetrical - Sizes 1-2 (KIT-ALxS)	1	



This information is intended to demonstrate the Newclip Technics portfolio of medical devices. Always refer to the package insert, product label and/or user instructions before using any Newclip Technics product. These products must be handled and/or implanted by trained and qualified staff who have read the instructions before use. A surgeon must always rely on her or his own professional clinical judgement when deciding whether to use a particular product when treating a particular patient. 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.



Implants material: Titanium TA6V - ISO 5832-3 / ASTM F136 - Non contractual pictures
Degree of accuracy for devices with a measuring function : $\pm 1,0$ mm

NEWCLIP TECHNICS (HQ)
PA de la Lande Saint Martin
45 rue des Garottières
44115 Haute-Goulaine, France
+33 (0)2 28 21 23 25
orders@newcliptechnics.com
www.newcliptechnics.com

NEWCLIP TECHNICS IBERIA
Calle Frederic Mompou, 4b
Sant Just Desvern
08960 Barcelona, España
+34 938 299 526
contact@newclipiberia.com
www.newcliptechnics.com

NEWCLIP TECHNICS USA
Newclip USA
642 Larkfield Center
Santa Rosa CA 95403, USA
+1 707 230 5078
customerservice@newclipusa.com
www.newclipusa.com

NEWCLIP TECHNICS GERMANY
Newclip GmbH
Pröllstraße 11, D-86157 Augsburg,
Deutschland
+49 (0)821 650 749 40
info@newclipgmbh.com
www.newclipgmbh.de

NEWCLIP TECHNICS JAPAN
Newclip Technics Japan K.K.
KKK Bldg. 502, 3-18-1 Asakusabashi
Taito-Ku, Tokyo, 111-0053, Japan
+81 (0)3 58 25 49 81
www.newcliptechnics.com

NEWCLIP TECHNICS AUSTRALIA
Newclip Australia
3B/11 Donkin Street
West End 4101, Australia
+61 (0)2 81 886 110
solutions@newclipaustralia.com
www.newcliptechnics.com

