SINGLE USE KIT STERILE R

NEWCLIP-TECHNICS

INITIAL™

Clavicle

With a non sterile
standard kit

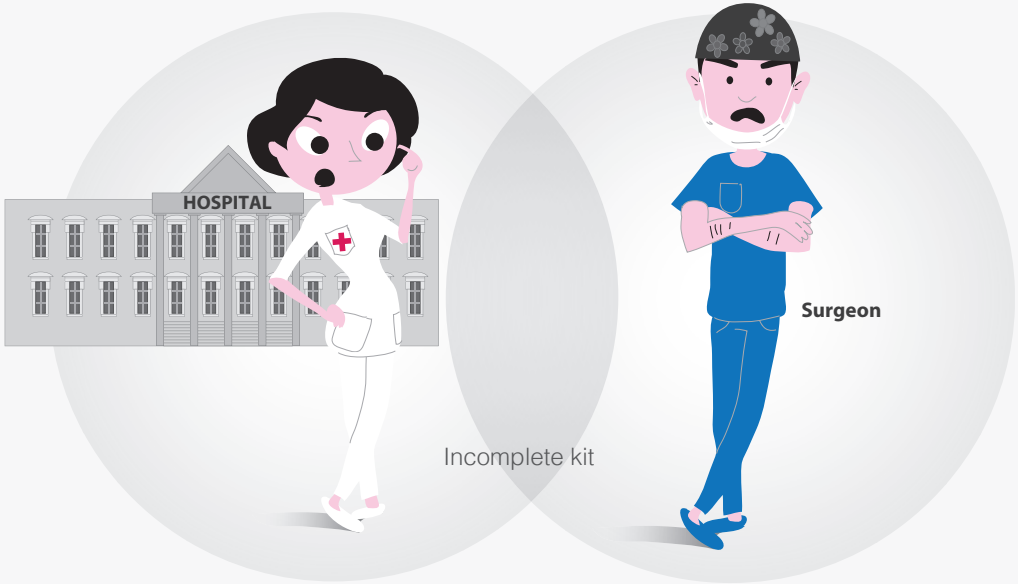
Calling on medical staff

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

URGENT SURGICAL CASES COMPROMISED

Defective sterilization + Incomplete kit + Damaged instrumentation = **INCREASED RISKS** / **NON OPTIMIZED surgery**

With the INITIAL™ kit

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

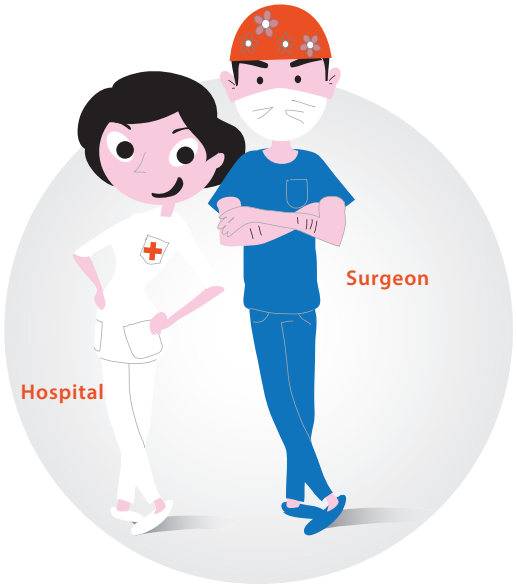
Cost efficiency

Controlled stocks
Simplified control

- 0 Cleaning
- 0 Decontamination
- 0 Sterilization

Sundry expenses

Optimized storage



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 C™ 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.

Available when needed:

The Initial C™ kit comes pre-sterilized and ready to use.
The combination of sterile implants and single use instrumentation in a single packaging makes Initial C™ ideal for use in urgent surgical cases.

INITIAL™ innovation

Storage:

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

Costs:

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

Initial C™ kits
Technical features

The Initial C range is part of the Alians Clavicle range.

Indications for use

The implants of the Alians Clavicle range are dedicated to the fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle in adults.

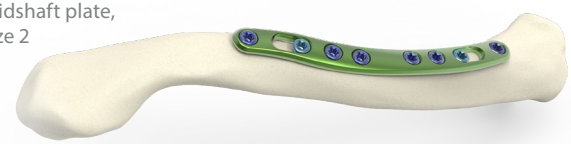
Contraindications

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

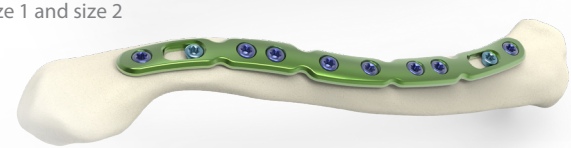
A comprehensive range of plates

Plates dedicated to the midshaft part of the clavicle

> Midshaft plate, size 2

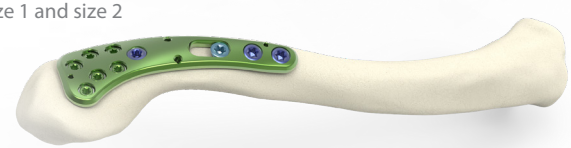


> Bendable midshaft plate, size 1 and size 2

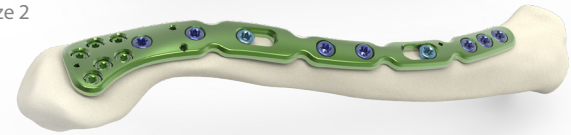


Plates dedicated to the lateral part of clavicle

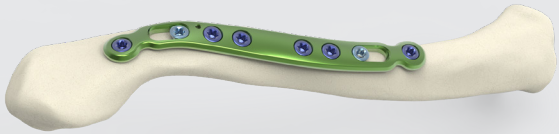
> Lateral plate, size 1 and size 2



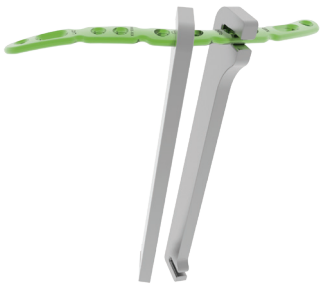
> Lateral bendable plate, size 2



Midshaft lateral plate



The midshaft lateral plate (size 1 and size 2) is an additional solution for the treatment of middle-third clavicle fractures, positioned at the level of the coracoclaviclar ligament.



Precontoured implant

Optimized anatomical congruence

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

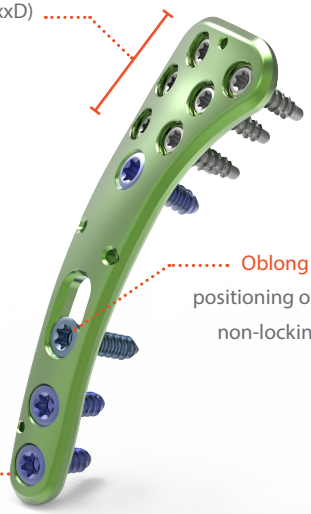
▶ BENDABLE PLATES

Bendable plates offer bendable areas which allow an optimized adjusting of the plate with 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 of the fixation.

Initial C™ kits
Technical features

> Fixations and screws

Polyaxial holes: Ø2.8 mm locking screws (SDT2.8LxxD)

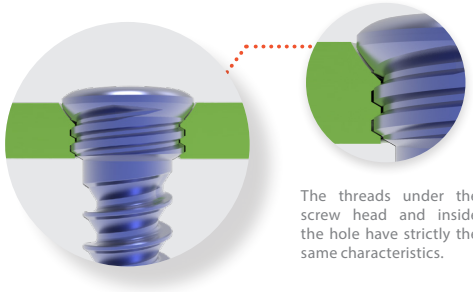


Oblong hole to facilitate the positioning of the plate: Ø3.5 mm non-locking screw (CT3.5LxxD)

Monoaxial holes:
A versatile fixation system which offers one type of hole for two types of screws:
> Ø3.5 mm non-locking screw (CT3.5xxD),
> Ø3.5 mm locking screw (SOT3.5LxxD).

Hexalobe screw socket design.

> Monoaxial locking system



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

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

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

The DTS3 technology ensures the locking of the screw into the plate while allowing its angulation. The DTS3 polyaxial locking holes are located in the epiphyseal area. This system helps for the insertion of the screws in diverging or converging directions.

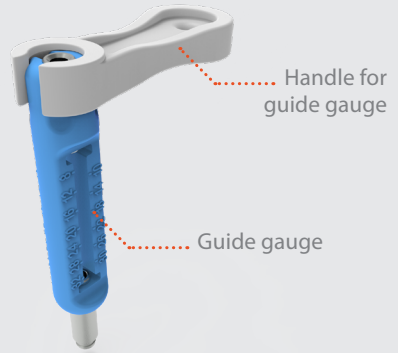
Dualtec System® III Technology
Polyaxial locking fixation

Initial C™ kits
Surgical technique

Example: surgical technique with a lateral midshaft plate (KIT-CML2D-US)

Handle for guide gauge

Before performing the drilling into the oblong hole, snap the handle for guide gauge on the desired guide gauge.

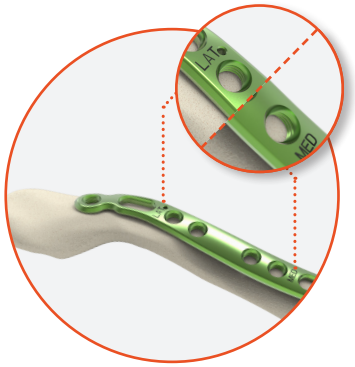


Initial C™ kits

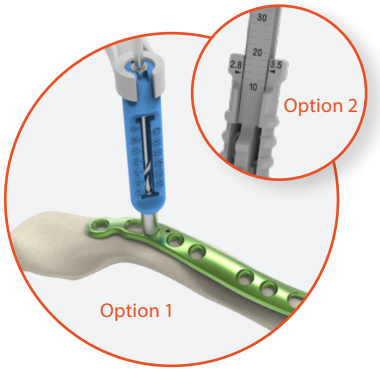
Surgical technique

Example: surgical technique with a lateral midshaft plate (KIT-CML2D-US)
Applicable for all kits with Ø3.5 mm screws only (midshaft and lateral midshaft)

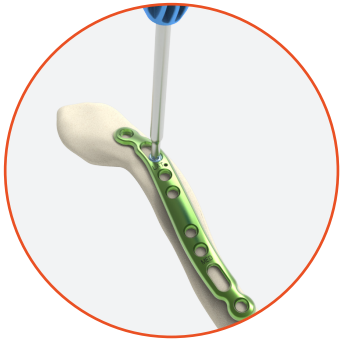
1. Using the midshaft and midshaft lateral templates (ANC838), define the suitable plate, then determine the appropriate kit.



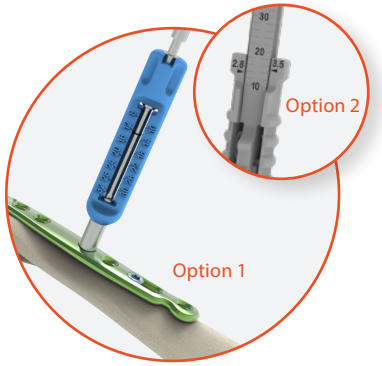
2. Position the plate using the 'LAT' and 'MED' marks.



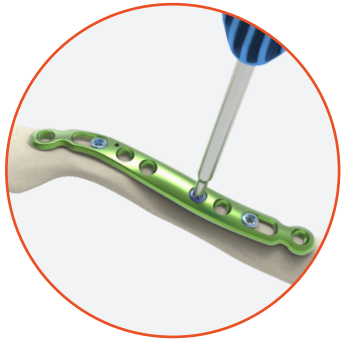
3. Snap the handle for guide gauge and perform the drilling using Ø2.7 mm threaded guide gauge into the lateral oblong hole.
Option 1: Determine the screw length using the drill bit and guide gauge.
Option 2: Determine the screw length using the length gauge, by reading the drilling depth indicated by the «3.5» arrow.



4. Then insert the Ø3.5 mm light blue non-locking screw using the T15 screwdriver. Repeat the same procedure for the medial oblong hole.



5. Insert the Ø2.7 mm threaded guide gauge starting from the holes located near the fracture to those located at each end of the plate 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, by reading the drilling depth indicated by the '3.5' arrow.



6. Insert the Ø3.5 mm blue locking screw using the T15 screwdriver.

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

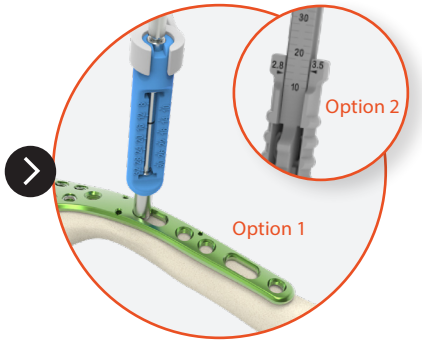
Initial C™ kits

Surgical technique

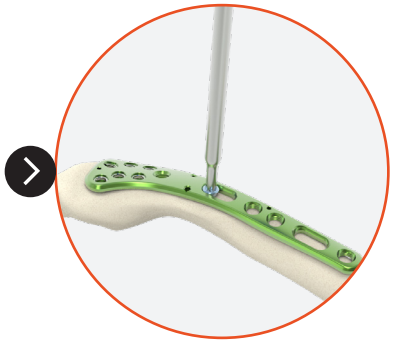
Example: surgical technique
with a lateral plate (KIT-CL2D)

Applicable for all kits with Ø2.8
and Ø3.5 mm screws (lateral plates)

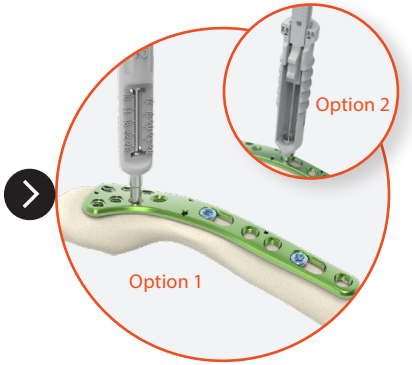
1. Using the lateral templates (ANC839), define the suitable plate, then determine the appropriate kit.



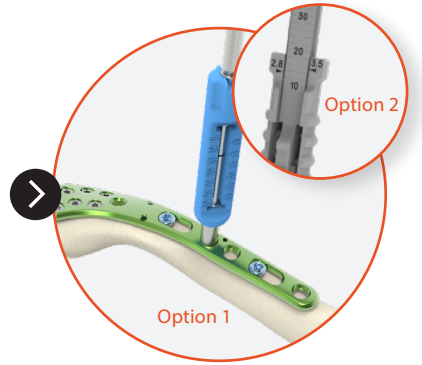
2. Snap the handle for guide gauge and perform the drilling using the Ø2.7 mm threaded guide gauge (blue) into the lateral oblong hole.
Option 1: Determine the screw length using the drill bit and guide gauge.
Option 2: Determine the screw length using the length gauge, by reading the drilling depth indicated by the «3.5» arrow.



3. Insert the Ø3.5 mm light blue non-locking screw using the T15 screwdriver (blue). Repeat the same procedure for the medial oblong hole.

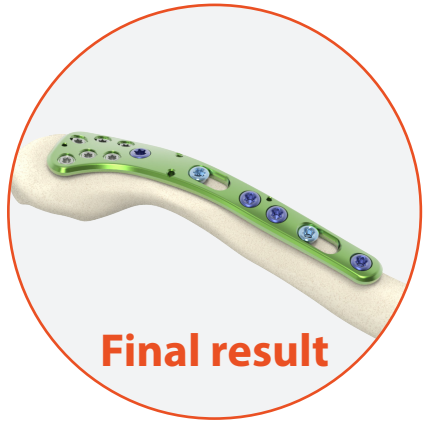


4. Insert the Ø2.0 mm threaded guide gauge (grey) into
one of the polyaxial lateral hole. Then angulate as required and perform the drilling (Ø2.0 mm).
Option 1: Determine the screw length using the drill bit and guide gauge.
Option 2: Determine the screw length using the length gauge, by reading the drilling depth indicated by the '2.8' arrow.



5. Insert a Ø2.8 mm non anodized screw using the T8 screwdriver (grey).
Repeat steps 4 & 5 for the remaining Ø2.8 mm lateral polyaxial holes.

Insert the Ø2.7 mm threaded guide gauge (blue) and perform the drilling (Ø2.7 mm) in the Ø3.5 mm holes.
Option 1: Determine the screw length using the drill bit and guide gauge.
Option 2: Determine the screw length using the length gauge, by reading the drilling depth indicated by the '3.5' arrow.
Insert a Ø3.5 mm blue locking screw using the T15 screwdriver (blue).



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

Initial C™ kits - References

Midshaft and lateral midshaft clavicle kits content

INITIAL C™ KITS - MIDSHAFT PLATES AND LATERAL MIDSHAFT PLATES	
Ref.	Description
KIT-CM2D	Clavicle kit - Superior - Midshaft - Size 2 - Right
KIT-CM2G	Clavicle kit - Superior - Midshaft - Size 2 - Left
KIT-CML1D	Clavicle kit - Superior - Lateral midshaft - Size 1 - Right
KIT-CML1G	Clavicle kit - Superior - Lateral midshaft - Size 1 - Left
KIT-CML2D-US	Clavicle kit - Superior - Lateral midshaft - Size 2 - Right
KIT-CML2G-US	Clavicle kit - Superior - Lateral midshaft - Size 2 - Left

INITIAL C™ KITS - BENDABLE PLATES	
Ref.	Description
KIT-CBM1D	Clavicle kit - Superior - Midshaft bendable - Size 1 - Right
KIT-CBM1G	Clavicle kit - Superior - Midshaft bendable - Size 1 - Left
KIT-CBM2D	Clavicle kit - Superior - Midshaft bendable - Size 2 - Right
KIT-CBM2G	Clavicle kit - Superior - Midshaft bendable - Size2 - Left

INITIAL C™ KITS CONTENT - INSTRUMENTS			
Description	KIT-CMxD/G	KIT-CMLxD/G	KIT-CBMxD/G
T15 prehensor screwdriver	1	1	1
Ø2.7 mm threaded guide gauge for Ø3.5 mm screws	1	1	1
Ø2.7 mm quick coupling drill bit - L 110 mm	1	1	1
Handle for guide gauge	1	1	1
Length gauge for Ø2.8 and Ø3.5 mm screws	1	1	1
Pin Ø1.2 L120 mm	1	1	1

INITIAL C™ KITS CONTENT - IMPLANTS			QUANTITY PER KIT				
	Ref.	Description	KIT-CM2D/G	KIT-CML1D/G	KIT-CML2D/G-US	KIT-CBM1D/G	KIT-CBM2D/G
PLATES	CTDM2D or CTGM2D	Midshaft clavicle plate - Superior - Size 2 - Right or Left	1	-	-	-	-
	CTDML1D or CTGML1D	Lateral midshaft clavicle plate - Superior - Size 1 - Right or Left	-	1	-	-	-
	CTDML2D or CTGML2D	Lateral midshaft clavicle plate - Superior - Size 2 - Right or Left	-	-	1	-	-
	CBTDM1D or CBTGM1D	Midshaft bendable clavicle plate - Superior - Size 1 - Right or Left	-	-	-	1	-
	CBTDM2D or CBTGM2D	Midshaft bendable clavicle plate - Superior - Size 2 - Right or Left	-	-	-	-	1
NON-LOCKING SCREWS Ø3.5 MM	CT3.5L12D	Ø3.5 mm non-locking screw - L12 mm	-	1	2	1	1
	CT3.5L14D	Ø3.5 mm non-locking screw - L14 mm	2	1	4	1	1
	CT3.5L16D	Ø3.5 mm non-locking screw - L16 mm	2	1	3	1	1
	CT3.5L18D	Ø3.5 mm non-locking screw - L18 mm	-	1	-	1	1
LOCKING SCREWS Ø3.5 MM	SOT3.5L12D	Ø3.5 mm locking screw - L12 mm	1	1	-	1	2
	SOT3.5L14D	Ø3.5 mm locking screw - L14 mm	3	2	2	2	4
	SOT3.5L16D	Ø3.5 mm locking screw - L16 mm	3	2	2	2	3
	SOT3.5L18D	Ø3.5 mm locking screw - L18 mm	1	1	-	1	2

Initial C™ kits - References

Lateral clavicle kits content

INITIAL C ™ KITS - LATERAL PLATES	
Ref.	Description
KIT-CL1D	Clavicle kit - Superior - Lateral - Size 1 - Right
KIT-CL1G	Clavicle kit - Superior - Lateral - Size 1 - Left
KIT-CL2D	Clavicle kit - Superior - Lateral - Size 2 - Right
KIT-CL2G	Clavicle kit - Superior - Lateral - Size 2 - Left
KIT-CBL2D	Clavicle kit - Superior - Lateral bendable - Size 2 - Right
KIT-CBL2G	Clavicle kit - Superior - Lateral bendable - Size 2 - Left

INITIAL C™ KITS CONTENT - INSTRUMENTS		
Description	KIT-CLxD/G	KIT-CBL2D/G
T15 prehensor screwdriver	1	1
Ø2.7 mm threaded guide gauge for Ø3.5 mm screws	1	1
Ø2.7 mm quick coupling drill bit - L 110 mm	1	1
Handle for guide gauge	1	1
Length gauge for Ø2.8 and Ø3.5 mm screws	1	1
Pin Ø1.2 L120 mm	3	3
T8 prehensor screwdriver	1	1
Ø2.0 mm threaded guide gauge for Ø2.8 mm screws	1	1
Ø2.0 mm quick coupling drill bit - L 125 mm	1	1

INITIAL C™ - CLAVICLE KITS CONTENT - IMPLANTS			QUANTITY PER KIT		
	Ref.	Description	KIT-CL1D/G	KIT-CL2D/G	KIT-CBL2D/G
PLATES	CTDL1D or CTGL1D	Lateral clavicle plate - Superior - Size 1 - Right or Left	1	-	-
	CTDL2D or CTGL2D	Lateral clavicle plate - Superior - Size 2 - Right or Left	-	1	-
	CBTDL2D or CBTGL2D	Lateral bendable clavicle plate - Superior - Size 2 - Right or Left	-	-	1
LOCKING SCREWS Ø2.8 MM	SDT2.8L10D	Ø2.8 mm locking screw - L10 mm	1	1	1
	SDT2.8L12D	Ø2.8 mm locking screw - L12 mm	2	2	2
	SDT2.8L14D	Ø2.8 mm locking screw - L14 mm	2	2	2
	SDT2.8L16D	Ø2.8 mm locking screw - L16 mm	2	2	2
	SDT2.8L18D	Ø2.8 mm locking screw - L18 mm	1	1	1
NON-LOCKING SCREWS Ø3.5 MM	CT3.5L12D	Ø3.5 mm non-locking screw - L12 mm	1	1	1
	CT3.5L14D	Ø3.5 mm non-locking screw - L14 mm	1	1	1
	CT3.5L16D	Ø3.5 mm non-locking screw - L16 mm	1	1	1
	CT3.5L18D	Ø3.5 mm non-locking screw - L18 mm	-	1	1
LOCKING SCREWS Ø3.5 MM	SOT3.5L12D	Ø3.5 mm locking screw - L12 mm	1	1	1
	SOT3.5L14D	Ø3.5 mm locking screw - L14 mm	2	2	2
	SOT3.5L16D	Ø3.5 mm locking screw - L16 mm	1	2	2
	SOT3.5L18D	Ø3.5 mm locking screw - L18 mm	1	1	3

Initial C™ - References

Additional kits

Additional implants

Sterile screws packaged in the supplemental sterile screw caddy

LOCKING SCREWS - Ø2.8 mm*		
Ref.	Description	Qty
SDT2.8L10D-ST	Ø2.8 mm locking screw - L10 mm - STERILE	2
SDT2.8L12D-ST	Ø2.8 mm locking screw - L12 mm - STERILE	2
SDT2.8L14D-ST	Ø2.8 mm locking screw - L14 mm - STERILE	2
SDT2.8L16D-ST	Ø2.8 mm locking screw - L16 mm - STERILE	2
SDT2.8L18D-ST	Ø2.8 mm locking screw - L18 mm - STERILE	2
SDT2.8L20D-ST	Ø2.8 mm locking screw - L20 mm - STERILE	1
SDT2.8L22D-ST	Ø2.8 mm locking screw - L22 mm - STERILE	1
SDT2.8L24D-ST	Ø2.8 mm locking screw - L24 mm - STERILE	1

*Not anodized.

LOCKING SCREWS - Ø3.5 mm*		
Ref.	Description	Qty
SOT3.5L10D-ST	Ø3.5 mm locking screw - L10 mm - STERILE	1
SOT3.5L12D-ST	Ø3.5 mm locking screw - L12 mm - STERILE	1
SOT3.5L14D-ST	Ø3.5 mm locking screw - L14 mm - STERILE	1
SOT3.5L16D-ST	Ø3.5 mm locking screw - L16 mm - STERILE	1
SOT3.5L18D-ST	Ø3.5 mm locking screw - L18 mm - STERILE	1
SOT3.5L20D-ST	Ø3.5 mm locking screw - L20 mm - STERILE	2
SOT3.5L22D-ST	Ø3.5 mm locking screw - L22 mm - STERILE	2
SOT3.5L24D-ST	Ø3.5 mm locking screw - L24 mm - STERILE	1

* Blue anodized.

NON-LOCKING SCREWS – Ø3.5 mm*		
Ref.	Description	Qty
CT3.5L10D-ST	Ø3.5 mm non-locking screw - L10 mm - STERILE	1
CT3.5L12D-ST	Ø3.5 mm non-locking screw - L12 mm - STERILE	1
CT3.5L14D-ST	Ø3.5 mm non-locking screw - L14 mm - STERILE	1
CT3.5L16D-ST	Ø3.5 mm non-locking screw - L16 mm - STERILE	1
CT3.5L18D-ST	Ø3.5 mm non-locking screw - L18 mm - STERILE	1
CT3.5L20D-ST	Ø3.5 mm non-locking screw - L20 mm - STERILE	2
CT3.5L22D-ST	Ø3.5 mm non-locking screw - L22 mm - STERILE	2
CT3.5L24D-ST	Ø3.5 mm non-locking screw - L24 mm - STERILE	2
CT3.5L26D-ST	Ø3.5 mm non-locking screw - L26 mm - STERILE	1

* Light blue anodized.

Removal kits

Sterile instruments

REMOVAL KITS		
Ref.	Description	Content
KIT-REMOVE-2	Removal kit for T8 hexalobe	T8 prehensor screwdriver
KIT-REMOVE-3	Removal kit for T15 hexalobe	T15 prehensor screwdriver

Rescue kits

Sterile instruments

RESCUE KITS		
Ref.	Description	Content
KIT-RESCUE-2	Rescue kit for Ø2.8 mm screws - Initial C & Initial A	- Ø2.0 mm threaded guide gauge for Ø2.8 mm screws - Ø2.0 mm quick coupling drill bit - L 125 mm
KIT-RESCUE-3	Rescue kit for Ø3.5 mm screws - Initial C	- Ø2.7 mm threaded guide gauge for Ø3.5 mm screws - Ø2.7 mm quick coupling drill bit - L 110 mm - Handle for guide gauge - Length gauge for Ø2.8 and Ø3.5 mm screws - L 10-32 mm - Pin Ø1.2 L120 mm (x3)

Templates

INITIAL C™ TEMPLATES PLATE		
Ref.	Description	Qty
ANC838	Templates for clavicle kit - Superior - Midshaft & Lateral midshaft - Sizes 1-2 - Left & Right (KIT-CMxx/CMLxx)	1
ANC839	Templates for clavicle kit - Superior - Lateral - Sizes 1-2 - Left & Right (KIT-CLxx)	1

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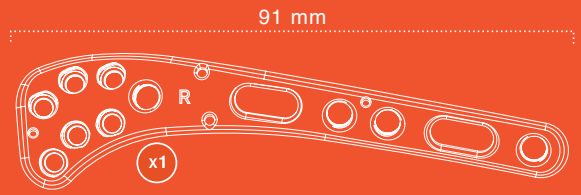
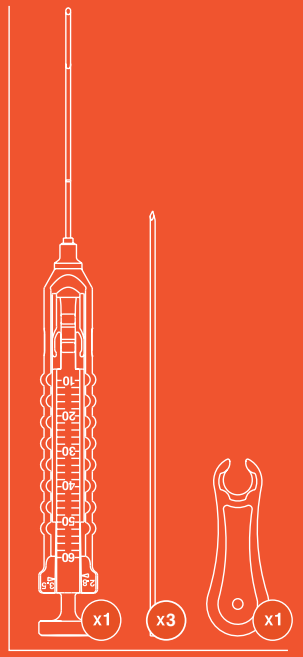
KIT-CL2D

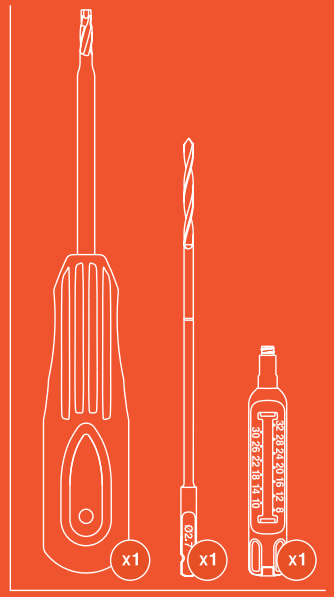
Right Superior Clavicle
Lateral
Size 2



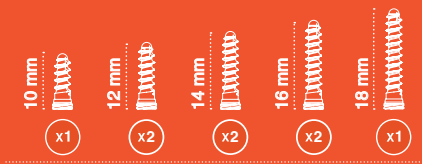
Ø2.8 mm screws



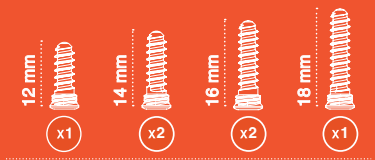
Ø2.8 & 3.5 mm screws



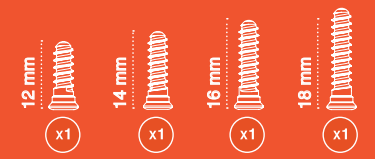
Ø3.5 mm screws



Locking screws ø2.8 mm



Locking screws ø3.5 mm



Non-locking screws ø3.5 mm

NEWCLIP TECHNICS
45 rue des Garottières
44115 Haute-Goulaine, France
Tél. : +33 (0)2 28 21 37 12
Fax : +33 (0)2 40 63 68 37
www.newcliptechnics.com

Example of kit content.

Implants material: Titanium TA6V - ISO 5832-3 / ASTM F136 Non contractual pictures.
Degree of accuracy for devices with a measuring function : ± 1.0 mm

Non contractual pictures.