SINGLE USE KIT STERILE R

NEWCLIP-TECHNICS

INITIAL™

Clavicle

With a non sterile
standard kit

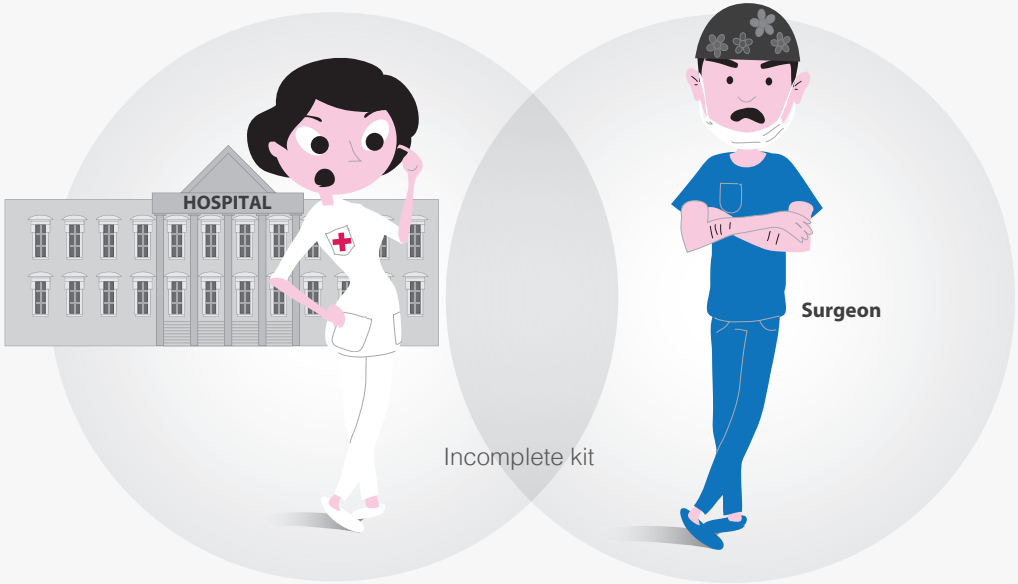
Calling on medical staff

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 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 OPTIMIZED surgery**

With the INITIAL™ kit

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

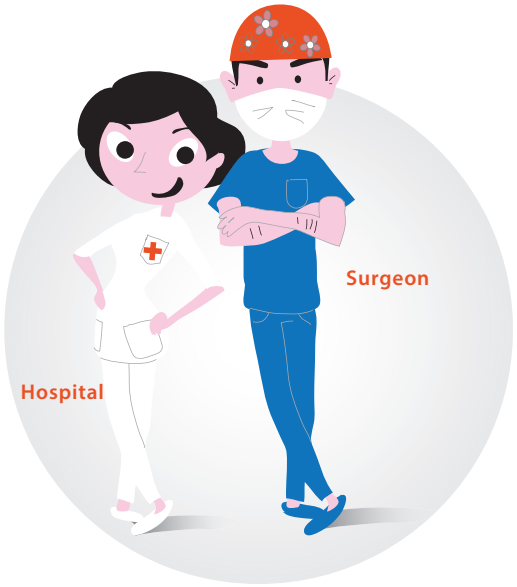
Cost efficiency

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

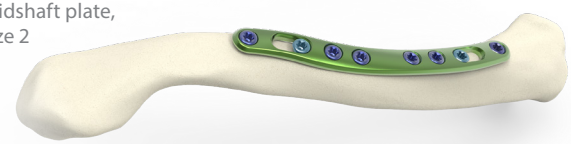
Indications
The implants of the Initial C™ range are dedicated to the fixation of fractures, mal-unions, non-unions, and osteotomies of the clavicle in adults.

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 implant into the bone.
- Muscular deficit, neurological deficiency or behavioural disorders which could submit the osteosynthesis 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.

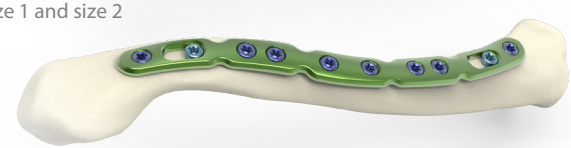
A comprehensive range of plates

Plates dedicated to the midshaft part of the clavicle

> Midshaft plate, size 2

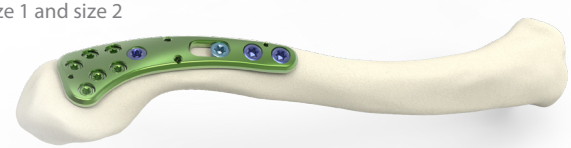


> Bendable midshaft plate, size 1 and size 2

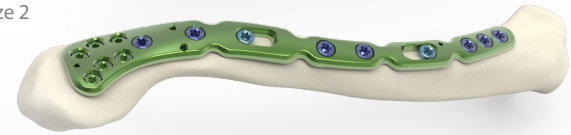


Plates dedicated to the lateral part of clavicle

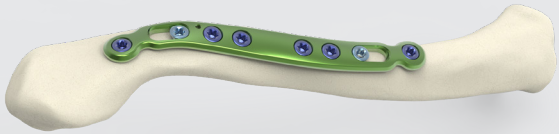
> Lateral plate, size 1 and size 2



> Lateral bendable plate, size 2



Midshaft lateral plate

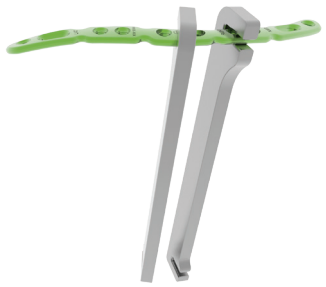


The midshaft lateral plate (size 1 and size 2) is an additional solution for the treatment of middle-third clavicle fractures, positioned at the level of the coracoclaviclar ligament.

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.



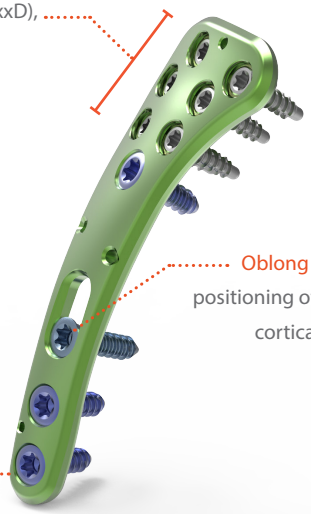
▶ BENDABLE PLATES

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

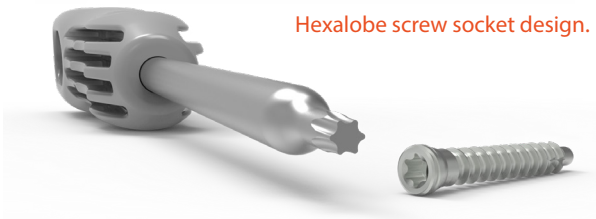
> Fixations and screws

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



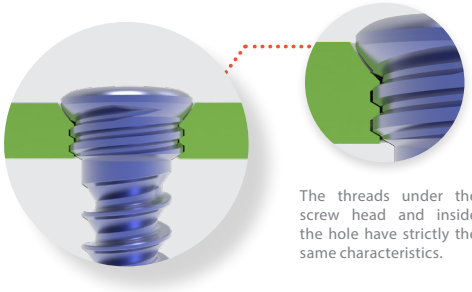
Oblong hole to facilitate the positioning of the plate: Ø3.5 mm cortical screw (CT3.5LxxD),

Monoaxial holes:
A versatile fixation system which offers one type of hole for two types of screws:
> Ø3.5 mm cortical 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 and strengthens the assembly.

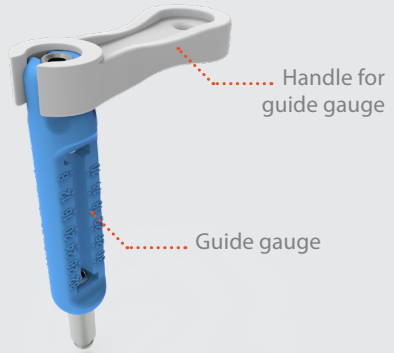
Dualtec System® III Technology
Polyaxial locking fixation

Initial C™ kits
Surgical technique

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

Handle for guide gauge

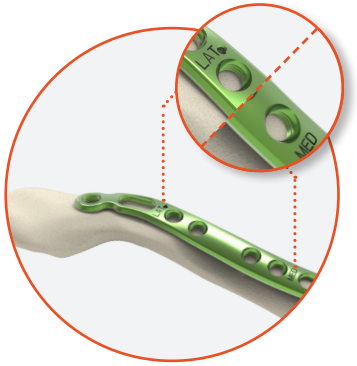
Before performing the drilling into the oblong hole, snap the handle for guide gauge on the desired guide gauge.



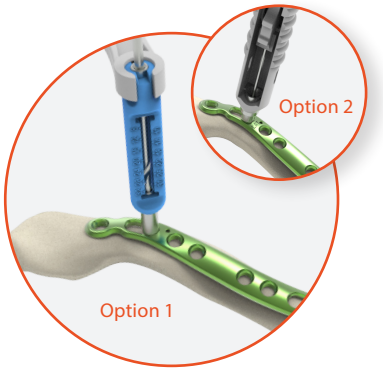
Initial C™ kits

Surgical technique

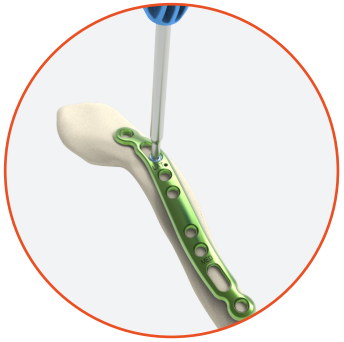
1. Using the midshaft and midshaft lateral templates (ANC838), define the suitable plate, then determine the appropriate kit.



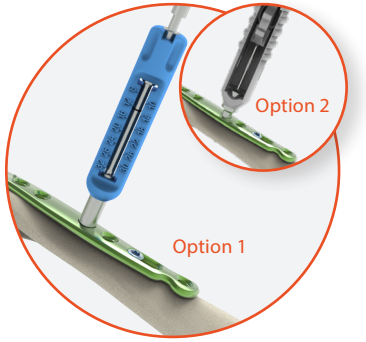
2. Position the plate using the 'LAT' and 'MED' marks.



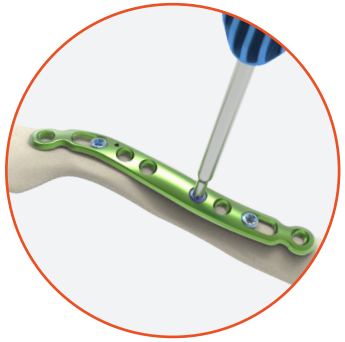
3. Snap the handle for guide gauge and perform the drilling using Ø2.7 mm threaded guide gauge into the lateral oblong hole.
Option 1: Determine the screw length using the gauge.
Option 2: Determine the screw length using the length gauge.



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



5. Using the Ø2.7 mm threaded guide gauge, drill (Ø2.7 mm).
Option 1: Determine the screw length using the gauge.
Option 2: Determine the screw length using the length gauge.



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

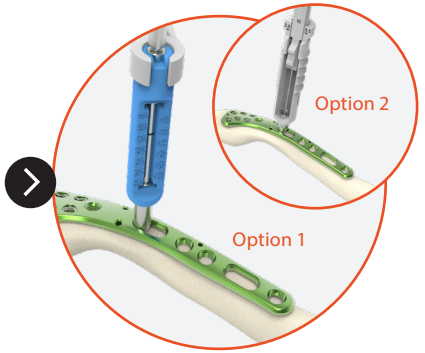
Repeat previous steps to insert the remaining Ø3.5 mm locking screws in the plate.

Initial C™ kits

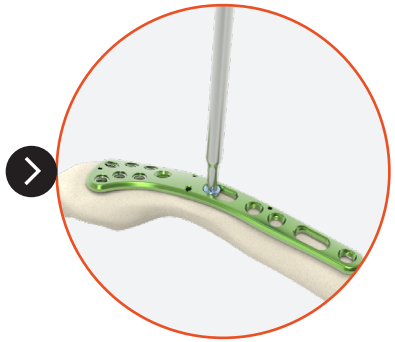
Surgical technique

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

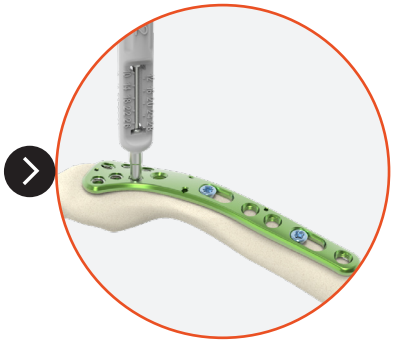
1. Using the lateral templates (ANC839), define the suitable plate, then determine the appropriate kit.



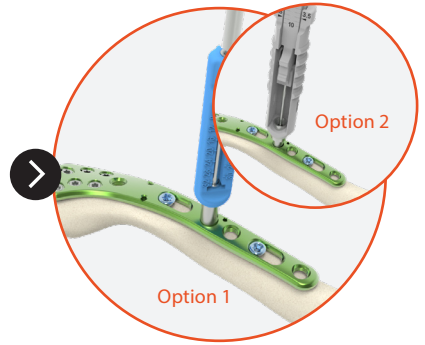
2. Snap the handle for guide gauge and perform the drilling using the Ø2.7 mm threaded guide gauge (blue) into the lateral oblong hole.
Option 1: Determine the screw length using the gauge.
Option 2: Determine the screw length using the length gauge.



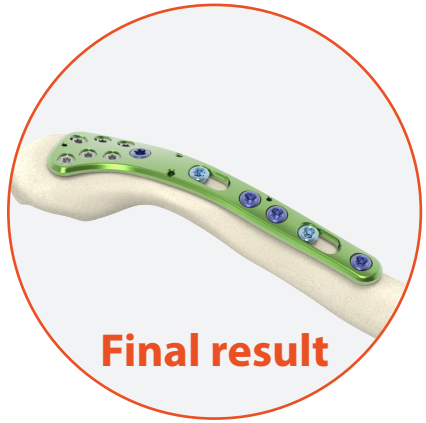
3. Insert the Ø3.5 mm light blue cortical screw using the T15 screwdriver (blue). Repeat the same procedure for the medial oblong hole.



4. 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 screws length directly on the gauge or with the length gauge.
Using the T8 screwdriver (grey), insert and lock the Ø2.8 mm non anodized screws.



5. Using the Ø2.7 mm threaded guide gauge (blue), drill (Ø2.7 mm).
Option 1: Determine the screw length using the gauge.
Option 2: Determine the screw length using the length gauge.
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 midshaft lateral clavicle kits content

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

INITIAL C™ KITS - BENDABLE PLATES	
Ref.	Description
KIT-CBM1D	Clavicle kit - Bendable - Midshaft part - Size 1- Right
KIT-CBM1G	Clavicle kit - Bendable - Midshaft part - Size 1 - Left
KIT-CBM2D	Clavicle kit - Bendable - Midshaft part - Size 2 - Right
KIT-CBM2G	Clavicle kit - Bendable - Midshaft part - Size 2 - 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	KIT-CBM1D/G	KIT-CBM2D/G
PLATES	CTDM2D or CTGM2D	Clavicle plate - Midshaft part - Size 2 - Right or Left	1	-	-	-	-
	CTDML1D or CTGML1D	Clavicle plate - Lateral midshaft part - Size 1 - Right or Left	-	1	-	-	-
	CTDML2D or CTGML2D	Clavicle plate - Lateral midshaft part - Size 2 - Right or Left	-	-	1	-	-
	CBTDM1D or CBTGM1D	Bendable clavicle plate - Midshaft part Size 1 - Right or Left	-	-	-	1	-
	CBTDM2D or CBTGM2D	Bendable clavicle plate - Midshaft part Size 2 - Right or Left	-	-	-	-	1
STANDARD CORTICAL SCREWS Ø3.5 MM	CT3.5L12D	Standard cortical screw - Ø3.5 mm - L 12 mm	-	1	-	1	1
	CT3.5L14D	Standard cortical screw - Ø3.5 mm - L 14 mm	2	1	2	1	1
	CT3.5L16D	Standard cortical screw - Ø3.5 mm - L 16 mm	2	1	2	1	1
	CT3.5L18D	Standard cortical screw - Ø3.5 mm - L 18 mm	-	1	-	1	1
LOCKING SCREWS Ø3.5 MM	SOT3.5L12D	Locking screw - Ø3.5 mm - L 12 mm	1	1	2	1	2
	SOT3.5L14D	Locking screw - Ø3.5 mm - L 14 mm	3	2	4	2	4
	SOT3.5L16D	Locking screw - Ø3.5 mm - L 16 mm	3	2	3	2	3
	SOT3.5L18D	Locking screw - Ø3.5 mm - L 18 mm	1	1	-	1	2

Initial C™ kits - References

Lateral clavicle kits content

INITIAL C ™ KITS - LATERAL PLATES	
Ref.	Description
KIT-CL1D	Clavicle kit - Lateral part - Size 1 - Right
KIT-CL1G	Clavicle kit - Lateral part - Size 1 - Left
KIT-CL2D	Clavicle kit - Lateral part - Size 2 - Right
KIT-CL2G	Clavicle kit - Lateral part - Size 2 - Left
KIT-CBL2D	Clavicle kit - Bendable - Lateral part - Size 2 - Right
KIT-CBL2G	Clavicle kit - Bendable - Lateral part - 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	Clavicle plate - Lateral part - Size 1 - Right or Left	1	-	-
	CTDL2D or CTGL2D	Clavicle plate - Lateral part - Size 2 - Right or Left	-	1	-
	CBTDL2D or CBTGL2D	Bendable clavicle plate - Lateral part - Size 2 - Right or Left	-	-	1
LOCKING SCREWS Ø2.8 MM	SDT2.8L10D	Locking screw - Ø2.8 mm - L 10 mm	1	1	1
	SDT2.8L12D	Locking screw - Ø2.8 mm - L 12 mm	2	2	2
	SDT2.8L14D	Locking screw - Ø2.8 mm - L 14 mm	2	2	2
	SDT2.8L16D	Locking screw - Ø2.8 mm - L 16 mm	2	2	2
	SDT2.8L18D	Locking screw - Ø2.8 mm - L 18 mm	1	1	1
STANDARD CORTICAL SCREWS Ø3.5 MM	CT3.5L12D	Standard cortical screw - Ø3.5 mm - L 12 mm	1	1	1
	CT3.5L14D	Standard cortical screw - Ø3.5 mm - L 14 mm	1	1	1
	CT3.5L16D	Standard cortical screw - Ø3.5 mm - L 16 mm	1	1	1
	CT3.5L18D	Standard cortical screw - Ø3.5 mm - L 18 mm	-	1	1
LOCKING SCREWS Ø3.5 MM	SOT3.5L12D	Locking screw - Ø3.5 mm - L 12 mm	1	1	1
	SOT3.5L14D	Locking screw - Ø3.5 mm - L 14 mm	2	2	2
	SOT3.5L16D	Locking screw - Ø3.5 mm - L 16 mm	1	2	2
	SOT3.5L18D	Locking screw - Ø3.5 mm - L 18 mm	1	1	3

Initial C™ - References

Additional kits

Additional implants

Sterile screws

LOCKING SCREWS - Ø2.8 mm*		
Ref.	Description	Qty
SDT2.8L10D-ST	Locking screw - Ø2.8 mm - L 10 mm - Sterile	2
SDT2.8L12D-ST	Locking screw - Ø2.8 mm - L 12 mm - Sterile	2
SDT2.8L14D-ST	Locking screw - Ø2.8 mm - L 14 mm - Sterile	2
SDT2.8L16D-ST	Locking screw - Ø2.8 mm - L 16 mm - Sterile	2
SDT2.8L18D-ST	Locking screw - Ø2.8 mm - L 18 mm - Sterile	2
SDT2.8L20D-ST	Locking screw - Ø2.8 mm - L 20 mm - Sterile	1
SDT2.8L22D-ST	Locking screw - Ø2.8 mm - L 22 mm - Sterile	1
SDT2.8L24D-ST	Locking screw - Ø2.8 mm - L 24 mm - Sterile	1

*Non anodized.

LOCKING SCREWS - Ø3.5 mm*		
Ref.	Description	Qty
SOT3.5L10D-ST	Locking screw - Ø3.5 mm - L 10 mm - Sterile	1
SOT3.5L12D-ST	Locking screw - Ø3.5 mm - L 12 mm - Sterile	1
SOT3.5L14D-ST	Locking screw - Ø3.5 mm - L 14 mm - Sterile	1
SOT3.5L16D-ST	Locking screw - Ø3.5 mm - L 16 mm - Sterile	1
SOT3.5L18D-ST	Locking screw - Ø3.5 mm - L 18 mm - Sterile	1
SOT3.5L20D-ST	Locking screw - Ø3.5 mm - L 20 mm - Sterile	2
SOT3.5L22D-ST	Locking screw - Ø3.5 mm - L 22 mm - Sterile	2
SOT3.5L24D-ST	Locking screw - Ø2.8 mm - L 24 mm - Sterile	1

* Blue anodized.

STANDARD CORTICAL SCREWS – Ø3.5 mm*		
Ref.	Description	Qty
CT3.5L10D-ST	Standard cortical screw - Ø3.5 mm - L 10 mm - Sterile	1
CT3.5L12D-ST	Standard cortical screw - Ø3.5 mm - L 12 mm - Sterile	1
CT3.5L14D-ST	Standard cortical screw - Ø3.5 mm - L 14 mm - Sterile	1
CT3.5L16D-ST	Standard cortical screw - Ø3.5 mm - L 16 mm - Sterile	1
CT3.5L18D-ST	Standard cortical screw - Ø3.5 mm - L 18 mm - Sterile	1
CT3.5L20D-ST	Standard cortical screw - Ø3.5 mm - L 20 mm - Sterile	2
CT3.5L22D-ST	Standard cortical screw - Ø3.5 mm - L 22 mm - Sterile	2
CT3.5L24D-ST	Standard cortical screw - Ø3.5 mm - L 24 mm - Sterile	2
CT3.5L26D-ST	Standard cortical screw - Ø3.5 mm - L 26 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	Initial C rescue kit for Ø2.8mm screws	- Ø2.0 mm threaded guide gauge for Ø2.8 mm screws - Ø2.0 mm quick coupling drill bit - L 125 mm
KIT-RESCUE-3	Initial C rescue kit for Ø3.5mm screws	- 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)

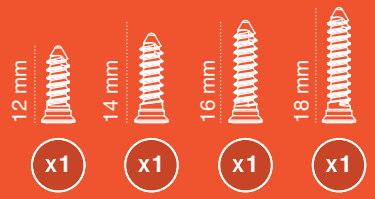
Templates

INITIAL C™ TEMPLATES PLATE		
Ref.	Description	Qty
ANC838	Midshaft and midshaft lateral clavicle plates templates	1
ANC839	Lateral clavicle plates templates	1

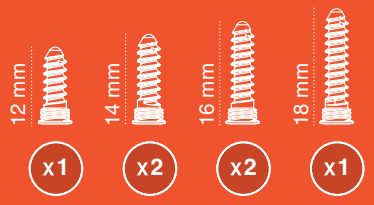
KIT-CL2D

SINGLE USE KIT STERILE R

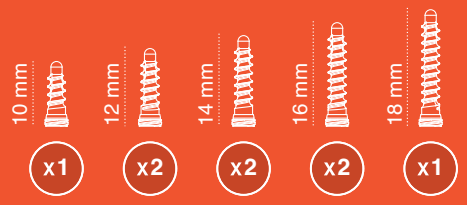
Example of kit content.



Cortical screws
Ø3.5 mm



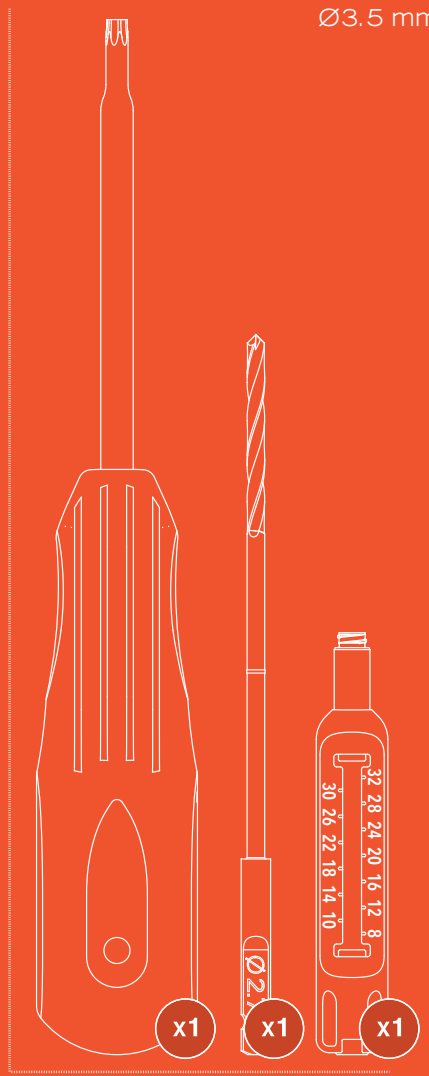
Locking screws
Ø3.5 mm



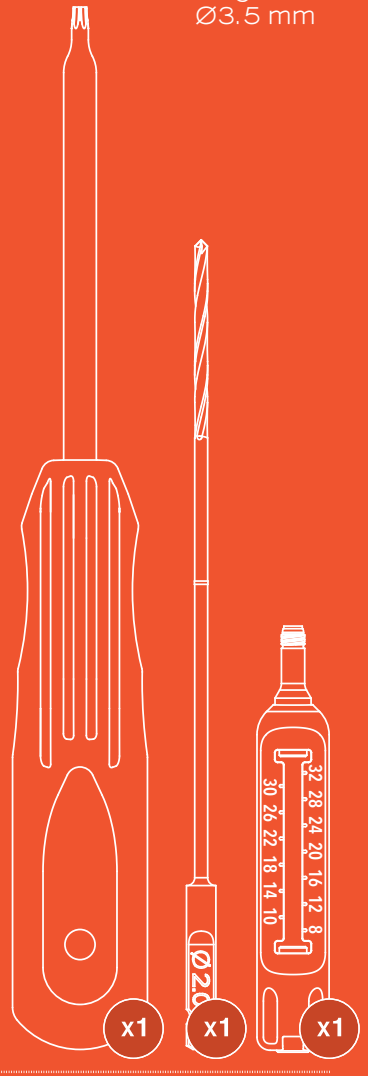
Locking screws
Ø2.8 mm

Right Clavicle Superior Lateral Size 2

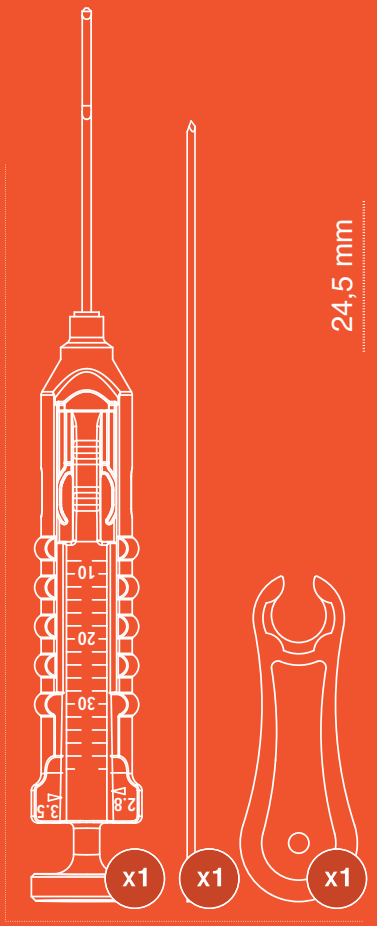
Implants material: Titanium TA6V - ISO 5832-3 / ASTM F136
Degree of accuracy for devices with a measuring function: ± 0.8 mm



For Ø3.5 mm screws



For Ø2.8 mm screws



For both Ø

PA de la Lande Saint Martin - 45 rue des Garottières
44115 Haute-Goulaine - France
Tel.: +33 (0)2 28 21 37 12 - Fax : +33 (0)2 40 63 68 37
www.newcliptechnics.com

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

Non contractual pictures.

Brochure EN - Initial-C - Ed.4 - 08/2018 - Medical devices: class IIb - CE 1639SGS BE - US Class: II - Read labeling and instructions before use.