NEWCLIP TECHNICS

ACTIV FUSE

ANKLE FUSION

ACTIV FUSE

Intended purpose: The implants of the Activ Fuse range are intended for bone reconstruction of the ankle joint in adults including fractures fixation and arthrodeses of the ankle, distal tibia, talus, and calcaneus.
Contra-indications:
- 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

ANTERIOR APPROACH

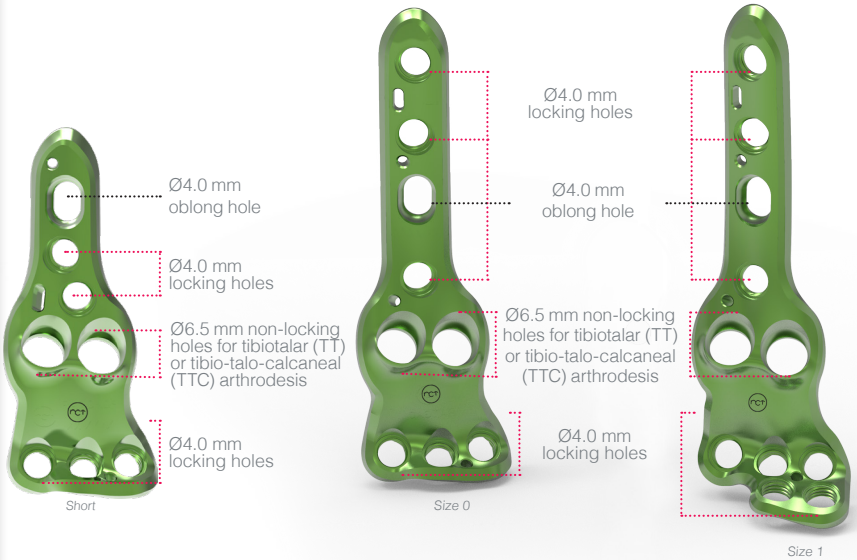
ANTERIOR PLATES

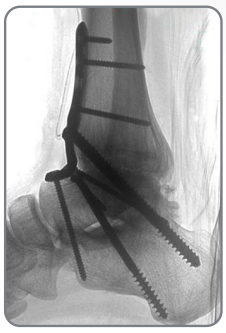
- The five distal holes of the size 1 plate maximize fixation possibilities in the talus.
- Size 0 plate with a single row of screws in the talus suitable for short talar neck.
- Short plate suitable with less invasive approach than standard plates.
- The two transarticular screws going through the ankle, and subtalar joint if need be, allow compression of TT or TTC joints.

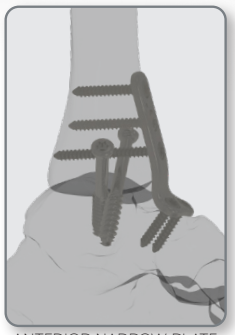
ANTERIOR NARROW PLATE

- Stabilization of the ankle joint fusion first achieved by the combination of two Ø6.5 mm crossed screws of the Activ Screw going through the joint. The anterior narrow plate is placed on the anterior part of the ankle.

Remark : This plate is intended **to always be used as a support** fixation for ankle arthrodesis in combination with the Ø6.5 mm screws of the Activ Screw range. **In no circumstances should the plate be used alone.**




ANTERIOR PLATE


ANTERIOR NARROW PLATE

Ø6.5 mm cannulated screws available in the Activ Screw range.

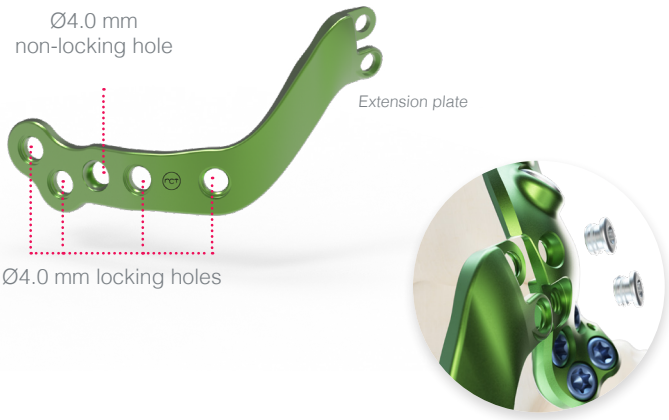
NB: For locking holes, Newclip Technics recommends the use of locking screws. However, if need be, the use of non-locking screws in locking holes is left to the surgeon's discretion.

ACTIV FUSE

ANTEROLATERAL APPROACH

ANTEROLATERAL PLATES

- The anterolateral plates are designed for a lateral approach.
- The five distal holes of the plates maximize fixation possibilities in the talus.
- The two transarticular screws going through the ankle, and subtalar joint if need be, allow compression of TT or TTC joints.
- Optional lateral support allowing additional stability for TTC fusion.

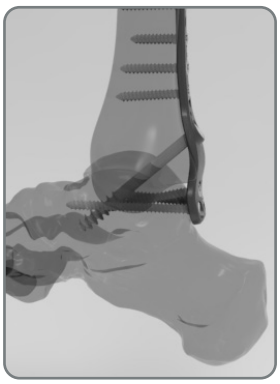


ACTIV FUSE

POSTERIOR APPROACH

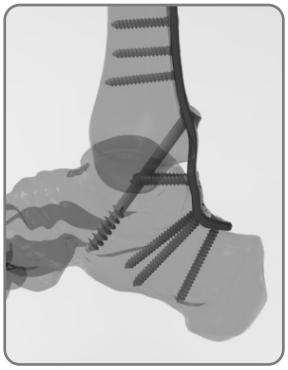
TT PLATE

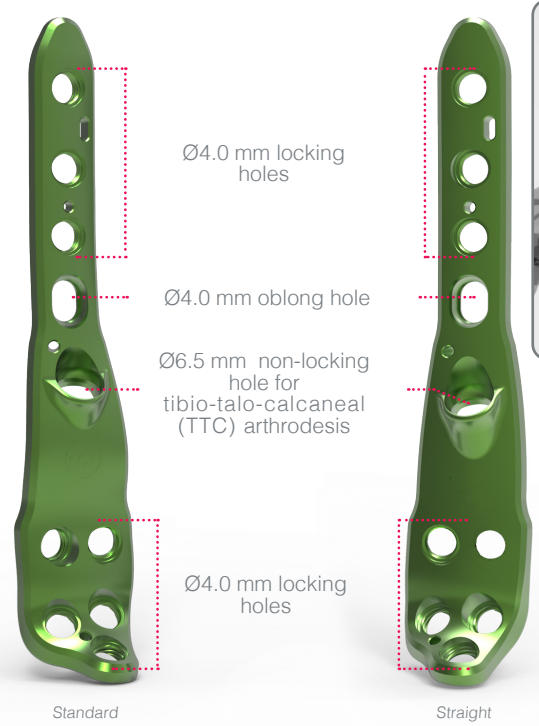
- The three distal holes of the plate maximize fixation possibilities in the talus.
- The transarticular screw going through the ankle allows compression of TT joint.

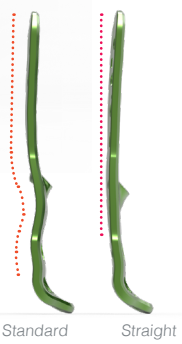


TTC PLATES

- Two designs adapted to different anatomies: standard or straight plate.
- The five distal holes of the plate maximize fixation possibilities in the talus and the calcaneum.
- The transarticular screw going through the ankle and subtalar joint allows compression of TTC joints.





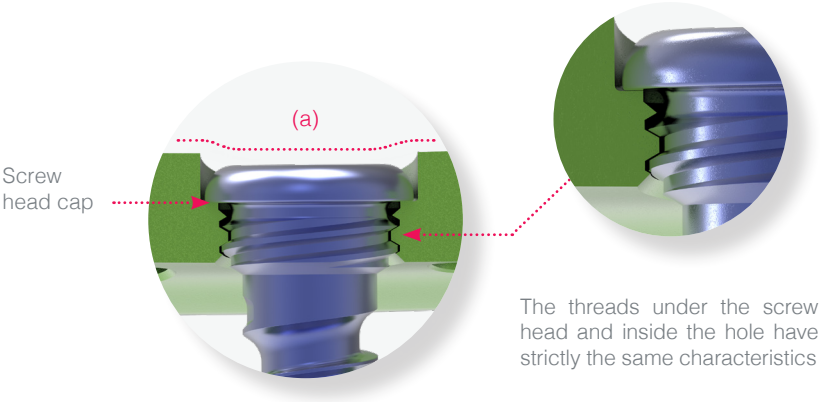


TECHNICAL FEATURES

PRECONTOURED IMPLANTS

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

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 by its cap, ensuring the locking,
- The screw head is buried in the plate (a),
- Plates and screws are all made of titanium alloy.

Complete coaptation of both profiles during locking.

- Two types of Ø4.0 mm screws: **locking** (SOT4.0LxxD) and **non-locking screws** (CT4.0LxxD)
- Two types of transarticular screws for **TT (tibiotalar)** and **TTC (tibio-talo-calcaneal)** arthrodeses:
  - **Compression screws** (QT6.5LxxD): partially threaded for lag effect
  - **Neutralization screws** (CT6.5LxxD): fully threaded for stabilization
- **Hexalobular stamp** T20* for all the screws enabling torque transmission.

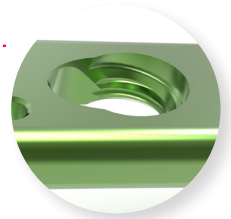
*** The fixation screws of the anterolateral plate extension have a T8 stamp.**

TECHNICAL FEATURES

ANTERIOR NARROW PLATE SPECIFIC FIXATIONS

Locking ramp oblong hole

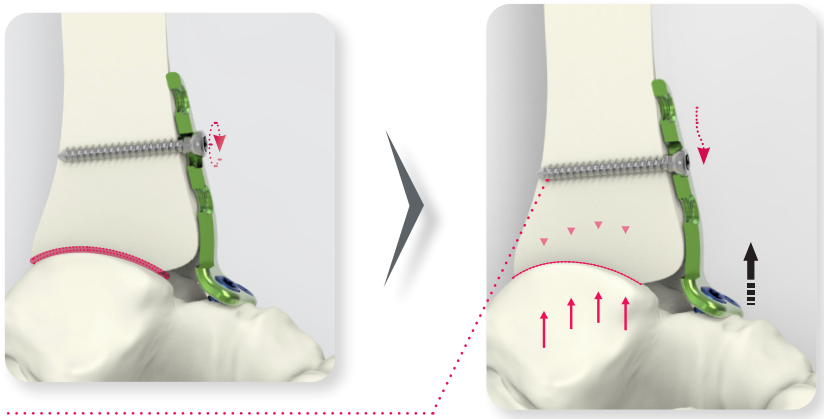
The ramp oblong hole allows compression by the screw/plate interface.



⚠ In order to achieve compression, Ø4.0 mm non-locking screws (CT4.0LxxD) can be used. They must be inserted in the proximal part of the ramp oblong hole.

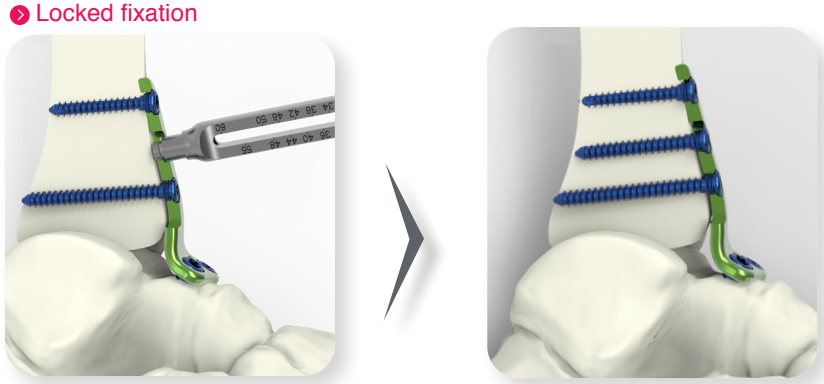
If no additional compression is required, a Ø4.0 mm locking screw (SOT4.0LxxD) can be inserted into the distal part of the hole. To do so, use the Ø3.0 mm threaded guide gauge (ANC847).

Dynamic compression



Compression of the joint up to 2.5 mm

Locked fixation



SPECIFIC MEASUREMENT AND LAG EFFECT

Length measurement: one drill, two measures

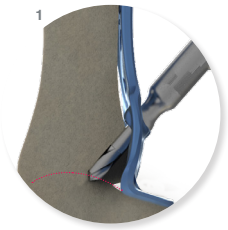
When inserting a Ø4.0 mm screw (CT4.0LxxD or SOT4.0LxxD) into a locking hole or non-locking hole, in order to determine the appropriate screw length, use the **Ø3.0 mm drill bit marking** (ANC852) and the threaded guide gauge (ANC847).

ANC852 ANC847

When inserting a Ø6.5 mm lag screw (QT6.5LxxD), in order to determine the appropriate screw length, use the **Ø3.0 mm drill bit graduations** (ANC852) and read directly the required length at the rear of the Ø3.0 mm drill guide (ANC855).

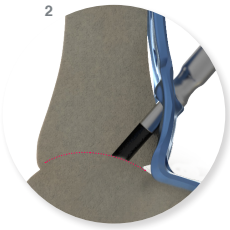
ANC852 ANC855

Lag effect



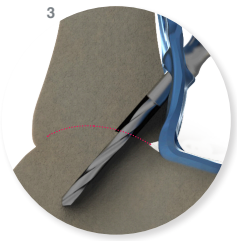
Ø4.7 mm drilling up to the joint

ANC848

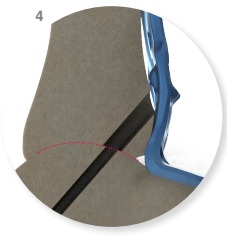


Insertion of the Ø3.0 mm drill guide into the hole previously made

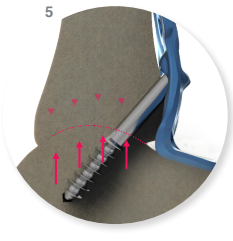
ANC855



Ø3.0 mm drilling up to the desired length



Drilling result



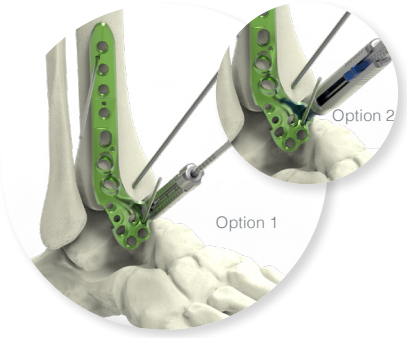
Compression effect

ANTEROLATERAL PLATE

Example of the anterolateral plate size 1 (RATDB1). The surgical technique will be identical for the other plates of the range.

1. Prepare joint surfaces and stabilize the ankle by inserting one or two Ø2.5 mm pins (33.0225.180) through the joint.

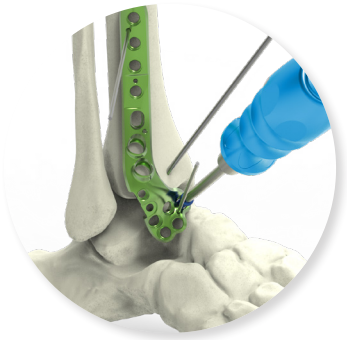
2. Position and stabilize the plate by using the Ø1.6 mm pins (33.0216.150).



3. Lock the Ø3.0 mm threaded guide gauge (ANC847) into one of the distal locking holes and drill using the Ø3.0 mm drill bit (ANC852). Then measure the corresponding screw length.

   Option 1: Determine the screw length using the Ø3.0 mm threaded guide gauge (ANC847) and the Ø3.0 mm drill bit marking (ANC852).

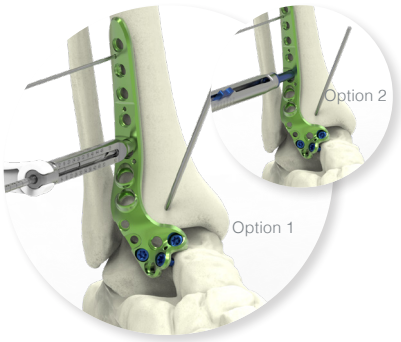
   Option 2: Determine the screw length using the length gauge (ANC856).



4. Insert a Ø4.0 mm locking screw (SOT4.0LxxD) using the T20 screwdriver (ANC854).

   Repeat the previous steps at least once and until the plate is stable on the talus bone.

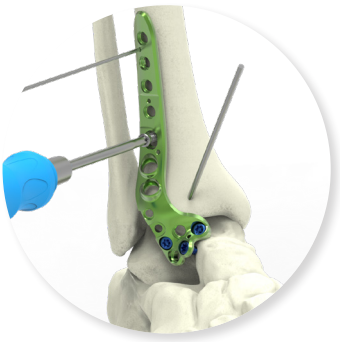
   Remove the distal Ø1.6 mm pin (33.0216.150).



5. Position the guide gauge (ANC847) into the **proximal part of the oblong hole**. Drill using the Ø3.0 mm drill bit (ANC852) and measure the corresponding screw length.

   Option 1: Determine the screw length using the Ø3.0 mm threaded guide gauge (ANC847) and the Ø3.0 mm drill bit marking (ANC852).

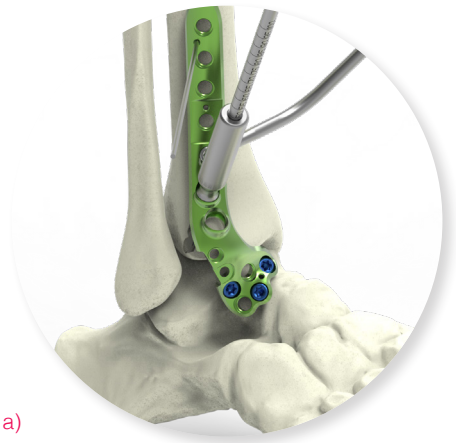
   Option 2: Determine the screw length using the length gauge (ANC856).



6. Insert a Ø4.0 mm standard cortical screw (CT4.0LxxD) using the T20 screwdriver (ANC854).

SURGICAL TECHNIQUE

7- Alternative 1 : fixation with compression screw (Ø6.5 mm lag screw: QT6.5LxxD)



a)

Insert the Ø4.7 mm bent drill guide (ANC848) into one of the transarticular holes and drill using the Ø4.7 mm drill bit (ANC851) **up to the joint**.
Remove both the drill bit and the drill guide.

b)

In order to achieve a lag effect, insert the Ø3.0 mm drill guide (ANC855) into the same transarticular hole and make sure the drill guide is inserted into the previously drilled hole. Drill to the desired depth using the Ø3.0 mm drill bit (ANC852).
Determine the screw length at the rear of the Ø3.0 mm drill guide (ANC855) using the graduations on the Ø3.0 mm drill bit (ANC852) (see specific measurment).
It is also possible to use the length gauge for Ø6.5 mm screws (ANC853).

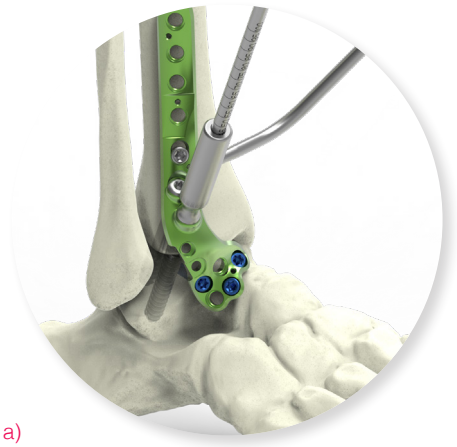
c)

Remove the pins.
Insert a Ø6.5 mm lag screw (QT6.5LxxD) using the T20 screwdriver (ANC854).

Remark:
Before the Ø6.5 mm lag screw insertion, slightly release the Ø4.0 mm standard cortical screw in the oblong hole to optimize the compression.
Then retighten the Ø4.0 mm standard cortical screw when the desired compression is reached.

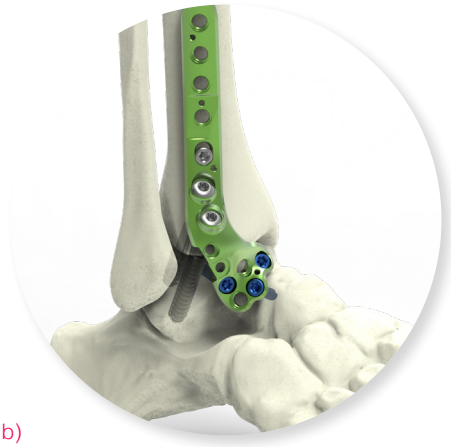
7- Alternative 2 : fixation with neutralization screw

(Ø6.5 mm non-locking screw: CT6.5LxxD)



a)

Insert the Ø4.7 mm bent drill guide (ANC848) into one of the transarticular holes and drill using the Ø4.7 mm drill bit (ANC851).
Determine the screw length at the rear of the Ø4.7 mm bent drill guide (ANC848).
It is also possible to use the length gauge for Ø6.5 mm screws (ANC853).



b)

Insert the Ø6.5 mm non-locking screw (CT6.5LxxD) using the T20 screwdriver (ANC854).

8.

8. Insert the remaining distal and proximal Ø4.0 mm locking screws (SOT4.0LxxD) according to steps 3 and 4.

N.B.: To insert the lateral extension, you can refer to the following page.

OPTION : CALCANEAL LATERAL EXTENSION

Surgical approaches are the responsibility of the health professional. The recommendations in this document are provided for informational purposes only. Each surgeon must evaluate the relevance of the procedures based on his training and experience.

1. Lock the Ø3.0 mm threaded guide gauge (ANC847) in the most anterior locking hole to manipulate the plate.

2. Insert the assembly through the existing incision.

3. Assemble the extension on the plate then lock the assembly with the two fixing screws (RATxB1-VIS) **using the T8 screwdriver** (ANC575).

4. Perform a second short incision following the conventional calcaneal surgical approach.
   Insert the Ø3.0 mm threaded gauge (ANC847) into the non-locking hole. Drill using the Ø3.0 mm drill bit (ANC852) and determine the appropriate screw length. Insert the standard Ø4.0 mm non-locking screw (CT4.0LxxD) using the T20 screwdriver (ANC854).

5. Insert the remaining locking screws (SOT4.0LxxD).

IMPLANTS REFERENCES

→ ANTERIOR PLATES

RATxASS

RATxA0

RATxA1

ANTERIOR PLATES	
Ref.	Description
RATGASS	Anterior plate - Ankle arthrodesis - Left - Short
RATDASS	Anterior plate - Ankle arthrodesis - Right - Short
RATGA0	Anterior plate - Ankle arthrodesis - Left - Size 0
RATDA0	Anterior plate - Ankle arthrodesis - Right - Size 0
RATGA1	Anterior plate - Ankle arthrodesis - Left - Size 1
RATDA1	Anterior plate - Ankle arthrodesis - Right - Size 1

RATxAN

ANTERIOR PLATES - NARROW	
Ref.	Description
RATGAN	Anterior plate - Ankle arthrodesis - Left - Narrow - Size 1
RATDAN	Anterior plate - Ankle arthrodesis - Right - Narrow - Size 1

→ ANTEROLATERAL AND CALCANEAL LATERAL EXTENSION PLATES

RATxB0

RATxB1

RATxB1-E1

ANTEROLATERAL AND CALCANEAL LATERAL EXTENSION PLATES	
Ref.	Description
RATGB0	Anterolateral plate - Ankle arthrodesis - Left - Size 0
RATDB0	Anterolateral plate - Ankle arthrodesis - Right - Size 0
RATGB1	Anterolateral plate - Ankle arthrodesis - Left - Size 1
RATDB1	Anterolateral plate - Ankle arthrodesis - Right - Size 1
RATGB1-E1	Anterolateral plate extension - Ankle arthrodesis - Left - Size 1
RATDB1-E1	Anterolateral plate extension - Ankle arthrodesis - Right - Size 1

→ POSTERIOR PLATES

RATxT1

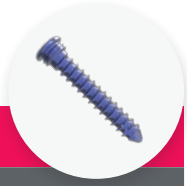
RBTxT1

RCTxT1

POSTERIOR PLATES	
Ref.	Description
RATGT1	Posterior TT plate - Ankle arthrodesis - Left - Size 1
RATDT1	Posterior TT plate - Ankle arthrodesis - Right - Size 1
RBTGT1	Posterior TTC plate - Ankle arthrodesis - Left - Size 1
RBTDT1	Posterior TTC plate - Ankle arthrodesis - Right - Size 1
RCTGT1	Posterior TTC plate - Straight - Ankle arthrodesis - Left - Size 1
RCTDT1	Posterior TTC plate - Straight - Ankle arthrodesis - Left - Size 1

IMPLANTS REFERENCES

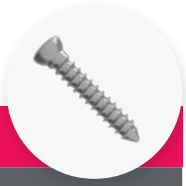
→ Ø4.0 MM SCREWS



LOCKING SCREWS*

Ref.	Description
SOT4.0LxxD	Locking screw - Ø4.0 mm - L 12 to 60 mm (2 mm increments from 12 to 50 mm) (5 mm increments from 50 to 60 mm)

* Blue anodized.

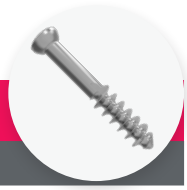


NON-LOCKING SCREWS*

Ref.	Description
CT4.0LxxD	Non-locking screw Ø4.0 mm - L 12 to 60 mm (2 mm increments from 12 to 50 mm) (5 mm increments from 50 to 60 mm)

* Not anodized.

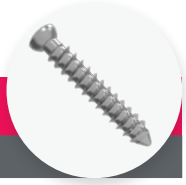
→ Ø6.5 MM SCREWS



LAG SCREWS*

Ref.	Description
QT6.5LxxD-ST	Lag screw - Ø6.5 mm - L 30 to 35 mm - Sterile**
QT6.5LxxD	Lag screw - Ø6.5 mm - L 40 to 100 mm (5 mm increments)

* Not anodized. ** These screws are only provided on specific request.

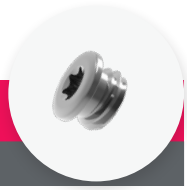


NON-LOCKING SCREWS*

Ref.	Description
CT6.5LxxD-ST	Non-locking screw - Ø6.5 mm - L 30 to 35 mm - Sterile**
CT6.5LxxD	Non-locking screw - Ø6.5 mm - L 40 to 100 mm (5 mm increments)

* Not anodized. ** These screws are only provided on specific request.

→ FIXATION SCREWS



EXTENSION FIXATION SCREW*

Ref.	Description
RATxB1-VIS	Fixation screw - Anterolateral plate extension - Ankle arthrodesis
RATxB1-VIS-ST	Fixation screw - Anterolateral plate extension - Ankle arthrodesis - STERILE **

* Not anodized. ** These screws are only provided on specific request.

→ ADDITIONAL IMPLANTS

ADDITIONAL IMPLANTS : STAND-ALONE SCREWS*

Ref	Description
H2.6QT6.5LxxD	Ø6.5 mm compressive screw - cannula Ø2.6 - short thread - L40 to L120 mm (5 mm increments)
H2.6JT6.5LxxD	Ø6.5 mm compressive screw - cannula Ø2.6 - long thread - L45 to L120 mm (5 mm increments)
H2.6CT6.5LxxD	Ø6.5 mm standard cortical screw - cannula Ø2.6 - full thread - L40 to L120 mm (5 mm increments)

* For more information, see the Activ Screw range sales brochure.

Remark: Please note that the «xx» in the references represents the length of the screw. The length of the screw replaces the «xx».
Eg. : The reference for the Locking screw - Ø4.0 mm - L 12 mm is «SOT4.0L12D»

Remark: Please note that all implants are also available in sterile packaging. An '-ST' code is added at the end of the reference.
Eg. : « SOT4.0L12D-ST ».
Please consult your local sales representative to check the availability of the sterile products.

INSTRUMENTS REFERENCES

INSTRUMENTATION CONTENTS

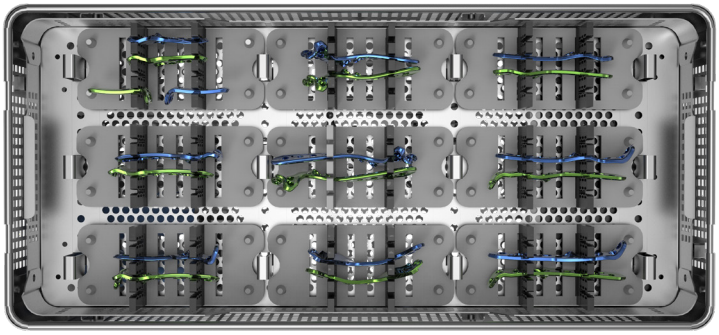
Ref.	Description	Qty
ANC350	Ø4.5 mm AO quick coupling handle - Size 1	1
ANC351	Ø4.5 mm AO quick coupling handle - Size 2	1
ANC575	T8 quick coupling screwdriver	1
ANC845	Ø6.0 mm countersink - cannula Ø1.4 mm	1
ANC847	Ø3.0 mm threaded guide gauge for Ø4.0 mm screws	2
ANC848	Ø4.7 mm bent drill guide for Ø6.5 mm screws	2
ANC851	Ø4.7 mm quick coupling drill bit - L195 mm	2
ANC852	Ø3.0 mm quick coupling drill bit - L 195 mm	2
ANC853	Length gauge for Ø6.5 mm screws	1
ANC854	T20 prehensor screwdriver	2
ANC855	Ø3.0 mm drill guide for Ø6.5 mm screws	2
ANC856	Length gauge for Ø4.0 mm screws	1
33.0216.150	Pin Ø1.6 L150 mm	6
33.0225.180	Pin Ø2.5 L180 mm	6

ADDITIONAL INSTRUMENTS FOR STAND-ALONE SCREWS

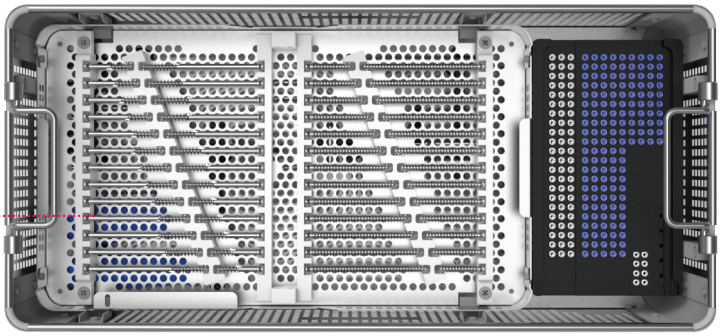
Ref.	Description	Qty
ANC442	Ø11 mm cannulated quick coupling straight handle	1
ANC443	Ø11 mm cannulated quick coupling T-handle	1
ANC453	Quick coupling adaptator Ø11 mm - AO Ø4.5 mm	1
ANC727	Ø4.6 mm drill bit - Cannula Ø2.6 mm - L260 mm	1
ANC730	2 in 1: T25 screwdriver Ø2.6 mm cannulated - Ø8.0 mm countersink	2
ANC733	Length gauge for pin Ø2.5 mm - L210 mm	1
ANC735	Ø2.5 mm pin guide	1
ANC754	Soft tissue protection sleeve	1
33.0225.230	Pin Ø2.5 mm L230mm	6

Removal kit : If you have to remove Activ Fuse implants, make sure to order the Newclip Technics removal set, which includes the following instruments:

- ANC351: Ø4.5 mm AO quick coupling handle - Size 2
- ANC575: T8 quick coupling screwdriver
- ANC980: T20 screwdriver with AO quick coupling system



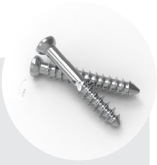
Insert
ANC895/I

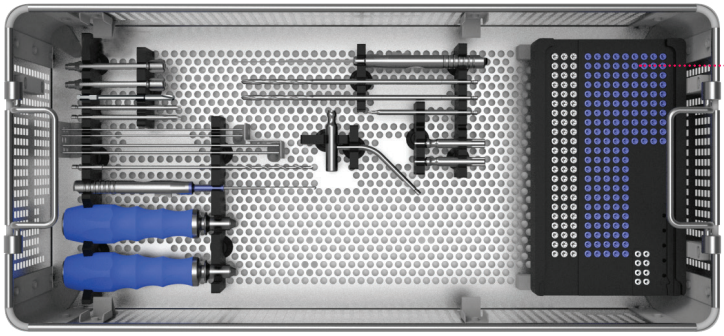


Screw Insert
ANC895/R2

Remark : The following Ø6.5 mm implants are only available in sterile and on request:

- QT6.5L30D-ST
- QT6.5L35D-ST
- CT6.5L30D-ST
- CT6.5L35D-ST





Screw tray
ANC895/R1

Base
ANC895/B

The information presented in this brochure is intended to demonstrate a NEWCLIP TECHNICS product. Always refer to the package insert, product label and/or user instructions before using any NEWCLIP TECHNICS product. Surgeons must always rely on their own clinical judgment when deciding which products and techniques to use with their patients. Products may not be available in all markets. 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.

Non-contactual pictures.

Manufacturer: Newclip Technics - Brochure EN - Activ Fuse - Ed8 - 03/2023 - Medical device EC: class IIb - CE1639 SGS BE - Read labeling and instructions before use. These products must be handled and/or implanted by trained and qualified staff who have read the instructions before use.

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