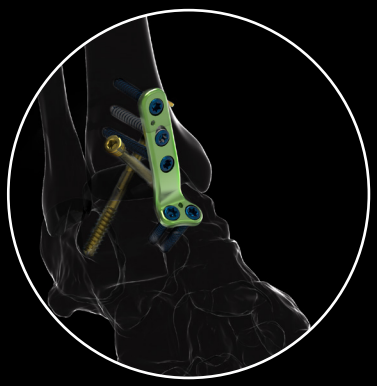
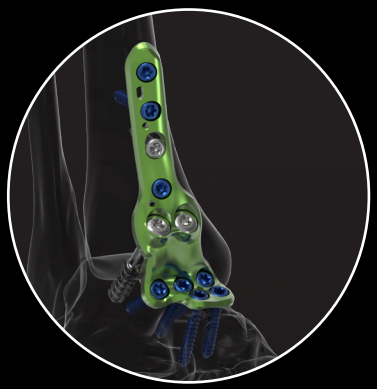
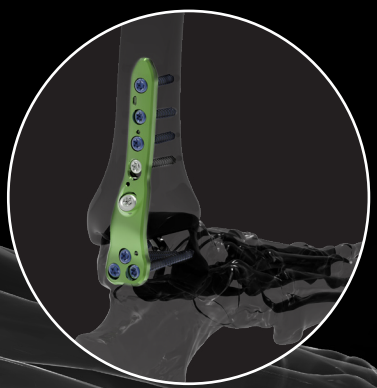
NEWCLIP TECHNICS







# ACTIV FUSE

## ANKLE FUSION

# ACTIV FUSE

Indications: 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.

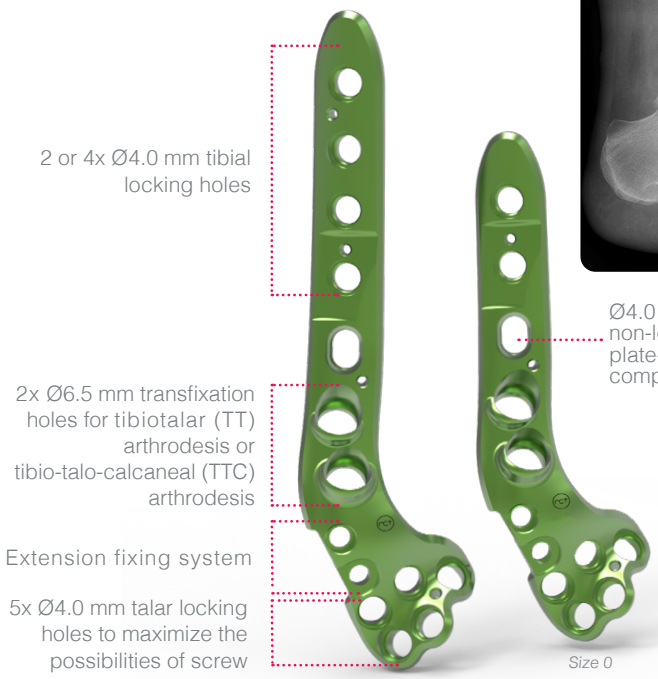
Contra-indications:
- Serious vascular deterioration, bone devitalization.
- Pregnancy.
- Acute or chronic local or systemic infections.
- Lack of musculo-cutaneous cover, severe vascular deficiency affecting the concerned area.
- Insufficient bone quality preventing a good fixation of the implants into the bone.
- Muscular deficit, neurological deficiency or behavioral disorders, which could submit the implant 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.

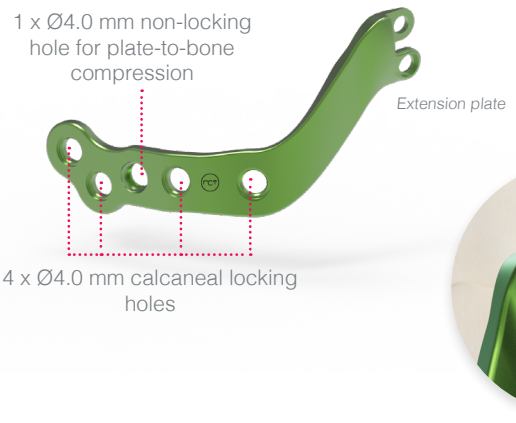
## A COMPREHENSIVE RANGE OF PLATES

### ANTEROLATERAL APPROACH

#### ANTEROLATERAL PLATES

- The anterolateral plate positionning preserves the fibula and avoids fibulectomies.
- The 5 distal holes of the plate maximize fixation possibilities in the talus. This optimizes the plate anchorage and allows for a better adjustment to bone deformations.
- The 2 transfixation screws going through the joint allow compression and optimize the ankle's stability.
- Optional lateral support allowing additional anchorage in the calcaneum in case of major instability or bone defect.
- Shorter size 0 plate, for less invasive surgical incision.



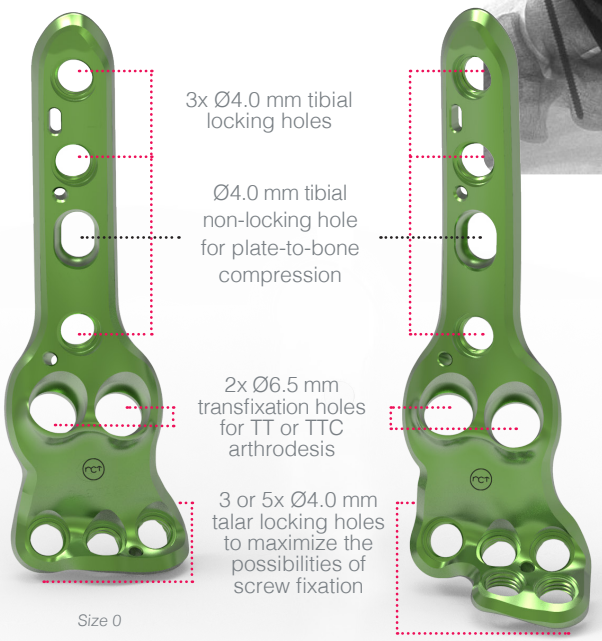




# ACTIV FUSE

## ANTERIOR APPROACH

### ANTERIOR PLATES

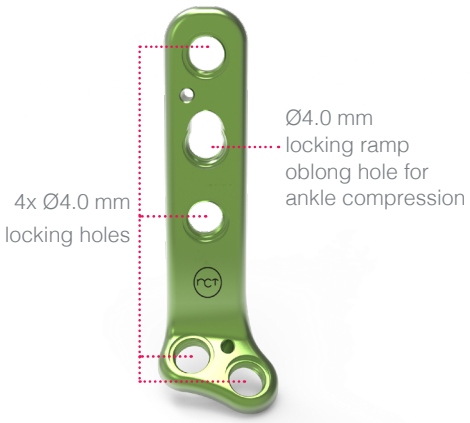
- The 5 distal holes of the plate maximize fixation possibilities in the talus. This optimizes the plate anchorage and allows for a better adjustment to bone deformations.
- The 2 transfixation screws going through the joint allow compression and optimize the stability of the ankle.
- Size 0 plate with a single row of screws in the talus suitable for short talar neck.

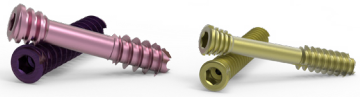



### ANTERIOR NARROW PLATE

- Stabilization of the ankle joint fusion first achieved by the combination of two crossed screws of the Stand-Alone Screws (Ø6.0 or Ø8.0 mm) 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 screws of the Stand-Alone Screws (Ø6.0 or Ø8.0 mm). **In no circumstances should the plate be used alone.**



Cannulated screws (Ø6.0 mm and Ø 8.0mm) available in the Stand-Alone Screws range.

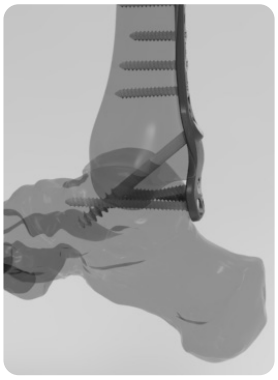
*NB: For locking holes, Newclip Technics recommends the use of locking screws. However, if need be, the use of non-locking screws in locking holes is left to the surgeon's discretion.*

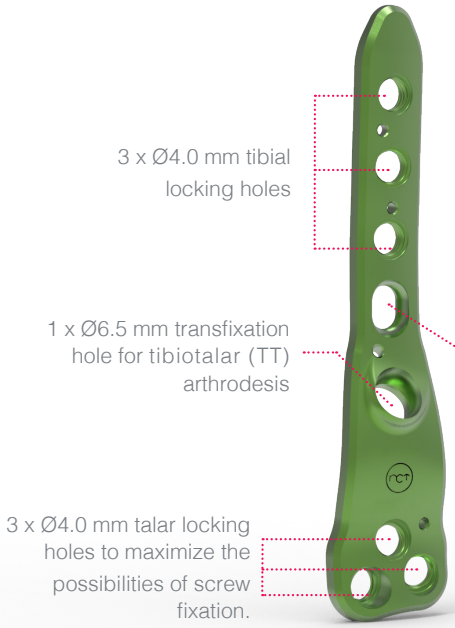
# ACTIV FUSE

## POSTERIOR APPROACH

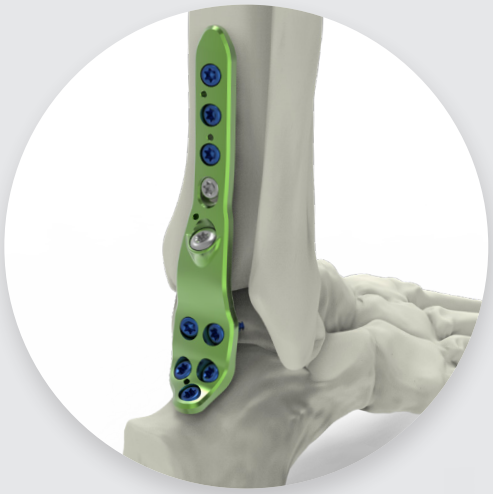
### TT PLATE

- The 3 distal holes of the plate maximize fixation possibilities in the talus.
- The transfixation screw going through the joint allows compression and optimizes the stability of the ankle.

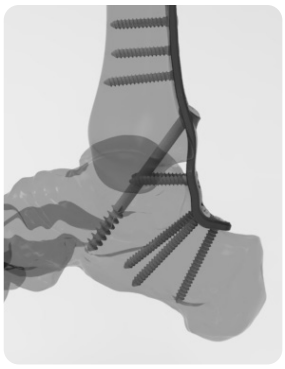


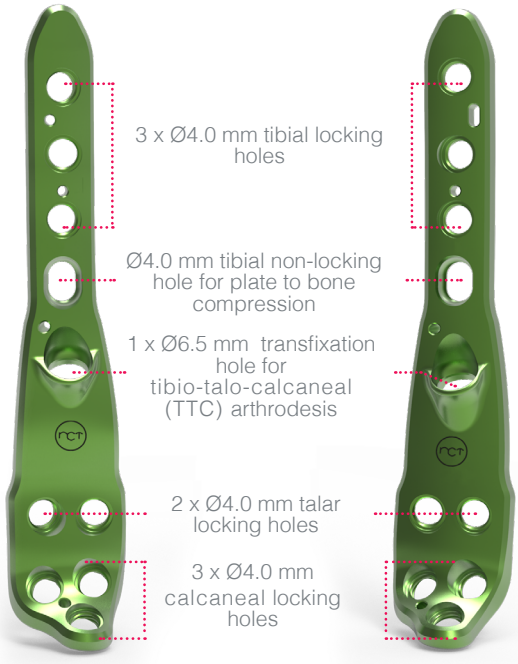


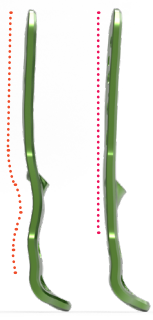

### TTC PLATES



- Two designs adapted to different anatomies: standard or straight plates.
- The 5 distal holes of the plate maximize fixation possibilities in the talus and the calcaneum.
- The transfixation screw going through the ankle and subtalar joint allows compression and optimizes the stability of the ankle.





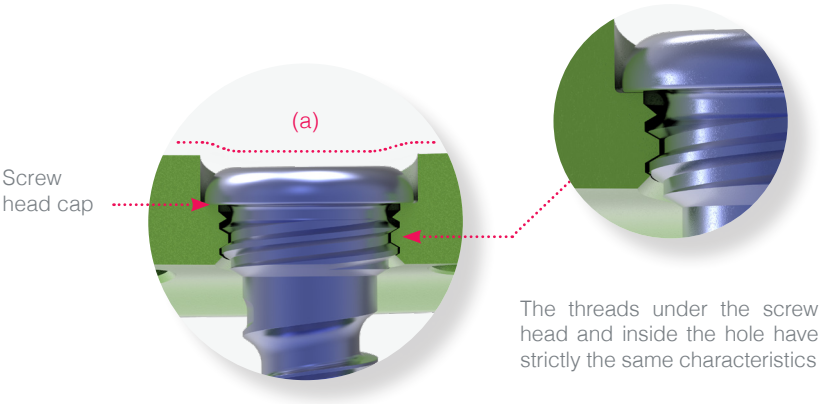



# IMPLANTS TECHNICAL FEATURES

## 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



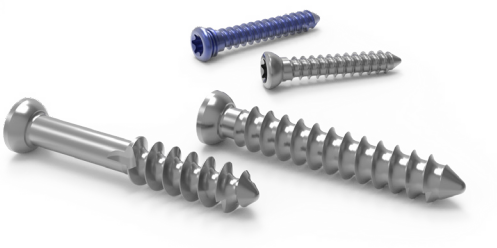

The threads under the screw head and inside the hole have strictly the same characteristics

**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.

Optimized coaptation of both profiles during locking.

- 2 types of Ø4.0 mm screws: **Locking** (SOT4.0LxxD) and **non-locking screws** (CT4.0LxxD)
- 2 types of transfixation screws for **TT (Tibio-Talar)** and **TTC (Tibiotalocalcaneal)** fixation:
  - **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 optimized torque transmission.



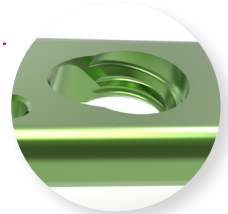
*** The fixation screws of the anterolateral plate extension have a T8 stamp.**

# INSTRUMENTATION TECHNICAL FEATURES

## ANTERIOR NARROW PLATE SPECIFIC FIXATIONS

### Locking ramp oblong hole

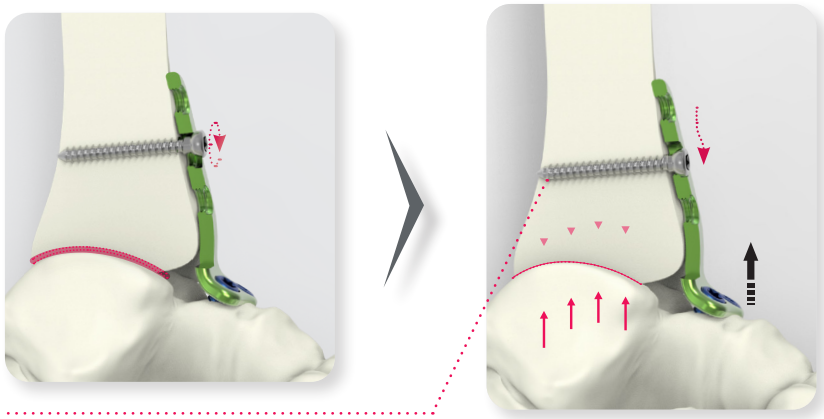
The ramp oblong hole allows a simple and controlled compression by the screw/plate interface.



⚠ 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.

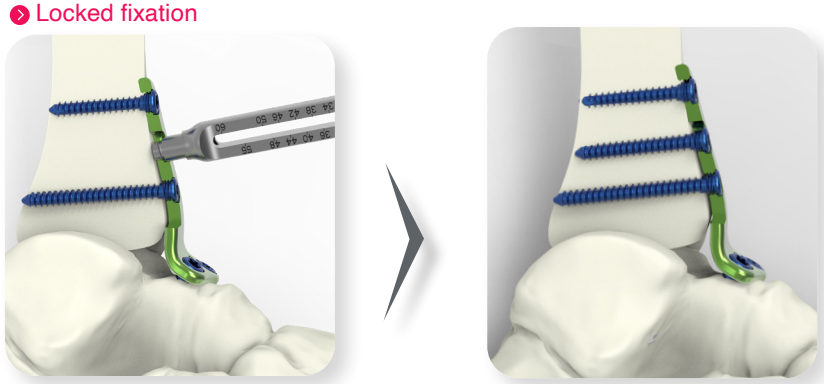
If no additional compression is required, a Ø4.0 mm locking screw (SOT4.0LxxD) can be inserted into the distal part of the hole. To do so, use the Ø3.0 mm threaded guide gauge (ANC847).

### Dynamic compression



Compression of the joint up to 2.5 mm

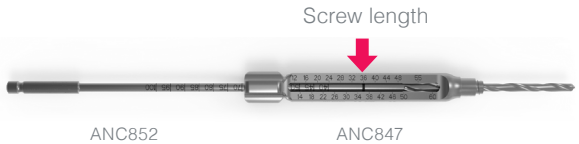
### Locked fixation



## SPECIFIC MEASUREMENT AND LAG EFFECT

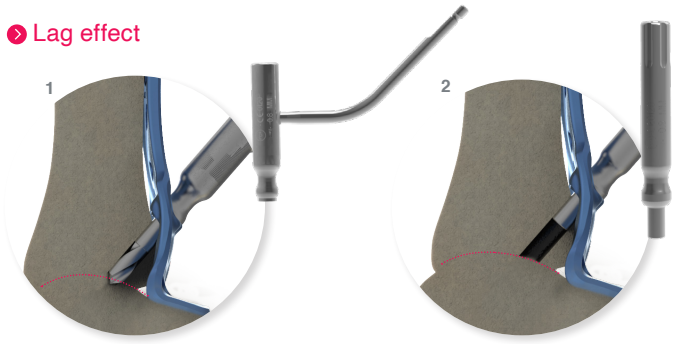
### Length measurement: 1 drill, 2 measures

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).



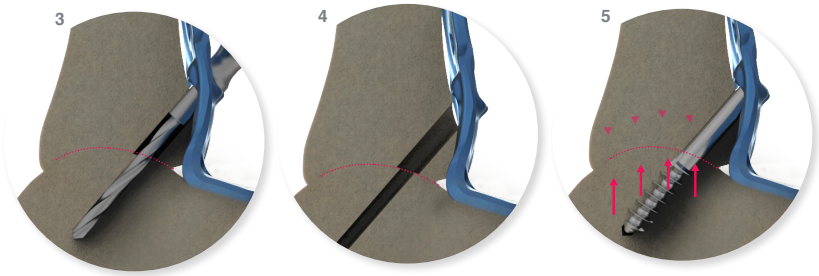

When inserting a Ø6.5 mm lag screw (QT6.5LxxD), in order to determine the appropriate screw length, use the **Ø3.0 mm drill bit graduations** (ANC852) and read directly the required length at the rear of the Ø3.0 mm drill guide (ANC855).


### Lag effect




Ø4.7mm drilling up to the joint

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



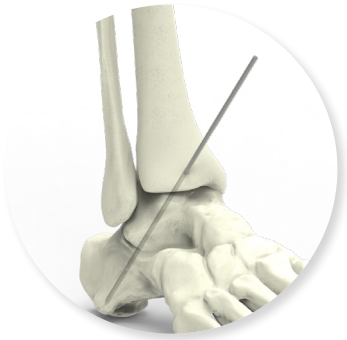

Ø3.0 mm drilling up to the desired length

Drilling result

Compression effect

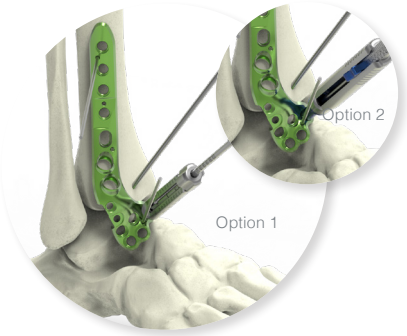
## ANTEROLATERAL PLATE

Example of the anterolateral plate. 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.

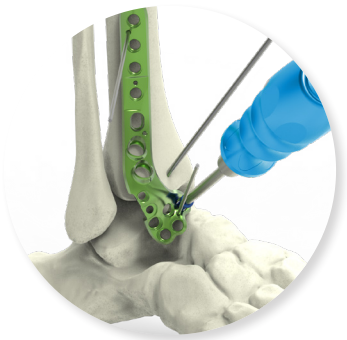
2. Position and stabilize the plate by using the Ø1.6 mm pins (33.0216.150).




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).

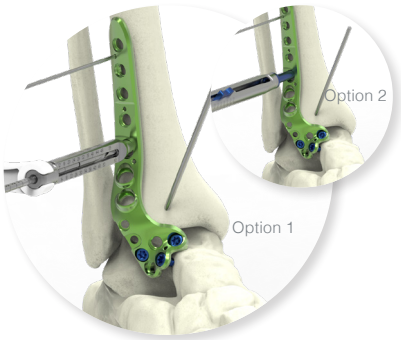
Option 2: Determine the screw length using the length gauge (ANC856).



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.

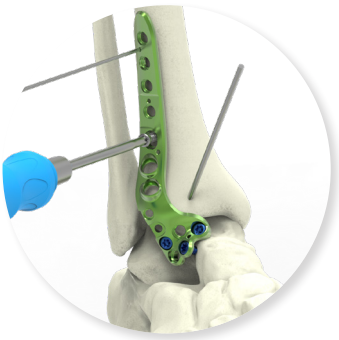
Remove the distal Ø1.6 mm pin (33.0216.150).




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).

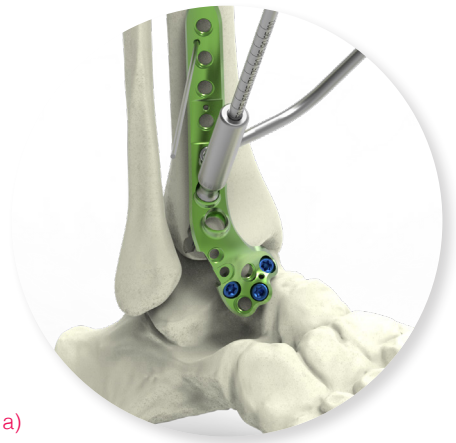
Option 2: Determine the screw length using the length gauge (ANC856).



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

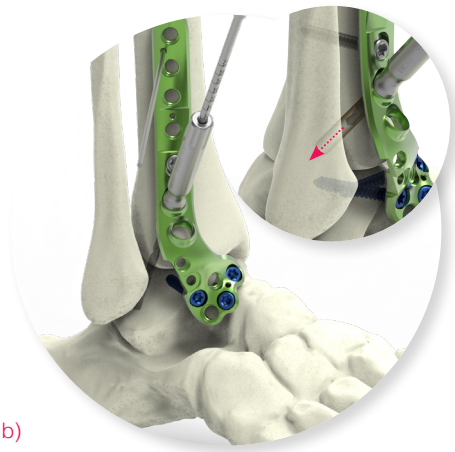
# SURGICAL TECHNIQUE

## 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 transfixation hole 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 transfixation 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).

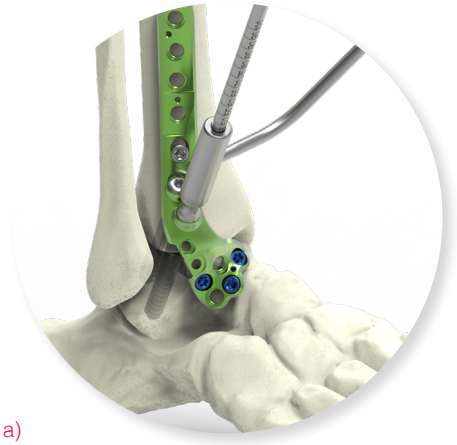
c)

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.

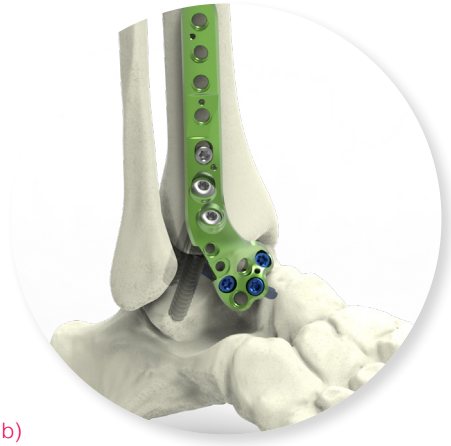
## 7- Alternative 2 : fixation with neutralization screw

(Ø6.5 mm standard cortical screw: CT6.5LxxD)



a)

Insert the Ø4.7 mm bent drill guide (ANC848) into one of the transfixation 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 standard cortical 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 step 3 and 4.


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

# SURGICAL TECHNIQUE

## 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.

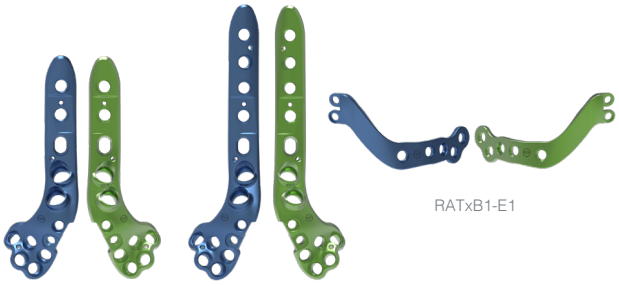
3. Assemble the extension on the plate then lock the assembly with the two fixing screws (RATxB1-VIS) **using the T8 screwdriver** (ANC575) and **torque limiter handle** 1N.m (TD-111401 - 1.0NM-B).

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 cortical screw (CT4.0LxxD) using the T20 screwdriver (ANC854)


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

# IMPLANTS REFERENCES

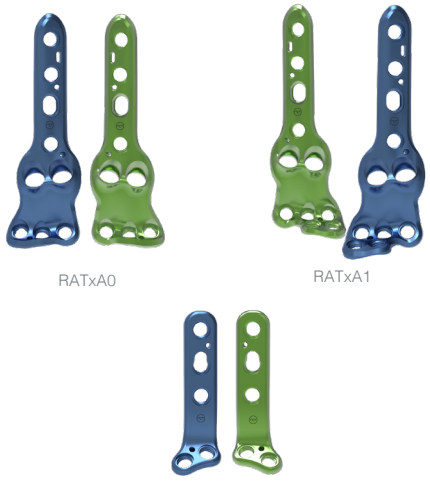
## → ANTEROLATERAL AND CALCANEAL LATERAL EXTENSION PLATES



RATxB0 RATxB1 RATxB1-E1

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

## → ANTERIOR PLATES



RATxA0 RATxA1 RATxAN

| ANTERIOR PLATES | |
|---|---|
| Ref. | Description |
| RATGA0 | Anterior plate for Ankle Arthrodesis - Left - Size 0 |
| RATDA0 | Anterior plate for Ankle Arthrodesis - Right - Size 0 |
| RATGA1 | Anterior plate for Ankle Arthrodesis - Left - Size 1 |
| RATDA1 | Anterior plate for Ankle Arthrodesis - Right - Size 1 |

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

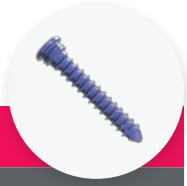
## → POSTERIOR PLATES

RATxT1 RBTxT1 RCTxT1

| POSTERIOR PLATES | |
|---|---|
| Ref. | Description |
| RATGT1 | Posterior TT plate for Ankle Arthrodesis - Left - Size 1 |
| RATDT1 | Posterior TT plate for Ankle Arthrodesis - Right - Size 1 |
| RBTGT1 | Posterior TTC plate for Ankle Arthrodesis - Left - Size 1 |
| RBTDT1 | Posterior TTC plate for Ankle Arthrodesis - Right - Size 1 |
| RCTGT1 | Posterior straight plate for Ankle Arthrodesis TTC - Left - Size 1 |
| RCTDT1 | Posterior straight plate for Ankle Arthrodesis TTC - Right - Size 1 |

# IMPLANTS REFERENCES

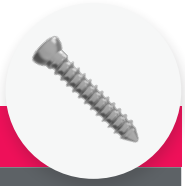
## → Ø4.0 MM SCREWS



### LOCKING SCREWS*

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

* Blue anodized.

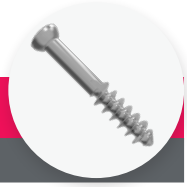


### NON LOCKING SCREWS*

| Ref. | Description |
|---|---|
| CT4.0LxxD | Standard cortical screw Ø4.0 mm - L 12 to 60 mm<br>(2 mm increments from 12 to 50 mm)<br>(5 mm increments from 50 to 60 mm) |

* Not anodized.

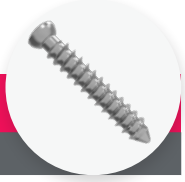
## → Ø6.5 MM SCREWS



### 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<br>(5 mm increments) |

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

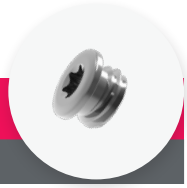


### CORTICAL SCREWS*

| Ref. | Description |
|---|---|
| CT6.5LxxD-ST | Standard cortical screw - Ø6.5 mm - L 30 to 35 mm - Sterile** |
| CT6.5LxxD | Standard cortical screw - Ø6.5 mm - L 40 to 100 mm<br>(5 mm increments) |

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

## → FIXATION SCREWS



### EXTENSION FIXATION SCREW*

| Ref. | Description |
|---|---|
| RATxB1-VIS | Fixation screw for anterolateral plate extension for Ankle arthrodesis |
| RATxB1-VIS-ST | Fixation screw for anterolateral plate extension for Ankle arthrodesis-STERILE ** |

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

## → ADDITIONAL IMPLANTS

### ADDITIONAL IMPLANTS : STAND-ALONE SCREWS*

| Ref | Description |
|---|---|
| H1.7GFT6.0Lxx | Self-drilling positioning screw - Ø6.0 mm - cannulated Ø1.7 mm - L40 to L100 mm (5 mm increment) |
| H1.7IFT6.0Lxx | Self-drilling self-compressive screw - Ø6.0 mm - cannulated Ø1.7 mm - L40 to L100 mm (5 mm increment) |
| H2.7GFT8.0Lxx | Self-drilling positioning screw - Ø8.0 mm - cannulated Ø2.7 mm – L40 to L100 mm (5 mm increment) |
| H2.7IFT8.0Lxx | Self-drilling self-compressive screw - Ø8.0 mm - cannulated Ø2.7 mm - L40 to L100 mm (5 mm increment) |

* For more information, see the Stand-Alons Screws 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 Lag screw Ø6.5 mm - L 30 is «QT6.5L30D».

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.

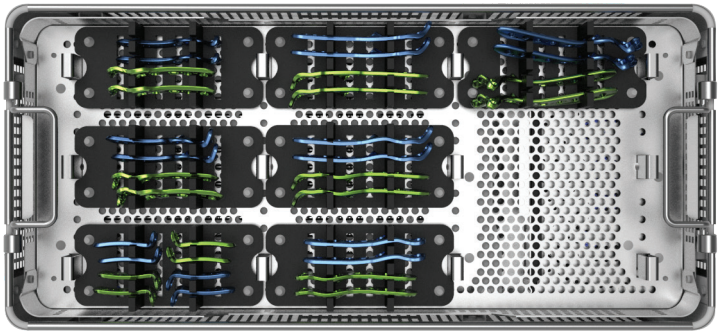
# INSTRUMENTS REFERENCES

## INSTRUMENTATION CONTENTS

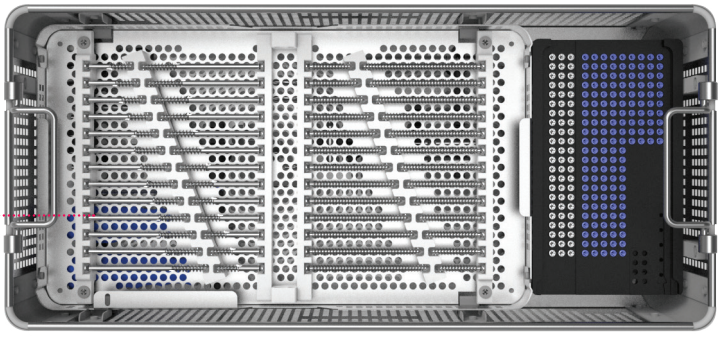
| Ref. | Description | Qty |
|---|---|---|
| ANC351 | Ø4.5 mm AO quick coupling handle - Size 2 | 1 |
| ANC575 | T8 quick coupling screwdriver | 1 |
| ANC847 | Ø3.0 mm threaded guide gauge | 2 |
| ANC848 | Ø4.7 mm bent drill guide | 2 |
| ANC851 | Ø4.7 mm quick coupling drill bit - L 195 mm | 2 |
| ANC852 | 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 | 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 |
| TD-111401-1.0NM-B | Ø4.5 mm AO quick coupling handle with torque Driver 1Nm | 1 |

## ADDITIONAL INSTRUMENTS FOR STAND-ALONE SCREWS

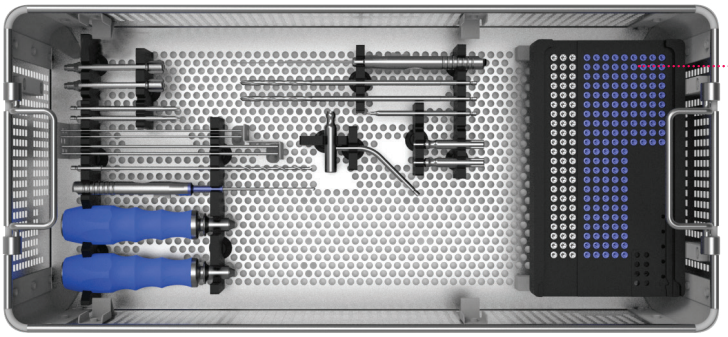
| Ref. | Description | Qty |
|---|---|---|
| ANC412 | Ø11 quick coupling extension stem | 1 |
| ANC415 | Ø4.1 mm drill bit – cannula 1.7 mm – L 170 mm – AO Ø4.5 mm quick coupling | 1 |
| ANC416 | Ø5.6 mm drill bit – cannula Ø2.7 mm – L 170 mm – Ø11 quick coupling | 1 |
| ANC418 | Ø4.1 mm reamer tip – cannula Ø1.7 mm | 1 |
| ANC419 | Ø5.6 mm reamer tip – cannula Ø2.7 mm | 1 |
| ANC421 | 3.5 mm hexagonal screwdriver tip – cannula 1.7 mm | 1 |
| ANC422 | 4.0 mm hexagonal screwdriver tip – cannula 2.7 mm | 1 |
| ANC429 | Guide for Ø1.6 mm pin | 1 |
| ANC430 | Guide for Ø2.5 mm pin | 1 |
| ANC441 | Soft tissue protection sleeve | 1 |
| ANC442 | Ø11 mm cannulated quick coupling straight handle | 1 |
| ANC443 | Ø11 mm cannulated quick coupling T-handle | 1 |
| ANC453 | Quick coupling adaptor Ø11 mm – AO Ø4.5 mm | 1 |
| 33.0216.180 | Pin – Ø1.6 mm L 180 mm | 6 |
| 33.0225.180 | Pin Ø2.5 mm L 180 mm | 6 |



Insert
ANC895/I



Screw Insert
ANC895/R2



Screw tray
ANC895/R1

Base
ANC895/B

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

Images non contactuelles.



Brochure EN - Activfuse - Ed6 - 05/2020 - Medical device EC: class IIb - CE1639 SGS BE - Read labeling and instructions before use.

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