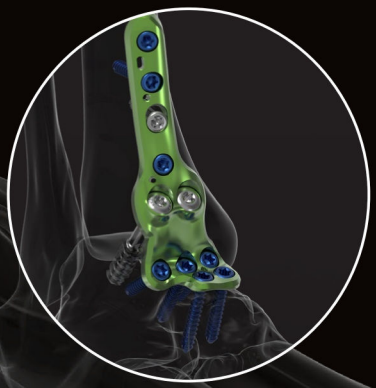
Lavender Medical

NEWCLIP-TECHNICS

INNOVATION MEANS MOTION



ACTIV FUSE
ANKLE FUSION

- Precontoured implants for ankle fusion
- Transfixation screws for compression and neutralization
- Multiple points of talar fixation

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.

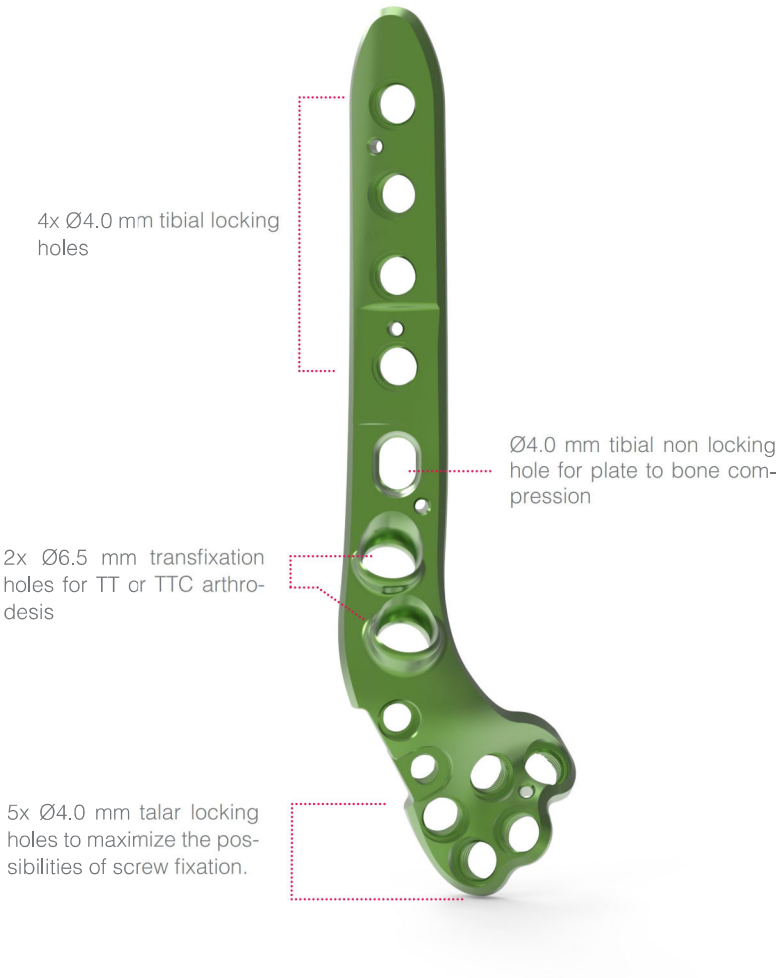
Contra-indications:
- Serious vascular deterioration, bone devitalization,
- Pregnancy.
- Acute or chronic local or systemic infections.
- Lack of musculo-cutaneous cover, severe vascular deficiency affecting the concerned area.
- Insufficient bone quality preventing a good fixation of the implants into 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 PLATE

- The anterolateral plate positionning preserves the fibula and avoids fibulectomies.
- The 5 distal holes of the plate maximize fixation possibilities in the talus. It 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.



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ACTIV FUSE

ANTERIOR APPROACH

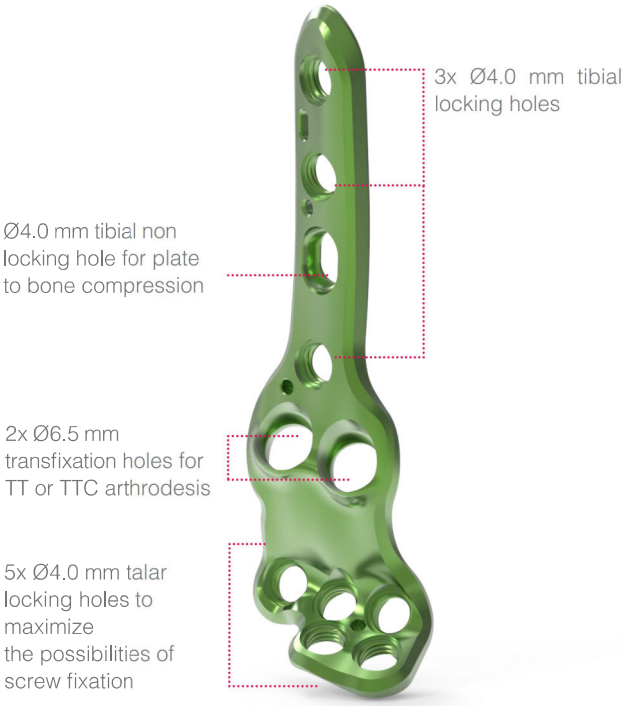
ANTERIOR PLATE

- The 5 distal holes of the plate maximize fixation possibilities in the talus. It 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.

ANTERIOR NARROW PLATE

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



Cannulated screws (Ø6.0 mm and Ø 8.0mm) available in Footmotion Large 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.

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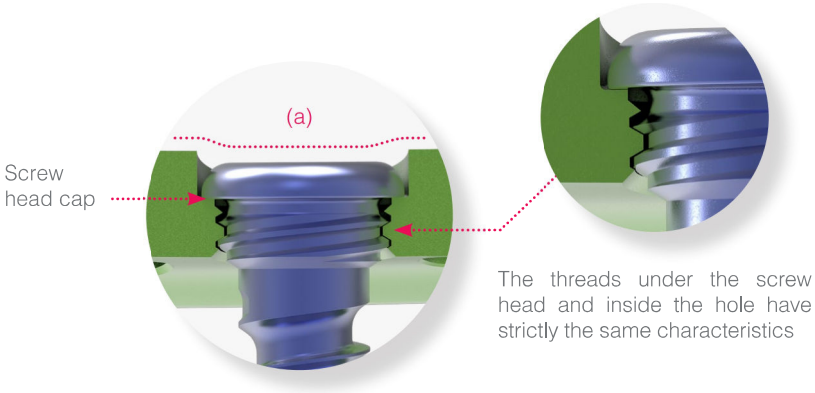
IMPLANTS TECHNICAL FEATURES

PRECONTOURED IMPLANTS

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

EFFICIENT LOCKING



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.

Construct limiting cold welding risks for improved removal properties. Optimized coaptation of both profiles during locking.

FIXATION AND SCREWS

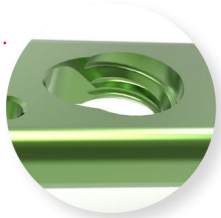
- 2 types of Ø4.0 mm screws: **Locking** (SOT4.0LxxD) and **non-locking screws** (CT4.0LxxD)
- 2 types of transfixation screws for **TT (Tibio-Talar)** and **TTC (Tibiotalocalcaneal)** fixation:
  - **Compression screws** (QT6.5LxxD): partially threaded for lag effect
  - **Neutralization screws** (CT6.5LxxD): fully threaded for stabilization
- **Hexalobular stamp** T20 for all the screws

INSTRUMENTATION TECHNICAL FEATURES

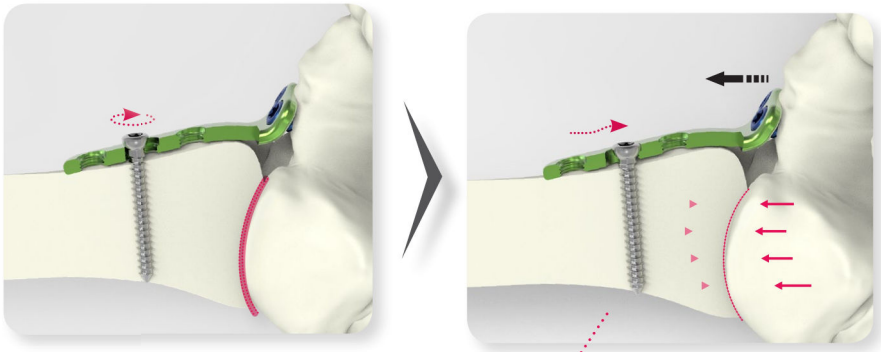
ANTERIOR NARROW PLATE SPECIFIC FIXATIONS

Ramp oblong hole

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

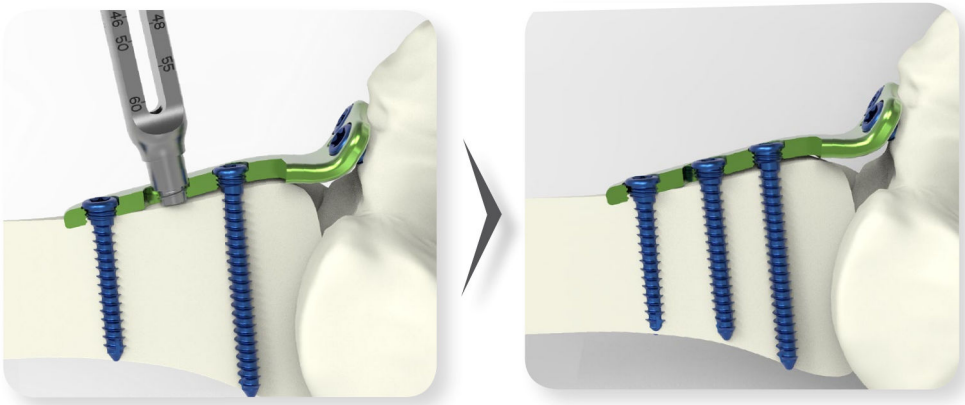


⚠ In order to achieve compression, only Ø4.0 mm non-locking screws (CT4.0LxxD) can be used. They must be inserted in the proximal part of the ramp oblong hole.



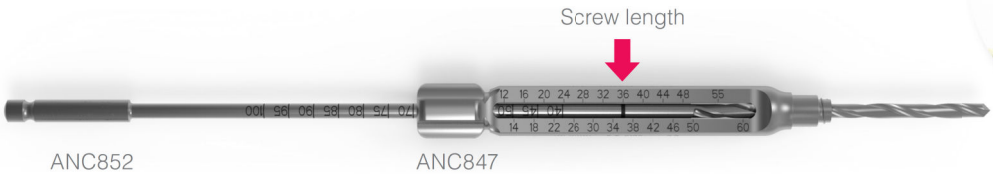
Compression of the joint up to 2.5 mm

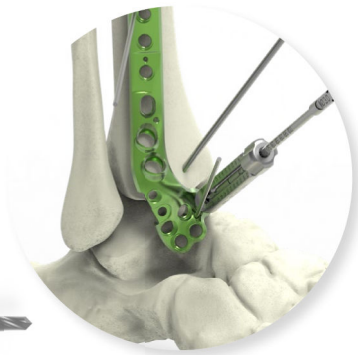
If no additional compression is required, a Ø4.0 mm locking screw (SOT4.0LxxD) can be inserted into the distal part of the hole. To do so, use the Ø3.0 mm threaded guide gauge (ANC847).



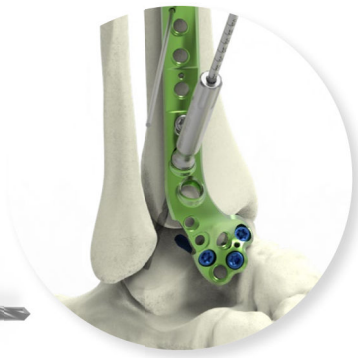
SPECIFIC MEASUREMENT

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 directly read the required length at the rear of the Ø3.0 mm drill guide (ANC855).



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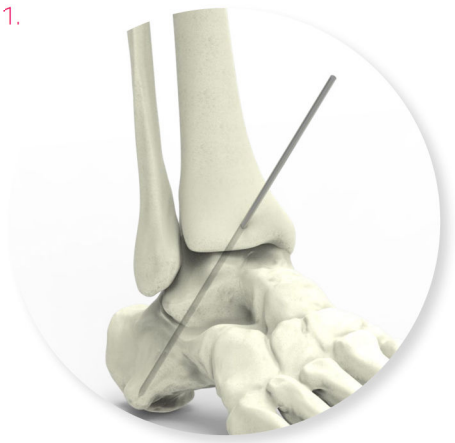
SURGICAL TECHNIQUE

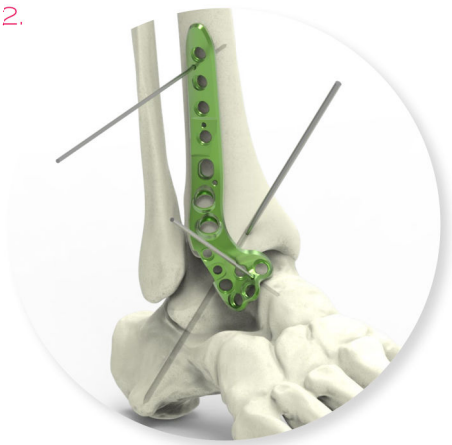
ANTEROLATERAL PLATE

1.



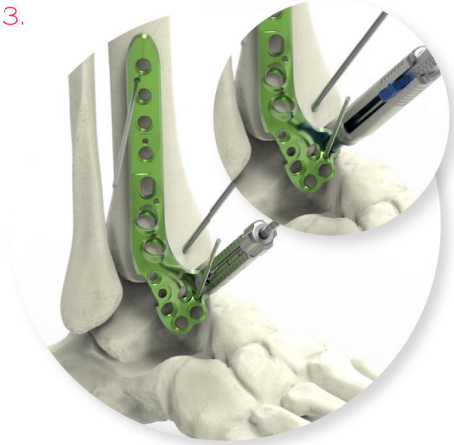
1. Prepare joint surfaces and stabilize the ankle by inserting one or two Ø2.5 mm pins (33.0225.180) through the joint.

2.



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

3.



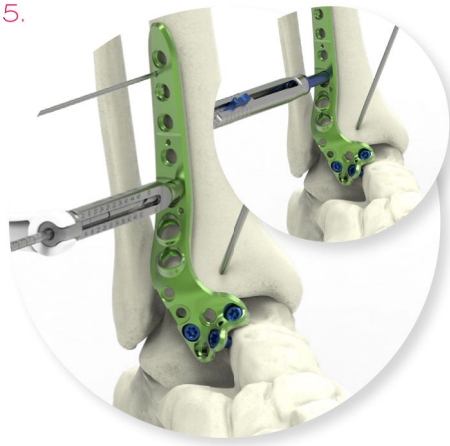
3. Lock the Ø3.0 mm threaded guide gauge (ANC847) into one of the distal locking holes and drill using the Ø3.0 mm drill bit (ANC852). Then measure the corresponding screw length.

Option 1: Determine the screw length using the Ø3.0 mm threaded guide gauge (ANC847) and the Ø3.0 drill bit marking (ANC852).
Option 2: Determine the screw length using the length gauge (ANC856).

4.

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. .

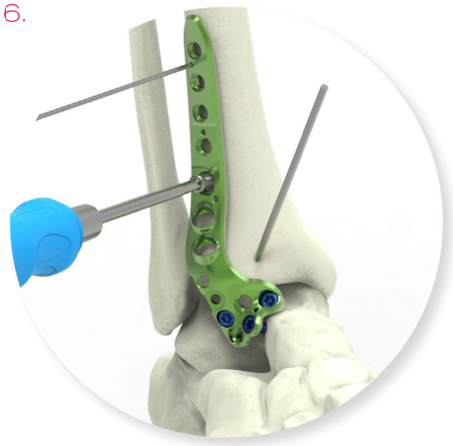
5.



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.

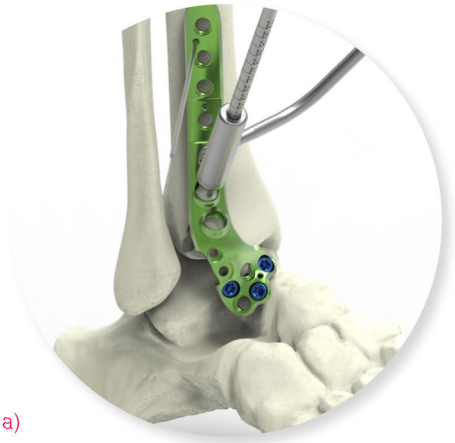
Option 1: Determine the screw length using the Ø3.0 mm threaded guide gauge (ANC847) and the Ø3.0 drill bit marking (ANC852).
Option 2: Determine the screw length using the length gauge (ANC856).

6.



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

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 markings on the Ø3.0 mm drill bit (ANC852) (see technical features).

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.

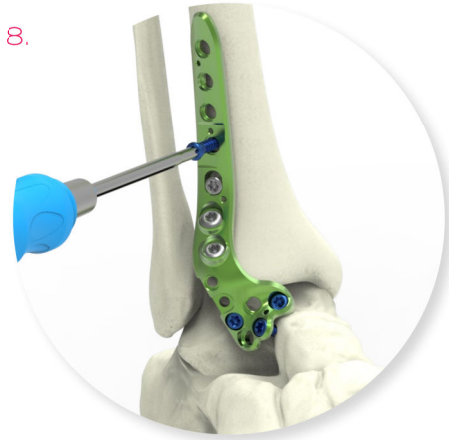
7- Alternative 2 : fixation with neutralization screw
(Ø6.5 mm neutralization screw: CT6.5LxxD)

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).

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.

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SURGICAL TECHNIQUE

ANTERIOR PLATE

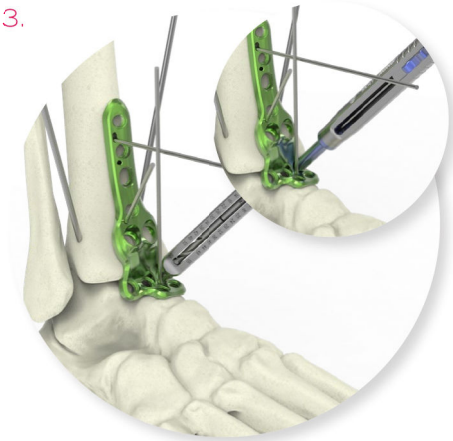
1.

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

2.

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 drill bit marking (ANC852).
Option 2: Determine the screw length using the length gauge (ANC856).

4.

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. .

5.

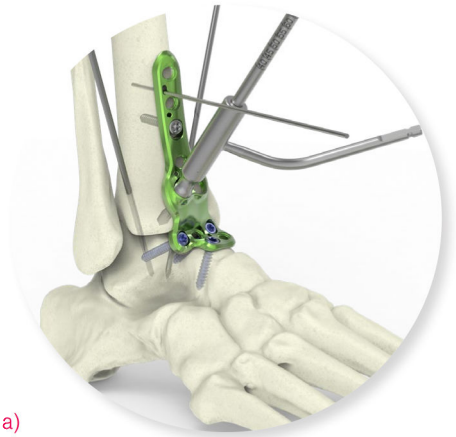
5. Position the guide gauge (ANC847) into the proximal part of the oblong hole. Drill using the Ø3.0 mm drill bit (ANC852) and measure the corresponding screw length.

Option 1: Determine the screw length using the Ø3.0 mm threaded guide gauge (ANC847) and the Ø3.0 drill bit marking (ANC852).
Option 2: Determine the screw length using the length gauge (ANC856).

6.

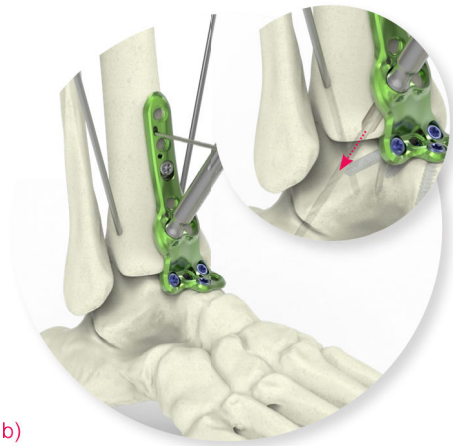
6. Insert a Ø4.0 mm standard cortical screw (CT4.0LxxD) using the T20 screwdriver (ANC854).

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 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 markings on the Ø3.0 mm drill bit (ANC852) (see technical features).

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 neutralization 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).

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.

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IMPLANTS REFERENCES

→ ANTEROLATERAL PLATES

ANTEROLATERAL PLATES	
Ref.	Description
RATDB1	Anterolateral plate for Ankle Arthrodesis - Right - Size 1
RATGB1	Anterolateral plate for Ankle Arthrodesis - Left - Size 1

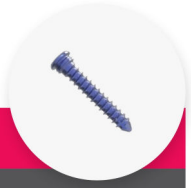
→ ANTERIOR PLATES

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

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

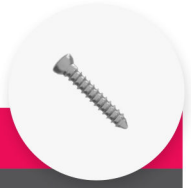
IMPLANTS REFERENCES

→ Ø4.0 MM SCREWS



LOCKING SCREWS*	
Ref.	Description
SOT4.0L12D	Locking screw - Ø4.0 mm - L 12 mm
SOT4.0L14D	Locking screw - Ø4.0 mm - L 14 mm
SOT4.0L16D	Locking screw - Ø4.0 mm - L 16 mm
SOT4.0L18D	Locking screw - Ø4.0 mm - L 18 mm
SOT4.0L20D	Locking screw - Ø4.0 mm - L 20 mm
SOT4.0L22D	Locking screw - Ø4.0 mm - L 22 mm
SOT4.0L24D	Locking screw - Ø4.0 mm - L 24 mm
SOT4.0L26D	Locking screw - Ø4.0 mm - L 26 mm
SOT4.0L28D	Locking screw - Ø4.0 mm - L 28 mm
SOT4.0L30D	Locking screw - Ø4.0 mm - L 30 mm
SOT4.0L32D	Locking screw - Ø4.0 mm - L 32 mm
SOT4.0L34D	Locking screw - Ø4.0 mm - L 34 mm
SOT4.0L36D	Locking screw - Ø4.0 mm - L 36 mm
SOT4.0L38D	Locking screw - Ø4.0 mm - L 38 mm
SOT4.0L40D	Locking screw - Ø4.0 mm - L 40 mm
SOT4.0L42D	Locking screw - Ø4.0 mm - L 42 mm
SOT4.0L44D	Locking screw - Ø4.0 mm - L 44 mm
SOT4.0L46D	Locking screw - Ø4.0 mm - L 46 mm
SOT4.0L48D	Locking screw - Ø4.0 mm - L 48 mm
SOT4.0L50D	Locking screw - Ø4.0 mm - L 50 mm
SOT4.0L55D	Locking screw - Ø4.0 mm - L 55 mm
SOT4.0L60D	Locking screw - Ø4.0 mm - L 60 mm

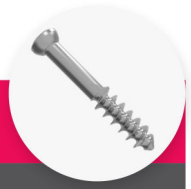
* Blue anodized.



NON LOCKING SCREWS*	
Ref.	Description
CT4.0L12D	Standard cortical screw Ø4.0 mm - L 12 mm
CT4.0L14D	Standard cortical screw Ø4.0 mm - L 14 mm
CT4.0L16D	Standard cortical screw Ø4.0 mm - L 16 mm
CT4.0L18D	Standard cortical screw Ø4.0 mm - L 18 mm
CT4.0L20D	Standard cortical screw Ø4.0 mm - L 20 mm
CT4.0L22D	Standard cortical screw Ø4.0 mm - L 22 mm
CT4.0L24D	Standard cortical screw Ø4.0 mm - L 24 mm
CT4.0L26D	Standard cortical screw Ø4.0 mm - L 26 mm
CT4.0L28D	Standard cortical screw Ø4.0 mm - L 28 mm
CT4.0L30D	Standard cortical screw Ø4.0 mm - L 30 mm
CT4.0L32D	Standard cortical screw Ø4.0 mm - L 32 mm
CT4.0L34D	Standard cortical screw Ø4.0 mm - L 34 mm
CT4.0L36D	Standard cortical screw Ø4.0 mm - L 36 mm
CT4.0L38D	Standard cortical screw Ø4.0 mm - L 38 mm
CT4.0L40D	Standard cortical screw Ø4.0 mm - L 40 mm
CT4.0L42D	Standard cortical screw Ø4.0 mm - L 42 mm
CT4.0L44D	Standard cortical screw Ø4.0 mm - L 44 mm
CT4.0L46D	Standard cortical screw Ø4.0 mm - L 46 mm
CT4.0L48D	Standard cortical screw Ø4.0 mm - L 48 mm
CT4.0L50D	Standard cortical screw Ø4.0 mm - L 50 mm
CT4.0L55D	Standard cortical screw Ø4.0 mm - L 55 mm
CT4.0L60D	Standard cortical screw Ø4.0 mm - L 60 mm

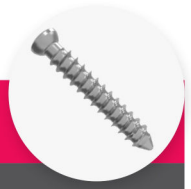
* Not anodized.

→ Ø6.5 MM SCREWS



Ø6,5 mm LAG SCREWS*	
Ref.	Description
QT6.5L40D	Lag screw - Ø6.5 mm - L 40 mm
QT6.5L45D	Lag screw - Ø6.5 mm - L 45 mm
QT6.5L50D	Lag screw - Ø6.5 mm - L 50 mm
QT6.5L55D	Lag screw - Ø6.5 mm - L 55 mm
QT6.5L60D	Lag screw - Ø6.5 mm - L 60 mm
QT6.5L65D	Lag screw - Ø6.5 mm - L 65 mm
QT6.5L70D	Lag screw - Ø6.5 mm - L 70 mm
QT6.5L75D	Lag screw - Ø6.5 mm - L 75 mm
QT6.5L80D	Lag screw - Ø6.5 mm - L 80 mm
QT6.5L85D	Lag screw - Ø6.5 mm - L 85 mm
QT6.5L90D	Lag screw - Ø6.5 mm - L 90 mm
QT6.5L95D	Lag screw - Ø6.5 mm - L 95 mm
QT6.5L100D	Lag screw - Ø6.5 mm - L 100 mm

* Not anodized



Ø6,5 mm CORTICAL SCREWS*	
Ref.	Description
CT6.5L40D	Standard cortical screw - Ø6.5 mm - L 40 mm
CT6.5L45D	Standard cortical screw - Ø6.5 mm - L 45 mm
CT6.5L50D	Standard cortical screw - Ø6.5 mm - L 50 mm
CT6.5L55D	Standard cortical screw - Ø6.5 mm - L 55 mm
CT6.5L60D	Standard cortical screw - Ø6.5 mm - L 60 mm
CT6.5L65D	Standard cortical screw - Ø6.5 mm - L 65 mm
CT6.5L70D	Standard cortical screw - Ø6.5 mm - L 70 mm
CT6.5L75D	Standard cortical screw - Ø6.5 mm - L 75 mm
CT6.5L80D	Standard cortical screw - Ø6.5 mm - L 80 mm
CT6.5L85D	Standard cortical screw - Ø6.5 mm - L 85 mm
CT6.5L90D	Standard cortical screw - Ø6.5 mm - L 90 mm
CT6.5L95D	Standard cortical screw - Ø6.5 mm - L 95 mm
CT6.5L100D	Standard cortical screw - Ø6.5 mm - L 100 mm

* Not anodized.

→ ADDITIONAL IMPLANTS

ADDITIONAL IMPLANTS : LARGE SCREWS*	
Ref	Description
H1.7IFT6.0LXX	Self-drilling self-compressive screw - Ø6.0 mm cannulated Ø1.7 mm - L40 to L100 mm (5 mm increment)
H2.7IFT8.0Lxx	Self-drilling self-compressive screw – Ø8.0 mm – cannulated Ø2.7 mm – L40 mm to L100 mm (5 mm incrementation)

* For more information, see the Large Screws range sales brochure.

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.

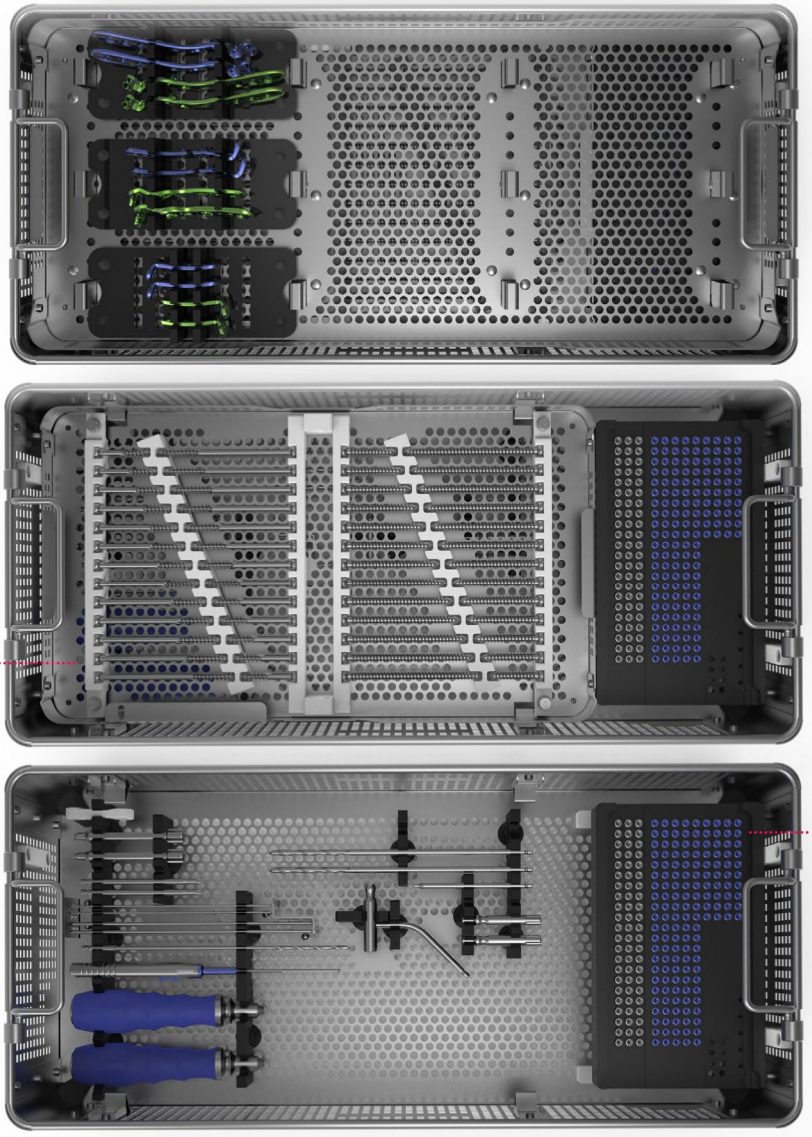
INSTRUMENTS REFERENCES

INSTRUMENTATION CONTENTS

Ref.	Description	Qty
ANC351	Ø4.7 mm AO quick coupling handle - Size 2	2
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
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

ADDITIONAL INSTRUMENTS FOR LARGE 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	Length gauge for Ø4.0 mm screws	1
ANC442	Pin Ø1.6 L150 mm	1
ANC443	Pin Ø2.5 L180 mm	1
ANC453	Quick coupling adaptor Ø11 mm – AO Ø4.5 mm	1
33.0216.180	Pins – Ø1.6 mm L 180 mm	6



Non contractual pictures.

Brochure EN - Activfuse - Ed2 - 10/2018 - Medical device EC: class IIb - CE0120 SGS UK - US Class: II - Read labeling and instructions before use.

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