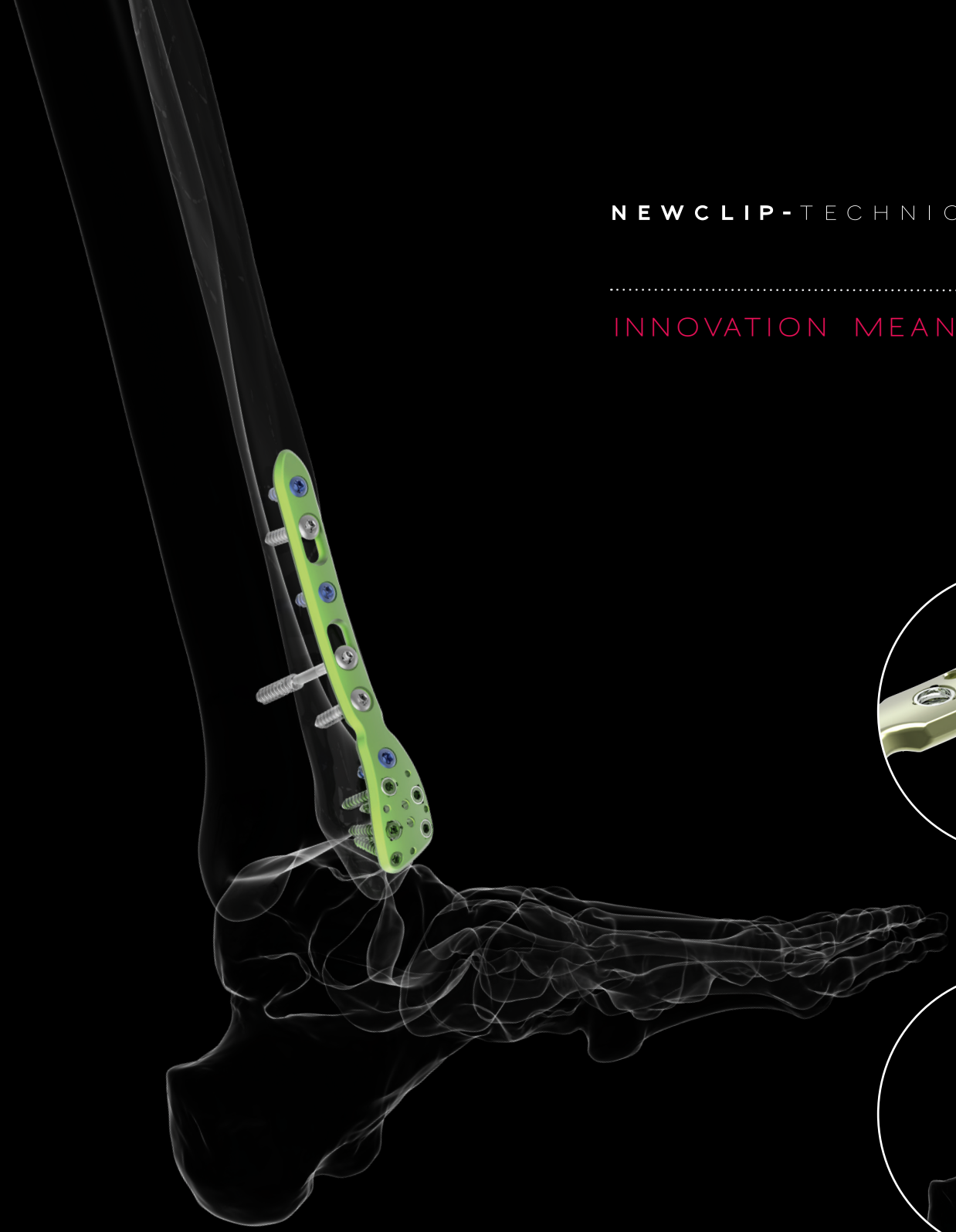
NEWCLIP-TECHNICS

INNOVATION MEANS MOTION



ACTIV ANKLE
DISTAL AND DIAPHYSEAL FIBULA
MEDIAL MALLEOLUS

POLYAXIAL LOCKING FIXATION
DUALTEC SYSTEM ® II

- Precontoured implants
- Polyaxiality of 20°
- 2 surgical approaches: lateral and posterolateral
- Medial malleolus fixation

ACTIV ANKLE

Indications: The Activ Ankle range is intended for the fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the syndesmotic repair in adults.

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 the correct insertion 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.

DISTAL FIBULA PLATES

LATERAL APPROACH

STANDARD PLATE

- Fixation of osteoporotic bones and complex fractures with or without syndesmosis injuries.

NARROW PLATE

- Fixation of simple fractures with or without syndesmosis injuries.

POSTEROLATERAL APPROACH

POSTEROLATERAL PLATE

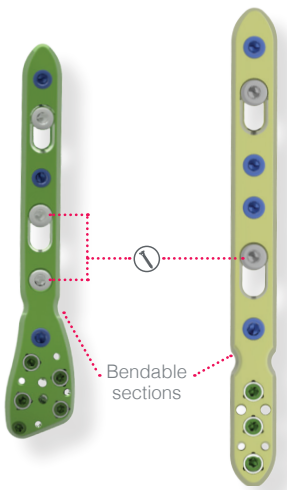
- Fixation of short oblique fractures (Type B, as defined by the AO and Weber Classifications).

TECHNICAL FEATURES

A COMPREHENSIVE RANGE OF PLATES

LATERAL STANDARD

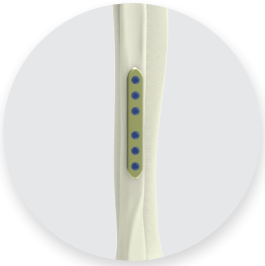
LATERAL NARROW



POSTEROLATERAL

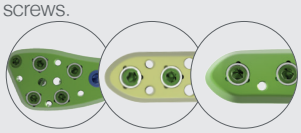
DIAPHYSEAL PLATE

For diaphyseal simple fractures

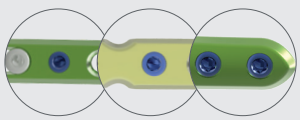


Ø3.5 mm cortical screws (CT3.5Lxx) or Ø4.0 mm lag screws (QT4.0Lxx) for the syndesmosis fixation.

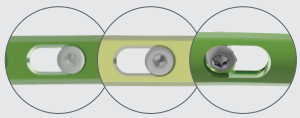
- DTS2® polyaxial holes for locking and non-locking Ø2.8 mm screws.



- Holes for locking and non-locking Ø3.5 mm screws.



- Oblong holes for Ø3.5 mm cortical screws.



TECHNICAL FEATURES

A PRECONTOURED IMPLANT

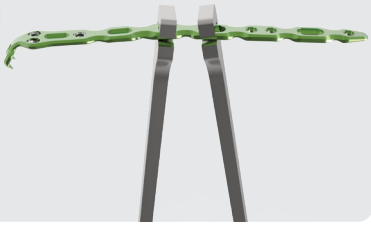
→ OPTIMAL ANATOMICAL CONGRUENCE

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

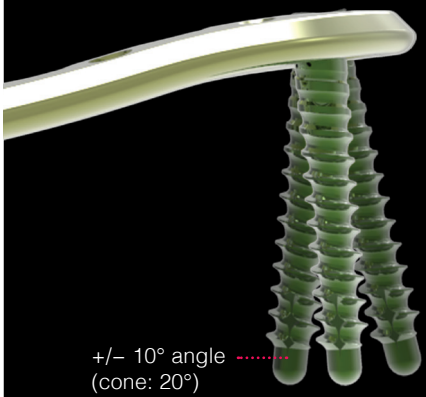
PLATE BENDING

The diaphyseal part of the fibula can vary from one patient to the other. In the case of long plates, it is possible to bend the diaphyseal part of plates at each appropriate area using bending irons (ANC542) for an optimal fit to the bone anatomy, following the instructions below:

> Bending is only possible in the areas intended for this purpose,
> A bendable area should be bent only once and in one direction,
> Bending should not be performed excessively,
> The holes must be protected so as to avoid damaging the fixation.



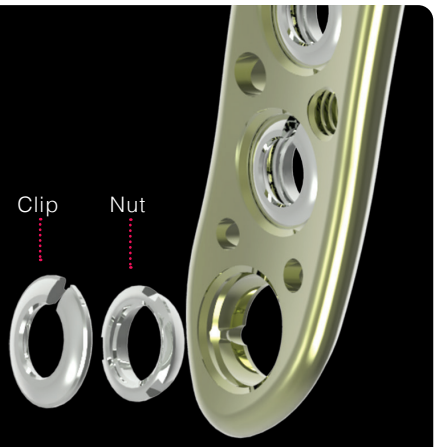
ANGULAR RANGE: +/- 10° POLYAXIAL LOCKING FIXATION



→ THE DTS2® TECHNOLOGY ALLOWS THE SCREW TO LOCK INTO THE PLATE WHILE PERMITTING AN ANGULATION OF THE SCREW.

Newclip Technics plates combine both polyaxial and locking technologies to create a fixed-angle construct particularly useful for poor bone quality and/or multifragmentary fractures.

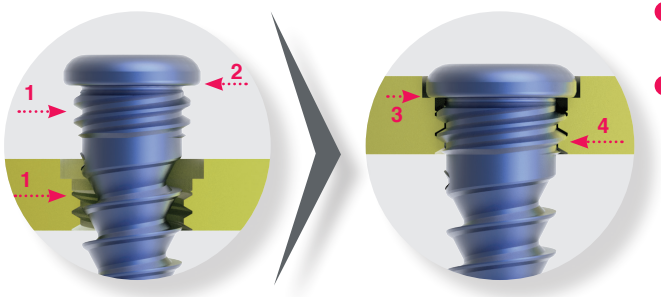
The DTS2® polyaxial locking holes are located in the epiphyseal area, thus facilitating the insertion of the epiphyseal screws in diverging or converging directions and allowing for optimal strength of the assembly.



MONOAXIAL LOCKING FIXATION

→ FEATURES

- The threaded sections under the screw head and inside the hole have **the same characteristics** (1):
  - Cylindrical internal thread profile,
  - Cylindrical external thread profile,
- Screw head cap (2),
- Plate and screw made from the same material: titanium alloy.

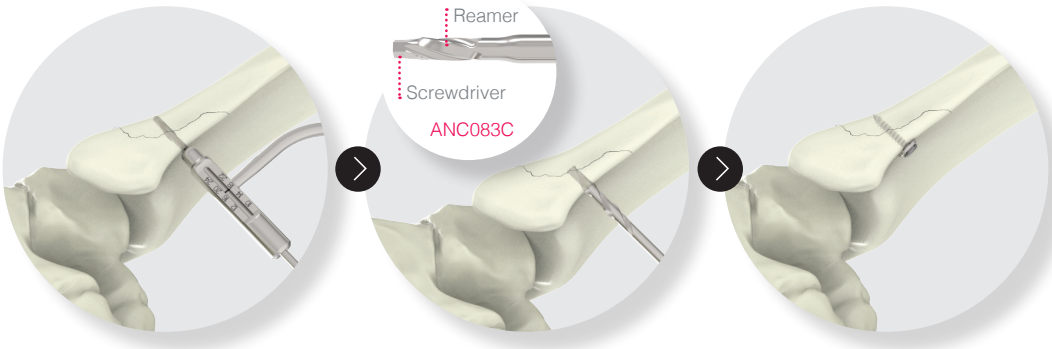


→ RESULTS

- The screw is stopped in the hole by its cap, insuring the locking (3),
- A perfect coaptation of both profiles during locking (4).

PLACEMENT OF THE LATERAL PLATE

→ PRELIMINARY REDUCTION OF THE FRACTURE WITH A SCREW



1. Reduce and temporarily maintain the fracture with bone reduction forceps (ANC504), making sure not to hinder the subsequent positioning of the screw.
Drill with the Ø2.7 mm drill bit (ANC089C) using the guide gauge[1] (ANC191). The drilling should be perpendicular to the line of fracture.

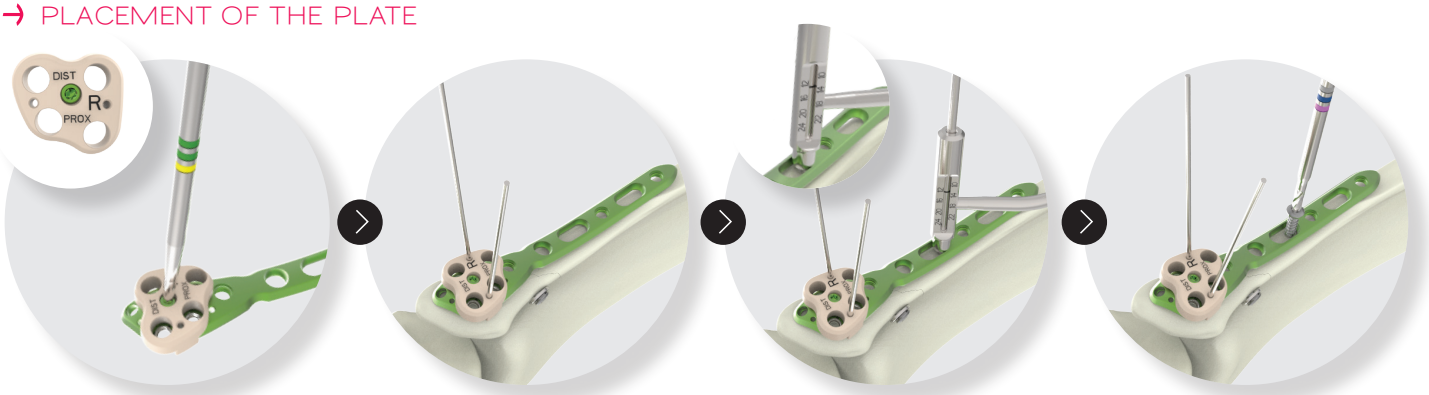
2. When a lag effect is desired, over-drill the anterior cortex only by using the Ø3.5 mm drill bit (ANC542) according to the allowed compression principles. To simplify the procedure, it is also possible to use the reamer part of the 2 in 1 instrument (ANC083C).

3. Insert the Ø3.5 mm cortical screw (CT3.5Lxx) through the line of fracture using the screwdriver part of the 2 in 1 instrument (ANC083C).
In the case of osteoporotic bone, a compression washer (WASH-T4) can be added under the screw head so as to obtain optimized compression.

Remark:
As an osteosynthesis screw used alone cannot bear weight and resist shear stresses, a plate should be used to allow early mobilization.

(1) The screw length can be directly read on the guide gauge. Always ensure that the guide gauge sits flush against the bone surface.

→ PLACEMENT OF THE PLATE

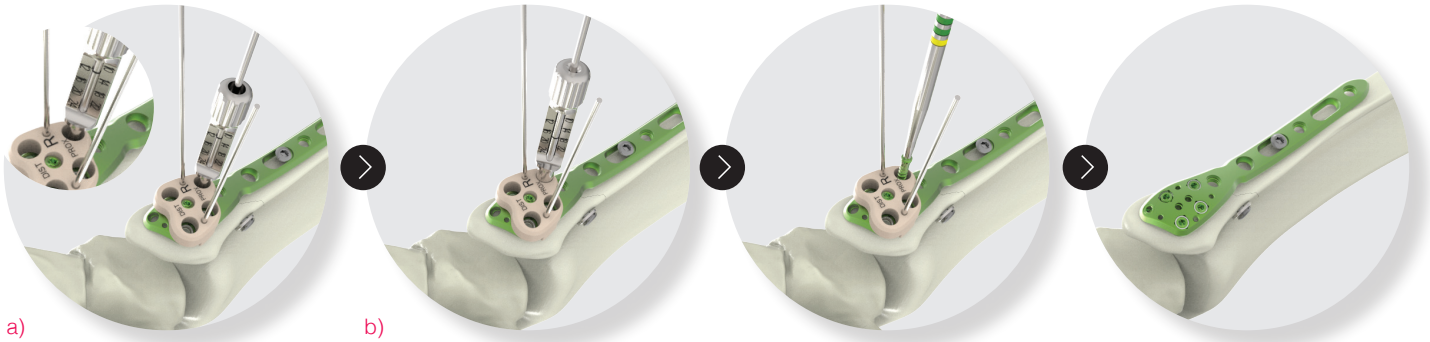


4. Check the positioning of the fast guide thanks to the 'DISTAL' and 'PROXIMAL' marks.
Lock the fast guide onto the plate with the screwdriver (ANC082E).
.

5. The plate can be temporarily held in position with Ø1.3 mm pins (33.0213.120).

6. Drill (ANC089C) using the guide gauge (ANC191). The screw length can be directly read on the guide gauge.

7. Insert a Ø3.5 mm cortical screw (CT3.5Lxx) into the oblong hole with the screwdriver part of the 2 in 1 instrument (ANC083C). For optimal positioning, slide the plate using the oblong hole and tighten the cortical screw.



a)

b)

8. For the epiphyseal fixation, drill using the threaded guide gauge (ANC268C) for polyaxial fixation (a) or the non-threaded guide gauge (ANC046C) for monoaxial fixation (b) through the pre-angled fast guide. The screw length can be directly read on the guide gauge. For the monoaxial distal hole, drill (ANC088C) using the threaded guide gauge (ANC268C).

9. Insert a Ø2.8 mm locking screw (SDT2.8Lxx) through the fast guide using the screwdriver (ANC082E).

10. Repeat the whole procedure to insert the remaining distal Ø2.8 mm locking screws (SDT2.8Lxx) and remove the fast guide.

SURGICAL TECHNIQUE

11. For the diaphyseal fixation, drill using the guide gauge (ANC186) and insert the Ø3.5 mm locking screws (SOT3.5Lxx). For the Ø3.5 mm cortical screws (CT3.5Lxx) insertion, repeat this procedure using the guide gauge (ANC191)[2]. The final tightening of the screws must be performed by hand.

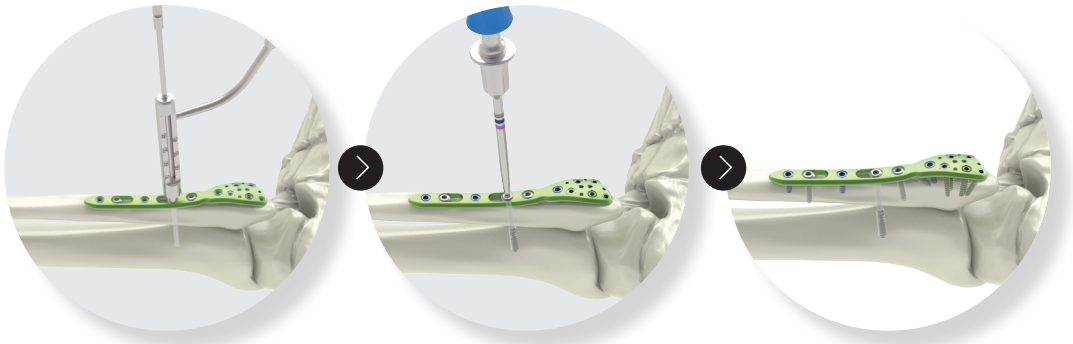
NB: To ease the insertion of the Ø3.5 mm locking screws (SOT3.5Lxx), use the reamer part of the 2 in 1 instrument (ANC083C) to widen the first cortex previously drilled.

FINAL RESULT

Remark:
The fixation steps remain unchanged for Narrow (RTSL-Nx) or Posterolateral plates (RTxQ1).

(2) In the case of a bicortical fixation, the drilling depth can be checked on the length gauge (ANC124).

SYNDESMOSIS FIXATION



1. Drill (ANC256M) through the holes designed for syndesmosis screws using the guide gauge (ANC261M). The screw length can be directly read on the guide gauge.

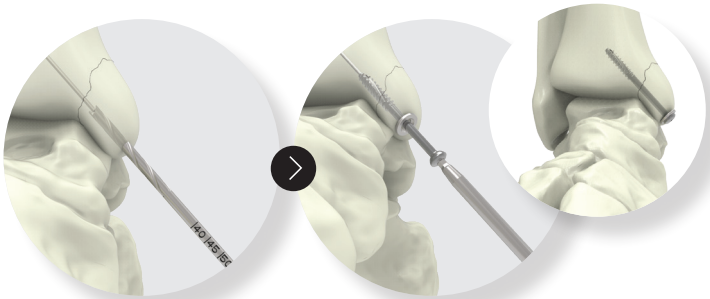
2. Insert (ANC083C) a syndesmosis screw: Ø3.5 mm solid cortical screw (CT3.5Lxx) or Ø4.0 mm solid lag screw (QT4.0Lxx) into the appropriate oblong hole and/or standard hole designed for that purpose.

FINAL RESULT

MEDIAL MALLEOLUS FIXATION

→ OPTION 1: WITH A CANNULATED SCREW

(Ø4.0 mm cannulated compressive screw)

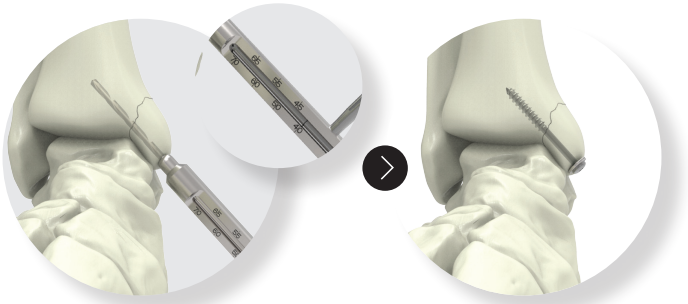


1. Insert the guiding Ø1.3 mm pin (33.0213.120). Then, introduce the Ø2.9 mm cannulated drill bit (ANC414M) onto the guiding pin and drill. Read the screw length on the drill bit.

2. Insert the Ø4.0 mm compressive cannulated screw (H1.4QT4.0Lxx) using the cannulated screwdriver (ANC388) then remove the pin.

→ OPTION 2: WITH SOLID SCREW

(Ø3.5 mm solid cortical screw / Ø4.0 mm solid lag screw)



1. Drill (ANC089C) using the guide gauge (ANC191). The screw length can be directly read on the guide gauge. Always ensure that the guide gauge sits flush against the bone surface.

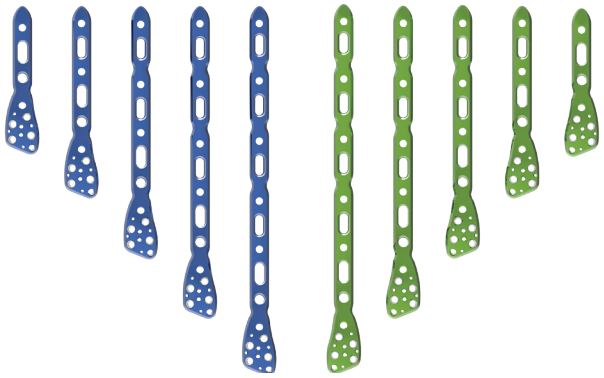
2. Insert the Ø4.0 mm lag screw (QT4.0Lxx) or the Ø3.5 mm cortical screw (CT3.5Lxx) using the screwdriver part of the 2 in 1 instrument (ANC083C).

Remarks:

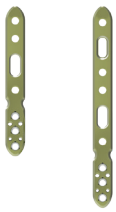
1. In the case of osteoporotic bone, add a compression washer (WASH-T4) under the screw head so as to obtain optimal compression (see above).
2. Follow the whole procedure for adding a second screw.

IMPLANTS REFERENCES

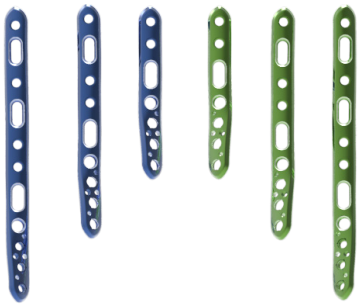
→ DISTAL PLATES



LATERAL STANDARD PLATES	
Ref.	Description
RTGLS1	Lateral plate for distal fibula - Standard Left - Size 1
RTDLS1	Lateral plate for distal fibula - Standard Right - Size 1
RTGLS2	Lateral plate for distal fibula - Standard Left - Size 2
RTDLS2	Lateral plate for distal fibula - Standard Right - Size 2
RTGLS3	Lateral plate for distal fibula - Standard Left - Size 3
RTDLS3	Lateral plate for distal fibula - Standard Right - Size 3
RTGLS4	Lateral plate for distal fibula - Standard Left - Size 4
RTDLS4	Lateral plate for distal fibula - Standard Right - Size 4
RTGLS5	Lateral plate for distal fibula - Standard Left - Size 5
RTDLS5	Lateral plate for distal fibula - Standard Right - Size 5



LATERAL NARROW PLATES	
Ref.	Description
RTSLN1	Lateral plate for distal fibula - Narrow symmetrical - Size 1
RTSLN2	Lateral plate for distal fibula - Narrow symmetrical - Size 2



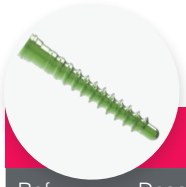
POSTEROLATERAL PLATES	
Ref.	Description
RTGQ1	Posterolateral plate for distal fibula - Left - Size 1
RTDQ1	Posterolateral plate for distal fibula - Right - Size 1
RTGQ2	Posterolateral plate for distal fibula - Left - Size 2
RTDQ2	Posterolateral plate for distal fibula - Right - Size 2
RTGQ3	Posterolateral plate for distal fibula - Left - Size 3
RTDQ3	Posterolateral plate for distal fibula - Right - Size 3

→ DIAPHYSEAL PLATE

DIAPHYSEAL PLATE	
Ref.	Description
FTS1	Plate for diaphyseal fibula fracture - Size 1

IMPLANTS REFERENCES

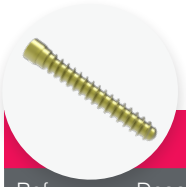
→ Ø2.8 MM SCREWS



LOCKING SCREWS*

Ref.	Description
SDT2.8L10	Ø2.8 mm locking screw - L10 mm
SDT2.8L12	Ø2.8 mm locking screw - L12 mm
SDT2.8L14	Ø2.8 mm locking screw - L14 mm
SDT2.8L16	Ø2.8 mm locking screw - L16 mm
SDT2.8L18	Ø2.8 mm locking screw - L18 mm
SDT2.8L20	Ø2.8 mm locking screw - L20 mm
SDT2.8L22	Ø2.8 mm locking screw - L22 mm
SDT2.8L24	Ø2.8 mm locking screw - L24 mm

* Green anodized.



NON LOCKING SCREWS*

Ref.	Description
QDT2.8L10	Ø2.8 mm non locking screw - L10 mm
QDT2.8L12	Ø2.8 mm non locking screw - L12 mm
QDT2.8L14	Ø2.8 mm non locking screw - L14 mm
QDT2.8L16	Ø2.8 mm non locking screw - L16 mm
QDT2.8L18	Ø2.8 mm non locking screw - L18 mm
QDT2.8L20	Ø2.8 mm non locking screw - L20 mm
QDT2.8L22	Ø2.8 mm non locking screw - L22 mm
QDT2.8L24	Ø2.8 mm non locking screw - L24 mm

* Golden anodized.

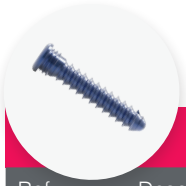
Remark:

Please note that all implants are also available in sterile packaging.

An '-ST' code is added at the end of the reference.

Eg. : « SDT2.8L10-ST »

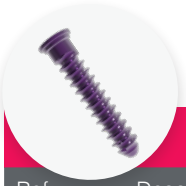
→ Ø3.5 MM SCREWS



LOCKING SCREWS*

Ref.	Description
SOT3.5L10	Ø3.5 mm locking screw - L10 mm
SOT3.5L12	Ø3.5 mm locking screw - L12 mm
SOT3.5L14	Ø3.5 mm locking screw - L14 mm
SOT3.5L16	Ø3.5 mm locking screw - L16 mm
SOT3.5L18	Ø3.5 mm locking screw - L18 mm
SOT3.5L20	Ø3.5 mm locking screw - L20 mm
SOT3.5L22	Ø3.5 mm locking screw - L22 mm
SOT3.5L24	Ø3.5 mm locking screw - L24 mm

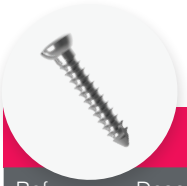
* Blue anodized.



NON-LOCKING SCREWS*

Ref.	Description
QOT3.5L10	Ø3.5 mm non locking screw - L10 mm
QOT3.5L12	Ø3.5 mm non locking screw - L12 mm
QOT3.5L14	Ø3.5 mm non locking screw - L14 mm
QOT3.5L16	Ø3.5 mm non locking screw - L16 mm
QOT3.5L18	Ø3.5 mm non locking screw - L18 mm
QOT3.5L20	Ø3.5 mm non locking screw - L20 mm
QOT3.5L22	Ø3.5 mm non locking screw - L22 mm
QOT3.5L24	Ø3.5 mm non locking screw - L24 mm

* Purple anodized.

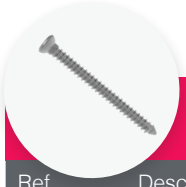


CORTICAL SCREWS*

Ref.	Description
CT3.5L10	Ø3.5 mm cortical screw - L10 mm
CT3.5L12	Ø3.5 mm cortical screw - L12 mm
CT3.5L14	Ø3.5 mm cortical screw - L14 mm
CT3.5L16	Ø3.5 mm cortical screw - L16 mm
CT3.5L18	Ø3.5 mm cortical screw - L18 mm
CT3.5L20	Ø3.5 mm cortical screw - L20 mm
CT3.5L22	Ø3.5 mm cortical screw - L22 mm
CT3.5L24	Ø3.5 mm cortical screw - L24 mm

* Not anodized or light blue anodized for sterile screws.

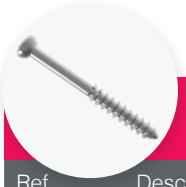
→ SYNDESMOSIS AND MEDIAL MALLEOLUS SCREWS



Ø3.5 mm CORTICAL SCREWS*

Ref.	Description
CT3.5L40	Ø3.5 mm cortical screw - L40 mm
CT3.5L45	Ø3.5 mm cortical screw - L45 mm
CT3.5L50	Ø3.5 mm cortical screw - L50 mm
CT3.5L55	Ø3.5 mm cortical screw - L55 mm
CT3.5L60	Ø3.5 mm cortical screw - L60 mm
CT3.5L65	Ø3.5 mm cortical screw - L65 mm
CT3.5L70	Ø3.5 mm cortical screw - L70 mm

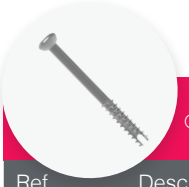
* Not anodized or light blue anodized for sterile screws.



Ø4.0 mm LAG SCREWS*

Ref.	Description
QT4.0L40	Ø4.0 mm lag screw - L40 mm
QT4.0L45	Ø4.0 mm lag screw - L45 mm
QT4.0L50	Ø4.0 mm lag screw - L50 mm
QT4.0L55	Ø4.0 mm lag screw - L55 mm
QT4.0L60	Ø4.0 mm lag screw - L60 mm
QT4.0L65	Ø4.0 mm lag screw - L65 mm
QT4.0L70	Ø4.0 mm lag screw - L70 mm

* Not anodized.



Ø4.0 mm CANNULATED SCREWS* (for medial malleolus **only**)**

Ref.	Description
H1.4QT4.0L40	Self-drilling compressive screw - Ø4.0 mm - cannulated Ø1.4 mm - L40 mm
H1.4QT4.0L45	Self-drilling compressive screw - Ø4.0 mm - cannulated Ø1.4 mm - L45 mm
H1.4QT4.0L50	Self-drilling compressive screw - Ø4.0 mm - cannulated Ø1.4 mm - L50 mm
H1.4QT4.0L55	Self-drilling compressive screw - Ø4.0 mm - cannulated Ø1.4 mm - L55 mm
H1.4QT4.0L60	Self-drilling compressive screw - Ø4.0 mm - cannulated Ø1.4 mm - L60 mm
H1.4QT4.0L65	Self-drilling compressive screw - Ø4.0 mm - cannulated Ø1.4 mm - L65 mm
H1.4QT4.0L70	Self-drilling compressive screw - Ø4.0 mm - cannulated Ø1.4 mm - L70 mm

* Not anodized.

** Optional, as a replacement for QT4.0Lxx

→ COMPRESSION WASHER, OPTIONAL

WASH-T4: Washer

INSTRUMENTS REFERENCES

INSTRUMENTS		
Ref.	Description	Qty
ANC046C	Ø2.0 mm non-threaded guide gauge for Ø2.8 mm screws	1
ANC082E	2.0 mm quick coupling hexagonal prehensor screwdriver	1
ANC083C	2-in-1: 2.5 mm hexagonal prehensor screwdriver - Ø3.5 mm countersink	2
ANC084	Ø2.8 mm quick coupling countersink	1
ANC088C	Ø2.0 mm quick coupling drill bit - L125 mm	2
ANC089C	Ø2.7 mm quick coupling drill bit - L125 mm	2
ANC102	Length gauge for Ø2.8 mm screws	1
ANC103	2.0 mm hexagonal non prehensor screwdriver	1
ANC107	2.5 mm quick coupling hexagonal non prehensor screwdriver	1
ANC124	Length gauge for Ø3.5 mm cortical screws	1
ANC186	Ø2.7 mm threaded guide gauge for Ø3.5 mm screws	2
ANC191	Ø2.7 mm non-threaded bent guide gauge for Ø3.5 mm screws	1
ANC252	Fast drilling guide for RTGLSx plates	1
ANC253	Fast drilling guide for RTDLSx plates	1
ANC256M	Ø2.7 mm quick coupling drill bit - L180 mm	1
ANC261M	Ø2.7 mm non-threaded bent long guide gauge for Ø3.5 and Ø4.0 mm screws	1
ANC268C	Ø2.0 mm threaded guide gauge for Ø2.8 mm screws	2
ANC349	15 cm verbrugge forceps	2
ANC350	Ø4.5 mm AO quick coupling handle - Size 1	2

INSTRUMENTS		
Ref.	Description	Qty
ANC452	Bending iron	2
ANC454	Fast drilling guide for RTGQx plates	1
ANC455	Fast drilling guide for RTDQx plates	1
ANC456	Fast drilling guide for RTSLNx plates	1
ANC463	Ø3.5 mm quick coupling countersink	1
ANC503	150 mm Reduction forceps	1
ANC504	150 mm pointed reduction forceps	1
ANC542	Ø3.5 mm quick coupling drill bit - L125 mm	*
33.0213.120	Pin Ø1.3 L120 mm	6
A10407M	12 cm pin for washers	*
30920	Prehensive plier	*

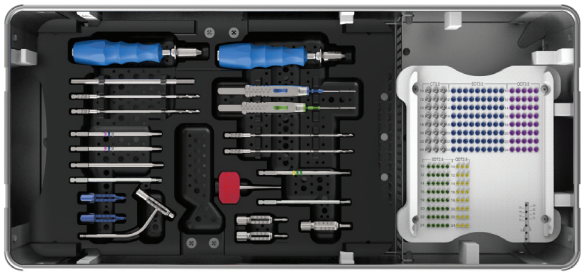
*: Optional

INSTRUMENTS FOR CANNULATED SCREWS (optional)		
Ref	Description	Qty
ANC388	2.5 mm quick coupling hexagonal non prehensor screwdriver - cannula Ø1.4 mm	1
ANC414M	Quick coupling drill bit Ø2.9 mm - cannula 1.4 mm - L125 mm	1

REMOVAL SET

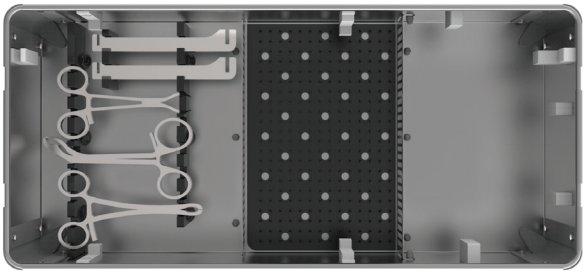
If you have to remove Activ Ankle implants, make sure to order the Newclip Technics removal set which includes the following instruments :
- ANC103 for Ø2.8 mm screws: 2.0 mm hexagonal non prehensor screwdriver
- ANC107 or ANC016 for Ø3.5 mm and Ø4.0 mm screws: 2.5 mm hexagonal screwdrivers
- ANC350: Ø4.5 mm AO quick coupling handle - Size 1

SET DESCRIPTION



INSTRUMENTS TRAY (ANC254/I2)

SCREWS RACK (ANC254/R)

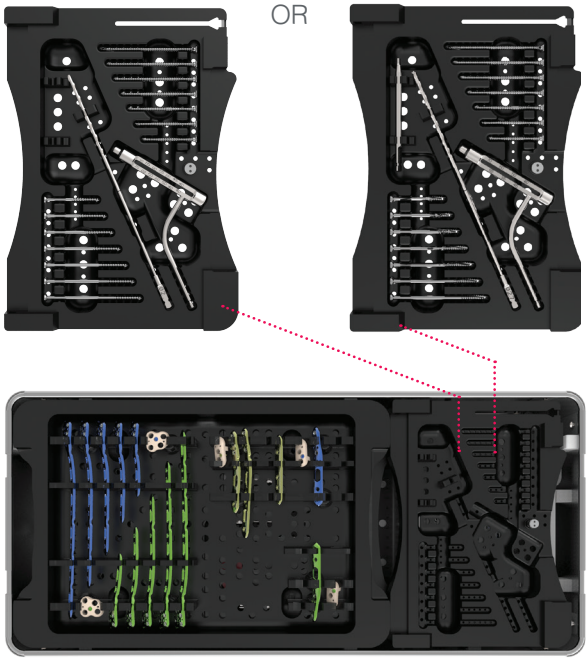


BASE (ANC254/B)

ANC254/I3 for CT3.5Lxx and QT4.0Lxx

OR

ANC254/I3 for CT3.5Lxx and H1.4QT4.0Lxx



IMPLANTS TRAY (ANC254/I1)

Brochure US - Activ Ankle - ED6 - 05/2021 - Medical device class IIb - CE 1639 SGS BE - US class II - Read labeling and instructions before use.

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