

ACTIV ANKLE.



DISTAL AND
DIAPHYSEAL FIBULA
MEDIAL MALLEOLUS



ACTIV ANKLE

Intended purpose: The implants of the Activ Ankle range are 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.

Contraindications:

- Pregnancy.
- Acute or chronic local or systemic infections.
- Allergy to one of the materials used or sensitivity to foreign bodies.

TECHNICAL FEATURES

DISTAL FIBULA PLATES

LATERAL APPROACH



STANDARD PLATE

➤ Available in 5 sizes.



NARROW PLATE

➤ Available in 2 sizes.

POSTEROLATERAL APPROACH

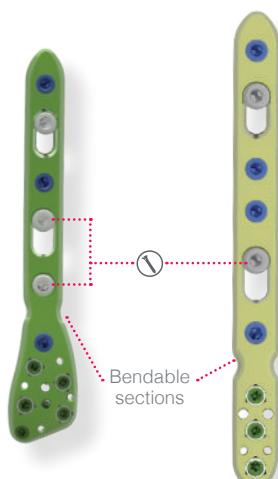


POSTEROLATERAL PLATE

➤ Available in 3 sizes.

A COMPREHENSIVE RANGE OF PLATES

LATERAL
STANDARD



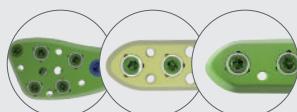
LATERAL
NARROW

POSTEROLATERAL

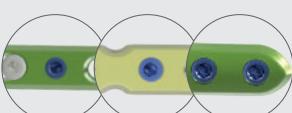
DIAPHYSEAL
PLATE

➤ Ø3.5 mm non-locking screw (CT3.5Lxx) or Ø4.0 mm lag screws (QT4.0Lxx) for the syndesmosis fixation.

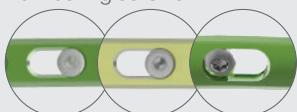
➤ DTS2® polyaxial holes for locking and non-locking Ø2.8 mm screws.



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



➤ Oblong holes for Ø3.5 mm non-locking screws.



TECHNICAL FEATURES

DISTAL TIBIA STANDARD AND HOOK PLATES

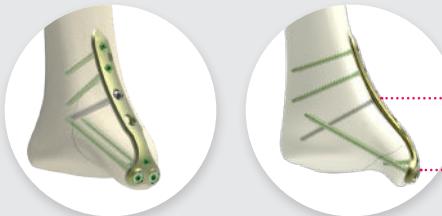
- Anatomical implants for the fixation of distal tibia.
- 3 plates :
 - **2 standard** plates (size 0 and size 1) with 2 upward screws.
 - **Hook plate** with 1 upward screw.
- Implants adapted to vertical and transverse fractures. (See below)



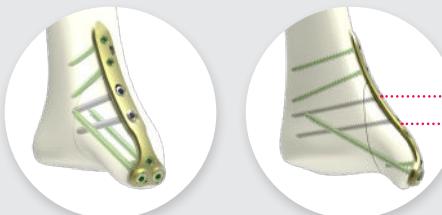
FIXATION

STANDARD PLATES

- Fixation for transverse fractures



- Fixation for vertical fractures



Ramp oblong hole for compression
Upward screws through the fracture line

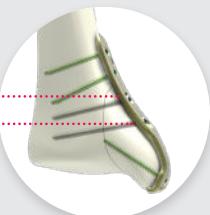
Ramp oblong hole (without compression)
Pre-angled compression hole

HOOK PLATE

- Fixation for transverse fractures



- Fixation for vertical fractures



A PRECONTOURED IMPLANT

→ ANATOMICAL CONGRUENCE

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



PLATE BENDING

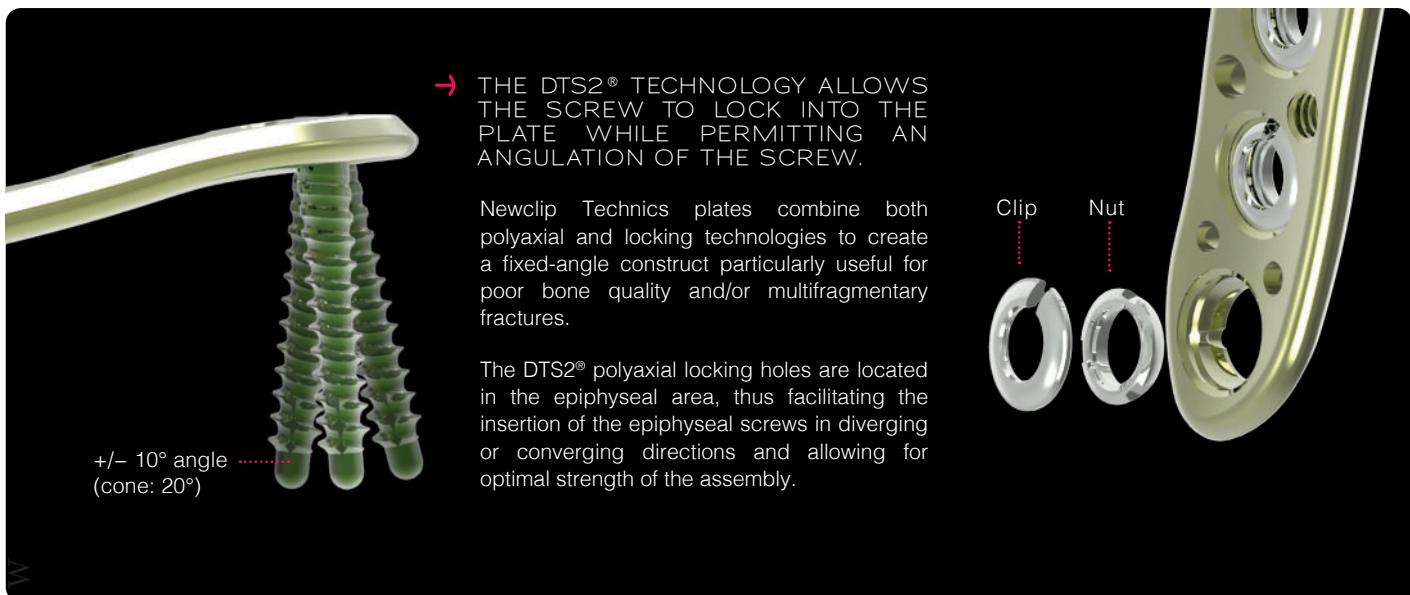
The diaphyseal part of the fibula can vary from one patient to the other. In the case of long plates, it is possible to bend the diaphyseal part of plates at each appropriate area using bending irons (ANC542) for an optimal fit to the bone anatomy, following the instructions below:

- 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.



TECHNICAL FEATURES

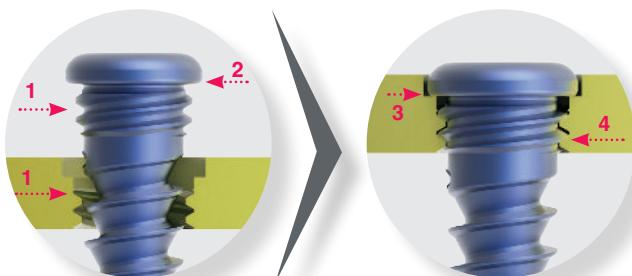
ANGULAR RANGE: +/- 10° POLYAXIAL LOCKING FIXATION



MONOAXIAL LOCKING FIXATION

FEATURES

- The threaded sections under the screw head and inside the hole have strictly **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

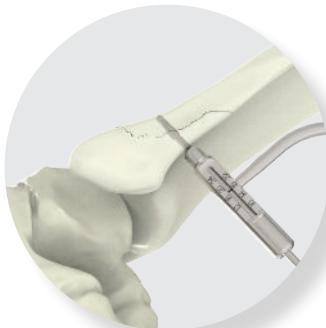
- The screw is stopped in the hole by its cap, insuring the locking (3),
- A complete coaptation of both profiles during locking (4) without threads deformation.

SURGICAL TECHNIQUE

PLACEMENT OF THE LATERAL PLATE

Example using the size 2 lateral standard plate (RTDLS2)

→ 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 gauge¹ (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).

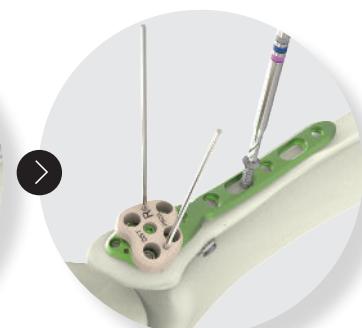
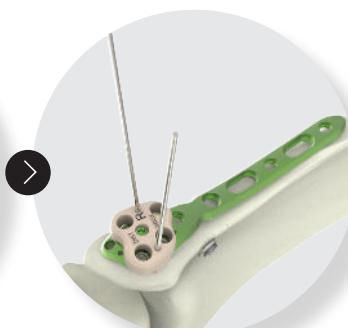
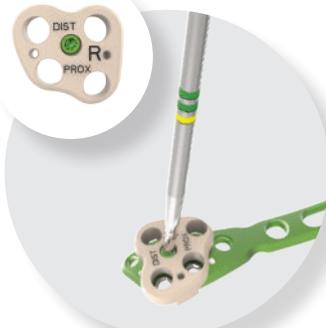
3. Insert the Ø3.5 mm non-locking screw (CT3.5Lxx) through the line of fracture using the screwdriver part of the 2-in-1 instrument (ANC083C). In the case of osteoporotic bone, a compression washer (WASH-T4) can be added under the screw head.

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

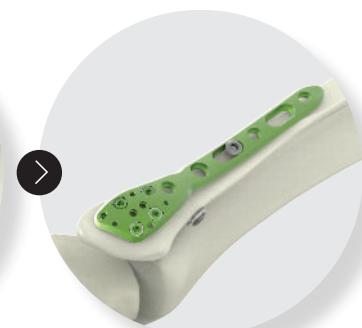
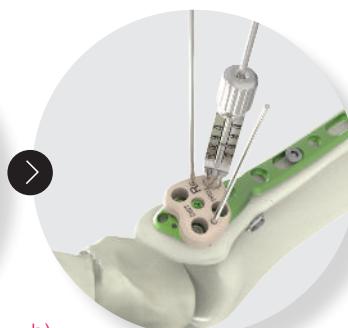
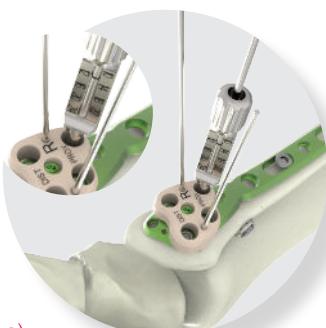


4. Check the positioning of the fast guide thanks to the 'DISTAL' and 'PROXIMAL' marks. Lock the fast guide onto the plate with the screwdriver (ANC082E).

5. The plate can be temporarily held in position with pins.

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 non-locking 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 non-locking screw. To do so, remove the pins.

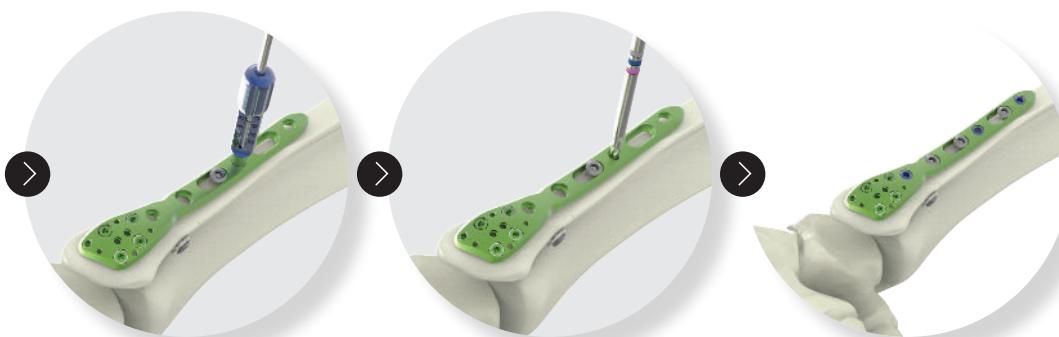


a)
8. For the epiphyseal fixation, drill using the threaded guide gauge (ANC268C) for polyaxial fixation (a) or the non-threaded guide gauge (ANC046C) for monoaxial fixation (b) through the pre-angled fast guide. The screw length can be directly read on the guide gauge. For the monoaxial distal hole,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

b)
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 non-locking screw (CT3.5Lxx) insertion, repeat this procedure using the guide gauge (ANC191)².

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).

SYNDESMOYSIS 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 non-locking 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.

Remark:

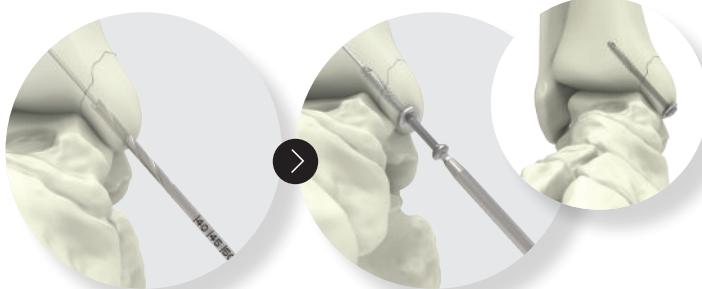
The syndesmosis screw must be removed (using the 'Safety Key' (ANC107)) once the syndesmosis has healed, usually after six to eight weeks.

FINAL RESULT

MEDIAL MALLEOLUS FIXATION

→ OPTION 1: WITH A CANNULATED SCREW

(Ø4.0 mm cannulated compressive screw)

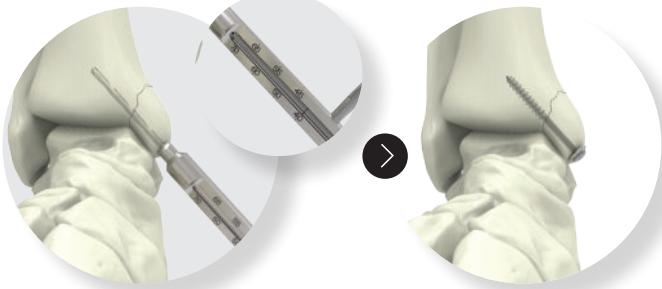


1. Insert the guiding pin (33.0213.120). Then, introduce the Ø2.9 mm cannulated drill bit (ANC414M) onto the guiding pin and drill. Read the screw length on the drill bit.

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 non-locking 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 non-locking screw (CT3.5Lxx) using the screwdriver part of the 2-in-1 instrument (ANC083C).

Remarks:

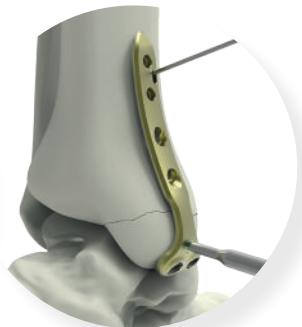
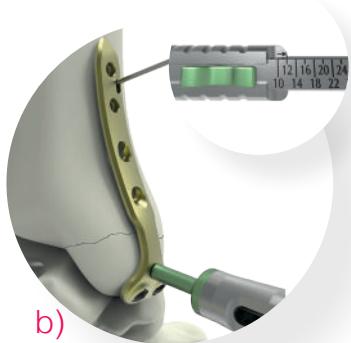
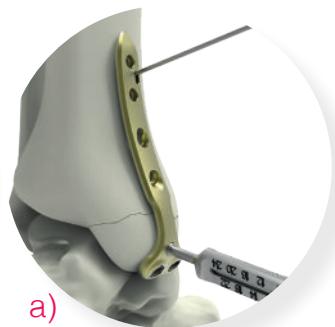
1. In the case of osteoporotic bone, add a compression washer (WASH-T4) under the screw head (see above).
2. Follow the whole procedure for adding a second screw.

SURGICAL TECHNIQUE

CASE 1: TRANSVERSE FRACTURE REDUCTION USING STANDARD PLATE

Example using the size 1 standard plate (RITSM1)

→ PLATE POSITIONING



1. Perform an antero medial approach and temporarily reduce the fracture using a bone reduction forceps or using two parallel pins. Position the plate and stabilize it temporarily using a Ø1.3 mm pin (33.0213.120) in the most proximal part of the pin oblong hole.

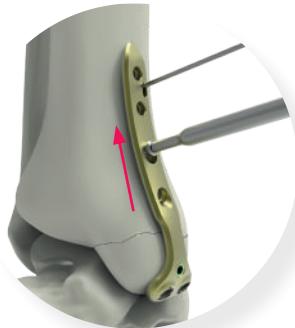
2. a) Lock the Ø2.0 mm short threaded guide gauge (ANC268C) in the most distal monoaxial hole and drill using the Ø2.0 mm short drill bit (ANC088C). The drilling depth can be read directly on the short threaded guide gauge (ANC268C).

b) The drilling depth can be read directly on the length gauge (ANC689).

3. Insert a Ø2.8 mm locking screw (SDT2.8Lxx) using the screwdriver (ANC082E).

⚠ The screw must be short enough to avoid its insertion into the tibiotalar joint.

→ COMPRESSION USING THE RAMP OBLONG HOLE



4. In the most proximal part of the ramp oblong hole, drill using Ø2.0 mm drill bit (ANC690). The drilling depth can be read on the bent non threaded guide gauge (ANC692). 2 mm must be removed from the depth measurement.

1. The screw must be short enough to avoid its insertion into the tibio fibular joint.
2. If the compression is not required, the drilling is performed in the distal part of the ramp oblong hole and the drilling depth is read directly on the bent non threaded guide gauge (ANC692).

5. Insert a Ø2.8 mm non-locking screw (CT2.8Lxx) and then perform the compression using the screwdriver (ANC082E).

NB: During this step the screw leans against the plate in the ramp oblong hole allowing the compression of the fracture site.

→ PLATE FIXATION FINALIZATION



6. a) In case of standard plate fixation

In the two distal polyaxial holes, insert the threaded guide gauge (ANC691), and angulate it in the desired direction in order to be perpendicular to the fracture site. Drill (ANC690), then read the drilling depth directly on the long threaded guide gauge (ANC691) or use the length gauge (ANC689).

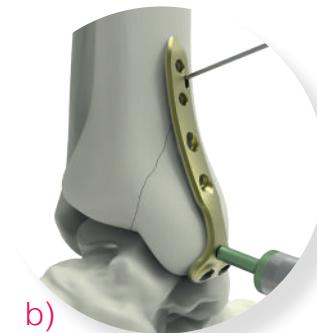
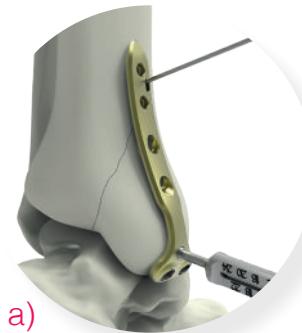
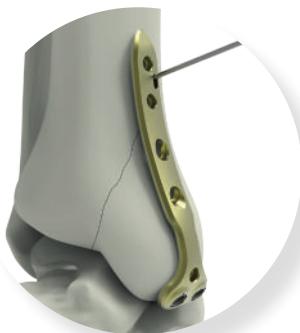
6. b) In case of hook plate fixation
In the distal hole, drill (ANC690) using the long threaded guide gauge (ANC691). Then read the drilling depth directly on the long threaded guide gauge or use the length gauge (ANC689).

7. Insert the Ø2.8 mm locking screws (SDT2.8Lxx) using the screwdriver (ANC082E). Complete inserting the two Ø2.8 mm locking screws (SDT2.8Lxx) in the two remaining proximal holes.

SURGICAL TECHNIQUE

CASE 2: VERTICAL FRACTURE REDUCTION USING STANDARD PLATE

→ PLATE POSITIONING



1. Perform an anteromedial approach and temporarily reduce the fracture using a reduction forceps or using two parallel pins. Position the plate and stabilize it temporarily using a Ø1.3 mm pin (33.0213.120).

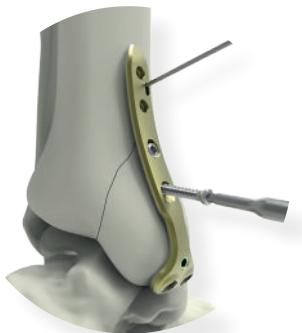
2.a) Lock the Ø2.0 mm short threaded guide gauge (ANC268C) in the most distal monoaxial hole and drill using the Ø2.0 mm short drill bit (ANC088C). The drilling depth can be directly read on the threaded guide gauge (ANC268C).

b) The drilling depth can be also directly read using the length gauge (ANC689).

 **The screw must be short enough to avoid its insertion into the tibiotar joint.**

3. Then insert a Ø2.8 mm locking screw (SDT2.8Lxx), using the screwdriver (ANC082E).

→ COMPRESSION USING THE COMPRESSION HOLES



4. In the most distal part of the ramp oblong hole, angulate the non threaded bent guide gauge (ANC692) in the desired direction in order to be perpendicular to the fracture site. Drill (ANC690), and read the drilling depth directly on the non threaded bent guide gauge (ANC692).

NB: In case of bi-cortical screw, the screw length can be read on the length gauge (ANC689).

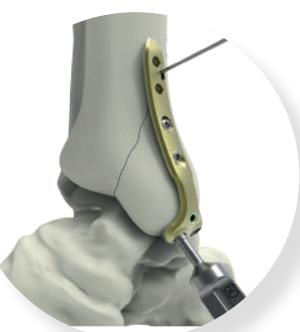
Insert a Ø2.8 mm non-locking screw (CT2.8Lxx) using the screwdriver (ANC082E).

NB: During that step the ramp oblong hole is not used to perform the compression.

5. In the standard hole, angulate the non threaded bent guide gauge (ANC692) in the desired direction in order to be perpendicular to the fracture site. Drill (ANC690), and read the drilling depth directly on the guide gauge.

6. Insert the Ø2.8 mm non-locking screw (CT2.8Lxx) using the screwdriver (ANC082E).

→ PLATE FIXATION FINALIZATION



7. a) In case of standard plate fixation

In the two polyaxial distal holes, insert the threaded guide gauge (ANC691) and angulate it in the desired direction. Drill (ANC690), and read the drilling depth directly on the long threaded guide gauge (ANC691) or on the length gauge (ANC689). Insert two Ø2.8 mm locking screws (SDT2.8Lxx) using the screwdriver (ANC082E).

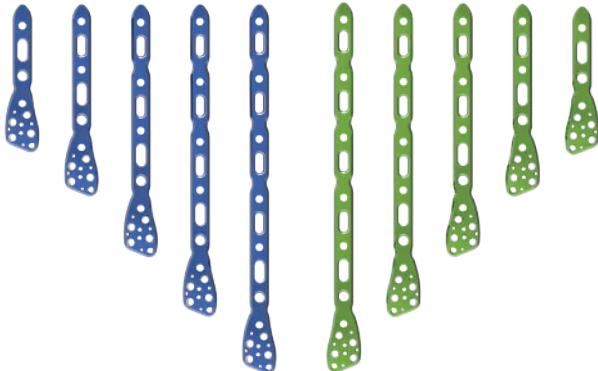
7. b) In case of hook plate fixation

In the distal hole, drill Ø2.0 mm (ANC690) using the threaded guide gauge (ANC691). Then read the drilling depth directly on the threaded guide gauge (ANC691) or on the length gauge (ANC689). Insert one Ø2.8 mm locking screws (SDT2.8Lxx) using the screwdriver (ANC082E).

8. Finalize the fixation by inserting the two Ø2.8 mm locking screws (SDT2.8Lxx) in the two remaining proximal holes.

IMPLANTS REFERENCES

→ DISTAL PLATES



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



LATERAL NARROW PLATES	
Ref.	Description
RTSLN1	Lateral plate - Distal fibula - Narrow - Symmetrical - Size 1
RTSLN2	Lateral plate - Distal fibula - Narrow - Symmetrical - Size 2



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

→ DIAPHYSEAL PLATE



DIAPHYSEAL PLATE	
Ref.	Description
FTS1	Straight plate - Diaphyseal fibula - Symmetrical - Size 1

→ DISTAL TIBIA PLATES



PLATES	
Ref.	Description
RITSM0	Standard plate - Distal tibia - Symmetrical - Size 0
RITSM1	Standard plate - Distal tibia - Symmetrical - Size 1
RITSMH1	Hook plate - Distal tibia - Symmetrical - Size 1

IMPLANTS REFERENCES

→ Ø2.8 MM SCREWS

NON LOCKING SCREWS*	
Ref.	Description
QDT2.8L10 TO QDT2.8L24	Ø2.8 mm non-locking screw - L10 to L24 mm (2 mm increment)

* Yellow anodized.

LOCKING SCREWS*	
Ref.	Description
SDT2.8L10 TO SDT2.8L24	Ø2.8 mm locking screw - L10 to L24 mm (2 mm increment)
SDT2.8L30 TO SDT2.8L50	Ø2.8 mm locking screw - L30 to L50 mm (2 mm increment)
SDT2.8L50 TO SDT2.8L60	Ø2.8 mm locking screw - L50 to L60 mm (5 mm increment)

Remark:

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

An '-ST' code (or «-STI for SDT2.8LXX screws) is added at the end of the reference.

Eg. : « SDT2.8L10-STI » or « CT3.5L20-ST »

NON-LOCKING SCREWS*	
Ref.	Description
CT2.8L30 TO CT2.8L50	Ø2.8 mm non-locking screw - L30 to L50 mm (2 mm increments)
CT2.8L50 TO CT2.8L60	Ø2.8 mm non-locking screw - L50 to L60 mm (5 mm increments)

* Not anodized or light pink for sterile screws.

→ Ø3.5 MM SCREWS

LOCKING SCREWS*	
Ref.	Description
SOT3.5L10 TO SOT3.5L24	Ø3.5 mm locking screw - L10 to L24 mm (2 mm increment)

* Blue anodized.

NON-LOCKING SCREWS*	
Ref.	Description
QOT3.5L10 TO QOT3.5L24	Ø3.5 mm non-locking screw - L10 mm to L24 mm (2mm increment)

* Fuchsia anodized.

NON-LOCKING SCREWS*	
Ref.	Description
CT3.5L10 TO CT3.5L32	Ø3.5 mm non-locking screw - L10 to L32 mm (2 mm increment)
CT3.5L40 TO CT3.5L70	Ø3.5 mm non-locking screw - L40 to L70 mm (5 mm increment)

* Not anodized or light blue anodized for sterile screws.

→ Ø4.0 MM SCREWS

Ø4.0 mm LAG SCREWS*	
Ref.	Description
QT4.0L40 TO QT4.0L70	Ø4.0 mm lag screw - L40 to L70 mm (5 mm increment)

* Not anodized.

Ø4.0 mm CANNULATED SCREWS* (for medial malleolus <u>only</u>)**	
Ref.	Description
H1.4QT4.0L40 TO H1.4QT4.0L70	Ø4.0 mm compressive screw - cannula Ø1.4 - short thread - L40 to L70 mm (5 mm increment)

* Not anodized.

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

→ COMPRESSION WASHER, OPTIONAL



WASH-T4: Compression washer
for Ø4.0 mm compressive screws

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 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 lateral plate - Distal fibula - Standard - Left (RTGLSx)	1
ANC253	Fast drilling guide for lateral plate - Distal fibula - Standard - Right (RTDLSx)	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
ANC452	Bending iron	2
ANC454	Fast drilling guide for posterolateral plate - Distal fibula - Left (RTGQx)	1
ANC455	Fast drilling guide for posterolateral plate - Distal fibula - Right (RTDQx)	1
ANC456	Fast drilling guide for lateral plate - Distal fibula - Narrow - Symmetrical (RTSLNx)	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 (optional)	1
ANC689	Length gauge for Ø2.8 mm screws - Measures 10 - 60 mm	1
ANC690	Ø2.0 mm quick coupling drill bit - L180 mm	1
ANC691	Ø2.0 mm threaded long guide gauge for Ø2.8 mm screws	1
ANC692	Ø2.0 mm non threaded bent guide gauge for Ø2.8 mm screws	1
33.0213.120	Pin Ø1.3 - L120 mm	6
33.0214.120	Pin Ø1.4 - L120 mm	6
A10407M*	12 cm pin for washers (optional)	1
30920**	Prehensive plier (optional)	1

INSTRUMENTS		
Ref.	Description	Qty
ANC042	Mini set - Base	1
ANC042/CB	Mini set - Cambered lid	1

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

BENDABLE PLATES

Some plates from ACTIV ANKLE range offer bending areas. It is possible to bend the plate with the bending irons (ANC452) 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 of the fixation. There is a risk of distortion of the holes when bending the plate.

* Manufacturer: Oury - Medical device class: I

** Manufacturer: Medlane - Medical device class: I

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
- ANC107 or ANC016 for Ø3.5 mm and Ø4.0 mm screws
- ANC350 : Ø4.5 mm AO quick coupling handle - Size 1

To remove any of the Activ Ankle plates, first loosen all the screws without completely removing them (this prevents rotation of the plate when removing the last screw). Finally, completely remove all screws and the plate.

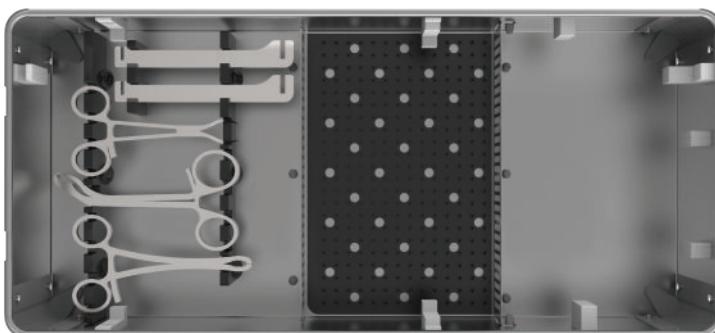
INSTRUMENTS REFERENCES

→ SET DESCRIPTION



INSTRUMENTS TRAY (ANC254/I2)

SCREWS RACK (ANC254/R)

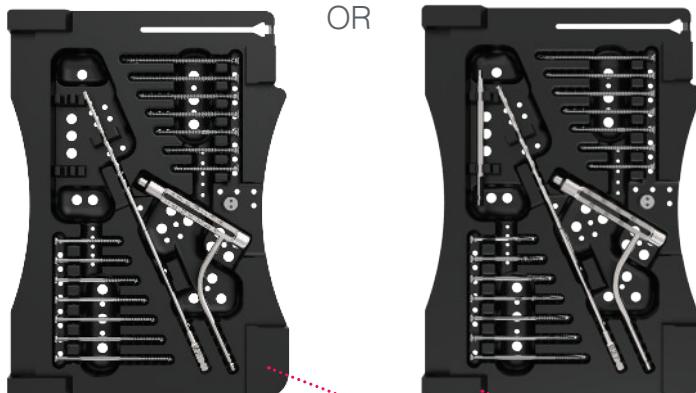


BASE (ANC254/B)

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

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

OR



IMPLANTS TRAY (ANC254/I1)

This information is intended to demonstrate the Newclip Technics portfolio of medical devices. Always refer to the package insert, product label and/or user instructions including cleaning and sterilization before using any Newclip Technics product. These products must be handled and/or implanted by trained and qualified staff who have read the instructions before use. A surgeon must always rely on her or his own professional clinical judgement when deciding whether to use a particular product when treating a particular patient. 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.

Manufacturer: Newclip Technics – Brochure EN – Activ Ankle – ED7 – 11/2024 - Medical device EC: class IIb – CE1639 SGS BE. Read labelling and instructions before the use of Newclip Technics medical devices. These products must be handled and/or implanted by trained and qualified staff who have read the instructions before use.
Newclip Technics - 45 rue des Garottières - 44115 Haute Goulaine, France. Our subsidiaries: Newclip USA - Newclip Australia - Newclip GMBH - Newclip Japan - Newclip Iberia - Newclip Belgium.

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