NEWCLIP TECHNICS

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

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

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Contra-indications:

- Serious vascular deterioration, bone devitalization.
- Pregnancy.
- Acute or chronic local or systemic infections.
- Lack of musculo-cutaneous cover, severe vascular deficiency touching the focus.
- Insufficient bone quality preventing the correct insertion of the screws 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



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).

DTS2[®] polyaxial holes for locking

and non-locking Ø2.8 mm

Holes for locking and non-locking

Oblong holes for Ø3.5 mm

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cortical screws.

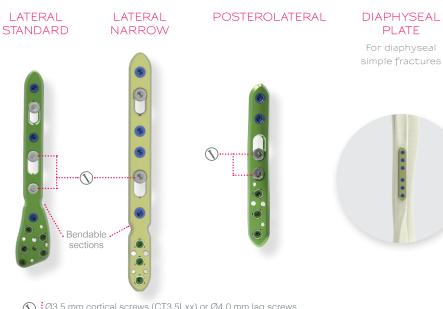
Ø3.5 mm screws.

screws.

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TECHNICAL FEATURES

A COMPREHENSIVE RANGE OF PLATES



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

TECHNICAL FEATURES

A PRECONTOURED IMPLANT

-) OPTIMAL ANATOMICAL CONGRUENCE

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

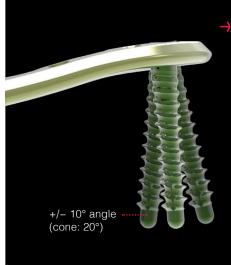


PLATE BENDING

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





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

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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.

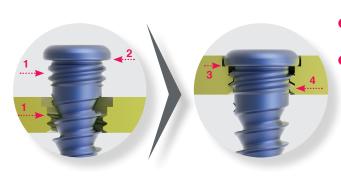
The DTS2[®] polyaxial locking holes are located in the epiphyseal area, thus facilitating the insertion of the epiphyseal screws in diverging or converging directions and allowing for optimal strength of the assembly.



MONOAXIAL LOCKING FIXATION

→ FEATURES

- The threaded sections under the screw head and inside the hole have 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),
- Construct limiting cold welding risks for improved removal properties: A perfect coaptation of both profiles during locking (4),

SURGICAL TECHNIQUE

PLACEMENT OF THE LATERAL PLATE

ightarrow 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.

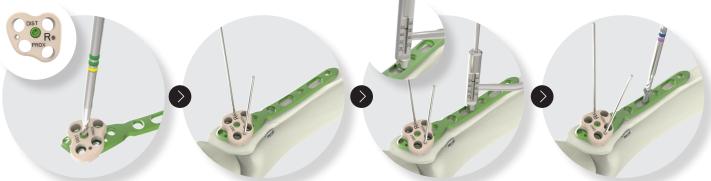
Drill with the Ø2.7 mm drill bit (ANC089C) using the guide gauge¹ (ANC191). The drilling should be perpendicular to the line of fracture. 2. When a lag effect is desired, over-drill the anterior cortex only by using the Ø3.5 mm drill bit (ANC542) according to the allowed compression principles. To simplify the procedure, it is also possible to use the reamer part of the 2-in-1 instrument (ANC083C). 3. Insert the Ø3.5 mm 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



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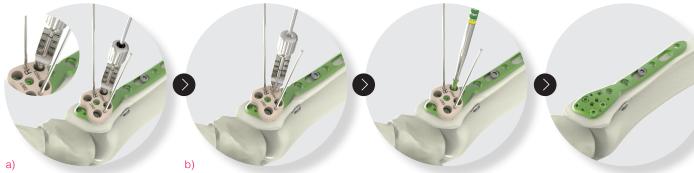
4. Check the positioning of the fast guide thanks to the 'DISTAL' and 'PROXIMAL' marks.

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 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.



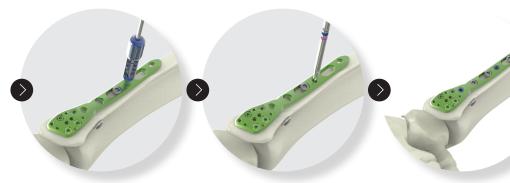
8. For the epiphyseal fixation, drill using the threaded guide gauge (ANC268C) for polyaxial fixation (a) or the non-threaded guide gauge (ANC046C) for monoaxial fixation (b) through the pre-angled fast guide. The screw length can be directly read on the guide gauge. For the monoaxial distal hole, drill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



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.

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.



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.

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.

FINAL RESULT

FINAL RESULT



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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).

Remark:

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

→ 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).

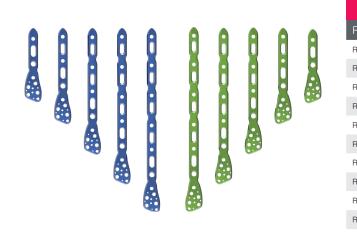
Remarks:

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

→ DIAPHYSEAL PLATE

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

IMPLANTS REFERENCES

→ Ø2.8 MM SCREWS

	1	
	Ň	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
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	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.

Green anodized.

→Ø3.5 MM SCREWS

3	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. 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 Pink 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 »

1	
3	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 o	r light blue anodized for sterile screws.

→ SYNDESMOSIS AND MEDIAL MALLEOLUS SCREWS

		Ø3.5 mm CORTICAL SCREWS*	
	Ref.	Description	Re
	CT3.5L40	Ø3.5 mm cortical screw - L40 mm	QT
	CT3.5L45	Ø3.5 mm cortical screw - L45 mm	QT
	CT3.5L50	Ø3.5 mm cortical screw - L50 mm	QT
	CT3.5L55	Ø3.5 mm cortical screw - L55 mm	QT
	CT3.5L60	Ø3.5 mm cortical screw - L60 mm	QT
	CT3.5L65	Ø3.5 mm cortical screw - L65 mm	QT
	CT3.5L70	Ø3.5 mm cortical screw - L70 mm	QT
,	Not anodized o	r light blue anodized for sterile screws.	* No

LAG SCREWS* Ø4.0 mm lag screw - L40 mm 4.0L40 4.0L45 Ø4.0 mm lag screw - L45 mm 4.0L50 Ø4.0 mm lag screw - L50 mm 4.0L55 Ø4.0 mm lag screw - L55 mm 4.0L60 Ø4.0 mm lag screw - L60 mm 4.0L65 Ø4.0 mm lag screw - L65 mm Ø4.0 mm lag screw - L70 mm 4.0L70 Not anodized

Ref.	Ø4.0 mm CANNULATED SCREWS* (for medial malleolus <u>only</u>)** 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

WASH-T4: Washer

COMPRESSION WASHER, OPTIONAL

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 reamer	2		
ANC084	Ø2.7 mm quick coupling reamer	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 long bent guide gauge for Ø3.5 - 4.0 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 reamer	1		
ANC503	Reduction forceps 150 mm	1		
ANC504	150 mm pointed reduction forceps	1		
ANC542	Ø3.5 mm quick coupling drill bit - L125 mm (optional)	1		
33.0213.120	Pin - Ø1.3 L120 mm	6		
A10407M	12 cm pin for washers (optional)	1		
30920	Prehensive plier for washer (optional)	1		

INSTRUMENTS FOR CANNULATED SCREWS (optional)

Ref	Description	Qty
ANC388	$2.5~\mathrm{mm}$ quick coupling hexagonal non prehensor screwdriver - cannula Ø1.4 mm	1
ANC414M	Ø2.9 mm quick coupling drill bit - 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

- ÁNC103 for Ø2.8 mm screws

- ANC107 or ANC016 for Ø3.5 mm and Ø4.0 mm screws

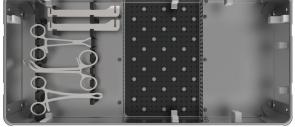
- ANC350 : Ø4.5 mm AO quick coupling handle - Size 1

- SET DESCRIPTION

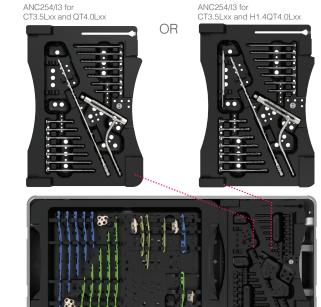


INSTRUMENTS TRAY (ANC254/I2)

SCREWS RACK (ANC254/R)



BASE (ANC254/B)



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.

NEWCLIP TECHNICS (HQ)

PA de la Lande Saint Martin 45 rue des Garottières 44115 Haute-Goulaine, France +33 (0)2 28 21 23 25 orders@newcliptechnics.com www.newcliptechnics.com NEWCLIP TECHNICS IBERIA

Calle Frederic Mompou, 4b Sant Just Desvern 08960 Barcelona, España +34 938 299 526 contact@newclipiberia.com

contact@newclipiberia.com www.newcliptechnics.com

NEWCLIP TECHNICS USA Newclip USA 642 Larkfield Center Santa Rosa CA 95403, USA

Santa Rosa CA 95403, USA +1707 230 5078 +49 (0)821 650 749 40 customerservice@newclipusa.com www.newclipusa.com www.newclipusa.com

NEWCLIP TECHNICS GERMANY

NY NEWCLIP TECHNICS JAPAN

 Newclip GmbH
 Newclip Technics Japan K.K.

 Pröllstraße 11, D-86157 Augsburg,
 KKK Bldg. 502, 3-18-1 Asakusabashi

 Deutschland
 Taito-Ku, Tokyo, 111-0053, Japan

 +49 (0)821 650 749 40
 +81 (0)3 58 25 49 81

www.newcliptechnics.com

NEWCLIP TECHNICS AUSTRALIA

Newclip Australia 3B/11 Donkin Street West End 4101, Australia +61 (0)2 81 886 110 solutions@newclipaustralia.com

www.newcliptechnics.com

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