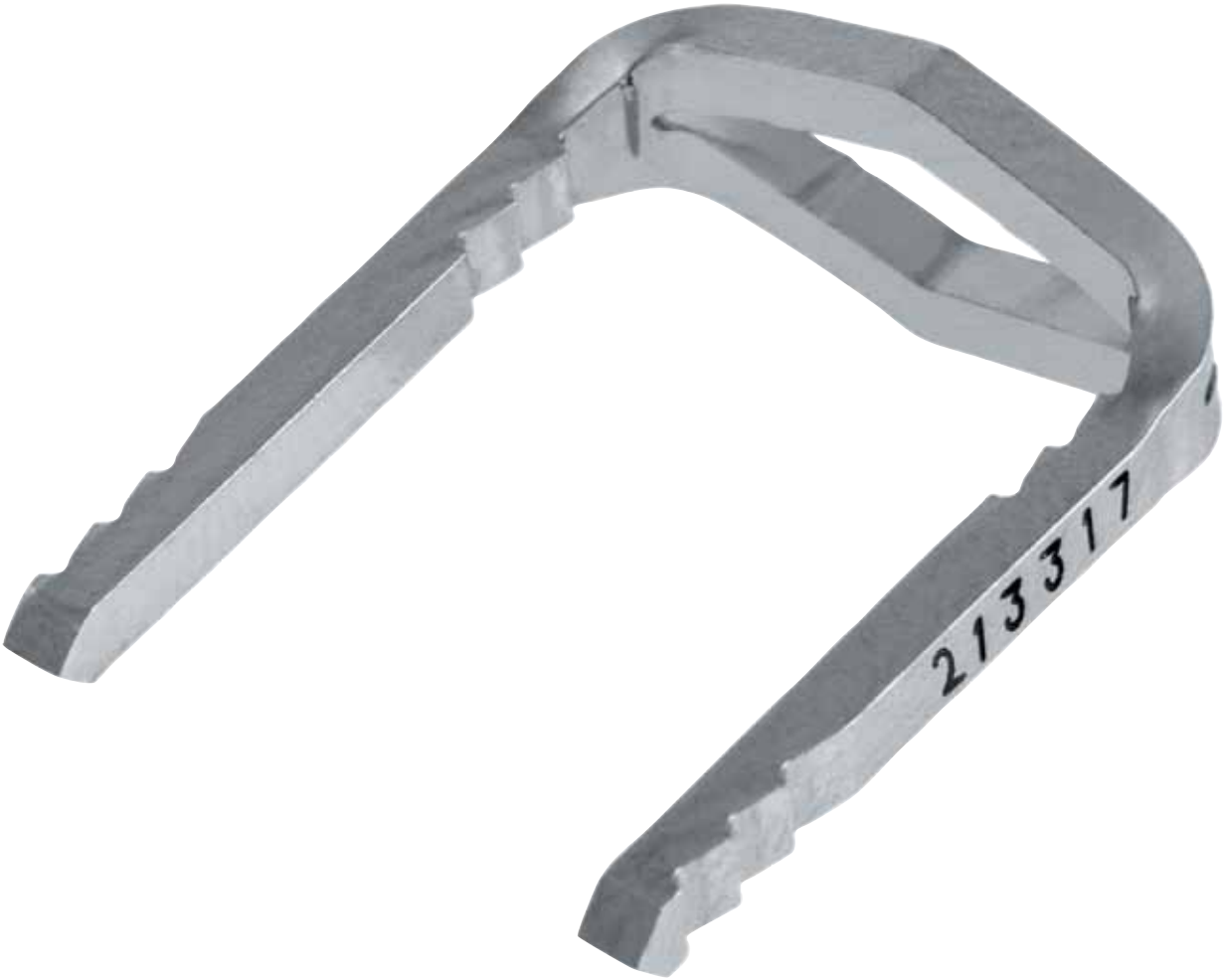


UNI-CLIP®

COMPRESSION STAPLE



SURGICAL TECHNIQUE

**LOWER
EXTREMITY
SOLUTIONS**

 **INTEGRA™**
Extremity Reconstruction

SURGICAL TECHNIQUE



As the manufacturer of this device, Integra LifeSciences does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

INTRODUCTION

The Uni-Clip® staple is a mechanical osteosynthesis device allowing for a compression between two bone fragments. The application of this device is easy, however it is necessary to understand the principles as well as its limits.

The Uni-Clip is manufactured from surgical stainless steel. Compression is achieved by a manual and controlled deformation of the shape of the olive. This staple can be applied in different indications such as: phalangeal shortening osteotomies, Akin osteotomies, Lisfranc arthrodesis and other indications in the midfoot.

The phalangeal shortening osteotomy is well known today. It will reduce the excessive length of the great toe or, it will reduce the phalangeal lever arm. A diaphysial phalangeal wedge will be carefully removed. The resection will be cylindrical for a stand alone shortening. However, it will be trapezoidal in order to achieve a variation and/or rotation (supination) combined with the shortening.

Mostly, the osteosynthesis devices which are offered to the surgeons for fixation are too complex or not in compliance with the surgical practice when a simple, efficient and quick osteosynthesis is required.

The Uni-Clip allows fixation and compression of the bone fragments in order to achieve an early bone healing. Following information will clarify its use and go “step by step” through the surgical technique

SURGICAL APPROACH

- Through a medial surgical approach of the great toe, it is possible to have a perfect phalangeal view. A guide pin (1 mm diameter K-wire) will be inserted into the anatomic fossa which is located at the proximal part of the phalanx. The guide pin should be transcortical and horizontal (no upward or downward direction) (01).

USE OF THE DRILL GUIDE

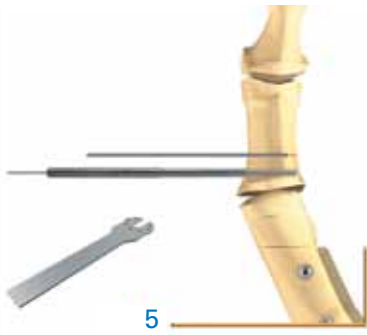
- A cannulated drill (2.2 mm diameter) is placed over the guide pin. A 2.2 mm hole will be drilled through both cortices, taking care to stop drilling as soon as the lateral cortex is perforated. The cannulated drill remains in place (02).
- The drill guide is adjusted in the desired position relative to the interaxis (size of implant) of the Uni-Clip. The drill guide is positioned over the 2.2 mm diameter cannulated drill (03). The level of the proximal cut is determined at mid-distance between the two legs of the drill guide (04).

1

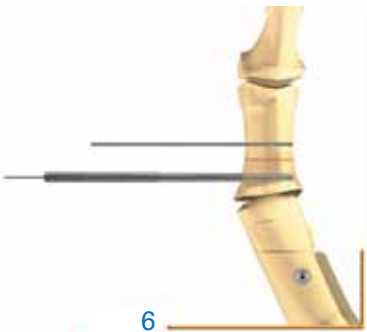
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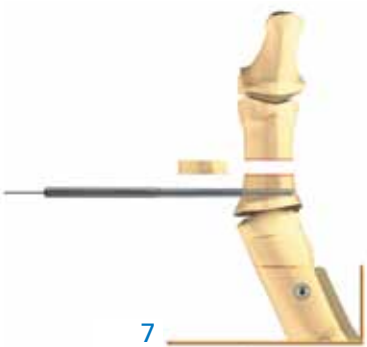
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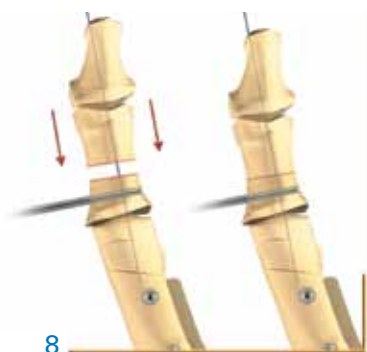
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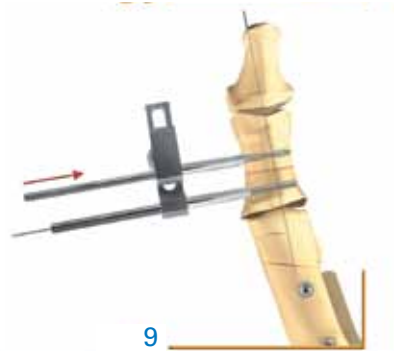
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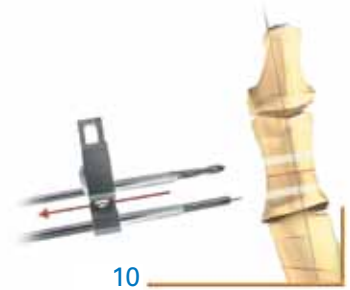
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9



10

THE RESECTION

- At first, the proximal cut is performed. The cut should be parallel to the 2.2 mm cannulated drill which is still on place. The proximal cut will not be finished completely at first in order to maintain some stability (05).
- Then, the distal cut is performed (06) which takes into account an eventual variation and/or rotation (supination). Finally, the proximal cut is completely finished.
- The bone segment is then removed (07). A temporary axial wire (100 mm) is placed as dorsally as possible in order not to compromise the following surgical steps. The reduction of the bone fragments will be performed handling this temporary wire, whereas the dorsal phalangeal aspect will be restored in a sagittal plane (08).

DISTAL DRILLING

- The drill guide is repositioned over the remaining 2.2 mm proximal drill. The second distal drill hole is performed handling non-cannulated 2.2 drill. The guide should be placed so that the distal drill will enter as plantar as possible. Both cortices should be perforated (09).
- Once the two parallel holes are drilled, the drill guide, the 2.2 cannulated proximal drill and the proximal guide pin are all removed (10).
- The axial temporary wire is still in place. A final control of the reduction and position of the drill holes is performed.



SETTING THE STAPLE

- With the depth gauge, the length of the two legs of the staple is defined. If two different lengths are measured, the longest leg length will be chosen, and the shortest leg can be cut to the appropriate length (11).
- The spreading forceps is used to implant the staple. After inserting the forceps into the olive of the staple, a mild pressure on the forceps allows holding the staple.
- The staple is implanted in the phalanx. The axial wire is removed (12).

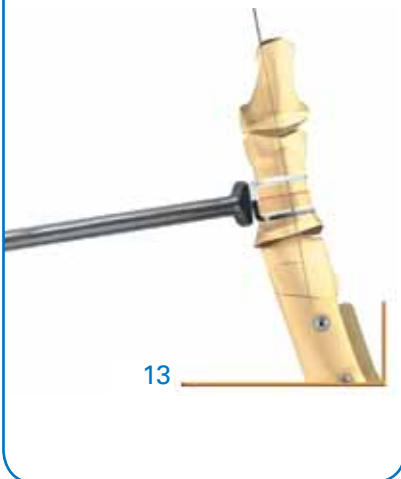


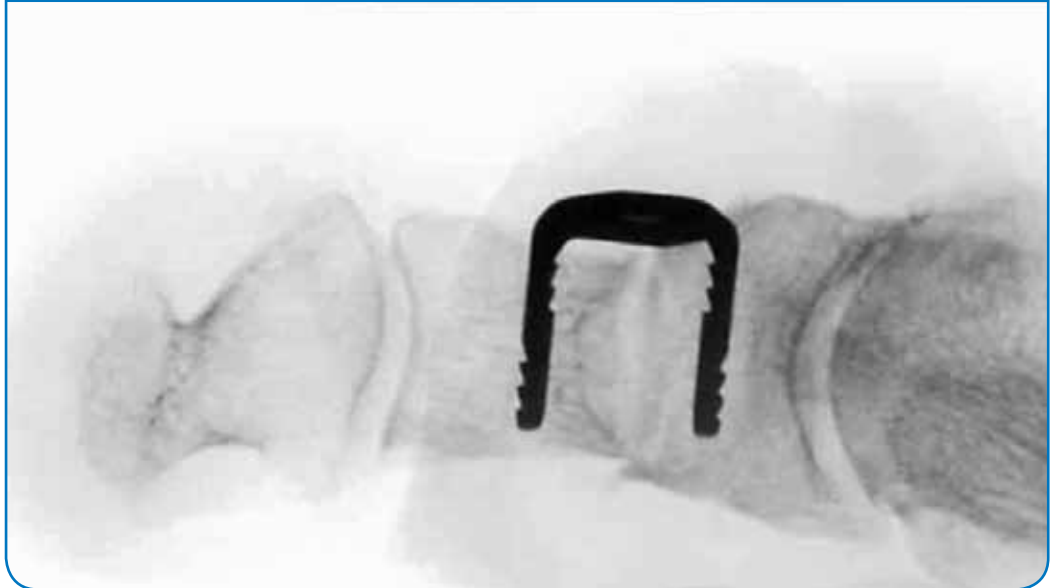
STAPLE COMPRESSION

- The staple is finally impacted using the staple impactor (13).
- Once the staple is in place, compression is performed by using the spreading forceps to open the olive. The spreading forceps is removed (14).

Attention: Legs can diverge if too much compression is applied. Drawing 15 shows the mechanical mechanism of the Uni-Clip.

- Drawing 16 demonstrates placement of the Uni-Clip in the phalangeal shortening osteotomy.

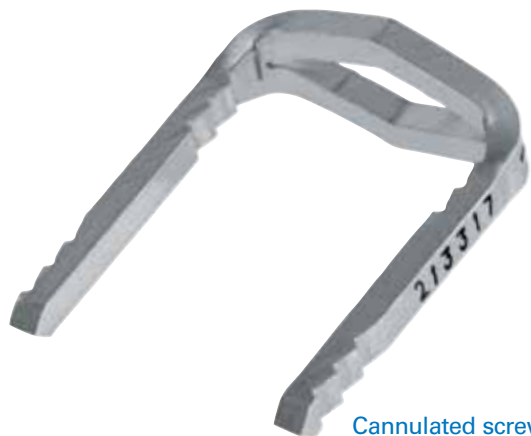




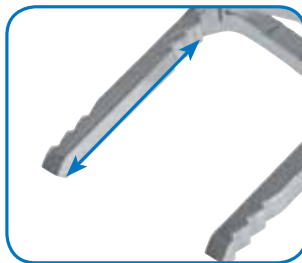
X-RAYS

- The x-rays demonstrate the surgical application of Uni-Clip.

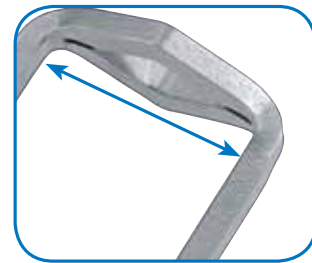
UNI-CLIP® COMPRE



Cannulated screw

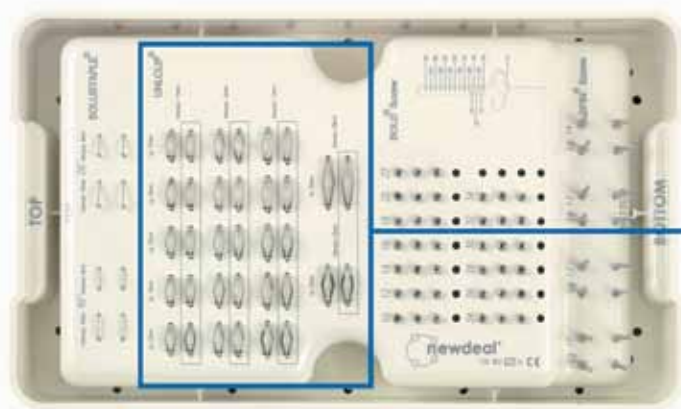


7 leg length:
13, 14, 15, 16, 17, 12 & 20 mm



5 sizes of interaxis:
11, 12, 13, 15 & 20 mm

FOREFOOT SET



UNI-CLIP STAPLES



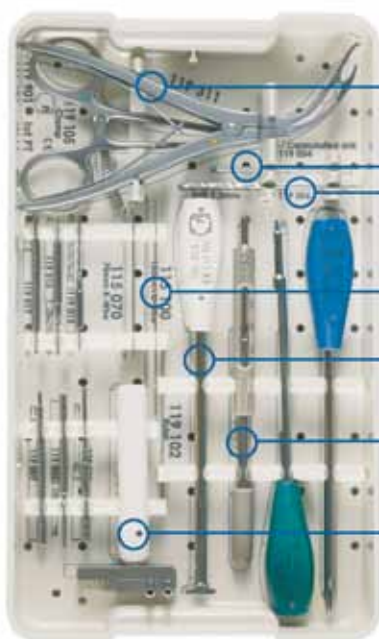
Lot number and reference marking for easier product traceability



Internal notches



External notches



UNI-CLIP SPREADING FORCEPS

CANNULATED DRILL DIAM. 2.2 MM
DRILL DIAM. 2.2 MM

K-WIRE LENGTH 100 MM

UNI-CLIP IMPACTOR

DEPTH GAUGE

UNI-CLIP DRILL GUIDE

UNI-CLIP®

COMPRESSION STAPLE

Uni-Clip

Interaxis: 11 Reference	Length	Interaxis: 12 Reference	Length	Interaxis: 13 Reference	Length
213 113ND	13 mm	213 213ND	13 mm	213 313ND	13 mm
213 114ND	14 mm	213 214ND	14 mm	213 314ND	14 mm
213 115ND	15 mm	213 215ND	15 mm	213 315ND	15 mm
213 116ND	16 mm	213 216ND	16 mm	213 316ND	16 mm
213 117ND	17 mm	213 217ND	17 mm	213 317ND	17 mm
Interaxis: 15 Reference	Length	Interaxis: 20 Reference	Length		
213 512ND	12 mm	213 820ND	20 mm		

Uni-Clip (Sterile)

Interaxis: 11 Reference	Description	Interaxis: 12 Reference	Description	Interaxis: 13 Reference	Description
213 113SND	13 mm	213 213SND	13 mm	213 313SND	13 mm
213 114SND	14 mm	213 214SND	14 mm	213 314SND	14 mm
213 115SND	15 mm	213 215SND	15 mm	213 315SND	15 mm
213 116SND	16 mm	213 216SND	16 mm	213 316SND	16 mm
213 117SND	17 mm	213 217SND	17 mm	213 317SND	17 mm
519 920ND	Lid				
Interaxis: 15 Reference	Description	Interaxis: 20 Reference	Description		
213 512SND	12 mm	213 820SND	20 mm		

Instrumentation

Reference	Description
119 004ND	Cannulated drill diam. 2.2 mm
119 006ND	Drill diam. 2.2 mm
119 301ND	Uni-clip drill guide
119 307ND	Measurer
119 309ND	
119 311ND	Impactor
115 100ND	
119 900ND	Uni-clip spreading forceps
	K-wire 10/10 length 100 mm
	Sterilization container

•The products are manufactured and referenced within the frame of the standards in force.
 •Implantation procedures are described in the surgical technique.
 •The manufacturer reserves the right, without prior notice, to modify its products in order to improve their quality.
 •WARNING: Federal law (USA) restricts this device to sale by or on the order of a physician.



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