

Integra®

Solustaple®
Standard staple

Uni-Clip®
Compression staple

SURGICAL TECHNIQUE



INTEGRA®
LIMIT UNCERTAINTY

Table of Contents

Solustaple® Standard staple04

Implants Details.....04

Indications.....04

Instruments Details.....04

Surgical Technique05

X-ray: Akin Osteotomy.....06

Instruments06

Uni-Clip® Compression staple.....07

Implants Details.....08

Indications.....08

Instruments Details.....08

Surgical Technique09, 10, 11

X-ray: Phalanx Shortening.....12

X-ray: Arthrodesis of the First MTP.....12

References13

Instruments13

Integra®

Solustaple®
Standard staple

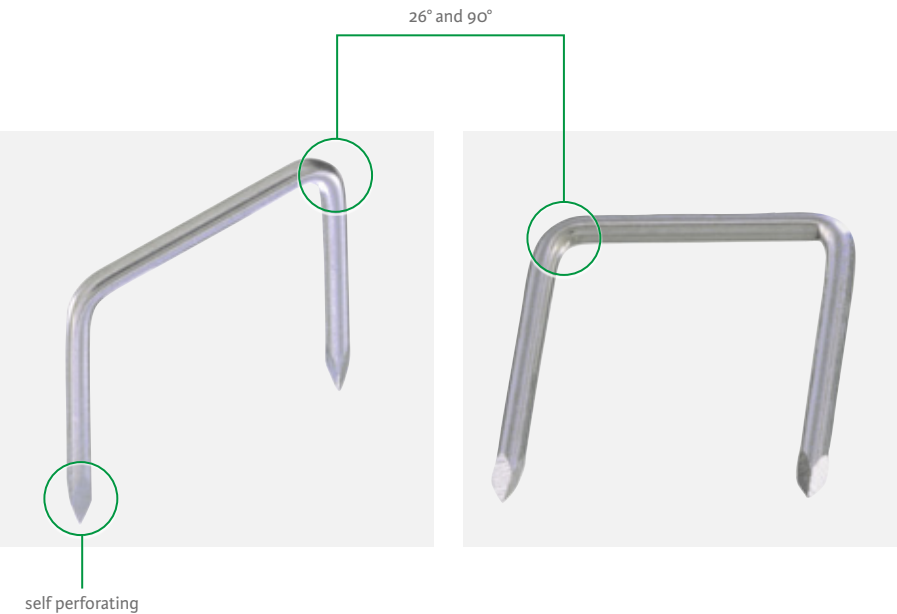
SURGICAL TECHNIQUE





Implants Details

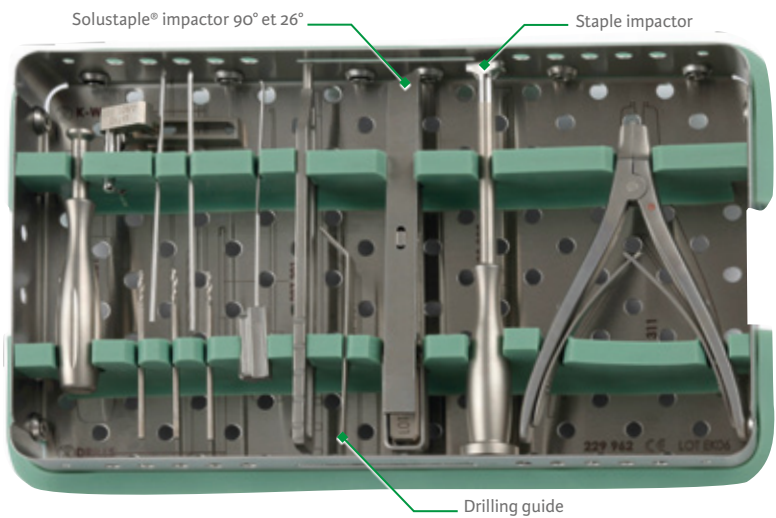
- Material: 316L ISO 5832-1 ASTM F138 & F139.
- Stainless Steel Staple.
- 2 shapes: 90° & 26°.
- 2 interaxis 8 & 10mm.
- Leg length 10mm.
- Diameter 1mm.
- Laser mark: lot number & references.
- Sterile and non sterile implants.



Indications

- For Akin type osteotomy.

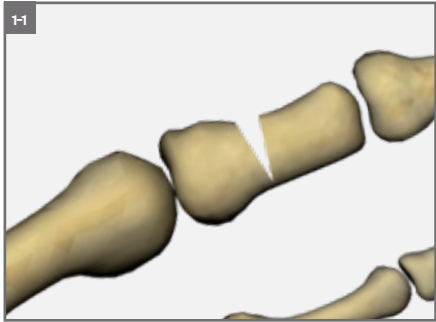
Instruments Details



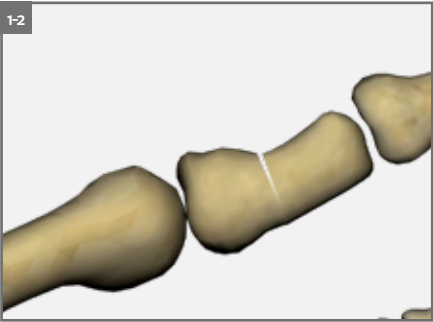
Surgical Technique

1 Akin Osteotomy

- It is a monocortical osteotomy.
- Then closure of the osteotomy.



Osteotomy



Closure

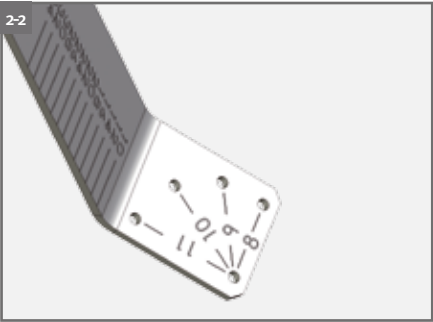
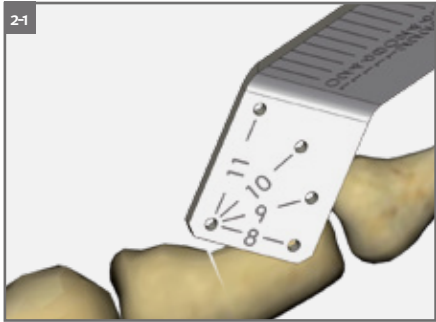
2 Measurement

Measure the suitable staple interaxis: 8 or 10 mm thanks to the drilling guide (229 101) (fig. 2-1 and 2-2).

Optional: Although the Solustaple® device is self perforating, in case of hard bone, use the K-wire (115 070(S)) and the drilling guide to pre drill holes.

If more compression is desired:

- pre drill at 9mm for a 8 mm interaxis staple.
- pre drill at 11mm for a 10 mm interaxis staple.

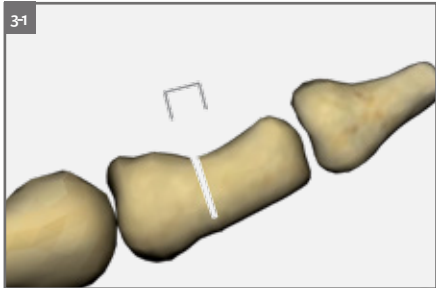


3 Solustaple® Fixation

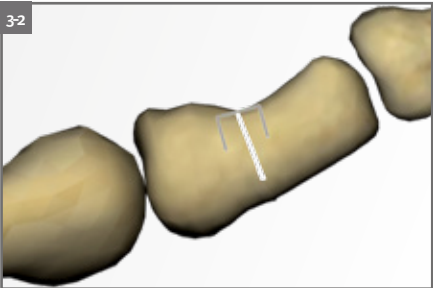
Depending on the bone anatomy, choose the 26° or the 90° Staple.

Hold and impact the desired Solustaple® standard staple with the dedicated solus impactor (229 102).

For a better fitting with the bone, use the impactor (229 202).



Impaction

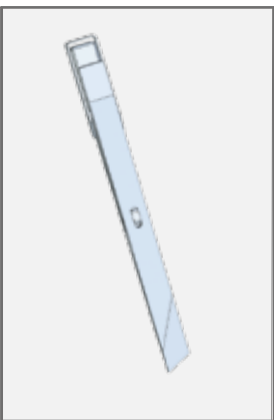
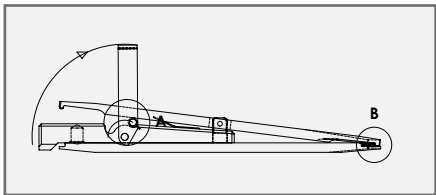
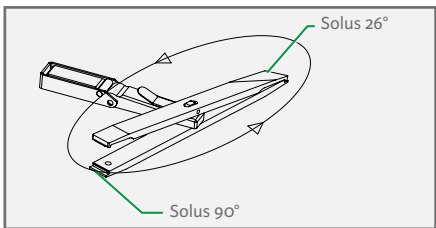


Final result

Solus Impactor 90° & 26° (229 102)

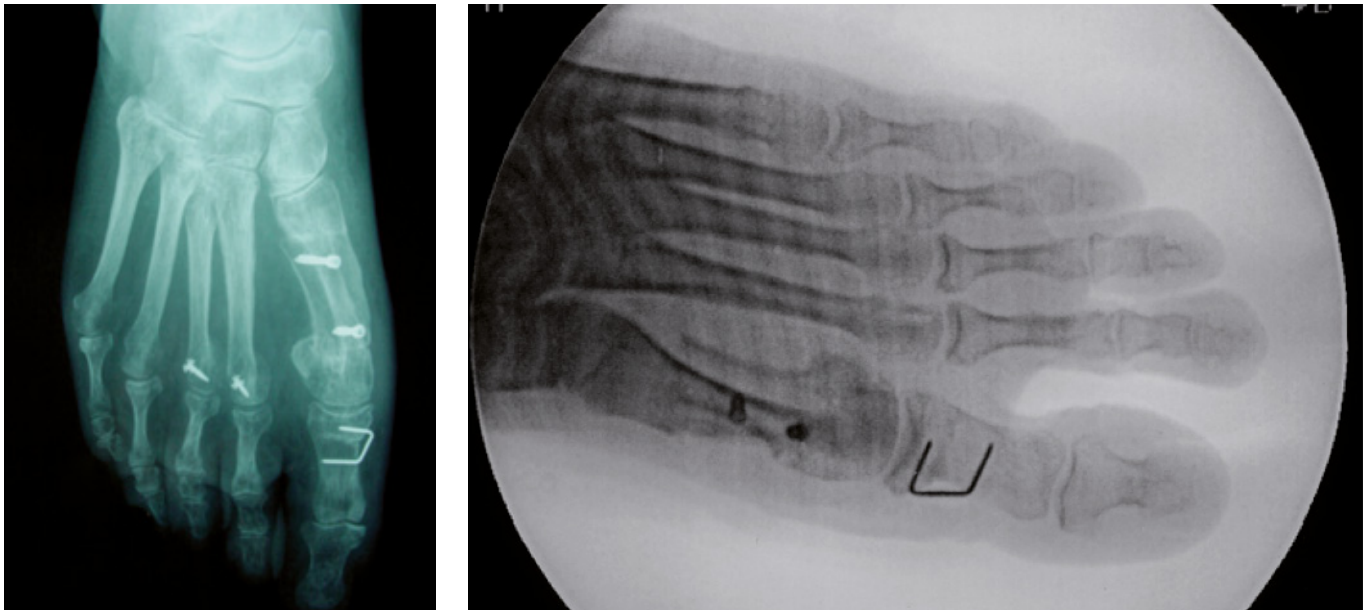
Reversible anvil: rotate 360° along one of the 2 shapes (26° or 90°) chosen.

To lock the system, raising the handle until the abutment.



Solustaple® Impactor

X-Ray: Akin Osteotomy

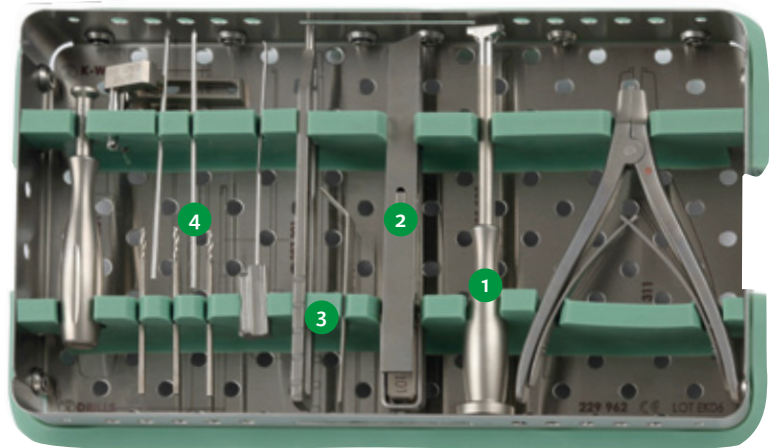


Solustaple® Staples	
Reference	Description
114 002(S)	90° Interaxis 08 mm
114 004(S)	90° Interaxis 10 mm
114 023(S)	26° Interaxis 08 mm
114 025(S)	26° Interaxis 10 mm

*(S): delivered sterile and non sterile.



Solustaple® Instruments		
#	Reference	Description
1	229 202	Staple impactor
2	229 102	Solus impactor 90° & 26°
3	229 101	Solus drilling guide
4	115 070(S)	K-wire diam 1.0 - length 70 mm - sterile
	229 952	Staples container which includes:
	229 962	tray
	229 970	lid



Integra®

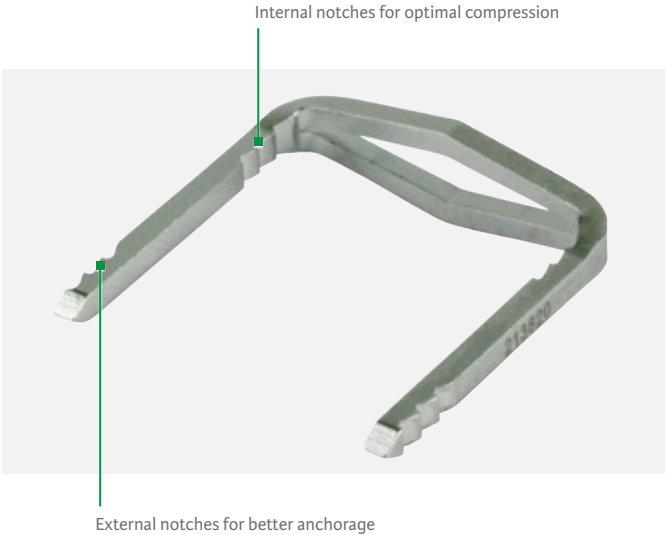
Uni-Clip®
Compression staple

SURGICAL TECHNIQUE



Implants Details

- Material: Stainless steel 316L ISO 5832-1 ASTM F138 & F139.
- Compression staple.
- Interaxis: 11, 12, 13, 15, 20 mm.
- Leg lengths: 13,14, 15, 16, 17, 12 & 20 mm.
- Sterile and non sterile.

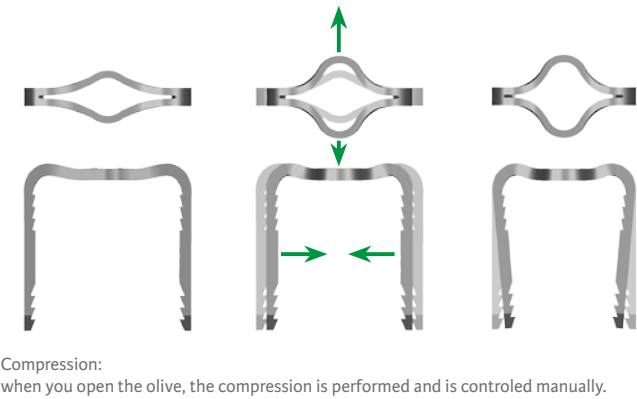


Indications

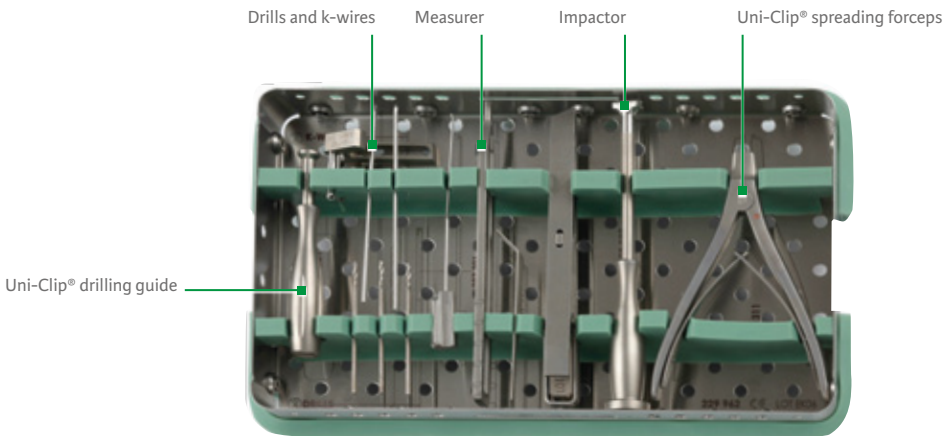
For fixation of bone fractures or for bone reconstruction.

Examples include:

- Arthrodesis in hand or foot surgery.
- Fractures management in the foot or hand.
- Mono or Bi-cortical osteotomies in the foot or hand.
- Distal or proximal metatarsal or metacarpal osteotomies.
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.).



Instruments Details

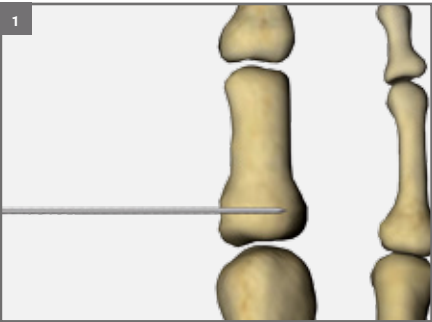


NEWDEAL as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device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

Surgical Technique
Eg. Fixation of a Phalangeal Osteotomy

1 Medial Approach

Through a medial surgical approach of the great toe, it is possible to have a perfect phalangeal view. A k-wire diam 1.0 mm (length 70 mm: 115 070(S) or length 100 mm: 115 100(S)) is inserted into the anatomic fossa which is located at the proximal part of the phalanx. (Fig. 1)

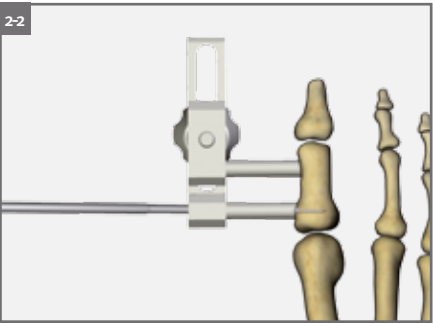
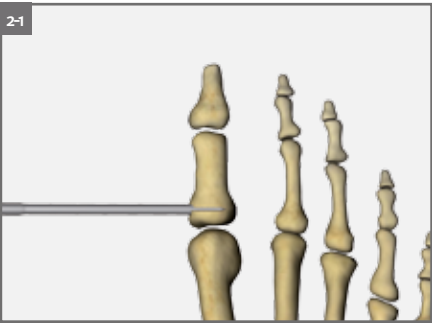


The k-wire should be horizontal and bi-cortical and perpendicular to the phalangeal axis.

2 Proximal Drill Hole

A 2.2 mm diameter cannulated (119 004(S)) drill is placed over the k-wire. A 2.2 mm hole is drilled through both corticals, taking care to stop drilling as soon as the lateral cortical is perforated.

The cannulated drill remains in place. (Fig. 2-1)



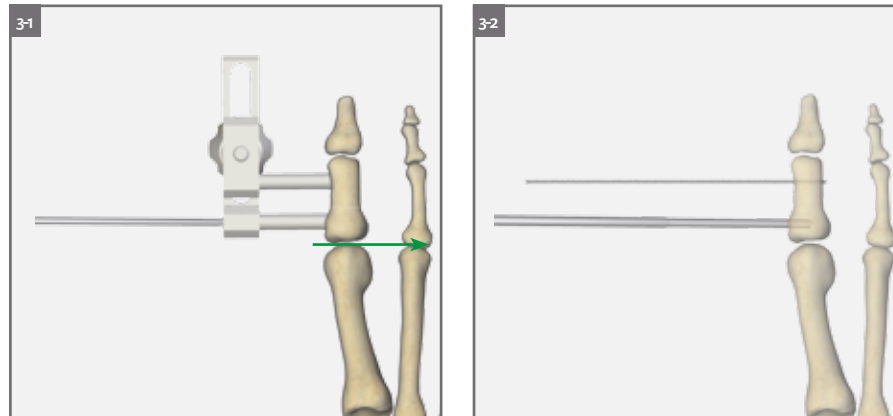
Drill Diam. 2.2 mm	
Reference	Description
119 004(S)	Uni-Clip® - drill - dia 2,2 L90mm - cannulated
119 006(S)	Uni-Clip® - drill - DIA 2,2 L80mm



3 P1 osteotomy

The osteotomy cut is performed in the middle of the legs of the drill guide. (Fig. 3-1)

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 is not finished completely, in order to maintain some stability. (Fig. 3-2)

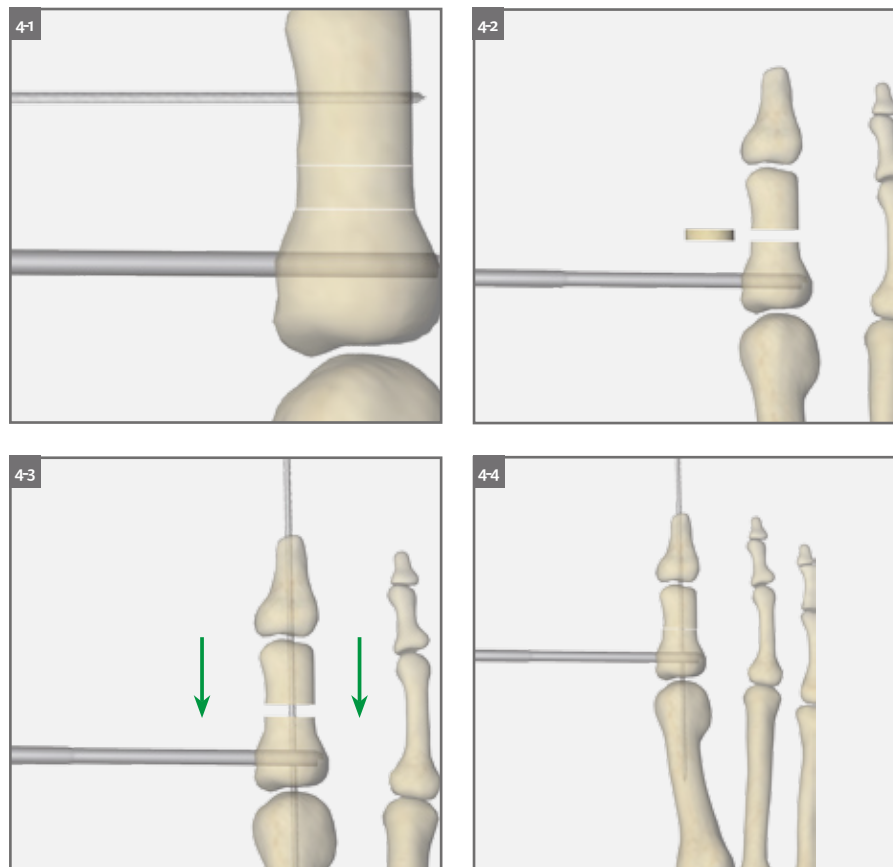


4 Phalanx Shortening

The distal cut is performed and proximal cut is completely finished. (Fig. 4-1)

The bone segment is then removed. (Fig. 4-2)

A temporary axial k-wire diam 1.0 mm (Length 100 mm: 115 100(S)) is placed as dorsally as possible in order not to compromise the following surgical steps. The reduction of the bone fragments is performed handling this temporary k-wire whereas also the dorsal phalangeal aspect is restored in a sagittal plane. (Fig. 4-4)

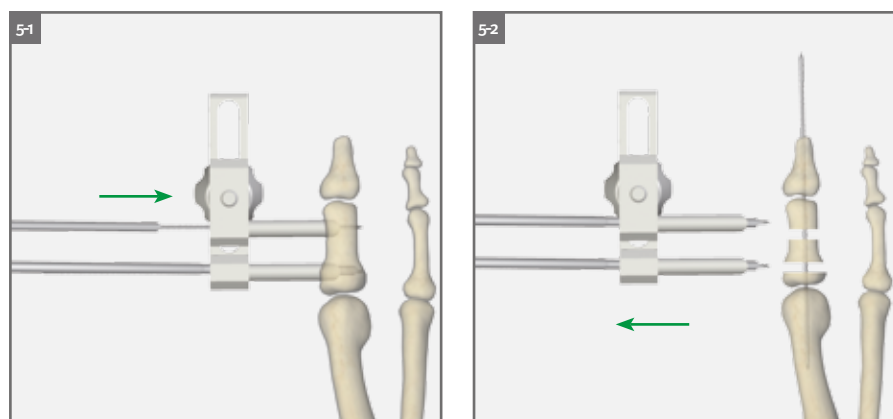


5 Distal Drill Hole

The drill guide (229 201) is repositionned over the remaining 2.2 mm diameter proximal drill (119 004(S) or 119 006(S)).

The second distal drill hole is performed. Both cortices should be perforated. (Fig. 5-1)

- Once the two parallel holes are drilled, Drills and guide can be removed. (Fig. 5-2)
- The axial temporary wire is kept in place. A final control of the reduction and the position of the drill holes is performed.



6 Fixation of Uni-Clip® Compression Staple

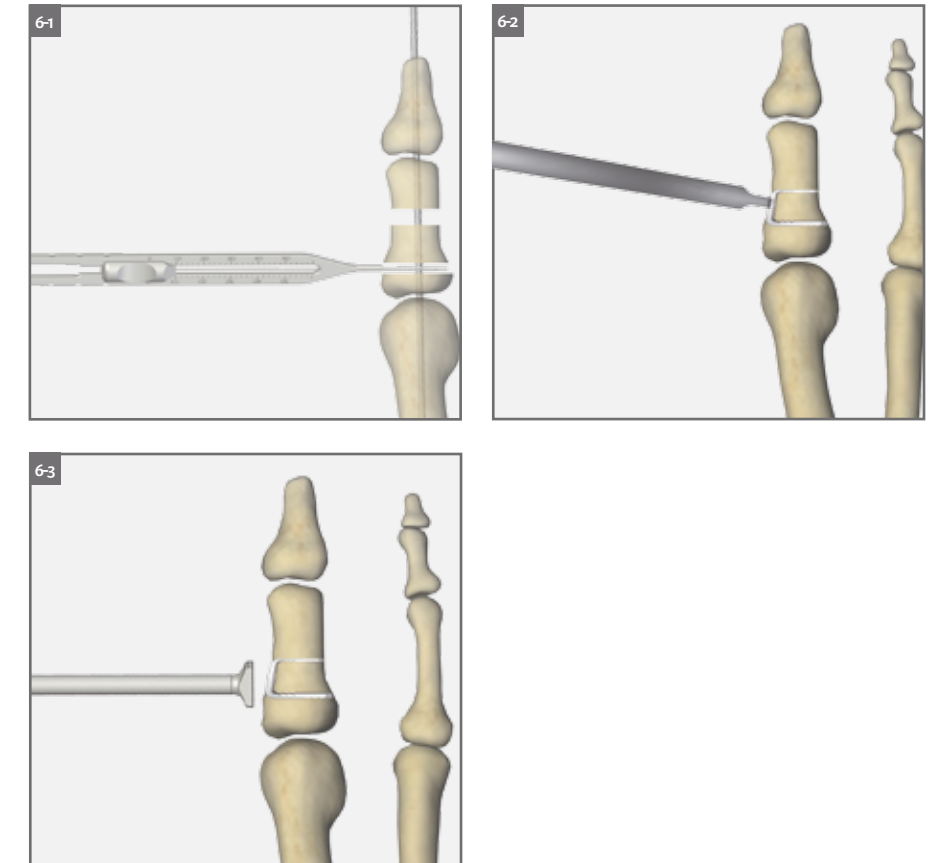
With the measurer (997 301), the length of the two legs of the staple is defined (Fig. 6-1).

If two different lengths are measured, the longest leg length is chosen, and the other leg can be cut to the appropriate length.

The spreading forceps (119 311) is handled 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 k-wire is removed. (Fig. 6-2)

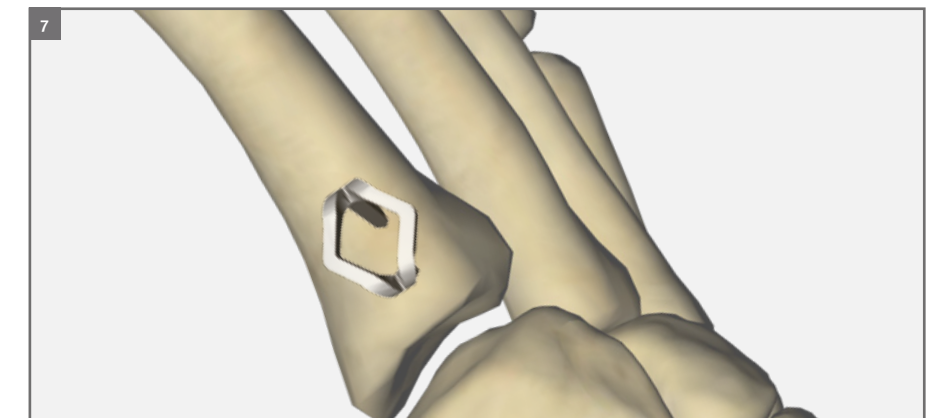
The staple is finally impacted using the staple impactor (229 002). (Fig. 6-3)



7 Compression

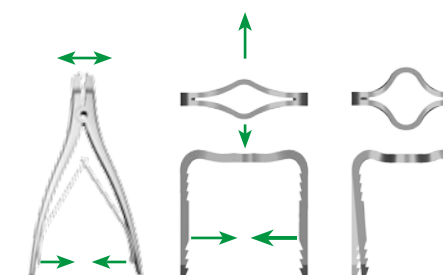
Place the spreading forceps (119 311) specific to the Uni-Clip® staples in the diamond of the staple.

By squeezing the spreading forceps, the diamond will expand and legs of the staple will come together. Compression is thus applied and fixation achieved.



Caution

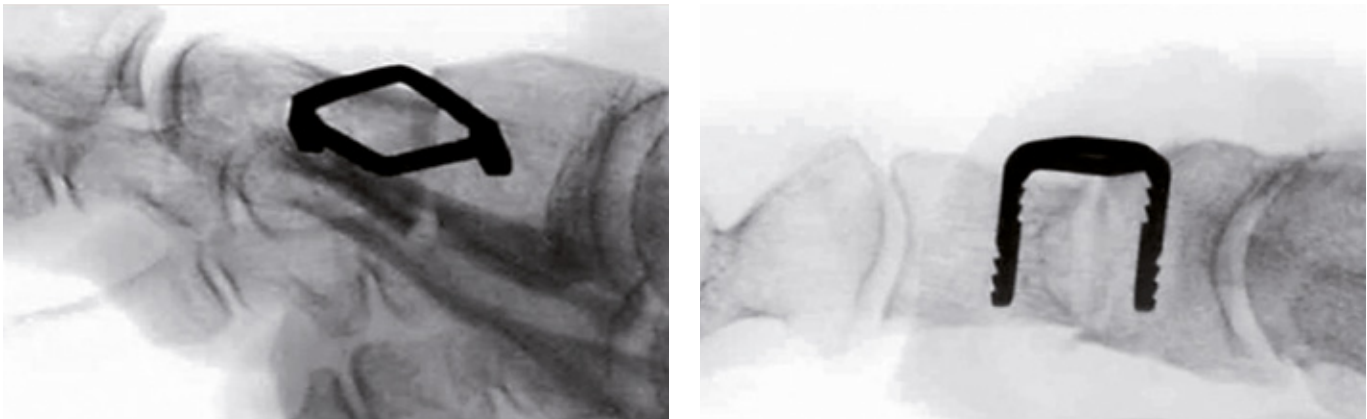
Compression (by opening the olive), should be discontinued when the bone fragments are in contact with each other.



Caution

The action provided by the spreading forceps should not be used to approximate the positioning of the osseous fragments. The fragments should have been previously well positioned at the step 2, along with any reduction that may be necessary. In this way, the spreading forceps provides compression between fragments.

X-Ray: Phalanx Shortening



X-Ray: Arthrodesis of the First MTP

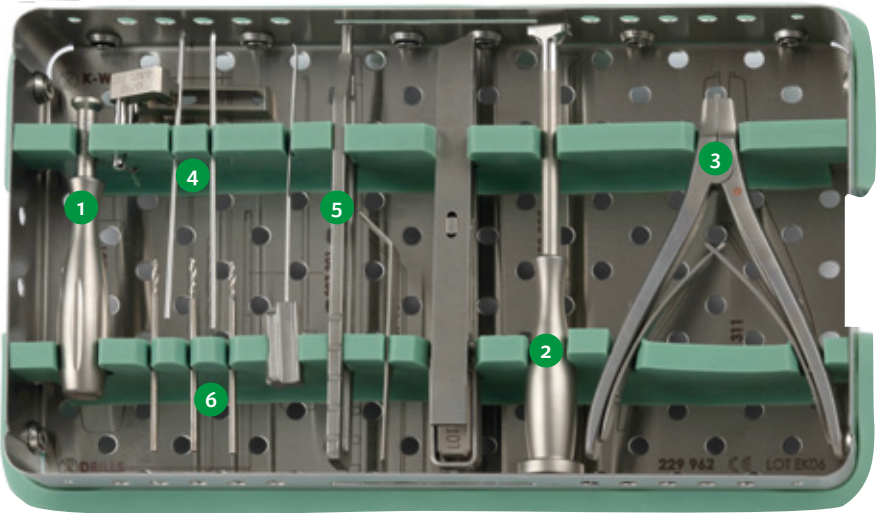


References

Uni-Clip® Interaxis: 11 mm		Uni-Clip® Interaxis: 12 mm		Uni-Clip® Interaxis: 13 mm		Uni-Clip® Interaxis: 15 mm	
Reference	Description	Reference	Description	Reference	Description	Reference	Description
213 113(S)	Length 13 mm	213 213(S)	Length 13 mm	213 313(S)	Length 13 mm	213 512(S)	Length 12 mm
213 114(S)	Length 14 mm	213 214(S)	Length 14 mm	213 314(S)	Length 14 mm	Uni-Clip® Interaxis: 20 mm	
213 115(S)	Length 15 mm	213 215(S)	Length 15 mm	213 315(S)	Length 15 mm	Reference	Description
213 116(S)	Length 16 mm	213 216(S)	Length 16 mm	213 316(S)	Length 16 mm	213 820(S)	Length 20 mm
213 117(S)	Length 17 mm	213 217(S)	Length 17 mm	213 317(S)	Length 17 mm		

Uni-Clip® Instruments			Drill: 2.2 mm		
#	Reference	Description	#	Reference	Description
1	229 201	Uni-Clip® Drilling guide	6	119 004(S)	Uni-Clip® - Drill - Dia 2,2 L90 mm - cannulated
2	229 202	Staple impactor	6	119 006(S)	Uni-Clip® - Drill - Dia 2,2 L80mm
3	119 311	Uni-Clip® spreading forceps		229 952	Staples container which includes:
4	115 070(S)	K-wire diam 1.0 Length 70 mm		229 962	tray
4	115 100(S)	K-wire diam 1.0 Length 100 mm		229 970	lid
5	997 301	Measurer			

*(S): delivered sterile and non sterile.



Integra

Solustaple® Standard staple

Uni-Clip® Compression staple

Integra LifeSciences Services (France) SAS

Sales & Marketing EMEA
Immeuble Séquoia 2 • 97 allée Alexandre Borodine
Parc technologique de la Porte des Alpes
69800 Saint Priest • FRANCE
Phone: +33 (0)4 37 47 59 00 • Fax: +33 (0)4 37 47 59 99
emea.info@integralife.com • integralife.eu

Customer Service

International: +33 (0)4 37 47 59 50 • +33 (0)4 37 47 59 25 (Fax) • csmea@integralife.com
United Kingdom: csuk.ortho@integralife.com
France: +33 (0)4 37 47 59 10 • +33 (0)4 37 47 59 29 (Fax) • cs-ortho@integralife.com
Benelux: +32 (0)2 257 4130 • +32 (0)2 253 2466 (Fax) • custsvcbenelux@integralife.com
Switzerland: +41 (0)2 27 21 23 30 • +41 (0)2 27 21 23 99 (Fax) • custsvcsuisse@integralife.com

 Newdeal SAS
Immeuble Séquoia 2 • 97 allée Alexandre Borodine
Parc technologique de la Porte des Alpes
69800 Saint Priest • FRANCE
Phone: +33 (0)4 37 47 51 51 • Fax: +33 (0)4 37 47 51 52

©2011 Integra LifeSciences Corporation. All rights reserved. ILS-08-07-104-01-11
PRODUCTS FOR SALE IN EUROPE, MIDDLE-EAST and AFRICA ONLY.

Distributed by



Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region. • Always refer to the appropriate instructions for use for complete clinical instructions. • Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality. • WARNING: Applicable laws restrict these products to sale by or on the order of a physician. • Solustaple, Uni-Clip, Integra and the Integra logo are trademarks or registered trademarks of Integra LifeSciences Corporation or its subsidiaries. All the references numbers mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices, unless specifically identified as "NOT CE MARKED."

CE
0120