UNI-CLIP® / LARGE UNI-CLIP®

Compression Staples

Notched Uni-Clip®

Straight Large Uni-Clip®

Offset Large Uni-Clip®

Surgical Technique

newdeal®

New ideas for foot surgery™

Table of contents

Uni-clip® rationale

The UNI-CLIP® compression staple is a quick and effective mechanical osteosynthesis system that provides compression between two osseous fragments. While its implementation is simple, the principles and limits of such a compression system must be respected.

The UNI-CLIP® is manufactured from surgical stainless steel. The compression is achieved with manually and controlled deformation of the diamond in the bridge of the staple. This staple has various indications, including:
forefoot, midfoot and hindfoot osseous procedures.

Details

- Material: Stainless Steel, *316L ISO 5832-1 ASTM F138 & F139.*

LARGE UNI-CLIP®
Straight staple

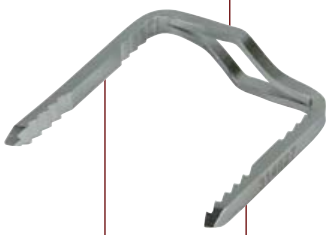
2 interaxis sizes:
20, 25 mm.

2 leg lengths:
20, 25 mm.

Internal notches

LARGE UNI-CLIP®
Offset staple

2 interaxis sizes:
25, 30 mm.

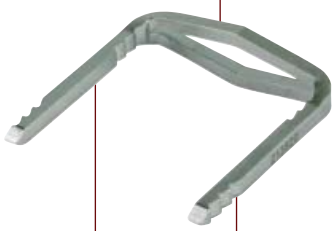


2 leg lengths:
20/25, 27/32 mm.

Internal notches

UNI-CLIP®
Straight staple

2 interaxis sizes:
15, 20 mm.



2 leg lengths:
15, 20 mm.

Internal and external notches

Indications

The UNI-CLIP® and LARGE UNI-CLIP® staples are indicated for fixation of bone fractures or for bone reconstruction:

- Arthrodesis in foot surgery.
- Fractures management in the foot.
- Mono or bi-cortical osteotomies in the foot.
- Distal or proximal metatarsal osteotomies.
- Fixation of osteotomies for Hallux Valgus treatment.

The size of the chosen staple should be adapted to the specific indication.

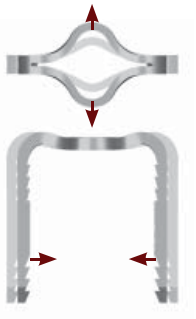
OTHER POSSIBLE INDICATIONS:

- Arthrodesis for hand surgery.
- Fracture management in the hand.
- Mono or bi-cortical osteotomies in the hand.
- Distal or proximal metacarpal osteotomies.

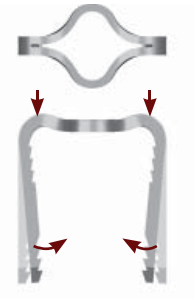
Instrument rationale

0 Starting position

1 Parallel compression



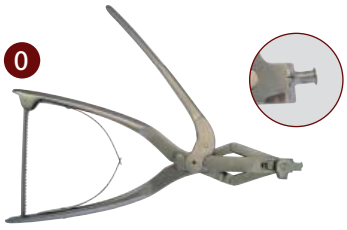
2 Convergent compression



LARGE UNI-CLIP®

*A specific spreading forceps was developed for the **LARGE UNI-Clip®** staples.*
With the first action, the device provides compression by pulling legs together in a parallel fashion.
A second, separate action can then be applied to converge the staple legs toward one another, creating additional compression.

0



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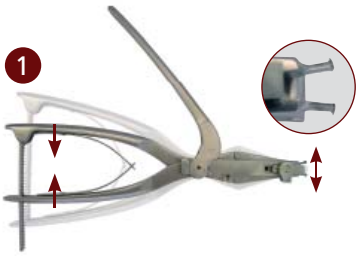

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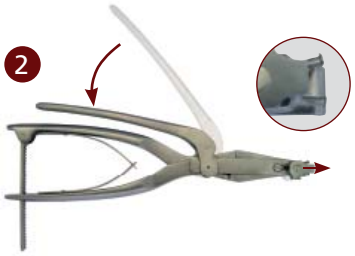


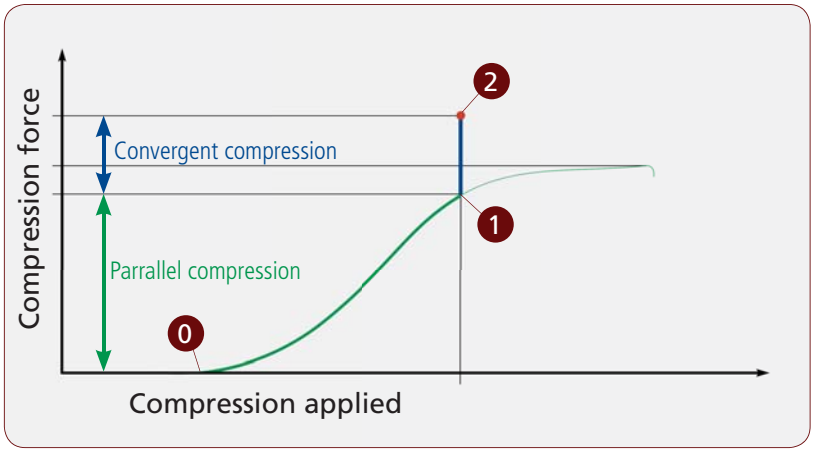
UNI-CLIP®

*The UNI-CLIP® forceps applies a parallel compression to the **UNI-CLIP®** staple.*

0

1

No convergent compression for the Uni-clip®



Initial compression by tightening the legs

Additional compression by convergence of the legs

Optimum compression

Depending on bone quality and parrallel compression, on average, convergent compression can increase initial compression by 65%.

UNI-CLIP®

Surgical technique

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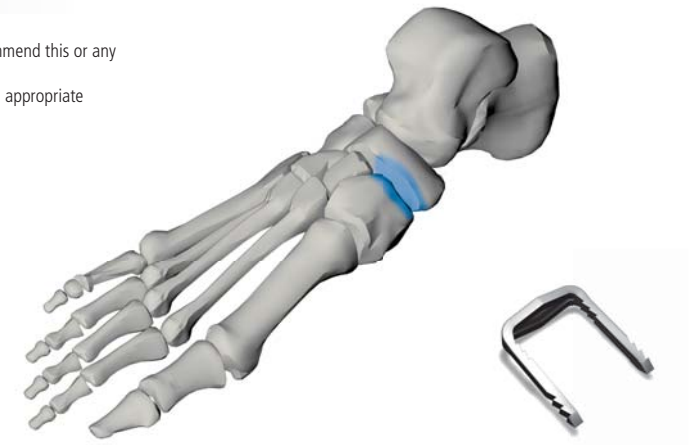
The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

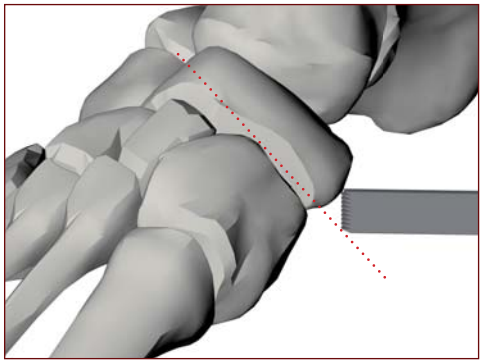


Case

Example of a navicular first joint cuneiform joint arthrodesis.

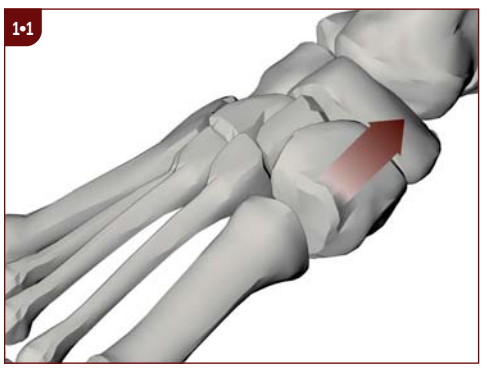
Procedure

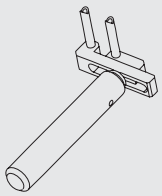
Prepare the joint surfaces with an oscillating saw blade, an osteotome and/or a rongeur.



STEP 1 • MANUAL COMPRESSION

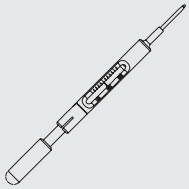
1•1 Manually compress the prepared surfaces.





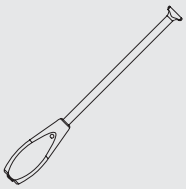
119 301
UNI-CLIP® drill guide

119 016 (x2)
Drill diam. 2.2 mm Lg. 180 mm with AO attachment



119 307
UNI-CLIP® depth gauge

119 311
UNI-CLIP® spreading forceps

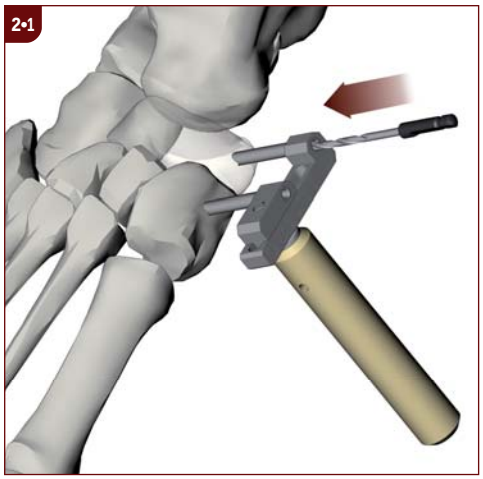


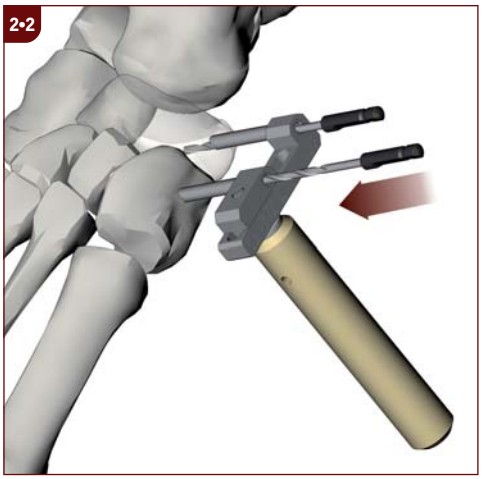
119 309
UNI-CLIP® staple impactor

STEP 2 • DRILLING

2•1 Position the drill guide **(119 301)** according to the selected staple inter-axis. The joint should be in the middle between the two sleeves.
Dril **(119 016)** the proximal hole and leave drill in place.

2•2 Maintaining the compression, drill the distal hole. Both the drills and the guide can be removed at the same time.



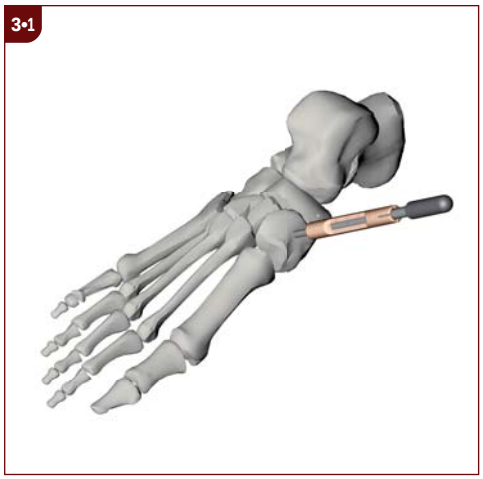


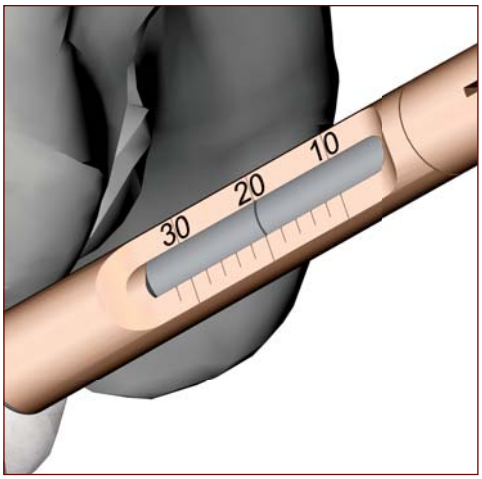
STEP 3 • MEASUREMENT

3•1 Using the depth gauge **(119 307)**, measure the length of the legs.

TIP

This implant may be implanted in mono or bi-cortical ways. Staple legs length can be shortened if needed, with a pin cutter (not in the set).

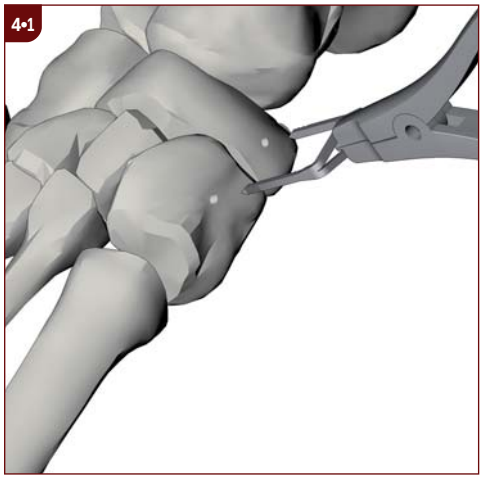




STEP 4 • STAPLE POSITIONING AND IMPACTION

4•1 The correct staple is inserted with the UNI-CLIP® spreading forceps **(119 311).**

4•2 If needed, use the UNI-CLIP® staple impactor **(119 309)** in order to ensure that the staple is flush with the surfaces of the bone.



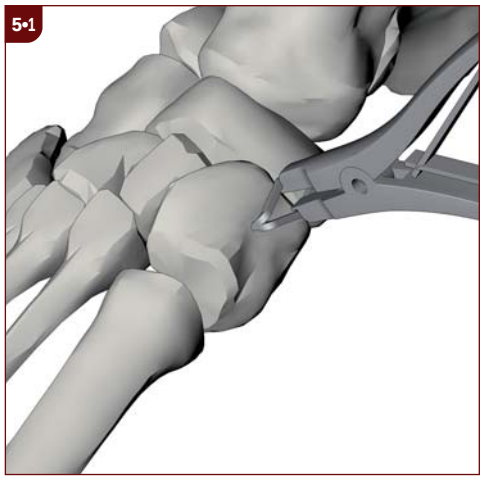
119 311
UNI-CLIP® spreading forceps

STEP 5 • COMPRESSION

WARNING

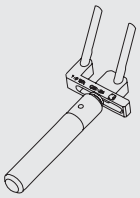
Never use the LARGE UNI-CLIP® spreading forceps (119 314) with an UNI-CLIP® staple. This implant was not designed to undergo the convergence supported by the LARGE UNI-CLIP®.

5•1 Place the UNI-CLIP® spreading forceps **(119 311)** 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.

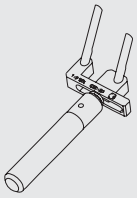


WARNING

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.



119 322
Drill guide for straight staple



119 324
Drill guide for offset staple

Surgical technique

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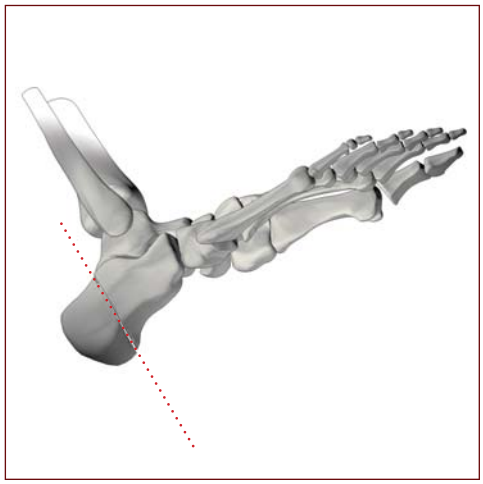
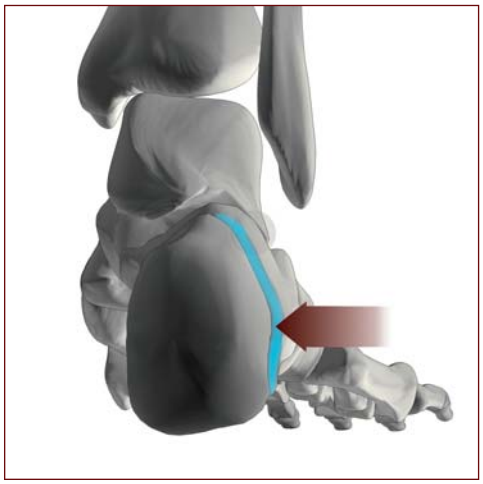
The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Case

Example of a calcaneal osteotomy.





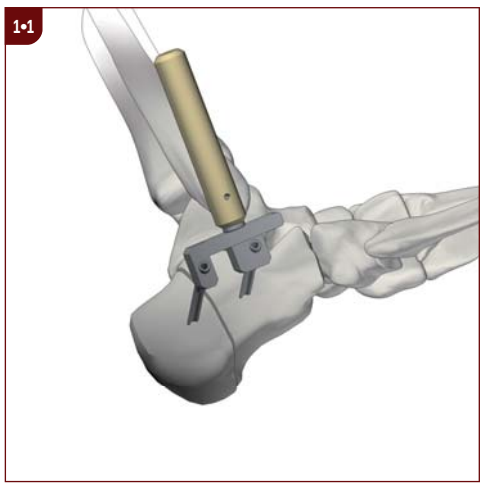
Procedure

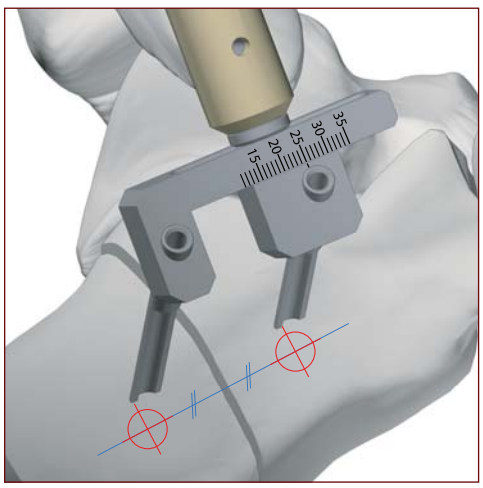
Bicortical osteotomy of the calcaneous with internal displacement.

STEP 1 • DRILL GUIDE POSITIONING

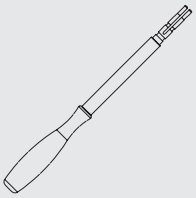
1•1 Choose the appropriate implant (straight or offset).
Adjust the drill guide **(119 322-straight or 119 324-offset)** according to the chosen staple's inter-axis.

The drill guide is positioned with the osteotomy centered between the two sleeves.

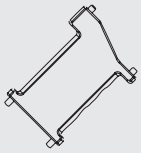




219 545 (x2)
Drill Diam. 3.0 mm



119 319
Impactor handle



119 321
Impactor attachment

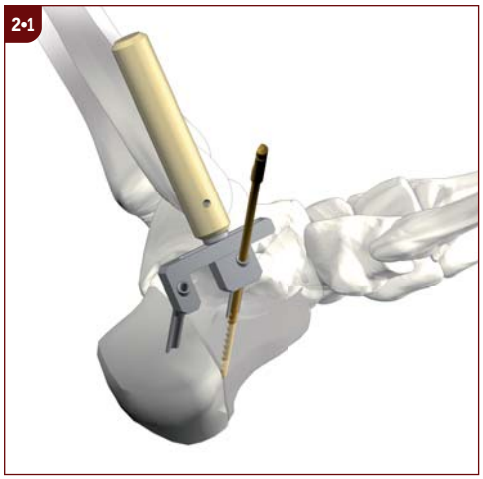
STEP 2 • DRILLING

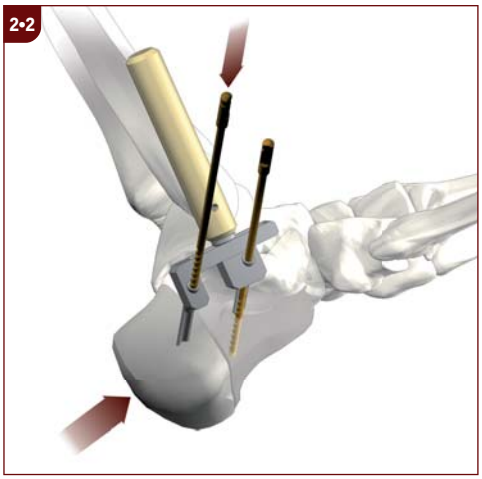
2•1 Prepare the first, proximal, hole with the drill **219 545**, and leave the drill in place

2•2 The distal hole should then be prepared with the second drill. Prior drilling, approximate the osteotomy.

IMPORTANT

Leave both drills in place.
LARGE UNI-CLIP® staples are of mono-cortical use: ***no measurements are needed.***

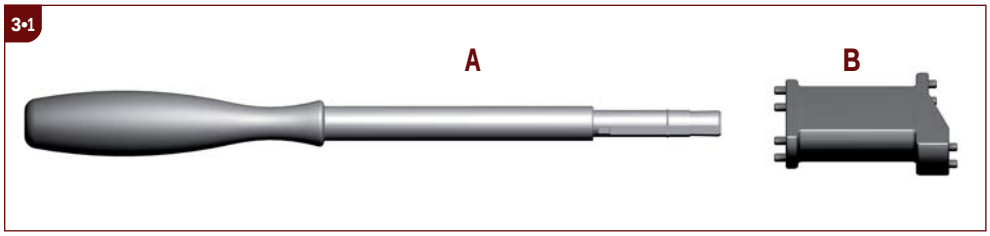


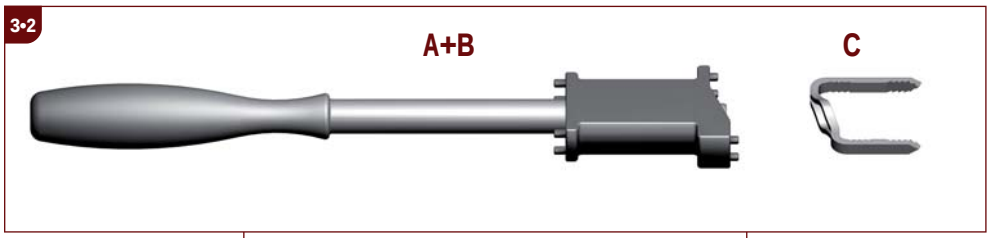


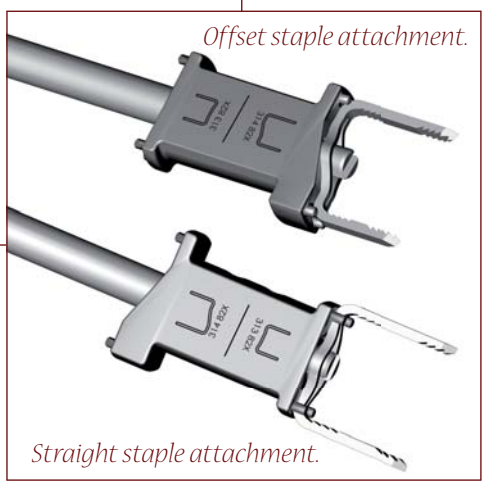
STEP 3 • ASSEMBLY OF IMPLANT WITH IMPACTOR

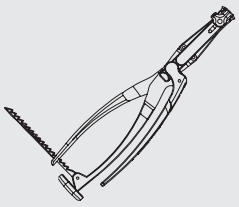
3•1 Assemble the impactor handle **A (119 319)** with the impactor attachment **B (119 321)**.
The side of the impactor attachment **(119 321)** is determined by the staple being used **C**.

3•2 Assemble the impaction device, placing the chosen staple on the end.







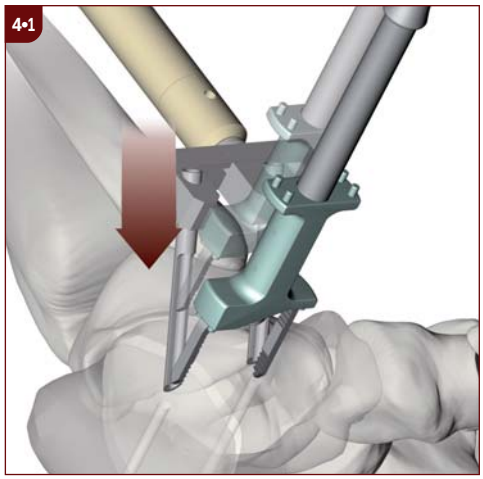


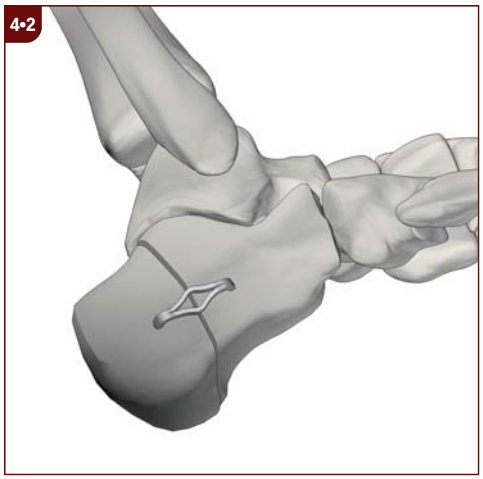
119 314
LARGE UNI-CLIP® spreading forceps

STEP 4 • SETTING THE STAPLE

4•1 Once the impaction device is fully assemble, remove the drills from the drill guide, while maintaining contact between the guide and the drill holes.
Lean the guide, keeping it in contact with the holes. Introduce the UNI-CLIP® staple by sliding the legs down the open side of the sleeves on the drill guide.
Remove the drill guide.

4•2 Impact the staple with the impactor (in case it is not flush with the surface).

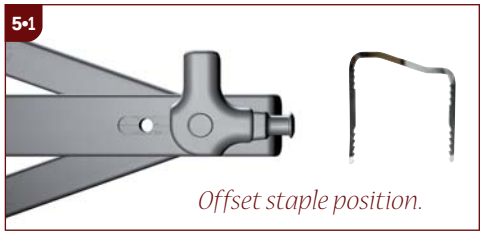




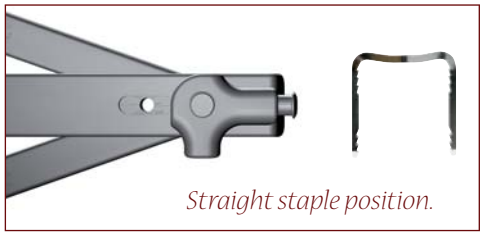
STEP 5 • SET SPREADING FORCEPS

5•1 Set the spreading forceps on the desired position, correspondent to the implant (straight or offset)

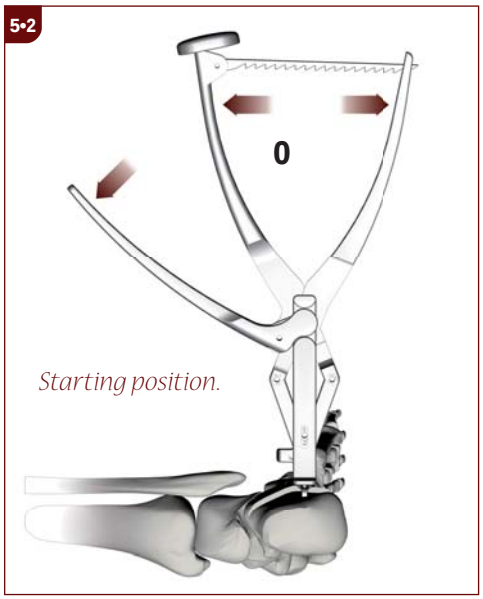
5•2 Ensure the clamp is in starting position, then insert the end of the spreading forceps **(119 314)** into the diamond of the staple.



Offset staple position.



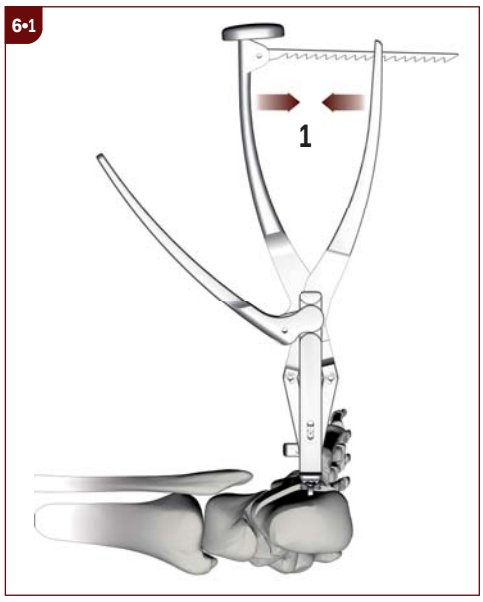
Straight staple position.

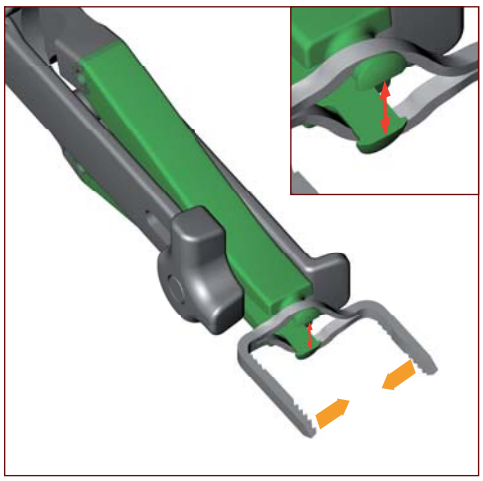


Starting position.

STEP 6 • COMPRESSION

6•1 Slightly apply compression by bringing together the two arms of the spreading forceps. The legs of the staple will come together in a parallel fashion.





WARNING

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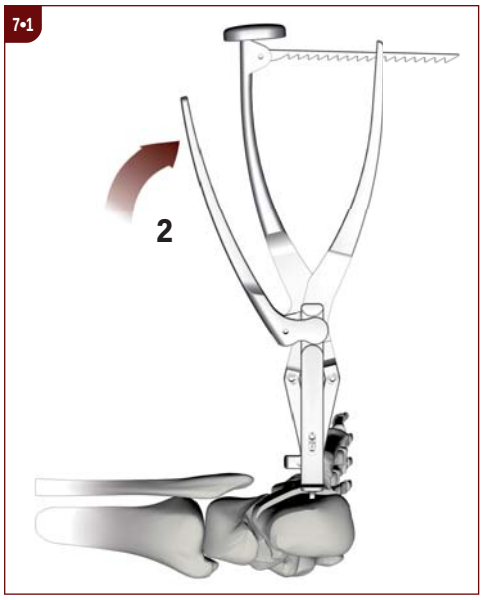
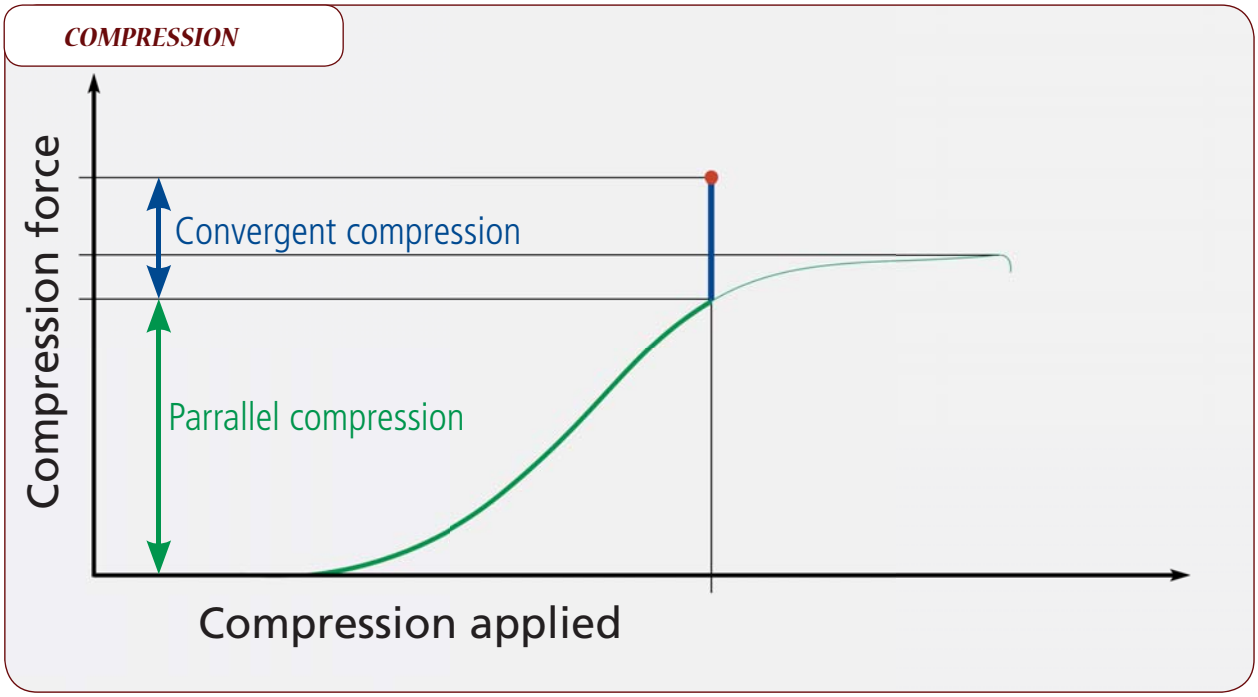
In this way, the spreading forceps provide compression between fragments.

STEP 7 • CONVERGENCE

7•1 After the initial compression, the lever of the instrument can then be used to apply the second level of compression. The staple legs now converge, providing additionnal compression.





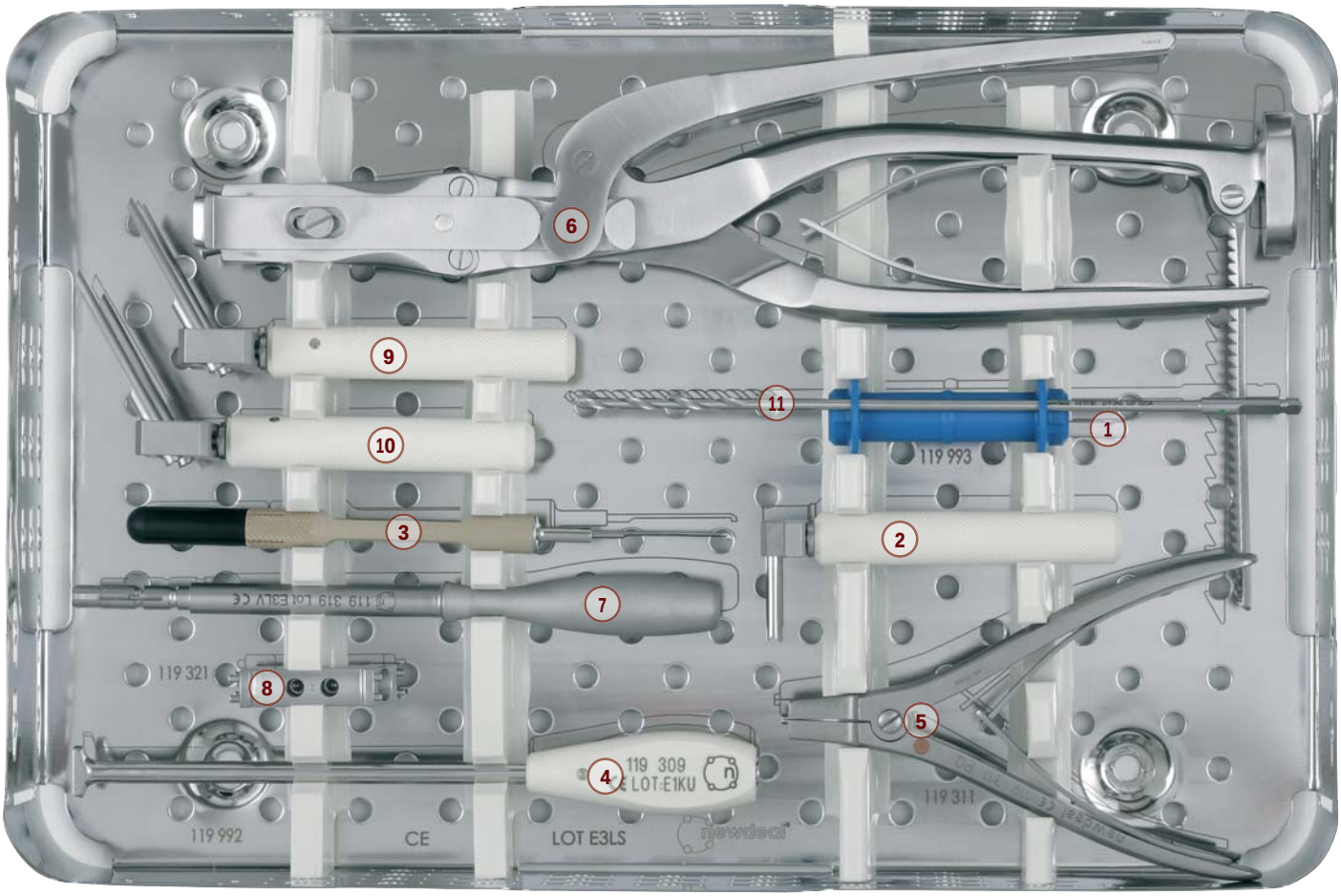
— Initial compression by tightening the legs

— Additional compression by convergence of the legs

• Optimum compression

Depending on bone quality and parrallel compression, on average, convergent compression can increase initial compression by 65%.

Instrumentation



Instruments

	Reference	Description
1•	119 016	Drill diam. 2.2 mm Lg. 180 mm AO attachment
2•	119 301	UNI-CLIP drilling guide
3•	119 307	UNI-CLIP depth gauge
4•	119 309	UNI-CLIP staple impactor
5•	119 311	UNI-CLIP spreading forceps
6•	119 314	LARGE UNI-CLIP spreading forceps
7•	119 319	LARGE UNI-CLIP impactor handle
8•	119 321	LARGE UNI-CLIP impactor attachment
9•	119 322	LARGE UNI-CLIP straight drilling guide
10•	119 324	LARGE UNI-CLIP offset drilling guide
11•	219 545	Drill diam 3.0 mm AO attachment

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Instructions for use

INSTRUCTIONS FOR USE • NON STERILE IMPLANTS • SINGLE USE

In accordance with EEC directive 93/42 relative to medical devices, this product must be handled and/or implanted by WELL-TRAINED, QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

1 - Description of the medical devices:
The implants - delivered non sterile - are:
- The deformable staples are found in different Interaxis and leg lengths.
- They are made out of Stainless steel 316L within the ranges of the standard NF ISO 5832-1 – ASTM F138 & F139;

2 - Indications:
The UNI-CLIP® STAPLE is indicated 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.)
The size of the chosen staple should be adapted to the specific indication.

3 - Contraindications:
The implant should not be used in a patient who has currently, or who has a history of:
- Local or systemic acute or chronic inflammation;
- Active infection or inflammation;
- Suspected or documented metal allergy or intolerance.

4 - Warnings:
Serious post-operative complications may occur from use of the implant in a patient who :
- Lacks good general physical condition;
- Has severe osteoporosis;
- Demonstrates physiologic or anatomic anomalies;
- Has immunological responses, sensitization, or hypersensitivity to foreign materials;
- Systemic or metabolic disorders;

5 - Precautions for use:
Physician must determine if implant is appropriate for patients who have any of the following conditions :
- Drug and/or alcohol and/or smoke addiction and/or abuse;
- Infectious disease;
- Malignancy;
- Local bone tumors;
- Systemic or metabolic disorders or replacement;
- Compromised wound healing;;
- Obesity;
- Demonstrated psychological instability, displayed a lack of understanding, inappropriate motivation, or attitude;
- Unwillingness to accept the possibility of multiple surgeries for revision or replacement;
- Lacks an understanding that a metallic implant is not as strong as normal healthy bone and will bend, loosen, or fracture if excessive demand is placed on it;
- Lacks an understanding that their preoperative capacity may not be fully recovered even after successful implantation;
Knowledge of surgical techniques, proper reduction , selection and placement of implants, and post-operative patient management are considerations essential to a successful outcome.
Criteria for patient selection is the responsibility of the surgeon. Information contained within this document should be taken into consideration during the selection process. Recognition of the appropriate indications and contraindications and the selection of the proper surgical procedures and techniques determined to be best for the patient are the responsibility of the surgeon. Each surgeon must evaluate the appropriateness of the procedure and instruments used during the procedure based on his or her own training and experience.
The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.
Each patient must be evaluated by the surgeon to determine the specific risk/benefit relationship in light of the patient's condition and the surgeon's practice, training, experience, and knowledge of the related medical literature.
Complications with the use staples have been reported in the medical literature. Any patient undergoing a surgical procedure is subject to intra-operative and post-operative complications. Each patient's tolerance to surgery, medication, and implantation of a foreign object may be different.
Possible risks, adverse reactions, and complications associated with surgery and the use of the staples should be discussed with and understood by the patient prior to surgery.
The implant is composed of stainless steel materials 316L; therefore, it is subject to possible reactions and complications, including those listed herein. The patient should not be led to unrealistic expectations as to the performance or results that the surgery and implant can provide. The patient should be informed that the life expectancy of the device is unpredictable once implanted, and that successful results cannot be guaranteed.
IT IS THE RESPONSIBILITY OF THE SURGEON TO PROVIDE THE PATIENT WITH INFORMATION PRIOR TO SURGERY.
Complications may include but are not limited to :
- Pain, discomfort, or abnormal sensations due to presence of the implant ;
- Bending, loosening , and/or breakage, which could make removal impracticable or difficult ;
- Risk of additional injury from post-operative trauma ;
- Migration of the implant position or implant material resulting in injury ;
- Bone loss due to stress shielding ;
Side effects may include but are not limited to :
- Infections ;
- Hematoma ;
- Allergy ;
- Thrombosis ;
- Bone non union or delayed union.
Adverse effects may necessitate re-operation, revision or removal surgery , arthrodesis of the involved joint, and /or amputation of the limb.
Implant removal should be followed by adequate postoperative management to avoid fracture or re-fracture.
Interference risks during medical imaging : MRI/SCANNER : ask the patient to systematically mention that he/she has undergone a surgical intervention.

6 - Instructions for reprocessing:
This product is sold non sterile.
Check the integrity of the packaging and labelling before opening the packing.
Remove all the products from their packaging prior to sterilization
All products should be cleaned, decontaminated, and sterilized before use.
Always immediately clean and decontaminate all devices that have been soiled.
Repeated reprocessing has little effect on these products.
Preparation: Double instruments (ex. Internal screwdriver and associated external screwdriver) should be separated prior to cleaning.
Cleaning: Cleaning can be performed manually, automatically or ultrasonically in accordance with the specifications designated by the manufacturer of the hospital's equipment.
Manual cleaning: Manual cleaning consists of using aldehyde free cleaners (neutral or alkaline), applied with a soft brush, taking special care to threaded parts and parts difficult to reach.
Note : Certain solutions such as those containing bleach or formalin may damage the devices, and they must not be used. Use of metallic brushes or other abrasive products is also forbidden.
Cleaning should be immediately followed by profusely rinsing with deionized water. Check that water flows out the cannulated parts.
Automatic cleaning: Automatic cleaning is performed in a cleaning/disinfecting machine using neutral cleaners, with a cleaning cycle of 5 minutes minimum and a rinsing cycle of 3 minutes.
Check the complete removal of visible dirt, especially in the cannulated parts.
If necessary, repeat the full process or proceed to a manual cleaning.
Disinfection: If an automatic cleaning is used, final rinsing at 95°C during 10 minutes can be performed.
Drying: Drying temperature should not exceed 95°C.
Controls, servicing and tests: No specific requirements. The implants are single use. They should therefore never be re-used.
Packaging: No specific requirements.
Sterilisation: Newdeal's implants and instruments are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital.
The following two methods have been validated by the manufacturer and can thus be used :

• Method : steam	• Method : steam
• Cycle : wrapped gravity	• Cycle : wrapped gravity
• Temperature : 132°C	• Temperature : 134°C
• Exposure time : 45 minutes	• Exposure time : 18 minutes

Other sterilization method and cycles may also be used. However, individuals or hospitals not using the recommended method are advised to validate the alternative method using appropriate laboratory techniques.
EtO sterilization or cold sterilization techniques are not recommended.

7 - Use of the implant:
The surgeon must use the instrumentations recommended in accordance with the operative technique available from the manufacturer. The medical device must be used in compliance with the use of the profession and the standard of art. Do not attemp a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility. Alternate fixation methods should be available intraoperatively.
Opening of the instruments set must be done according to aseptic condition.
When handling the implants, avoid any contact with other material or tools which may damage the implant surface. Under no circumstances should the implant be modified .

8 - Re-use of the implants:
Orthopaedic implants already implanted must never be re-used. The company accepts no responsibility for such re-use.

9 - Re-sterilization of non implanted products:
Re-sterilization is only allowed for non implanted products. Such non implanted products can be sterilized several times in the same conditions as those described above.

10 - Preventative actions for the patient to avoid post-operative complications:
- Avoid extreme position such as flexion-extension
- wear orthopaedic shoes according to the surgeon's prescription
- receive prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.

11 - Storage: Store in dry place

12 Product information disclosure / Liability:
Newdeal, an Integra LifeSciences Company, has exercised reasonable care in the selection of materials and the manufacture of these products. Newdeal excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Newdeal shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Newdeal neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these products. Newdeal intends that this device should be used only by physicians having received proper training in orthopedic surgery technique for use of the device.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

INFORMATION: Should any information regarding the products or their uses be required,

LARGE UNI-CLIP® / UNI-CLIP®

OFFSET LARGE UNI-CLIP®

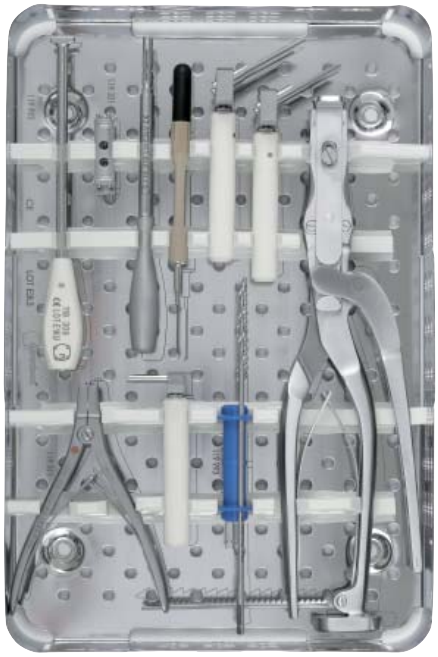
Reference	Description
INTERAXIS 25 MM	
314 820S	LENGTH 20/25 MM
INTERAXIS 30 MM	
314 827S	LENGTH 27/32 MM

STRAIGHT LARGE UNI-CLIP®

Reference	Description
INTERAXIS 20 MM	
313 820S	LENGTH 20 MM
INTERAXIS 25 MM	
313 825S	LENGTH 25 MM

NOTCHED UNI-CLIP®

Reference	Description
INTERAXIS 15 MM	
213 512(S)	LENGTH 12 MM
INTERAXIS 20 MM	
213 820(S)	LENGTH 20 MM



INSTRUMENTS

Reference	Description
119 016	DRILL DIAM. 2.2 MM LG. 180 MM AO ATTACHMENT
119 301	UNI-CLIP DRILLING GUIDE
119 307	UNI-CLIP DEPTH GAUGE
119 309	UNI-CLIP STAPLE IMPACTOR
119 311	UNI-CLIP SPREADING FORCEPS
119 314	LARGE UNI-CLIP SPREADING FORCEPS
119 319	LARGE UNI-CLIP IMPACTOR HANDLE
119 321	LARGE UNI-CLIP IMPACTOR ATTACHMENT
119 322	LARGE UNI-CLIP STRAIGHT DRILLING GUIDE
119 324	LARGE UNI-CLIP OFFSET DRILLING GUIDE
219 545	DRILL DIAM. 3.0 MM AO ATTACHMENT

CONTAINER

Reference	Description
119 990	UNI-CLIP CONTAINER
119 991	UNI-CLIP CONTAINER LID
119 992	UNI-CLIP CONTAINER BASIS
119 993	UNI-CLIP CONTAINER CYLINDER

• The products are manufactured and referenced within the frame of the standards in force.
• Implantation procedures are described in the surgical technique.
• Non contractual document. The manufacturer reserves the right, without prior notice, to modify the 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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CE 0120

- See instructions for use
- Single use
- Sterile

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609-275-5363 • www.integra-ls.com

NEWDEAL SAS
10, place d'Helvetie • 69006 Lyon • FRANCE
+33 (0)4 37 47 51 51 • +33 (0)4 37 47 51 52
newdeal@newdeal.info • www.newdeal.info

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