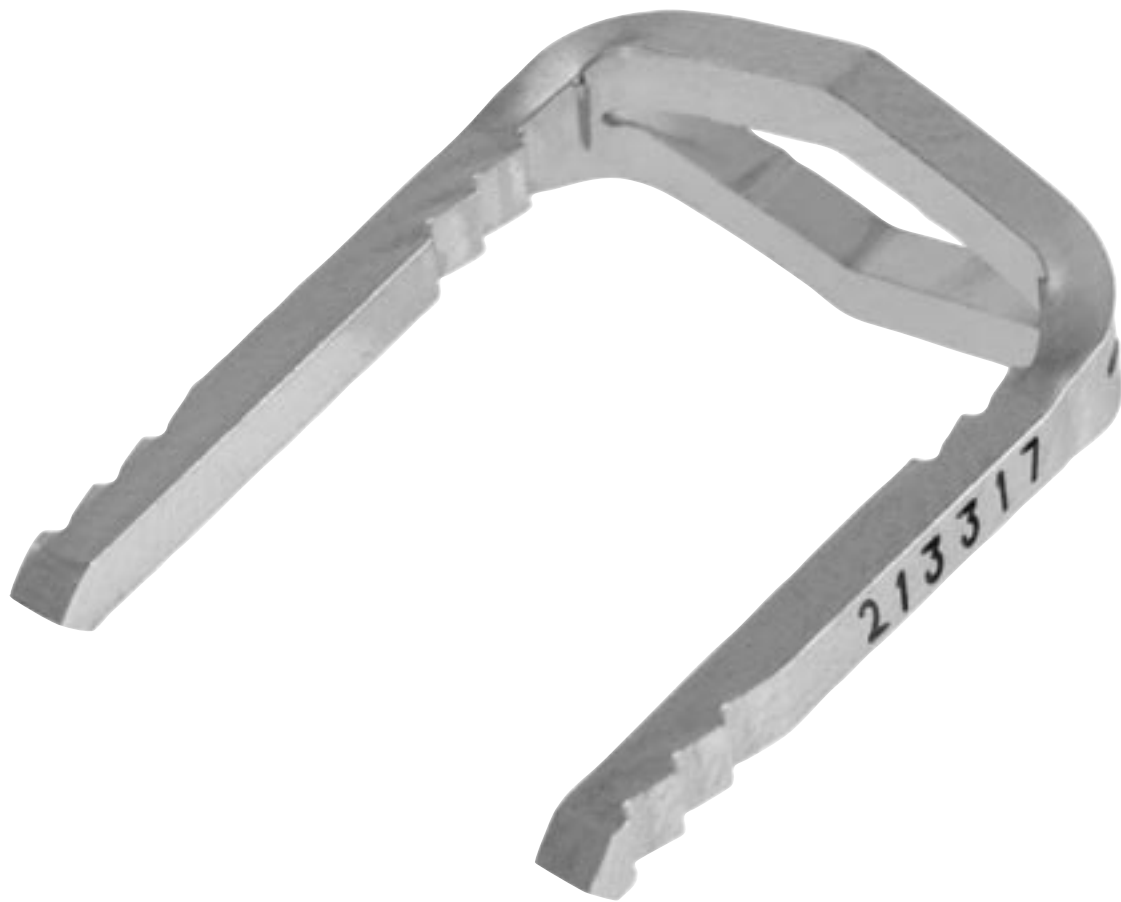


UNI-CLIP®

SURGICAL TECHNIQUE



Compression staple

FOREFOOT SOLUTIONS™

Newdeal® as the manufacturer of this device, does not practice medicine and does not recommended 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

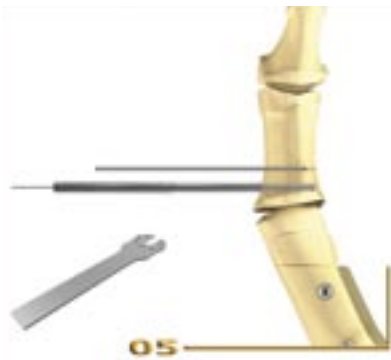
SURGICAL APPROACH

- 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).

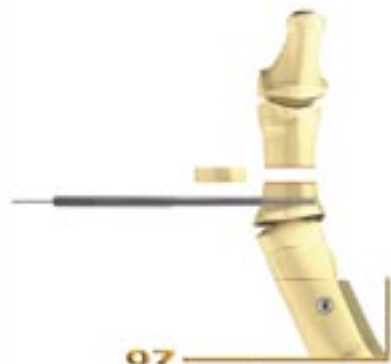




05



06



07



08



09



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®.

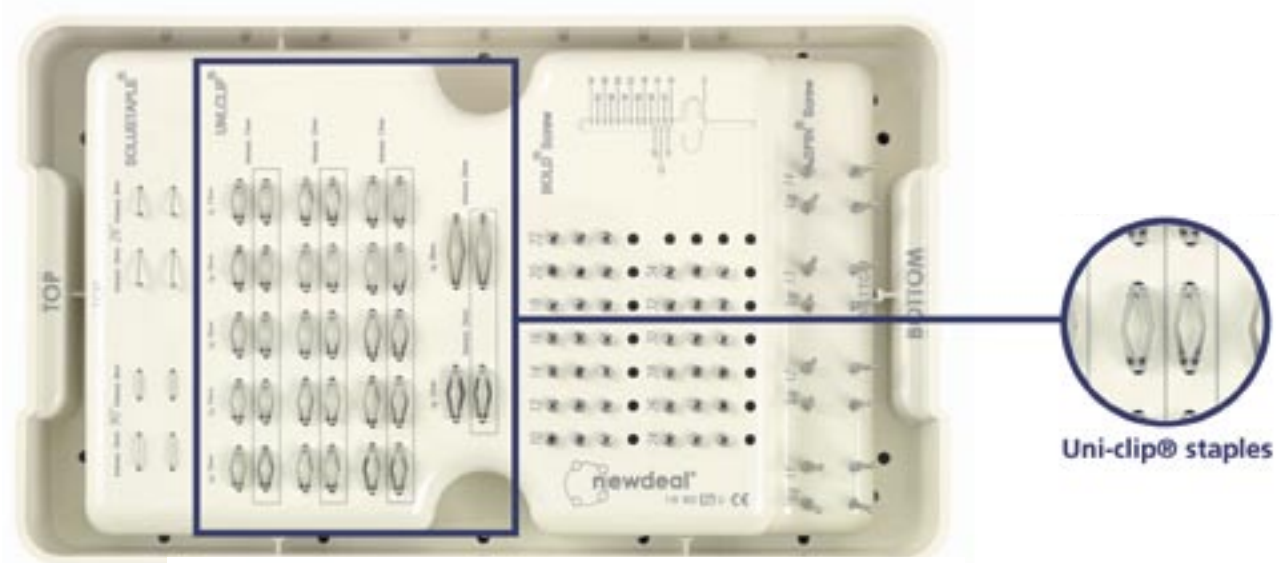


X-RAYS

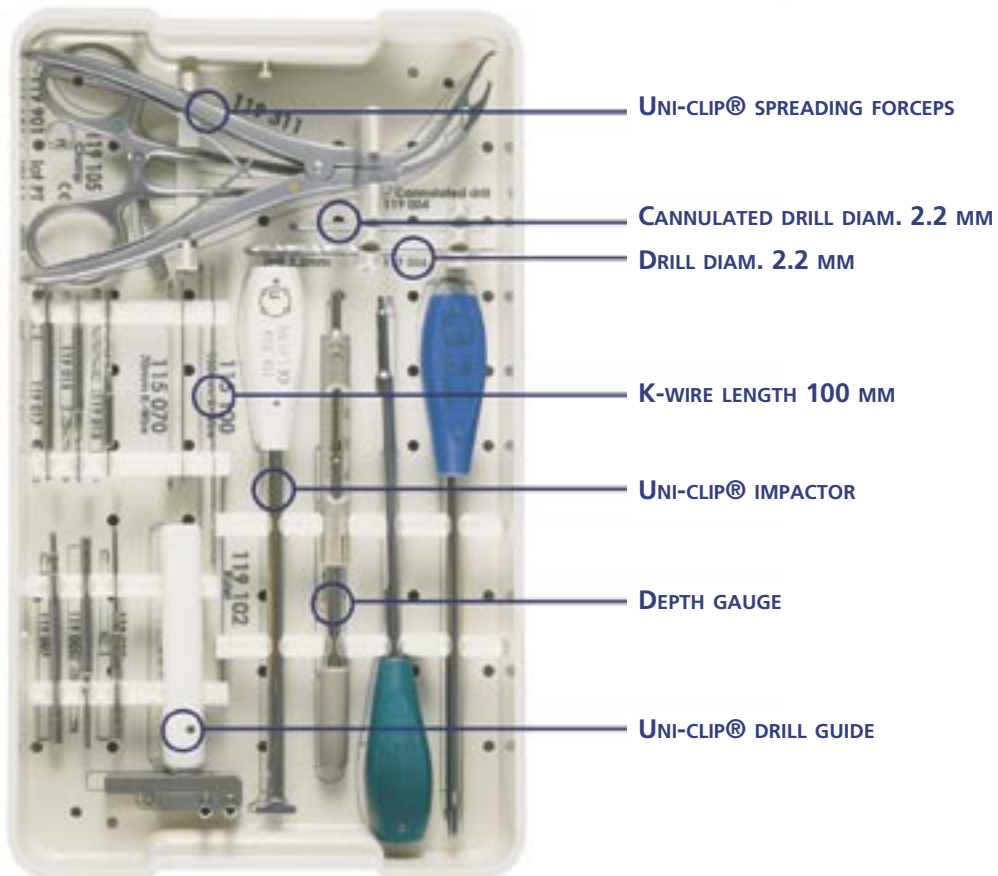




FOREFOOT CONTAINER



Uni-clip® staples



INSTRUCTIONS FOR USE

Non-sterile IMPLANTS FOR SURGERY • 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 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:

- Has Severe osteoporosis;
 - Has Immunological responses, sensitization, or hypersensitivity to foreign materials;
 - Lacks good general physical conditions;
 - Demonstrates physiologic or anatomic anomalies that might result in significant post-operative complications.
- Systemic or metabolic disorders;

5 - Precautions for use:

Physician must determine if implant is appropriate for patients who have any of the following conditions:

- Infectious disease.
- Malignancy;
- Local bone tumors;
- Drug and/or alcohol and/or smoke addiction and/or abuse;
- Obesity;
- Compromised wound healing;
- Demonstrates psychological instability, displays 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 of compression 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 compression staples should be discussed with and understood by the patient prior to surgery. The implant is composed of stainless steel materials; 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 was implanted with a metallic device.

6 - Instructions for reprocessing:

This product is sold non-sterile.

Check the integrity of the packaging and labeling 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 80°C during 10 minutes can be performed.

Drying: Drying temperature should not exceed 80°C.

Controls, servicing and tests: No specific requirements.

The implants are single use. They should therefore never be re-used.

Packaging: No specific requirements.

Sterilization: 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 standards of the art. Do not attempt 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:

Orthopedic 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 orthopedic 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 - Liability:

Newdeal shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Newdeal neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Newdeal intends that this device should be used only by physicians having received appropriate training in orthopedic surgery techniques.

WARNING: Federal law (USA) restricts this device to sale by or on the order of a physician.

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, please contact your representative or distributor or directly contact the manufacturer.

UNI-CLIP®

NOTCHED UNI-CLIP®

INTERAXIS : 11

CATALOG NUMBER	DESCRIPTION
213 113ND	LENGTH 13 mm
213 114ND	LENGTH 14 mm
213 115ND	LENGTH 15 mm
213 116ND	LENGTH 16 mm
213 117ND	LENGTH 17 mm

INTERAXIS : 12

CATALOG NUMBER	DESCRIPTION
213 213ND	LENGTH 13 mm
213 214ND	LENGTH 14 mm
213 215ND	LENGTH 15 mm
213 216ND	LENGTH 16 mm
213 217ND	LENGTH 17 mm

INTERAXIS : 13

CATALOG NUMBER	DESCRIPTION
213 313ND	LENGTH 13 mm
213 314ND	LENGTH 14 mm
213 315ND	LENGTH 15 mm
213 316ND	LENGTH 16 mm
213 317ND	LENGTH 17 mm

INTERAXIS : 15

CATALOG NUMBER	DESCRIPTION
213 512ND	LENGTH 12 mm

INTERAXIS : 20

CATALOG NUMBER	DESCRIPTION
213 820ND	LENGTH 20 mm

ASSOCIATED INSTRUMENTS

CATALOG NUMBER	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	IMPACTOR
119 311ND	UNI-CLIP SPREADING FORCEPS
115 100ND	K-WIRE 10/10 LENGTH 100 mm
119 900ND	STERILIZATION CONTAINER



- 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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