SURGICAL TECHNIQUE

Snap-off® screw

FOREFOOT SOLUTIONS™
WEIL OSTEOTOMY

In order to treat static disorders of the lesser rays, Dr. L.S. Weil (Chicago, USA) has developed a surgical technique with the following characteristics:

• Easy approach
• Reliable
• Stable
• Quickness

The Weil osteotomy answers the above mentioned characteristics. It is a long horizontal osteotomy allowing:

• A proximal displacement of the head without lowering.
• The bone surface offers an initial stability.
• Lateral, rotary, and dorsal displacement.

SURGICAL APPROACH

• The procedure is performed by dorsal approach, starting within the intermetatarsal interspace. There is good exposure to cut between the two extensor tendon muscles, extending as distally as possible (1 & 2).

The bone cuts should be as parallel (horizontal) to the sole as possible, usually about 25 degrees (3). In case of pes planus, the cut may be too long (4), whereas in pes cavus, the cut may be too short (5). Therefore, it is necessary to adapt the cuts to the condition of the forefoot.
PREPARING THE CUT

• It is the aim to obtain an index plus minus (M1=M2). The head can be positioned and held in place by an important plantar flexion of the toe. However, it is easier to maintain the head in place with a Museux forceps or a Banaleck clamp (6).

• The cut is horizontal and parallel to the sole. It starts in the cartilage of the head (2 mm from the dorsal border) and should be as long as possible (2.5 to 3 cm in standard foot condition) (7).

• The cut is performed with an oscillating saw (8).

CUT AND PLACEMENT

• Immediately after the Weil osteotomy, the metatarsal head will move proximally. The metatarsal formula will be controlled and/or restored (9).

• Then, the Spin® screw is placed. It is not necessary to prepare the dorsal bone since the Spin® is a self-cutting and self-tapping screw, which is introduced by a power drill (Jacobs Chuck) (10). Sometimes it is necessary to initiate the snap-off effect by moving the drill forward (osteoporotic bone) (11), whereas sometimes a predrill with a K-wire (1 mm diameter) can be advised in extremely solid cortical bone.
**FINAL FIXATION**

- When the head of the Spin® gets into contact with the dorsal cortex, the holding device snaps off. If necessary, the screw setting can be finalized by handling the specific screwdriver.

- Once the osteotomy is stabilized, the peak is removed handling the saw or the bonecutter. If necessary, the extensors can be lengthened by a Z-shaped release (Green Technique) after the metatarsal shortening (12).

**OTHER CASES**

- In case of metatarso-phalangeal luxation, the metatarsal shortening should be at least equivalent to the initial phalangeal retraction (13).
FOREFOOT CONTAINER

SPIN® screw

SPIN® screwdriver
INSTRUCTIONS FOR USE
NON-STERILE IMPLANTS FOR FOOT SURGERY • SINGLE USE
In accordance with EU 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 Snap-off Screw existing in different diameters and lengths.
- They are made out of Titanium alloy within the frame of the standard ISO 5832-3 - ASTM F136.

2 - Indications:
The SPIN® SCREW is indicated for fixation of bone fractures or for bone reconstruction.
Examples include:
- Fixation of small bone fragments.
- Wrist osteotomy
- Cervical Fixation
- Osteotomies and fractures fixation in the foot and hand.

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

5 - Precautions for use:
- Infection disease;
- Malignancy;
- Local bone tumors;
- Compromised wound healing;
- Drug and/or alcohol and/or smoke addiction and/or abuse;
- Obesity;
- 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 their preparative capacity may not be fully recovered even after successful implantation;
- 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.

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 screws 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 screws should be discussed with and understood by the patient prior to surgery. The implant is composed of Titanium alloy 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 has undergone a surgical intervention.

6 - Instructions:
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 soaked.
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 alcohol 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 bleaches 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.

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:

<table>
<thead>
<tr>
<th>Method: steam</th>
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<tbody>
<tr>
<td>Cycle: wrapped gravity</td>
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<tr>
<td>Temperature: 132°C</td>
<td>Temperature: 134°C</td>
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<tr>
<td>Exposure time: 45 minutes</td>
<td>Exposure time: 18 minutes</td>
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Other sterilization methods 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. E.O sterilization or cold sterilization techniques are not recommended.

7 - Use of the implant:
The surgeon must use the instrumentation 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 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 positions 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 – 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.
Snap-off® screw

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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<td>112 014ND</td>
<td>DIAM. 2 MM - LENGTH 14 MM</td>
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<td>119 201ND</td>
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<tr>
<td>119 900ND</td>
<td>STERILIZATION CONTAINER</td>
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**ASSOCIATED INSTRUMENTS**

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