Instructions for use

INSTRUCTIONS FOR USE
OSTEOSYNTHESIS SYSTEMS
SINGLE USE

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

Description

Newdeal®'s osteosynthesis systems are designed for the fixation of fractures, fusions and osteotomies, more especially for foot, ankle and hand surgery.
Newdeal®'s products are made from materials as described in the table/appendix.
These devices do not contain phtalates unless this is indicated on the label.

Indications

For fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of small bone fragments.
- Weil osteotomy
- Mono-cortical fixation
- Osteotomies and fractures fixation in the foot and hand.

Material: Ti-6Al-4V (ISO 5832-3 / ASTM F136).

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.

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;

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;
- 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 are 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 osteosynthesis systems 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 osteosynthesis systems should be discussed with and understood by the patient prior to surgery. The implant is made from metallic alloys; 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.

Packaging - sterility :

This product is sold either sterile or non sterile.
The sterilization method is specified on the packaging. Components sterilized by radiation are exposed to a minimum of 25 kGy of gamma irradiation.
If the product is not labeled « STERILE», it must be sterilized prior to use, in compliance with current regulations.
If the product has been removed from packaging but not used, it may be re-sterilized.
Check packaging and labeling integrity before use. The sterility is guaranteed as long as the packaging has not been damaged or opened and before the expiration date.
Do not use any implant for which the packaging has been opened or damaged outside the operating theatre.
Inner packaging should be handled under sterile conditions (persons/instruments).

Use of the products :

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 standard 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.
The multi-component devices (such as plates-screws systems) should only associate the appropriated Newdeal® products and should never be used in conjunction with components of any other manufacturers, as these products may not be compatible. The company accepts no responsibility for such use.
Specific cautions for plates
The plates should never been excessively bent, nor reverse bent.

Re-use of the implants :

Orthopedic implants already implanted must never be re-used. Re-use would incur the risk of modifying the properties and performance of the implant and of increasing the likelihood of the complications and/or undesirable effects mentioned earlier arising.The company accepts no responsibility for such re-use.

Re-sterilization of non-implanted implants and sterilization of non-sterile products:

Unless supplied sterile and clearly labeled as such, all implants and instruments must be steam autoclaved prior to use in surgery. Re-sterilization is only allowed for non-implanted products. Remove delivery packaging in compliance with current regulations to sterilize non-sterile products. Newdeal's osteosynthesis implants are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital. The implants can be sterilized several times in the same conditions.
The following two methods have been validated by the manufacturer:
Newdeal® Plastic (Radel®) sterilization trays

Cycle	*Gravity Displacement 5 pulses (Maximum 900 mbar; Minimum 200 mbar)*	*Pre-Vacuum 3 pulses (Maximum 26.0 psig (2.8 bar); Minimum 10 inHg (339 mbar))*
Minimum Temperature	*134°C (273° F)*	*132°C (270° F)*
Exposure Time	*18 minutes*	*9 minutes*
Purge	*-*	*2-3 minutes*
Vacuum drying	*20 minutes*	*20 minutes*

For the Forefoot tray in a pre-vacuum cycle, the user MUST disassemble the locking nuts for devices 119401 and 119403 within the Forefoot Set and place them in the base of the container prior to sterilizing. Devices 119401: 90° Solustaple Holder & Impactor and 119403: 26° Solustaple Holder & Impactor are located in the middle level of the tray system.
Newdeal® Stainless Steel sterilization trays

Cycle	*Gravity Displacement 5 pulses (Maximum 900 mbar; Minimum 200 mbar)*	*Pre-Vacuum 3 pulses (Maximum 26.0 psig (2.8 bar); Minimum 10 inHg (339 mbar))*
Minimum Temperature	*134°C (273° F)*	*132°C (270° F)*
Exposure Time	*18 minutes*	*4 minutes*
Purge	*-*	*2-3 minutes*
Vacuum drying	*20 minutes*	*20 minutes*

These sterilization parameters assume that all instruments have been properly decontaminated prior to sterilization. The parameters are validated to sterilize specific configurations as noted in the tray markings. If other products are added to the tray or to the sterilizer, the recommended parameters may not be valid and new cycle parameters may need to be validated by the user. The autoclave must be properly installed, maintained and calibrated.
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.

Information related to postoperative care:

- The patient should be advised that a second more minor procedure for the removal of the implants is usually necessary
- While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not suggested.
- Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending, or breaking the device. Patients who are obese or non-compliant, as well as patients who could be predisposed to delayed or non-union must have auxiliary support.
- Even after full healing, the patient should be cautioned that re-fracture is more likely with the implant in place and soon after its removal, rather than later, when the voids in the bone left by implant removal have been filled in completely.
- Patients should be cautioned against unassisted activity that requires walking or lifting.
- Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident.
- The patient should be encouraged to report to his/her surgeon any unusual changes of the operated extremity. If evidence suggests loosening of the implant (particular pain and progressive changes in the radiographs) an intensified schedule of check-ups is advised and new warning and instructions to the patient may be appropriate regarding further activity restrictions.
- The patient should be encouraged to receive prompt medical attention for any infection that could occur, whether at the operated-member level or elsewhere in the body.

Storage:

Store in dry place.

Product disclosure / Liability:

Newdeal an Integra LifeSciences Company, has exercised reasonable care in the selection of materials and the manufacture of these products and warrant that the products are free from manufacturing defects. Newdeal excludes all other 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, please contact your representative or distributor or directly contact the manufacturer.

Date of last revision: 01/15/2010.

X ray - Weil osteotomy

SPIN® 2.0: Break off screw - sterile

Reference	Description
112 011S	DIA 2.0 - LENGTH 11 MM
112 012S	DIA 2.0 - LENGTH 12 MM
112 013S	DIA 2.0 - LENGTH 13 MM
112 014S	DIA 2.0 - LENGTH 14 MM

SPIN® 2.7: Break off screw - sterile

Reference	Description
112 111S	DIA 2.7 - LENGTH 11 MM
112 112S	DIA 2.7 - LENGTH 12 MM
112 113S	DIA 2.7 - LENGTH 13 MM
112 114S	DIA 2.7 - LENGTH 14 MM

Associated instruments

#	Reference	Description
1	**229 301**	SPIN SCREWDRIVER
	115 070S	K-WIRE DIA 1.0 - LENGTH 70 MM

229 951	**SCREWS CONTAINER WHICH INCLUDES:**
229 961	BASE
229 970	LID
229971	MAT

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SPIN® 2.0 - SPIN® 2.7

Break-off screw

Surgical Technique

ORTHOPEDICS
LOWER EXTREMITY

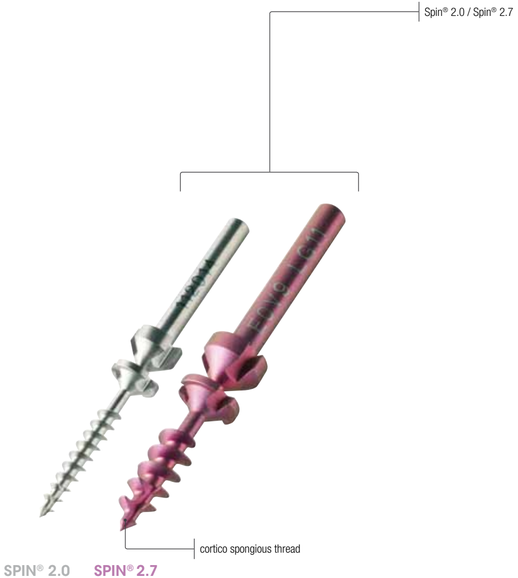
newdeal
New ideas for foot surgery™

- 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.
- Spin, Newdeal, New ideas for foot surgery and the Integra wave logo are trademarks or registered trademarks of Integra LifeSciences Corporation or its subsidiaries.

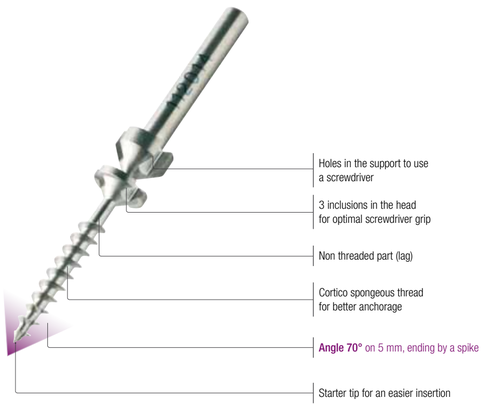
INTEGRA™

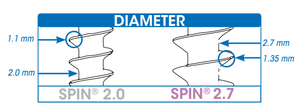
229 301
Spin® Screwdriver

115 070S
K-wire
diam. 1.0 mm
L70 mm



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.





- Self drilling, self tapping with starter tip
- Reduced soft tissue irritation with low profile head
- Power or screwdriver (3 head inclusions) implantation
- Non threaded part (lag) for optimal compression

Instruments details

- Spin screwdriver

Implants details

- Material: Titanium alloy, TiAl6VA, ISO 5832-3 ASTM F136.
- Sterile implant.
- Lengths: 11, 12, 13, 14 mm.
- Lot n° and reference marking.
- Only Spin® screw 2.7: cortico spongious thread ; recommanded for porotic bones.

Indications

For fixation of bone fractures or for bone reconstruction.

Examples include:

- Weil osteotomy.
- Fixation of small bone fragments.
- Mono-cortical fixation.
- Osteotomies and fractures fixation in the foot and hand.

Surgical technique

1 · Weil osteotomy

Immediately after the Weil osteotomy, the metatarsal head will move proximally. The metatarsal formula will be controlled and/or restored. (fig. 1)

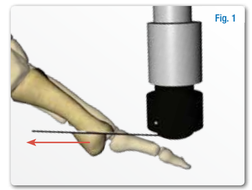


Fig. 1

warning

During screwing, the screwdriver should be in the axis of the screw to avoid any lever effect which could lead to an inappropriate breakage of the screw.

2 · Fixation

Then, the Spin® 2.0 or Spin® 2.7 screw is introduced by a power drill (Jacobs Chuck) or screwdriver (229 301). (fig. 2)

Although the Spin® 2.0 or Spin® 2.7 screw is self-drilling and self-tapping in most bone, it may be necessary to drill the cortex in certain cases with a k-wire diam 1.0mm (Length 70 mm: 115 070S), notably in extremely solid cortical bone. (fig. 3)

Sometimes (osteoporotic bone), it is necessary to initiate the snap off effect by moving forward the power drill or screwdriver. (fig. 4)

When the head of the Spin® screw gets into contact with the dorsal cortex, the holding device snaps off. If necessary, screw setting can be finalised by handling specific screwdriver (229 301). (fig. 5)

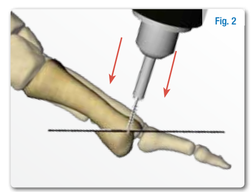


Fig. 2


Fig. 3

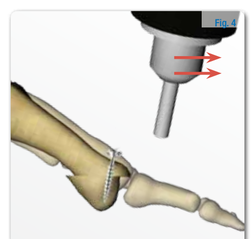


Fig. 4


Fig. 5

Once the osteotomy is stabilised, the peak is removed handling the saw or the bonecutter. (fig. 6a and 6b)

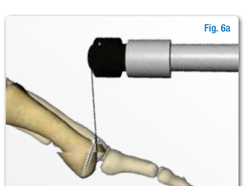


Fig. 6a


Fig. 6b