ENG

Integra®

Large Qwix®

Positioning and Fixation Screw

SURGICAL TECHNIQUE

INTEGRA®
LIMIT UNCERTAINTY

Table of Contents

Concept

The Large QWIX® positioning and fixation screws were designed for extremity fixation, to provide speed and precision for challenging surgical situations. The Large QWIX® screw's unique design allows:

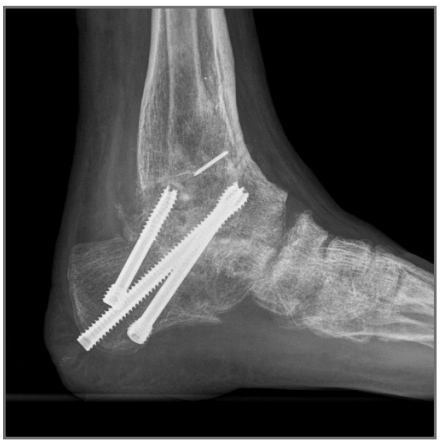
- Optimal and reproducible compression (fixation screws)
- Accurate insertion with minimal soft tissue conflict: the head is totally embedded in the bone
- Address multiple fixation and osteotomy sites: two available diameters (5.5 mm and 7.5 mm) with two different designs:
  - positioning screws (fully threaded), for stabilizing without any compression (e.g. bone graft)
  - fixation screws (partially threaded), for fixation with compression
- Precise placement over a K-Wire (cannulated screws)

Indications

The Large QWIX® Screws are indicated for fixation of bone fractures or for bone reconstruction:

1. Arthrodesis in foot (mid & hindfoot) and ankle surgery
2. Fractures management in the foot and ankle
3. Mono or bi-cortical osteotomies in the foot and ankle

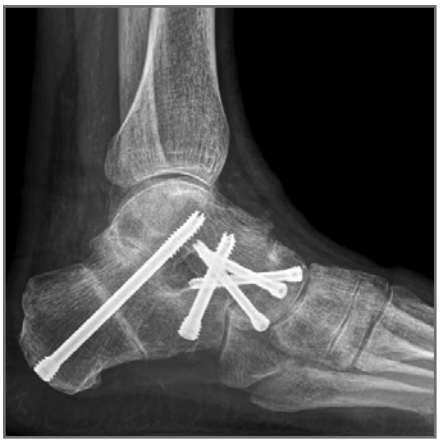
The size and length (partially or fully threaded) of the chosen screw should be adapted to the specific indication.



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



Implant Details

- Material: Titanium alloy Ti-6Al-4V (ISO 5832-3 / ASTM F136
- Cannulated screw
- Hexagonal screw head
- Totally bone embedded
- Self drilling and self tapping screw
- Fluted distal part to allow easy insertion
- Color code for the screws and instruments
  (Purple for diam. 7.5 mm and yellow for the 5.5 mm)

Fixation Screws

- Variable lag part to allow compression
- Conical head with self-tapping notches

Diam. 7.5 mm

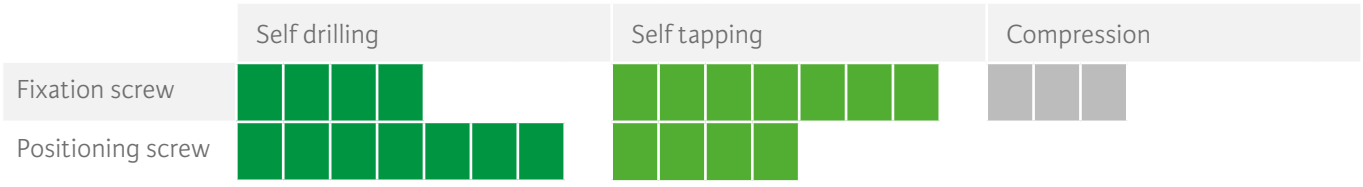
Diam. 5.5 mm

Positioning Screws

- Fully threaded
- Specially indicated for bone graft fixation

Diam. 7.5 mm

Diam. 5.5 mm



Description

Titanium screw diameters 5.5 mm and 7.5 mm.

- Cannulated screws: K-wire guided drilling and insertion
- Self-drilling and self-tapping
- Totally intra-osseous fixation
- Large range of screw lengths in 5 mm increment for the 2 diameters and designs
- 2 designs:
  - Fixation screws: compression screw with a lag part (partially threaded and decreased thread at the head)
  - Positioning screws: no compression (fully threaded)
- Variable lags designed specifically for extremity fixation
- Manufactured from Titanium alloy. Ti-6Al-4V, ISO 5832-3 ASTM F136
- Sterily packaged
- Large QWIX® system is color coded:
  - Yellow for dia. 5.5 mm screws
  - Purple for dia. 7.5 mm screws

115 516 / 529 061
K-wire

119 151 / 119 171
Internal
protection sleeve

119 152 / 119 172
Drilling guide

119 153 / 119 173
External
protection sleeve

Designed in conjunction with Prof. Beat Hintermann, Liestal - Switzerland.
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

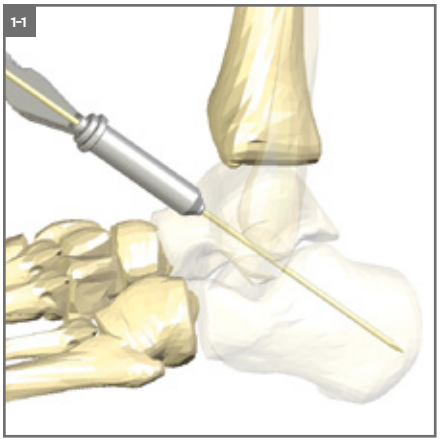
Text corresponding to the Large QWIX® screw dia. 5.5 mm

Text corresponding to the Large QWIX® screw dia. 7.5 mm

Positioning of the Pin

1-1 A 1.6 / 2.5 mm diameter K-wire, 200 / 250 mm long (115 516 / 529 061), is introduced into the site where the Large QWIX® screw is to be implanted. The K-wire is implanted by means of a drilling guide and soft tissue protector (119 151, 119 152 and 119 153 / 119 171, 119 172 and 119 173). Failure to use the drilling guide and protection sleeve when inserting the K-wire may result in soft tissues entrapment. Care should be taken when K-wire is inserted to respect neighbouring blood vessels, nerves and tissues. The depth of insertion of the k-wire depends upon the surgeon will to achieve a mono or bi-cortical osteosynthesis.
The use of x-rays is recommended to check the good positioning and depth insertion of the k-wire.

1-1



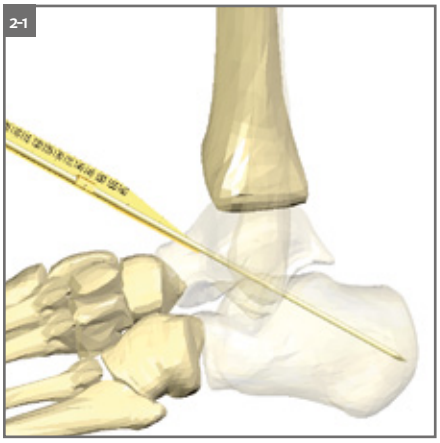
Determination of the Length of the Screw to be Implanted

At insertion of the K-wire, the appropriate length of screw is determined from a measurer (119 150). Large QWIX® measurer can be used according to two methods: direct read and indirect read.

2-1

Direct Read

Determined with the measurer, it is placed so the thin side is aligned with the base of the k-wire. Care should be taken to hold the measurer in perfect alignment with the visible part of the k-wire. The appropriate screw length is then read directly from the measurer, marked on the side "K-wire 200 mm" / "K-wire 250 mm".



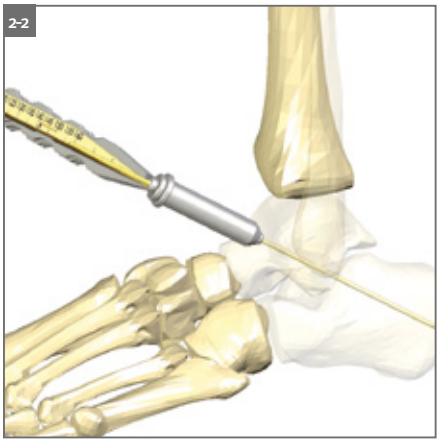
2-2

Indirect Read

The drilling guide and soft tissue protector should be left in place. The measurer is then placed so that the thin side is aligned with the base of the drilling guide and soft tissue protector (119 151, 119 152 and 119 153 / 119 171, 119 172 and 119 173). Care should be taken to hold the measurer in perfect alignment with the visible part of the k-wire. The appropriate screw length is then determined by deducting the length visible on the internal protection sleeve handle from the measure read from the measurer, marked on the side "K-wire 200 mm" / "K-wire 250 mm".

The surgeon may decide to add or deduct a few milli-meters to/from the length read from the ruler. For example, if needed, a few millimeters may be deducted to ensure that the second cortex will not be penetrated.

The superior part of the measurer (119 150) allows for the control of the screw to be implanted. The head of the Large QWIX® screw is positioned on the top of it, the distal part directed towards the thin part of the measurer.



Caution
When the method of direct read does not enable to determine all the screws lengths, especially the smallest sizes (the length 30mm for the screw dia. 5.5 mm and 40 mm for the screw dia. 7.5mm), the method 2 - indirect read should be used.

Note
The measurement taken from the ruler/k-wire is directly related to the positioning of the k-wire and cannot therefore be considered ideal unless the K-wire is correctly positioned. The positioning of the K-wire can be validated by means of peri-operative X-ray or fluoroscopy.

119 156 / 119 176
Hexagonal screwdriver tip

119 157
Straight handle quick couplings

119 177
T-handle quick coupling

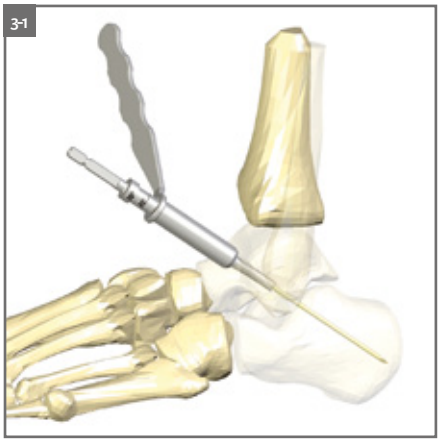
Use of the Drills

Once the 1.6 / 2.5 mm diameter K-wire is in place, the drills are used to prepare the insertion of the screw.
Although the Large QWIX® screws are self-drilling and self-tapping, preparing the insertion of the screw thanks to the drill is recommended, specially in case of sclerotic bone.

3-1

Preparation of the Screw Head (Fixation Screws)

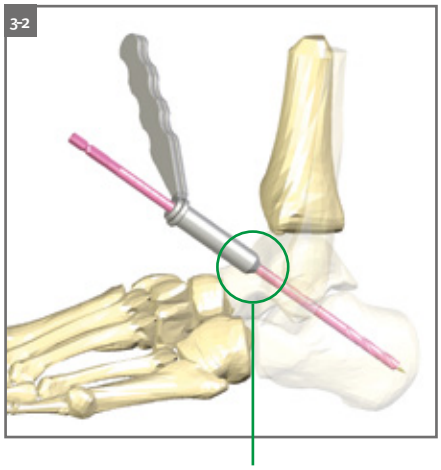
The short cannulated drill (119 155 / 119 175) is used to prepare the location of the screw head. The external protecting sleeve (119 153 / 119 173) must be used during this stage.
The short drill will be inserted in the sleeve before drilling. This allows to limit the depth of reaming thanks to marks on the drill.
When the drill is used perpendicular to the bone, the mark 90° must be flushed to the top side of the sleeve.
When the drill has a 45° angulation, the mark 45° will be aligned with the top side of the sleeve. It is only when there is a 30° degree orientation that the drill will be fully engaged in the protection sleeve.
This allows for reaming only to a sufficient depth.



3-2

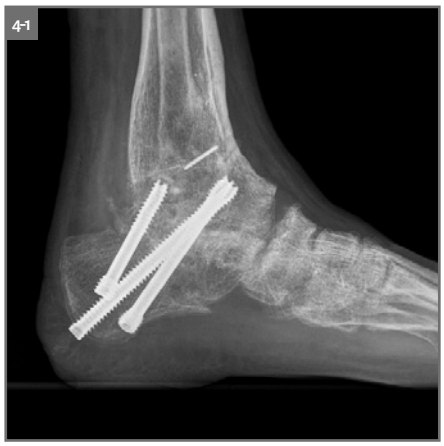
Preparation of the Distal Cortex (Fixation and Positioning Screws)

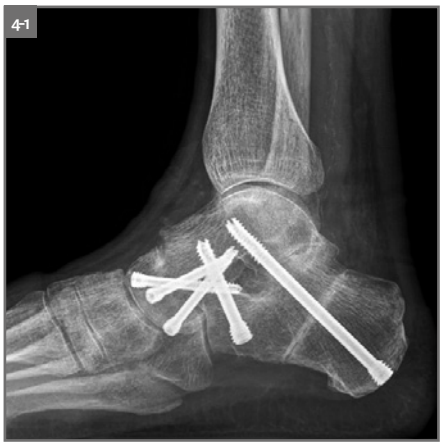
Use the long cannulated drill (119 154 / 119 174) over the k-wire left in place and through the drilling guide (119 152 / 119 172), itself placed into the external protection sleeve used during previous step (119 153 / 119 173). This drill allows to prepare the distal cortex; its use is only recommended in case of bicortical fixation. It is graduated so that the drilled depth can be read directly. The visible number nearest to the point of entry of the drill into the bone is the length of the buried part of the drill.

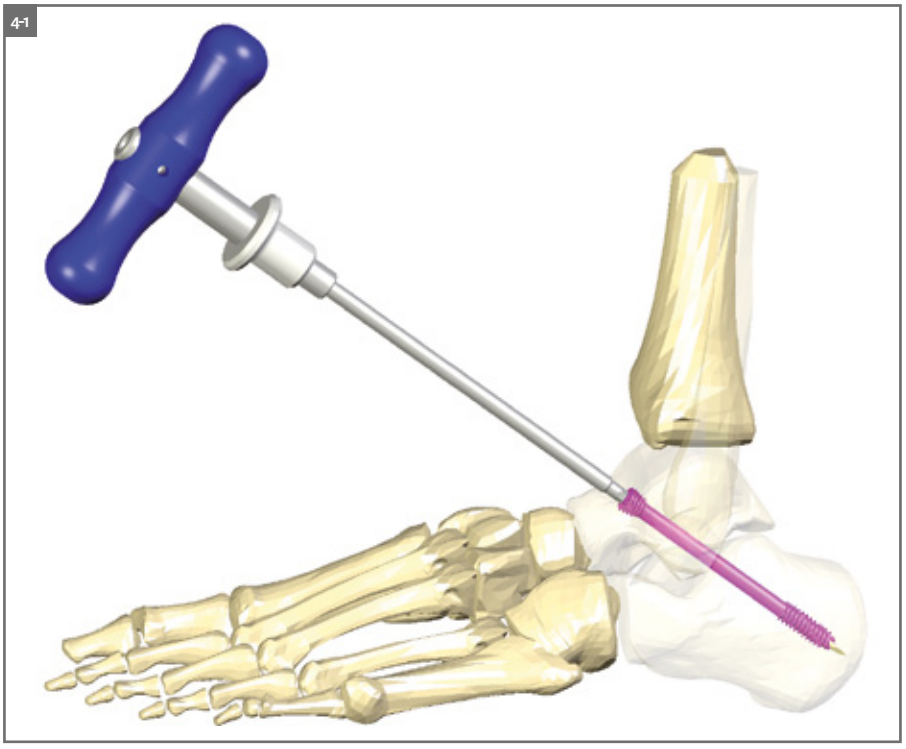


Screw Insertion

4-1 With the K-wire still in place, the Large QWIX® screw is selected and introduced by means of a cannulated screwdriver tip (119 156 / 119 176) powered, attached on the T-handle quick coupling (119 177) or straight handle quick coupling (119 157). The extremity of the head of the screw should be flush to the bone cortex.







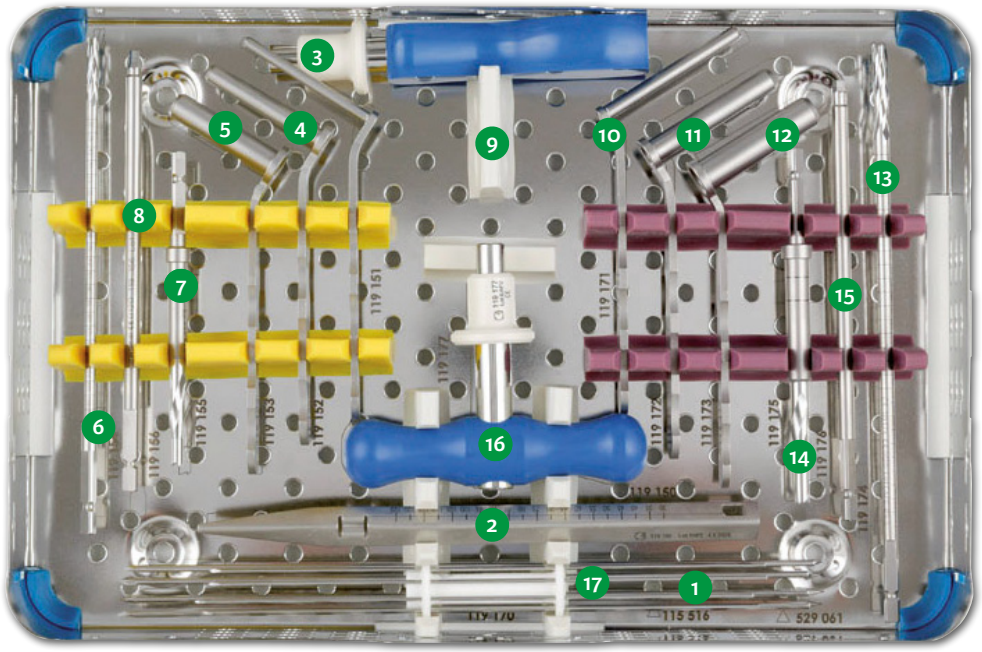
References

Ø 7.5 mm Large QWIX® sterile fixation screw	
Reference	Length
111 740 S	40 mm
111 745 S	45 mm
111 750 S	50 mm
111 755 S	55 mm
111 760 S	60 mm
111 765 S	65 mm
111 770 S	70 mm
111 775 S	75 mm
111 780 S	80 mm
111 785 S	85 mm
111 790 S	90 mm
111 795 S	95 mm
111 800 S	100 mm
111 805 S	105 mm
111 810 S	110 mm
111 815 S	115 mm
111 820 S	120 mm

Ø 7.5 mm Large QWIX® sterile positioning screw	
Reference	Length
121 740 S	40 mm
121 745 S	45 mm
121 750 S	50 mm
121 755 S	55 mm
121 760 S	60 mm
121 765 S	65 mm
121 770 S	70 mm
121 775 S	75 mm
121 780 S	80 mm
121 785 S	85 mm
121 790 S	90 mm
121 795 S	95 mm
121 800 S	100 mm
121 805 S	105 mm
121 810 S	110 mm
121 815 S	115 mm
121 820 S	120 mm

Ø 5.5 mm Large QWIX® sterile fixation screw	
Reference	Length
111 530 S	30 mm
111 535 S	35 mm
111 540 S	40 mm
111 545 S	45 mm
111 550 S	50 mm
111 555 S	55 mm
111 560 S	60 mm
111 565 S	65 mm
111 570 S	70 mm
111 575 S	75 mm
111 580 S	80 mm

Ø 5.5 mm Large QWIX® sterile positioning screw	
Reference	Length
121 530 S	30 mm
121 535 S	35 mm
121 540 S	40 mm
121 545 S	45 mm
121 550 S	50 mm
121 555 S	55 mm
121 560 S	60 mm
121 565 S	65 mm
121 570 S	70 mm
121 575 S	75 mm
121 580 S	80 mm



Instruments		
#	Reference	Description
1	115 516	K-wire dia. 1.6 mm / L. 200 mm
2	119 150	Measurer 200 and 250 mm
3	119 151	Internal protection sleeve for 5.5 mm screws
4	119 152	Drilling guide for 5.5 mm screws
5	119 153	External protection sleeve for 5.5 mm screws
6	119 154	Cannulated drill dia. 4.2/1.8 x L. 180 mm
7	119 155	Short cannulated drill for 5.5 mm screws
8	119 156	Hexagonal screwdriver tip 3 mm
9	119 157	Straight handle quick coupling
10	119 171	Internal protection sleeve for 7.5 mm screws
11	119 172	Drilling guide for 7.5 mm screws
12	119 173	External protection sleeve for 7.5 mm screws
13	119 174	Cannulated drill dia. 5.5/2.7 x L. 210 mm
14	119 175	Short cannulated drill for 7.5 screws
15	119 176	Hexagonal screwdriver Tip 4 mm
16	119 177	T-Handle quick coupling
17	529 061	K-wire dia. 2.5 x L. 250 mm
	121 950	Instrumentation set, including:
	121 951	Basis
	996 200	Lid
	119 170	Cylinder

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

Indications
(See table/appendix)

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 postoperative comp lications. 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, as these devices have not been evaluated for safety and compatibility and can potentially cause heating and/or migration in the MR environment. the Uni-CP™ device has not been evaluated for safety and compatibility in the MR enviroment. The Uni-CP™ device has not been tested for heating or migration in the MR environment.

Packaging - sterility
This product is sold either sterile or non sterile (Except the UNI-CP™ U shape plates S1, S2 and S3 sold sterile only) 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 cleaned, decontaminated (according to the parameters described in "Instruments" Instructions for use: 01931, §4) and sterilized prior to use, in compliance with current regulations.
If the product has been removed from packaging but not used, it may be re-cleaned, redecontaminated and 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 cleaned, decontaminated (according to the parameters described in "Instruments" Instructions for use: 01931, §4) and 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 cleaned, decontaminated (according to the parameters described in "Instruments" Instructions for use: 01931, §4) and sterilized by the steam autoclaving procedure regularly used in the hospital. The implants can be sterilized several times in the same conditions. The following methods have been validated by the manufacturer:
A • The following products are offered in plastic trays:
B-BOP® Plate, Calcanea® Plate System, Forefoot I, Hallu®-Fix Plate System, I.CO.S® Screws, Qwix® Screws.

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
Note	This sterilization method is recommended for use in some countries outside of the USA	This sterilization method is recommended for use in the USA. The fully loaded implant and instrument tray is recommended to be steam sterilized by the hospital using an FDA cleared wrap.

For the Forefoot I 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. The sterilization of the Newdeal® range Forefoot set was validated composed of 8 drills.
B • The following products are offered in metallic trays: Advansys® Plating System, Basal Dorsal Plating System, B-BOP® Plate, Hallu®-Fix Plating System, I.CO.S® Screws, Large Qwix®, Tibiaxys® Plating 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
Note	This sterilization method is recommended for use in some countries outside of the USA	This sterilization method is recommended for use in the USA. The fully loaded implant and instrument tray is recommended to be steam sterilized by the hospital using an FDA cleared wrap.

Forefoot new revised instrumentation / Uni-CP™ Compression Plate System (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
Vacuum drying	10 minutes	30 minutes
Note	This sterilization method is recommended for use in some countries outside of the USA	This sterilization method is recommended for use in the USA. The sterilization pre-vaccum cycle of the Uni-CP™ Compression Plate System set was validated without the UNI-CP™ U shaped plates (330021S, 330023S and 330025S provided sterile), the trial implant (339004) and Uni-Clip® staples. Do not include these three plates, the staples and the trial implant in the set during the pre-vaccum cycle of the sterilization. The fully loaded implant and instrument tray is recommended to be steam sterilized by the hospital using an FDA cleared wrap

The sterilization of the Newdeal® range Forefoot new instrumentation set was validated composed of 6 drills in the screw module and 2 drills in the staple module. 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.

Warning: Newdeal cannot guarantee sterility for products that have been cleaned or (re)sterilized by the purchaser or user.

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 noncompliant, as well as patients who could be predisposed to delayed or nonunion 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.
- Post Operative Treatment : It is important that post-operative immobilization with a slipper shoe (solid rigid sole) be worn by the patient during the initial 6 weeks postoperatively, or longer, if deemed required by the surgeon for some specific patients, pathologies, or associated surgical procedures. The immobilization with the slipper shoe (solid rigid shoe) should be worn until fusion is confirmed by x-rays. Failure to comply with postoperative recommendations could result in failure of the fusion and/or plate breakage.

Storage:
Store in dry place.

Product disclosure / Liability
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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: 06/23/2011.

Notes

Notes

Large Qwix®
Positioning and Fixation Screws

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CE 0120