EN

Integra®

HALLU®-Fix and HALLU®-Lock MTP Arthrodesis Systems

SURGICAL TECHNIQUE

INTEGRA®
LIMIT UNCERTAINTY

Products for sale in Europe, Middle-East and Africa only

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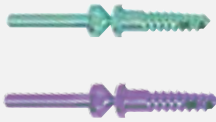
HALLU®-Fix

HALLU®-C plate
MTP arthrodesis plate
plate designed by Dr Coughlin, USA

HALLU®-S plate
Revision MTP arthrodesis plate
plate designed by Prof. Stephens, Ireland



Snap-Off® screw
dia. 2.7 mm and 3.0 mm

HALLU®-Lock

HALLU®-Lock C plate
MTP arthrodesis plate

HALLU®-Lock S plate
Revision MTP arthrodesis plate

Surfix® Standard Screw and Lock Screw
dia. 2.7 mm and 3.0 mm

Surfix® Alpha variable angle Screw and lock Screw
dia. 2.7 mm and 3.0 mm

HALLU®-Ream
Metatarsal reamer:
anatomical design

HALLU®-Ream
Phalangeal reamer:
anatomical design

Description

a

Plate design

D.R.Ax: Dual Rotational Axis

The anatomy of the first MTP joint requires that the bending axes of a dorsal arthrodesis plate in the transversal and sagittal planes are different to respect the dorsal alignment of the bone.

Bending axis in the sagittal plane (varus-valgus) runs through the metatarsal head centre, when the bending axis in the transverse plane (dorsi-flexion) is located over the joint surface, and is thus distal compared to the metatarsal head.

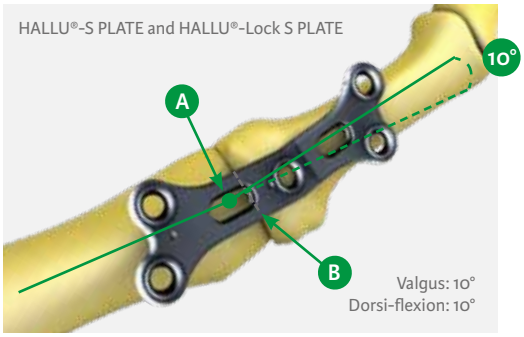
When respecting this D.R.Ax. (Dual Rotational Axis) concept, the HALLU® plates best respect the anatomical axes of the MTP joint.

An accurate positioning of the plate is possible thanks to a 1 mm k-wire hole located over the centre of the metatarsal head.

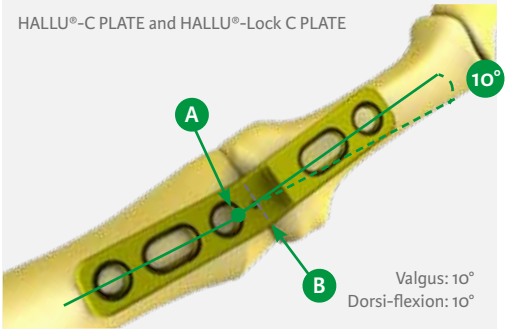
A Varus-valgus bending axis running through the centre of the metatarsal head.

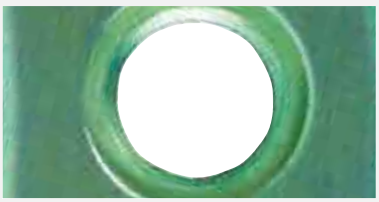
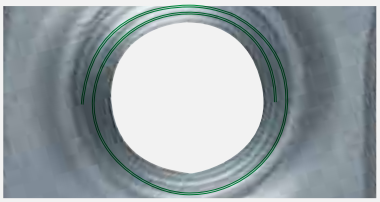
B Dorsi-flexion bending axis, located over the joint surface.

HALLU®-S PLATE and HALLU®-Lock S PLATE



HALLU®-C PLATE and HALLU®-Lock C PLATE



HALLU®-Fix		HALLU®-Lock
	C - plate Dorsal flexion bending adjustment possibility to match specific patient anatomy if required. Benders are included into the instrumentation set.	
	S - plate Anatomical design plate providing optimal bone coverage. Centered hole for graft fixation (Keller revision).	
		
	Distal and proximal off-settled convergent fixation screws to allow fixation to a short proximal phalanx.	

b System features

b1. Plate description HALLU®-Fix

Snap-Off® screw fixation

Thickness of the plate: 1.27 mm

b1. Plate description HALLU®-Lock

Surfix® system fixation

Thickness of the plate:
Between the holes: 1.30 mm .
On holes: 2.0 mm

Caution
In oblong holes: Do not use Surfix® Alpha variable angle screws. Do not insert lock screw on Surfix® standard screws.

Pre-bent plates

10° valgus
10° dorsi-flexion
with 2 different axes of rotation.

Holes design
to match screw head profile,
and enable screw / bone / plate interface.

Centering hole (1mm k-wire)
for precise positioning of the plate.

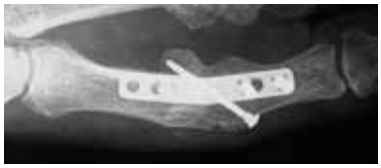
Color code
for size identification.

Contoured low profile titanium plate
for optimal anatomic adaptation.

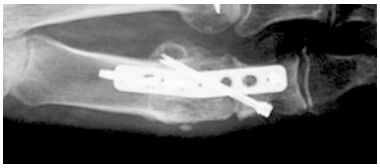
Oblong holes
for versatile
and compressive screw fixation.

Laser marking
for product identification.

Material
Titanium alloy ISO 5832-3, ASTM F136.



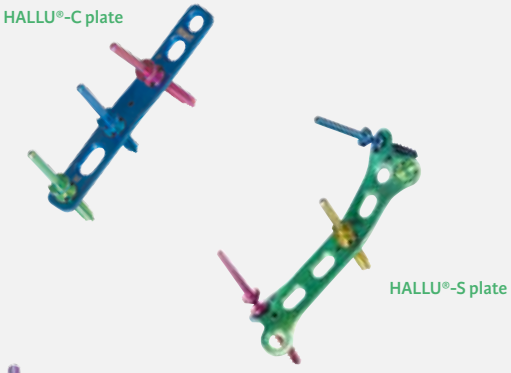
HALLU® C plate



HALLU®-Lock C plate

b2. Screw description
HALLU®-Fix

Snap-Off® screw fixation



Snap-off® screws:

When the screw is totally inserted in the bone, the distal part of the screw breaks.

b2. Screw description
HALLU®-Lock

Surfix® system fixation

Surfix® standard or Surfix® Alpha variable angle locking screws:

Strong monobloc fixation screw/plate/bone.

Color code for length identification.
Laser marking for product identification.
2 diameters: 2.7 mm & 3.0 mm.
Cortical threads.
Material: Titanium alloy ISO 5832-3, ASTM F136.

3 inclusions in the screw head for optimal screwdriver grip.

Self-tapping.

Smooth tip to protect soft tissues.

Low profile head design.

Snap-Off® barrel (diam. 2 mm) for an easy introduction, using powered fixation or cannulated driver.

2 kind of screws:

- Surfix® standard locking screw (angle with plate 90°)
- Surfix® Alpha locking screw (angle with plate 90° ±15°)

Screws must be positioned with a lock-screw excepted in the oblong holes.

Caution
Do not use Surfix® Alpha variable angle screws in oblong holes of the plate.

Fixation of the screw to the plate for better stability and elasticity.

Symetric profile head design.

One star shape screwdriver for the 2 screw designs and diameters (standard and variable angle, 2.7 and 3.0 mm) for an easy surgery.

Snap-Off® screw range:

- Snap-Off® screws
  dia. 2.7 mm
  length 10 to 34 mm
- Snap-Off® screws
  dia. 3.0 mm
  length 10 to 18 mm for osteoporotic bones

Screws are colour coded for easy identification.

Screw color code for 2.7 and 3.0 mm diameters

L 10 mm	L 12 mm	L 14 mm
L 16 mm	L 18 mm	L 20 mm
L 22 mm	L 24 mm	L 26 mm
L 28 mm	L 30 mm	L 32 mm
L 34 mm		


Dia 2.7 mm


Dia 3.0 mm

Screwdriver

Locking of the plantar joint

Snap-Off® screw (dia. 2.7 mm) length 28 to 34 mm for interfragmentary compression and plantar fixation.

Surfix® locking screw range:

- Surfix® standard screws
  dia. 2.7 mm or dia. 3.0 mm
  length 10 to 34 mm
- Surfix® Alpha variable angle screws
  dia. 2.7 mm and 3.0 mm,
  length 10 to 34 mm

Screws are color-coded for easy identification.

Star shape screwdriver (219 227 - 219 127) can be used for both screws and lock-screws.

Screw color code

Surfix® Dia 2.7 mm	Surfix® Alpha Dia 2.7 mm	Surfix® Dia 3.0 mm	Surfix® Alpha Dia 3.0 mm

Surfix® standard screws


Dia 2.7 mm


Dia 3.0 mm

Surfix® Alpha Screws (Variable angle)


Dia 2.7 mm


Dia 3.0 mm

Screwdriver

Locking of the plantar joint

Qwix® screw (dia. 3.0 mm) length 28 to 34 mm for interfragmentary compression and plantar fixation.

Instruments for Qwix® screw insertion are included into the HALLU®-Lock set.

Technical Note
Placement of a screw crossing the joint is strongly recommended for optimal arthrodesis consolidation. The screw can be placed either before or after the plate, as per surgical practice.

Indications

For use in fixation of fractures, osteotomies or arthrodesis of the first metatarso-phalangeal joint, including cases of:

- Hallux rigidus
- Severe hallux valgus
  (IM angle > 20° and HV angle > 40°)
- Deformity from rheumatoid arthritis
- Failed previous surgical procedure
- Traumatic arthritis
- Neuromuscular instability

Addition of a screw crossing the joint is strongly recommended for optimal arthrodesis consolidation.

HALLU®-S plates can be used in specific conditions such as revision of:

- Keller osteotomy
- Failed arthroplasty
- Failed fusion.

Contraindications

The implant should not be used in a patient who has currently, or who has a history of:

- Local, systemic acute or chronic inflammation
- Active infection or inflammation
- Suspected or documented metal allergy or intolerance

This technique has been developed with the help of Michael Stephens, FRCSI (HALLU®-S plate) and Michael Coughlin, MD, (HALLU®-C plate).

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

The foot is prepped and draped following normal sterile technique.

The surgery is done under tourniquet to avoid bleeding.

1 Incision

A dorsal longitudinal incision is commonly used. This enables correct exposure of the metatarso phalangeal joint.

The incision is centered just medial to the extensor HALLUcis longus, and deepened to the joint capsule, through the subcutaneous tissues.

The joint capsule is released and retractors are placed to expose the base of the proximal phalanx and metatarsal head.

2 Preparation of the joint surfaces with HALLU®-Ream system

The amount of the bone resection depends upon the desired right-size of the first metatarsal.

Note: some revision cases will not require extensive resection.

A power saw may be used to resect the base of the proximal phalanx and the articular surface of the first metatarsal head.

A cut, resecting a small wafer of bone, perpendicular to the axis of the proximal phalanx is made just distal to the articular surface. A similar cut is made in the metatarsal head perpendicular to the long axis of the metatarsal shaft.

These cuts are made in order to decompress the joint, allowing the use of the reamers. Osteophytes should be carefully removed. Medial exostosis of the first metatarsal bone may also be resected.

115 116
k-wire
dia 1.6 x L.150 mm

115 216
k-wire
dia 1.6 x L.150 mm

129 714-16-18-20-22
Metatarsal reamer

129 710
Quick coupling

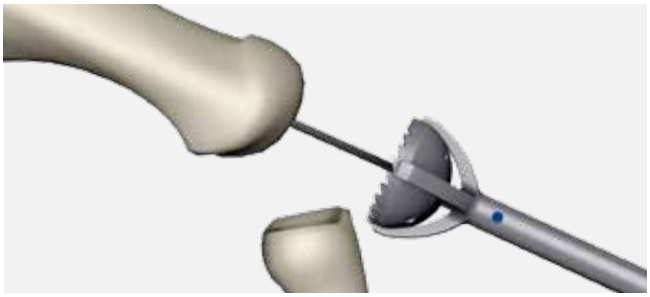
2-1 Metatarsal preparation

The phalanx is plantar flexed to gain access to the metatarsal head.

A 1.6 mm k-wire (115 116, 115 216) is then introduced into the centre of the metatarsal head (and driven in a proximal direction) along the axis of the diaphysis.

The appropriate size of cannulated metatarsal reamer is selected by placing a reamer in front of the articular surface of the metatarsal head.

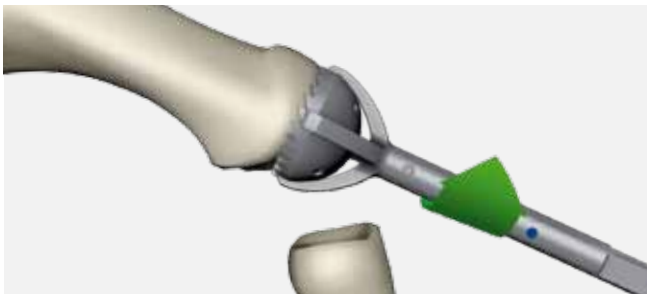
It is advisable to begin by using the largest size reamer, and then downsizing to match the diameter of the metatarsal head.



Diameter (mm)	14	16	18	20	22
Metatarsal reamer - Reference	129 714	129 716	129 718	129 720	129 722

The 2 in 1 metatarsal reamer is bell shaped to allow barrel reaming and articular preparation in one step.

Using the Quick coupling device (129 710) the HALLU®-ream reamer is then engaged over the 1.6 mm k-wire, and the metatarsal head is reamed.

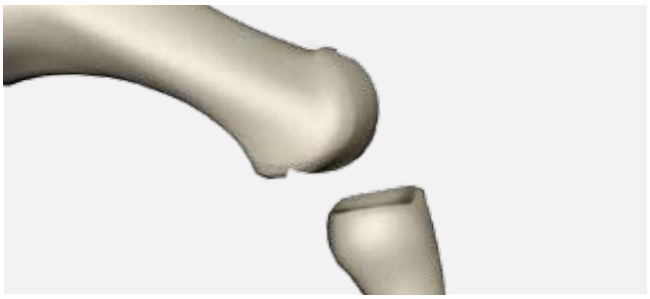


The metatarsal metaphysis is reduced to a cylinder of constant diameter, while the metatarsal head surface is reamed to a convex cup-shaped surface.

The metatarsal reamer is removed. The k-wire can be held to elevate the metatarsal head to enable the removal of the bone on the plantar aspect.

Excess bone is removed with an osteotome or a rongeur.

Debris and bone fragments are cleaned and irrigated.



2-2 Phalangeal preparation

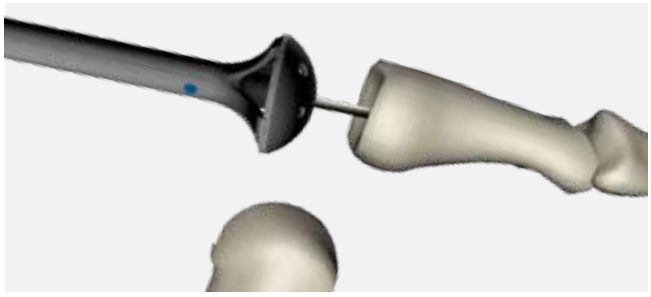
The proximal phalanx is plantar flexed.

A Hohmann retractor usually helps to expose the phalanx.

A 1.6 mm diameter k-wire (115 116, 115 216) is placed in the center of the prepared base of the proximal phalanx (and driven in a distal direction) along the axis of the HALLUx.

Care is taken not to penetrate the interphalangeal joint.

Reaming must begin by using the smallest size of phalangeal reamer, size 14 mm; in order to avoid any excessive reaming.



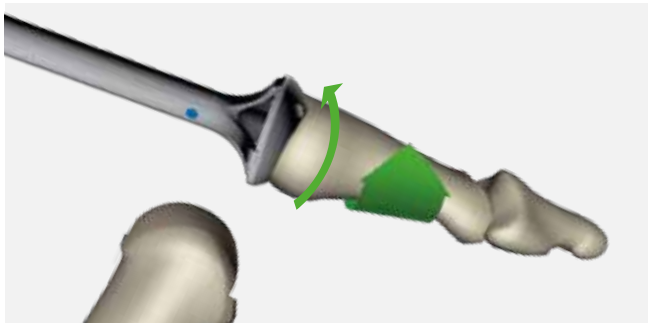
Diameter (mm)	14	16	18	20	22
Phalangeal reamer - Reference	129 724	129 726	129 728	129 730	129 752

The metatarsal head should be protected when reaming.

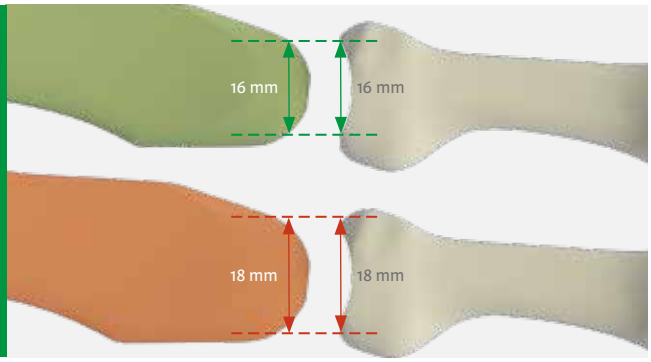
Using the quick-coupling device (129 710), the reamer is placed on the 1.6 mm k-wire, and the surface of the phalanx is reamed creating a concave cup-shaped surface.

If necessary, due to the diameter of the articular surface of the phalanx, superior sizes of the phalangeal reamers can be used until the dimensions match the size used for the metatarsal reamer.

When an additional bone graft is required, bone debris in the reamer can be used after the reaming process is complete.



Caution
The same size metatarsal and phalangeal reamers must be used to obtain congruent surfaces. (Example: if metatarsal reaming has been achieved with a 18 mm reamer, the largest and last reamer to be used for the phalanx should also be an 18 mm).

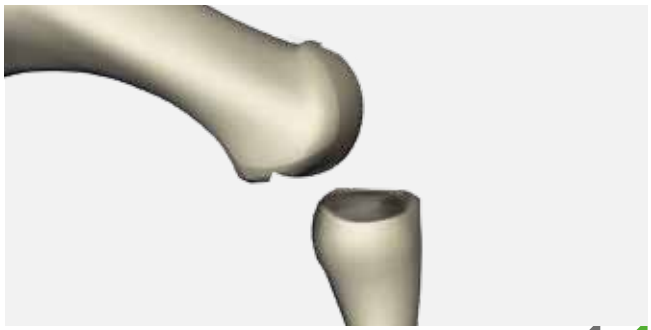


The reamer and k-wire are then removed.

The cup shaped surfaces can be aligned in any desired position. It is then possible to rotate the surfaces, change the dorsi flexion, plantar flexion and valgus angles.

A temporary k-wire can be introduced from the phalanx to the metatarsal to stabilize the joint in the adequate position for final arthrodesis.

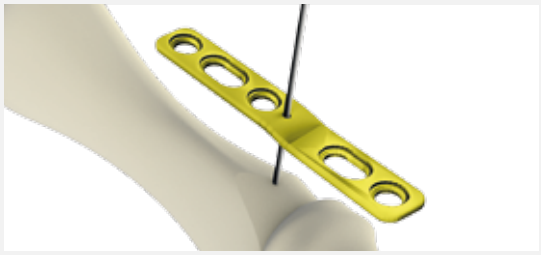
Bone graft can then be placed into the joint.



129 731 (left)
129 732 (right)
Plate benders

3 HALLU®-Fix sizing

The selection of the appropriate size of the HALLU®-C or HALLU®-S plate (4, 5, or 6 holes) is done by positioning a plate on the dorsal aspect of the bone surfaces and assessing its dimensions.



Technical Note

Placement of a screw crossing the joint is strongly recommended for optimal arthrodesis consolidation.
The screw can be placed either before or after the plate, as per surgical practice.
For details of screw insertion, please refer to chapter 5.

The small central hole should be positioned over the centre of the metatarsal head.

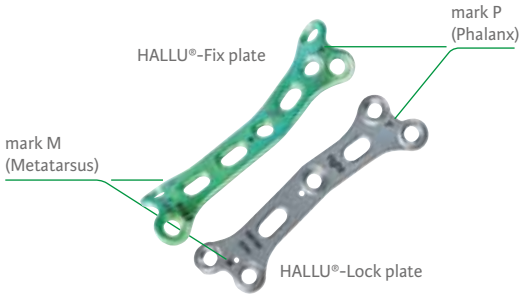
In case of Revision (HALLU®-S plate), the positioning hole is used as "landmark" to create the center of the joint.

4 Plate positioning

The plate has 2 marks on its dorsal aspect:

P stands for Phalanx and M for Metatarsal.

This orientation is mandatory.



HALLU®-fix plates color code (HALLU®-S and HALLU®-C plates)

Left & Right	S1	S2	S3

299 010
Trial plate holder

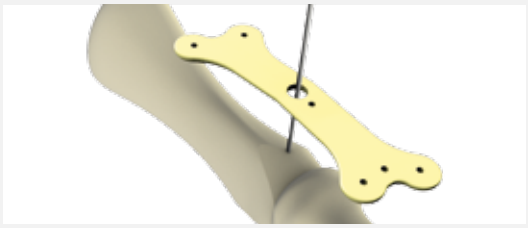
299 070 (left)
299 080 (right)
Plate benders

299 150-155-160 (right)
299 250-255-260 (left)
HALLU®-lock S trials

299 340-345-350 (right)
299 440-445-450 (left)
HALLU®-lock C trials

3 HALLU®-Lock sizing

The choice of the appropriate size of the HALLU®-Lock C (4, 5, or 6 holes) or HALLU®-Lock S (3 holes) plate is made by positioning a trial plate on the dorsal aspect of the bone surfaces and assessing the dimensions. The trial plate is held thanks to the special holder (299 010).



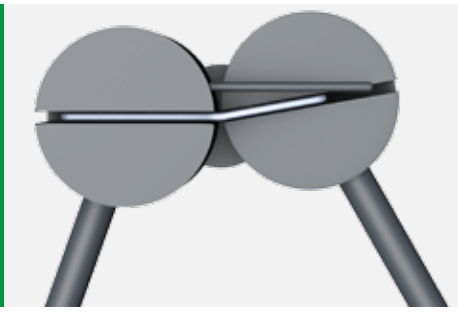
Technical Note
Placement of a Qwix® (3.0 mm diameter) screw across the joint is strongly recommended for optimal arthrodesis consolidation. The screw can be placed either before or after placement of the plate, as per surgical practice.
For details of screw insertion, please refer to chapter 7.

The HALLU® plates both have a 10° lateral angulation (10° valgus) as well as a 10° dorsal flexion.

The C plate can be bent by using 2 benders (129 731, 129 732 (HALLU®-C plates), 299 070, 299 080 (HALLU®-Lock C plates), right & left, to match the degree of dorsal flexion required by the case or by the activity of the patient. The C plate can be bent only once and not excessively.

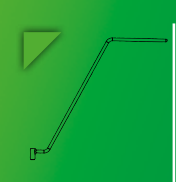
The S plate must not be bent.

Caution
Do not bend the S plate.
The C plate may be bent only once and should not be bent excessively.



HALLU®-Lock plates color code (HALLU®-Lock S and HALLU®-Lock C plates)

Left	S1	S2	S3
Right	S1	S2	S3



129 734
Drilling guide
dia. 1.9 mm

119 618
Drill 1.9 x L.100mm

129 736
Depth gauge

129 733
Cannulated
screwdriver

129 735
Screwdriver tip

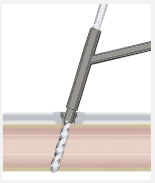
115 100
k-wire
dia.1.0XL.100mm

5 HALLU®-Fix plate fixation

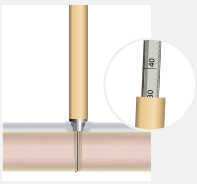
Insertion of a 1 mm k-wire

Once the correct size and type of plate has been chosen, and adequate alignment achieved, a 1 mm diameter k-wire is inserted through the central hole of the plate in the metatarsal head for temporary stabilization. The k-wire allows for rotation of the plate in order to obtain the ideal position.

Steps required for Snap-Off® screws



Preparation of the screw holes
The 1.9mm diameter drill (119 618), through the drilling guide (129 734), is used to prepare the holes in the dorsal cortex of the bone through the holes of the plate.

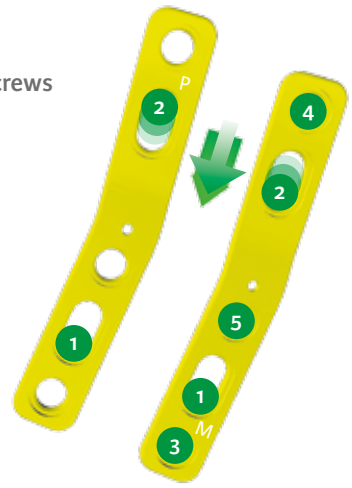


Measuring of the depth
The depth gauge (129 736) measures the adequate length of the screw.

Insertion of the screw
The selected Snap-Off® screw is engaged into the cannulated screwdriver (129 733) or into the screwdriver tip (129 735) connected to a power driver.
When the head of the screw comes in contact with the plate, the barrel of the screw automatically snaps off.

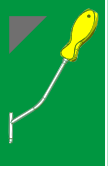
Plate fixation: recommendation of order of screws

- Push P against M



299 005 or
299 050 (AO)
Drill 2.0 x L.100mm
or Drill AO
2.0 x L.100mm

219 627
Surfix® drilling guide



219 027
Surfix® Alpha drilling guide dia. 2.0mm

299 020
Depth gauge

219 127
Star shape screwdriver T7

219 227
Star shape screwdriver tip T7

5 HALLU®-Lock plate fixation

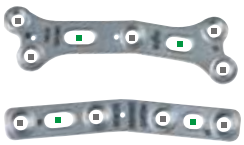
Insertion of a 1 mm k-wire

Once the correct size and type of plate has been chosen, and adequate alignment achieved, a 1 mm diameter k-wire is inserted through the central hole of the plate in the metatarsal head for temporary stabilization. The k-wire allows for rotation of the plate in order to obtain the ideal position.

Choice of the screws

The choice of using Surfix® or Surfix® Alpha variable angle locking screws (dia. 2.7 mm or 3.0 mm) depends on the need for angulation and orientation of the screws.

The larger diameter screw (3.0 mm) should be chosen to achieve optimal stability when bone quality is poor. The oblong holes allow for compressive screw fixation. Surfix® standard screws only should be placed in the oblong holes without the lock screw.
The central k-wire should be removed when solid fixation of the plate is achieved.



▪ : Circular holes
Surfix® standard or
Surfix® Alpha screws
+ lock screws

▪ : Compression oblong holes
Surfix® standard screw
- Without lock screw

Caution
Screw and lock-screw insertion in each threaded hole of HALLU®-Lock plates is mandatory to have good stability, specifically in the four extremity holes of the HALLU®-Lock S plate.
In oblong holes: Do not use Surfix® Alpha variable angle screws.
Do not insert the lock-screw on Surfix® standard screws.

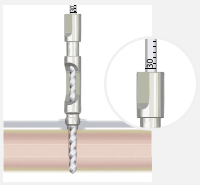
Steps required for Surfix® standard screws insertion

Note: There is a color code for the differentiation of Surfix® screw insertion (blue) and Surfix® Alpha screws insertion (green). Please note that all black bold references are common to Surfix® and Surfix® Alpha screws.

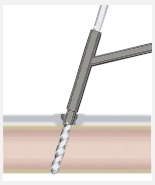
Caution
Steps 1 to 6 should be performed for a screw before starting the whole procedure for the following screw. If this is not the case, co-axiality between the screw and the prepared hole may not be maintained.

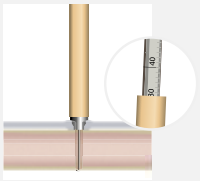
Configuration for Surfix® standard screws

Configuration for Surfix® alpha variable angle screws

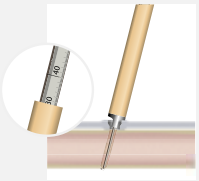


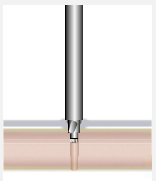
Preparation of the screw holes
Prepare the holes with the 2.0mm drill (299 005 or 299 050) through the Surfix® drilling guide (219 627) screwed in the plate or with the Surfix® Alpha drilling guide (219 027) orientated the correct way and inserted into the hole of the plate. The screw length can be read from the calibrated scale on the drill, on the top of the drilling guide.



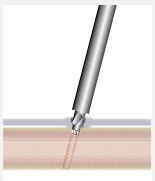


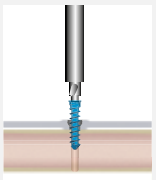
Measuring of the depth
Alternatively, measure for the necessary screw length using the depth gauge (299 020), after having removed the drilling guide.



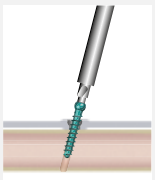


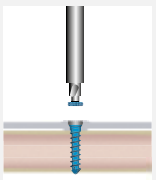
Chamfering of the hole
Chamfer the drill hole with the screwdriver (219 127). Ensure that the threaded hole of the plate is not damaged when performing the chamfering.



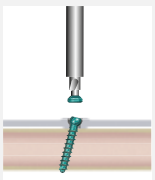


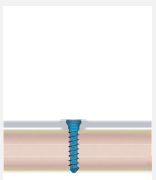
Insertion of the screw
Insert the screw with the screwdriver (219 127 - 219 227) into the prepared hole until screw head comes in contact with the plate. The screw should be fully seated in the plate. Clean the threaded hole before and after introducing the screw. Maintain co-axiality between the screw and the threaded hole.



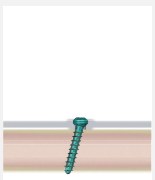


Positioning of the lock-screw
Assemble the lock-screw to the screwdriver (219 127). Lock-screw should be inserted after each screw, and before preparation and insertion of the subsequent screw. This prevents potential damage to threaded holes. Note that the spherical shaped lock screw of the Surfix®-Alpha screw has to be inserted perpendicularly to the plate in order to be screwed properly.





Locking of the system
Fully seat the lock-screw in the plate hole. The lock-screw should be flushed with the top of the plate when it is fully inserted. The lock-screw on the head of the screw should block the hole of the plate remaining parallel to the plate (the screw is maintained in an oblique position).



129 733
Cannulated
screwdriver

129 735
Screwdriver tip

6 **HALLU®-Fix compression device (oblong holes)**

Snap-Off® screws are inserted as described in the previous steps.
The screw is tightened down with the screwdriver from the HALLU®-Fix system.

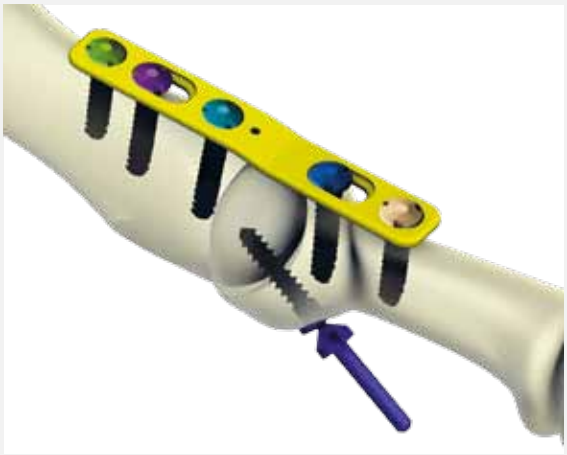
The oblong holes allow for angled and compressive screw fixation.

The central k-wire should be removed when solid fixation of the plate is achieved.

Caution
The insertion of a fixation screw in each of the 4 “extremities-holes” (the 2 most proximal and the 2 most distal) of a HALLU®-S plate is mandatory for appropriate stability.

7 **HALLU®-Fix consolidation :**
Snap-Off® dia. 2.7 mm screw insertion

Technical Note
Placement of a screw crossing the joint is strongly recommended for optimal arthrodesis consolidation.
The screw can be placed either before or after the plate, as per surgical practice.



Closure is then performed in the normal and routine fashion.

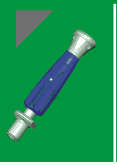
8 **Post-Operative treatment**

It is important that post-operative immobilization with a slipper shoe (solid rigid sole) be worn by the patient during the initial 6 weeks or longer, if required by the surgeon for some specific patients, pathologies, or associated surgical procedures.

The slipper 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.

115 070
k-wire dia. 1.0 x L 70 mm



119 133
Handle AO

119 135
AO screwdriver tip

159 027S
Drill AO 2in1 dia. 2.2 x L 90mm

6 HALLU®-Lock compression device (oblong holes)

Surfix® standard screws are inserted as described in the previous steps, without any locking with the lock-screws.

The oblong holes provide compressive fixation with the screws.

The central k-wire should be removed when solid fixation of the plate is achieved.

Caution
Do not use Surfix® Alpha variable angle screws in oblong holes of the plate.

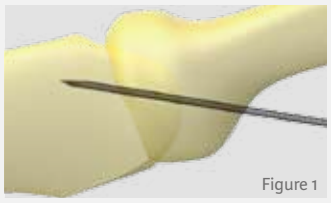


Figure 1

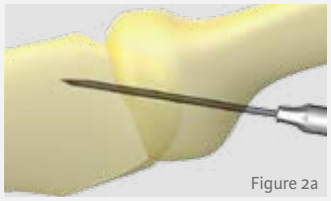


Figure 2a

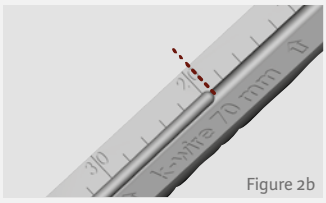


Figure 2b

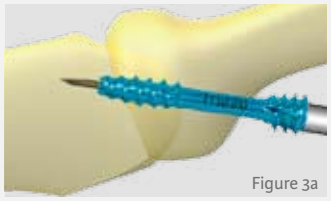


Figure 3a

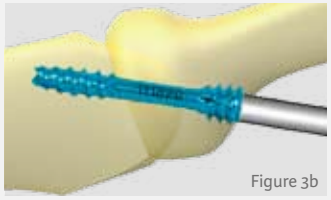


Figure 3b

7 HALLU®-Lock consolidation : Qwix® dia. 3.0 mm screw insertion

Technical Note
Placement of a Qwix® (3.0 mm diameter) screw across the joint is strongly recommended for optimal arthrodesis consolidation. The screw can be placed either before or after placement of the plate, as per surgical practice.

The instruments needed for the Qwix® stabilization screw are included into the HALLU®-Lock instrumentation set.

Step 1

A k-wire (115 070) is inserted in the correct place for the Qwix® screw. The position should be checked under fluoroscopy.
This k-wire will guide the screw *(Figure 1)*.

Step 2

Measure the screw length. The length read on the cannulated screwdriver is equal to the length of k-wire inserted in the bone plus 1.5 mm. Insert the appropriate cannulated screwdriver (119 135) on the k-wire *(Figure 2a)*. Read the indicated screw length directly from the scale *(Figure 2b)* and subtract 1.5 mm to determine appropriate screw length.

Step 3

Optional. Although the Qwix® screw is self-drilling and self-tapping in most bone, it may be necessary to drill the cortex in some cases. Prepare the cortex by power or manually with the drill (159 027S).

Step 4

The Qwix® screw can be inserted totally under power (119 135) then completed by hand (assembling the dia. 3.0 mm screwdriver tip (119 135) to the AO handle (119 133) *(Figure 3a)*. The head of the screw must be completely embedded in the cortex to obtain optimal compression *(Figure 3b)*. Complete insertion is also recommended to prevent soft tissue irritation.

Instructions of use

Hallu® Plates & Screws

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.

1. 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.

2. Indications:
(See table/appendix)

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.

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.

4. 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 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.

5. 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, re-decontaminated 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).

6. 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.

7. 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.

8. 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	**Pre-vaccum**	**Pre-vaccum, 3 pulses**
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.

9. 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.
- 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.

10. Storage:
Store in dry place.

11. Product disclosure / Liability
Newdeal, an Integra LifeSciences Company, has exercised reasonable care in the selection of materials and the manufacture of these products and warrants 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: 06/23/2011.

ND 01831-11-11

Instruments

INSTRUCTIONS FOR USE INSTRUMENTS

handled and/or implanted by WELL-TRAINED and QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

These instruments are intended for use in surgery, and should be used only for the introduction of associated Newdeal® and Surfix® products ranges.

None of the instruments should be implanted.

Only medical professionals who are thoroughly familiar with the instruments function, application, and use should use them in surgery.

Only a surgeon qualified to perform the orthopedic surgery required by the particular patient should use the surgical instruments.

Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose, or even dangerous to the patient or surgical staff.

These devices do not contain phtalates unless this is indicated on the label.

Products are sold either sterile or non-sterile.

1. Single use instruments :

The single use orthopaedic instruments manufactured by Newdeal® must not be re-used. Re-use would incur the risk of modifying the properties and performance of the instrument. The company accepts no responsibility for such re-use.

2. Packaging (product sold STERILE only) :

Instruments manufactured by Newdeal® and sold sterile have been sterilized by gamma radiation or using ethylene oxide (ETO).

The sterilization method is specified on the packaging. Components sterilized by radiation are exposed to a minimum of 25 kGy of gamma irradiation. The products considered to be non-sterile can be (re)sterilized unpacked before use, in compliance with current regulations.

Check packaging and labeling integrity before use. The sterility is guaranteed as long as the packaging has not been damaged (film scratched, label missing, questionable packing…) and before the end of the sterility validity.

Do not use any product for which the packaging has been opened or damaged outside the operating theatre.

Inner packaging should be handled under sterile conditions (persons/instruments).

Recommendations for (re)sterilization:

Re-sterilization is only allowed for non-used products. Remove delivery packaging in compliance with current regulations to (re)sterilize non-sterile products. Newdeal® recommends to sterilize its products by the steam autoclaving procedure regularly used in the hospital. (cf. Handling and Reprocessing).

3. Re-use of the instruments :

Unless labelled for single use the instruments could be re-used.

However active surgical instruments have a limited lifespan.

4. Handling and reprocessing (NON-STERILE product or considered to be) :

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 95°C during 10 minutes can be performed.

Drying: Drying temperature should not exceed 95°C.

Packaging: No specific requirements.

Sterilization:

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, Hallu®-Ream Instrument, I.CO.S® Screws, Kalix® implant, 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, Astus® Arthrodesis Fixation, Basal Dorsal Plating System, B-BOP® Plate, B-BOP®-Lock Plate, Hallu®-Fix Plating System,I.CO.S® Screws, Ipp-On® Implant, Large Qwix®, Metis® Metatarso Phalangeal Prosthesis, Midfoot Plating System, Tibiaxys® Plating System and Surfix® products range, Large Uni-Clip®, DPR system Minimal Invasive foot surgery.

Newdeal® and Surfix® 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	**Pre-Vacuum**	**Pre-Vacuum 3 pulses**
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 implantand 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.

Panta* (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**	**40 minutes minimum, followed by a 20 minutes "cracked*" phase**
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.**

***Please note that the "cracked" phase of drying refers to a period of 20 minutes in which the sterilizer door is opened approximately 6 inches (15 cm) while the tray remains inside.**

Hintegra® (Stainless Steel sterilization trays)		
Cycle	**Gravity Displacement 5 pulses [Maximum 900 mbar; Minimum 200 mbar]**	**Pre-Vacuum 3 pulses**
Température mini	**134°C (273° F)**	**132°C (270° F)**
Durée d'exposition	**18 minutes**	**5 minutes**
Séchage	**20 minutes**	**20 minutes**
Note	**This sterilization method is recommended for use in some countries outside of the USA**	**The container must firstly be divided into two sets; each set must be individually packaged. 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.**

Hallu®Lock (Stainless Steel sterilization trays)		
Cycle Type	**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**	**60 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.

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.

5. Examination :

Instruments must always be examined by the user prior to use in surgery.

Examination should be thorough, and in particular should take into account the presence of any cracks, bending, or distortion, and that all components of the instrument are complete.

Never use instruments with obvious signs of excessive wear, damage, incomplete or otherwise unfunctional.

6. Safety (active surgical instruments) :

Safety glasses are recommended when using any active surgical instrument.

The cannulated active surgical instruments should not be used without the appropriate corresponding Newdeal® K-wire inside the cannulated part.

The K-wire must be renewed for each procedure.

The active surgical instruments should not exceed the recommended speed of the instrument manufacturer's specifications (1500 revs/minute). In particular, the DPR System Minimal Invasive foot surgery burrs manufactured by Newdeal® should not exceed the recommanded speed of 8000 revs/minute.

The surgeon using the active surgical instrument is responsible for the proper operation of the instrument as well as any accessories or equipment, including power equipment that may be necessary for the use of the active surgical instrument. Avoid using excessive force, twisting, or bending of the active surgical instrument in any unnatural or unintended way.

The active surgical instrument must be properly inserted and securely locked into the proper instrument before the instrument is turned on and/or operated. All accessories must be properly inserted, sealed, and locked before turning on and/or engaging the active surgical instrument.

The active surgical instrument may become hot from friction and the surgeon should take appropriate care to ensure that the patient is not harmed.

Minimize the tissue contact to avoid possibility of burns.

The active surgical instrument must not be used for any purpose other than its intended use in the orthopedic surgical procedure.

The active surgical instrument must not be modified.

Resharpening of active surgical instrument should not be performed under any circumstances.

Contact with other metal objects could cause damage to the active surgical instrument and may necessitate replacement.

Newdeal® informs the surgeon that repeated uses of the active surgical instrument can lead to incidents which would compromise the surgical technique or the results of the procedure.

7. Measuring instruments :

Some surgeries require the use of instruments which incorporate a measuring function.

Ensure that these are not worn, that any surface engravings are clearly visible.

Except if another specific indication is indicated on the instrument itself, the measures provided by these instruments with a measuring function, have the following characteristics:

Measure of a length: Unit: millimeter (mm) - Accuracy: length read +/- 1mm.

Measure of an angle: Unit: angle (°) - Accuracy: angle read +/- 1°.

8. Responsibility of the Surgeon :

Newdeal® does not practice medicine and does not recommend any specific surgical technique.

It is the surgeon's responsibility to select the appropriate surgical technique and instruments for each individual patient, in accordance with the surgeon's practice, experience, training, standard of care and knowledge of the relevant medical literature. Newdeal® is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

Criteria for patient selection are the responsibility of the surgeon. 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 device being implanted in the surgical procedure. The surgeon should refer to the instructions for use accompanying the device.

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.

9. Product information disclosure / Liability

Newdeal®, an Integra LifeSciences Company, has exercised reasonable care in the selection of materials and the manufacture of these products and warrants 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.

Information : Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

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.

Newdeal, Surfix, B-BOP, Calcanea, Hallu, I.CO.S, KALIX, Qwix, Solustaple, Advansys, Astus, Ipp-On, Metis, Tibiaxys, Uni-CP, Panta, Hintegra, Integra and the logo Integra are trademarks or registered trademarks of Integra Lifesciences or its subsidiaries. Radel is a registered trademark of its owner

Date of last revision: 01/25/2012.

ND 01931-16-12

Screws and lock screws

INSTRUCTIONS FOR USE
Surfix® and Surfix®- Alpha - Screws and lock screws • SINGLE USE

AWARE OF THESE DIRECTIONS FOR USE.

1. Description
- Surfix® _ fixed angle locking system
- Surfix®- Alpha _Variable angle locking system

Those screws exist in different diameters and lengths.

They are made of either 316L stainless steel that complies with the NF ISO 5832-1 or ASTM F138 & F139 standards or of titanium alloy Ti-6Al-4V that complies with the NF ISO 5832-3 or ASTM F136 standard.

These devices do not contain phtalates unless this is indicated on the label.

2. Indications

For fixing plates which are fitted with Surfix® threaded plugs of adequate diameter(s), and which are manufactured by Newdeal or Integra LifeSciences Corporation and pertaining to the Newdeal®, Surfix® or Integra Orthopaedics Upper Extremity products range.

Refer to the Plates Instructions for Use and Surgical Technique for appropriate screw and lock-screw size.

Warning: The choice between Surfix® or Surfix®- Alpha screws depends on whether or not there is a need for a variable angle locking system. A screw may need to have a variable angle lock for example to fix several bone fragments which are not aligned with the plate's hole. If it is not necessary for the screw to have a variable angle lock, it is recommended to use the Surfix® fixed angle locking system. If it is necessary to use a Surfix®- Alpha variable angle locking screw, please refer to the plate's surgical technique for restrictions on the use of these screws.

The Surfix®- Alpha variable angle locking system must be used with Newdeal®, Surfix® and Integra Orthopaedics Upper Extremity plates made of the same material.

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.

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.

4. 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 intraoperative 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 refracture.

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.

5. 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 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, re-decontaminated 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).

6. 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®, Surfix® or Integra Orthopaedics Upper Extremity 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.

Warning: Selecting the best Surfix®, Newdeal® or Integra Orthopaedics Upper Extremity plate-screw combination is the surgeon's responsibility.

7. SURFIX® or SURFIX®-Alpha fixation system

The Surfix® fixed angle or Surfix®-Alpha variable angle locking system involves creating a single unit of screw and implant in the bone with theosteosynthesis screw being introduced into the bone via the plate holes and then fixed by lockscrews inserted into the threaded lipped socket of each hole to lock the head of each screw. The system looses some of its mechanical qualities if not properly locked and much more if it is not locked at all. The plate will then have the same mechanical features as those of a standard screwed plate. The synthesis of the plate onto the bone with the Surfix® fixed angle or Surfix®-Alpha variable angle locking system is not only secured by a tight union between the plate and the bone - as is the case with an ordinary screwed plate – but also because of the good adjustment of the screws into the bone. The screws must be adjusted into the bone as accurately as possible. The screws must be driven if possible through both cortical areas in the case of a synthesis in the metaphyso-diaphysiary area.

Warning: When fixing a Newdeal®, Surfix® or Integra Orthopaedics Upper Extremity plate the same number of screws and lock screws as there are threaded holes on the plate must be used.

8. Precautions to observe when fixing

The Surfix® fixed angle or Surfix®-Alpha variable angle locking system with lock screws requires that there is no movement between the screw and the implant to be effective. It is essential:
- To drive the screw co-axially through the threaded lipped socket, by using Surfix®, Newdeal® or Integra Orthopaedics Upper Extremity drill guides which can be fitted into any plates. The drill guide and the drill must have the same diameter.
- That the screw remains co-axial until it has been locked by the lock screw. Consequently, it is necessary to:
- Make sure that the screw can be easily driven into the bone until its collar has reached the bottom of its hole. It may be necessary to widen the top of the hole in the bone. Be careful not to damage the threaded lipped socket, if this is the case.
- Stop screwing as soon as the screw head has reached the bottom of its hole. Further screwing could draw the plate against the bone by exerting a pull-in effect if the implant is not in contact with the bone. This could change the axis of both the screw and the socket.
- Implement each fixation in succession, from the guided drilling to the tightening of the lock screw. The tightening of the screw by the lock screw should always be carried out immediately after the positioning of the screw and before implementing any other operation that could alter the position of the plate against the bone and, consequently, against the screw.
- Remove any foreign bodies that may be found between the implant, the screw and the lock screw.
- Tighten the lock screw.

9. 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.

10. 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 leaned, 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. Osteosynthesis implants manufactured by Newdeal are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital.

The implants can be cleaned, decontaminated (according to the parameters described in "Instruments" Instructions for use: 01931, §4) and sterilized several times in the same conditions.

The following two methods have been validated by the manufacturer:

- Surfix® and Newdeal® Stainless Steel sterilization trays:

Advansys® Plating System, B-BOP®-Lock Plate, Midfoot Plating System, Tibiaxys® Plating System and Surfix® products range

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.

- Uni-CP™ Compression Plate System (Stainless Steel sterilization trays)

Cycle	Pre-Vacuum 3 pulses	Pre-Vacuum 3 pulses
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(TM) Compression Plate System set was validated without the UNI-CP(TM) U shaped plates (330021S, 330023S and 330025S provided sterile), the trial implant (339004) and Uni-Clip(r) staples. Do not include these three plates, the staples and 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.

- Hallu®Lock (Stainless Steel sterilization trays)

Cycle Type	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	60 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.

- Integra Orthopaedics Upper Extremity sterilization trays : refer to the Integra Orthopaedics Upper Extremity plate Instructions for Use

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.

11. 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 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.

12. Storage

Store in dry place.

13. Product information 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.
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.

Newdeal, Surfix, Advansys, B-BOP, HALLU, Tibiaxys, Uni-CP, Integra and the logo Integra are trademarks or registered trademarks of Integra Lifesciences or its subsidiaries.

Date of last revision: 01/02/2012

ND 04131-06-12

HALLU® Lock

INSTRUCTIONS FOR USE
HALLU® Lock • 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.

1. Description :
- Osteosynthesis plates, existing in different models and sizes.
- They are made out of Titanium alloy within the frame of the standard NF ISO 5832-3 and ASTM F136.

These devices do not contain phtalates unless this is indicated on the label.

2. Indications :
For use in fixation of fractures, osteotomies or arthrodesis of the first metatarso-phalangeal joint, including cases of :
- Hallux rigidus
- Severe hallux valgus (IM angle >20° and HV angle > 40°)
- Deformity from rheumatoid arthritis
- Failed previous surgical procedure
- Traumatic arthritis
- Neuromuscular instability.

HALLU® Lock Newdeal® plates must be fixed with the Surfix® fixed angle locking system and with the Surfix® -Alpha variable angle locking system of 2.7mm or 3.0mm diameter (screws and lock-screws).

Addition of a Newdeal® QWIX® screw crossing the joint is strongly recommended for optimal arthrodesis consolidation.

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.

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.

4. 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 intraoperative 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 refracture.

Interference risks during medical imaging:

MRI/SCANNER: ask the patient to systematically mention that he/she was implanted with a metallic device.

5. 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).

6. 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® or Surfix® 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.

Warning: Selecting the best Surfix® or Newdeal® plate -screw combination is the surgeon's responsibility.

7. SURFIX® fixation system :
The Surfix® system involves creating a single unit of screw and implant in the bone with theosteosynthesis screw being introduced into the bone via the plate holes and then fixed by lockscrews inserted into the threaded lipped socket of each hole to lock the head of each screw. The system looses some of its mechanical qualities if not properly locked and much more if it is not locked at all. The plate will then have the same mechanical features as those of a standard screwed plate. The synthesis of the plate onto the bone with the Surfix® system is not only secured by a tight union between the plate and the bone - as is the case with an ordinary screwed plate – but also because of the good adjustment of the screws into the bone. The screws must be adjusted into the bone as accurately as possible. The screws must be driven if possible through both cortical areas in the case of a synthesis in the metaphyso-diaphysiary area.

Warning: When fixing a Newdeal® or Surfix® plate the same number of screws and lock screws as there are threaded holes on the plate must be used. Do not use Surfix® Alpha variable angle screws in the oblong holes of the plate.

8. Precautions to observe when fixing :
The Surfix® system locking with lock screws requires that there is no movement between the screwand the implant to be effective. It is essential that:
- Drive the screw co-axially through the threaded lipped socket, by using Surfix® or Newdeal® drill guides, which can be fitted into any plates. The drill guide and the drill must have the same diameter.
- The screw must remain co-axial until it has been locked by the lock screw. Consequently, it is necessary to:
- Make sure that the screw can be easily driven into the bone until its collar has reached the bottom of its hole. It may be necessary to widen the top of the hole in the bone. Be careful not to damage the threaded lipped socket, if this is the case.
- Stop screwing as soon as the screw head has reached the bottom of its hole. Further screwing could draw the plate against the bone by exerting a pull-in effect if the implant is not in contact with the bone. This could change the axis of both the screw and the socket.
- Implement each fixation in succession, from the guided drilling to the tightening of the lock screw. The tightening of the screw by the lock screw should always be carried out immediately after the positioning of the screw and before implementing any other operation that could alter the position of the plate against the bone and, consequently, against the screw.
- Remove any foreign bodies that may be found between the implant, the screw and the lock screw.
- Tighten the lock screw.

9. 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.

10. 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® Stainless Steel sterilization trays

Cycle Type	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	60 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

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.

11. Information related to postoperative care :
- 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.
- 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 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.

12. Storage :
Store in dry place.

13. Product information 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.

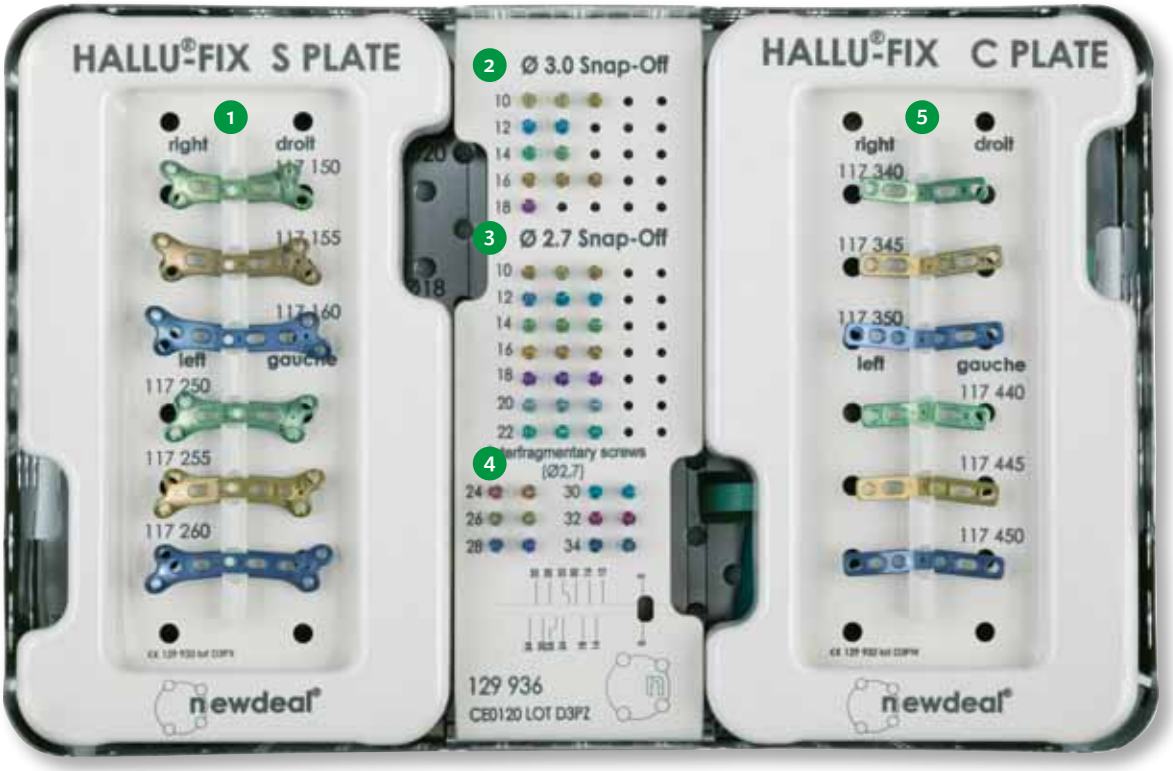
WARNING
This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

INFORMATION
Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.
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.

Date of last revision: 01/21/2010

ND 04231-05-10

HALLU®- Fix Instrumentation set



HALLU®-Fix Implants References

HALLU®-C plate

#	Reference	Designation
5	117 340 (S)	Right - Size 1 : L.40 mm - 4 holes
5	117 345 (S)	Right - Size 2 : L.45 mm - 5 holes
5	117 350 (S)	Right - Size 3 : L.50 mm - 6 holes
5	117 440 (S)	Left - Size 1 : L.40 mm - 4 holes
5	117 445 (S)	Left - Size 2 : L.45 mm - 5 holes
5	117 450 (S)	Left - Size 3 : L.50 mm - 6 holes

HALLU®-S plate
(numbers of holes exclude the 4 extremity holes)

#	Reference	Designation
1	117 150 (S)	Right - Size 1 : L.45 mm - 3 holes
1	117 155 (S)	Right - Size 2 : L.50 mm - 4 holes
1	117 160 (S)	Right - Size 3 : L.55 mm - 5 holes
1	117 250 (S)	Left - Size 1 : L.45 mm - 3 holes
1	117 255 (S)	Left - Size 2 : L.50 mm - 4 holes
1	117 260 (S)	Left - Size 3 : L.55 mm - 5 holes

(S) means available in sterile and non sterile

Snap-Off® screw, ø 2.7 mm

#	Reference	Length
3	117 010 (S)	L. 10 mm
3	117 012 (S)	L. 12 mm
3	117 014 (S)	L. 14 mm
3	117 016 (S)	L. 16 mm
3	117 018 (S)	L. 18 mm
3	117 020 (S)	L. 20 mm
3	117 022 (S)	L. 22 mm
4	117 024 (S)	L. 24 mm
4	117 026 (S)	L. 26 mm
4	117 028 (S)	L. 28 mm
4	117 030 (S)	L. 30 mm
4	117 032 (S)	L. 32 mm
4	117 034 (S)	L. 34 mm

Snap-Off® screw, ø 3.0 mm

#	Reference	Length
2	117 110 (S)	L. 10 mm
2	117 112 (S)	L. 12 mm
2	117 114 (S)	L. 14 mm
2	117 116 (S)	L. 16 mm
2	117 118 (S)	L. 18 mm

HALLU®-Fix Instruments References

HALLU®-Ream Metatarsal Reamer

#	Reference	Diameter
6	129 714	14 mm
6	129 716	16 mm
6	129 718	18 mm
6	129 720	20 mm
6	129 722	22 mm

HALLU®-Ream Phalangeal Reamer

#	Reference	Diameter
6	129 724	14 mm
6	129 726	16 mm
6	129 728	18 mm
6	129 730	20 mm
6	129 752	22 mm

Instrumentation

#	Reference	Designation
7	129 710	Quick coupling
8	129 735	Screwdriver tip
10	129 731	HALLU®-C plate bender Left
13	129 732	HALLU®-C plate bender Right
14	129 736	Depth gauge
15	129 733	Cannulated screwdriver
16	129 734	Drilling guide 1.9 mm

Kirschner wires

#	Reference	Designation
11	115 100	k-wire dia. 1.0 x L. 100 mm
12	115 216	k-wire dia. 1.6 x L. 150 mm
12	115 070	k-wire dia. 1.0 x L.70 mm

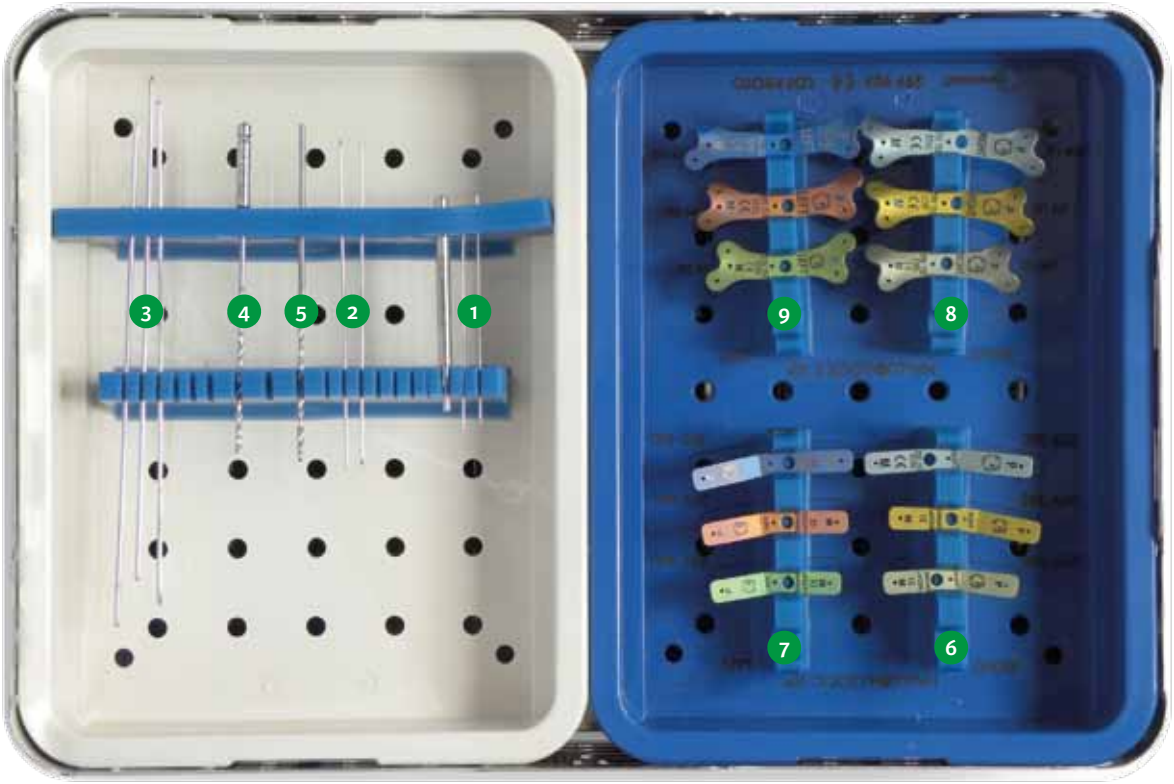
Container

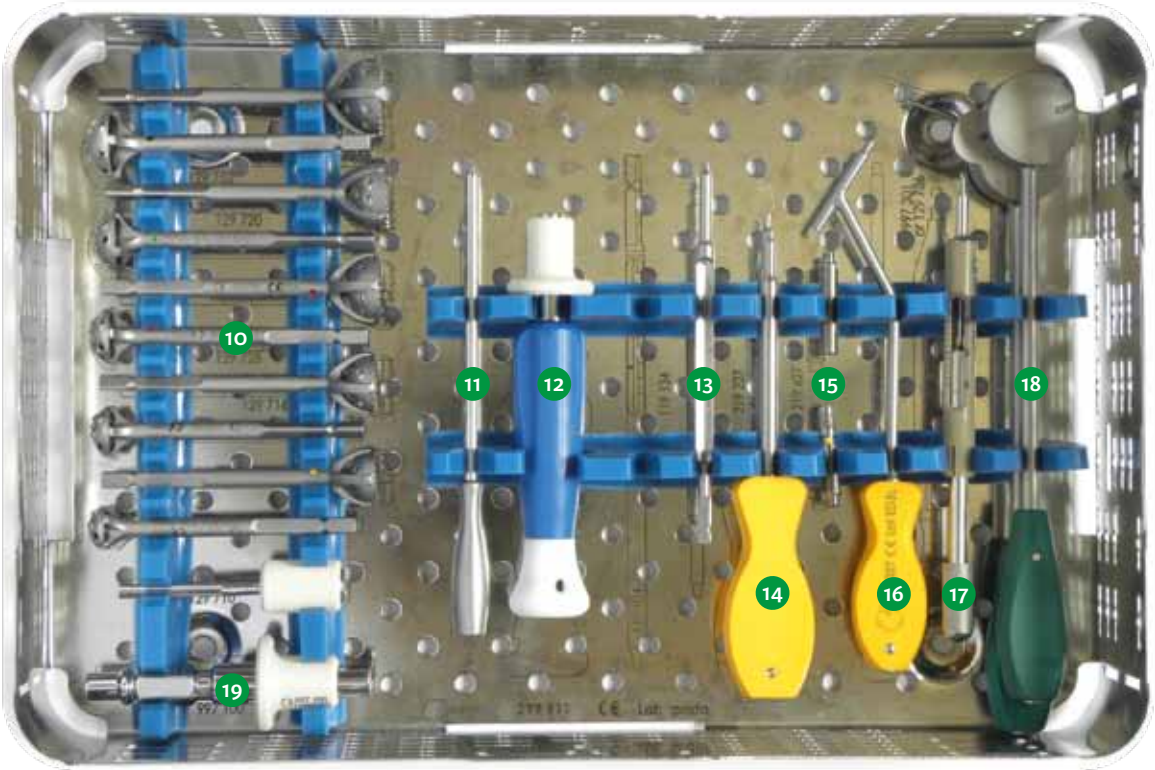
Reference	Designation
129 930	Sterilisation container
Including	
129 931	basis
129 932	HALLU®-C plate rack
129 933	HALLU®-S plate rack
129 936	HALLU®-Fix screw rack
996 200	Lid

Drill

#	Reference	Description
9	119 618	Drill dia. 1.9 mm

HALLU®- Lock Instrumentation set





HALLU®-Lock Instruments References

HALLU®-Ream Metatarsal Reamer

#	Reference	Diameter
10	129 714	14 mm
10	129 716	16 mm
10	129 718	18 mm
10	129 720	20 mm
10	129 722	22 mm

HALLU®-Ream Phalangeal Reamer

#	Reference	Diameter
10	129 724	14 mm
10	129 726	16 mm
10	129 728	18 mm
10	129 730	20 mm
10	129 752	22 mm

Kirschner wires

#	Reference	Designation
1	115 070	k-wire dia. 1.0 x L.70 mm
2	115 100	k-wire dia. 1.0 x L.100 mm
3	115 116	k-wire dia. 1.6 x L.150 mm

Drills

#	Reference	Description
4	159 027S	AO 2 in 1 cannulated drill dia. 2.2/3.0 x L. 90mm
5	299 005	Drill dia. 2.0 x L.100 mm
5	299 050	AO Drill dia. 2.0 x L.100 mm

Trial implants

#	Reference	Description
6	299 440	Trial implant HALLU®-Lock C Left-S1
6	299 445	Trial implant HALLU®-Lock C Left-S2
6	299 450	Trial implant HALLU®-Lock C Left-S3
7	299 340	Trial implant HALLU®-Lock C Right-S1
7	299 345	Trial implant HALLU®-Lock C Right-S2
7	299 350	Trial implant HALLU®-Lock C Right-S3
8	299 250	Trial implant HALLU®-Lock S Left-S1
8	299 255	Trial implant HALLU®-Lock S Left-S2
8	299 260	Trial implant HALLU®-Lock S Left-S3
9	299 150	Trial implant HALLU®-Lock S Right-S1
9	299 155	Trial implant HALLU®-Lock S Right-S2
9	299 160	Trial implant HALLU®-Lock S Right-S3

Instruments

#	Reference	Description
11	299 010	Trial plate holder
12	119 133	Handle AO Qwix®
13	119 135	AO screwdriver tip Qwix® dia 3.0 mm
14	219 227	AO Star shape screwdriver T7
14	219 127	Star shape screwdriver T7
15	219 627	Surfix® drilling guide dia. 2.0 mm
16	219 027	Surfix® Alpha drilling guide dia. 2.0 mm
17	299 020	Depth gauge
18	299 070	HALLU®-Lock C plate bender left (proximal)
18	299 080	HALLU®-Lock C plate bender right (distal)
19	129 710	Quick-coupling
19	997 100	Quick-coupling AO

HALLU®-Lock Container

Reference	Designation
299 900	HALLU®-Lock Container
Including	
299 901	Basis
299 903	Trial implants tray
299 904	k-wire tray
996 200	Lid

HALLU®-Lock Implants References

All HALLU®-Lock implants references are provided in a sterile packaging

HALLU®-Lock C plate 10°

Reference	Designation
290 340S	Right-Size 1: L. 40 mm – 4 holes
290 345S	Right-Size 2 : L. 45 mm – 5 holes
290 350S	Right-Size 3 : L. 50 mm – 6 holes
290 440S	Left-Size 1: L. 40 mm – 4 holes
290 445S	Left-Size 2 : L. 45 mm – 5 holes
290 450S	Left-Size 3 : L. 50 mm – 6 holes

HALLU®-Lock S plate 10°

Number of holes excludes the 4 extremity ones

Reference	Designation
290 150S	Right-Size 1: L. 45 mm – 3 holes
290 155S	Right-Size 2 : L. 50 mm – 3 holes
290 160S	Right-Size 3 : L .55 mm – 3 holes
290 250S	Left-Size 1: L. 45 mm – 3 holes
290 255S	Left-Size 2 : L. 50 mm – 3 holes
290 260S	Left-Size 3 : L. 55 mm – 3 holes

Surfix® standard screw ø 2.7 mm + lock-screw

Reference	Lenght
285 210S	10 mm
285 212S	12 mm
285 214S	14 mm
285 216S	16 mm
285 218S	18 mm
285 220S	20 mm
285 222S	22 mm
285 224S	24 mm
285 226S	26 mm
185 200S	lock-screw

Surfix® Alpha variable angle screw ø 2.7 mm + lock-screw

Reference	Lenght
295 210S	10 mm
295 212S	12 mm
295 214S	14 mm
295 216S	16 mm
295 218S	18 mm
295 220S	20 mm
295 222S	22 mm
295 224S	24 mm
295 226S	26 mm
195 200S	lock-screw

Surfix® standard screw ø 3.0 mm + lock-screw

Reference	Lenght
285 110S	10 mm
285 112S	12 mm
285 114S	14 mm
285 116S	16 mm
285 118S	18 mm
285 120S	20 mm
285 122S	22 mm
285 124S	24 mm
285 126S	26 mm
185 100S	lock-screw

Surfix® Alpha variable angle screw ø 3.0 mm + lock-screw

Reference	Lenght
295 110S	10 mm
295 112S	12 mm
295 114S	14 mm
295 116S	16 mm
295 118S	18 mm
295 120S	20 mm
295 122S	22 mm
295 124S	24 mm
295 126S	26 mm
195 100S	lock-screw

Qwix® compressive screw ø 3 mm

Reference	Lenght
111 328S	28 mm
111 330S	30 mm
111 332S	32 mm
111 334S	34 mm

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