EFFICIENT MOBILITY

DynafitSystem®
Surgical Technique

DynafitSystem®

Superelastic staples
Varisation staples*

neosteo
EFFICIENT MOBILITY

*Not 510K cleared

DynafitSystem® - Staples

SURGICAL TECHNIQUE

INTRODUCTION

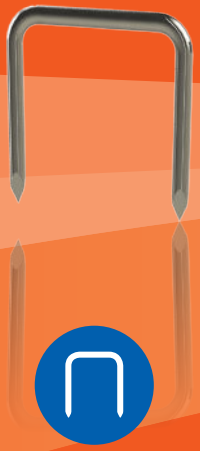
Neosteo offers a New Superelastic Staple System. This new staple completes the existing varisation staples range. Superelastic Staples are designed to provide suitable bone fixation and constant compression on small bone fragments.

Superelastic staples are available sterile packed in various sizes to cover fixation of small bone fragments, osteotomy fixation and joint arthrodesis of the hand and foot bones.

Varisation staples are used for fracture repair and osteotomy of the first phalange. Staples are available sterile or non sterile packed. Smart instrumentation set allows precise and easy handling.

Superelastic staples

Varisation staples*



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CONTENTS

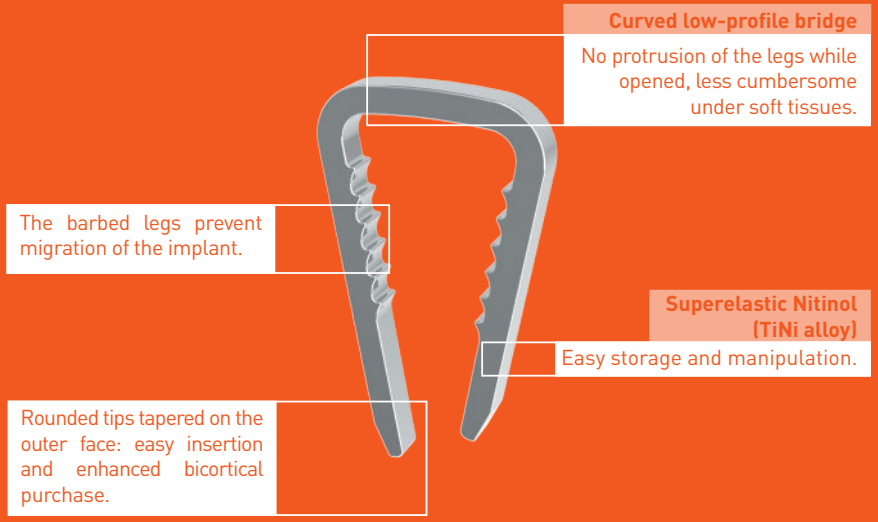
SUPERELASTIC STAPLES

- CONTINUOUS ACTIVE COMPRESSION
- SECURE FIXATION
- STERILE IMPLANT
- LARGE VARIETY OF IMPLANTS SIZES

PRESENTATION

Neosteo DynafitSystem® superelastic staples are intended for hand and foot bore fragments osteotomy fixation and joint arthrodesis.

Superelastic staples are made of superelastic TiNi alloy (Nitinol®), which enables stable osteotomies fixation, thanks to a natural and dynamic compression during bone healing.



DEVICE DESCRIPTION

Pre-angled legs provide compression once the staple is opened using the specific clamp.

Barbed legs provide secure fixation and resist migration and back-out during healing.

In order to provide optimized stable fixation, it is recommended to implant the device in a bi-cortical way. Superelastic staples are available in different bridge lengths : 8, 10, 12, 15, 18, 20 and 25mm, to match the anatomy the best way, depending on the indication.

After bone drilling to prepare the bone fragments for legs insertion, the staple is inserted using a specific clamp. Tapered tips facilitate insertion.

Extremities are rounded, in order to preserve soft tissues when staples are implanted in a bi-cortical way.

CAUTION

This description is insufficient for immediate use of the instrumentation. Instructions for instrumentation handling, delivered by an experimented surgeon, is highly recommended.

SUPERELASTIC STAPLES

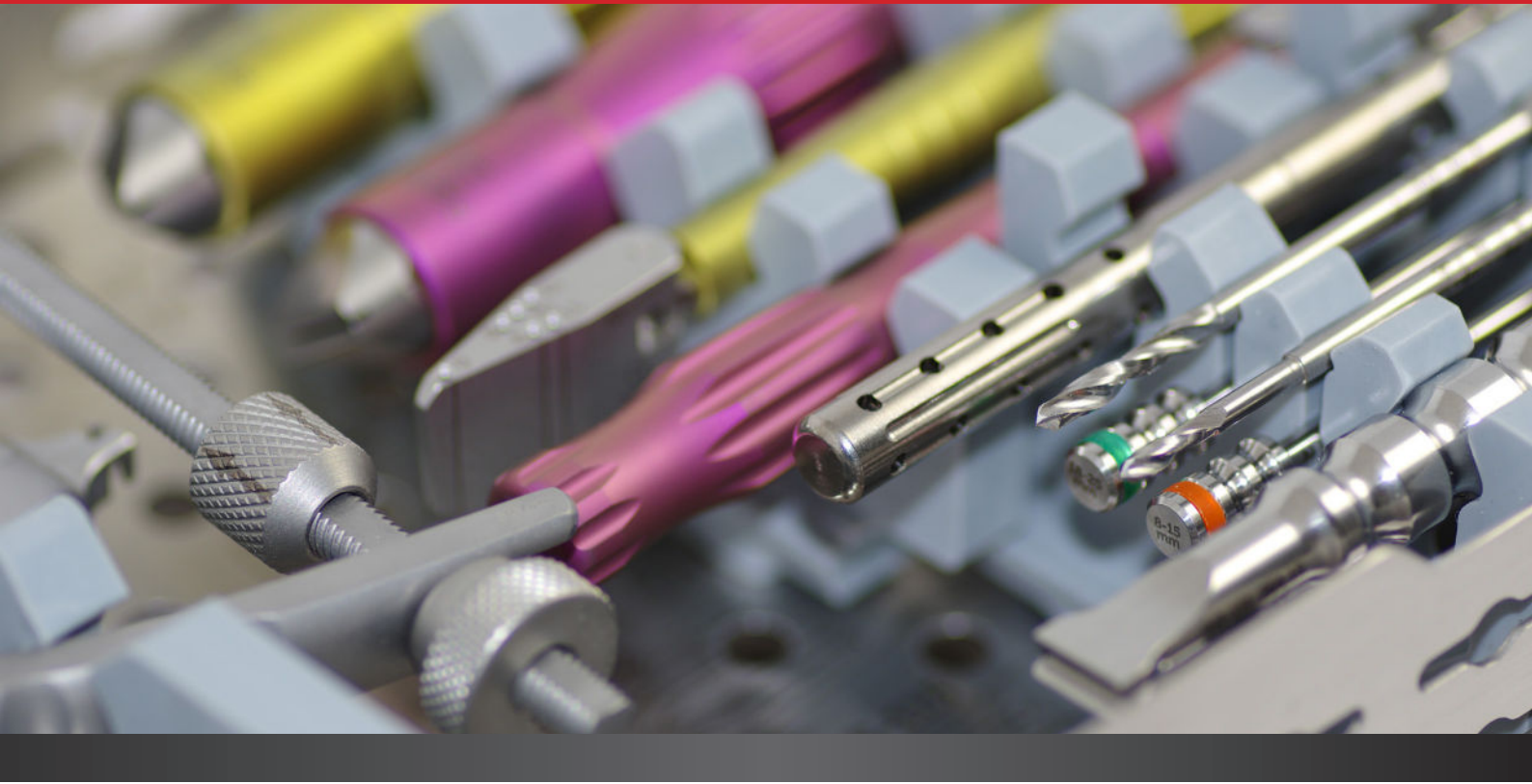
IMPORTANT
SUPERELASTIC NITINOL

The staple is naturally elastic at room temperature (around 20°C) and at body temperature (around 37°C). No particular storage, handling or activating procedure is required.

The staple is delivered sterile, is single-use, it shall be neither re-sterilized, nor re-used.

The staple can be stored at room temperature, in no case it shall be placed in freezer or heated using a particular device (electronic surgery knife, shape-memory staple heating device...)

The staples legs shall not be opened beyond their opening position.



SUPERELASTIC STAPLES

1 PRE-OPERATIVE ASSESSMENT

Whatever the procedure is, it is compulsory to plan the correction and the approach, using x-rays for instance.

Note :

The osteotomy depicted hereafter is intended to illustrate the surgical procedure for implanting Neosteo DynafitSystem® superelastic staples. It is a varisation - shortening for the first phalanx of the foot, during Hallux Valgus treatment.

2 OSTEOTOMY CUT AND STABILIZATION

The osteotomy is cut using a saw blade. The staple legs shall not pass by the cut line.

Hold the osteotomy reduction manually or with a temporary K-wire.

3 STAPLE PREPARATION FIRST HOLE DRILLING

Determine the appropriate bridge length of the staple, using the staple drill guide. In order to avoid fracture of the cortex, especially when it is weak, let a minimum of 4mm between the cut line and the staple leg axis.

Put the drill guide against bone surface, so that both of the drill guide tips are against the cortex.

Drill the first hole, using the appropriate drill bit (orange ring : 8-15mm superelastic staples drill bit / green ring : 18-25mm superelastic staples drill bit).

The depth can be read directly on the drill bit (for instance, on figure above : 17mm).

IMPORTANT

The drill bit shall be left in the drill guide and bone, in order to preserve the correct bridge length determination.

4 STAPLE PREPARATION SECOND HOLE DRILLING

Choose the staple size using the drill guide. In order to prevent bone fracture, especially on a weak cortex, let at least 4mm between the cutting line and the staple legs axis.

Put the drill guide against the bone surface, so that both tips are touching the cortex.

Drill the first hole, with the appropriate drill bit (orange ring : 8-15mm staples / green ring : 18-25mm staples).

Drill depth can be read directly on the graduated drill bit (e.g. on figure 2 : 17mm).

5 MEASURING USING THE DEPTH GAUGE

If the bone depth has not been determined during drilling, use the depth gauge to measure the staple legs length. Hook the far cortex using the superelastic Nitinol shaft of the gauge.

6 PREPARING THE SPREADER

Choose the appropriate spreader, corresponding to the determined bridge length (8-15mm or 18-25mm). Place the knurled stop on the appropriate dimension (figure above : the bridge length selected is 10mm).

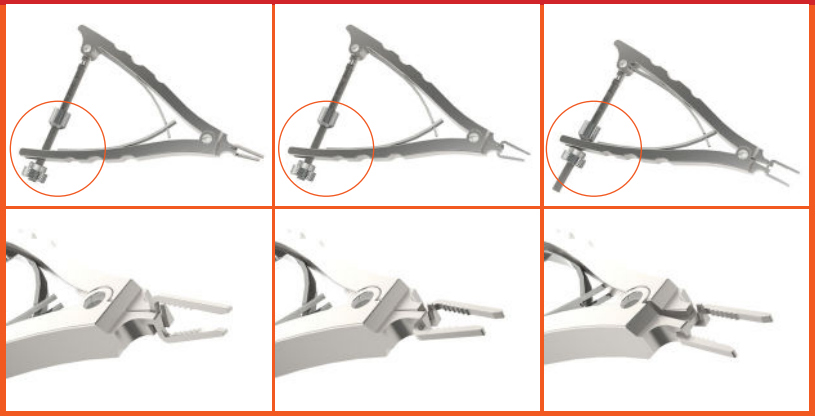
IMPORTANT

In order to preserve the interleg distance and parallelism, put the appropriate positioning pin (orange ring : 8-15mm staples / green ring : 18-25mm staples) instead of the drill bit.

Reminder : *Bi-cortical purchase is recommended*

SUPERELASTIC STAPLES

7 STAPLE OPENING



Manually place the staple bridge between both bits, turn the implant so that it is axially maintained. Open the spreader until the knurled stop, eventually adjust the stop to find the perfect parallel legs position. (see figure above). When this position is determined, it is recommended to lock the spreader with the threaded knurled knob, at the extremity of the threaded shaft.

8 INSERTING THE STAPLE

Insert the staple in the drilled holes, and progressively release pressure on the spreader (unlock the knurled knob, if necessary). Make a 90° turn to liberate the staple bridge from the bits, and remove the the spreader from the implant (see the previous STAPLE OPENING figure).

9 FINALIZING IMPACTION

The spreader bits size is necessary to finalize the impaction using the superelastic staples tamper, for an optimal congruency to the bone. Place the tamper on the staple bridge and hit it using a mallet.

10 FINAL CONTROL

Final x-rays control.

Preserve the lateral cortex allows to secure the correction and limits pseudarthrosis risks.

Tissue suture should be done under classical surgical procedure.

Postoperative protocol should be assessed under surgeons responsibility. The classical AO protocol for forefoot osteotomies is 3 weeks of partial weight bearing, with orthopaedic footwear, then full weight bearing of the patient.

IMPORTANT

Impact the implant carefully when a bone hinge is left.

SUPERELASTIC STAPLES

IMPLANT CATALOG

STERILE

Designation	Reference
Superelastic staple 8 x 8 x 8mm	A5080808
Superelastic staple 10x10x10mm	A5101010
Superelastic staple 10x13x17mm	A5101315
Superelastic staple 10x15x17mm	A5101517
Superelastic staple 10x17x19mm	A5101719
Superelastic staple 12x10x10mm	A5121010
Superelastic staple 12x13x15mm	A5121315
Superelastic staple 12x15x17mm	A5121517
Superelastic staple 12x17x19mm	A5121719
Superelastic staple 15x12x12mm	A5151212
Superelastic staple 15x15x15mm	A5151515
Superelastic staple 18x12x12mm	A5181212
Superelastic staple 18x15x15mm	A5181515
Superelastic staple 18x15x17mm	A5181517
Superelastic staple 18x17x19mm	A5181719
Superelastic staple 20x16x16mm	A5201616
Superelastic staple 20x20x20mm	A5202020
Superelastic staple 25x22x22mm	A5252222

Designation	Reference
Superelastic staple 12x12x10mm 0 degrees	A6121000
Superelastic staple 12x12x12mm 0 degrees	A6121200
Superelastic staple 12x12x13mm 0 degrees	A6121300
Superelastic staple 12x12x15mm 0 degrees	A6121500
Superelastic staple 12x12x10mm 5 degrees	A6121005
Superelastic staple 12x12x12mm 5 degrees	A6121205
Superelastic staple 12x12x13mm 5 degrees	A6121305
Superelastic staple 12x12x15mm 5 degrees	A6121505
Superelastic staple 12x12x10mm 10 degrees	A6121010
Superelastic staple 12x12x12mm 10 degrees	A6121210
Superelastic staple 12x12x13mm 10 degrees	A6121310
Superelastic staple 12x12x15mm 10 degrees	A6121510
Superelastic staple 15x12x10mm 0 degrees	A6151000
Superelastic staple 15x12x12mm 0 degrees	A6151200
Superelastic staple 15x12x13mm 0 degrees	A6151300
Superelastic staple 15x12x15mm 0 degrees	A6151500
Superelastic staple 15x12x10mm 5 degrees	A6151005
Superelastic staple 15x12x12mm 5 degrees	A6151205
Superelastic staple 15x12x13mm 5 degrees	A6151305
Superelastic staple 15x12x15mm 5 degrees	A6151505
Superelastic staple 15x12x10mm 10 degrees	A6151010
Superelastic staple 15x12x12mm 10 degrees	A6151210
Superelastic staple 15x12x13mm 10 degrees	A6151310
Superelastic staple 15x12x15mm 10 degrees	A6151510

INDICATIONS

The Superelastic Staples are indicated for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

CONTRAINDICATIONS

- Acute or chronic local or systemic infections
- Absence of musculo-cutaneous coverage, severe vascular defects affecting the parts concerned
- Bone damage inconsistent with correct purchase of the staple in the bone
- Muscular or neurological deficiency or behavioral disorders which risk exposing the internal fixation to abnormal mechanical forces
- Allergy to nickel or titanium

INSTRUMENTATION

Intended use	Implant Size
Akin	**8 - 10 mm**
Bunion repair	**10 - 12 mm**
MP Arthrosis	**15 - 18 mm**
N/C (Navicular Cuneiform) Fusion	**15 - 18 mm**
Lisfranc arthrodesis	**15 - 18 mm**
Lapidus	**18 - 20 mm**
Closing Wedge	**15 - 18 - 20 mm**
Osteotomy - Base Wedge	**15 - 18 - 20 mm**
T/N (Talar/Navicular) Arthrodesis	**20 - 25 mm**
Calcaneal/Cuboid arthrodesis	**20 - 25 mm**
Tibio - Tarsal arthrodesis	**20 - 25 mm**

Designation	Reference	Qty
Kirschner wire dispenser tube	INS-115	1
Spreader for 8-15mm superelastic staples	INS-127	1
Spreader for 18-25mm superelastic staples	INS-130	1
Tamper for superelastic staples	INS-131	1
Drill guide for superelastic staples	INS-132	1
Drill bit for 8-15 mm superelastic staples	INS-134	1
Drill bit for 18-25 mm superelastic staples	INS-135	1
Instruments tray STAPLES	INS-136	1
Positioning pin for 8-15 mm superelastics staples	INS-169	1
Instruments tray cover	INS-170	1
Positioning pin for 18-25 mm superelastics staples	INS-174	1
Kirschner wire Ø1,0 mm, length 80 mm with Lancet/Round tip	004-0523-010	1

STERILE IMPLANTS

VARISATION STAPLES*

- QUICK & EASY PLACEMENT
- SELF - PENETRATING
- STERILE IMPLANT
- INTUITIVE INSTRUMENTATION

HIGHLY ADVANCED IMPLANTS

Dynafit varisation staples are ideal for the realization of osteotomies and arthrodesis of small fragments. Simple and ergonomic, their design allows easy insertion and removal. Dynafit varisation staples are made of stainless steel to guarantee rigid stabilization of osteotomies. Dynafit varisation staples are mono-cortical. Owing to the choice of two angulations and two different widths, this staple meets best with the shape of the cortices.

*Not 510K cleared

Dynafit staples are available on :
- 26°angled - 90° straight
- 2 sizes, 8 &10 mm legs lengths.

The intuitive and simple instrumentation is composed of dedicated (oblique or parallel) drill guides for making preholes and dedicated impactors for inserting the implant into the cortical bone.

DYNAFIT 90° straight staples

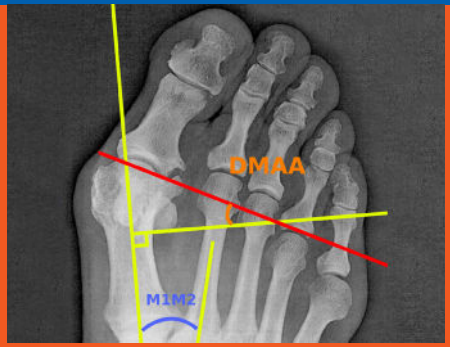
DYNAFIT 26° angled staples

Traceability for non sterile

Traceable batch number

VARISATION STAPLES

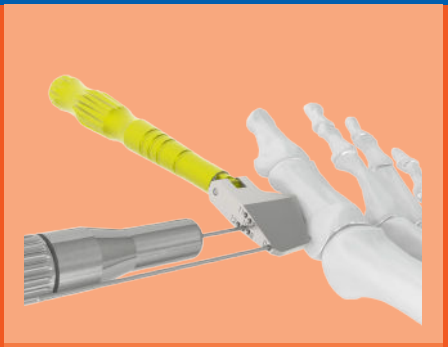
1 PRE-OPERATIVE ASSESSMENT



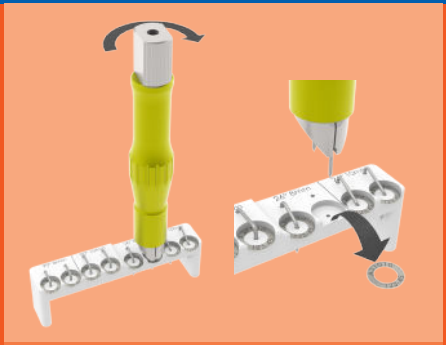
In the Hallux Valgus surgical treatment, often, an osteotomy of the proximal phalanx is performed to correct a possible malrotation or malalignment.
DynafitSystem® varisation staples are intended for great toe proximal phalanx osteotomy « Akin osteotomy ».
DynafitSystem® varisation staples can also be used in the foot or hand to stabilize small bone fractures.
Using x-ray of the feet while bearing weight, determine the corrections to be carried out according to the severity of the pathology, using (amongst others) angles M1 and P1.

2 OSTEOTOMY CUT AND STABILIZATION

The surgeon performs the first osteotomy cut parallel to the metatarsophalangeal joint.
It is recommended to preserve the lateral cortex intact to allow a hinge effect.
Second cut is performed and the bony wedge is removed.



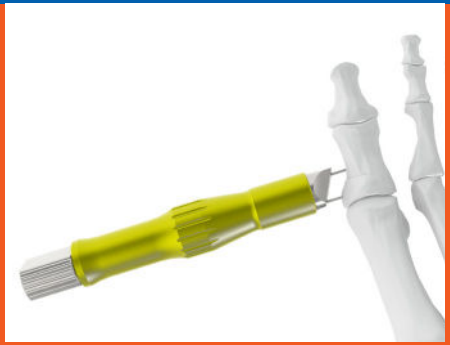
Using **Dynafit**System® Drill Guide, a 1 mm K-wire is placed according staple axis implantation till to reach the desired depth (distal extremity of the staple).
The surgeon selects the appropriate Drill Guide for staple 90°or 26°.
This K-wire guide the staple placement.
A second K-wire is placed according selected axis (check the marking on the Drill Guide).



Select the appropriate oblique or parallel handle / impactor.
Retrieve the traceability washer by sliding it along the rack.

The traceability batch number data is engraved on this washer.

3 STAPLE PREPARATION



The staple is inserted using the appropriate oblique or parallel impactor.
Insert the staple in the pre-drilled holes.
The Handle/Impactor allows handling the implant without touching the implant.
To handle the staple, screw the knob of the impactor till catching the implant
Unscrew the knob in order to release the implant and remove the impactor
The impaction can be finished by applying the tip of the impactor against the bridge of the staple.

The staple is impacted using the handle.

4 FINAL CONTROL

Final X-Ray control.

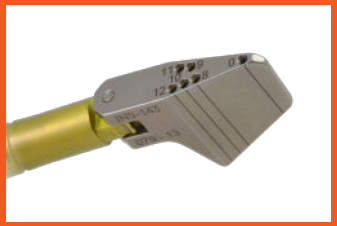
Preserve the lateral cortex allows to secure the correction and limits pseudoarthrosis risks.

VARISATION STAPLES

IMPLANT CATALOG

Designation	Reference
Varisation Staple 90° 10 x 08 x 1 mm	A10810
Varisation Staple 90° 10 x 08 x 1 mm **STERILE**	A30810
Varisation Staple 90° 10 x 10 x 1 mm	A11010
Varisation Staple 90° 10 x 10 x 1 mm **STERILE**	A31010
Varisation Staple 26° 10 x 08 x 1 mm	A20810
Varisation Staple 26° 10 x 08 x 1 mm **STERILE**	A40810
Varisation Staple 26° 10 x 10 x 1 mm	A21010
Varisation Staple 26° 10 x 10 x 1 mm **STERILE**	A41010

Traceability



Precise instruments

Intuitive instruments

Easy handle with no touch

INDICATIONS

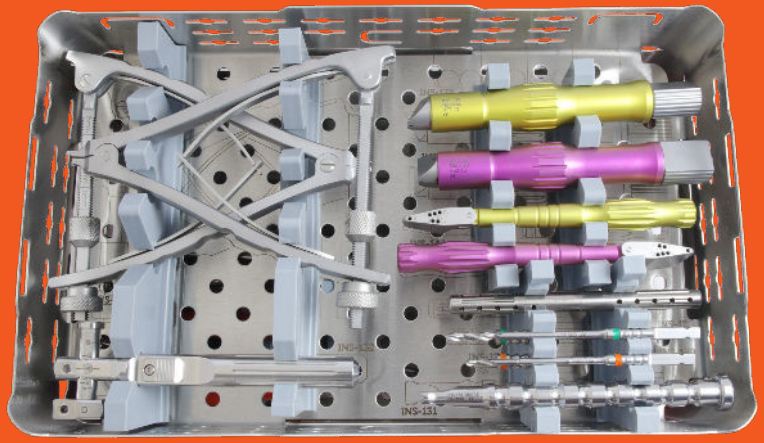
Fixation of bone fractures, osteotomies and arthrodesis in foot and hand surgery
- Stabilization of varisation osteotomies of the first phalanx (Akin osteotomy), for Hallux Valgus correction
- Stabilization of the osteotomies of small fragments for the foot and the hand
- Small fragments fractures reduction for the foot and the hand

CONTRAINDICATIONS

- Acute or chronic local or systemic infections
- Absence of musculo-cutaneous coverage, severe vascular defects affecting the parts concerned
- Bone damage inconsistent with correct purchase of the staple in the bone
- Muscular or neurological deficiency or behavioral disorders which risk exposing the internal fixation to abnormal mechanical forces
- Allergy to stainless steel

INSTRUMENTATION

Designation	Reference	Qty
Kirschner wire dispenser tube	INS-115	1
Impactor for staples 90°	INS-128	1
Impactor for staples 26°	INS-129	1
Drill guide for staples 90°	INS-142	1
Drill guide for staples 26°	INS-143	1
Instruments tray cover	INS-170	1



STERILE IMPLANTS

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EFFICIENT MOBILITY

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