

# Telya

Varisation staple

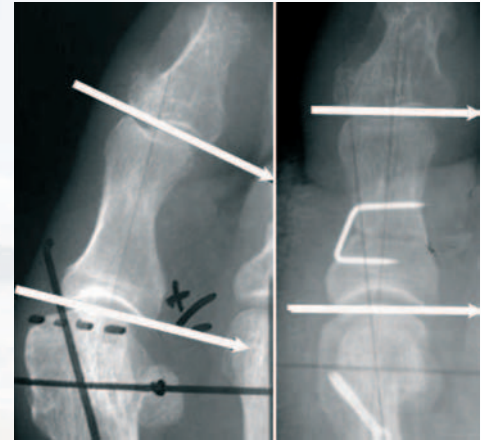
Surgical Technique



## Indications

The Telya variation staple is used to stabilize an osteotomy of the great toe proximal phalanx (Akin osteotomy), in order to correct :

- Hallux valgus interphalangeus,
- Phalangeal pronation,
- Wind swept toes.



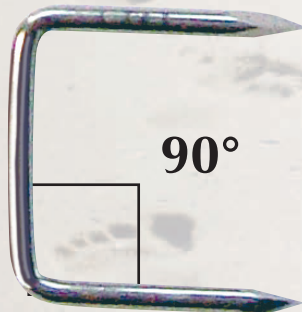
## Characteristics

TELYA 26° angled



Length of legs : 10 mm  
Diameter of the staple : 1.0 mm

TELYA 90° straight



Traceable lot number

## Description

Positional staple for fixation of uni-cortical osteotomies of the proximal phalanx of the great toe.

- The use of the Telya variation staple allows treatment of a residual valgus or pronation, following 1st metatarsal osteotomy.
- 2 types of staples (26 degree angled and 90 degree straight) are available.
- 10 mm legs lengths.
- Self-penetrating (pre-drilling with a 1 mm K-wire may be necessary in hard bone).
- Lot number and reference marquing for traceability.
- Un-sterile implants - separately packed sterile implants available.
- Manufactured in stainless steel 316L (ISO 5832-1)

# Telya

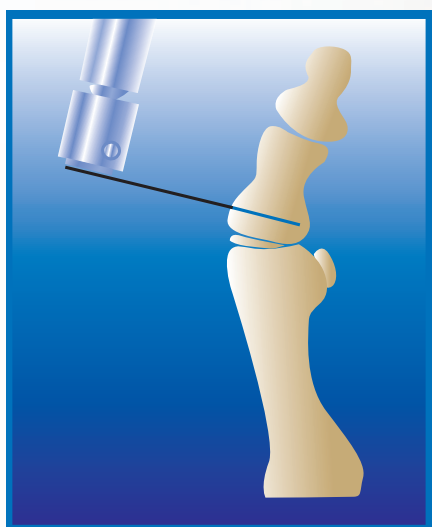
Irish Distributer: O'Mara Medical

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# Surgical Technique

## Great toe proximal phalanx osteotomy « Akin osteotomy » :

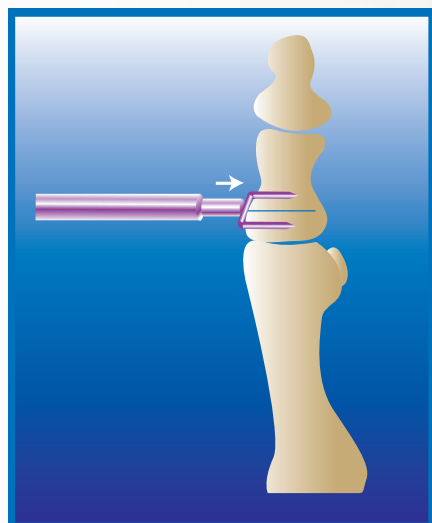
The aim of an osteotomy of the proximal phalanx is to correct a possible malrotation or malalignment. The phalangeal osteotomy should not be used to compensate for an undercorrected metatarsal osteotomy. Pronation of the phalanx should be corrected with a lateral release of the phalangeal-sesamoid complex. A phalangeal osteotomy should not be used to compensate for undercorrection. A shortening osteotomy may be combined with varisation. However, as the lateral cortex is breached, the osteotomy is unstable and requires more rigid stabilization.



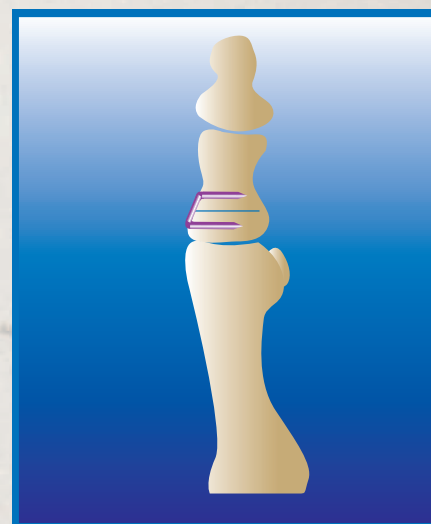
The first osteotomy cut is parallel to the metatarsophalangeal joint. The lateral cortex is kept intact to allow a hinge effect.



The bony wedge is removed after a second cut is made, often approximating to the angle of the interphalangeal joint (parallel to the nail bed).



In hard cortical bone the staple insertion sites may need to be pre-drilled with a 1 mm K-wire. The staple is inserted using the appropriate oblique or parallel impactor.



Correction held with a 26 degree varisation staple.

# Telya

# Instructions for use leaflet

NP0  
03/08

## FOOT IMPLANTS / INTERNAL FIXATION IMPLANTS NON STERILE DISPOSABLE PRODUCTS

CE  
0120  
June 1998 - Feb. 2000  
March 02 - Jan.05

According to decree no. 95-292 of 16 March 1995 (directive 93/42/CEE) relating to medical devices, this product must be handled and/or implanted by trained QUALIFIED PEOPLE who have READ AND UNDERSTOOD this INSTRUCTIONS FOR USE LEAFLET.

### 1 - Description of the medical devices:

The implants, which are delivered, non-sterile are:

- Screws: scored compression screws of different diameters and several lengths. They are manufactured from titanium alloy.
- Staples: of different widths, sections and leg lengths. They are manufactured from stainless steel titanium or titanium alloy.
- Kirschner pins of different diameters and lengths. They are manufactured from stainless steel.

### 2 - Indications:

#### Screws

- Mono and bi-cortical internal fixation
- Weil osteotomies
- Distal and proximal metatarsal osteotomies
- Internal fixation of the carpal scaphoid bone.
- SCARF/chevron osteotomies

#### Staples

- Phalangeal shortening osteotomies
- Metatarso-phalangeal arthrodeses
- Proximal or distal phalangeal osteotomies
- Arthrodeses of the middle and hind foot.
- Internal fixations requiring mono or bi-cortical compression.

#### Pins

- Temporary or definitive mini-fragment fixation.

### 3 - Contra-indications:

- Acute or chronic local or systemic infections.
- Factors liable to compromise the success of implantation:
  - Inappropriate physical activity.
  - Infectious diseases.
  - Obesity
  - Systemic or metabolic disorders.
  - Severe osteoporosis.
  - Local bone tumours.
  - Allergies to implant components.
  - Smoking.

It is important that the patient is informed of these factors and the influence which they may have on the success of implantation.

#### - Undesirable effects: Allergy to metal.

- Risk of interference with medical imaging investigations: MRI/CT SCAN. The material used is non-magnetic.

### 4 - Precaution before use:

This product is sold non sterile. New products must always be handled following Good Clinical Practice. These products cannot be implanted without prior cleaning and decontamination, before sterilisation. The material from which the products are made must be taken into account for this procedure. The product and its ancillary instrumentation must be autoclave sterilised. We recommend (water) steam sterilisation at 134°C for 18 minutes.

### 5 - Precaution for use:

The surgeon must use the ancillary instrumentation provided observing the conditions stated in the operating procedure where applicable. When handling the implants avoid any contact with foreign material liable to harm their surface state.

Rectilinear PAREOS supports: it is formerly recommended that the supports not be bent.

**The EOS company SARL takes no responsibility in the event of changes in the initial characteristics of the device or when its products are associated with parts of different origin.**

### 6 - Re-use:

Previously implanted products must never be reused. The EOS company takes no responsibility for reuse.

### 7 - Re-sterilisation of products:

Only non-implanted products are permitted to be sterilised. Where applicable this is performed under the same conditions as described in paragraph 4.

### 8 - Preventative procedures to avoid post-operative complications:

- Avoid forced extreme positions such as flexion/extension.
- Avoid violent sports.
- Avoid overweight.
- Wear orthopaedic footwear following the surgeon's prescriptions.
- Avoid carrying heavy loads.
- Ensure that a doctor treats any infection which develops either in the operated limb or in any other part of the body rapidly.

### 9 - Ancillary instrumentation:

Please consult the ancillary instrumentation leaflet before implantation

### INFORMATION:

Please contact our representative or distributor, or EOS sarl directly, for any further information about products or their use.

#### Manufactured by the EOS company sarl

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### Symbol legends:



Commercial catalogue reference



Do not reuse – Disposable



Batch code



Warning, see instructions for use leaflet

# Telya

## IMPLANTS

REFERENCE	EOS VARISATION STAPLE
P04.026.080	Varisation staple 26° width 08 mm
P04.026.100	Varisation staple 26° width 10 mm
P04.090.080	Varisation staple 90° width 08 mm
P04.090.100	Varisation staple 90° width 10 mm

## ASSOCIATED INSTRUMENTS

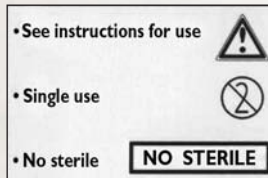
REFERENCE	DESCRIPTION
K01.010.070	1.0 mm K-wire Lg 70 mm
AP04.001	Driver-impactor for 90° varisation staple
AP04.002	Driver-impactor for 26° varisation staple
AP03.004	Staple impactor



The products are manufactured and referenced within the frame of the standards in force. Implantation procedures are described in the surgical technique.

Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

**WARNING :** Federal law (USA) restricts this device to sale by or on the order of a physician.



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