



# NeoFit<sup>®</sup>

## METATARSO-PHALANGEAL ARTHRODESIS PLATE



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- ▶ The NeoFit® MTP arthrodesis plate is manufactured in Ti6Al4V titanium alloy.
- ▶ The NeoFit® plate is available in four sizes for the right side and in four sizes for the left side.
- ▶ The plate is delivered straight but may be shaped when implanted so that it precisely matches the patient's metatarsophalangeal angulation.
- ▶ It is delivered sterile.



## LOW PROFILE

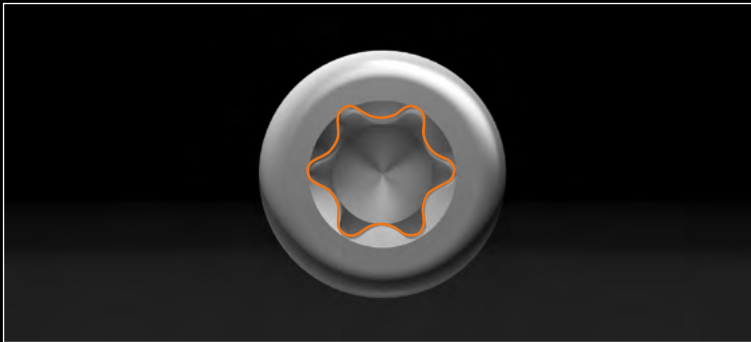
- ▶ The NeoFit® plate is specifically designed to avoid conflicts with surrounding tissue.



## FIXATION

- ▶ Different fixation resources can be used:
  - > locking screws,
  - > non-locking screws.
- ▶ The oblong hole offers a compression system ① enables good contact with the arthrodesis site.
- ▶ Pre oriented holes within the plate allow the possibility of a  $-/+5^\circ$  angulation of the screws.





## TORX IMPRINT

- ▶ The range of screws for the NeoFit® system has a Torx (T8) imprint: The star shape enables better distribution of the tightening forces, and thus protects the screw imprint during tightening and untightening.



## ANGLE OF ATTACK

- ▶ The thread profile enables its self-tapping properties to be ensured.
- ▶ The round tip of the NeoFit® screws limits the occurrence of plantar conflicts.

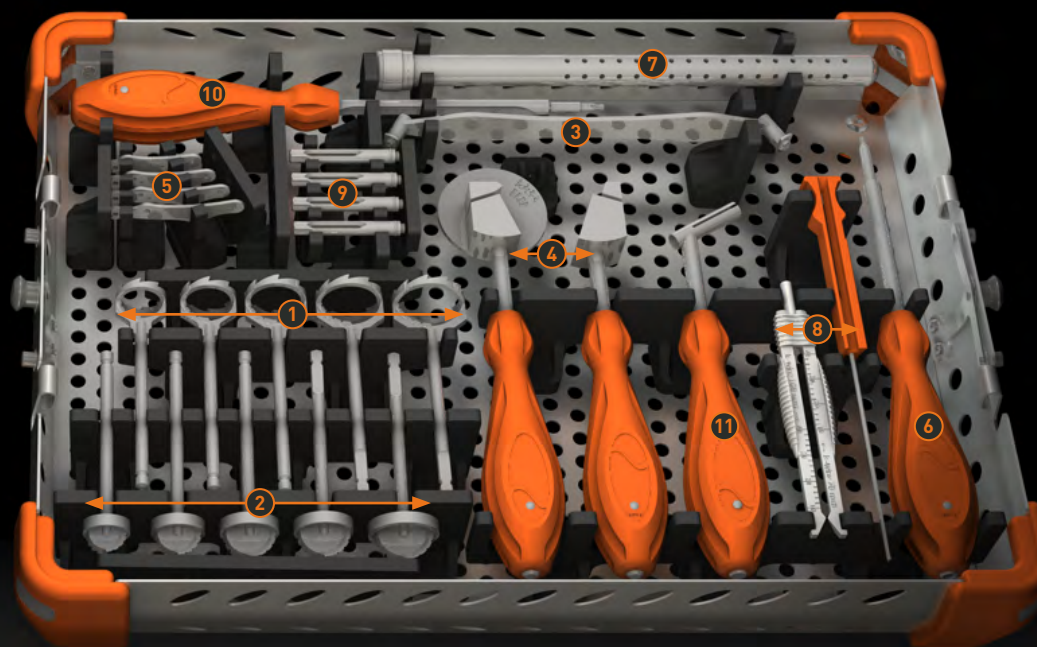
Product name	Screw diameter	Color code	Screw type	Screw imprint	Length* 2mm incremental
NeoFit® screw 2.7	2.7 mm		locking and non-locking	Torx 8	10 > 20mm
NeoFit® screw 3.0	3.0 mm		locking and non-locking	Torx 8	10 > 20mm

\* Screws, L. 22 and 24mm, are available upon request

## INSTRUMENTATION

► The NeoFit® set contains the following instrumentation:

- › METATARSAL REAMERS ①
- › PHALANGEAL REAMERS ②
- › DOUBLE SIDED DRILL GUIDE ③
- › NEOFIT® PLATE BENDERS ④
- › TRIAL PLATES ⑤
- › NON CANNULATED SCREWDRIVER T8 ⑥
- › K-WIRES ⑦
- › DRILL DIAMETER 2.0MM LG 100 ⑧
- › DEPTH GAUGE AND MEASURER ⑨
- › DRILL MEASURING GUIDE ⑩
- › NON STERILE K-WIRE ⑪
- › CANNULATED SCREWDRIVER T8 ⑫
- › DRILL GUIDE HOLDER ⑬



## INDICATIONS

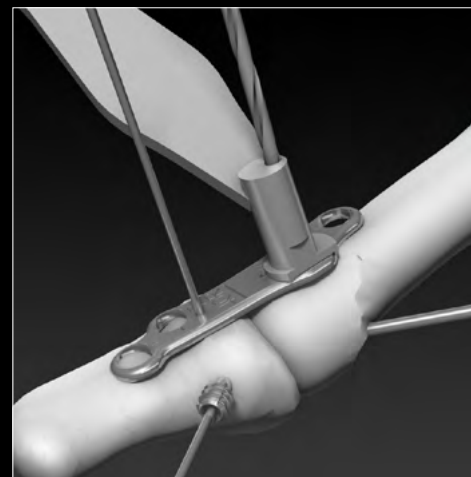
- ▶ The NeoFit® MTP arthrodesis system is indicated in the fixation of fractures, osteotomies and arthrodesis of the first metatarsophalangeal articulation, and in particular in the case of:
  - › Hallux rigidus
  - › Severe hallux valgus (IM angle  $>20^{\circ}$  - HV angle  $>40^{\circ}$ )
  - › Deformation due to rheumatoid arthritis
  - › Post-trauma arthrosis
  - › Neuromuscular instability
- ▶ The addition of an oblique compression screw through the joint is necessary (for example IBS® screw) in order to ensure the closure of the plantar hinge and reinforce the stability of the arthrodesis.

## CONTRAINDICATIONS

- ▶ The implant should not be used in a patient who has currently, or who has history of:
  - › Acute or chronic inflammations, whether local or systemic
  - › Active infections
  - › Sensitivity/allergies to the implant materials

# NEOFIT®

## SURGICAL TECHNIQUE



In2Bones® as the manufacturer of this device, does not practice medicine. The surgeon who performs any implant procedure is responsible for determining and using the appropriate surgical techniques for implanting the device in each patient. This Surgical Technique Manual is furnished for information purposes, as an aid to use properly the device and its dedicated instruments.

**THIS TECHNIQUE WAS DEVELOPED IN COLLABORATION  
WITH M. WILFRID GRAFF AND M. ANTOINE MOUTON,  
HÔPITAL DES DIACONESSES, PARIS.**

## 1 - INCISION

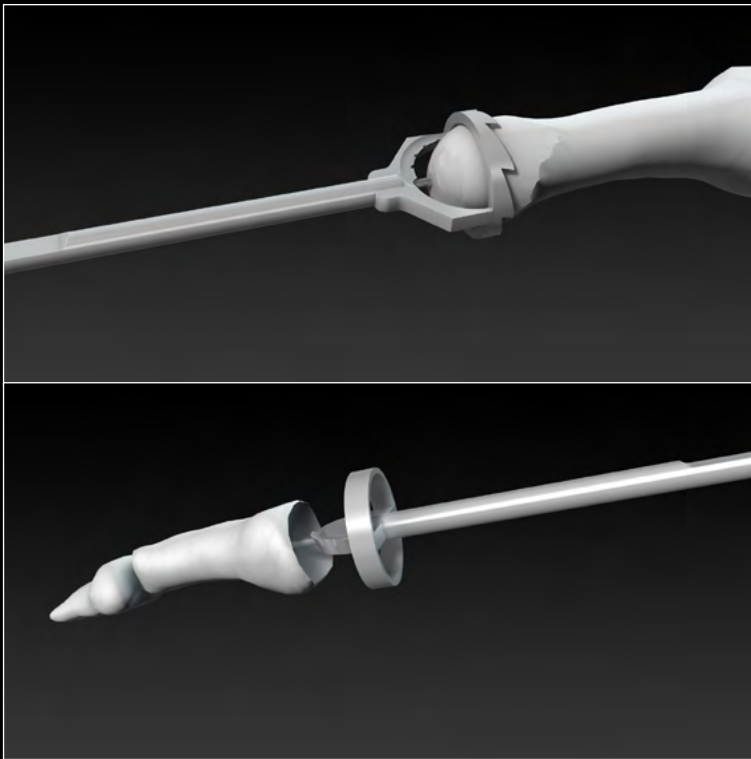


- ▶ The incision is preferentially medial, centered on the metatarsophalangeal (MP1) interline. It extends to the junction of dorsal/plantar skin until level with the first dorsal skin crease of the interphalangeal.
- ▶ This distance is taken back from above the MP1. The arthrotomy is performed without capsular excision. This excision will be performed if necessary at the end of the intervention.
- ▶ The metatarsophalangeal articulation is exposed, and then the upper part of the metatarsal, then that of the phalanx and its inferomedial proximal metaphysis.
- ▶ Though we recommended the approach described above, incision is being made per surgeon's preference.

**A too dorsal cut may create difficulties  
in positioning the lower screw.**

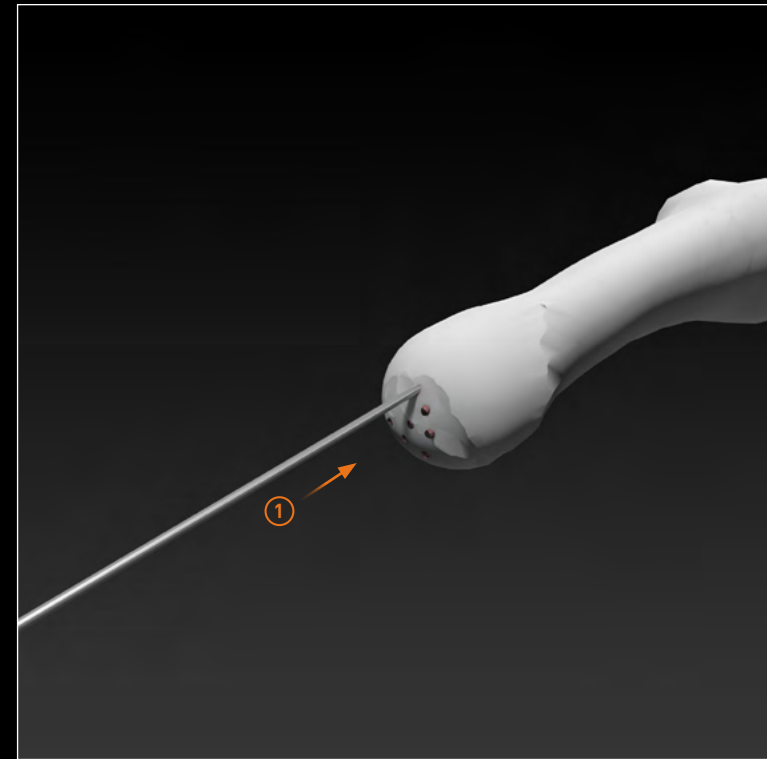


## 2 - PREPARATION OF THE SURFACES



- ▶ The upper and medial osteophytes are removed with the saw or gouge-tongs.
- ▶ The cut of the articular surfaces is performed using a flat or spherical method according to surgeon's preference.
- ▶ For spherical preparation there are reamers of different sizes. If using reamers to prepare the joint, determine the appropriate size by placing it over the metatarsal head to ensure adequate coverage.
- ▶ Reamers range from 14-22 mm in diameter and have an AO quick connect attachment.

**This should be performed size by size.**

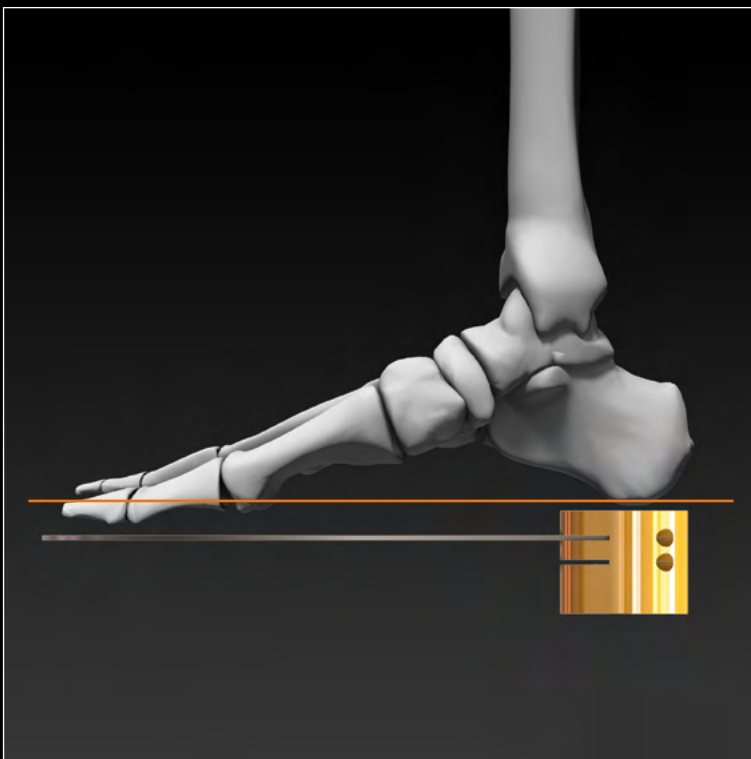


- ▶ A pin of diameter 1.6 mm is used to guide the reamers.

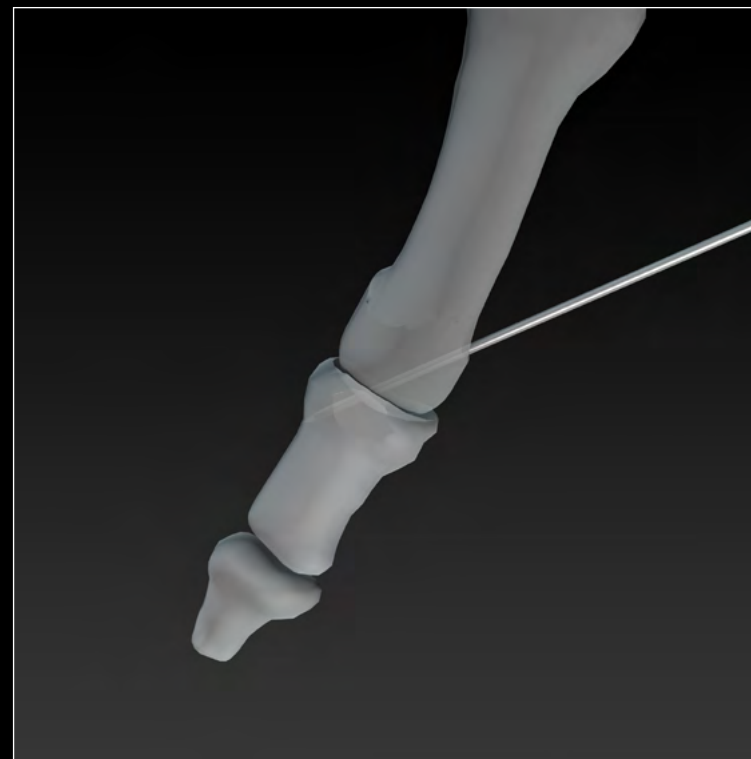
	Diam. 14mm	Diam. 16mm	Diam. 18mm	Diam. 20mm	Diam. 22mm
Metatarsal reamer	P01 00051	P01 00061	P01 00071	P01 00391	P01 00401
Phalangeal reamer	P01 00081	P01 00091	P01 00101	P01 00411	P01 00421

- ▶ It is recommended to start with the metatarsal surface.
- ▶ Once reaming has been completed, the surfaces can be drilled to encourage blood flow in the bone fusion zone. ①

### 3 - ADJUSTMENT OF THE ARTHRODESIS

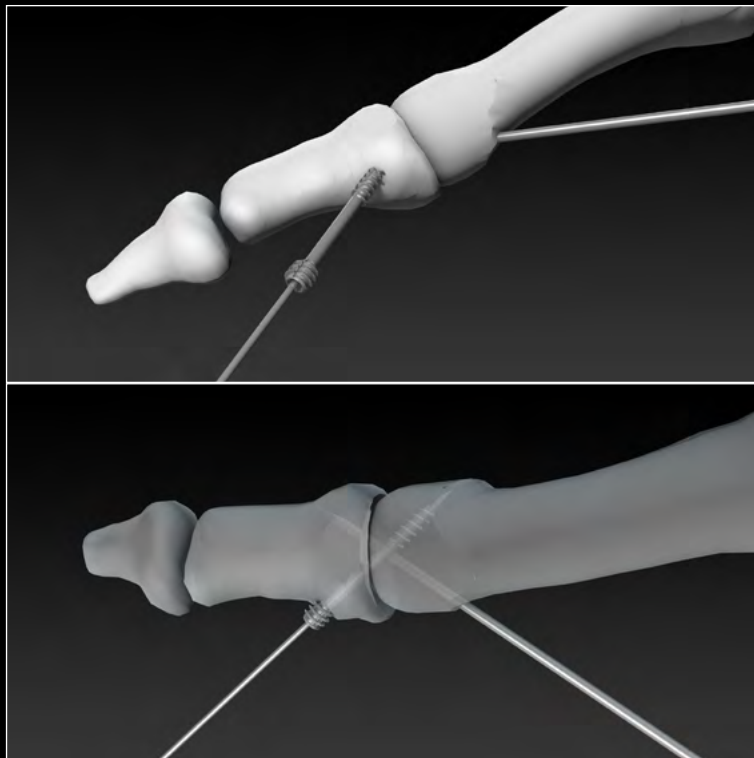


- ▶ Adjustment of the arthrodesis depends on the usual practices of the surgeon.
- ▶ We recommend dorsi-flexion angle such that the projection of the axis of the phalanx, on a foot in a load bearing profile, passes between the calcaneum and the floor. During the joint preparation, care should be taken to avoid excessive dorsiflexion of the fused joint.



- ▶ Secure temporarily the MTP joint with a 1.6mm wire in the desired dorsi-flexion (Fig XX)
- ▶ (Optional) Using the Dorsal Flexion Guide, simulate load bearing to control the arthrodesis alignment (Ref. P01 00351 and P01 00361)

#### 4 - TRANSFOCAL SCREW



- ▶ Insert a 1mm kwire at the level of the P1 metaphysis through the joint aiming at the lateral process of M1.
- ▶ Insert an IBS 3.0 or 3.5mm compression or neutralization screw on the kwire (using the Torx T8 screwdriver) without engaging the head of the screw into the bone.

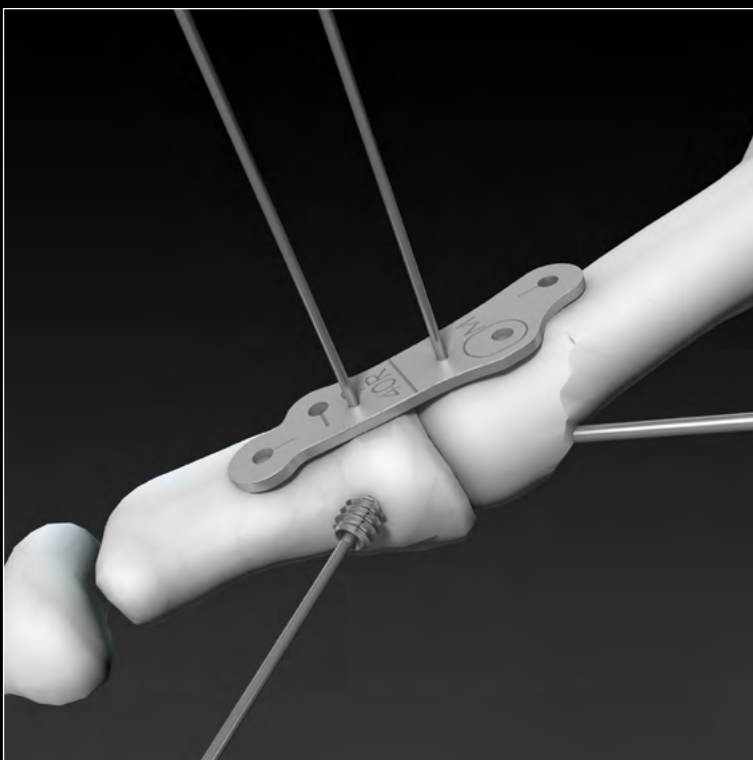
#### 5 - PRESENTATION OF THE IMPLANT



- ▶ The NeoFit® MTP plate is available in 4 sizes (35, 40, 45 and 50mm).

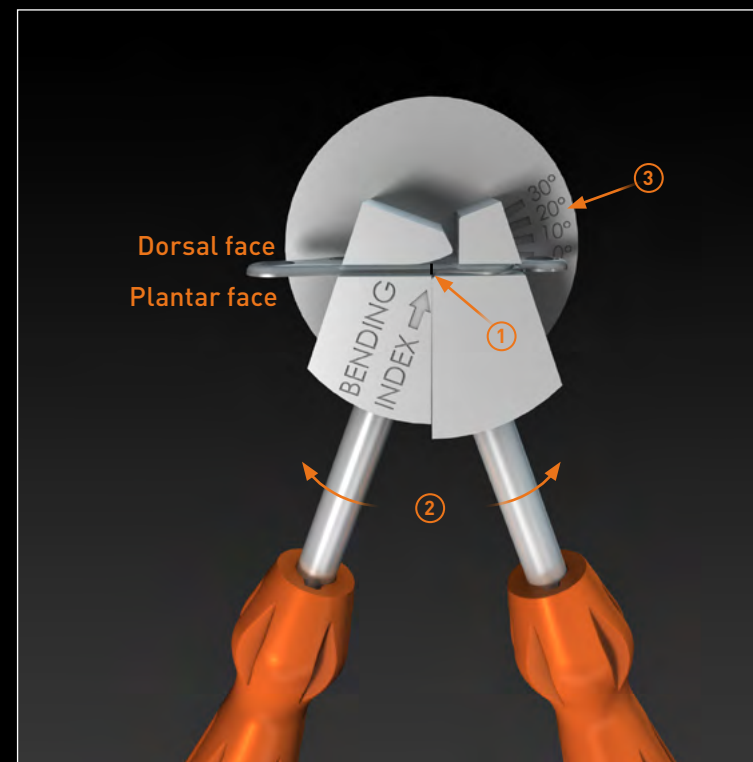
	Size 1 L. 35mm	Size 2 L. 40mm	Size 3 L. 45mm	Size 4 L. 50mm
NeoFit® RIGHT	P10 ST 135	P10 ST 140	P10 ST 145	P10 ST 150
NeoFit® LEFT	P10 ST 235	P10 ST 240	P10 ST 245	P10 ST 250

## 6 - CHOICE OF SIZE OF THE IMPLANT



- ▶ Once the size is determined, position the plate across the joint line. The M and P marks of the plate provide the orientation to be given [M stands for Metatarsal, while P for Phalangeal].
- ▶ The trial plate may be secured with one or two 1mm K-wire.

## 7 - SHAPING OF THE PLATE

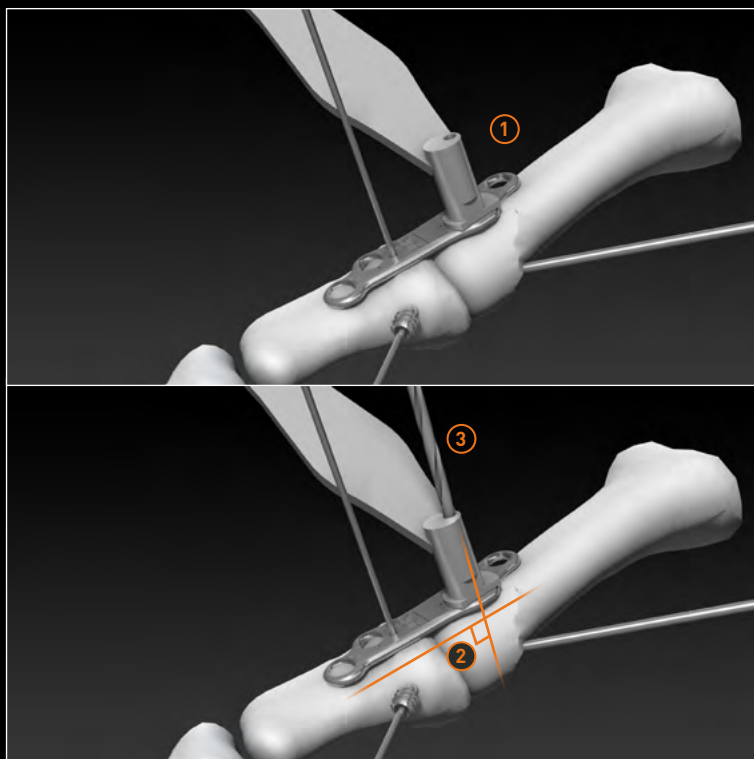


- ▶ At this point, the angulation of the plate may be adapted using the benders available in the instrumentation set, to fit the patient's anatomy.
  - › Dorsal flexion: The plate must be placed with the dorsal face upwards in the upper grooves of the plate benders. Position the plate between the two plate benders such that the articular line is located at their junction. ①
  - › Maneuver the plate benders to achieve the desired flexion ②
  - › The reading of the angle of flexion is taken directly from the plate benders. ③

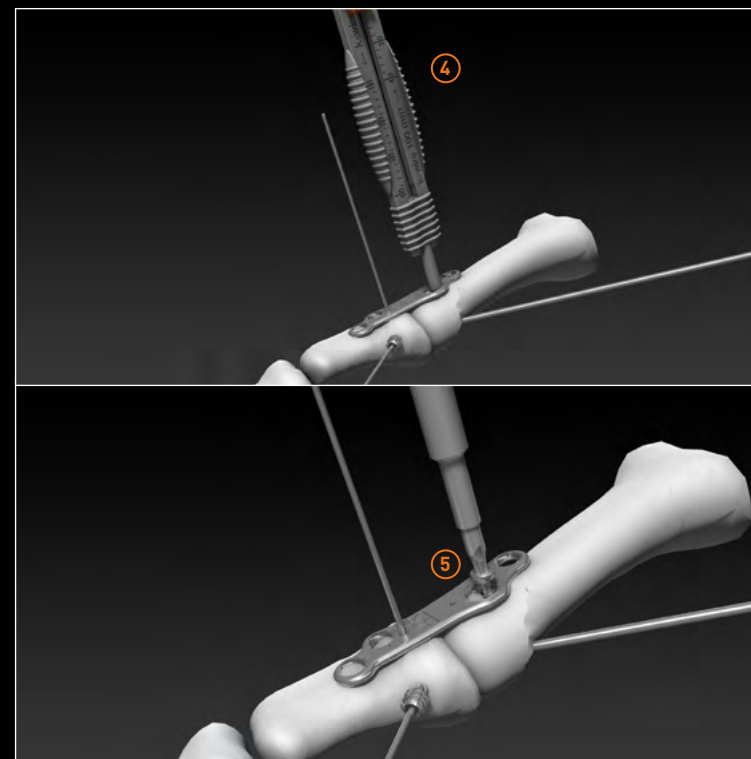
**Though the plate's tolerance may go as up to +/-30°, we strongly recommend not to go further +/-15°. In any case should the plate be bent repeatedly, in many directions.**

- ▶ In the case of a plantar flexion, position the plate with the plantar face oriented upwards and proceed as described above.

## 8 - INSERTION OF THE COMPRESSION SCREW (OBLONG HOLE)

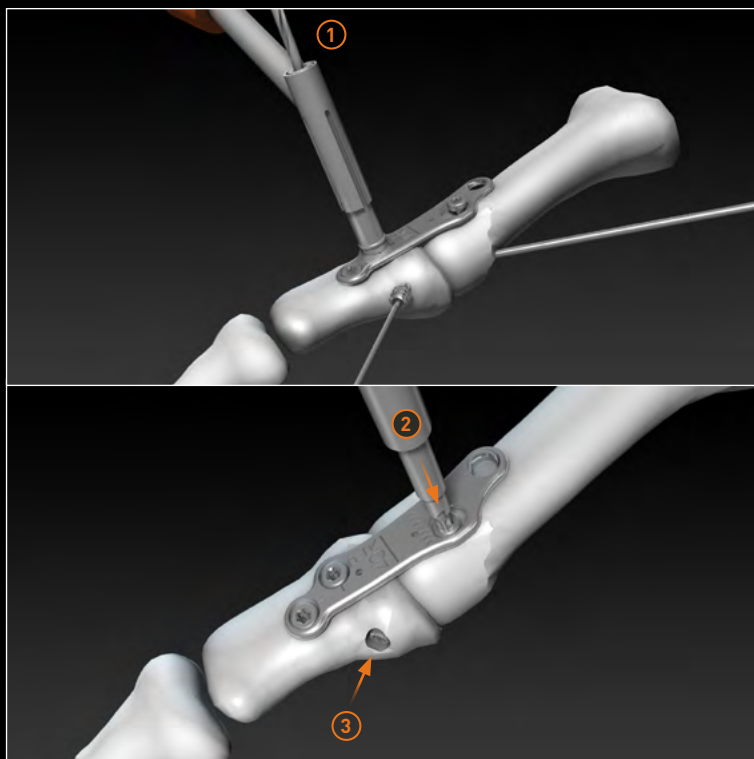


- ▶ Remove the trial plate, leaving in place the kwire(s). The definitive implant is positioned on the k-wire.
- ▶ The Oblong drilling guide P01 00281 is positioned on the oblong hole. The laser mark «M» should coincide with the point of reference M on the implant ①. The guide enables drilling on the longitudinal axis of the plate ②, enabling the application of compression on the arthrodesis,
- ▶ Drilling is performed using a 2.0 mm diameter drill. ③

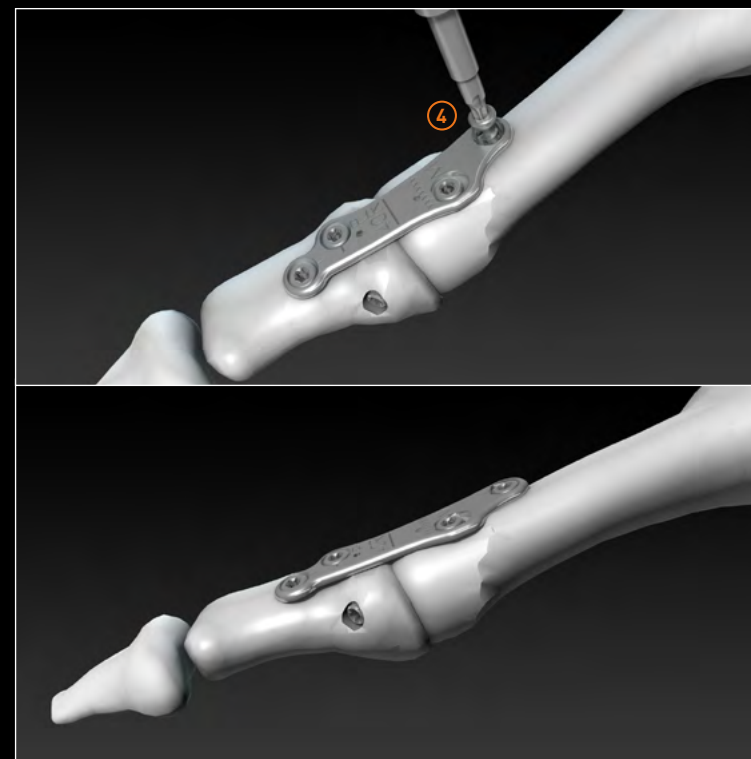


- ▶ The length of the screw is determined using a depth gauge. ④ Refer to the depth gauge assembly before processing.
- ▶ The screw is inserted into the metatarsal using the T8 screwdriver. The screw should not be locked into the plate. ⑤
- ▶ This screw guides the plate during the compression phase for the transfocal screw.

## 9 - FIXATION OF THE PLATE



- ▶ For the holes **A**, **C** and **D**, locking or non-locking screws are available according to the preference of the surgeon.
- ▶ Holes **C** and **D** are prepared in the phalanx using the drilling guide for a cylindrical hole and the 2.0 mm diameter drill. The screws are inserted after having determined their lengths using the depth gauge. **①**
- ▶ The screw for the oblong hole **B** is locked. **②**
- ▶ The trans-focal compression screw is fully inserted in the phalanx. **③**



- ▶ Finally, the preparation and positioning of the screw **A** is performed. **④**

**If the stability of the assembly is considered to be insufficient, the path of the second trans-focal pin can be used to insert a second I.B.S.™ screw C or N.**

## 10 - CLOSURE :

- ▶ Medial bone regularisation then lavage. Closure is on three planes. A rigid sole postoperative shoe should be used during 6 weeks.

## NEOFIT®

Reference	Designation		
P10ST135	NEOFIT® Right	Sterile	Taille 1 - 35 mm
P10ST140	NEOFIT® Right	Sterile	Taille 2 - 40 mm
P10ST145	NEOFIT® Right	Sterile	Taille 3 - 45 mm
P10ST150	NEOFIT® Right	Sterile	Taille 4 - 50 mm
P10ST235	NEOFIT® Left	Sterile	Taille 1 - 35 mm
P10ST240	NEOFIT® Left	Sterile	Taille 2 - 40 mm
P10ST245	NEOFIT® Left	Sterile	Taille 3 - 45 mm
P10ST250	NEOFIT® Left	Sterile	Taille 4 - 50 mm

## SCREWS\*

Reference Diam. 2.7mm Non-locking	Length	Reference Diam. 2.7mm Locking
V27ST010	10 mm	V27ST110
V27ST012	12 mm	V27ST112
V27ST014	14 mm	V27ST114
V27ST016	16 mm	V27ST116
V27ST018	18 mm	V27ST118
V27ST020	20 mm	V27ST120

Reference Diam. 3.0mm Non-locking	Length	Reference Diam. 3.0mm Locking
V30ST010	10 mm	V30ST110
V30ST012	12 mm	V30ST112
V30ST014	14 mm	V30ST114
V30ST016	16 mm	V30ST116
V30ST018	18 mm	V30ST118
V30ST020	20 mm	V30ST120

\* Screws, L. 22 and 24mm, are available upon request

## INSTRUMENTS

Reference	Designation
P01 20011	Container Neofit®
P01 00051	Metatarsal reamer diam 14mm
P01 00061	Metatarsal reamer diam 16mm
P01 00071	Metatarsal reamer diam 18mm
P01 00391	Metatarsal reamer diam 20mm
P01 00401	Metatarsal reamer diam 22mm
P01 00081	Phalangeal reamer diam 14mm
P01 00091	Phalangeal reamer diam 16mm
P01 00101	Phalangeal reamer diam 18mm
P01 00411	Phalangeal reamer diam 20mm
P01 00421	Phalangeal reamer diam 22mm
P01 00431	Drill measuring guide
P01 00441	Double sided drill guide
P01 00451	Drill guide holder
P01 00311	NeoFit® plate bender - Left
P01 00321	NeoFit® plate bender - Right
P01 00371	Trial plate - Drill guide - 35mm
P01 00241	Trial plate - Drill guide - 40mm
P01 00251	Trial plate - Drill guide - 45mm
P01 00261	Trial plate - Drill guide - 50mm
G01 00862	Cannulated screwdriver T8
G01 00281	Non cannulated screwdriver T8
G01 40021	Kwires tube holder
K10 NS100	K-wire non Sterile - diam. 1mm - lg 100mm
K10 NS102	K-wire non Sterile - diam. 2mm - lg 100mm
K10 NS150	K-wire non Sterile - diam. 1.6mm - lg 150mm
P01 00381	Drill - diam. 2mm - gradué
G01 00901	Depth gauge
G01 00891	Measurer

## RECOMMENDATION

- ▶ It is recommended to carefully read the instructions for use in the package insert.


## DEVICES

- ▶ Plate and screw : EC Class IIb - CE0086
- ▶ Instruments :
  - › Instruments with a measuring function : EC class Im - CE0086
  - › Instruments connected to a power driver and trial plate : EC class IIa - CE0086
  - › Reusable surgical instruments : EC class I - CE

## REIMBURSEMENT

- ▶ Reimbursement may vary from countries to countries. Check with local authorities.

## MANUFACTURER

- ▶  In2Bones SAS  
28, chemin du Petit Bois  
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Fax: +33 (0)4 72 29 26 29

## DOCUMENT

- ▶ Reference : ST-DIG-NEOFIT-EN-062018

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

Always refer to the appropriate instructions for use for complete clinical instructions.

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

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

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