

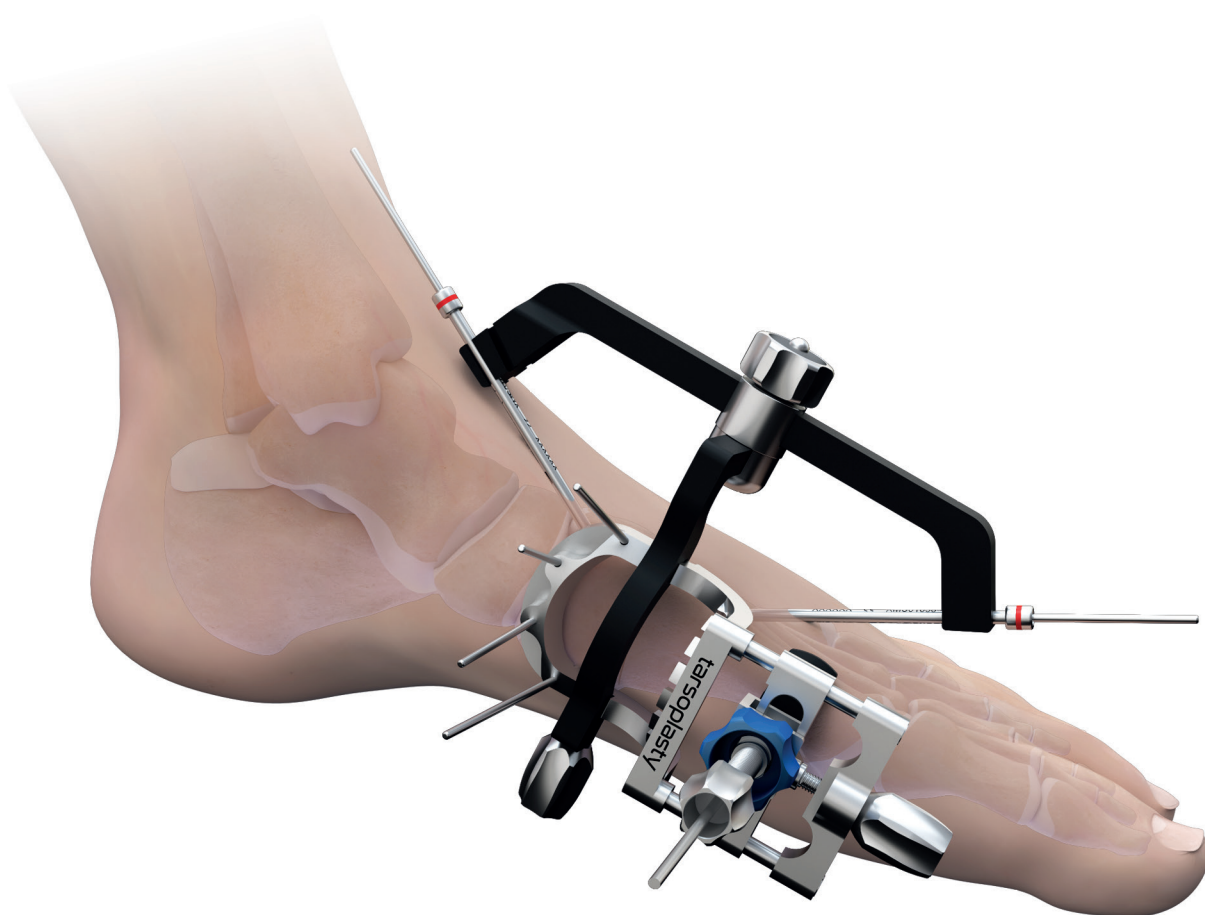
# tarsoplasty<sup>®</sup>

Percutaneous Lapidus Correction



## OPERATIVE TECHNIQUE

MIDFOOT  
SURGERY



- . **Guided** percutaneous preparation
- . **Controlled** triplanar correction
- . **Accurate** implants position

*Creating  
Better  
Together™*

# tarsoplasty<sup>®</sup>

Percutaneous Lapidus Correction

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# INTRODUCTION

The Tarsoplasty® system allows guided and controlled Lapidus for simple, precise and reproducible correction of Hallux valgus in percutaneous surgery.

Associated with PECA® and PECA® Compressive implants, the Tarsoplasty® system ensures triplanar correction and stable construction to restore natural alignment of the first metatarsal.

## Indications & Contraindications

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### Indications

The osteosynthesis screws are indicated for arthrosis, hallux valgus and other bone alignment defaults (pes cavus, flatfoot, malalignment secondary to previous trauma).

#### Example of use:

Surgical correction of hallux valgus performing percutaneous Lapidus arthrodesis and Akin osteotomy.

**Note:** Detailed information on each medical device is provided in the instruction for use. Refer to the instruction for use for a complete list of side effects, warnings, precautions for use, and directions for use.

### Contraindications

Osteosynthesis screws should not be used in case of any of the following:

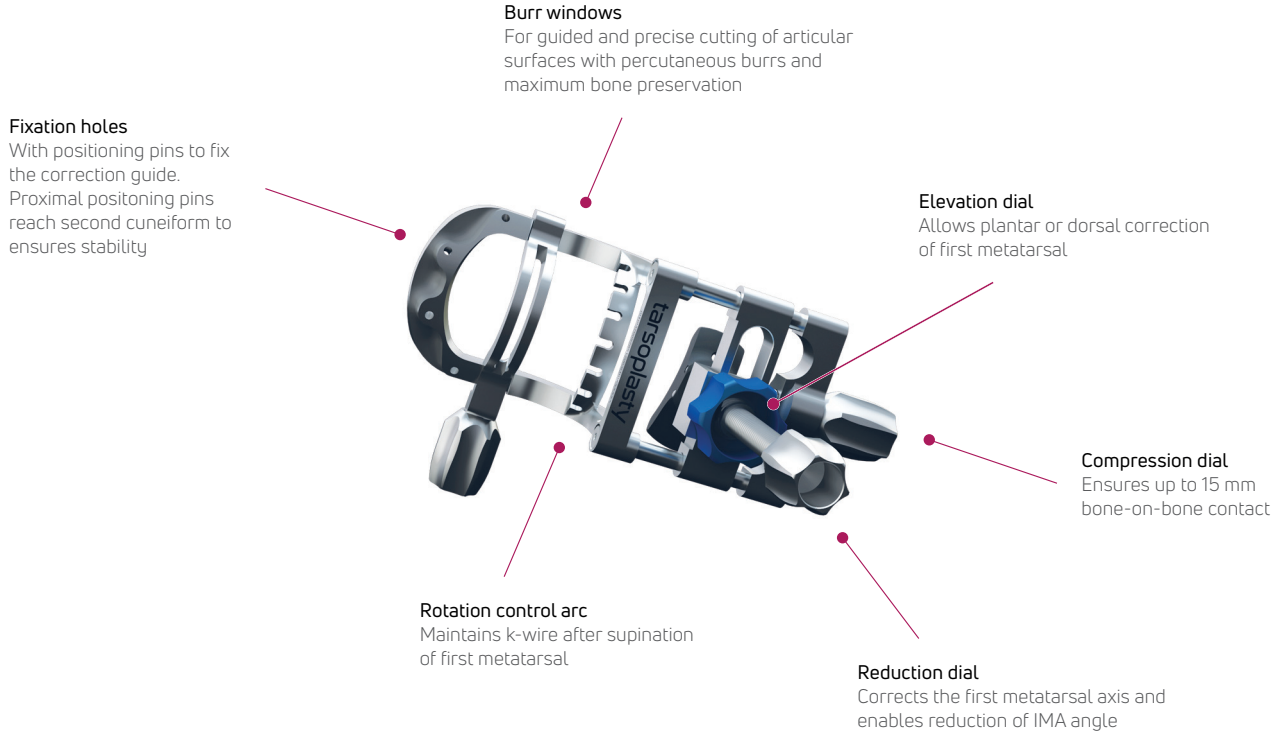
- . Severe muscular, neurological or vascular deficiency in the extremity concerned.
- . Bone destruction or poor bone quality, likely to impair implant stability.
- . Hypersensitivity to vanadium and/or aluminium.

# DESIGN FEATURES

## 1 - Tarsoplasty® guide

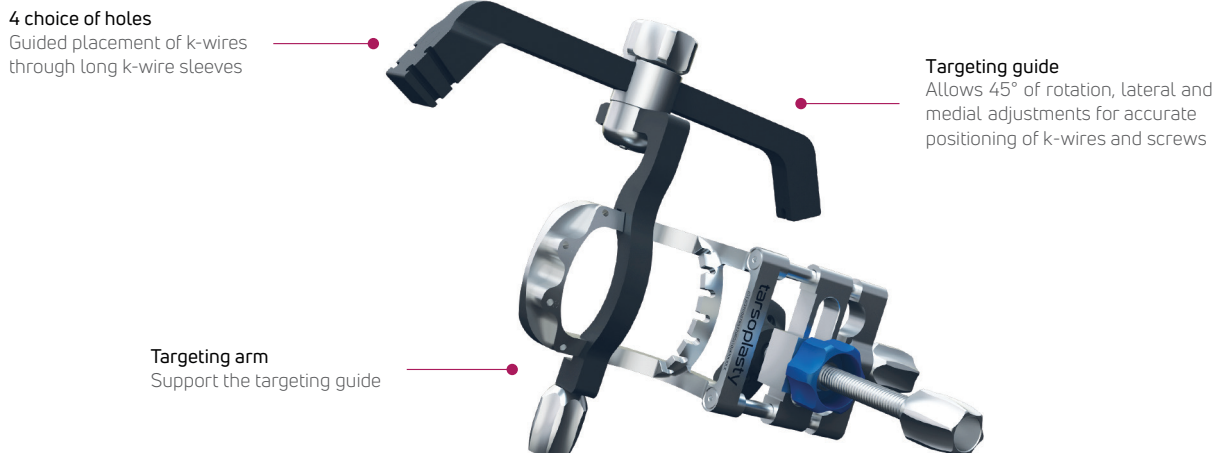
### Keys features

#### Correction guide



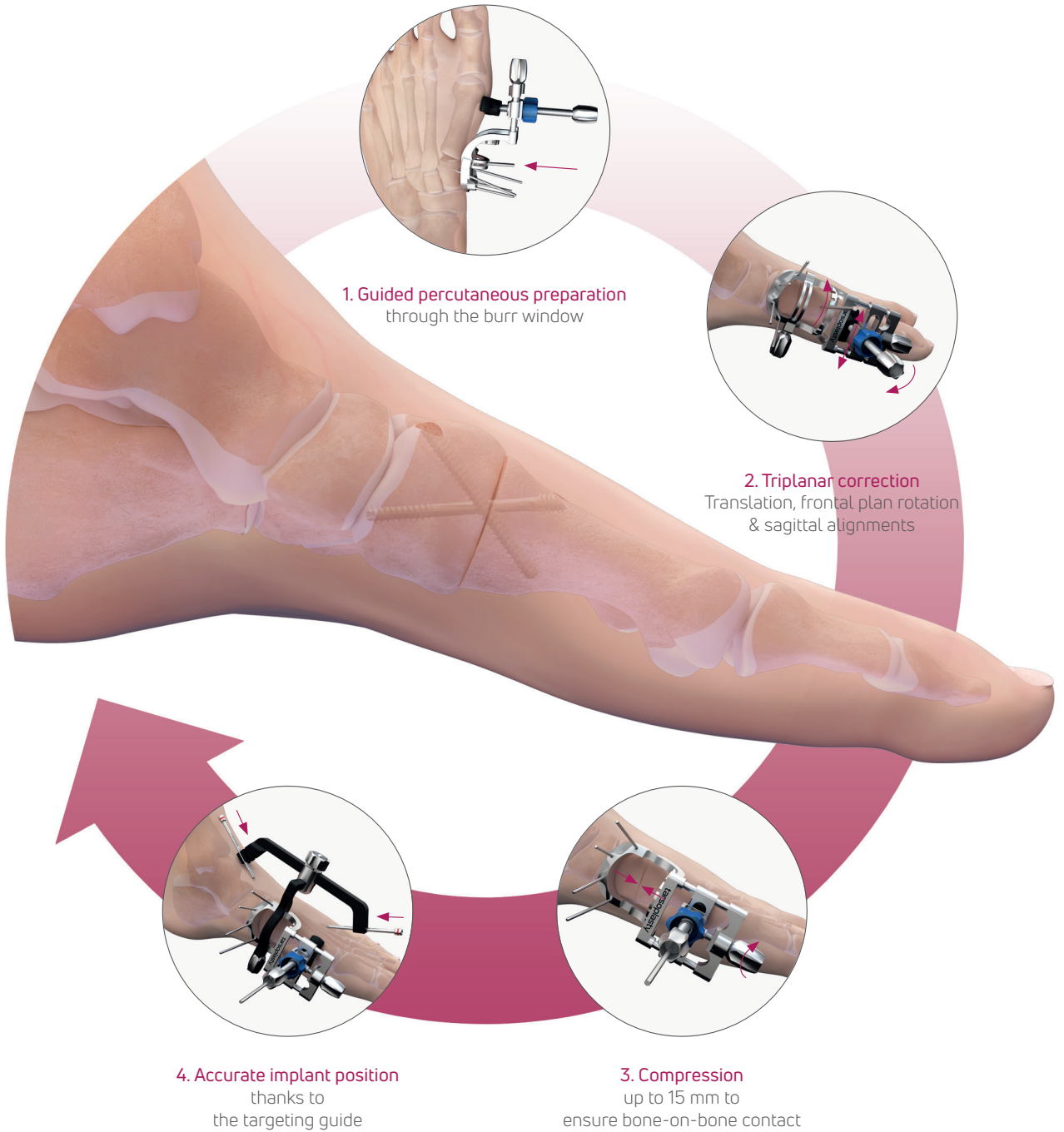
#### Targeting guide

**Note:** Targeting arm and targeting guide are radiolucent.



# DESIGN FEATURES

Guided technique, technical features



# DESIGN FEATURES

## 2 - Assembly

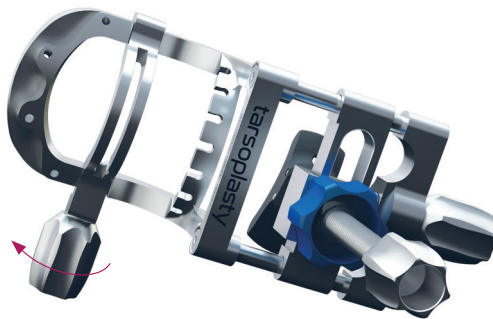
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4 parts / 2 configurations of the Tarsoplasty® guide:



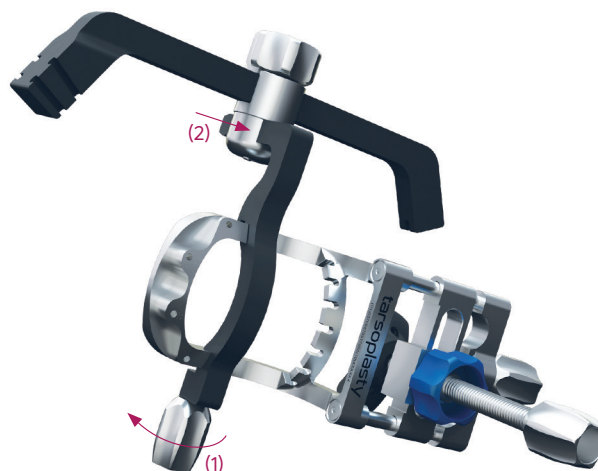
### 1<sup>st</sup> configuration: A + B

Attach the locking wheel to the burr window and position the burr window on the dedicated part of the correction guide and fix it by turning the locking dial: the dial can be oriented up or down at the surgeon's preference. Ensure the reduction dial is fully unscrewed before positioning the Tarsoplasty® correction guide on the foot.



### 2<sup>nd</sup> configuration (after removing burr window): A + C + D

Attach the locking wheel to the targeting arm and position the targeting guide on the dedicated part of the correction guide and fix it by turning the locking dial (1). Slide the targeting guide on the targeting arm, control the rotation and lock it with the dial (2).



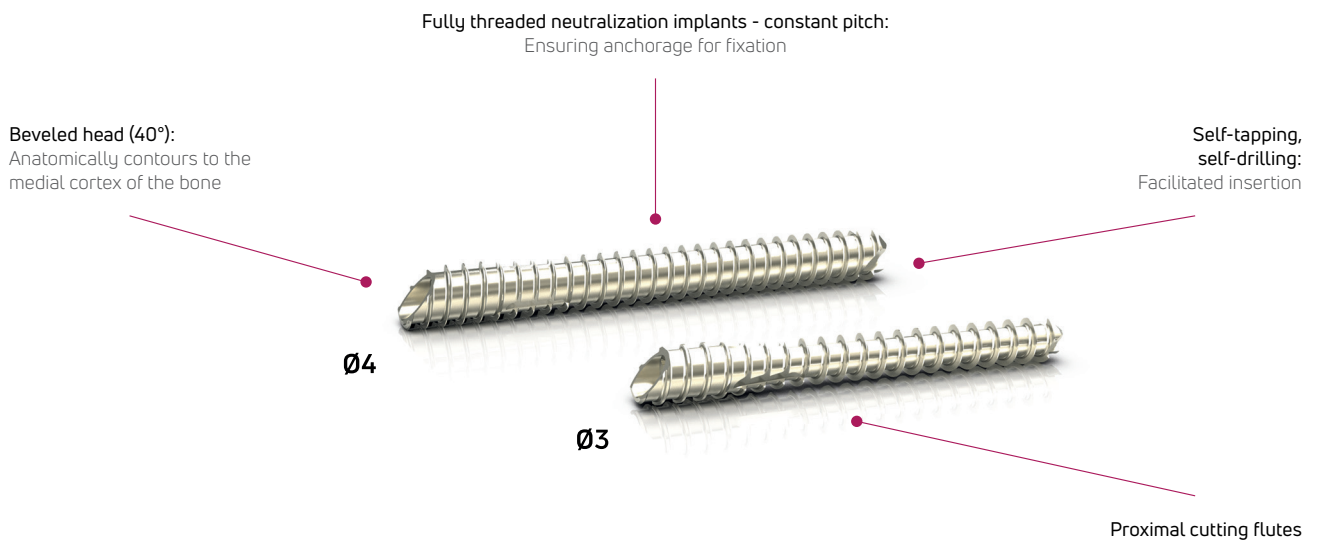
# DESIGN FEATURES

## 3 - PECA<sup>®</sup>, PECA<sup>®</sup>-C implants & Nexis<sup>®</sup> MIS screws



### PECA<sup>®</sup> Ø 4 & Ø 3 - Bunion implants

1



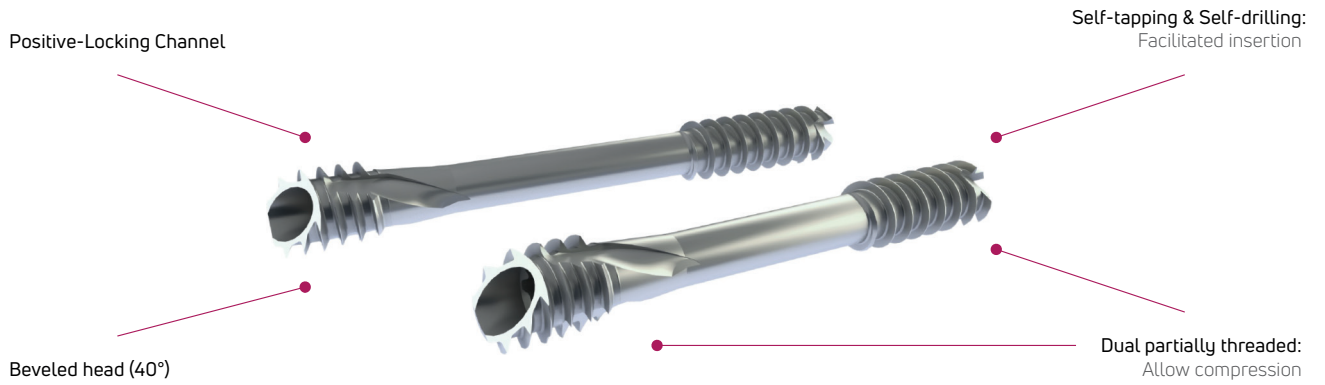
**Exact-T<sup>®</sup> recess:** Allows exact beveled implant head positioning



# DESIGN FEATURES

## PECA®-C Ø 4 - Beveled compressive implants

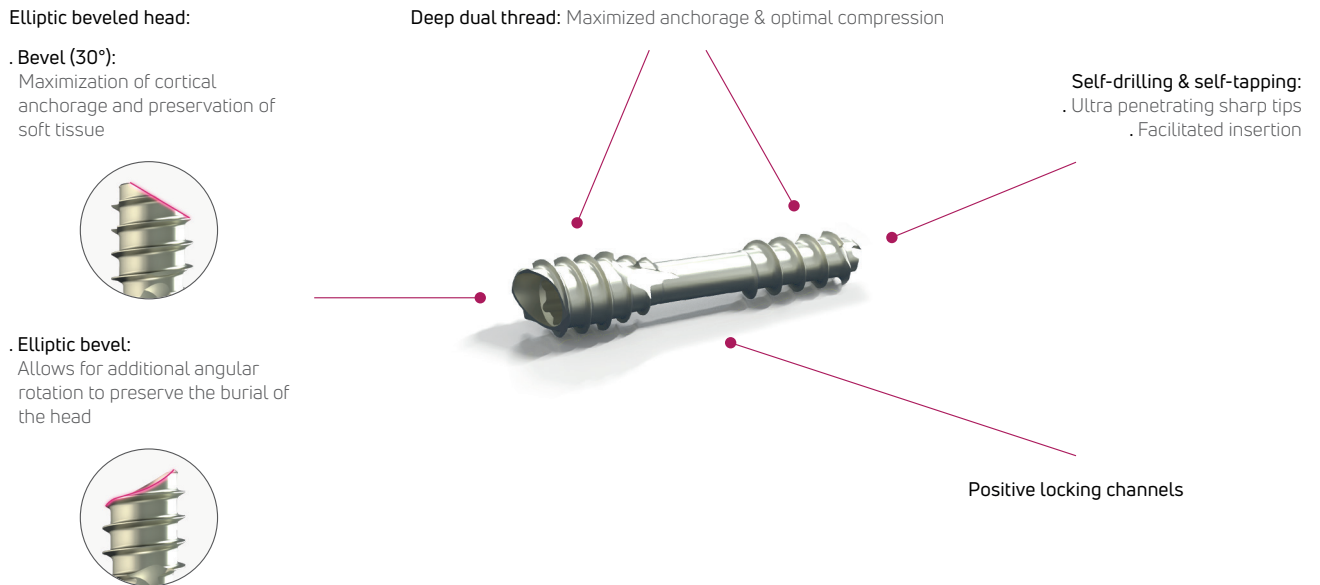
2



Exact-T® recess: Allows exact beveled implant head positioning



## Nexis® MIS Ø 2.7 - Beveled compressive screws for Akin osteotomy



Exact2-T recess: Specific & universal



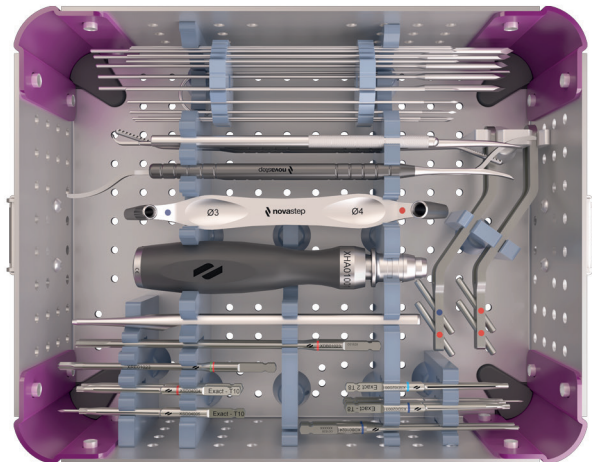







# DESIGN FEATURES

## 4 - PECA®, PECA®-C & Nexis® MIS instruments

The PECA® set combines specific instrumentation for PECA®, PECA®-C and Nexis® MIS implants, and percutaneous instrumentation including periosteal elevator, rasps, reduction device and beaver blade holder for fast, accurate and dedicated percutaneous surgery.

### Percutaneous instruments



-  Percutaneous rasps
-  Periosteal elevator double tip
-  Periosteal elevator single tip
-  *Reduction device double tip - optional*
-  Beaver handle

### Instruments

#### Exact-T® Technology: patented innovation

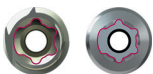
Exact-T® - Patent pending - facilitates correct placement of implant upon insertion.

#### PECA® screws



**Exact-T® recess:**  
**Specific:** easy indexing of the Exact-T® screwdriver tip.  
 Allows exact driver positioning in one direction only.

#### Nexis® MIS screws



**Exact2-T recess:**  
**Specific:** easy indexing of the Exact2-T8 screwdriver tip.  
**Universal:** possible removal with standard instrumentation.

#### Visual guideline:

The black laser marking aligns with the beveled head of the implant, identifying the medial cortex of the first metatarsal, ensuring proper placement when implanted.



### Sterile percutaneous burrs

Intelligently designed single use burrs offer precision bone resection and removal without violating soft tissue structures.



# SURGICAL TECHNIQUE

This document provides technical guidance for the proper usage of PECA® and PECA®-C implants with Tarsoplasty® guide. However Enovis™ does not practice medicine and does not recommend this or any other surgical technique. Each surgeon must consider the specific needs of each patient and is responsible for making applicable adjustments and determining and using the appropriate techniques for implanting the device in each cases.

## Step 1 - Percutaneous incision & feeler positioning

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Perform a percutaneous incision at the dorsal lateral aspect of the 1st MTP joint and use a beaver blade to release the suspensor ligament. Check the lowering of the sesamoids and cut the joint tendon if necessary.

Identify the middle of the cuneo-metatarsal joint and make a vertical percutaneous incision. Introduce the joint feeler fully across the 1st cuneo-metatarsal joint. Make sure that the laser markings are correctly oriented: M1 towards the metatarsal and C1 towards the cuneiform.

**Note:** Graduations on the feeler allow to know the depth of the joint for the correct articular surfaces preparation.



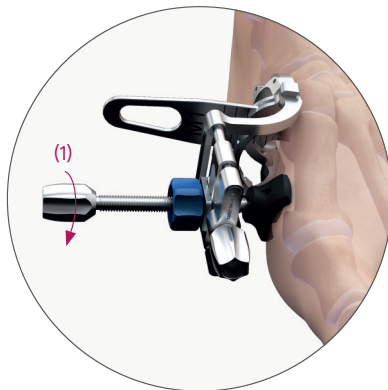
## Step 2 - Tarsoplasty® correction guide placement

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Refer to page 5 for guide assembly.

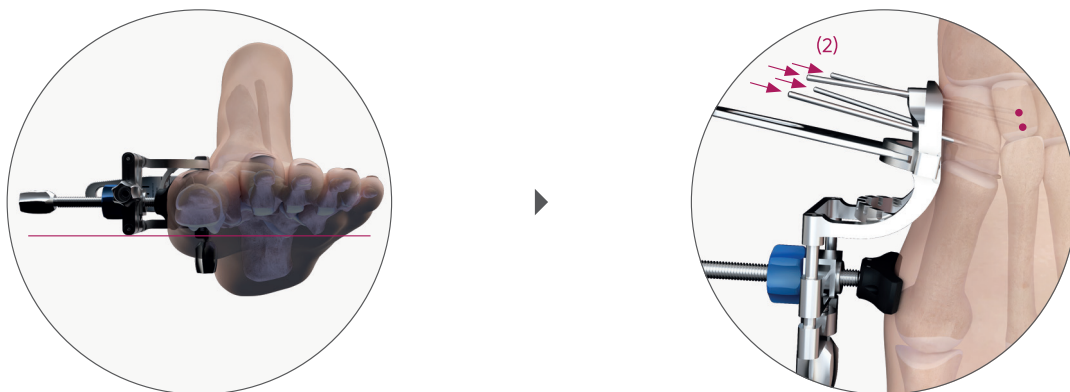
Place the correction guide on the foot by sliding the burr window over the feeler.

Ensure the guide is positioned medial to the first metatarsal and turn the reduction dial clockwise until the black support is in contact with the head of the first metatarsal (1).



# SURGICAL TECHNIQUE

Align the guide with the plantar arch and once positioned in the appropriate orientation, fix the position of the guide with the four positioning pins (2). The two K-Wires secured through the center holes of the guide should span across the middle cuneiform to increase stability.

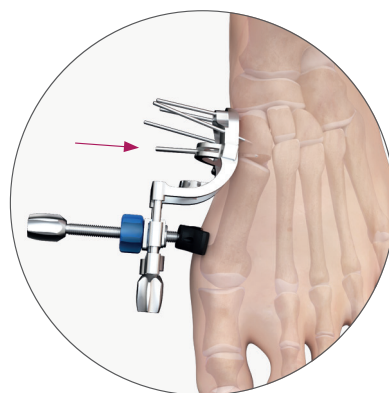


## Step 3 - First cuneiform preparation

Perform the cut of the articular surface of the first cuneiform using a Shannon Longa Ø 2.2 Lg 22 mm percutaneous burr through the burr window.

Perform fluoroscopic control throughout the joint preparation to avoid cutting into the base of the 2nd metatarsal.

**Note:** The surgeon may opt to use the Shannon Larga Ø 3.0 Lg 20 mm burr if more resection is desired.



# SURGICAL TECHNIQUE

## Step 4 - Translation, Frontal plane rotation & Sagittal alignment

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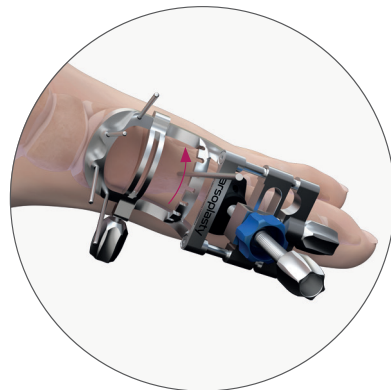
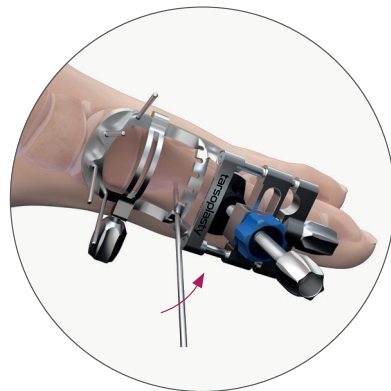
### 1 - Translation

To reduce the intermetatarsal angle turn the reduction dial until desired correction is obtained.



### 2 - Frontal plane rotation

Once the correction in the transverse plane is achieved, introduce a  $\varnothing$  1.8 x 150 mm K-wire through plantar hole in the rotation control arc. Rotate the k-wire dorsally until the sesamoids are covered by the 1st metatarsal under image intensification. Lock the k-wire in one of the holes of the rotation arc.

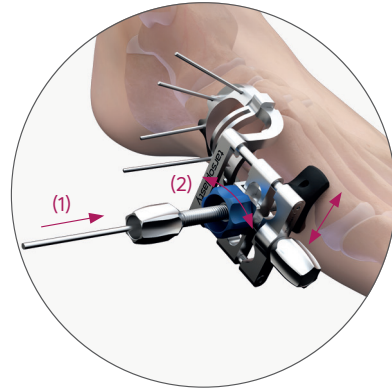


# SURGICAL TECHNIQUE

## 3 - Sagittal alignment

Insert a second  $\varnothing$  1.8 Lg 150 k-wire (1) through the reduction dial wheel to fix the correction. Then remove the first k-wire from the rotation control arc.

Unlock the blue elevation dial by turning it (2) to raise or lower the first metatarsal head. Turn the blue dial clockwise to lock the position when the desired head height is reached.



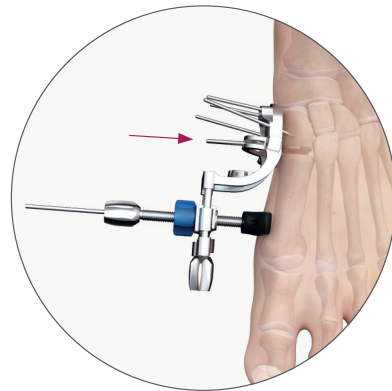
## Step 5 - First metatarsal preparation

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Insert a Shannon Longa  $\varnothing$  2.2 Lg 22 mm percutaneous burr through the burr window to perform the cut of the articular surface at the base of first metatarsal.

**Note:** If there is no resistance during the cutting of the first metatarsal, turn the compression dial clockwise to bring the first metatarsal closer to the first cuneiform.

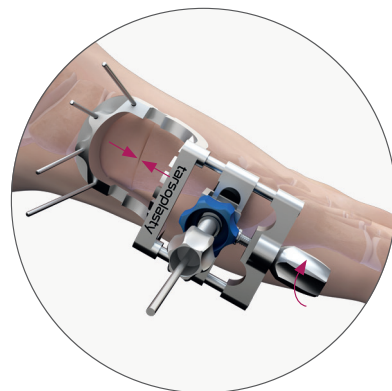
Remove the burr window and clean the joint to remove bone fragments. Use a fluoroscopy view to confirm the correct preparation of the articular surfaces.



## Step 6 - Compression

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Turn the compression dial clockwise to bring the first metatarsal and first cuneiform closer to induce compression of the articular surfaces.



Up to 15 mm maximum compression

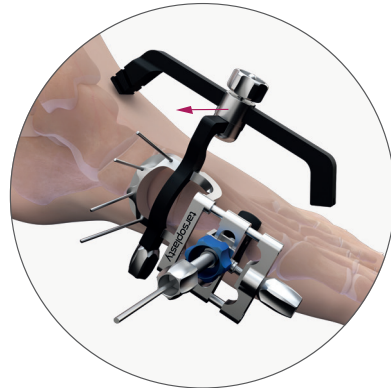
# SURGICAL TECHNIQUE

## Step 7 - Targeting guide placement

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Position the radiolucent targeting arm on the guide instead of the cutting window and fix it by turning its dial clockwise.

Slide the radiolucent targeting guide on the targeting arm.



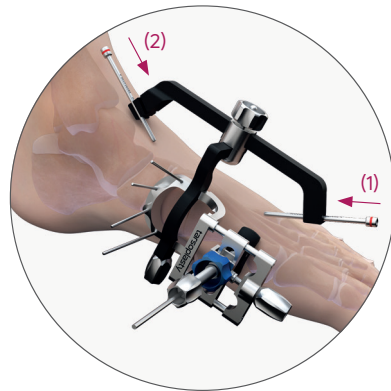
## Step 8 - K-wires positioning

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### 1 - K-wire sleeves positioning

Place the PECA® long k-wire sleeves in the holes of the extremities of the targeting guide. Start by the distal k-wire sleeve placement (1) and make sure that the k-wire sleeve tip is in the axis of the first metatarsal. Then, place the proximal k-wire sleeve (2).

**Note:** 4 holes are available on the proximal extremity of the targeting guide providing a variation angle of 5° to ensure proper placement of the k-wire sleeves depending on the patient's anatomy.



### 2 - Targeting guide adjustment

Adjust the positioning of the targeting guide by lateral or rotational movements (45° maximum around the apex) and turn the dial on the targeting guide to lock the position. Use a fluoroscopy view to confirm entry points of k-wires.



# SURGICAL TECHNIQUE

## 3 - K-wires insertion

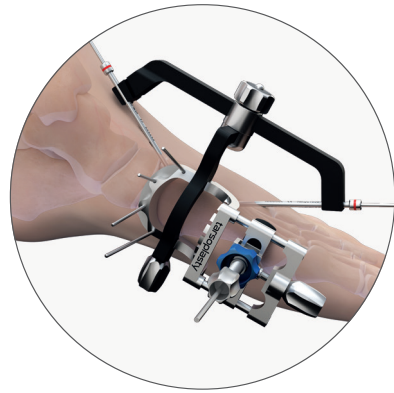
Perform a percutaneous incision in the prolongation of the distal k-wire sleeve. Insert the distal k-wire through the k-wire sleeve, passing the two cortices. Keep the sleeve in position and repeat the steps for the proximal k-wire.

### Ideal screws positioning:

- . **Distal k-wire:** The point of entry is at the crest of the first metatarsal. Aim the medial proximal corner of the cuneiform.
- . **Proximal k-wire:** Aim the cuneiform.

Remove the k-wire sleeves and perform a fluoroscopic control to confirm the correct placement of the k-wires.

**Note:** Targeting arm and targeting guide are radiolucent.



# SURGICAL TECHNIQUE

## Step 9 - PECA® & PECA®-C implants insertion

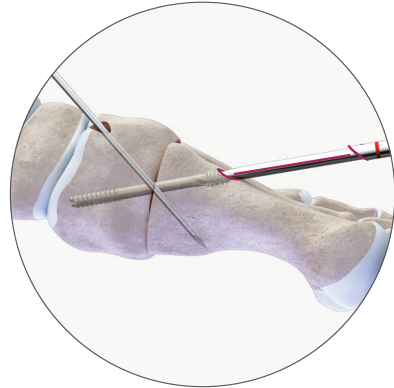
Let the Tarsoplasty® correction guide in place to maintain the correction.

Determine the required distal screw length with the ruler. A PECA®-C implant is chosen that is shorter than the measured length to ensure that the implant is fully recessed after insertion.

Overdrill the distal K-wire using the Ø 3.2 drill bit and insert the distal PECA®-C Ø 4 implant with the Exact-T®10 AO screwdriver tip. Use oblique fluoroscopy view to confirm the placement of the screw.

Repeat the steps for the proximal PECA® Ø 4 implant.

Use oblique fluoroscopy view to confirm the placement of the screw and remove the correction guide.



**Note:** The choice of implants between PECA® Ø 4 or PECA®-C Ø 4 is at the surgeon's discretion depending of the need of stabilization or additional compression needed at the Lapidus joint.  
If needed, an additional screw can be added on C1-C2, M1-M2 or M1-C2.



# SURGICAL TECHNIQUE

## Additional step - Akin osteotomy

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If interphalangeous deformity is noted after the metatarsal osteotomy, an Akin may be performed.

### 1 - Incisions

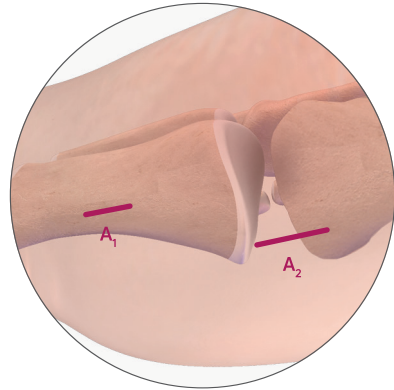
Two percutaneous incisions are made:

#### A1 – Phalanx osteotomy incision:

At the meta-diaphyseal margin of the medial proximal phalanx.

#### A2 – Implant insertion incision:

At the medial base of the hallux proximal phalanx.



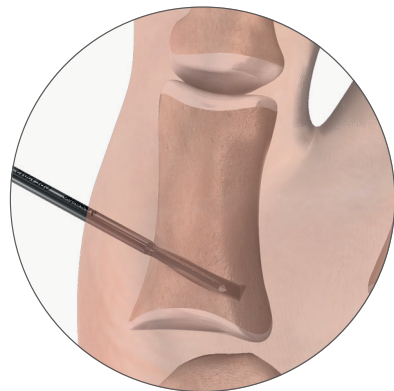
### 2 - Osteotomy

Under fluoroscopic guidance, the Shannon recta Ø2 Lg 12 mm burr is inserted through incision A1, through the medial cortex, midaxially. Aim the burr proximally for an oblique Akin osteotomy, while preserving the lateral cortex.

The dorsal limb is completed while holding the hallux interphalangeal joint dorsiflexed to prevent damage to the extensor hallucis longus tendon.

The plantar limb is completed with the hallux interphalangeal joint plantarflexed to prevent damage to the flexor hallucis longus tendon.

The hallux is placed in varus to correct any remaining valgus deformity and to ensure that the hallux is not touching the second toe.

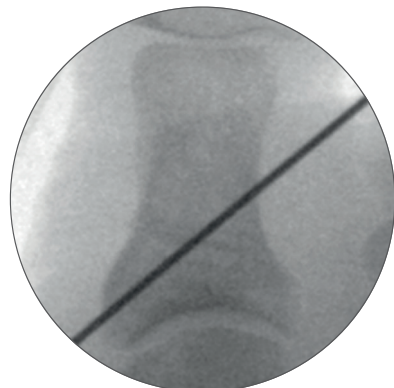


### 3 - Nexis® MIS Ø 2.7 mm

A Ø 1.0 mm K-wire for the Nexis® MIS Ø 2.7 mm insertion screw is then placed percutaneously through incision A2 from the medial base of the hallux proximal phalanx across the Akin osteotomy site and through the distal lateral cortex.

The position is checked on AP and lateral fluoroscopy views.

The K-wire is then measured with the Nexis® / PECA® ruler. A Nexis® MIS screw is chosen that is 2-4 mm shorter than the measured length to ensure that the implant is fully recessed after insertion.



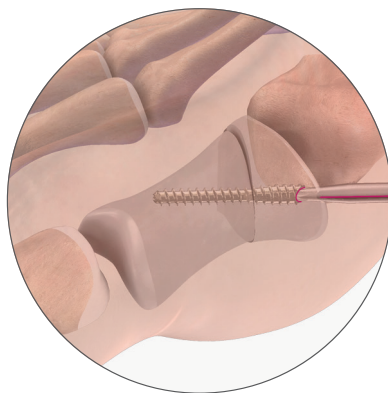
**Option:** The Nexis® MIS screw can also be used with a Ø 1.2 mm K-wire.

# SURGICAL TECHNIQUE

Insert the Nexis® MIS Ø 2.7 mm screw with the Exact-2 T8 screwdriver.

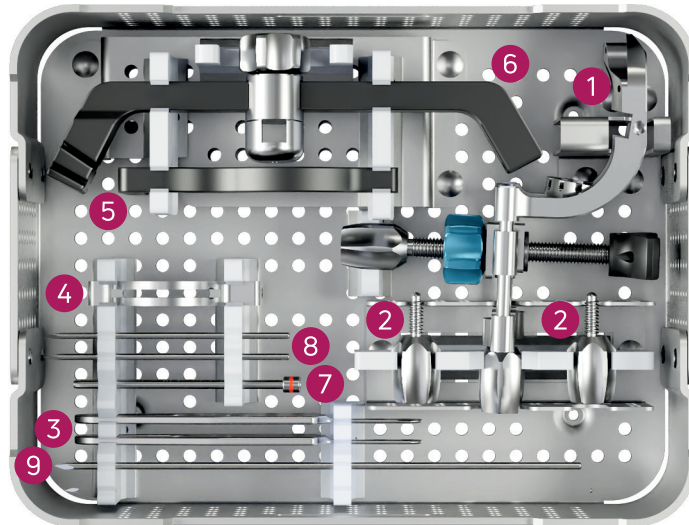
Final AP and lateral fluoroscopy views of the hallux are checked.

**Option:** The PECA® Ø 3 stabilization implant can also be used for this step. In this case, be sure to use the associated Exact®-T8 screwdriver.



# REFERENCES

## 1 - Tarsoplasty® guide



### Targeting guide instrumentation

Number	Ref	Description	Qty
-	ACC1020P0001	Tray	1
-	ACC1020P0002	Lid	1
1	XMS01041-1	Correction guide	1
2	XMS01041-6	Locking wheel	2
3	XMS01041-2	Feeler	2
4	XMS01041-4	Burr window	1
5	XMS01041-5	Targeting arm	1
6	XMS01041-3	Targeting guide	1
7	XMS01038-7	Long K-wire sleeve	2
8	SKW05005	Threaded k-wire Ø 1.8 Lg 70 - sterile <sup>(1) (2)</sup>	5
9	SKW01022	K-wire Ø 1.8 Lg 140 TR-RD - sterile <sup>(1) (2)</sup>	3



<sup>(1)</sup>K-wire supplied separately

<sup>(2)</sup>Non-sterile k-wire is also available

# REFERENCES

## 2 - PECA<sup>®</sup>, PECA-C<sup>®</sup> implants & Nexis<sup>®</sup> MIS screws

### PECA<sup>®</sup> & PECA-C<sup>®</sup> implants



Length (mm)	PECA <sup>®</sup> Bunion implant Ø 4	PECA <sup>®</sup> -C Beveled compressive implant Ø 4
18	-	PS050118
20	-	PS050120
22	-	PS050122
24	-	PS050124
26	PS050026	PS050126
28	PS050028	PS050128
30	PS050030	PS050130
32	PS050032	PS050132
34	PS050034	PS050134
36	PS050036	PS050136
38	PS050038	PS050138
40	PS050040	PS050140
42	PS050042	PS050142
44	PS050044	PS050144
46	PS050046	PS050146
48	PS050048	PS050148
50	PS050050	PS050150
52	PS050052	-
54	PS050054	-
55	-	PS050155
56	PS050056	-
58	PS050058	-
60	PS050060	PS050160

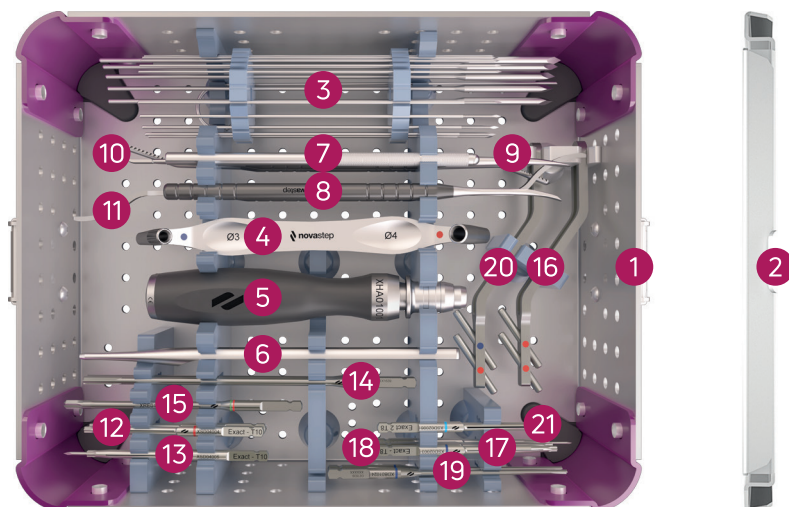
### Nexis<sup>®</sup> MIS beveled compressive screw Ø 2.7



Length (mm)	Nexis <sup>®</sup> MIS Ø 2.7 mm
14	SC090014
16	SC090016
18	SC090018
20	SC090020
22	SC090022
24	SC090024
26	SC090026
28	SC090028
30	SC090030

# REFERENCES

## 3 - PECA®, PECA®-C & Nexis® MIS instruments



### Universal instruments

Number	Ref	Description	Qty
1	ACC1001P0022	Tray	1
2	ACC1001P0024	Lid	1
3	ACC1001P0023	K-wires holder	1
	CKW03001	Reduction wire	5 <sup>(2)</sup>
	CKW02004 <sup>(1)</sup>	K-wire Ø 1.0 Lg 150 TR/RD CoCr	5 <sup>(2)</sup>
	CKW02005 <sup>(1)</sup>	K-wire Ø 1.4 Lg 150 TR/RD CoCr	8 <sup>(2)</sup>
	XKW01001	Cleaning pin Ø 0.9	1
	XKW01002	Cleaning pin Ø 1.4	1
4	XDG01024	PECA® / PECA®-C - Tissue protector	1
5	XHA01001	AO handle	1
6	XGA01009	Nexis® / PECA® - Ruler Lg 150	1

<sup>(1)</sup> K-wire supplied separately.

<sup>(2)</sup> Maximum quantity of the K-wire holder.

### Percutaneous instruments

Number	Ref	Description	Qty
7	SF13 <sup>(3)</sup>	Long beaver handle	1
8	XMS01011	Perioestal elevator single tip	1
9	XMS01008	Perioestal elevator double tip	1
10	XMS01009	Percutaneous rasps	1
11	XMS01027	Reduction device double tip	Optional

<sup>(3)</sup> Reference supplied separately - availability depending on your market.

### PECA® Ø 4 instruments


Number	Ref	Description	Qty
12	XSD04004	Exact-T®10 AO screwdriver tip	2
13	XSD04005	Solid Exact-T®10 AO screwdriver tip	Optional
14	XDB01023	AO drill bit Ø 3.2	2
15	XRE01007	Nexis® / PECA®-C - Countersink Ø 3.7	Optional
16	XMS01038-6	PECA® Ø 4 - Ø 4 - Parallel guide	Optional

# REFERENCES

## PECA® Ø 3 instruments

Number	Ref	Description	Qty	
17	XSD02003	Exact-T®8 AO screwdriver tip	1	
18	XSD02004	Solid Exact-T®8 AO screwdriver tip	Optional	
19	XDB01024	AO drill bit Ø 2	2	
20	XMS01038-5	PECA® Ø 3 - Ø 4 - Parallele guide	Optional	

## Nexis® MIS Ø 2.7 instruments

Number	Ref	Description	Qty	
21	XSD02006	Exact-2 T8 AO screwdriver tip	2	
	XGA01013	Ruler Lg 100 / 150	Optional	
	-	K-wire Ø 1.2 Lg 100 TR/RD <sup>(4)</sup>	Optional	
	-	K-wire Ø 1.2 Lg 150 TR/RD <sup>(5)</sup>	Optional	

<sup>(4)</sup> K-wire supplied separately - Medetechnik® K-wire or Novastep® K-wire (CKW01014) are available depending on your market.

<sup>(5)</sup> K-wire supplied separately - Medetechnik® K-wire or Novastep® K-wire (CKW01015) are available depending on your market.

## 4 - Percutaneous burrs

Ref	Description	
CRE12008	Shannon Corta Ø 2.0 Lg 8 mm	
CRE12012	Shannon Recta Ø 2.0 Lg 12 mm	
CRE12212	Shannon Helical Ø 2.0 Lg 12 mm	
CRE12222	Shannon Longa Ø 2.2 Lg 22 mm	
CRE13020	Shannon Larga Ø 3.0 Lg 20 mm	
CRE13030	Shannon X-Larga Ø 3.0 Lg 30 mm	
CRE23113	Wedge Ø 3.1	
CRE24113	Wedge Ø 4.1	



# tarsoplasty<sup>®</sup>

Percutaneous Lapidus Correction

**Please note:**

Carefully read the enclosed Instructions For Use (IFU) and all packaging label information. Devices: Implants: Class IIb-CE1639 / Instruments: Class I / Class Ir-CE1639 / Class IIa-CE1639.

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