

pecaplasty[®]

Percutaneous Bunion Correction



OPERATIVE TECHNIQUE

FOREFOOT



- . Easy positioning on the foot
- . Controlled translation of metatarsal head
- . Accurate placement of k-wires

*Creating
Better
Together[™]*

pecaplasty®

Percutaneous Bunion Correction

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In memory of Lilian Gazonnet

Lead Designer of Pecaplasty® Percutaneous Bunion Correction System.
September 30th, 1976 - February 26th, 2022.
The engineer who turned a concept into a reality

Surgeons contributing to writing the surgical technique:

. **Dr Tristan Meusnier**, MD - Clinique Saint-Charles, Lyon, France.
. **Dr Bradley P. Abicht**, DPM, FACFAS - Gunderson Health System, La Crosse, WI. USA.

Introduction

With its easy positioning on the foot, the Pecaplasty® targeting guide allows for a simple, precise and reproducible correction of Hallux Valgus in percutaneous surgery.

Associated with Pecaplasty®, PECA® implant system provides a complete and versatile portfolio of beveled fully threaded implants. The Exact-T® Recess provides high precision in fluoro percutaneous implant positioning.

Indications & Contraindications

Indications

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

Example of use:

Surgical correction of hallux valgus performing percutaneous metatarsal and Akin osteotomies.

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:

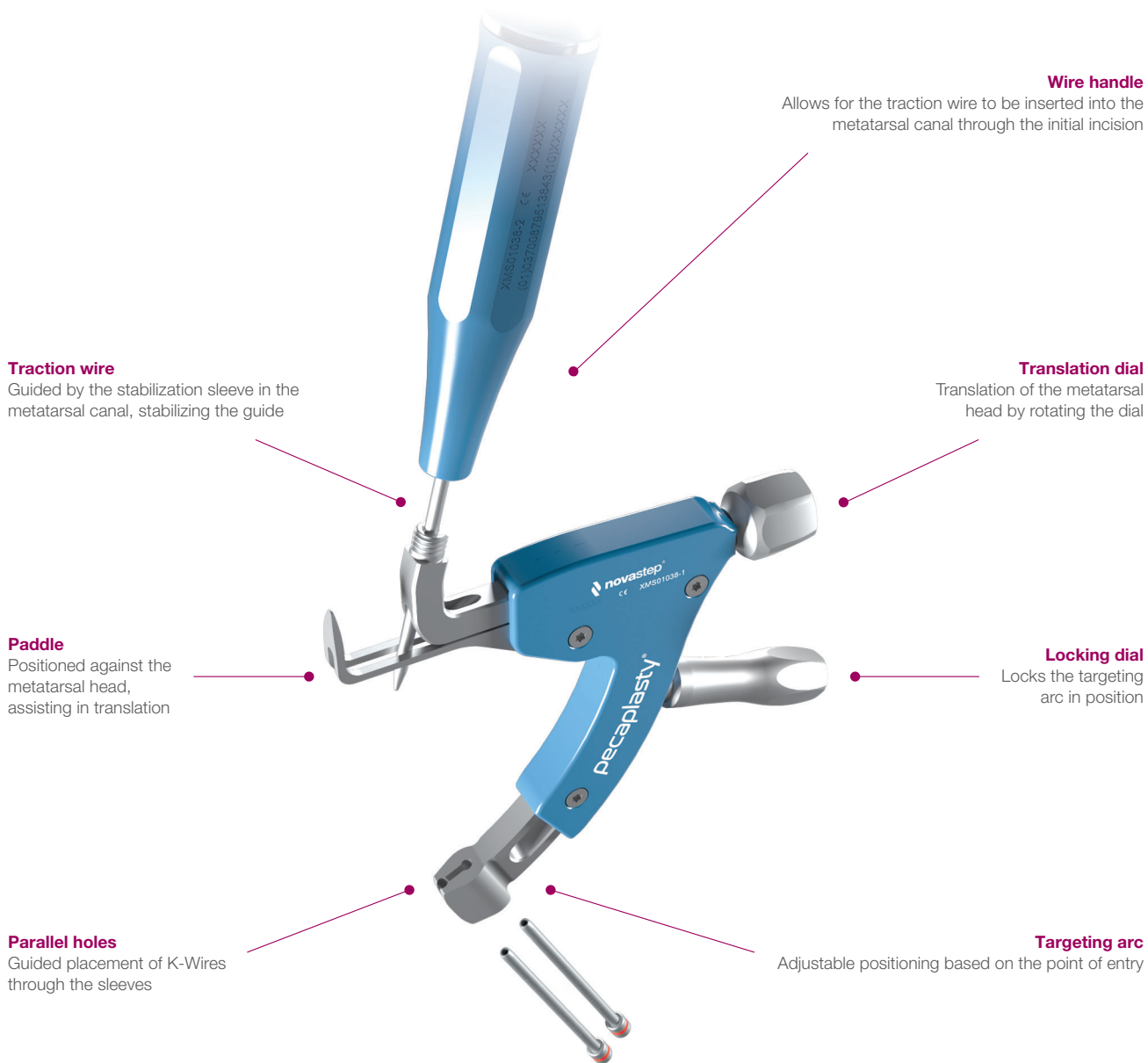
- Severe muscular, neurological or vascular deficiency in the extremity concerned.
- Bone destruction or poor bone quality, likely to impair implant stability.
- Hypersensitivity to vanadium and/or aluminium.



Design Features

1 - Pecaplasty® targeting guide

Key features

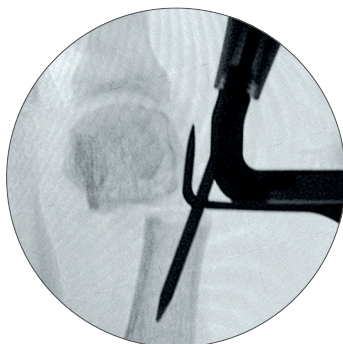
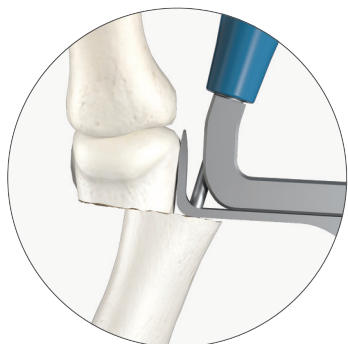


PATENT PENDING

Design Features

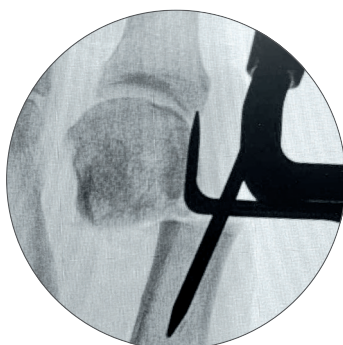
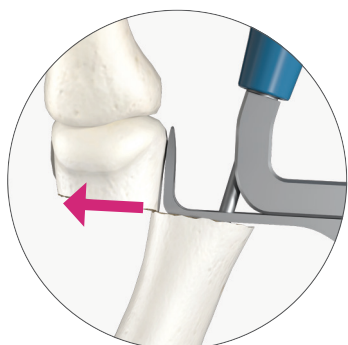
Guided & reproducible procedure

1 Easy positioning on the foot



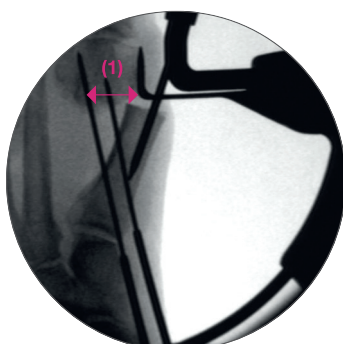
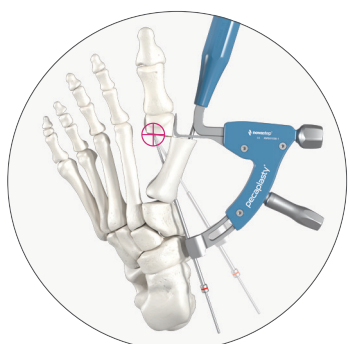
POSITION the guide by inserting the paddle underneath the medial capsule through initial incision, after a transverse osteotomy.

2 Controlled translation of metatarsal head



TRANSLATE the metatarsal head using the translation dial.

3 Accurate placement of K-Wires

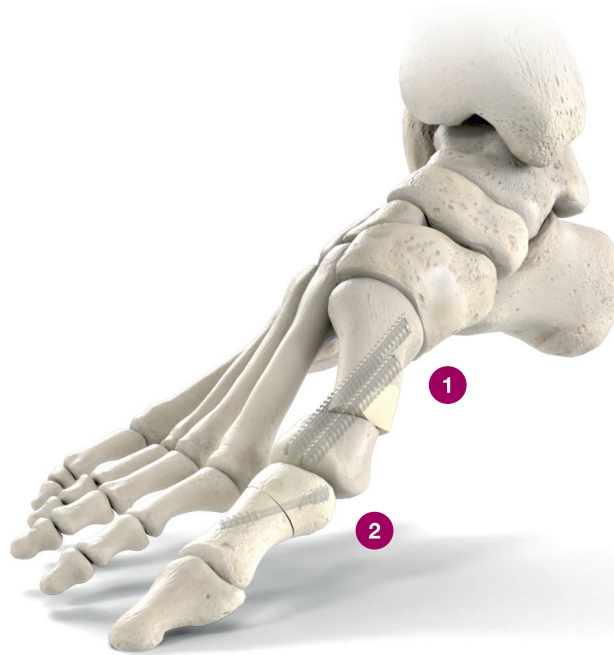


ADJUST the arc around its center of rotation to allow proper placement of the k-wires.

- Insertion point must be as proximal as possible to ensure bicortical fixation.
- Aiming point is fixed, always 14 mm (1) from the paddle.

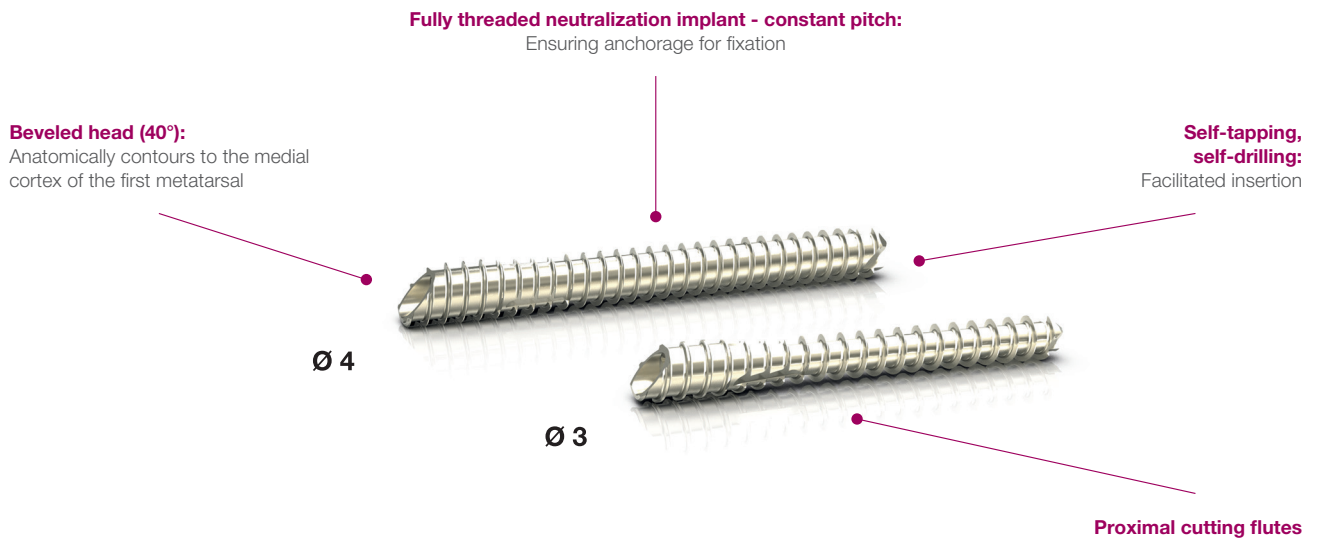
Design Features

2 - PECA[®] implants & Nexis[®] MIS screws



PECA[®] Ø 3 & Ø 4 - Stabilization screws

1



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



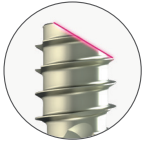
Design Features

Nexis® MIS Ø 2.7 - Beveled compressive screws

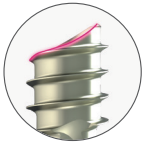
2

Elliptic beveled head:

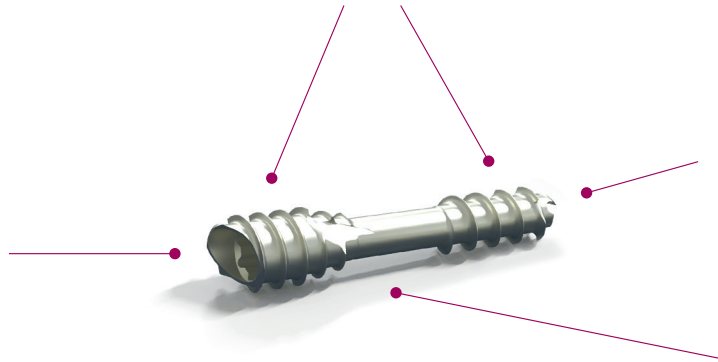
- **Bevel (30°):**
Maximization of cortical anchorage and preservation of soft tissue



- **Elliptic bevel:**
Allows for additional angular rotation to preserve the burial of the head



Deep dual thread: Maximized anchorage & compression



Self-drilling & self-tapping:

- Penetrating sharp tips
- Facilitated insertion

Positive locking channel

Exact2-T recess: Specific & universal

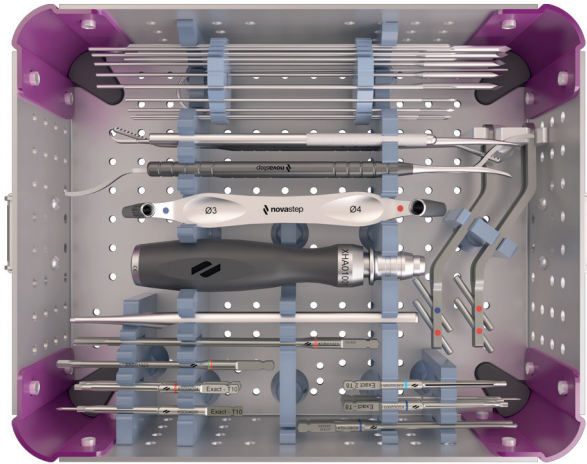







Design Features

3 - PECA® instruments

The PECA® set combines specific instrumentation for PECA® 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.

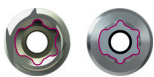
PECA® screws



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 Nexis® MIS 2.7 implants. However Novastep® 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 - Patient positioning

The procedure may be performed with or without use of a tourniquet and is at the discretion of the surgeon. If tourniquet is utilized, periodic irrigation should be considered when using the percutaneous burrs in order to limit potential risks for thermal soft tissue injury or osseous necrosis. Tourniquet should be positioned above the ankle so as not interfere when inserting the K-wires.

The patient is positioned supine with the ankle of the operated foot resting on a round wedge and the heel in the void to easily use the C-arm. The position of the C-arm is at the discretion of the surgeon.



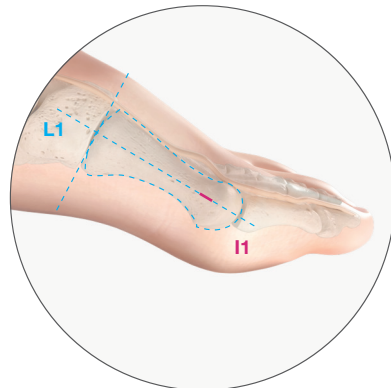
Step 2 - Transverse osteotomy of the first metatarsal

2.1 - Landmarks & incision

With a marking pen, draw the longitudinal bisection of the first metatarsal (L1). The bunion and the first tarsometatarsal joint can also be drawn.

A percutaneous longitudinal incision is made along the medial aspect of the first metatarsal neck and behind the exostosis (I1). Use a periosteal elevator to create a working space above and under the metatarsal neck.

Through the incision, make a vertical incision from the capsule to its proximal insertion at the edge of the head.



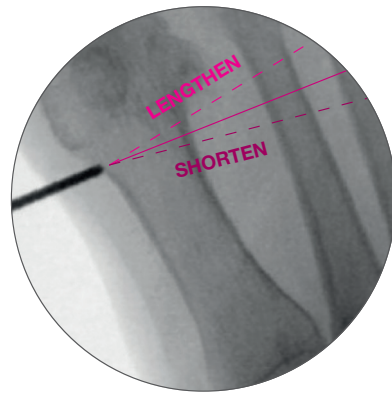
Surgical Technique

2.2 - Transverse osteotomy

Use a Shannon Longa Ø 2.2 Lg 22 burr to perform a transverse osteotomy, perpendicular to M2. Insert the burr through the initial percutaneous incision slightly proximal to the sesamoid complex.

Ensure proper burr orientation and angle that will result in the desired first ray length following the osteotomy.

Note: The burr will resect 2-3 mm of bone, which must be taken into account when performing the osteotomy.



Step 3 - Pecaplasty® targeting guide placement

3.1 - Targeting guide preparation

- 1 Turn the translation dial to bring the stabilization sleeve closer to the targeting guide.
- 2 Loosen the locking dial and retract the targeting arc. Tighten the locking dial to lock the arc.



3.2 - Paddle & stabilization sleeve positioning

Through the initial incision, introduce the paddle underneath the medial capsule on the metatarsal head (1).

The placement of the paddle underneath the capsule assists maintaining proper positioning.

Turn the translation dial (2) to bring the stabilization sleeve closer to the skin (3). A stop prevents excessive pressure on the soft tissue.



Surgical Technique

3.3 - Traction wire insertion

Insert the traction wire, fastened with the wire handle, through the initial incision and into the medullary canal through the opening in the stabilization sleeve (1).



Once into the canal, maneuver the wire handle towards the hallux until it is seated in the axis of the metatarsal, against the medial cortex (2). Fasten it into the Pecaplasty® targeting guide (3).



3.4 - Targeting guide positioning

Proper positioning increases the accuracy of the Pecaplasty® targeting guide.

The paddle should be oriented parallel with the long axis of the second metatarsal. The arm of the paddle should be oriented perpendicular to the long axis of the second metatarsal.

Keep the guide positioned against the diaphyseal cut in the axis of the metatarsal.

Note: The Pecaplasty® targeting guide should be held parallel to the longitudinal bisection of the first metatarsal previously drawn.



Surgical Technique

Step 4 - Controlled metatarsal head translation

The hallux is held against the wire handle in order to control the rotation while the metatarsal head is held between the thumb and forefinger to control the dorso-plantar position of the metatarsal head, until K-wires are placed. Keep holding the guide against the diaphyseal cut.



Engage the paddle against the capital fragment by turning the translation dial in clockwise fashion to translate the capital fragment laterally until the appropriate correction is achieved. This can be confirmed through direct clinical visualization and with fluoroscopy.

Note: Naturally, the metatarsus varus will increase and lock the CM1 joint in abutment.



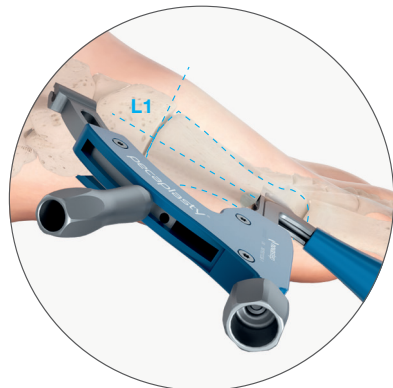
Step 5 - K-wires placement

5.1 - Arc deployment

Unlock the locking dial to extend the arc until it comes in contact with the skin. The locking dial is then turned clockwise to lock the targeting arc in extension once the guide is in appropriate position.

Adjust the position of the targeting guide to make sure the guide is held parallel to the longitudinal bisection of the first metatarsal, at the level of the L1 line.

Note: The Pecaplasty® targeting guide should be parallel to the plantar sole of the foot.



Maintain a soft pressure in order not to lose contact of the paddle with the proximal part of M1.

Surgical Technique

Keep holding the toe against the wire handle and the metatarsal head between your thumb and forefinger in order to control the rotation and dorso-plantar position of the metatarsal head.



5.2 - K-wires insertion

Note: Starting by positioning the distal K-wire allows the stabilization of the guide in position, which will enable the proximal K-wire and associated screw to be positioned as proximally as possible.

Position the PECA® Ø 4 - K-wire sleeve in the distal screw hole until it touches the skin. From the point of contact and in the extension of the sleeve, make a percutaneous incision on the L1 line to the bone. Bring the tip of the sleeve in contact with the bone. Control the height of the metatarsal head by holding the osteotomy between the thumb and forefinger to ensure alignment of the dorsal cortices of the metatarsal head and shaft. Insert the Ø 1.4 mm K-wire by passing the two cortices without pushing on the K-Wire. Let the distal K-wire sleeve in place and repeat the steps for the proximal sleeve.



Surgical Technique

Note: A PECA® Ø 4 implant is recommended at this step. The Ø 1.4 mm K-wire is recommended over the Ø 1.0 mm K-wire for reliable positioning, and the larger implant provides more stability to the construct.

Option: A PECA® Ø 3 implant, with Ø 1.0 mm K-wire, could be used if the patient has a smaller deformity or smaller diameter of the metatarsal.

Obtain AP and lateral fluoroscopy views to confirm correct head positioning and K-wires placement.

Option - PECA Parallel guide: PECA® Ø 4 - Ø 4 and PECA® Ø 3 - Ø 4 Parallel guides are available as option in the PECA® sets. For example, if after insertion of both K-wires, the distal K-wire is well positioned and should be used as the proximal one, then the PECA® Parallel guide can be useful to slide over the K-wire in position and guide the second one, without having to reposition the Pecaplasty® targeting guide. The interaxis is the same as the Pecaplasty® targeting guide.



Step 6 - PECA® implants insertion

6.1 - Targeting guide removal

If the positions of the K-wires are satisfactory, the Pecaplasty® targeting guide is then disassembled and removed from the percutaneous incisions.

Unscrew and remove the wire handle (1).

Turn the locking dial counterclockwise to unlock the guide (2) and remove the sleeves (3). The K-wires pass through the notch of the parallel guide and the targeting arc is retracted before removing the guide (4).



Surgical Technique

6.2 - PECA® implants insertion

The first implant length is then read with the PECA® ruler. A PECA® implant is chosen that is 6-8 mm shorter than the indicated length to ensure that the implant is fully recessed after insertion.



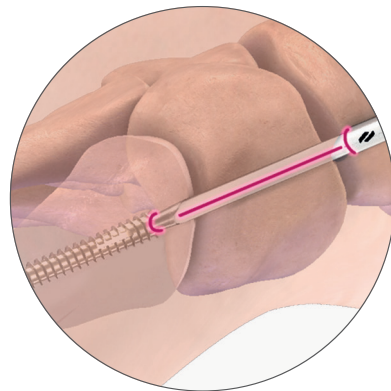
Option: To preserve soft tissue, position the tissue protector over the k-wire before drilling and inserting the screw.

Over-drill the K-wire using the drill bit \varnothing 3.2.

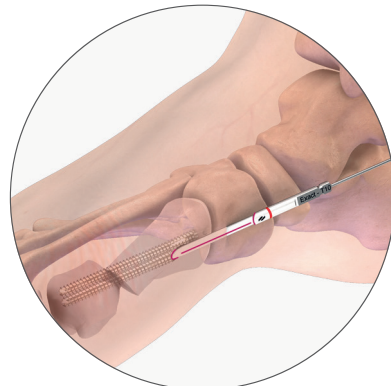
Trick: Drill from the medial cortex and stop before the lateral cortex of the metatarsal. Be careful not to remove the wire when removing the drill.

Place the PECA® \varnothing 4 implant over the wire to secure the osteotomy, using the Exact-T®10 AO screwdriver tip. The screwdriver will only engage the head of the PECA® implant in one direction, corresponding to the chamfer of the implant. Insert the PECA® \varnothing 4 implant with a power tool or by hand until the chamfer of the implant head sit flush with the medial cortex of the first metatarsal shaft after insertion.

Use oblique fluoroscopy view to confirm.



Repeat the steps for the distal PECA® implant.



Surgical Technique

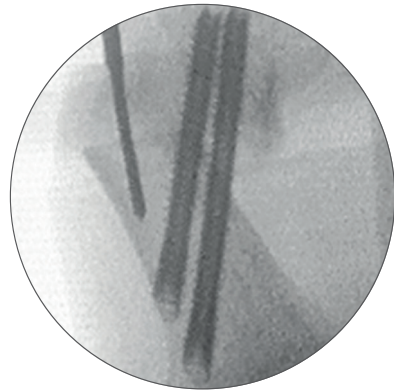
6.3 - Bone spikes removal

The proximal medial prominence of the proximal fragment of first metatarsal bone is removed using a \varnothing 2.2 Lg 22 mm Shannon Burr through the proximal PECA® implant insertion from proximal to distal (**Option 1**), or through the osteotomy incision from distal to proximal (**Option 2**), at the surgeon's discretion. Insert the burr and cut the bone dorsally then plantarly from inside out.

Trick: The entry point of the burr can be first located with the help of a K-wire.

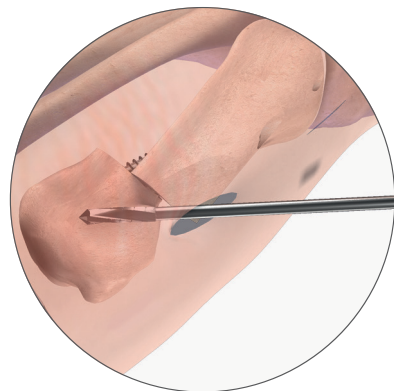


Option 1



Option 2

Then the dorso-medial eminence of the first metatarsal shaft bone is excised with a \varnothing 3.1 Lg 13 mm wedge burr through the metatarsal osteotomy incision if necessary.



Step 7 - Akin osteotomy

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

7.1 - Incisions

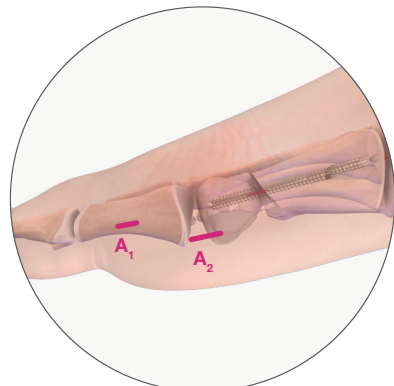
Two percutaneous incisions are made:

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.



Surgical Technique

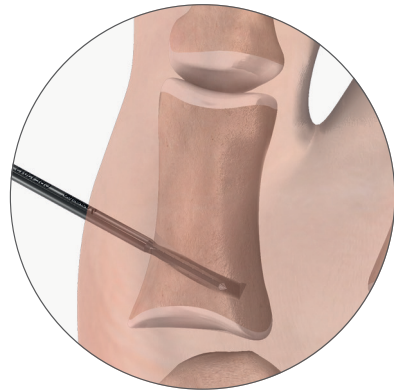
7.2 - Osteotomy

Under fluoroscopic guidance, the Ø 2 Lg 12 mm Shannon 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.



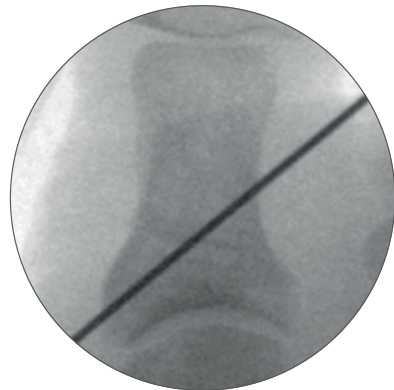
7.3 - Nexis® MIS screw

A Ø 1.0 mm K-wire for the Nexis® MIS 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 screw length is then read on the Nexis® / PECA® ruler. A Nexis® MIS screw is chosen that is 2-4 mm shorter than the indicated length to ensure that the implant is fully recessed after insertion.

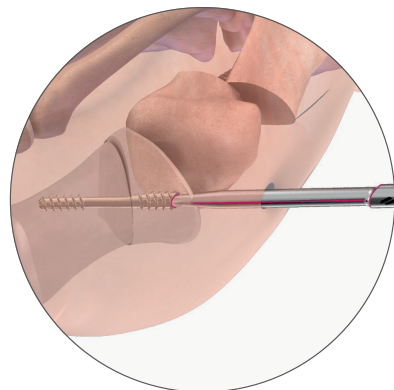
Option: The Nexis® MIS screw can also be used with a Ø 1.2 mm K-wire.



Insert the Nexis® MIS screw with the Exact-2 T8 screwdriver tip with a power tool or by hand until the lateral cortex has been reached.

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

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



Surgical Technique

Step 8 - Dressing

The incisions can be closed with the sutures or sterile strips and dressed with a nonadherent layer and 4 x 4 inch gauze. Softband or wool is placed over the foot and ankle. This is overwrapped with an ACE wrap. This dressing is left in place for two to four weeks.



References

1 - Implants

PECA® bunion implants



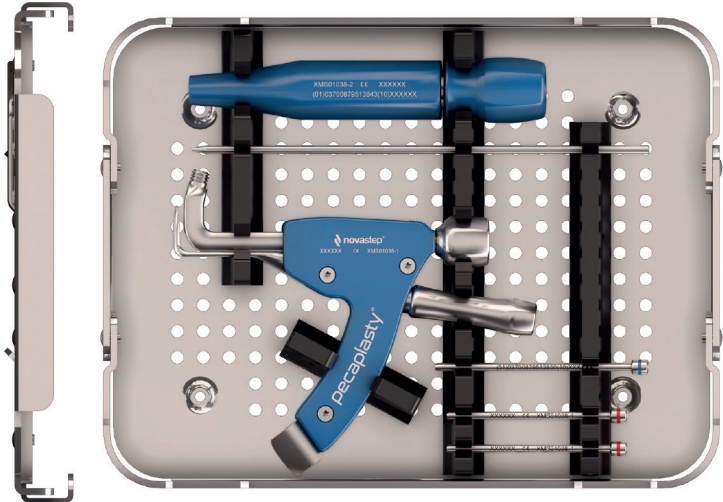
Length (mm)	PECA® Ø 3 mm	PECA® Ø 4 mm
16	PS020016	-
18	PS020018	-
20	PS020020	-
22	PS020022	-
24	PS020024	-
26	PS020026	PS050026
28	PS020028	PS050028
30	PS020030	PS050030
32	PS020032	PS050032
34	PS020034	PS050034
36	PS020036	PS050036
38	PS020038	PS050038
40	PS020040	PS050040
42	PS020042	PS050042
44	PS020044	PS050044
46	PS020046	PS050046
48	PS020048	PS050048
50	-	PS050050
52	-	PS050052
54	-	PS050054
56	-	PS050056
58	-	PS050058
60	-	PS050060

Nexis® MIS beveled compressive screw Ø 2.7

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

References

2 - Pecaplasty® targeting guide

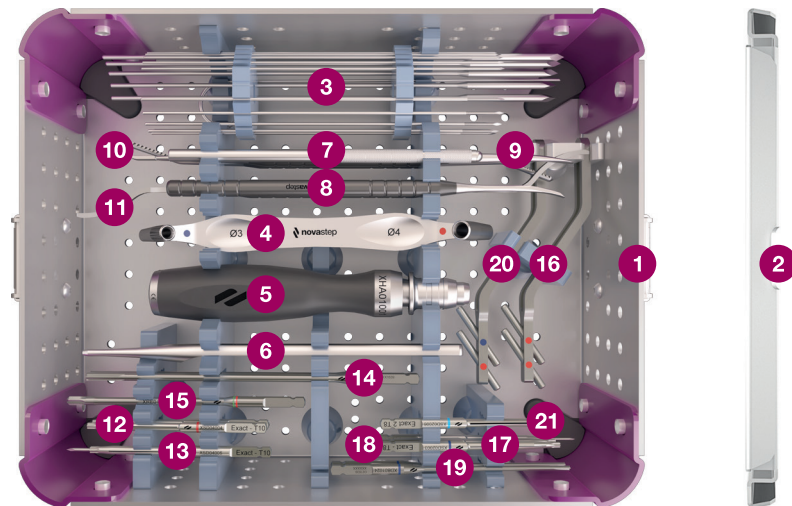


Reference	Designation	Qty	
XMS01038-1	Targeting guide	1	
XMS01038-2	Wire handle for targeting guide	1	
SKW06002 ⁽¹⁾	Traction wire Ø 2.5 lg 128 - Sterile	5	
XMS01038-3	Peca® Ø 3 - K-wire sleeve	1	
XMS01038-4	Peca® Ø 4 - K-wire sleeve	2	

⁽¹⁾Sterile traction wire supplied separately.

References

3 - PECA® implants & Nexis® MIS screws



Universal instruments

Number	Ref	Description	Qty
1	ACC1001P0022	Tray	1
2	ACC1001P0024	Lid	1
3	ACC1001P0023	K-wires holder	1
	CKW03001	Reduction wire Ø 3.5	5 ⁽²⁾
	CKW02004 ⁽¹⁾	K-wire Ø 1.0 Lg 150 TR/RD CoCr	5 ⁽²⁾
	CKW02005 ⁽¹⁾	K-wire Ø 1.4 Lg 150 TR/RD CoCr	8 ⁽²⁾
	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	PECA® - Ruler Lg 150	1

⁽¹⁾K-wire supplied separately.

⁽²⁾Maximum quantity of the K-wire holder.

Percutaneous instruments

Number	Ref	Description	Qty
7	SF13 ⁽³⁾	Fine surgical 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

⁽³⁾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	Removal 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® - Parallel guide Ø 4 - Ø 4	Optional

References

PECA® Ø 3 instruments

Number	Ref	Description	Qty	
17	XSD02003	Exact-T®8 AO screwdriver tip	1	
18	XSD02004	Removal Exact-T®8 AO screwdriver tip	Optional	
19	XDB01024	AO drill bit Ø 2	2	
20	XMS01038-5	PECA® - Parallele guide Ø 3 - Ø 4	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 ⁽⁴⁾	Optional	
	-	K-wire Ø 1.2 Lg 150 TR/RD ⁽⁵⁾	Optional	

⁽⁴⁾K-wire supplied separately - Medetchnik® K-wire (33-T10-R-12-100) or Novastep® K-wire (CKW01014) are available depending on your market.

⁽⁵⁾K-wire supplied separately - Medetchnik® K-wire (33-T10-R-12-150) or Novastep® K-wire (CKW01015) are available depending on your market.

4 - Percutaneous burrs

Ref	Description	
CRE12008	Shannon Corta Ø 2 Lg 8	
CRE12012	Shannon Recta Ø 2 Lg 12	
CRE12212	Shannon Helical Ø 2 Lg 12	
CRE12222	Shannon Longa Ø 2.2 Lg 22	
CRE13020	Shannon Larga Ø 3 Lg 20	
CRE13030	Shannon X-Larga Ø 3 Lg 30	
CRE23113	Wedge Ø 3.1 Lg 13	
CRE24113	Wedge Ø 4.1 Lg 13	

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Percutaneous Bunion 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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