peca®

OPERATIVE TECHNIQUE

FOREFOOT

Percutaneous bunion correction system
Bunion implants Ø 3 / Ø 4 mm

. **Exact-T® recess -** Precision
. **Beveled head -** Soft tissue preservation
. **Reduction wire -** Controlled metatarsal translation

Creating Better Together™

peca®

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Introduction

PECA® Implant System provides a complete and versatile portfolio of beveled fully threaded implants intended for the fixation of osteotomy and arthrodesis of the foot.
The Exact-T® Recess provides precision in fluoro percutaneous implant positioning.
Specialized soft-tissue sparing burrs and percutaneous instrumentation are used in combination with the PECA® bunion implant system to perform bone cuts and provide stable fixation.

1. 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:
Hallux valgus with percutaneous chevron and akin osteotomies.

2. Contra-indications

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

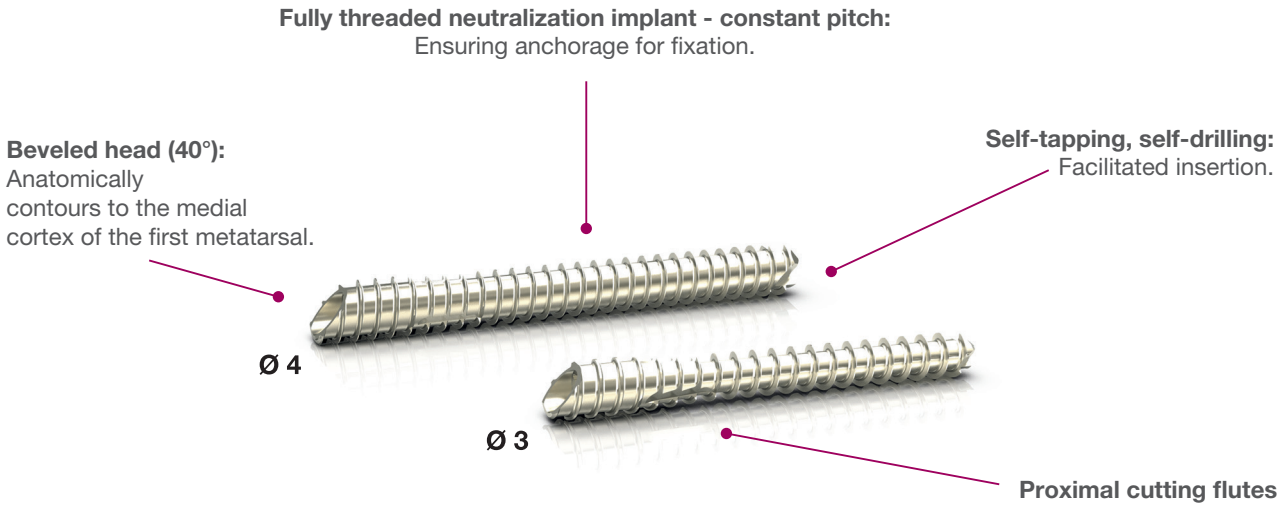
- Sever muscular, neurological or vascular deficiency in the extremity concerned
- Bone destruction or poor bone quality, likely to impair implant stability
- Hypersensitivity to vanadium and/or aluminium

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 us.

peca® System: Implants & Instruments

1 - Technical Features

Made of Titanium alloy (TA6V Eli anodised), the PECA® bunion implants are available in 3 and 4 mm diameters.



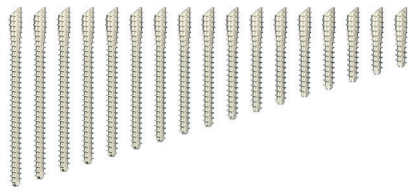
Exact-T® recess: Allows Exact beveled implant head positioning.

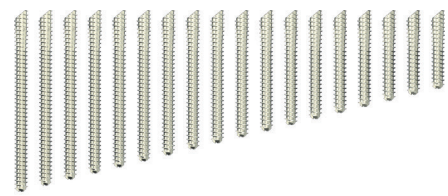
2 - PECA® Range

Instrumentation is color-coded for convenient identification.

	Ø3 peca Ø 3 mm	Ø4 peca Ø 4 mm
Driver	Exact-T®8	Exact-T®10
Length	16 - 48 mm*	26 - 60 mm*
K-wire	CoCr Ø 1.0 mm	CoCr Ø 1.4 mm
Drill Bits	Ø 2 mm	Ø 3.2 mm

** 2 mm increments.*

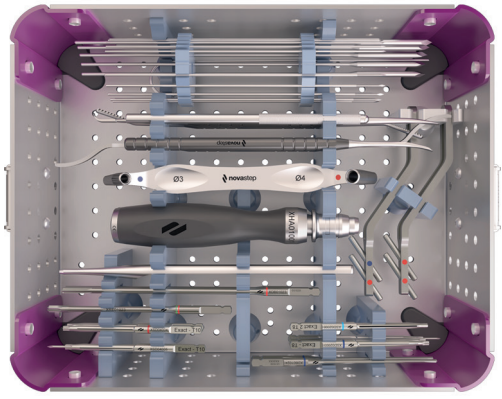




peca® System: Implants & Instruments

3 - Instrumentation

The PECA® set combines specific instrumentation for PECA® implants and percutaneous instrumentation including periosteal elevator, rasps, reduction device and beaver blade holder for percutaneous surgery.



Percutaneous instruments

Percutaneous rasps

Periosteal elevator double tip

Periosteal elevator single tip

Reduction device double tip - optional

Beaver handle

PECA® Instruments

Exact-T® Technology: patented innovation
Exact-T® - Patent pending - facilitates correct placement of implant upon insertion.

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

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.

peca® System: Implants & Instruments

Sterile burrs:

Hammertoe,
Akinette:
Shannon Corta Ø 2 Lg 8 mm

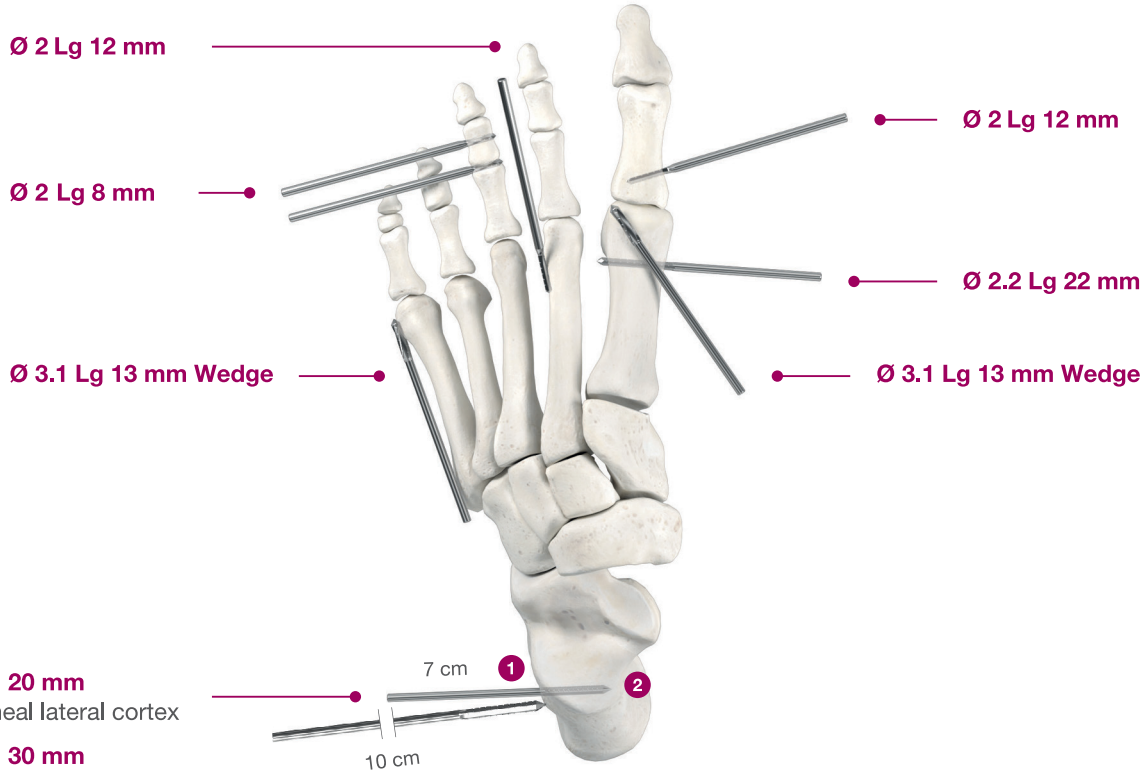
Akin, DMMO:
Shannon Recta Ø 2 Lg 12 mm
Shannon Helical Ø 2 Lg 12 mm

Bunion,
Joint Prep:
Shannon Longa Ø 2.2 Lg 22 mm

Calcaneal Slide:
Shannon Larga Ø 3 Lg 20 mm (7cm)
Shannon X-Larga Ø 3 Lg 30 mm (10cm)

Cheilectomy,
Osteophyte:
Wedge Ø 3.1 Lg 13 mm

Cheilectomy,
Osteophyte:
Wedge Ø 4.1 Lg 13 mm



1 **Ø 3 Lg 20 mm**
Calcaneal lateral cortex

2 **Ø 3 Lg 30 mm**
Calcaneal medial cortex

Operative Technique

This document provides technical guidance for the proper usage of PECA® bunion 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 adjustment and determining and using the appropriate techniques for implanting the device in each cases.

Hallux Valgus correction through Percutaneous Technique

1 - Patient Set-up

The procedure may be performed with or without a tourniquet. Use of tourniquet may increase the chance of bone necrosis so adequate irrigation is necessary.

The patient is positioned with the foot off the end of bed to facilitate AP and lateral fluoroscopy views of the forefoot with minimal adjustment of the mini C-arm.

The operative leg can be elevated relative to the contralateral extremity on blankets or a bump.

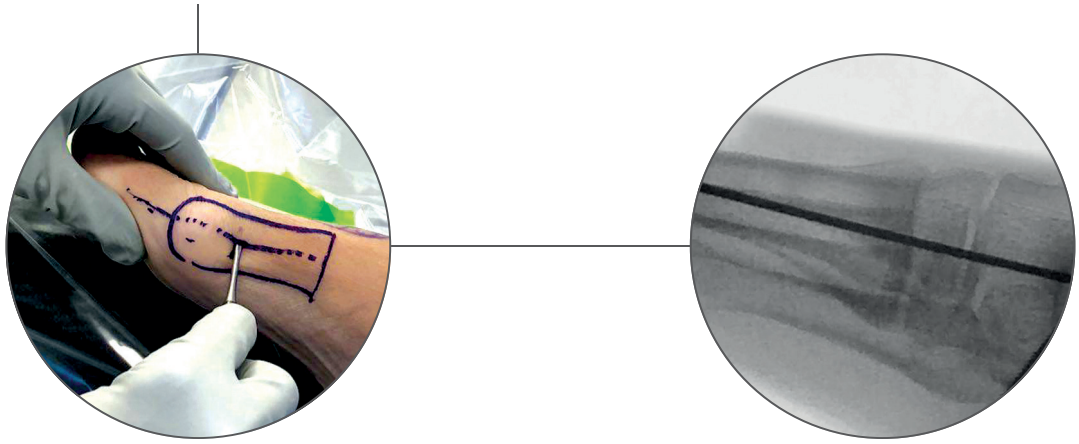
The surgeon's dominant hand dictates C-arm location. For a right-handed surgeon, the C-arm should be positioned on the right side of the patient; for a left-handed surgeon, C-arm is on the left.

Operative Technique

2 - Distal First Metatarsal Osteotomy

2.1 - Drawings

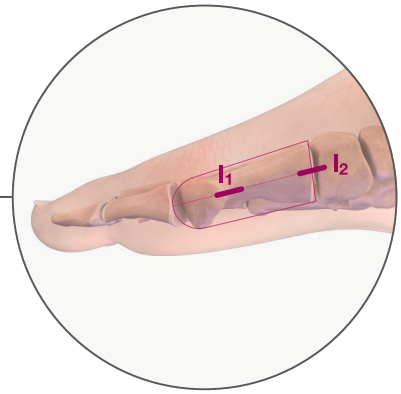
Draw the contour of the first metatarsal with a marking pen. Using palpation, or if needed, fluoroscopic guidance, draw the center line bisecting the first metatarsal and great toe longitudinally. In addition, mark out the first tarsometatarsal and metatarsophalangeal joints. This will help guide percutaneous wire placement.



Locate the two incisions:

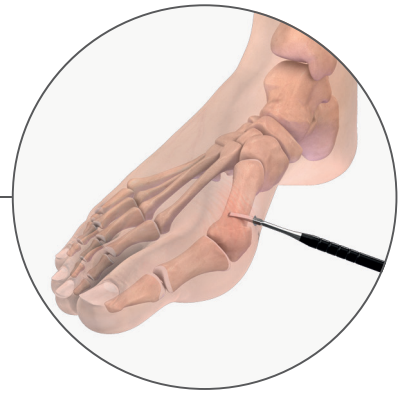
I_1 - First metatarsal osteotomy incision:
medial, longitudinal at the base of the flare of the medial eminence (distal diaphyseal-metaphyseal junction) of the first metatarsal.

I_2 - PECA® implants insertion incision:
just distal to the medial aspect of the first tarsometatarsal joint.



2.2 - Incisions

Use a beaver blade to make the two incisions. Take care to avoid damaging the dorsomedial sensory nerve branch. A periosteal elevator is used to dissect down to bone through incision I_1. Do not clear soft tissue from the plantar surface to avoid damaging the blood supply to the first metatarsal head.



Operative Technique

2.3 - Osteotomy

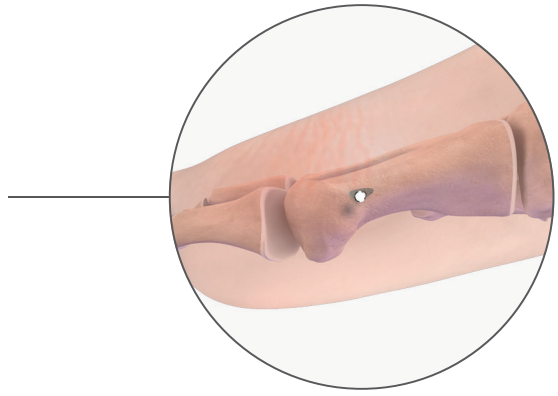
Tricks:

- With use of the burr, the surgeon should use gentle irrigation of the incision to prevent burning the skin.

- The Ø 2.2 Lg 22 mm Shannon burr is then inserted under AP fluoroscopic guidance into the base of the medial first metatarsal head. Angling the burr distally or proximally will allow for elongating or shortening the first metatarsal depending on the surgeon's goals for correction. The burr will remove 2 mm of bone that will result in slight shortening. Typically angling slightly distally, about 10 degrees, will compensate for the shortening occurring from bone removal.

Option 1: Chevron Osteotomy

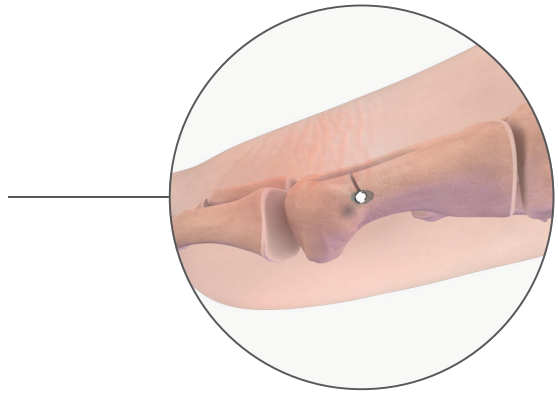
Trough incision I_1, start burr:
- Slightly more dorsal than plantar: 1/3 dorsal and 2/3 plantar;
- Angled 10 degrees plantarly to reduce the risk of first ray dorsiflexion and secondary second metatarsalgia;
- Perpendicular to the 2nd metatarsal axis or oriented more distally, depending on the surgeon goal of shortening or lengthening the first ray.



Once the burr tip has reached the lateral cortex, an AP fluoroscopy view is obtained to confirm the trajectory of the burr. The burr is then passed through the lateral cortex to create the apex of the chevron osteotomy.

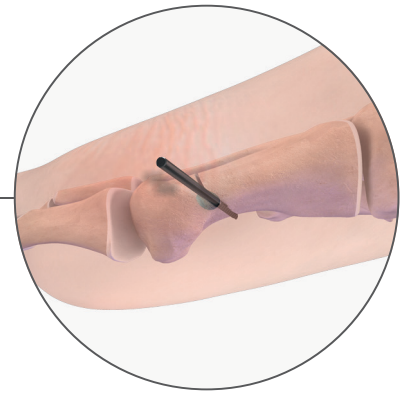
Trick:
For each limb of the osteotomy, the surgeon should envision the end point of their hand position prior to each cut.

Complete the dorsal vertical limb of the short chevron osteotomy by rotating the hand plantarly, using the medial cortex osteotomy hole as the center of rotation (fulcrum).
As the osteotomy is performed, the surgeon should gently oscillate the burr in and out to ensure that they have cut the far cortex.



Operative Technique

Next return the burr to the apex of the osteotomy. Complete the plantar limb of the chevron osteotomy by rotating the hand dorsally and slightly distally (60-70 degrees), again using the medial cortex osteotomy hole as the center of rotation for the osteotomy. Take care to keep the plantar limb short and fairly vertical.

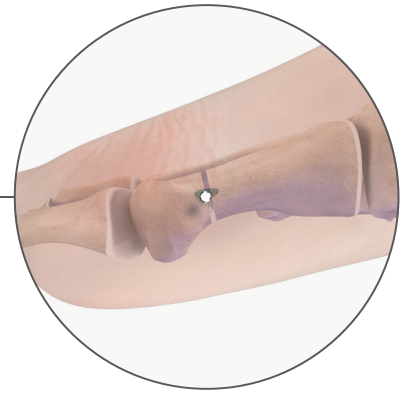


Trick:
Keep the plantar limb of the chevron cut quite vertical as this will allow for easier translation and secure fixation of the implant.

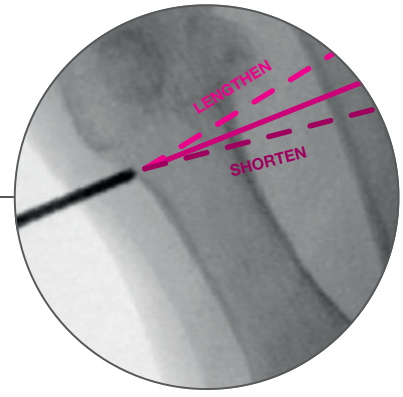
Prior to each step, fluoroscopy should be used to confirm position of the burr.

Option 2: Transverse Osteotomy

A vertical plantar limb osteotomy to create a transverse osteotomy may be performed if more rotational correction is desired for pronation deformities.
A Ø 2.2 Lg 22 mm burr may be used to perform this osteotomy.



Angling the burr distally or proximally will allow for elongating or shortening the first metatarsal.



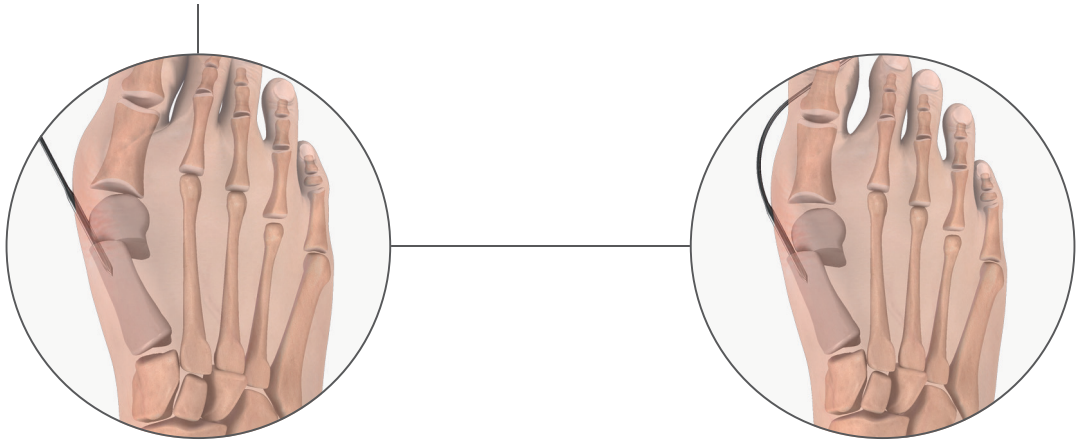
Operative Technique

2.4 - First Metatarsal Correction & Fixation

2.4.A - PECA® Reduction Wire

Once the capital fragment is mobile, pull traction on the hallux to insert the thick end of the head-shifting tool through the same first metatarsal medial eminence incision (incision I_1) in the plane of the osteotomy. Then rotate the reduction wire to insert it into the first metatarsal shaft.

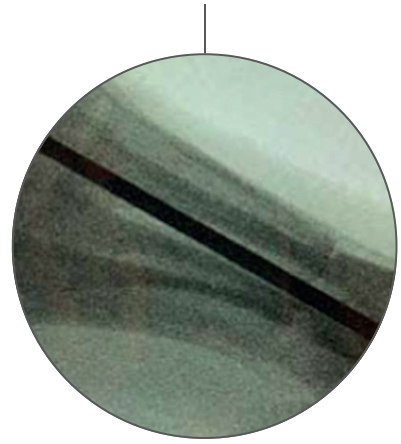
Bend the flexible wire portion under the base of the hallux proximal phalanx to prevent plantar migration of the capital fragment.
Place a varus stress on the metatarsal head to create the lateral shift, taking care to maintain proper dorsal / plantar alignment of the head relative to the shaft.



2.4.B - K-wires Placement

The Ø 1.4 mm proximal K-wire for the Ø 4 mm PECA® bunion implant is inserted through the proximal medial cortex midaxially at the base of first metatarsal shaft.

Check AP and lateral fluoroscopy views to ensure that the trajectory of the wire is correct.

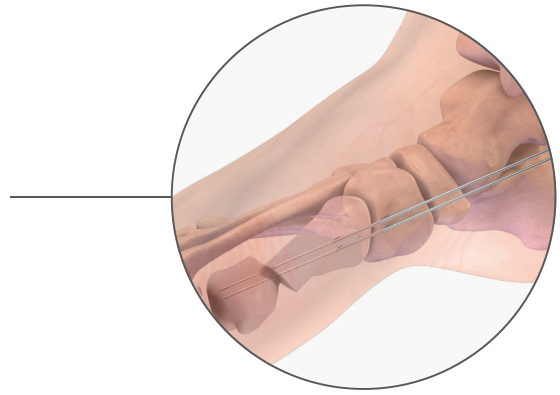


Aim the K-wire to exit about 1 cm proximal to the osteotomy at the lateral cortex. The Ø 1.4 mm K-wire must be placed through the proximal medial and the distal lateral first metatarsal shaft cortices prior to engaging the capital fragment for stability of the construct.

Operative Technique

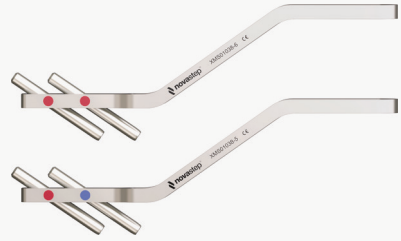
Trick:
More proximal placement of the K-wire and implant increases stability of the construct.

Then, insert a Ø 1.4 mm distal K-wire through incision I_2, through the medial proximal first metatarsal cortex and into the capital fragment.
Check AP and lateral fluoroscopy views to confirm K-wire position.



Option: Parallel guide: PECA® Ø 4 - Ø 4 or PECA® Ø 3 - Ø 4 Parallel guides are available on request.

Insert the PECA® Parallel guide over the proximal K-wire and insert the appropriate second K-wire in the PECA® sleeve.
Remove the parallel guide, letting the K-wires in position.



2.4.C - PECA® Implants Insertion

The proximal implant length is then read on the PECA® ruler. A PECA® implant is chosen that is 4-6 mm shorter than the indicated length to ensure that the implant is fully recessed after insertion.

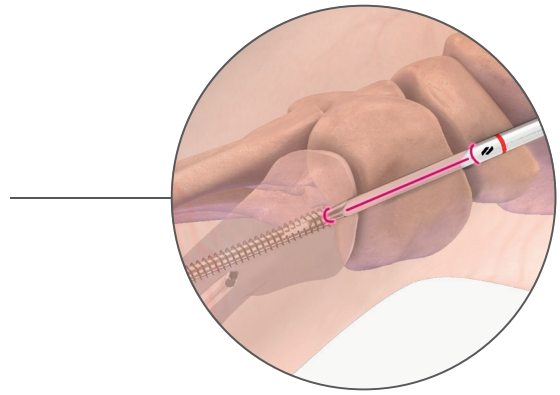
Option:
To preserve soft tissue, position the tissue protector over the k-wire before drilling and inserting the implant.

Overdrill the K-wire using the AO drill bit Ø 3.2 mm. Take care to drill across both the medial and lateral first metatarsal shaft cortices.

Trick:
For patients with hard bone, gently drill into the first metatarsal head while stabilizing the correction manually. Otherwise, drilling into the head will result in removal of the K-wire when the drill is withdrawn.

Operative Technique

Place the Ø 4 mm PECA® implant over the wire to secure the osteotomy, using the Exact-T®10 AO screwdriver tip. Take care to maintain the position of the correction both in the sagittal and horizontal planes. The screwdriver will only engage the head of the PECA® bunion implant in one direction, corresponding to the chamfer of the implant. Insert the Ø 4 PECA® 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.

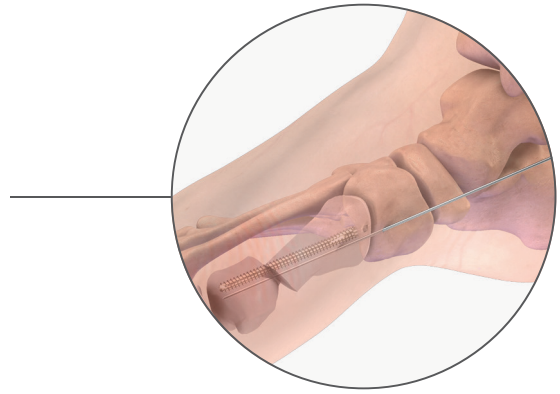


Use oblique fluoroscopy view to confirm.

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

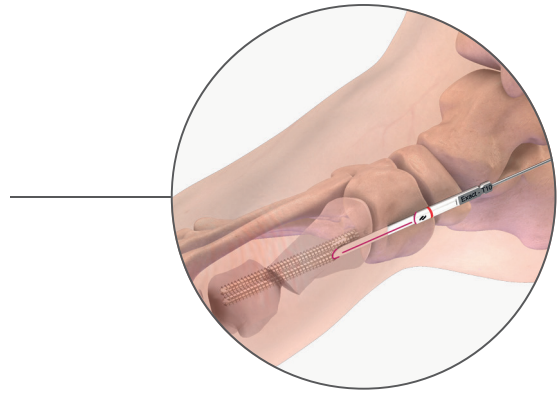
Option: A PECA® Ø 3 bunion implant, with Ø 1,0 mm K-wire, could be used if the patient has a smaller deformity or smaller diameter of the metatarsal.

When the first proximal PECA® implant is inserted, read the distal implant length on the ruler and chose a PECA® implant that is 4-6 mm shorter than the indicated length to ensure that the implant is fully recessed after insertion.



Overdrill the wire with the corresponding drill and place the second PECA® implant over the wire for final fixation as described above.

AP, oblique, and lateral fluoroscopic views are checked to confirm proper hallux valgus correction and that the implant heads are not prominent or entering the first metatarsophalangeal joint.



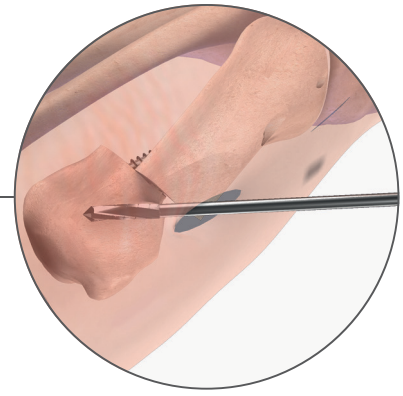
Operative Technique

2.5 - Bone Spikes Removal

The proximal medial prominence of the proximal fragment of first metatarsal bone is removed using a Ø 2.2 Lg 22 mm Shannon Burr through the proximal PECA® bunion implant insertion incision (incision I_2). Insert the burr parallel to the distal implant 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.

Then the dorso-medial eminence of first metatarsal shaft bone is excised with a Ø 3.1 Lg 13 mm wedge burr through the metatarsal osteotomy incision (incision I_1).



Operative Technique

3 - Akin Osteotomy

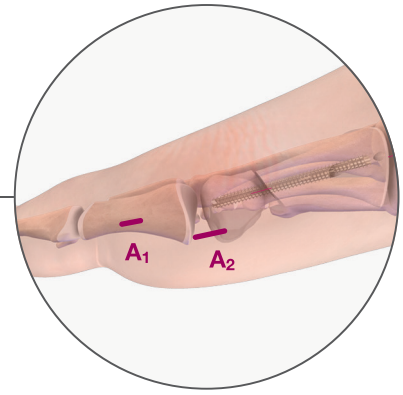
If interphalangeous deformity is noted after the metatarsal osteotomy, an Akin may be performed.

3.1 - Incisions

Two percutaneous incisions are made:

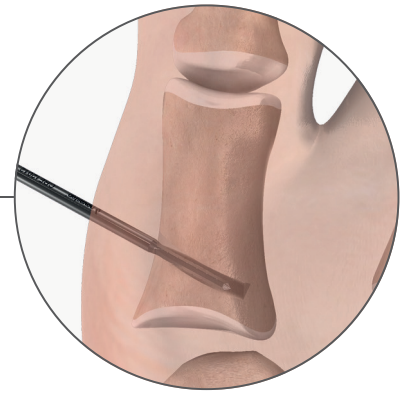
A_1 - Phalanx osteotomy incision:
at the meta-diaphyseal margin of the medial proximal phalanx.

A_2 - Implant insertion incision:
at the medial base of the hallux proximal phalanx.



3.2 - Osteotomy

Under fluoroscopic guidance, the Ø 2 Lg 12 mm Shannon burr is inserted through incision A_1, through the medial cortex, midaxially. Aim the burr proximally for an oblique Akin osteotomy, while preserving the lateral cortex.

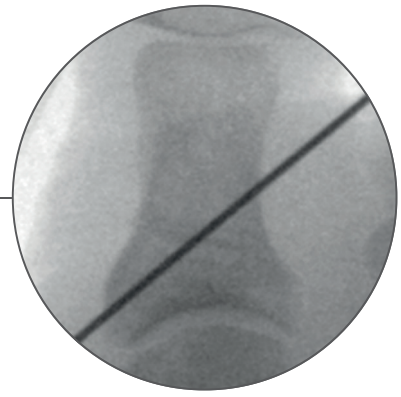


The dorsal limb is completed while holding the hallux interphalangeal joint dorsiflexed to prevent damage to the extensor hallucis longus tendon.
The plantar limb is completed with the hallux interphalangeal joint plantarflexed to prevent damage to the flexor hallucis longus tendon.
The hallux is placed in varus to correct any remaining valgus deformity and to ensure that the hallux is not touching the second toe.

Operative Technique

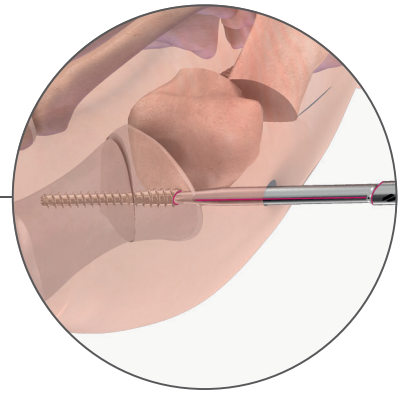
3.3 - PECA® 3 Implant

A Ø 1 mm k-wire for the Ø 3 mm PECA® bunion implant is then placed percutaneously through incision A_2 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 implant length is then read on the PECA® ruler.



Trick:
For patients with hard bone, it is possible to drill through the medial cortex using the AO drill bit Ø2 mm. Be careful not to drill through the lateral cortex, to allow compression of the osteotomy as the implant is advanced into the lateral cortex.

A Ø 3 mm PECA® bunion implant that is 2 mm shorter than the indicated length is then inserted with the Exact-T®8 screwdriver tip, using a power tool or by hand. Final AP and lateral fluoroscopy views of the hallux are checked.

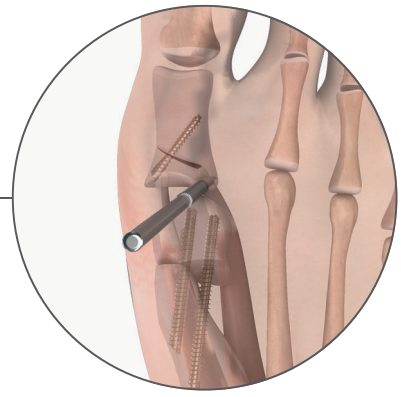


Option:
The Nexis® MIS Ø 2.7 screw can also be used for this step. In this case, be sure to use the associated Exact2-T8 screwdriver tip.

Operative Technique

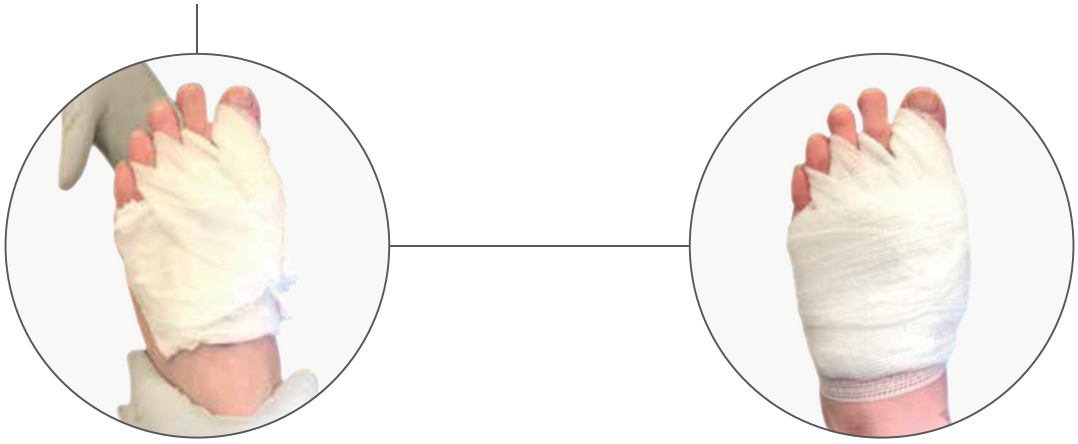
4 - Optional Lateral Release

A lateral release of the lateral metatarsosesamoid ligament, lateral head of the flexor hallucis brevis, and adductor tendon may be performed percutaneously through a dorsal lateral first metatarsophalangeal joint incision using a beaver blade.
Avoid cutting the lateral collateral ligament and flexor hallucis longus tendon.



5 - Dressing

The incisions can be closed with 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 weeks.



Operative Technique

6 - Implant Removal

If a PECA® implant has to be removed, Removal Exact-T®10 AO screwdriver tip are available for a percutaneous use.
Its integrated *extra-sharp* wire can be inserted into the implant cannula to withdraw the bone inside the implant head, so as to insert the driver into the recess, in the axis of the implant.

References

1 - Implants

PECA® bunion implants

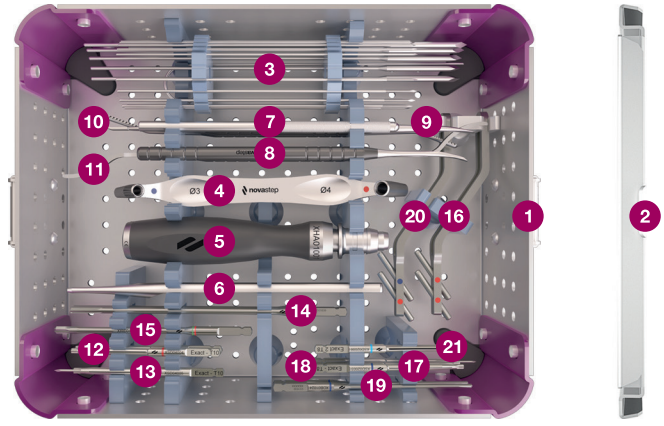
Length (mm)	Ø 3	Ø 4
16	PS020016	-
18	PS020018	-
20	PS020020	-
22	PS020022	-
24	PS020024	-
26	PS020026	PS050026
28	PS020028	PS050028
30	PS020030	PS050030
32	PS020032	PS050032
34	PS020034	PS050034
36	PS020036	PS050036
38	PS020038	PS050038
40	PS020040	PS050040
42	PS020042	PS050042
44	PS020044	PS050044
46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

Nexis® MIS beveled compressive screws Ø 2.7

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

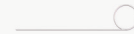
2 - Instruments

2.A - PECA® tray



References

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	
	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 K-wires holder.*

Percutaneous Instruments

Number	Ref	Description	Qty	
7	-	Fine surgical handle[3]	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 SF13 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 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	

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® - Parallel 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 - Medetechnik® K-wire (33-T10-R-12-100) or Novastep® K-wire (CKW01014) are available depending on your market.*
[5]*K-wire supplied separately - Medetechnik® K-wire (33-T10-R-12-150) or Novastep® K-wire (CKW01015) are available depending on your market.*

References

2.B - 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	

Notes

peca®

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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Reference: PECA-ST-Ed3-07-24-EN