ST

SURGICAL
TECHNIQUE

enovis

PECA®

BUNION IMPLANTS Ø3 / Ø4MM

BUNION SYSTEM

TABLE OF CONTENTS

INDICATIONS & CONTRAINDICATIONS 3
DESIGN FEATURES 4
SURGICAL TECHNIQUE 9
ORDERING INFORMATION 21

Novastep® S.A.S is a manufacturer of orthopedic implants and does not practice medicine. This surgical technique was prepared in conjunction with licensed health care professionals. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

See package insert for complete list of potential adverse effects, contraindications, warnings and precautions.

A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions, if applicable. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient.

Some implants / instruments are not available in all territories. For more information, please contact your local sales representative.

INDICATIONS & CONTRAINDICATIONS

INDICATIONS

The osteosynthesis screws are indicated for arthrosis, hallux valgus, metatarsalgia, and other bone alignment defaults (pes cavus, flatfoot, 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

- 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

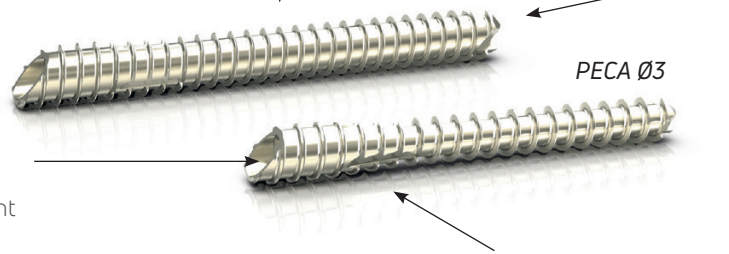
IMPLANT

The PECA® Implant sytem provides a complete and versatile portfolio of beveled, fully threaded implants intended for the osteotomy fixation and arthrodesis of the foot. The Exact2-T Recess provides high 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.

BEVELED HEAD (40°)
Anatomically contours to the metaratsal cortex of the first metatarsal

FULLY THREADED NEUTRALIZATION IMPLANT - CONSTANT PITCH
Ensuring anchorage for fixation

SELF-TAPPING, SELF-DRILLING
Facilitated insertion



EXACT2-T RECESS
Allows exact beveled implant head positioning.

PROXIMAL CUTTING FLUTES

PECA® RANGE

Made of Titanium alloy (TA6V Eli anodised), PECA® Bunion implants are available in 3mm and 4mm diameters Instrumentation is color-coded for convenient identification.

COLOR-CODED INSTRUMENTATION

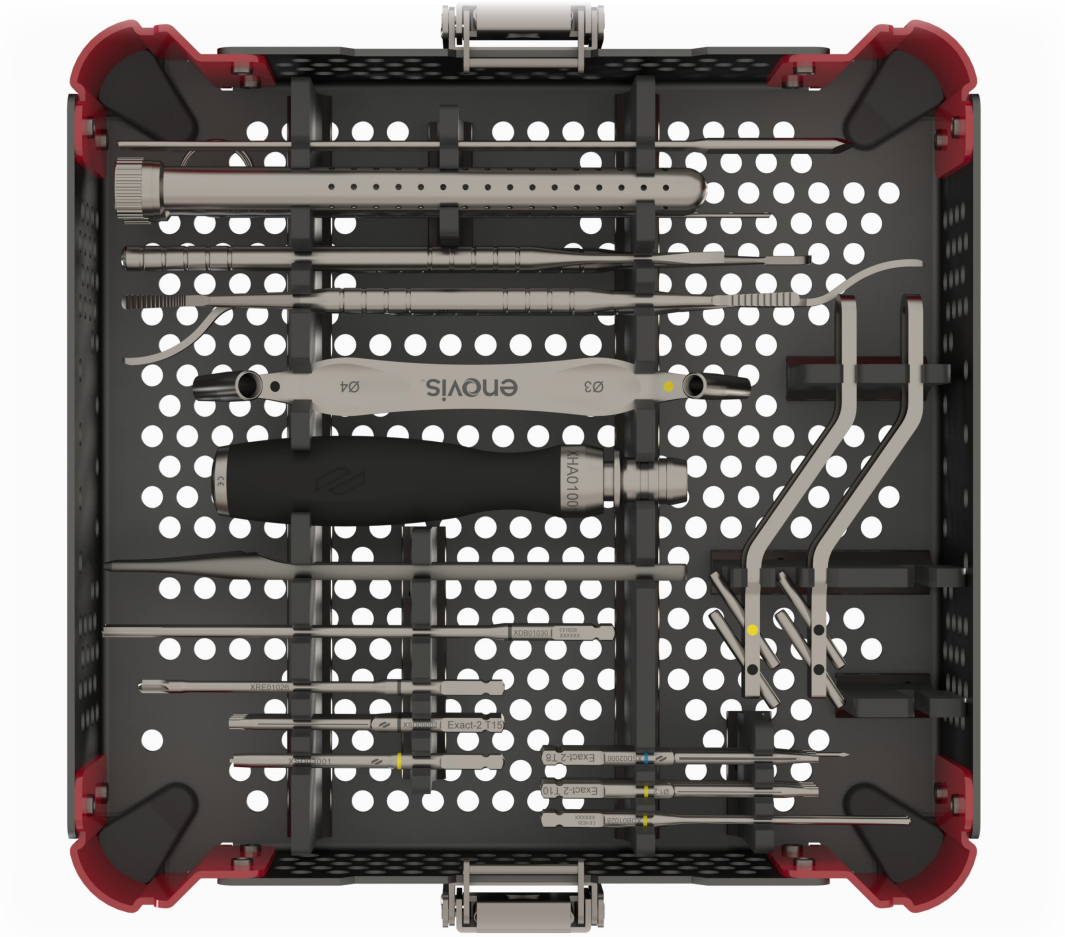
Ø3 peca

Ø4 peca

	Ø3mm	Ø4mm
DRIVER	EXACT2-T10	EXACT2-T15
LENGTH	16-48mm	26-60mm
K-WIRE	Ø1.2mm	Ø1.6mm
DRILL BIT	Ø2mm	Ø3.2mm

PERCUTANEOUS INSTRUMENTATION

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



PERCUTANEOUS RASPS

PERIOSTEAL ELEVATOR DOUBLE TIP

PERIOSTEAL ELEVATOR SINGLE TIP

REDUCTION DEVICE DOUBLE TIP - OPTIONAL

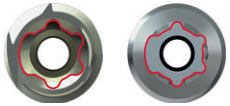
BEAVER HANDLE (FINE SURGICAL HANDLE)

DESIGN FEATURES

EXACT2-T TECHNOLOGY

Exact2-T facilitates correct placement of implant upon insertion.

EXACT2-T RECESS



SPECIFIC
Easy indexing of the Exact2-T screwdriver tip.

UNIVERSAL
Possible removal with standard instrumentation.

STERILE PERCUTANEOUS BURRS

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

STERILE PERCUTANEOUS BURRS

HAMMERTOE, AKINETTE
SHANNON CORTA Ø2 LG 8MM

AKIN, DMMO
SHANNON RECTA Ø2 LG 12MM
SHANNON HELICAL Ø2 LG 12MM

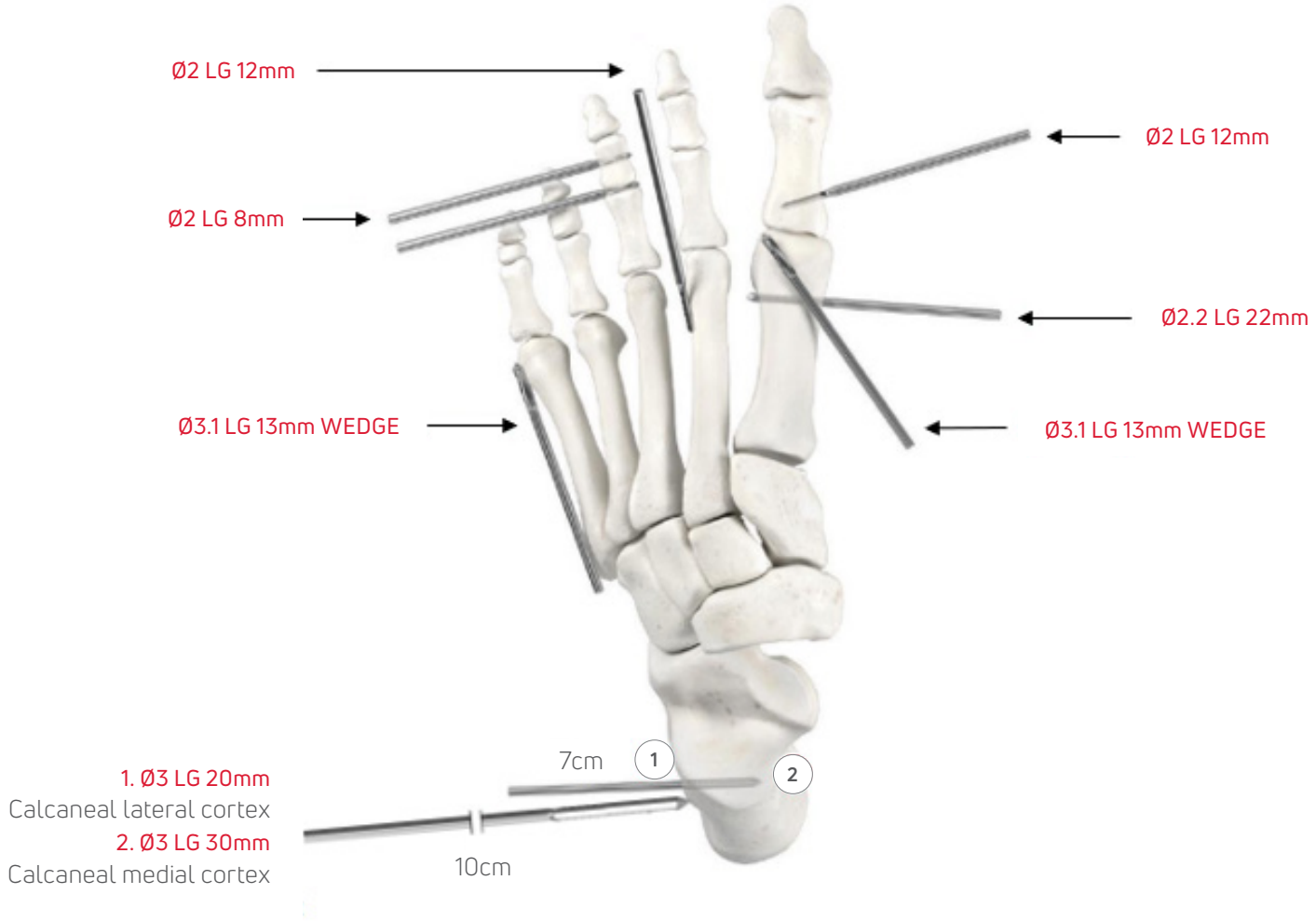
BUNION, JOINT PREP
SHANNON LONGA Ø2.2 LG 22MM

CALCANEAL SLIDE
SHANNON LARGA Ø3 LG 20MM (7CM)
SHANNON X-LARGA Ø3 LG 30MM (10CM)

CHEILECTOMY, OSTEOPHYTES
WEDGE Ø3.1 LG 13MM

CHEILECTOMY, OSTEOPHYTES
WEDGE Ø4.1 LG 13MM

STERILE PERCUTANEOUS BURRS



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 (FIGURE 1).

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 (FIGURE 2).

FIGURE 1

FIGURE 2

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. (FIGURE 3A&B).

Locate the two incisions (FIGURE 4).

I1 - FIRST METATARSAL OSTEOTOMY INCISION

medial, longitudinal at the base of the flare of the medial eminence (distal diaphyseal-metaphyseal junction) of the first metatarsal.

I2 - PECA® IMPLANTS INSERTION INCISION

just distal to the medial aspect of the first tarsometatarsal joint.

FIGURE 3A

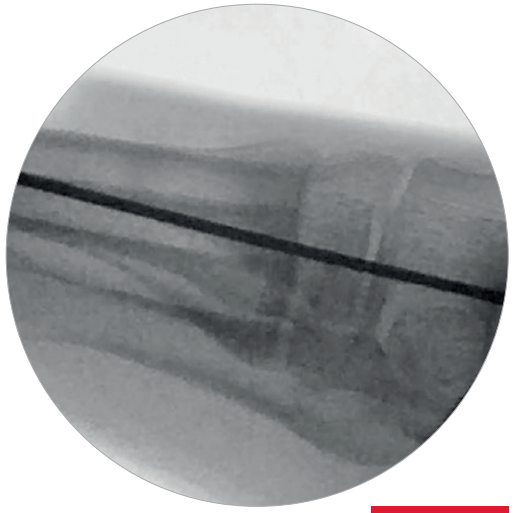


FIGURE 3B

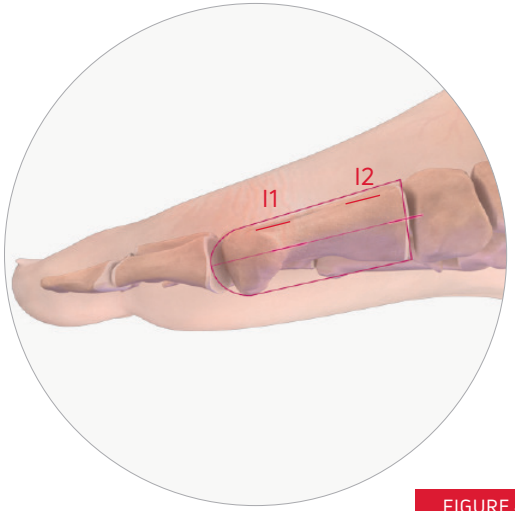


FIGURE 4

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 I1. Do not clear soft tissue from the plantar surface to avoid damaging the blood supply to the first metatarsal head (FIGURE 5).

2.3 OSTEOTOMY

TIP:

- Using the burr, the surgeon should use gentle irrigation of the incision to prevent burning the skin.
- The Ø2.2 Lg 22mm 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 2mm of bone that will result in slight shortening. Typically angling slightly distally, about 10˚, will compensate for the shortening occurring from bone removal.

FIGURE 5

OPTION 1: CHEVRON OSTEOTOMY

Through incision I1, start burr (FIGURE 6):

- 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.

> TIP: 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 (FIGURE 7).

FIGURE 6

FIGURE 7

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. (FIGURE 8):

> TIP: 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.

FIGURE 8

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 Ø2.2 Lg 22mm burr may be used to perform this osteotomy.

Angling the burr distally or proximally will allow for elongating or shortening the first metatarsal (FIGURE 9A&B).

FIGURE 9A

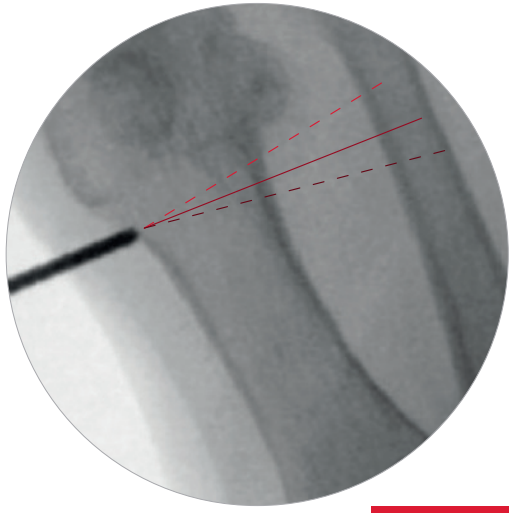


FIGURE 9B

3. FIRST METATARSAL CORRECTION & FIXATION

3.1 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 I1) 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. (FIGURE 10A&B).

3.2 K-WIRE PLACEMENT

The Ø1.6mm proximal K-wire for the Ø4mm PECA® bunion implant is inserted through the proximal medial cortex midaxially at the base of the first metatarsal shaft. (FIGURE 11A&B).

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

Aim the K-wire to exit about 1cm proximal to the osteotomy at the lateral cortex. The Ø1.6mm 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.

FIGURE 10A

FIGURE 10B

FIGURE 11A

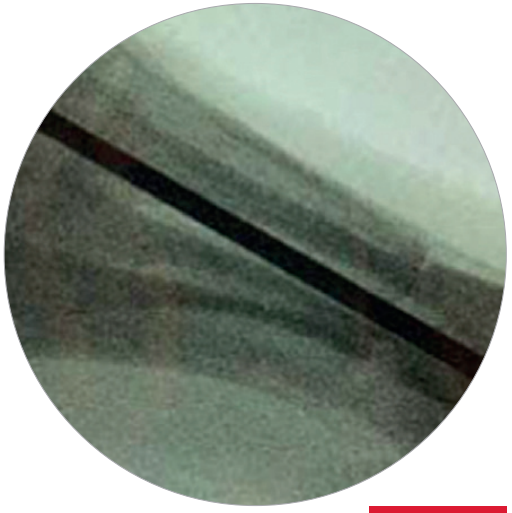


FIGURE 11B

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

Then insert a Ø1.6mm distal K-wire through incision I2, through the medial proximal first metatarsal cortex and into the capital fragment.

Check AP and lateral fluoroscopy views to confirm K-wire position (FIGURE 12).

OPTIONAL: PECA® Ø4 - Ø4 and PECA® Ø3 - Ø4 Parallel guides are available as option in the PECA® sets. (FIGURE 13)

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.

FIGURE 12

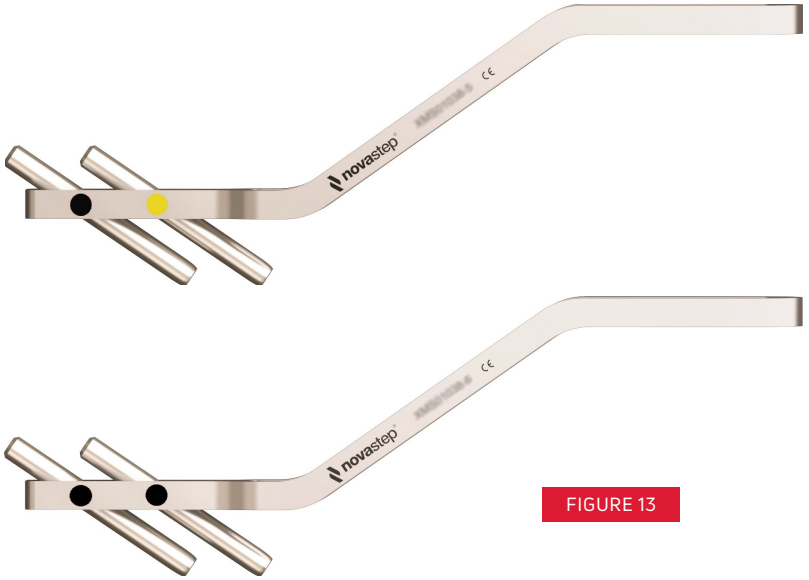


FIGURE 13

3.3 PECA IMPLANT INSERTION

The proximal implant length is then read on the PECA® ruler (FIGURE 14). 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.

OPTIONAL: 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.

> TIP: 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.

Place the Ø 4 mm PECA® implant over the wire to secure the osteotomy, using the Exact2-T15 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 PECA® Ø 4 implant with a power tool or by hand depending on the bone quality. Finish the insertion by hand until the chamfer of the implant head sit flush with the medial cortex of the first metatarsal shaft after insertion. (FIGURE 15).

Use oblique fluoroscopy view to confirm screw positioning.

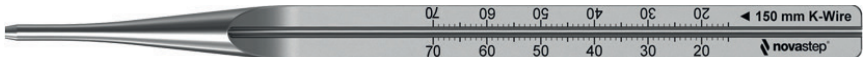


FIGURE 14

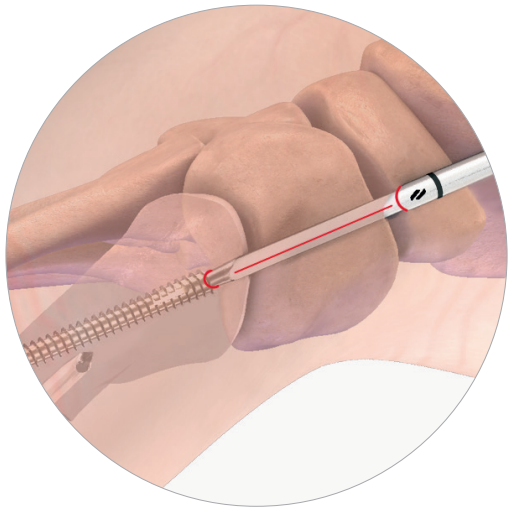


FIGURE 15

NOTE: A PECA® Ø4 bunion implant is recommended at this step. The Ø1.6mm K-wire is recommended over the Ø1.2mm K-wire for a reliable positioning, and the larger implant provides more stability to the construct.

OPTIONAL: A PECA® Ø3 bunion implant, with Ø1.2 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 choose a PECA® implant that is 4-6mm shorter than the indicated length to ensure that the implant is fully recessed after insertion (FIGURE 16).

Overdrill the wire with the corresponding drill and place the second PECA® implant over the wire for final fixation as described above (FIGURE 17).

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.

FIGURE 16

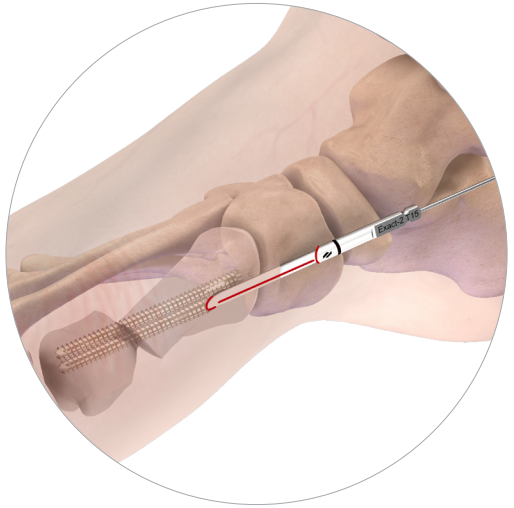


FIGURE 17

3.4 BONE SPIKE REMOVAL

The proximal medial prominence of the proximal fragment of first metatarsal bone is removed using a Ø2.2 Lg 22mm Shannon Burr through the proximal PECA® implant insertion from proximal to distal (FIGURE 18). Insert the burr and cut the bone dorsally then plantarly from inside out.

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

Excise the dorso-medial eminence of the first metatarsal shaft bone with a Ø3.1 Lg 13mm wedge burr through the metatarsal osteotomy incision if necessary (FIGURE 19).

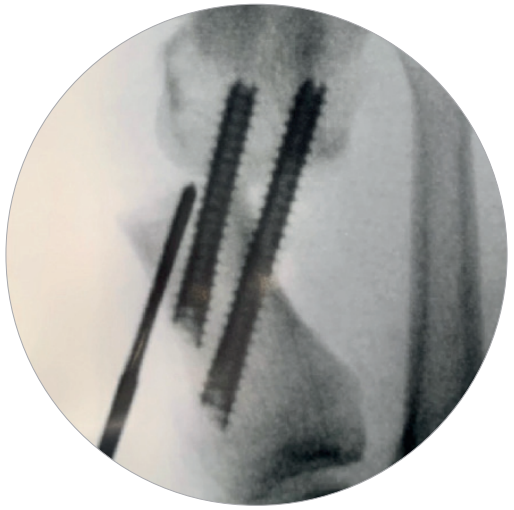


FIGURE 18

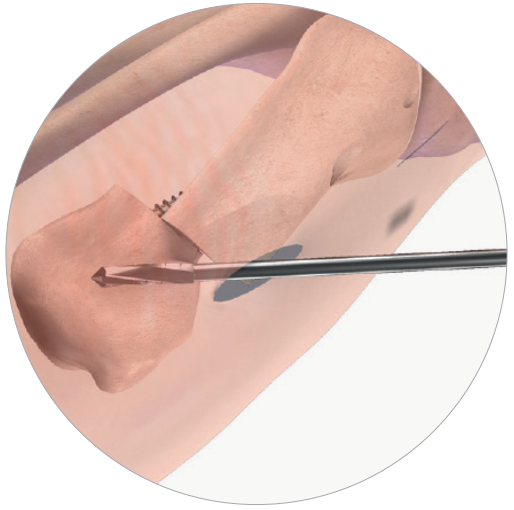


FIGURE 19

4. AKIN OSTEOTOMY

If a phalangeal deformity is present after correction of the first metatarsal, an Akin osteotomy can be performed.

4.1 INCISIONS

Two percutaneous incisions are made:

1. AKIN OSTEOTOMY INCISION

At the meta-diaphyseal margin of the medial proximal phalanx (FIGURE 20, 1).

2. IMPLANT INSERTION INCISION

At the medial base of the hallux proximal phalanx (FIGURE 20, 2).

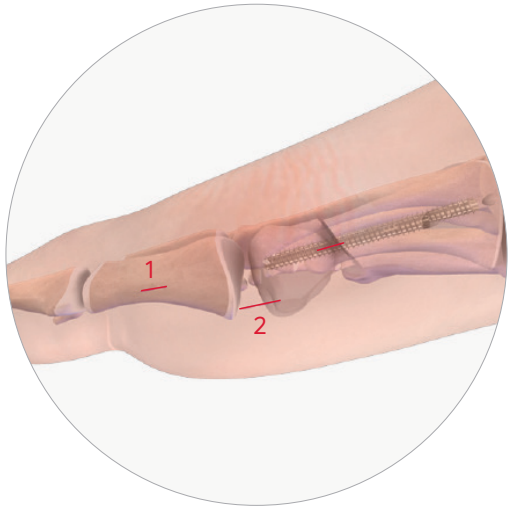


FIGURE 20

4.2 OSTEOTOMY

Under fluoroscopic guidance, the Ø2 Lg 12mm Shannon burr is inserted through incision 1, through the medial cortex midaxially (FIGURE 21). Aim the burr proximally for an oblique Akin osteotomy while preserving the lateral cortex.

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

Complete the plantar limb 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.

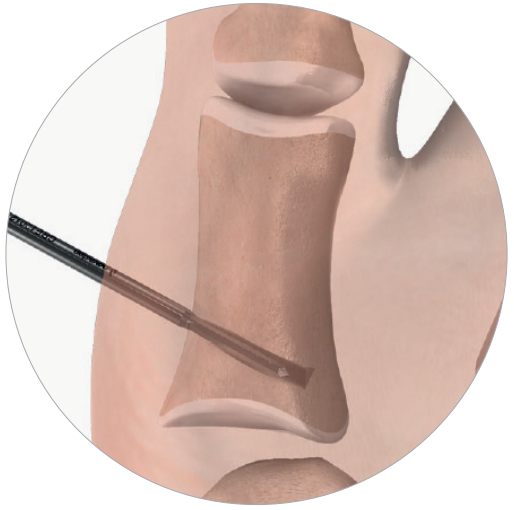


FIGURE 21

4.3 PECA® 3 IMPLANT INSERTION

A Ø 1.2mm K-wire for the Ø 3mm PECA® bunion implant 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 implant length is then read on the PECA® ruler. (FIGURE 22)

> TIP: For patients with hard bone, it is possible to drill through the medial cortex using the AO drill bit Ø2mm. 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 Ø3mm PECA® bunion implant that is 2mm shorter than the indicated length is then inserted with the Exact2-T10 screwdriver tip with a power tool or by hand depending on bone quality. Finish the insertion by hand until the lateral cortex has been reached (FIGURE 23).

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

OPTIONAL: 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.

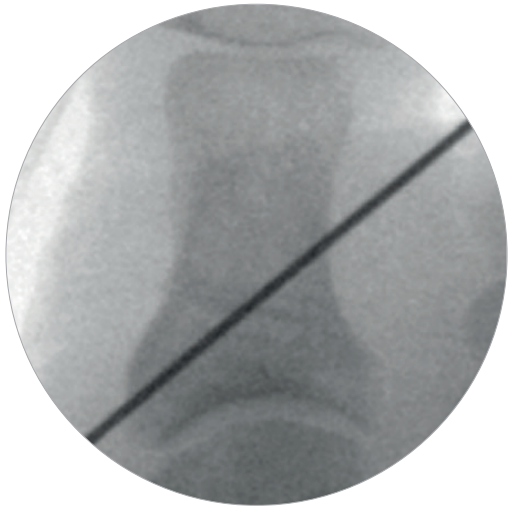


FIGURE 22

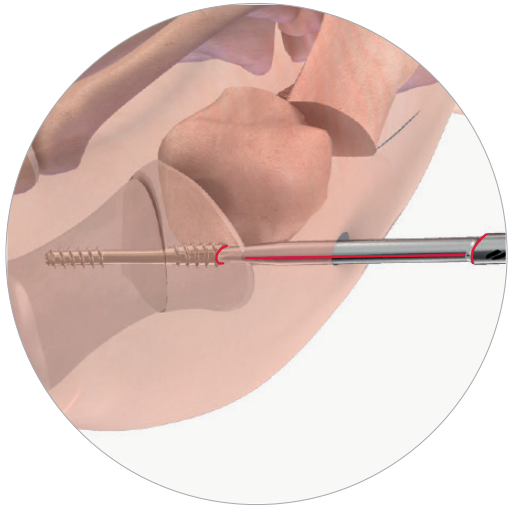


FIGURE 23

5. 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. (FIGURE 24).

FIGURE 24

6. DRESSING

The incisions can be closed with sutures or sterile strips and dressed with a nonadherent layer and 4"x 4" gauze. Softband or wool is placed over the foot and ankle. This is overwrapped with an ACE wrap (FIGURE 25). This dressing is left in place for two weeks.

FIGURE 25

7. IMPLANT REMOVAL

If a PECA® implant has to be removed, Removal A0 T15 or T10 screwdriver tip is 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. (FIGURE 26).

FIGURE 26

ORDERING INFORMATION

IMPLANTS

PECA® BUNION IMPLANTS

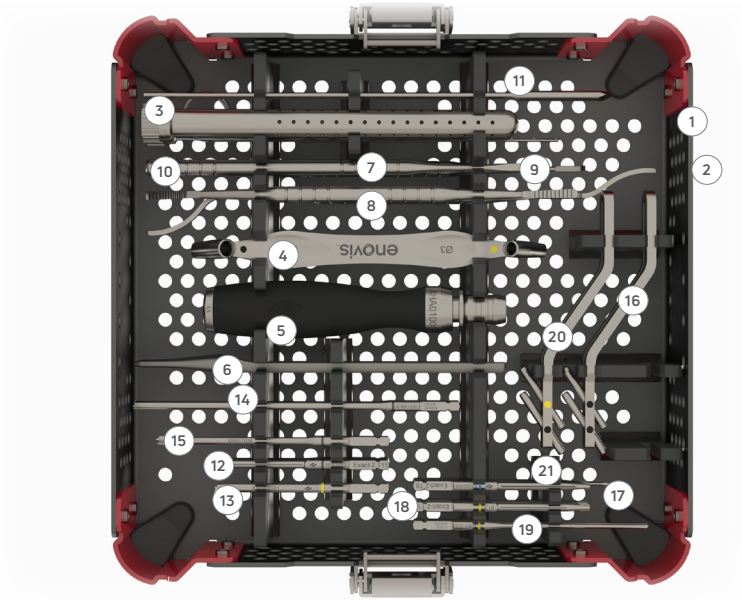
LENGTH (mm)	PECA® Ø3mm	PECA® Ø4mm
16	PS070016	-
18	PS070018	-
20	PS070020	-
22	PS070022	-
24	PS070024	-
26	PS070026	PS060026
28	PS070028	PS060028
30	PS070030	PS060030
32	PS070032	PS060032
34	PS070034	PS060034
36	PS070036	PS060036
38	PS070038	PS060038
40	PS070040	PS060040
42	PS070042	PS060042
44	PS070044	PS060044
46	PS070046	PS060046
48	PS070048	PS060048
50	-	PS060050
52	-	PS060052
54	-	PS060054
56	-	PS060056
58	-	PS060058
60	-	PS060060

NEXIS® MIS BEVELED COMPRESSIVE SCREW

LENGTH (mm)	NEXIS® Ø2.7mm
14	SC090014
16	SC090016
18	SC090018
20	SC090020
22	SC090022
24	SC090024
26	SC090026
28	SC090028
30	SC090030

ORDERING INFORMATION

PECA® IMPLANTS & NEXIS® MIS SCREWS INSTRUMENTATION



UNIVERSAL INSTRUMENTS

#	DESCRIPTION	PART #	QTY
1	TRAY	ACC1023P0001	1
2	LID	ACC1023P0002	1
3	K-WIRE TUBE	XMS01001[1]	1
	REDUCTION WIRE Ø3.5	CKW03001	5[2]
	K-WIRE Ø1.2 LG 150 TR/RD	CKW01015[3]	5[2]
	K-WIRE Ø1.6 LG 150 TR/RD	CKW01003[4]	8[2]
	CLEANING PIN Ø0.9	XKW01001	1
	CLEANING PIN Ø1.4	XKW01002	1
4	TISSUE PROTECTOR	XDG01033	1
5	AO HANDLE	XHA01001	1
6	RULER LG 150	XGA01009	1

[1] *Holder type may vary*
[2] *Maximum quantity of k-wires holder*
[3] *K-wire supplied separately - Medetechnik® K-wire (33-T10-R-12-150) or Novastep® K-wire (CKW01015) are available depending on your market.*
[4] *K-wire supplied separately - Medetechnik® K-wire (33-T10-R-16-150) or Novastep® K-wire (CKW01003) are available depending on your market.*

PERCUTANEOUS INSTRUMENTS

#	DESCRIPTION	PART #	QTY
7	FINE SURGICAL HANDLE	SF13[5]	1
8	PERIOESTAL ELEVATOR SINGLE TIP	XMS01011	1
9	PERIOESTAL ELEVATOR DOUBLE TIP	XMS01008	1
10	PERCUTANEOUS RASPS	XMS01009	1
11	REDUCTION DEVICE DOUBLE TIP	XMS01027	OPTION

[5] *Reference supplied separately - availability depending on your market.*

PECA® Ø4 INSTRUMENTS

#	DESCRIPTION	PART #	QTY
12	EXACT2-T15 AO SCREWDRIVER TIP	XSD09002	2
13	REMOVAL AO T15 SCREWDRIVER TIP	XSD09001	OPTION
14	AO DRILL BIT Ø 3.2	XDB01030	2
15	COUNTERSINK Ø 3.7	XRE01026	OPTION
16	PARALLEL GUIDE Ø 4 - Ø 4	XDG01034	OPTION

PECA® Ø3 INSTRUMENTS

#	DESCRIPTION	PART #	QTY
17	EXACT2-T10 AO SCREWDRIVER TIP	XSD10002	2
18	REMOVAL AO T10 SCREWDRIVER TIP	XSD10001	OPTION
19	AO DRILL BIT Ø 2	XDB01034	2
20	PARALLEL GUIDE Ø 3 - Ø 4	XDG01035	OPTION

NEXIS® MIS Ø2.7 INSTRUMENTS

#	DESCRIPTION	PART #	QTY
21	EXACT2-T8 AO SCREWDRIVER TIP	XSD02006	2
	RULER LG 100/150	XGA01013	OPTION
	K-WIRE Ø 1.2 LG 100 TR/RD[6]		OPTION

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

ORDERING INFORMATION

PERCUTANEOUS BURRS

DESIGNATION	REFERENCE
SHANNON CORTA Ø2 LG 8	CRE12008
SHANNON RECTA Ø2 LG 12	CRE12012
SHANNON HELICAL Ø2 LG 12	CRE12212
SHANNON LONGA Ø2.2 LG 22	CRE12222
SHANNON LARGA Ø3 LG 20	CRE13020
SHANNON X-LARGA Ø3 LG 30	CRE13030
WEDGE Ø3.1 LG 13	CRE23113
WEDGE Ø4.1 LG 13	CRE24113

NOTES

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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.

REFERENCE: PECA-2.0-ST-ED9-03-26-EN