ST

SURGICAL TECHNIQUE

enovis

PECAPLASTY®

WIRES FIRST PERCUTANEOUS BUNION CORRECTION

BUNION SYSTEMS

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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.

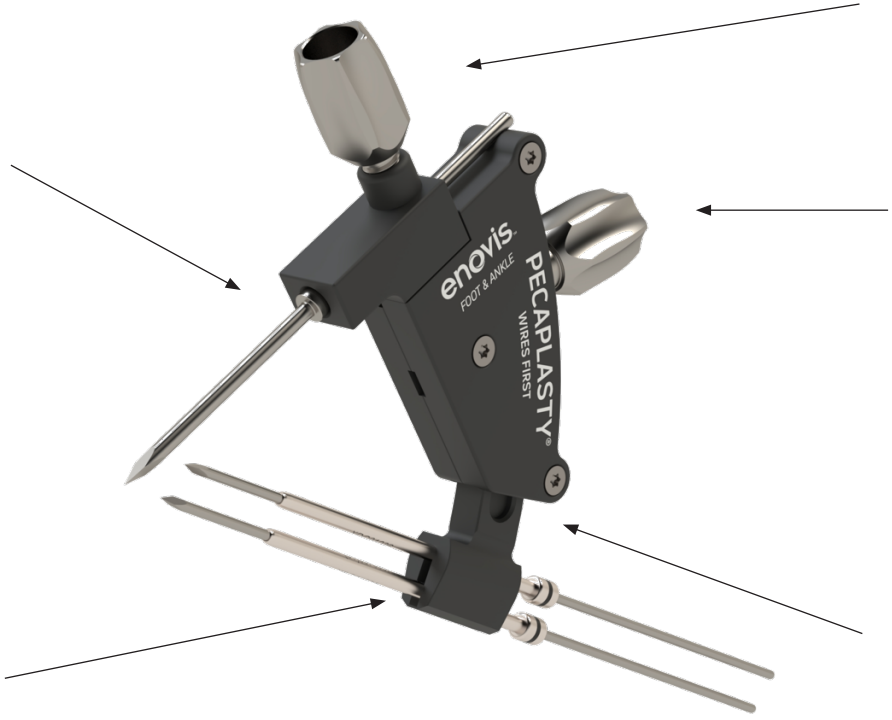
DESIGN FEATURES

The Pecaplasty® Wires First system allows for simple, precise and reproducible correction of Hallux Valgus in percutaneous surgery. With its easy positioning on the foot, the Pecaplasty® Wires First Targeting Guide allows accurate K-wires placement before the osteotomy.

TARGETING GUIDE

REFERENCE WIRE LOCKING DIAL
Locks the reference wire in position

REFERENCE WIRE
Inserted into the osteotomy location to correctly position the guide and targets the proximal wire trajectory



LOCKING DIAL
Locks the targeting arc in position

PARALLEL HOLES
Guided placement of K-Wires through the sleeves

TARGETING ARC
Adjustable positioning based on the point of entry

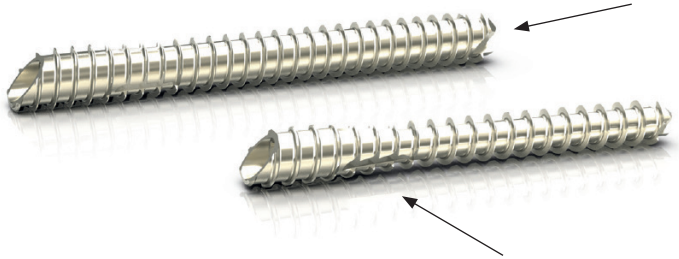
DESIGN FEATURES - SCREWS

1. PECA Ø3 & Ø4 - BUNION IMPLANTS

FULLY THREADED NEUTRALIZATION IMPLANT - CONSTANT PITCH
Ensuring anchorage for fixation

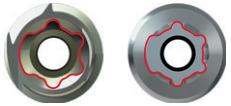
SELF-TAPPING, SELF-DRILLING
Facilitated insertion

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



PROXIMAL CUTTING FLUTES

EXACT2-T RECESS



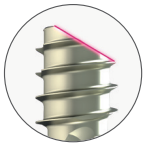
SPECIFIC
Easy indexing of the Exact2-T screwdriver tip.
UNIVERSAL
Possible removal with standard instrumentation.

COLOR-CODED INSTRUMENTATION

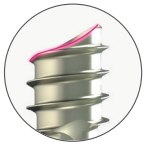
	Ø3 peca	Ø4 peca
DRIVER	Exact2-T10	Exact2-T15
LENGTH	16 - 48 mm	26 - 60 mm
K-WIRE	Ø 1.2 mm	Ø 1.6 mm
DRILL BIT	Ø 2 mm	Ø 3.2 mm

2. NEXIS MIS Ø2.7 - BEVELED COMPRESSIVE SCREWS

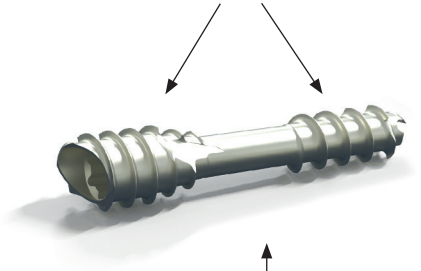
ELLIPTIC BEVELED HEAD (30°)
Maximization of cortical anchorage and preservation of soft tissue



Allows for additional angular rotation to preserve the burial of the head



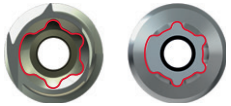
DEEP DUAL THREAD
Maximized anchorage & compression



POSITIVE LOCKING CHANNEL

SELF-DRILLING & SELF-TAPPING
Penetrating sharp tips facilitate insertion

EXACT2-T RECESS



SPECIFIC
Easy indexing of the Exact2-T screwdriver tip.
UNIVERSAL
Possible removal with standard instrumentation.

COLOR-CODED INSTRUMENTATION

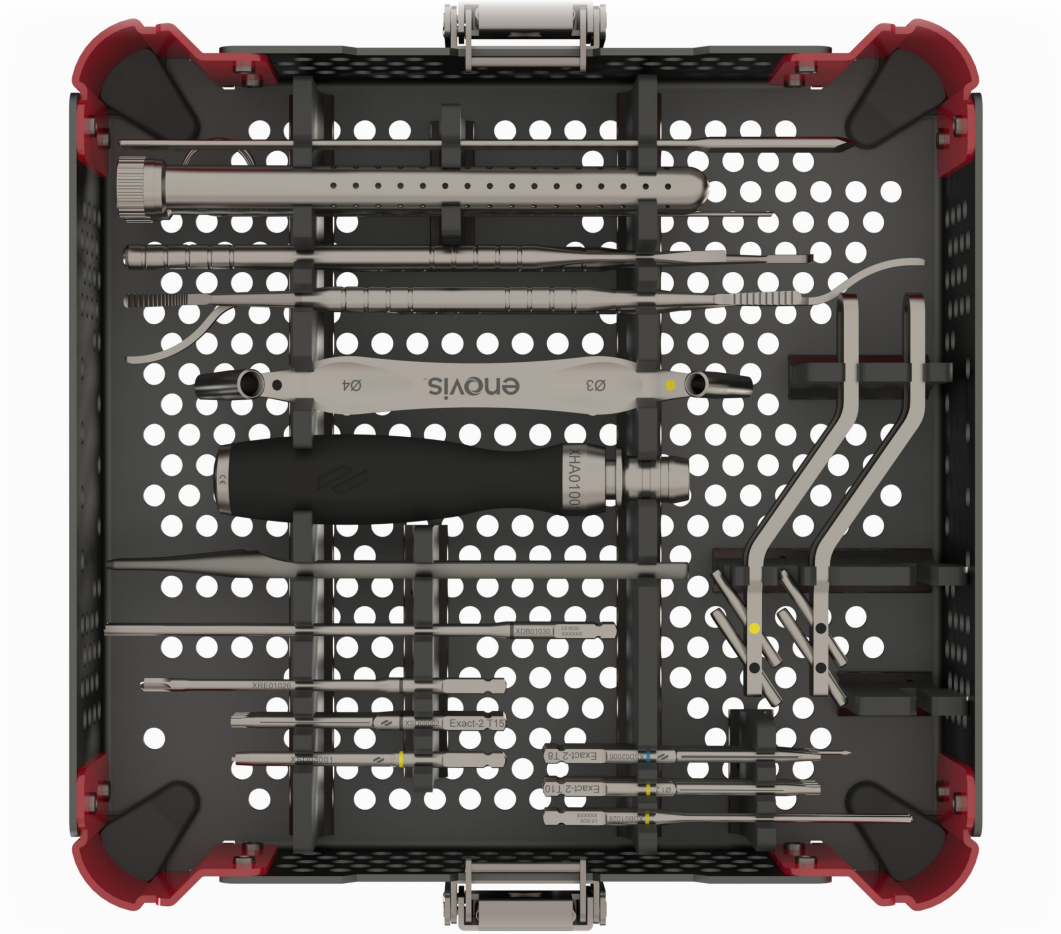
Ø2.7
nexis

DRIVER	Exact2-T8
LENGTH	14 - 30 mm
K-WIRE	Ø 1.2 mm

DESIGN FEATURES - 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 INSTRUMENTATION



PERCUTANEOUS RASPS

PERIOSTEAL ELEVATOR DOUBLE TIP

PERIOSTEAL ELEVATOR SINGLE TIP

REDUCTION DEVICE DOUBLE TIP - OPTIONAL

BEAVER HANDLE / FINE SURGICAL HANDLE

DESIGN FEATURES - INSTRUMENTATION

STERILE PERCUTANEOUS BURRS

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

1. PATIENT POSITIONING

The procedure may be performed with or without use of a tourniquet and is at the discretion of the surgeon. Use of tourniquet may increase the chance of bone necrosis so adequate irrigation is necessary. The 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 operative foot resting on a round wedge and the heel in the void to easily use the C-arm (FIGURE 1). The position of the C-arm is at the discretion of the surgeon.

FIGURE 1

2. IDENTIFICATION OF KEY ANATOMIC LANDMARKS

Once the foot is appropriately prepped and draped, direct attention to the operative foot. Identify and mark the landmarks of the ray by using palpation and/or fluoroscopy.

Key landmarks to be drawn include the first tarsometatarsal joint, the first metatarsophalangeal joint, and the longitudinal bisection of the first metatarsal in the sagittal plane. (FIGURE 2)

If considering a percutaneous Akin osteotomy, marking the longitudinal bisection of the proximal phalanx of the hallux may also be helpful.

FIGURE 2

3. INCISION & PERIOSTEAL PREPARATION

Using a beaver blade or a similar small scalpel, make a 1–2mm percutaneous incision through the skin along the longitudinal bisection of the first metatarsal at the desired osteotomy location, which is recommended to be slightly proximal to the sesamoid complex (FIGURE 3). A periosteal elevator is used to create a working space along the dorsal capsule at the surgeon's discretion. To preserve blood flow to the metatarsal head, the plantar capsule should not be stripped or violated.

FIGURE 3

4. REFERENCE WIRE INSERTION

Using a wire driver, insert the Reference Wire into the metatarsal at the desired osteotomy location, ensuring the wire entry point is along the midline of the metatarsal in the sagittal plane with a trajectory parallel to the ground. The osteotomy should be located in the distal first metatarsal, slightly proximal to the sesamoid complex. (FIGURE 4 A&B)

The depth of the Reference Wire is critical to proper implant placement, as the trajectory of the proximal-lateral screw intersects with the tip of the Reference Wire. It is recommended to insert the Reference Wire until the tip is aligned with the lateral aspect of the fibular sesamoid, however the surgeon should use their own judgement based on the severity of the bunion along with any other anatomic considerations.

Keep in mind that the 2.2mm x 22mm Shannon Burr removes a greater width of bone than a traditional saw blade. Proper burr orientation is essential to achieve the desired first ray length, as capital fragment translation will have both a lateral and a proximal-distal component to it.

FIGURE 4A

FIGURE 4B

5. GUIDE PLACEMENT

Slide the Pecaplasty® Wires First Guide over the Reference Wire until it contacts the olive. Align the Pecaplasty® Wires First Guide so that it is parallel to the midline of the metatarsal shaft and use the more distal knob to lock the Pecaplasty® Wires First Guide to the Reference Wire. Verify placement on a lateral x-ray of the first metatarsal (FIGURE 5). Use the more proximal knob to adjust the length of the targeting arm until it contacts the skin near the base of the metatarsal.

Insert the guide wire sleeves through the parallel guide on the targeting arm. Make percutaneous incisions to allow insertion of the proximal and distal guide wire sleeves down to bone along the proximal medial first metatarsal. Ensure the proximal sleeve contacts the most proximal medial extent of the metatarsal.

Using AP fluoroscopy, ensure the wire sleeves are in contact with the metatarsal and that they indicate the desired screw trajectory. Adjust the arch position as necessary.

6. WIRES INSERTION

Insert wires until they make contact, but do not penetrate through, with the lateral cortex of the metatarsal. This approach ensures the stability of the wire's position without creating a hole in the lateral cortex until fluoroscopy is used to confirm implant position.

If the screw trajectory is satisfactory on AP and lateral fluoroscopy, advance the proximal-lateral wire through the lateral cortex. The distal-medial wire will be advanced at a later step to ensure it does not block reduction of the capital fragment. (FIGURE 6)

Remove the sleeves from the targeting arm and detach the Pecaplasty® Wires First Guide from the Reference Wire. Then, remove the Reference Wire.

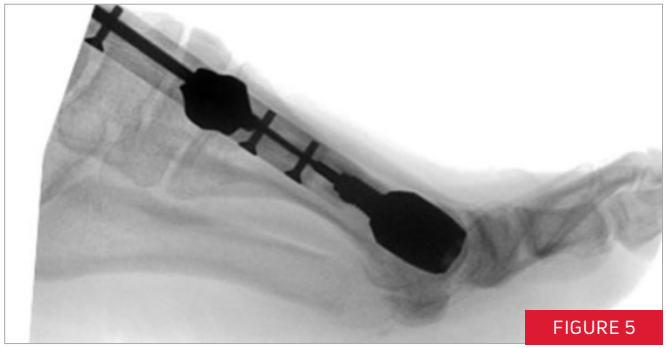


FIGURE 5

FIGURE 6

7. OSTEOTOMY AND CORRECTION

Insert the 2.2mm x 22mm Shannon Burr into the hole left by the Reference Wire. Use the burr to create the osteotomy.

Use the Head Shifting Device with its Adjustable Offset in the intramedullary canal of the metatarsal to shift the capital fragment laterally until the desired position is reached, based on AP and lateral fluoroscopy. (FIGURE 7)

⚠ WARNING: Avoid the use of excessive force, which can lead to fracture of the medial cortex of the metatarsal shaft, particularly in patients with osteopoenic or osteoporotic bone.

FIGURE 7

8. BONE PREPARATION FOR IMPLANTS

8.1 SCREW LENGTH MEASUREMENT

While maintaining the desired position of the capital fragment, advance the proximal-lateral wire, followed by the distal-medial wire, into the capital fragment to the desired screw depth. Confirm wire placement using AP and lateral fluoroscopy. (FIGURE 8)

The K-wires are then measured for two appropriately sized PECA implants (FIGURE 9). It is recommended to select PECA implants that are 4-6mm shorter than the measured length to ensure that the implants are fully recessed into the medial cortex of the metatarsal after insertion.

FIGURE 8

FIGURE 9

8.2 PECA® IMPLANT INSERTION

Over-drill the K-wire using the Ø3.2 drill bit.

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

TIP: 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® Ø4 implant over the wire to secure the osteotomy, using the Exact2-T15 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® Ø4 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 11 A&B)

Use oblique fluoroscopy view to confirm screw insertion.

FIGURE 11A

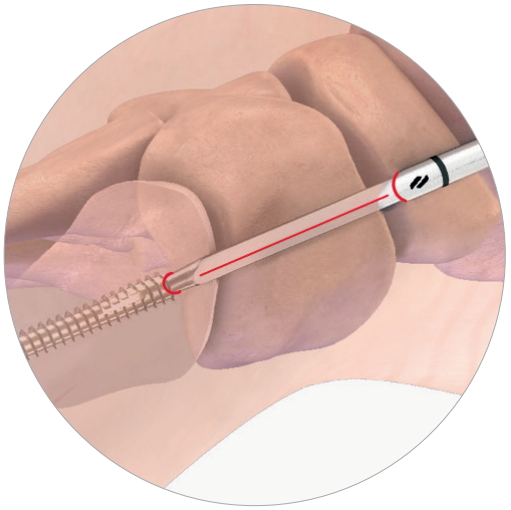


FIGURE 11B

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 12).

Overdrill the wire with the corresponding drill and place the second PECA® implant over the wire for final fixation as described above (FIGURE 13).

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 12

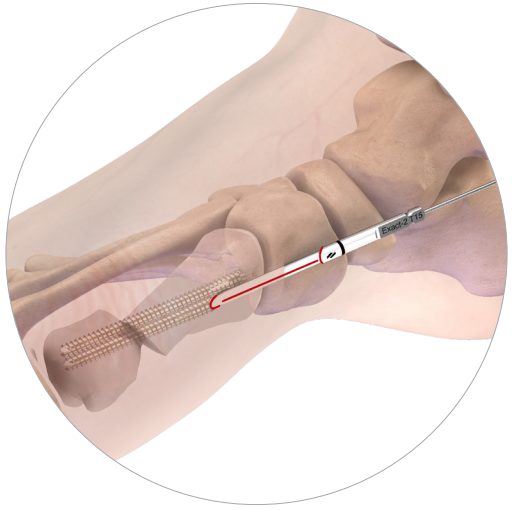


FIGURE 13

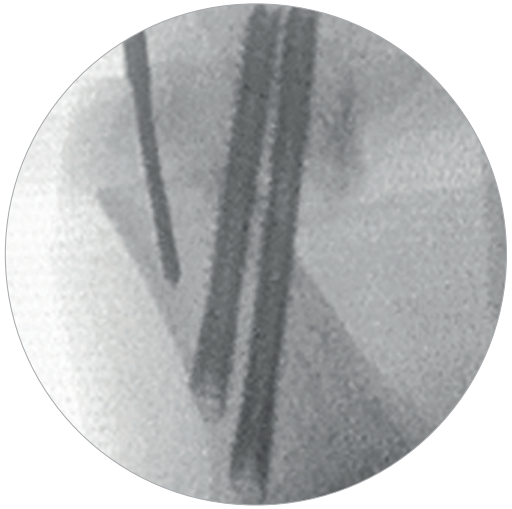
9. MEDIAL SPIKE REMOVAL

Remove the proximal medial prominence of the proximal fragment of the first metatarsal bone using a Ø2.2 Lg 22mm Shannon Burr through the proximal PECA® implant insertion from proximal to distal (FIGURE 14, OPTION 1), or through the osteotomy incision from distal to proximal (FIGURE 14, OPTION 2). 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 15).

OPTION 1



OPTION 2

FIGURE 14

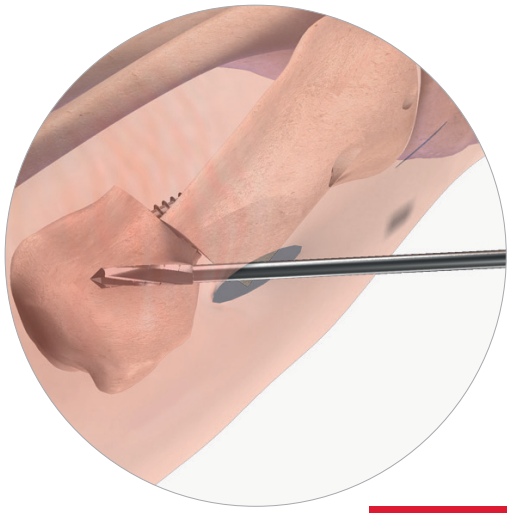


FIGURE 15

10. AKIN OSTEOTOMY

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

10.1 INCISIONS

Make two percutaneous incisions:

1. PHALANX OSTEOTOMY INCISION

At the meta-diaphyseal margin of the medial proximal phalanx (FIGURE 16, 1).

2. IMPLANT INSERTION INCISION

At the medial base of the hallux proximal phalanx (FIGURE 16, 2).

10.2 OSTEOTOMY

Under fluoroscopic guidance, the Ø2 Lg 12mm Shannon burr is inserted through incision 1, through the medial cortex midaxially (FIGURE 17). 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.

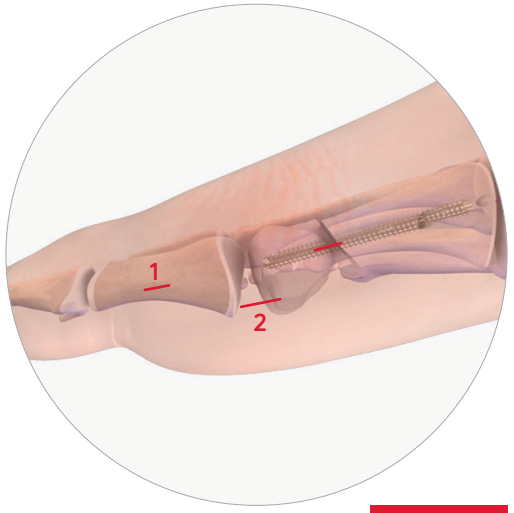


FIGURE 16

FIGURE 17

10.3 NEXIS® MIS SCREW INSERTION

Place a Ø1.2mm K-wire for the Nexis® MIS insertion screw percutaneously through incision 2 from the medial base of the hallux proximal phalanx across the Akin osteotomy site and through the distal lateral cortex.

Check position on AP and lateral fluoroscopy views. (FIGURE 20)

Read the screw length on the Nexis®/PECA® ruler and choose a Nexis® MIS screw that is 2-4mm shorter than the indicated length to ensure that the implant is fully recessed after insertion.

Insert the Nexis® MIS screw with the Exact-2 T8 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 21)

Check final AP and lateral fluoroscopy views of the hallux.

OPTIONAL: The PECA® Ø 3 implant can also be used for this step. In this case, be sure to use the associated Exact2-T10 screwdriver tip.

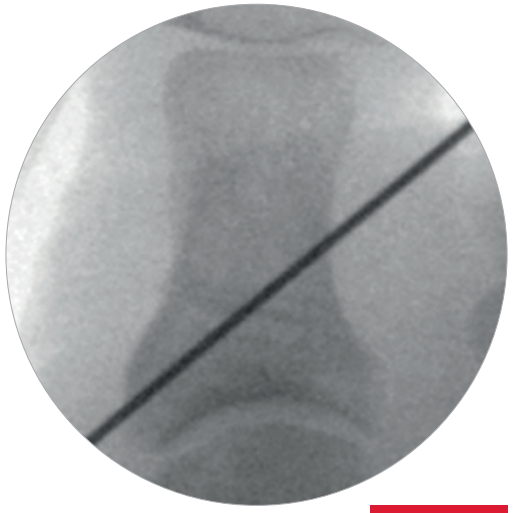


FIGURE 20

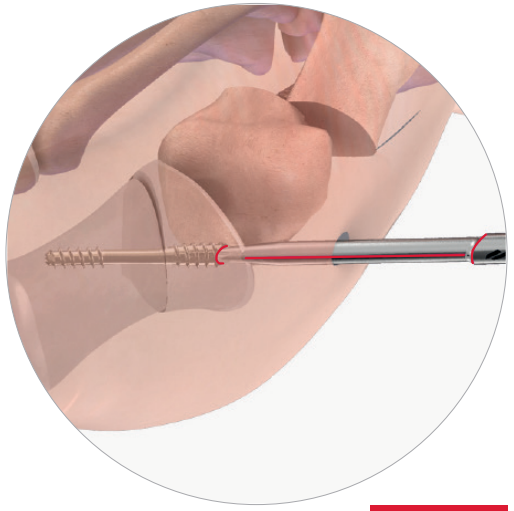


FIGURE 21

11. PROCEDURE COMPLETION

Utilize fluoroscopy to confirm appropriate correction of hallux valgus deformity on AP and lateral views. (FIGURE 22 A&B)

The incisions can be closed with sutures or sterile strips and dressed with a nonadherent layer and 4x4 inch gauze. Softband or wool is placed over the foot and ankle and then overwrapped with an ACE wrap (FIGURE 23A&B). Leave dressing in place for two to four weeks.

FIGURE 22A

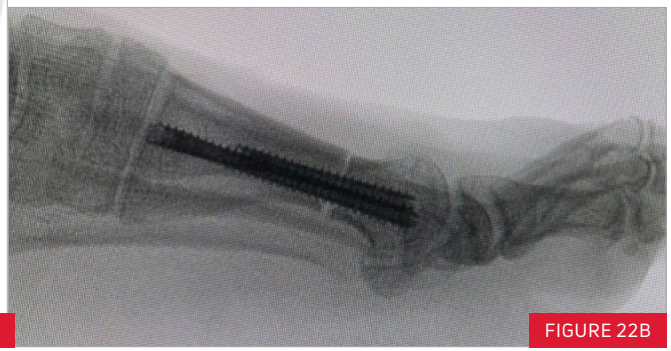


FIGURE 22B

FIGURE 23A

FIGURE 23B

IMPLANTS

PECA® BUNION IMPLANTS

LENGTH (mm)	PECA® Ø3mm	PECA® Ø4mm
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

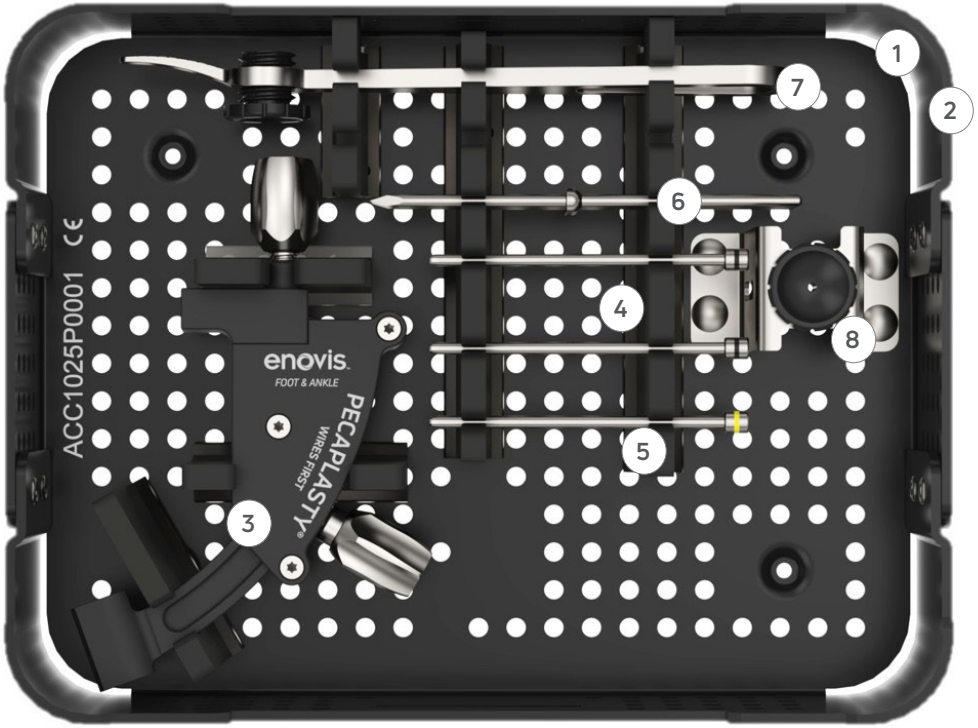
LENGTH (mm)	NEXIS® Ø2.7mm
14	SC090014
16	SC090016
18	SC090018
20	SC090020
22	SC090022
24	SC090024
26	SC090026
28	SC090028
30	SC090030

ORDERING INFORMATION

PERCUTANEOUS BURRS

DESCRIPTION	PART #
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

ORDERING INFORMATION



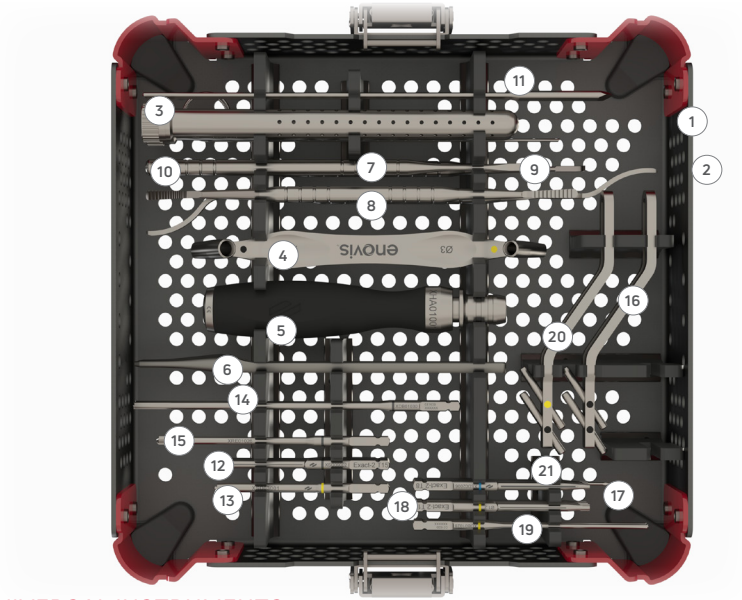
PECAPLASTY® WIRES FIRST SET

#	DESCRIPTION	PART #	QTY
1	TRAY WIRES FIRST	ACC1025P0001	1
2	LID WIRES FIRST	ACC1025P0002	1
3	TARGETING GUIDE 2.0 WIRES FIRST	XMS01050	1
4	PECA Ø4 K WIRE SLEEVE	XDG01036	2
5	PECA Ø3 K WIRE SLEEVE	XDG01037	1
6	POSITIONING PIN5[1]	CKW09001	1
7	HEAD SHIFTING DEVICE	XMS01055-1	1
8	ADJUSTABLE OFFSET	XMS01055-2	2

[1] The Positioning Pin is mentioned as Reference Wire in the surgical steps

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[3]	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 available depending on your market

PERCUTANEOUS INSTRUMENTS

#	DESCRIPTION	PART #	QTY
7	FINE SURGICAL HANDLE	SF13[4]	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

[4] 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[5]		OPTION

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

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-WF-ST-ED01-01-26-EN