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SURGICAL
TECHNIQUE

enovis

PECAPLASTY®

PERCUTANEOUS BUNION CORRECTION

BUNION SYSTEM

TABLE OF CONTENTS

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.

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

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

TARGETING GUIDE*

WIRE HANDLE
Allows for the traction wire to be inserted into the metatarsal canal through the initial incision

TRACTION WIRE
Guided by the stabilization sleeve in the metatarsal canal, stabilizing the guide

TRANSLATION DIAL
Translation of the metatarsal head by rotating the dial

PADDLE
Positioned against the metatarsal head, assisting in translation

LOCKING DIAL
Locks the targeting arc in position

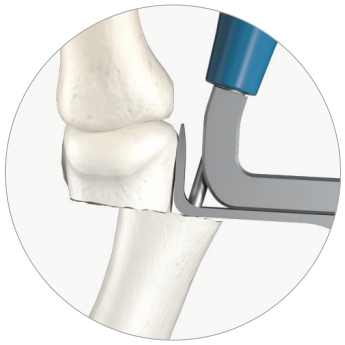
PARALLEL HOLES
Guided placement of K-Wires through the sleeves

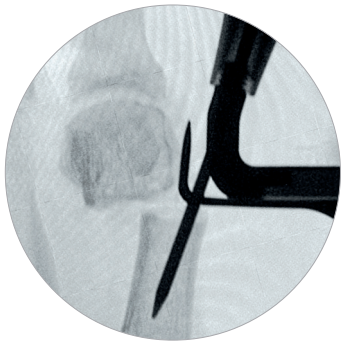
TARGETING ARC
Adjustable positioning based on the point of entry

**Patent pending*

GUIDED AND REPRODUCIBLE PROCEDURE

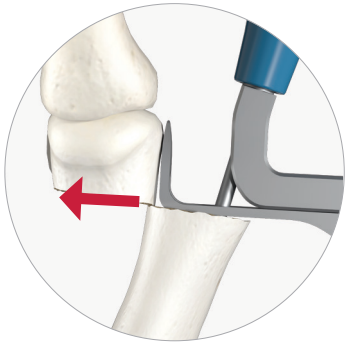
1. EASY POSITIONING ON THE FOOT

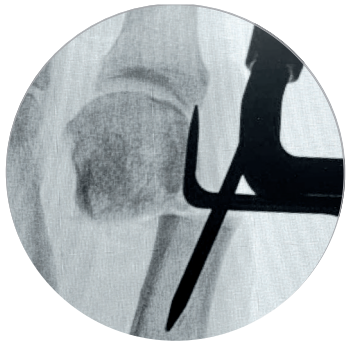




POSITION the guide by inserting the paddle underneath the medial capsule through initial incision, after a transverse osteotomy.

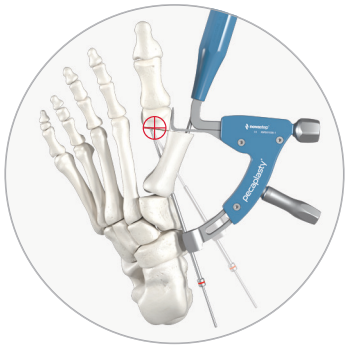
2. CONTROLLED TRANSLATION OF METATARSAL HEAD

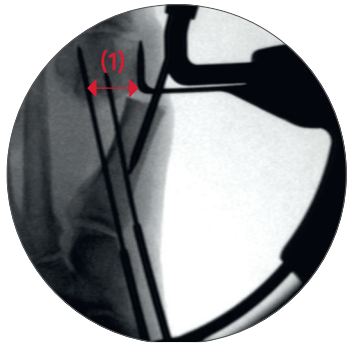




TRANSLATE the metatarsal head using the translation dial.

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.

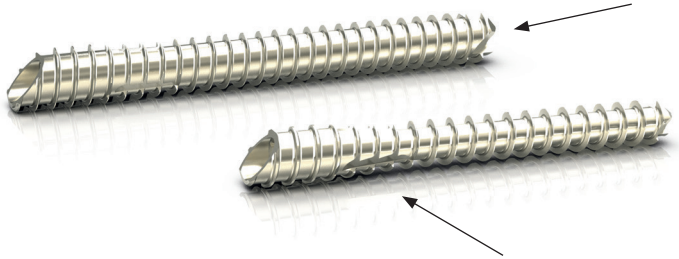
DESIGN FEATURES - SCREWS

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 metaratsal cortex of the first metatarsal

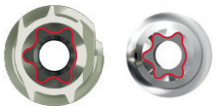


PROXIMAL CUTTING FLUTES

EXACT-T® TECHNOLOGY: PATENTED INNOVATION

Exact-T® (patent pending) facilitates correct placement of implant upon insertion.

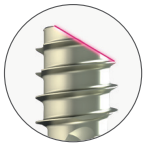
EXACT-T® RECESS - PECA® IMPLANTS



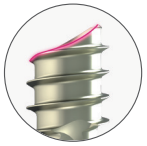
SPECIFIC
Easy indexing of the Exact-T® screwdriver tip allows exact driver positioning in one direction only

2. NEXIS MIS Ø2.7 - BEVELED COMPRESSIVE SCREWS

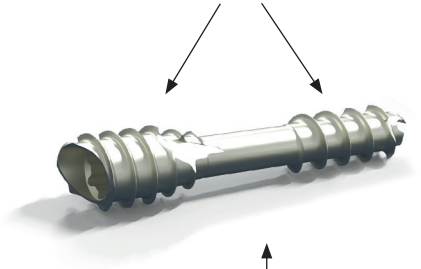
ELLIPTIC BEVELED HEAD (30°)
Maximization of cortical anchorage and preservation of soft tissue



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



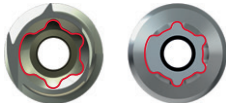
DEEP DUAL THREAD
Maximized anchorage & compression



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

POSITIVE LOCKING CHANNEL

EXACT2-T RECESS - NEXIS® MIS SCREWS

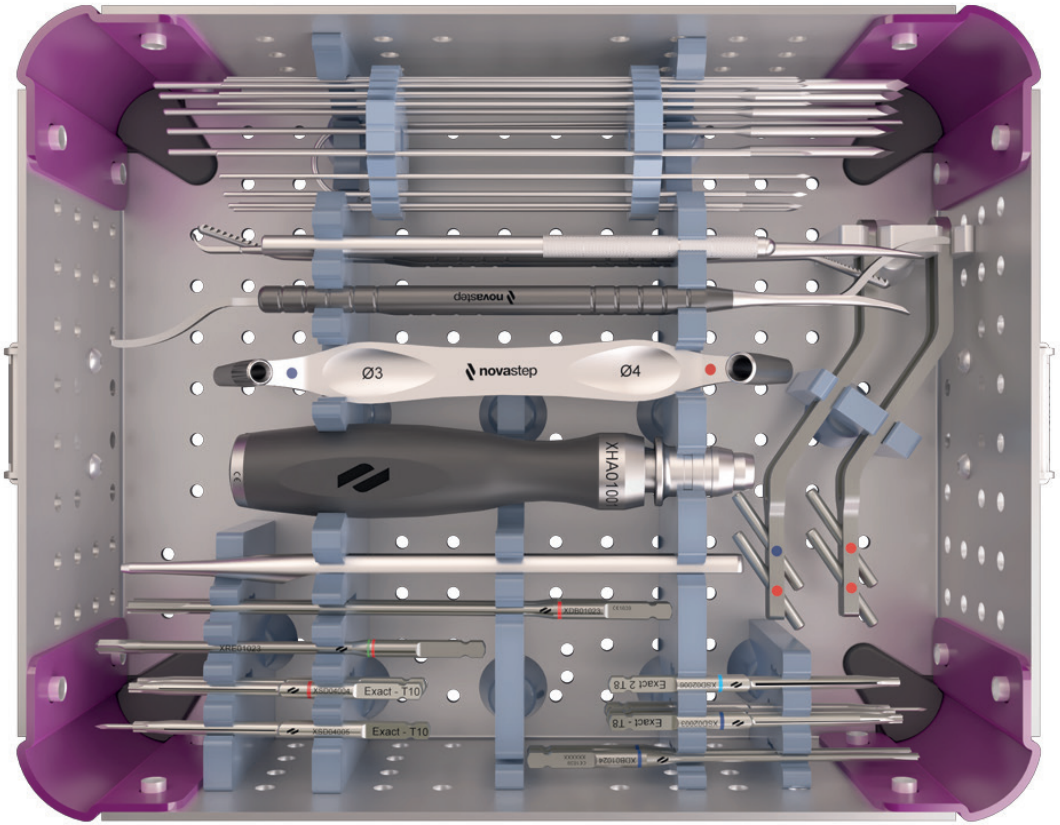


SPECIFIC
Easy indexing of the Exact2-T screwdriver tip.
UNIVERSAL
Possible removal with standard instrumentation.

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 blade holder 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. If a tourniquet is utilized, periodic irrigation should be considered when using the percutaneous burrs in order to limit potential risk of thermal soft tissue injury or osseous necrosis. 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. TRANSVERSE OSTEOTOMY OF THE FIRST METATARSAL

2.1 LANDMARKS & INCISION

With a marking pen, draw the longitudinal bisection of the first metatarsal (FIGURE 2, **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 (FIGURE 2, **L2**). 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.

FIGURE 2

2.2 TRANSVERSE OSTEOTOMY

Use a Shannon Longa Ø2.2 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 for 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.

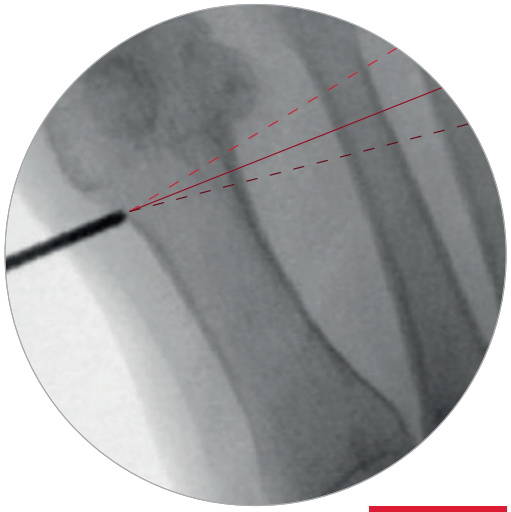


FIGURE 3

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 (FIGURE 5, 1).

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

Turn the translation dial (FIGURE 5, 2) to bring the stabilization sleeve closer to the skin (FIGURE 5, 3). A stop prevents excessive pressure on the soft tissue.

FIGURE 4

FIGURE 5

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 (FIGURE 6, 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 (FIGURE 6, 2). Fasten it into the Pecaplasty® targeting guide (FIGURE 6, 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 (FIGURE 7).

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.

FIGURE 6

FIGURE 7

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 (FIGURE 8).

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.

FIGURE 8

5. K-WIRE 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 in FIGURE 9.

> 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.

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 (FIGURE 10).

FIGURE 9

FIGURE 10

5.2 K-WIRE 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 (FIGURE 11).

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.

Leave the distal K-wire sleeve in place and repeat the steps for the proximal sleeve (FIGURE 12).

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.

OPTIONAL: 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.

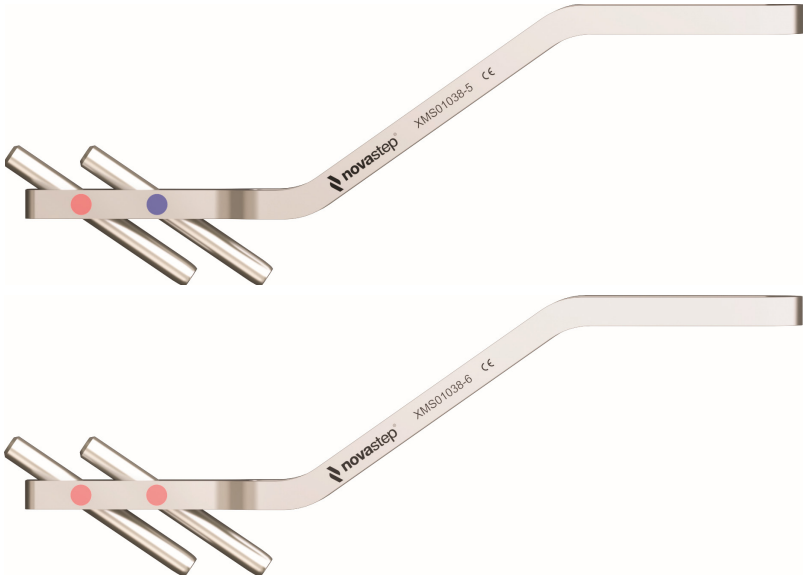
FIGURE 11

FIGURE 12

OPTIONAL: PECA® Ø4 - Ø4 and PECA® Ø3 - Ø4 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.



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 (FIGURE 13, 1).

Turn the locking dial counterclockwise to unlock the guide (FIGURE 13, 2) and remove the sleeves (FIGURE 13, 3). The K-wires pass through the notch of the parallel guide and the targeting arc is retracted before removing the guide (FIGURE 13, 4).

FIGURE 13

6.2 PECA® IMPLANT INSERTION

The first implant length is then read with the PECA® ruler (FIGURE 14). Choose a PECA® implant that is 6-8mm shorter than the indicated length to ensure that the implant is fully recessed after insertion.

> NOTE: 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 Ø3.2 drill bit.

> 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 Exact-T®10 AO screwdriver tip (FIGURE 15). 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.

Use oblique fluoroscopy view to confirm.

FIGURE 14

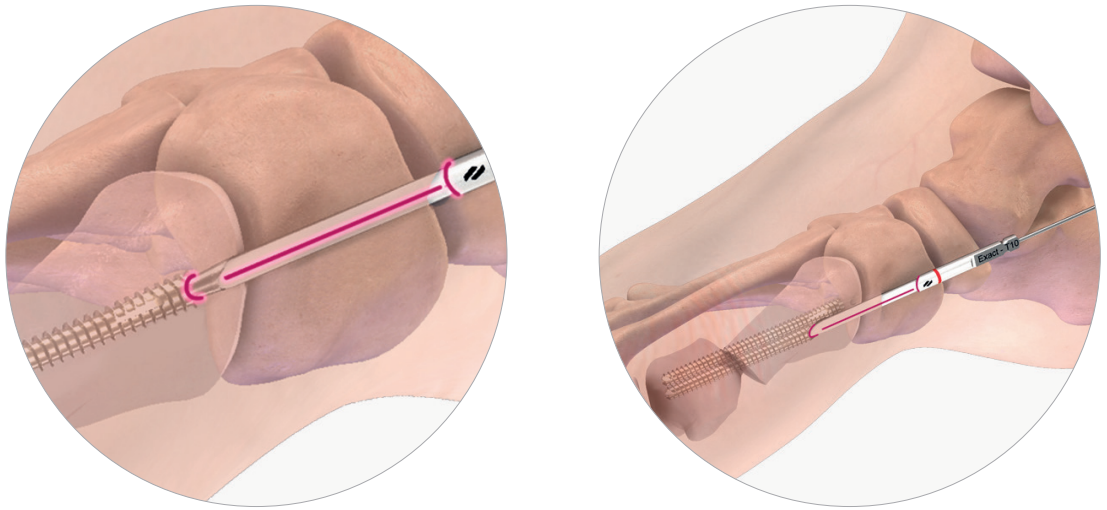


FIGURE 15

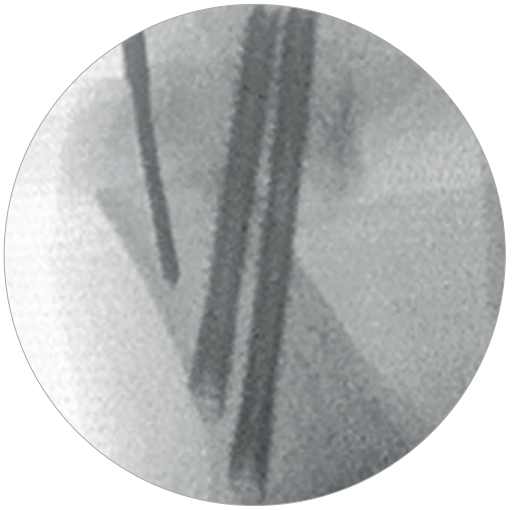
6.3 BONE SPIKE REMOVAL

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 16, OPTION 1), or through the osteotomy incision from distal to proximal (FIGURE 16, OPTION 2), at the surgeon's discretion. 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 17).

OPTION 1



OPTION 2

FIGURE 16

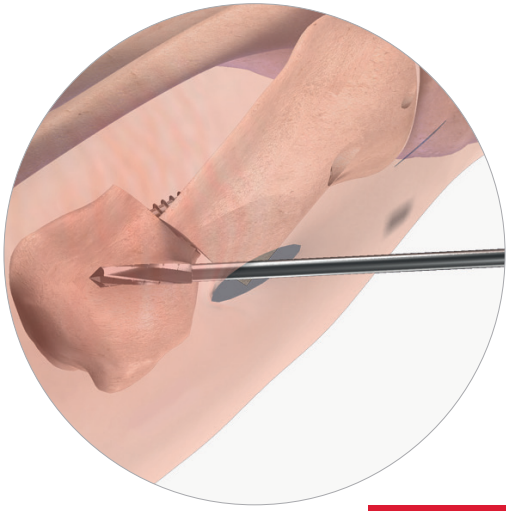


FIGURE 17

7. AKIN OSTEOTOMY

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

7.1 TARGETING GUIDE REMOVAL

Make two percutaneous incisions:

1. PHALANX OSTEOTOMY INCISION

At the meta-diaphyseal margin of the medial proximal phalanx (FIGURE 18, 1).

2. IMPLANT INSERTION INCISION

At the medial base of the hallux proximal phalanx (FIGURE 18, 2).

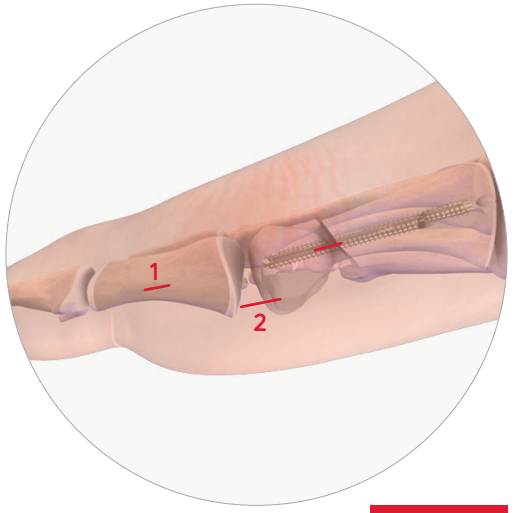


FIGURE 18

7.2 OSTEOTOMY

Under fluoroscopic guidance, the Ø2 Lg 12mm Shannon burr is inserted through incision 1, through the medial cortex midaxially (FIGURE 19). 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 19

7.3 NEXIS® MIS SCREW INSERTION

Place a Ø1.0mm 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.

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.

OPTIONAL: 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 depending on bone quality. Finish the insertion by hand until the lateral cortex has been reached.

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 Exact®-T8 screwdriver tip.

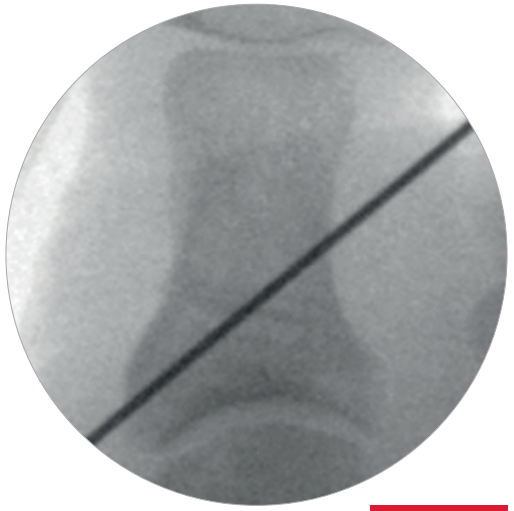


FIGURE 20

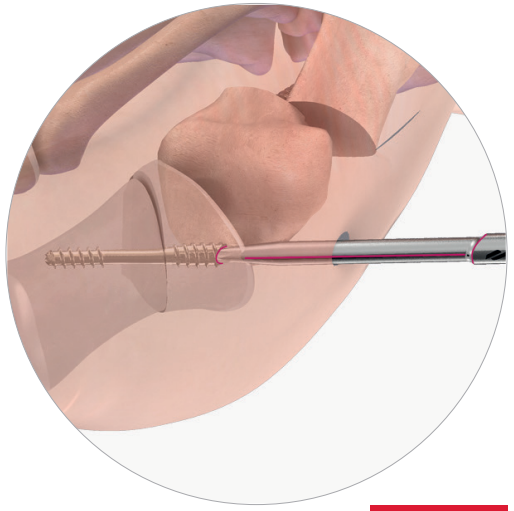


FIGURE 21

8. DRESSING

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 22). Leave dressing in place for two to four weeks.

FIGURE 22

IMPLANTS

PECA® BUNION IMPLANTS

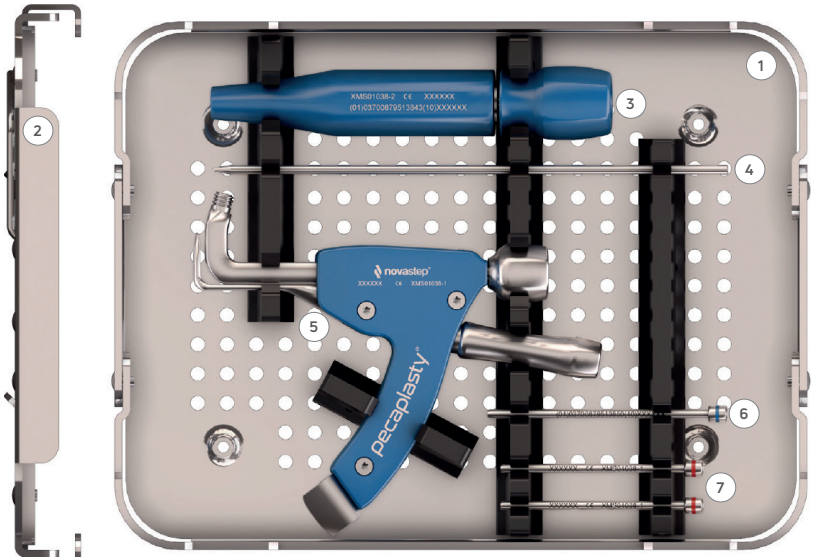
LENGTH (mm)	PECA® Ø3mm	PECA® Ø4mm
16	PS020016	-
18	PS020018	-
20	PS020020	-
22	PS020022	-
24	PS020024	-
26	PS020026	PS050026
28	PS020028	PS050028
30	PS020030	PS050030
32	PS020032	PS050032
34	PS020034	PS050034
36	PS020036	PS050036
38	PS020038	PS050038
40	PS020040	PS050040
42	PS020042	PS050042
44	PS020044	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

INSTRUMENTS

PECAPLASTY® TARGETING GUIDE

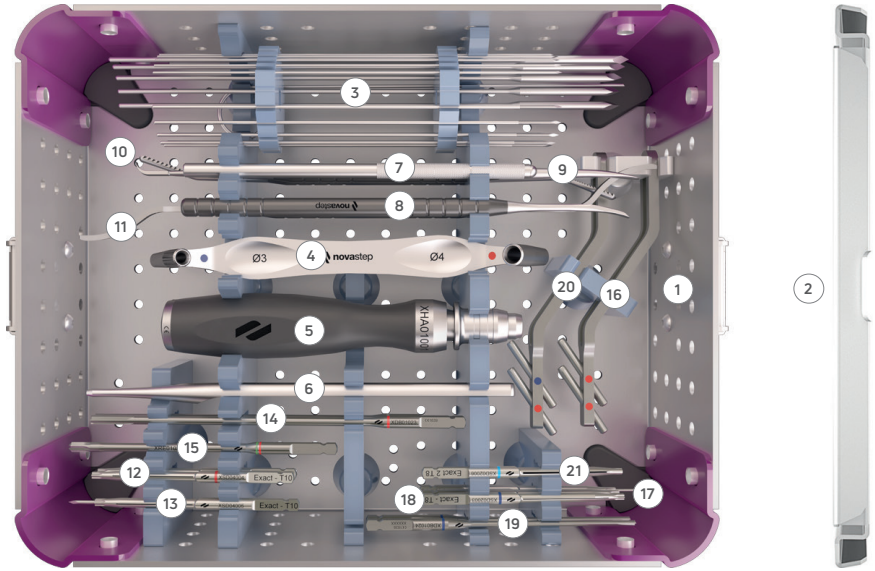


#	DESCRIPTION	PART #WW	QTY
1	TRAY	ACC1019P0001	1
2	LID	ACC1019P0002	1
3	TARGETING GUIDE	XMS01038-1	1
4	WIRE HANDE FOR TARGETING GUIDE	XMS01038-2	1
5	TRACTION WIRE Ø2.5 LG 128 - STERILE	SKW06002[1]	5
6	PECA® Ø3 - K-WIRE SLEEVE	XMS01038-3	1
7	PECA® Ø4 - K-WIRE SLEEVE	XMS01038-4	2

[1] Sterile traction wire supplied separately. Non sterile traction wire is also available (Ref: CKW06002)

ORDERING INFORMATION

PECA® IMPLANTS & NEXIS® MIS SCREWS



UNIVERSAL INSTRUMENTS

#	DESCRIPTION	PART #	QTY
1	TRAY	ACC1001P0022	1
2	LID	ACC1001P0024	1
3	K-WIRES HOLDER	ACC1001P0023	1
	REDUCTION WIRE Ø3.5	CKW03001	5[2]
	K-WIRE Ø1 LG 150 TR/RD CoCR	CKW02004[1]	5[2]
	K-WIRE Ø1.4 LG 150 TR/RD CoCR	CKW02005[1]	8[2]
	CLEANING PIN Ø0.9	XKW01001	1
	CLEANING PIN Ø1.4	XKW01002	1
4	TISSUE PROTECTOR	XDG01024	1
5	AO HANDLE	XHA01001	1
6	RULER LG 150	XGA01009	1

[1] *K-wire supplied separately.*
[2] *Maximum quantity of k-wires holder*

PERCUTANEOUS INSTRUMENTS

#	DESCRIPTION	PART #	QTY
7	FINE SURGICAL HANDLE	SF13[3]	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

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

PECA® Ø4 INSTRUMENTS

#	DESCRIPTION	PART #	QTY
12	EXACT-T®10 AO SCREWDRIVER TIP	XSD04004	2
13	REMOVAL EXACT-T®10 AO SCREWDRIVER TIP	XSD04005	OPTION
14	AO DRILL BIT Ø 3.2	XDB01023	2
15	NEXIS® / PECA®-C - COUNTERSINK Ø 3.7	XRE01007	OPTION
16	PECA® - PARALLEL GUIDE Ø 4 - Ø 4	XMS01038-6	OPTION

PECA® Ø3 INSTRUMENTS

#	DESCRIPTION	PART #	QTY
17	EXACT-T®8 AO SCREWDRIVER TIP	XSD02003	1
18	REMOVAL EXACT-T®8 AO SCREWDRIVER TIP	XSD02004	OPTION
19	AO DRILL BIT Ø 2	XDB01024	2
20	PECA® - PARALLEL GUIDE Ø 3 - Ø 4	XMS01038-5	OPTION

NEXIS® MIS Ø2.7 INSTRUMENTS

#	DESCRIPTION	PART #	QTY
21	EXACT-2 T8 AO SCREWDRIVER TIP	XSD02006	2
	RULER LG 100/150	XGA01013	OPTION
	K-WIRE Ø 1.2 LG 100 TR/RD[4]		OPTION
	K-WIRE Ø 1.2 LG 150 TR/RD[5]		OPTION

[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.*

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

NOTES

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T +33 (0) 2 99 33 86 50 F + 33 (0) 9 70 29 18 95

Legal manufacturer: Novastep® S.A.S
2 Allée Jacques Frimot | 35000 Rennes | France
contact-intfa@enovis.com
www.int.novastep.life

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-Tar-ST-ED4-05-25-EN