ST

SURGICAL
TECHNIQUE

enovis

# PECA®

BUNION IMPLANTS Ø3 / Ø4MM

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.

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 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

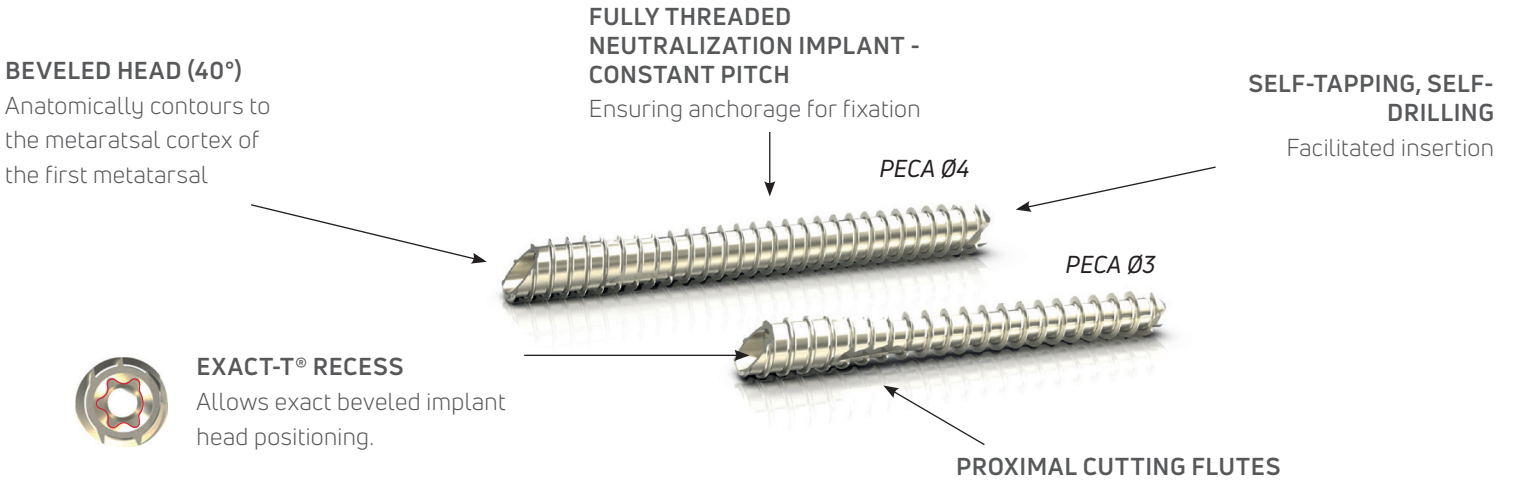
- Severe muscular, neurological or vascular deficiency in the extremity concerned.
- Bone destruction or poor bone quality, likely to impair implant stability.
- Hypersensitivity to vanadium and/or aluminium.

# 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 Exact-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.




## PECA® RANGE

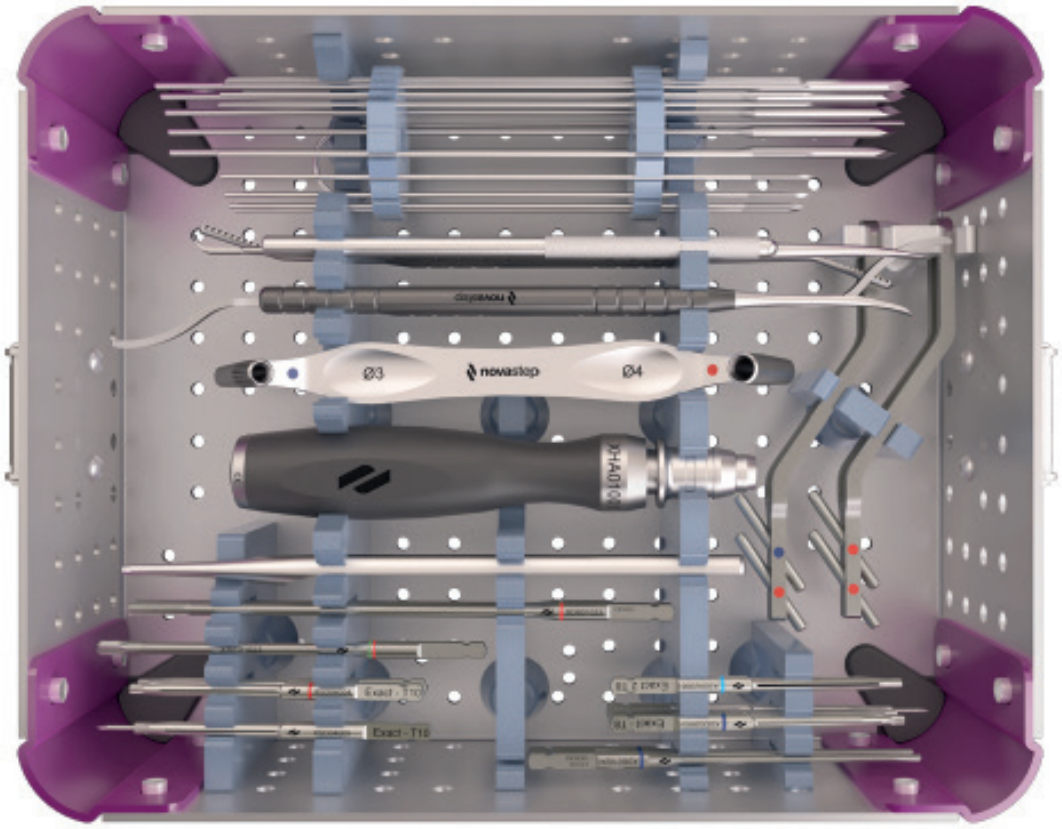
Made of Titanium alloy (TA6V Eli anodised), PECA® Bunion implants are available in 3mm and 4mm diameters Instrumentation is color-coded for convenient identification.

| | Ø3mm | Ø4mm |
|---|---|---|
| DRIVER | EXACT-T8 | EXACT-T10 |
| LENGTH | 16-48mm | 26-60mm |
| K-WIRE | CoCr Ø1mm | CoCr Ø1.4mm |
| DRILL BIT | Ø2mm | Ø3.2mm |

**Patent pending*

## 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 blade holder for fast, accurate and dedicated percutaneous surgery.




PERCUTANEOUS RASPS

PERIOSTEAL ELEVATOR DOUBLE TIP

PERIOSTEAL ELEVATOR SINGLE TIP

*REDUCTION DEVICE DOUBLE TIP - OPTIONAL*

BEAVER - FINE SURGICAL HANDLE

# DESIGN FEATURES



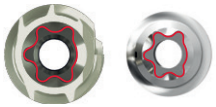
## STERILE PERCUTANEOUS BURRS

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

## EXACT-T® TECHNOLOGY: PATENTED INNOVATION

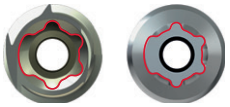
Exact-T® (patent pending) facilitates correct placement of implant upon insertion.

### EXACT-T® RECESS - PECA® IMPLANTS



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

### EXACT2-T RECESS - NEXIS® MIS SCREWS



**SPECIFIC**
Easy indexing of the Exact2-T screwdriver tip.

**UNIVERSAL**
Possible removal with standard instrumentation.

# DESIGN FEATURES



## STERILE PERCUTANEOUS BURRS

**HAMMERTOE, AKINETTE**
SHANNON CORTA Ø2 LG 8mm

**AKIN, DMMO**
SHANNON RECTA Ø2 LG 12mm
SHANNON HELICAL Ø2 LG 12mm

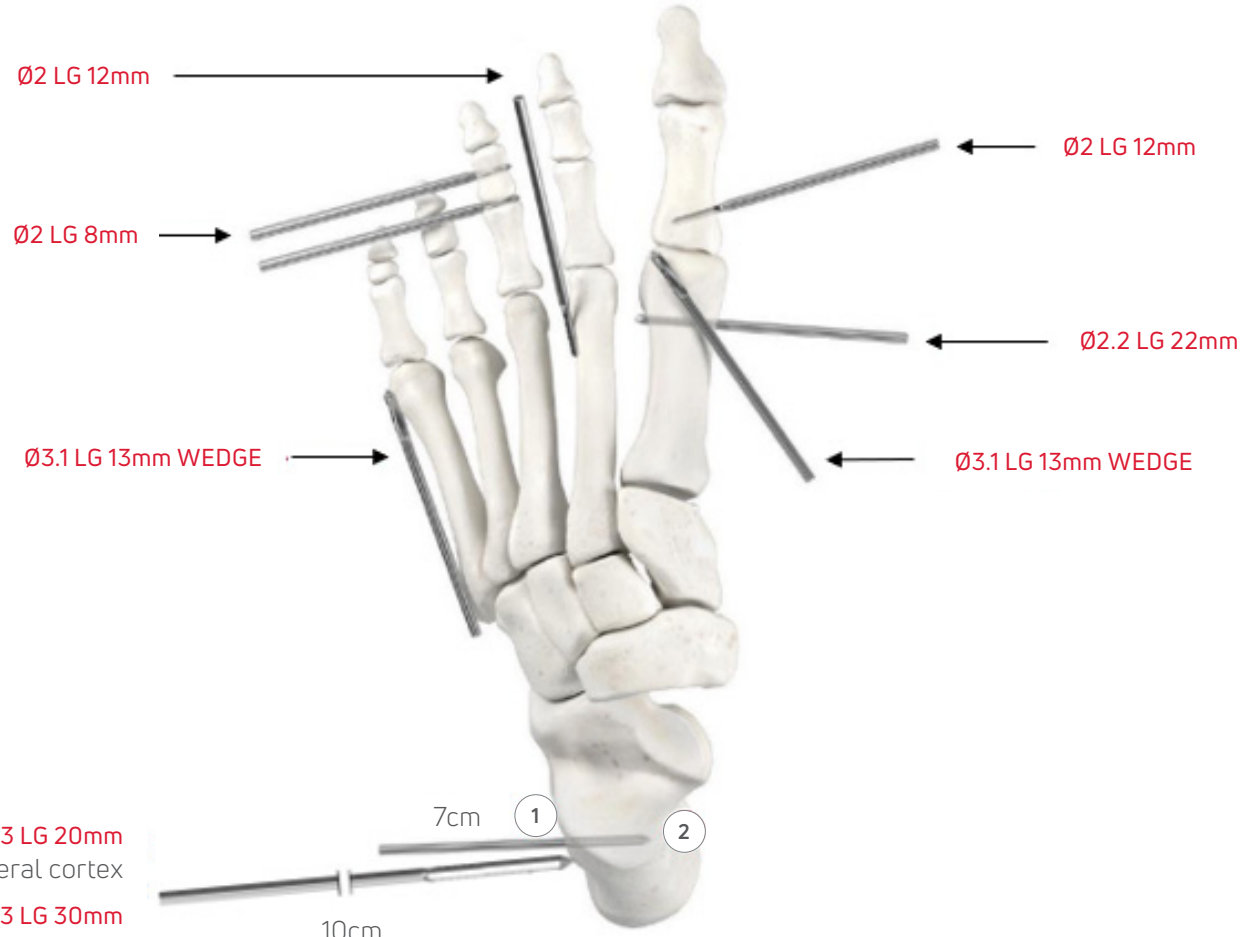
**BUNION, JOINT PREP**
SHANNON LONGA Ø2.2 LG 22mm

**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.** Ø3 LG 20mm
Calcaneal lateral cortex

**2.** Ø3 LG 30mm
Calcaneal medial cortex

## 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 3 A & 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

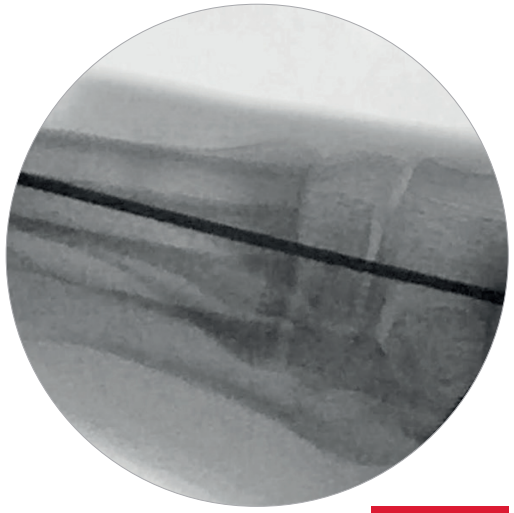


FIGURE 3B

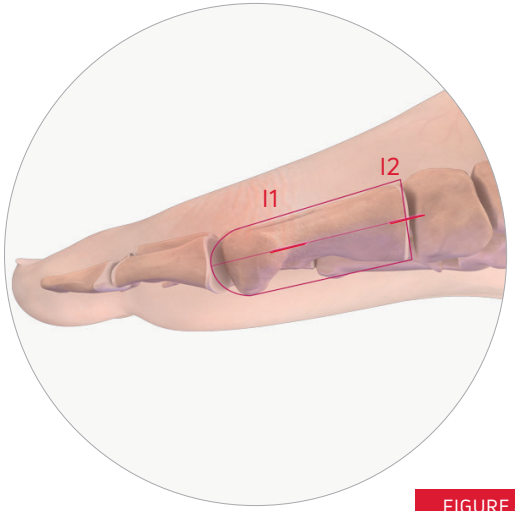



FIGURE 4

## 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:

- When 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, insert the 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.

## 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 9 A & B).

FIGURE 8

FIGURE 9A

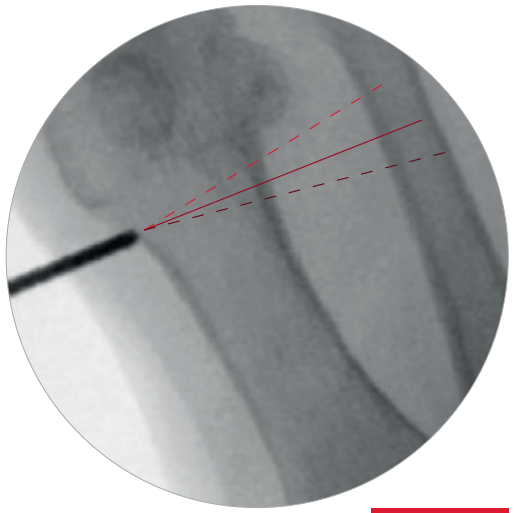


FIGURE 9B

## 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 10 A & B).

### 3.2 K-WIRE PLACEMENT

The Ø1.4mm 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 11 A & 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 Ø1.4mm 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

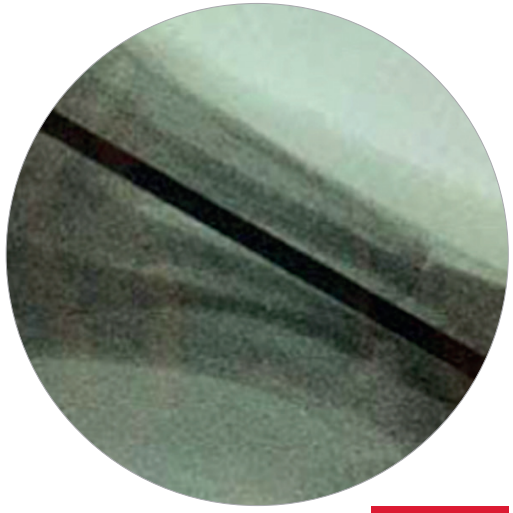


FIGURE 11B

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

Then insert a Ø1.4mm distal K-wire through incision I2, through the medial proximal first metatarsal cortex and into the capital fragment.

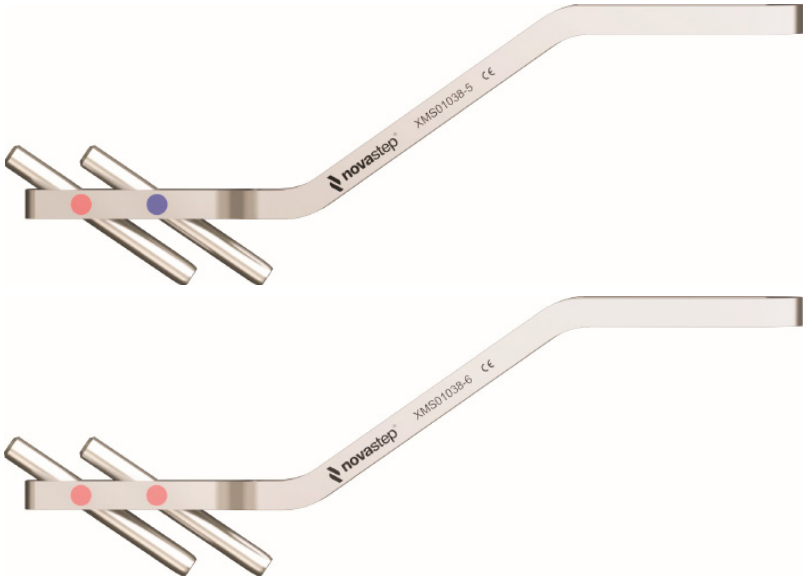
Check AP and lateral fluoroscopy views to confirm K-wire position (FIGURE 12).

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

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.

FIGURE 12



### 3.3 PECA IMPLANT INSERTION

The proximal implant length is then read on the PECA® ruler (FIGURE 13). 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 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 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 14).

Use oblique fluoroscopy view to confirm.

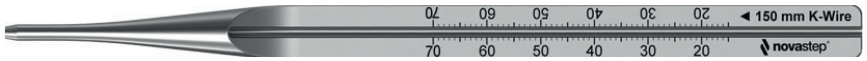



FIGURE 13

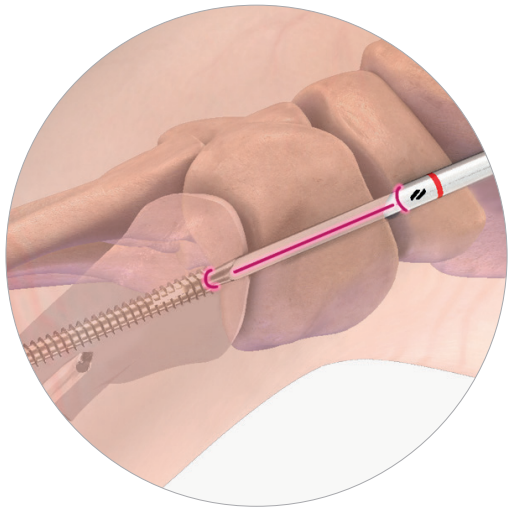


FIGURE 14

NOTE: A PECA® Ø4 bunion implant is recommended at this step. The Ø1.4mm K-wire is recommended over the Ø1.0mm K-wire for a reliable positioning, and the larger implant provides more stability to the construct.

OPTIONAL: A PECA® Ø3 bunion implant, with Ø1,0 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 4-6mm shorter than the indicated length to ensure that the implant is fully recessed after insertion (FIGURE 15).

Overdrill the wire with the corresponding drill and place the second PECA® implant over the wire for final fixation as described above (FIGURE 16).

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 15

FIGURE 16

### 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 17). 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 18).

FIGURE 17

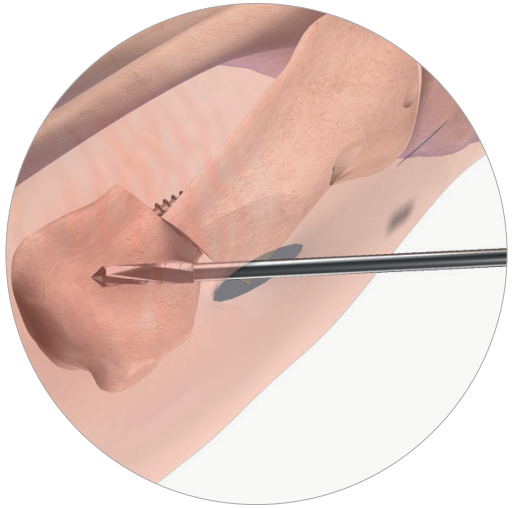


FIGURE 18

## 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 19, 1).

**2. IMPLANT INSERTION INCISION**

At the medial base of the hallux proximal phalanx (FIGURE 19, 2).

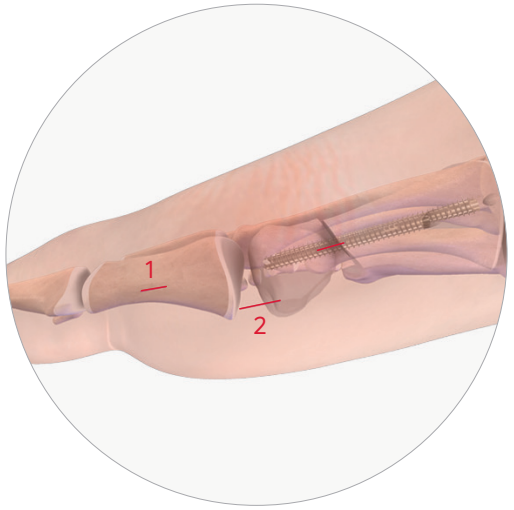



FIGURE 19

### 4.2 OSTEOTOMY

Under fluoroscopic guidance, the Ø2 Lg 12mm Shannon burr is inserted through incision 1, through the medial cortex midaxially (FIGURE 20). 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.

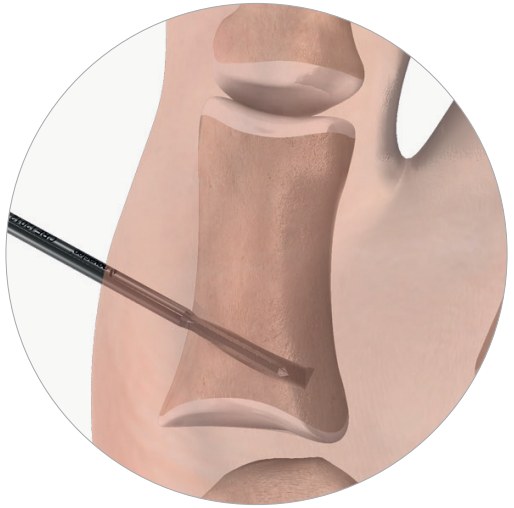


FIGURE 20

### 4.3 PECA® 3 IMPLANT INSERTION

A Ø 1 mm K-wire for the Ø 3 mm 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 21).

> 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 Exact-T®8 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 22).

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.

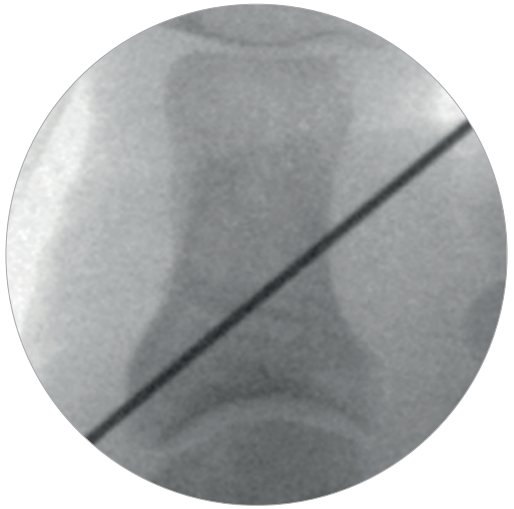


FIGURE 21

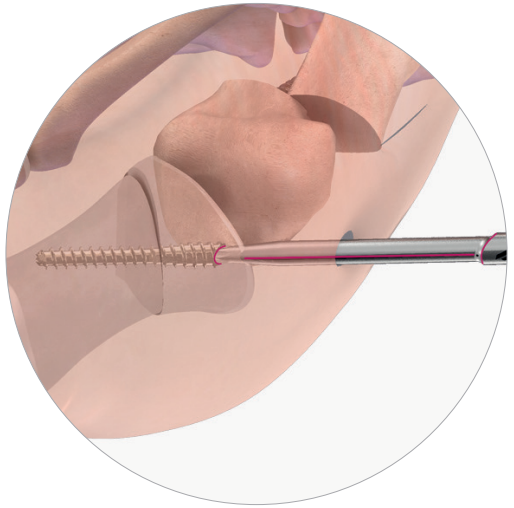


FIGURE 22

## 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 23).

FIGURE 23

## 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 24 A & B). This dressing is left in place for two weeks.

FIGURE 24A

FIGURE 24B

## 7. 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. (FIGURE 25).


FIGURE 25

# ORDERING INFORMATION



## 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 |

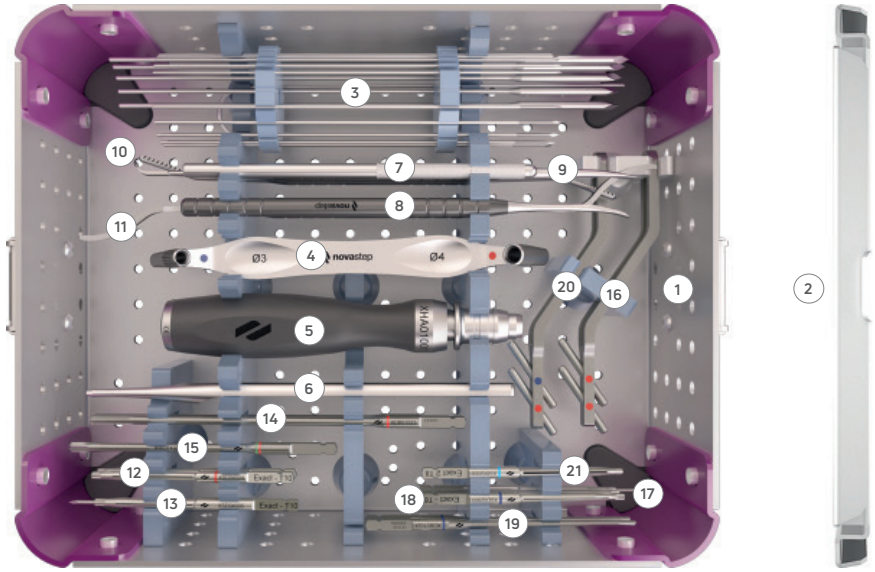
### NEXIS® MIS BEVELED COMPRESSIVE SCREW

| LENGTH (mm) | NEXIS® Ø2.7mm |
|---|---|
| 14 | PS020016 |
| 16 | PS020018 |
| 18 | PS020020 |
| 20 | PS020022 |
| 22 | PS020024 |
| 24 | PS020026 |
| 26 | PS020028 |
| 28 | PS020030 |
| 30 | PS020032 |

# ORDERING INFORMATION



## PECA® IMPLANTS & NEXIS® MIS SCREWS INSTRUMENTATION




## 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[1] | 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

| 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-ST-ED5.1-06-25-EN