



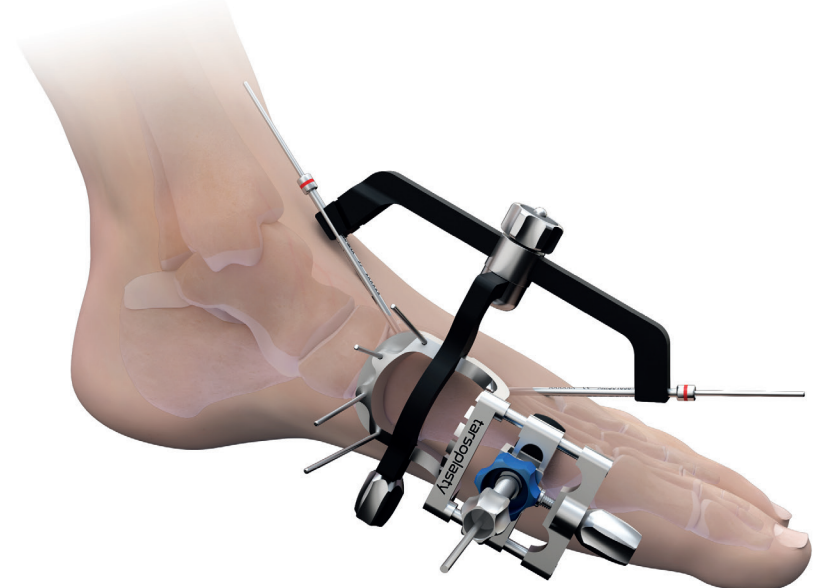
SURGICAL
TECHNIQUE

enovis™

TARSOPLASTY®

PERCUTANEOUS LAPIDUS CORRECTION
PECA, PECA-C, NEXIS MIS SCREWS

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

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 Lapidus arthrodesis and Akin osteotomy.

CONTRAINDICATIONS

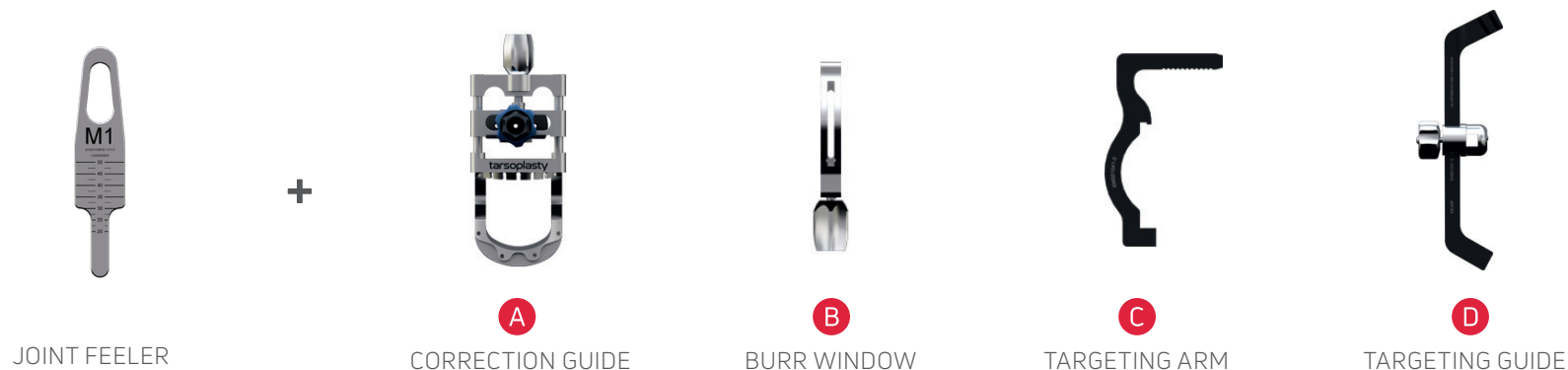
- Severe muscular, neurological or vascular deficiency in the extremity concerned.
- Bone destruction or poor bone quality, likely to impair implant stability.
- Hypersensitivity to vanadium and/or aluminium.

 **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.

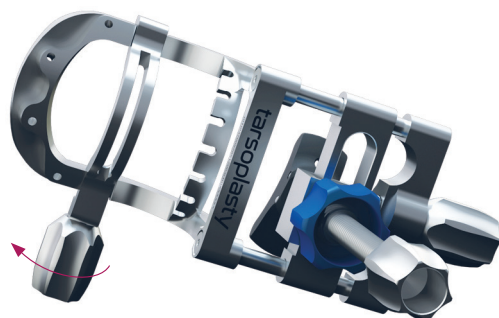
The Tarsoplasty® system allows guided and controlled percutaneous Lapidus procedure for simple, precise and reproducible correction of Hallux valgus. Associated with PECA® and PECA® Compressive screws, the Tarsoplasty® system ensures triplanar correction and stable construction to restore natural alignment of the first metatarsal.

ASSEMBLY

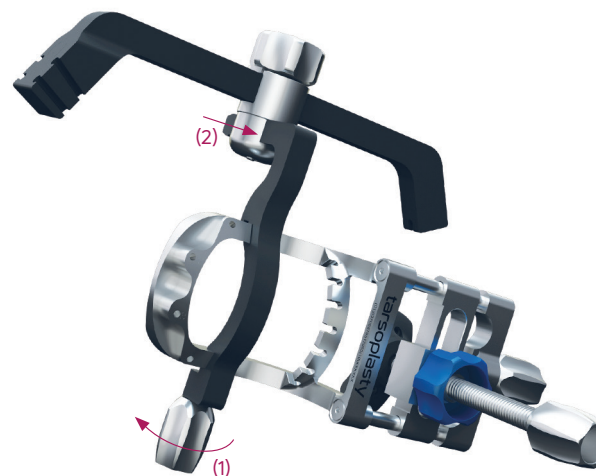
Joint feeler + 4 parts / 2 configurations of the Tarsoplasty® guide:



1st configuration: A + B



2nd configuration: A + C + D



Position the burr window on the dedicated part of the correction guide and fix it by turning the locking wheel: the dial can be oriented up or down at the surgeon's preference. Ensure the reduction dial is fully unscrewed before positioning the Tarsoplasty® correction guide on the foot.

Position the targeting arm on the dedicated part of the correction guide and fix it by turning the locking wheel (1). Slide the targeting guide on the targeting arm, control the rotation and lock it with the dial (2).

KEY FEATURES - PATENT PENDING

Correction guide

FIXATION HOLES

With positioning pins to fix the correction guide. Proximal positioning pins reach second cuneiform to ensure stability



FEELER

Allows the localisation of the lapidus joint. Ensures the correct positioning of the correction guide by sliding it along the feeler through its burr window

BURR WINDOW

For guided and precise cutting of articular surfaces with percutaneous burrs and maximum bone preservation

ELEVATION DIAL

Allows plantar or dorsal correction of first metatarsal

COMPRESSION DIAL

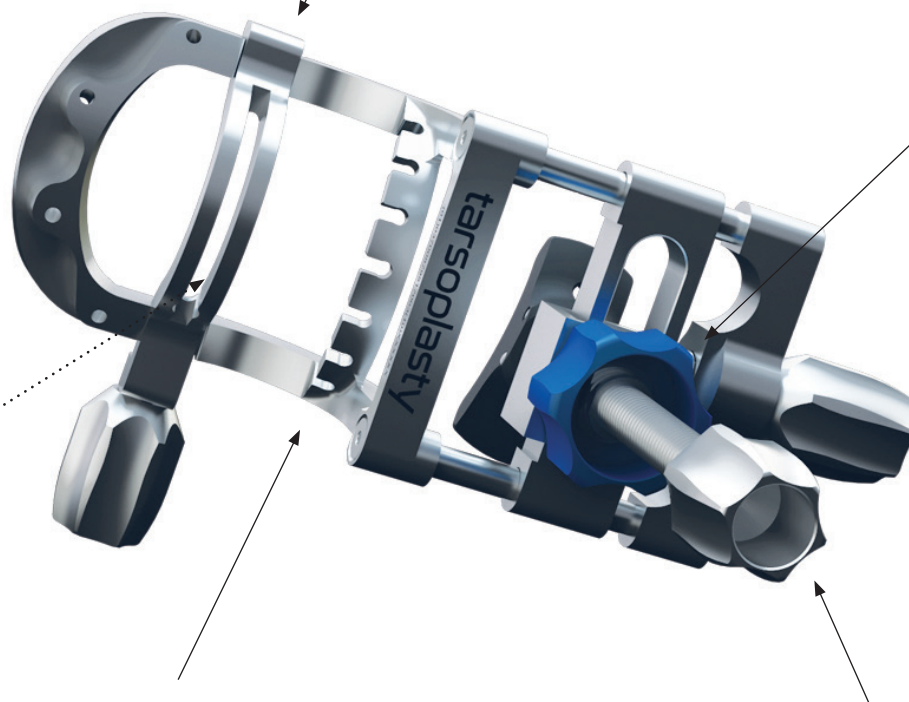
Ensures up to 15 mm bone-on-bone displacement to enable contact

ROTATION CONTROL ARC

Maintains K-wire after supination of first metatarsal

REDUCTION DIAL

Corrects the first metatarsal axis and enables reduction of IMA angle



Targeting guide

NOTE: Targeting arm and targeting guide are radiolucent.

4 CHOICE OF HOLES

Guided placement of K-wires through long K-wire sleeves

TARGETING GUIDE

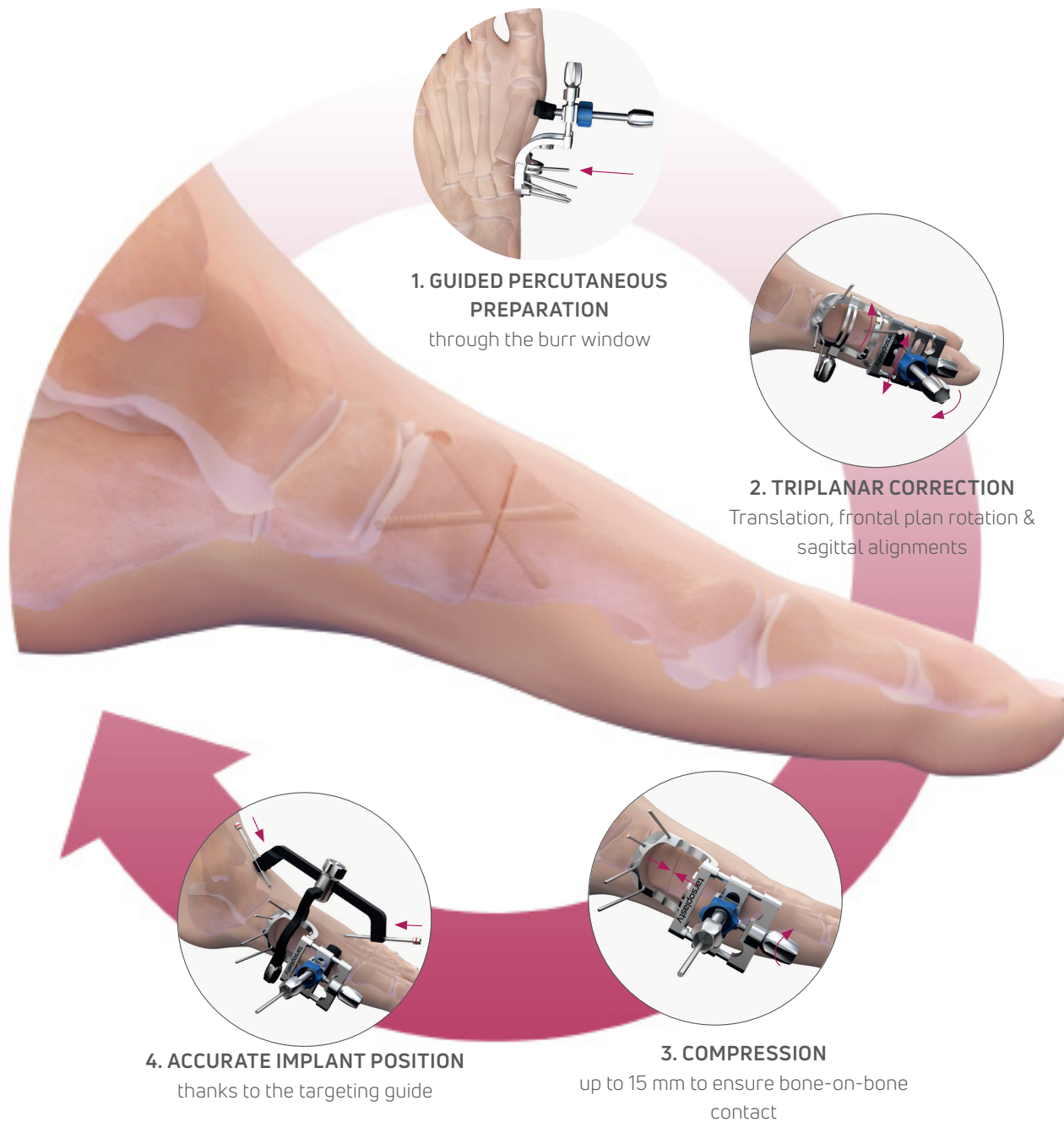
Allows 15° of rotation, lateral and medial adjustments for accurate positioning of K-wires and screws

TARGETING ARM

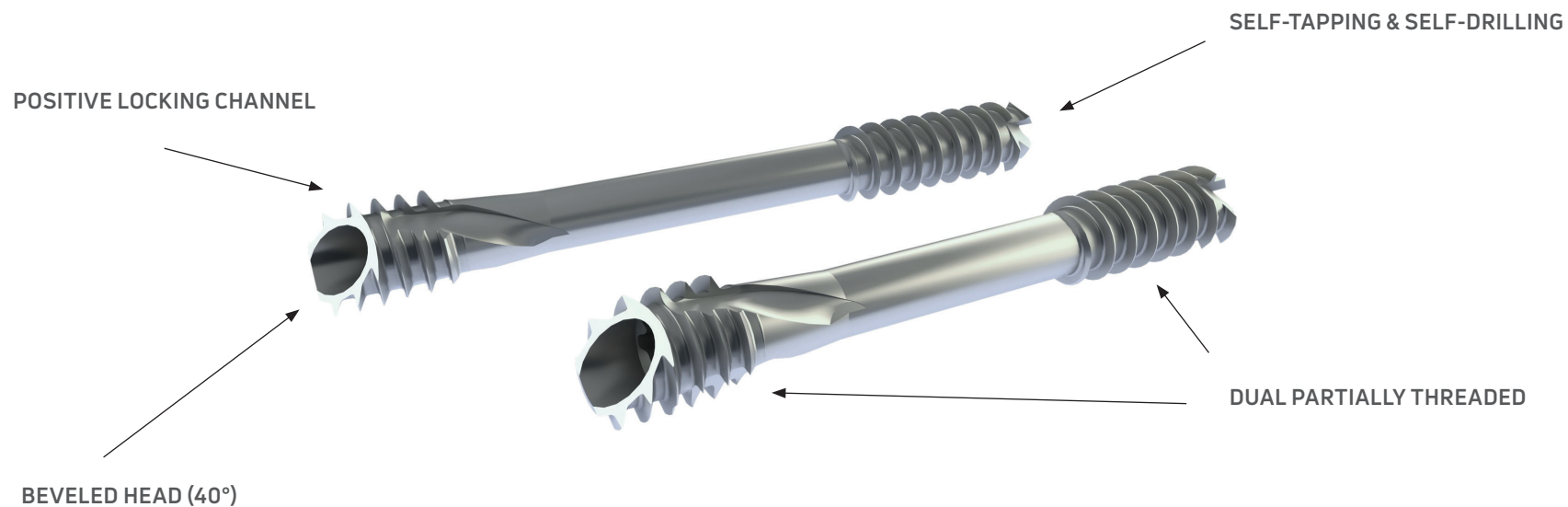
Support the targeting guide



GUIDED TECHNIQUE



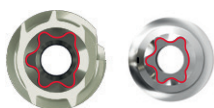
1. PECA COMPRESSIVE Ø4 - BEVELED COMPRESSIVE SCREWS



EXACT-T® TECHNOLOGY: PATENTED INNOVATION

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

EXACT-T® RECESS - PECA® IMPLANTS

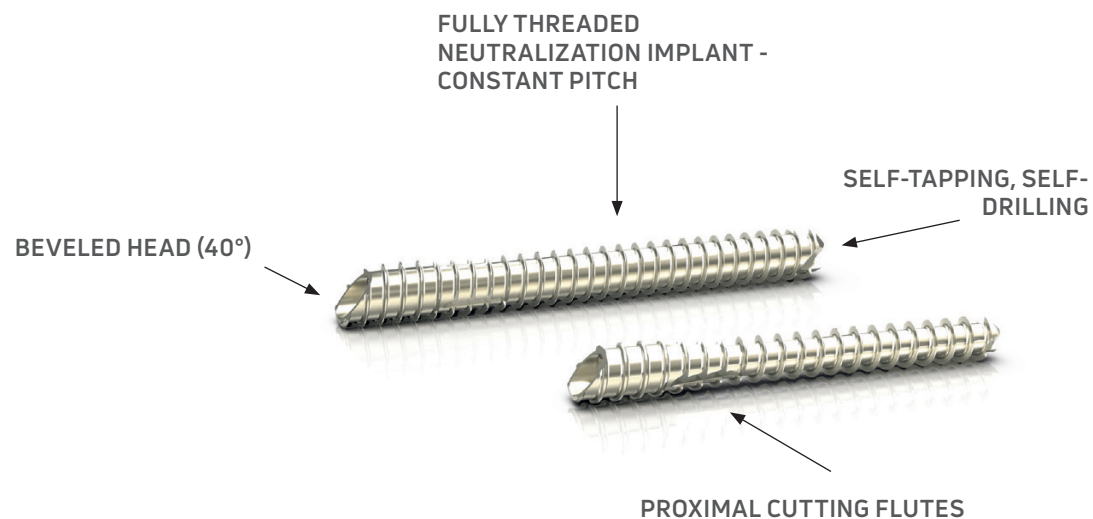


SPECIFIC

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



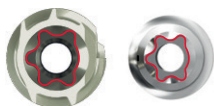
2. PECA Ø4 - BUNION IMPLANTS



EXACT-T® TECHNOLOGY: PATENTED INNOVATION

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EXACT-T® RECESS - PECA® IMPLANTS



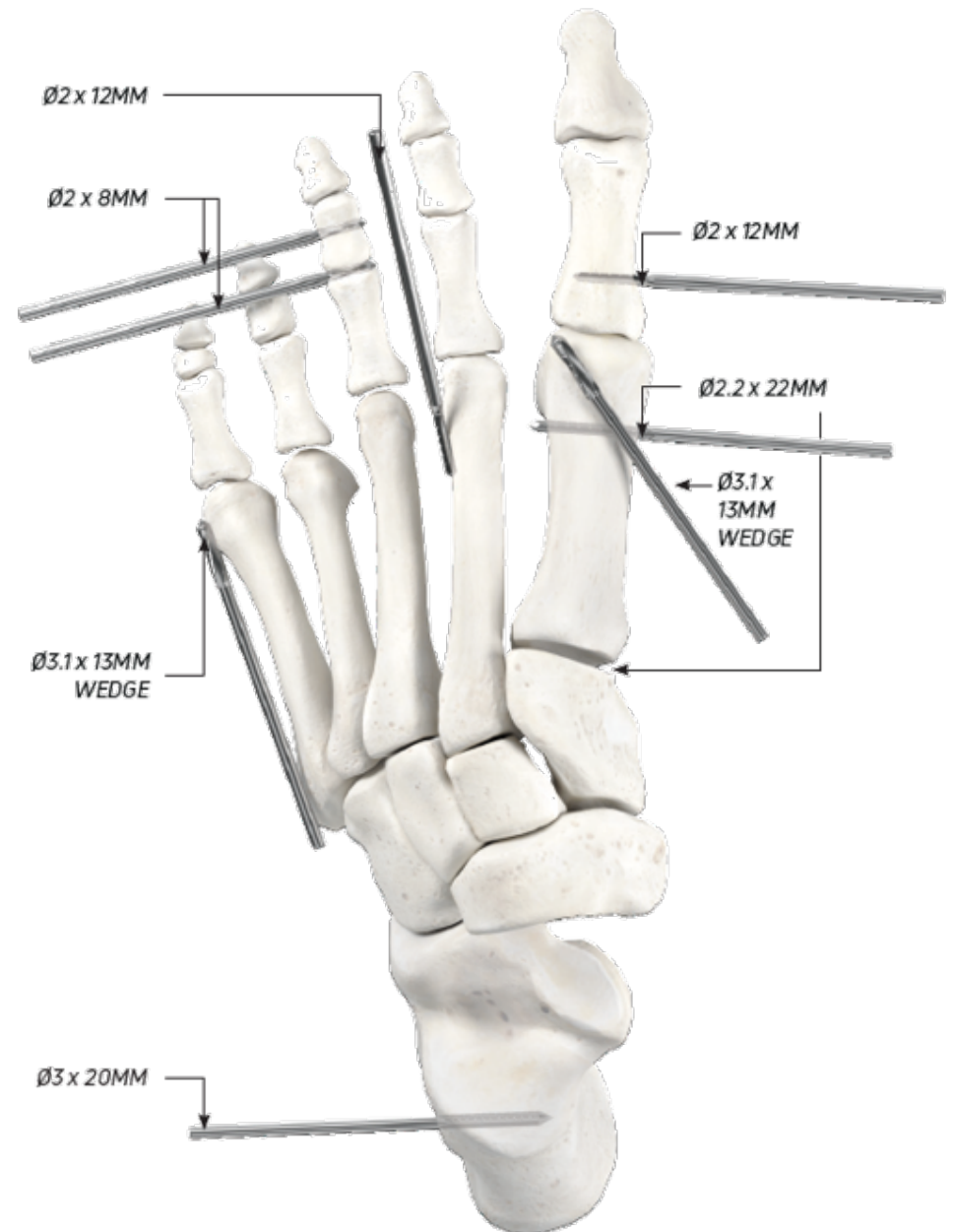
SPECIFIC

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



STERILE PERCUTANEOUS BURRS

Offer precision bone resection and removal without violating soft tissue structures.



This document provides technical guidance for the proper usage of PECA® and PECA®-C implants. However, Enovis does not practice medicine and does not recommend this or any other surgical technique. Each surgeon must consider the specific needs of each patient and is responsible for making applicable adjustments and determining and using the appropriate techniques for implanting the device in each case

1. PERCUTANEOUS INCISION & FEELER POSITIONING

Perform a percutaneous incision at the dorsal lateral aspect of the 1st MTP joint and use a beaver blade to release the suspensor ligament. Check the lowering of the sesamoids and cut the joint tendon if necessary. (FIGURE 1)

Using image intensification take a lateral image of the 1st metatarsal. Using a guide-wire bisect the long axis of the 1st metatarsal & outline using a marking pen to the medial cuneiform. Outline the 1st tarsometatarsal joint using the same method.

Identify the middle of the cuneo-metatarsal joint and make a vertical percutaneous incision (FIGURE 2). Introduce the joint feeler fully across the 1st cuneo-metatarsal joint (FIGURE 3). Make sure that the laser markings are correctly oriented: M1 towards the metatarsal and C1 towards the cuneiform.

NOTE: Graduations on the feeler allow to know the depth of the joint for the correct articular surfaces preparation.



FIGURE 1

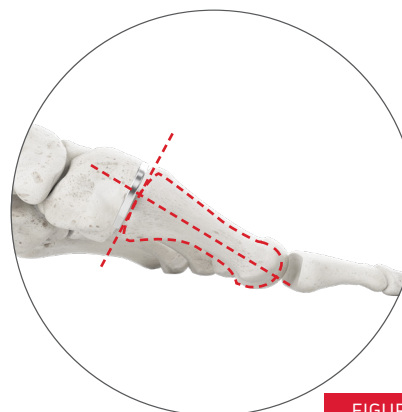


FIGURE 2



FIGURE 3

2. TARSOPLASTY® CORRECTION GUIDE PLACEMENT

Refer to page 4 for guide assembly.

Place the correction guide on the foot by sliding the burr window over the feeler.

Ensure the guide is positioned medial to the first metatarsal and turn the reduction dial clockwise until the black pusher is in contact with the skin (**FIGURE 4**).

Align the guide with the plantar arch (**FIGURE 5A**) and once positioned in the appropriate orientation, secure the guide to the medial cuneiform by introducing the 2.2x70mm threaded K-wires through the four holes on the body of the Tarsoplasty® guide (**FIGURE 5B**). The K-Wires secured through the center holes of the guide should span across the middle cuneiform to increase stability.



FIGURE 4



FIGURE 5A

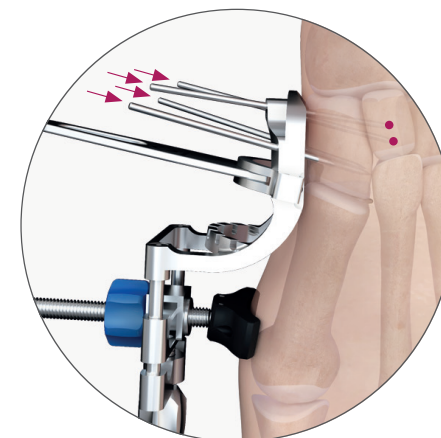


FIGURE 5B

3. JOINT PREPARATION

Introduce the Shannon Longa Ø 2.2 Lg 22 mm percutaneous burr through the burr window. The burr will only engage with the anterior aspect of the medial cuneiform. Supinate and pronate the burr to perform resection.

Perform fluoroscopic control throughout the joint preparation to avoid cutting into the base of the 2nd metatarsal (**FIGURE 6**).

NOTE: The surgeon may opt to use the Shannon Larga Ø 3.0 Lg 20 mm burr if more resection is desired.

If needed, use the Shannon X-Larga Ø 3.0 Lg 30 mm burr to capture the lateral side. Adjust your gesture to preserve the 2nd metatarsal.

4. TRANSLATION, FRONTAL PLANE ROTATION & SAGITTAL ALIGNMENT

4.1 TRANSLATION

To prepare the base of the 1st metatarsal, gradually turn the translation dial clockwise and begin resection using the 2.2x22mm burr. The joint should be fully resected upon reduction. (**FIGURE 7**).

NOTE: Compression may be used in conjunction with translation to resect the 1st metatarsal base.

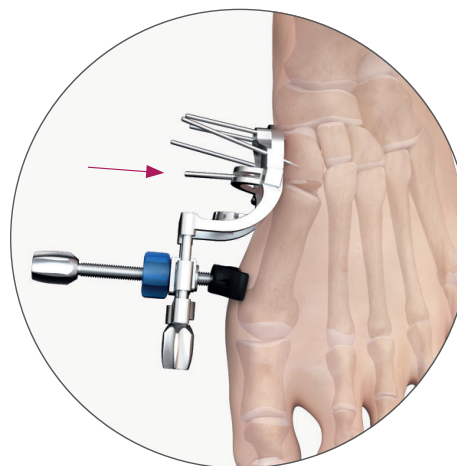


FIGURE 6



FIGURE 7

4.2 FRONTAL PLANE ROTATION

Once the correction in the transverse plane is achieved, introduce a Ø 1.8 x 140 mm K-wire through plantar hole in the rotation control arc. Rotate the K-wire dorsally until the sesamoids are covered by the 1st metatarsal under image intensification. (FIGURE 8A)

Lock the K-wire in one of the holes of the rotation arc. (FIGURE 8B).

4.3 SAGITTAL ALIGNMENT

Insert a second Ø 1.8 x 140 mm K-wire (FIGURE 9-1) through the reduction dial wheel to fix the correction. Place the wire bicortically across the 1st metatarsal head. Remove the first 1.8mm x 140 mm K-wire from the rotation comb as the positioning of the 1st metatarsal is secured distally.

Unlock the blue elevation dial by turning it (FIGURE 9-2) to raise or lower the first metatarsal head. Turn the blue dial clockwise to lock the position when the desired head height is reached.

NOTE: The lid from the instrument tray can be applied to the foot to simulate weight bearing & proper positioning of the 1st metatarsal.

Remove the burr window and clean the joint to remove bone fragments. Use a fluoroscopy view to confirm the correct preparation of the articular surfaces.

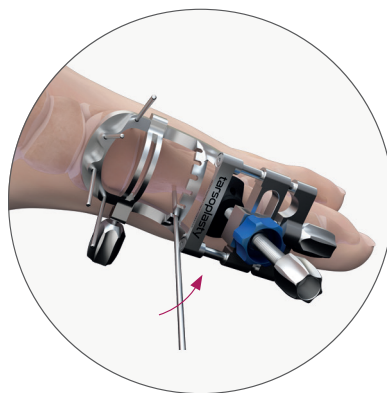


FIGURE 8A

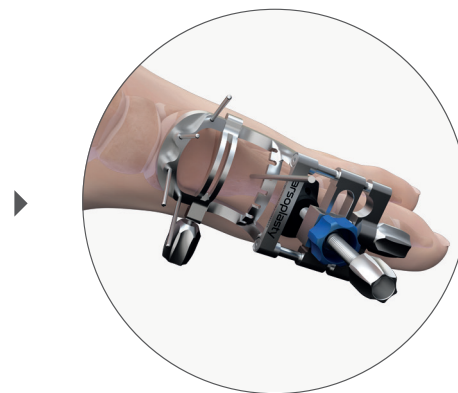


FIGURE 8B

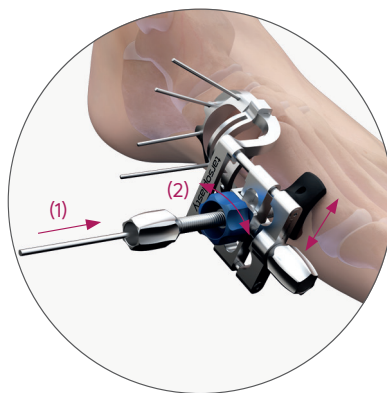


FIGURE 9

5. COMPRESSION

Once anatomical alignment has been achieved, up to 15mm of compression can be applied by turning the compression dial clockwise (**FIGURE 10**).

If additional resection is desired to the base of the 1st metatarsal, reapply the burr and gradually compress the joint until it makes contact with the burr to resect.

A percutaneous rasp or pituitary rongeur may be used to remove any bony debris in the tarsometatarsal joint. It is recommended to irrigate the joint space prior to applying compression.

NOTE: The positioning of the sagittal plane may dorsiflex or plantarflex when fully compressed. If this is noticed, distract the joint and readjust by unlocking the blue dial to reset the position.

6. TARGETING GUIDE PLACEMENT

Position the radiolucent targeting arm on the guide instead of the cutting window and fix it by turning its dial clockwise (**FIGURE 11**).

Slide the radiolucent targeting guide on the targeting arm (**FIGURE 12**).

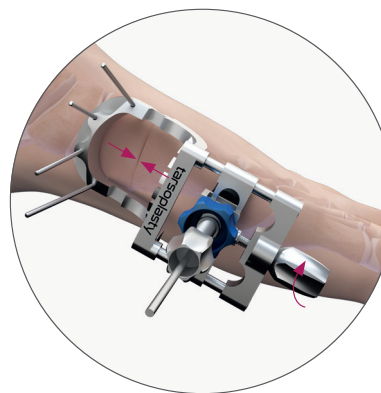


FIGURE 10

UP TO 15 MM MAXIMUM COMPRESSION

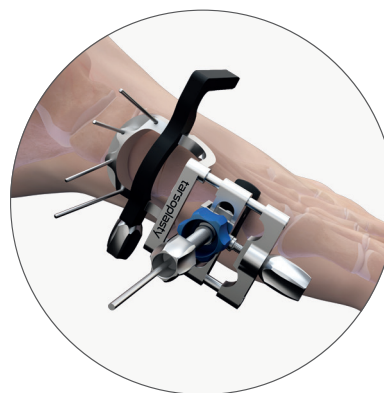


FIGURE 11

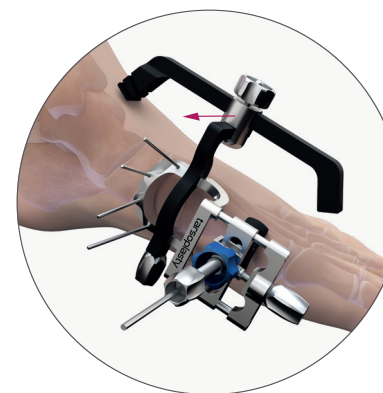


FIGURE 12

7. K-WIRES POSITIONING

7.1 K-WIRE SLEEVES POSITIONING

Place the PECA® long K-wire sleeves in the holes of the extremities of the targeting guide. Start by the distal K-wire sleeve placement (**FIGURE 13-1**) and make sure that the K-wire sleeve tip is in the axis of the first metatarsal. Then, place the proximal K-wire sleeve (**FIGURE 13-2**).

NOTE: 4 holes are available on the proximal extremity of the targeting guide providing a variation angle of 5° to ensure proper placement of the K-wire sleeves depending on the patient's anatomy.

NOTE: To ensure correct screw positioning, the aiming guide shouldn't be positioned in the center of the metatarsal.

7.2 TARGETING GUIDE ADJUSTEMENT

Adjust the positioning of the targeting guide by lateral or rotational movements (15° around the apex) and turn the dial on the targeting guide to lock the position. Use a fluoroscopy view to confirm entry points of K-wires. (**FIGURE 14**).

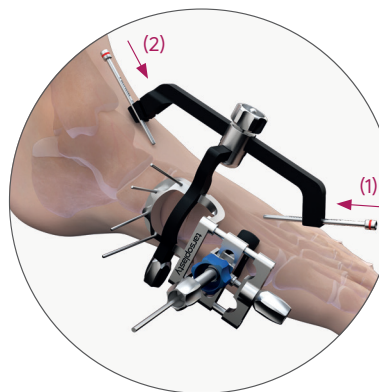


FIGURE 13



FIGURE 14

7.3 K-WIRES INSERTION

Perform a percutaneous incision in the prolongation of the distal K-wire sleeve. Insert the distal K-wire through the K-wire sleeve, passing the two cortices. Keep the sleeve in position and repeat the steps for the proximal K-wire (**FIGURE 15**).

IDEAL SCREWS POSITIONING:

- . Distal K-wire: The point of entry is at the crest of the first metatarsal. Aim the medial proximal corner of the cuneiform.
- . Proximal K-wire: Aim the cuneiform.

Remove the K-wire sleeves and perform a fluoroscopic control to confirm the correct placement of the K-wires.

NOTE: Targeting arm and targeting guide are radiolucent (**FIGURE 16**).



FIGURE 15



FIGURE 16

8. PECA® & PECA®-C IMPLANTS INSERTION

Let the Tarsoplasty® correction guide in place to maintain the correction.

Determine the required distal screw length with the Nexis® / PECA® ruler. Use fluoroscopy to confirm accurate measurement if needed.

Overdrill the distal K-wire using the Ø 3.2 drill bit and insert the distal PECA®-C Ø 4 implant with the Exact-T®10 AO screwdriver tip. (FIGURE 17)

Use oblique fluoroscopy view to confirm the placement of the screw.

Repeat the steps for the proximal PECA® Ø 4 implant. (FIGURE 18)

Use oblique fluoroscopy view to confirm the placement of the screw and remove the correction guide.

NOTE: The choice of implants between PECA® Ø 4 or PECA®-C Ø 4 is at the surgeon's discretion depending of the need of stabilization or additional compression needed at the Lapidus joint.

If needed, an additional screw can be added on C1-C2, M1-M2 or M1-C2.

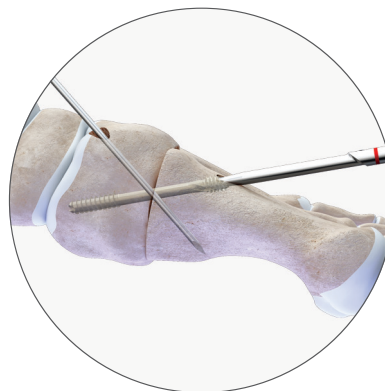


FIGURE 17



FIGURE 18

9. ADDITIONAL STEP - AKIN OSTEOTOMY

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

9.1 INCISIONS

Make two percutaneous incisions:

1. Phalanx 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**).

9.2 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 19



FIGURE 20

9.3 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. **(FIGURE 21)**

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 Ø1.2 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. **(FIGURE 22)**

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.

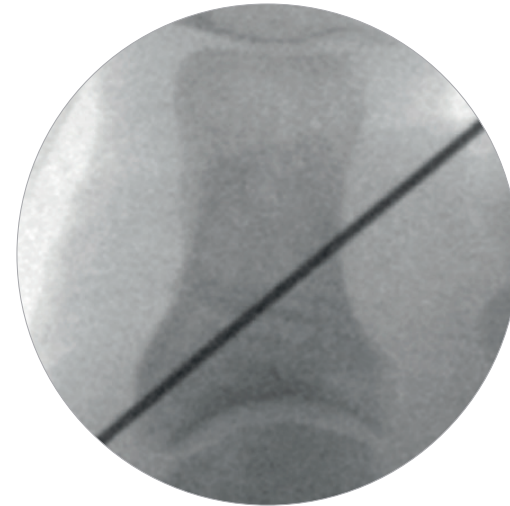


FIGURE 21

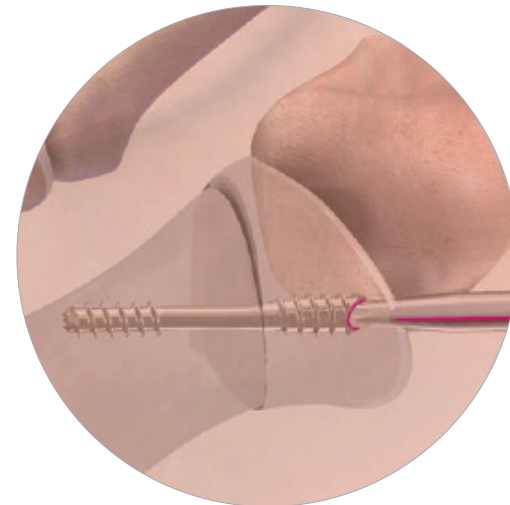
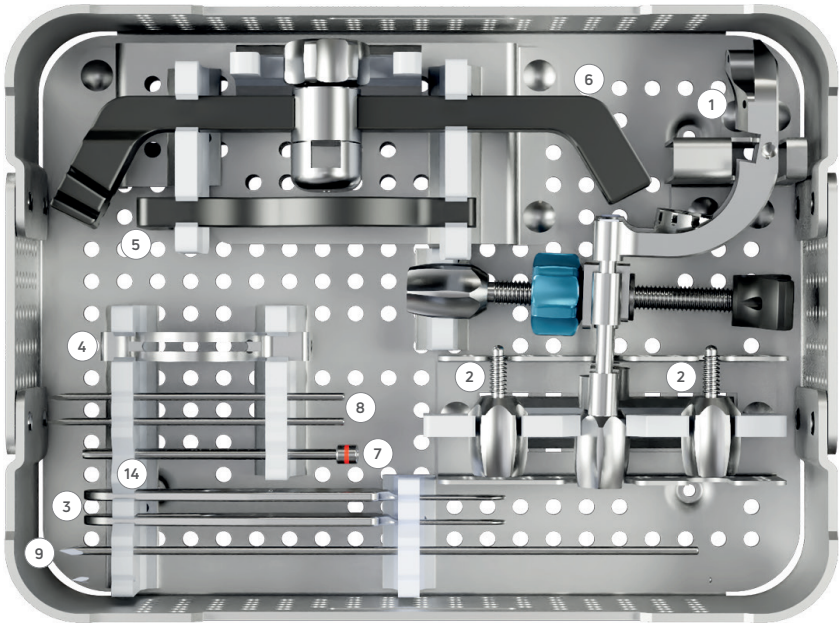


FIGURE 22

INSTRUMENTS

TARSOPLASTY® GUIDE



TARSOPLASTY® INSTRUMENTATION

#	DESCRIPTION	PART NO.	QTY
-	TRAY	ACC1020P0001	1
-	LID	ACC1020P0002	1
1	CORRECTION GUIDE	XMS01041-1	1
2	LOCKING WHEEL	XMS01041-6	2
3	FEELER	XMS01041-2	2
4	BURR WINDOW	XMS01041-4	1
5	TARGETING ARM	XMS01041-5	1
6	TARGETING GUIDE	XMS01041-3	1
7	LONG K-WIRE SLEEVE	XMS01038-7	2

K-WIRES - SUPPLIED SEPARATELY

#	DESCRIPTION	PART NO.	QTY
8	THREADED K-WIRE Ø 2.2 LG 70 TR/RD - STERILE	SKW05006	5
9	K-WIRE Ø1,8 LG 140 TR/RD - STERILE	SKW01022	3

IMPLANTS

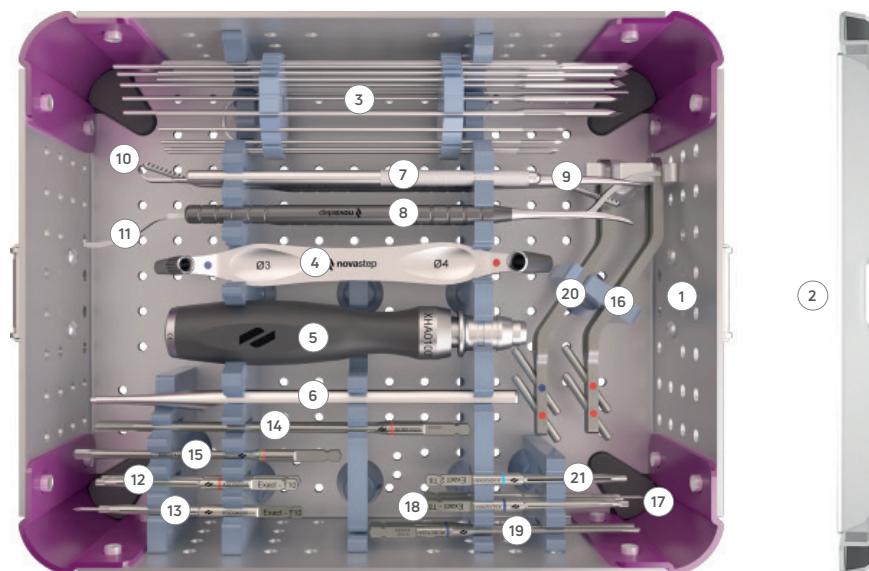
PECA® & PECA®-COMPRESSIVE IMPLANTS

LENGTH (MM)	PECA® Ø3MM	PECA® Ø4MM	PECA®- C Ø4MM
16	PS020016	-	PS050116
18	PS020018	-	PS050118
20	PS020020	-	PS050120
22	PS020022	-	PS050122
24	PS020024	-	PS050124
26	PS020026	PS050026	PS050126
28	PS020028	PS050028	PS050128
30	PS020030	PS050030	PS050130
32	PS020032	PS050032	PS050132
34	PS020034	PS050034	PS050134
36	PS020036	PS050036	PS050136
38	PS020038	PS050038	PS050138
40	PS020040	PS050040	PS050140
42	PS020042	PS050042	PS050142
44	PS020044	PS050044	PS050144
46	PS020046	PS050046	PS050146
48	PS020048	PS050048	PS050148
50		PS050050	PS050150
52		PS050052	-
54		PS050054	-
55		-	PS050155
56		PS050056	-
58		PS050058	-
60		PS050060	PS050160

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

PECA® IMPLANTS & NEXIS® MIS SCREWS INSTRUMENTATION



UNIVERSAL INSTRUMENTS

#	DESIGNATION	REFERENCE	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

#	DESIGNATION	REFERENCE	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

#	DESIGNATION	REFERENCE	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

#	DESIGNATION	REFERENCE	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

#	DESIGNATION	REFERENCE	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 - Medetech® K-wire (33-T10-R-12-100) or Novastep® K-wire (CKW01014) are available depending on your market.⁽⁵⁾ K-wire supplied separately - Medetech® K-wire (33-T10-R-12-150) or Novastep® K-wire (CKW01015) are available depending on your market.

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



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