

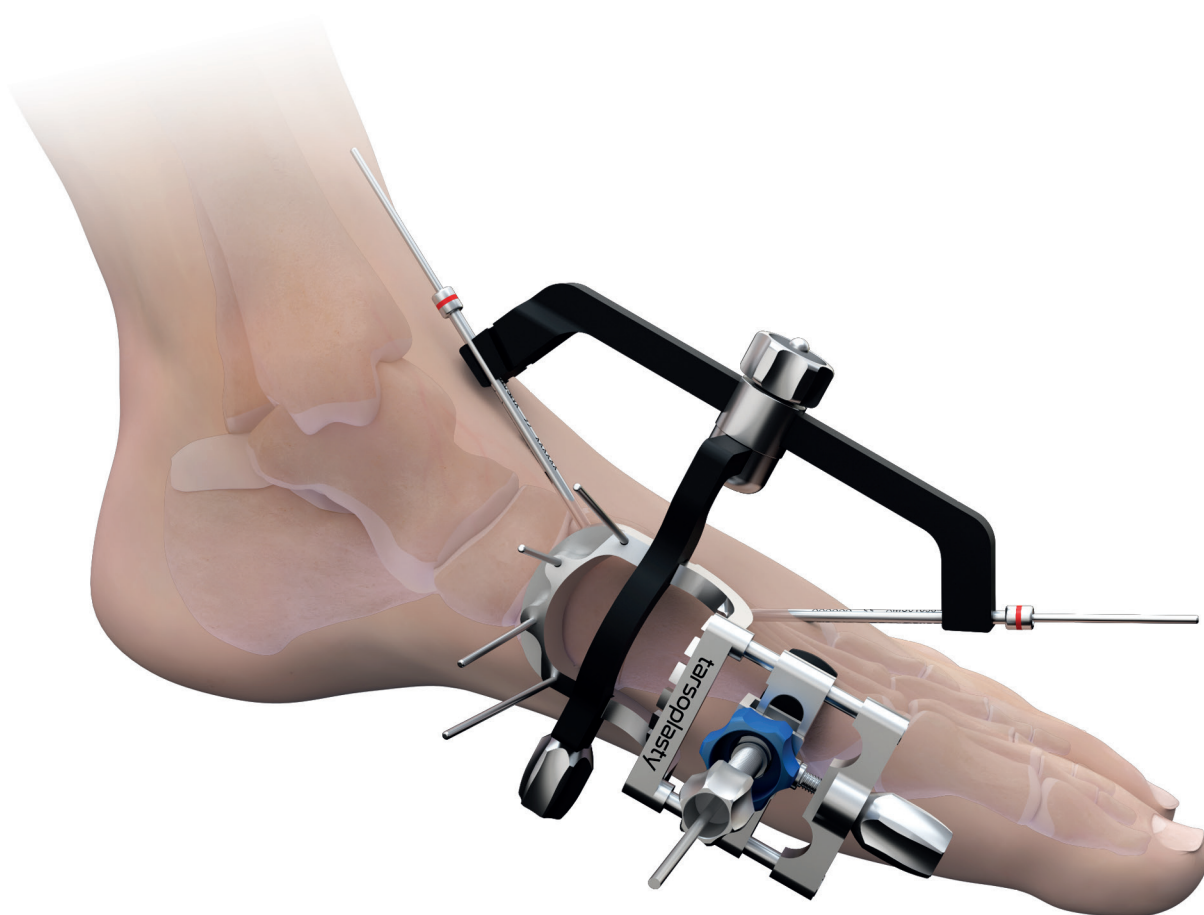
tarsoplasty[®]

Percutaneous Lapidus Correction



OPERATIVE TECHNIQUE

MIDFOOT
SURGERY



- . **Guided** percutaneous preparation
- . **Controlled** triplanar correction
- . **Accurate** implants position

*Creating
Better
Together[™]*

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INTRODUCTION

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

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 Lapidus arthrodesis and Akin osteotomy.

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

1 - Tarsoplasty® guide

Keys features

Correction guide

Fixation holes

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

Burr windows

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

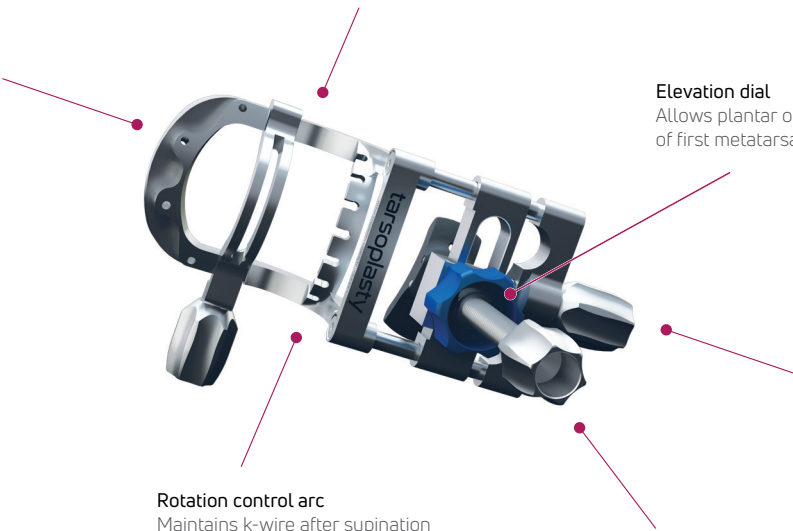
Ensures up to 15 mm bone-on-bone contact

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

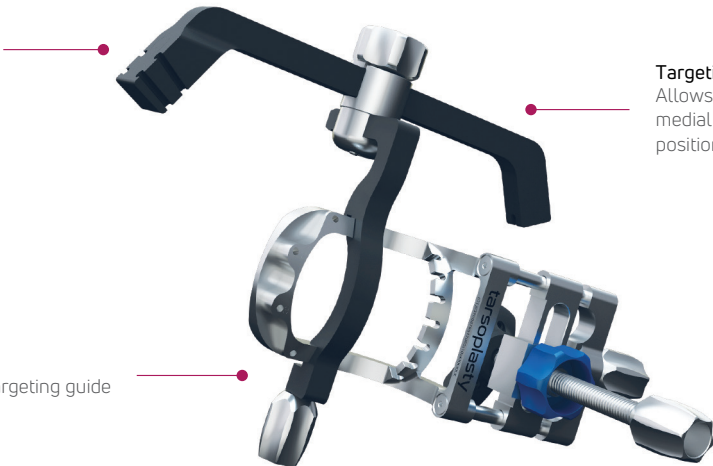
Guided placement of k-wires through long k-wire sleeves

Targeting guide

Allows 45° of rotation, lateral and medial adjustments for accurate positioning of k-wires and screws

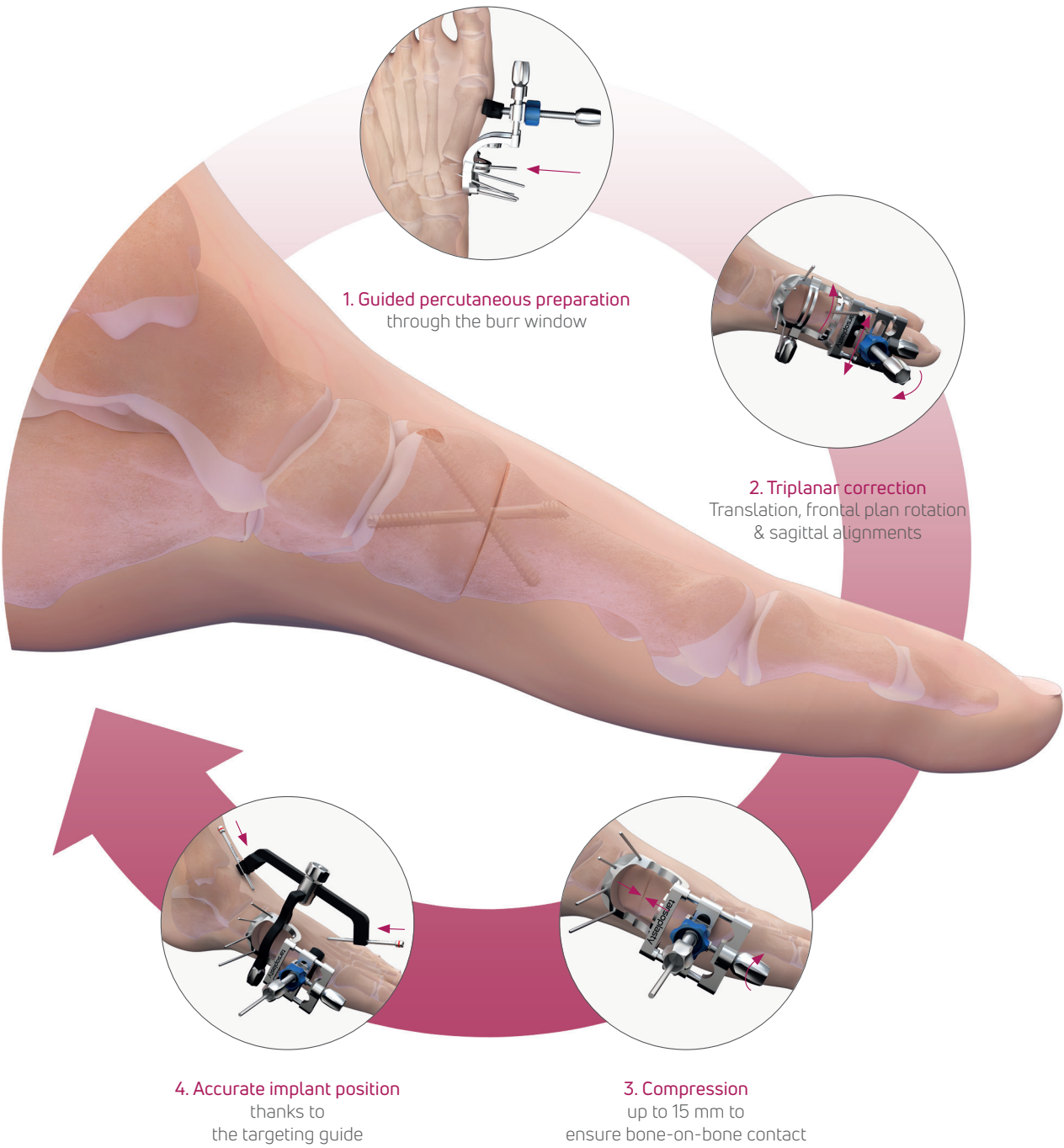
Targeting arm

Support the targeting guide



DESIGN FEATURES

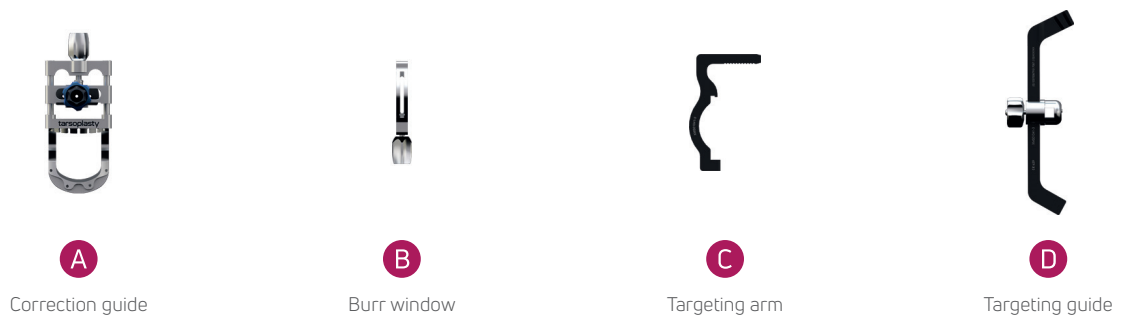
Guided technique, technical features



DESIGN FEATURES

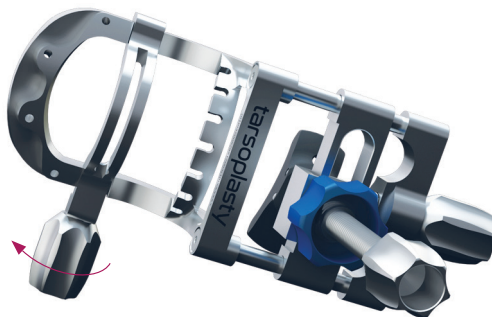
2 - Assembly

4 parts / 2 configurations of the Tarsoplasty® guide:



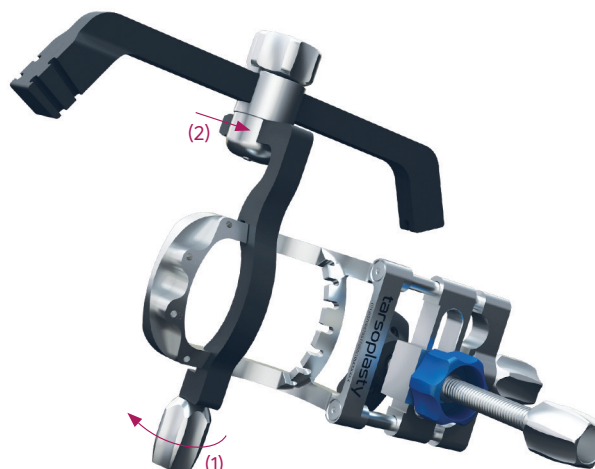
1st configuration: A + B

Attach the locking wheel to the burr window and position the burr window on the dedicated part of the correction guide and fix it by turning the locking dial: 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.



2nd configuration (after removing burr window): A + C + D

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



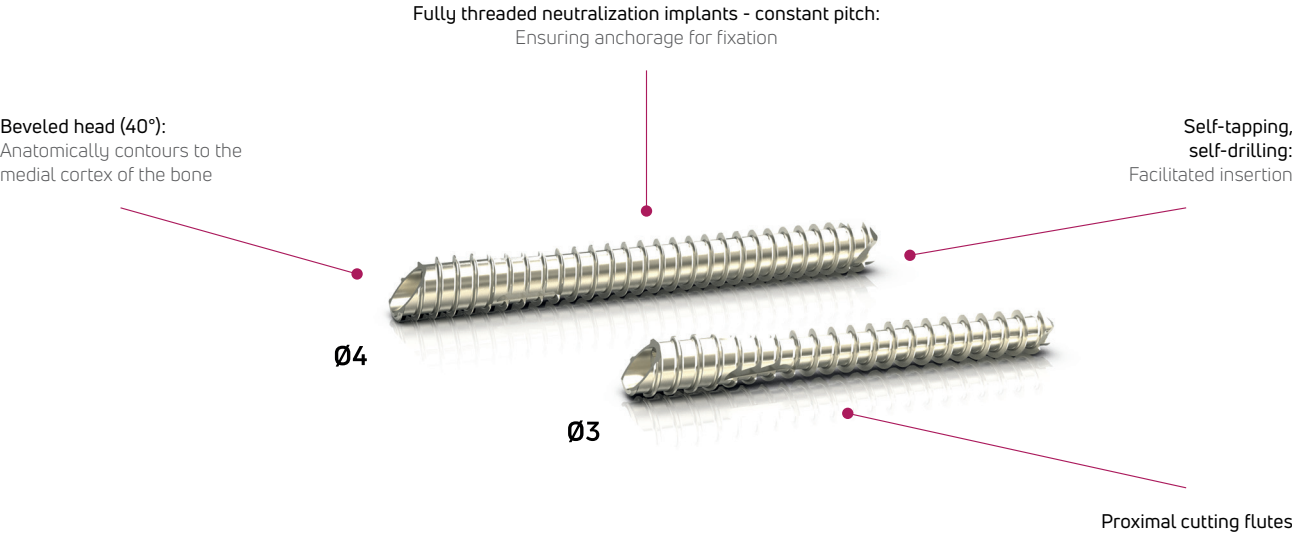
DESIGN FEATURES

3 - PECA[®], PECA[®]-C implants & Nexis[®] MIS screws



PECA[®] Ø 4 & Ø 3 - Bunion implants

1



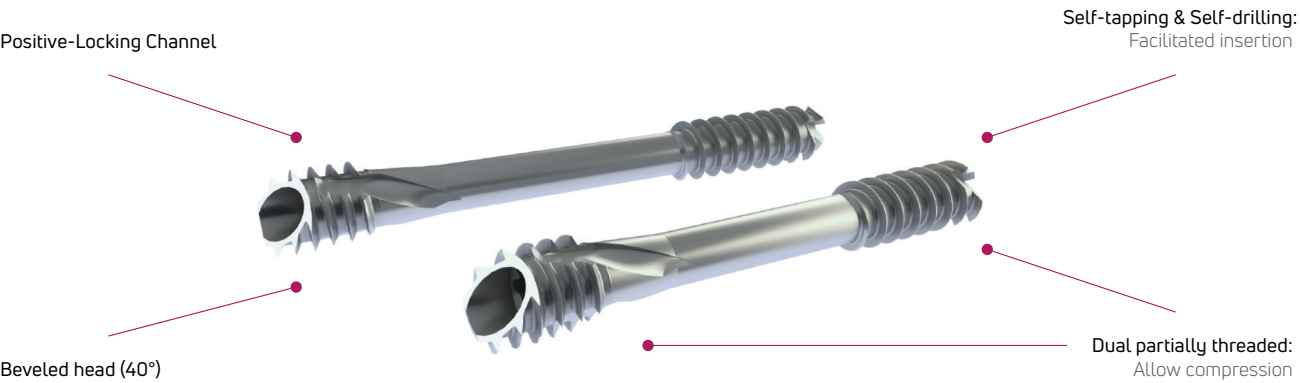
Exact-T[®] recess: Allows exact beveled implant head positioning



DESIGN FEATURES

PECA®-C Ø 4 - Beveled compressive implants

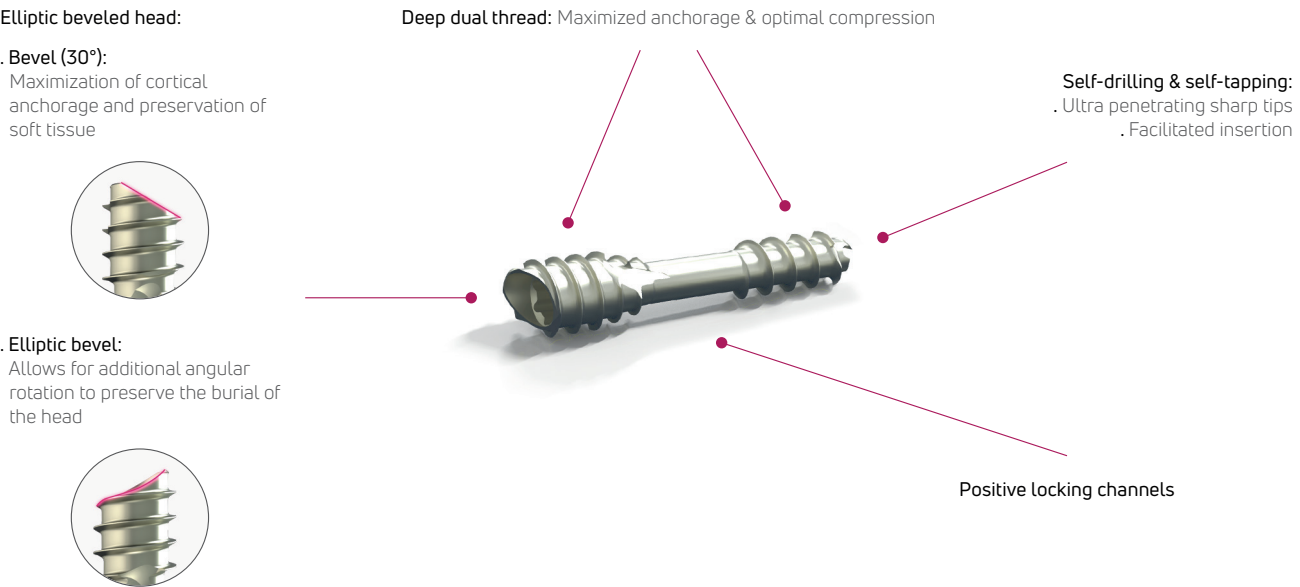
2



Exact-T® recess: Allows exact beveled implant head positioning



Nexis® MIS Ø 2.7 - Beveled compressive screws for Akin osteotomy



Exact2-T recess: Specific & universal

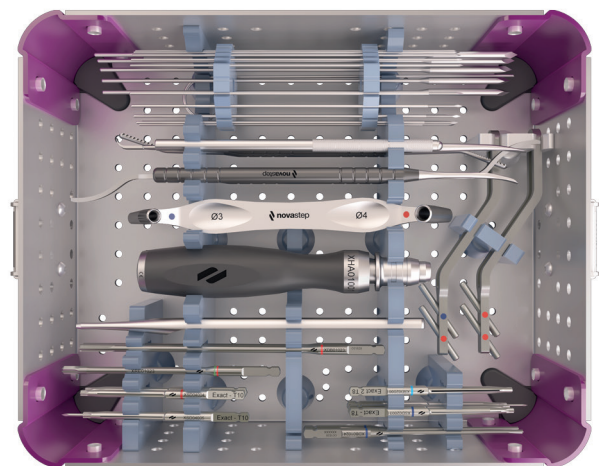







DESIGN FEATURES

4 - PECA®, PECA®-C & Nexis® MIS instruments

The PECA® set combines specific instrumentation for PECA®, PECA®-C 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 instruments



-  Percutaneous rasps
-  Periosteal elevator double tip
-  Periosteal elevator single tip
-  Reduction device double tip - optional
-  Beaver handle

Instruments

Exact-T® Technology: patented innovation

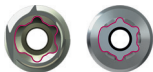
Exact-T® - Patent pending - facilitates correct placement of implant upon insertion.

PECA® screws



Exact-T® recess:
Specific: easy indexing of the Exact-T® screwdriver tip.
Allows exact driver positioning in one direction only.

Nexis® MIS screws



Exact2-T recess:
Specific: easy indexing of the Exact2-T8 screwdriver tip.
Universal: possible removal with standard instrumentation.

Visual guideline:

The black laser marking aligns with the beveled head of the implant, identifying the medial cortex of the first metatarsal, ensuring proper placement when implanted.



Sterile percutaneous burrs

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



SURGICAL TECHNIQUE

This document provides technical guidance for the proper usage of PECA® and PECA®-C implants with Tarsoplasty® guide. 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 cases.

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

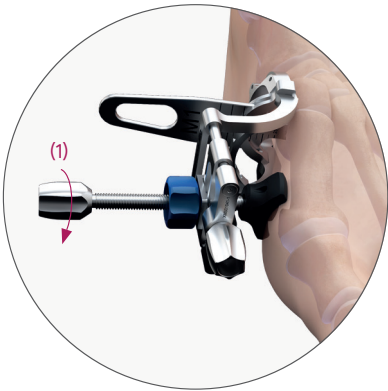
Note: Graduations on the feeler allow to know the depth of the joint for the correct articular surfaces preparation.



Step 2 - Tarsoplasty® correction guide placement

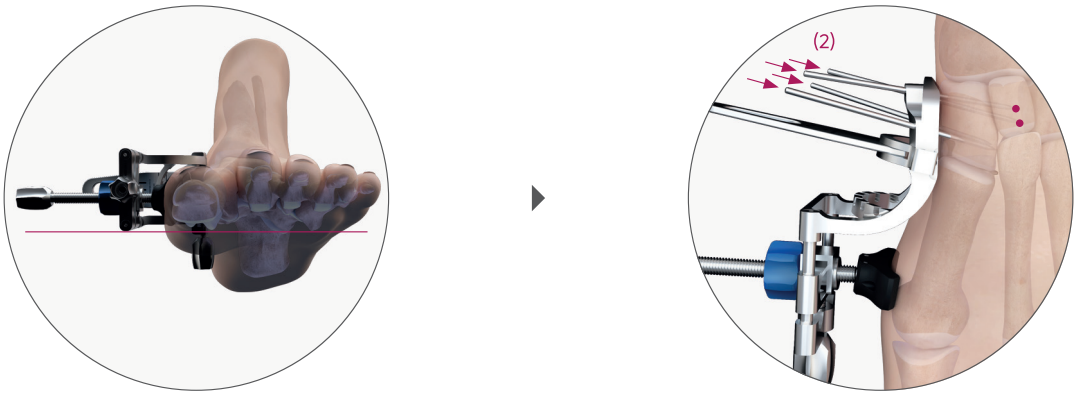
Refer to page 5 for guide assembly.

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 support is in contact with the head of the first metatarsal (1).



SURGICAL TECHNIQUE

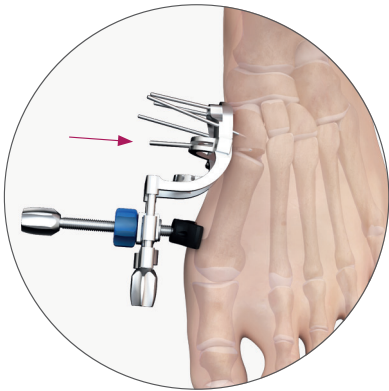
Align the guide with the plantar arch and once positioned in the appropriate orientation, fix the position of the guide with the four positioning pins (2). The two K-Wires secured through the center holes of the guide should span across the middle cuneiform to increase stability.



Step 3 - First cuneiform preparation

Perform the cut of the articular surface of the first cuneiform using a Shannon Longa Ø 2.2 Lg 22 mm percutaneous burr through the burr window. Perform fluoroscopic control throughout the joint preparation to avoid cutting into the base of the 2nd metatarsal.

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



SURGICAL TECHNIQUE

Step 4 - Translation, Frontal plane rotation & Sagittal alignment

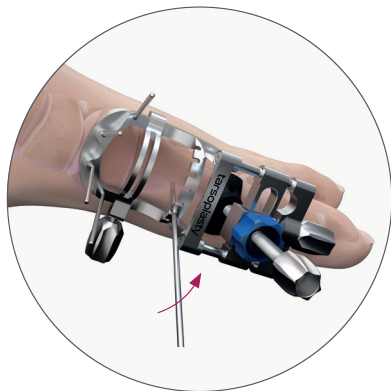
1 - Translation

To reduce the intermetatarsal angle turn the reduction dial until desired correction is obtained.



2 - Frontal plane rotation

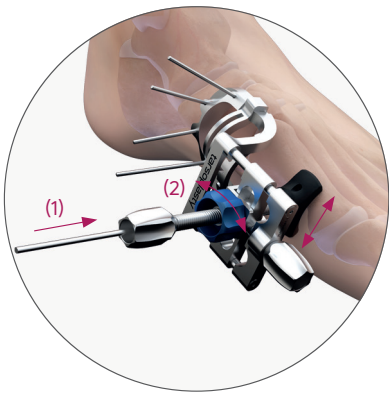
Once the correction in the transverse plane is achieved, introduce a $\varnothing 1.8 \times 150$ mm K-wire through plantar hole in the rotation control arc. Rotate the k-wire dorsally until the sesamoids are covered by the 1st metatarsal under image intensification. Lock the k-wire in one of the holes of the rotation arc.



SURGICAL TECHNIQUE

3 - Sagittal alignment

Insert a second Ø 1.8 Lg 150 k-wire (1) through the reduction dial wheel to fix the correction. Then remove the first k-wire from the rotation control arc. Unlock the blue elevation dial by turning it (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.

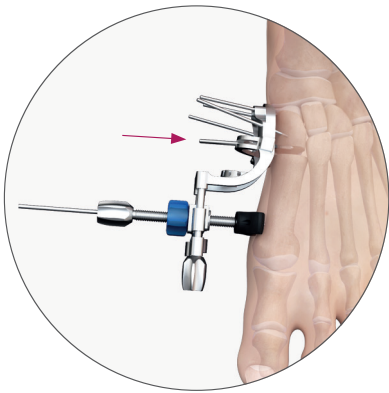


Step 5 - First metatarsal preparation

Insert a Shannon Longa Ø 2.2 Lg 22 mm percutaneous burr through the burr window to perform the cut of the articular surface at the base of first metatarsal.

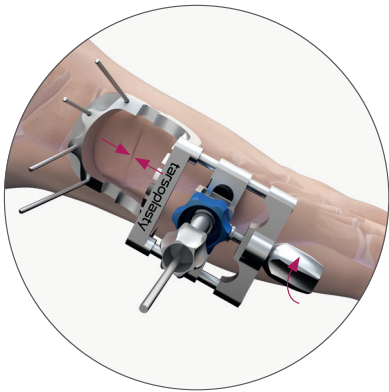
Note: If there is no resistance during the cutting of the first metatarsal, turn the compression dial clockwise to bring the first metatarsal closer to the first cuneiform.

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.



Step 6 - Compression

Turn the compression dial clockwise to bring the first metatarsal and first cuneiform closer to induce compression of the articular surfaces.



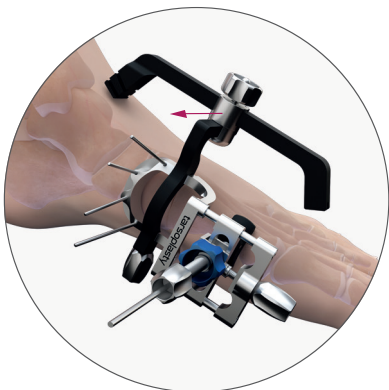
Up to 15 mm maximum compression

SURGICAL TECHNIQUE

Step 7 - Targeting guide placement

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

Slide the radiolucent targeting guide on the targeting arm.

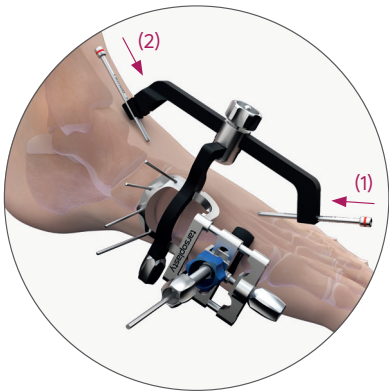


Step 8 - K-wires positioning

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 (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 (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.



2 - Targeting guide adjustment

Adjust the positioning of the targeting guide by lateral or rotational movements (45° maximum 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.



SURGICAL TECHNIQUE

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.

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.



SURGICAL TECHNIQUE

Step 9 - PECA® & PECA®-C implants insertion

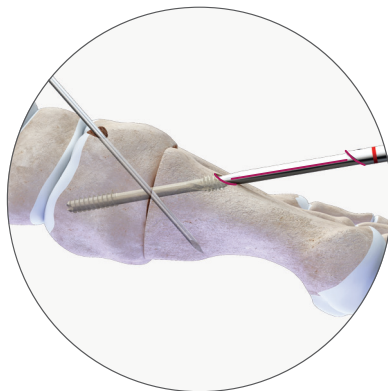
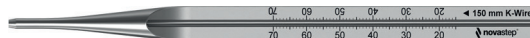
Let the Tarsoplasty® correction guide in place to maintain the correction.

Determine the required distal screw length with the ruler. A PECA®-C implant is chosen that is shorter than the measured length to ensure that the implant is fully recessed after insertion.

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

Repeat the steps for the proximal PECA® Ø 4 implant.

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.

SURGICAL TECHNIQUE

Additional step - Akin osteotomy

If interphalangeous deformity is noted after the metatarsal osteotomy, an Akin may be performed.

1 - Incisions

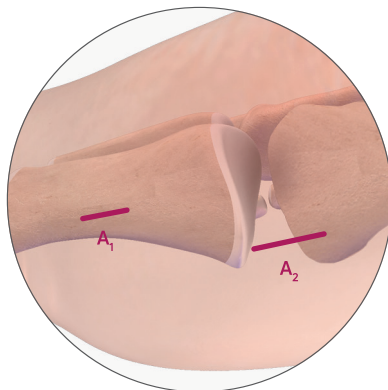
Two percutaneous incisions are made:

A1 – Phalanx osteotomy incision:

At the meta-diaphyseal margin of the medial proximal phalanx.

A2 – Implant insertion incision:

At the medial base of the hallux proximal phalanx.



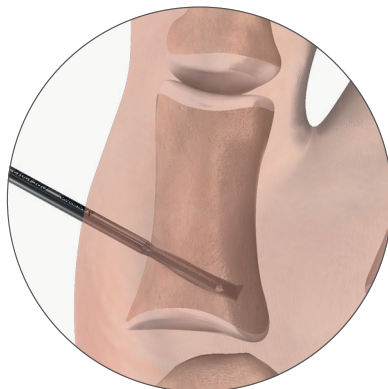
2 - Osteotomy

Under fluoroscopic guidance, the Shannon recta Ø2 Lg 12 mm burr is inserted through incision A1, through the medial cortex, midaxial-ly. Aim the burr proximally for an oblique Akin osteotomy, while preserving the lateral cortex.

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

The plantar limb is completed 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.

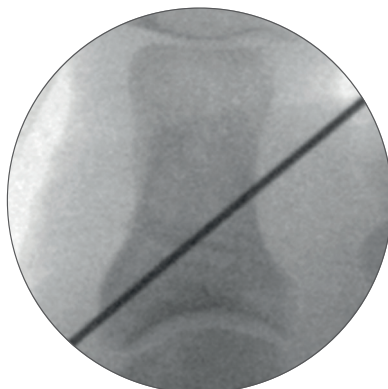


3 - Nexis® MIS Ø 2.7 mm

A Ø 1.0 mm K-wire for the Nexis® MIS Ø 2.7 mm insertion screw 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 K-wire is then measured with the Nexis® / PECA® ruler. A Nexis® MIS screw is chosen that is 2-4 mm shorter than the measured length to ensure that the implant is fully recessed after insertion.



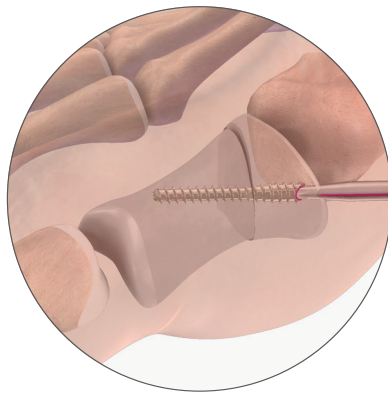
Option: The Nexis® MIS screw can also be used with a Ø 1.2 mm K-wire.

SURGICAL TECHNIQUE

Insert the Nexis® MIS Ø 2.7 mm screw with the Exact-2 T8 screwdriver.

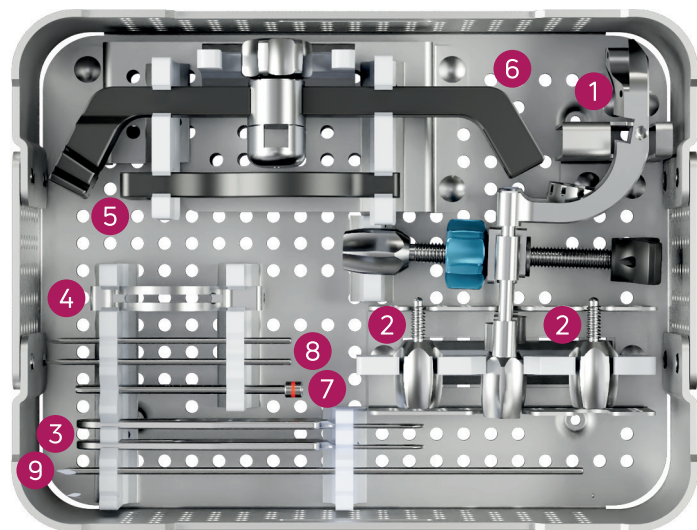
Final AP and lateral fluoroscopy views of the hallux are checked.

Option: The PECA® Ø 3 stabilization implant can also be used for this step. In this case, be sure to use the associated Exact®-T8 screwdriver.










REFERENCES

1 - Tarsoplasty® guide



Targeting guide instrumentation

| Number | Ref | Description | Qty | |
|--------|--------------|--|-----|---|
| - | ACC1020P0001 | Tray | 1 | |
| - | ACC1020P0002 | Lid | 1 | |
| 1 | XMS01041-1 | Correction guide | 1 |  |
| 2 | XMS01041-6 | Locking wheel | 2 |  |
| 3 | XMS01041-2 | Feeler | 2 |  |
| 4 | XMS01041-4 | Burr window | 1 |  |
| 5 | XMS01041-5 | Targeting arm | 1 |  |
| 6 | XMS01041-3 | Targeting guide | 1 |  |
| 7 | XMS01038-7 | Long K-wire sleeve | 2 |  |
| 8 | SKW05006 | Threaded k-wire Ø 2.2 Lg 70 - sterile ^{(1) (2)} | 5 | |
| 9 | SKW01022 | K-wire Ø 1.8 Lg 140 TR-RD - sterile ^{(1) (2)} | 3 | |



⁽¹⁾K-wire supplied separately

⁽²⁾Non-sterile k-wire is also available

REFERENCES


2 - PECA®, PECA-C® implants & Nexis® MIS screws

PECA® & PECA®-C implants



| Length (mm) | PECA® Bunion implant Ø 4 | PECA®-C Beveled compressive implant Ø 4 |
|-------------|--------------------------|---|
| 18 | - | PS050118 |
| 20 | - | PS050120 |
| 22 | - | PS050122 |
| 24 | - | PS050124 |
| 26 | PS050026 | PS050126 |
| 28 | PS050028 | PS050128 |
| 30 | PS050030 | PS050130 |
| 32 | PS050032 | PS050132 |
| 34 | PS050034 | PS050134 |
| 36 | PS050036 | PS050136 |
| 38 | PS050038 | PS050138 |
| 40 | PS050040 | PS050140 |
| 42 | PS050042 | PS050142 |
| 44 | PS050044 | PS050144 |
| 46 | PS050046 | PS050146 |
| 48 | PS050048 | PS050148 |
| 50 | PS050050 | PS050150 |
| 52 | PS050052 | - |
| 54 | PS050054 | - |
| 55 | - | PS050155 |
| 56 | PS050056 | - |
| 58 | PS050058 | - |
| 60 | PS050060 | PS050160 |

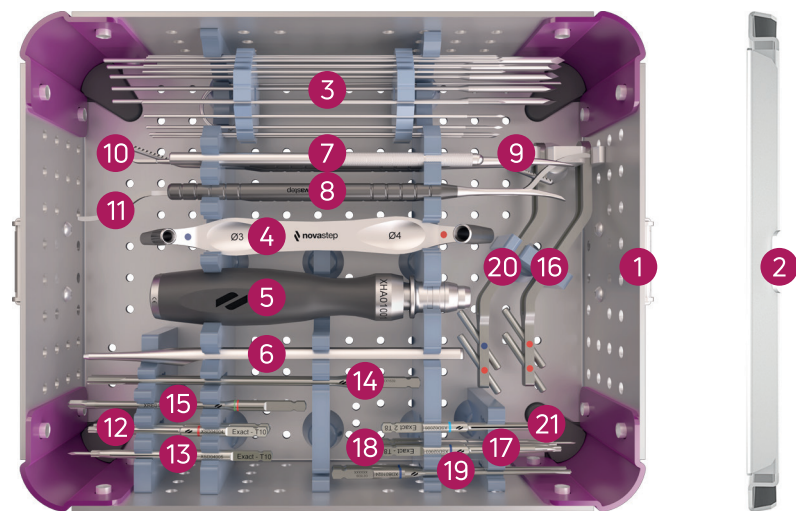
Nexis® MIS beveled compressive screw Ø 2.7




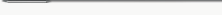



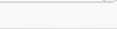
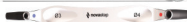


| Length (mm) | Nexis® MIS Ø 2.7 mm |
|-------------|---------------------|
| 14 | SC090014 |
| 16 | SC090016 |
| 18 | SC090018 |
| 20 | SC090020 |
| 22 | SC090022 |
| 24 | SC090024 |
| 26 | SC090026 |
| 28 | SC090028 |
| 30 | SC090030 |

REFERENCES

3 - PECA®, PECA®-C & Nexis® MIS instruments






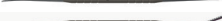

Universal instruments

| Number | Ref | Description | Qty | |
|--------|-------------------------|------------------------------------|------------------|---|
| 1 | ACC1001P0022 | Tray | 1 | |
| 2 | ACC1001P0024 | Lid | 1 | |
| 3 | ACC1001P0023 | K-wires holder | 1 |  |
| | CKW03001 | Reduction wire | 5 ⁽²⁾ |  |
| | CKW02004 ⁽¹⁾ | K-wire Ø 1.0 Lg 150 TR/RD CoCr | 5 ⁽²⁾ |  |
| | CKW02005 ⁽¹⁾ | K-wire Ø 1.4 Lg 150 TR/RD CoCr | 8 ⁽²⁾ |  |
| | XKW01001 | Cleaning pin Ø 0.9 | 1 |  |
| | XKW01002 | Cleaning pin Ø 1.4 | 1 |  |
| 4 | XDG01024 | PECA® / PECA®-C - Tissue protector | 1 |  |
| 5 | XHA01001 | AO handle | 1 |  |
| 6 | XGA01009 | Nexis® / PECA® - Ruler Lg 150 | 1 |  |

⁽¹⁾ K-wire supplied separately.


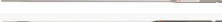
⁽²⁾ Maximum quantity of the K-wire holder.

Percutaneous instruments

| Number | Ref | Description | Qty | |
|--------|---------------------|--------------------------------|----------|---|
| 7 | SF13 ⁽³⁾ | Long beaver handle | 1 |  |
| 8 | XMS01011 | Perioestal elevator single tip | 1 |  |
| 9 | XMS01008 | Perioestal elevator double tip | 1 |  |
| 10 | XMS01009 | Percutaneous rasps | 1 |  |
| 11 | XMS01027 | Reduction device double tip | Optional |  |

⁽³⁾ Reference supplied separately - availability depending on your market.

PECA® Ø 4 instruments

| Number | Ref | Description | Qty | |
|--------|------------|--------------------------------------|----------|---|
| 12 | XSD04004 | Exact-T®10 AO screwdriver tip | 2 |  |
| 13 | XSD04005 | Solid Exact-T®10 AO screwdriver tip | Optional |  |
| 14 | XDB01023 | AO drill bit Ø 3.2 | 2 |  |
| 15 | XRE01007 | Nexis® / PECA®-C - Countersink Ø 3.7 | Optional |  |
| 16 | XMS01038-6 | PECA® Ø 4 - Ø 4 - Parallel guide | Optional |  |

REFERENCES

PECA® Ø 3 instruments

| Number | Ref | Description | Qty | |
|--------|------------|------------------------------------|----------|---|
| 17 | XSD02003 | Exact-T®8 AO screwdriver tip | 1 |  |
| 18 | XSD02004 | Solid Exact-T®8 AO screwdriver tip | Optional |  |
| 19 | XDB01024 | AO drill bit Ø 2 | 2 |  |
| 20 | XMS01038-5 | PECA® Ø 3 - Ø 4 - Parallele guide | Optional |  |

Nexis® MIS Ø 2.7 instruments

| Number | Ref | Description | Qty | |
|--------|----------|--|----------|---|
| 21 | XSD02006 | Exact-2 T8 AO screwdriver tip | 2 |  |
| | XGA01013 | Ruler Lg 100 / 150 | Optional |  |
| | - | K-wire Ø 1.2 Lg 100 TR/RD ⁽⁴⁾ | Optional |  |
| | - | K-wire Ø 1.2 Lg 150 TR/RD ⁽⁵⁾ | Optional |  |

⁽⁴⁾ K-wire supplied separately - Medetechnik® K-wire or Novastep® K-wire (CKW01014) are available depending on your market.

⁽⁵⁾ K-wire supplied separately - Medetechnik® K-wire or Novastep® K-wire (CKW01015) are available depending on your market.

4 - Percutaneous burrs

| Ref | Description | |
|----------|--------------------------------|---|
| CRE12008 | Shannon Corta Ø 2.0 Lg 8 mm |  |
| CRE12012 | Shannon Recta Ø 2.0 Lg 12 mm |  |
| CRE12212 | Shannon Helical Ø 2.0 Lg 12 mm |  |
| CRE12222 | Shannon Longa Ø 2.2 Lg 22 mm |  |
| CRE13020 | Shannon Larga Ø 3.0 Lg 20 mm |  |
| CRE13030 | Shannon X-Larga Ø 3.0 Lg 30 mm |  |
| CRE23113 | Wedge Ø 3.1 |  |
| CRE24113 | Wedge Ø 4.1 |  |

NOTES

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Percutaneous Lapidus Correction

Please note:

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.

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Reference: TAR-ST-Ed2-12-24-EN