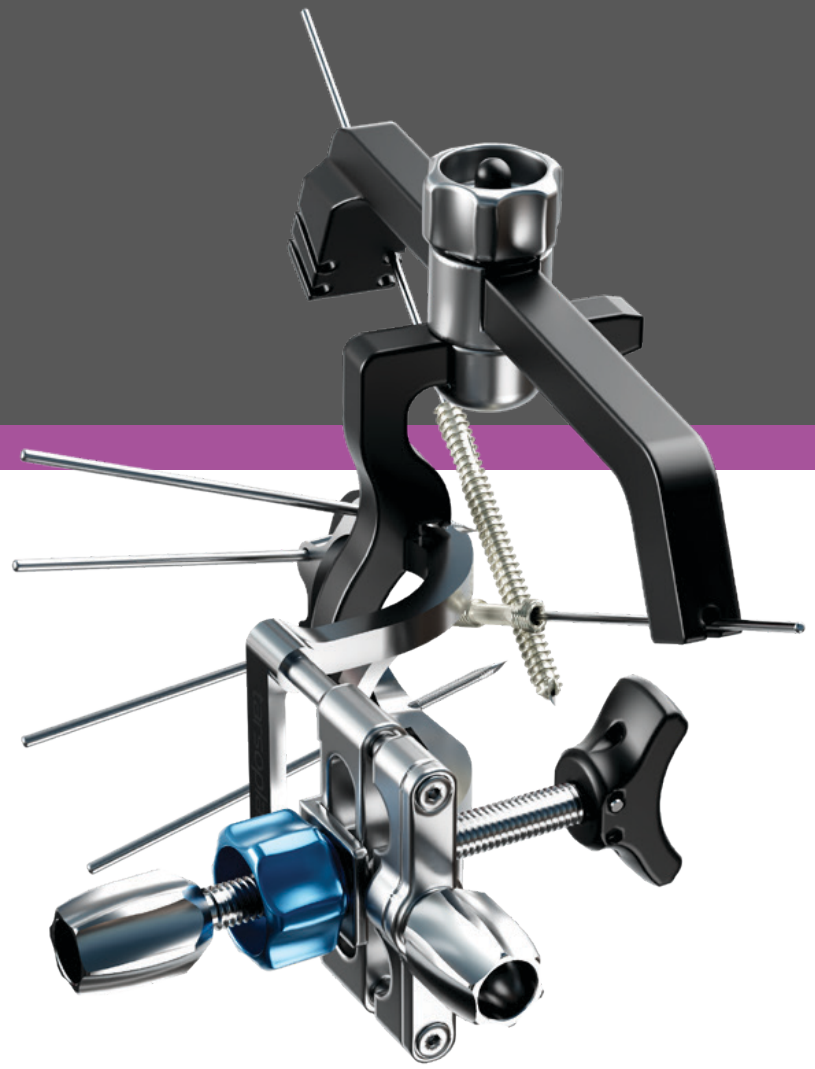
ST

SURGICAL TECHNIQUE

enovis™

TARSOPLASTY®

PERCUTANEOUS LAPIDUS CORRECTION



BUNION SYSTEMS

TABLE OF CONTENTS

Enovis® 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.

FEATURES & BENEFITS

STERILE BURRS

HAMMERTOE,
AKINETTE
Ø2 x 8mm – Cutting

CALCANEAL SLIDE
Ø3x20mm – Cutting
Ø3x30mm – Cutting

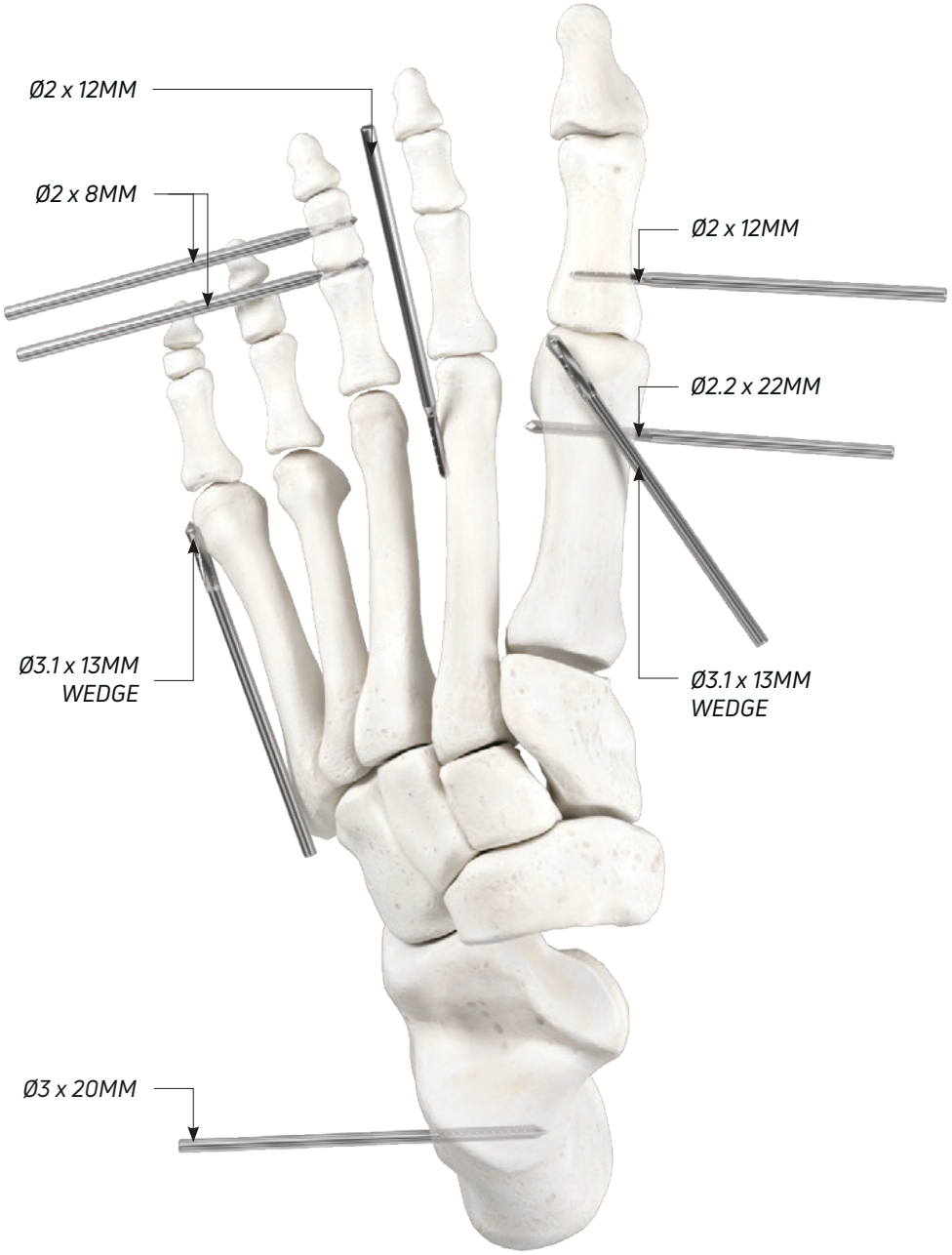
AKIN, DMMO
Ø2.0 x 12mm – Cutting

CHEILECTOMY,
OSTEOPHYTE
Ø3.1 x 13mm – Shaving

BUNION, JOINT PREP
Ø2.2 x 22mm – Cutting

CHEILECTOMY,
OSTEOPHYTE
Ø4.1 x 13mm – Shaving

CALCANEAL SLIDE
Ø3 x 20mm – Cutting

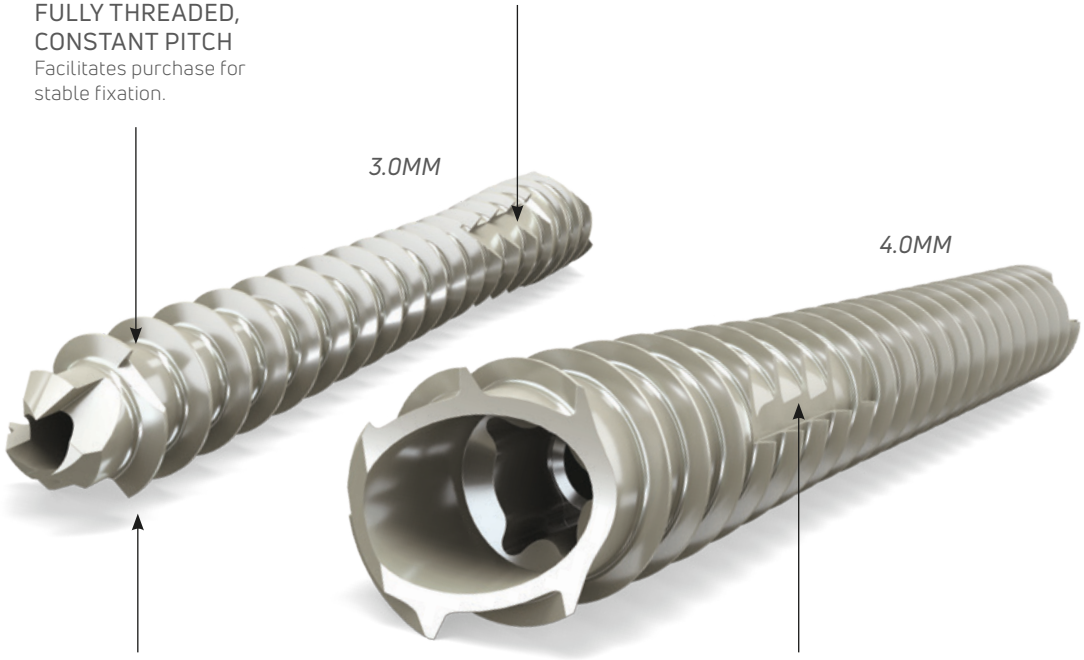


FEATURES & BENEFITS

PECA IMPLANTS

PECA implants are single use devices indicated for the osteosynthesis of small bones in surgical procedures on the extremities (foot, ankle). Examples of use: Hallux Valgus with Percutaneous Chevron and Akin osteotomies.

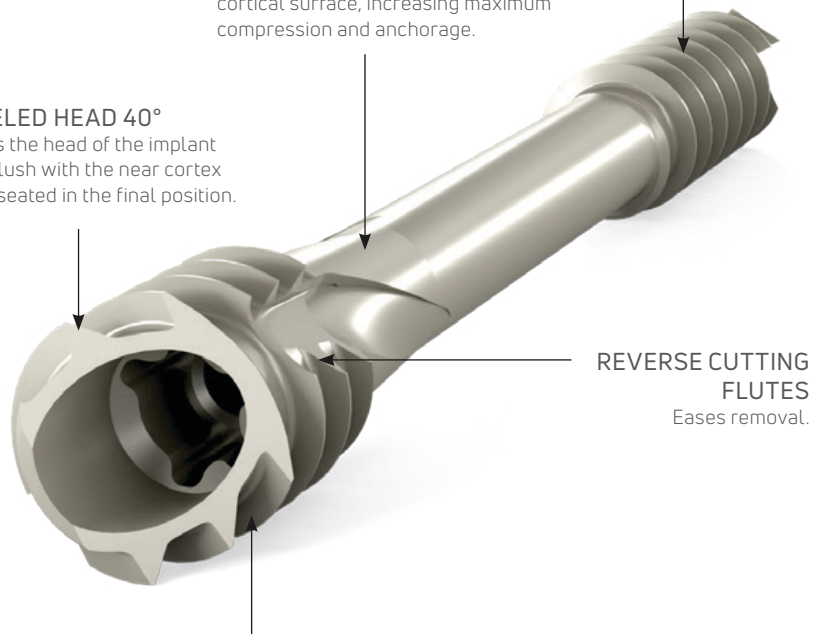
EXACT-T® RECESS
Allows exact driver positioning and provides optimal torque.



PECA-C IMPLANTS

Peca Compressive Implants were designed for percutaneous fixation in the foot and ankle.
The hybrid implant combines a partially threaded headless compression screw with a beveled head.
The bevel headless compression implant maximizes compression by seating flush with the cortex and preserving soft tissue by design.

EXACT-T® RECESS
Allows exact driver positioning and provides optimal torque.



SELF DRILLING
& SELF TAPPING
Facilitates insertion.

POSITIVE-LOCKING CHANNEL
As the implant is engaged into the bone, the Positive Locking Channel pushes the excess bone toward the cortical surface, increasing maximum compression and anchorage.

BEVELED HEAD 40°
Allows the head of the implant to sit flush with the near cortex when seated in the final position.

REVERSE CUTTING
FLUTES
Eases removal.

DUAL PARTIALLY
THREADED
Optimal compression.

4 PARTS OF THE TARSOPLASTY® GUIDE

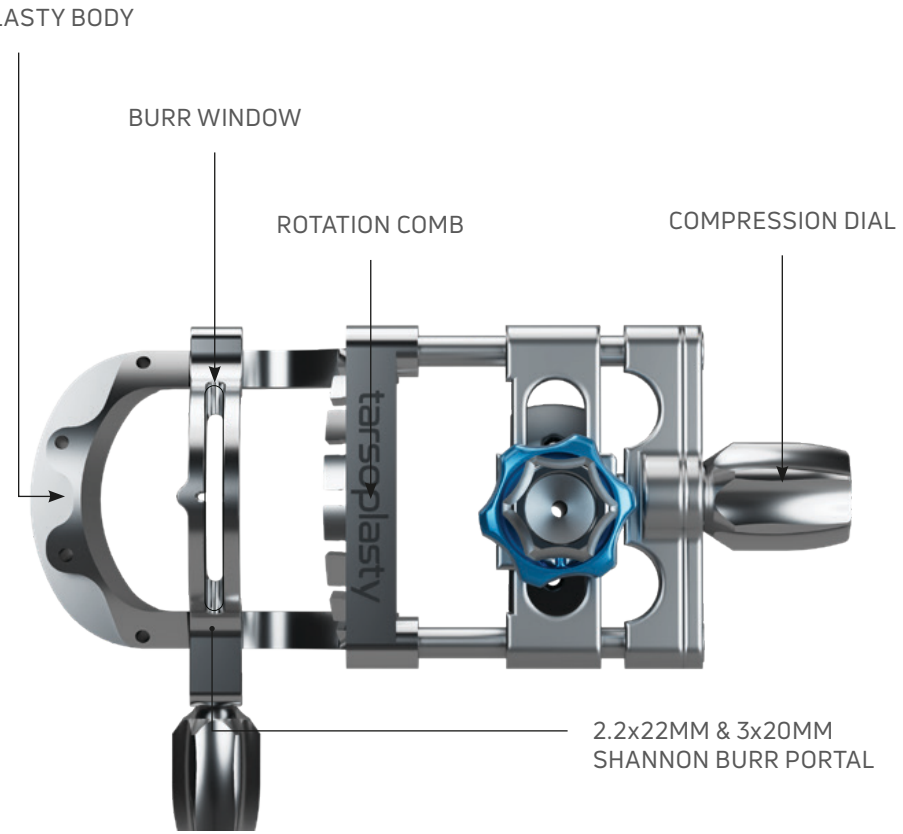
A. CORRECTION GUIDE

B. BURR WINDOW

C. TARGETING ARM

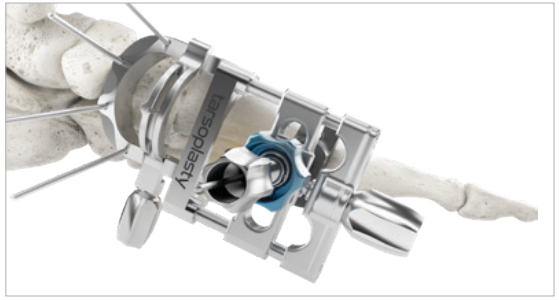
C. JOINT FEELER

D. TARGETING GUIDE

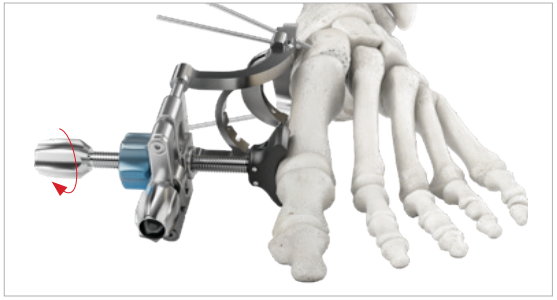


GUIDE ASSEMBLY

QUICK REFERENCE GUIDE

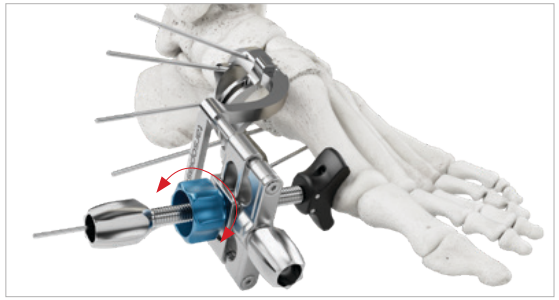


1. JOINT PREPARATION

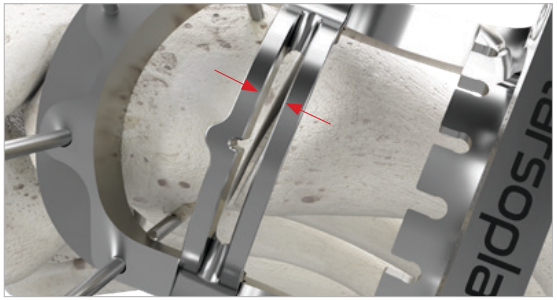


2. TRANSLATION

3. ROTATION



4. SAGITTAL ALIGNMENT



5. COMPRESSION

6. FIXATION

1. LATERAL RELEASE & POSITIONING

Perform a percutaneous incision at the dorsal lateral aspect of the 1st metatarsalphalangeal joint. Using a 64 beaver blade, release the suspensory ligament and tenotomize the conjoined tendon (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 and outline using a marking pen to the medial cuneiform. Outline the 1st tarsometatarsal joint using the same method.

Perform a medial 3mm incision is vertically, slightly inferior to where the lines intersect. Each side of the Joint Feeler is labeled to the corresponding side of the 1st tarsometatarsal joint (M1 & C1) (FIGURE 2). Introduce the Joint Feeler medially across the joint, confirming M1 is facing the base of the 1st metatarsal and C1 is facing the anterior aspect of the medial cuneiform (FIGURE 3).

NOTE: In cases of moderate to severe arthritis in the 1st TMT joint, dissection and use of a periosteal elevator may be necessary to assist the joint feeler into position.

FIGURE 1

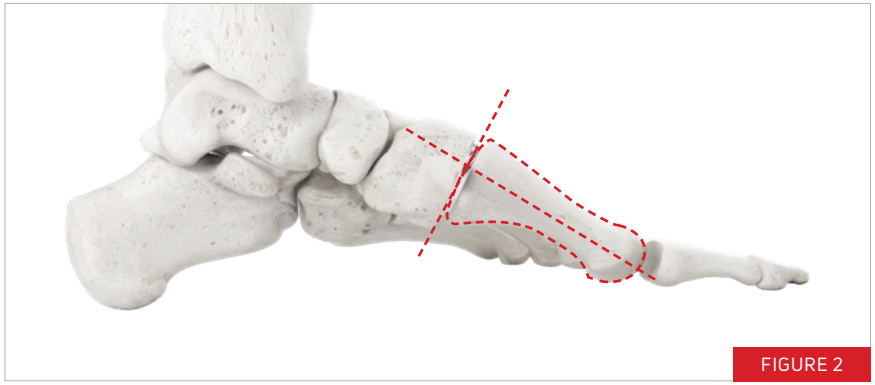


FIGURE 2

FIGURE 3

2. CORRECTION GUIDE ASSEMBLY

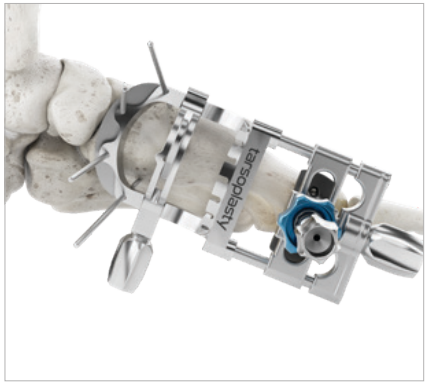
Attach the cutting window to the body of the Tarsoplasty Guide (FIGURE 4). The dial can be oriented either above or below the cutting window to the surgeon's preference. Secure the cutting window to the guide by turning the dial clockwise.

Apply the Tarsoplasty guide to the foot by sliding the cut guide over the joint feeler. Ensure the guide is positioned medial to the 1st metatarsal and the black pusher is flush with the skin. To engage the black pusher with the skin, turn the translation dial clockwise (FIGURE 5). 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.

K-wires secured though the center holes of the guide should span across the middle cuneiform to increase stability (FIGURE 6).

FIGURE 4

FIGURE 5



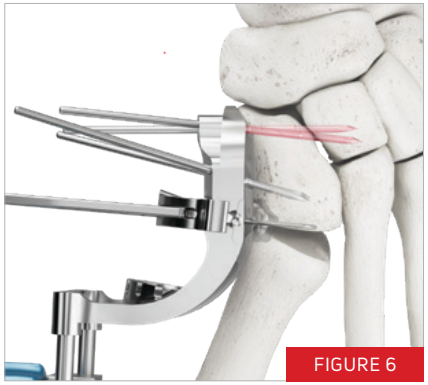


FIGURE 6

3. JOINT PREPARATION

Introduce the 2.2x22mm Shannon Burr through the cutting window (FIGURE 7). The burr will only engage with the anterior aspect of the medial cuneiform, supinate and pronate the burr, to perform resection (FIGURE 8). A 3.0x20mm or 30mm burr may be used if more resection is desired.

NOTE: It is suggested to use image intensification throughout the joint preparation to avoid cutting into the base of the 2nd metatarsal.

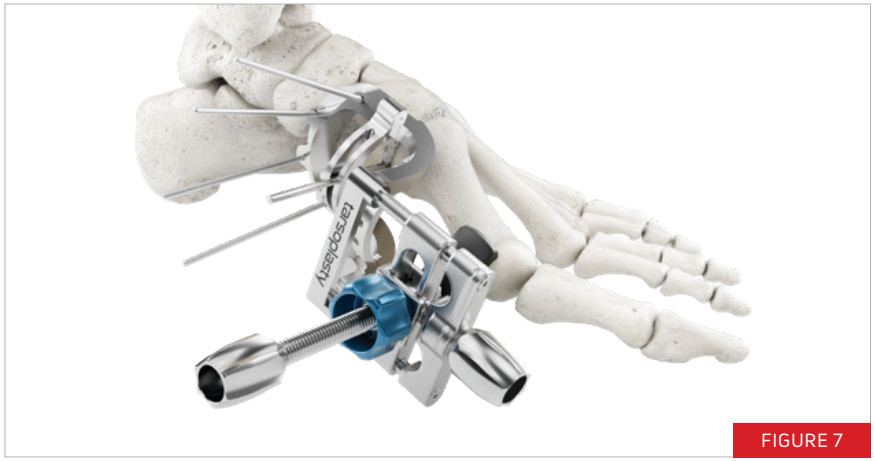


FIGURE 7

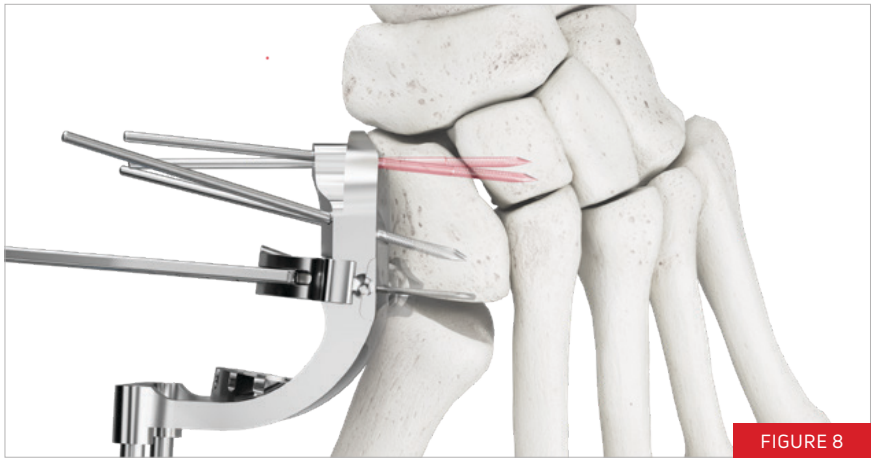


FIGURE 8

4. ANATOMICAL ALIGNMENT

1. TRANSVERSE PLANE

The 1st metatarsal will be mobile once the anterior aspect of the medial cuneiform has been adequately resected.

To prepare the base of the 1st metatarsal, gradually turn the translation dial clockwise and begin resection using the 2.2x22mm burr (FIGURE 9A & 9B). The joint should be fully resected upon reduction.

2. FRONTAL PLANE

Once the correction in the transverse plane is achieved, introduce a 1.8x140mm K-wire through plantar slot in the rotation comb at the body of the Tarsoplasty guide (FIGURE 10). Rotate the guidewire dorsally until the sesamoids are covered by the 1st metatarsal. Temporarily hold the 1.8x140mm K-wire in the desired slot (FIGURE 11).

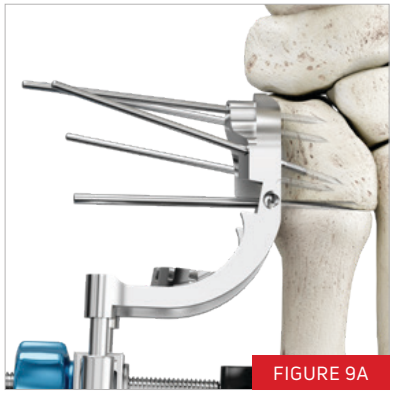


FIGURE 9A

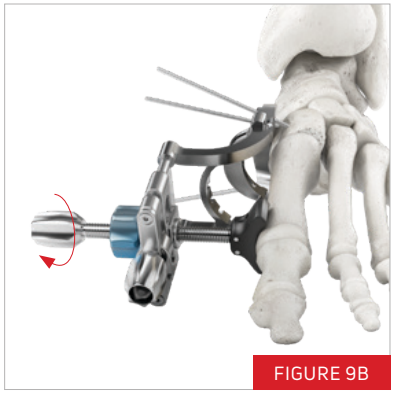


FIGURE 9B

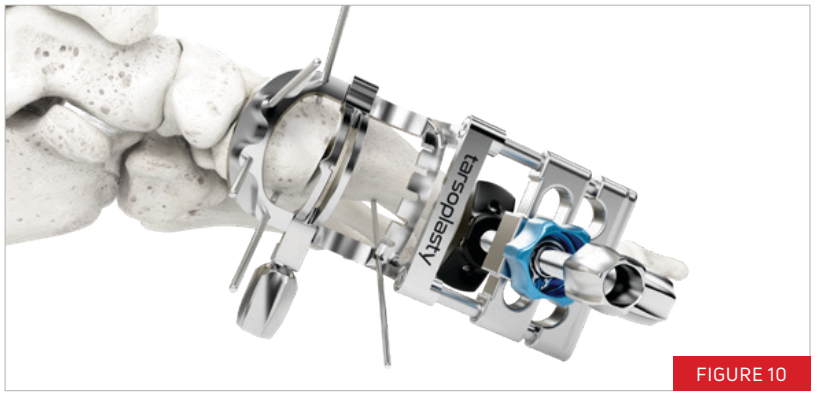


FIGURE 10

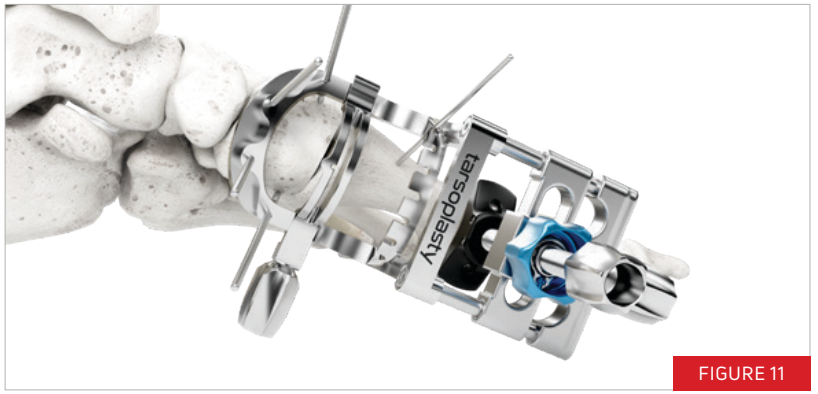


FIGURE 11

3. SAGITTAL PLANE

To adjust the sagittal plane, introduce a 1.8x140mm K-wire through the cannulated aspect of the reduction dial. Place the wire bicortically across the 1st metatarsal head.

Remove the 1.8x140mm K-wire from the rotation comb as the positioning of the 1st metatarsal is secured distally.

Unlock the blue elevation dial by turning counterclockwise to plantarflex or dorsiflex the position of the 1st metatarsal (FIGURE 12).

Using image intensification check AP and lateral views prior to compressing the joint.

NOTE: A lid from a tray can be applied to the foot to simulate weight bearing and proper positioning of the 1st metatarsal.

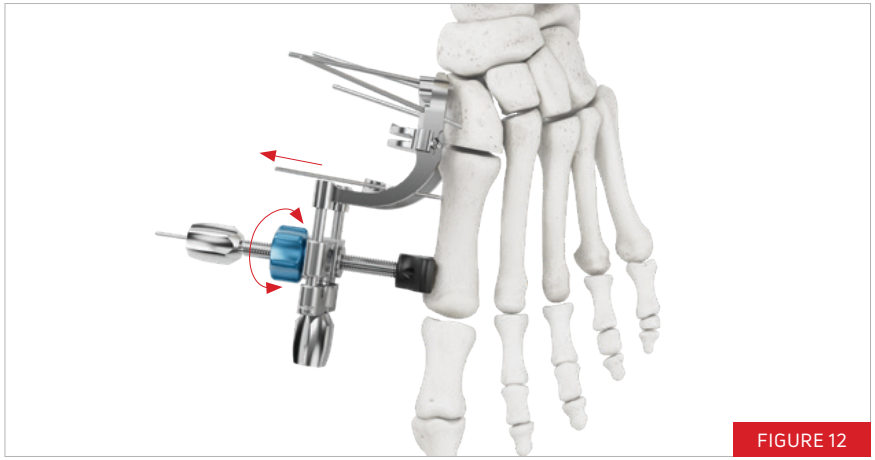


FIGURE 12

5. COMPRESSION

Once anatomical alignment has been achieved, up to 15mm of compression can be applied by turning the compression dial clockwise (FIGURE 13 & FIGURE 14). If additional resection to the base of the 1st metatarsal is desired, reapply the burr and gradually compress the joint until it makes contact with the burr (FIGURE 15).

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.

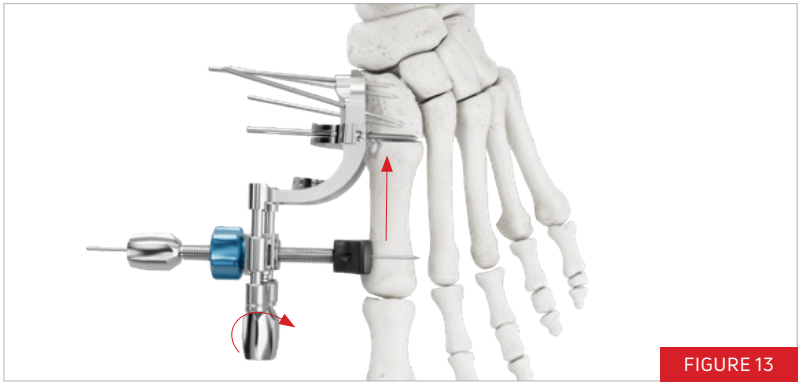


FIGURE 13

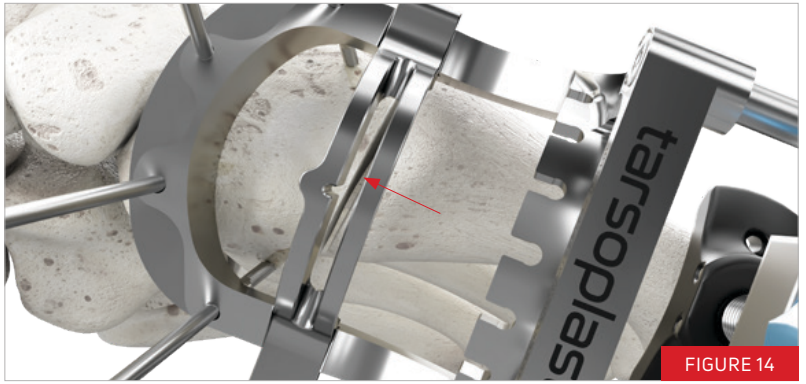


FIGURE 14

UP TO 15MM MAXIMUM COMPRESSION

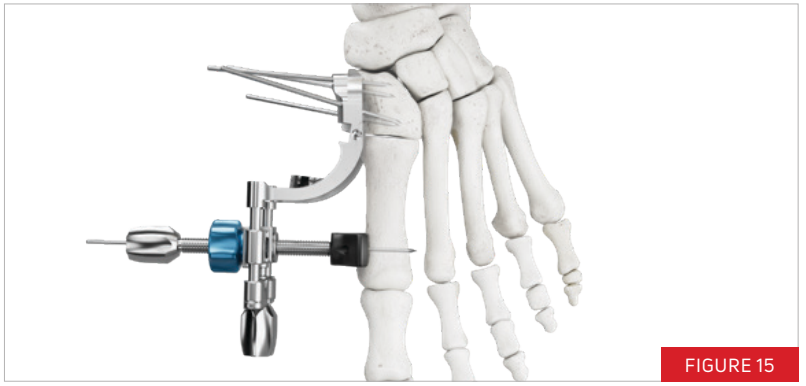


FIGURE 15

6. TARGETING

Attach the radiolucent targeting arm to the body of the Tarsoplasty and attach the targeting guide to the arm (FIGURE 16).

Insert the long K-wire sleeve in the distal aspect of the targeting guide; the user has two options to choose from based on the desired trajectory. Then, insert the K-wire sleeve in one of the four holes of the proximal part of the targeting guide (FIGURE 17). The targeting guide can move medially and laterally across the targeting arm, rotating 15° around the locking dial (FIGURE 18).

Position the targeting guide over the 1st metatarsal and parallel to the long axis of the 2nd metatarsal for accurate K-wire placement (FIGURE 19).

Insert the long K-wire sleeve into the distal aspect of the targeting guide and use image intensification before securing the position.

FIGURE 16

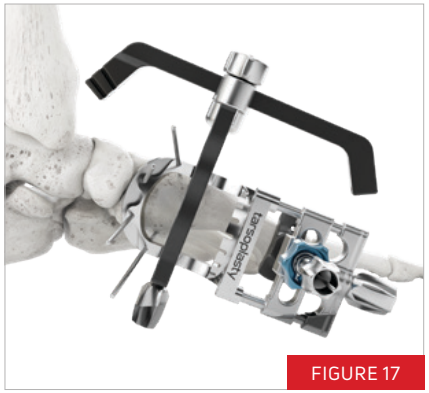


FIGURE 17

FIGURE 18

FIGURE 19

Place the 1.4x150mm K-wire into the shaft of the 1st metatarsal, targeting the lower ⅓ of the medial cuneiform. Once in position, place the proximal wire across the 1st tarsometatarsal joint (FIGURE 20).

Use image intensification to check AP and lateral views and ensure desired placement has been achieved (FIGURE 21). Once confirmed, remove the targeting tower from the body of the Tarsoplasty by removing the long K-wire sleeves and turning the knob counterclockwise. While temporarily fixated, drill over the distal 1.4 K-wire and fixate with a 4.0 Peca-C implant. Repeat the same steps for the proximal K-wire and fixate with a fully threaded 4.0 Peca Implant.

Explant the 1.8mm K-wire from the foot to remove the Tarsoplasty correction guide. It is suggested to implant a third stabilization screw to maintain the integrity of the construct in the preference of the surgeon.

FIGURE 20

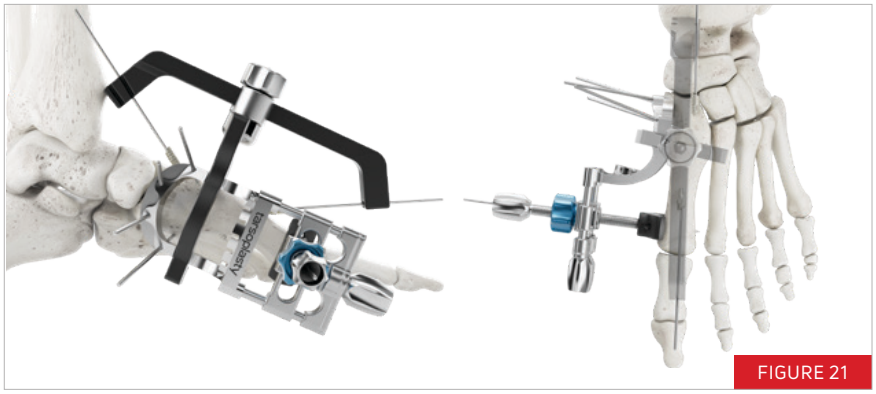


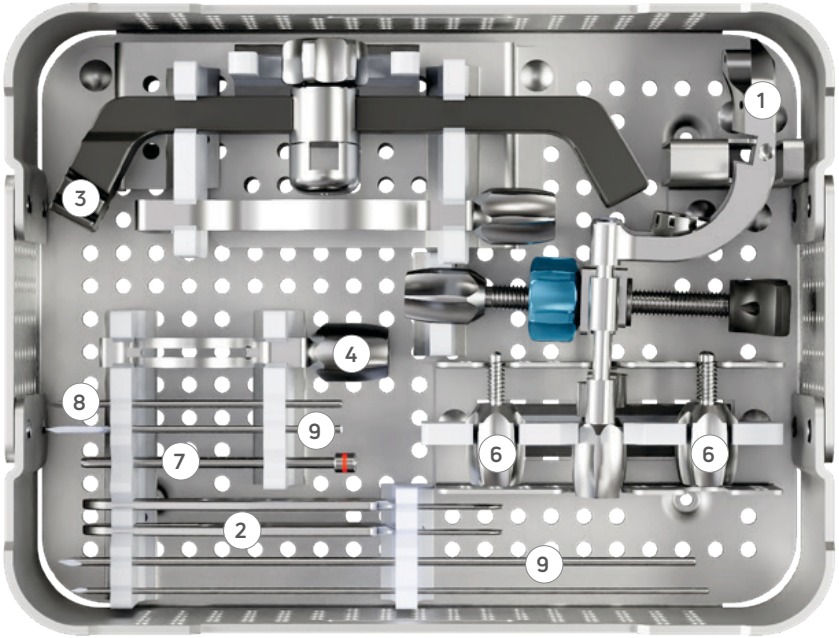
FIGURE 21

7. FINAL CONSTRUCT

BEFORE

AFTER

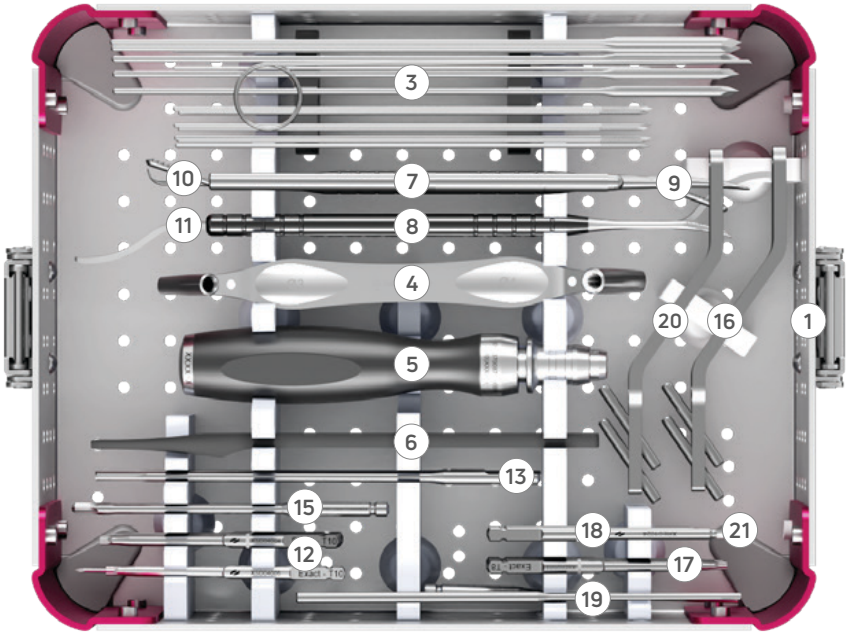
ORDERING INFORMATION



TARSOPLASTY® INSTRUMENT TRAY

#	DESCRIPTION	PART #	QTY
–	TARSOPLASTY® TRAY	ACC1020P0001	1
–	TARSOPLASTY® LID	ACC1020P0002	1
1	TARSOPLASTY® CORRECTION GUIDE	XMS01041-1	1
2	TARSOPLASTY® FEELER	XMS01041-2	2
3	TARSOPLASTY® TARGETING GUIDE	XMS01041-3	1
4	TARSOPLASTY® BURR WINDOW	XMS01041-4	1
5	TARSOPLASTY TARGETING ARM	XMS01041-5	1
6	LOCKING WHEEL	XMS01041-6	2
7	LONG K-WIRE SLEEVE	XMS01038-7	2
8	THREADED K-WIRE Ø2,2 LG 70 TR/RD	CKW05006	5
9	K-WIRE Ø1.8 LG 140 TR/RD	CKW01022	3

ORDERING INFORMATION



PECA INSTRUMENT TRAY

#	DESCRIPTION	PART #	QTY
1	TRAY	ACC1001 P0022	1
2	LID	ACC1001 P0024	1
3	K-WIRE HOLDER	ACC1001 P0023	5*
–	REDUCTION WIRE PECA	CKW03001	2
–	REDUCTION WIRE PECA Ø5	CKW03002	2
–	K-WIRE Ø1.0MM LG150 TR/RD COCR*	CKW03004	4
–	K-WIRE Ø1.4MM LG150 TR/RD COCR*	CKW02005	4
–	THREADED K-WIRE Ø1.4MM LG150 TR/RD COCR*	CKW07001	4
–	Ø0.9 CLEANING PIN	XKW01001	1
–	Ø1.4 CLEANING PIN	XKW01002	1
4	PECA / PECA-C TISSUE PROTECTOR	XDG01024	1
5	AO HANDLE	XHA01001	1
6	NEXIS / PECA RULER LG150	XGA01009	1

PECA UNIVERSAL INSTRUMENTS

#	DESCRIPTION	PART #	QTY
7	PERIOSTEAL ELEVATOR DOUBLE TIP	XMS01008	1
8	PERCUTANEOUS RASP	XMS01009	1
9	EXACT-T10 DRIVER	XSD04004	2
10	EXACT-T8 DRIVER	XSD02003	2

PECA Ø4 INSTRUMENTS

#	DESCRIPTION	PART #	QTY
11	EXACT-T 10 AO SCREWDRIVER TIP	XSD04004	2
12	Ø2 PECA 3 DRILL BIT SINGLE USE	XDB01017D	2
13	Ø3.2 PECA 3 DRILL BIT SINGLE USE	XDB01018D	2

PECA & PECA-C BUNION IMPLANTS

LENGTH	Ø4.0MM PECA IMPLANT	Ø4.0MM PECA-C IMPLANT	3.0MM PECA IMPLANT
16MM	–	–	PS020016
18MM	–	PS050118	PS020018
20MM	–	PS050120	PS020020
22MM	–	PS050122	PS020022
24MM	–	PS05010124	PS020024
26MM	PS050026	PS05010126	PS020026
28MM	PS050028	PS05010128	PS020028
30MM	PS050030	PS05010130	PS020030
32MM	PS050032	PS05010132	PS020032
34MM	PS050034	PS05010134	PS020034
36MM	PS050036	PS05010136	PS020036
38MM	PS050038	PS05010138	PS020038
40MM	PS050040	PS05010140	PS020040
42MM	PS050042	PS05010142	PS020042
44MM	PS050044	PS05010144	PS020044
46MM	PS050046	PS05010146	PS020046
48MM	PS050048	PS05010148	PS020048
50MM	PS050050	PS05010150	–
52MM	PS050052	–	–
54MM	PS050054	–	–
55MM	PS050055	PS05010155	–
56MM	PS050056	–	–
58MM	PS050058	–	–
60MM	PS050060	PS05010160	–

#	DESCRIPTION	PART #	QTY
1	SHANNON CORTA Ø2 X 08MM	CRE12008	2
2	SHANNON RECTA Ø2 X 12MM	CRE12012	2
3	SHANNON LONGA Ø2.2 X 22MM	CRE12222	2
4	SHANNON LARGA Ø3 X 20	CRE13020	2
5	SHANNON X-LARGA Ø3.0 X 30 MM	CRE13030	2
6	WEDGE Ø3.1X 13MM	CRE23113	2
7	WEDGE Ø4.1X 13MM	CRE24113	2

NOTES

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NOVASTEP
2 Allee Jacques Frimot
RENNES Bretagne, FR 35000