ST

SURGICAL
TECHNIQUE

enovis

CENTROLOCK®

GUIDED TRANSVERSE OSTEOTOMY SYSTEM

BUNION SYSTEM

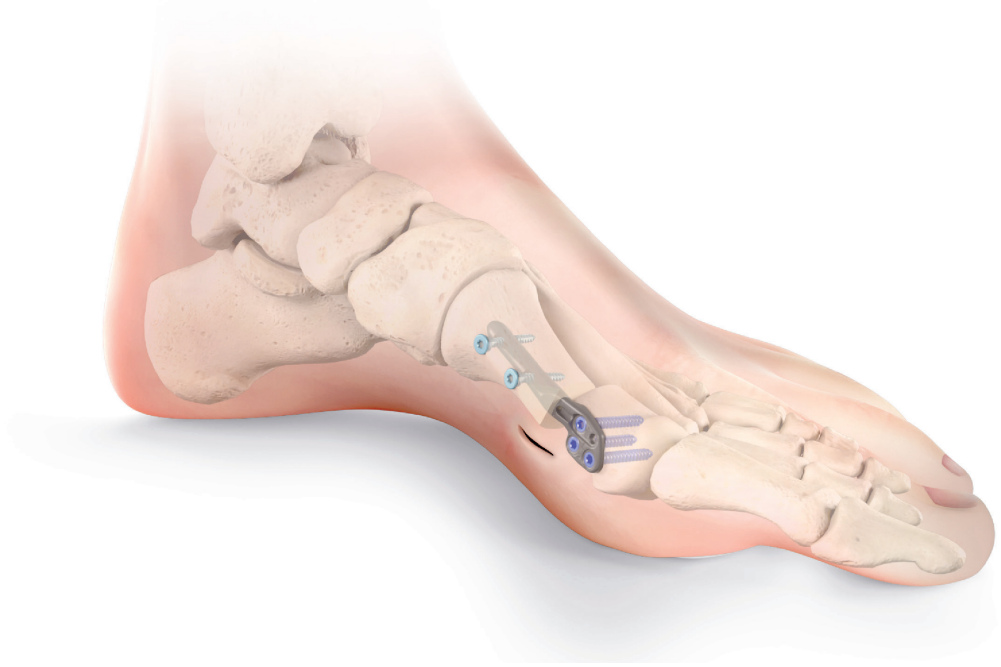


TABLE OF CONTENTS

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 screw-plate systems are indicated for Hallux Valgus.

LIMITATION OF USE

Hallux Valgus

NOTE: Detailed information on each medical device is provided in the instructions for use. Refer to the instructions for use for a complete list of side effects, warnings, precautions, and directions for use.

CONTRAINDICATIONS

- Bone destruction or poor bone quality likely to impair implant stability.
- Hypersensitivity to vanadium and/or aluminium.

INDICATIONS & CONTRAINDICATIONS

BUNION CORRECTION

TRANSVERSE OSTEOTOMY

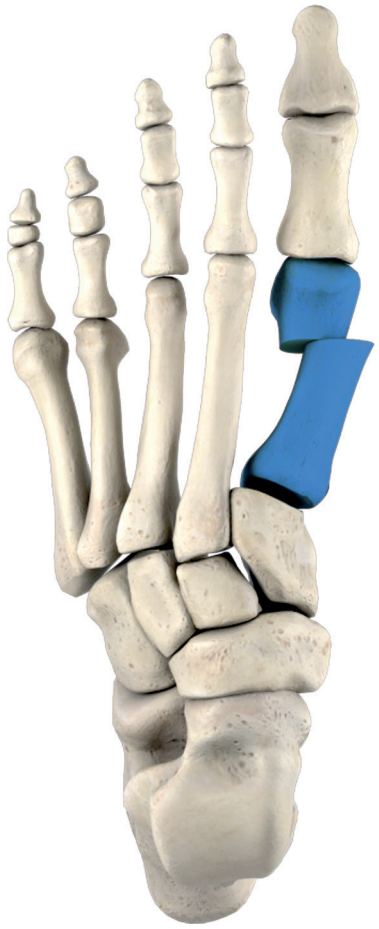
Centrolock® was designed to evolve the standard fixation and treatment methods to correct hallux valgus.

The transverse osteotomy provides powerful corrections in hallux valgus surgery. Utilizing this technique allows for easy manipulation in the frontal plane, while addressing severe intermetatarsal angles with up to 100% translation.

Surgeons may also choose to manipulate the plantar, dorsal, length and rotational alignments of the first ray. Centrolock® implant evolves the fixation for the transverse osteotomy, providing rigid fixation preventing the need for joint fusion (lapidus procedure) to correct hallux valgus.

TRANSVERSE BUNION CORRECTION

- Lateral translation.
- Plantar/dorsal alignment.
- Frontal plate & horizontal plane rotation.
- Length adjustment.



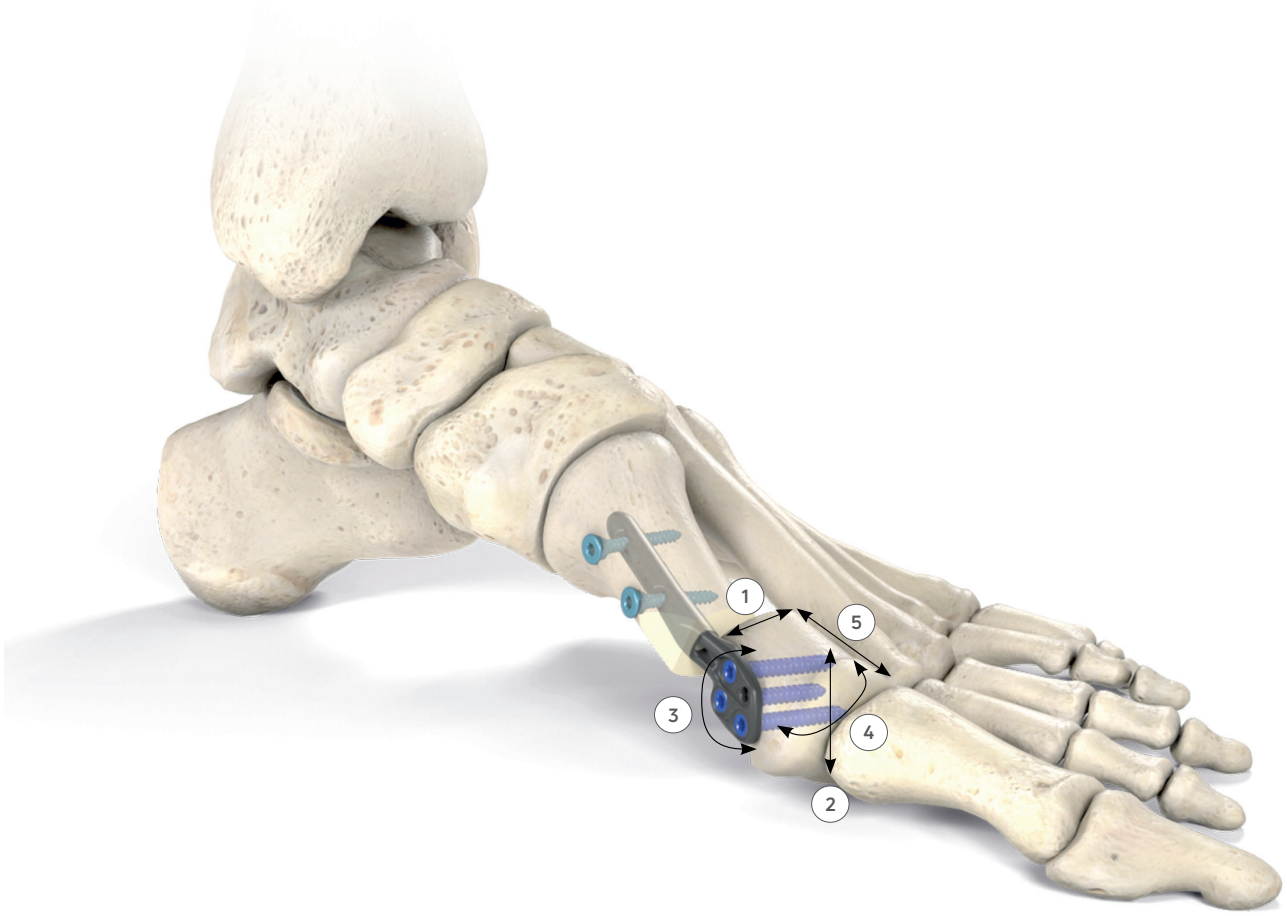
DESIGN FEATURES

Centrolock® Guided Transverse Osteotomy System was designed to evolve the standard fixation and treatment methods to correct hallux valgus. The innovative hybrid design combines a cannulated intramedullary stem with plate fixation on the metatarsal head. Powerful three plane corrections once achieved only by Lapidus, can now be performed through a distal minimally invasive guided approach.

The combination of guided instrumentation and the Centrolock® implant ensure reproducible clinical outcomes, refining hallux valgus treatment without joint fusion.

POWERFUL MULTIPLANAR CORRECTION

1. Lateral translation
2. Plantar/dorsal alignment
3. Frontal plane rotation
4. Horizontal plane rotation
5. Length adjustment



HYBRID INTRAMEDULLARY IMPLANT

METATARSAL PLATE

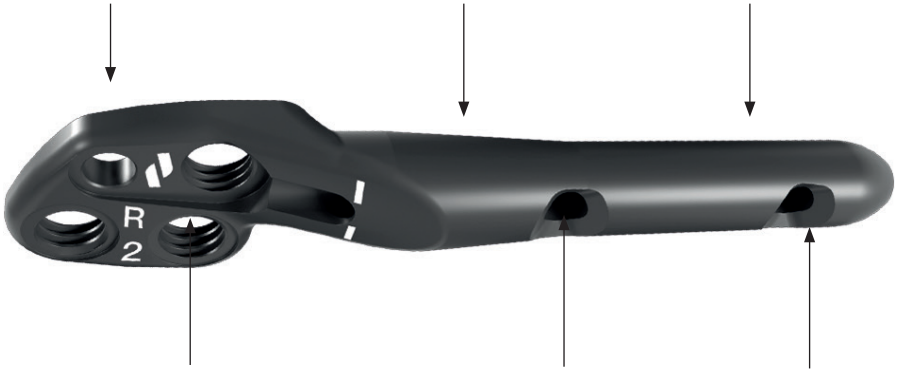
- 3 translation options
- Allows up to 100% translation

HYBRID INTRAMEDULLARY DESIGN

Combines metatarsal plate and cannulated stem

CANNULATED STEM

Enable implant positioning and eases frontal plan manipulation around the K-wire



LOCKING SCREWS HOLES

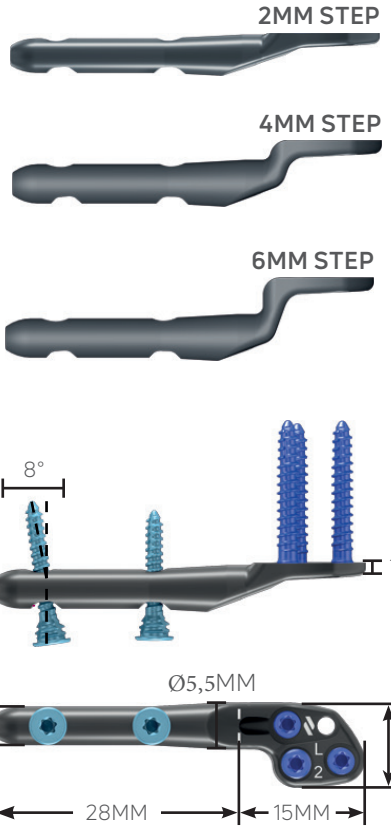
Ø2.5mm locking screws fix the capital fragment.

PROXIMAL FIXATION

Ø2mm cortical screws are implanted to securely fasten the intramedullary stem.

OFFSET ANGULATION

8° screw hole offset



GUIDED INSTRUMENTATION

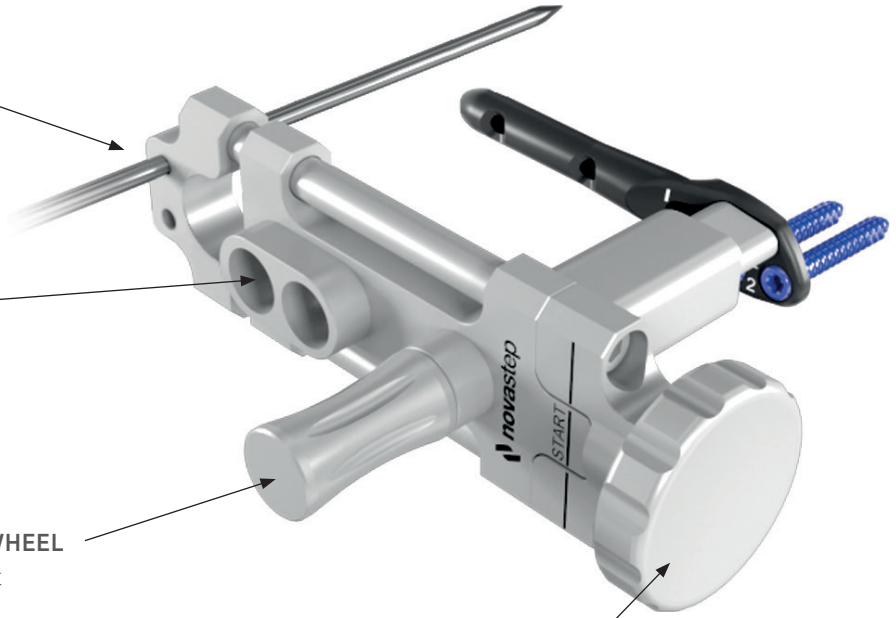
TARGETING GUIDE

STABILIZATION HOLE
Provisionally fixated with Ø2.0 K-wires

TARGETING GUIDE HOLE
Ensures accuracy when implanting cortical screws

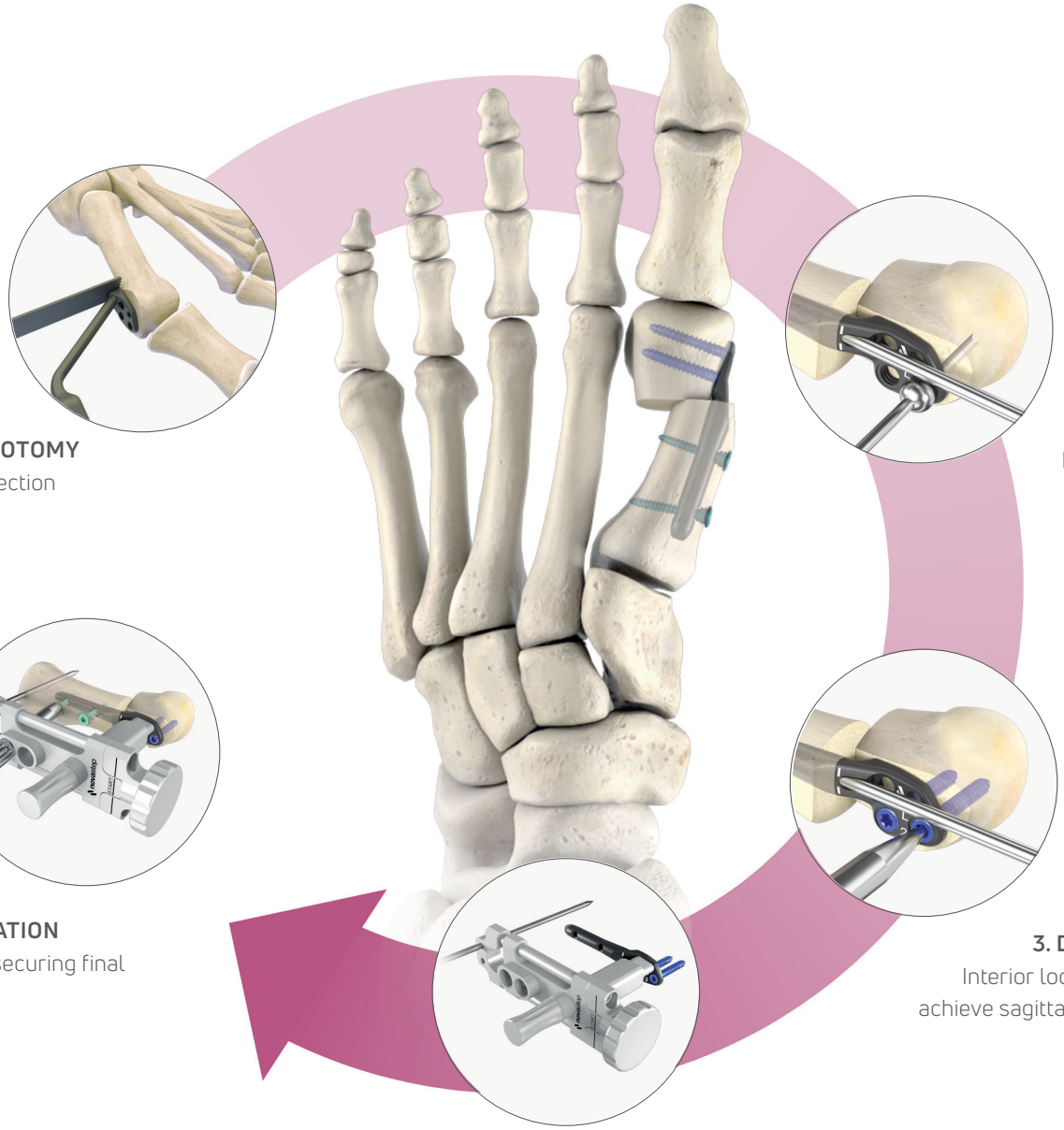
THREADED BOLT ATTACHMENT WHEEL
Attaches to the Centrolock® implant

COMPRESSION DIAL
Ensures bone on bone contact, providing up to 3mm of compression.



GUIDED TECHNIQUE

TECHNICAL FEATURES



1. TRANSVERSE OSTEOTOMY
Guided multiplane correction

2. IMPLANT POSITIONING
Intermetatarsal angle & sagittal plane correction

3. DISTAL FIXATION
Interior locking implanted to achieve sagittal plane correction

4. ROTATIONAL ALIGNMENT
Frontal plane alignment & compression

5. PROXIMAL FIXATION
Proximal fixation, securing final correction

1. TRANSVERSE OSTEOTOMY

1.1 INCISION & EXPOSURE

Patient is positioned supine. Intraoperative fluoroscopy is highly recommended. Make a dorsal-medial, longitudinal incision of 1.5 to 2.0cm overlying the first metatarsal head. Isolate and protect the neuro-vascular bundle. Incise the first metatarsal-phalangeal joint capsule according to the surgeon preference to expose the first metatarsal medial eminence (FIGURE 1).

FIGURE 1

1.1 MEDIAL EMINENCE RESECTION

Medial eminence resection is an important procedural step as it will impact lateral translation and positioning / rotation of the metatarsal head in the transverse and frontal plane.

First, resect the smallest amount of bone necessary so the implant can achieve a larger lateral translation of the first metatarsal head, thereby reducing the intermetatarsal angle.

Second, perform a wedge-shaped medial eminence resection, removing less bone proximally and more bone distally to rotate the metatarsal head in the transverse plane and achieve a congruous joint, thereby correcting the DMAA.

For optimal derotation of the head, aim at a resection perpendicular to the articular surface axis (FIGURE 2).

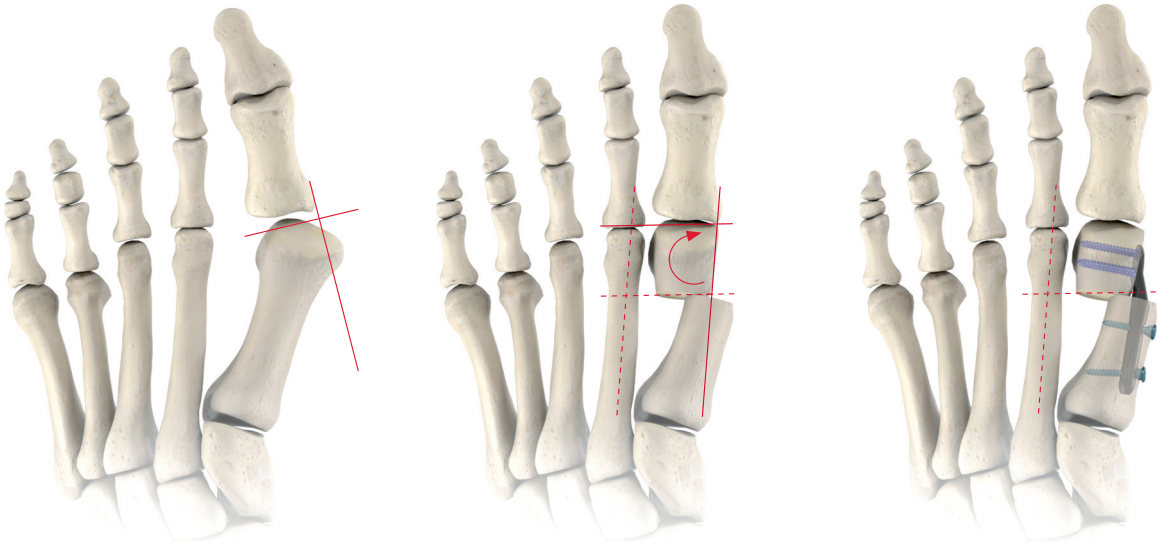


FIGURE 2

1.3 OSTEOTOMY

Lateral soft-tissue release can be performed either percutaneously, through a second incision overlying the first intermetatarsal space, or through a medial transarticular approach, per surgeon discretion.

Transect the lateral metatarsosesamoid suspensory ligament horizontally and release the lateral part of the conjoined tendon.

The lateral collateral ligament is respected to prevent iatrogenic hallux varus.

The ideal osteotomy location is at the level of the surgical neck, at the metaphyseal-diaphyseal junction, specifically just proximal to the sesamoids and vascular bundle to the inferior metatarsal.

Position the osteotomy cutting template against the flat part of the first metatarsal head, at the level of the resection of the medial eminence. Place the saw blade at the lower edge of the cutting template in order to make a perpendicular cut to the second metatarsal (FIGURE 3).

> NOTE: The transverse osteotomy must be perpendicular to the longitudinal axis of the second metatarsal (neutral translation) in the horizontal plane, unless there is a need for lengthening or shortening effects. (FIGURE 4).

Under image intensification, check the osteotomy position in relation to the placement of the cutting template.

Once the ideal osteotomy level has been verified, remove the cutting template, leaving the saw blade in place and perform the transverse osteotomy.

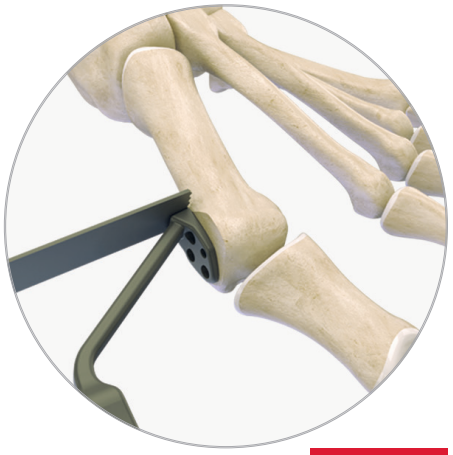
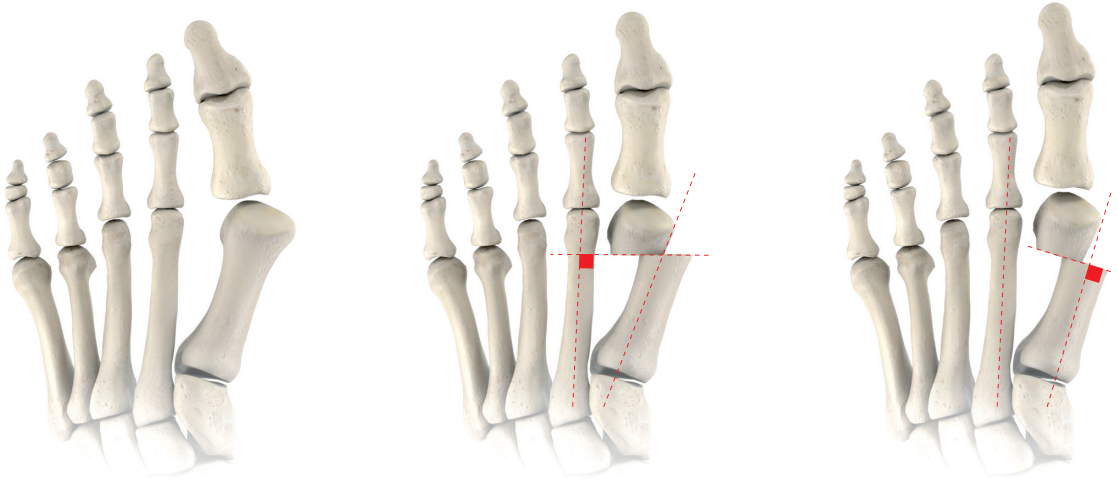


FIGURE 3



POST-OPERATIVE FOOT | TRANSLATION WITH NEUTRAL EFFECT | LENGTHENING EFFECT

FIGURE 4

2. IMPLANT POSITIONING

2.1 METATARSAL HEAD POSITIONING

Use the Centrolock® elevator to displace the first metatarsal head laterally. Stabilize it temporarily with a Ø 2.0 x 150 mm K-wire (FIGURE 5).

The K-wire must be inserted targeting the medial proximal corner of the metatarsal bone for optimal correction of DMAA. Advance the K-wire into the first metatarsal base subchondral bone (FIGURE 6).

Using fluoroscopic guidance, check the appropriate position of the K-wire prior to withdraw the elevator, leaving the K-wire in position (FIGURE 7).

NOTE: Advance the K-wire across the first metatarsal-cuneiform joint for additional stability of the construct. (FIGURE 8).

FIGURE 5

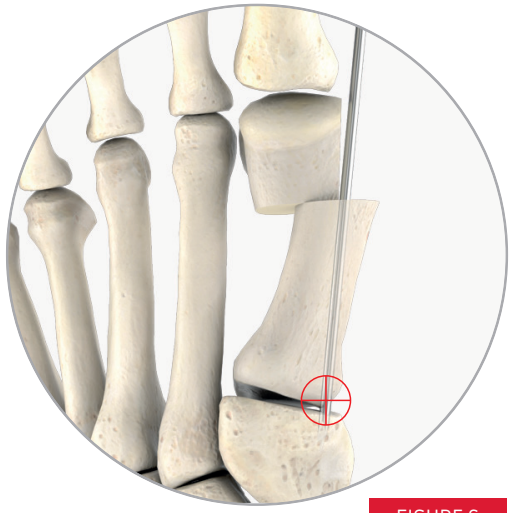


FIGURE 6

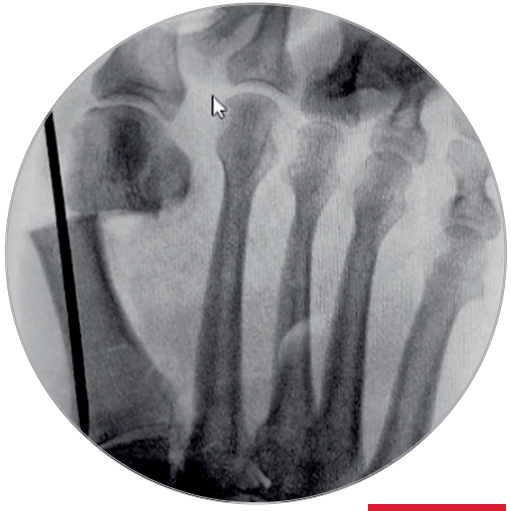


FIGURE 7

FIGURE 8

2.2 STEMLESS TRIAL SIZER SETTING UP

Use the Stemless trial sizer to validate the positioning of the K-Wire and the desired correction.

Insert the right or left Stemless trial sizer on the Ø 2.0 K-Wire depending on the degree of correction required (Step 2, 4 or 6 mm) (FIGURE 9).

> NOTE: Using the Stemless trial sizer before passing the hand reamer allows preservation of bone capital, which allows repositioning of the wire if necessary.

FIGURE 9

2.3 INTRAMEDULLARY REAMING

Insert the hand reamer over the Ø 2.0 K-wire and gently twist it to ream a channel for the intramedullary stem of the implant until the black laser marking is at the level of the first metatarsal osteotomy (FIGURE 10).

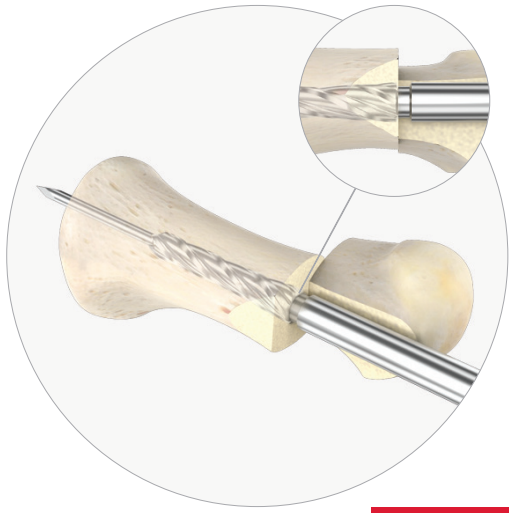


FIGURE 10

2.4 TRIAL IMPLANTS - LATERAL CORRECTION

To achieve the lateral correction needed, connect the correct side trial implant to the impactor and insert it over the Ø 2.0 K-wire to select the 2, 4 or 6 mm offset implant required (FIGURE 11).

NOTE: Centrolock® impactor setting: The impactor wheel is universal for left / right side and may be unscrewed to correlate with the correct implant. (FIGURE 12)

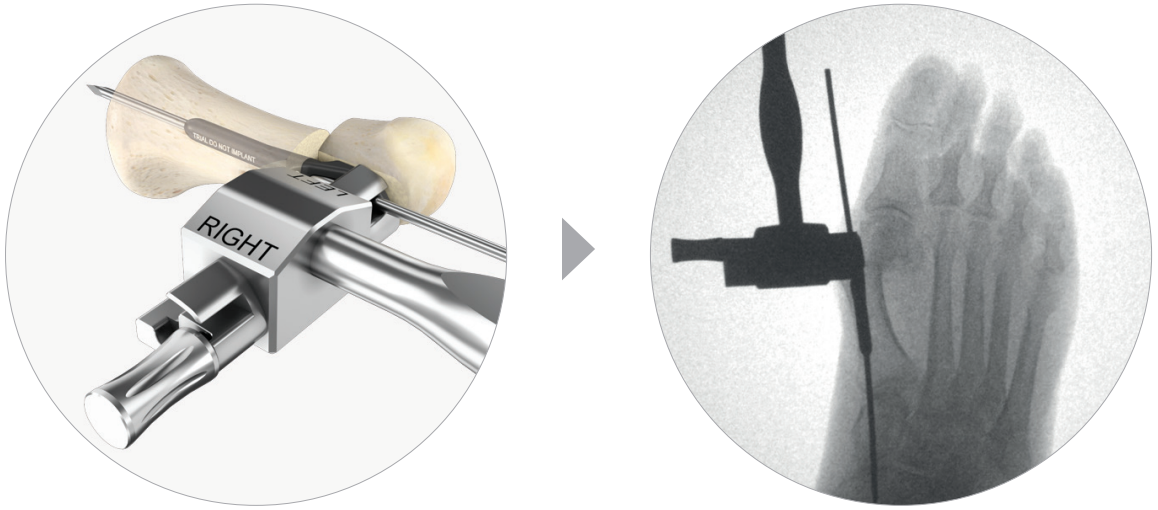


FIGURE 11

FIGURE 12

3.1 REDUCTION WIRE

Attach the selected implant to the impactor, insert it through the implant cannula over the Ø 2.0 K-wire and impact it until the laser marking on the implant is flush with the first metatarsal osteotomy (FIGURE 13)

NOTE: It is critical to ensure that the flat, medial surface of the first metatarsal head is in direct contact with the flat part of the implant. This can be achieved by pulling the hallux into varus.

NOTE: A free impactor may be used to seat implant more proximally, if deemed necessary.

FIGURE 13

If necessary, the first metatarsal head can be translated dorsally or plantarly at this step to correct any sagittal plane malalignment.

Once the optimum position of the first metatarsal head is achieved as confirmed under image intensification, withdraw the impactor by unscrewing the wheel. Stabilize the osteotomy with a temporary fixation pin inserted on the proximal inferior screw hole. (FIGURE 14)

NOTE: When positioning the implant in the sagittal plane, the subsequent frontal plane rotation may affect the plantar/dorsal position.

FIGURE 14

3. DISTAL FIXATION

3.1 INFERIOR LOCKING SCREWS INSERTION

The plate implant allows two inferior locking screw hole options in the distal screw clusters.

Thread the locking drill guide for the Ø 2.5 mm locking screw in the plantar proximal plate hole. Pre-drill using the Ø 1.8 mm drill with the screw length being measured directly off the drill-guide (FIGURE 15).

Remove the drill guide.

Insert the uni-cortical Ø 2.5 mm locking screw with the screwdriver. Remove the temporary fixation pin and repeat the step to insert the distal inferior locking screw. (FIGURE 16).

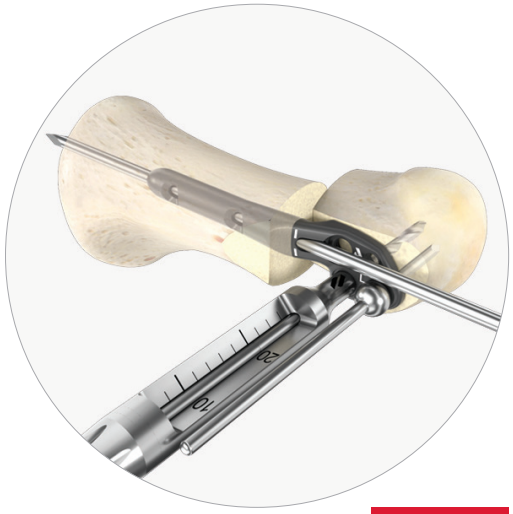


FIGURE 15

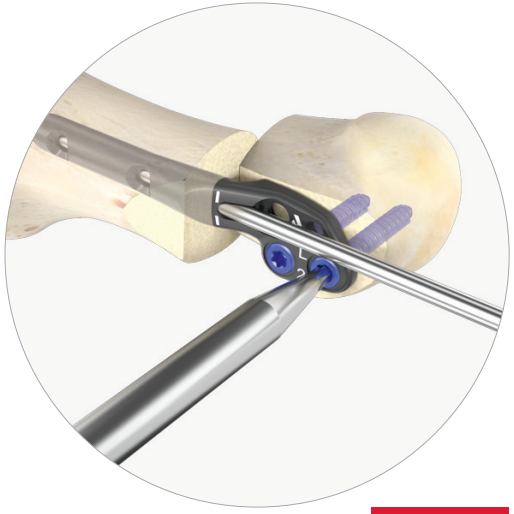


FIGURE 16

NOTE: If a gap between the metatarsal head and plate is present the surgeon can pull the hallux into varus. This maneuver will push the metatarsal head toward the plate, maintain this position when fixating (FIGURE 17).

Remove the central K-wire (FIGURE 18).

NOTE: A depth gauge is available to measure the required screw length if needed. Remove the drill guide to use the depth gauge. (FIGURE 19).

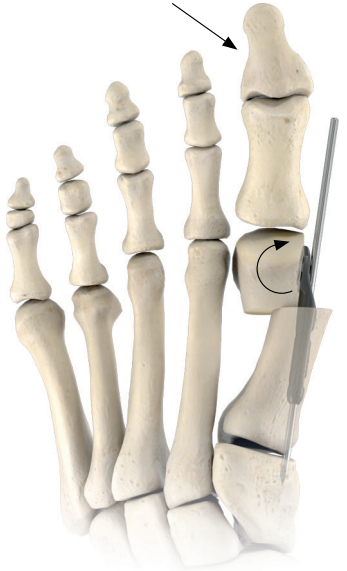


FIGURE 17

FIGURE 18

FIGURE 19

4. ROTATIONAL ALIGNMENT

4.1 FINAL METATARSAL HEAD ROTATION POSITIONING

Set up the Centrolock® Targeting / Compressing Guide compression wheel in START position (FIGURE 20).

The Guide is then attached to the superior locking hole of the implant and secured with the threaded bolt attachment wheel. (FIGURE 21 A& B).

NOTE: The use of a rongeur or saw blade to remove the medial spike at this step may be needed to avoid impingement with the edge of the Targeting guide.

FIGURE 20

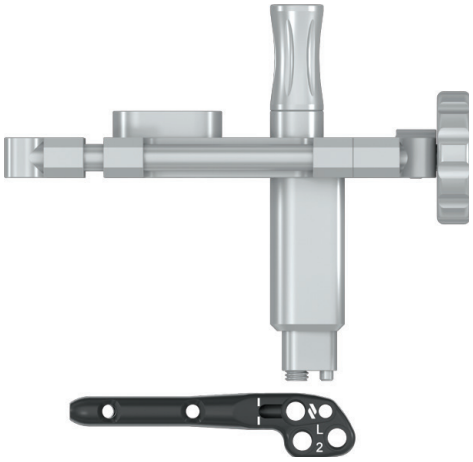


FIGURE 21 A

FIGURE 21 B

The final frontal plane rotation positioning check of the first metatarsal head is performed at this time. Once ideal positioning has been verified, insert one Ø 2.0 K-wire bicortically into the upper hole at the proximal end of the Targeting / Compressing Guide (FIGURE 22 A & B).

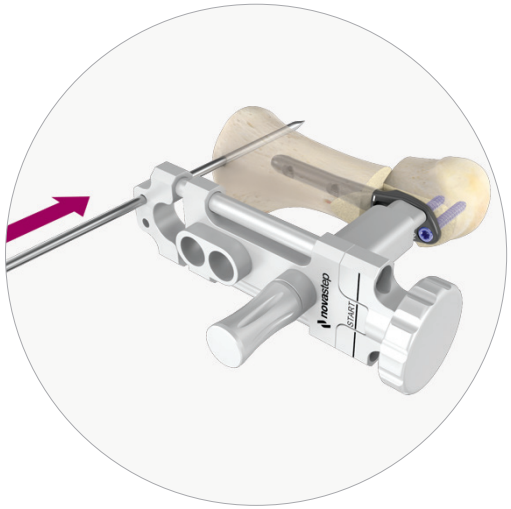


FIGURE 22 A

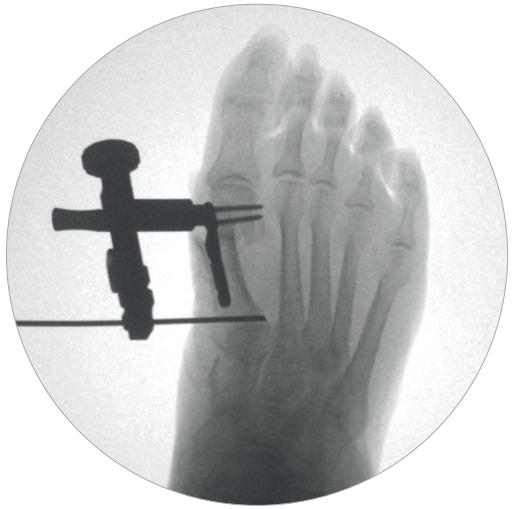


FIGURE 22 B

4.2 COMPRESSION ADJUSTMENT

If compression is needed, rotate the compression wheel clockwise until the desired amount of compression is achieved (FIGURE 23).

NOTE: A maximum of 3 mm of compression can be achieved with the Targeting / Compressing Guide. Take care not to over compress, as this may shorten the metatarsal or cause un-intentional mal-alignment of the metatarsal head.

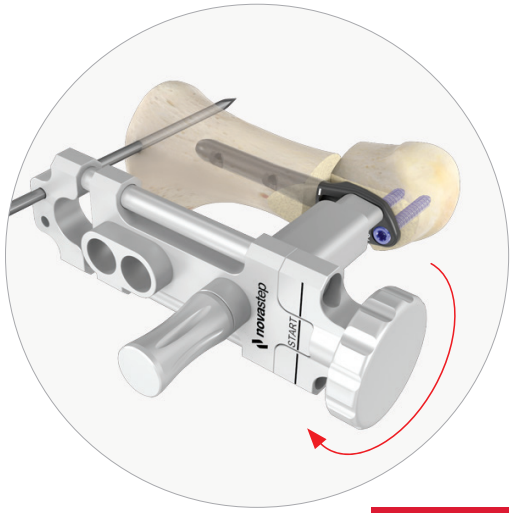


FIGURE 23

5. PROXIMAL FIXATION

5.1 CORTICAL SCREWS INSERTION

Two bi-cortical Ø 2.0 mm non-locking screws must be placed through the intramedullary stem of the implant to secure the implant positioning. Insert the drill guide for screw Ø 2.0 mm in the distal hole of the targeting and compressing guide. An incision is made before pre-drilling using a Ø 1.5 mm drill. A countersink is available to create the space for the screw head.

The screw length can be measured directly off the drill guide.The chosen Ø 2.0 mm screw is implanted bi-cortically with the screwdriver (FIGURE 24 A & B).

NOTE: Always start with inserting the distal Ø 2.0 mm cortical screw for a better construct stability.

NOTE: A depth gauge is available to measure the required screw length if needed.

Remove the drill guide to use the depth gauge. After length reading, re-insert the drill guide to insert the chosen screw with the screwdriver.

Repeat the step for the proximal Ø 2.0 mm cortical screw (FIGURE 25).

Rotate the compression wheel counterclockwise, before removing the Ø 2.0 mm K-wire. Then, remove the Targeting / Compressing Guide.

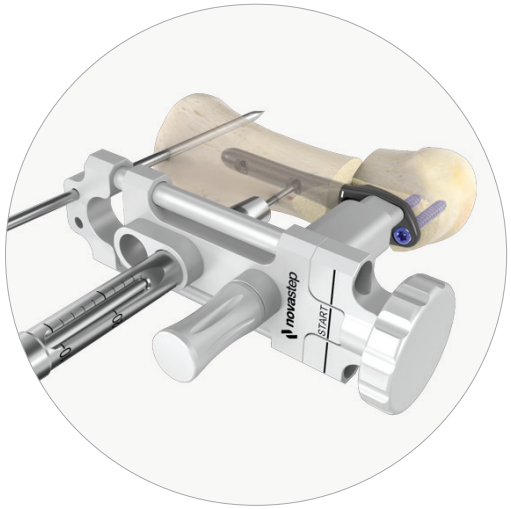


FIGURE 24 A

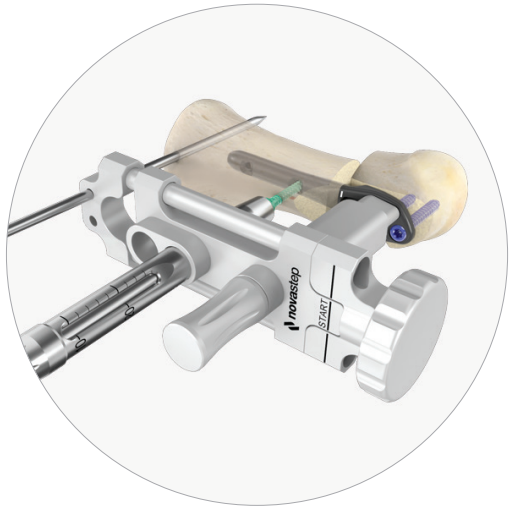


FIGURE 24 B

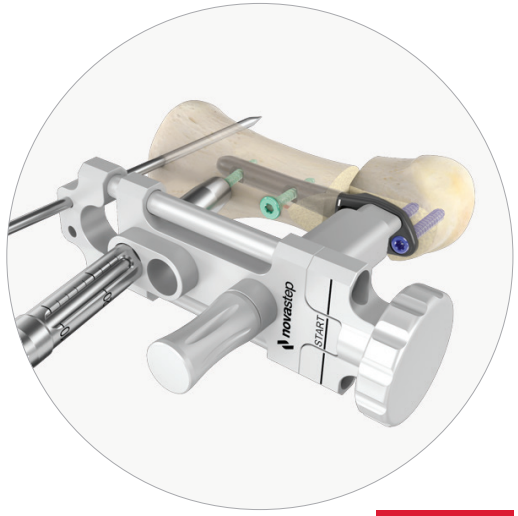


FIGURE 25

5.2 THIRD LOCKING SCREW INSERTION

Insert the third 2.5 mm locking screw into the first metatarsal head through the proximal-superior locking hole within the flat portion of the implant, following the same steps (FIGURE 26).

5.3 MEDIAL SPIKE RESECTION

If needed, the medial spike of the first metatarsal shaft can be resected at an oblique angle if this area remains prominent (FIGURE 27).

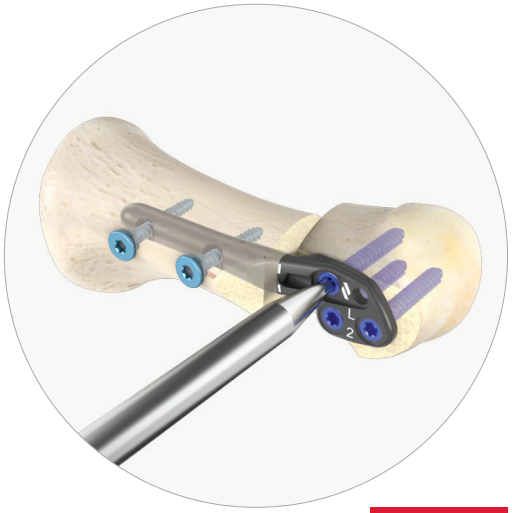
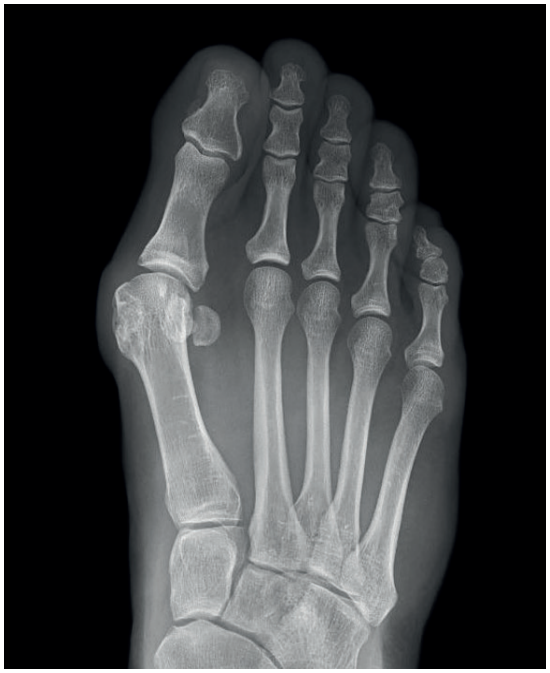


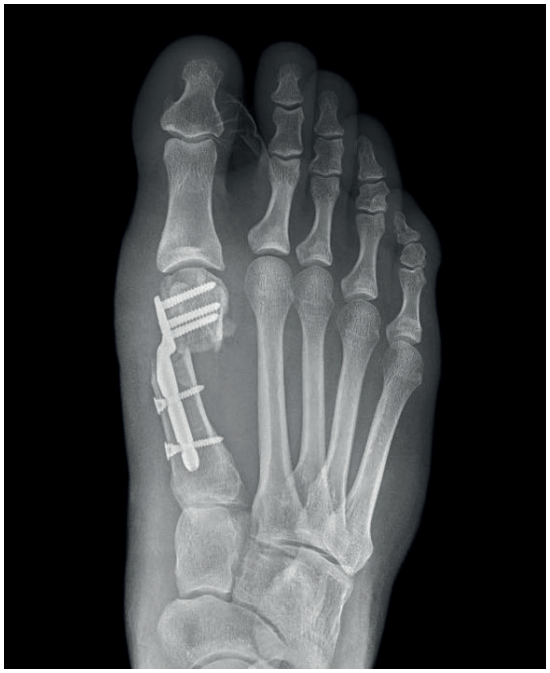
FIGURE 26

FIGURE 27

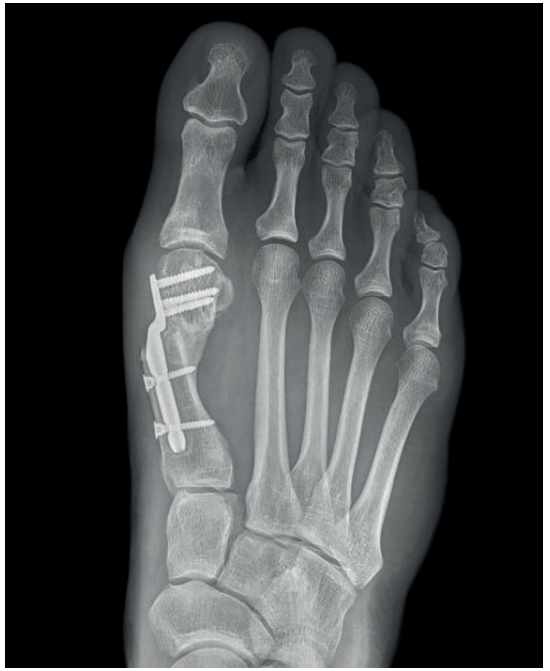
XRAYS



PRE-OPERATIVE



POST-OPERATIVE



FINAL IMPLANTATION AT 3 MONTHS

ORDERING INFORMATION

CENTROLOCK® IMPLANT – RIGHT

PART NO.	STEP (mm)
PL070102	2mm
PL070104	4mm
PL070106	6mm

CENTROLOCK® IMPLANT – LEFT

PART NO.	STEP (mm)
PL070202	2mm
PL070204	4mm
PL070206	6mm

CENTROLOCK® LOCKING SCREW

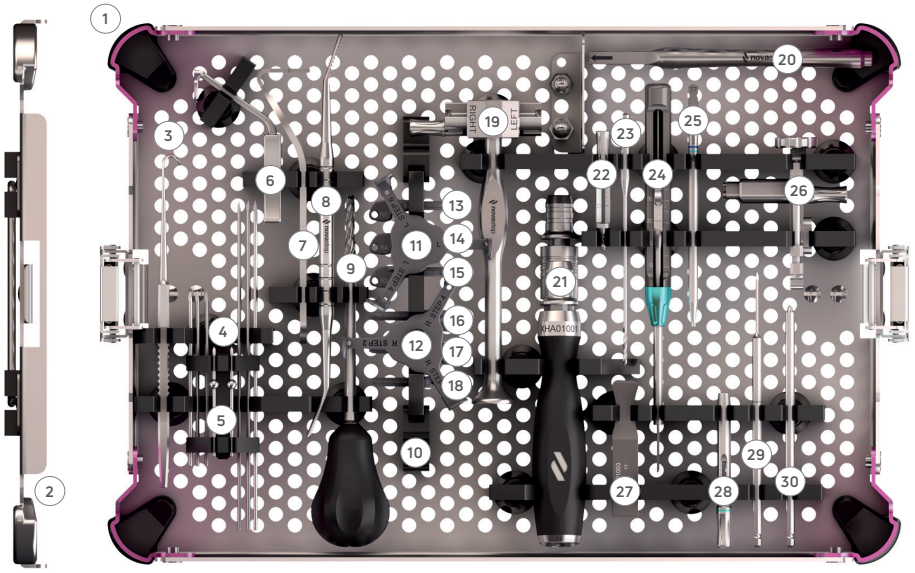
PART NO.	LENGTH (mm)
SP012510*	10mm*
SP012512	12mm
SP012514	14mm
SP012516	16mm
SP012518	18mm
SP012520	20mm
SP012522	22mm
SP012524*	24mm*
SP012526*	26mm*

** ON DEMAND*

CENTROLOCK® CORTICAL SCREW

PART NO.	LENGTH (mm)
SP032012	12mm
SP032014	14mm
SP032016	16mm
SP032018	18mm
SP032020	20mm
SP032022	22mm
SP032024	24mm

CENTROLOCK® INSTRUMENTATION



#	DESCRIPTION	PART NO.	QTY
1	TRAY	ACC1015P0001	1
2	LID	ACC1015P0002	1
3	RETRACTOR	XMS01033	2
4	K-WIRE HOLDER	ACC1001P0020	1
-	K-WIRE Ø2 LG 150 TR/RD[1]	-	4
-	K-WIRE Ø2 LG 150 TR/RD[2]	-	4
5	SPHERIC POSITIONING PIN	XPP01005	2
6	CUTTING TEMPLATE – RIGHT	XMS01040-1	1
6	CUTTING TEMPLATE – LEFT	XMS01040-2	1
7	ELEVATOR	XMS01029	1
8	PERCUTANEOUS RASPS	XMS01009	1

#	DESCRIPTION	PART NO.	QTY
9	CANNULATED REAMER	XRE01014	1
10	TRIAL IMPLANT HOLDER	ACC1015P0003	1
11	STEMLESS TRIAL SIZER – LEFT	XTI06010	1
12	STEMLESS TRIAL SIZER – RIGHT	XTI06020	1
13	2mm TRIAL IMPLANT – LEFT	XTI06012	1
14	4mm TRIAL IMPLANT – LEFT	XTI06014	1
15	6mm TRIAL IMPLANT – LEFT	XTI06016	1
16	2mm TRIAL IMPLANT – RIGHT	XTI06022	1
17	4mm TRIAL IMPLANT – RIGHT	XTI06024	1
18	6mm TRIAL IMPLANT – RIGHT	XTI06026	1
19	IMPACTOR	XMS01030	1
20	STRAIGHT IMPACTOR	XMS01036	1
21	AO HANDLE	XHA01001	1
22	LOCKING DRILL GUIDE FOR SCREW Ø2,5	XDG01019	2
23	DRILL BIT Ø1,8	XDB01020	2
24	DEPTH GAUGE	XGA01011	1
25	T7 AO SCREWDRIVER TIP	XSD01003	2
26	TARGETING - COMPRESSING GUIDE	XMS01026	1
27	SCREW LENGTH INDICATOR	XGA01003	1
28	DRILL GUIDE FOR SCREW Ø2	XDG01018	2
29	DRILL BIT Ø1,5	XDB01019	2
30	COUNTERSINK	XRE01022	1

[1] K-wire supplied separately - Medetechnik® K-wire (33-T10-R-20-100)
[2] K-wire supplied separately - Medetechnik® K-wire (33-T10-R-20-150)

NOTES

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

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

Carefully read the enclosed Instructions For Use (IFU) and all packaging label information. Devices: Implants: Class IIb-CE1639 / Instruments: Class I / Class Ir-CE1639 / Class IIa-CE1639.

REFERENCE: CEN-ST-ED7-06-25-EN