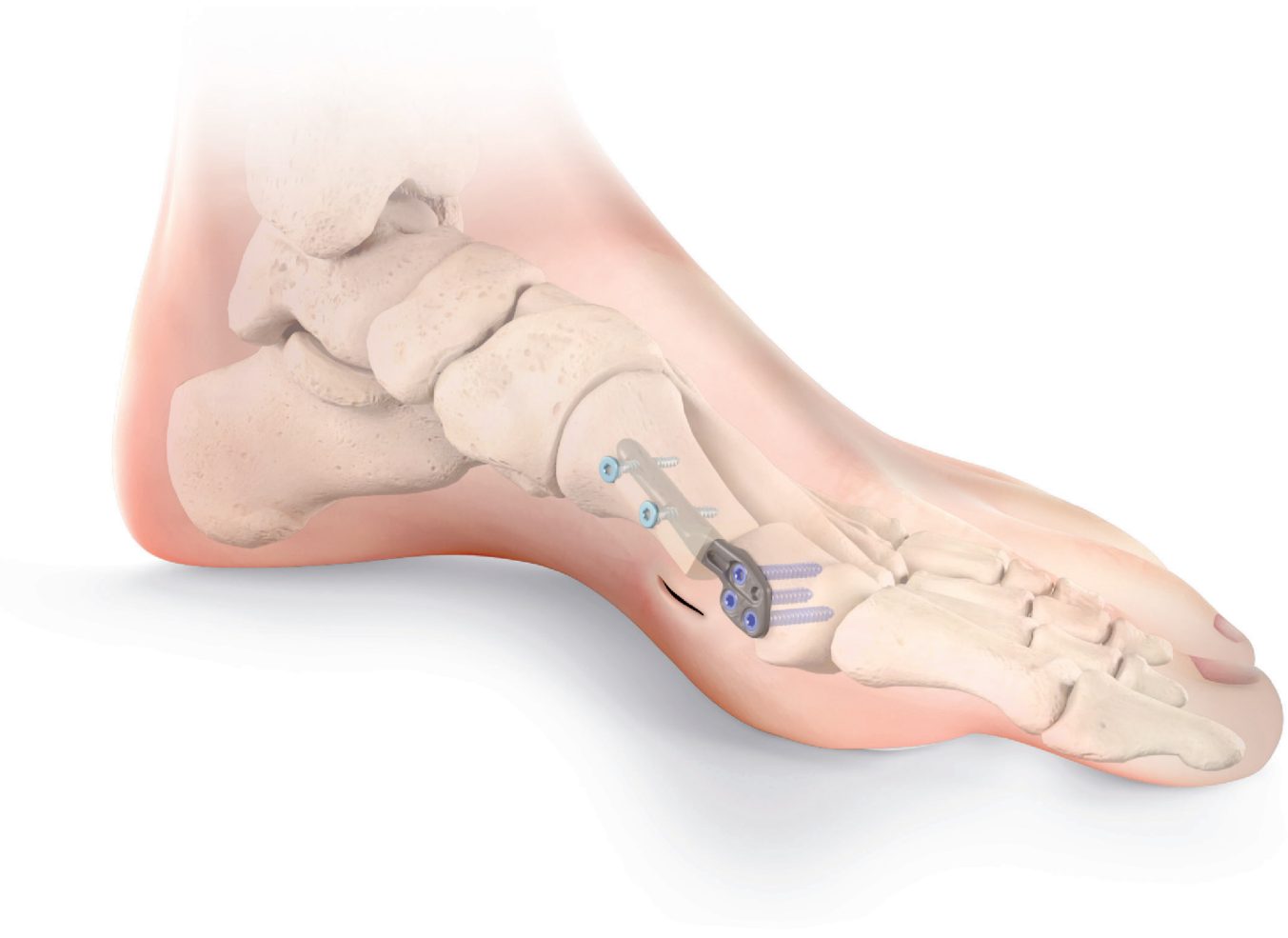
centroLock®

Guided Transverse Osteotomy System

OPERATIVE TECHNIQUE

FOREFOOT



. **Powerful multiplanar** correction of hallux valgus
. **Guided instrumentation,** reproducible outcomes
. **MIS Platform**

Creating Better Together™

centroLock®

Guided Transverse Osteotomy System

Table of contents

Surgeons contributing writing to the surgical technique:

. Dr Michel Maestro, PhD, IM2S - Institut Monégasque de Médecine & chirurgie Sportive, Monaco.
. Dr Martin Schramm, PhD, IM2S - Institut Monégasque de Médecine & chirurgie Sportive, Monaco.
. Dr Pietro Spennachio, PhD - Centre Hospitalier de Luxembourg, Luxembourg.
. Dr Thomas S. Roukis, DPM, PhD, FACFAS - University of Florida College of Medicine. Gainesville, FL. USA.
. Dr Jonathan J. Sharpe, DPM - Lake Health. Concord, OH. USA.

This publication sets forth detailed recommended procedures for using Novastep Centrolock® implants and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to first surgery.

Introduction

Indications & Contraindications

Indications

The osteosynthesis screw-plate systems are indicated for Hallux Valgus.

Limitation of use:

. Hallux valgus

Contra-indications

. Bone destruction or poor bone quality, likely to impair implant stability.

. Hypersensitivity to one or more components.

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, directions for use and contra-indications.

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.

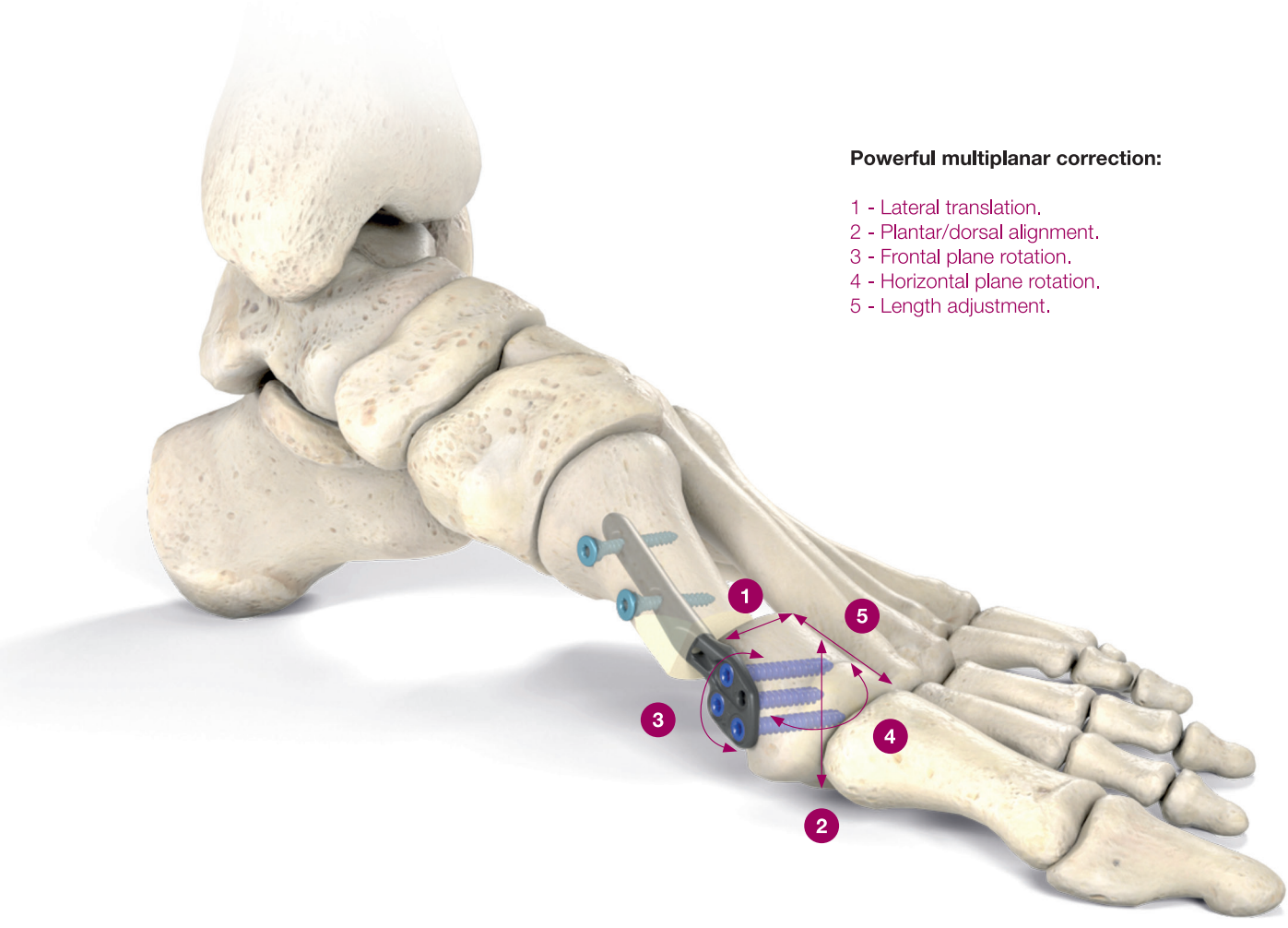
Transverse bunion correction:

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

Design Features

1 - Description

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.

Design Features

2 - Centrolock® implant

Metatarsal plate:
. 3 translation options.
. Allows up to 100% Translation.

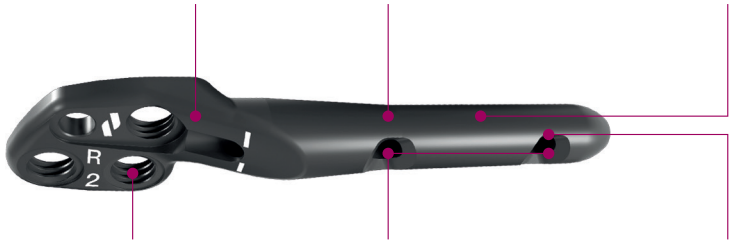
Hybrid intramedullary design:
Combines metatarsal plate and cannulated stem.

Cannulated stem:
Precise implant positioning, eases frontal plane manipulation around the K-Wire.

2 mm Step:

4 mm Step:

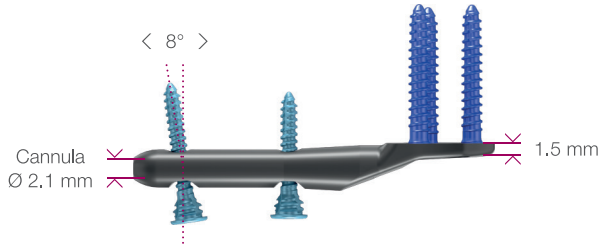
6 mm Step:

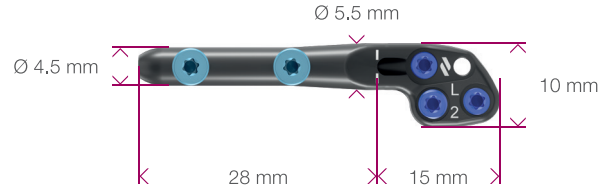


Locking screws holes:
Ø 2.5 mm locking screws secure the capital fragment.

Proximal fixation:
Ø 2.0 mm cortical screws are implanted to securely fasten the intramedullary stem.

Offset angulation:
8° screw hole offset to prevent migration of the implant.





3 - Guided instrumentation

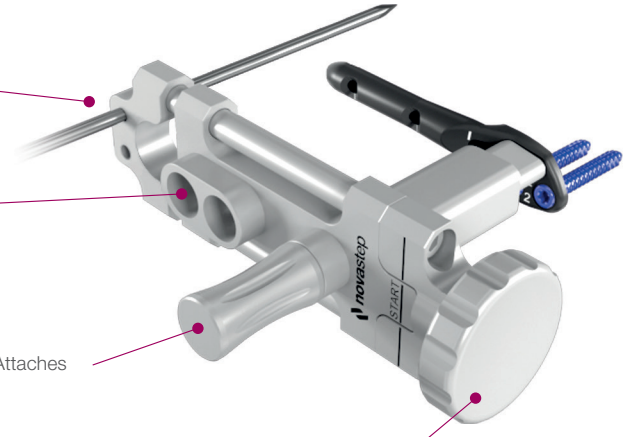
Targeting guide

Stabilization hole: Provisionally fixated with Ø 2.0 K-wires.

Targeting guide holes: Ensure accuracy when implanting cortical screws.

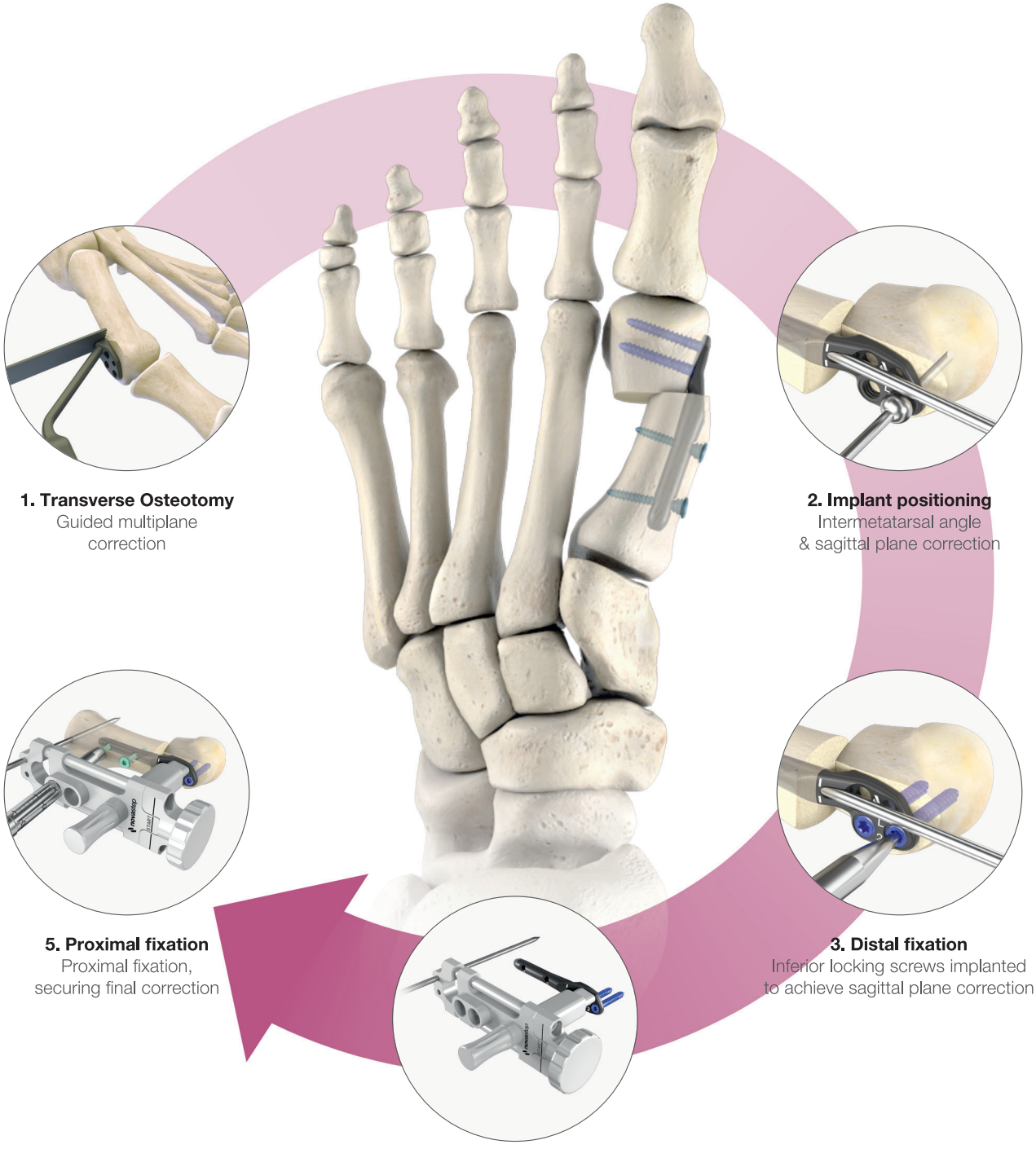
Threaded bolt attachment wheel: Attaches to the Centrolock implant.

Compression dial: Ensures bone on bone contact providing up to 3 mm of compression.



Design Features

4 - Guided technique, technical features



1. Transverse Osteotomy
Guided multiplane correction

2. Implant positioning
Intermetatarsal angle & sagittal plane correction

3. Distal fixation
Inferior locking screws implanted to achieve sagittal plane correction

4. Rotational alignment
Frontal plane alignment & compression

5. Proximal fixation
Proximal fixation, securing final correction

Surgical Technique

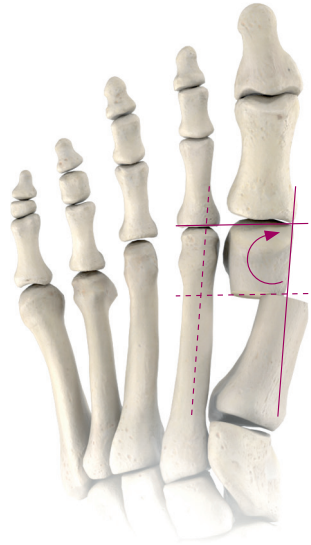
Step 1 - Transverse Osteotomy

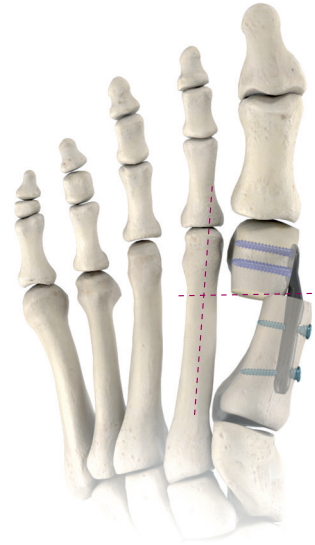
1.1 - Incision & exposure

Patient is positioned supine. Intraoperative fluoroscopy is highly recommended. A dorsal-medial, longitudinal incision of 1.5 to 2.0 cm is made overlying the first metatarsal head. The neuro-vascular bundle is isolated and protected. The first metatarsal-phalangeal joint capsule is incised according to the surgeon's preference to expose the first metatarsal medial eminence.

1.2 - 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, by resecting the smallest amount of bone necessary, the implant can achieve a larger lateral translation of the first metatarsal head thereby reducing the intermetatarsal angle.
Second, a wedge-shaped medial eminence resection removing less bone proximally and more bone distally will 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.





Surgical Technique

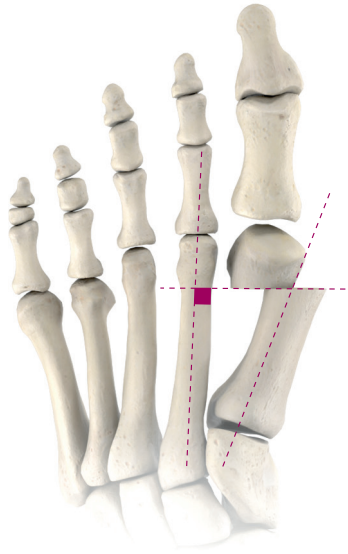
1.3 - Osteotomy

Lateral soft-tissue release can be performed either percutaneously, through a second incision overlying the first intermetatarsal space, or through a medial transarticular approach, at the surgeon discretion.
Transect horizontally the lateral metatarsosesamoid suspensory ligament and release 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.

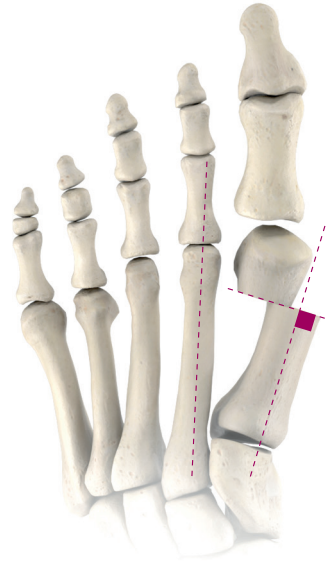
Position the osteotomy cutting template against the flat part of the first metatarsal head, at the level of the resection of the medial eminence. Place the saw blade at the lower edge of the cutting template, in order to make a perpendicular cut to the second metatarsal.

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.

Pre-operative foot



Translation with neutral effect



Lenthening effect

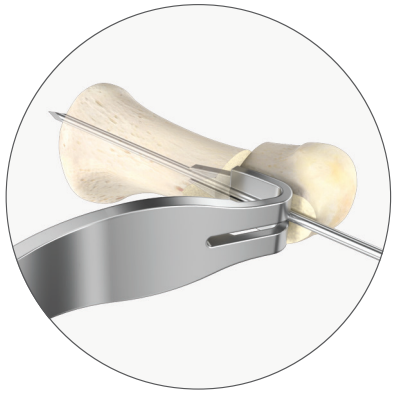
Under image intensification, check the osteotomy position in relation to the placement of the cutting template.
Once the ideal osteotomy level has been verified, remove the cutting template, leaving the saw blade in place and perform the transverse osteotomy.

Surgical Technique

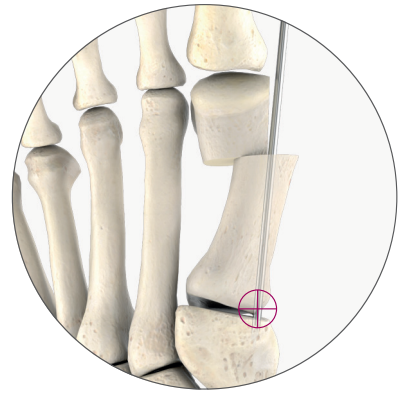
Step 2 - Implant positioning

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.



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.



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

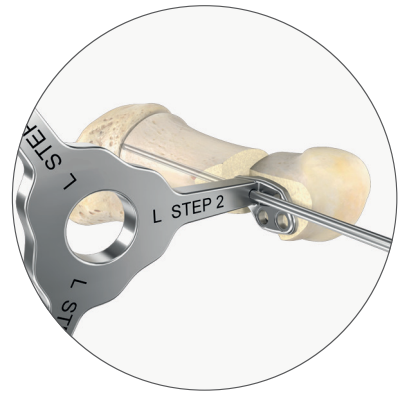
Note: Advance the K-wire across the first metatarsal-cuneiform joint for additional stability of the construct.

Surgical Technique

2.2 - Stemless trial sizer setting up

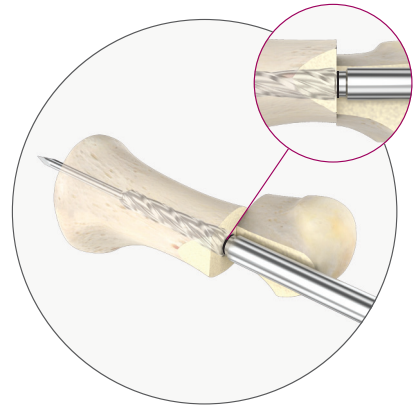
Use the Stemless trial sizer to validate the positioning of the K-Wire and the desired correction.
Insert the right or left Stemless trial sizer on the Ø 2.0 K-Wire depending on the degree of correction required (Step 2, 4 or 6 mm).

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



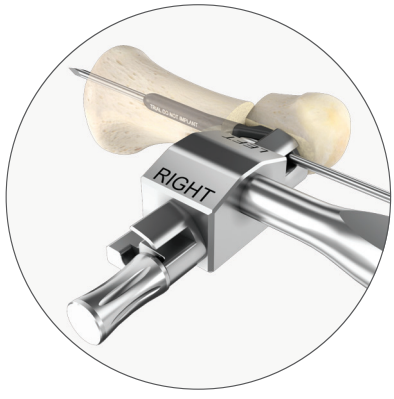
2.3 - Intramedullary reaming

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.



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.



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

Surgical Technique

2.5 - Intramedullary reaming

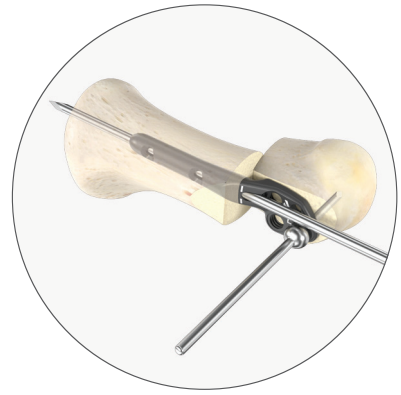
Attach the selected implant to the impactor, insert it through the implant cannula over the Ø 2.0 K-wire and impact it until the laser marking on the implant is flush with the first metatarsal osteotomy.

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.

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.

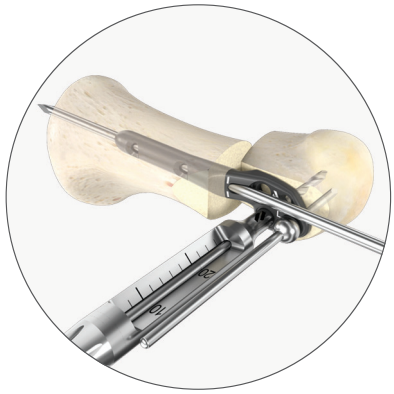
Note: When positioning the implant in the sagittal plane, the subsequent frontal plane rotation may affect the plantar/dorsal position.



Step 3 - Distal fixation

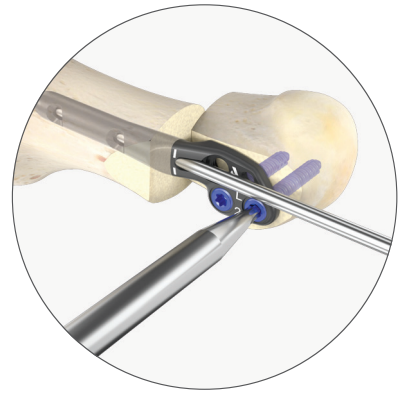
3.1 - Inferior locking screws insertion

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.



Remove the drill guide.

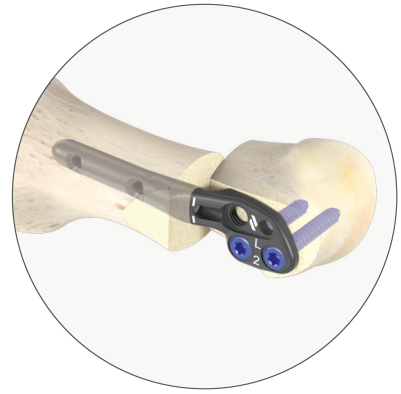
Insert the uni-cortical 2.5 mm locking screw with the screwdriver. Remove the temporary fixation pin and repeat the step to insert the distal inferior locking screw.



Surgical Technique

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.

Remove the central K-wire.



Note: A depth gauge is available to measure the required screw length if needed. Remove the drill guide to use the depth gauge.

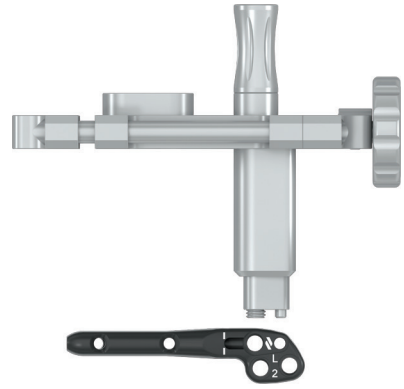
Surgical Technique

Step 4 - Rotational alignment

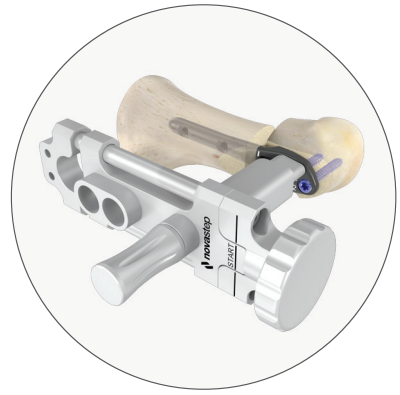
4.1 - Final metatarsal head rotation positioning

Set up the Centrolock® Targeting / Compressing Guide compression wheel in START position.

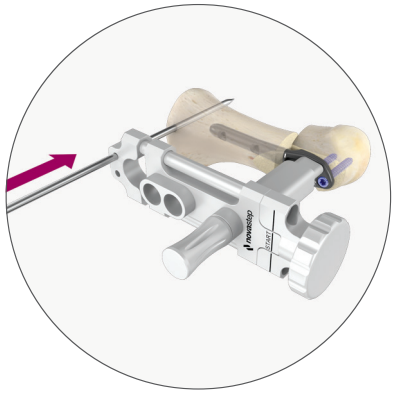
The Guide is then attached to the superior locking hole of the implant and secured with the threaded bolt attachment wheel.



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.



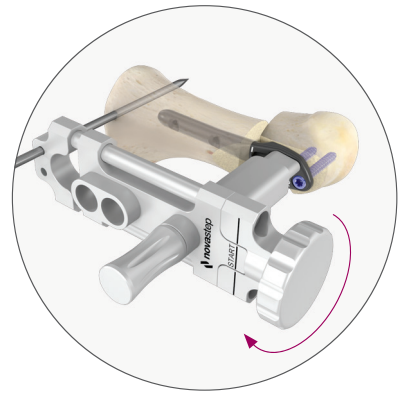
The final frontal plane rotation positioning check of the first metatarsal head is performed at this time. Once ideal positioning has been verified, insert one Ø 2.0 K-wire bicortically into the upper hole at the proximal end of the Targeting / Compressing Guide.



Surgical Technique

4.2 - Compression adjustment

If compression is needed, rotate the compression wheel clockwise until the desired amount of compression is achieved.

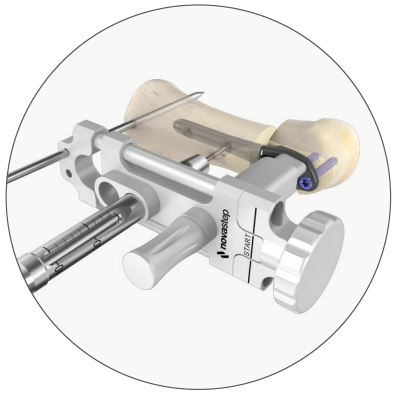


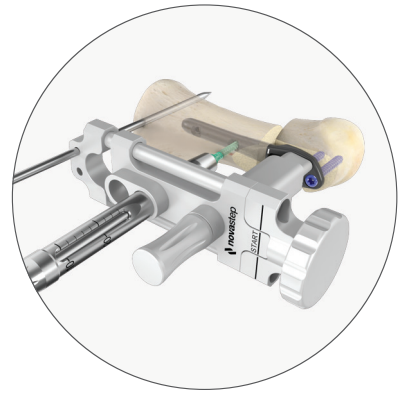
Note: A maximum of 3 mm of compression can be achieved with the Targeting / Compressing Guide. Take care not to over compress, as this may shorten the metatarsal or cause un-intentional mal-alignment of the metatarsal head.

Step 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.



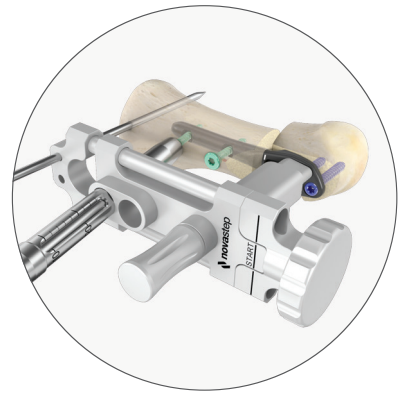


Note: Always start with inserting the distal Ø 2.0 mm cortical screw for a better construct stability.

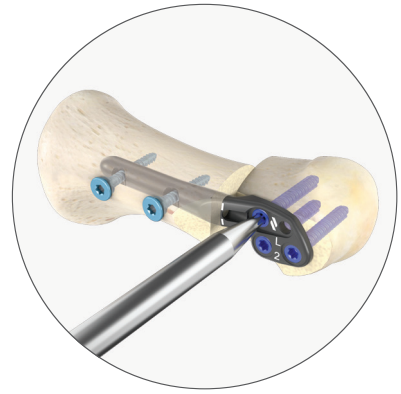
Note: A depth gauge is available to measure the required screw length if needed.
Remove the drill guide to use the depth gauge. After length reading, re-insert the drill guide to insert the chosen screw with the screwdriver.

Surgical Technique

Repeat the step for the proximal Ø 2.0 mm cortical screw. Remove the Ø 2.0 mm K-wire and the Targeting / Compressing Guide.

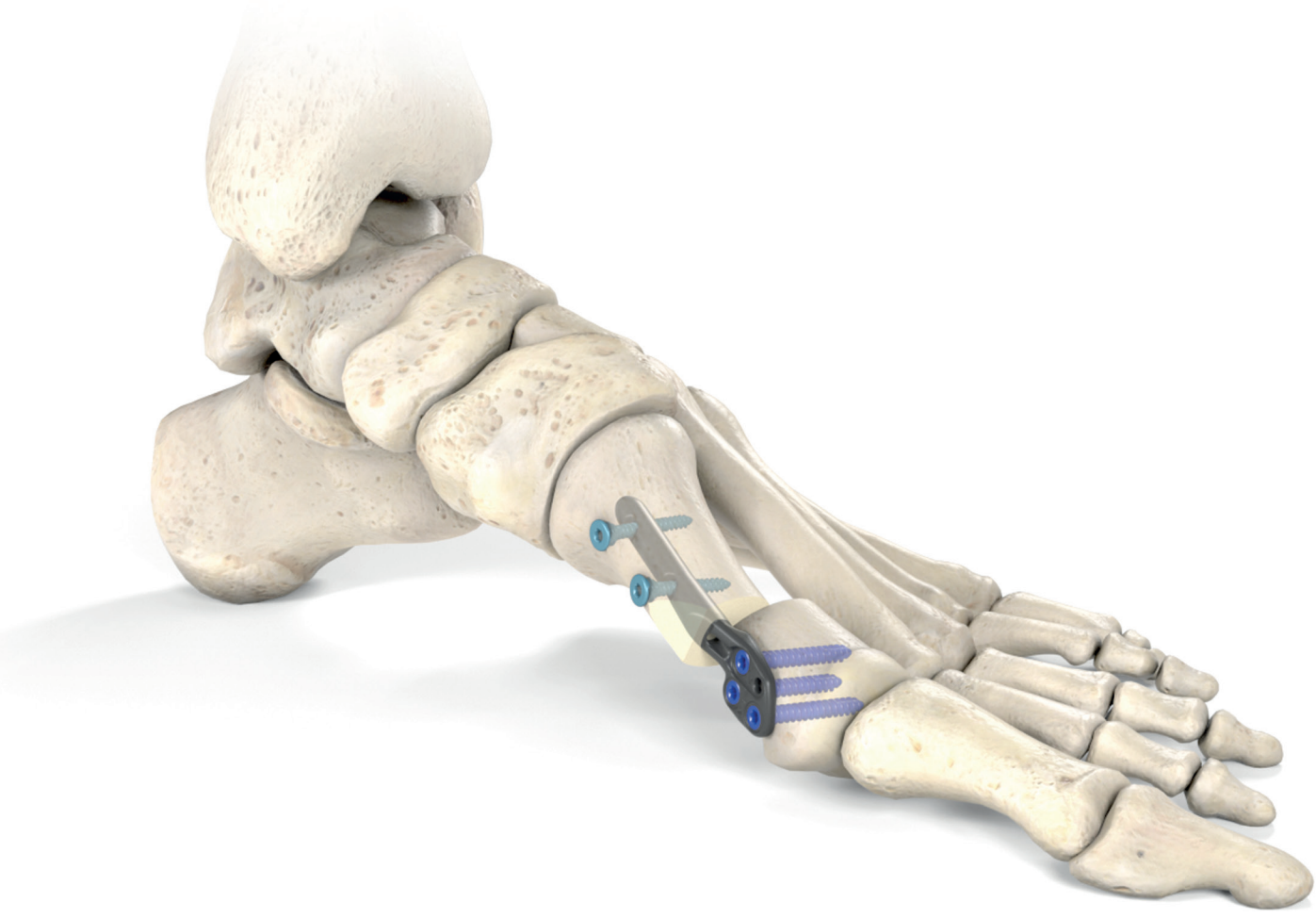


3rd locking screw insertion: Insert the third 2.5 mm locking screw into the first metatarsal head through the proximal-superior locking hole within the flat portion of the implant, following the same steps.



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.

Surgical Technique



X-rays

Pre-operative

Post-operative

Final implantation at 3 months

References

1 - Implants

Centrolock® implant right

Step (mm)	Reference
2 mm	PL070102
4 mm	PL070104
6 mm	PL070106

Centrolock® implant left

Step (mm)	Reference
2 mm	PL070202
4 mm	PL070204
6 mm	PL070206

Centrolock® locking screw

Length (mm)	Screw Ø 2.5 mm
10 mm *	SP012510 *
12 mm	SP012512
14 mm	SP012514
16 mm	SP012516
18 mm	SP012518
20 mm	SP012520
22 mm	SP012522
24 mm *	SP012524 *
26 mm *	SP012526 *

Centrolock® cortical screw

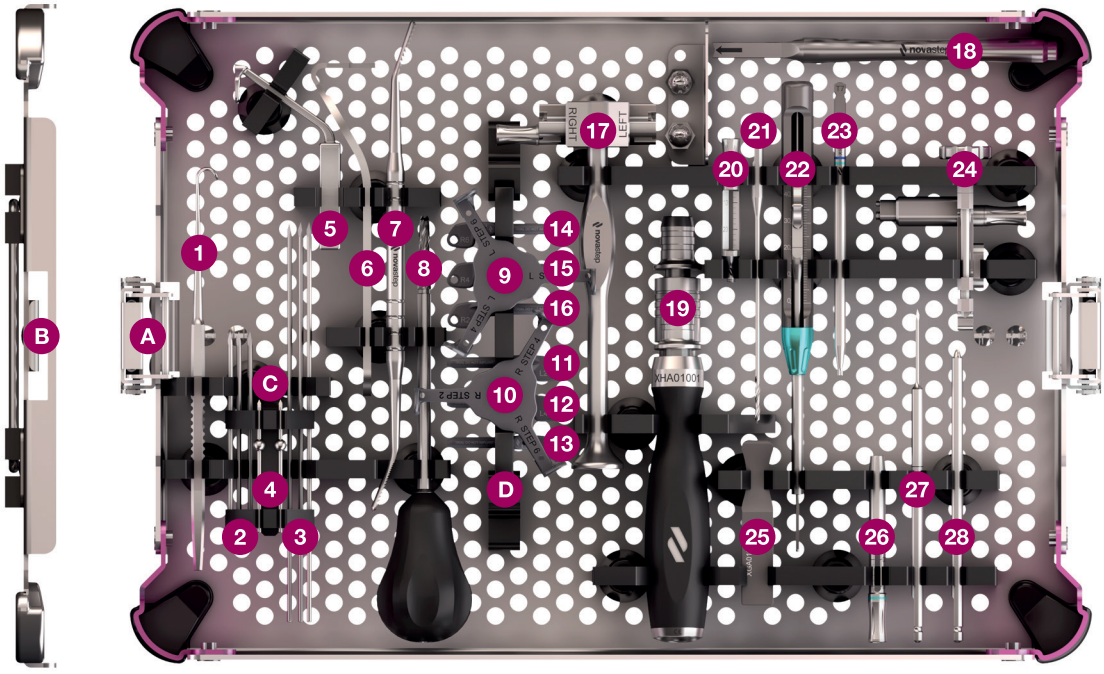
Length (mm)	Screw Ø 2.0 mm
12 mm	SP032012
14 mm	SP032014
16 mm	SP032016
18 mm	SP032018
20 mm	SP032020
22 mm *	SP032022 *
24 mm *	SP032024 *

** On demand.*

References

2 - Instruments

Tray layout



Centrolock® instrument tray

Letter / Number	Ref	Description	Qty
A	ACC1015P0001	Tray	1
B	ACC1015P0002	Lid	1
C	ACC1001P0020	K-wire holder	1
D	ACC1015P0003	Trial implant holder	1
1	XMS01003	Retractor	2
2	-	K-wire Ø 2 lg 100 TR-RD extra sharp[1]	4[3]
3	-	K-wire Ø 2 lg 150 TR-RD extra sharp[2]	4[3]
4	XPP01005	Spheric positioning pin	2
5	XMS01040-1	Cutting template right	1
	XMS01040-2	Cutting template left	1
6	XMS01029	Elevator	1
7	XMS01009	Percutaneous rasps	1
8	XRE01014	Cannulated reamer	1
9	XTI06010	Stemless trial sizer left	1
10	XTI06020	Stemless trial sizer right	1
11	XTI06012	2 mm trial implant left	1
12	XTI06014	4 mm trial implant left	1
13	XTI06016	6 mm trial implant left	1
14	XTI06022	2 mm trial implant right	1
15	XTI06024	4 mm trial implant right	1
16	XTI06026	6 mm trial implant right	1
17	XMS01030	Impactor	1
18	XMS01036	Straight impactor	1
19	XHA01001	AO handle	1
20	XDG01019	Locking drill guide for screw Ø 2.5	2
21	XDB01020	Drill bit Ø 1.8	2
22	XGA01011	Depth gauge	1

[1]K-wire supplied separately - Medetechnik® K-wire (33-T10-R-20-100) or Novastep® K-wire (CKW01012) are available depending on your market.
[2]K-wire supplied separately - Medetechnik® K-wire (33-T10-R-20-150) or Novastep® K-wire (CKW01013) are available depending on your market.
[3]Non-sterile item. Order a box of 10 units & replace as needed.

References

Centrolock® instrument tray

Number	Ref	Description	Qty
23	XSD01003	T7 AO screwdriver tip	2
24	XMS01026	Targeting / compressing guide	1
25	XGA01003	Screw indicator	1
26	XDG01018	Drill guide for screw Ø 2	2
27	XDB01019	Drill bit Ø 1.5	2
28	XRE01022	Countersink	1

Notes

Notes

Notes

Notes

centroLock®

Guided Transverse Osteotomy System

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.

Novastep:
2, Allée Jacques Frimot - 35000 RENNES - France
Tel : + 33 (0) 2 99 33 86 50 / Fax : + 33 (0) 9 70 29 18 95
contact@novastep-ortho.com / www.int.novastep.life

Reference: CEN-ST-Ed6-07-24-EN