



centroLock[®]

Guided Transverse Osteotomy System

Operative Technique

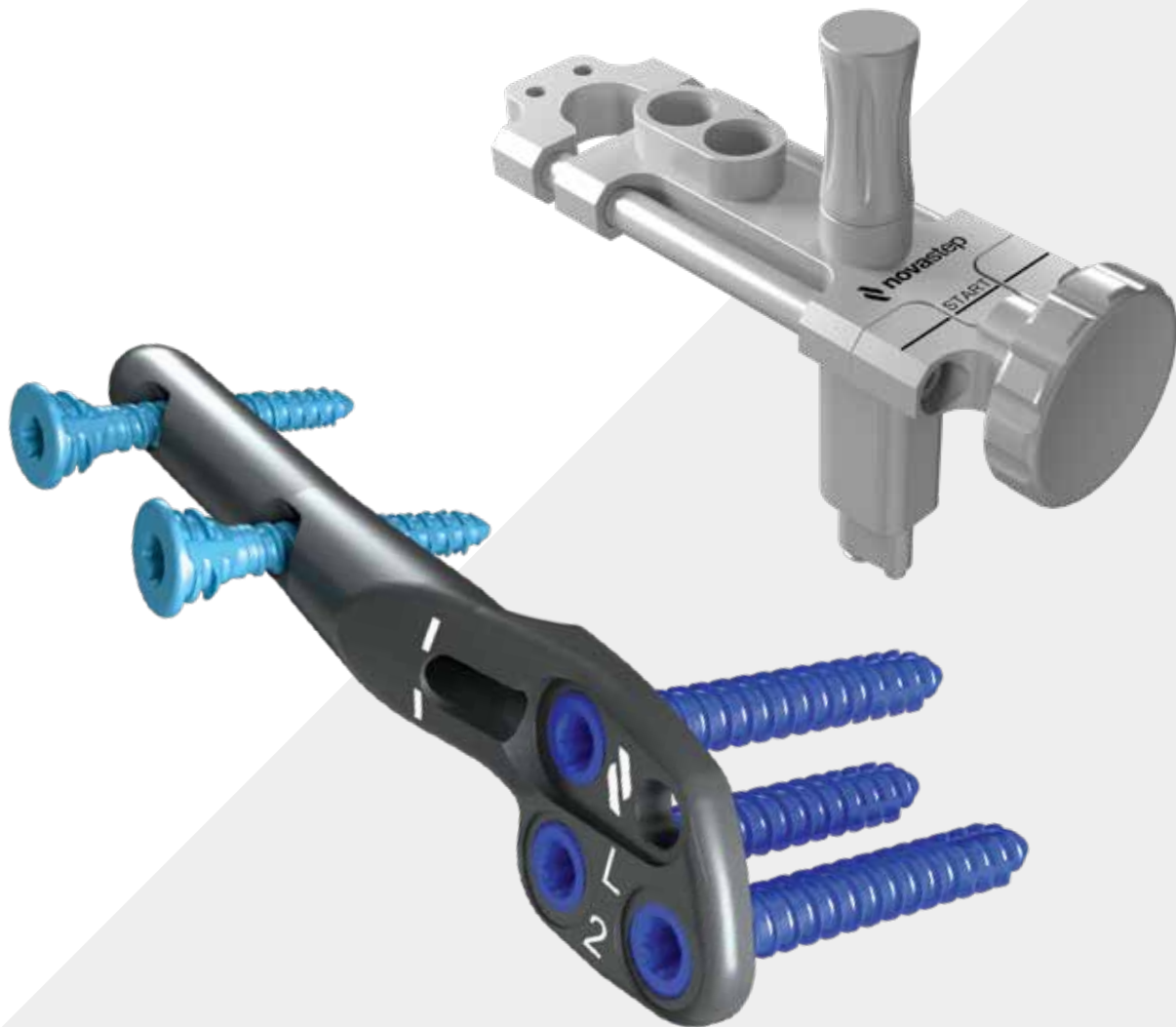


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This publication sets forth detailed recommended procedures for using Novastep Centrolock[®] implants and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of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

A workshop training is recommended prior to first surgery.

Indications & Contraindications

Indications

The Airlock® Centrolock (Centrolock Guided Transverse Osteotomy System) osteosynthesis implant system intended for fixation of the osteotomies for hallux valgus treatment.

The system may be used in adult patients.

The Centrolock® Guided Transverse Osteotomy System is specifically indicated for primary correction of mild to severe hallux valgus deformities and revision surgery of the first metatarsal.

Note:

See package insert for a complete list of potential adverse effects, warnings, precautions, contra-indications and instructions for use.

Contraindications

The Centrolock Guided Transverse Osteotomy System should not be used in case of any of the following:

- Severe muscular or vascular deficiency in the extremity concerned
- Bone destruction or poor bone quality, likely to impair implant stability
- Surgical procedure other than those listed in the Indications section
- Known or suspected allergy to any of the device components
- Use of this implant in combination with implants of another origin not recommended by Novastep

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 plane rotation
- Length adjustment

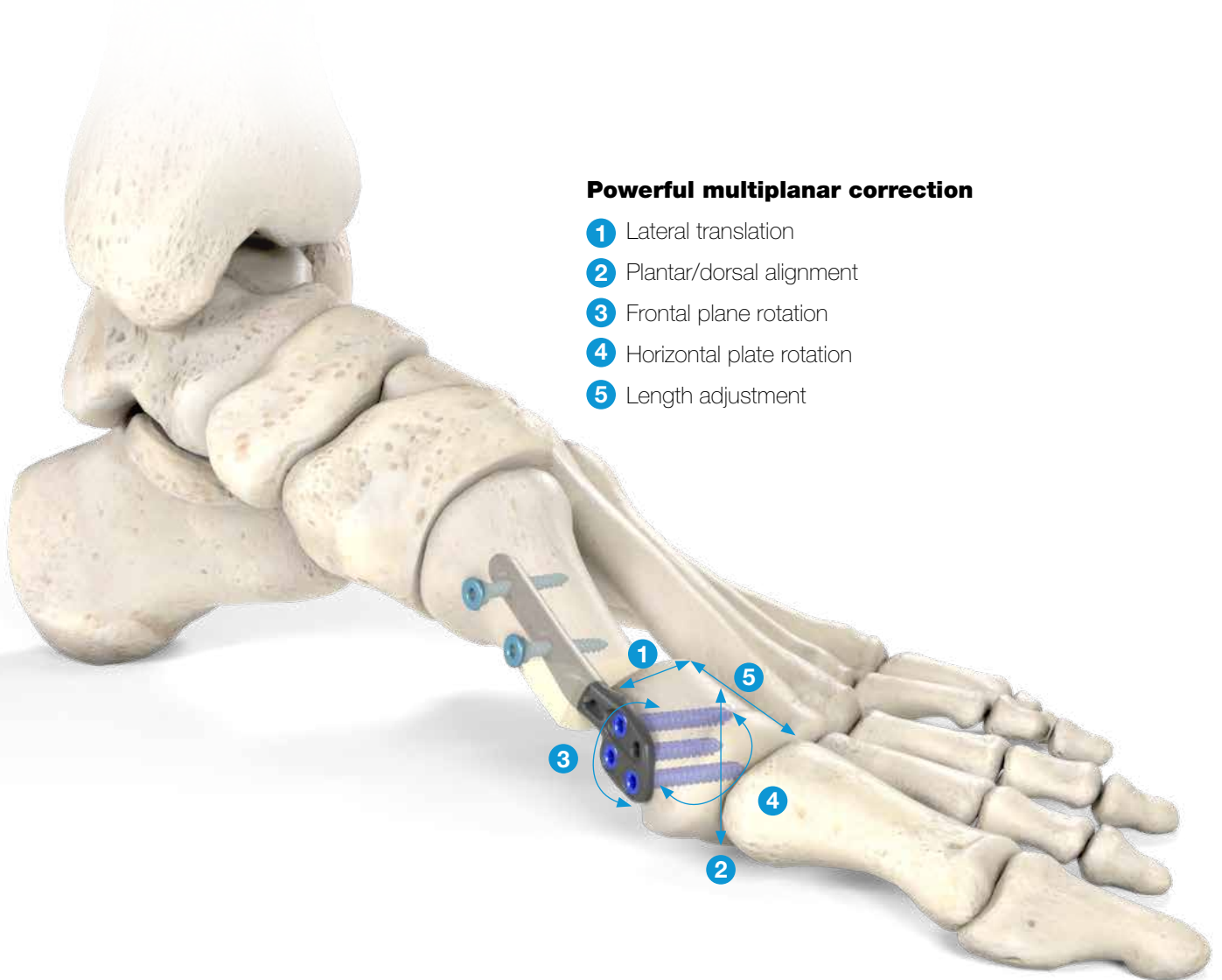


Design Features

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. The hybrid construct allows surgeons to immediately weight bear patients following the surgical procedure.



Technical Specifications

Centrolock Implant

Offset Angulation

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

Cannulated Stem

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

Metatarsal plate

- 3 translation options
- Allows up to 100% Translation

Proximal Fixation

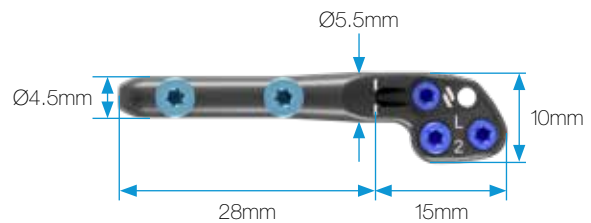
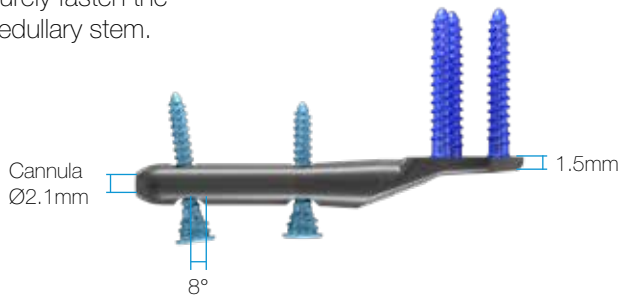
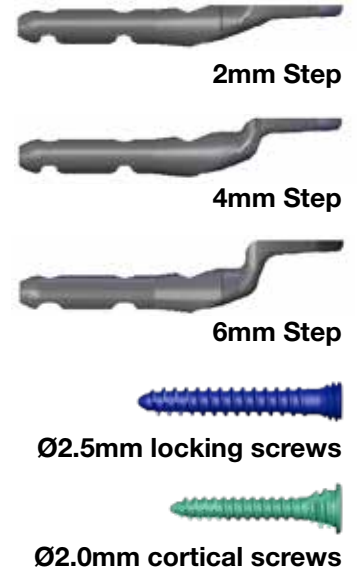
Ø2.0mm cortical screws are implanted to securely fasten the intramedullary stem.

Hybrid Intramedullary Design

Combines metatarsal plate and cannulated stem.

Locking screws holes

Ø2.5mm secures the capital fragment.



Guided Instrumentation

Targeting Guide

Stabilization hole

Provisionally fixated with Ø2.0 K-wire.

Targeting Guide Holes

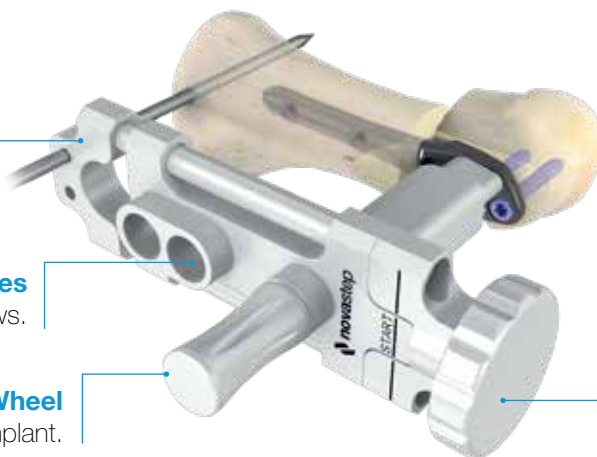
Ensures accuracy when implanting cortical screws.

Threaded Bolt Attachment Wheel

Attaches to the centrolock implant.

Compression Dial

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



Guided Technique

Multiplanar correction



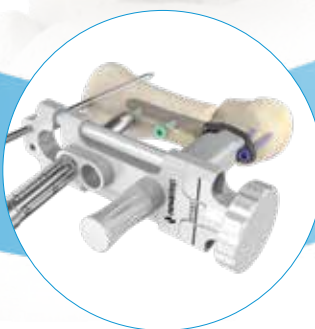
1 Transverse correction

Transverse osteotomy after thorough planification



2 Sagittal correction

Planter-dorsal positioning before distal fixation



3 Frontal Correction

Frontal plane rotation, compression and proximal fixation

Surgical Technique

Transverse Osteotomy

Step 1

1.1 Incision and exposure

Patient is positioned supine. Intraoperative fluoroscopy is highly recommended.

A dorsal-medial, longitudinal incision of 1.0cm – 1.5cm 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.



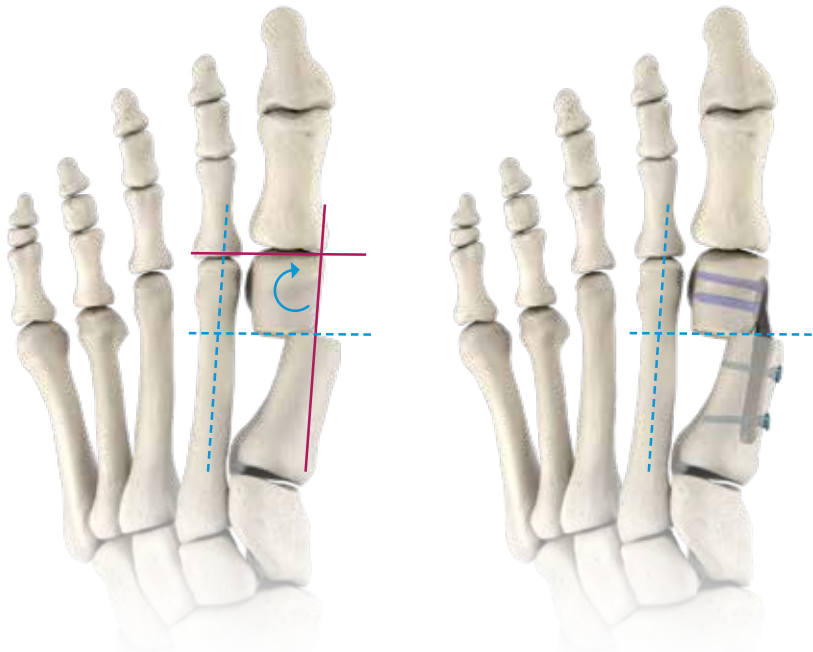
1.2 Medial eminence resection

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

Transverse Osteotomy

1.3 Osteotomy

Lateral soft-tissue osteotomy 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.



Osteotomy cutting template

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.

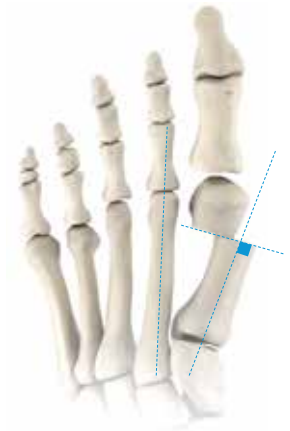
Position the osteotomy cutting template against the flat part of the first metatarsal head, at the level of the resection of the medial eminence. Place the saw blade at the lower edge of the cutting template, in order to make a perpendicular cut to the second metatarsal. The transverse osteotomy must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



Lengthening effect

Surgical Technique

Implant Positioning

Step 2

2.1 Metatarsal head positioning

Use the Centrolock® elevator to displace the first metatarsal head laterally. Stabilize it temporarily with a Ø2.0 x150mm K-wire.

The ideal K-wire position is based on preoperative 1-2 IM angle.

- If less than 15 degrees, the wire should be placed parallel to the medial cortex of the first metatarsal
- If greater than 15 degrees, it should be placed parallel to the long axis of the second metatarsal

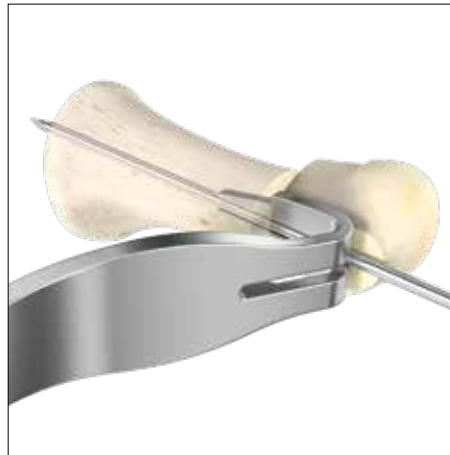
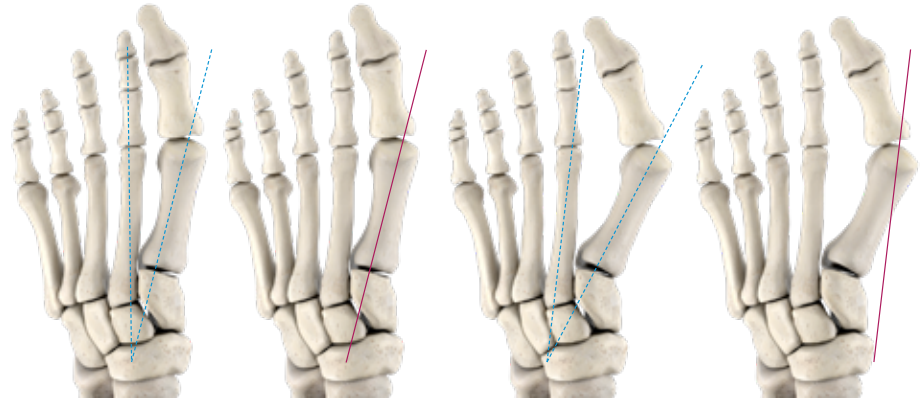
This ensures appropriate placement and orientation of the implant, allowing correct displacement of the capital fragment without undue head alignment in the varus/valgus plane.

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.



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 Ø2.0mm K-Wire. You can also select at this stage the 2, 4 or 6mm step depending on the degree of correction required.

Note:

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

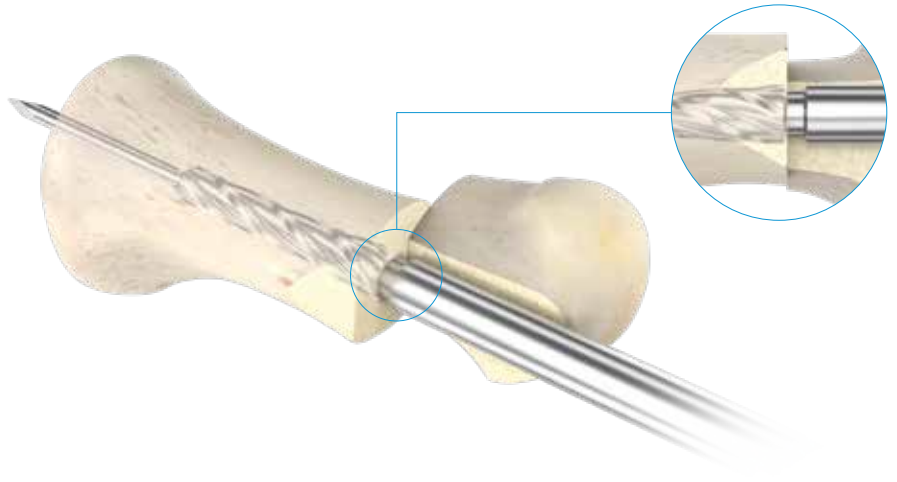


Surgical Technique

Implant Positioning

2.3 Intramedullary reaming

Insert the hand reamer over the Ø2.0 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.



Note:

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



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 Ø2.0 K-wire to select the 2, 4 or 6mm offset implant required.



2.5 Implant positioning Plantar-dorsal correction

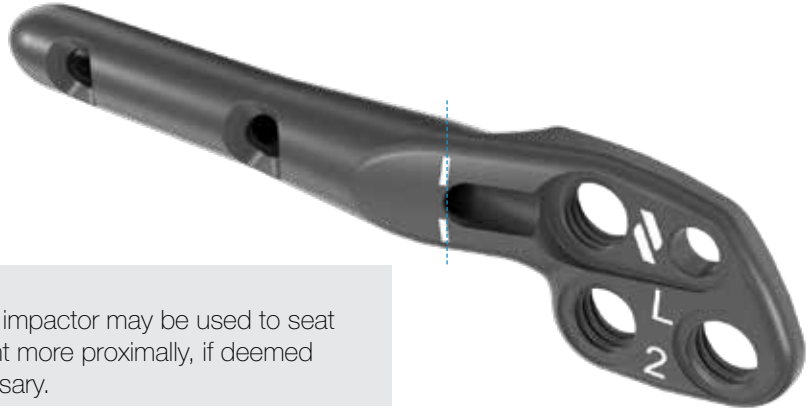
Attach the selected implant to the impactor, insert it through the implant cannula over the Ø2.0 K-wire and impact it until the laser marking on the implant is flush with the first metatarsal osteotomy.

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.

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

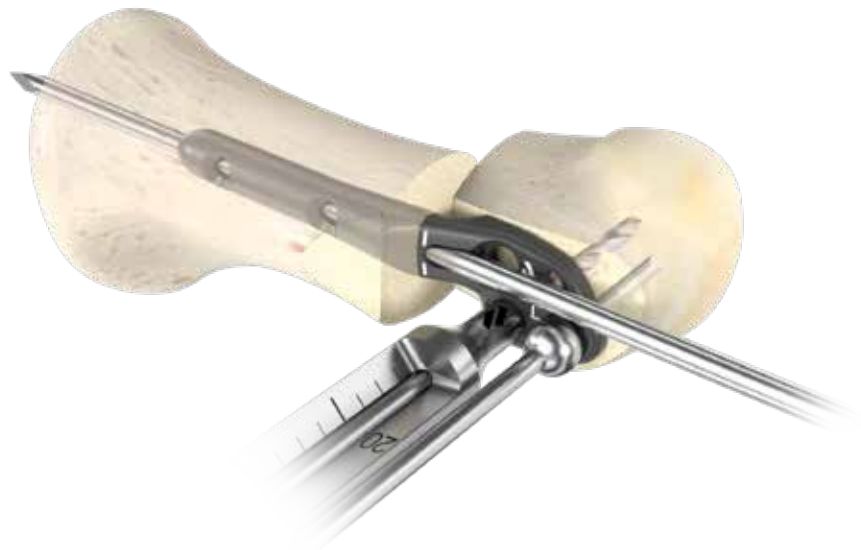
Distal Fixation

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 Ø2.5mm locking screw in the plantar proximal plate hole.

Pre-drill using the Ø1.8mm drill with the screw length being measured directly off the drill-guide.



Surgical Technique

Distal Fixation

Note:

If a gap between the metatarsal head and plate is present the surgeon can pull the hallux into varus. This manoeuvre will push the metatarsal head toward the plate, maintain this position when fixating.



Remove the drill guide.

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



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.



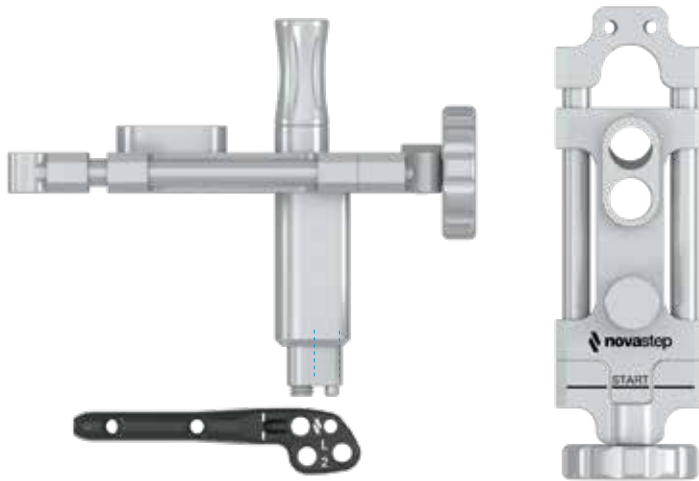
Surgical Technique

Rotational Alignment

Step 4

4.1 Final metatarsal head rotation positioning

Set up the Centrolock® Targeting and 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.

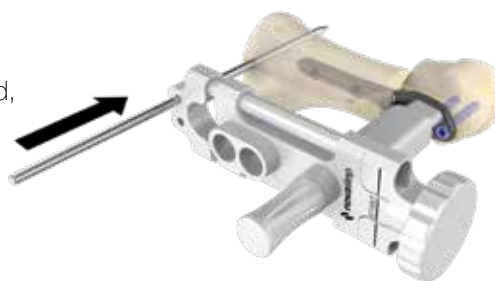


Note:

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 Ø2.0 K-wire bicortically into one of the two holes at the proximal end of the Targeting and Compressing Guide.



Surgical Technique

Rotational Alignment

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 3mm of compression can be achieved with the Targeting and 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 Ø2.0mm non-locking screws must be placed through the intramedullary stem of the implant to secure the implant positioning.

Insert the drill guide for screw Ø2.0mm in the distal hole of the targeting and compressing guide. An incision is made before pre-drilling using a Ø1.5mm 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 Ø2.0mm screw is implanted bi-cortically with the screwdriver.

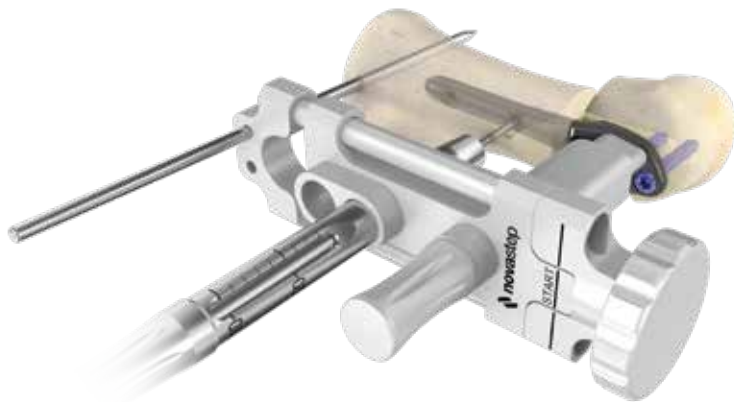
Note:

Always start with inserting the distal Ø2.0mm cortical screw for a better construct stability.

Note:

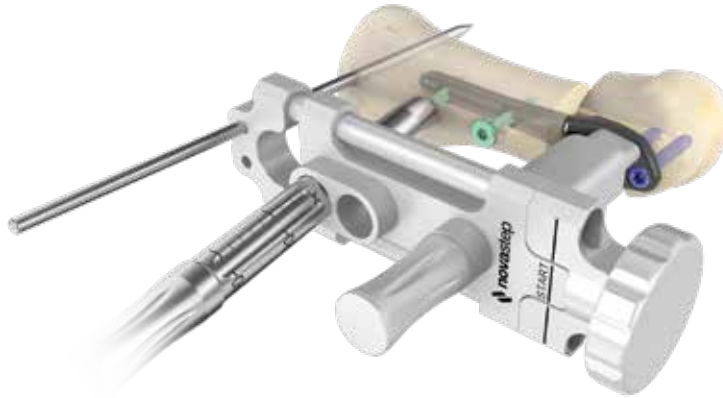
A depth gauge is available to measure the required screw length if needed.

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 $\text{\O}2.0\text{mm}$ cortical screw.

Remove the $\text{\O}2.0\text{mm}$ K-wire and the Targeting and Compressing Guide.



3rd locking screw insertion

Insert the 2.5mm 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



Final Implantation



Ordering Information



Step (mm)	centroLock Implant (Left)
2mm	PL070202
4mm	PL070204
6mm	PL070206



Step (mm)	centroLock Implant (Right)
2mm	PL070102
4mm	PL070104
6mm	PL070106

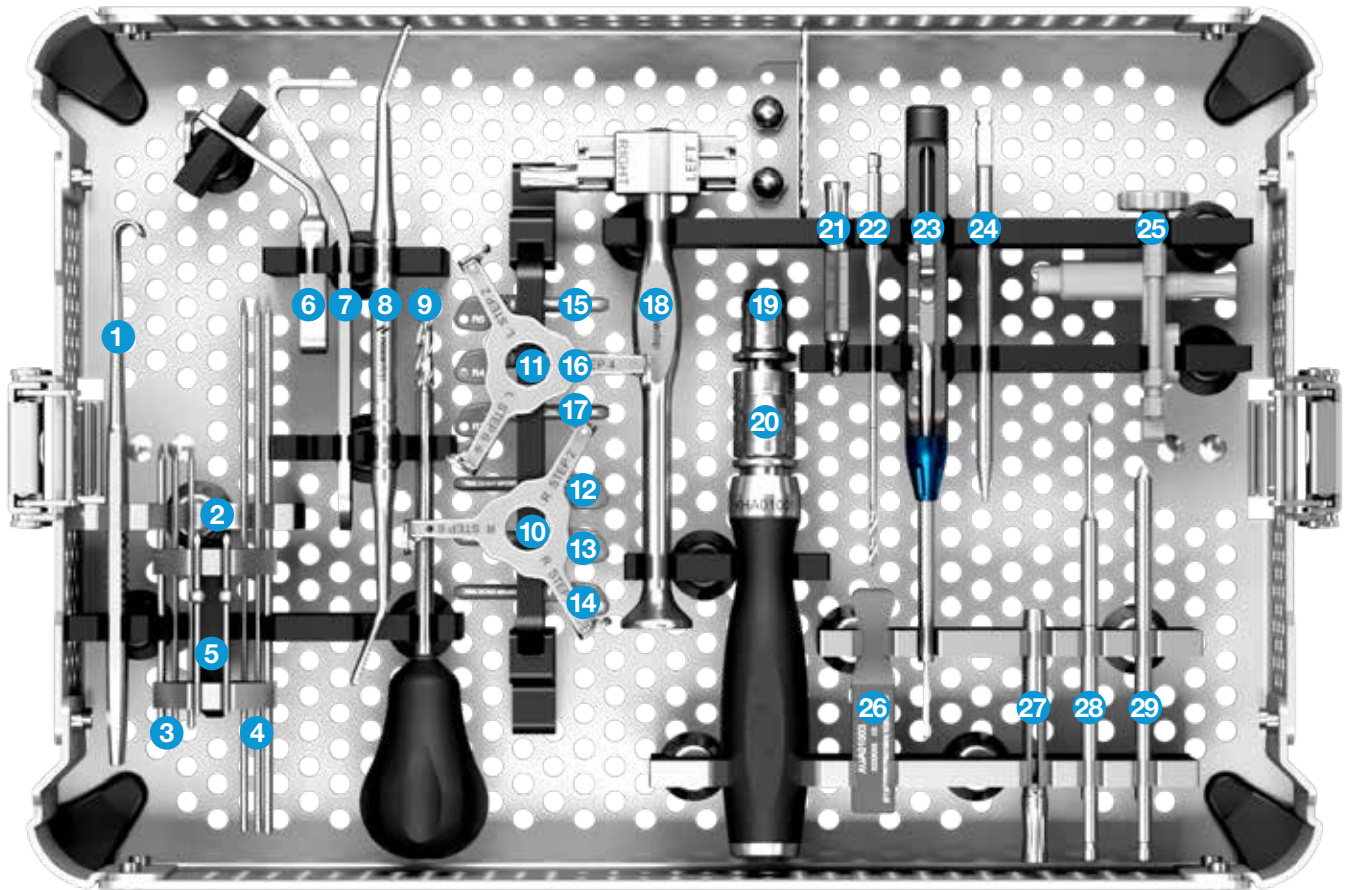


Length (mm)	centroLock locking screw (Ø2.5mm)
12mm	SP012512
14mm	SP012514
16mm	SP012516
18mm	SP012518
20mm	SP012520
22mm	SP012522



Length (mm)	centroLock cortical screw (Ø2mm)
12mm	SP032012
14mm	SP032014
16mm	SP032016
18mm	SP032018
20mm	SP032020

Tray Layout



CentroLock Instrument Tray

	Part#	Description	Qty.
1	XMS01033	Retractor	2
2	ACC1001P0020	Centrolock K-wires holder	1
3	CKW01012	K-wire Ø2 lg. 100 TR-RD extra sharp*	4
4	CKW01013	K-wire Ø2 lg. 150 TR-RD extra sharp*	4
5	XPP01005D	Centrolock temporary fixation pin*	2
6	XMS01040-1	Centrolock cutting template Right	1
	XMS01040-2	Centrolock cutting template Left	1
7	XMS01029	Centrolock elevator	1
8	XMS01009	Percutaneous rasps	Optional
9	XRE01014	Centrolock cannulated reamer	1
10	XTI06010	Centrolock® Stemless trial sizer Left	1
11	XTI06020	Centrolock® Stemless trial sizer Right	1
12	XTI06012	Centrolock trial implant - Left step 2mm	1
13	XTI06014	Centrolock trial implant - Left step 4mm	1
14	XTI06016	Centrolock trial implant - Left step 6mm	1
15	XTI06022	Centrolock trial implant - Right step 2mm	1
16	XTI06024	Centrolock trial implant - Right step 4mm	1
17	XTI06026	Centrolock trial implant - Right step 6mm	1

	Part#	Description	Qty.
18	XMS01030	Centrolock impactor	1
19	XHA01001	AO handle	1
20	XHA01002	AO Ratcheting Handle	1
21	XDG01019	Centrolock locking drill guide - screw Ø2.5mm	2
22	XDB01020D	Centrolock drill bit Ø1.8mm*	2
23	XGA01011	Centrolock depth gauge	1
24	XSD01003	Centrolock screwdriver tip T7	2
25	XMS01026	Centrolock targeting / compressing guide	1
26	XGA01003	Screw measurer	1
27	XDG01018	Centrolock drill guide - screw Ø2mm	2
28	XDB01019D	Centrolock drill bit Ø1.5mm*	2
29	XRE01022	Centrolock Countersink	1
-	XMS01036	Centrolock straight impactor	1



Please scan for more product information.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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