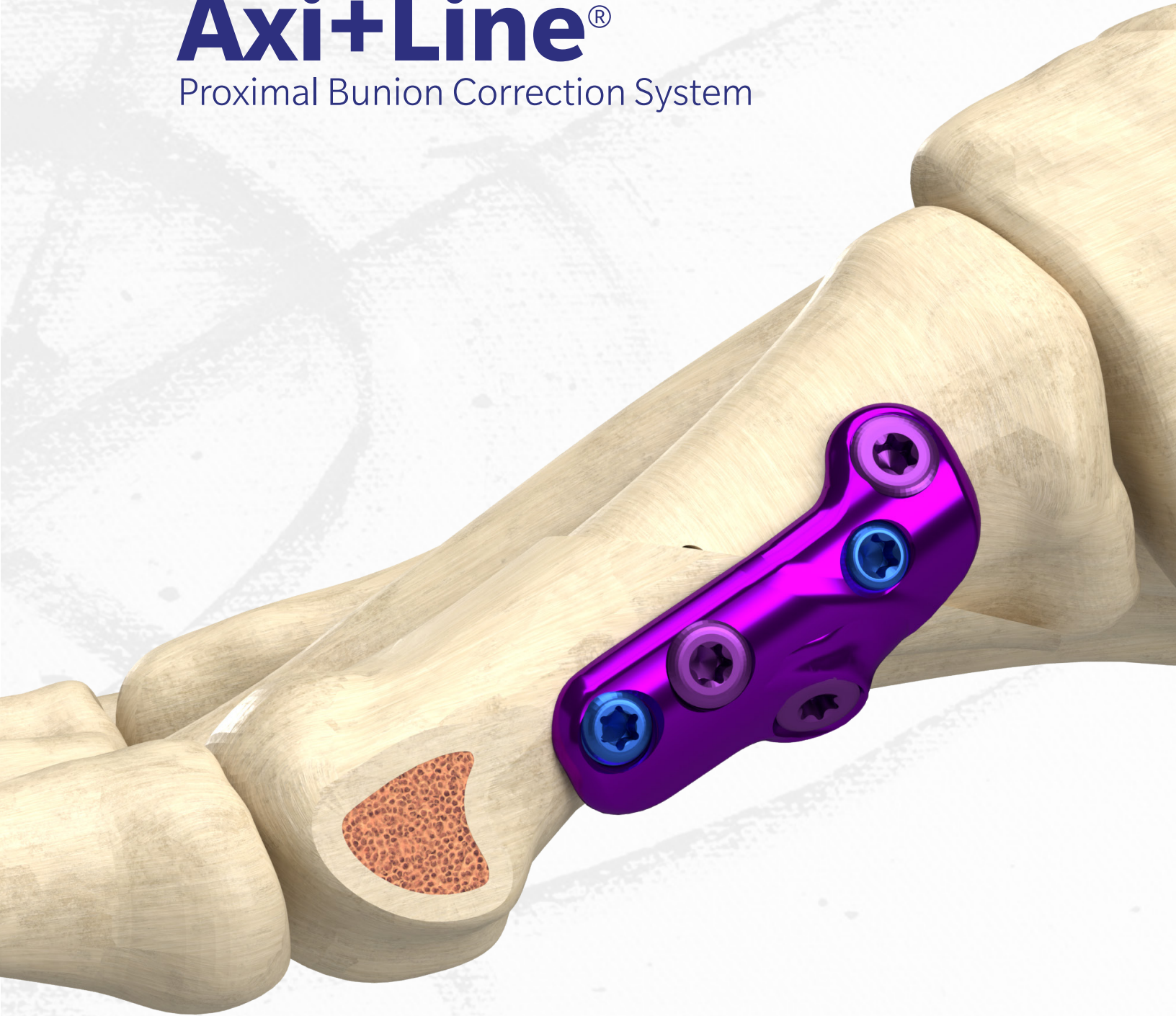


Introducing the  
**Axi+Line**®  
Proximal Bunion Correction System



# Axi+Line<sup>®</sup>

## Proximal Bunion Correction System

The Axi+Line Proximal Bunion Correction System addresses treatment of deformities and correction in the frontal plane. Through the use of a precise and repeatable long oblique Proximal Modified Mau osteotomy, this system not only corrects the IM angle, but also provides frontal plane rotation. The fully sterile Axi+Line Proximal Bunion Correction System instrumentation provides full control of all bone fragments during the procedure and allows for a seamless transition from templating to plating. The system includes 8 total plates, 4 left plates and 4 right plates, that provide correction from 5 degrees up to 12.5 degrees.





# Correction

## Provides Corrections of Intermetatarsal (IM) Angle and Frontal Plane Deformity

The long oblique Proximal Modified Mau osteotomy, used by the Axi+Line Proximal Bunion Correction System, is a transverse plane osteotomy that extends plantar-proximal to dorsal-distal when viewed in the sagittal plane. The defining feature of this osteotomy is the creation of a dorsal shelf which helps resist weight bearing forces.<sup>1</sup> The long oblique Proximal Modified Mau creates good bone apposition for fixation, resulting in the most intrinsic stability of all proximal osteotomies.<sup>2,3,4</sup>

### The Proximal Modified Mau:

- Provides superior intrinsic stability compared to most other midshaft, proximal osteotomies<sup>1,2,4</sup>
- Maximizes fusion surface area and provides the ability to correct moderate to large angular deformities<sup>1,3</sup>
- Avoids violating a healthy metatarsal-cuneiform joint compared to a Lapidus procedure
- Minimizes shortening of the metatarsal by eliminating the need to remove healthy bone while eliminating the need for interpositional grafts.<sup>3,5</sup>

In comparison with minimally invasive surgery (MIS) and Scarf osteotomies, the Proximal Modified Mau provides for maximum bone-to-bone apposition, as seen in the illustration below.



MIS Osteotomy



Proximal Modified Mau  
Osteotomy

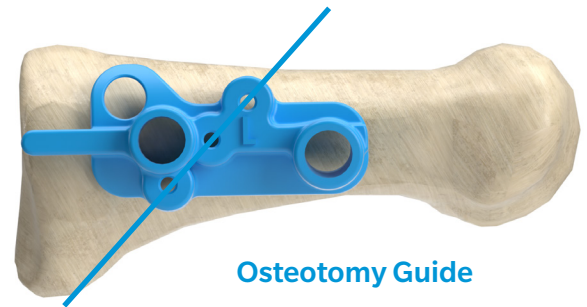


Scarf Osteotomy

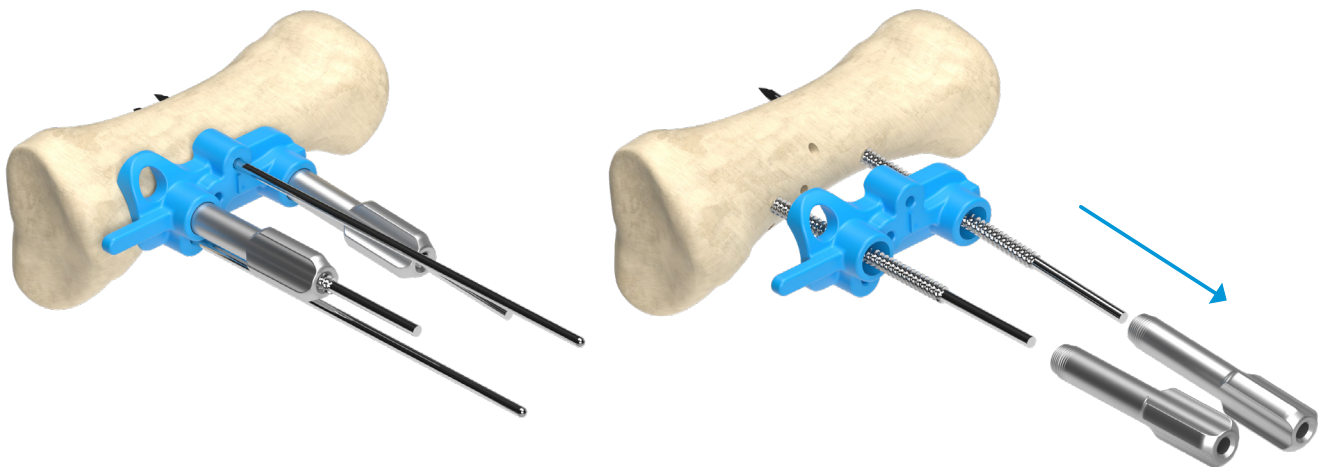
# Reproducible Osteotomy

## Through the Use of a Long Oblique Proximal Modified Mau Osteotomy

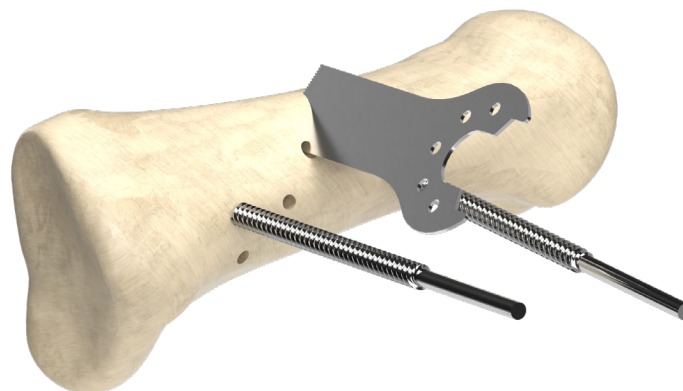
Precise and repeatable osteotomies are necessary in order to provide surgeons with accurate cuts each time a surgery is performed. The Axi+Line Proximal Bunion Correction System instrumentation provides full control of all bone fragments during the procedure and allows for a seamless transition from templating to plating. The system includes an **Osteotomy Guide** that provides a visible path for surgeons to cut a long oblique Proximal Modified Mau osteotomy.



As outlined in the surgical technique, a **K-wire** is driven through dorsal hole, ensuring the wire crosses both cortices. This **K-wire** is then removed and the process is repeated for the middle and plantar diagonal holes. Once completed, the non-threaded **K-wire** is removed from the plantar diagonal hole. Once the non-threaded **K-wires** have been removed, the **Drill Tubes** and **Osteotomy Guide** are removed, leaving the **Threaded Pins** in place.



Once the previous two steps are complete, the three holes created by the **K-wires** will now be visible and will act as a guiding line for the osteotomy. Keeping the saw blade parallel to the proximal **Threaded Pin**, a long oblique Proximal Modified Mau osteotomy is made by sawing along the line extending through the three holes. The three holes provide surgeons with a precise and repeatable osteotomy, providing patients with intrinsic stability and maximum fusion surface area.<sup>1,2,3,4</sup>

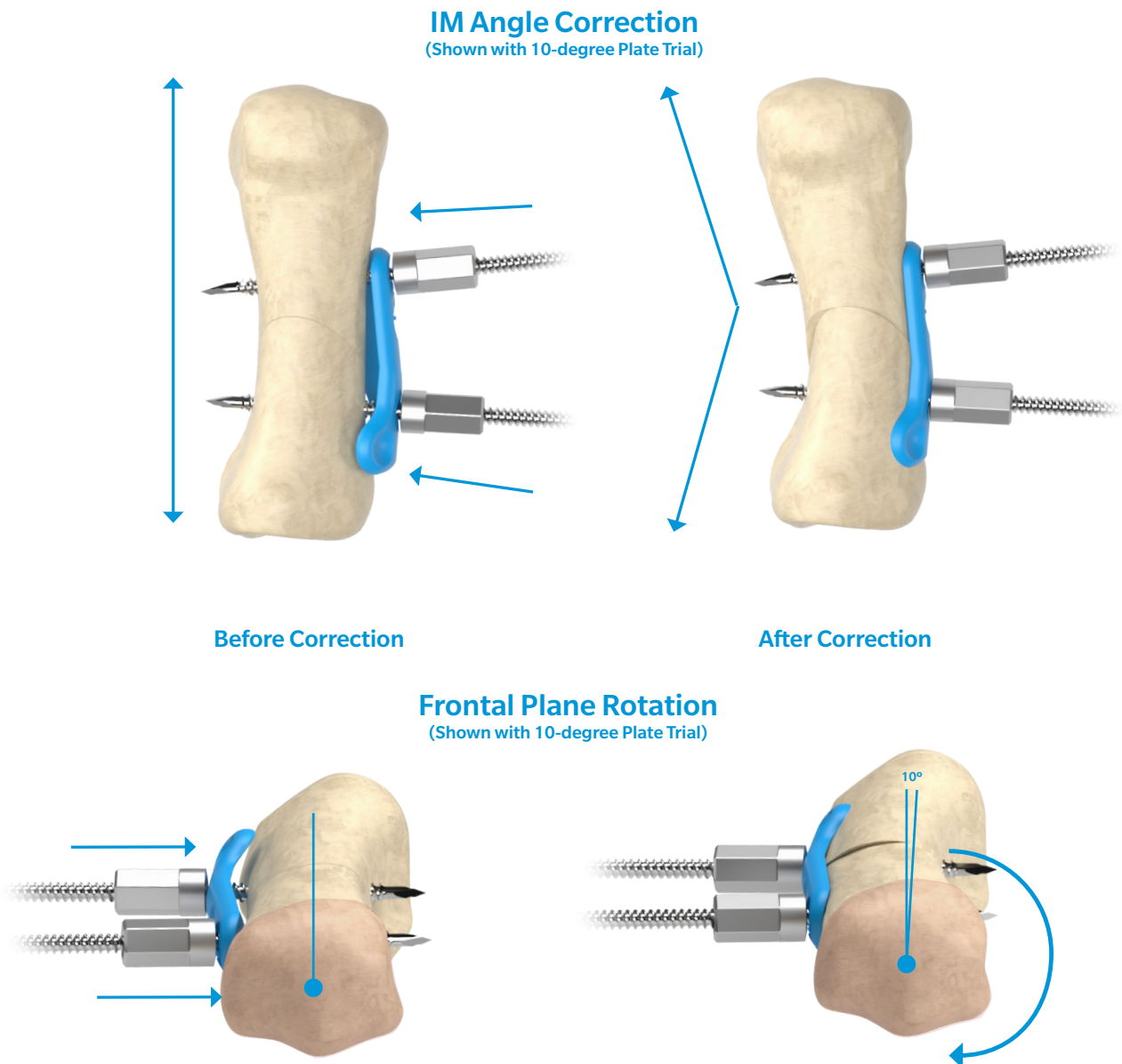


# Axi+Line Proximal Bunion Correction System

## IM Angle and Frontal Plane Deformity Correction

87.3% of patients with hallux valgus have abnormal frontal plane rotation, also known as pronation, of the 1st metatarsal.<sup>6</sup> Proximal/midshaft osteotomies, such as the Scarf, do not address frontal plane deformity, which in one study resulted in a recurrence rate of 78%.<sup>7</sup>

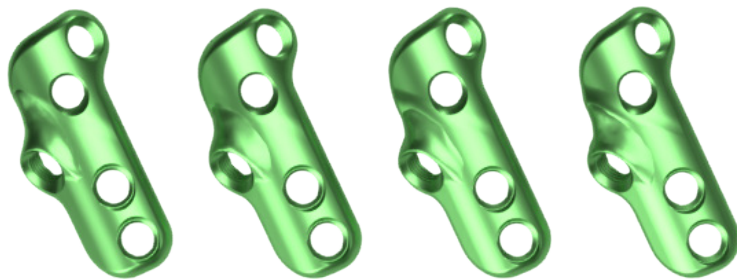
The design of the Axi+Line Proximal Bunion Correction System addresses both IM angle correction and frontal plane deformity correction by combining implant design with the use of a long oblique Proximal Modified Mau osteotomy. The **Plate Trial** allows surgeons to visualize the correction prior to selecting the **Plate** that will be used. Each **Plate** and corresponding **Plate Trial** are uniquely designed to correct both IM angle and frontal plane deformities when secured to the bone through the use of two **Threaded Nuts**. (See image below)



# Axi+Line Proximal Bunion Correction System

## Range of Correction

The Axi+Line Proximal Bunion Correction System can be used to correct IM angle deformities of up to 18 degrees. The system includes 4 left plates and 4 right plates. In the image below, each plate is pictured with its corresponding degrees of correction. Additionally, a cross section image of the plate is shown to highlight the IM angle correction that is implemented into the design of each plate.

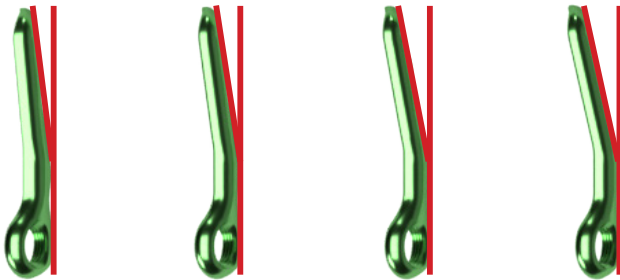


5°

7.5°

10°

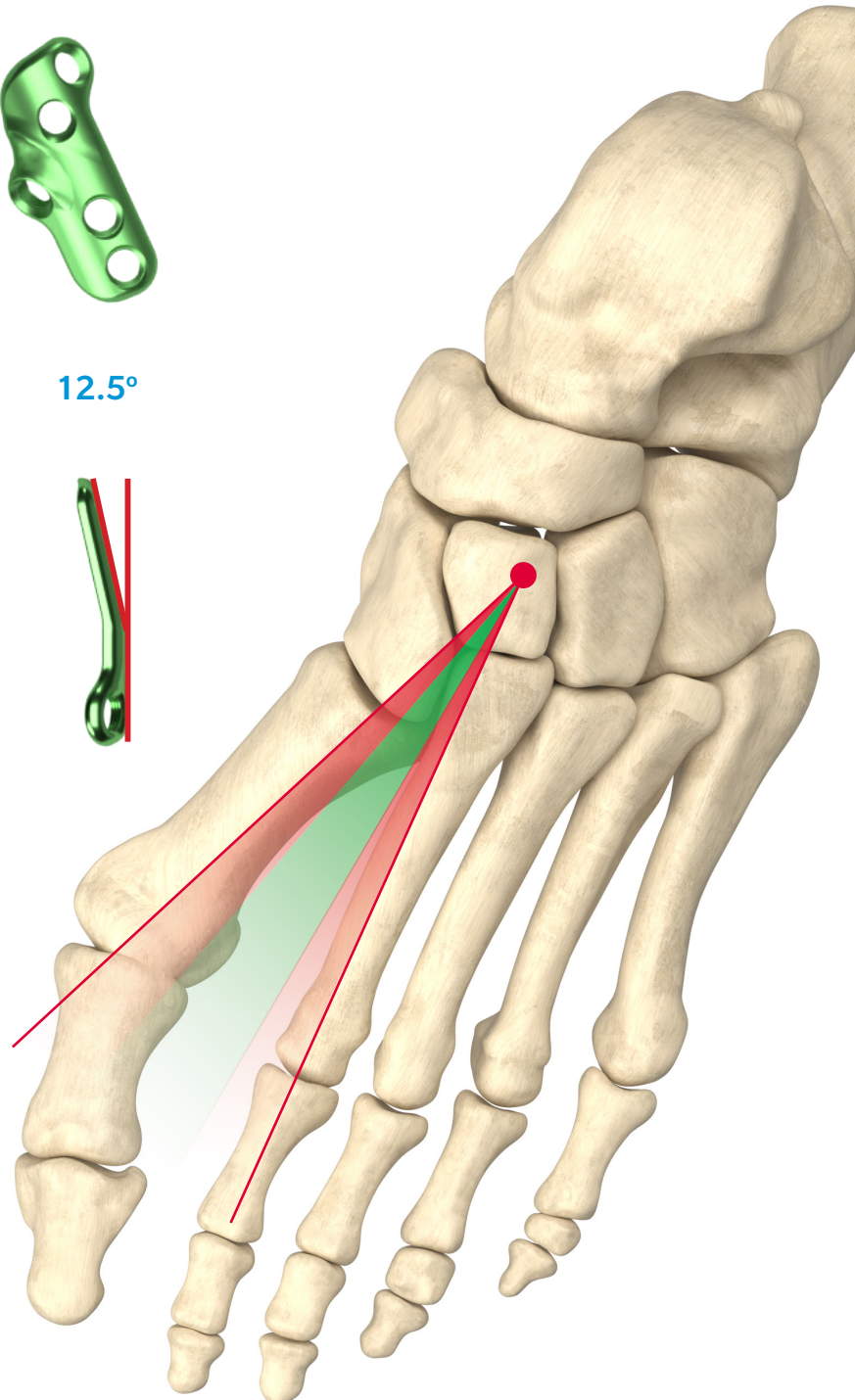
12.5°



Angle between 1st and 2nd Metatarsal

NORMAL RANGE	ABNORMAL RANGE
<b>6-9°</b>	<b>10-18°</b>

Abnormal range starts at angles above 10 degrees or higher.<sup>8</sup> This system corrects up to 18 degrees of hallux interphalangeus angle.



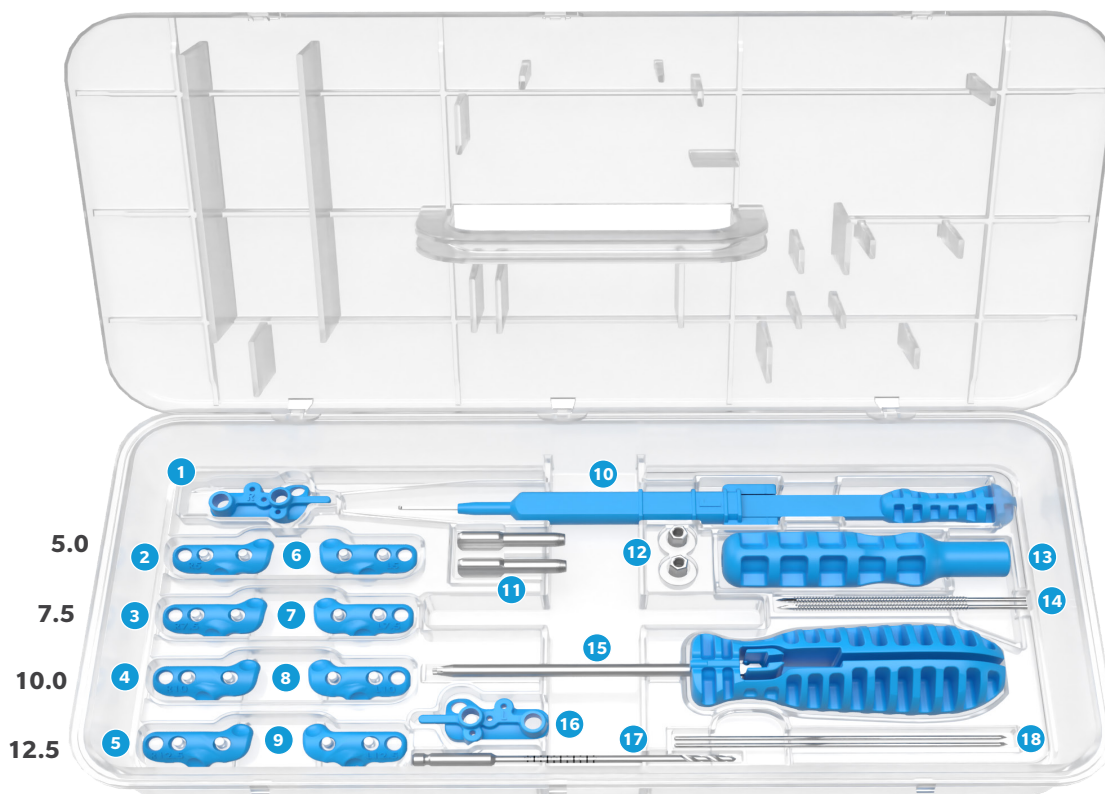


# Instrumentation

Instrumentation is designed to provide full control of all bone fragments during the procedure and allows for a seamless transition from templating to plating.

- All components in kits are pre-sterilized
- Instrumentation has never been used, damaged, or worn prior to surgery
- Time and cost savings as sterilization before surgery is no longer necessary
- Complete sets at delivery minimizes time at the back table

## Axi+Line Instrument Kit (AXL-INST)



1	Osteotomy Guide - Right
2	5.0 Plate Trial - Right
3	7.5 Plate Trial - Right
4	10.0 Plate Trial - Right
5	12.5 Plate Trial - Right
6	5.0 Plate Trial - Left
7	7.5 Plate Trial - Left
8	10.0 Plate Trial - Left
9	12.5 Plate Trial - Left

10	Depth Gauge
11	Drill Tubes (x2)
12	Threaded Nuts (x2)
13	Threaded Nut Handle
14	2.6mm Threaded Wires (x2)
15	T10 Driver
16	Osteotomy Guide - Left
17	2.6mm AO Drill
18	1.6mm x 4in K-Wires (x2)

## ORDERING INFORMATION - INSTRUMENT KITS, PLATES & SCREWS

Part No.	Description		
AXL-INST	Axi+Line Instrument Kit - Universal	AXL-DRV-T10	Axi-Line Individual Packaged Driver
AXL-050L	Axi+Line Plate 5.0 degree (LEFT)	AXL-050R	Axi+Line Plate 5.0 degree (RIGHT)
AXL-075L	Axi+Line Plate 7.5 degree (LEFT)	AXL-075R	Axi+Line Plate 7.5 degree (RIGHT)
AXL-100L	Axi+Line Plate 10.0 degree (LEFT)	AXL-100R	Axi+Line Plate 10.0 degree (RIGHT)
AXL-125L	Axi+Line Plate 12.5 degree (LEFT)	AXL-125R	Axi+Line Plate 12.5 degree (RIGHT)
Part No.	Description		
SCR-3510NL	3.5mm Cortical Headed Screw, Non-Locking – 10mm Length	SCR-3510L	3.5mm Cortical Headed Screw, Locking – 10mm Length
SCR-3512NL	3.5mm Cortical Headed Screw, Non-Locking – 12mm Length	SCR-3512L	3.5mm Cortical Headed Screw, Locking – 12mm Length
SCR-3514NL	3.5mm Cortical Headed Screw, Non-Locking – 14mm Length	SCR-3514L	3.5mm Cortical Headed Screw, Locking – 14mm Length
SCR-3516NL	3.5mm Cortical Headed Screw, Non-Locking – 16mm Length	SCR-3516L	3.5mm Cortical Headed Screw, Locking – 16mm Length
SCR-3518NL	3.5mm Cortical Headed Screw, Non-Locking – 18mm Length	SCR-3518L	3.5mm Cortical Headed Screw, Locking – 18mm Length
SCR-3520NL	3.5mm Cortical Headed Screw, Non-Locking – 20mm Length	SCR-3520L	3.5mm Cortical Headed Screw, Locking – 20mm Length
SCR-3522NL	3.5mm Cortical Headed Screw, Non-Locking – 22mm Length	SCR-3522L	3.5mm Cortical Headed Screw, Locking – 22mm Length
SCR-3524NL	3.5mm Cortical Headed Screw, Non-Locking – 24mm Length	SCR-3524L	3.5mm Cortical Headed Screw, Locking – 24mm Length
SCR-3526NL	3.5mm Cortical Headed Screw, Non-Locking – 26mm Length	SCR-3526L	3.5mm Cortical Headed Screw, Locking – 26mm Length
SCR-3528NL	3.5mm Cortical Headed Screw, Non-Locking – 28mm Length	SCR-3528L	3.5mm Cortical Headed Screw, Locking – 28mm Length
SCR-3530NL	3.5mm Cortical Headed Screw, Non-Locking – 30mm Length	SCR-3530L	3.5mm Cortical Headed Screw, Locking – 30mm Length

### References:

1. Thangarajah, T., Ahmed, U., Malik, S., Tillu, A. "The Early Functional Outcome of Mau Osteotomy for the Correction of Moderate-Severe Hallux Valgus." Orthopedic Reviews. (2013).
2. Acevedo, J.I., Sammarco, V.J., Boucher, H.R., Parks, B.G., Schon, L.C., Myerson, M.S. "Mechanical comparison of cyclic loading in five different first metatarsal shaft osteotomies." Foot Ankle Int. (2002).
3. Glover, J.P., Hyer, C.F., Berlet, G.C., and Lee, T.H. "Early Results of the Mau Osteotomy for Correction of Moderate to Severe Hallux Valgus: A Review of 24 Cases." The Journal of Foot & Ankle Surgery. (2008).
4. Trnka, H.J., Parks, B.G., Ivanic, G., Chu, I.T., Easley, M.E., Schon, L.C., Myerson, M.S. "Six first metatarsal shaft osteotomies: mechanical and immobilization comparisons." Clin Orthop Relat Res. (2000).
5. Fleming L., Savage TJ., Paden MH., and Stone PA. "Results of Modified Lapidus Arthrodesis Procedure Using Medial Eminence as an Interposition Autograft." The Journal of Foot & Ankle Surgery. (2001).
6. Kim, Y., Kim, J.S., Young, K.W., Naraghi, R., Cho, H.K., and Lee, S.Y. "A New Measure of Tibial Sesamoid Position in Hallux Valgus in Relation to the Coronal Rotation of the First Metatarsal in CT Scans." Foot & Ankle International. (2015).
7. Jeuken R.M., Schotanus M.G.M., Kort N.P., Deenik A., Jong B., Hendrickx R.P.M. "Long-Term Follow-up of a Randomized Controlled Trial Comparing Scarf to Chevron Osteotomy in Hallux Valgus Correction." Foot Ankle Int. (2016).
8. Nguyen J.K., Sullivan M., Alpuerto II B.B. Mueller S. Sly N. " A radiographic analysis of the abnormal hallux interphalangeus angle range: Considerations for surgeons performing Akin osteotomies" J Orthop Surg (Hong Kong). (2019).

**INDICATIONS:** The Axi+Line Proximal Bunion Correction System is indicated for fixation of fractures, osteotomies, non-unions and fusions of small bones and small bone segments in the foot and ankle.

**CONTRAINDICATIONS:** (1) Patient conditions including insufficient quantity or quality of bone; (2) Blood supply limitations and previous or active infections that may inhibit healing; (3) Surgical procedures other than for the indications listed; (4) Patients with conditions that limit their ability or willingness to follow postoperative care instructions; (5) The device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature; (6) Foreign-body sensitivity. Where material sensitivity is suspected, appropriate test should be made and sensitivity ruled out prior to implantation.

This material is intended for health care professionals. For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit [www.zimmerbiomet.com](http://www.zimmerbiomet.com) for additional product information.

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