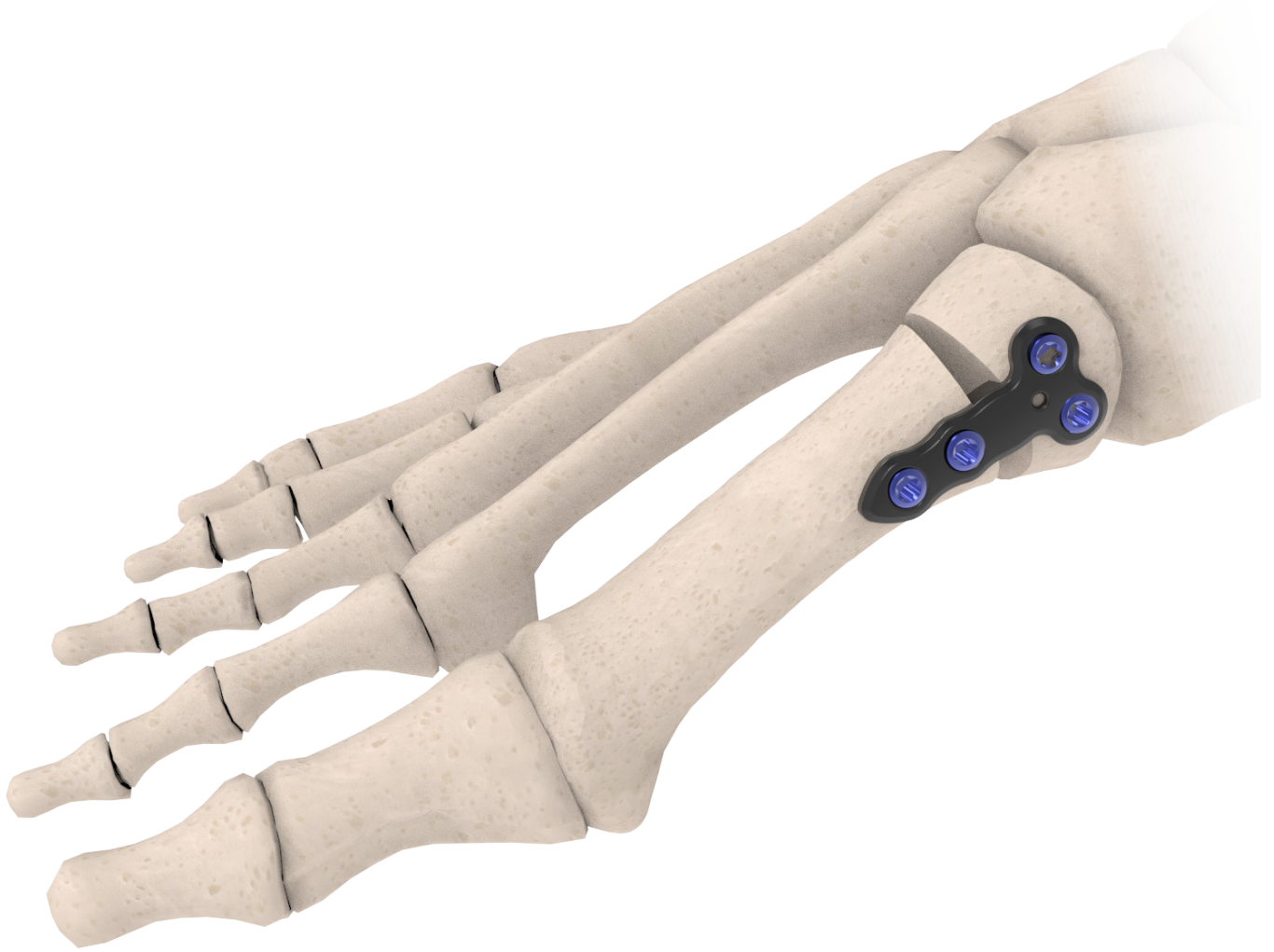


BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

Base Opening Wedge Plate

Surgical Technique



Contents

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Indications & Contraindications

Indications for use:

The intended use of the BioPro Foot Plating System is to draw two or more aligned bone fragments together to facilitate healing in an adult patient. It is composed of the following bone plate categories:

I. Forefoot System:

The BioPro Forefoot Plating System is indicated for use in fixation of small bones and small bone fragments in the foot (Phalanges and Metatarsals) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of small bones, revision surgeries and replantations in an adult patient. The Forefoot System is not for Spinal Use.

II. Mid & Hindfoot System:

The BioPro Mid & Hindfoot Plating System is indicated for use in fixation of medium/large bones and medium/large bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of medium/large bones, revision surgeries and replantations in an adult patient. The Mid & Hindfoot System is not for Spinal Use.

Contra-indications for use:

1. Infection.
2. Patient conditions including blood supply limitations, obesity and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. If material sensitivity is suspected, testing is required prior to implanting the device.

Adverse Effects:

In all surgical procedures, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Fracture of the implant due to excessive loading
- Incomplete or inadequate healing
- Implant migration and/or loosening
- Pain, discomfort or abnormal sensations due to the presence of an implant
- Nerve damage resulting from surgical trauma
- Bone necrosis or bone resorption
- Delayed or nonunion of bone fragments
- Allergic reaction to the implant materials

Warnings & Precautions:

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Implants which come in contact with human blood or tissue must not be re-used or re-sterilized.
- Improper insertion of the device during implantation may result in implant loosening or migration.
- Loosening or migration and loss of fixation due to incorrect implantation, delayed union, nonunion and incomplete healing may occur.
- Bending or fracture due to applied excessive stresses and load bearing may occur.
- Failure to follow postoperative care instructions may result in procedure complications or failure.
- Electrolytic action and corrosion due to implanting with other metallic devices of different chemical composition may occur.

MR Safety Information:

The BioPro Foot Plating System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the BioPro Foot Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. Contact surgeon if a change in performance or pain level is noticed.

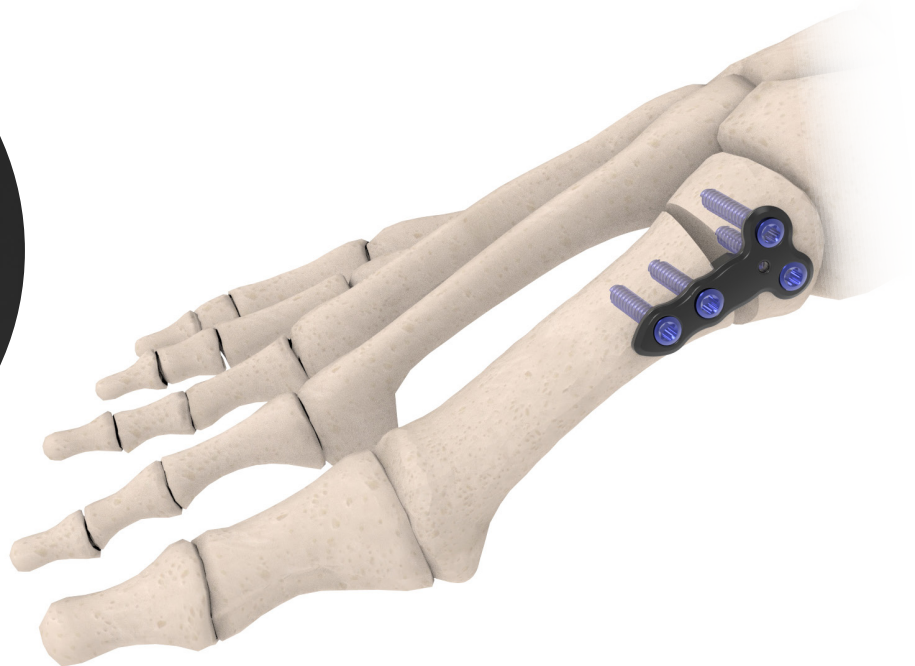
WARNING: Please note that a single use device (SUD) which comes in contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed. The instrument tray must be wrapped in FDA cleared wraps or containers for the steam sterilization process.

Implant Specifications

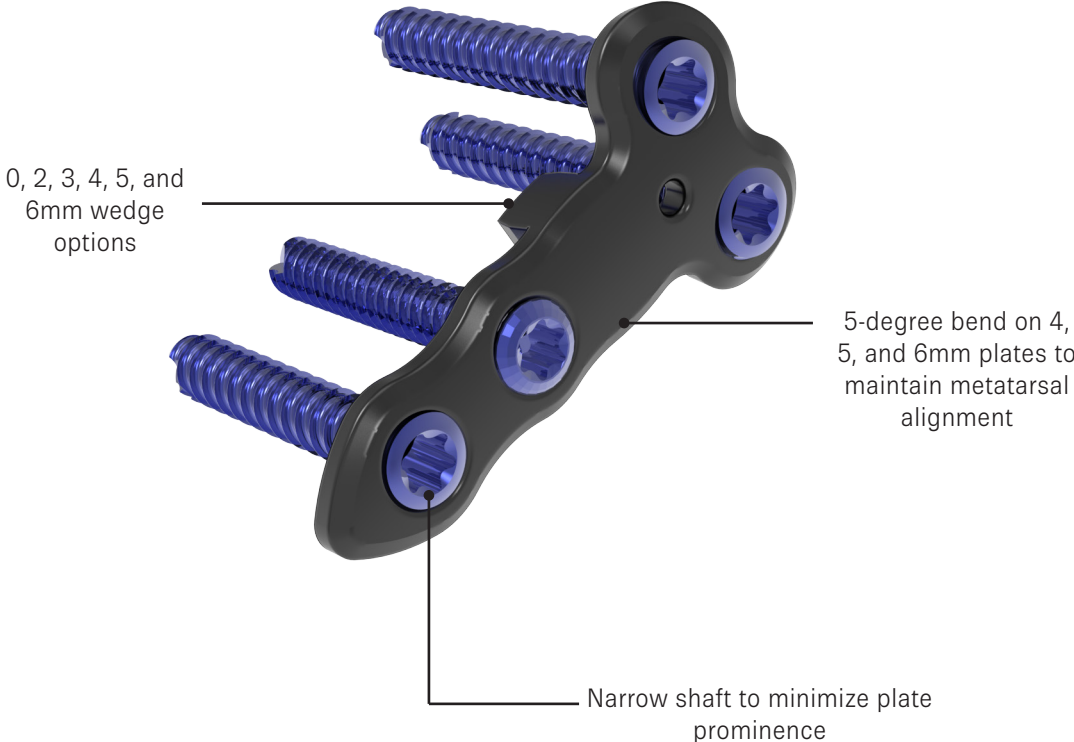
The BioPro® Foot Plating System offers a total of six Opening Wedge plates for the correction of hallux valgus. Opening Wedge plates are available in 0, 2, 3, 4, 5, and 6mm wedges each accepting 2.8mm screws.

The Opening Wedge Plates were designed to provide 2 degrees of correction per 1mm wedge while lengthening the metatarsal. The plates are engineered with dual proximal screw holes and a narrow shaft to minimize plate prominence often found in rectangular plates.

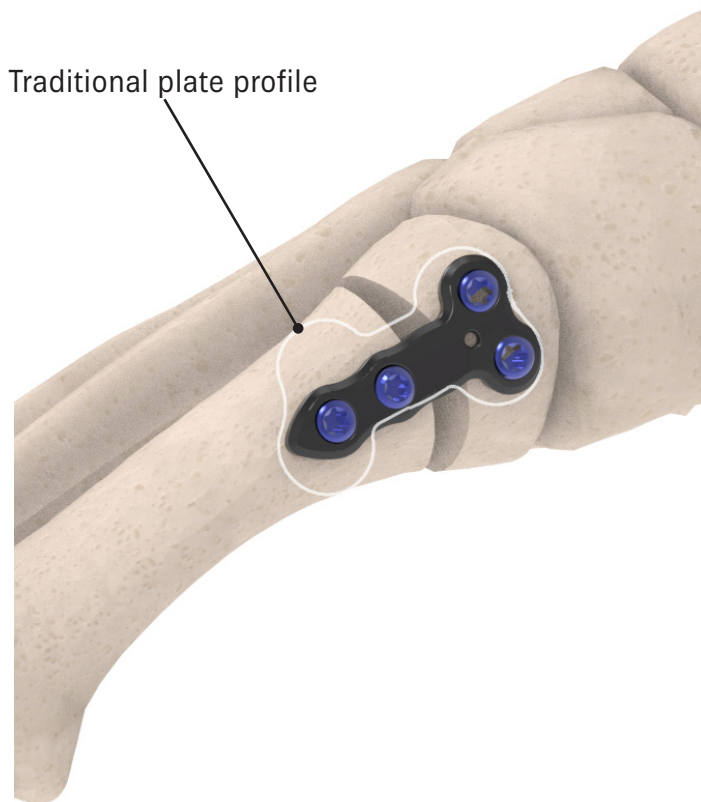
The 4, 5, and 6mm plates all feature a 5-degree bend to maintain the metatarsal corrected alignment during insertion of the two distal screws.



Implant Specifications



Implant Specifications

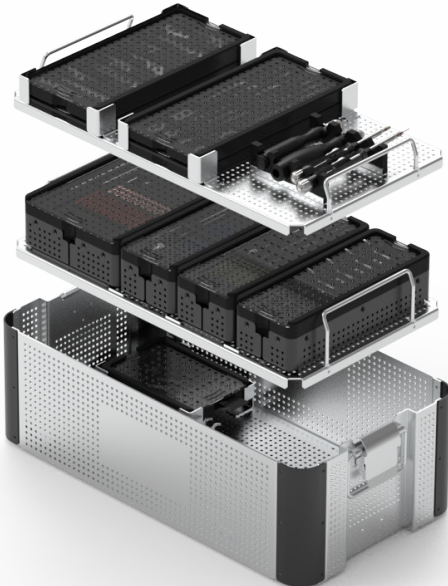
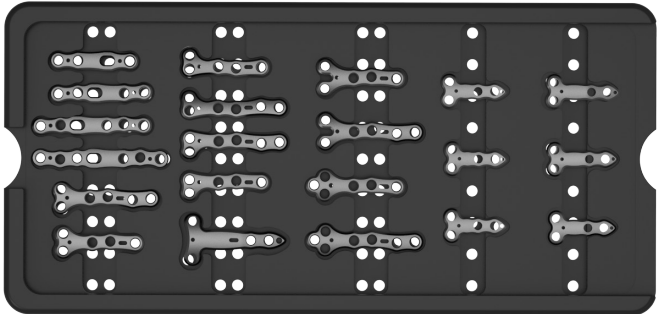
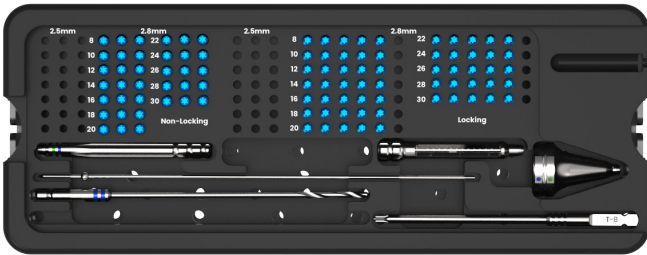


Unlike traditional plate designs that may result in hardware prominence, BioPro Opening Wedge plates are low profile with a narrow shaft.

Instrument Specifications

The Base Opening Wedge Plate technique requires the following modules from the BioPro Foot Plating System:

- Base Tray [ref #22925]
- 2.8 Screw Module [ref #22927]
- 2.8 Plate Module [ref #22930]



Surgical Technique



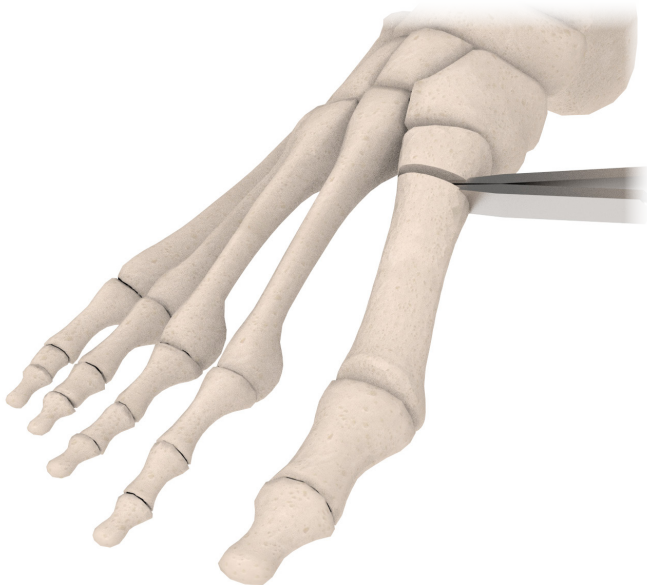
Step One:

A medial longitudinal incision begins at the base of the first metatarsal and is extended down to expose the first MTP joint for resection of the medial exostosis.



Step Two:

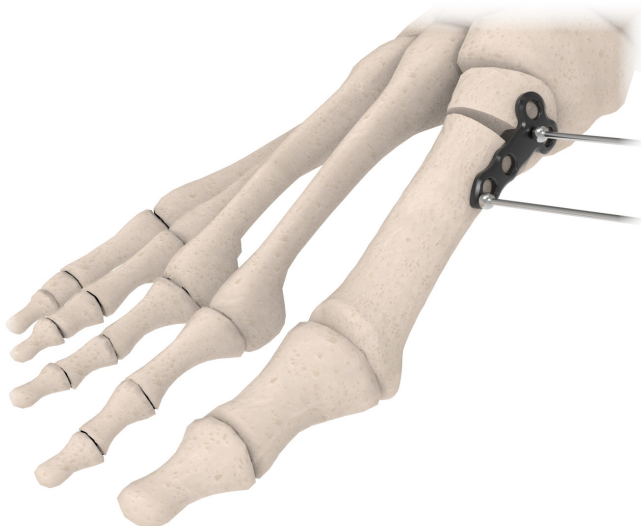
Identify the first tarsometatarsal joint and mark a site for osteotomy perpendicular to the long axis of the first metatarsal, approximately 14-15mm away from the joint. Proceed with an incomplete osteotomy, ensuring that the cut is perpendicular to the long axis of the first metatarsal while avoiding any breakage of the lateral cortex.



Step Three:

Conduct the opening wedge procedure using a spreader or small osteotomes overlapping each other to achieve the desired angular correction for the intermetatarsal angle. The lateral cortex serves as the hinge during this maneuver.

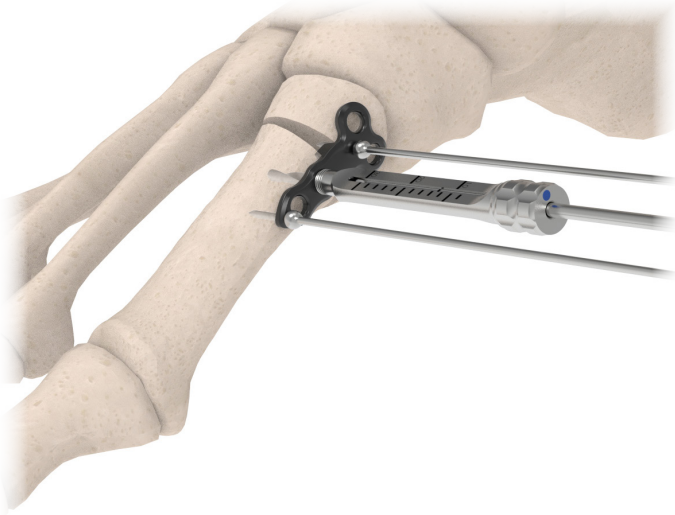
Note: In general, a 1mm wedge corresponds to a 2-degree basal correction. However, the specific correction may vary depending on the length of the metatarsal.



Step Four:

Insert the appropriate Opening Wedge plate into the osteotomy site and secure it in place. If necessary, olive k-wires can be used for temporary fixation.

Note: Prior to fixating the plate, you may place the medial exostosis or bone graft into the osteotomy site.

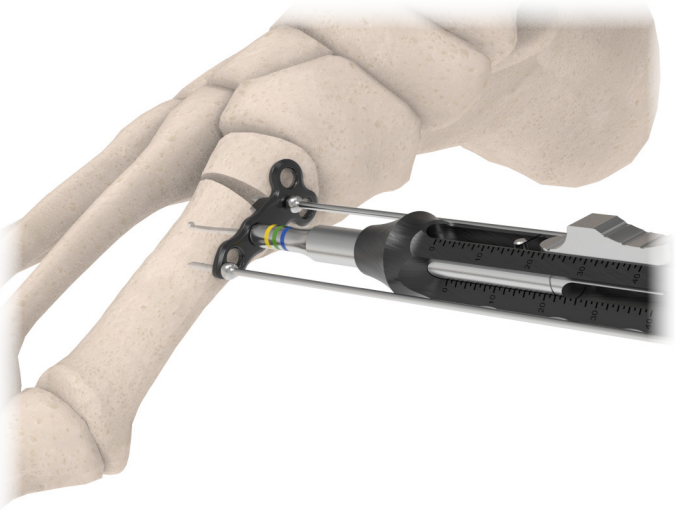


Step Five:

Thread the 2.8mm locking drill guide into one of the screw holes. After the locking drill guide is locked in place, drill bi-cortically using the blue 2.0mm drill bit.

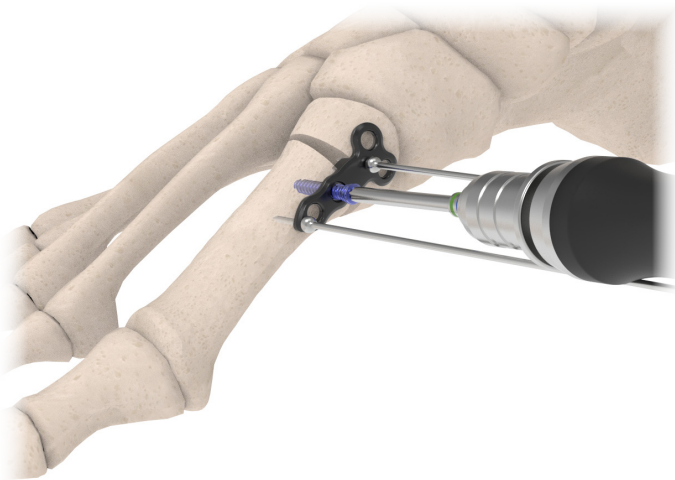
Note: While the locking drill guide is recommended, the MVA locking drill guide or double drill guide may also be used.

Note: If using the locking drill guide, the appropriate screw length can be determined through the measuring windows in the locking drill guide.



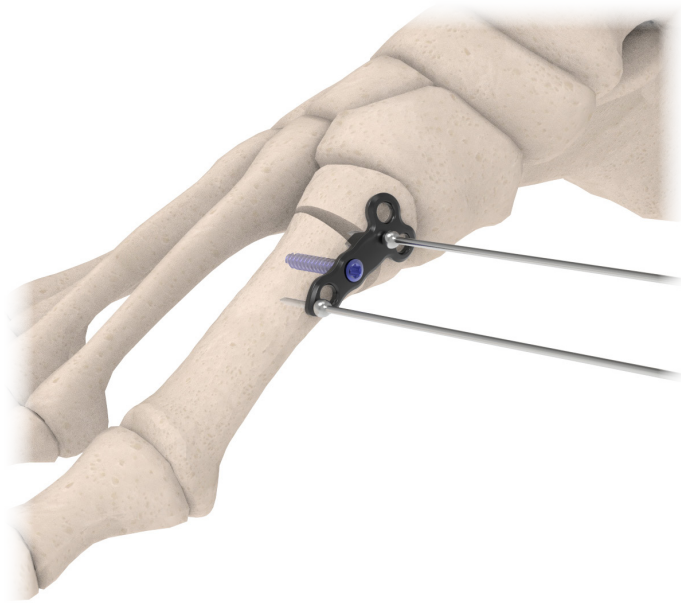
Step Six:

Confirm screw length by inserting the color-coded depth gauge into the drill hole. Expose the wire by sliding the lever back towards you. Hook the wire bi-cortically and slide the lever down until the shaft contacts the plate hole. Measure the screw length by the distal mark.



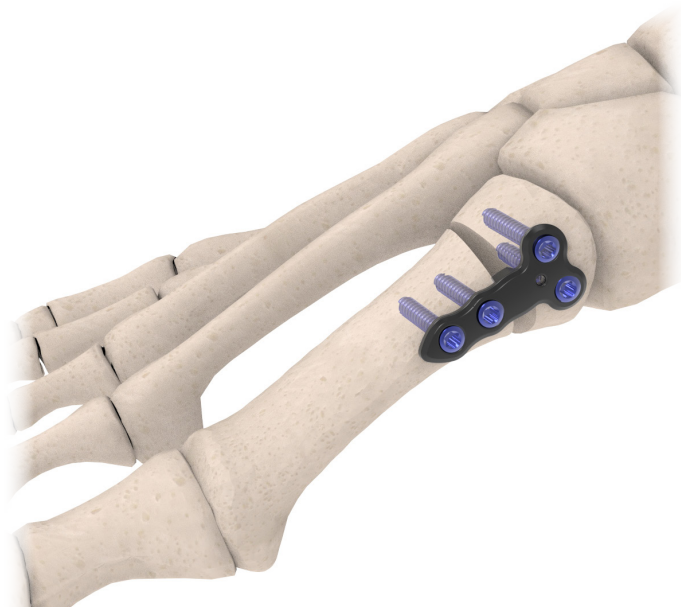
Step Seven:

Remove the desired screw from the screw caddy using the blue T8 torx screwdriver, insert the screw into the pilot hole and drive the screw into the plate.



Step Eight:

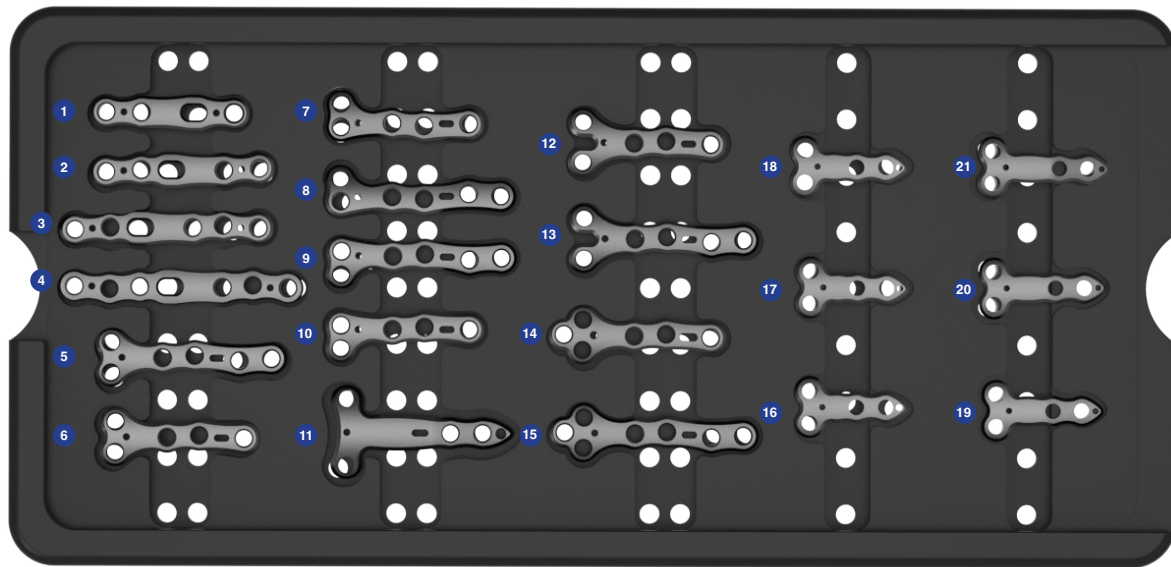
After screw insertion, verify plate placement.



Step Nine:

Repeat the drilling and measuring steps to fill the remaining screw holes and then remove all temporary fixation. Skin closure is completed per the surgeon's preferred method.

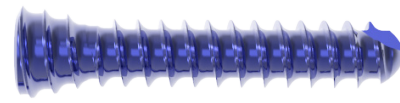
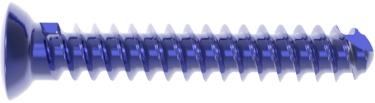
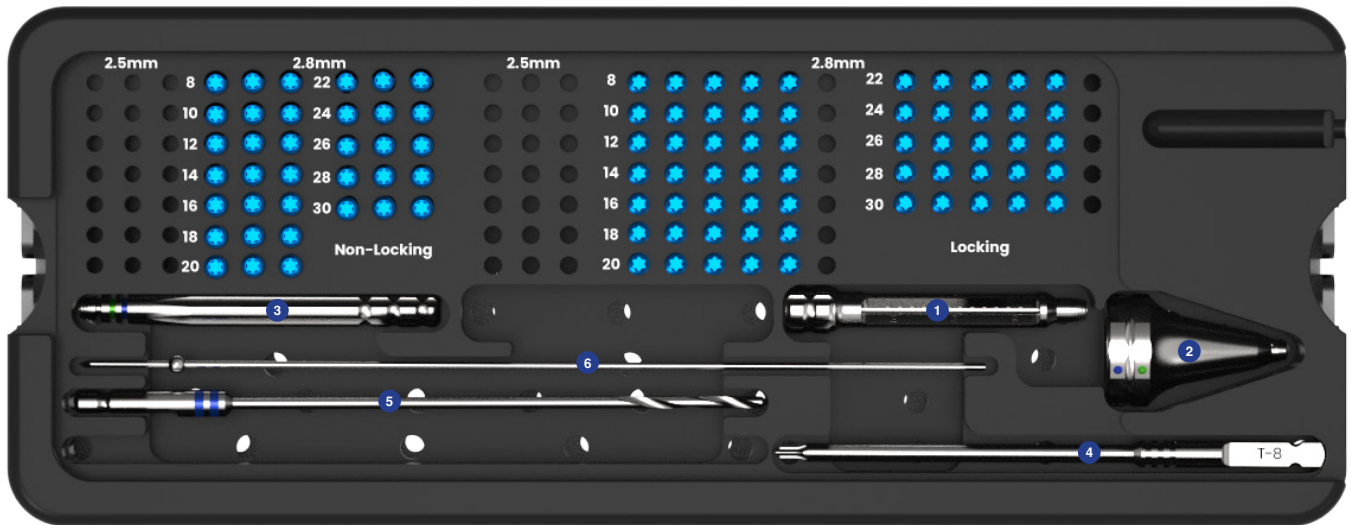
2.8 Plate Module [ref# 22930]



2.8 Plate Module - 22930

Location	Screw Color	Item #	Description	Qty
1	•	20614	Straight Fracture Plate, 2.5-2.8mm, 4 Hole	1
2	•	20615	Straight Fracture Plate, 2.5-2.8mm, 5 Hole	1
3	•	20616	Straight Fracture Plate, 2.5-2.8mm, 6 Hole	1
4	•	20617	Straight Fracture Plate, 2.5-2.8mm, 7 Hole	1
5	•	20624	T-Shape Fracture Plate, 2.5-2.8mm, 3 Hole	1
6	•	20625	T-Shape Fracture Plate, 2.5-2.8mm, 4 Hole	1
7	•	20622	L-Shape Fracture Plate, 2.5-2.8mm, 3 Hole, Right	1
8	•	20623	L-Shape Fracture Plate, 2.5-2.8mm, 4 Hole, Right	1
9	•	20620	L-Shape Fracture Plate, 2.5-2.8mm, 3 Hole, Left	1
10	•	20621	L-Shape Fracture Plate, 2.5-2.8mm, 4 Hole, Left	1
11	•	20756	Medial TMT-1 Fusion Plate, 2.8mm, 4 Hole	1
12	•	20618	Y-Shape Fracture Plate, 2.5-2.8mm, 3 Hole	1
13	•	20619	Y-Shape Fracture Plate, 2.5-2.8mm, 4 Hole	1
14	•	20626	Cloverleaf Plate, 2.5-2.8mm, 3 Hole	1
15	•	20627	Cloverleaf Plate, 2.5-2.8mm, 4 Hole	1
16	•	20628	Open Wedge Plate, 2.5-2.8mm, 0mm Wedge	1
17	•	20629	Open Wedge Plate, 2.5-2.8mm, 2mm Wedge	1
18	•	20630	Open Wedge Plate, 2.5-2.8mm, 3mm Wedge	1
19	•	20631	Open Wedge Plate, 2.5-2.8mm, 4mm Wedge	1
20	•	20632	Open Wedge Plate, 2.5-2.8mm, 5mm Wedge	1
21	•	20633	Open Wedge Plate, 2.5-2.8mm, 6mm Wedge	1

2.8 Screw Module [ref# 22927]



Item #	Description	Qty
20568	Cortical Screw, 2.8mm X 8mm	3
20569	Cortical Screw, 2.8mm X 10mm	3
20570	Cortical Screw, 2.8mm X 12mm	3
20571	Cortical Screw, 2.8mm X 14mm	3
20572	Cortical Screw, 2.8mm X 16mm	3
20573	Cortical Screw, 2.8mm X 18mm	3
20574	Cortical Screw, 2.8mm X 20mm	3
20575	Cortical Screw, 2.8mm X 22mm	3
20576	Cortical Screw, 2.8mm X 24mm	3
20577	Cortical Screw, 2.8mm X 26mm	3
20578	Cortical Screw, 2.8mm X 28mm	3
20579	Cortical Screw, 2.8mm X 30mm	3

Item #	Description	Qty
20556	Cortical Locking Screw, MVA, 2.8mm X 8mm	5
20557	Cortical Locking Screw, MVA, 2.8mm X 10mm	5
20558	Cortical Locking Screw, MVA, 2.8mm X 12mm	5
20559	Cortical Locking Screw, MVA, 2.8mm X 14mm	5
20560	Cortical Locking Screw, MVA, 2.8mm X 16mm	5
20561	Cortical Locking Screw, MVA, 2.8mm X 18mm	5
20562	Cortical Locking Screw, MVA, 2.8mm X 20mm	5
20563	Cortical Locking Screw, MVA, 2.8mm X 22mm	5
20564	Cortical Locking Screw, MVA, 2.8mm X 24mm	5
20565	Cortical Locking Screw, MVA, 2.8mm X 26mm	5
20566	Cortical Locking Screw, MVA, 2.8mm X 28mm	5
20567	Cortical Locking Screw, MVA, 2.8mm X 30mm	5

2.8 Screw Module [continued]



Location	Item #	Description	Qty
1	20638	Locking Drill Guide, 2.8mm	1



Location	Item #	Description	Qty
2	20641	MVA Drill Guide, 2.8mm	1



Location	Item #	Description	Qty
3	20663	Holding & Bending Pin - 2.8mm	2



Location	Item #	Description	Qty
4	20651	Screwdriver Blade - T8	2



Location	Item #	Description	Qty
5	22680	2.0mm x 115mm Drill Bit (Blue)	2



Location	Item #	Description	Qty
6	20940	Olive K-wire - 1.2mm	2

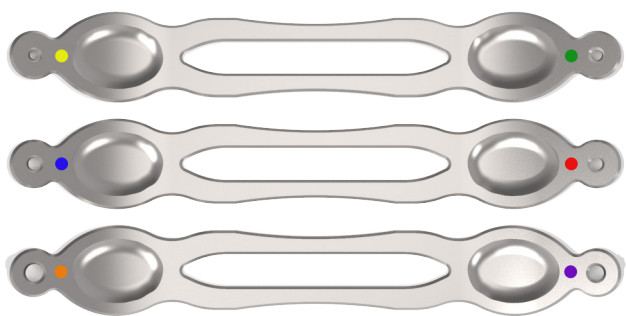
Base Tray General Instruments [ref #22925]



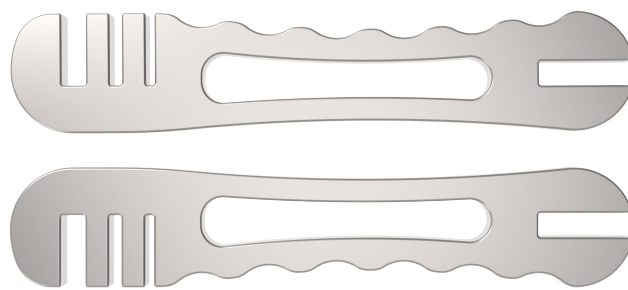
Item #	Description	Qty
20653	Screwdriver Handle – Small	1
20930	Screwdriver Handle – Medium	1



Item #	Description	Qty
20635	Depth Gauge 2.0/2.5/2.8 – 40mm	1
21337	Depth Gauge 3.0/3.5/4.0mm – 50mm	1



Item #	Description	Qty
20643	Double Drill Guide 2.0-2.5mm Screws	1
20922	Double Drill Guide 2.8-3.0mm Screws	1
20923	Double Drill Guide 3.5-4.0mm Screws	1



Item #	Description	Qty
20664	Bending Iron – Left	1
20665	Bending Iron – Right	1



Item #	Description	Qty
20934	Hohman Retractor, 8mm	1
20935	Hohman Retractor, 6mm	1

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