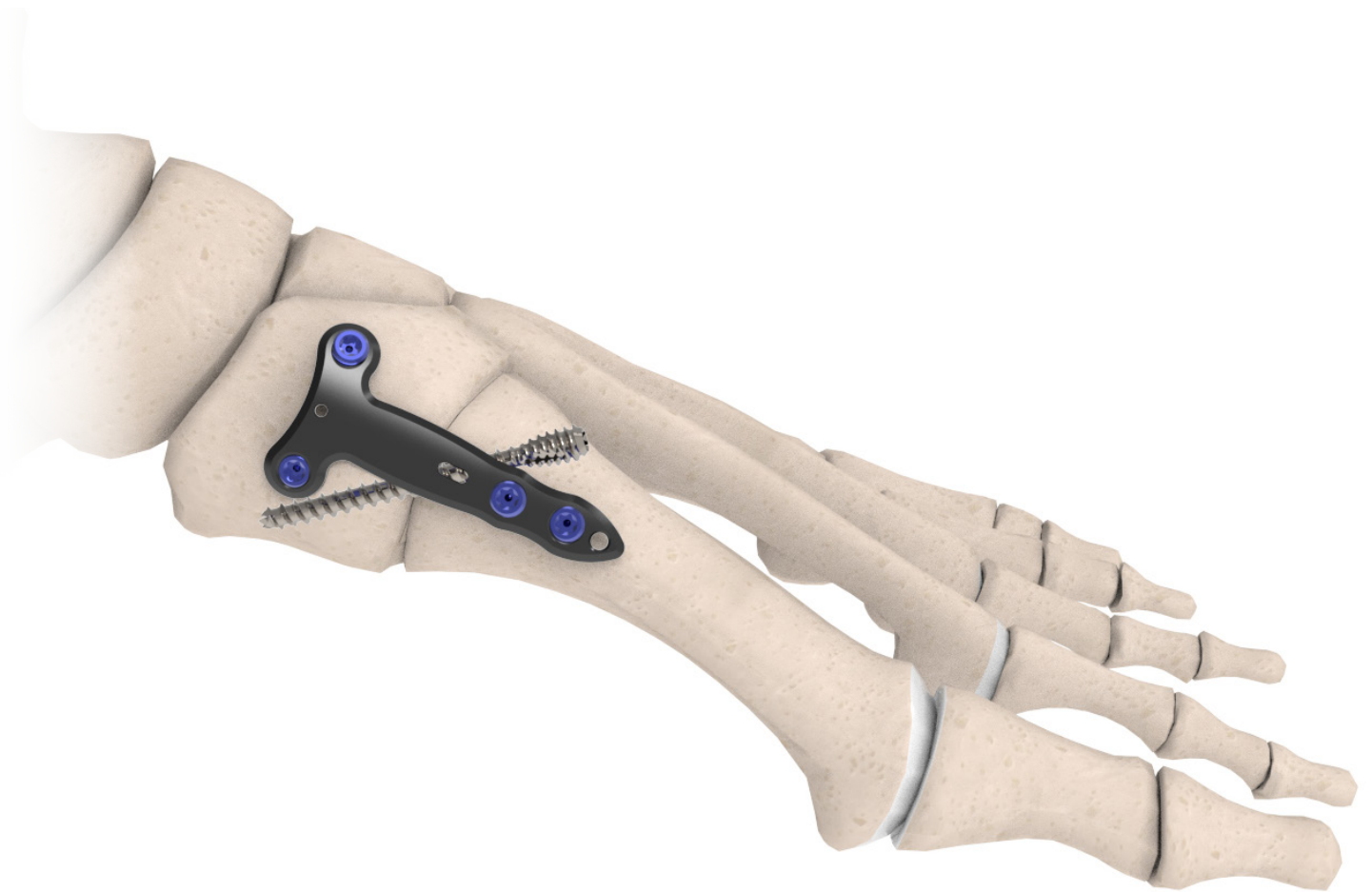


Medial Lapidus Plate

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.

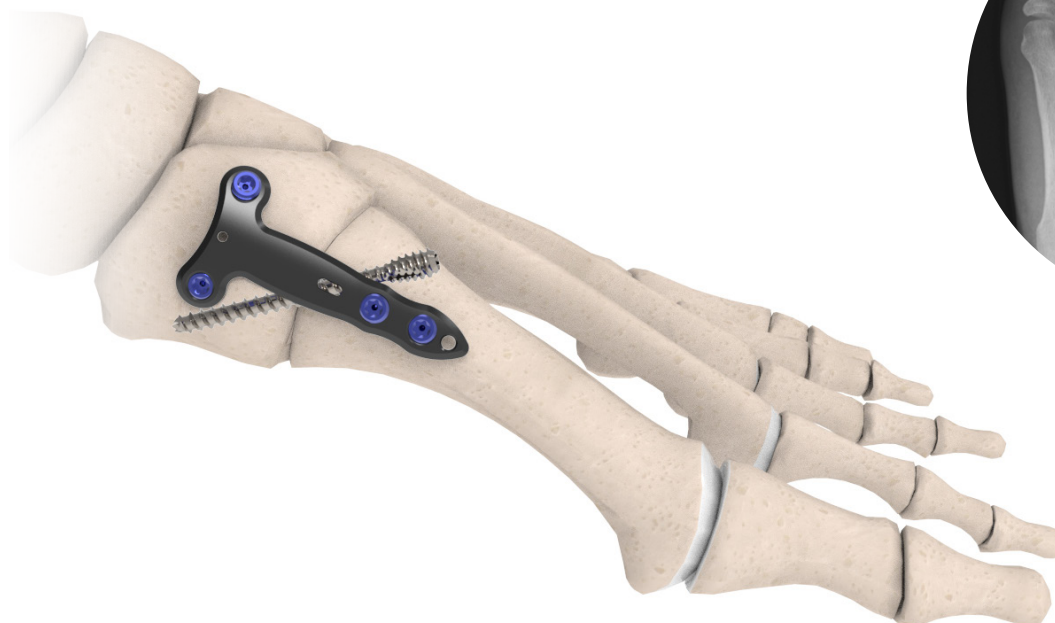
WARNING: Please note that a single use device (SUD) which comes in contact with human blood or tissue should not be re-used and should be returned to the manufacturer or properly disposed. The instrument tray must be wrapped in FDA cleared wraps or containers for the steam sterilization process.

Implant Specifications

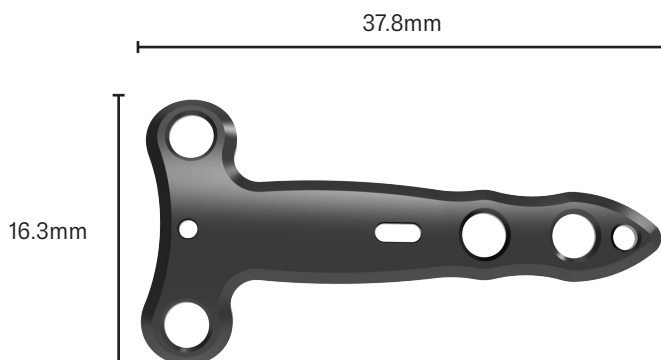
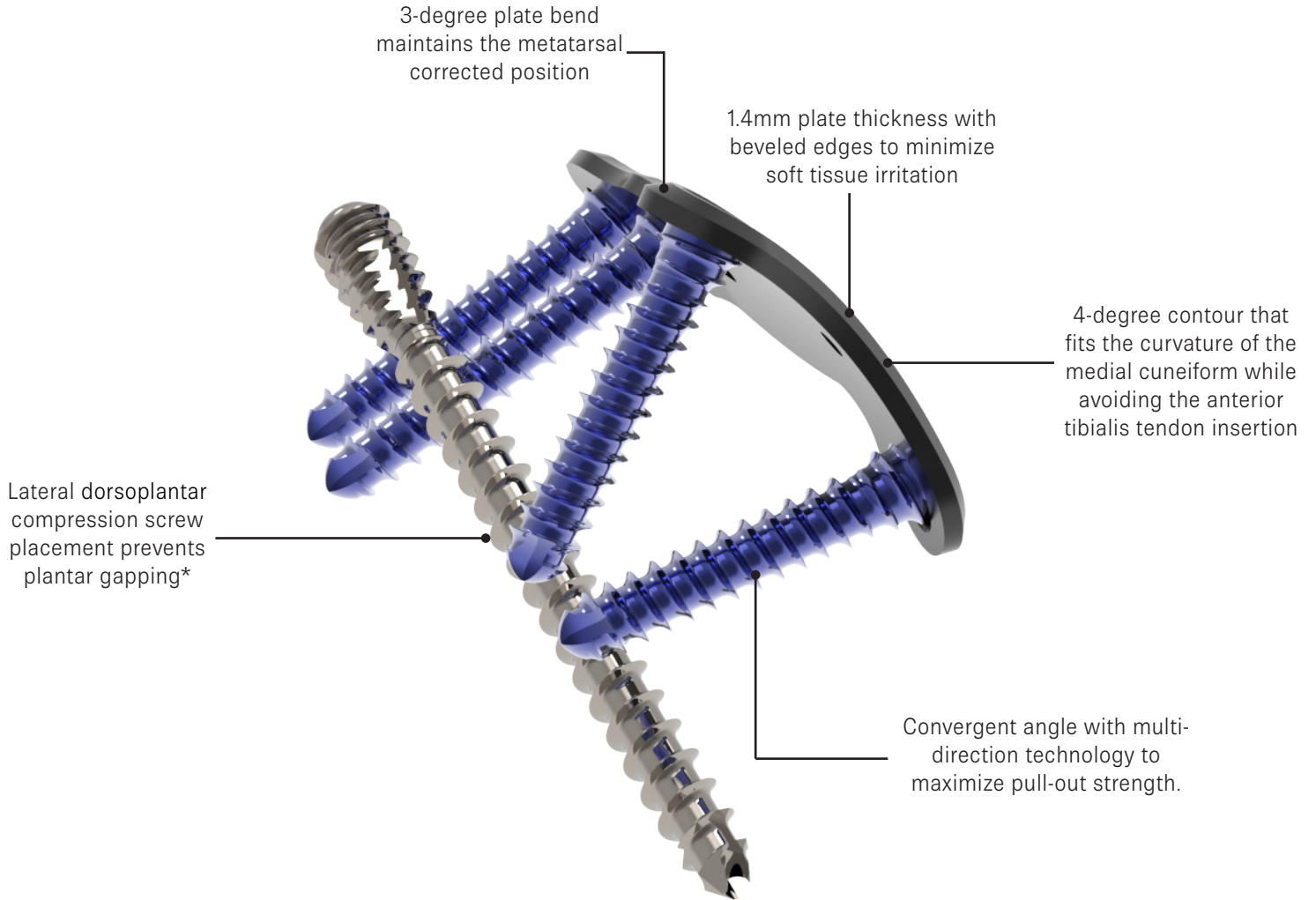
The BioPro® Foot Plating System offers a low-profile Medial Lapidus Plate for the fusion of the first tarsometatarsal joint.

The Medial Lapidus Plate accepts 2.8mm screws and is designed to function as a neutralization plate with an accompanying compression screw on the lateral side of the TMT-1 joint. This construct was chosen due to its inherent strength and ability to prevent plantar gapping through primary lag screw compression.

In a series of 300 patients, the use of the BioPro® Medial Lapidus Plate with compression screw(s) resulted in 100% union rate, less than 1% hardware removal, and no recurrence at 1 year postoperatively.



Implant Specifications



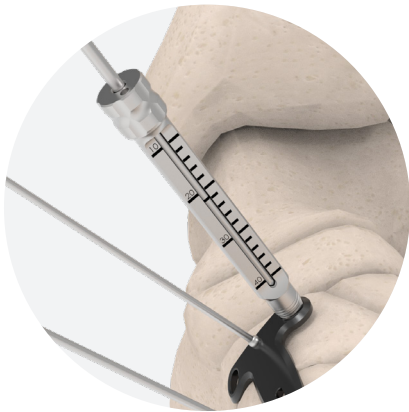
*Note: Use of a compression screw is recommended but is not required.

Instrument Specifications

Drill Guides

The BioPro Foot Plating System offers three standard drill guide types: locking drill guides, MVA drill guides and double drill guides. Each drill guide features color coded dots that coordinate with the drill and screw color.

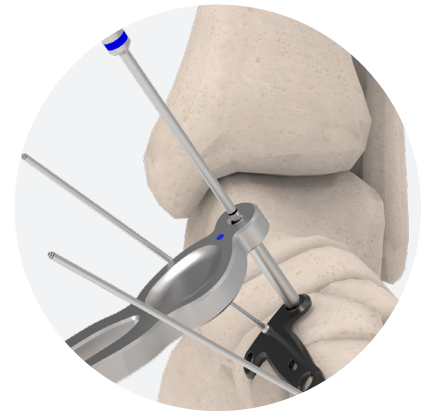
When inserting a compression non-locking screw, a double drill guide should always be used. Always use an MVA drill guide when drilling at a variable angle.



Locking Drill Guide



MVA Drill Guide



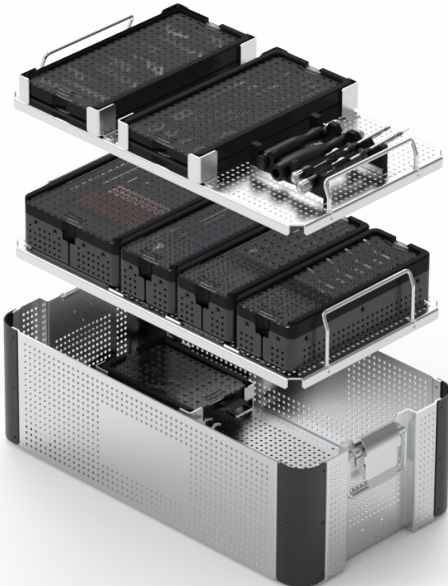
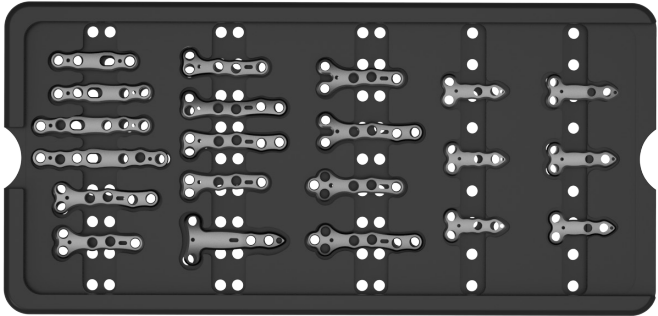
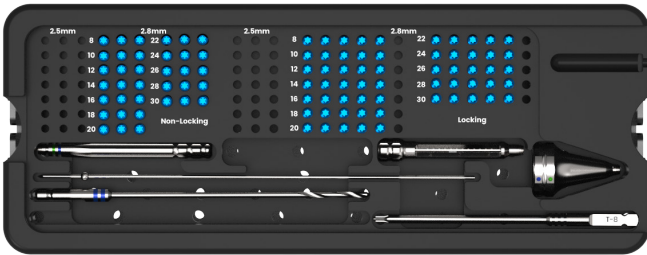
Double Drill Guide

Instrument Specifications

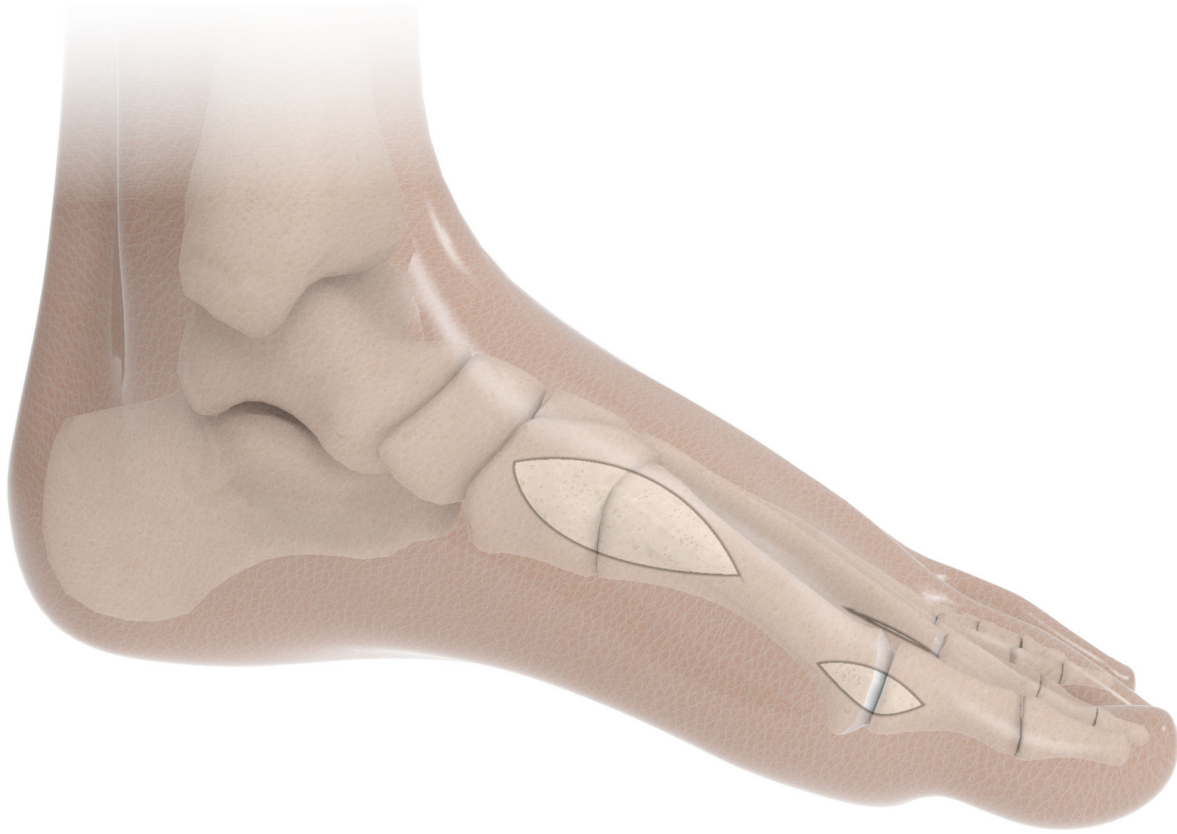
The Medial Lapidus Plate technique requires the following modules from the BioPro Foot Plating System:

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

You may request the 3.0/3.5 Screw Module [ref #22928] and the 3.0/3.5 Plate Module [ref #22931] for universal plate options.

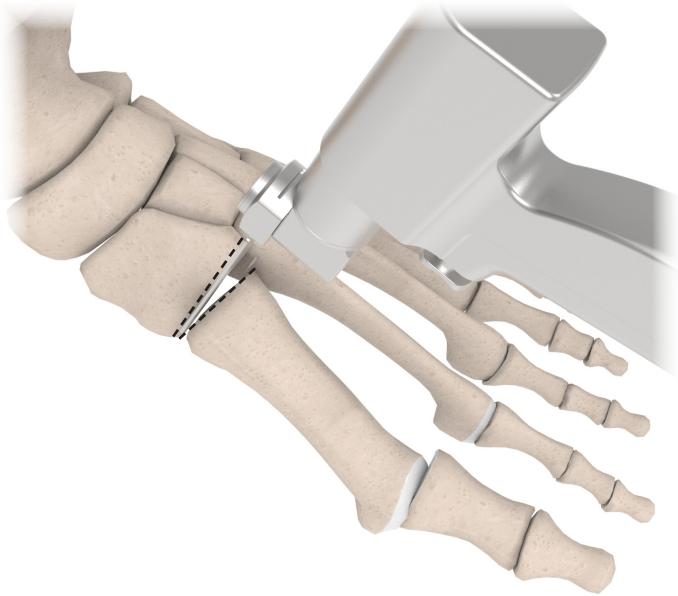


Surgical Technique



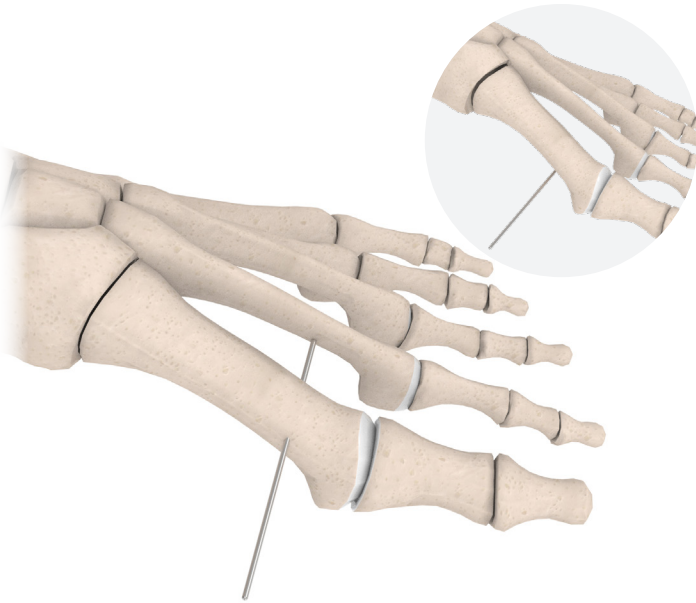
Step One:

A dorsomedial or medial longitudinal incision is centered over the first TMT joint. The joint is exposed through a vertical incision of the medial capsule. A second medial incision and first dorsal web incision to expose the first MTP joint for resection of the medial exostosis and lateral release should be performed. Alternatively, a single incision extending from the TMT joint to the MTP joint may be considered.



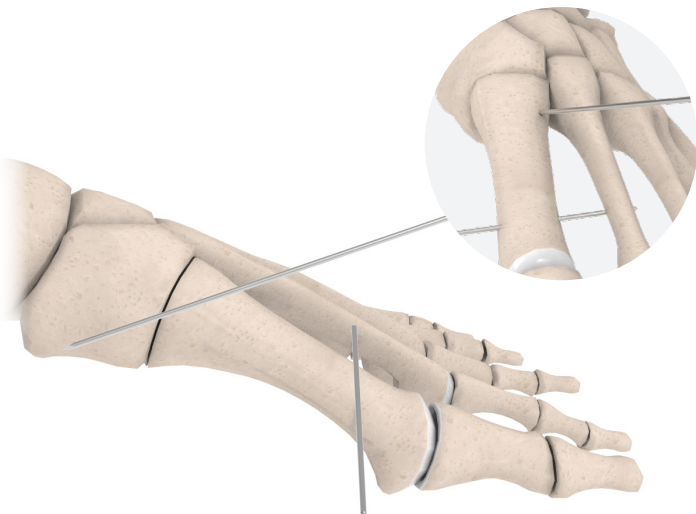
Step Two:

A resection is performed on the first metatarsal articular surface parallel to the base, only removing the cartilage. Then a resection is made on the medial cuneiform perpendicular to the second metatarsal creating a lateral wedge. Subchondral drilling may then be performed. Alternatively, debridement of cartilage may be performed with a small osteotome.



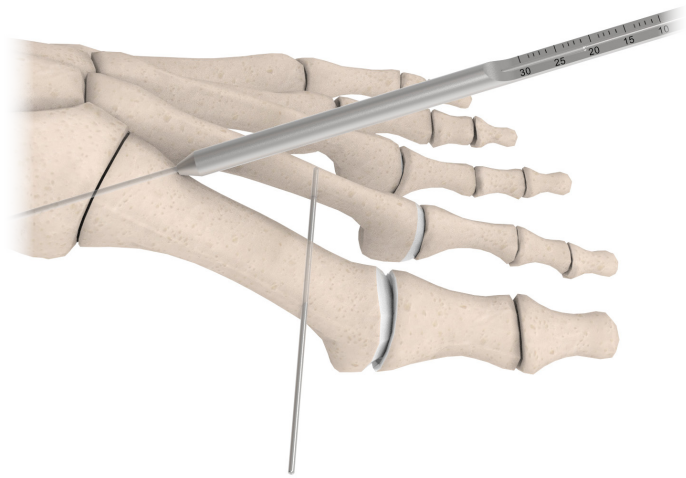
Step Three:

Realign the first metatarsal and secure in all three planes by passing a k-wire from the first metatarsal into the second metatarsal.



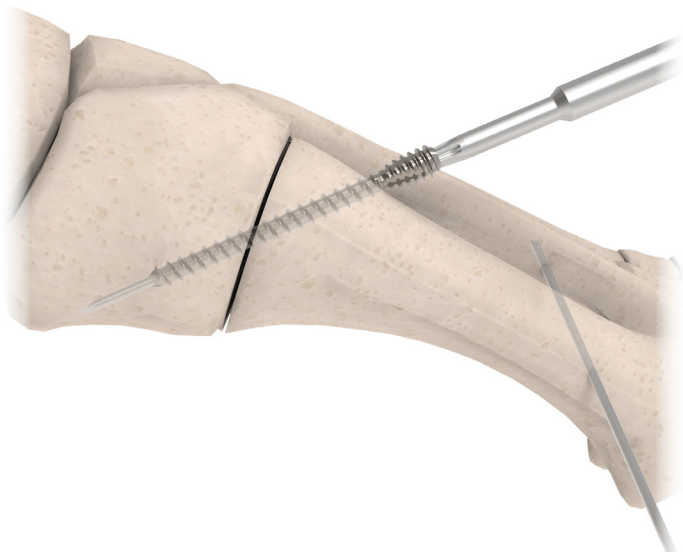
Step Four:

Insert a guide wire into the lateral aspect of the first TMT joint in a dorsoplantar direction. Proper alignment is confirmed under fluoroscopy.



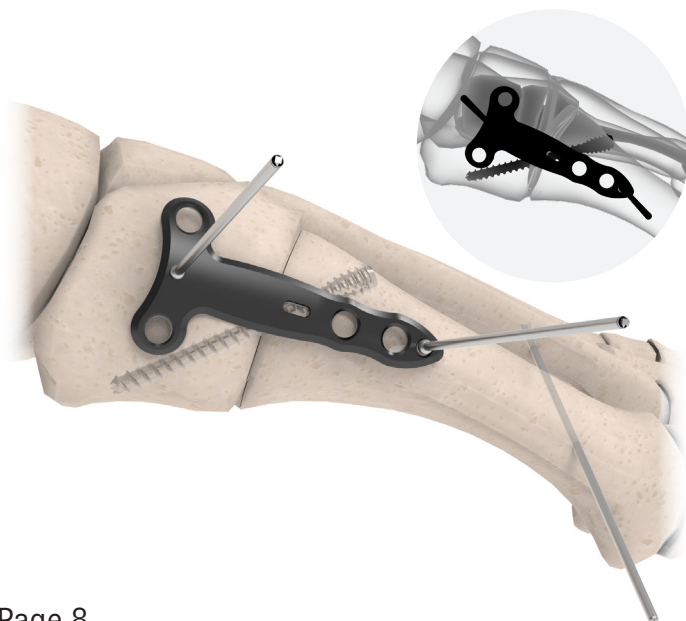
Step Five:

Insert the cannulated depth gauge over the guide wire to determine the proper screw length. A countersink or relief drill may be used to break the cortex prior to screw insertion. If using a headed screw, countersink prior to measuring.



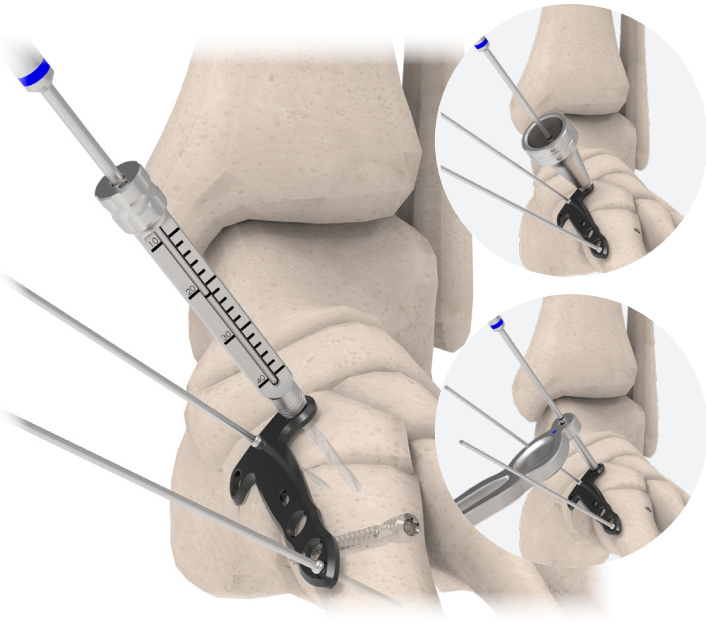
Step Six:

A BioPro Go-EZ™ headed or HBS® headless compression screw is inserted over the guide wire and across the first TMT joint to achieve compression. Remove the guide wire and ensure the screw is flush with the bone.



Step Seven:

Avoiding the Tibialis Anterior Tendon, place the BioPro Medial Lapidus Fusion plate over the joint and temporarily fixate with the provided olive k-wires. Proper anatomical placement is confirmed under fluoroscopy ensuring the compression screw will not interfere with plate screw placement.

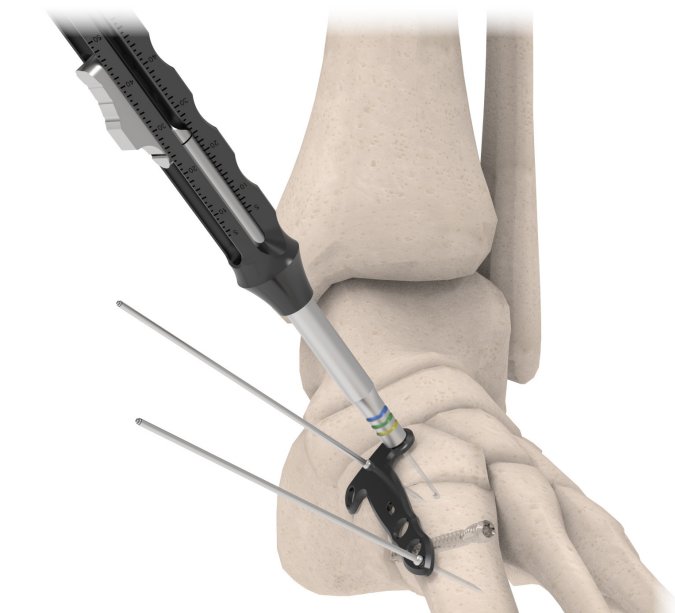


Step Eight:

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.

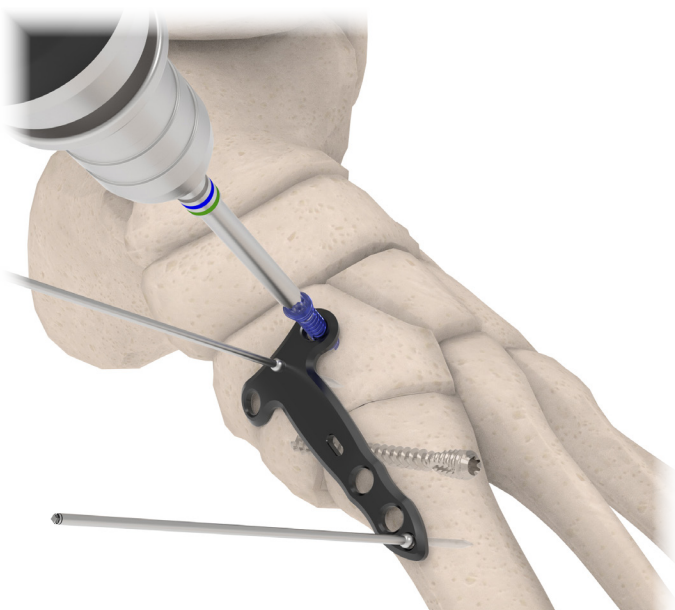
Note: While the locking drill guide is recommended, the MVA locking drill guide or double drill guide may also be used.

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



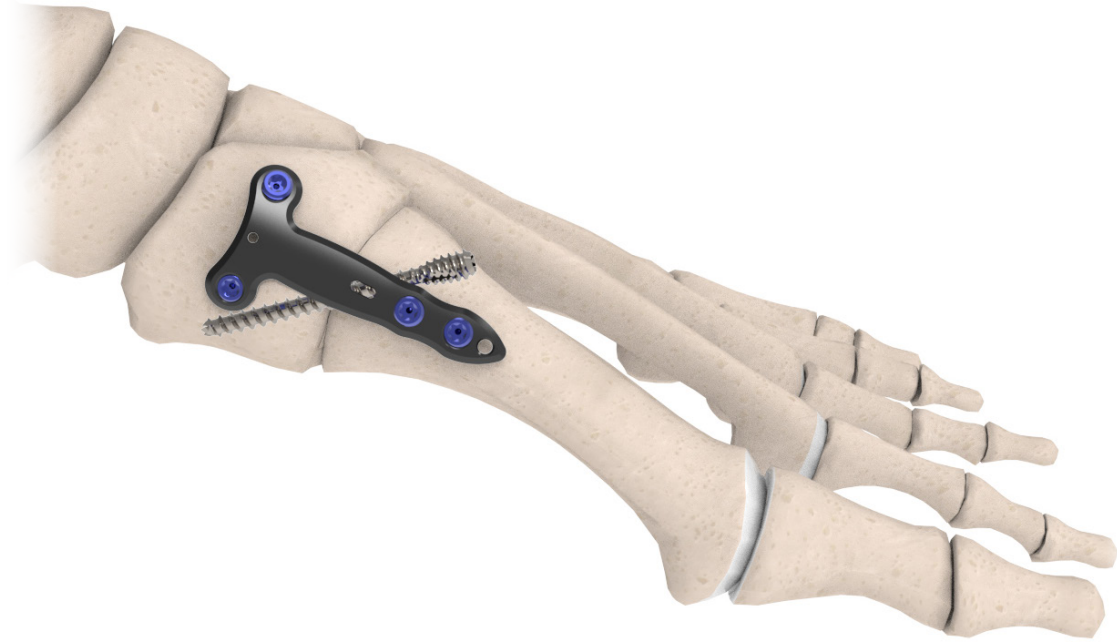
Step Nine:

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 Ten:

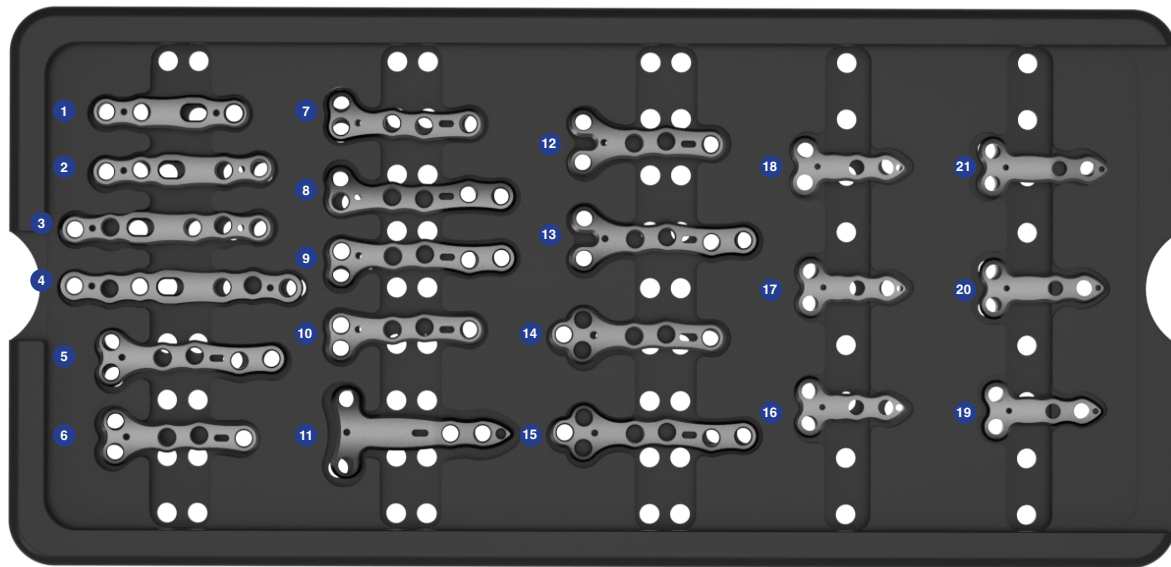
Remove the desired screw from the screw caddy using the blue T8 torx screwdriver, insert the screw into the pilot hole and drive the screw into the plate.



Step Eleven:

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.

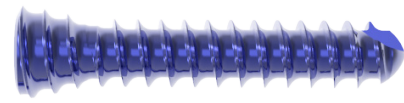
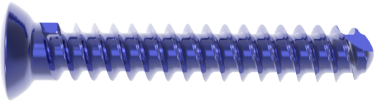
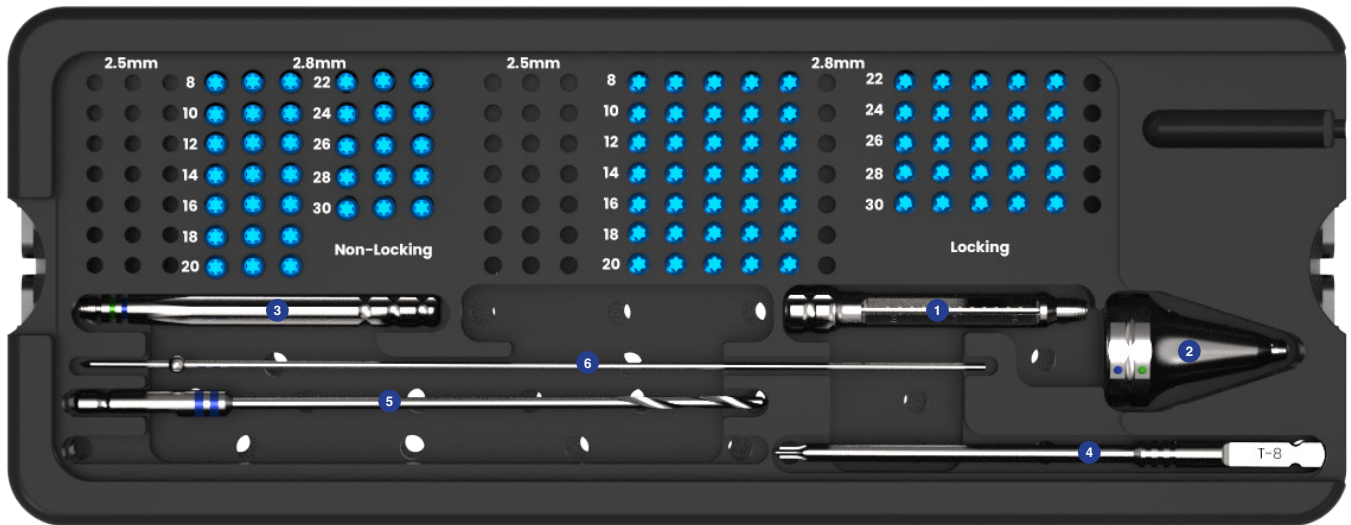
2.8 Plate Module [ref# 22930]



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

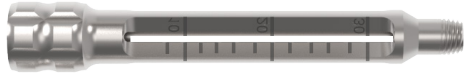
2.8 Screw Module [ref# 22927]



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

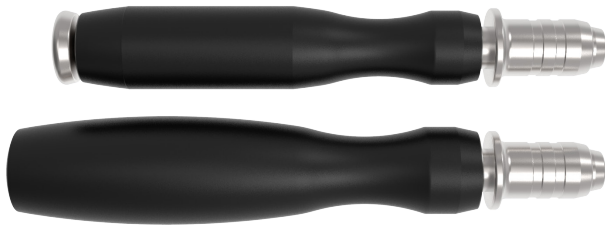


Location	Item #	Description	Qty
5	22680	2.0mm x 115mm Drill Bit (Blue)	2



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

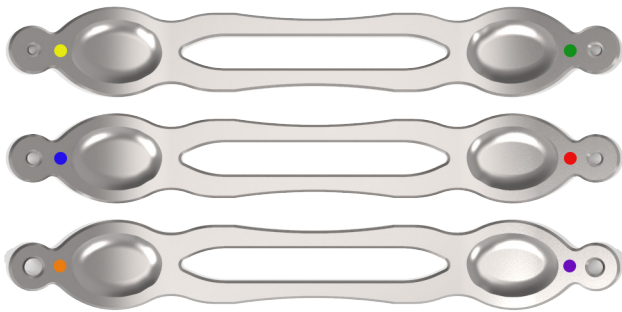
Based Tray General Instruments [ref #22925]



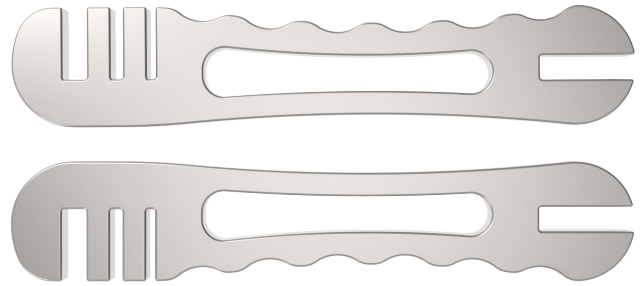
Item #	Description	Qty
20653	Screwdriver Handle – Small	1
20930	Screwdriver Handle – Medium	1



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

Headless Compression Screws

The following screws are individually sterile packaged and will be sent with a reusable instrument kit.

HBS SDST SCREWS			HBS Fully Threaded	
Length (mm)	Ø2.5 (Rose)	Ø3.0 (Blue)	Length (mm)	Ø3.0 (Silver)
10	20500	20516	10	22540
12	20501	20517	12	22541
14	20502	20518	14	22542
16	20503	20519	16	22543
18	20504	20520	18	22544
20	20505	20521	20	22545
22	20506	20522	22	22546
24	20507	20523	24	22547
26	20508	20524	26	22548
28	20509	20525	28	22549
30	20510	20526	30	22550
32	20511	20527	32	22551
34	20512	20528	34	22552
36	20513	20529	36	22553
38	20514	20530	38	22554
40	20515	20531	40	22555

Headed Compression Screws

The following screws are individually sterile packaged and will be sent with a reusable instrument kit.

Go-EZ Cannulated Screws								
Length (mm)	Ø2.0 (Blue)	Ø2.5 (Purple)	Ø3.0 (Gold)	Ø3.5 (Green)	Ø4.0 (Grey)	Ø4.5 (Brown)	Length (mm)	Ø6.5 (Rose)
6	18162	18172	18185	18203	18226	18239	30	19651
8	18163	18173	18186	18204	18227	18240	32	19652
10	18164	18174	18187	18205	18228	18241	34	19653
12	18165	18175	18188	18206	18229	18242	36	19654
14	18166	18176	18189	18207	18230	18243	38	19655
16	18167	18177	18190	18208	18231	18244	40	19656
18	18168	18178	18191	18209	18232	18245	45	19657
20	18169	18179	18192	18210	18233	18246	50	19658
22	18170	18180	18193	18211	18234	18247	55	19659
24	18171	18181	18194	18212	18235	18248	60	19660
26	19265	18182	18195	18213	18236	18249	65	19661
28	19266	18183	18196	18214	18237	18250	70	19662
30	19267	18184	18197	18215	18238	18251	75	19663
32	19268	19250	18198	18216	19041	19031	80	19664
34	19269	19251	18199	18217	19042	19032	85	19665
36	19270	19252	18200	18218	19043	19033	90	19666
38	19271	19253	18201	18219	19044	19034	95	19667
40	19272	19254	18202	18220	19045	19035	100	19668
42	19273	19255		18221	19046	19036	105	19669
44	19274	19256		18222	19047	19037	110	19670
46	19275	19257		18223	19048	19038	115	19671
48	19276	19258		18224	19049	19039	120	19672
50	19277	19259		18225	19050	19040		

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