BPSS Medial TMT Plate

Surgical Technique

Contents

Table of Contents

Indications & Contraindications

Indications for use:
The intended use of the BPSS 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 BPPS 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 BPPS 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.

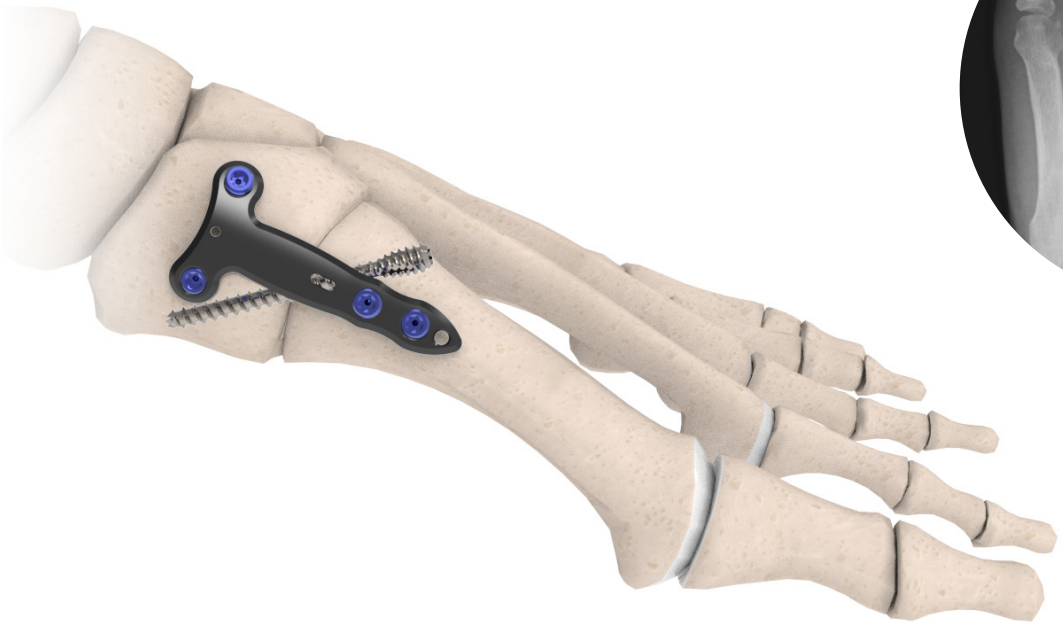
MR Safety Information:
The BPSS Foot Plating System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the BPSS Foot Plating System in the MR environment is unknown. Scanning a 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.

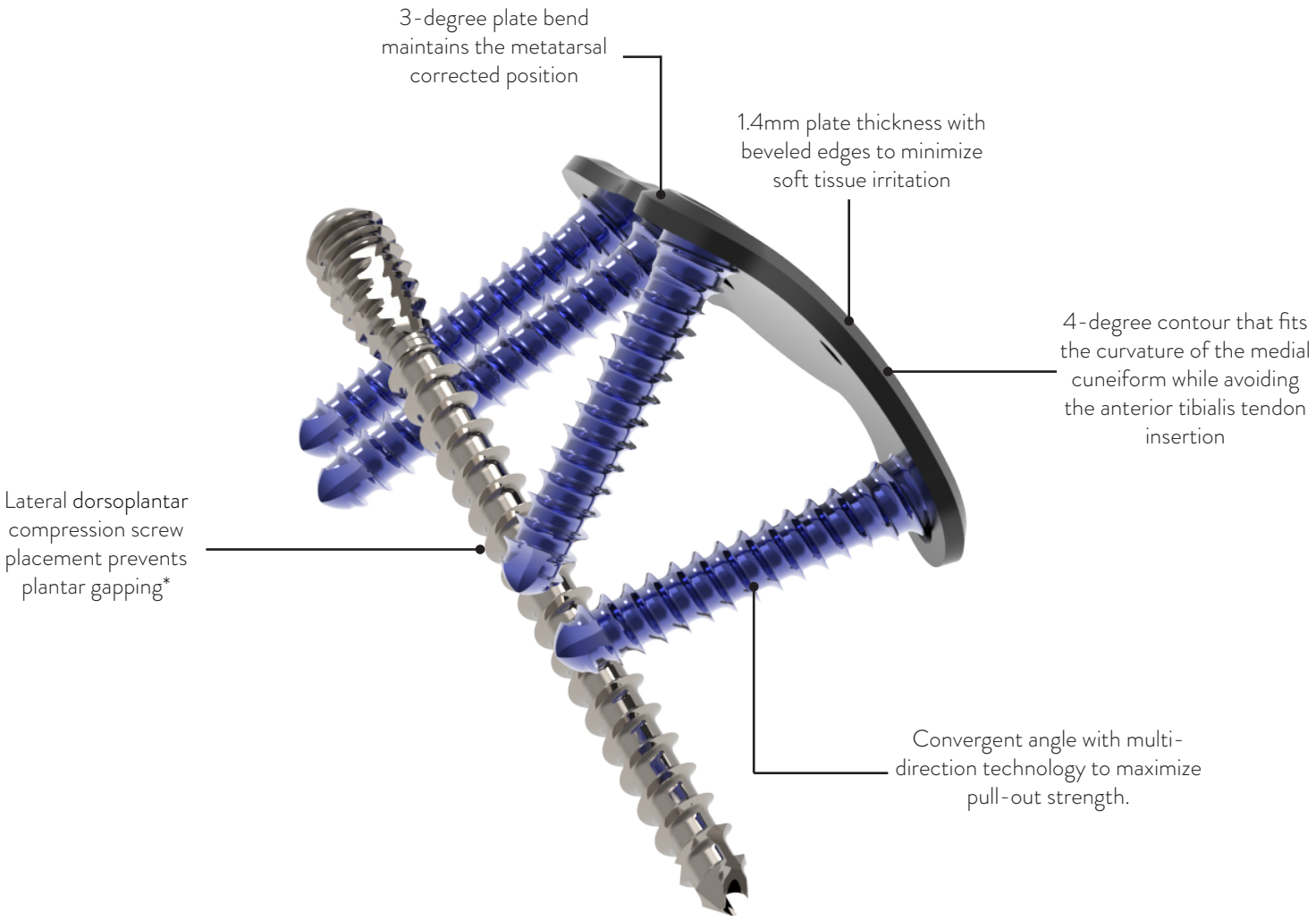
Implant Specifications

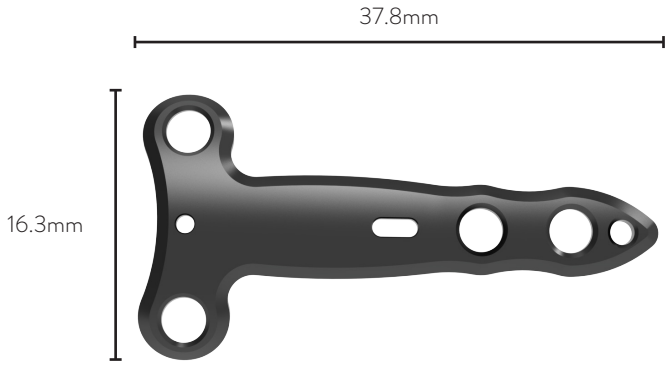
The BPPS Foot Plating System offers a low-profile Medial TMT-1 Plate for the fusion of the first tarsometatarsal joint.

The Medial TMT-1 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.



Implant Specifications





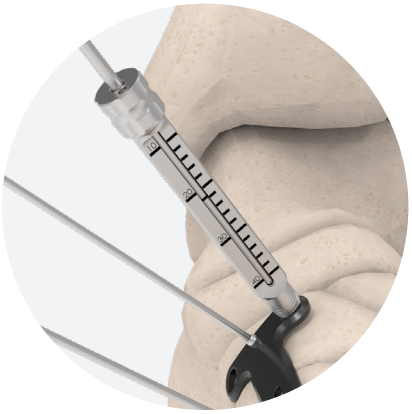
*Note: Use of a compression screw is recommended but is not required.

Instrument Specifications

Drill Guides

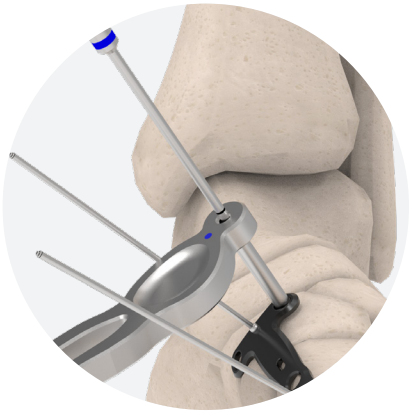
The BPPS Foot Plating System offers three standard drill guide types: locking drill guides, MVA drill guides and double drill guides. Each drill guide features color coded dots that coordinate with the drill and screw color.

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

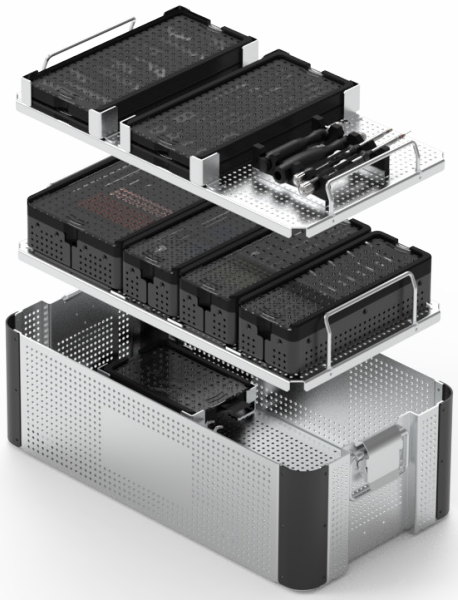


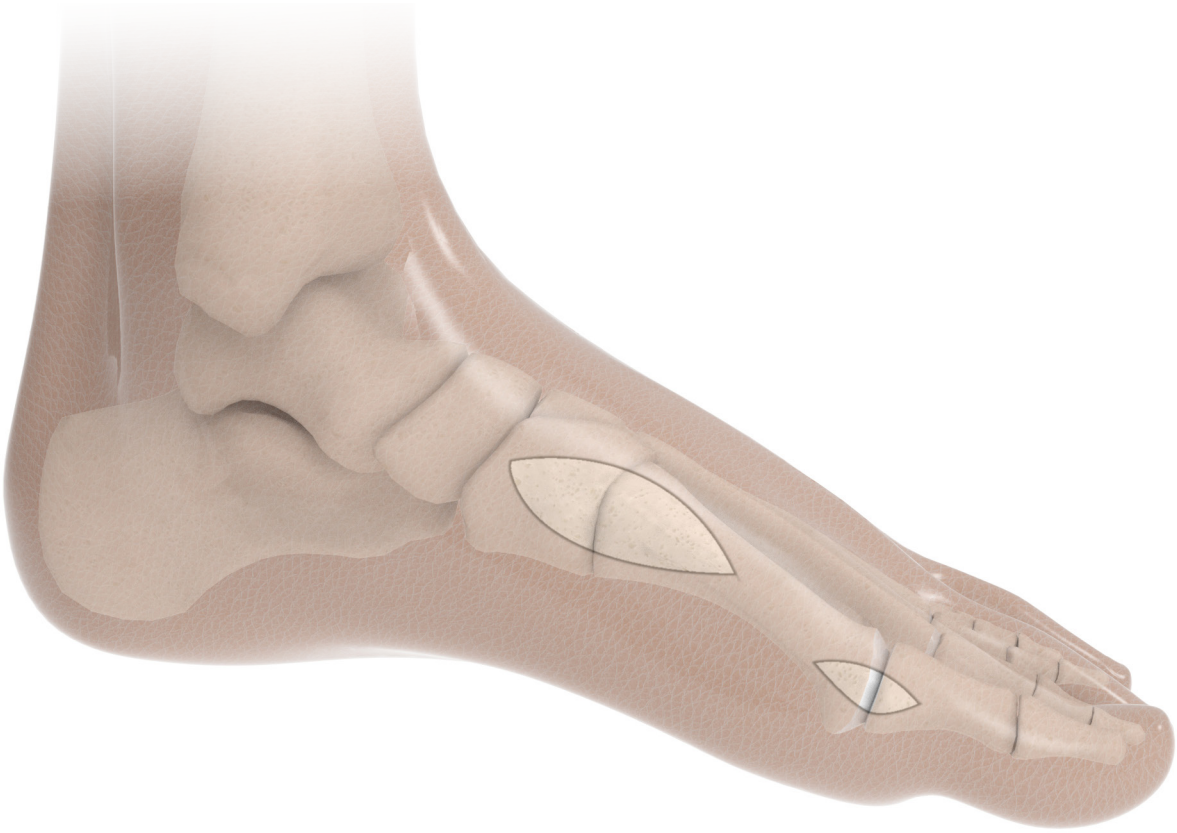
Double Drill Guide

Instrument Specifications

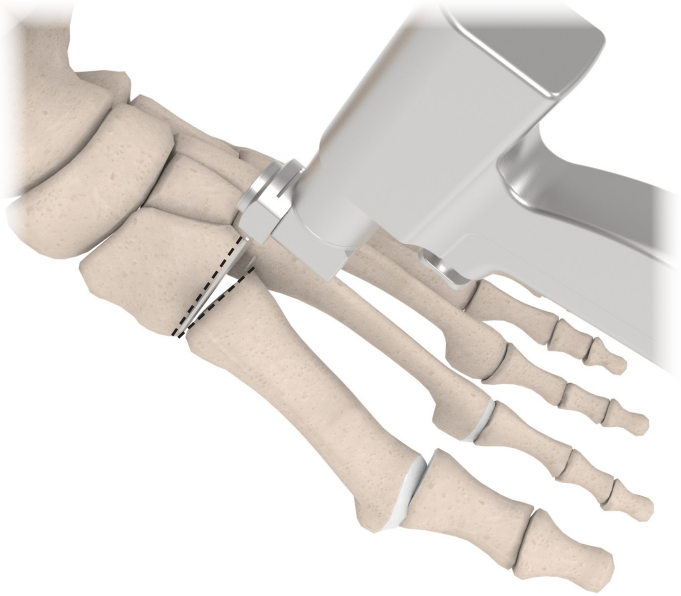
The Medial TMT-1 Fusion Plate technique requires the following modules from the BPSS Foot Plating System:

- 2.8 Plate Module
- 2.8 Screw Module

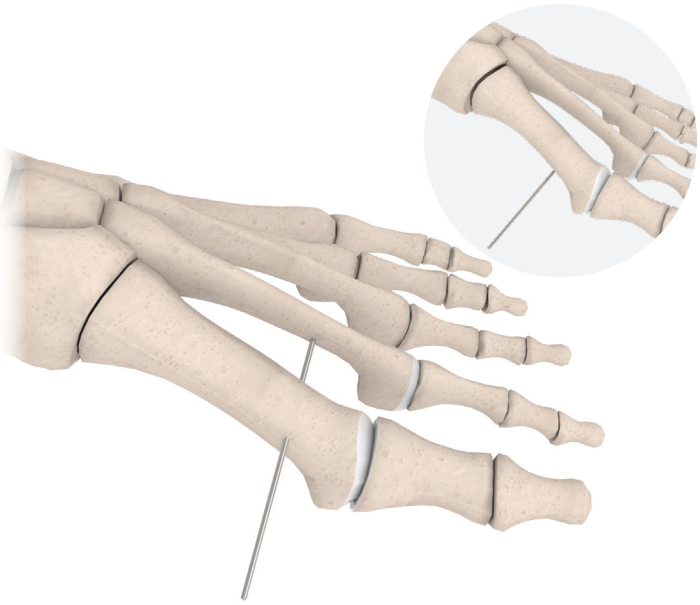




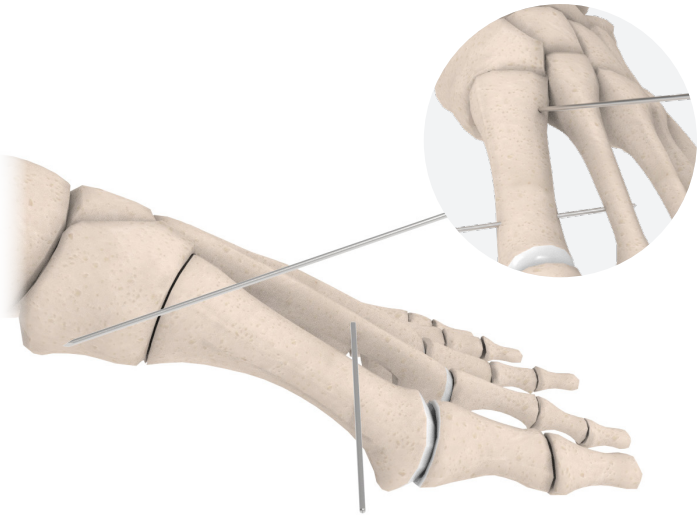
Step One:
A dorsomedial or medial longitudinal incision is centered over the first TMT joint. The joint is exposed through a vertical incision of the medial capsule. A second medial incision to expose the first MTP joint for resection of the medial exostosis and lateral release should be performed. Alternatively,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



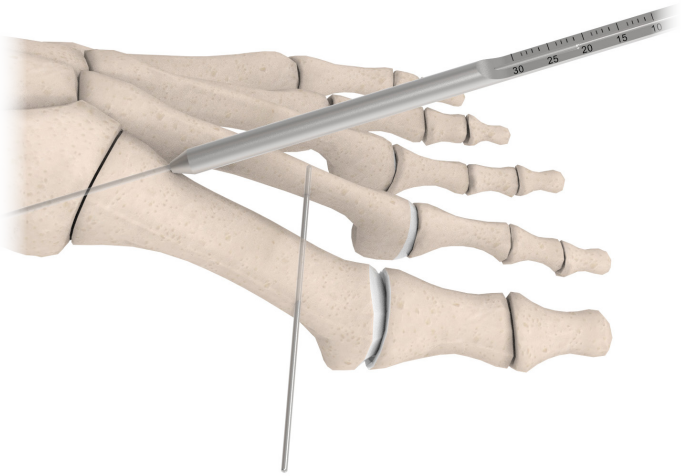
Step Two:
A resection is performed on the first metatarsal articular surface parallel to the base, only removing the cartilage. Then a resection is made on the medial cuneiform perpendicular to the second metatarsal creating a lateral wedge. Subchondral drilling may then be performed. Alternatively,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



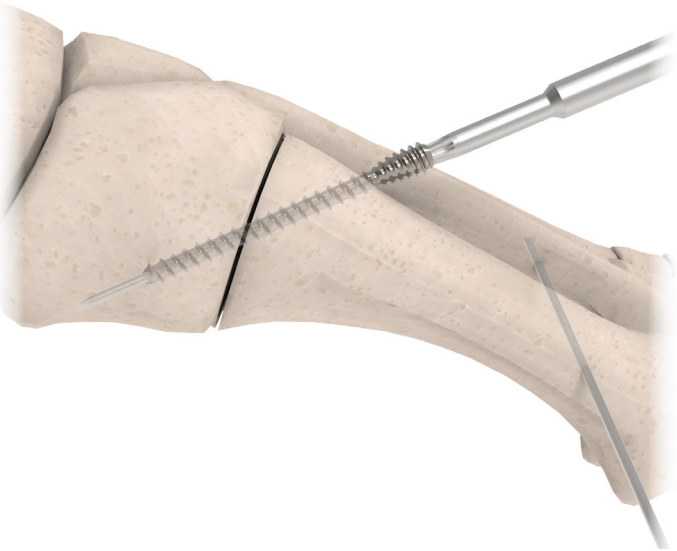
Step Three:
Realign the first metatarsal and secure in all three planes by passing a k-wire from the first metatarsal into the second metatarsal.



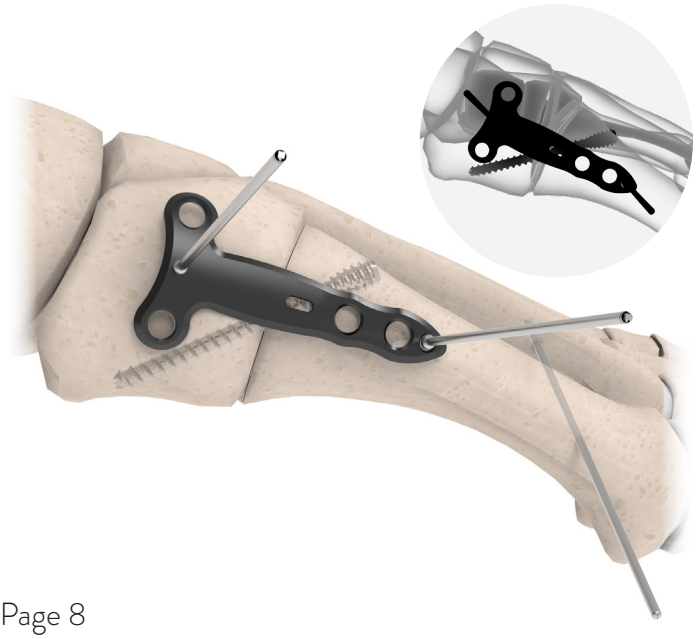
Step Four:
Insert a guide wire into the lateral aspect of the first TMT joint in a dorsoplantar direction. Proper alignment is confirmed under fluoroscopy.



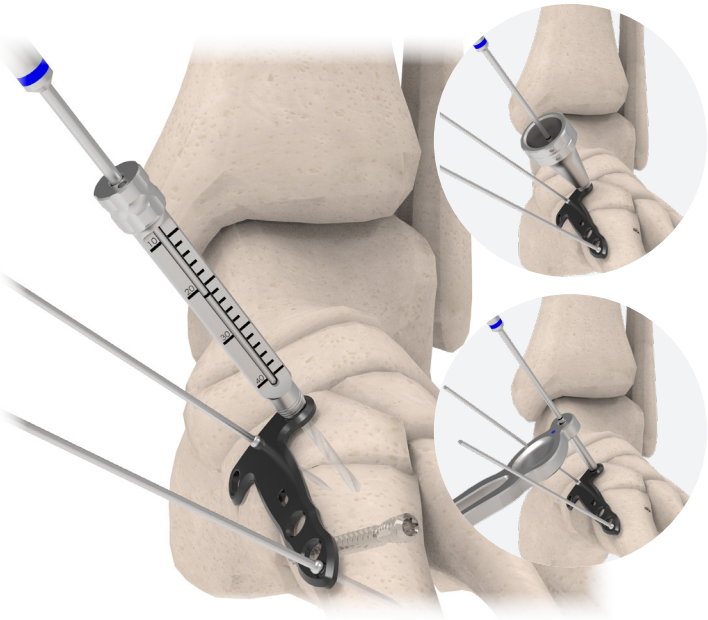
Step Five:
Insert the cannulated depth gauge over the guide wire to determine the proper screw length. A countersink or relief drill may be used to break the cortex prior to screw insertion. If using a headed screw, countersink prior to measuring.



Step Six:
A 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.



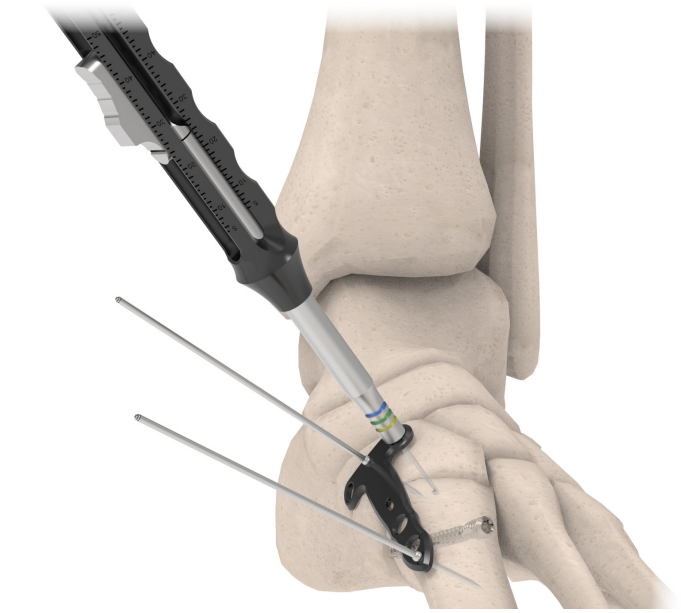
Step Seven:
Avoiding the Tibialis Anterior Tendon, place the BPSS Medial TMT-1 Fusion plate over the joint and temporarily fixate with the provided olive k-wires. Proper anatomical placement is confirmed under fluoroscopy ensuring the compression screw will not interfere with plate screw placement.



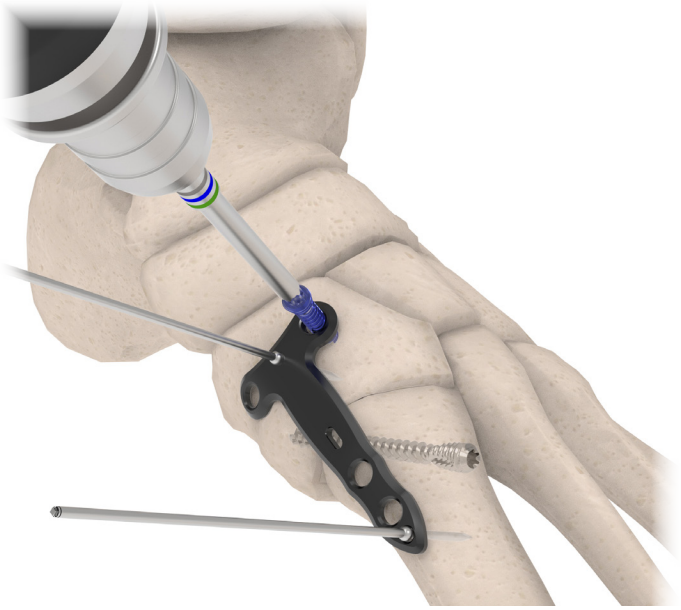
Step Eight:
Thread the 2.8mm locking drill guide into one of the screw holes. After the locking drill guide is locked in place, drill bi-cortically using the blue 2.0mm drill bit.

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

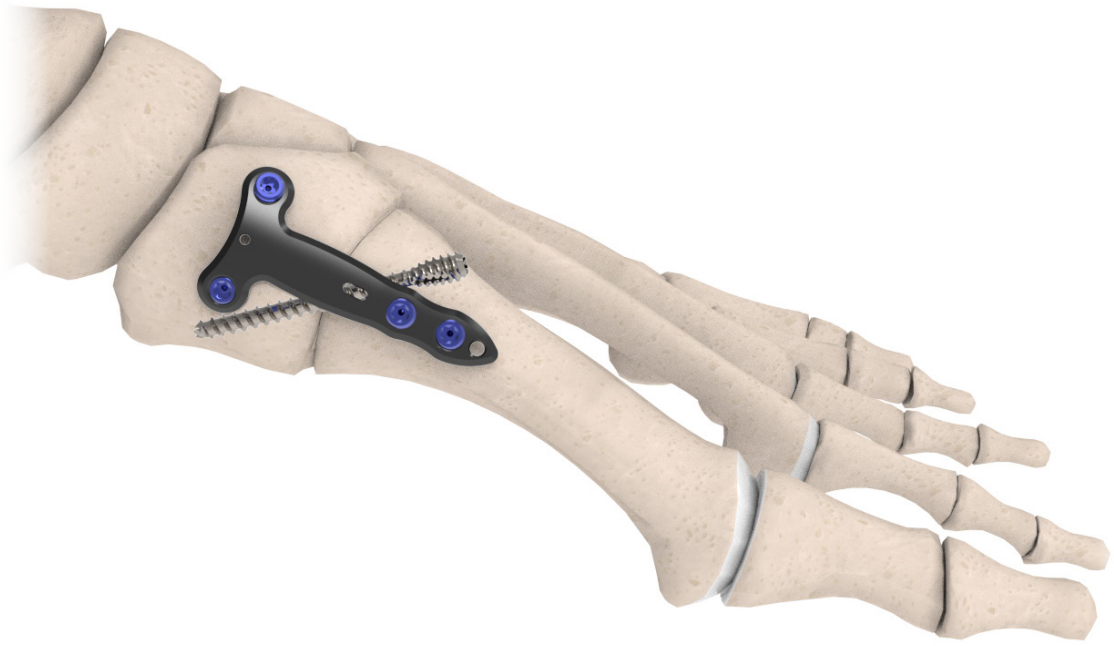
Note: If using the locking drill guide, the appropriate screw length can be determined through the measuring windows in the locking drill guide.



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.

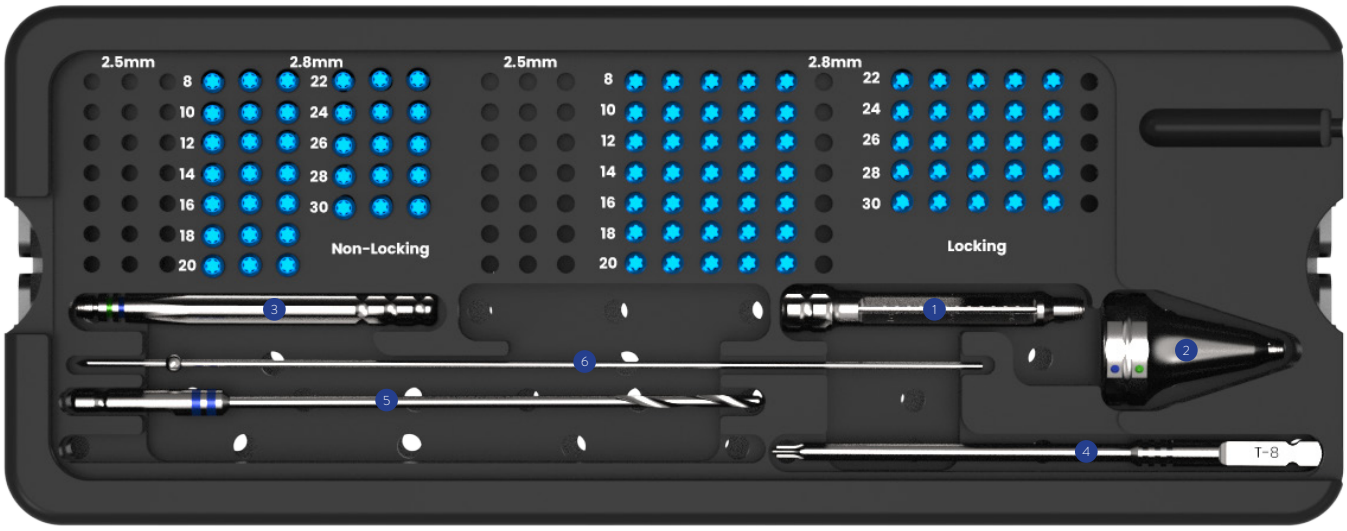


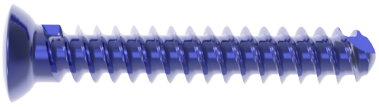
Step Eleven:
Repeat the drilling and measuring steps to fill the remaining screw holes and then remove all temporary fixation. Skin closure is completed per the surgeon's preferred method.

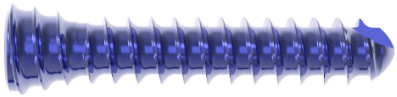
2.8 Plate Module - ONTRB-108

Item #	Description
ON-TRB-TMT	TMT Medial Reconstruction Plate

2.8 Screw Module -ONTRB-109







Item #	Description
ON-TRB-NL2812	2.8mmm x 12mm Non-Locking Screw
ON-TRB-NL2814	2.8mmm x 14mm Non-Locking Screw
ON-TRB-NL2816	2.8mmm x 16mm Non-Locking Screw
ON-TRB-NL2818	2.8mmm x 18mm Non-Locking Screw
ON-TRB-NL2820	2.8mmm x 20mm Non-Locking Screw
ON-TRB-NL2822	2.8mmm x 22mm Non-Locking Screw

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ON-TRB-L2812	2.8mmm x 12mm Locking Screw
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ON-TRB-L2818	2.8mmm x 18mm Locking Screw
ON-TRB-L2820	2.8mmm x 20mm Locking Screw
ON-TRB-L2822	2.8mmm x 22mm Locking Screw

Item #	Description
ONTRB-104	Locking Drill Guide

Item #	Description
ONTRB-103	MVA Drill Guide

Item #	Description
ONTRB-101	Holding Pin

Item #	Description
ONTRB-102	T8 Driver

Item #	Description
ON-TRB-DR20	2.0mm Drill

Item #	Description
ON-TRB-K12	1.2mm Olive Kwire

Item #	Description
ONTRB-105	Depth Gauge
ONTRB-106	2.8/3,0 Double Drill Guide

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