

Treace Medical Concepts Implant Fixation System-Plating System Surgical Technique

- Lapidus, Lesser TMT, and 1st MTP Fusion
- Distal Osteotomy

Lapidus Fusion

The Treace Medical Concepts (TMC) Implant Fixation System - Plating System is composed of a variety of plate designs and screw sizes. The correct plate and screw selection for the procedure is extremely important, and preoperative consideration of the proper fixation option will increase the potential for surgical success.

Surgical Approach

1. Perform a longitudinal incision dorsally over the 1st metatarsocuneiform (TMT) joint medial to the extensor hallucis longus. Release the plantar ligaments with an osteotome to allow for mobilization of the metatarsal. Make frontal (rotation), sagittal, and transverse plane adjustments to position the metatarsal in corrected alignment. Use a k-wire placed from the 1st metatarsal through the 2nd metatarsal to temporarily hold the correction in place. With a sagittal saw, remove the cartilage and small amount of subchondral bone from the base of the metatarsal and remove the excised material. Using the saw, make a cut to the face of the cuneiform and remove cut cartilage/bone fragment. Use the 2mm drill to expose bleeding bone on both cut surfaces to maximize fusion potential.

Note: Autograft or allograft may be utilized as needed to enhance fusion potential.

Provisional Fixation and Compression of the TMT Joint

- 2. Provisionally fixate and pre-compress the 1st metatarsal and cuneiform bones together in proper alignment using 2mm threaded olive wire(s) (40mm sub-olive length) and/or straight k-wire(s) as surgeon desires. Olive wires should be placed distal-dorsal to proximal plantar across the joint.
- 3. Select the TMC 4-hole curved plate or TMC 4-hole anatomic plate for the Lapidus fusion procedure that meets the specific needs associated with the patient's anatomy and surgical goals. Inspect the plate to ensure all four pre-installed drill guides are fully installed.
 - Note: One of the TMC 4-hole anatomic plates contain blue drill guides and the other contains gold drill guides. Reference the contents card found within the packaging carton to determine the appropriate plate and orientation for the procedure.
- 4. If bending of the plate is required to match the bony anatomy, insert the bending devices into the preassembled drill guides on the plate and make contour adjustments to the plate prior to fixating the plate to the bone.

Caution: Bending should only be performed with the bending devices inserted into drill guides installed on the plate. Do not bend the plate without all the drill guides installed.

Caution: Each bend should be in one direction only; reverse or repeated bending may weaken or cause the plate to break.

Caution: TMC plates are not designed to be cut.

5. Apply plate to bone surface dorsally or dorsal-medially in such a way that the solid mid-section of the plate spans the fusion site, ensuring that there is adequate room for two screws to be placed on either side of the fusion.

Provisional Plate Fixation

Note: Provisional fixation with short olive wires through the drill guides may be used to both stabilize the plate on the bone and to predict locking screw trajectory on fluoroscopy. If trajectory is deemed unacceptable, the surgeon may remove the plate and either reposition, and/or re-bend the plate to adjust final screw trajectory.

6. Using the olive wire with drill tip, drill through the drill guide/plate construct to desired depth for the hole located on the cuneiform side. Now remove the drill guide assembly with driver or hex feature on plate bender and remove the guide assembly from surgical site.

Note: To facilitate screw insertion, make multiple passes with the drill.

Note: The 1.3/1.6 square driver is for use with the Lapiplasty® System and the non-cannulated hexalobular #8 driver is for use with the Lapiplasty® System 1, Lapiplasty® System 2, Lapiplasty® System 3^R, Lapiplasty® System 4^A, Lapiplasty® Mini-Incision™ System, and Lapiplasty® Select.

Screw Insertion

7. Using hand pressure, manually insert the appropriate locking screw head into the driver tip securely to provide solid retention of the screw on the driver tip.

Note: If using the Lapiplasty® System 1, Lapiplasty® System 2, Lapiplasty® System 3^R, Lapiplasty® System 4^A, Lapiplasty® Mini-Incision™ System, or the Lapiplasty® Select, the TMC 2.7mm Long Screw Pack, TMC 3.0mm Long Screw Pack, or FastPitch™ High Pitch Locking Screws can be used for fixation as deemed necessary by the surgeon.

8. Insert the screw centered vertically into the plate hole that has just been drilled per step #6 until the tip of the screw engages the pre-drilled path in the underlying bone. Advance the screw into the plate to the point where locking threads under the head of the screw engage into the receiving threads in the plate. Continue advancing the screw into the bone until a firm stop is achieved signifying the complete lock of the screw head into the plate. When properly installed, the head of the screw should sit flush with the top surface of the plate.

Caution: Use care to not cross threads while inserting the screw head into the plate.

Caution: Use care to not over-tighten once the screw head locks into the plate, as this can result in stripping of the screw head or deforming the driver tip.

- 9. Insert the appropriate locking screw into the metatarsal-side hole following steps 6-8.
- 10. Remove the short olive wires used for provisional fixation of the plate to the bone and insert the appropriate, screws into the remaining metatarsal and cuneiform holes following steps 6-8.

Caution: Be sure to remove all drill guides from the surgical site prior to closing.

11. A second plate may be used in the procedure as deemed necessary by the surgeon. Select the appropriate TMC 4-hole curved plate, TMC 4-hole anatomic plate, MIS Plate (PlantarPower™ Plate), or the Plantar Python® 2 Plate for the appropriate surgical side. In the Lapidus fusion procedure, it would be advised to place the second plate at approximately a 90-degree circumferential offset (medial or medial-plantar position) to the first dorsally-located plate. Install second plate following same steps as described for the first plate. Care should be taken to avoid extensive dissection or periosteal stripping if using a second plate.

Note: The blue-colored drill guide on the Plantar Python® 2 Plate indicates the proximal end of the plate.

Lesser TMT Fusion

The Treace Medical Concepts (TMC) Implant Fixation System - Plating System is composed of a variety of plate designs and screw sizes. The correct plate and screw selection for the procedure is extremely important, and preoperative consideration of the proper fixation option will increase the potential for surgical success.

Surgical Approach and Joint Preparation

1. Perform a longitudinal dorsal incision over the selected lesser tarsometatarsal (TMT) joint. Expose the joint and use a sagittal saw to remove the articular cartilage from the joint surfaces. Use the 2mm drill to expose bleeding bone on both cut surfaces to maximize fusion potential.

Note: Autograft or allograft may be utilized as needed to enhance fusion potential.

Provisional Fixation and Compression of the TMT Joint

- 2. Provisionally fixate and pre-compress the metatarsal and cuneiform bones together in proper alignment using 2mm threaded olive wire(s) (40mm sub-olive length) and/or straight k-wire(s) as surgeon desires.
- 3. Select the TMC 4-hole curved plate for the TMT fusion procedure that meets the specific needs associated with the patient's anatomy and surgical goals. Inspect the plate to ensure all four preinstalled drill guides are fully installed.
- 4. If bending of the plate is required to match the bony anatomy, insert the bending devices into the preassembled drill guides on the plate and make contour adjustments to the plate prior to fixating the plate to the bone.

Caution: Bending should only be performed with the bending devices inserted into drill guides installed on the plate. Do not bend the plate without all the drill guides installed.

Caution: Each bend should be in one direction only; reverse or repeated bending may weaken or cause the plate to break.

Caution: TMC plates are not designed to be cut.

5. Apply plate to bone surface dorsally in such a way that the solid mid-section of the plate spans the fusion site, ensuring that there is adequate room for two screws to be placed on either side of the fusion.

Provisional Plate Fixation

Note: Provisional fixation with short olive wires through the drill guides may be used to both stabilize the plate on the bone and to predict locking screw trajectory on fluoroscopy. If trajectory is deemed unacceptable, the surgeon may remove the plate and either reposition, and/or re-bend the plate to adjust final screw trajectory.

6. Using the olive wire with drill tip, drill through the drill guide/plate construct to desired depth for the hole located on the cuneiform side. Now remove the drill guide assembly with driver or hex feature on plate bender and remove the guide assembly from surgical site.

Note: To facilitate screw insertion, make multiple passes with the drill.

Note: The 1.3/1.6 square driver is for use with the Lapiplasty® System and the non-cannulated hexalobular #8 driver is for use with the Lapiplasty® System 1, Lapiplasty® System 2, Lapiplasty® System 3^R, Lapiplasty® Select, and Lesser TMT Fixation Pack.

Screw Insertion

7. Using hand pressure, manually insert the appropriate locking screw head into the driver tip securely to provide solid retention of the screw on the driver tip.

Note: The Lesser TMT Fixation Pack includes 2.7x14mm and 2.7x18mm locking screw. Additionally, the TMC 2.7mm Long Screw Pack, TMC 3.0mm Long Screw Pack, or FastPitch™ High Pitch Locking Screws can be used for fixation as deemed necessary by the surgeon.

8. Insert the screw centered vertically into the plate hole that has just been drilled per step #6 until the tip of the screw engages the pre-drilled path in the underlying bone. Advance the screw into the plate to the point where locking threads under the head of the screw engage into the receiving threads in the plate. Continue advancing the screw into the bone until a firm stop is achieved signifying the complete lock of the screw head into the plate. When properly installed, the head of the screw should sit flush with the top surface of the plate.

Caution: Use care to not cross threads while inserting the screw head into the plate.

Caution: Use care to not over-tighten once the screw head locks into the plate, as this can result in stripping of the screw head or deforming the driver tip.

- 9. Insert the appropriate locking screw into the metatarsal-side hole following steps 6-8.
- 10. Remove the short olive wires used for provisional fixation of the plate to the bone and insert the appropriate screws into the remaining metatarsal and cuneiform holes following steps 6-8.

Caution: Be sure to remove all drill guides from the surgical site prior to closing.

1st Metatarsophalangeal (MTP) Fusion

The Treace Medical Concepts (TMC) Implant Fixation System - Plating System is composed of a variety of plate designs and screw sizes. The correct plate and screw selection for the procedure is extremely important, and preoperative consideration of the proper fixation option will increase the potential for surgical success.

Surgical Approach

1. Perform a longitudinal incision beginning just proximal to the interphalangeal joint and extending over the 1st MTP joint medial to the extensor hallucis longus. Expose the proximal phalanx and metatarsal head and release the sesamoids. Denude all cartilage surfaces with a rongeur or using your preferred method until bleeding subchondral bone is exposed.

Following joint preparation, provisionally fixate the joint at the desired angle with straight k-wire(s) and/or a 2mm threaded olive (40mm sub-olive length).

Plate placement

- 2. Select the TMC 4-hole curved plate for the MTP fusion procedure that meets the specific needs associated with the patient's anatomy and surgical goals. Inspect the plate to ensure that all four preinstalled drill guides are fully installed.
- 3. If bending of the plate is required to match the bony anatomy, insert bending devices into the preassembled drill guides on the plate and make adjustments to the plate prior to fixating the plate to the bone.

Caution: Bending should only be performed with the bending devices inserted into drill guides installed on the plate. Do not bend the plate without all the drill guides installed.

Caution: Each bend should be in one direction only; reverse or repeated bending may weaken the plate or cause the plate to break.

Caution: TMC plates are not designed to be cut.

4. Apply the plate to the bone surface dorsal-laterally in such a way that the solid mid-section of the plate spans the fusion site, ensuring that there is adequate room for two screws to be placed on either side of the fusion.

Provisional Plate Fixation

Note: Provisional fixation with short olive wires through the drill guides may be used to both stabilize the plate on the bone and to predict locking screw trajectory on fluoroscopy. If the trajectory is deemed unacceptable, the surgeon may remove the plate and either reposition, and/or re-bend the plate to adjust the trajectory.

5. Using the olive wire with drill tip, drill through the drill guide/plate construct to the desired depth for the hole located on the metatarsal side. Now remove the drill guide assembly with the driver or hex feature on plate bender and remove the guide assembly from the surgical site.

Note: To facilitate screw insertion, make multiple passes with the drill.

Note: The 1.3/1.6 square driver is for use with the Lapiplasty® System and the non-cannulated hexalobular #8 driver is for use with the Lapiplasty® System 1, Lapiplasty® System 2, Lapiplasty® System 3^R, and Lapiplasty® Select.

Screw Insertion

6. Using hand pressure, manually insert the appropriate locking screw head into the driver tip securely to provide solid retention of the screw on the driver tip.

Note: If using the Lapiplasty® System 1, Lapiplasty® System 2, Lapiplasty® System 3^R, or Lapiplasty® Select, the TMC 2.7mm Long Screw Pack, TMC 3.0mm Long Screw Pack, or FastPitch™ High Pitch Locking Screws can be used for fixation as deemed necessary by the surgeon.

7. Insert the screw centered vertically into the most proximal metatarsal plate hole (that has just been drilled per step #5) until the tip of the screw engages the pre-drilled path in the underlying bone. Advance the screw into the plate to the point where the locking threads under the head of the screw engage into the receiving threads in the plate. Continue advancing the screw into the bone until a firm stop is achieved signifying the complete lock of the screw head into the plate. When properly installed, the head of the screw should sit flush with the top surface of the plate.

Caution: Use care to not cross threads while inserting the screw head into the plate.

Caution: Use care to not over-tighten once the screw head locks into the plate, as this can result in stripping of the screw head or deforming the driver tip.

- 8. Insert the appropriate locking screw into the phalanx-side hole following steps 5-7.
- 9. Remove the short olive wires used for provisional fixation of the plate to the bone and insert the appropriate locking screws into the remaining phalanx and metatarsal holes following steps 5-7.

Caution: Be sure to remove all drill guides from the surgical site prior to closing.

10. Since two TMC 4-hole curved plates are available in the kit, a second plate may be used in the procedure as deemed necessary by the surgeon. In the MTP fusion procedure, it would be advised to place the second plate at approximately a 90-degree circumferential offset (dorsal-medial position) to the initial dorsal-lateral positioned plate. Install the second plate following the same steps as described for the first plate. Care should be taken to avoid extensive dissection or periosteal stripping if using a second plate.

1st Metatarsal Distal Osteotomy

The Treace Medical Concepts (TMC) Implant Fixation System - Plating System is composed of a variety of plate designs and screw sizes. The correct plate and screw selection for the procedure is extremely important, and preoperative consideration of the proper fixation option will increase the potential for surgical success.

Implant Assembly

Attach the implant to the Inserter instrument.

Surgical Approach

- 1. Insert a K-wire into the medial aspect of the 1st metatarsal neck. Confirm the osteotomy trajectory on fluoroscopy. Mark and perform a longitudinal incision (approximately 1.5-2cm) spanning each side of the K-wire.
- 2. Remove the K-wire and use a cutting device to perform a complete osteotomy through the 1st metatarsal. Under fluoroscopy confirm mobilization of the capital fragment.

Plate Placement

3. Select the appropriate intramedullary implant for the 1st metatarsal osteotomy procedure that meets the specific needs associated with the patient's anatomy and surgical goals.

Caution: TMC intramedullary implants are not designed to be cut or bent.

4. Insert the implant into the 1st metatarsal medullary canal, ensuring the Inserter instrument is fully seated, and confirm the implant position on fluoroscopy. Using the Positioner Cup adjust the position of the implant as needed. Use a K-wire to temporarily hold the correction in place.

Caution: Avoid excessive force or impaction when inserting the implant into the intramedullary canal.

Correction

- 5. Using the Inserter instrument, make desired transverse plane adjustments to position the metatarsal head in corrected alignment. Use a Tail Tack through the inserter or proximal hole of the Bicortical Screw Drill Guide to temporarily hold the correction in place.
- 6. To gain desired frontal and sagittal plane rotation correction use the Rotation Guide on the Inserter instrument, or other preferred method. Use K-wires to temporarily hold the correction in place.

Screw Insertion

- 7. Attach the Drill Guide onto the Inserter instrument. Drill through the dorsal Drill Guide hole. Drill through the plantar Drill Guide hole and leave the drill in place.
- 8. Using hand pressure, manually insert the appropriate size locking screw head onto the driver tip securely to provide solid retention of the screw on the non-cannulated hexalobular #8 driver tip.
- 9. Insert the locking screw into the dorsal hole and advance the screw into the plate to the point where the locking threads under the head of the screw engage into the receiving threads in the plate.
- 10. Remove the plantar drill and insert the appropriate size locking screw into the plantar hole and advance the screw until a firm stop is achieved signifying the complete lock of the screw head into the plate. When properly installed, the head of the screw should sit flush with the top surface of the plate. Confirm tightness of the dorsal locking screw after locking the plantar screw. Remove the Drill Guide.
- 11. Select only a single angled locking screw hole (proximal or distal) that ensures adequate fixation and bone bridge. Drill through the selected drill hole on the Inserter instrument. Insert the appropriate size locking screw and advance until the screw locks into the plate.
 - Caution: To ensure adequate bone bridge, avoid drilling and inserting a locking screw in both the angled locking screw holes.
- 12. If two bicortical screws are desired, use the second Tail Tack through the distal hole of the Bicortical Screw Drill Guide. Select the appropriate cannulated screw length and advance the screw through the Tail Tack hole on the Bicortical Screw Drill Guide to the desired length using a cannulated hexalobular #8 driver. A guidewire may be used to place the screw. Under fluoroscopy, confirm the head of the screw is fully seated in the medial cortex. Remove guidewire, if used.
- 13. Remove the proximal Tail Tack. Select the appropriate cannulated screw length and advance the screw through the Tail Tack hole to the desired depth using a cannulated hexalobular #8 driver. A guidewire may be used to place the screw. Under fluoroscopy, confirm the head of the screw is fully seated in the medial cortex. Remove guidewire, if used.
- 14. Confirm all locking screws are fully seated under fluoroscopy, then remove the Inserter instrument.

Caution: Use care to not cross threads while inserting the screw head into the plate.

Caution: Use care to not overtighten once the screw head locks into the plate, as this can result in stripping of the screw head or deforming the driver tip.

Caution: Be sure to remove all drill guides from the surgical site prior to closing.

Medial Spike Removal

15. Using a desired instrument, remove the remaining medial prominence.

Implant Removal

- 16. To remove the implant, engage the screws with the non-cannulated hexalobular #8 driver and remove them from the implant.
- 17. After screw removal, the implant may be removed by pulling it distally out of the medullary canal.

