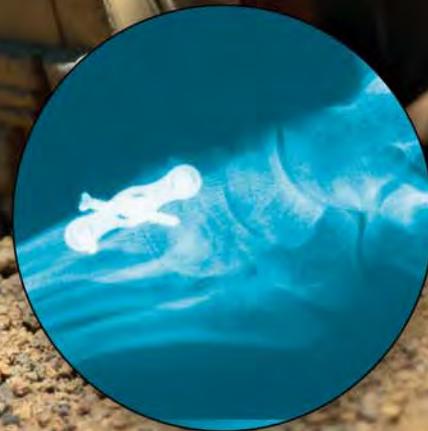
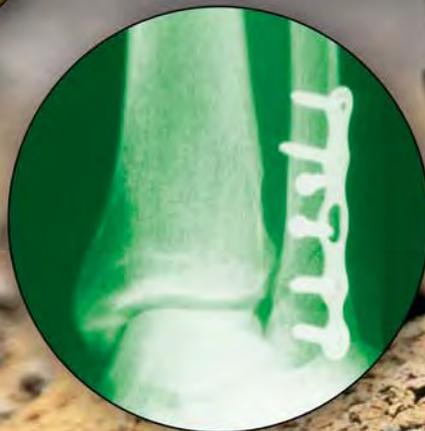


A&U MED[®]



LOWER EXTREMITY
CONGRUENT PLATING SYSTEM

FOOT AND ANKLE PLATES

Since 1988, Acumed has been designing solutions to the demanding situations facing orthopedic surgeons, hospitals and their patients. Our strategy has been to know the indication, design a solution to fit, and deliver quality products and instruments. The Lower Extremity Congruent Plating System exemplifies this philosophy.

Designed to address both fractures and reconstruction of the foot and ankle, the Lower Extremity Congruent Plating System offers indication specific plates that restore the anatomic geometry of the forefoot, midfoot, hindfoot and ankle enabling an early return to normal activities for the patient.

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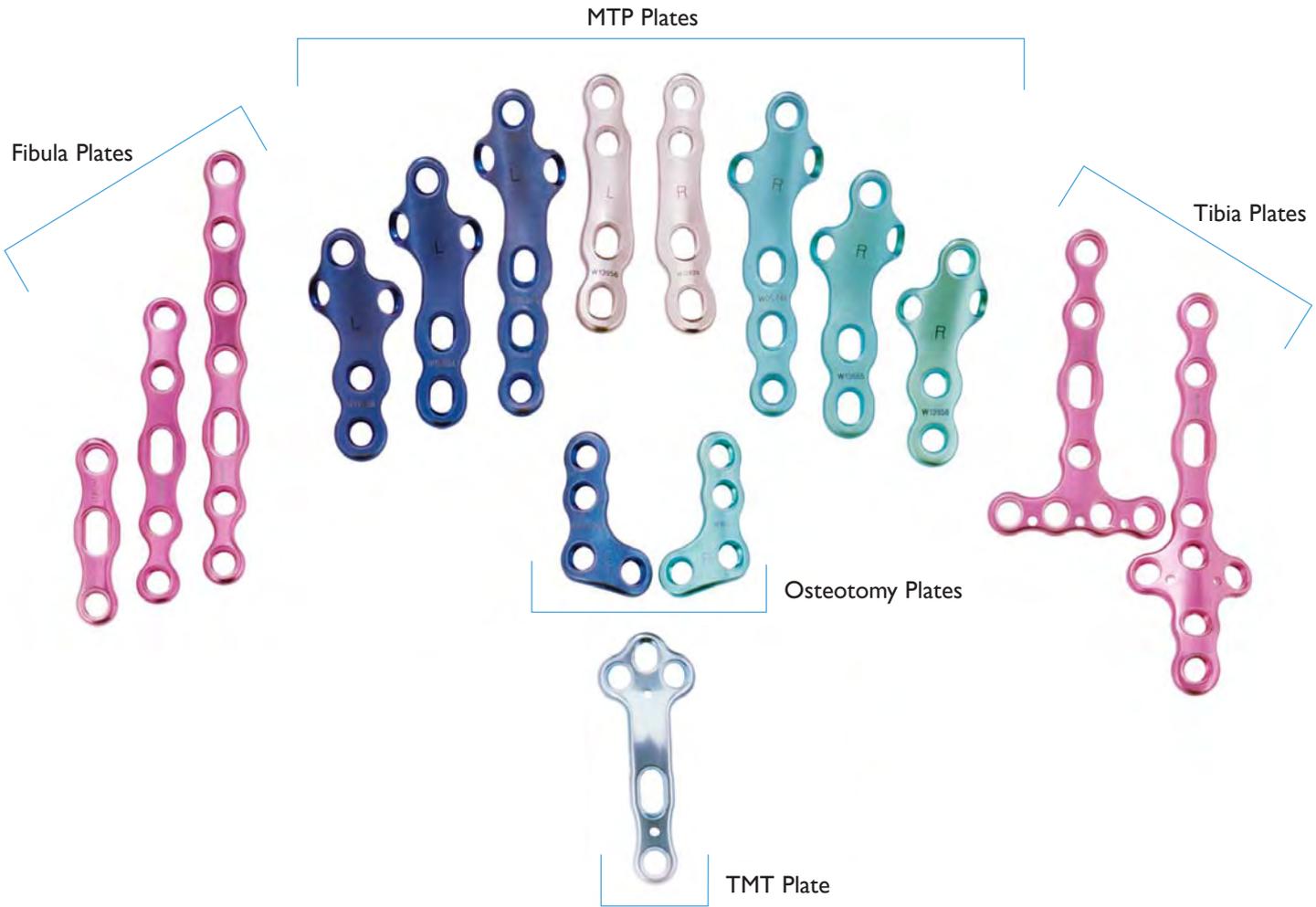
The Lower Extremity Congruent Plating System is designed to offer surgeons a single comprehensive, yet compact, system for foot and ankle surgery. The titanium plates in the system provide stability to allow for early patient rehabilitation after surgery, and the modular system works with the OR staff to improve the surgical experience. The system is the result of years of collaboration with foot and ankle surgeons across the globe.

To offer a full solution for the foot and ankle surgeon, Acumed designed the tray in four levels.

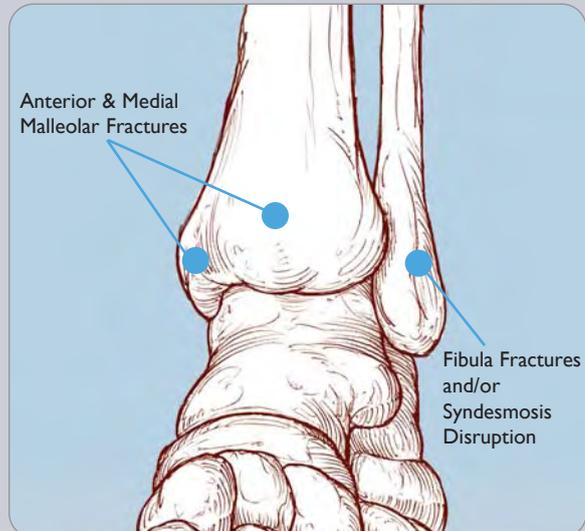
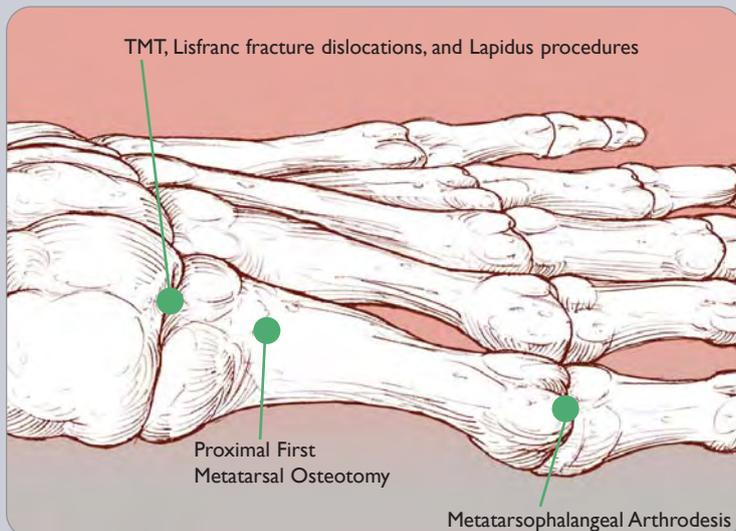
- Anatomically Precontoured Plates
- Soft Tissue Retractors, Clamps, and Instruments
- Implant Instrumentation
- Screw and Pin Fixation

Working with surgeons, Acumed designed this system to simplify and improve the treatment of some of the most common, yet challenging indications in orthopedics.

Lower Extremity Congruent Plating System



The Acumed Lower Extremity Congruent Plating System offers a comprehensive solution for treating indications from the fore-foot through the hindfoot, and up into the ankle.





Acumed's Congruent Forefoot and Midfoot Plates

Working with surgeons to expand the possibilities in the fore and midfoot, Acumed has developed a set of precontoured titanium plates for some of the most common indications in the lower extremity.

MTP fusions, Proximal Osteotomies and TMT disorders are all well handled by this set. And there is room in the tray for future plates.



Compatible with the 2.7 and 3.5mm cortical, and 4.0mm cancellous screws found in the system, these plates maximize their screw fixation for each indication. With 2.5mm hex heads this system provides secure insertion and, if needed, an easy path for removal.



Congruent 1st Metatarsal Base Osteotomy Plate

Plating of the proximal metatarsal osteotomy provides significant benefits over fixing the osteotomy with either K-wires or headed screws.

Strength

Placed dorsomedial, this plate is strong enough to allow early weightbearing and an early return to normal activities.

Angle maintenance

Whether used to fix a crescentic or wedge osteotomy, the Congruent 1st Metatarsal Osteotomy Plate provides a significant barrier to post-operative shifting of the distal metatarsal angle.



Low Profile

Rounded edges and lower screw/plate interface

MTP Plates

This family includes compression, non-compression, revision, and lower profile 'wingless' plates to provide lower extremity surgeons with more options for this common arthrodesis than any other system.

Strength

All plates are strong enough to enable solid fusions and allow early weightbearing for the patient.

Precontoured MTP Angle

Precontoured with 9° of dorsiflexion and 11° of lateral rotation, these plates aid in restoring a functional angle to the metatarsophalangeal joint.

Compliments the Acumed Small Joint Reamers found in the system.



TMT Plates

Precontoured to bridge the 1st tarsometatarsal joint, these plates are effective in larpus, lisfranc dislocations and other correctional procedures.

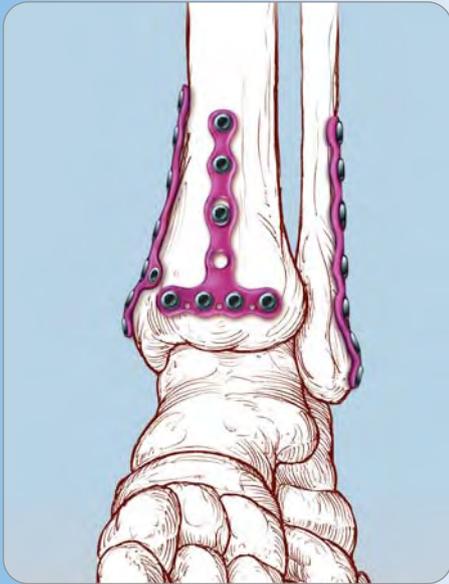
Stronger Medial Column Support

These plates work to restore the proper IM angle for the medial column and hold the correction through healing.

Strategic Screw Placement

Allowing three screw fixation in the medial cuneiform, these plates anchor the metatarsal firmly into the midfoot.





Complex ankle fractures are challenging on two fronts.

- 1. They require indication specific plates that maximize fixation in the periarticular fragments allowing a restoration of normal motion after healing.*
- 2. There is little soft tissue to cover the plates and supply the fracture with the blood it needs to heal.*

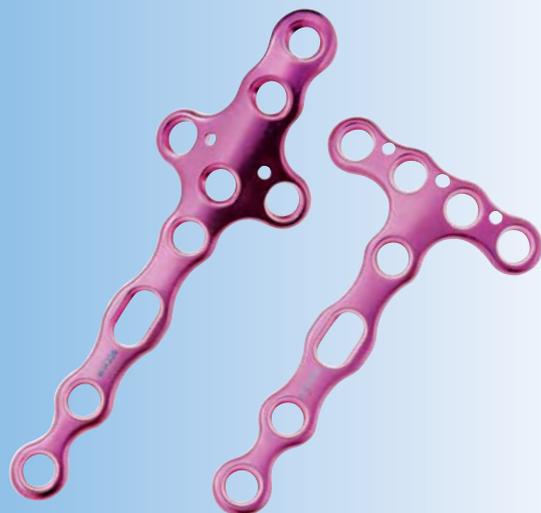
Acumed's distal tibia and fibula plates answer both challenges.



Congruent Distal Fibula Plates

Precountoured in titanium, these low profile anti-glide plates provide excellent fixation for ankle fractures with a minimal disruption to the soft tissues.

Compatible with the Acumed Syndesmosis Screw, the Congruent Fibula Plates can treat a wide range of fractures. Available in 3, 5, 7, and 11 holes.



Congruent Distal Tibia Plates

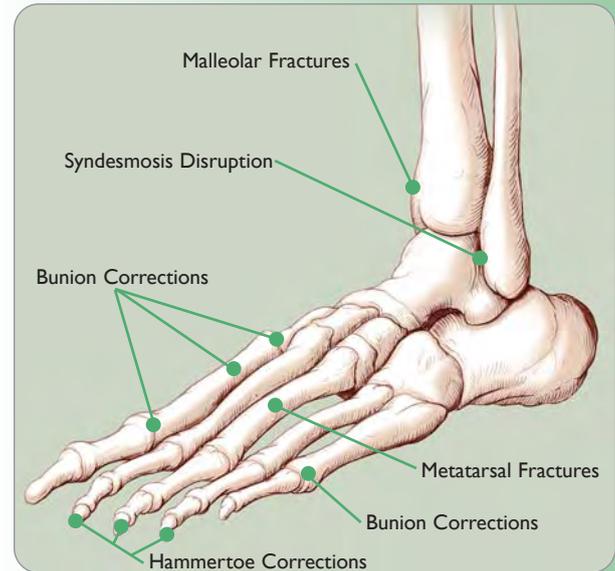
Designed to fit the anterior and medial malleolous, these two plates provide multiple options for screw placement parallel to the joint surface.

These two plates are ideal when used in conjunction with external fixation for complex pilon fractures.

SCREW / PIN FIXATION

Whether they are used in conjunction with plates or placed independently, the screws in this system provide excellent fixation, straightforward insertion techniques, and low- to no-profile heads.

All of the screws in the system are manufactured from titanium, making them fully compatible with the plates and the patient's body. Our goal is to provide fixation that does not require a second procedure for removal, thereby elevating patient care and reducing costs.



Congruent Screws

These fully-threaded titanium screws are designed with a low-profile head that interfaces with the plates in the system to minimize prominence and soft tissue irritation. 2.7 and 3.5mm cortical or 4.0mm cancellous thread are available.



AcuTwist™ Compression Pins

Using the same patented variable thread pitch as the Acutrak Screw, these snap-off pins provide good compression and 40% greater holding power* than threaded K-Wires, simple insertion, no need to remove, but a removal wrench, if needed.



Syndesmosis and Malleolar Lag Screws

These partially threaded lag screws are designed for indication specific usage. The larger 5.0mm syndesmosis screws offer excellent bite in the cancellous bone of the distal tibia, while the 4.0mm malleolar lag screws fit the need for medial or lateral fixation.



2.7, 3.5, 4.0mm Cannulated Extremity Screws

For fixation of fractures and osteotomies, these self-drilling, self-taping, cannulated screws provide excellent fixation with a simplified insertion technique. A self-contained module includes all the instrumentation needed to implant.



*Data on file at Acumed

LOWER EXTREMITY SYSTEM



Design Rationale

Lower extremity surgeons have made do with systems designed for other areas of the body for years. While their use of upper extremity, sports medicine, spine and various other tools is a testament to their creativity, it is also an indication that this area of orthopedic medicine needs, and is deserving of, more attention.

And more is what Acumed is giving.

- More focus on the distinct needs of the foot and ankle.
- More solutions that are needed for the everyday cases.
- More solutions for the unusual and challenging cases.
- More flexibility to allow the surgeon to customize the set to suit their needs.
- More instruments and tools designed for lower extremity surgeries.

In short, more dedication to the foot and ankle surgeon, the problems that they face, and the patients that they help.

Design Features and Benefits

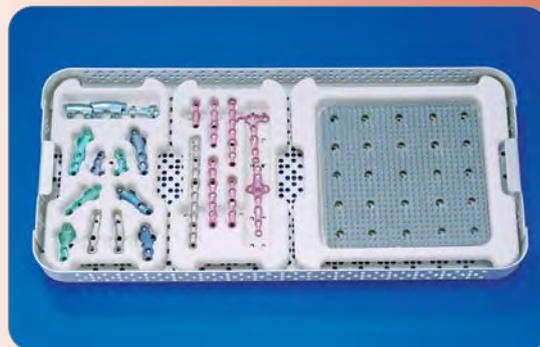
The Lower Extremity Congruent Plating System was designed in a modular fashion to allow for ease of use and customization.

With four levels - Plates, Soft Tissue Instruments, Implant Instruments, and Screw/Pin Fixation - this tray organizes its contents in a manner that works for the surgeon and the OR staff.

Future implants and instrumentation will be seamlessly integrated into this tray, extending the viability of the system and reducing hospital or surgery center costs.

Upper Tier

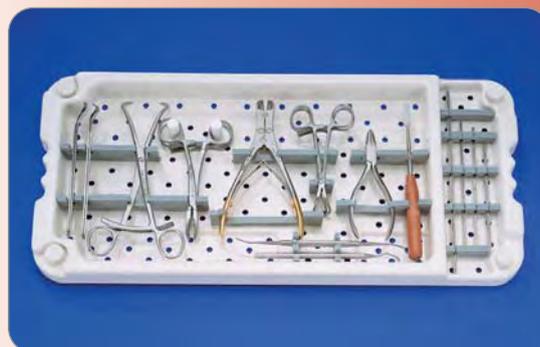
The top tray in the system contains all the congruent foot and ankle plates. Sectioned into forefoot/midfoot reconstruction, ankle trauma, and an open tray for future expansion, this tier is the heart of the system.



Second Tier

All the soft tissue instruments that are commonly needed in lower extremity procedures are housed in this tray.

Retractors, clamps, picks, elevators and more can be found here along with K-Wires.



Third Tier

The congruent plate instruments, small joint reamers, and AcuTwist Compression Pins are on this level. Drills, drill guides, depth gauge, drivers, plate benders and other instruments necessary for applying Acumed's plates are here.



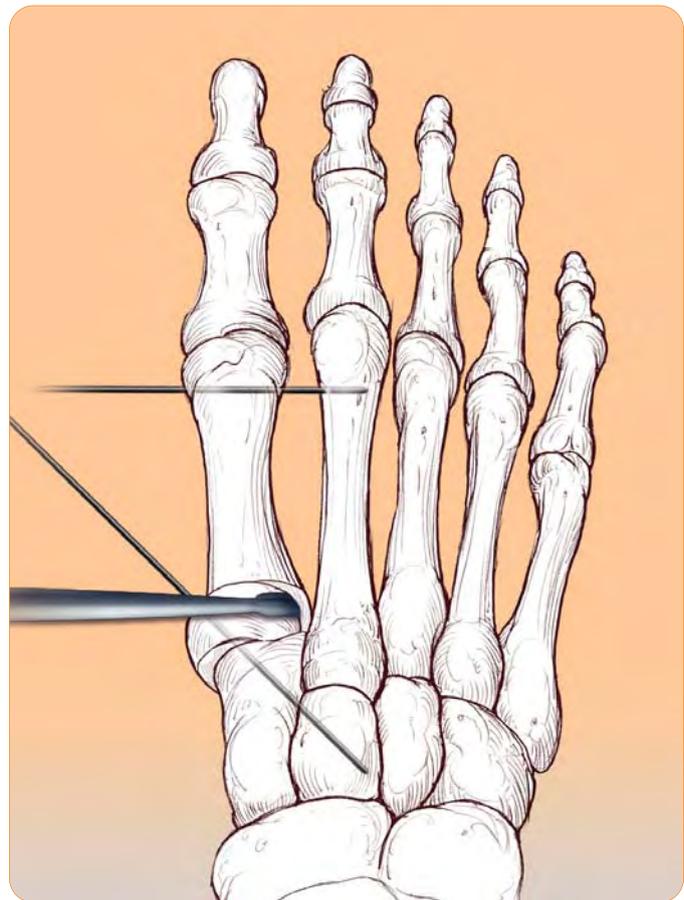
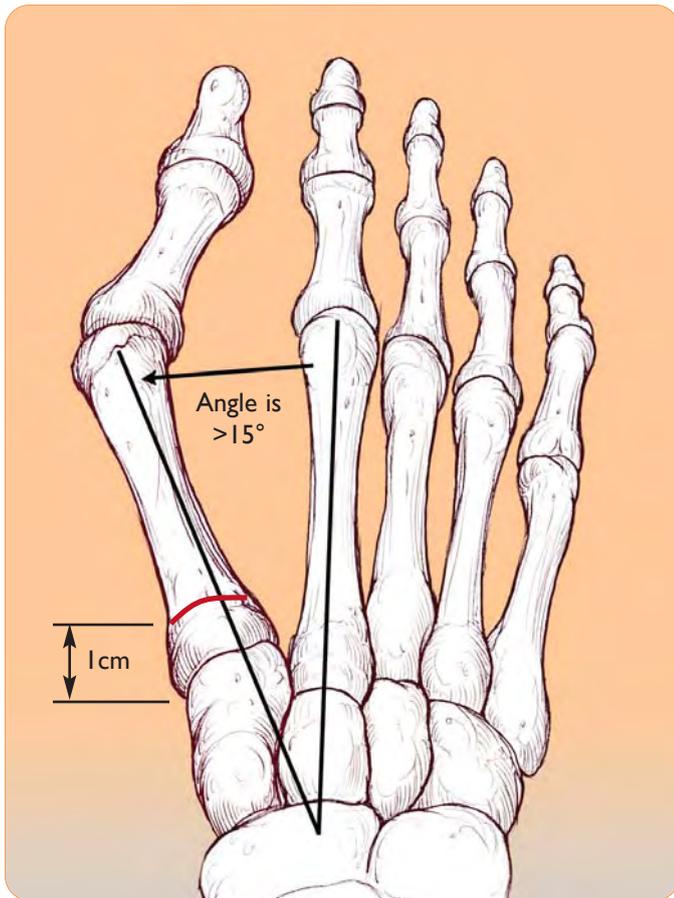
Lower Tier

Screws occupy the lower level of the tray. The 2.7, 3.5 and 4.0 mm screws for the congruent plates share their caddy with 5.0mm Syndesmosis and 4.0mm Malleolar Lag Screws. The 2.1-2.7mm cruciform screws and 2.7,3.5 and 4.0mm cannulated extremity screw sets each have their own organizer with all their instrumentation.



Osteotomy Plate - by William T. McPeake, MD

This section offers Acumed's suggested method for implanting the Osteotomy Plate from the Lower Extremity Congruent Plate System. For specific questions not addressed here, please contact your local Acumed representative or Acumed by phone at 888 627-9957 or on the web at www.acumed.net.



Hallux Valgus Correction

The proximal osteotomy of the first metatarsal is used in conjunction with a distal soft tissue correction of the hallux valgus deformity. It is usually indicated when the first metatarsal and second metatarsal angle is greater than 15° .

The patient is placed on the operating table in a supine position with the foot prepped appropriately. The osteotomy site is exposed through a dorsal incision 1.5" to 2" in length over the dorsum of the base of the first metatarsal. Care is taken to preserve the extensor tendons and small cutaneous nerves and vessels in this area. The periosteum over the base of the first metatarsal is opened and elevated away from the base of the first metatarsal. The first metatarsal joint is identified.

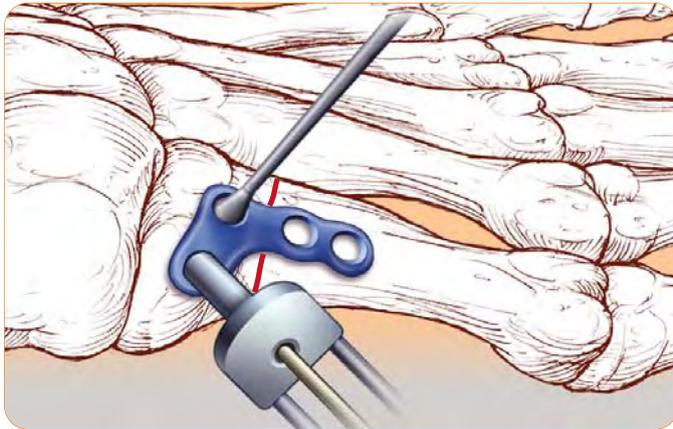
The osteotomy is positioned approximately one centimeter distal to the first metatarsal/cuneiform joint, and is made slightly oblique from perpendicular, allowing more room for the placement of the proximal screws. A crescentic oscillating saw is used. The concavity of the osteotomy is positioned facing towards the first metatarsal/cuneiform joint.

The angle between the first and second metatarsal is decreased with the aid of Ragnell retractor. The retractor is placed laterally over the proximal fragment pulling the distal end of the proximal fragment into a more medial position while lateral compression is placed across the distal fragment of the first metatarsal.

The corrected position of the first metatarsal is then maintained with K-wire fixation as recently described by James A. Amis, M.D. (*Foot and Ankle International* vol. 20 num. 11 p.752). An .062" K-wire is placed across the proximal fragment into the medial and middle cuneiform. A second K-wire is placed from the head of the first metatarsal into the second metatarsal.

The K-wire fixation allows tentative fixation of this osteotomy so the plate and screws can be attached without having to re-manipulate the osteotomy.

Fluoroscopy may be useful for evaluating alignment, correction, plate and screw placement.

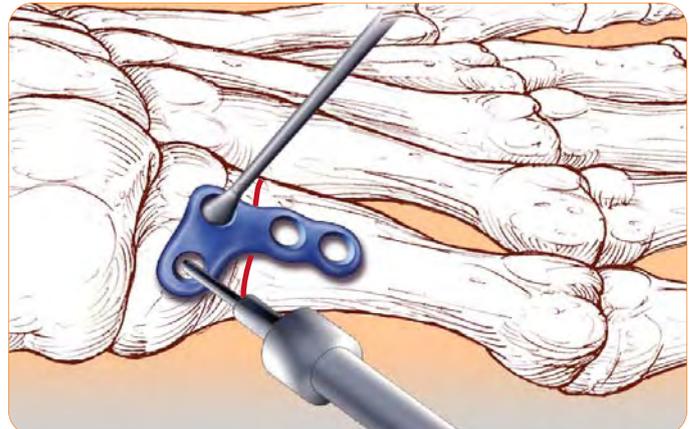


Step 1

Place the plate, either right or left, over the osteotomy site. This may then be held in place with the use of the plate tack. Place the standard drill guide into the proximal/lateral hole and drill through both cortices.

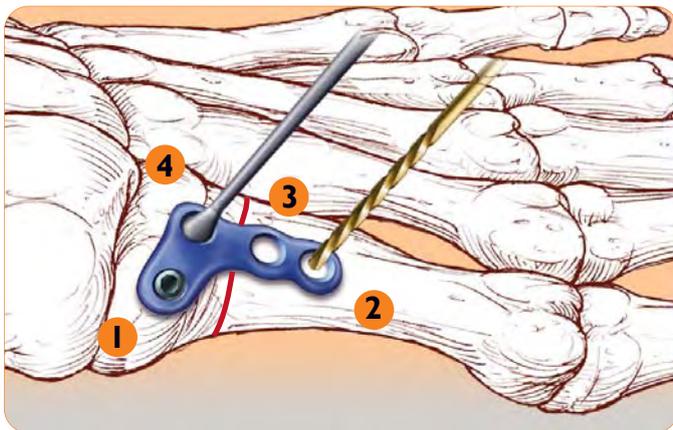
The 2.0mm drill is used for the 2.7mm cortical screws, and the 2.8mm drill for the 3.5mm cortical and 4.0mm cancellous screws. Tapping for the two distal screws is recommended.

The drill may be tilted up to 14° and still maintain a low profile screw/plate interface.



Step 2

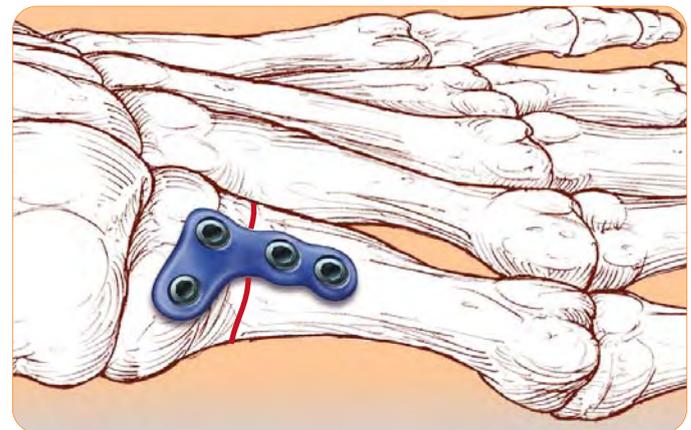
Use the depth gauge to determine the screw length by inserting it into the plate and hooking the far cortex. Choose the appropriate length self-tapping screw from the organizer and insert into the bone.



Step 3

Without using the drill guide, place the drill at the distal end of the screw hole. As the screw head makes contact with the plate, the distal fragment will be drawn towards the proximal fragment causing interfragmental compression.

Insert the second distal screw using the drill guide to center the screw in the plate. Screws may be placed in any order, an example of one order is shown above.



Step 4

The wound is irrigated. Bone graft material can be used for the distal soft tissue procedure from the excised medial extosis. This is placed at the osteotomy site usually about the lateral aspect of the osteotomy. The wound is then closed with appropriate closure. This osteotomy is performed in conjunction with the standard distal soft tissue procedure.

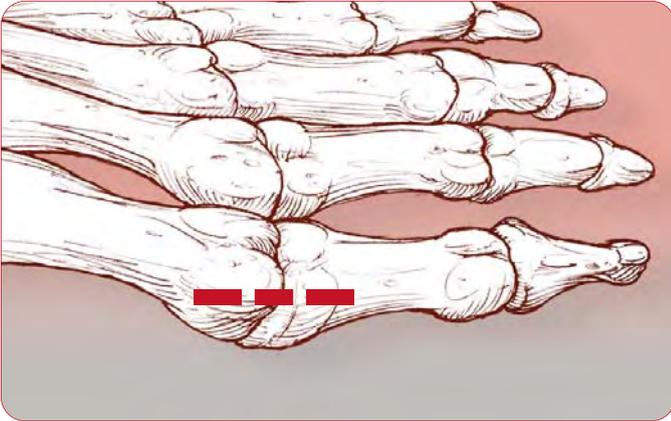
Postoperative Protocol:

The foot is protected with a wooden post-op shoe and dressing. The patient is allowed to proceed with weight bearing activities as tolerated. Usually at eight weeks the osteotomy is healed and conventional shoes can be resumed.

SURGICAL TECHNIQUE

MTP Fusion Plate

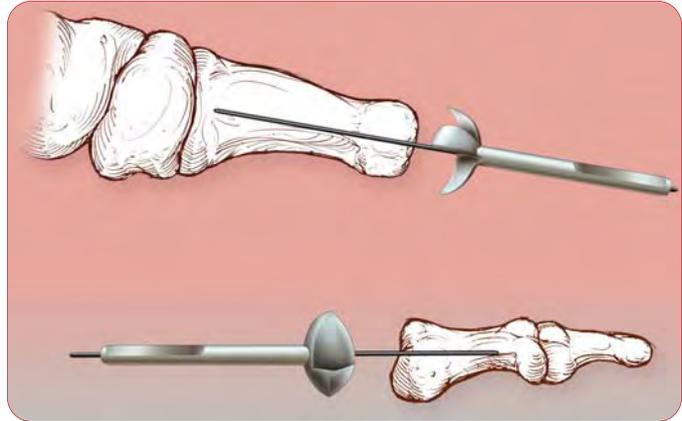
This section offers Acumed's suggested method for implanting the MTP Fusion Plate from the Lower Extremity Congruent Plate System. For specific questions not addressed here, please contact your local Acumed representative or Acumed by phone at (888) 627-9957 or on the web at www.acumed.net.



Step 1

Prepare the bone surface for optimal fusion position. Mark both sides of the joint to establish rotational alignment, and flatten the dorsal surface of both the metatarsal and proximal phalanx.

Note: The plates are pre-bent with 9° of dorsiflexion and 11° of lateral rotation.



Step 2

Using either a burr, rongeur, or Acumed's cannulated concave/convex reamers, remove the cartilage down to bleeding bone. Place the joint in the desired position and secure with a K-wire.

While a variety of methods are available for joint preparation, the goal should be to maximize the surface contact of the bones once the plate is applied.

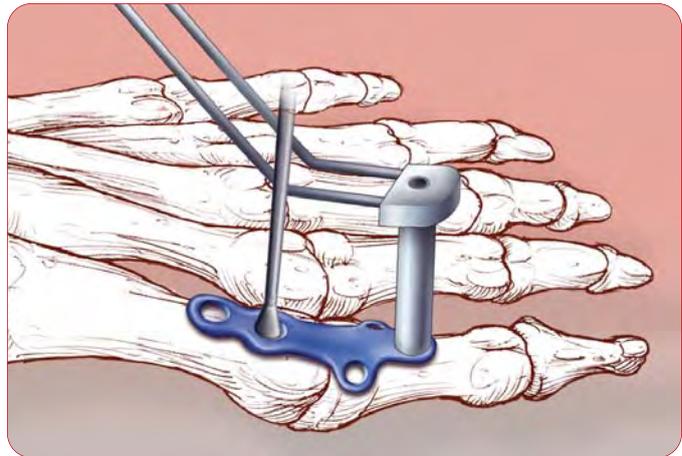


Step 3

Bend the plate to match the patient's anatomy. The plate benders have been designed to match the metatarsophalangeal joint geometry with little or no adjustments.

However, if bending the plate is required to match specific patient anatomy, the plate is secured in the plate holder. This provides a fixed reference plane and greater leverage while bending with the supplied plate bender.

Avoid over-bending the plate in order to reduce the amount of reverse bending that may need to occur.

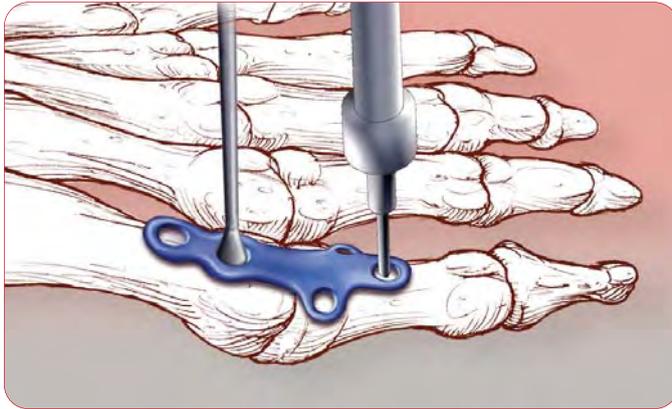


Step 4

Secure the plate to the metatarsal with a Plate Tack driven through the most distal hole in the metatarsal

Place the standard drill guide into the distal hole of plate and drill through both cortices.

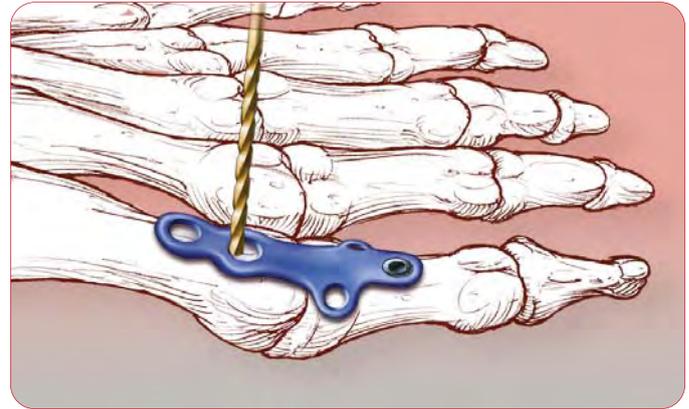
The 2.0mm drill is used for the 2.7mm cortical screws, and the 2.8mm drill is provided for the 3.5mm cortical and 4.0mm cancellous screws.



Step 5

Use the depth gauge to determine the screw length by inserting it into the plate and hooking the far cortex. Choose the appropriate length self-tapping screw from the organizer and insert into the bone.

2.7mm and 3.5mm taps are available if tapping is desired.



Step 6

Apply compression to the fusion site. Drill the pilot hole at the proximal end of the compression slot to apply 1mm of compression to the fusion site, as shown above. An additional 1mm of compression can be applied by drilling the second pilot hole at the proximal end of the second slot.



Step 7

Insert the next screw into the proximal compression slot. Take care to loosen the first compression screw before seating the head of the second. Re-tighten first compression screw.

Implant remaining screws.

An optional lag screw may be inserted across the joint.



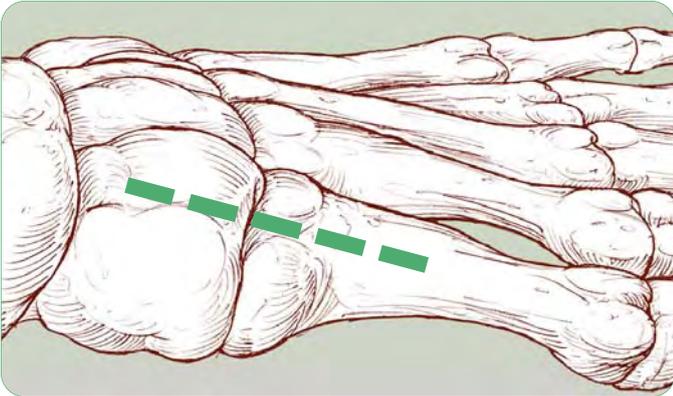
Postoperative Protocol:

The foot is protected with a wooden post-op shoe and dressing. The patient is allowed to proceed with weight bearing activities as tolerated. Usually at eight weeks the osteotomy is healed and conventional shoes can be resumed.

SURGICAL TECHNIQUE

TMT Fusion Plate - by Douglas N. Beaman, MD

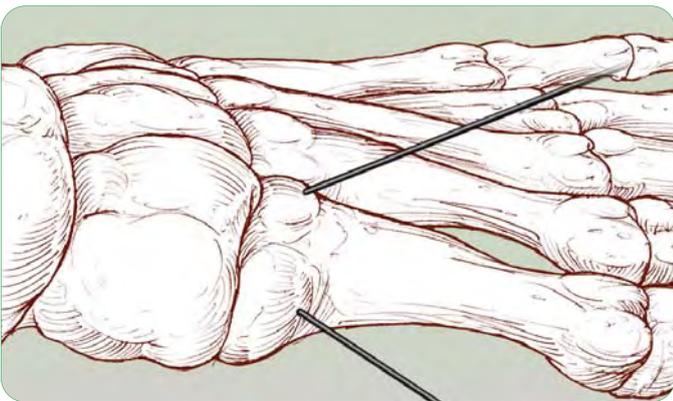
This section offers Acumed's suggested method for implanting the TMT Fusion Plate from the Lower Extremity Congruent Plate System. For specific questions not addressed here, please contact your local Acumed representative or Acumed by phone at (888) 627-9957 or on the web at www.acumed.net.



Step 1

The first TMT joint is exposed through the medial incision. Carry dissection down to expose the anterior tibialis tendon, which is protected. A portion of the tendon may need to be elevated from the medial cuneiform and metatarsal; however, this should be minimized. The joint is exposed medially then dorsally and plantarly, carefully avoiding the extensor hallucis longus tendon at the dorsal aspect of the joint.

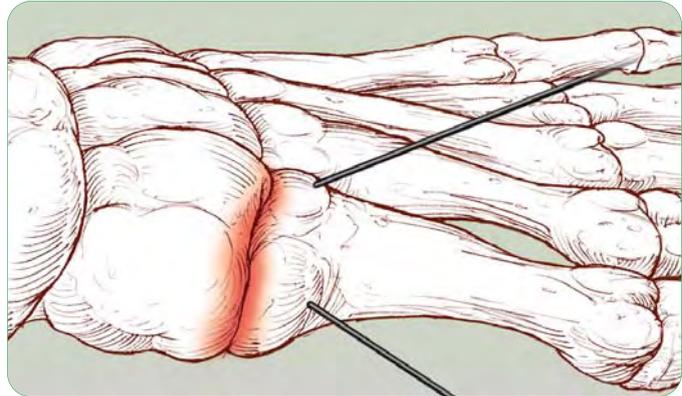
C-arm image intensification is recommended during this procedure to confirm joint reduction and placement of hardware.



Step 2b - For Trauma:

Reduce joint by aligning anatomic landmarks and fix provisionally with 1.2mm K-Wires placed superiorly and inferiorly across the joint to allow room for the plate.

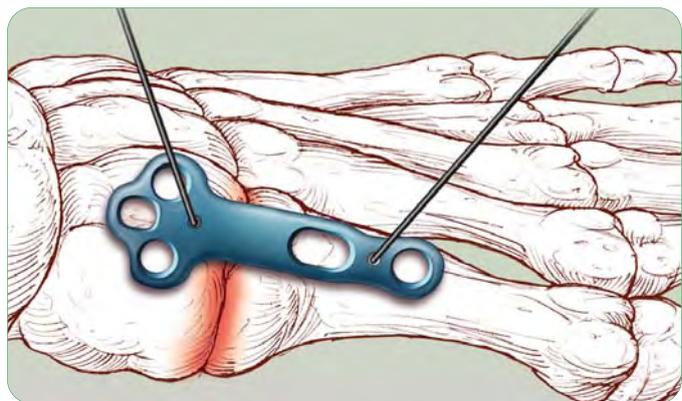
Definitive fracture stabilization of intra-articular fragments can be performed with intrafragmentary screw fixation.



Step 2a - For Arthrodesis:

Gain access to the first TMT joint, and perform joint preparation in the standard fashion with thorough removal of all articular cartilage and preparation of subchondral bone. Confirm the correct positioning of the metatarsal and cuneiform, and provisionally fix the joints involved with K-Wires placed superiorly and inferiorly to allow for the plate.

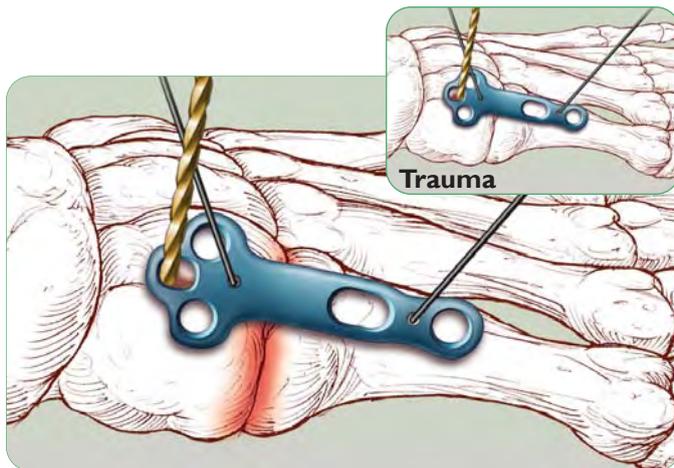
If interfragmentary lag screw fixation is desired to supplement the plate, it should be placed first, and typically oriented from the plantar aspect of the metatarsal base proximally into the medial cuneiform, as the plate sets dorso-medially. Lag screw fixation may also occur through the plate's slot.



Step 3

Apply the plate to the dorsal medial aspect of the TMT joint, and secure with Acumed Plate Tacks or K-wires.

The plate is pre-contoured to match the anatomy, but, using the instruments in the set, may be bent to fit a specific patient.



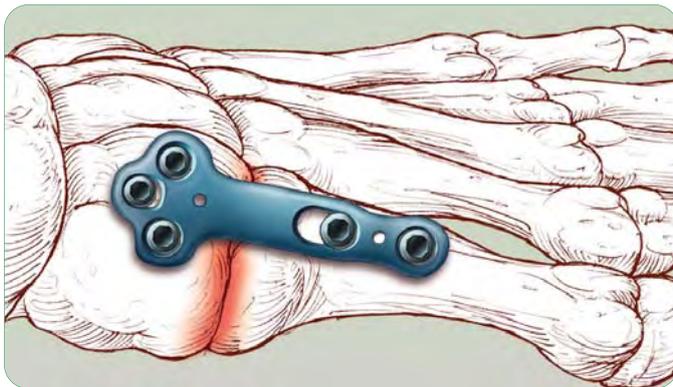
Step 4

Drill for the middle medial cuneiform screw. A 2.8mm drill is used for 3.5mm screws, and a 2.0mm drill is used for the 2.7mm screws.

Insert a 2.7 or 3.5mm screw, according to surgeon preference. Screw should be unicortical unless bridging of the first and second cuneiform is desired, in which case it may or may not be lagged per surgeon preference.

Note: If using the plate's slot for a trans-articular lag screw, the lag screw should be placed first.

Note: If compression is desired across the TMT joint, drill the middle cuneiform hole at the proximal end of the slot.



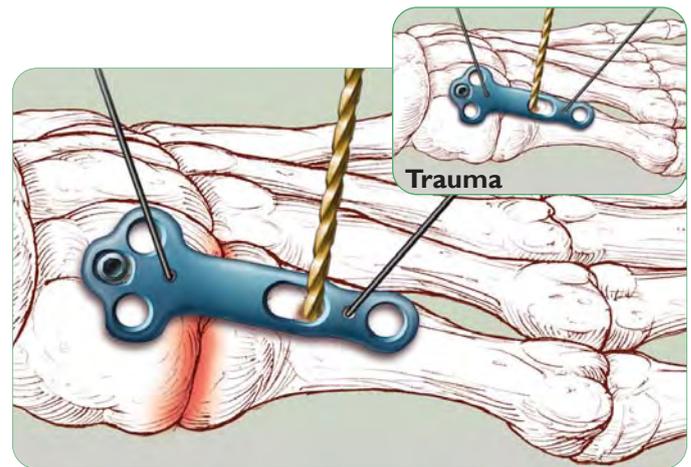
Step 6

Drill the distal metatarsal hole, and insert screw.

Drill the plantar cuneiform hole, and insert screw. This may cross into the other cuneiforms to optimize fixation as well as stabilize any intercuneiform disruptions.

Drill the dorsal cuneiform hole, and insert screw.

Following irrigation, close the wound with interrupted 4-0 nylon or proline suture.



Step 5

Drill for the proximal metatarsal screw. Insert a 2.7 or 3.5mm screw.

For Reconstruction:

Drill the hole offset, at the distal end of the slot, for compression across the TMT joint.

For Trauma:

Drill the hole neutral or offset proximally, to distract joint 1mm.



Postop Protocol:

Typically for both trauma and reconstructive purposes, the foot is placed in a neutral plantigrade position with a well-padded dressing incorporating below-knee plaster splints. This is typically changed at 7-14 days, with sutures removed after 10-14 days or once wound healing is completed.

For reconstructive purposes a short leg non-weightbearing cast is then applied for an additional four weeks for a total non-weightbearing period of six weeks. If there is evidence of union based on plain radiographs, weightbearing is initiated at this time in a short-leg walking cast.

For most trauma applications, the patient is advanced to a removable boot at approximately two weeks postop to allow ankle and hindfoot motion. Weightbearing is protected for 8-12 weeks in trauma applications depending on the particular injury pattern.

SURGICAL TECHNIQUE

Ankle Plates

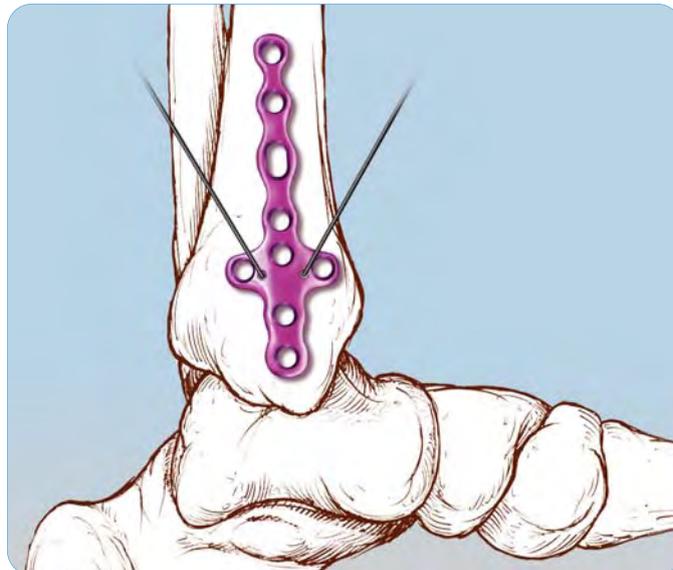
This section offers Acumed's suggested method for implanting the Ankle Plates from the Lower Extremity Congruent Plate System. For specific questions not addressed here, please contact your local Acumed representative or Acumed by phone at (888) 627-9957 or on the web at www.acumed.net.



Step 1

If needed, bend the plate to match patient anatomy. Secure the plate in the plate holder. This provides a fixed reference plane and greater leverage while bending with the plate bender.

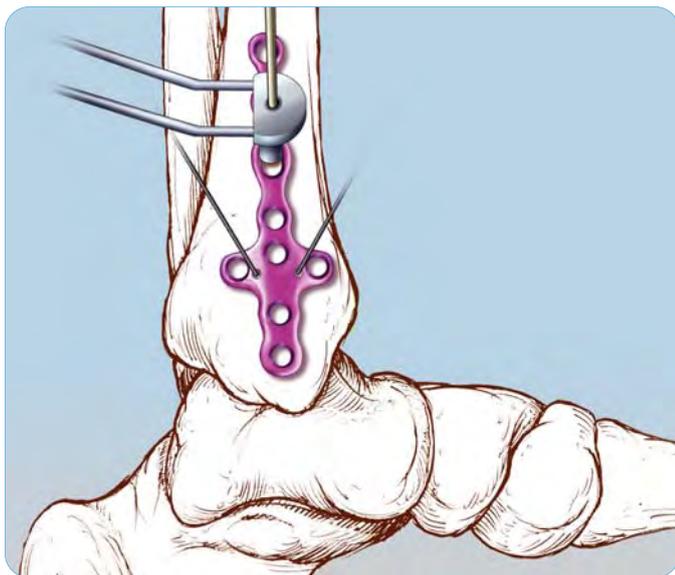
Once the plate is bent, avoid reverse bending.



Step 2

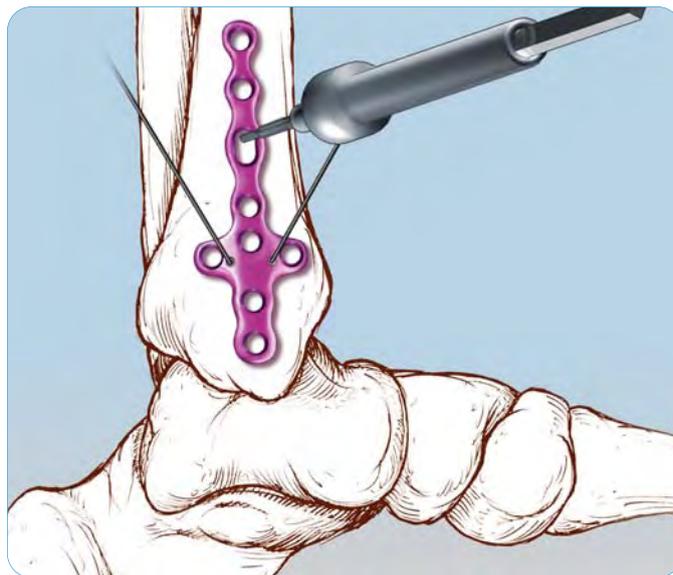
Temporarily stabilize the fracture using K-wires through the wire holes in the plate. Up to .062" K-wires may be used to stabilize the fracture.

Note: Fracture reduction must be achieved prior to plate application. Traction may be helpful in obtaining reduction.



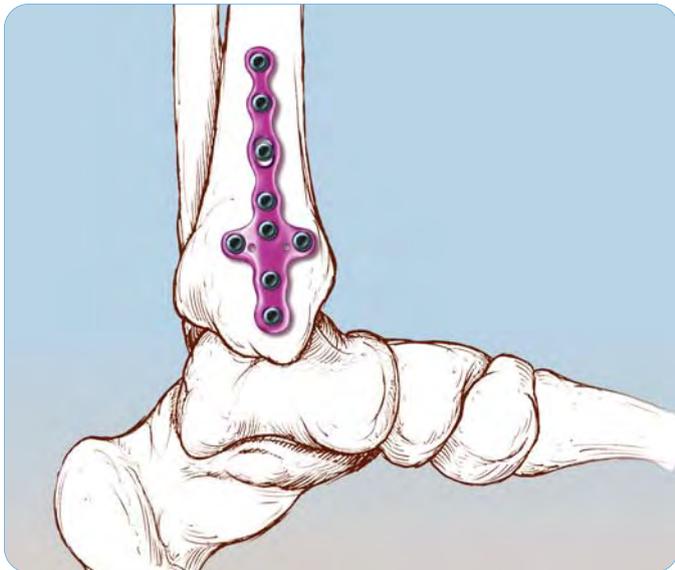
Step 3

Place the standard drill guide into the counterbore of the plate slot and drill through both cortices. The 2.0mm drill is used for the 2.7mm cortical screws, and the 2.8mm drill is used for the 3.5mm cortical and 4.0mm cancellous screws.



Step 4

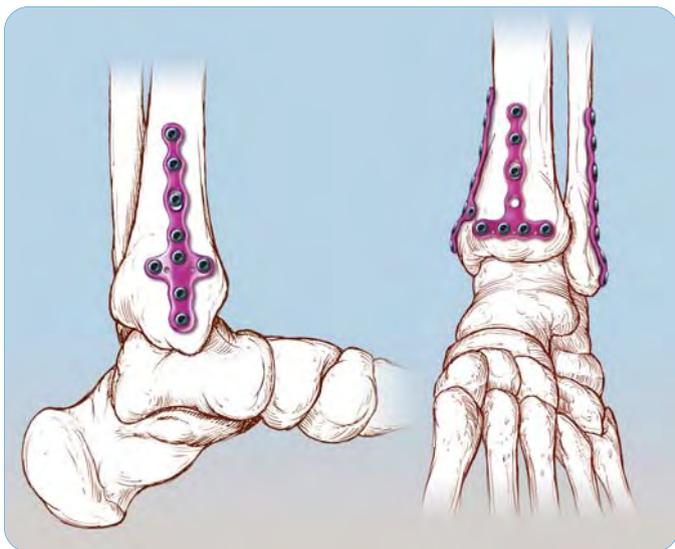
Use the depth gauge to determine the screw length by inserting it into the plate and hooking the far cortex. Choose the appropriate length self-tapping screw from the organizer and insert into the bone. 2.7mm and 3.5mm taps are available if tapping is desired.



Step 5

Complete reduction and stabilization of the fracture. Use K-wires, if necessary, to complete reduction and insert remaining screws in similar manner as previously described.

Maximum screw stability occurs when a minimum of 1 to 2 threads are through the second cortex.



The anterior tibia and fibula plates are implanted using a similar technique.



Postop Protocol

Follow a standard post-operative protocol, with consideration of the injury and patient.

Screw and Pin Fixation

AcuTwist™ Compression Pins

1. Reduce fragments and provisionally secure with K-wire(s). Take care to place provisional K-wires so that they will not interfere with placement of AcuTwist Compression Pins.
2. Template the length of the AcuTwist Compression Pin on radiograph or C-arm.
3. Using a power wire driver, place AcuTwist Compression Pin across fracture/joint/osteotomy. For maximum compression, placement should be perpendicular to fracture/joint/osteotomy.
4. Once the back end of the AcuTwist Compression Pin has been inserted to the level of the cortex, tilt driver to one side and then the other to bend at the fatigue groove proximal to the pin. This should break the pin off at the fatigue groove.
5. If the pin is prominent or needs to be removed post-operatively, the pin driver in the system may be used. Ensure that the hex socket is fully engaged prior to turning the pin driver.



Extremity Screws

1. Secure fracture by placing guide wire at screw placement depth and position.
2. Optional - When using the countersink option, drill over the guide wire to the groove on the countersink.
3. Next, slide the tapered end of the screw sizer over the guide wire and down to the bone to estimate screw size.
4. Install properly sized implant.

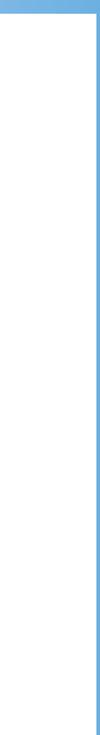


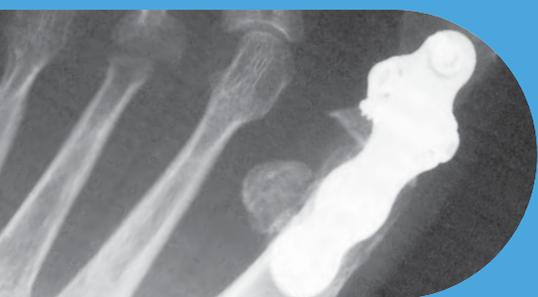
Syndesmosis Screws

This screw may be used alone with a washer for an isolated syndesmosis disruption, or in conjunction with the Acumed Congruent Fibula Plates for a syndesmosis disruption with an associated fibula fracture.

1. Using the 2.8mm drill, drill across the distal fibula, the syndesmosis joint and through the distal tibia. Depending on surgeon preference, the drill may either stop in the distal tibia, or go through both cortices.
2. Measure screw depth with depth gauge.
3. Tap the drill hole to ensure that the screw achieves maximum purchase in the tibia.
4. Using the 2.5 mm hex driver, insert screw through the distal fibula and into the distal tibia, compressing the joint.







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