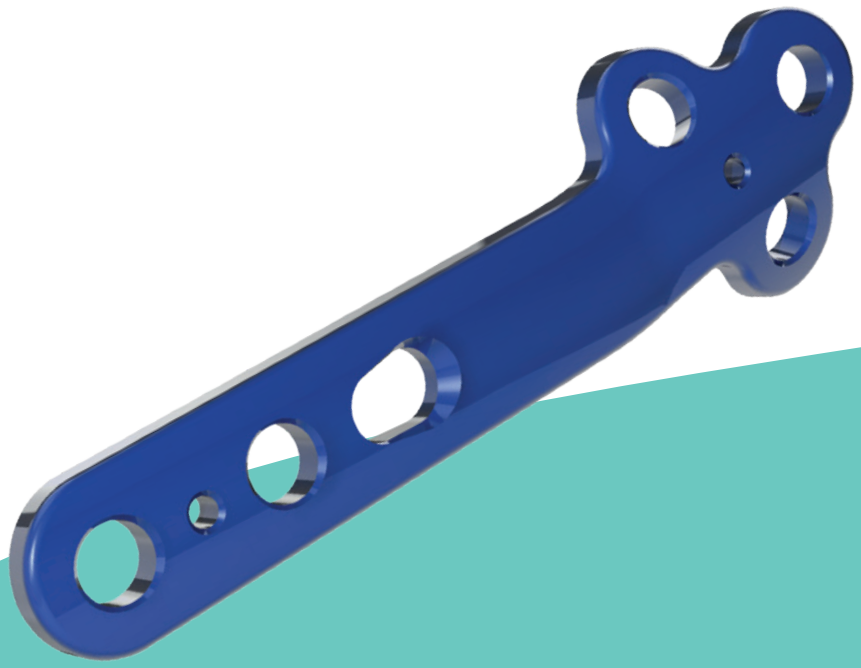
Smith+Nephew

TOTAL FOOT SYSTEM 2 (TSF2)

Forefoot/Midfoot

Surgical Technique



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Note Bena

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the product, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

System description

The Smith+Nephew TOTAL FOOT SYSTEM 2 (TFS2) is a system containing bone plates and screws designed for use in the skeletally mature foot. The plates and screws are intended to be used for stabilization and fixation of fresh fractures, intra-articular and extra-articular fractures, joint depression and multi-fragmentary fractures. TFS2 can also be used in revision procedures, joint fusion, and in reconstructing the small bones of the feet.

- Selection of plates and universal plates, designed for forefoot and midfoot procedures
- 2.2mm and 2.7mm diameter screws; fixed angle locking and lag screw options
- Titanium alloy plates and screws

Available plates, screws, and instrumentation are packaged as a single system and organized around the types of plates described below:

Forefoot Plates

1. Open Wedge Plates – Available with stems ranging from 2-5mm in 0.5mm increments, a 6mm stem, or without a stem.
2. Universal Forefoot Plates – Available in 7 sizes: 14mm, 16mm, 18mm, 20mm, 22mm, 24mm, and 30mm.
3. MTP Fusion Plates – Available in medium and long lengths and left and right configurations.
4. Tarsalis Plates – The 2-Hole Straight Tarsalis Plate is offered in short and long lengths. The 3-Hole and 10-Hole Straight Plates are included in the system as standard lengths. The 4-Hole Straight Tarsalis Plate is offered in both standard and short lengths. The Crescentic Tarsalis Plate is offered in left and right configurations. The 4-Hole Diamond Plate is available in left and right configurations. The T-Shaped Tarsalis Plates are offered in 4-hole, 5-hole, and, 6-hole configurations. The 5-hole designs are provided in straight, left, and right configurations. The 6-hole is only provided in straight configuration.

Note: Available upon request, the left and right 6-hole, 7-hole and 8-hole T-Shaped Tarsalis Plates are available.

Note: Cup and cone reamers are found in separate tray from TFS2 Forefoot/Midfoot instrumentation and plate tray.

Forefoot/Midfoot Screws

- 2.2mm silver, anodized titanium screw (locking and non-locking lag)
- 2.7mm purple, anodized titanium screw (locking and non-locking lag)

Specialty plates within Smith+Nephew TFS2 Forefoot/Midfoot Tray include:

Metatarsal Opening Wedge Osteotomy Plates

The low-profile, blue titanium plate comes in various size options for proximal metatarsal open wedge osteotomies.

Metatarsal Phalangeal (MTP) Joint Fusion Plates

The low-profile, blue titanium MTP fusion plates have a built-in 10° valgus angle and 5° of dorsal contour. Plate bending irons or plate bending handles are provided to allow customization for patient specific hallux dorsiflexion. Left and right configurations are available in standard and revision lengths.

Note: Cup and cone reamers are provided for preparation of joint surfaces. The reamers are available in four sizes to fit specific patient anatomy with matching diameters for congruent surfaces.

Sizes available:

- 16mm, 19mm, 21mm and 24mm diameter
- 2.0x150mm guide pins

Features and Benefits:

- Built with 5° of dorsal contour and 10° of valgus for fusion orientation and minimized need for intraoperative contouring
- Left and right anatomical plates available with two length options for standard or revision fusions
- Increased material around joint surfaces for a rigid construct
- 3 hole design in proximal phalanx for primary or revision cases with grafts
- Interfragmentary screw guides for optional guided interfragmentary screw placement
- Oblong hole on metatarsal side to provide additional oblique compression through the plate construct

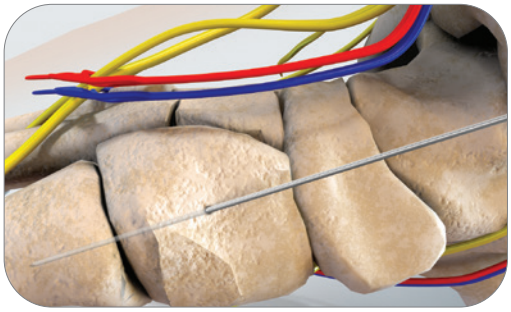


Figure 1-1

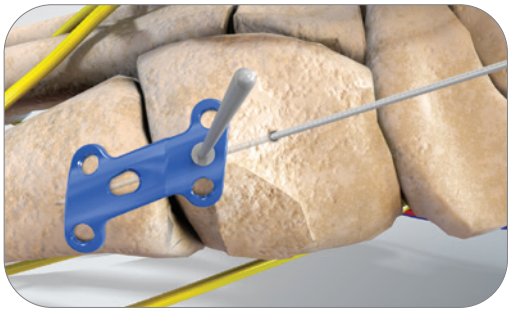


Figure 2-1

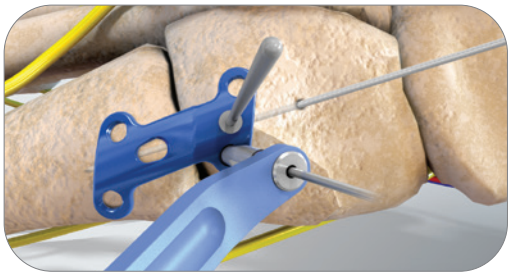


Figure 3-1a

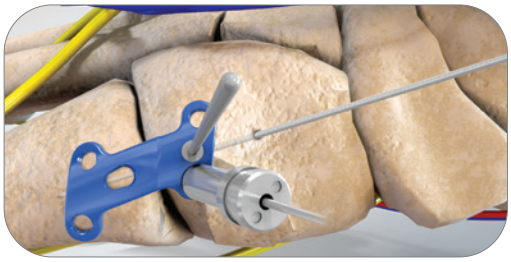


Figure 3-1b

TOTAL FOOT SYSTEM 2 (TFS2) general surgical technique

Step 1 ▪ Preparation and plate assessment

1-1 After completing an osteotomy or gaining access to the fracture or fusion site, temporarily fixate with K-wires and select the appropriate plate for fixation of the osteotomy, fracture or fusion.

Step 2 ▪ Plate positioning

2-1 Place the selected size plate against the osteotomy or fracture and secure with K-wires or Olive wires. The TFS2 plates are pre-contoured but may also be modified with the Plate Bending Irons or Plate Bending Handles to match specific patient anatomy.

Note: If bending near a locking hole, it is important to thread the 2.7mm screw-on Drill guides into the plate holes to protect the locking threads in the plate.

Step 3 ▪ Screw preparation

3-1 Non-locked plate configuration.

Screw holes are prepared using the 1.8mm drill bit (blue color-coding) through the snap-on Drill guide and double handle **(Figure 3-1a)**.

Locked plate configuration.

Screw holes are prepared using the 1.8mm drill bit (blue color-coding) through the locking screw-on Drill guide **(Figure 3-1b)**.

Each hole is drilled bicortically and then measured using the depth gauge (2204262) from the wire drill and guide caddy. Generally, if the depth measurement is between 2 screw lengths, the longer screw length is selected to ensure maximum fixation. However, if there are sensitive structures such as nerves, tendons or other soft tissue (i.e plantar surface of the foot) near the distal end of the screw, the shorter screw length should be selected.

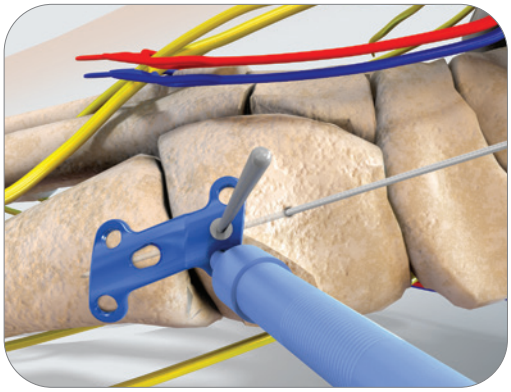


Figure 3-2

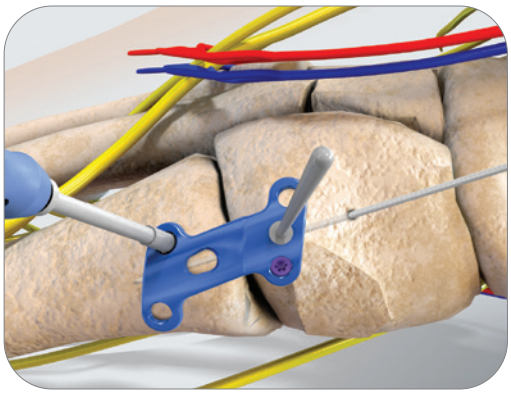


Figure 3-3

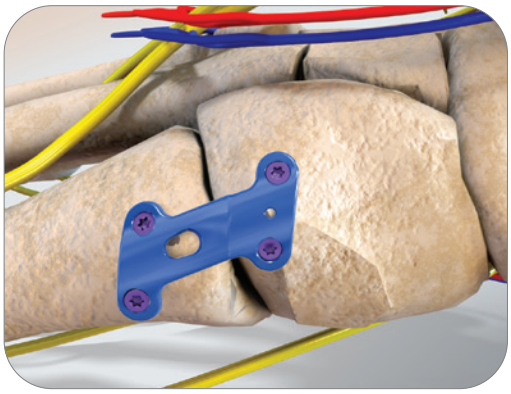


Figure 4-1

Step 3 ▪ Screw measurement

3-2 Remove screw-on or snap-on drill guide and measure the depth of the hole using the Depth Gauge **(Figure 3-2)**.

Note: The screw caddy has a measurement guide. This guide is not calibrated. Measurements should be verified with the Depth Gauge

Step 3 ▪ Screw placement

3-3 Once the screw length is determined, press the Torx T8 Hex Screwdriver with a Ratcheting Handle (TXD-TFS-08 and RM1011-S03) into the head of the selected screw to remove from the TFS2 screw caddy. Screw Holding Forceps (2204250) are also available. Use the Depth Gauge (2204262) to verify the correct screw length. Advance the appropriate screw through the plate hole until it is finger tight, and it is sufficiently locked within the plate. Do not over torque the screw.

Note: The TFS2 locking screws have a tapered head and may sit slightly above the surface of the plate when fully locked.

For the insertion of locking screws, ensure that the screw remains on axis with the pre-drilled hole.

Note: Plate Contouring (Bending)

It is recommended to insert one screw on each side of the osteotomy, through plate holes opposite-diagonal from each other. The plate contour can then be assessed and if necessary the unfixed corners of the plate can be further contoured to the bone using the plate bending handles **(Figure 3-3)**.

Repeat Step 3 for all remaining screws.

Step 4 ▪ Final screw fixation and assessment

4-1 To secure fragments that cannot be managed by the selected plate, optional screws can be placed across the osteotomy, fracture or fusion site outside of the plate construct at the surgeon's discretion.

An X-ray is taken to confirm proper hardware placement **(Figure 4-1)**.

Step 5 ▪ Closure

5-1 Proper care should be taken to repair ligament and soft tissue. Standard closure of the incision should be employed depending on the approach taken.

Metatarsal Opening Wedge Osteotmy Plate surgical technique

Preoperative preparation

Standing radiographs may be used to initially assess the desired amount of correction.

Note: As a general rule, one millimeter of opening wedge provides approximately 2° of correction to the intermetatarsal (IM) angle. For example, a 4mm opening wedge plate will provide approximately 8° of correction. The final amount of correction will vary with patient anatomy and plate placement. A more dorsal plate placement allows plantarflexion of the first ray but will provide less valgus displacement. It is strongly recommended that final plate selection and placement is verified with intraoperative assessment.

Additional corrective procedures

Although beyond the scope of this technique, additional procedures such as a distal soft tissue procedure for a hallux valgus (HV) correction, a dorsal cheilectomy for a hallux rigidus (HR) correction, or a posterior tibial tendon reconstruction for a posterior tibial tendon deficiency (PTTD), should be performed at the surgeon's discretion.

Step 1 ▪ Approach and incision

1-1 A straight medial or dorsomedial incision is made slightly distal to the first tarsometatarsal (TMT) joint. Care should be taken to avoid damaging neurovascular structures and the extensor hallucis longus (EHL) tendon. The incision is continued through the soft tissue layers until the first metatarsal can be visualized. Baby Hohmanns (not included in TFS2 Forefoot/Midfoot tray) should be placed on either side of the metatarsal to protect the soft tissues and help gauge the depth of the osteotomy. The 1st TMT joint does not need to be directly visualized and it is imperative that the joint not be destabilized by excessive ligament resection.

Step 2 ▪ Creating the Osteotomy

The starting point of the osteotomy will dictate the correction obtained.

- A direct medial osteotomy will result in valgus displacement of the 1st metatarsal as desired for hallux valgus correction.
- A dorsally placed osteotomy will result in planterflexion of the distal fragment and may be needed for the correction of hallux rigidus, forefoot supination, or assisting in the correction of a medial longitudinal arch during a PTTD reconstruction.
- An osteotomy placed between a pure medial or dorsal position, will provide biplanar correction.

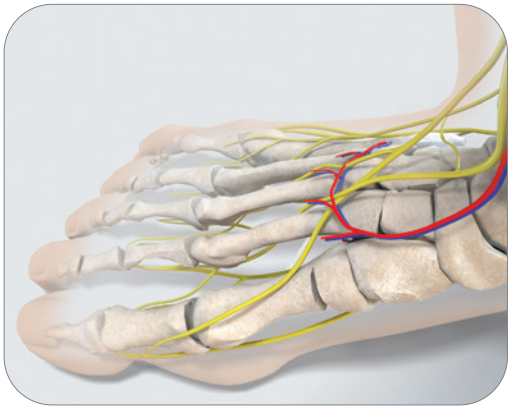


Figure 2-1

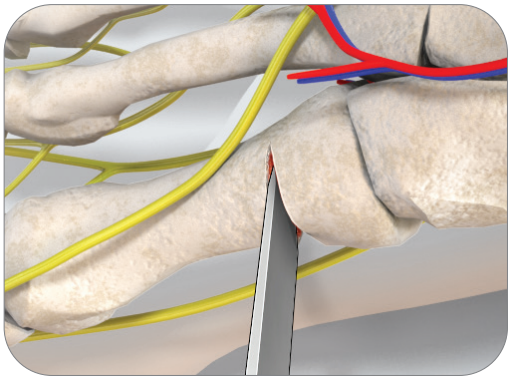


Figure 3-1

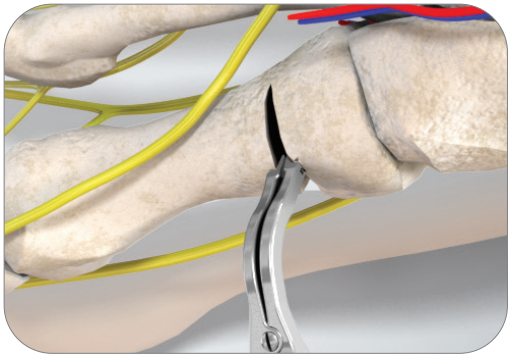


Figure 4-1a

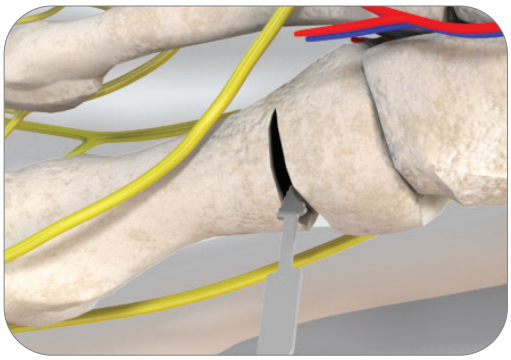


Figure 4-1b

Therefore, a hallux valgus deformity with first metatarsal elevatus and second ray metatarsalgia may benefit from an osteotomy angled 45° dorsomedial to provide both plantarflexion and varus correction.

It is important to note that compared to the direct medial osteotomy, the correction of the same metatarsus varus with a more dorsally placed osteotomy (to correct two planes) will require a larger opening wedge. The location of the osteotomy must be determined preoperatively, as the plane cannot be corrected once the osteotomy has been created.

2-1 A sagittal saw is used to create a perpendicular osteotomy between 1 and 1.5cm distal to the first TMT joint. This can be estimated by leaving just enough bone distal to the bony expansion of the 1st metatarsal for the plate. The cut should proceed from the medial cortex through approximately 75% of the metatarsal. It is critical to leave the final 25% of the metatarsal intact to serve as a hinge for the opening wedge. The hinge helps to maintain vascularity and helps to stabilize the osteotomy.

Step 3 ▪ Opening the Osteotomy

3-1 A straight osteotome (not included in TFS2 tray) can be used to gradually pry open the osteotomy. Care should be taken to prevent fracturing and displacing the lateral cortex.

Step 4 ▪ Assessing correction and wedge size (plate selection)

4-1 The appropriate opening wedge plate is selected based on intraoperative assessment. This system has several options to assess the correct wedge size. These include a calibrated spreader, (382000) **(Figure 4-1a)** or a distraction gauge, (FDGTFS01) **(Figure 4-1b)**. The beveled edge of the wedge will help to push the osteotomy open and seat the plate.

Note: If the desired correction is between two plate sizes, start by placing the smaller plate to see if it provides sufficient correction. If not, proceed to the next size plate and assess the correction. The most appropriate plate is chosen.

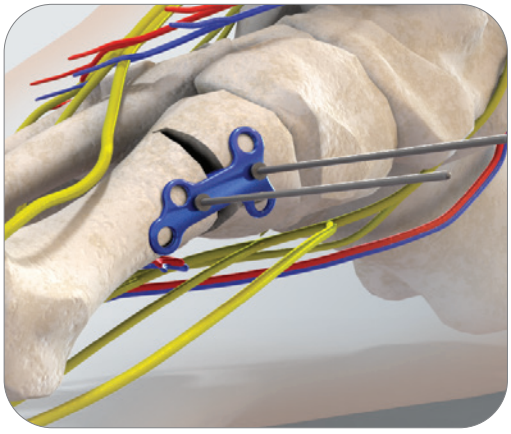


Figure 5-1

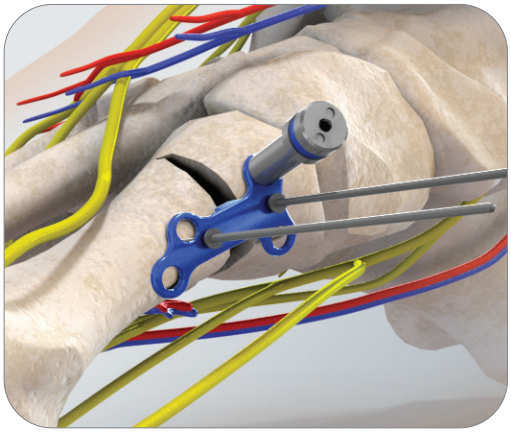


Figure 6-1

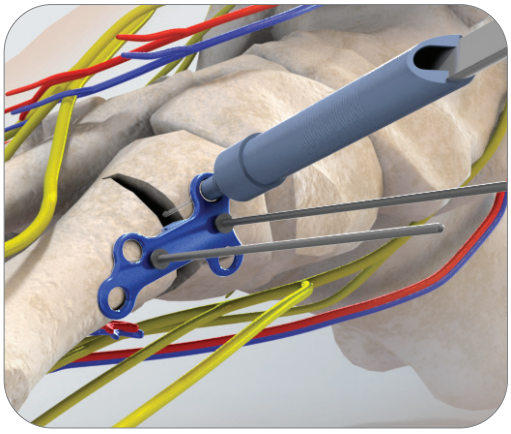


Figure 6-2

Step 5 ▪ The plate assessment and positioning

5-1 Use K-wires or Olive wires found in the drill, wire and guide caddy to provisonally fixate plate.

Step 6 ▪ Screw preparation

6-1 The plate holes provide fixed-angle locking or variable-angle non-locking options. When choosing the locking screw, it is imperative to utilize the locking screw-on Drill guide by threading the guide into the circular locking plate hole. For variable angle non-locking screws, attach the Drill guide to the Drill guide handle and orient inside the screw hole with 15° of variability.

Generally, a locked plate configuration is recommended to maximize plate stability and allow for non-structural bone grafting. This is particularly important in higher risk patients or in situations where the lateral cortex of the wedge is compromised.

Non-locked plate configuration

Screw holes are prepared using the 1.8mm drill bit (blue color-coding) through the snap-on drill guide and double handle.

Locked plate configuration

Screw holes are prepared using the 1.8mm drill bit (blue color-coding) through the locking screw-on drill guide **(Figure 6-1)**.

Step 6 ▪ Screw measurement

6-2 Each hole is drilled bicortically and then measured using the Depth Gauge (2204262) from the drill, wire, and guide caddy **(Figure 6-2)**.

Note: If the depth measurement is between 2 screw lengths, the longer screw length is selected to ensure maximum fixation.

If there are sensitive structures (nerves, tendon, plantar surface) near the distal end of the screw, the shorter screw length should be selected.

The screw caddy has a measurement guide. This guide is not calibrated. Measurements should be verified with the Depth Gauge.

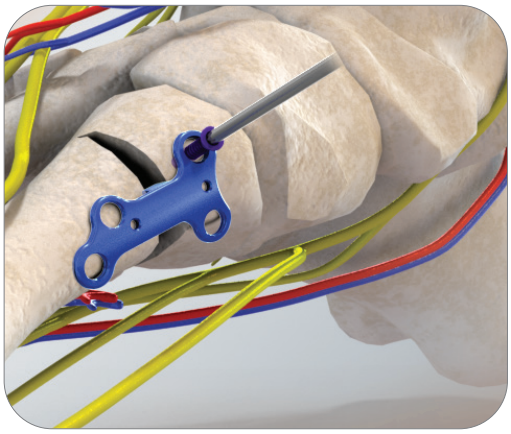


Figure 6-3

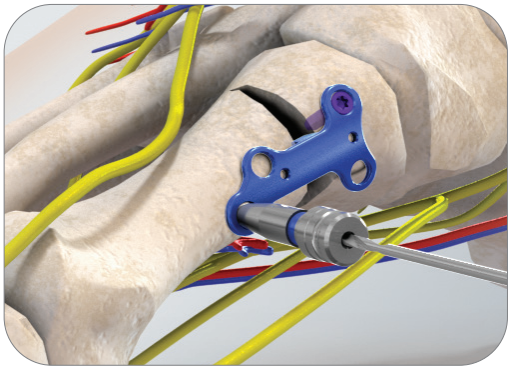


Figure 6-4a

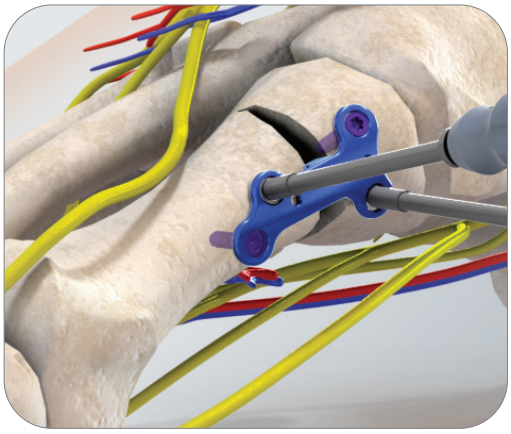


Figure 6-4b

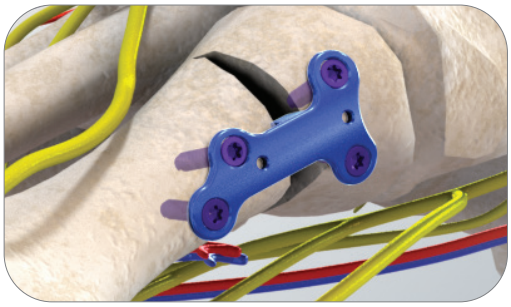


Figure 8-1a

Step 6 ▪ Screw measurement

6-3 Once the screw length is determined, press the Torx T8 Hex Screwdriver with a ratcheting handle (TXD-TFS-08 and RM1011-S03) into the head of the selected screw to remove from the TFS2 screw caddy. Screw Holding Forceps (2204250) are also available. Use the Depth Gauge (2204262) to verify the correct screw length. Advance the appropriate screw through the plate hole until it is finger tight, and it is sufficiently locked within the plate. Do not over torque the screw.

Note: The TFS2 locking screws have a tapered head and may sit slightly above the surface of the plate when fully locked.

Note: For the insertion of locking screws, ensure that the screw remains on axis with the pre-drilled hole.

Step 6 ▪ Final screw fixation and assessment

6-4 Note: Plate contouring (Bending)

It is recommended to insert one screw on each side of the osteotomy, through plate holes opposite-diagonal from each other. The plate contour can then be assessed and if necessary the unfixed corners of the plate can be further contoured to the bone using the plate bending handles (Figures 6-4a, 6-4b).

Repeat Step 6 for all remaining screws.

Step 7 ▪ Supplemental grafting (optional)

7-1 If desired, autograft or a bone graft substitute such as demineralized bone matrix may be used to pack the wedge site. The graft may be placed before or after place placement and fixation.

Step 8 ▪ Closure

8-1 Prior to closure, fluoroscopy is used to assess the correction of the hallux valgus angle. If sufficient, the incision is closed in layers per the surgeon's desired technique **(Figure 8-1)**.

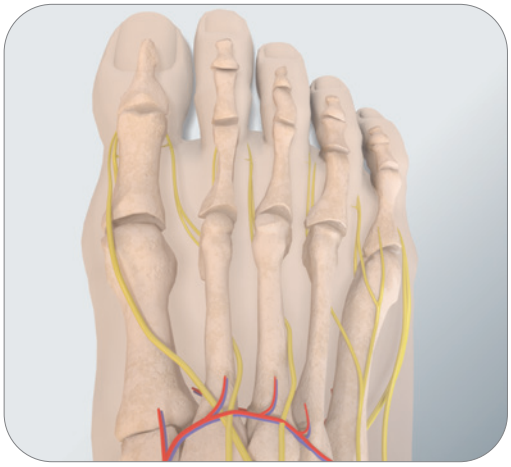


Figure 1-1

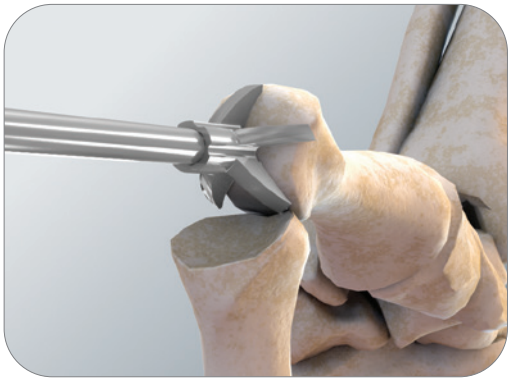


Figure 2-1

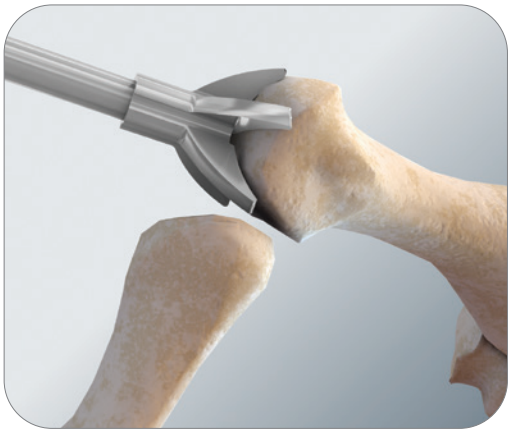


Figure 2-2

First Metatarsal Phalangeal (MTP) Joint Plate

Step 1 ▪ Approach and incision

1-1 The recommended technique for gaining exposure to the MTPJ is to make a dorsal longitudinal incision. For patients where healing of the skin flap may be problematic, a medial approach may be considered.

The initial incision begins just proximal to the interphalangeal joint and extends across the MTPJ, remaining medial to the extensor hallucis longus. The incision is deepened to the joint capsule through the subcutaneous tissue and ends 2-3cm proximal to the joint **(Figure 1-1)**. Release the joint capsule and place retractors (not included in TFS2 Forefoot/Midfoot tray) so that the base of the proximal phalanx and the metatarsal head are exposed.

Step 2 ▪ Metatarsal Joint preparation

2-1 Plantarflex the phalanx to expose the metatarsal head. A curved McGlamry Elevator or Hohmann Retractor (not included in TFS2 Forefoot/Midfoot tray) may be helpful in gaining exposure to the articular surface.

Cup Reamer Sizing and Selection

Start with the largest cup reamer and sequentially work down to determine the correct size. The correct reamer should adequately cover the metatarsal head when contacting the surface **(Figure 2-1)**.

Using the cup reamer as a guide, insert a 1.1mm K-wire through the reamer into the center of the metatarsal head and drive it proximally into the diaphysis.

Connect the cup reamer to a powered device.

Note: Make note of the final cup reamer used. The corresponding phalangeal cone reamer will be used for final preparation of the phalanx. Measurements should be verified with the Depth Gauge.

2-2 Reaming Technique

Begin reaming action before advancing onto the bone in order to avoid aggressive bone removal. Gently ream until bleeding of subchondral bone is visible at the joint surface. While reaming, make sure the soft tissue is properly retracted and the sesamoids are protected.

Start to remove cartilage with the selected cup reamer and work down to smallest required reamer to remove diseased cartilage **(Figure 2-2)**.

Figure 3-1

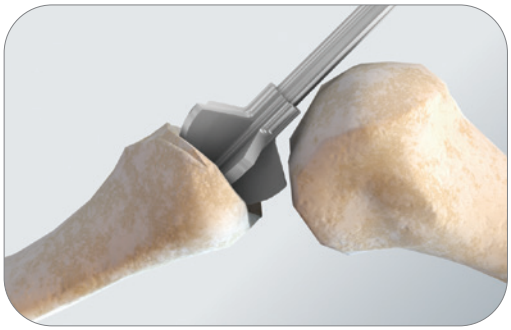


Figure 3-2

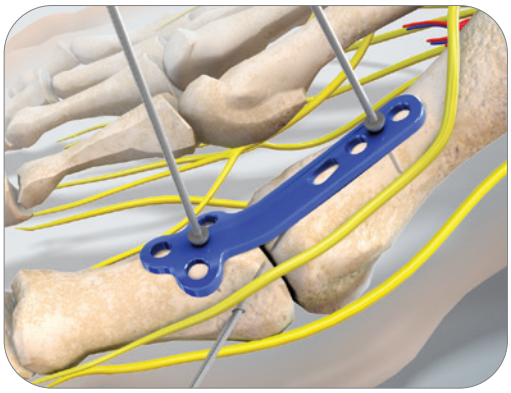


Figure 4-1a

Figure 4-1b

Step 3 ▪ Phalangeal Joint preparation

3-1 Preparation of the proximal phalanx is similar to that of the metatarsal head. Plantarflex the proximal phalanx.

Cone Reamer Sizing and Selection

Start with the smallest cone reamer and work up to the required final reamer size to remove diseased cartilage. The final phalangeal reamer size should correspond with the final metatarsal reamer used. This will ensure congruency between the prepared bone surfaces **(Figure 3-1)**.

Using the cone reamer as a guide, insert a 1.1mm K-wire through the reamer into the center of the base of the phalanx and drive it distally into the diaphysis.

Connect the cone reamer to a powered device.

3-2 Reaming Technique

Begin the reaming action before advancing onto the bone in order to avoid aggressive bone removal. Gently ream until bleeding of subchondral bone is visible at the joint surface. Take care not to penetrate the inter-phalangeal joint **(Figure 3-2)**.

Step 4 ▪ MTP Plate positioning and Dorsiflexion assessment

4-1 Reduce the joint and orient the hallux into the desired position for fusion. Stabilize the orientation by inserting a K-wire beginning at the plantar medial aspect of the phalanx, 1cm distal to the joint line, and extending diagonally through the lateral cortex of the metatarsal, approximately 1.5cm proximal to the joint line.

Select the correct size MTP plate from the forefoot plate caddy. Place the plate on the dorsal surface of the joint so that the 10° valgus bend is angled laterally from the metatarsal to the phalanx. Temporarily attach the plate to the metatarsal and phalanx by inserting a K-wire or Olive wire into the K-wire holes in the plate found in wire, drill, and guide caddy **(Figure 4-1a)**.

Plate Contouring (Bending)

The plate is built with 5° of dorsal contour; however, if adjustments are necessary, remove the plate and use the plate bending irons or Plate Bending Handles **(Figure 4-1b)** to reach the desired degree of dorsiflexion. Important factors to consider when adding dorsiflexion are pathology and activity level. If bending near a locking hole, it is important to assemble the screw-on Drill guide (wire, drill, guide caddy) to the plate to maintain the integrity of the locking construct.

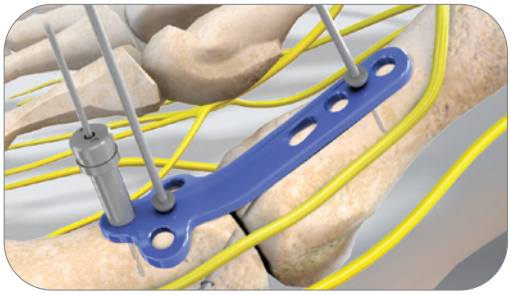


Figure 5-1

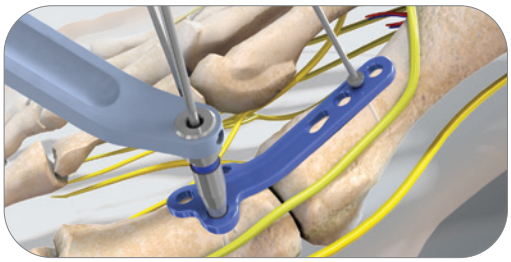


Figure 5-2

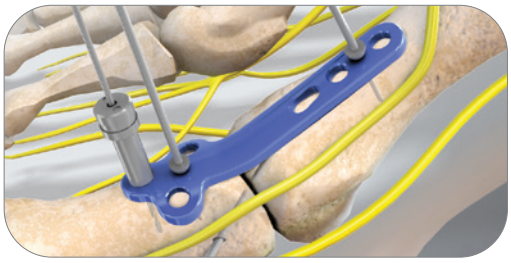


Figure 5-3

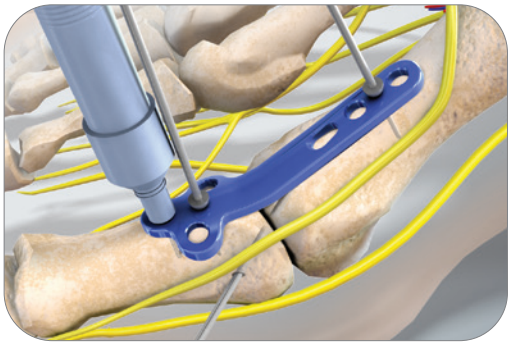


Figure 5-4

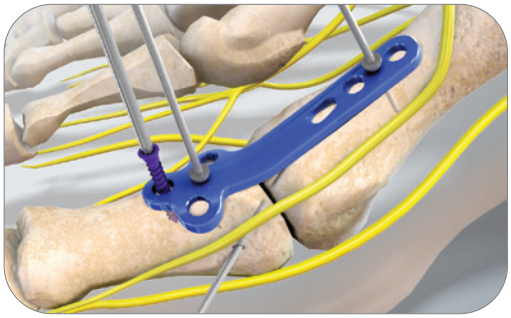


Figure 6-1

Step 5 ▪ Proximal Phalanx screw preparation

5-1 Note: When using a locking screw, it is imperative to use the screw-on Drill guide by threading the guide into the circular locking plate hole **(Figure 5-1)**. For variable angle non-locking screws, attach the snap-on Drill guide to the Drill guide handle and orient inside the screw hole with 15° of variability.

Note: Bicortical fixation is not generally required with locking plates, but may be considered in osteopenic bone. In the case of MTPJ fusion, care should be taken to avoid placing screws beyond the plantar cortex of the phalanx or metatarsal.

5-2 For non-locked plate fixation, screw holes are prepared using the 1.8mm drill bit with the snap-on Drill guide and double Drill guide handle in the drill, wire, and guide caddy **(Figure 5-2)**.

5-3 For locked plate fixation, screw holes are prepared using the 1.8mm drill bit with the screw-on Drill guides **(Figure 5-3)**.

Each hole is drilled bicortically and then measured using the depth gauge (2204262).

Note: If the depth measurement is between 2 screw lengths, the shorter screw length is selected to ensure the screw does not extend past the plantar cortex.

The screw caddy has a measurement guide. This guide is not calibrated. Measurements should be verified with the Depth Gauge.

5-4 Remove screw-on or snap-on Drill guide and measure the depth of the hole using the depth gauge **(Figure 5-4)**.

Step 6 ▪ Screw placement

Once the screw length is determined, press the T8 Torx screwdriver with ratcheting handle (TXDTFS08, RM1011S03) into the head of the selected screw to remove from the TFS2 screw caddy. Use the Depth Gauge (2204262) located in the screw caddy to verify the screw length.

6-1 Begin by placing screws one at a time into the distal 3 holes located on the proximal phalanx. Advance the appropriate screw through the plate hole until it is finger tight, and it is sufficiently locked within the plate. Do not over torque the screw **(Figure 6-1)**. Repeat this insertion technique for the remaining phalangeal screws.

Note: The TFS2 locking screws have a tapered head and may sit slightly above the surface of the plate when fully locked.

Note: For locking screws, ensure that the screw remains on axis with the pre-drilled hole during insertion.

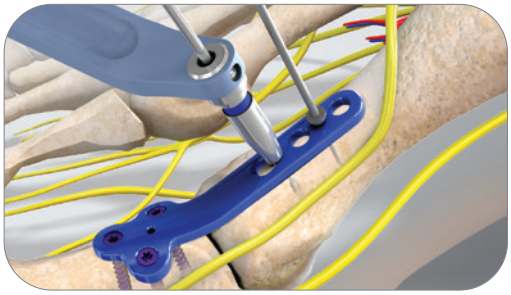


Figure 7-1a

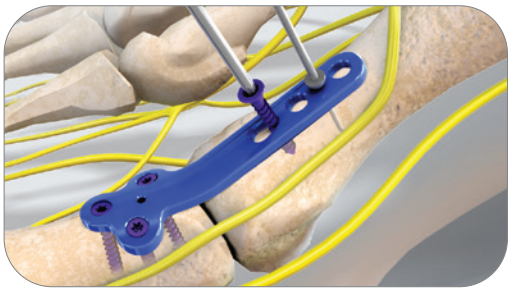


Figure 7-1b

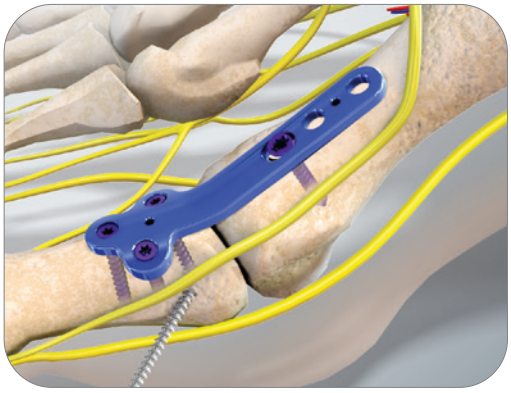


Figure 7-2

Step 7 ▪ Compression and plantar tension band

Note: Once the proximal phalanx is fixed to the plate, compression of the MTPJ is assessed. Compression may be achieved through one of two methods, placing a lag screw outside of the plate across the joint obliquely or using the compression slot on the plate to realize up to 1.5mm of compression. If the compression slot is utilized, it is recommended to insert a screw across the joint as a tension band to limit the risk of plantar gapping.

7-1 Compression Through the Plate Technique:

If compression though the plate is desired attach the Drill guide to the Drill guide handle. Place the snap-on guide with the double Drill guide handle into the proximal portion of the compression slot and drill bicortically **(Figure 7-1a)**. Insert the screw and as the screw contacts the plate assure that it slides the plate proximally until the head is seated down on the plate **(Figure 7-1b)**. Remove the proximal K-wire and interfragmentary K-wire before seating the screw so that joint compression can be fully realized.

7-2 Compression Using Interfragmentary Screw Technique:

TFS2 provides two options if placing a lag screw is desired.

Manual Lag Screw Placement

If manual screw placement is preferred, follow the specific surgical technique for the chosen screw system. Insert a screw from distal medial to proximal lateral across the MTPJ **(Figure 7-2)**.

Guided Lag Screw Placement

If guided lag screw placement is desired, the MTPJ interfragmentary Drill guide found in drill, wire, guide and guide caddy, can be used to ensure the lag screw does not interfere with the plate fixation screws.

The appropriate interfragmentary Drill guide (red for right MTPJ plates and green for left MTPJ plates) is assembled to distal end of the plate with one of the 1.8mm screw-on Drill guides.

Note: The interfragmentary Drill guide has a cutout to accommodate the distal plate geometry. The K-wire holes in the plate and the interfragmentary Drill guide should be used to align the guide with the plate prior to assembly with the 1.8mm screw-on Drill guide.

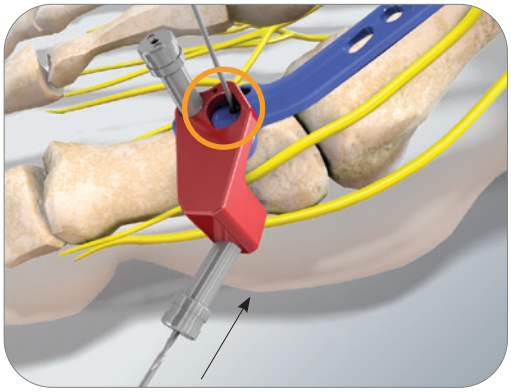


Figure 7-3

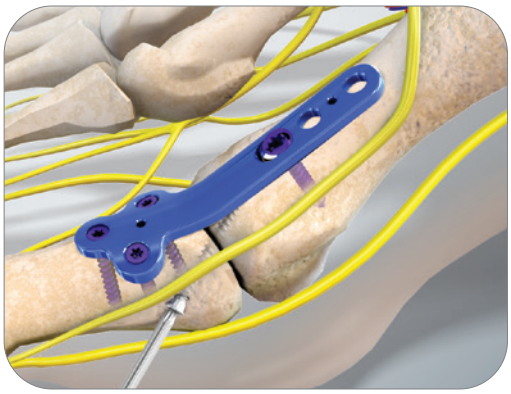


Figure 7-4

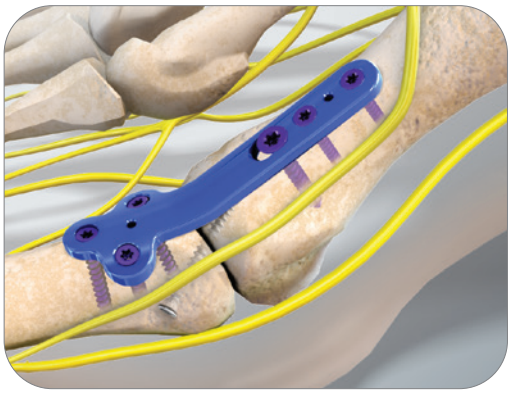


Figure 8-1

7-3 The second 1.8mm screw-on Drill guide is threaded into the front of the interfragmentary Drill guide and the 1.8mm drill bit (blue color coding) is used to prepare the interfragmentary screw hole **(Figure 7-3)**. The drill bit should be advanced across the fusion site and through the lateral cortex of the distal metatarsal.

Note: Once the plate is placed on the bone, a 1.1mm K-wire is placed through the interfragmentary drill guide and the plate to provide additional rotational stability. The insertion of the K-wire is circled in **Figure 7.3**.

7-4 The 1.8mm drill bit is removed and the 2.7mm drill bit (magenta color) is inserted until it reaches the prepared joint site. The 2.7mm drill bit clears out enough bone in the proximal phalanx to allow the 2.7mm screws in the system to pass clearly and compress the fusion site **(Figure 7-4)**.

Note: Care should be taken not to advance the drill bit into the metatarsal as it will reduce or eliminate lag screw fixation.

The lag screw length can be determined by using the scale on the 1.8mm drill bit or by removing the 1.8mm screw-on Drill guide and using the Depth Gauge (2204262).

Step 8 ▪ Final screw selection and placement

8-1 Utilizing the screw preparation and insertion technique described in Step 5, insert the remaining proximal screws in the metatarsal **(Figure 8-1)**.

Step 9 ▪ Closure

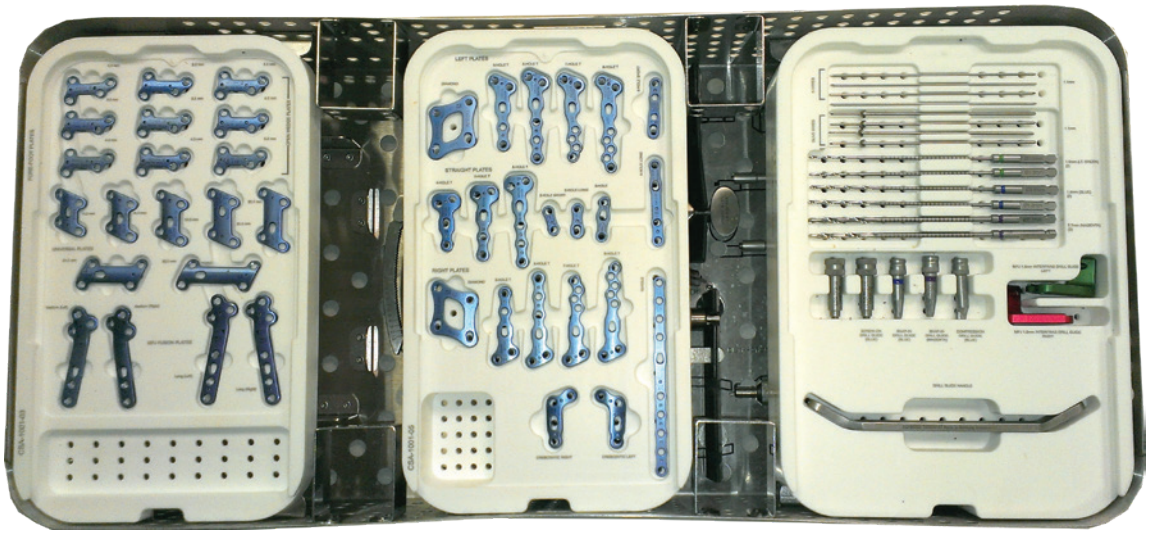
9-1 Proper care should be taken to repair ligament and soft tissues. Standard closure of the incision should be employed depending on the approach taken.

Warnings and precautions

- No metallic surgical implant should be reused. Any metal implant, once used, should be discarded. Even though it appears undamaged, it may already have small defects and internal stress patterns which may lead to fatigue failure.
- Correct handling of the implant is extremely important. Avoid contouring metallic implants whenever possible. If necessary, or allowed by design, the device should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce defects in the surface finish and internal stress concentrations, which may become the focal point for eventual failure of the appliance.
- If metal plates or other metallic devices are to be used together with the TFS2, all such devices should be manufactured from a metal that has a similar composition to avert possibility of galvanic corrosion or other metallic reactions.
- Correct selection of the implant is extremely important. The potential for success in fracture fixation is increased by the selection of the proper size, shape and design of the implants. The patient's anatomy and indication will determine the size of the TFS2 plate to be used. The size and shape of the human bones presents limiting restrictions on the size and strength of implants.
- Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to breakage of the implant requiring revision surgery to remove the device.
- The use of TFS2 provides the surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. The implants are intended as a guide to normal healing and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue. All metal surgical implants are subject to repeated stress in use which can result in metal fatigue.
- Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device prior to the healing of the fracture. Due to normal metal fatigue, these stresses can cause eventual bending or breakage of the device. Therefore, it is important that immobilization of the fracture site is maintained until firm bony union (confirmed by clinical and roentgenographic examination) is established.
- No partial weight bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight bearing. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement at the fracture site and delay healing.
- Detailed written instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending or breakage of the device are complications which may occur as a result of the weight bearing or muscle activity. An active patient or a debilitated or demented patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation.
- While the surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger more active patients.
- The MR environment presents risks to patients with metal implants. Review of the available literature documents that metal implants may heat resulting in tissue damage and may migrate out of position. They may also cause artifact affecting image quality. Physicians should take these risks into consideration when recommending MRI imaging for patients with metal implants.

Note: Smith+Nephew TFS2 has not been evaluated for safety and compatibility in the MR environment. The Smith+Nephew TFS2 has not been tested for heating or migration in the MR environment.

Product information



Forefoot plates

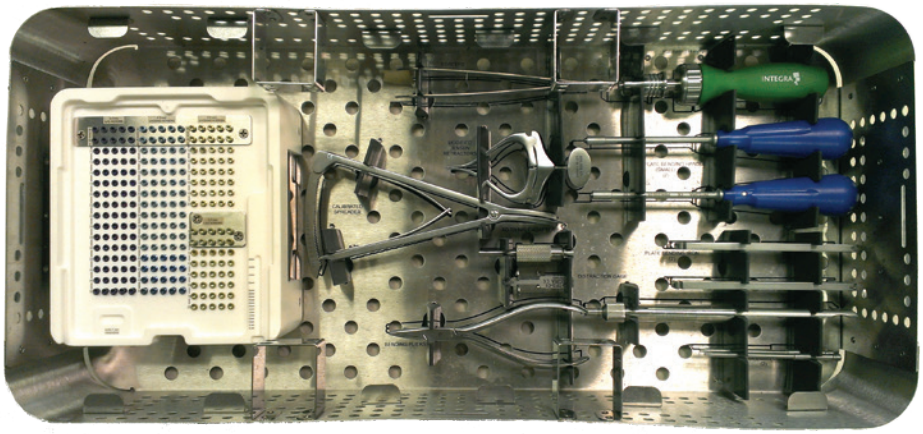
Catalog Number	Size
Open Wedge Plate	
2832100	0mm
2832102	2mm
2832152	2.5mm
2832103	3mm
2832153	3.5mm
2832104	4mm
2832154	4.5mm
2832105	5mm
2832106	6mm
Forefoot Universal Plate	
2801214	14mm
2801216	16mm
2801218	18mm
2801220	20mm
2801222	22mm
2801224	24mm
2801230	30mm
MTPJ Fusion Plate	
2805016	Medium Left
2805017	Medium Right
2805018	LongLeft
2805019	Long Right

Midfoot plates

Catalog Number	Size
Tarsalis Plate	
2807001	2-Hole Straight Short
2807002	2-Hole Straight Long
2807003	3-Hole Straight
2807054	4-Hole Straight Short
2808004	4-Hole Straight
2807010	10-Hole Straight
2807202	4-Hole Crescentic Left
2807201	4-Hole Crescentic Right
2807403	4-Hole Diamond Left
2807404	4-Hole Diamond Right
2807104	4-Hole T Shape Straight
2808105	5-Hole T Shape Straight
2808305	5-Hole T Shape Left
2808205	5-Hole T Shape Right
2808106	6-Hole T Shape Straight
2808306	6-Hole T Shape Left
2808206	6-Hole T Shape Right
2808207	7-Hole T Shape Left
2808107	7-Hole T Shape Right
2808208	8-Hole T Shape Left

Forefoot and Midfoot Wire and Drill Caddy

Catalog Number	Description
2228611	K-Wires 100 x 1.1mm
2227711	Olive Wires 100 x 1.1mm
DRL-TFS-15	1.5mm Drill Bit w/ AO (Lt. green)
DRL-TFS-18	1.8mm Drill Bit w/ AO (Blue)
DRL-TFS-27	2.7mm Drill Bit w/ AO (Magenta)
LDG-TFS-18	1.8mm Screw-on Drill Guide (Blue)
SDG-TFS-18	1.8mm Snap-on Drill Guide (Blue)
SDG-TFS-27	2.7mm Snap-on Drill Guide (Magenta)
CDG-TFS-18	1.8mm Compression Drill Guide (Blue)
RIG-TFS-18	MTPJ 1.8mm Interfrag Drill Guide Right
LIG-TFS-18	MTPJ 1.8mm Interfrag Drill Guide Left
2204157	Double Drill Guide Handle
2808305	5-Hole T Shape Left
2808205	5-Hole T Shape Right
2808106	6-Hole T Shape Straight
2808306	6-Hole T Shape Left
2808206	6-Hole T Shape Right
2808207	7-Hole T Shape Left
2808107	7-Hole T Shape Right
2808208	8-Hole T Shape Left



Forefoot and Midfoot Locking Screws

Catalog Number	Size
2.7mm Plate Locking Screw	
2835008	8mm
2835010	10mm
2835012	12mm
2835014	14mm
2835016	16mm
2835018	18mm
2835020	20mm
2835022	22mm
2835024	24mm
2835026	26mm
2835028	28mm
2835030	30mm
2835035	35mm
2835040	40mm
2835045	45mm
2835050	50mm
2.2mm Plate Locking Screw	
2822006	6mm
2822008	8mm
2822010	10mm
2822012	12mm
2822014	14mm
2822016	16mm
2822018	18mm
2822020	20mm

Forefoot and Midfoot Non-Locking/Lag Screws

Catalog Number	Size
2.7mm Plate Locking Screw	
2837126	26mm
2837128	28mm
2837130	30mm
2837135	35mm
2837140	40mm
2837145	45mm
2837150	50mm
2.2mm Plate Lag Screw	
2822106	6mm
2822108	8mm
2822110	10mm
2822112	12mm
2822114	14mm
2822116	16mm
2822118	18mm
2822120	20mm
2.7mm Plate Lag Screw	
2837108	8mm
2837110	10mm
2837112	12mm
2837114	14mm
2837116	16mm
2837118	18mm
2837120	20mm
2837122	22mm
2837124	24mm
2823027	Washer for 2.2/2.7 mm Screws

Reusable instrumentation

Catalog Number	Description
TXD-TFS-08	Torx 8 Driver, Non-Cannulated w/ AO
RM1011-S03	Ratcheting Handle w/AO QC
5010-001	AO to Trinkle Adapter
2204250	Plate and Screw Holding Forceps
2204262	Depth Gauge For Plate Screws
2204124	Bending Pliers
RTK-TFS-01	Modified Jensen Retractors
PBI-800-00	Plate Bending Iron
PBH-800-01	Plate Bending Handles (Small)
FDG-TFS-01	Forefoot Distraction Gauge
382000	Calibrated Spreader

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