Integra®
Total Foot System 2 Rearfoot

SURGICAL TECHNIQUE
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Introduction

Thank you to Dr. Michael Romash, MD – Chesapeake, VA – Calcaneal Fracture Plate Techniques, Lapidus Technique

Indications

The Integra® Total Foot System 2 (TFS2) is intended for skeletally mature patients for the following:

- Stabilization and fixation of fresh fractures.
- Intra-articular and extra-articular fractures, joint depression, and multi-fragmentary fractures.
- Revision procedures, joint fusion and reconstruction of small bones of the feet.

Contraindications

- Plates and screws are contraindicated in: active infection, conditions which tend to retard healing such as blood supply limitations, previous infections, insufficient quantity or quality of bone to permit stabilization of the fracture complex, conditions that restrict the patient’s ability or willingness to follow postoperative instructions during the healing process and foreign body sensitivity.
- Cases with malignant primary or metastatic tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized.
- Foreign body sensitivity – where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implementations.
- These 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 non-unions 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 subjected to repeated stress in use, which can result in metal fatigue.

System Overview

The Integra® 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. The subject devices can also be used in revision procedures, joint fusion, and in reconstructing the small bones of the feet.

Unique, gold titanium plates are designed to address these indications and are anatomically shaped, giving you more intraoperative choices. Plate benders are included to allow for fine plate adjustments to fit specific patient anatomy. Multiple fixed-angle locking screw lengths minimize micro-motion and standard screws allow for variable-angle screw placement. TFS2 includes the following functional components:

- Specific Rearfoot Plates
- 3.5mm screw options
Available plates, screws, and instrumentation are packaged as a single system and organized around the types of plates described below:

**Rearfoot Plates**

1. Lapidus Plates – Designed with a 0-6mm step in 1mm increments (7 sizes) to displace the bones.
2. Interpositioning Plates – Available with or without a stem to space apart two bones or a joint, with stems being offered in widths 2-12mm in 2mm increments.
3. Universal Rearfoot Plates – Available in 7 sizes: 14mm, 16mm, 18mm, 20mm, 22mm, 24mm, and 30mm.
4. Rearfoot Reconstruction Plates – Available in 7-hole, 9-hole and 14-hole versions.
5. Flat line Arthrodesis Plates – Available in 12mm, 14mm and 16mm sizes.
6. Dwyer Displacement Plates – Available with three different step sizes; 8mm, 10mm, and 12mm.
7. Calcaneus Plates – Available in small, medium, extra small, mini and mini-long sizes.
8. Fibular Plates – Available in 3-hole, 4-hole, and 5-hole versions.
   - The tubular plates are available 4-hole, 6-hole, and 8-hole versions.

**Rearfoot Screws**

- 3.5mm silver, anodized titanium screw (locking and non-locking compression)

Specialty plates within Integra TFS2 Rearfoot Tray include:

**Mini Calcaneus Fracture Plates**

- Gold, low-profile, titanium plates available for calcaneal fracture procedures
- Reduces the need for a large calcaneal flap incision for adequate exposure and fracture reduction
- The posterior row of screws on the Mini-Long Calcaneus Plate can be slid under skin and applied percutaneously

This procedure has evolved over time from a large extensile lateral approach, risking high levels of wound complication, to Integra’s minimally invasive approaches using implants and instrumentation specifically engineered to address the challenges faced by surgeons.

**Fibular Plates**

- Precontoured plate design closely mimics the average anatomical shape of the distal fibula, requiring less intraoperative plate contouring
- Low profile plate and reduced screw head profile minimizes soft tissue irritation
- Distal screw cluster allows for multiple points of fixation to treat comminuted fractures or fractures with limited distal bone stock

**Lapidus Plates**

- Dynamic compression hole to allow compression through the plate
- T-shaped design with increased radius step for optimal anatomic positioning and less intraoperative contouring required

**Interpositioning Plate**

- Anatomical T-shaped design with increased width and stem depth for ease of insertion and less intraoperative contouring required
- Wedge stem design proximal to the screw holes for proper placement
Surgical Technique

As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Total Foot System 2 (TFS2) Rearfoot 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 (PBI800000) or Plate Bending Handles (PBH800000) to match specific patient anatomy.

Note:
If bending near a locking hole, it is important to thread the 2.5mm screw-on drill guides into the plate holes to protect the locking threads in the plate. Bending and repeated sterilization of the plates may result in discoloration which does not affect the safety and structural integrity of the plating system.

Step 3: Screw Preparation

3-1 Non-locked plate configuration. Screw holes are prepared using the 2.5mm drill bit (yellow color-coding) through the snap-on drill guide and double handle.

Locked plate configuration. Screw holes are prepared using the 2.5mm drill bit (yellow color-coding) through the locking screw-on drill guide (Figures 3-1a, 3-1b).
Step 3: Screw Measurement

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.

Remove screw-on or snap-on drill guide and measure the depth of the hole using the Depth Gauge (2204262) (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

Once the screw length is determined, press the 2.5mm Hex Screwdriver with a ratcheting handle (HXD-TFS-25 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 that one screw is placed catty corner on either side of the osteotomy. 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.

Repeat Step 3 for all remaining screws.

Step 4: Final Screw Fixation and Assessment

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.

Step 5: Closure

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

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Lapidus Plates Surgical Technique

Step 1: Incision and Approach

Begin with a dorsomedial incision over Tarso-Metatarsal (TMT) joint. The incision should be extended 2–3cm on either side of the TMT joint to allow proper exposure.

Care should be taken to protect and preserve the cutaneous branch of the saphenous nerve. Deepen the incision through the fascial layers to expose the dorsal capsule of the TMT joint. Use blunt dissection to release the EHL off of the first TMT joint and retract the tendon laterally. Perform a capsulotomy at the superior aspect of the joint to expose the entire joint. A pin-based distractor can be utilized to expose the entire joint for better visibility during joint debridement.

Step 2: Joint Preparation

Completely decorticate the joint surfaces using bone curettes, small osteotomes and/or burrs until dense subchondral bone is completely exposed on each side of the joint, taking care not to create thermal necrosis. With a small drill or K-wire, thoroughly perforate the subchondral plates until rich cancellous bone is exposed.

Assess the lateral aspect of the proximal metatarsal. If this is wide and impinges on the base of the second metatarsal, or if there is a well-developed lateral facet that articulates with the second metatarsal, these will impede correction of the metatarsus primus varus. Debridement of this area is required to allow for correction of the inter-metatarsal angle.

Applying bone graft to the fusion sites to fill any voids or incongruities is optional at this point of the procedure.

Step 3: Positioning and Correction Assessment

The joint is positioned appropriately by correcting the varus and ensuring the metatarsal is not dorsiflexed. This can be accomplished by moving the articular line of the joint without any “wedging.” To account for any shortening of the first ray, translate the base of the metatarsal plantarly and temporarily fix the joint with K-wires found in drill, wire and guide caddy.
Step 4: Plate Assessment and Positioning

The correction and possible shortening may cause a step-off at the TMT joint. Select the Lapidus Plate that best fits the step-off. Plates are available in 0, 1, 2, 3, 4, 5, and 6mm step-offs.

Place the plate dorsally and provisionally fixate with K-wires (Figure 4-1).

In the instance of metatarsus primus varus, the plate can also be placed dorso-medially to allow for translation of the metatarsal base both plantarly and laterally.

Confirm positioning of the plate using fluoroscopy and adjust if necessary.

**Note:** Plate Contouring (Bending)

If necessary, plate-bending irons or plate-bending handles are provided to make fine plate adjustments to fit specific patient anatomy. When bending near a locking hole, it is important to thread the 2.5mm screw-on drill guides (yellow color coding) into the plate to protect the locking threads.

Step 5: Screw Assessment and Selection

Remove screw-on or snap-on drill guide from the prepared hole. Measure the screw depth using the Depth Gauge (2204262). Bicortical fixation is not generally required with locking plates, but may be considered in osteopenic bone.

Once the screw length is determined, use the 2.5mm Hex Driver with ratcheting handle (HXDTFS25, RM1011S03) or Screw Holding Forceps (2204250) to remove the selected screw from the screw caddy. Use the Depth Gauge (2204262) to verify the correct screw length prior to insertion. 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.

Repeat Step 5 for the remaining screw holes in the plate.
Step 6: Screw Preparation (Drilling)

6-1  Non-locked plate configuration
Screw holes are prepared using the 2.5mm drill bit (yellow color coding) with the matching screw-on drill guide.

Locked plate configuration
For locked plate fixation, screw holes are prepared using the 2.5mm drill bit (yellow color coding) with the screw-on drill guide.

Step 6: Screw Measurement

6-2  Each hole is drilled bicortically and then measured using the Depth Gauge (2204262), (Figure 6-2a). 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 6-2b).

An optional stabilization screw can be placed obliquely across the plantar aspect of the TMT joint.

Confirm plate positioning with intraoperative imaging prior to incision closure.

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

Step 7: Closure

7-1  The incision is closed in layers per the surgeon’s preferred technique.

Postoperative Management

A well-padded post-operative splint is recommended for the first 10-14 days during healing.

The leg should be supported in a short, non-weight-bearing cast for 8 weeks.
Surgical Technique

As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Fibular Plates

Step 1: Incision and Approach

A standard lateral incision is created over the distal fibula. Care is taken to avoid any neurovascular structures. The fracture is identified and any soft tissue or excessive hematoma is removed from the fracture site.

Step 2: Fracture Reduction

The distal fragment is clamped using the Reduction Clamp (321010) or Serrated Bone Clamp (321012) in the TFS2 Rearfoot Tray or the surgeon’s preferred clamp, and is manipulated to anatomically reduce the fracture. A second clamp is used to secure the reduction temporarily.

Step 3: Interfragmentary Screw Preparation

An interfragmentary compression screw is placed perpendicular to the fracture as follows. The 2.5mm drill (yellow color coding) is passed across the fracture (Figure 3-1).

The 3.5mm drill (purple color coding) is then used to drill the near cortex. Overdrilling the near cortex allows compression using the 3.5mm screws in the TFS2 Rearfoot Tray (Figure 3-2).
Step 4: Interfragmentary Screw Selection and Placement

The screw length is measured using the Depth Gauge (2204262) (Figure 4-1a). Once the screw length is determined, use the Hex Screwdriver with ratcheting handle or Screw Holding Forceps (HXDTFS25, RM1011S03) to remove the selected screw from the screw caddy. Use the Depth Gauge (2204262) to verify the correct screw length prior to insertion.

The screw is inserted and the reduction is checked under fluoroscopy (Figure 4-1b).

Step 5: Plate Assessment and Placement

The appropriate length lateral plate is selected and temporarily held in place with K-wires, Olive wires (Figure 5-1) or a clamp.
Step 6: Screw Selection and Placement

**Non-locked plate configuration**
For non-locked plate fixation, screw holes are prepared using the 2.5mm drill bit (yellow color coding) with the matching snap-on drill guide.

**Locked plate configuration**
For locked plate fixation, screw holes are prepared using the 2.5mm drill bit (yellow color coding) with the screw-on drill guide.

Recommended screw placement order:

1. Using the 2.5mm drill (yellow color coding) and the desired drill guide, prepare the hole distal to the fracture. If the hole is at or distal to the ankle joint, unicortical fixation is recommended (Figure 6-1).

2. Remove Screw-on or Snap-on Drill Guide from the prepared hole. Measure the screw depth using the Depth Gauge (2204262).

3. Once the screw length is determined, use the Hex Screwdriver with ratcheting handles or Screw Holding Forceps (HXDTFS25, RM1011S03) to remove the selected screw from the screw caddy. Use the measuring gauge located in the screw caddy to verify the correct screw length prior to insertion. 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.

4. The hole just proximal to the fracture is then prepared and screw inserted using the steps listed above (Figure 6-2).

5. Provisional fixation may now be removed.

6. The remaining distal and proximal holes are then prepared and screws are inserted (Figure 6-3).

Step 7: Optional Syndesmosis Fixation

7-1 After repairing the fracture, the surgeon may intraoperatively assess the stability of syndesmosis joint using the Cotton, fibula translation, external rotation or other test. Preoperative imaging studies including an X-ray, MRI or CT scan may also be useful in diagnosing a syndesmotic injury. The syndesmotic injury is addressed at the surgeon’s discretion.

A large reduction clamp is used to reduce and stabilize the position of the syndesmosis joint. The reduction should be assessed using an X-ray or by direct exposure if feasible.

3.5mm variable angle screws from the TFS2 tray may be placed through the plate or next to the plate to fixate the syndesmosis joint. Fixation through the plate requires at least one open screw hole at the distal straight portion of the plate.
Step 7: Optional Syndesmosis Fixation (Continued)

7-1 Place the Snap-on Drill Guide into the appropriate plate screw hole and use the 2.5mm Drill (yellow color coding) to prepare the screw hole. Drill through the fibula and through the first tibial cortex is only tri-cortical fixation is desired (Figure 7-1).

7-2 The far tibial cortex is drilled if four cortices of fixation are desired. Excessive screw angulation should be avoided to provide a low profile construct. In general a maximum of 10-15° of angulation is recommended. The 3.5mm Drill (purple color coding) is used to overdrill the fibula (Figure 7-2).

7-3 The screw length is measured using the Depth Gauge (2204262) and the appropriate screw is inserted (Figure 7-3a). The screw position is verified using X-ray (Figure 7-3b).

If a second screw is desired, follow the above steps to prepare the bones and insert the screw.

Step 8: Final Reduction and Closure

8-1 Final reduction is checked under fluoroscopy and if satisfactory, closure is performed following standard technique.
Surgical Technique

As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Calcaneus Fracture Plates

Lateral Approach using the Mini Calcaneus Long Plate

A Mini Calcaneus Long Plate is available if the surgeon elects to use a lateral plate through a lateral incision only, but still wishes to capture the posterior aspect of the fracture.

Step 1: Incision and Approach

The lateral incision is initiated slightly behind the distal aspect of the lateral malleolus, extending roughly 5cm in line with the 4th and 5th metatarsal toward the cuboid. The incision is made above the sural nerve and retracted posteriorly with the peroneal tendons. The sinus tarsis mobilized and the subtalar joint is exposed using a lamina spreader.

Step 2: Fracture Reduction

The fracture must be disimpacted and reduced.

The tuberosity has usually translated lateral and cephalad and has tilted into varus. The lateral aspect of the posterior facet has been impacted into the body of the calcaneus and has rotated with the anterior portion being more depressed than the posterior aspect of the fragment. A joint depression or tongue pattern may be present.

Usually a door into the body of the calcaneus can be identified in the lateral wall. A Baby Inge lamina spreader, not included in the TFS2 Rearfoot Tray, can be introduced into the sinus tarsi. As the lamina spreader is opened, the sustentacular fragment is visualized as the medial fragment. A “Joker” elevator can be placed below the depressed lateral facet fragment and this can be mobilized and elevated. This permits the surgeon to mobilize the tuberosity fragment, using a “Joker” or osteotome (not included in TFS2 Rearfoot tray).
Step 2: Fracture Reduction (Continued)

A Steinmann Pin or Schanz Screw (not included in TFS2 Rearfoot Tray) can be placed through the tuberosity fragment (Figure 2-1a). With traction and angular correction this fragment can be positioned under the posterior facet, and with elevation of the posterior lateral facet fragment, the lateral wall will be reduced and the posterior facet/subtalar joint will be reduced. The angle of Gissane should be reduced. The anterior calcaneus, which may be split, is reduced.

Temporary fixation is then accomplished with K-wires and Steinmann Pins (not included in TFS2 Rearfoot Tray). A Steinmann Pin may be placed through the tuberosity into the sustentacular fragment. K-wires are placed through the posterior lateral fragment into the sustentacular fragment holding the subtalar joint reduction. An oblique wire may be placed from the anterior fragment into the posterior construct under the subtalar joint. If needed, another wire can be placed across the anterior calcaneus (Figure 2-1b).

If desired, bone graft may now be placed through the lateral door in the calcaneus before it is closed and the plate is applied.

The following X-rays should be used to confirm the reduction:

- Lateral View to check Böhler’s Angle, length and shape of heel. It is helpful to have a lateral X-ray of the uninjured foot.
- Axial Heel – shows the medial wall reduction.
- AP Foot – shows calcaneocuboid joint.
- “Broden’s” Views – shows articular surface of subtalar joint.

Adjustments to the reduction are performed accordingly.

Step 3: Plate Selection and Placement

The Mini Calcaneus Plate is placed on the reduced calcaneus and contoured as necessary. There is some flexibility in the plate that will permit the superior arm to contour when screws are applied. Plate Bending Irons or Plate Bending Handles are very helpful in contouring the plate. If locking screw fixation is going to be used it is important to place the screw-on drill guides in the plate holes in the vicinity of contouring to protect the threads (Figure 3-1).

The plate is provisionally fixed to the calcaneus using K-wires or Olive wires through the fixation slots in the plate. The slots allow small intraoperative adjustments to the plate position prior to screw fixation.

The plate position is assessed using an X-ray and adjusted as necessary.
Step 4: Screw Selection, Measurement, and Final Placement

4-1 Non-locked plate configuration
For non-locked plate fixation, screw holes are prepared using the 2.5mm drill bit (yellow color coding) with the matching snap-on drill guide.

Locked plate configuration
For locked plate fixation, screw holes are prepared using the 2.5mm drill bit (yellow color coding) with the screw-on drill guide.

Note:
It is recommended to begin with the more distal screws, moving proximal posterior to address the tuberosity.

4-2 Using the 2.5mm drill (yellow color coding) and the desired drill guide, prepare the hole distal to the fracture. If the hole is at or distal to the ankle joint, unicortical fixation is recommended (Figure 4-2).

4-3 Remove Screw-on or Snap-on Drill Guide from the prepared hole. Measure the screw depth using the Depth Gauge (2204262) (Figure 4-3).

4-4 Once the screw length is determined, use the 2.5mm Hex Driver with Ratcheting Handle (HXDTS25, RM1011S03) or Screw Holding Forceps (2204250) to remove the selected screw from the screw caddy. Use the Depth Gauge (2204262) to verify the correct screw length prior to insertion. 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 4-4).

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

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

4-5 Continue drilling, measuring, and inserting screws until percutaneus screw placement is required. Using fluoroscopy, make a stab incision over each posterior screw hole for passing of instrumentation and screw insertion.

Place the remaining screws (Figure 4-5).

Step 5: Final Reduction and Closure

5-1 Final reduction is checked under fluoroscopy and if satisfactory, closure is performed following standard technique.
Surgical Technique

As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Calcaneus Fracture Plates

Lateral Approach using Lateral “Perimeter” Plate Technique

Step 1: Incision and Approach

The patient is placed in lateral decubitus position with injured limb up, supported on a radiolucent bolster.

The lateral extensile approach is used. An “L” shaped incision is made just anterior to the Achilles tendon to the junction of plantar/lateral skin at which point it is extended toward the toes along this margin, past the cuboid (Figure 1-1).

At the apex of the incision it is important that the blade carries down to the bone. The flap is then raised subperiosteally from the apex anterior and dorsal. It is important not to create multiple layers, but to elevate a full thickness flap. This flap goes under the sural nerve, peroneal tendon sheath and tendons. It permits the tendons to be moved anterior to the fibula. The sinus tarsi and calcaneo cuboid (CC) joint are exposed.

Steinmann Pins (not included in TFS2 Rearfoot Tray) are placed in the fibular malleolus and neck of the talus as “no touch” retractors, holding the flap out of the way. The lateral wall should be exposed, allowing visualization of the subtalar joint through the sinus tarsi. The CC joint should also be visible.

Step 2: Fracture Reduction

The fracture must be disimpacted and reduced.

The tuberosity has usually translated lateral and cephalad and has tilted into varus. The lateral aspect of the posterior facet has been impacted into the body of the calcaneus and has rotated with the anterior portion being more depressed than the posterior aspect of the fragment. A joint depression or tongue pattern may be present.

Usually a door into the body of the calcaneus can be identified in the lateral wall. A Baby Inge lamina spreader, (not included in the TFS2 Rearfoot Tray), can be introduced into the sinus tarsi. As the lamina spreader is opened, the sustentacular fragment is visualized as the medial fragment. A “joker” elevator (not included in the TFS2 Rearfoot Tray) can be placed below the depressed lateral facet fragment and this can be mobilized and elevated. This permits the surgeon to mobilize the tuberosity fragment, using a “joker” or osteotome (not included in the TFS2 Rearfoot Tray).
Step 2: Fracture Reduction (Continued)

A Steinmann Pin or Schanz Screw (both not included in the TFS2 Rearfoot Tray) can be placed through the tuberosity fragment. With traction and angular correction this fragment can be positioned under the posterior facet, and with elevation of the posterior lateral facet fragment, the lateral wall will be reduced and the posterior facet/subtalar joint will be reduced. The angle of Gissane should be reduced. The anterior calcaneus which may be split is reduced.

Temporary fixation is then accomplished with K-wires and Steinmann Pins (not included in TFS2 Rearfoot Tray). A Steinmann Pin may be placed through the tuberosity into the sustentacular fragment. K-wires are placed through the posterior lateral fragment into the sustentacular fragment holding the subtalar joint reduction. An oblique wire may be placed from the anterior fragment into the posterior construct under the subtalar joint. If needed, another wire can be placed across the anterior calcaneus.

Note:
If desired, bone graft may now be placed through the lateral door in the calcaneus before it is closed and the plate is applied.

The following X-rays should be used to confirm the reduction:

- Lateral View to check Böhler’s Angle, length and shape of heel. It is helpful to have a lateral X-ray of the uninjured foot.
- Axial Heel – shows the medial wall reduction.
- AP Foot – shows calcaneocuboid joint.
- “Broden’s” Views – shows articular surface of subtalar joint.

Adjustments to the reduction are performed accordingly.

Step 3: Plate Selection and Placement

The appropriate perimeter style TFS2 plate placed on the reduced calcaneus and contoured as necessary. There is some flexibility in the plate that will permit the superior arm to contour when screws are applied. Plate Bending Irons (PBI800000) or Plate Bending Handles (PBH800000) are very helpful in contouring the plate.

If locking screw fixation is going to be used it is important to place the screw-on drill guides in the plate holes in the vicinity of contouring to protect the threads (Figure 3-1).

The plate is provisionally fixed to the calcaneus using K-wires or Olive wires through the fixation slots in the plate. The slots allow small intraoperative adjustments to the plate position prior to screw fixation.
Step 4: Screw Selection, Measurement, and Final Placement

4-1 Using the 2.5mm drill (yellow color coding) and the Snap-on Drill Guide, drill a hole through the plate through the lateral fragment and into the sustentacular fragment. The 3.5mm drill (purple color coding) is then used to overdrill the lateral fragment (Figure 4-1) found in the drill, wire, and guide caddy.

**Note:**
Be very aware that the subtalar joint slopes distal/plantar from the lateral side and care must be taken to ensure that the screws are not intraarticular in the medial aspect of the joint.

4-2 Remove the Snap-on Drill Guide from the prepared hole and measure the screw depth with the Depth Gauge (2204262) (Figure 4-2).

4-3 Once the screw length is determined, use the 2.5mm Hex Driver with Ratcheting Handle (HXDTFS25, RM1011S03) or Screw Holding Forceps (2204250) to remove the selected Lag Screw from the screw caddy. Use the Depth Gauge (2204262) to verify the correct screw length prior to insertion. Advance the appropriate screw through the plate hole until it is finger tight, and it is sufficiently locked within the plate. Do not overtorque the screw.

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

The compression screw will compress the fragments creating a washer effect with the plate (Figure 4-3).

In similar fashion, a compression screw can be placed across the anterior calcaneus if the anterior facet is split.

The remainder of the holes in the plate are then filled with locking screws. Use the Screw-on Drill Guide and 2.5mm Drill (yellow color coding) to prepare the holes and place the remaining screws.
Step 5: Final Reduction and Closure

Final reduction is checked using an X-ray (Figure 5-1).

The tourniquet is deflated, Steinmann Pin retractors are removed, peroneal tendons are reduced and the wound is closed. A small drain may be placed under the flap.

A bulky compressive dressing, splints or cast are applied. “A-V sole compression bladders” are optional, but helpful in managing swelling.

Post-operative Therapy Management

Post-operative management is surgeon’s discretion, based on reduction and fixation. Either early motion or protection. Keep patient in a non-weight bearing cast until union is established.
Surgical Technique

As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Combined Medial and Lateral Approach using the Mini Calcaneus Short Plate and Rearfoot Universal Plate

Initial Medial Incision and Fracture Reduction (Combined Medial and Lateral Approach)

Step 1: Medial Incision and Approach

1-1 The patient is placed in the supine position with the affected leg in a figure four orientation to expose the medial side of the foot. A 5 to 6cm long medial incision is performed over the posterior tuberosity, three fingerbreadths below the medial malleolus.

The neurovascular bundle will be at the anterior aspect of the wound. The approach is deepened through the fascia, mobilizing the neurovascular bundle and vital structures, retracting anteriorly. The medial wall of the calcaneus is then exposed by elevating the short flexors. Typically, the tuberosity has shifted laterally and proximally. A “shingle” effect is visualized as the medial wall of the sustentacular fragment overhangs the superior edge of the tuberosity fragment. The fracture pattern can be confirmed under fluoroscopy (Figure 1-1).

Step 2: Fracture Reduction

2-1 The fracture is disimpacted using an elevator under the lateral facet, raising the facet for ease of reducing the tuberosity. A Steinmann Pin (not included in TFS2 Rearfoot Tray) is placed medially through the posterior inferior aspect of the tuberosity until the pin protrudes laterally by approximately 5cm. Place a surgical towel under the pin on the table to prevent the pin from penetrating the drapes. The tip of the pin will be used as a fulcrum to reduce the tuberosity. The tuberosity is then rotated out of varus by pulling the opposite end of the pin both distally and posteriorly (Figure 2-1).

Step 3: Medial Plate Assessment

3-1 With the fracture reduced, fixation may be applied to the medial side of the foot. An inverted TFS2 Universal Rearfoot Plate is the recommended method of fixation. The existing contour of plate fits well on the anatomical shape of the medial aspect of the calcaneus (Figure 3-1).

Confirm positioning of the plate using an X-ray and adjust if necessary.
Step 4: Screw Selection, Measurement and Final Placement

4-1 Thread the Locking Screw-on Drill Guide into one of the proximal screw holes.

**Non-locked plate configuration**
For non-locked plate fixation, screw holes are prepared using the 2.5mm drill bit (yellow color coding) with the matching snap-on drill guide. (Figure 4-1).

**Locked plate configuration**
For locked plate fixation, screw holes are prepared using the 2.5mm drill bit (yellow color coding) with the screw-on drill guide.

Using the 2.5mm drill (yellow color coding) and the desired drill guide, prepare the hole distal to the fracture. If the hole is at or distal to the ankle joint, unicortical fixation is recommended (Figure 4-1).

4-2 Remove Screw-on or Snap-on Drill Guide from the prepared hole. Measure the screw depth using the Depth Gauge (2204262) (Figure 4-2).

4-3 Once the screw length is determined, use the 2.5mm Hex Driver with Ratcheting Handle (HXDTFS25, RM1011S03) or Screw Holding Forceps (2204250) to remove the selected screw from the screw caddy. Use the Depth Gauge (2204262) to verify the correct screw length prior to insertion. 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 4-3).

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

**Note:**
Shorter locking screws are recommended to minimize interference with the lateral fracture reduction.

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

4-4 The remainder of the holes in the plate are then filled with locking or non-locking screws.

4-5 Check fluoroscopy to confirm placement.
**Step 5: Lateral Incision and Approach**

The patient is placed in lateral decubitus position with injured limb up, supported on a radiolucent bolster.

The lateral extensile approach is used. An “L” shaped incision is made just anterior to the Achilles tendon to the junction of plantar/lateral skin at which point it is extended toward the toes along this margin, past the cuboid.

At the apex of the incision it is important that the blade carries down to the bone. The flap is then raised sub periosteally from the apex anterior and dorsal. It is important not to create multiple layers, but to elevate a full thickness flap. This flap goes under the sural nerve, peroneal tendon sheath and tendons. It permits the tendons to be moved anterior to the fibula. The sinus tarsi and calcaneo cuboid (CC) joint are exposed.

Steinmann Pins (not included in TFS2 Rearfoot Tray) are placed in the fibular malleolus and neck of the talus as “no touch” retractors, holding the flap out of the way. The lateral wall should be exposed, allowing visualization of the subtalar joint through the sinus tarsi. The CC joint should also be visible.

**Step 6: Lateral Fracture Reduction**

The fracture must be disimpacted and reduced.

The tuberosity has usually translated lateral and cephalad and has tilted into varus. The lateral aspect of the posterior facet has been impacted into the body of the calcaneus and has rotated with the anterior portion being more depressed than the posterior aspect of the fragment. A joint depression or tongue pattern may be present.

Usually a door into the body of the calcaneus can be identified in the lateral wall. A Baby Inge lamina spreader, (not included in the TFS2 Rearfoot Tray), can be introduced into the sinus tarsi. As the lamina spreader is opened, the sustentacular fragment is visualized as the medial fragment. A “Joker” elevator (not included in the TFS2 Rearfoot Tray) can be placed below the depressed lateral facet fragment and this can be mobilized and elevated. This permits the surgeon to mobilize the tuberosity fragment, using a “Joker” or osteotome (not included in the TFS2 Rearfoot Tray).
Step 6: Lateral Fracture Reduction (Continued)

A Steinmann Pin or Schanz Screw (both not included in the TFS2 Rearfoot Tray) can be placed through the tuberosity fragment. With traction and angular correction this fragment can be positioned under the posterior facet, and with elevation of the posterior lateral facet fragment, the lateral wall will be reduced and the posterior facet/subtalar joint will be reduced. The angle of Gissane should be reduced. The anterior calcaneus which may be split is reduced.

Temporary fixation is then accomplished with K-wires and Steinmann Pins (not included in TFS2 Rearfoot Tray). A Steinmann Pin may be placed through the tuberosity into the sustentacular fragment. K-wires are placed through the posterior lateral fragment into the sustentacular fragment holding the subtalar joint reduction. An oblique wire may be placed from the anterior fragment into the posterior construct under the subtalar joint. If needed, another wire can be placed across the anterior calcaneus.

**Note:**
If desired, bone graft may now be placed through the lateral door in the calcaneus before it is closed and the plate is applied.

The following X-rays should be used to confirm the reduction:

- Lateral View to check Böhler’s Angle, length and shape of heel. It is helpful to have a lateral X-ray of the uninjured foot.
- Axial Heel – shows the medial wall reduction.
- AP Foot – shows calcaneocuboid joint.
- “Broden’s” Views – shows articular surface of subtalar joint.

Adjustments to the reduction are performed accordingly.

Step 7: Lateral Plate Selection and Placement

Depending on surgeon preference, the Mini-Short or the Mini-Long Calcaneous Plate can be placed on the lateral aspect of the calcaneous to fixate the posterior facet, anterior calcaneus and to link the posterior construct to the anterior calcaneus.

If locking screw fixation is going to be used it is important to place the screw-on drill guides in the plate holes in the vicinity of contouring to protect the threads.

The plate is provisionally fixed to the calcaneus using K-wires or Olive wires through the fixation slots in the plate. The slots allow small intraoperative adjustments to the plate position prior to screw fixation.
Step 8: Screw Selection, Measurement, and Final Placement

8-1 Using the 2.5mm drill (yellow color coding) and the Snap-on Drill Guide, drill a hole through the plate through the lateral fragment and into the sustentacular fragment. The 3.5mm drill (purple color coding) is then used to overdrill the lateral fragment (Figure 8-1) found in the drill, wire, and guide caddy.

Note: Be very aware that the subtalar joint slopes distal/plantar from the lateral side and care must be taken to ensure that the screws are not intraarticular in the medial aspect of the joint.

8-2 Remove the Snap-on Drill Guide from the prepared hole and measure the screw depth with the Depth Gauge (2204262) (Figure 8-2).
Once the screw length is determined, use the 2.5mm Hex Driver with ratcheting handle (HXDTFS25, RM1011S03) or Screw Holding Forceps (2204250) to remove the selected Lag Screw from the screw caddy. Use the Depth Gauge (2204262) to verify the correct screw length prior to insertion. 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.

The lag screw will compress the fragments creating a washer effect with the plate (Figure 8-3).

In similar fashion, a compression screw can be placed across the anterior calcaneus if the anterior facet is split.

The remainder of the holes in the plate are then filled with locking screws. Use the Screw-on Drill Guide and 2.5mm Drill (yellow color coding) to prepare the holes and place the remaining screws.

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

**Step 9: Final Fixation and Closure**

Final screws placed and checked using an X-ray (Figure 9-1).

Closure is performed in layers per the surgeon’s preferred technique.
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## Wires, Drills and Guides

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### Product Ordering Information

![Image of surgical instruments]

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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: Integra TFS2 has not been evaluated for safety and compatibility in the MR environment.

Adverse Events

- Loosening, bending, cracking or fracture of the screw or loss of fixation in bone attributable to nonunion.
- Loss of anatomic position with nonunion or mal-union with rotation or angulation.
- Infection, both deep and superficial.
- Allergies and other reaction to the device material.
Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region. 

- Always refer to the appropriate instructions for use for complete clinical instructions.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

Additional information for EMEA Customers only:
Products mentioned in this document are CE class I, IIa, IIb or III devices. Contact Integra if you need any additional information on devices classification. All the medical devices mentioned in this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as “NOT CE MARKED”.

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