Integra®
Total Foot System
Metatarsal Opening Wedge
Osteotomy (MOWO) Plate
# Table of Contents

## Introduction
- System Design Description .................................................................................................................. 2
- Features .................................................................................................................................................. 2
- Indications for Use ................................................................................................................................. 2
- Contraindications .................................................................................................................................. 2

## Surgical Technique
- Preoperative Preparation ....................................................................................................................... 3
- Additional Corrective Procedures ........................................................................................................ 3
- Step 1: Incision ..................................................................................................................................... 3
- Step 2: Creating the Osteotomy ............................................................................................................ 3
- Step 3: Opening the Osteotomy .............................................................................................................. 4
- Step 4: Assessing Correction and Plate Selection .................................................................................. 4
- Step 5: Plate Assembly and Anchoring .............................................................................................. 5
- Step 6: Screw Preparation .................................................................................................................. 5
- Step 7: Screw Insertion ......................................................................................................................... 5
- Step 8 (Optional): Supplemental Grafting ......................................................................................... 6
- Step 9: Closure ..................................................................................................................................... 6

## Essential Product Information
.................................................................................................................................................................................. 6

## Ordering Information
..................................................................................................................................................................... Back Cover

## Fixation Plates and Screws
..................................................................................................................................................................... Back Cover
System Design Description

This titanium anatomically designed plate comes in various size options for proximal metatarsal osteotomies.

Features

• 2 mm stem size added to address smaller degrees of correction to the IM angle
• New size range: 0, 2, 3, 4, 5, and 6mm
• Stems deepened and tapered for distraction of osteotomy during insertion and solid contact against cortical bone
• Distal screw holes narrowed for an anatomic fit along the distal metatarsal
• Stems moved proximally on plate to minimize potential interference with proximal joint

Indications For Use

Integra Total Foot System is indicated for skeletally mature patients for the following:

• Stabilization and fixation of fresh fractures
• Intra and Extra articular fractures, joint depression, multi-fragmentary fractures
• Revision procedures, joint fusion, and reconstruction of small bones in 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.
Surgical Technique
This technique has been developed with the help of Alan Tuckman, MD.

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.

Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner.

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 degrees of correction to the IM angle. E.g., a 4mm opening wedge plate will provide approximately 8 degrees 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 guide, proximal 1st metatarsal opening wedge osteotomies have been used in the correction of hallux valgus, hallux rigidus, and the midfoot sag seen in posterior tibial tendon dysfunction. 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 • Incision
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 Hohmann’s should be placed on either side of the metatarsal to protect the soft tissues and help to gauge the depth of the osteotomy. The first 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
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.
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. Therefore a hallux valgus deformity with first metatarsal elevatus and second ray metatarsalgia may benefit from an osteotomy angled 45 degrees 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.

Step 3 • Opening the Osteotomy

A straight osteotome can be used to gradually pry open the osteotomy. Care should be taken to prevent fracturing and displacing the lateral cortex. A small laminar spreader placed on the medial cortex may also be used to “dial-in” the desired correction. Care should be taken not to place the laminar spreader into the osteotomy as this may lead to distraction of the lateral cortex.

Step 4 • Assessing Correction and Plate Selection

Plates are available in 0, 2, 3, 4, 5 and 6mm wedge configurations.

The appropriate opening wedge plate is selected based on intraoperative assessment. The chamfered edge of the wedge will help to push the osteotomy open and seat the plate. 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.
Step 5 • Plate Assembly and Anchoring

5-1 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 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.

5-2 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
If an unlocked plate configuration is preferred the plate can be provisionally fixed using the olive wires in the instrument tray.

Locked plate configuration
The locking drill guides are assembled to the appropriate holes in the plate. Olive wires can be used to secure the plate in the appropriate position.

Step 6 • Screw Preparation

Non-locked plate configuration
For non-locked plate fixation, screw holes are prepared using the 2.0mm drill through the variable angle drill guide.

6-1 For locked plate fixation, screw holes are prepared using the 2.0mm drill through the locking drill guide.

6-2 Each hole is drilled bicortically and then measured using the depth gage from the instrument tray. If the depth measurement is between 2 screw lengths, the longer screw length is selected to ensure maximum fixation.

Step 7 • Screw Insertion

7-1 Once the screw length is determined, press the screwdriver into the head of the selected screw to remove from the TFS screw caddy. Use the measuring gauge located in the screw caddy to verify the correct screw length. Advance the appropriate screw through the plate hole until it is flush with the plate. For the insertion of locking screws, ensure that the screw remains on axis with the pre-drilled hole. Repeat this insertion technique for all remaining screws.

7-2 It is recommended that one screw is placed caddy 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 joystick plate benders.
Step 8 (Optional) • Supplemental Grafting

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 plate placement and fixation.

Step 9 • Closure

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.

Essential Product Information

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 Total Foot System, 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 Total Foot System 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 Total Foot System 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 nonweight 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 Integra Total Foot System has not been evaluated for safety and compatibility in the MR environment. The Integra Total Foot System has not been tested for heating or migration in the MR environment.
Titanium Locking and Non-Locking Screws
2.7mm; 8–30mm in 2mm increments
2.7 x 8mm  28.25.108

Standard Screw

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>28.25.112</td>
<td>2.7 x 12mm</td>
</tr>
<tr>
<td>28.25.114</td>
<td>2.7 x 14mm</td>
</tr>
<tr>
<td>28.25.116</td>
<td>2.7 x 16mm</td>
</tr>
<tr>
<td>28.25.118</td>
<td>2.7 x 18mm</td>
</tr>
<tr>
<td>28.25.120</td>
<td>2.7 x 20mm</td>
</tr>
<tr>
<td>28.25.122</td>
<td>2.7 x 22mm</td>
</tr>
<tr>
<td>28.25.124</td>
<td>2.7 x 24mm</td>
</tr>
<tr>
<td>28.25.126</td>
<td>2.7 x 26mm</td>
</tr>
<tr>
<td>28.25.128</td>
<td>2.7 x 28mm</td>
</tr>
<tr>
<td>28.25.130</td>
<td>2.7 x 30mm</td>
</tr>
</tbody>
</table>

Locking Screw

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>28.25.008</td>
<td>2.7 x 8mm</td>
</tr>
<tr>
<td>28.25.012</td>
<td>2.7 x 12mm</td>
</tr>
<tr>
<td>28.25.014</td>
<td>2.7 x 14mm</td>
</tr>
<tr>
<td>28.25.016</td>
<td>2.7 x 16mm</td>
</tr>
<tr>
<td>28.25.018</td>
<td>2.7 x 18mm</td>
</tr>
<tr>
<td>28.25.020</td>
<td>2.7 x 20mm</td>
</tr>
<tr>
<td>28.25.022</td>
<td>2.7 x 22mm</td>
</tr>
<tr>
<td>28.25.024</td>
<td>2.7 x 24mm</td>
</tr>
<tr>
<td>28.25.026</td>
<td>2.7 x 26mm</td>
</tr>
<tr>
<td>28.25.028</td>
<td>2.7 x 28mm</td>
</tr>
<tr>
<td>28.25.030</td>
<td>2.7 x 30mm</td>
</tr>
</tbody>
</table>

Fixation Plates

Open-Wedge Plate
Plate fixation for a variety of proximal metatarsal osteotomies

T: 1.2mm
X L: 26mm:
Catalog No:

<table>
<thead>
<tr>
<th>0mm stem</th>
<th>2mm stem</th>
</tr>
</thead>
<tbody>
<tr>
<td>28.32.100</td>
<td>28.32.102</td>
</tr>
<tr>
<td>3mm stem</td>
<td>4mm stem</td>
</tr>
<tr>
<td>28.32.103</td>
<td>28.32.104</td>
</tr>
<tr>
<td>5mm stem</td>
<td>6mm stem</td>
</tr>
<tr>
<td>28.32.105</td>
<td>28.32.106</td>
</tr>
</tbody>
</table>

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.

Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

For more information or to place an order, please contact:

United States, Canada, Asia, Pacific, Latin America
USA 800-654-2873 • 888-980-7742 fax
International +1 609-936-5400 • +1 609-750-4259 fax
integrallife.com/contact

Manufacturer:
Ascension Orthopedics, Inc.
1101 Metric Blvd
Austin, TX 78758 • USA