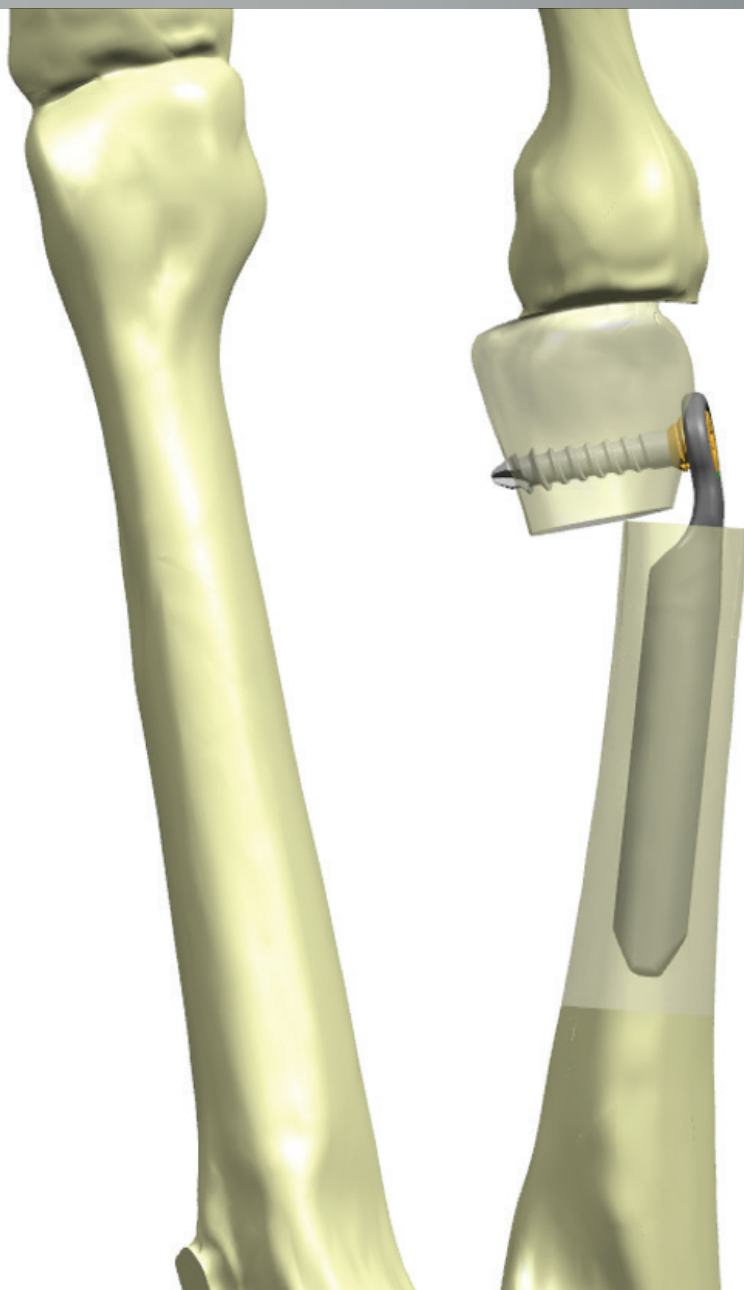


PROstep™ TBI

MIS Bunionette

Operative technique



PROstep™ TBI

MIS Bunionette

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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this operative technique and the package insert is available on the website listed.

▲ CAUTION

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

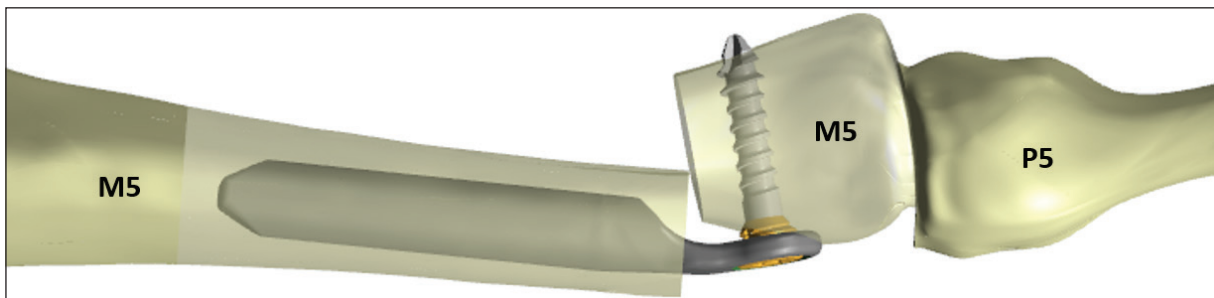
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Introduction

The PROstep Minimally Invasive System (MIS) bunionette is the first implant that combines the strength of an intramedullary rod with the security of a locking plate for use in tailor's bunion deformity correction. Tailor's bunion (also called bunionette) is a notoriously difficult deformity to correct due to the small size of the distal fifth metatarsal, which often limits both the stability of shifting osteotomies as well as the ability to place hardware in mechanically stable locations. For example, a common practice is to place a k-wire parallel to the fifth ray that is only driven into the proximal fragment, with the goal of merely buttressing the distal fragment from shifting back to its previous position. This leaves the distal fragment unfixed and potentially able to shift dorsally or plantarly, or even rotate axially. The PROstep MIS bunionette system gives the surgeon a means to more fully fixate the distal fragment while avoiding relying on a k-wire sticking out of the end of the toe, and it is still performed in a minimally invasive procedure.

Device description

The implant in the PROstep MIS bunionette system is designed to provide a much more robust fixation of the distal fragment while also providing a more secure fixation into the proximal fragment when compared to a buttressing k-wire technique. It achieves this by using a larger proximal intramedullary rod than typically seen with k-wires. This makes the implant more suitable to remaining stable in the patient. Also, instead of merely buttressing the distal fragment, the implant is furnished with a distal locking hole to accept a 2.4mm Ortholoc Locking Screw (12mm length variant is included in the implant sets). This helps prevent dorsal subluxation of the distal fragment when compared to the buttressing k-wire technique. In order to achieve good proximal fixation, Broaches are included with the system to create a supportive shell of bone, rather than removing that bone with a drill. The implants also have 15° of varus built in to correct the valgus of the fifth metatarsal (metatarsus quintus valgus) at the level of the metatarsal head.



PROstep MIS Bunionette Implant construct **Figure 1**

Indications

The PROstep MIS Bunionette (TBI or tailor's bunion implant) System is indicated for fixation of fifth metatarsal osteotomies made in the correction of tailor's bunion.

Contraindications

There are no product-specific contraindications.

Preoperative planning

Preoperative planning is left to the discretion of the surgeon. A determination of the radiographic classification of the tailor's bunion deformity should be performed. For a lateral-bowing-type tailor's bunion deformity, the metatarsal diaphysis may have a more severe curve than the broach and intramedullary rod can traverse, but this will be dependent on individual patient anatomy, osteotomy location, and implant size selection. If the lateral border of the fifth metatarsal head comes to a prominent, sharp edge, a partial head excision in addition to the medial displacement osteotomy may also be considered. Similar principles apply to the translation of the fifth metatarsal head in tailor's bunion deformity correction as they do to the translation of the first metatarsal head in a typical hallux valgus procedure.

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Operative technique

Incision/dissection

The patient is placed in a supine position on the operating room table. The metaphysis of the fifth metatarsal head is identified and a small stab incision is made at the start of the metaphyseal flare. The periosteum at this level of the metatarsal is then minimally elevated dorsally and plantarly to allow for extra-capsular osteotomy. Both the blade and elevator can be found in the PROstep Sterile Instrument Pack (57S1MI07).



PROstep Elevator
found in 57S1MI07

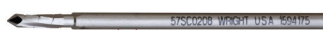
If indicated, or for tailor's bunion deformities involving a large lateral prominence of the metatarsal head, the lateral eminence may be lightly shaved down at this stage.

NOTICE

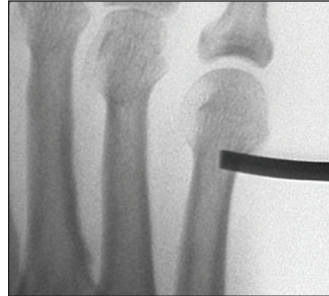
Throughout this procedure, take care to avoid injury to the sural nerve and/or the lateral dorsal cutaneous nerve.

Osteotomy

Select between the 8mm length and the 12mm length option of the 2mm diameter PROstep Burr (57SC0208 or 57SR0212) based on the width of the fifth metatarsal at the previously identified start of the metaphyseal flare. At this starting point, create a transverse osteotomy by plunging the burr bi-cortically and then sweeping first dorsally then plantarly to complete the cut. Ensure the plane of the osteotomy is perpendicular, depending on surgeon preference, to the axis of the fourth or the fifth metatarsal. Use of the non-dominant hand as well as auditory cues are very helpful when gauging whether or not the burr has fully transected and exited the dorsal and plantar cortex.



57SC0208 or 57SR0212
2mm diameter PROstep Burr



Location of incision **Figure 2**



Creating the osteotomy **Figure 3**

Initial shift and canal pre-broach

Now that the stab incision has been used to guide the osteotomy location, extend the incision to about 1 cm-1.5cm distally. Using a sufficiently small elevator, find the intramedullary canal in the proximal fragment, insert the elevator tip (aiming for the center of the canal), and lever the distal fragment medially. Continue to insert the elevator until the tip is approximately 25mm proximal to the osteotomy site.

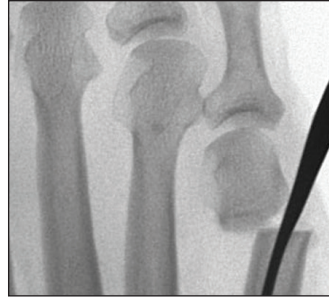


Figure 4
Initial shift and pre-broach

Broaching the intramedullary canal

Open the PROstep MIS Bunionette Broach Set (977TBRST). Starting with the smallest broach (SML), and with manual force only, broach the intramedullary canal of the proximal fragment until the start of the plastic handle nearly touches the proximal fragment.



977TBRST
PROstep TBI Broach Set

Review AP and ML radiographs and evaluate the snugness of the fit in bone to determine if this size of broach adequately fills the intramedullary canal. If it does not, remove the broach from the canal and size up incrementally to the medium and then only if necessary to the large broach until it does. Once the proper size has been identified, open the PROstep Bunionette Implant Set corresponding to that size (977TIMPS, 977TIMPM, or 977TIMPL).

NOTICE

If the broach is difficult to remove from the canal, the screwdriver from the set may be inserted into one of the holes in the broach handle and used as a lever to gently back-mallet the broach until free.

CAUTION

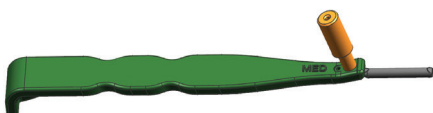
For tailor's bunion deformities involving severe lateral bowing, take additional care while inserting the small broach, as it may not be able to traverse the bowed intramedullary canal. If moving up in broach size is needed, take equal care while inserting the larger sizes.



Figure 5
Broaching the intramedullary canal

Implant insertion

Retrieve the MIS bunionette implant, which comes pre-attached to its inserter and drill guide, from the selected implant set. Insert the implant down the broached intramedullary canal. Ensure that the implant is appropriately angled about the axis of the metatarsal (the drill guide axis should be oriented in the same plane as the desired distal fragment shift). Continue to insert the implant until the distal end of the inserter nearly touches the proximal fragment, or approximately where the entirety of the implant's full diameter section is within the intramedullary canal. Ensure that no skin is being impinged between the distal end of the inserter and the distal fragment.



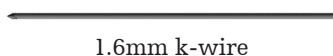
MIS bunionette implant assembly

Drilling for the distal fragment screw

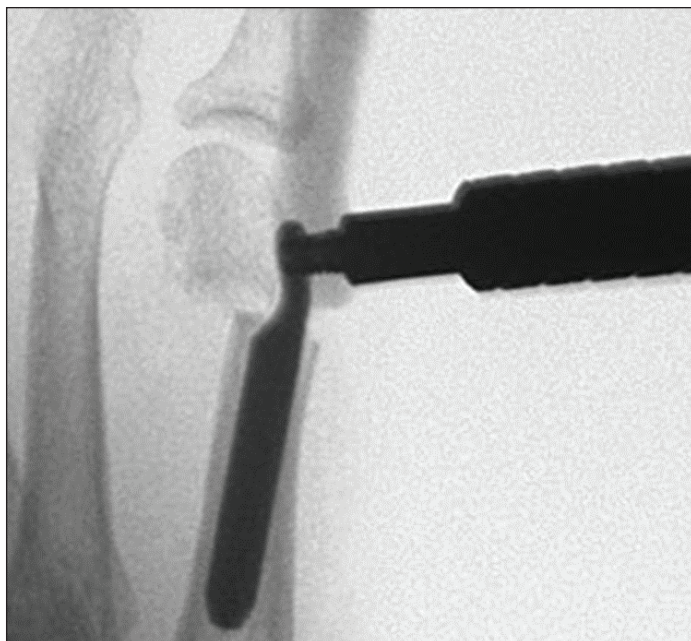
Retrieve the two 1.6mm k-wires from the implant set. The first wire will be used to temporarily fixate the inserter, the fifth metatarsal head, and the fourth metatarsal together. The second wire will be used to pre-drill for the Ortholoc Screw.

To ensure the distal fragment is appropriately positioned before temporarily fixating, it is recommended to utilize the thumb and forefinger of the non-dominant hand to pinch medially and slightly distally of the distal fragment. The intent of this step is twofold—firstly, to ensure the distal fragment is aligned properly in the dorsal-plantar direction, and secondly, to ensure the distal fragment makes good contact laterally and proximally onto the implant surface and onto the proximal fragment. Correct any misalignment and reduce any gapping laterally and proximally, and while holding this correction, drive the first k-wire through the hole in the inserter just proximal to the drill guide to temporarily fixate the distal fragment. The trajectory of this wire should be through the distal fragment and into the fourth metatarsal.

Using the second k-wire, drill through the distal fragment bi-cortically through the drill guide.



1.6mm k-wire



Implant insertion **Figure 6**



Figure 7
Aligning the distal fragment

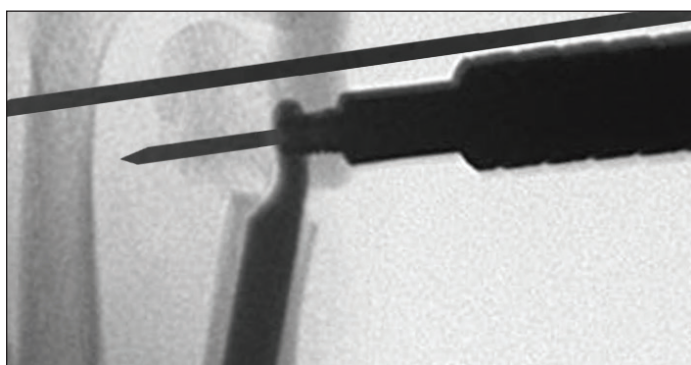
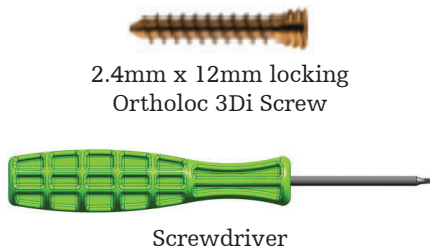


Figure 8
Stabilization and drilling

Instrument removal and screw insertion

Unscrew and remove the drill guide from the pre-assembled implant and inserter. Retrieve the included 2.4mm x 12mm locking Ortholoc 3Di Screw for final distal fragment fixation. Use the screwdriver (self-retaining) included in the implant set to insert the screw until hand-tight. If the inserter handle is still in place, the hole in the handle over the implant's locking hole (previously utilized by the drill guide) allows the screw to be inserted through it.

After the screw is in place, the temporary fixation k-wire and the inserter may be removed.



Screw insertion **Figure 9**

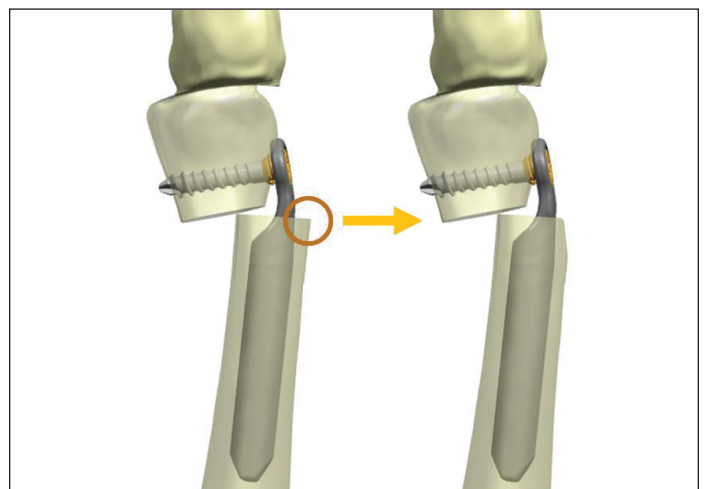
NOTICE

The 2.4mm x 12mm locking Ortholoc 3Di Screw is included in the PROstep MIS Bunionette Sets for convenience. If an alternate length of locking screw is required, additional sizes may be found in the Ortholoc 2 Small Bone Plating System.

Smoothing and closure

Smooth over the distal-lateral corner of the proximal fragment to avoid a noticeable, sharp prominence after closure. A PROstep Burr may be used for this purpose.

If any lateral bump shaving was indicated and completed, be sure to thoroughly wash out all debris from the area and meticulously verify that none remains in the joint space.



Smoothing the distal lateral corner **Figure 10**

Postoperative care

Postoperative care is left to the discretion of the surgeon.

Explant information

To remove the Ortholoc Screw, engage the screw with the appropriate star 7 screwdriver (5202000016 or 49510102).

After screw removal, and after additional bone resection medial to the implant's screw hole as needed, the implant may be removed by pulling it distally out of the medullary canal. An appropriate threaded drill guide (52031316) may aid in this step by engaging with the threaded plate hole.

The screwdrivers and the drill guide listed above may be found in the Ortholoc Small Bone Fracture Instrument Kit (5202KIT1).

If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer, using the contact information located on the back cover of this operative technique, to receive instructions for returning the explanted device to the manufacturer for investigation.

Ordering information

PROstep MIS Bunionette devices

Part number	Description
977TBRST*	PROstep MIS Bunionette Broach Set
977TIMPS*	PROstep MIS Bunionette Implant Set, small
977TIMPM*	PROstep MIS Bunionette Implant Set, medium
977TIMPL*	PROstep MIS Bunionette Implant Set, large

*All four should be brought to surgery unless sizing is determined preoperatively

General PROstep devices

Part number	Description
57S1MI07	PROstep Sterile Instrument Pack
57SC0208	PROstep Burr, 2mm x 8mm
57SR0212	PROstep Burr, 2mm x 12mm
957SW3113	PROstep Wedge Burr, 3.1mm x 13mm
5771KIT1	PROstep Power Box and Hand Piece

Foot & Ankle

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