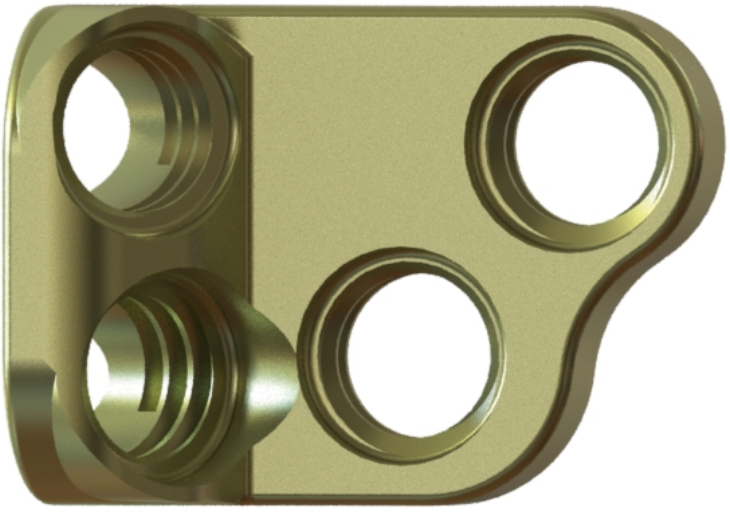
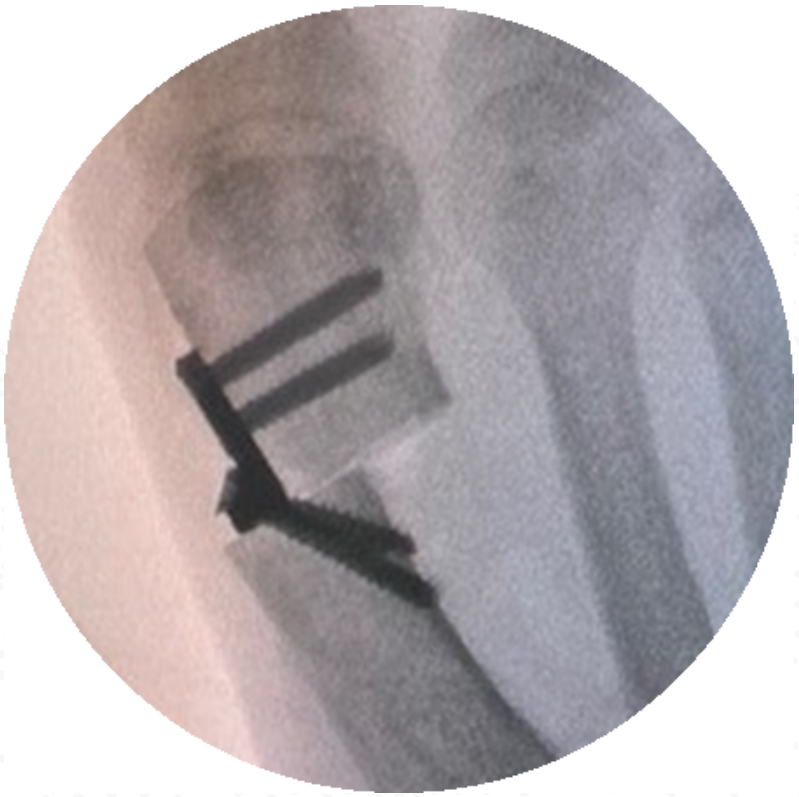
radian™

MIS BUNION CORRECTION SYSTEM

Surgical Technique Guide





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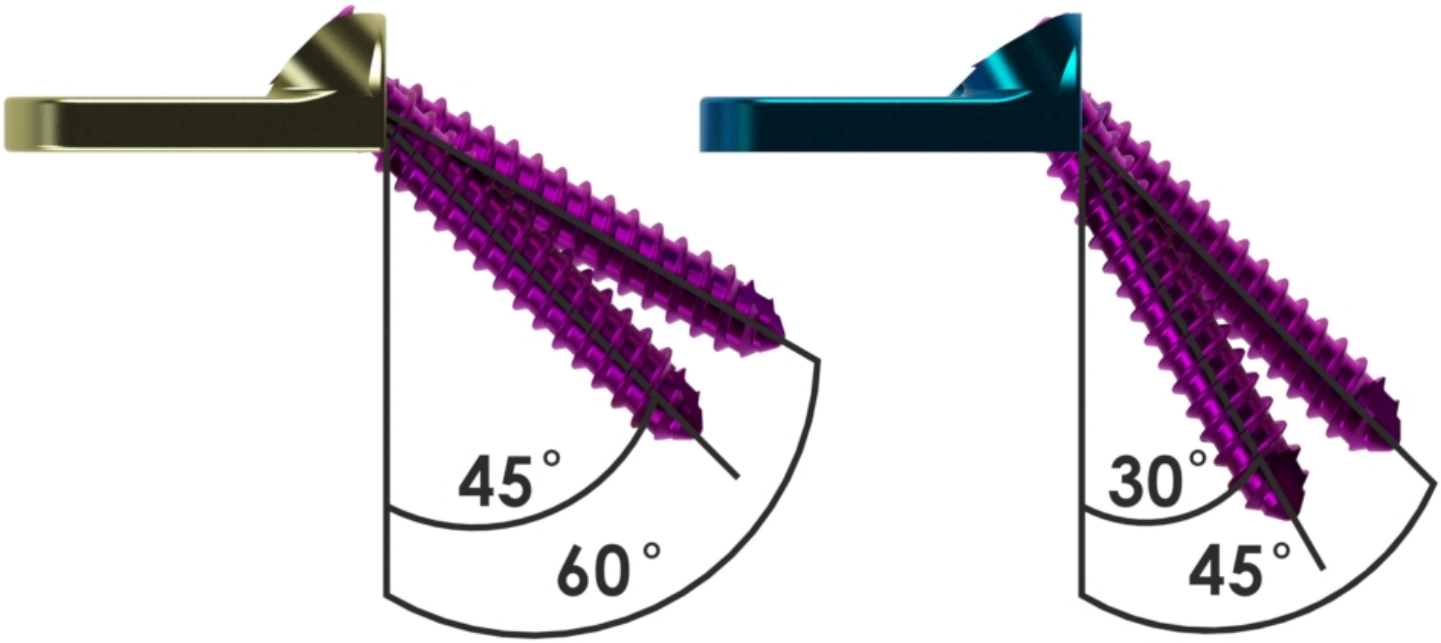


Introduction

The **Radian™ MIS Bunion System** is indicated for fixation of osteotomies and correction of hallux valgus. The construct consists of a titanium alloy plate and four locking screws that provide fixation for the correction of a first metatarsal bunion. The design allows for medial insertion of the two distal screws and intramedullary insertion of the two proximal screws.

The Radian™ MIS Bunion System allows the plate to be attached to the metatarsal head prior to making the osteotomy. This allows for control of the capital fragment at all stages of the procedure.

The plate is provided in two configurations, a gold plate for IM shifts greater than 10 deg, a blue plate for IM shift less than 10 deg.

Step 1 - Surgical Incision

Using intraoperative fluoroscopy, make a 1cm – 2cm longitudinal incision along the medial aspect of the first metatarsal. The incision should grant access to the distal metaphyseal-diaphyseal junction of the first metatarsal.

Step 2 - Alignment

If needed, perform a condylectomy of the medial protuberance of the first metatarsal while keeping the plane of resection in alignment with the long axis of the first metatarsal.

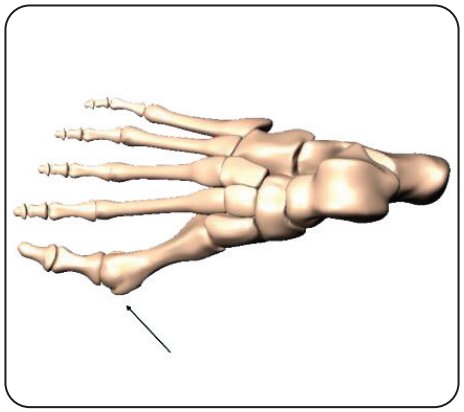
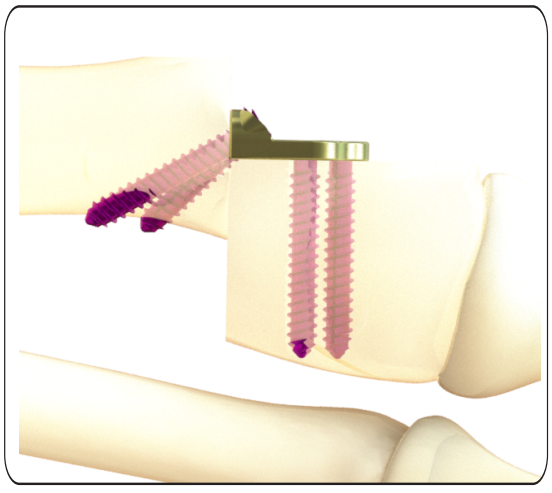
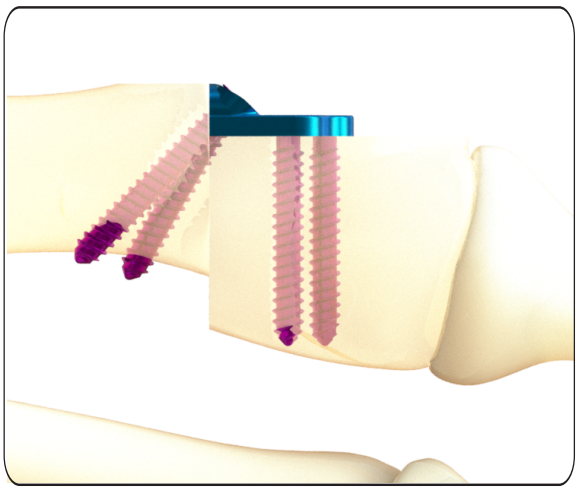


Plate Selection

If IM shift will be greater than 10 deg, use the gold plate. If IM shift will be less than 10 deg, use the blue plate.





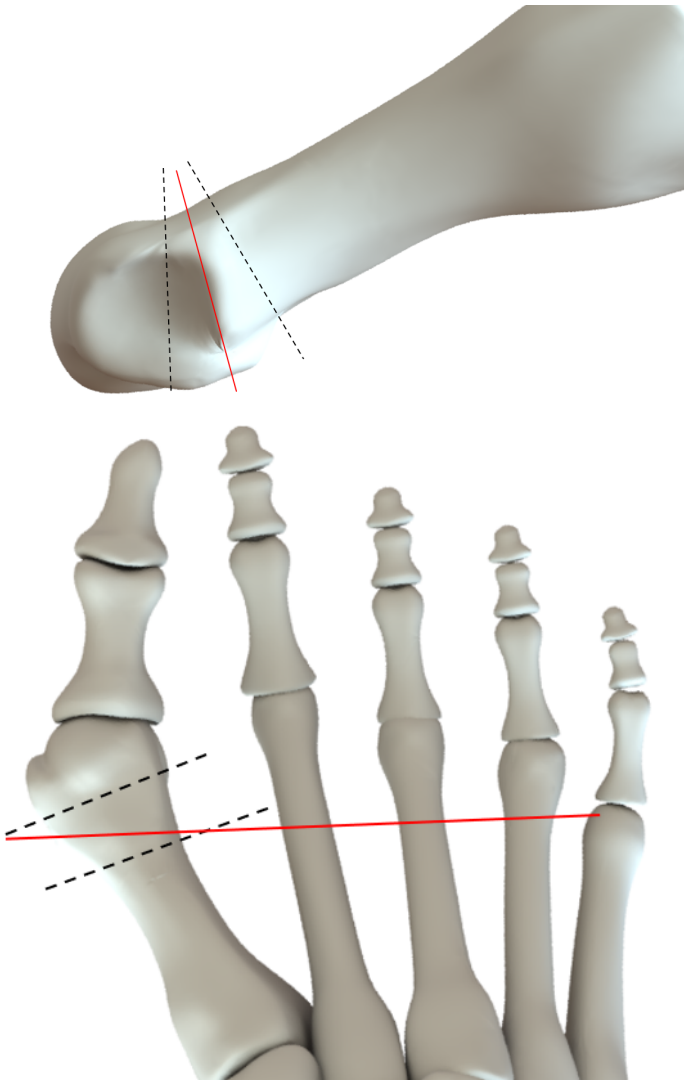
Osteotomy Planning - Do not cut until plate is placed

Draw a line perpendicular to the long axis of the metatarsal shaft near the meta-diaphyseal neck.

Draw an additional line perpendicular to the weight bearing surface.

The ideal osteotomy cut falls between these 2 lines, angling back toward the 5th metatarsal head.

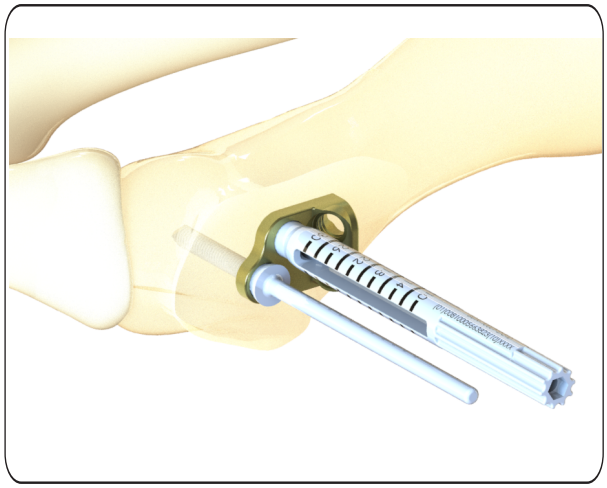
Required: When placing the plate, ensure the proximal surface of the plate lies along the intended osteotomy cut line.

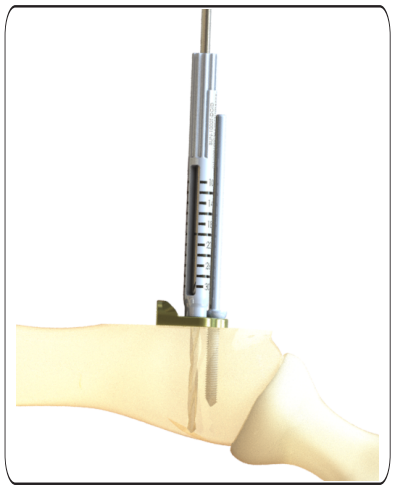


Note: A cut perpendicular to the first metatarsal lengthens the metatarsal, tensions the EHL and FHL, restricting lateral translation and results in a dorsiflexory force on the toe at the first MTPJ. Under these circumstances, an additional cut attempt is recommended.

Step 3 - Attachment

Use a small olive pin on the most distal hole to temporarily fixation the plate to the metatarsal head prior to making the osteotomy. Thread the drill guide into the second distal hole, drill through the tower, measuring with the laser markings.

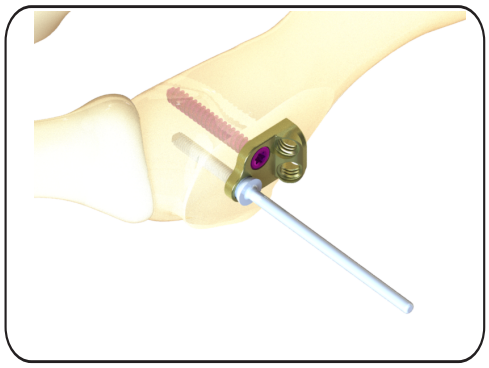


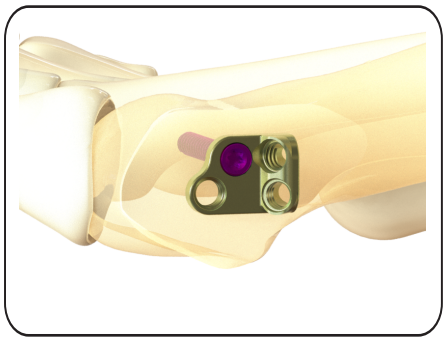


Note: Place the plate slightly plantar if rotation of the head of metatarsal will be needed to correct sesamoid positioning.

Step 4 - Fixating the Plate

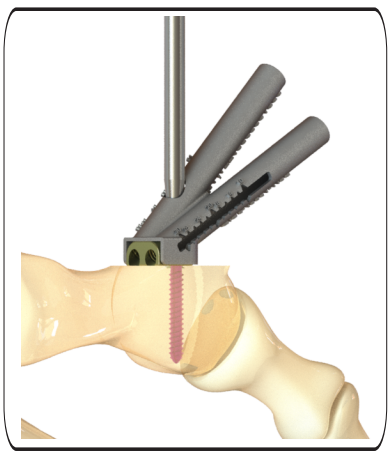
Remove the tower and place corresponding screw. Remove the small olive pin.

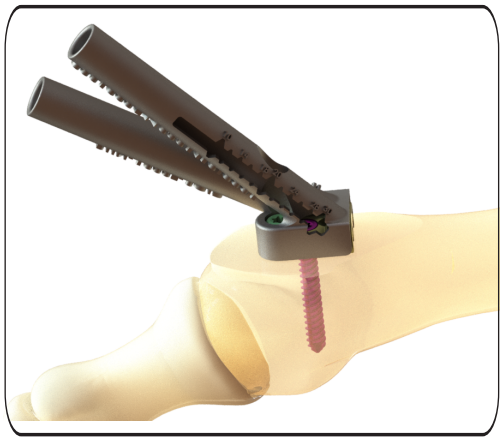




Step 5 - Attaching the Jig

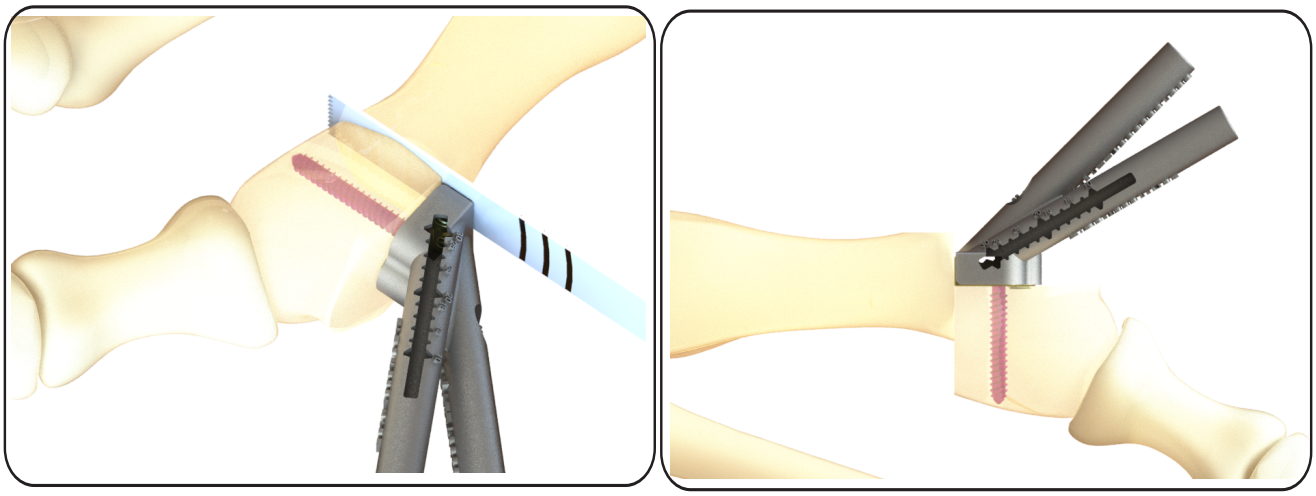
Place the drill/screw guide on the plate aligning the set screw with the most distal hole and tighten with the screw inserter. If difficulty engaging set screw, it can be viewed under the tower.





Step 6 - Osteotomy

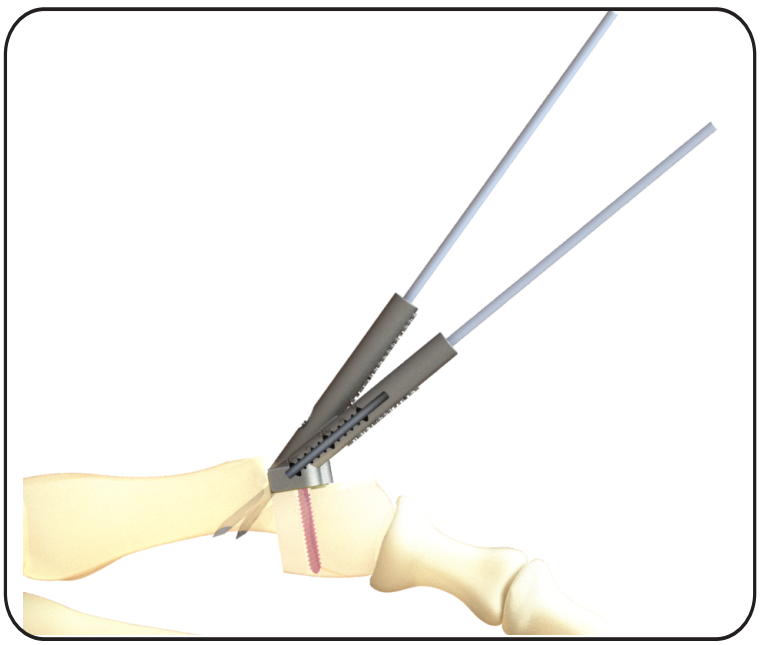
Once the set screw is tightened to secure the drill/screw guide to the plate make the osteotomy along the proximal aspect of the plate. Use the drill/screw guide to control the head and make the correction.



Note: The capital fragment may shift 1-2mm plantar after osteotomy. To ensure bicortical purchase, it is recommended that the capital fragment is realigned prior to varus derotation and temporary fixation.

Step 7 - Correction

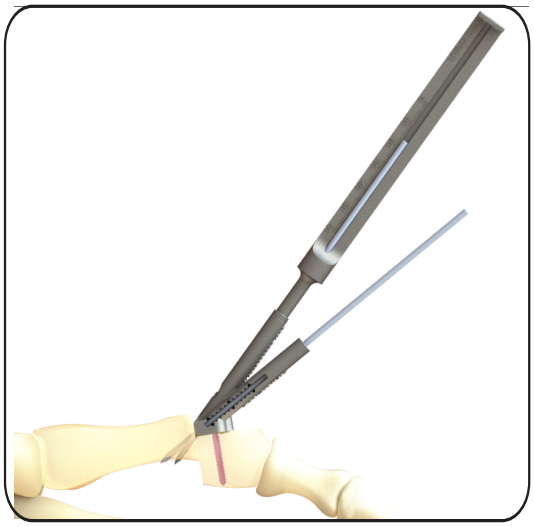
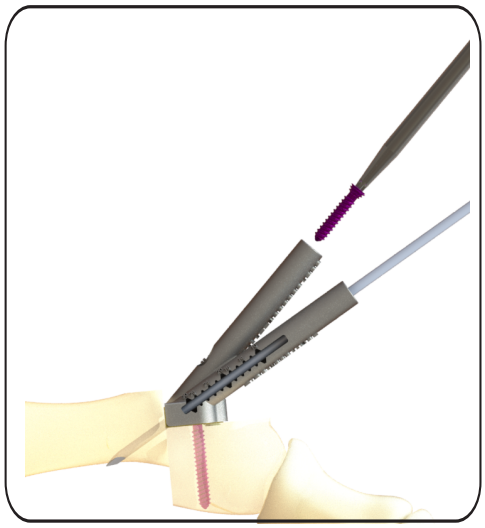
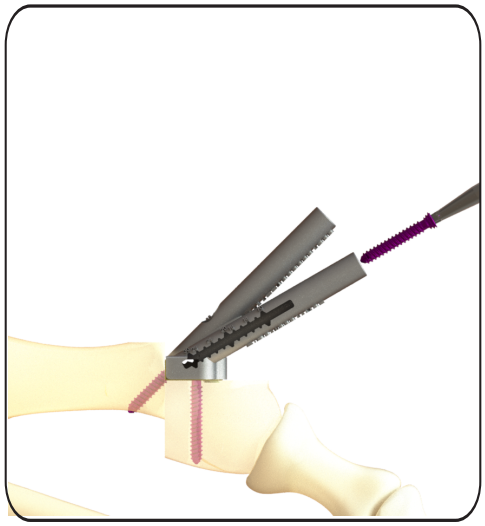
Use the 2.4mm diameter pins to temporarily fixate the head, place pins at desired depth. Take images to assure correction.



Note: for additional compression, replace one of the Steinmann pins with a threaded olive pin

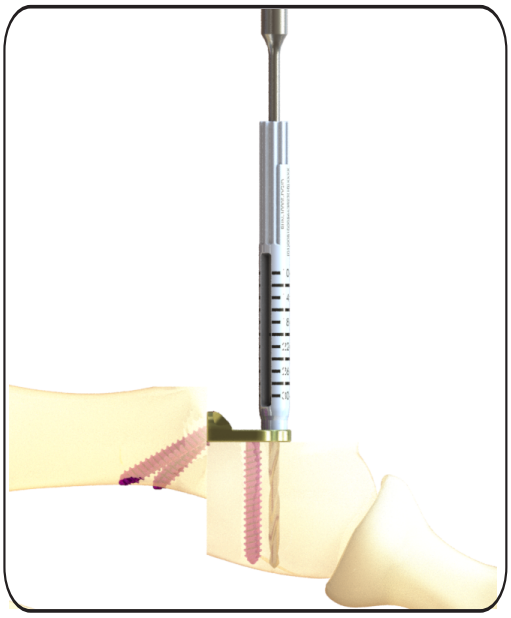
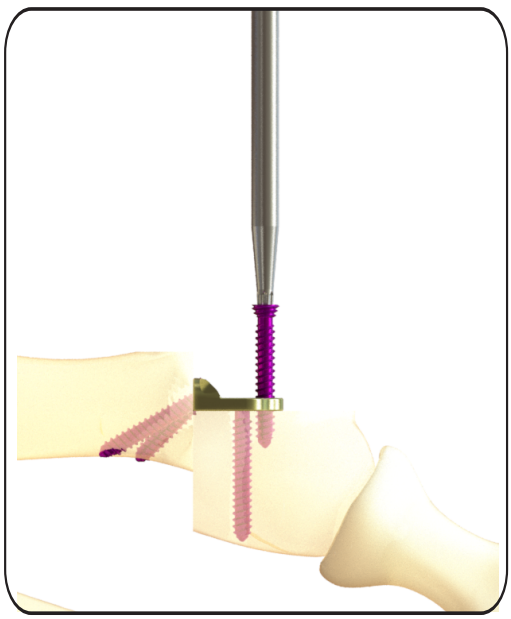
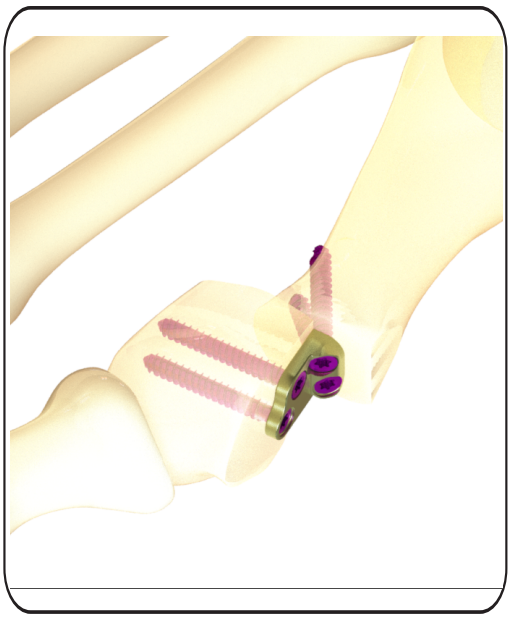
Step 8 - Screw Placement

Slide the depth gauge over the pins to determine screw length. Remove the depth gauge and pin and insert screw through the targeting jig. Temporary fixation pins function as the drill, no additional drilling necessary. Repeat for other proximal screw.

Step 9 - Lateral Correction

Remove drill/screw guide and attach threaded drill guide for final distal hole. Drill through tower to measure depth, remove tower and place final screw.

Note: It is recommended that multiple fluorscopy angles are taken to view final screw placement as dorsiflexion, plantarflexion, and varus/valgus positioning can give a false image showing no bicortical purchase of the screws.

Contraindications

Prior to using the Radian™ MIS Bunion System™, ensure that none of the following patient conditions are present: active or latent infection, sepsis, osteoporosis, insufficient quantity, or quality of bone and/or soft tissue, material sensitivity (if sensitivity is suspected, tests are performed prior to implantation), or patients who are unwilling or incapable of following post-operative care instructions.

Warnings and Precautions

Warnings

- The patient must be cautioned, preferably in writing, about the use, limitations, and potential adverse effects of this device including the possibility of delayed union, nonunion, device or treatment failure as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the device.
- The patient should be informed about the importance of following the prescribed post-operative rehabilitation protocol and to understand the possible limitations in activities of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- For safe effective use of the implant, the surgeon must be thoroughly familiar with the surgical technique for the device, implant, and associated instruments. Potential failures of the Radian™ MIS Bunion System may include delayed union, nonunion, loosening of fixation, stress fractures of the bones, or incomplete healing as a result of excessive activity, overloading or noncompliance to post-operative rehabilitation.
- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive physical activity. Device breakage may occur when the implant is subjected to excessive loading associated with delayed union or nonunion. Improper insertion of the device during implantation may also increase the possibility of loosening, or migration. DO NOT reuse any of Radian™ MIS Bunion System implantable components. Reuse may compromise the structural integrity of the plate and screws and/or lead to failure, which may result in patient injury.

Precautions

- Protect the Radian™ MIS Bunion System's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the Radian™ MIS Bunion System, inspect all implants and instruments for wear, disfiguration and physical damage. If evidence of wear, disfiguration or physical damage is found, DO NOT use and contact your local Nvision representative or the Nvision Customer Care Department.
- DO NOT permanently implant the Nvision K-Wires; they are only intended to be used for provisional fixation and guidance.
- Do not mix implant components from different manufacturers for metallurgical, biomechanical and functional reasons.
- DO NOT use screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate over time, requiring revision surgery to replace the implant or to carry out alternative procedures. Note: To maintain traceability of the Radian™ MIS Bunion System implantable components, record each of the respective components LOT numbers in the patient records post implantation.

Potential Adverse Effects

- Possible adverse effects associated with Radian™ MIS Bunion System are infection, pain, stiffness, discomfort, or abnormal sensations and nerve or soft tissue damage due to the use of an implant or due to surgical trauma. The implant may break due to excessive activity, prolonged loading, Incomplete healing, or excessive force on the implant during insertion. Metal sensitivity or histological or allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

MR Safety Information

The Radian™ MIS Bunion System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Radian™ MIS Bunion System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Disclaimers

This publication details recommended procedures for using Nvision Biomedical Technologies' devices and instruments. It offers guidance but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to the first surgery. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling. For additional information please refer to the instructions for use (IFU) delivered with each implant. The surgeon must discuss all relevant risks, including the finite lifetime. All possible complications listed are not typical of Nvision Biomedical Technologies products but are in principle observed with any implant. Promptly inform Nvision Biomedical Technologies as soon as complications occur in connection with implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality, or mechanical stability is suspected, please provide Nvision Biomedical Technologies with explant(s) in a cleaned, disinfected, and sterile condition. Nvision cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of osseous implant bed in the case of implants, incorrect indication or surgical technique, or with any incorrect patient information and consequent incorrect patient behavior.

Additional Information

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. This brochure describes the surgical technique used by Nvision Biomedical Technologies development surgeons. As the manufacturer of this device, Nvision Biomedical Technologies does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

Nvision Biomedical Technologies
4590 Lockhill Selma
San Antonio, TX 78249

Notes

Notes

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MIS BUNION CORRECTION SYSTEM

Ordering Information

Plates:

Part Number	Description
BUN-PLT-05	5.0mm Correction L-Bunion Plate 60 deg
BUN-PLT-03	5.0mm Correction L-Bunion Plate 30 deg

Screws:

Part Number	Description
TB-30-14L	Headed, Locking Screw 3.0mmD, 14mmL
TB-30-16L	Headed, Locking Screw 3.0mmD, 16mmL
TB-30-18L	Headed, Locking Screw 3.0mmD, 18mmL
TB-30-20L	Headed, Locking Screw 3.0mmD, 20mmL
TB-30-22L	Headed, Locking Screw 3.0mmD, 22mmL
TB-30-24L	Headed, Locking Screw 3.0mmD, 24mmL
TB-30-26L	Headed, Locking Screw 3.0mmD, 26mmL
TB-30-28L	Headed, Locking Screw 3.0mmD, 28mmL
TB-30-30L	Headed, Locking Screw 3.0mmD, 30mmL

Instruments:

Part Number	Description
BUN-1000T-DGID	Threaded Drill Guide
BUN-1000T-DR30	Drill for 3.0 Screws
BUN-1000T-OPIN	Olive Pin
BUN-1001T-DPG	Depth Gauge
HAN-1000T-AOSM	Handle
BUN-1000T-SPIN	Small Olive Pin
CSRW-1000T-352	2.4mm x 150mm K-Wire
BUN-1000T-KDG	K-Wire Depth Gauge
BUN-1000T-SDIG	Drill and Screw Guide 60 deg
BUN-1000T-SD30	Drill and Screw Guide 30 deg

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01/24/2023