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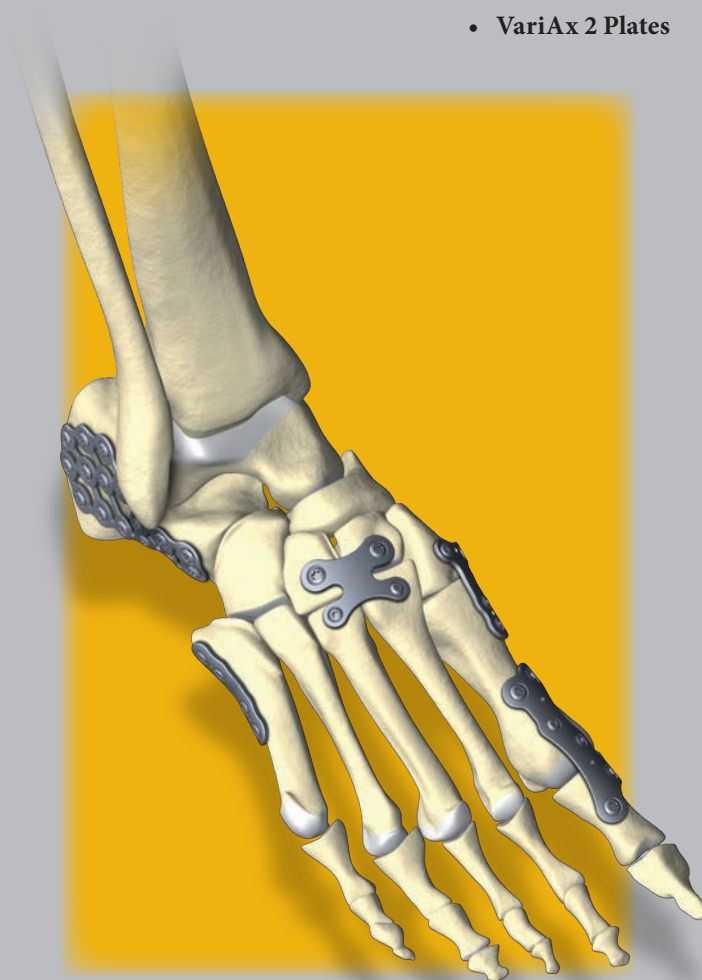
VariAx[®]

Foot Plating System

Operative Technique

- Trauma and Deformity Correction
- Polyaxial Locking Technology
- Comprehensive Calcaneal
- Fracture Plates
- VariAx 2 Plates

Foot & Ankle



VariAx Foot Plating System

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, 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.

WARNING

- Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1).
- All non-sterile devices must be cleaned and sterilized before use.

WARNING

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling.

Consult Instructions for Use (www.ifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.

The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.

WARNING

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future due to medical reasons.

WARNING

The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

WARNING

In the event of contamination, or expiration of shelf life or in the case of products supplied non-sterile, the product must be subjected to an appropriate cleaning process and sterilized by means of a validated sterilization procedure before use, unless specified otherwise in the product labeling or respective product technical guides.

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Introduction

The Stryker VariAx Foot Plating System represent a new generation of implant technology for foot surgery.

The reconstruction and fixation of bones in the foot can now be accomplished by means of the patented SmartLock polyaxial locking mechanism. This powerful feature allows a surgeon to insert polyaxial Locking or Non-locking screws at variable angles with respect to

the plate, so that they may be targeted to address the location and geometry of a given fracture or osteotomy. Each plate can be configured with a combination of locking and /or non-locking screws which are designed to address the intraoperative requirements of a particular case, without constraint or reliance on any pre-existing plate designs.



Product Specifications

- **Complete Plating System**

Multiple indication based plate designs are included in the Stryker VariAx Foot Plating System, which are engineered to address specific foot trauma and deformity indications.

- **Polyaxial Drill Guide**

Allows placement of Locking Screws at a variable angle (up to $\pm 15^\circ$).

- **Low Profile Plate Design and Reduced Screw Head Prominence**

Each plate is designed to minimize soft tissue irritation by having a low profile design (1mm – 1.5mm thickness). Furthermore, the screws are designed to have minimal head prominence when fully inserted in a plate, which further reduces the risk of irritation.

- **Full-Range of 2.7mm and 3.5mm Locking and Non-Locking Screws**

Offers intraoperative solutions to cover a broad range of clinical situations.

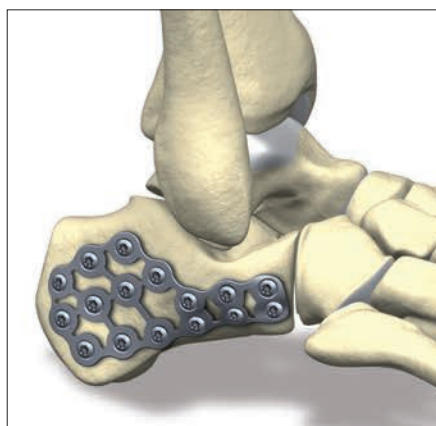
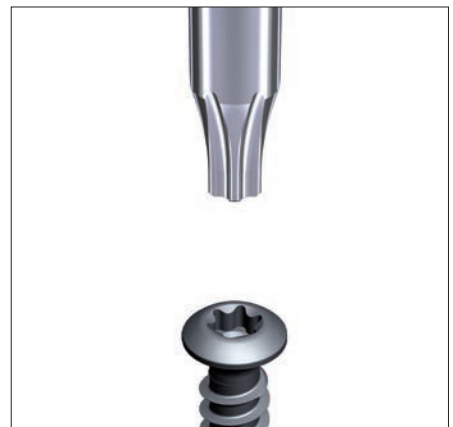
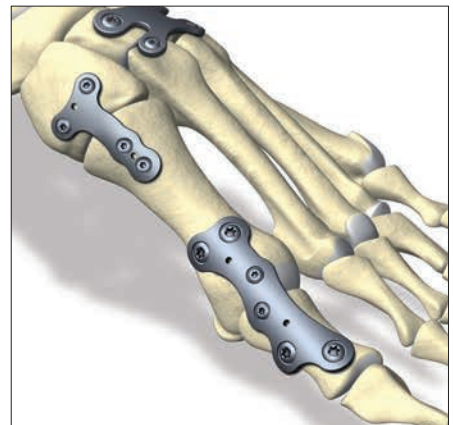
- **T7 or T10 Screw Head Design**

All Stryker VariAx Foot Plating System screws are designed with either a T7 head (for 2.7mm screws), or a T10 head (for 3.5mm screws). This screw head design facilitates efficient force transmission from the screwdriver blade to the screw, and reduces the risk of screw head stripping.

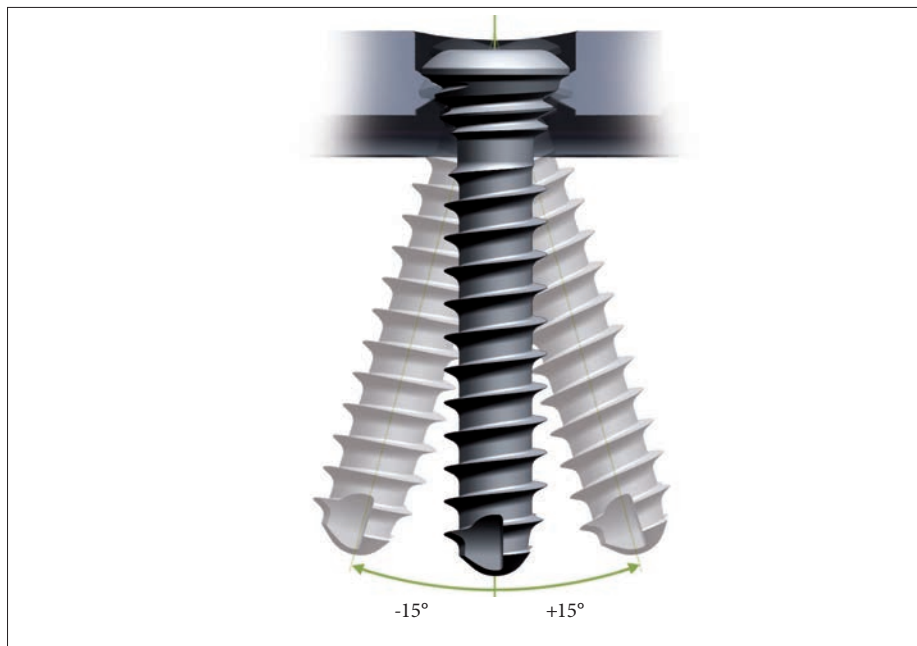
- **Anodization Type II**

- **Two Dedicated Calcaneal Plate Designs**

The Stryker VariAx Foot Plating System offer two distinct calcaneal plate designs, each incorporating a different design philosophy. The mesh design offers surgeons an extremely low profile plate that may be easily contoured, and has many screw placement options. The standard plate design offers surgeons a strong plate that may be easily contoured to the superior surface of the calcaneus.



Introduction



- **Patented Polyaxial Locking Technology**
Each screw is made of titanium alloy (Grade V), which is slightly harder than the plates, which are made from commercially pure titanium (Grade II). When a locking screw is used, the thread in the head of the harder screw reshapes the softer titanium used in the plate, thus creating a secure form-fitting geometry. This process is designed to allow for a solid, locked connection between the head of the screw, and the plate.

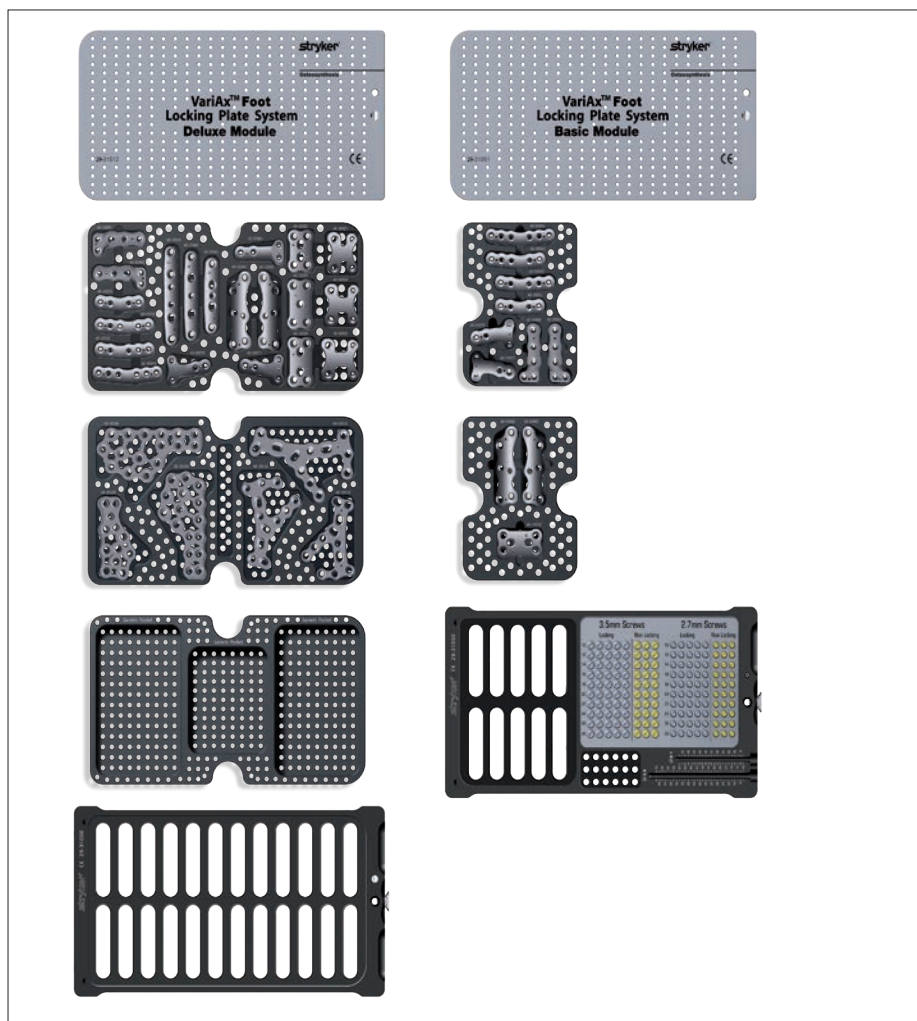
- **One-Step Locking**
Achieved by simply inserting a locking screw within the polyaxial locking range of $\pm 15^\circ$, without the need for further steps.

- **Compression and Locking in One-Step**
As a screw is inserted and tightened into an oval compression hole, compression can be achieved. If a locking screw is used, the screw can then be locked into the plate in a single step.

- **Deluxe or Basic Configurations** The Stryker VariAx Foot Plating System is available in two renditions: a Deluxe configuration, and a Basic configuration. The Deluxe set contains every implant design, while the Basic set includes a selection with plates most commonly needed for foot surgery.

- **Modular System Design**
The modular instrumentation system is designed for seamless integration of other products from the Stryker Foot Solutions portfolio.

- **Color Coding of Instruments**
The instruments are color coded to facilitate ease-of-use during surgery.



Overview

Plate Options



H-Plate
Plate



Rectangular
Plate



T-Plate



L-Plate



Oblique
T-Plate



3-D Plate



Broad Straight
Plate



Curved
Plate



Calcaneus Standard
Plate



Calcaneus Mesh
Plate

New VariAx 2 Plates



NCM (Medical Column
Fusion) Plate



TN (Talo-
Navicular) Plate



NC (Navicular-
Cuneiform) Plate



Cuboid



Talar Neck
Plate



Navicular
Plate

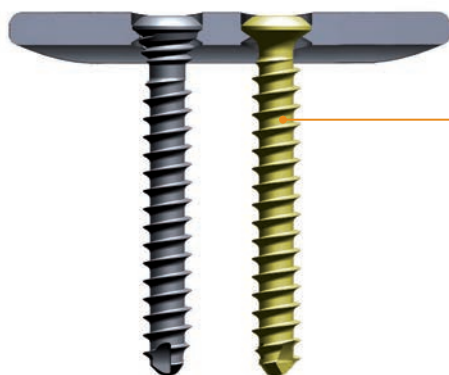


LCL (Lateral Column
Lengthening) Plate

Screw Options

2.7mm
Locking

2.7mm
Non-
Locking

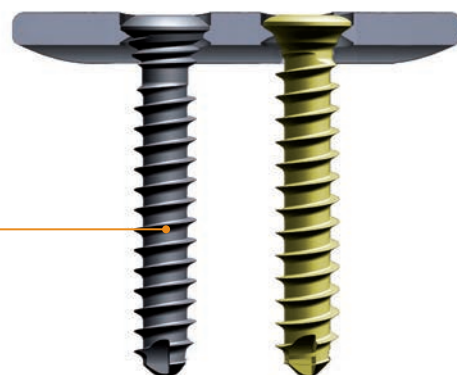


Smaller plate holes fit 2.7mm screws

Larger plate holes fit 3.5mm screws

3.5mm
Locking

3.5mm
Non-
Locking



Indications and Contraindications

Stryker Foot Plating System

Indications

The Stryker VariAx Foot Plating System is intended for use in internal fixation, reconstruction or arthrodesis of small bones, including the fore, mid- and hind foot and ankle.

Examples of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.

Contraindications

- Inadequate bone quantity and quality.
- Patients with active infections.
- Patients with metal allergies and foreign body sensitivity.
- Severely non-compliant patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions.
- Patients with limited blood supply or insufficient quality or quantity of bone
- Patients with unstable physical and/or mental health conditions.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.

- Patients having inadequate tissue coverage over the operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

CAUTION

The Stryker VariAx Foot Plating 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 the Stryker VariAx Foot Plating 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.

Indications and Contraindications

VariAx 2 Foot System

Indications

VariAx 2 Foot System is indicated for internal fixation of bones in the foot, ankle, hand, and wrist in adult and adolescent (12-21 years) patients, which includes replantation, joint fusions, corrective osteotomies, and osteopenic bone.

The table below lists several common surgical foot indications, together with the VariAx Foot implants that are suggested to treat these indications.

Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.

- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

For MRI Safety Information of the VariAx 2 Foot refer to the Operative Technique VariAx 2 Foot.

Application

Implant	Cuboid plate	Navicular plate	Talar neck plate	Navicular, Cuneiform Metatarsal (NCM) Plate	Navicular Cuneiform (NC) Plate	Talonavicular (TN) Plate	Evans 0/ 6-12mm wedge	Curved plate	Oblique t-plate	3-D plate	Broad straight plate	Rectangular plate	H-plate	L-plate	T-plate	Calcaneus mesh plate	Calcaneus standard plate
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1St MPJ Arthrodesis								x	x	x	x			x	x		
Lapudis Fusion								x	x				x				
Lisfranc Arthrodesis								x				x	x				
Isolated Lisfranc Arthrodesis								x	x					x	x		
Proximal Osteotomy Mt 2-5								x	x					x	x		
Tn Arthrodesis						x						x	x				
Nc Arthrodesis					x												
Cc Arthrodesis					x	x						x	x				
Extended Medial Column Fusion				x													
Cuboid Fractures	x																
Navicular Fractures		x															
Talus Fracture			x												x		
Bone Defect Bridging				x													
Lateral Column Lengthening (Evans)							x										
Calcaneus Fractures																x	x

Operative Technique

The Operative Technique listed below is designed to provide a general overview on the instruments and procedure required to implant a VariAx Foot Plate.

Planning and Preparation

Clear identification and classification of the fracture, osteotomy, or fusion site should first be established preoperatively using the appropriate methods and visualization. Appropriate surgical incisions are performed to expose the implantation site, and an osteotomy can then be performed if necessary. The Coughlin Reamer System can then be used to prepare the articular surfaces, prior to fixation with certain VariAx Foot Plates. Use the appropriate size of reamer according to the diameter of the joint surface.

Optional: Joint Preparation in Metatarsophalangeal Arthrodesis using Coughlin Small Joint Reamers

The convex phalangeal reamer is used to prepare a concave surface. The reamers are available in sizes 10-18mm, however, it is important that the same sized metatarsal and phalangeal reamers are used (Fig. 1). A 1.4mm K-Wire (REF 45-80200) is driven into the center of the proximal phalanx, and advanced approximately 1.5cm. The phalangeal reamer is placed over the K-Wire, and the phalangeal surface is reamed creating a concave surface. The reamer and K-Wire are then removed.

CAUTION

- Reaming should be limited.
- Care should be taken not to apply excessive pressure to avoid damage to the fusion surface.
- Provide cooling with saline irrigation.
- Ensure that drilling and cutting tools are sharp

A K-Wire is then centered on the prepared metatarsal surface and driven in a proximal direction (Fig. 2) approximately 1.5cm. The same size barrel reamer is then placed over the K-Wire, and the metatarsal metaphysis is reduced to a cylinder of constant dimension.

The barrel reamer is removed, and debris and excess bone fragments are removed in a circumferential fashion.

CAUTION

Adequate retraction of soft tissues is important throughout the joint preparation process (Fig. 3).

Finally, the same sized concave reamer is then used to prepare a convex surface to match the proximal phalanx.



Fig. 1



Fig. 2

Operative Technique

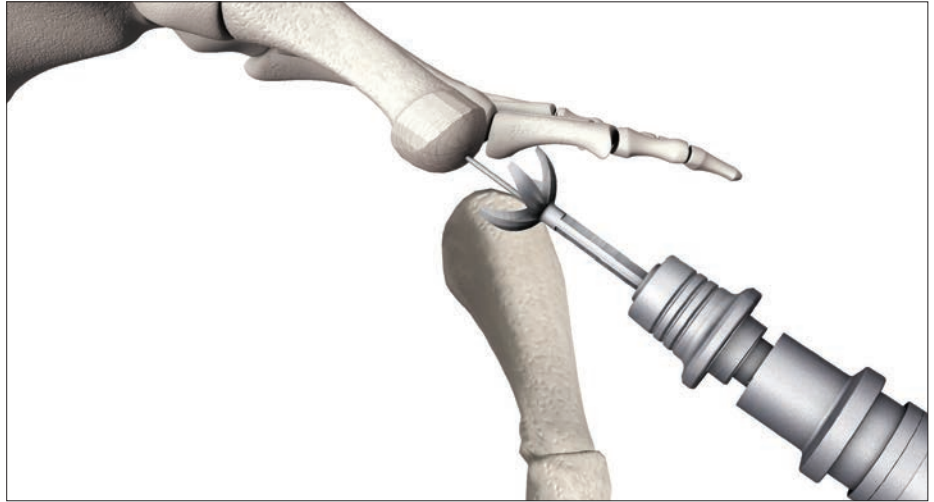


Fig. 3

Joint Alignment

By creating cup-shaped surfaces, any desired alignment may be achieved (Fig. 4). The desired alignment is typically valgus of 15° to 20° and dorsiflexion of 20° to 30° (in reference to the metatarsophalangeal axis and neutral rotation). The cup-shaped surfaces allow any one of these dimensions to be changed without altering another dimension. (For example, rotation may be changed without affecting dorsiflexion or valgus).



Fig. 4

Stabilization, Provisional Plate Placement

Establish primary stabilization of the fracture, osteotomy, or fusion site, using the included 1.4mm K-Wires (REF 45-80200).

VariAx Foot Plates can be removed from the plate tray and handled using the Forceps with Grasping Lips (REF 64-20129) (Fig. 5).



Fig. 5

Operative Technique

Most VariAx Foot Plates include K-Wire holes that are designed to accommodate 1.4mm Trocar Tipped K-Wires (Fig. 6), for use in temporarily stabilizing the plates to bone.

The K-Wire Cutting Pliers (REF 45-80020) (Fig. 7) can be used to cut the K-Wires to the desired length. This instrument includes a silicon inlay which prevents the cut end of a K-Wire from being ejected from the instrument.

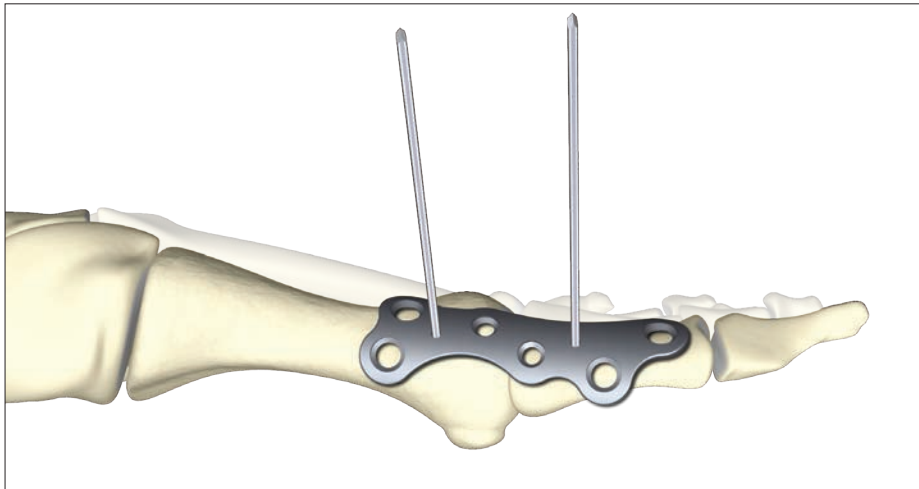


Fig. 6

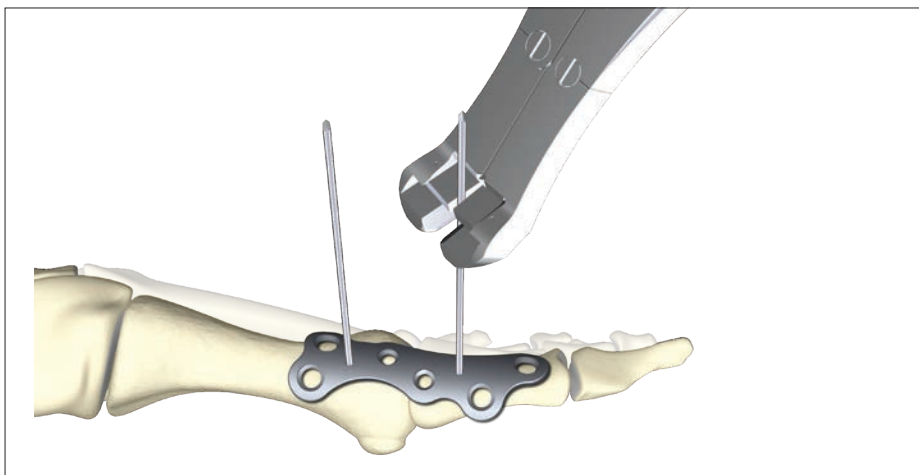


Fig. 7

Although some VariAx Foot Plates are pre-contoured (Fig. 8), additional contouring of the plates is possible using the Plate Bending Pliers (REF 45-80010).

WARNING

- Contouring or bending of an implant should be avoided where possible, because it may reduce its fatigue strength and can cause failure under load.
- If contouring is necessary, allowed by design and prescribed by Stryker, the physician should avoid sharp bends, reverse bends or bending the device at a screw hole. Such action must be performed with Stryker instruments and in accordance with the specified procedures (see Operative Technique).



Fig. 8

Operative Technique

Plate Hole Configurations

Important:

1. Each round screw hole in a VariAx Foot Plate is designed to accommodate a specific size of screw - the smaller holes accommodate 2.7mm screws, and the larger holes accommodate 3.5mm screws. These screws and holes are **NOT** interchangeable.

NOTICE

A 3.5mm screw must not be used in a 2.7mm screw hole, and a 2.7mm screw must not be used in a 3.5mm screw hole.

2. Some VariAx Foot Plates include oval locking compression holes, which are designed to accommodate a specific size of screw - the smaller oval holes accommodate 2.7mm screws, and the larger oval holes accommodate 3.5mm screws. These screws and holes are **NOT** interchangeable.

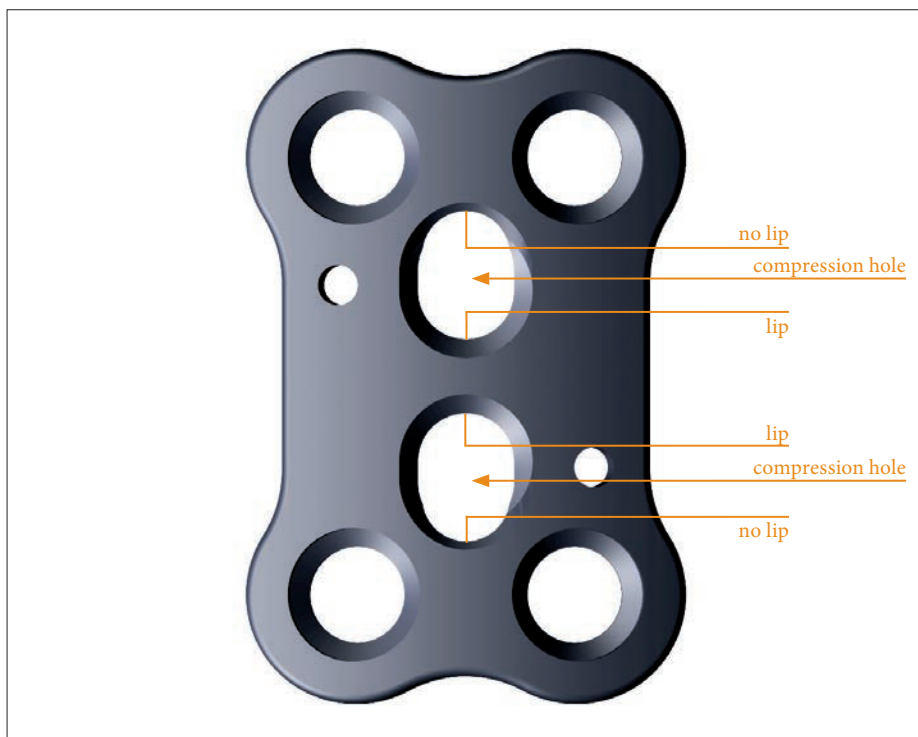
NOTICE

A 3.5mm screw must not be used in a 2.7mm compression hole, and a 2.7mm screw must not be used in a 3.5mm compression hole.

The oval holes allow for the active compression of different bone segments along the long axis of an oval hole. In a compression hole, a drill hole can be created in an eccentric position in the part of the oval hole that has no lip. As the screw is tightened, the screwhead glides into the area of the hole that has a lip. If a locking screw is used, the screw can then be locked into the plate in a single step.

⚠ CAUTION

It is important that any nonlocking screw is inserted before any locking screw.



Operative Technique

Preparation for Screw Insertion

A Drill Guide must first be placed into a corresponding plate screw hole (in a plate), prior to pre-drilling a pilot hole. The Drill Guide for Circular Locking Holes (REF 45-80001) must be used in circular holes.

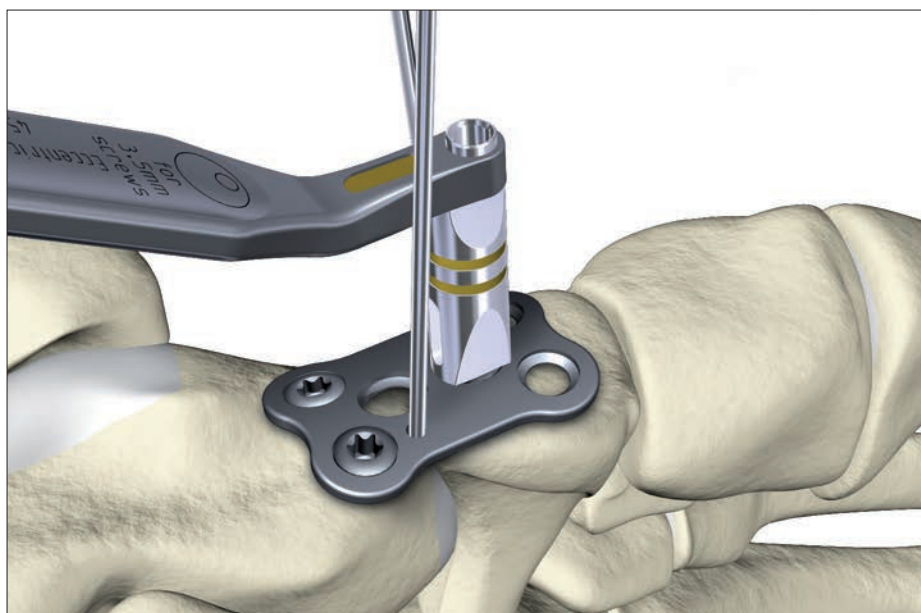
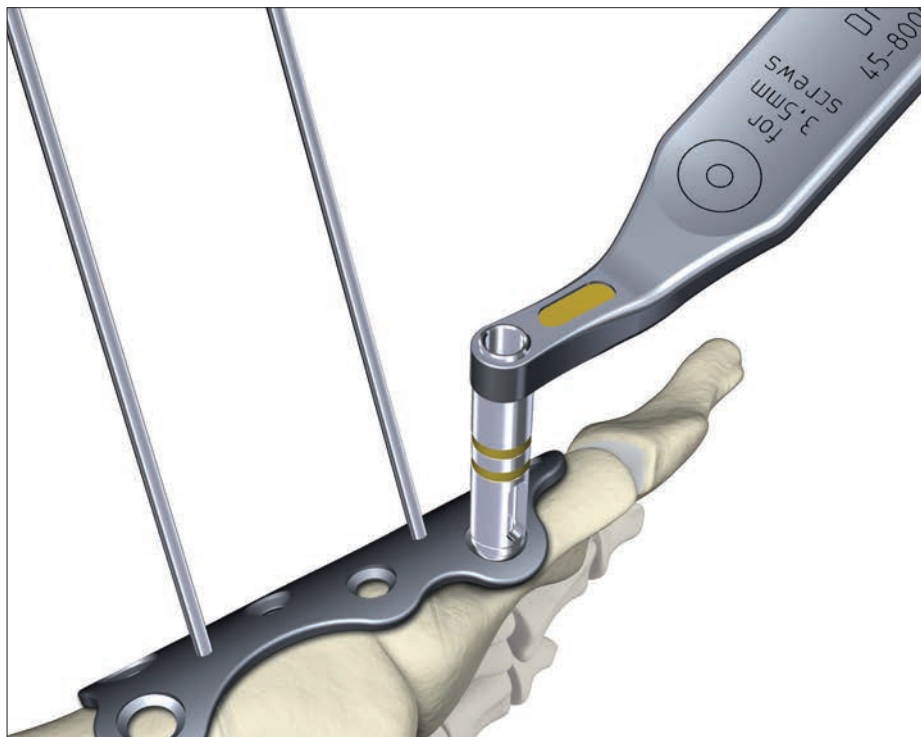
This instrument has two ends: one end is designed only to be used when pre-drilling for 2.7mm screws (and is indicated with black lines), and the other end is designed only to be used when pre-drilling for 3.5mm screws (and is indicated by yellow lines).

The Drill Guide is designed to limit drilling to a $\pm 15^\circ$ angle with respect to the plate. Drilling at an angle greater than $\pm 15^\circ$ may prevent locking from taking place, and is not recommended.

If drilling through an oval compression hole, the Drill Guide for Oval Compression Holes (REF 45-80005) must be used.

This drill guide has two ends: one end is designed only to be used when pre-drilling for 2.7mm screws (and is indicated with black lines), and the other end is designed only to be used when pre-drilling for 3.5mm screws (and is indicated by yellow lines). This drill guide is marked showing an eccentric position of the drill hole with respect to the plate screw hole.

Compression is only possible in one direction, and the drill guide must be positioned such that the drill hole will be created on the side of the oval compression hole which does not have a locking lip.



NOTICE

Drill guides should always fit securely within a screw hole – a mismatch between the drill guide and the plate hole indicates that the wrong dimension drill guide has been chosen.

CAUTION

- The Drill Guide for Oval Compression Holes must be placed at a 90° angle to the plate, and cannot be angulated.
- Ensure to insert drill guide for compression screw perpendicularly to the plate.

CAUTION

Locking screws should not be used in the oblong holes of the plate.

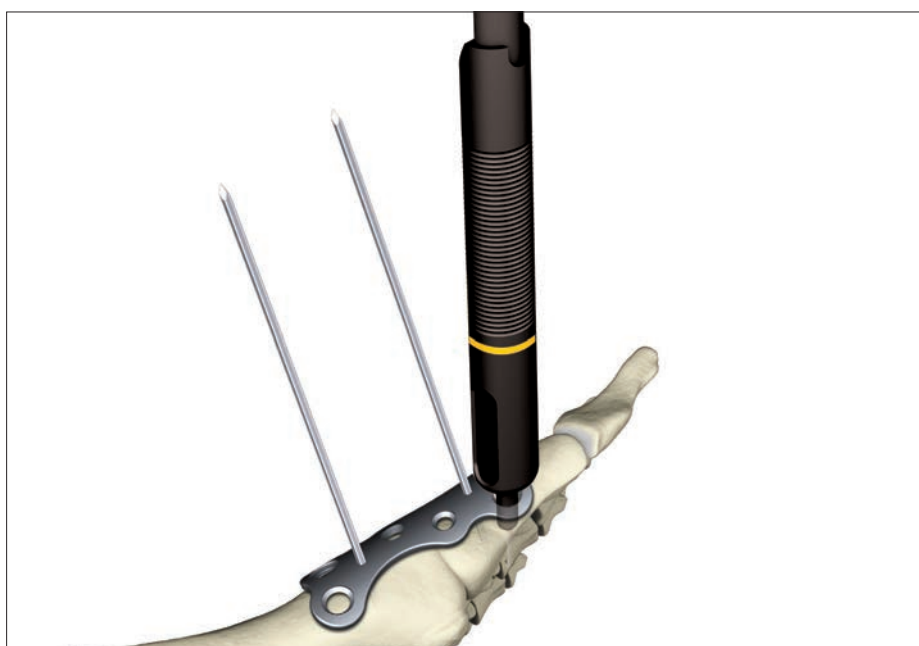
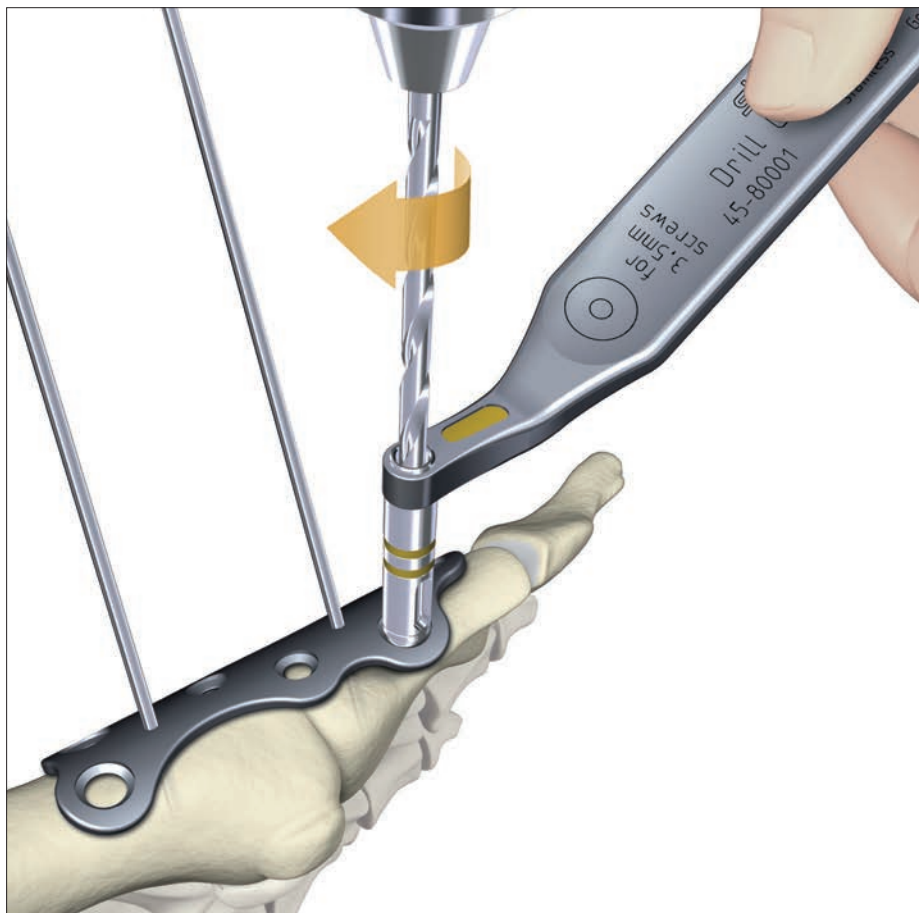
Operative Technique

Preparation for Screw Insertion

Use the appropriate twist drill to create a pilot hole through the drill guide. The twist drills are color coded to match the color associated with the drill guide: the 2.7mm drill guide has a black line on it, which matches the black line on the 2.0mm Twist Drill (REF 45-27010, which is used to pre-drill for 2.7mm screws). Similarly, the 3.5mm drill guide has a yellow line on it, which matches the yellow line on the 2.6mm Twist Drill (REF 45-35010, which is used to pre-drill for 3.5mm screws).

Measure the depth of the pre-drilled hole using the Depth Gauge for 3.5mm screws (45-35002). Always measure the depth of the pre-drilled hole by inserting the depth gauge first through the plate, and then into the pre-drilled hole. Use depth gauge to attain appropriate screw length. The sleeve of the depth gauge must be fully inserted into the respective plate hole prior to measuring. Measuring without a plate will result in a false reading. The depth gauges are designed to measure for bicortical screws only, and the hook of the depth gauge must be hooked onto the surface of the opposite cortex. The sleeve of the depth gauge must be fully inserted into the respective plate hole prior to measuring. Failure to measure without a plate will result in a false reading.

Although the locking and non-locking screws found in the VariAx Foot System are self-tapping, there may be certain circumstances when the use of a tap may be desired. For 2.7mm screw holes, use the Tap for 2.7mm Screws (REF 45-27005), and for 3.5mm holes, use the Tap for 3.5mm Screws (REF 45-35005). The taps are similarly color coded black (2.7mm), and yellow (3.5mm).



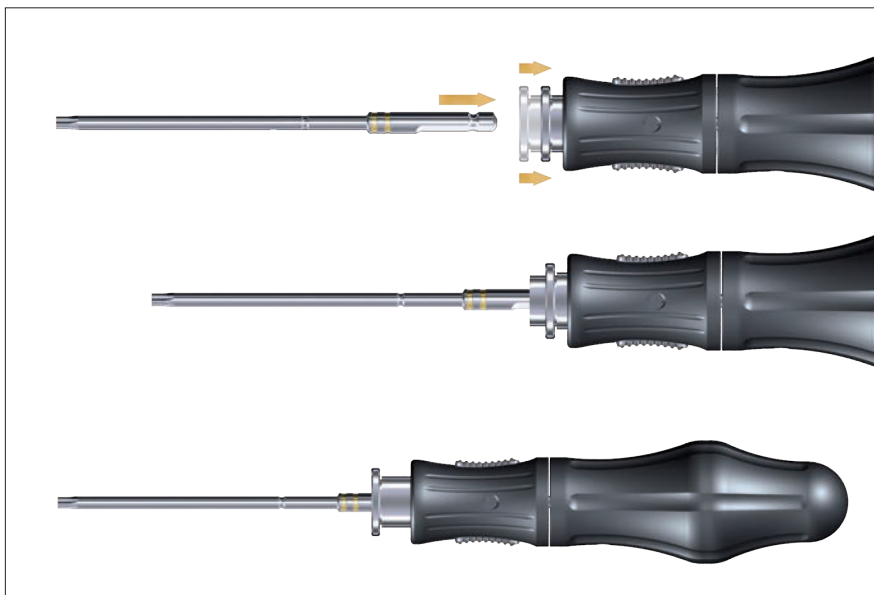
Operative Technique

Preparation for Screw Insertion

Assemble the appropriate Screwdriver Blade (with AO fitting) with the Screwdriver Handle, Revolving/Rigid, AO (45-85000).

NOTICE

- The yellow color-coded Screwdriver Blade, AO, T10 (45-35015) or Self Retaining Screwdriver Blade, AO, T10(703667) can be used to insert 3.5mm screws.
- Begin by pushing the AO quick connect sleeve towards the body of the Screwdriver Handle, insert the screwdriver blade into the AO quickconnect coupling, and then release the sleeve.



NOTICE

The black coded Screwdriver Blade, AO, T7 (REF 45-27015) is used to insert 2.7mm screws, and the yellow coded Screwdriver Blade, AO, T10 (REF 45-35015) is used to insert 3.5mm screws.

Holding sleeves for screws can be used to securely attach a screw to the screwdriver during screw insertion. The yellow coded Holding Sleeve for 3.5mm Screws (REF 45-35030), and the black coded Holding Sleeve for 2.7mm Screws (REF 45-27030) are used for 3.5mm, or 2.7mm screws, respectively. Assemble the appropriate holding sleeve and slide it over the screwdriver until it engages, as shown (Fig. 9).

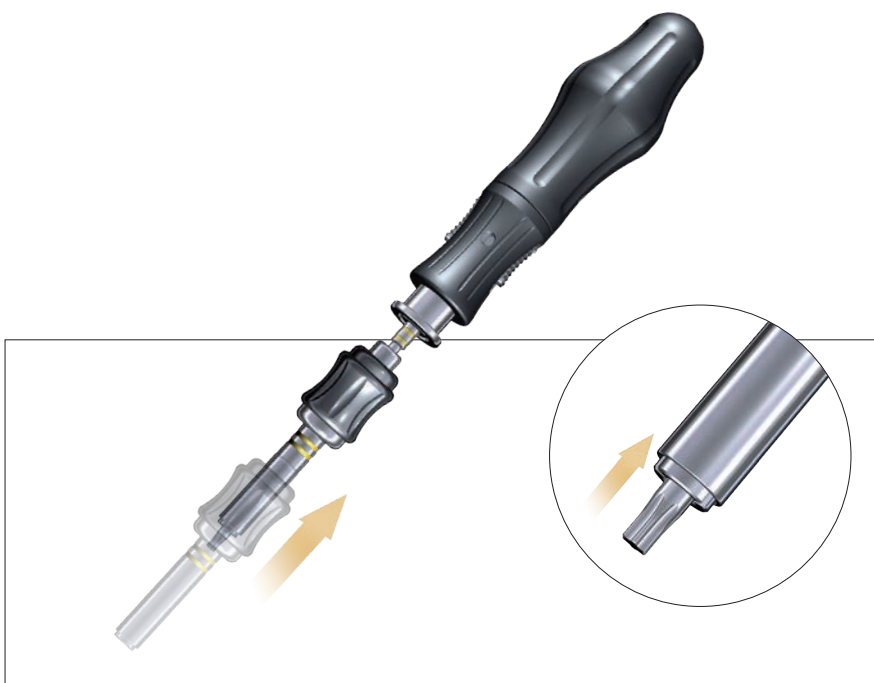


Fig. 9

Push the holding sleeve back so that the tip of the screwdriver becomes visible. Engage the screwdriver tip with the head of the chosen screw, then push the Holding Sleeve forward, as shown (Fig. 10). The holding sleeve will engage with the head of the screw, firmly holding it in place. The screw can then be removed securely from the screw rack, and the screw can be inserted into the plate.



Fig. 10

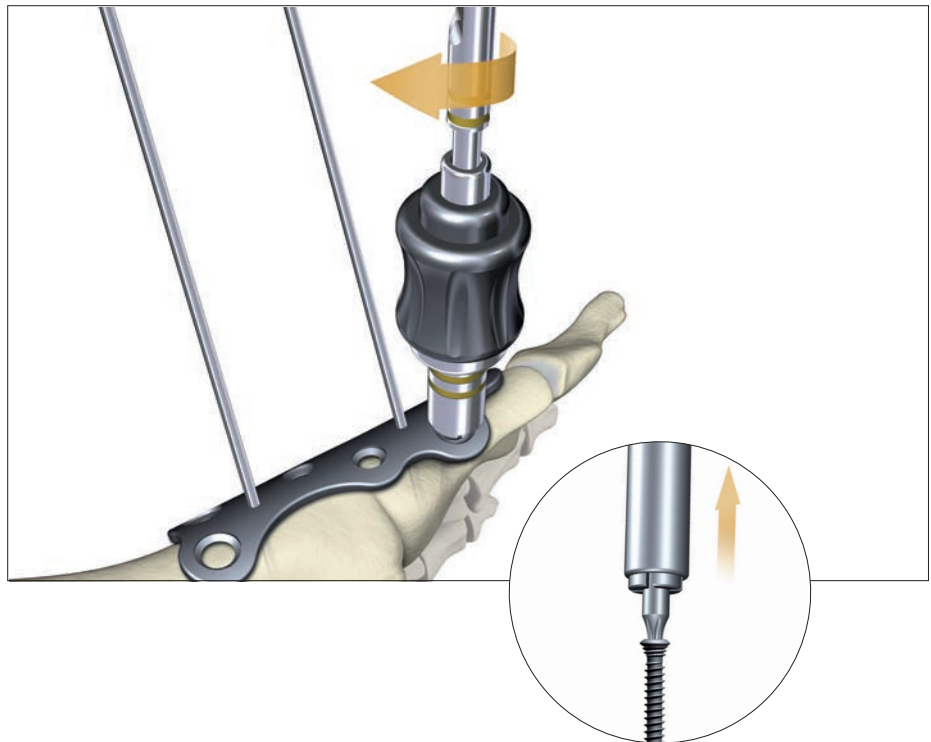
Operative Technique

Screw Insertion

Insert the screw into the predrilled hole using the screwdriver assembly.

Prior to final tightening, as the screw head approaches the plate, draw the holding sleeve back from the screw head, and remove the screwdriver from the screw. Final tightening is not recommended until all desired screws have been provisionally inserted into a plate.

Repeat drilling, measuring, and placement of locking or non-locking screws in the remaining holes, as required. Always remember to use the appropriate sized drill guide.



The highly efficient T7 interface (for 2.7mm screws) and T10 interface (for 3.5mm screws) facilitates effective transmission of torque from the screwdriver blade to the screw. Accordingly, applying excessive torque during screw insertion is not recommended, and may result in damage to the screwdriver blade.

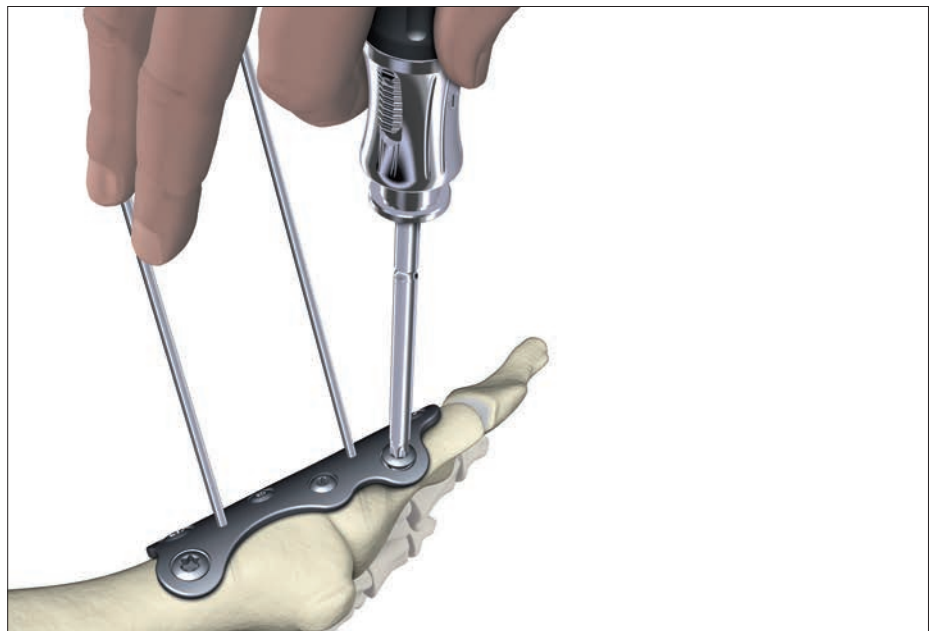
CAUTION

Verify proper placement of screws by use of fluoroscopy to ensure that there is no penetration of joint spaces.

NOTICE

The screwdriver handle contains a switch which allows the metal and plastic segments of the handle to either independently rotate, or to be rigidly locked together. When performing final tightening, the switch on the screwdriver handle must be in the fully-locked position (in which the position of the switch is closest to the base of the handle).

Final Tightening



Operative Technique

LCL Plate

Preparation for Osteotomy

Start incision at the distal tip of the Fibula and angle to the Calcaneal-Cuboid joint.

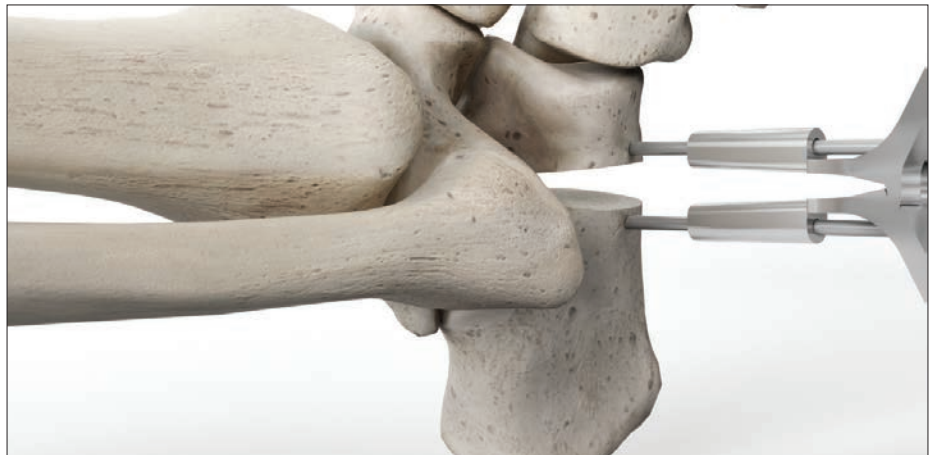


LCL Plate Placement

The osteotomy is made approximately 1-2cm (distance may vary based on surgeon preference) proximal, and parallel, to the calcaneal-cuboid joint. Select the Joint Distraction Forceps (product#45-80030) into osteotomy location.

NOTICE

Joint Distraction Forceps need to stay engaged in the opening position of the osteotomy site until insertion of screws.



Screws into Plate

Once you have spread open the wedge, fit LCL Plate wedge on top of osteotomy location (middle part of plate lines up with newly created wedge). Drill screw holes by using 2.6mm Twist Drill (REF 45-35010, which is used to pre-drill for 3.5mm screws), proximal side of plate first.

NOTICE

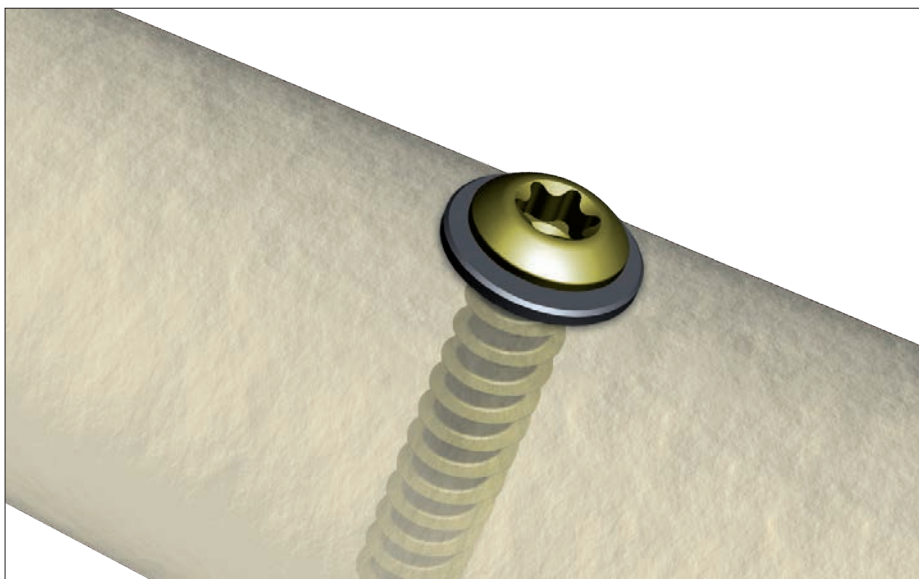
The option of using autograph or allograft is left to the surgeon's discretion.



Operative Technique

Optional: Washers

VariAx Foot non-locking screws can also be used as independent implants, separate from a plate. If indicated, non-locking screws can also be used together with a washer, to increase the surface contact area between the head of a screw, and bone. For 3.5mm screws, use a Washer for 3.5mm Screws (REF 40-35900), and for 2.7mm screws, use a Washer for 2.7mm Screws (REF 40-27900).



This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the product label and/or Instructions for Use, including the instructions for Cleaning and Sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The Instructions for Use, Operative Techniques, Cleaning instructions, patient information leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com.

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