stryker

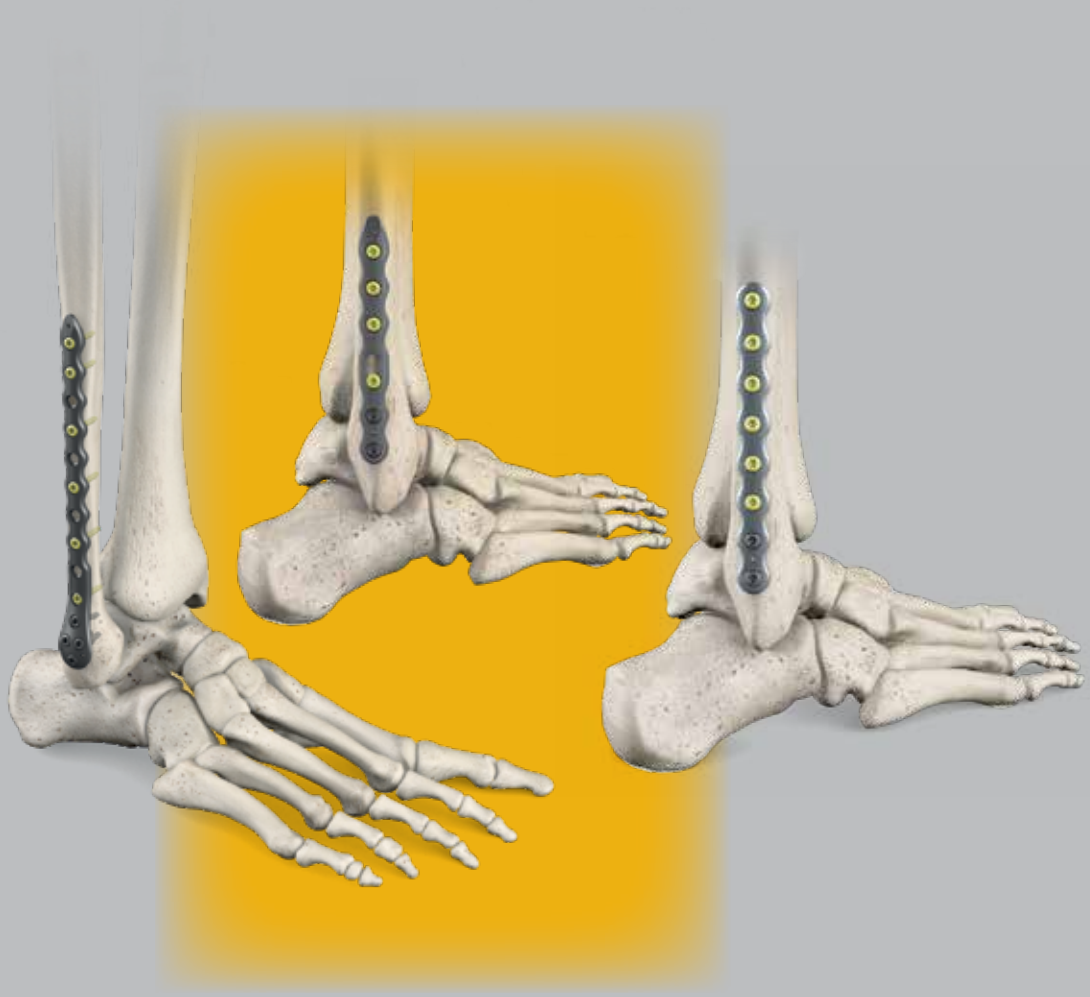
Trauma & Extremities

VariAx® Distal Fibula
Locking Plate System

Foot & Ankle

Operative Technique

- Distal Fibula Fracture Repair
- Polyaxial Locking Technology
- Low Profile Design
- VariAx 2 One Third Tubular Plating System



VariAx Distal Fibula Locking Plate System

Contributing Surgeon

Bradley R. Merk, MD
Associate Professor of Orthopaedic Surgery Director of Orthopaedic Trauma Feinberg School of Medicine Northwestern University
Chicago, USA

John Early, MD
Clinical Professor of Orthopaedic Surgery, University of Texas South Western Medical Centre,
Dallas, USA

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.

Table of Contents

Indications & Contraindications
VariAx Distal Fibula Locking Plate System

Indications

The VariAx Distal Lateral Plate is intended for use in internal fixation of the distal fibula.

The VariAx Fibula Straight Plates are intended for use in internal fixation of the distal fibula.

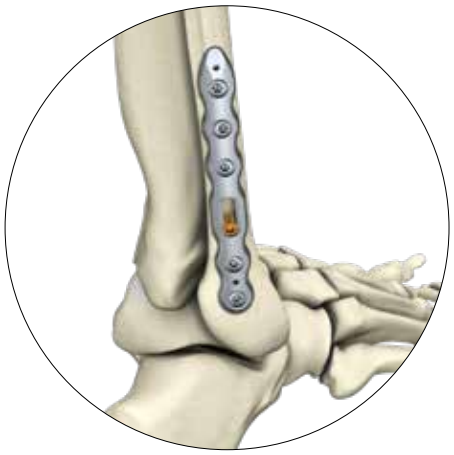
⚠CAUTION

The Stryker VariAx Distal Fibula Locking Plate System has not been evaluated for safety and compatibility in Magnetic Resonance (MR) environment and has not been tested for heating or migration in the MR environment.

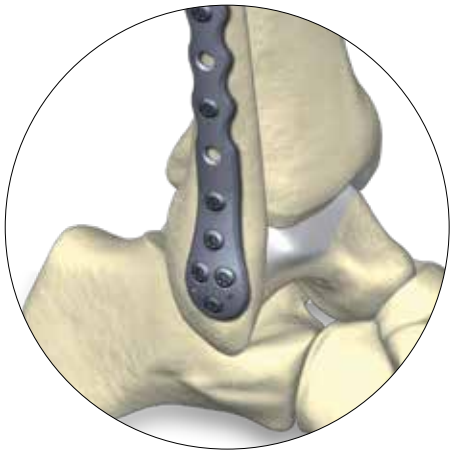
Contraindications

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 the operative site
- Bone stock compromised by disease, infection or prior implantation that can not 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

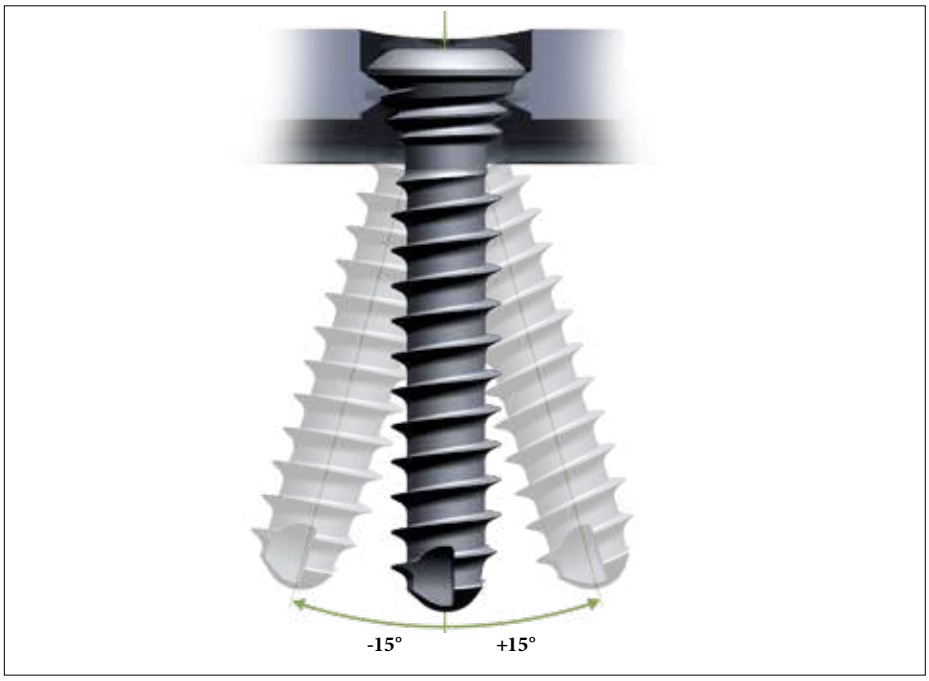


Straight plate positioned posterior lateral



Distal lateral fibula plate

Introduction
VariAx



- **The VariAx Distal Fibula Locking Plate System represents a new generation of implant technology**
  The reconstruction and fixation of distal fibular fractures may now be enhanced by means of the SmartLock polyaxial locking mechanism. This feature allows a surgeon to insert 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
- **Polyaxial Locking Technology**
  When a locking screw is used, the thread in the head of the screw is designed to re-shape the titanium used in the plate, which may allow for a secure form-fitting geometry. This process is designed to offer 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 ±15°, without the need for further steps
- **Modular System Design**
  The modular instrumentation system is designed for seamless integration of other products from the Stryker Foot portfolio
- **Color-Coding of Instruments**
  The instruments are color-coded to facilitate ease-of-use during surgery

⚠CAUTION

- During bone screw insertion in an oblong hole, the surgeon should rely on tactile feedback to prevent excessive torque which may result in thread / bone stripping, screw damage / pull through, or screwdriver damage
- Proper observation of bone quality, screw size and instrumentaion can help determine the appropriate insertion torque during insertion and final tightening of the screw in the plate
- When the screw is fully seated during final tightening, an increase of resistance indicates sufficient screw fixation

Indications & Contraindications
VariAx 2 One Third Tubular Plating System

Indications

The Stryker VariAx 2 One-Third Tubular Plating System is intended for internal fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, distal fibula, small bones in the ankle, fore, mid-and hind-foot in adult patients.

Indications include the following:

- Osteotomies and non-unions
- Fixation of fractures
- Normal bone density and osteopenic bone

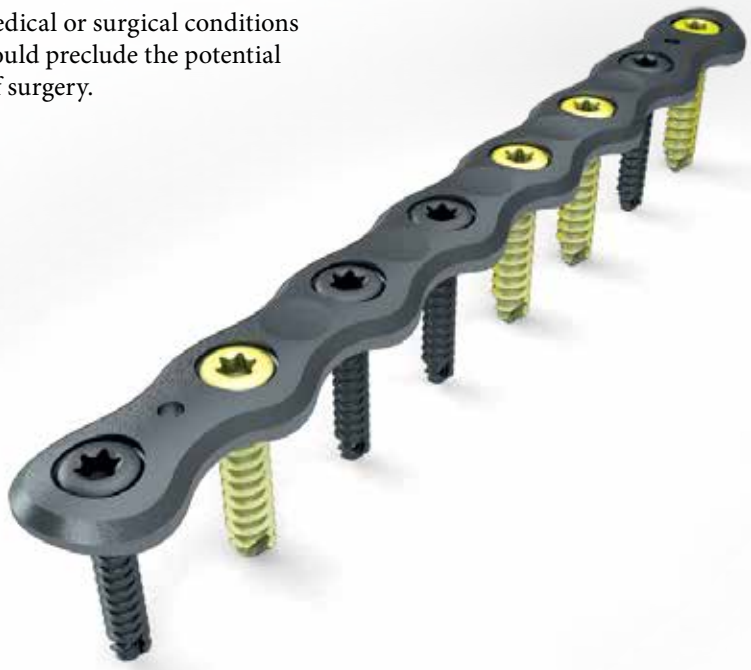
⚠CAUTION

The Stryker VariAx 2 One Third Tubular Plating System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating and migration, or image artifact in the MR environment. The safety of the VariAx 2 One Third Tubular Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 the 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.



Overview

Plate Options

Distal Lateral Fibula Plate

Range: 3 Holes – 12 Holes
Length: 77 – 185mm
Profile Shaft: 2.0mm
Distal End: 1.3mm

Straight Fibula Plate

Range: 2 Holes – 16 Holes
Length: 28.5 – 204mm
Profile: 2.0mm

VariAx 2 One Third Tubular Plating System

Range: 2 Holes – 16 Holes
Length: 23 – 191mm
Profile: 1.7mm

Screw Options

3.5mm Locking **3.5mm Non-Locking**

Locking Screws

Diameter: 3.5mm
Length: 10 – 70mm

Non-Locking Screws

Diameter: 3.5mm
Length: 10 – 70mm

Operative Technique

The Operative Technique listed below is designed to provide a general overview on the instruments and procedure required to implant a plate in the distal fibula.

This operative technique will focus on the placement and fixation of the Straight Fibula plate and Distal Lateral Fibula Plate. The VariAx 2 One Third Tubular Plating system uses the same techniques and instrumentation.

Planning and Preparation

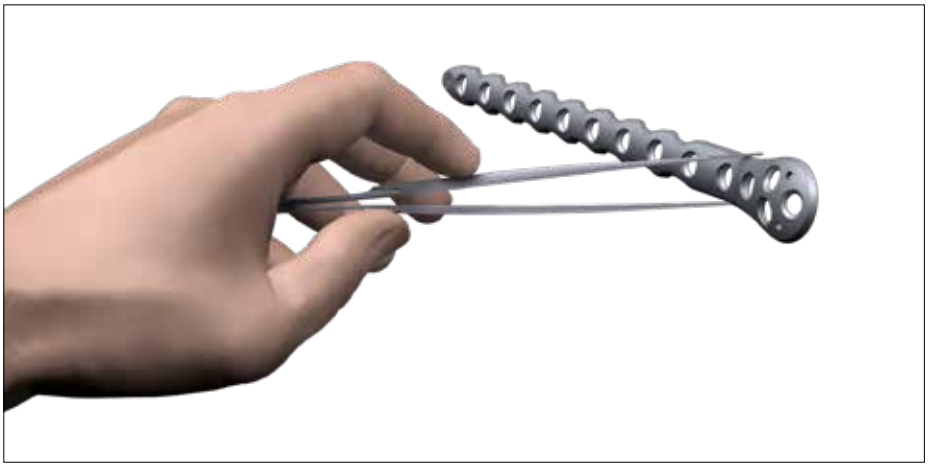
Clear identification and classification of the fracture site should first be established pre-operatively using the appropriate methods and visualization.

A lateral incision is typically used to perform an extra-periosteal exposure of the distal fibula. A direct reduction and provisional fixation of the fracture can frequently be achieved. If the fracture morphology is amenable, an independent lag screw can be inserted first (see page 14). Alternatively, indirect reduction techniques may be employed such as a distal fibula plate.

Although the lateral plates are pre-contoured, additional contouring of both the lateral and straight plates is possible using the Plate Bending Pliers (45-80010) when required based on local patient factors or anatomy. In order to reduce the likelihood of a stress riser effect and avoid reducing the fatigue properties of the implant, care should be taken to bend the plate in between holes. Always attach the bending pliers to two adjacent holes to prevent deformation of the screw holes.

⚠ 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)



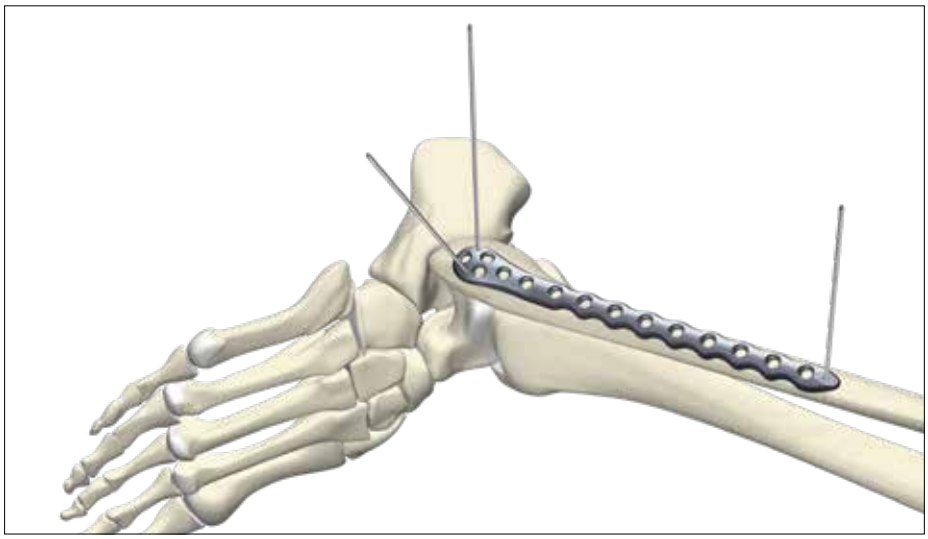
⚠ CAUTION

- The plate bending pliers are designed to be used only in circular holes
- If the oblong hole in the VariAx Straight Plate is deformed, there may be potential for a screw to pass through the hole upon insertion

Operative Technique

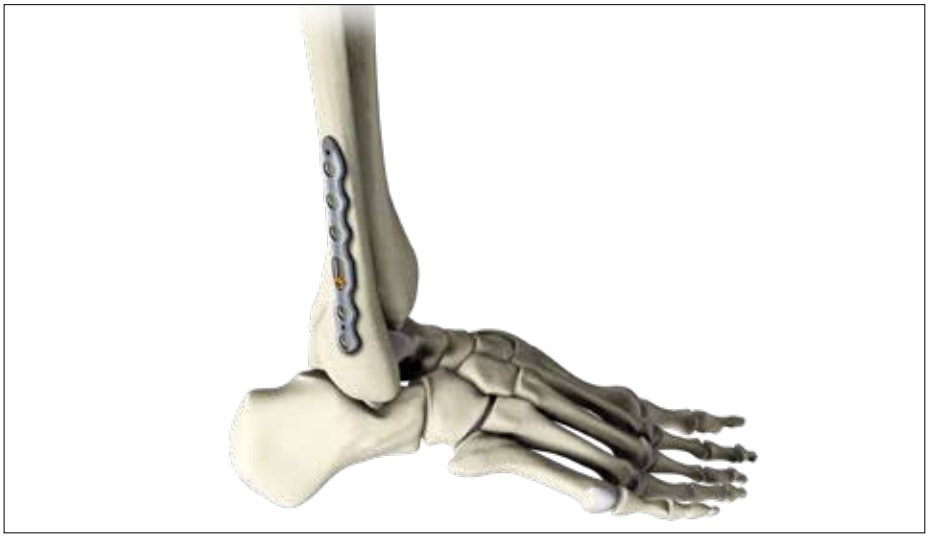
Lateral Plate Positioning

Having achieved reduction, the plate is selected and applied to the direct lateral surface of the distal fibula. The position should be adjusted to optimize fit and to allow for optimal screw fixation as per the fracture pattern and the pre-operative plan. Fluoroscopy can be utilized as needed to confirm position. The plate can then be stabilized by the insertion of K-Wires to ensure anatomical alignment (proximally and distally).



Posterior Lateral Plate Placement

The VariAx straight fibula plate and the VariAx 2 one third tubular plate may be applied laterally (as described) or posterior laterally, as an antiglide plate to resist proximal migration and rotation of the distal fragment. To place the plate in a posterior lateral position, an incision more posterior to the fibula may be made. Individual patient anatomy should be assessed, as some bending of the straight plate may be required. Bending of the distal lateral fibula plate, straight fibula plate, or the one third tubular plate can be achieved using the Bending Pliers (45-80010) as illustrated on page 8.

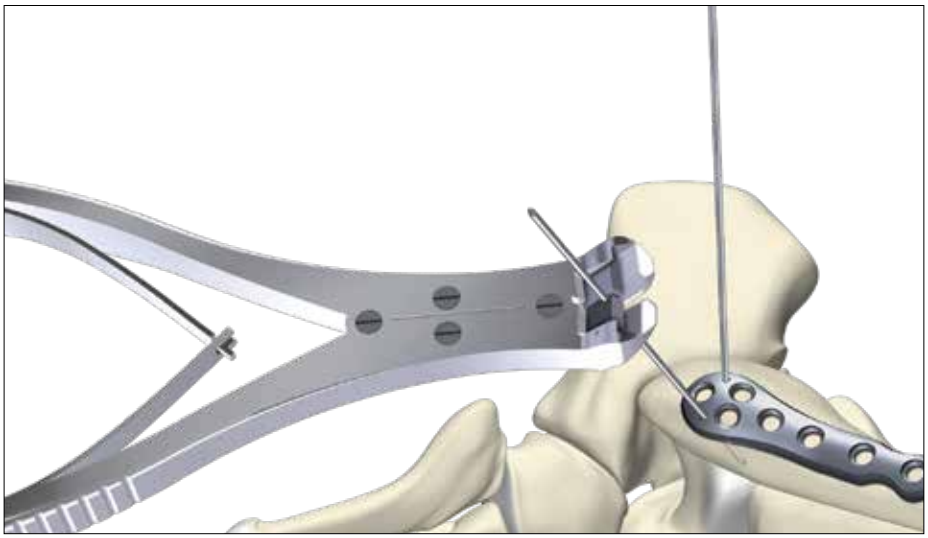


The elongated oblong hole is designed to assist in allowing flexibility with plate placement. A non-locking screw can be initially placed through the hole, allowing for some stability until the ideal plate placement is determined. This hole will not accept a locking screw. As such, the locking Drill Guide (45-80001) will not engage into the plate (it will sit on top of the hole).

⚠CAUTION

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

The K-Wire Cutting Pliers 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.

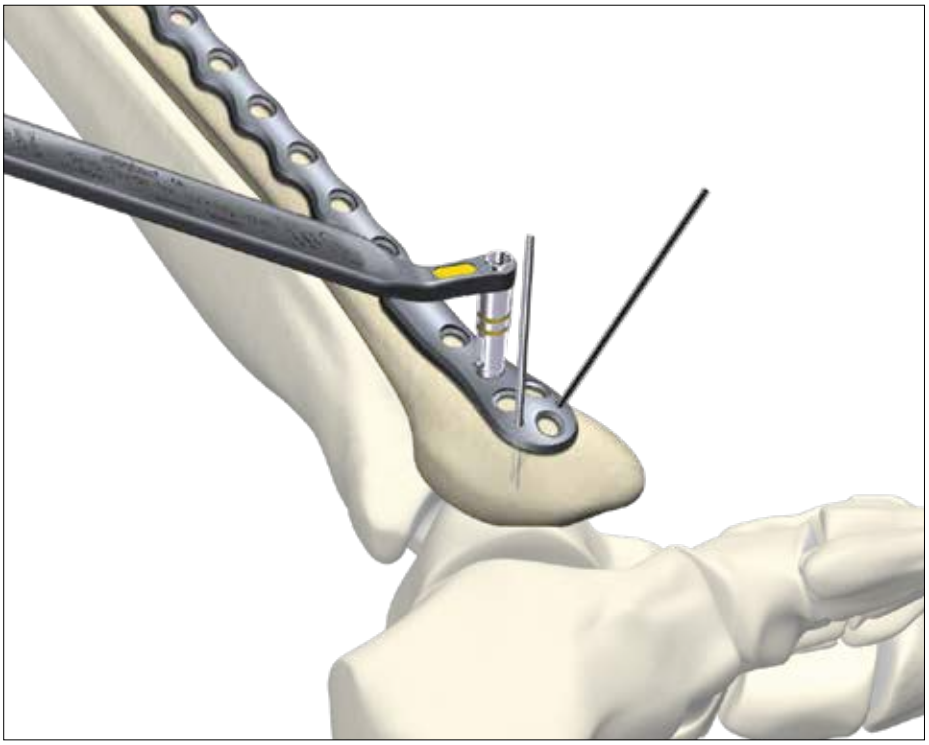


Operative Technique

Preparation for Screw Insertion

⚠CAUTION

- 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 (45-80001) must be used in all VariAx Distal Fibula Plate holes.



Use the end of the drill guide indicated with yellow color-coded lines to pre-drill for VariAx Distal Fibula plating procedures. Yellow color-coding is associated with 3.5mm VariAx Foot and Ankle screws.

NOTICE

The other end of the drill guide is indicated with black color-coded lines, and is designed for use with VariAx Foot and Ankle Plates that accept 2.7mm screws. This end of the drill guide must not be used for VariAx Distal Fibula procedures.

The drill guide is designed to limit drilling to a ±15° angle with respect to the plate. Drilling at an angle greater than ±15° may prevent locking from taking place, and should be avoided.

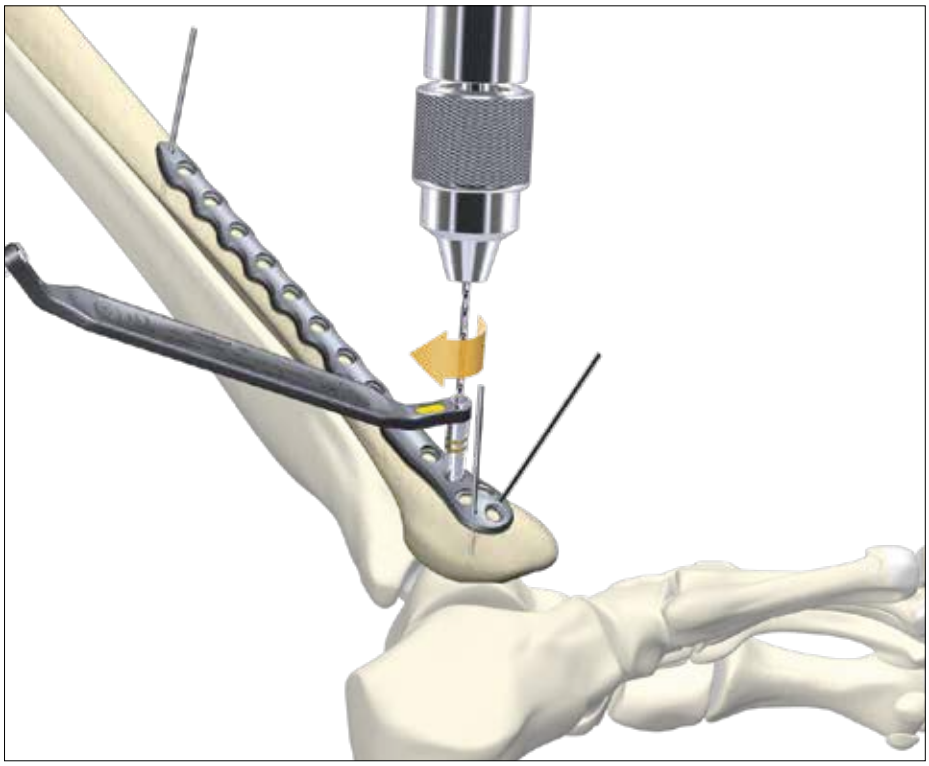
⚠CAUTION

Always use the drill guide when pre-drilling a pilot hole, either for a locking or non-locking 3.5mm screw.

NOTICE

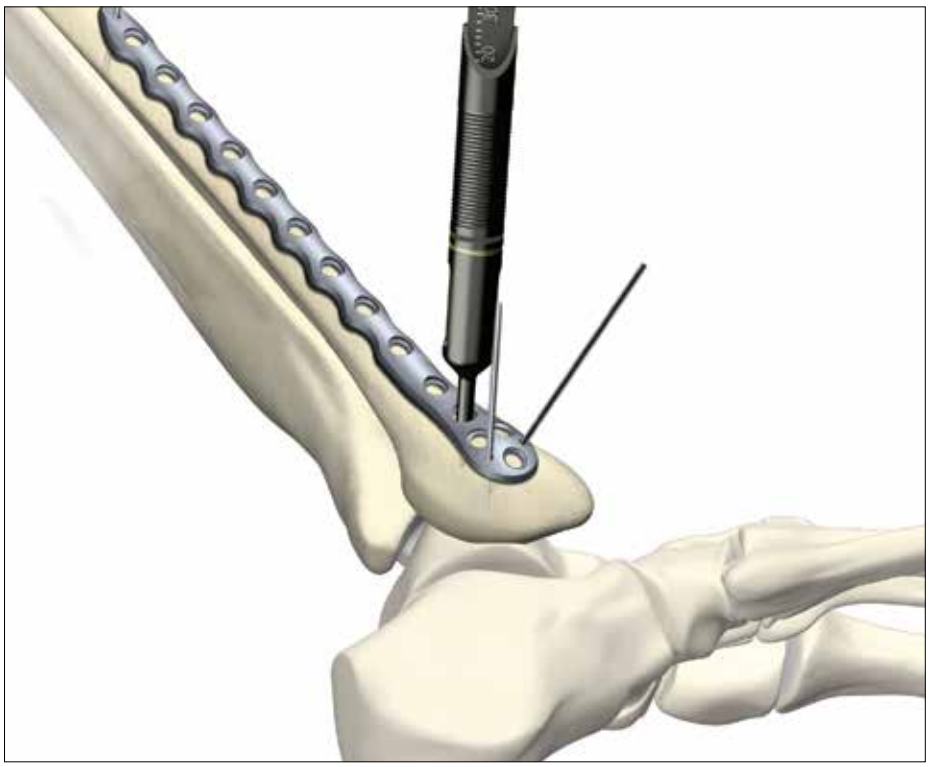
Drill guides should always fit securely within a screw hole – a mis-match between the drill guide and the plate hole indicates that the wrong dimension drill guide has been chosen.

Operative Technique



Use the drill to create a pilot hole through the drill guide. The 2.6mm Twist Drill (45-35010) is color-coded yellow to match the color associated with the 3.5mm drill guide (double yellow).

Although the locking and non-locking screws found in the VariAx Foot and Ankle system are self-tapping, when encountering hard bone a tap may be required. For 3.5mm screws the appropriate tap is accordingly color-coded yellow (45-35005).



Measure the depth of the pre-drilled hole using the Depth Gauge (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.

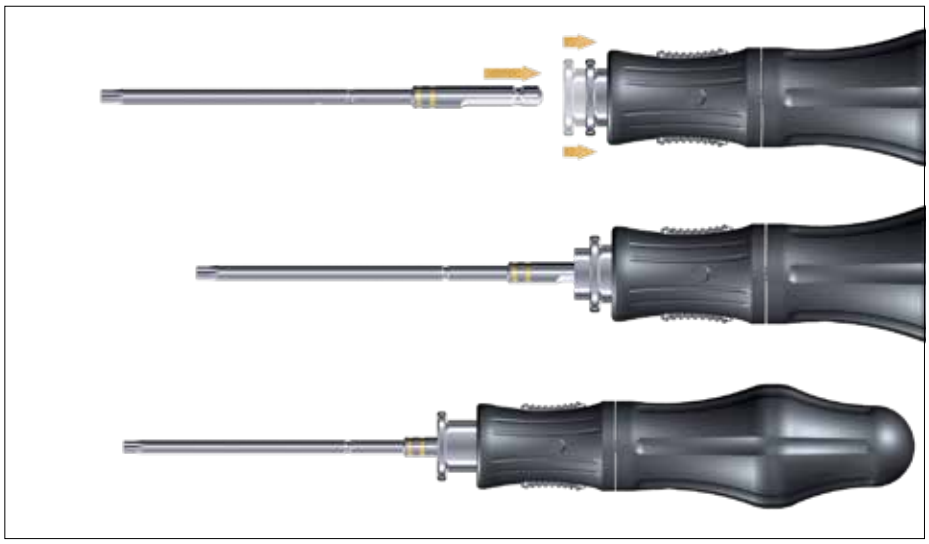
Operative Technique

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.

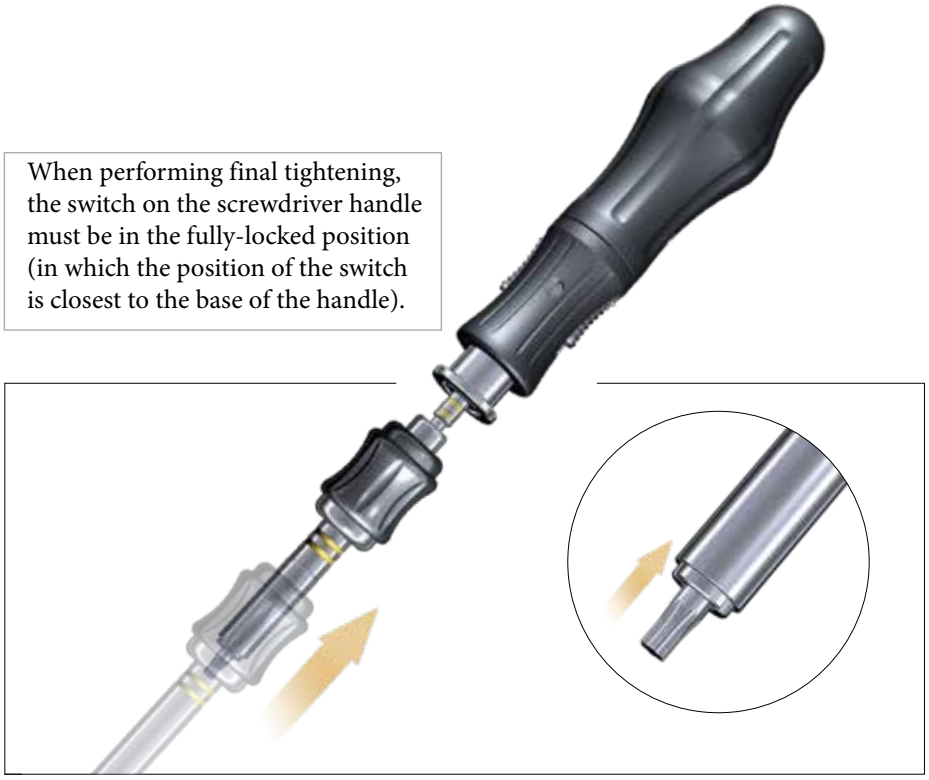
Begin by pushing the AO quick-connect sleeve towards the body of the Screwdriver Handle, insert the screwdriver blade into the AO quick-connect coupling, and then release the sleeve.



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).



Holding sleeves for screws can be used to securely attach a screw to the yellow color-coded Screwdriver Blade (45-35015) during screw insertion. The yellow color-coded Holding Sleeve for 3.5mm screws (45-35030), must be used. Assemble the appropriate holding sleeve and slide it over the screwdriver until it engages, as shown.

NOTICE

The Self Retaining Screwdriver Blade (703667) does not require a screw holding sleeve and it cannot be attached to it.

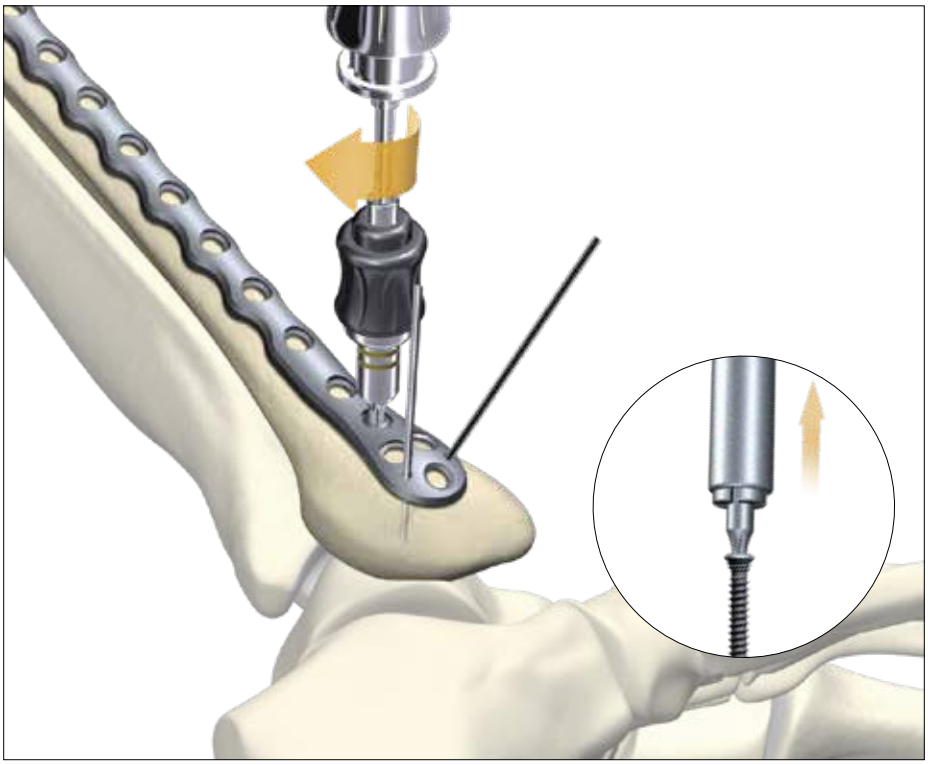
⚠CAUTION

Always make sure that drill bit and drill guide are matching by verifying the laser mark and color ring marking on the drill bit with the laser mark and color marking on the drill guide.

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. 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.

Operative Technique

Screw Insertion

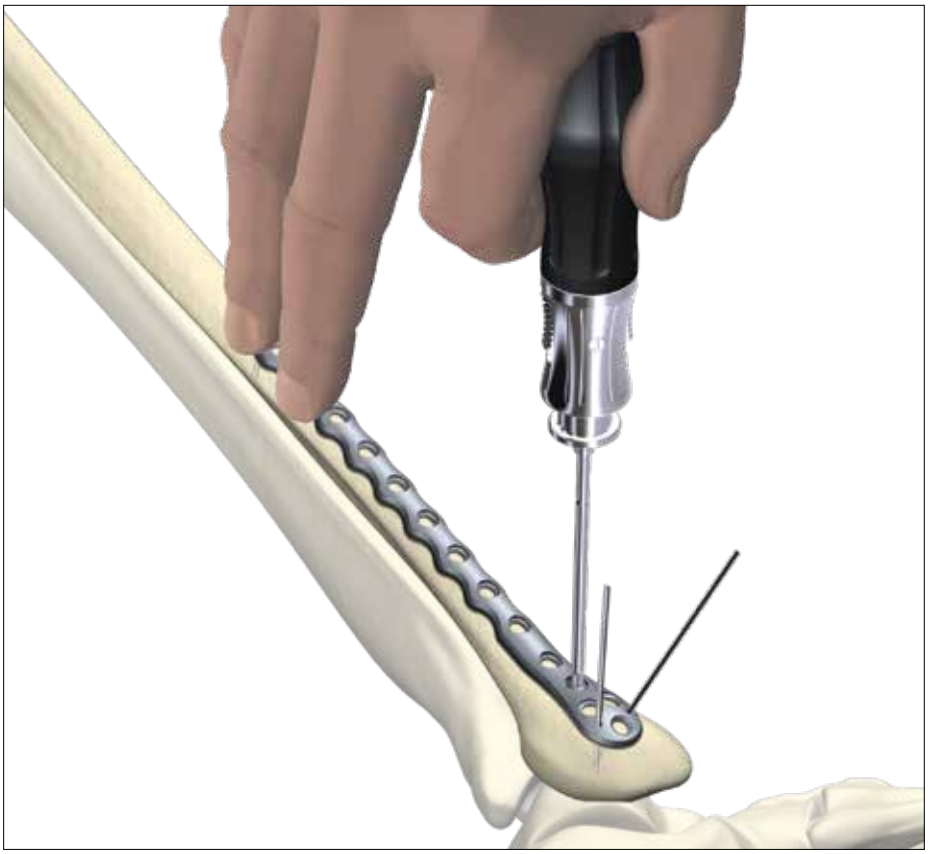


Insert the screw into the pre-drilled hole using the screwdriver assembly.

As the screw head approaches the plate, draw the holding sleeve back from the screw head, and continue with final tightening then remove the screwdriver from the screw.

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.

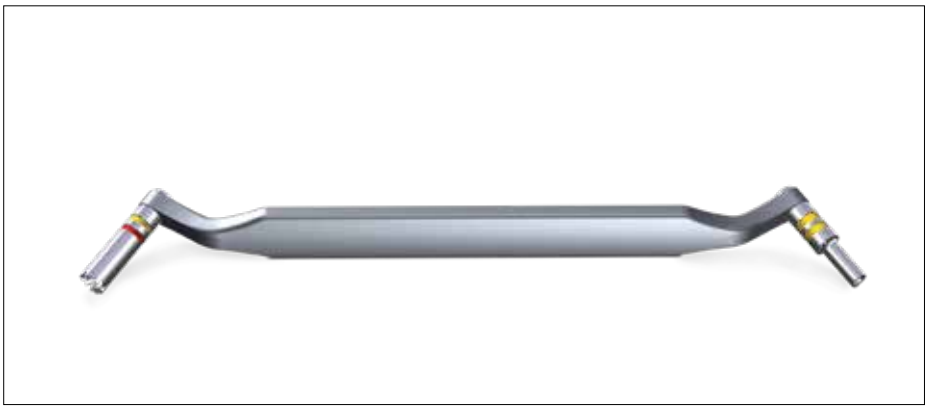
Final Steps

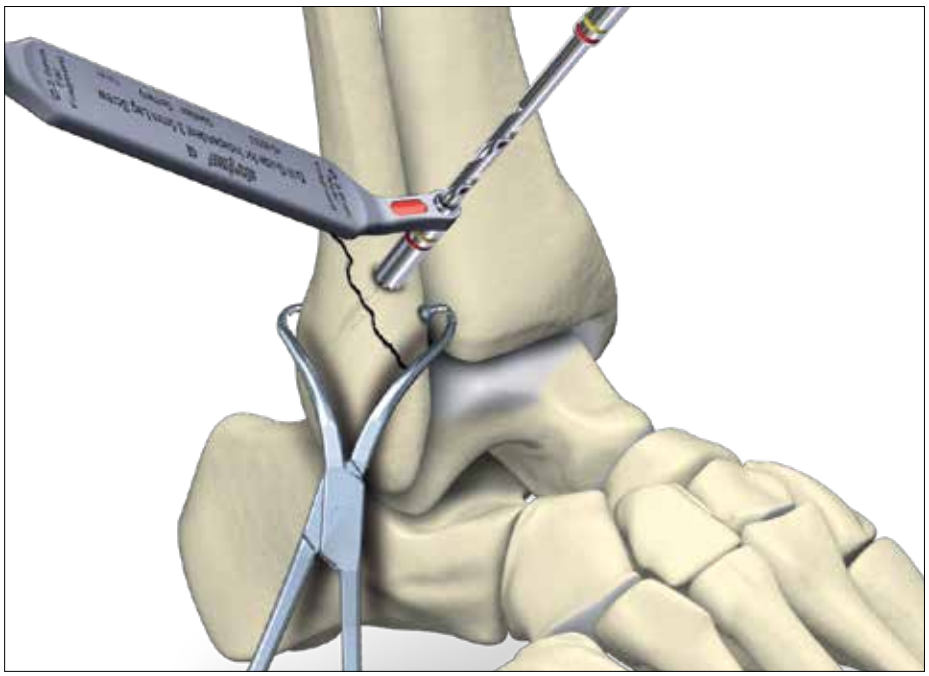


- The T10 interface is designed to facilitate effective transmission of torque from the screwdriver blade to the screw
- Intra-operative fluoroscopy is performed to confirm appropriate reduction and implant placement

Optional: Independent Lag Screw Technique

A 3.5mm VariAx Foot and Ankle Non-Locking Screw can be used as an independent lag screw to reduce fibula fractures, prior to fixation using a VariAx Distal Fibula plate. The VariAx Foot and Ankle instrumentation system includes a Drill Guide for a 3.5mm Independent Lag Screw (45-80003), which is designed to only be used when drilling and overdrilling a hole for independent lag screw fixation using a 3.5mm screw. **This technique must not be performed through a plate due to the locking mechanism.**





⚠CAUTION

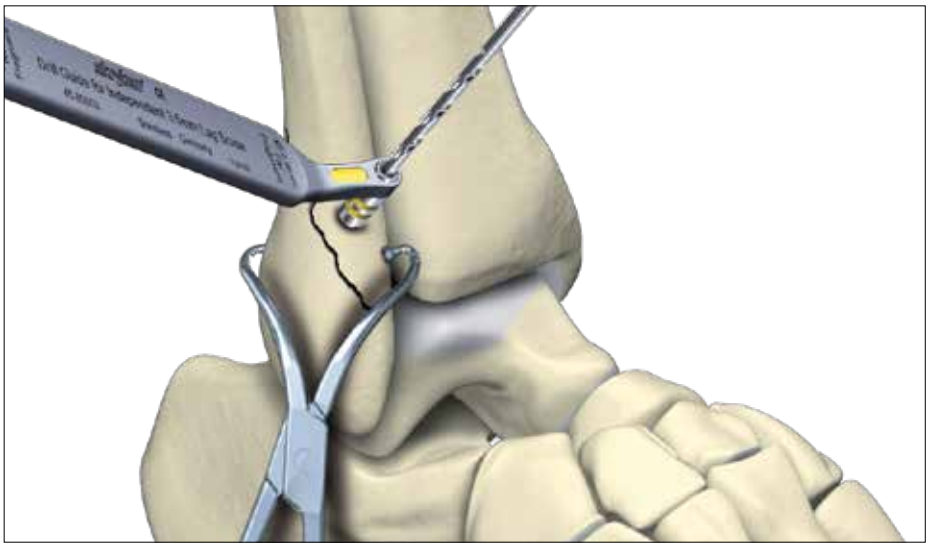
Do not use the Independent Lag Screw Guide for overdrilling through a plate hole as this could damage the plate hole.

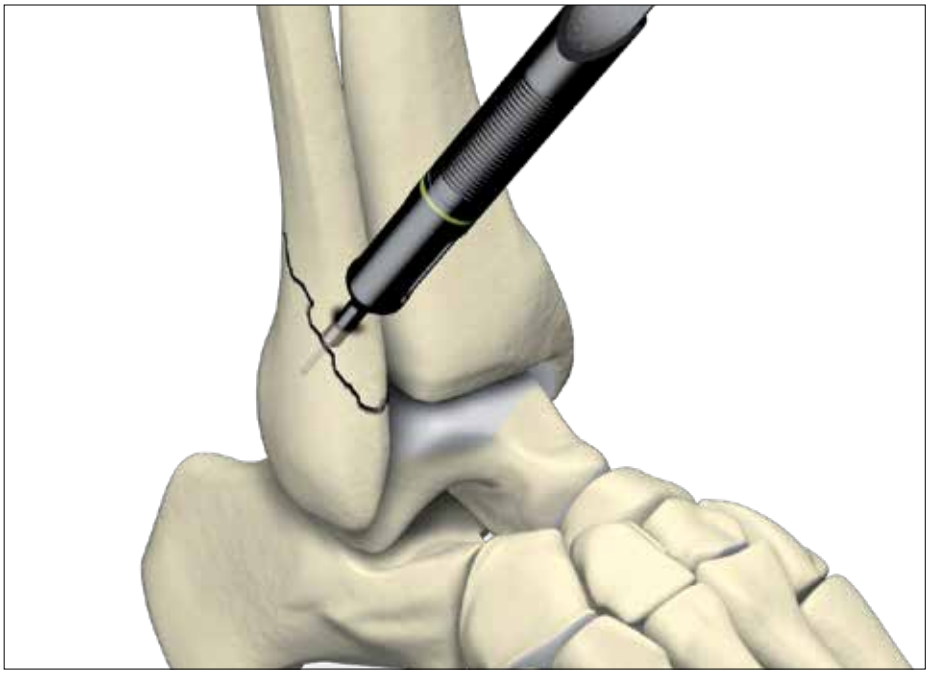
2.7mm T10 Lag Screw Technique instrumentation is available.

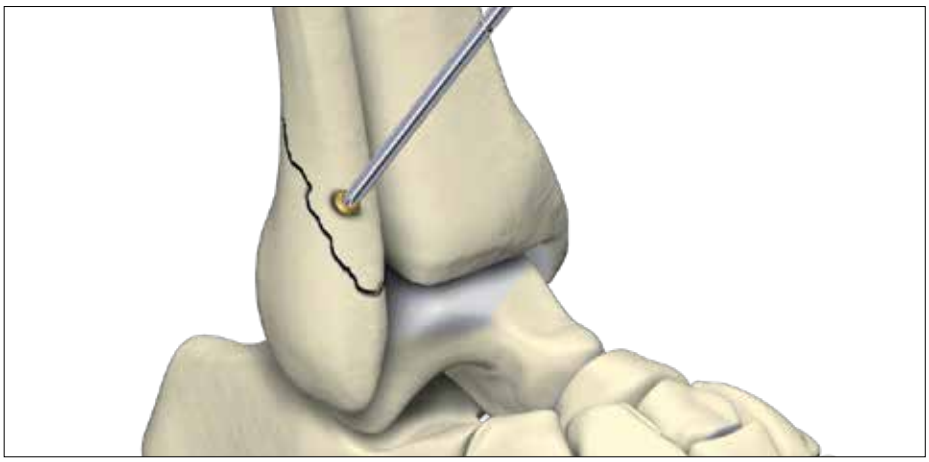
The procedure for preparing a hole for independent lag screw insertion is as follows:

1. Anatomic reduction is achieved and maintained with a pointed reduction clamp.
2. Identify the appropriate drill guide. For 3.5mm screws, use the Drill Guide for 3.5mm Independent Lag Screws (45-80003). This drill guide has two sides/sleeves. Identify the side labeled "Near Fragment", which is color-coded red and yellow.
3. The correct overdrill is directly placed against bone for drilling the near fragment. For 3.5mm screws, use the overdrill that is color-coded with a red and yellow line (45-35020).
4. The red and yellow color-coded drill bit is then inserted through the identical red and yellow drill guide, and drilling is performed completely through the near fragment to create a gliding hole. This drilling must completely pass through the near fragment, and into the interfragmentary space, otherwise lagging of the far fragment will not be possible.

Operative Technique

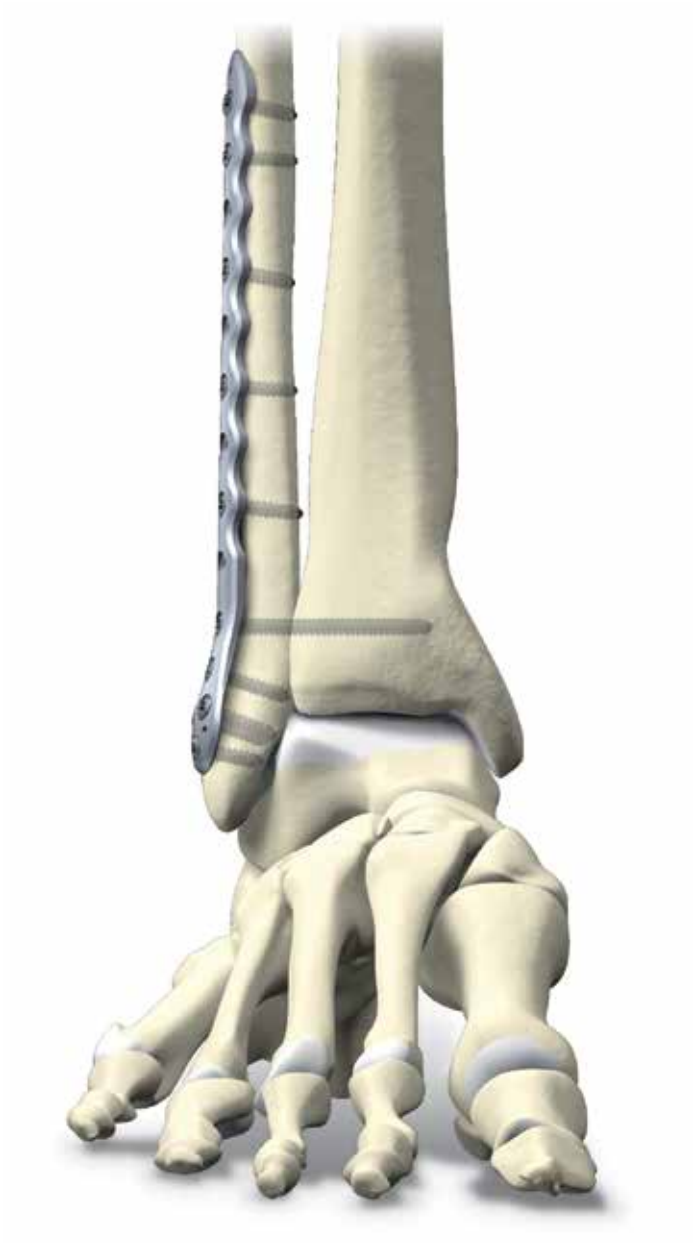






5. The other side of the drill guide, which is yellow color-coded, is then fully inserted into the newly created gliding hole. This drill guide must be inserted as deep as possible into the overdrilled hole. Drilling is performed using the yellow color-coded 2.6mm drill (45-35010), into the far fragment. The end result of the drilling process will be a co-linear hole through the near fragment, and into the far fragment, where the diameter of the hole in the near fragment will be bigger than the diameter of the hole in the far fragment (thus allowing for lagging).
6. When appropriate, use the countersink (45-80040) to minimize screw head prominence and reduce stress riser effects to the bone during final screw tightening.
7. Screw length is then measured using the Depth Gauge (45-35002).
8. The screw can then be inserted. A washer (40-35900) could also be used if necessary due to bone quality. If a washer is intended to be used the countersink should not be applied before.

Optional: Syndesmotic Screw Fixation Technique



- After completion of all fixation, an intra-operative Cotton test or external rotation stress test is performed under fluoroscopy to assess syndesmotic stability. Fixationis performed as needed
  - A stab incision is made medially near the metaphysis.
  - A large peri-articular clamp is used to obtain and maintain an anatomic syndesmotic reduction which should be confirmed fluoroscopically on the A/P, mortise, lateral view by inspection or palpation via the surgical exposure. Using the drill guide the 2.6mm yellow color-coded drill bit is used to make a pilot hole parallel to the tibio-talar articulation and the trans-malleolar axis. Care must be taken to avoid excessive angulation through the plate beyond 15°.
- One or two tri-cortical or tetra-cortical 3.5mm non-locking screws can be used to achieve syndesmotic fixation based on patient factors, injury factors, and surgeon preference

Notes

Notes

Notes

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 package insert, 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, Instructions for Cleaning, Sterilization, Inspection and Maintenance (OT-RG-1), Patient Information Leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com. If saving the Instructions for Use, Operative Techniques and the Instructions for Cleaning, Sterilization, Inspection and Maintenance from the above mentioned websites, please make sure you always have the most up to date version prior to use.

This document is applicable to US and Canada.

Content ID: VAX-ST-33, 06 - 2021

Manufacturer:
Stryker GmbH
Bohnackerweg 1
2545 Selzach, Switzerland
www.stryker.com