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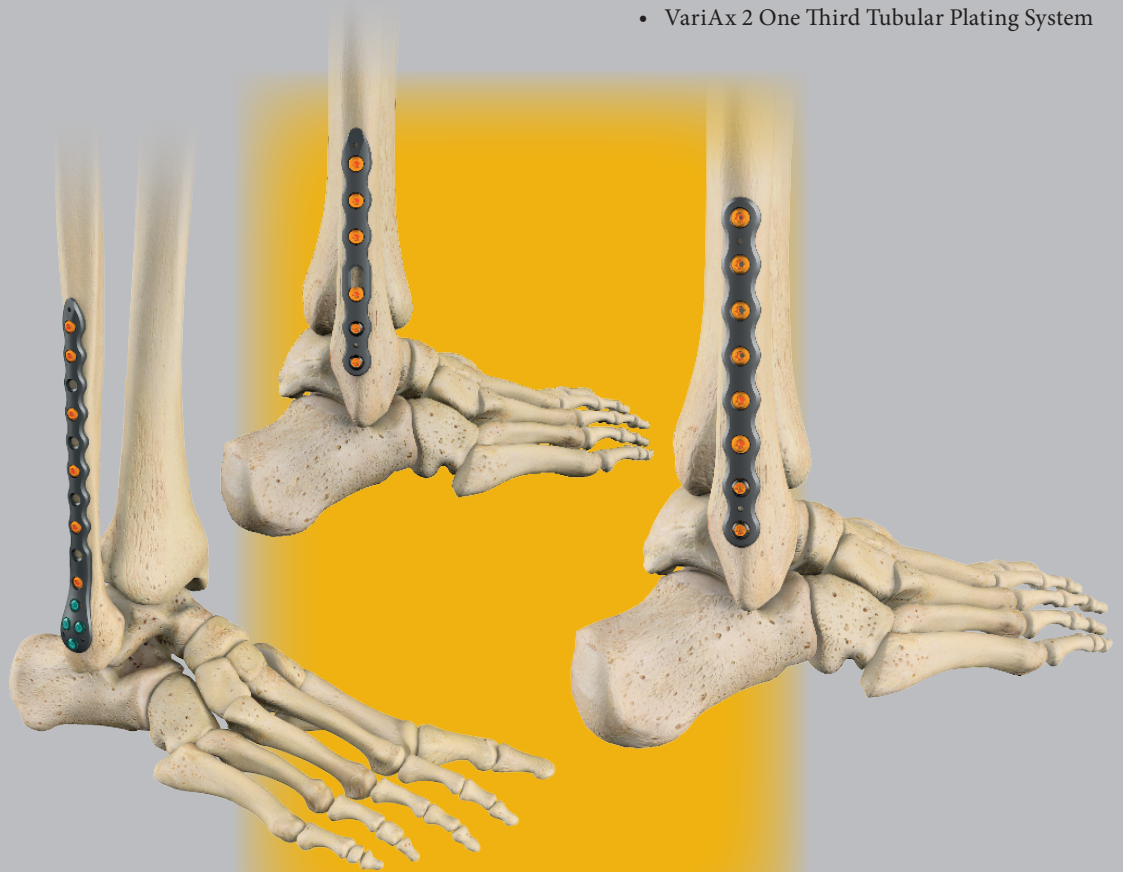
Trauma & Extremities

VariAx® Distal Fibula

Locking Plate System

Operative Technique

- Distal Fibula Fracture Repair
- Polyaxial Locking Technology
- Low Profile Design
- VariAx 2 Color Coded Screws and Instruments
- VariAx 2 One Third Tubular Plating System



Foot & Ankle

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.

A workshop training is recommended prior to performing your first surgery.

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000). 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 have not been tested unless specified otherwise in the product labeling.

See package insert (Instruction for Use) [V15011, V15013, 90-03300] for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.

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Indications, Precautions & 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.

Note:

When using the VariAx 2 Screws with this system, plates are only compatible with T10 3.5mm and T10 2.7mm screws.

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

Warnings & Precautions

See package insert for warnings, precautions, adverse effects and other essential product information.

Stryker Systems have not been evaluated for safety and compatibility in Magnetic Resonance (MR) environment and have not been tested for heating or migration in the MR environment.

- 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

Overview

VariAx 2 Screws

Screw Angulations

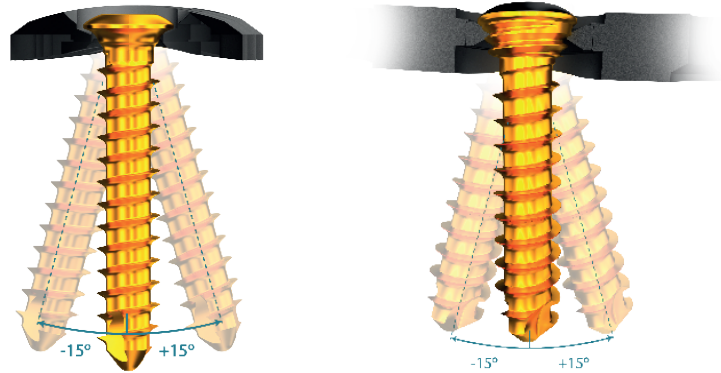
All screws can be angulated up to ± 15 degrees in circular holes. In oblong holes, non-locking screws placed in the neutral position can be angled up to 15 degrees in the off-axis plane. These angles are controlled by using the appropriate polyaxial drill guide (REF 703882 for 3.5mm screws and REF 703883 for 2.7mm screws) when drilling.

Note:

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 instrumentation 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.



Locking or Non-Locking Screws

The circular holes in the plates provide an option for locking and non-locking.

In order to distinguish a locking screw from a non-locking screw, the top of the locking screw heads are laser marked with a black circular ring and inner dot as shown here.

SmartLock technology is patented by Prof. Wolter, Hamburg, Germany.

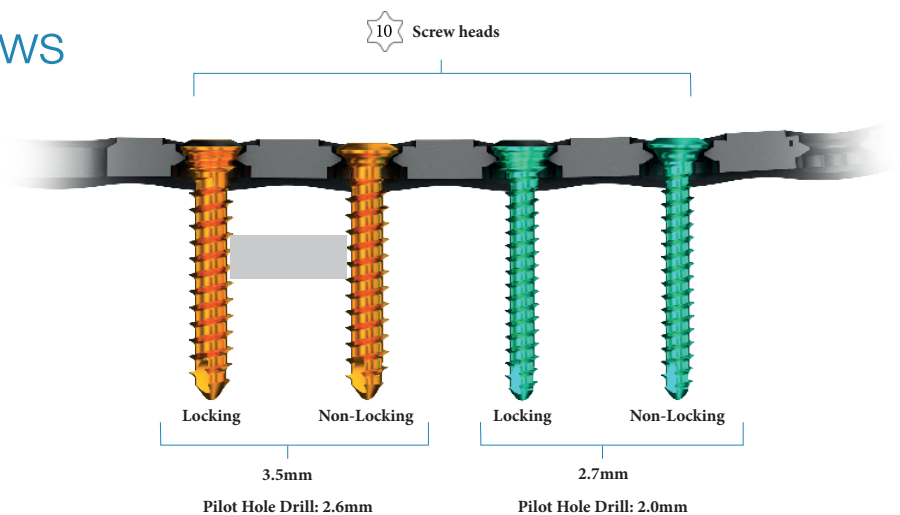


3.5mm or 2.7mm Screws

The VariAx 2 Plates are used with either 3.5mm or 2.7mm screws, giving the choice of screws size based on the anatomy and fracture pattern. Additionally, all screws in the system are inserted with the same T10 screwdriver for ease of use.

Locking Screws Non-Locking Screws

Diameter: 3.5mm	Diameter: 3.5mm
Length: 8 – 70mm	Length: 8 – 70 mm
Diameter: 2.7mm	Diameter: 2.7mm
Length: 8 – 70mm	Length: 8 – 70mm



Indications, Precautions & 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

Contraindications

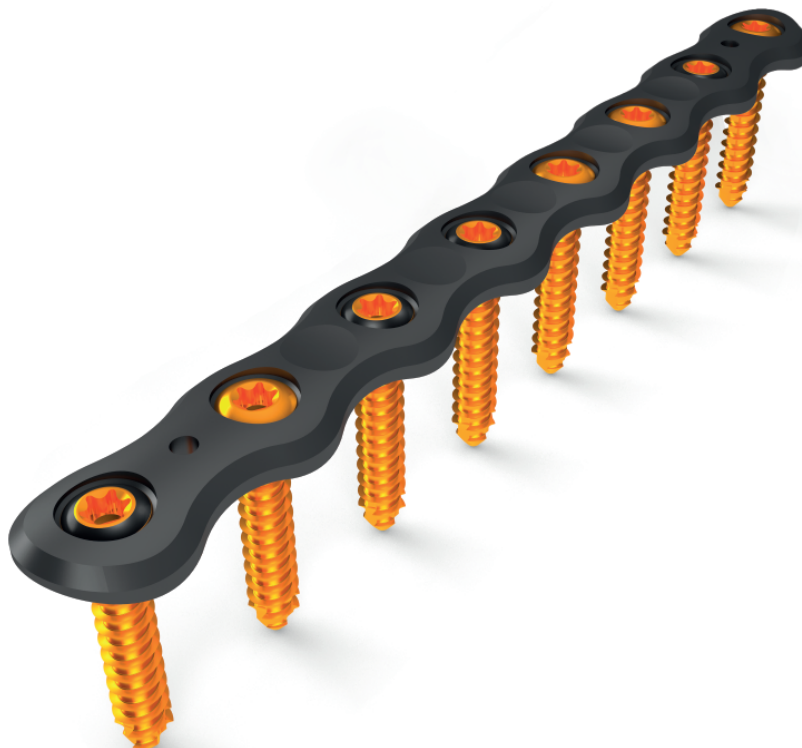
The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- 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.

Precautions

The Stryker VariAx 2 One Third Tubular Plating System has not been evaluated for safety and compatibility in the MR environment and 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, unless specified otherwise in the product labeling.

- 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



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

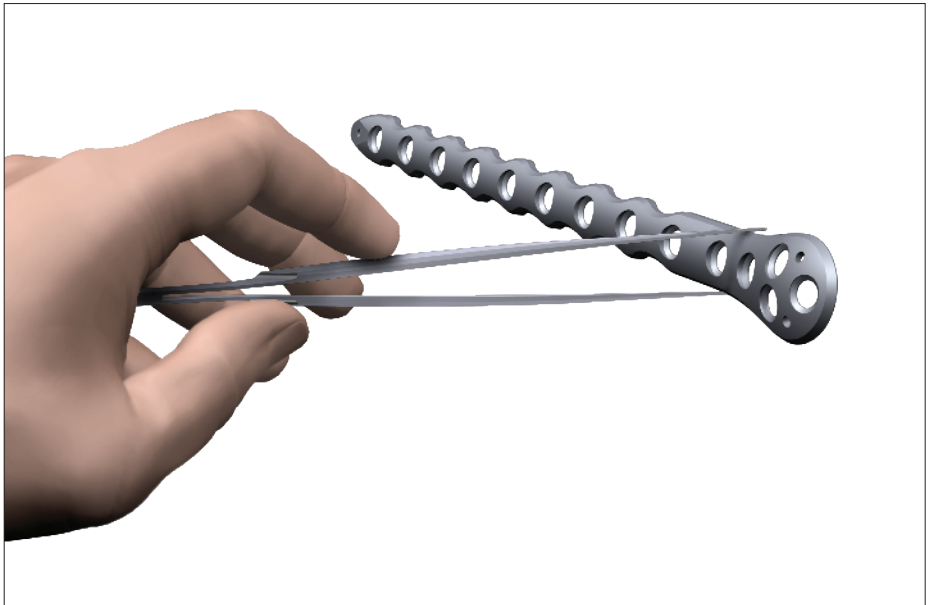
Clear identification and classification of the fracture site should first be established pre-operatively using the appropriate methods and visualization.

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.

Note:

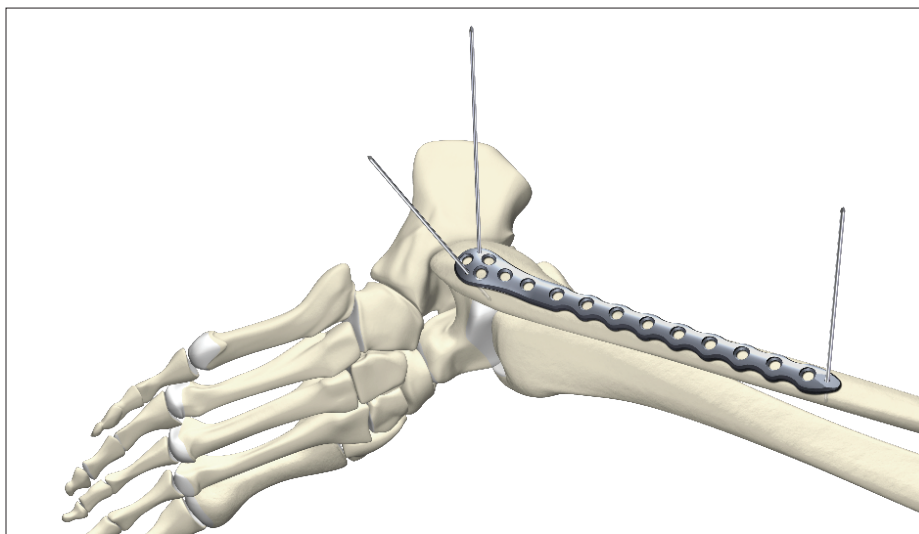
- Excessive plate bending may lead to failure of the locking mechanism and should be avoided. Do not re-bend plates.
- The plate bending pliers are designed to be used only in circular holes.
- If the oblong hole in the VariAx Straight Plate is deformed, there may be potential for a screw to pass through the hole upon insertion.



Operative Technique

Lateral Plate Positioning

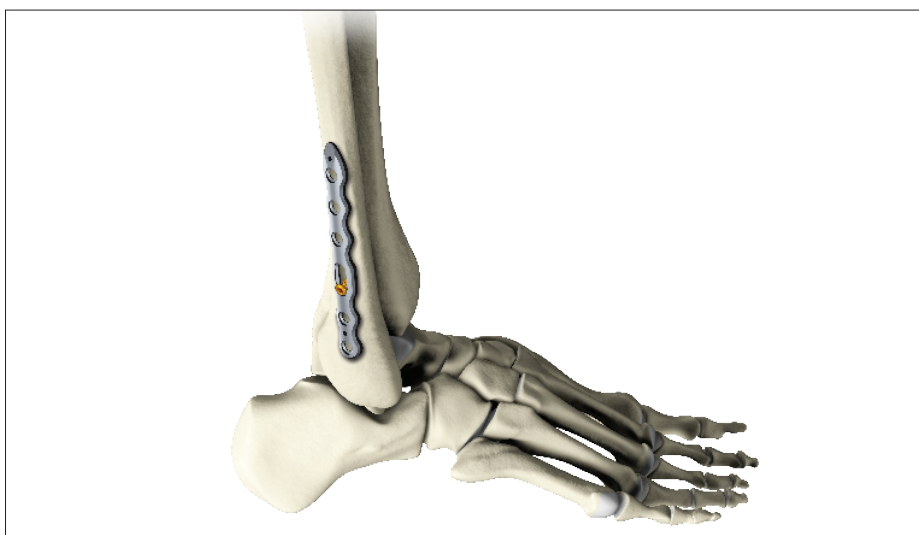
Having achieved reduction, the plate is selected and applied to the direct lateral surface of the distal fibula. The position should be adjusted to optimize fit and to allow for optimal screw fixation as per the fracture pattern and the pre-operative plan. Fluoroscopy can be utilized as needed to confirm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



Posterior Lateral Plate Placement

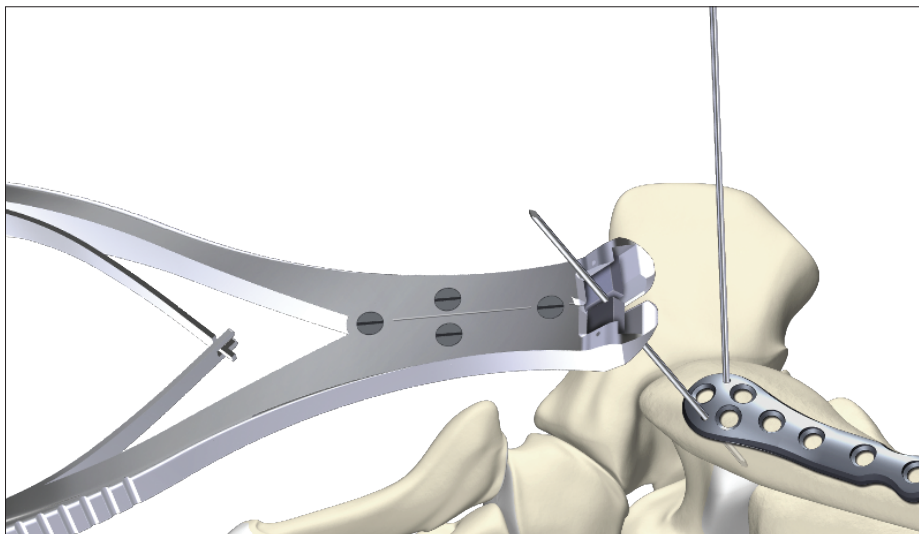
The VariAx straight fibula plate and the VariAx 2 one third tubular plate may be applied laterally (as described) or posterior laterally, as an antiglide plate to resist proximal migration and rotation of the distal fragment.

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 (REF 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 (REF 703882) will not engage into the plate (it will sit on top of the hole).

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

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 (Drill Guide T10 - 2.7mm REF 703883 or T10 - 3.5mm REF 703882) must be used in all VariAx Distal Fibula Plate holes. Use the end of the drill guide indicated with Orange / Turquoise Blue color-coded lines to pre-drill for VariAx Distal Fibula plating procedures.

Note:

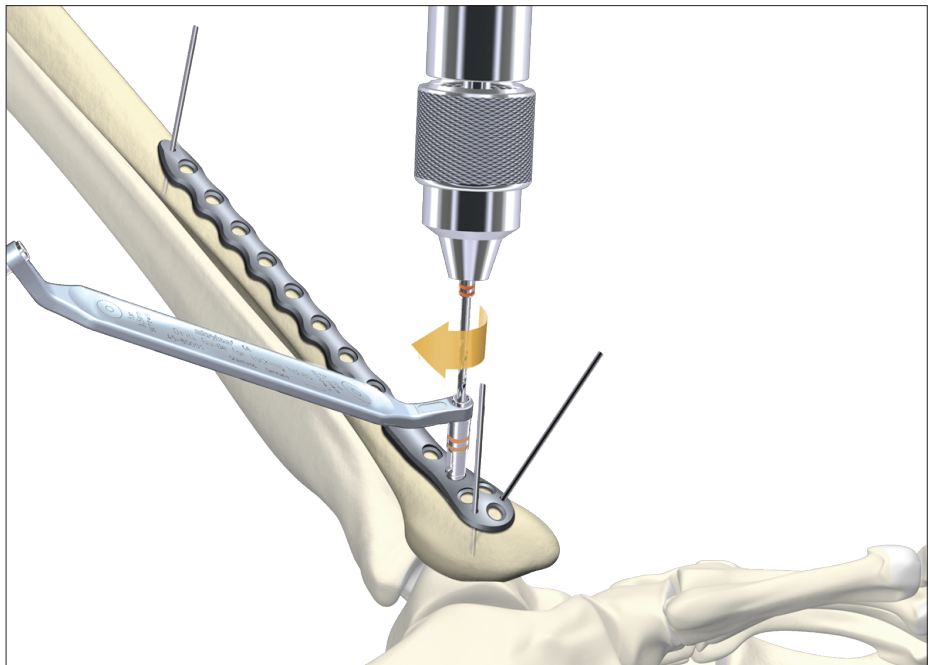
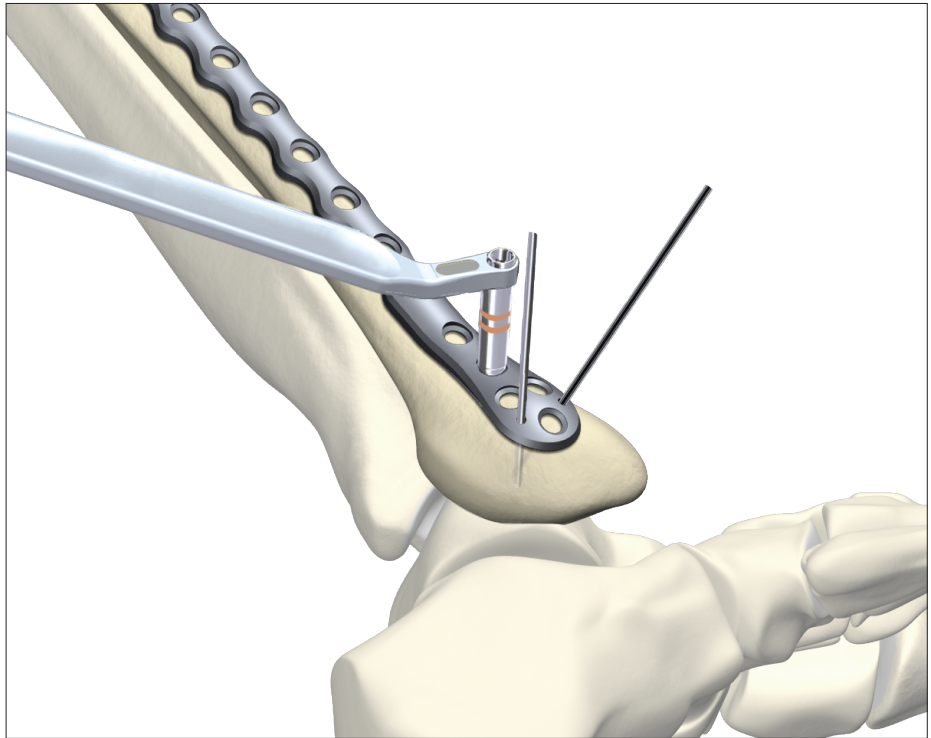
When using the VariAx 2 Screws and instrumentation the system is only compatible with T10 3.5mm and T10 2.7mm screws.

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 should be avoided.

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

- 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.

Use the drill to create a pilot hole through the drill guide. The 2.6mm Twist Drill (REF 703691) is color-coded orange to match the color associated with the 3.5mm drill guide (double orange).

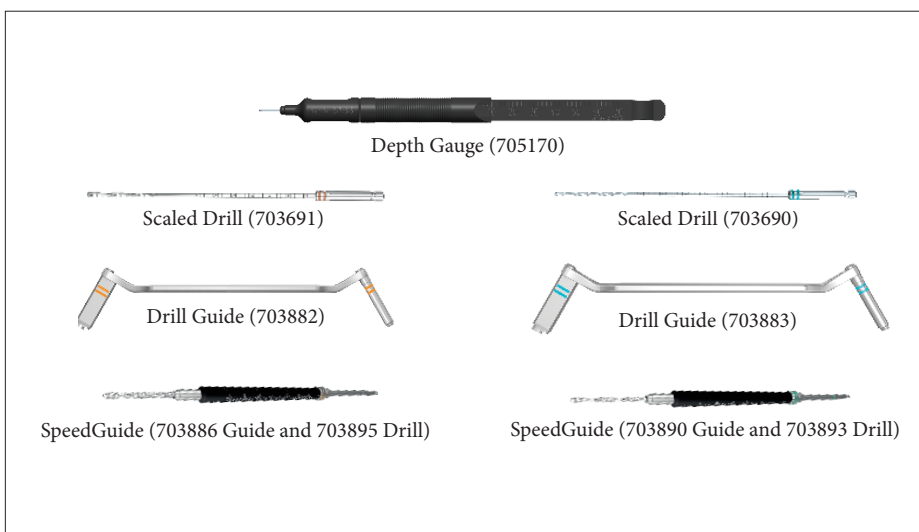
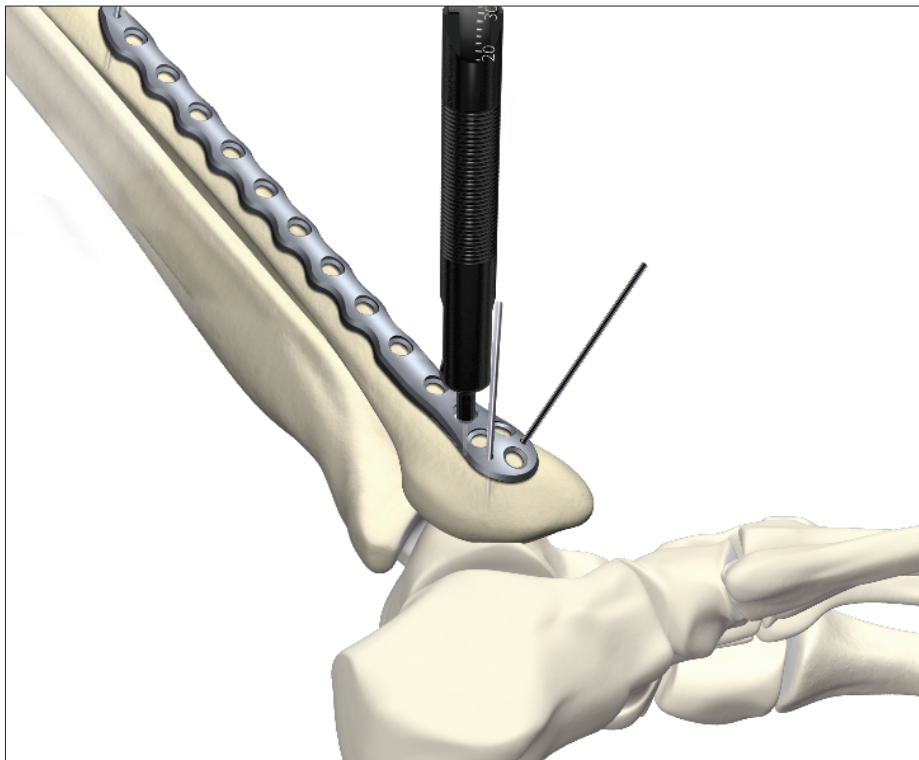


Although the locking and non-locking screws found in the VariAx 2 system are self-tapping, when encountering hard bone a tap may be required (REF 703898 or REF 703899).

Operative Technique

Measure the depth of the pre-drilled hole using the Depth Gauge (REF 705170). 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.



Depth Measurement Options for 2.7mm and 3.5mm screws

Operative Technique

VariAx 2 Instrumentation Usage

Color Coding System

Color coding of the screws and appropriate instruments helps identify the components during surgery as the color identifies the screw diameter.

All instruments having the Orange color code are used with the 3.5mm screws, and all of the Turquoise Blue colored instruments are used with the 2.7mm screws. Additionally, all drills are laser marked with the corresponding drill diameter.

Note:

Always match the color ring marking on the drill bit with the color marking on the drill guide. Additionally, always match the screw anodization color with at least one of the color ring markings.

The VariAx 2 System has a variety of different blades to choose from. The self-retaining blade is identified with a  symbol and has the word "RETAINING" on the AO coupling interface. Its conical tip helps ensure a friction fit connection with the screw head.

Note:

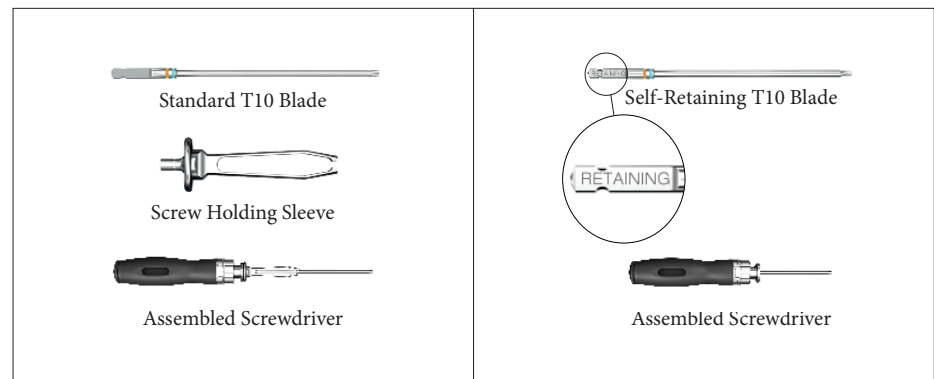
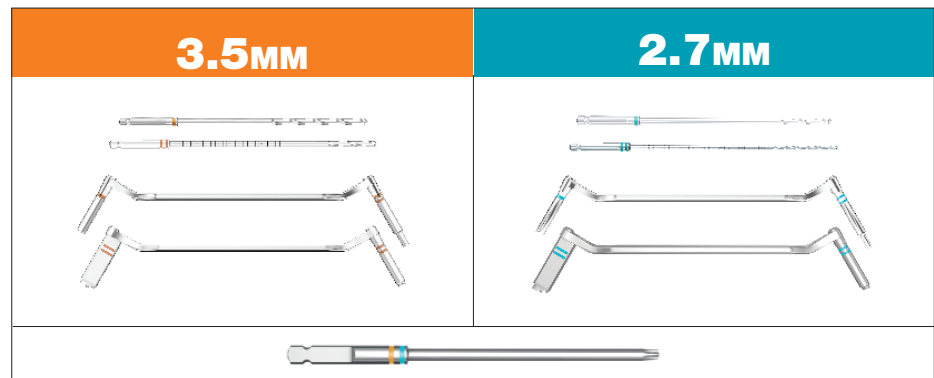
The self-retaining blade cannot be used with the screw holding sleeve.

Modular Handle

VariAx 2 offers a modular handle system. This is composed of two handle grip sizes (medium and large) that can be interchanged with either a bi-directional ratcheting AO-Coupling insert or a standard AO-Coupling insert. Both handle sizes are equipped with a spin-cap to allow insertion using a two-finger technique. In order to disengage the insert from the handle, push down on the button on the distal part of the handle and pull the insert away from the handle.

Note:

The inserts must be removed



from the handles before cleaning.

The ratcheting insert can work in three modes: clockwise ratcheting, counterclockwise ratcheting or neutral. To switch between the different modes,

simply twist the distal part of the insert to the desired driving direction.

Note:

To ensure appropriate ratcheting function, perform appropriate maintenance on the insert by applying medical-grade lubricant oil through the marked cut-outs.

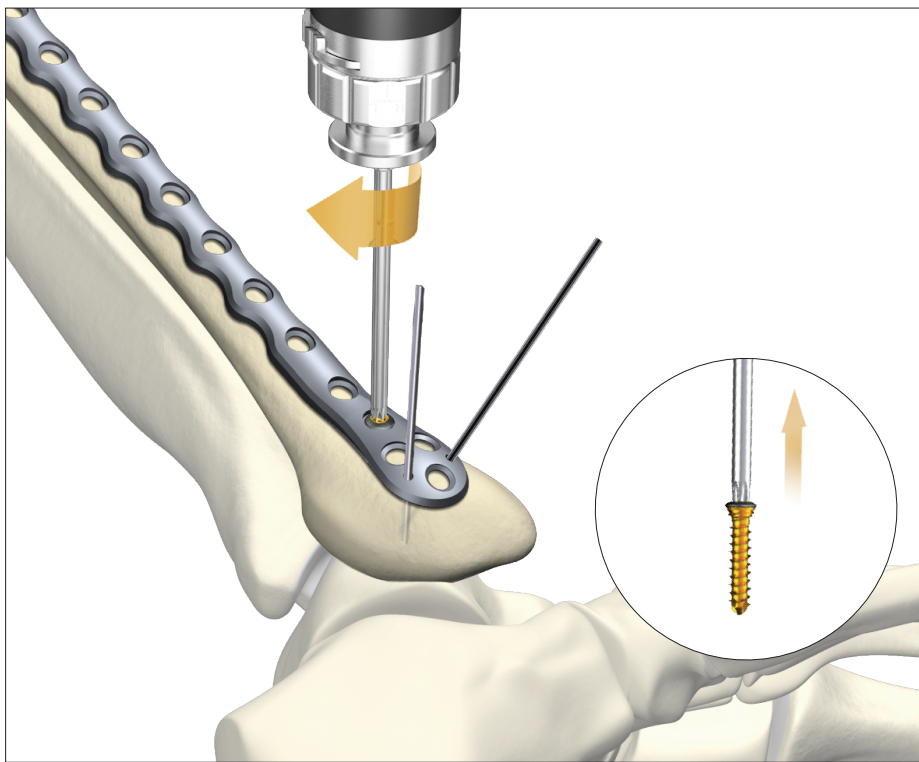
Operative Technique

Screw Insertion

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

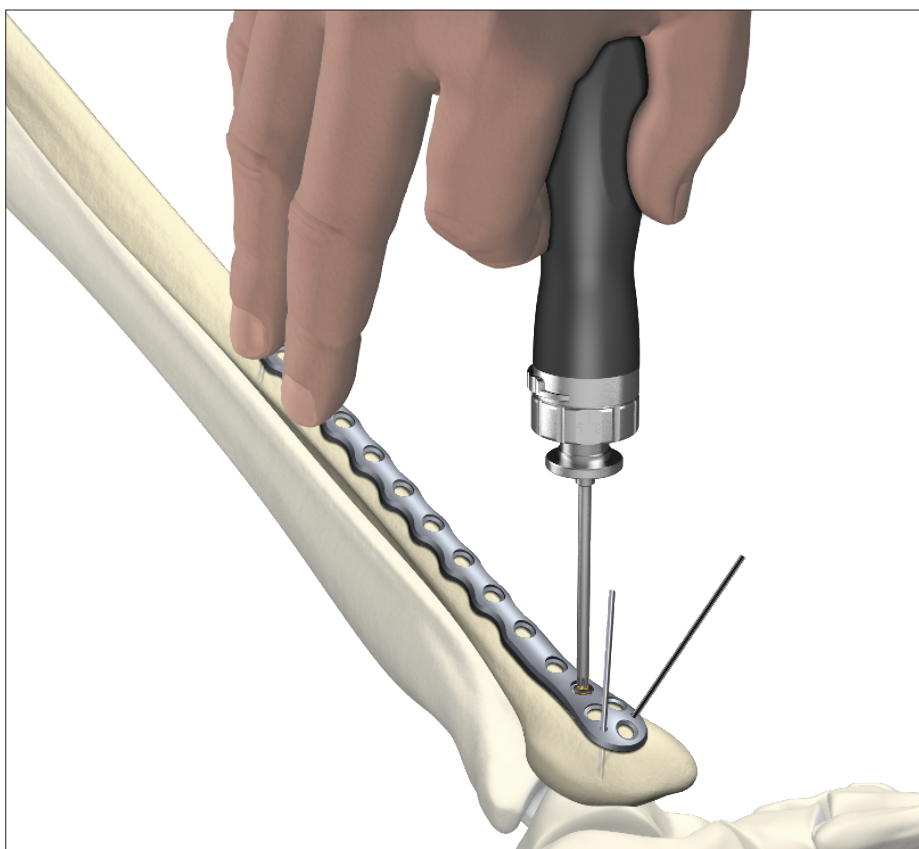
As the screw head approaches the plate, draw the holding sleeve back from the screw head, and continue with final tightening then remove the screwdriver from the screw.

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



Operative Technique

Optional: Independent Lag Screw Technique

A 3.5mm VariAx 2 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 2 instrumentation system includes a Drill Guide for a 3.5mm Independent Lag Screw (REF 703686), 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.**

- Note:**
- 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.

Drill & Drill Guides		
Drill Diameter	Drill Bit	Drill Guide
Overdrill 2.7mm	703695	703687
Overdrill 3.5mm	703694	703686



Scaled Drill and Drill Guide

Optional: Instruments

SpeedGuides up to 30mm		
Drill Diameter	Drill Bit	SpeedGuide
2.0	703892	703887
2.6	703894	703886



SpeedGuides



Tap for 3.5mm 2.7mm Screws



Countersink

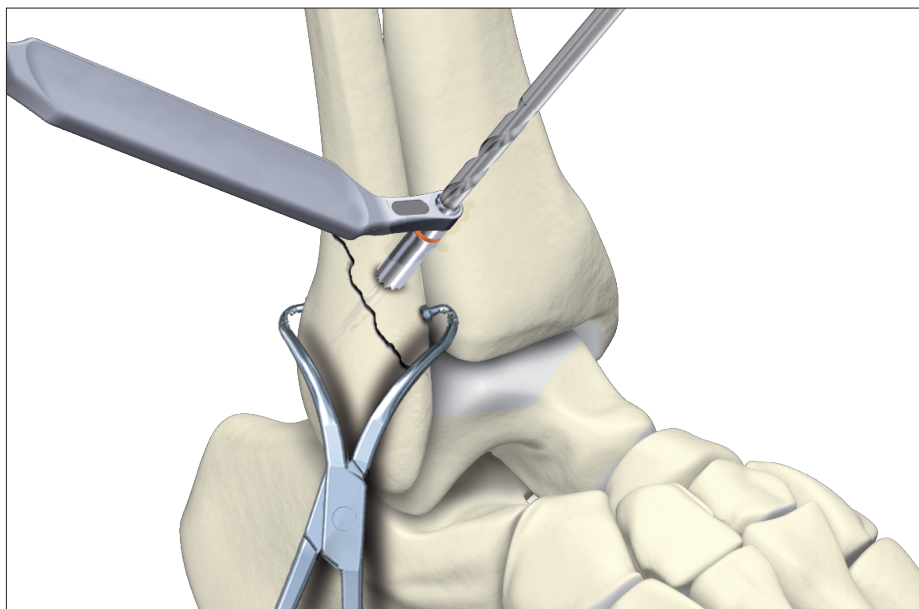
Operative Technique

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 (REF 703686). This drill guide has two sides/sleeves. Identify the side by a single orange band.
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 Single Orange line (REF 703694).
For 2.7mm screws, use the overdrill that is color coded with a turquoise blue line (REF 703695).
4. The orange color-coded drill bit is then inserted through the orange 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.

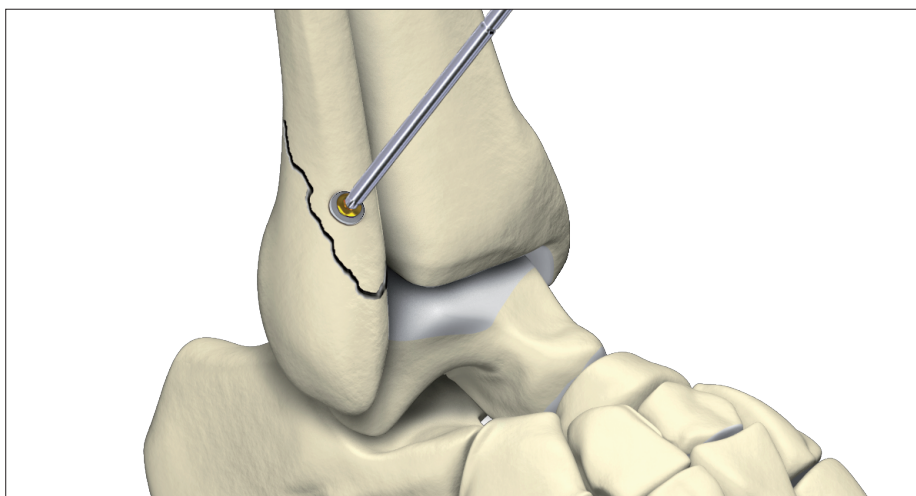
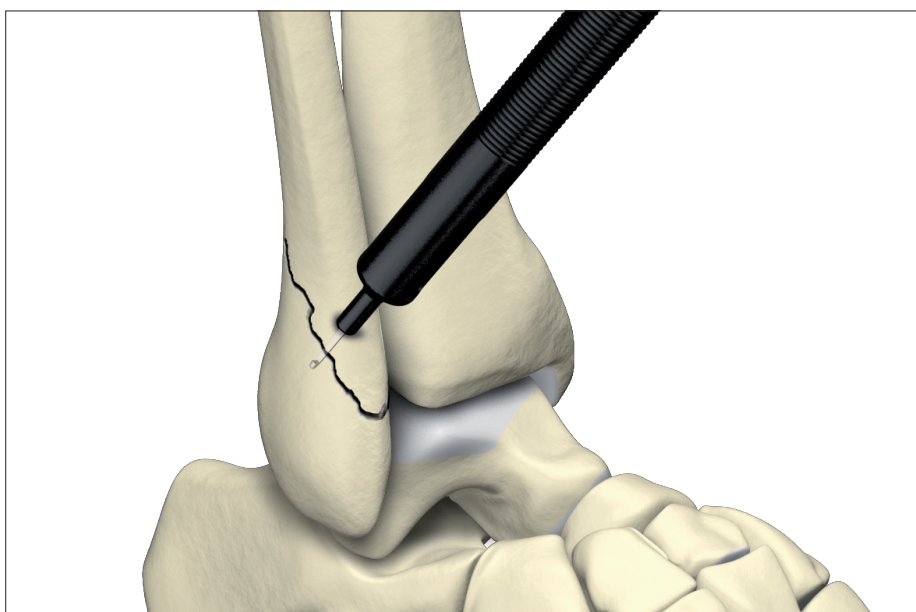
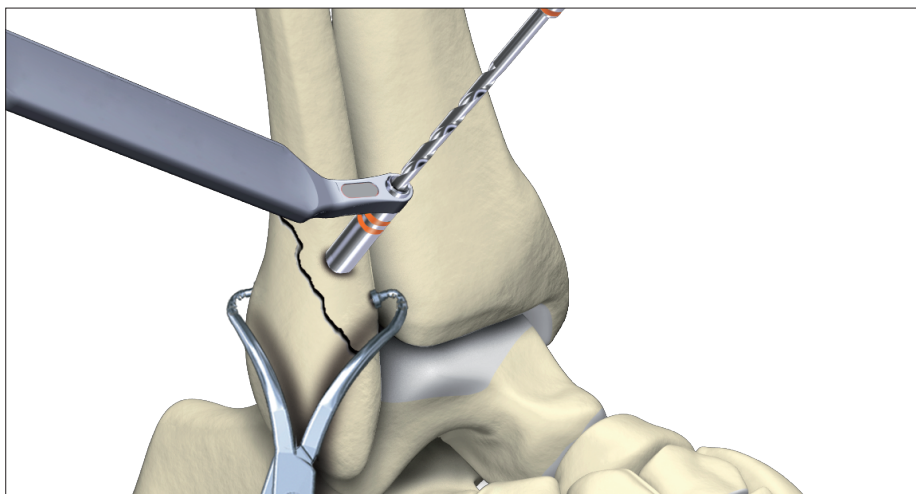
Note:

Always match the color ring marking on the drill bit with the color marking on the drill guide. Additionally, always match the screw anodization color with at least one of the color ring markings.



Operative Technique

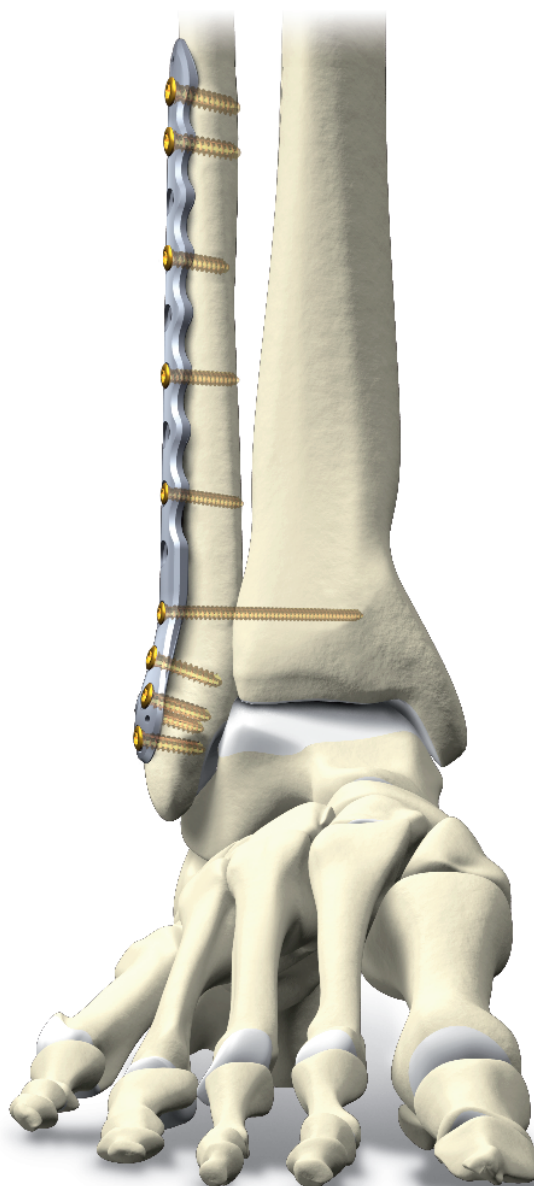
5. The other side of the drill guide, which is orange color-coded, is then fully inserted into the newly created gliding hole. This drill guide must be inserted as deep as possible into the overdrilled hole. Drilling is performed using the orange color-coded 2.6mm drill (REF 703691), into the far fragment. 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 (REF 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 (REF 705170).
8. The screw can then be inserted. A washer (REF 619920) 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.



Operative Technique

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. Fixation is 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 orange 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 T10 3.5mm or T10 2.7mm non-locking screws can be used to achieve syndesmotic fixation based on patient factors, injury factors, and surgeon preference.



Notes



Reconstructive

Hips
Knees
Trauma & Extremities
Foot & Ankle
Joint Preservation
Orthobiologics & Biosurgery

MedSurg

Power Tools & Surgical Accessories
Computer Assisted Surgery
Endoscopic Surgical Solutions
Integrated Communications
Beds, Stretchers & EMS
Reprocessing & Remanufacturing

Neurotechnology & Spine

Craniomaxillofacial
Interventional Spine
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Spinal Implants

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Manufacturer:

Stryker GmbH
Bohnackerweg 1
2545 Selzach
Switzerland

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