

VariAx 2[®]

Plating Solutions

Operative technique

VariAx 2 Foot System
Stryker Foot Plating System



VariAx 2

Plating Solutions

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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

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.

WARNING

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

Indications and contraindications

Indications for VariAx 2 Foot System

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.

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.

Indications for Stryker Foot Plating System

The Stryker 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.



MRI safety information:

Non-clinical testing has demonstrated the VariAx 2 Foot System is MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T.
- Maximum spatial field gradient of 3000 gauss/cm (30 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operation Mode).

Under the scan conditions defined above, the VariAx 2 Foot System construct is expected to produce a maximum temperature rise of less than 7°C after 15 minutes of continuous scanning at 3T.

In non-clinical testing, the image artifact caused by the device extends approximately 28mm from the VariAx 2 System construct when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.

CAUTION

The MRI safety information provided is based on testing which did not include supplementary devices. If there are supplementary devices (i.e. plates, screws, wires, etc) present in proximity to the System / Construct, this could result in additional MRI effects and the information provided above may not apply.

The safety of Stryker VariAx Foot Plating System in the MR environment is unknown, refer to the Operative Technique VariAx Foot Plating System.

VariAx 2 Foot system

Tray layout

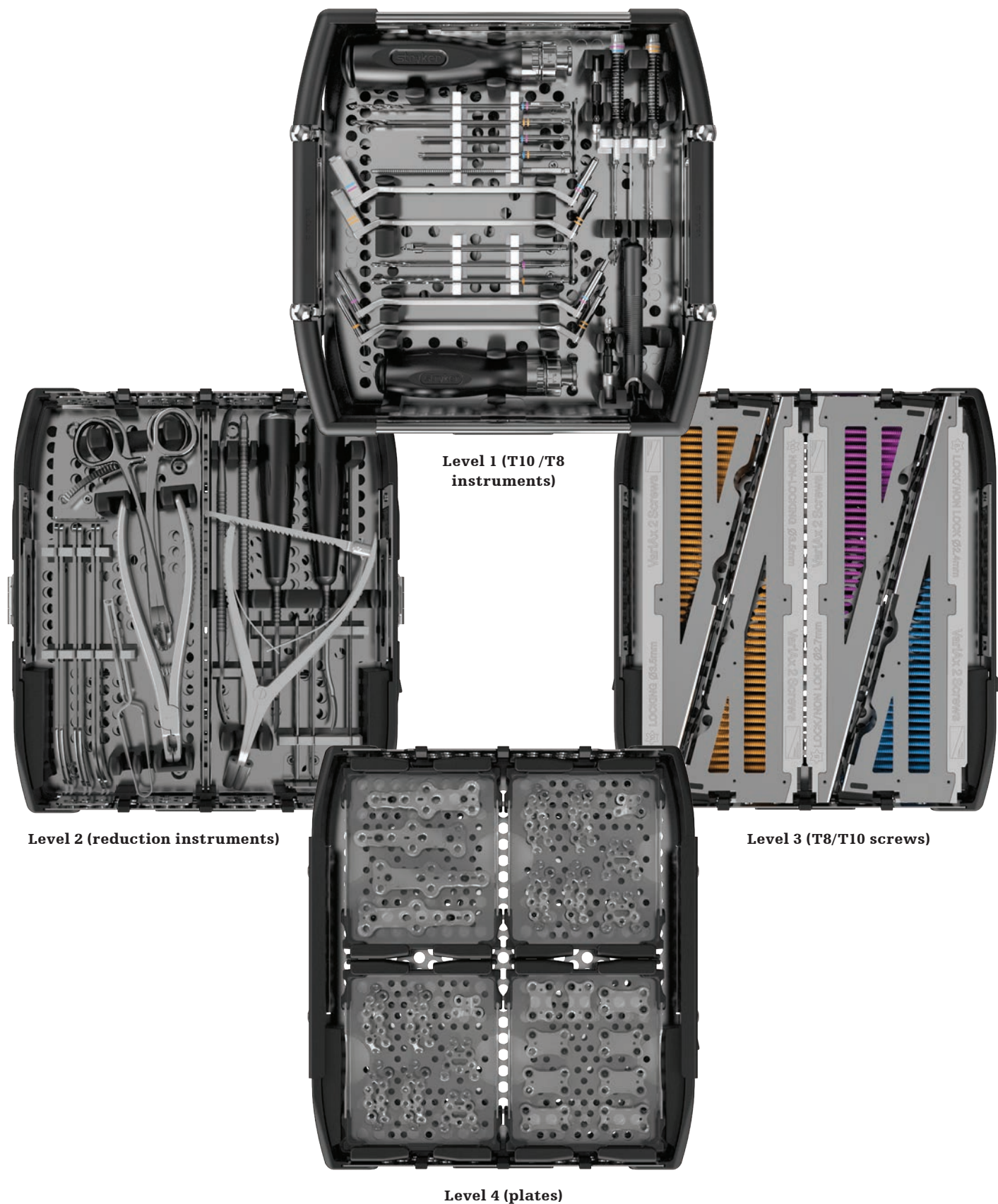
Modular system design

The trays for the Foot & Ankle Plating solutions utilize interchangeable modules to allow you to customize the contents of your tray. Select the appropriate interchangeable modules to build in extra inventory of frequently used parts or to integrate other components of Stryker's Foot and Ankle portfolio.



The trays are designed with swing-clip locks, which allows to exchange the lower 2-level trays.

Tray contents



Instrumentation

Plate positioning instrumentation

The joystick for T10 holes can be used in any large VariAx circular hole and the joystick for T8 holes can be used in any small VariAx circular hole to aid in plate positioning. Additionally, they can also be used to temporarily fix the plate to the bone by inserting a K-wire with a diameter up to 1.6mm through a joystick that is already engaged in the plate hole.

⚠ CAUTION

Do not insert a K-wire through a joystick on the compression side of the fracture if compression is needed.

After inserting the joystick tip in the circular hole, turn the knob on the upper part of the joystick clockwise to fix it in the hole. To remove the joystick, simply remove any K-wire and turn the knob counter-clockwise to disengage the tip from the hole.

⚠ WARNING

Do not use the engaged joystick to apply bending to the plate as this may damage the plate or joystick.

Joint distraction forceps

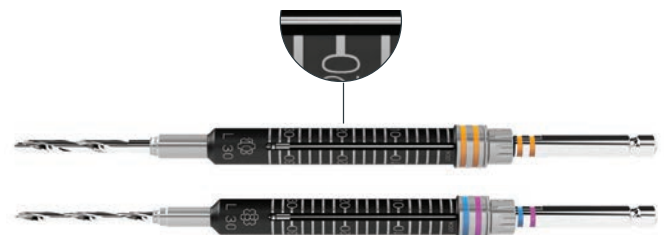
Use the joint distraction forceps with ratcheting function to achieve and hold a reduction.

Depth measurement options

The drills are scaled to allow for estimating correct screw length.

A SpeedGuide allows the surgeon to drill and measure the hole depth in one step with a single instrument. For further information on the SpeedGuide, please refer to the SpeedGuide Operative Technique.

A standard depth gauge can be used either independently or through a plate hole.



SpeedGuides



Depth gauge

Taps and countersink

A countersink is available for reducing the screw head prominence when the screw is used independently of a plate.

Screws are all self-tapping. Taps are available in 2.4, 2.7 and 3.5mm.

CAUTION

If excessive resistance is felt during screw insertion or if the bone is dense it is recommended to use a tap.



Countersink



Tap for 2.7mm screws



Tap for 3.5mm screws

Modular self-ratcheting and fixed handles

Handles are self-ratcheting or fixed and come in both medium and large sizes.

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.

CAUTION

The inserts must be removed from the handles before cleaning.

The ratcheting insert can work in three modes: clockwise ratcheting, counter-clockwise ratcheting or neutral. To switch between the different modes, simply twist the distal part of the insert to the desired driving direction.

NOTICE

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



Large handle



Medium handle



Ratcheting insert

Instrumentation

Drill bits and guides

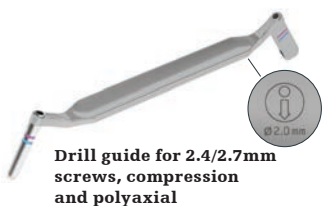
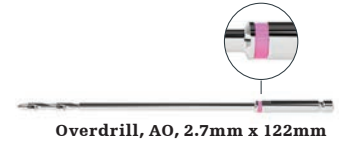
Screw color coding	Screw diameters	Drill guides	Interface	Drill bits diameter	Overdrill diameter
Blue and purple ● ●	2.4mm & 2.7mm	2.0mm	T8	2.0mm	2.7mm
Turquoise ●	2.7mm	2.0mm	T10	2.0mm	2.7mm
Orange ●	3.5mm	2.6mm	T10	2.6mm	3.5mm

CAUTION

Always use the correct Drill Guide for drilling.

WARNING

- 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 instrument markings.
- The drill guides facilitate drilling of pilot hole for either a non-locking or locking screw. Additionally, the opposite side of the guide facilitates fixed angle drilling for use in a compression hole when compression is desired.



CAUTION

Ensure to insert drill guide for compression screw perpendicularly to the plate.

Please make sure the arrow marked on the compression side of the drill guide is pointing toward the fracture line/ osteotomy site. When angulating the compression drill guide, there is a risk that the screw will not properly sit in the plate or slip through the compression hole.

Overdrills and drill guides for interfragmentary lagging technique are available for all screw sizes. The drill bits, lagging drill guides and screws are also color coded.

Implants

VariAx 2 screw platform

Locking

Non-locking

2.4mm screws
T8 interface

Locking

Non-locking

2.7mm screws
T8 interface

Locking

Non-locking

3.5mm screws
T10 interface

Locking

Non-locking

2.7mm screws
T10 interface

These 2.7mm T10 screws are optional. They are not included in the standard set.

Screwdriver blade

Screwdriver blade

Color coding

The VariAx 2 screws and instruments follow a standardized color-coding scheme whereby the screw color matches the corresponding instrument's color.

The drill bits, lagging drill guides and screws are also color coded.

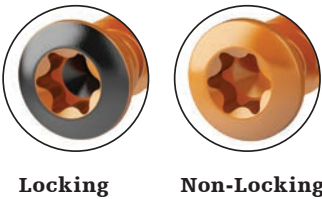
Screw type		Lengths	Plate hole size
2.4mm screws	●	8-38mm	
2.7mm screws	●	8-50mm	
2.7mm screws	●	8-70mm	
3.5mm screws	●	8-70mm	

Locking and non-locking screws

Locking and non-locking screws are available in 2.4mm, 2.7mm and 3.5mm diameters. All holes in the locking plates provide an option for locking and non-locking screws. If a locking screw is used in a compression hole, the screw can apply compression and then lock into the plate.

NOTICE

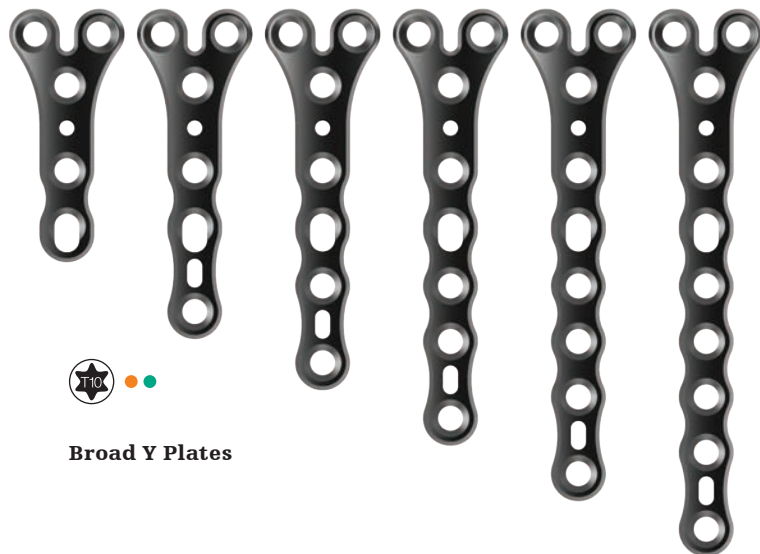
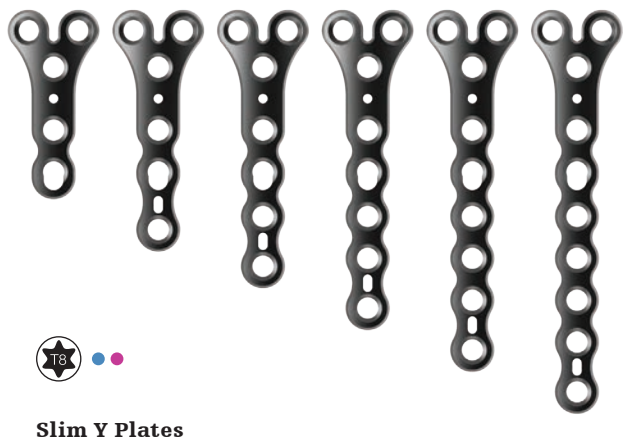
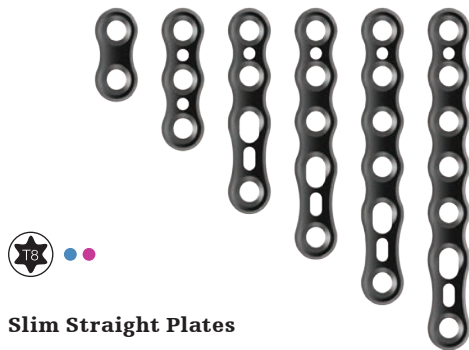
Locking screws are laser marked with a 'dot' and 'ring' marking on the screw head to differentiate them from non-locking screws.



Implants

VariAx 2 Foot

The Slim Straight, Broad Straight, Slim Y, and Broad Y plates shown below are indicated for foot, ankle, hand, and wrist.



VariAx 2 Foot

These plates depicted below are **only** indicated for foot and ankle.



Talar Neck Plate



Navicular Plate



Cuboid Plate



NCM (Medial Column Fusion) Plate



LCL (Lateral column lengthening) Plate



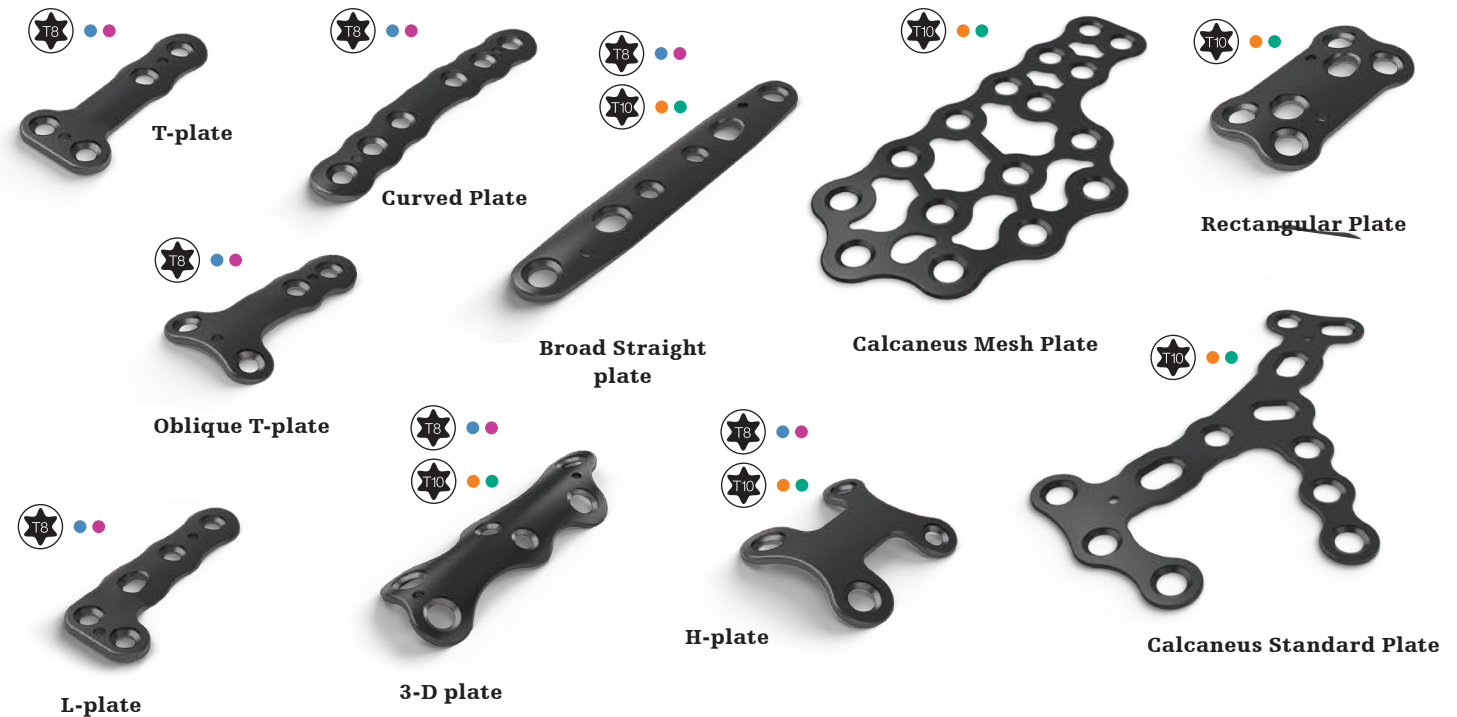
TN (Talo-navicular) plate



NC (Navicular-cuneiform) plate

Stryker Foot Plating System

These plates depicted below are **only** indicated for foot and ankle.



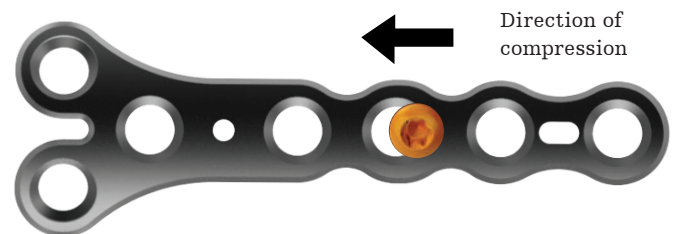
CAUTION

The Stryker Foot Plating System Calcaneus Standard Plate oblong holes (see figure to right) are intended to be used for positioning of plate only. Applying high torque during final tightening of screw in oblong holes may create potential for T10 screws to not sit properly or slip through the hole.



Compression holes

Allow for active compression of different bone segments along the axis of an oblong hole. Place screw on the narrower component of the oblong hole such that the screw may glide from initial positioning to final locking position when tightened.



Operative technique

NC (navicular-cuneiform) fusion-surgical technique

Exposure and reduction

The incision can be extended distally for access to the cuneiforms, first metatarsal base and naviculocuneiform and intertarsal joints.

Preparation of joint

Remove cartilage in the NC joint. If there is significant damage to tissue in the joints between the navicular and cuneiform, the remaining cartilage is removed. If the foot is misaligned, the bones need to be positioned correctly using a K-wire.



⚠ CAUTION

A drill guide must first be placed into a corresponding screw hole in the plate prior to pre-drilling a pilot hole.

Preparation for screw insertion

The plates shown in this surgical technique allow for compression in a single direction, so the drill guide must be positioned such that the drill hole will be created on the side of the oval compression hole opposite the locking lip.

The drill guide for oval compression holes must be placed at a 90° angle to the plate, and cannot be angulated.



⚠ CAUTION

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. The sleeve of the depth gauge must be fully inserted into the respective plate hole prior to measuring.

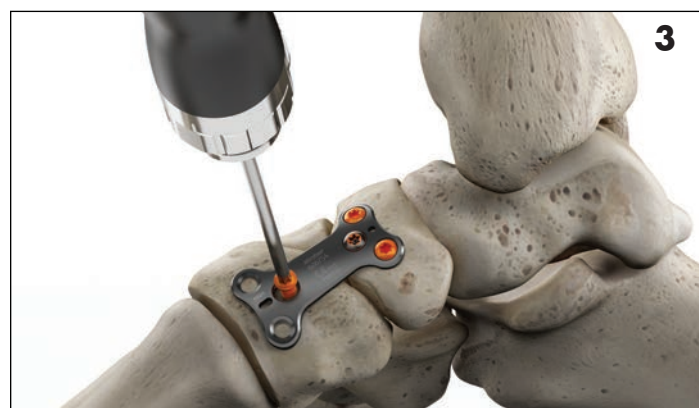
⚠ CAUTION

Compression drill guides must always fit securely within a compression hole. Using the wrong size or type of drill guide or angulating a compression drill guide could cause the screw head to pull through the hole.

Screw insertion

Insert the screw into the pre-drilled hole using the screwdriver* assembly. Final tightening is not recommended until all desired screws have been provisionally inserted into a plate.

*VariAx 2 offers two screwdriver handle grip sizes (medium and large).



⚠ CAUTION

Fluoroscopy is required to ensure correct length and angulation.

1st Metatarsal fracture procedure

Exposure and reduction

The first metatarsal is exposed through an incision. Carry dissection down to expose the fracture site while protecting soft tissue.

Reduce metatarsal fractures and provisionally stabilize with clamps and/or K-wires.

Plate application

Apply the T10 Broad Straight Plate to the metatarsal shaft at the fracture site and secure with a K-wire or olive K-wire. For additional temporary fixation - Insert a K-wire for provisional fixation in an oblong hole of the plate to allow for maximum compression.

⚠ CAUTION

Insert K-wire at end of oblong K-wire hole identified by a white laser marking, to allow for compression without removal of K-wire.

Place the T10 drill guide into the most proximal hole and drill using the 2.6mm drill through the bone cortices, depending on injury pattern. Use the depth gauge to determine screw length. Choose the appropriate screw and insert into the bone.



Compression

Plates that allow for compression only go in a single direction. Position the compression drill guide so it fits securely within the oblong screw hole. Please note that a mismatch between the drill guide and the plate hole indicates that the wrong dimension drill guide has been chosen. The drill must be placed at a 90° angle to the plate, and cannot be angulated.

⚠ CAUTION

A drill guide must first be placed into a corresponding screw hole in the plate prior to pre-drilling a pilot hole.

The compression drill guide must be positioned such that the drill hole will be created on the side of the oval compression hole opposite the locking lip.

Once compression drill guide is seated correctly within oblong hole, drill into metatarsal and verify length using the depth gauge.

Insert and fully seat the appropriately sized T10 non-locking or locking screw using the self retaining screw drive blade.

Final fixation

Place T10 drill guide into desired screw location and drill through both cortices of the metatarsal. Measure and insert remaining screws.

Close the treatment site using standard closure techniques

⚠ CAUTION

Fluoroscopy is required to ensure correct length and angulation.



⚠ CAUTION

Compression drill guides must always fit securely within a compression hole. Using the wrong size or type of drill guide or angulating a compression drill guide could cause the screw head to pull through the hole.



5th Metatarsal fracture procedure

Exposure and reduction

Expose the tuberosity of the fifth metatarsal. Manually reduce the fracture and stabilize the fracture with K-wires or forceps.

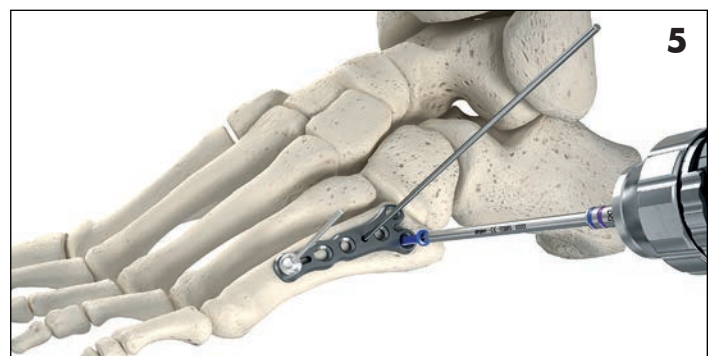
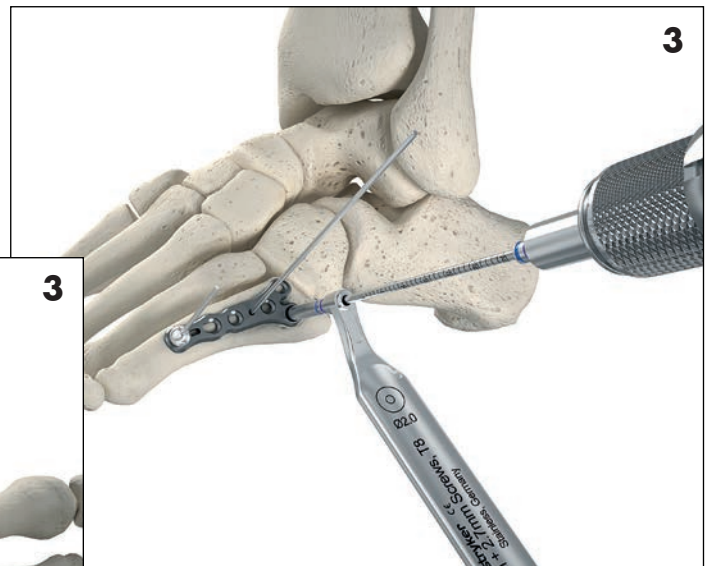
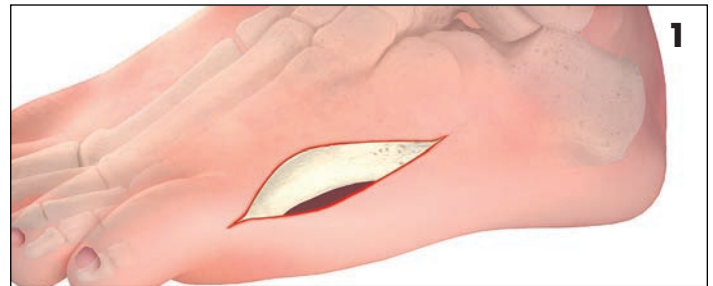
Plate application

Position the selected plate implant on the tuberosity.

Insert a K-wire through circular K-wire hole. For additional temporary fixation, an olive K-wire may be applied within screw holes.

Please note the use of olive and straight K-wires can be chosen according to surgeon preference.

Select the T8 drill guide and 2.0mm drill at the most proximal hole of the plate. Insert the depth gauge until it passes through bi-cortical. Retract the stem until the lip catches against the bone to determine proper measurement. Select a VariAx 2 T8 2.4 or 2.7mm screw of appropriate length and verify length with the VariAx 2 screw rack lid.



Compression

Plates that allow for compression only go in a single direction. Position the compression drill guide so it fits securely within the oblong screw hole. Please note that a mismatch between the drill guide and the plate hole indicates that the wrong dimension drill guide has been chosen. The drill must be placed at a 90° angle to the plate, and cannot be angulated.

⚠ CAUTION

A drill guide must first be placed into a corresponding screw hole in the plate prior to pre-drilling a pilot hole.

The compression drill guide must be positioned such that the drill hole will be created on the side of the oval compression hole opposite the locking lip.

Once compression drill guide is seated correctly within oblong hole, drill into metatarsal and verify length using the depth gauge.

Insert and fully seat the appropriately sized T8 non-locking or locking screw using the self retaining screw drive blade.

Final fixation

Insert any additional distal screws as needed.

Close the treatment site using standard closure techniques.

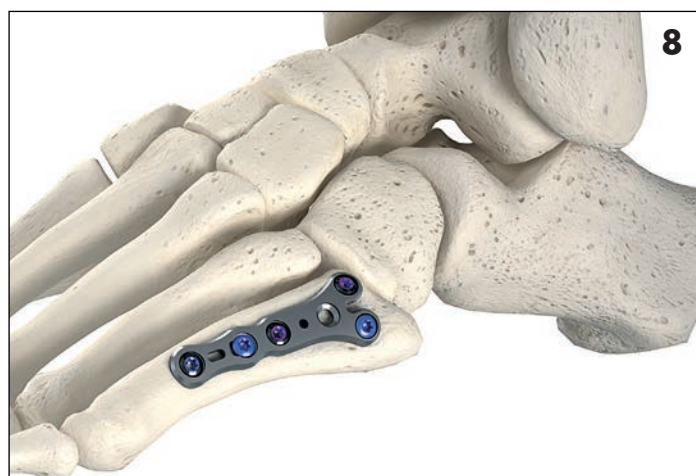
⚠ CAUTION

Fluoroscopy is required to ensure correct length and angulation.



⚠ CAUTION

Compression drill guides must always fit securely within a compression hole. Using the wrong size or type of drill guide or angulating a compression drill guide could cause the screw head to pull through the hole.



Lesser tarsometatarsal fusion/fracture procedures

Exposure and reduction

Make a 2-4cm longitudinal incision to expose the mid-foot. Manually reduce the fusion or fracture and stabilize with K-wires or forceps.

Center the selected plate on the affected bone.

CAUTION

Insert K-wire at end of oblong K-wire hole, identified by a white laser marking, to allow for compression without removal of K-wire.

Plate bending

Additional contouring of all 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 only bend the plate in between holes.



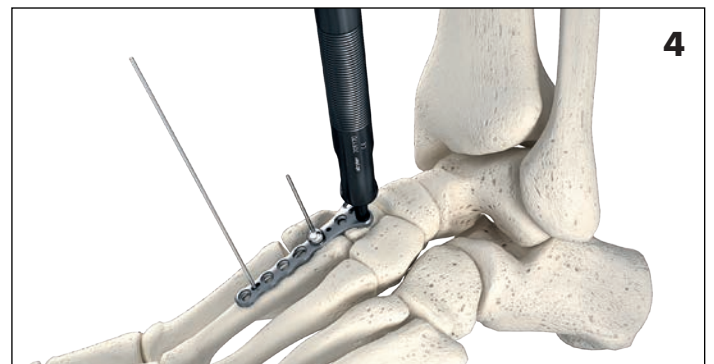
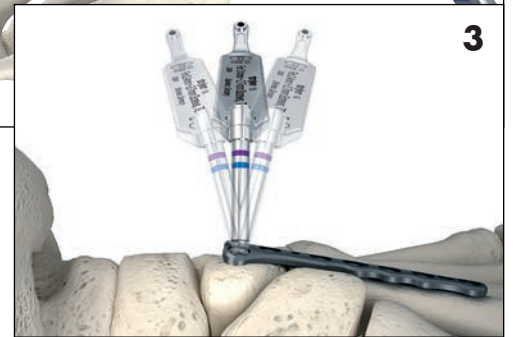
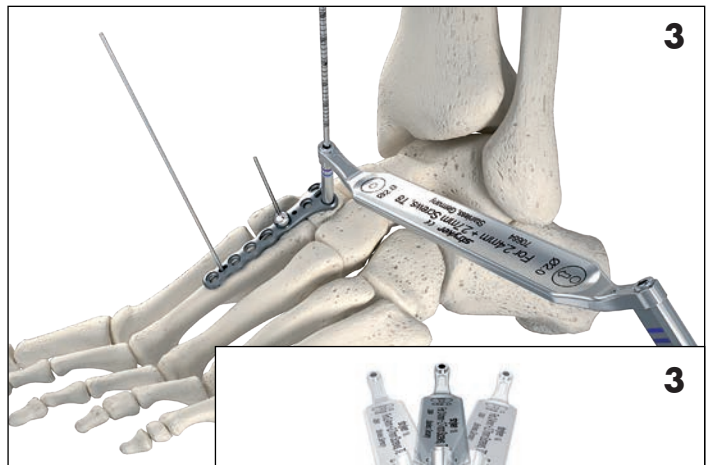
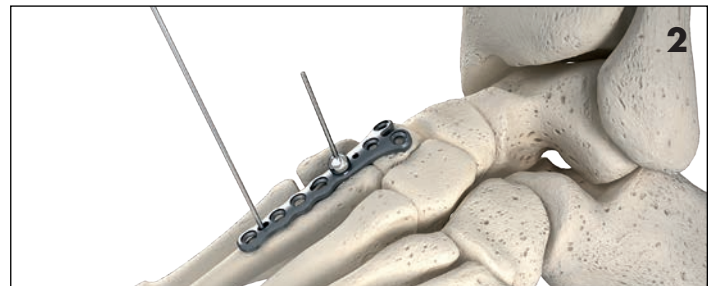
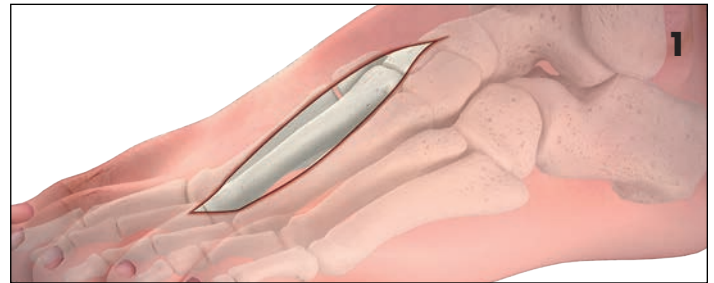
WARNING

- 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).
- The plate bending pliers are designed to be used only in circular holes.
- If the oblong compression holes are deformed, there may be potential for a screw to pass through the hole upon insertion.
- Always attach the bending pliers to two adjacent holes to prevent deformation of the screw holes.

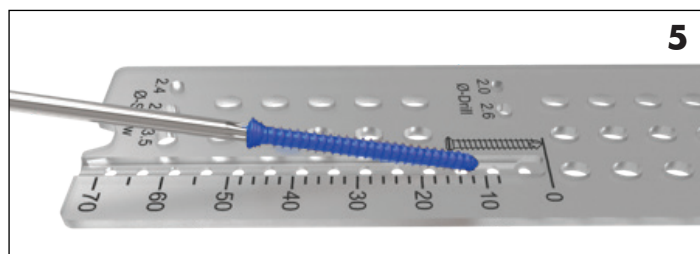
Use the T8 drill guide and 2.0mm drill at the most proximal screw holes. Insert the depth gauge until it passes through bi-cortical. Retract the stem until the lip catches against the bone to determine proper measurement.

Plate application

Insert K-wires through plate for provisional fixation.



Select the VariAx 2 T8 2.4/2.7mm screw of appropriate length and verify length after pick-up from screw rack with the VariAx 2 screw rack lid.



Compression

Plates that allow for compression only go in a single direction. Position the compression drill guide so it fits securely within the oblong screw hole. Please note that a mismatch between the drill guide and the plate hole indicates that the wrong dimension drill guide has been chosen. The drill must be placed at a 90° angle to the plate, and cannot be angulated.

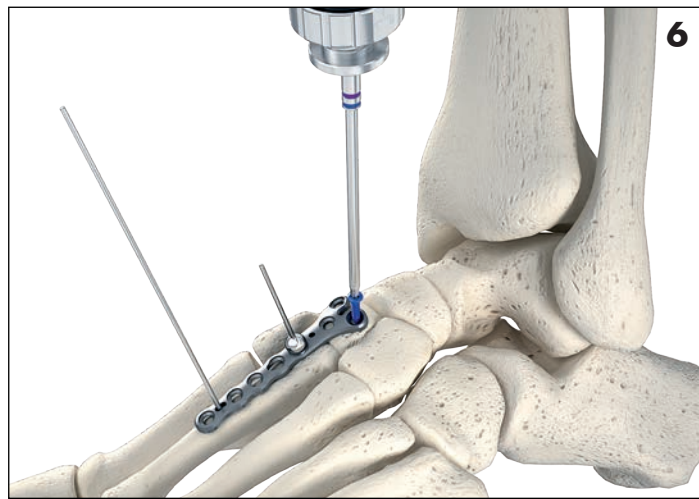
⚠ CAUTION

A drill guide must first be placed into a corresponding screw hole in the plate prior to pre-drilling a pilot hole.

The compression drill guide must be positioned such that the drill hole will be created on the side of the oval compression hole opposite the locking lip.

Once the compression drill guide is seated correctly within oblong hole, drill into metatarsal and verify length using the depth gauge.

Insert and fully seat the appropriately sized T8 non-locking or locking screw using the self retaining screw driver blade.



Final fixation

Insert any additional distal screws as needed.

Close the treatment site using standard closure techniques.

⚠ CAUTION

Fluoroscopy is required to ensure correct length and angulation.



Lateral column lengthening - surgical technique

*The procedure described below is only to be used with the VariAx 2 Foot System.

Preparation for osteotomy

Start incision at the distal tip of the fibula and angle to the calcaneal-cuboid joint.

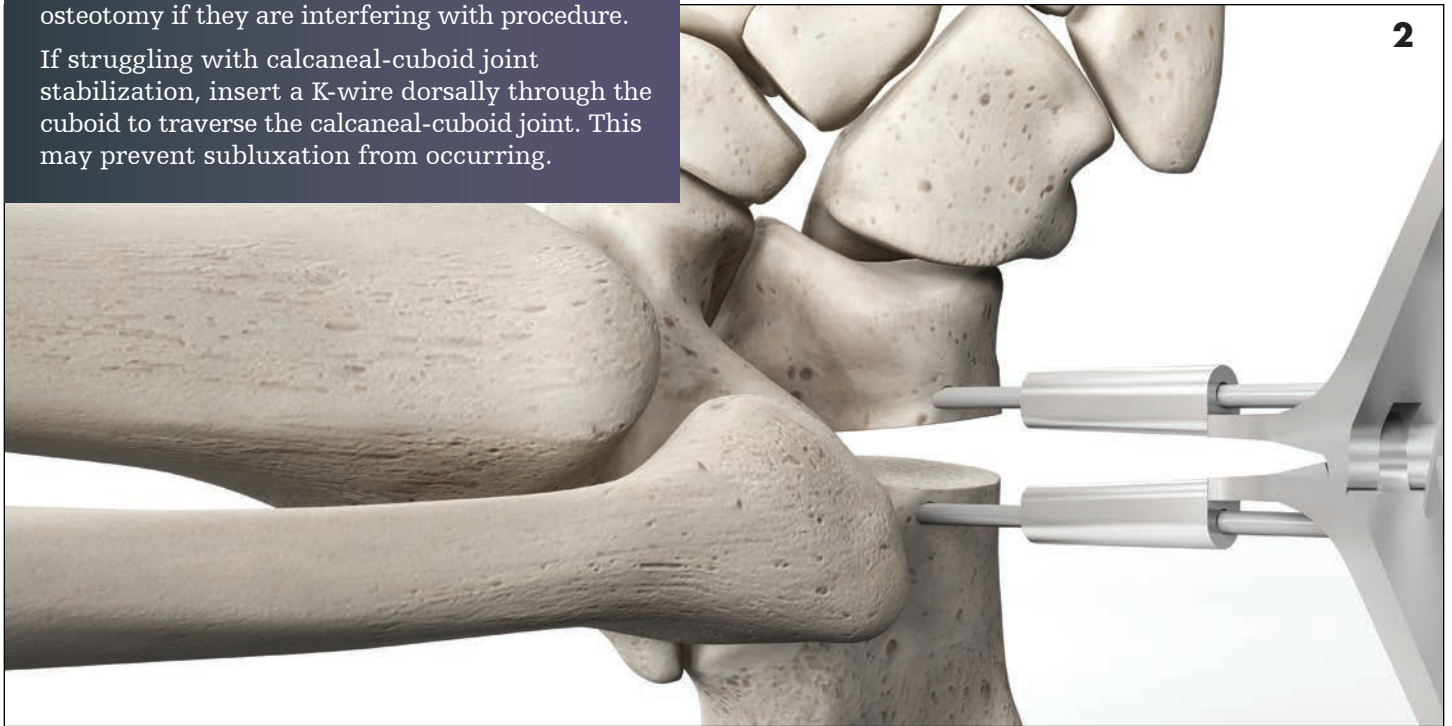
LCL plate placement

The osteotomy is made approximately 1-2cm (distance may vary based on surgeon preference) proximal, and parallel, to the calcaneal-cuboid joint.

Utilize the joint distraction forceps (product #45-80030) into the osteotomy site.



Dr. John G. Anderson and Dr. Donald R. Bohay
Spread joint distraction forceps away from osteotomy if they are interfering with procedure.
If struggling with calcaneal-cuboid joint stabilization, insert a K-wire dorsally through the cuboid to traverse the calcaneal-cuboid joint. This may prevent subluxation from occurring.

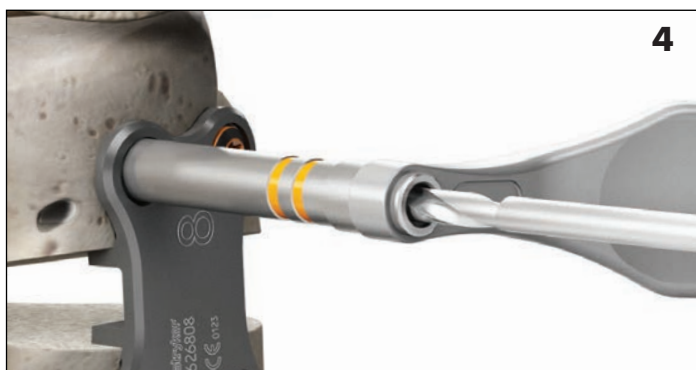


The wedge trial instrument comes in four sizes: 6mm, 8mm, 10mm and 12mm.

NOTICE

Care should be taken to match up the LCL plate size with the used Wedge Instrument that created the desired correction.





Screw placement

Once you have spread open the wedge, insert the 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 scaled drill bit for 3.5mm screws, distal side of plate first.

To determine screw size, insert the depth gauge to measure for precise screw size. Insert remaining screws and verify final positioning under fluoroscopy.

CAUTION

Fluoroscopy is required to ensure correct length and angulation.




Typical plating options

   All T8 plates accept locking and non-locking T8 screws



Navicular Plate

Navicular Fracture Plate - left
Navicular Fracture Plate - right

   All T10 plates accept locking and non-locking T10 screws



NCM (Medial Column Fusion) Plate

NCM Plate - short/left NCM-Plate - short/right
NCM Plate - long/left NCM-Plate - long/right



Cuboid Plate

Cuboid Plate



NC (Navicular-cuneiform) Plate

NC Plate - short/left NC Plate - short/right
NC Plate - long/left NC Plate - long/right



All T8 plates accept locking and non-locking T8 screws



Talar Neck Plate lateral
Talar Neck Plate



All T10 plates accept locking and non-locking T10 screws



TN (Talo-navicular) Plate
TN Plate - long
TN Plate - short



Slim Y-Plate
2 - 7 shaft holes
also available in Broad/T10 versions



Broad Straight Plate
2 - 7 holes
also available in Slim/T8 versions

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.

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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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