stryker

VariAx® 2
MIS Calcaneus

Operative technique

VariAx® 2
MIS Calcaneus

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

- All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1).
- Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.
- 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.

Please remember that the compatibility of different product systems have 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, 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.

Table of contents

Introduction

Stryker VariAx 2 MIS Calcaneus is indicated for fractures of the calcaneus. This operative technique contains a step-by-step procedure for the implantation of MIS calcaneal plates through a Minimally Invasive Surgical (MIS) procedure using the MIS instruments.

Plates and screws used in the MIS procedure are shown in this operative technique guide:

Plates

VariAx 2 MIS Calcaneal Plates

MIS Calcaneal Plate, U5, 5 holes (622098)

MIS Calcaneal Plate, U6, 6 holes (622100)

MIS Calcaneal Plate, S7, 7 holes (622102)

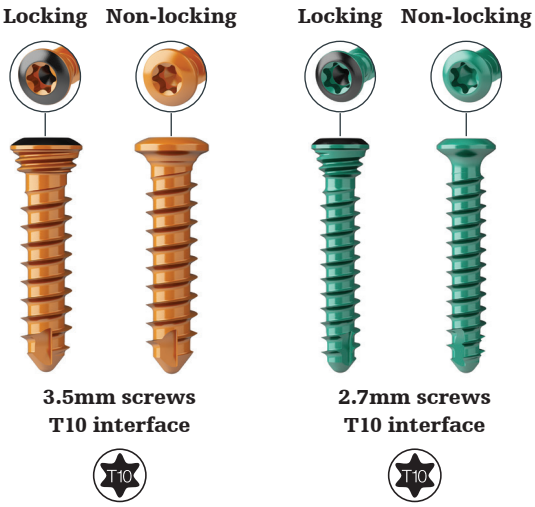
MIS Calcaneal Plate, M8, 8 holes (622104)

MIS Calcaneal Plate, L9, 9 holes (622106)

Screws

VariAx 2 Screws

The plates within the VariAx 2 MIS Calcaneus are compatible with the VariAx 2 screws. Refer to Page 6, for additional details.



Material

Please note that VariAx 2 MIS calcaneal plates are commercially pure (CP) Titanium grade 2 and VariAx 2 screws are titanium alloy (Ti6Al4V), and are not compatible with any stainless-steel plates or screws.

Indications, precautions and contraindications

Indications

Stryker VariAx 2 MIS Calcaneus is indicated for fractures of the calcaneus.

Precautions

See Instructions for Use for warnings, precautions, adverse effects and other essential product information.

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.
- 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.
- Sanders Classification type IV when the MIS Calcaneus implant is used as a standalone device

MRI safety information

A patient with the VariAx 2 MIS Calcaneus may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Device Name	VariAx 2 MIS Calcaneus
Static Magnetic Field Strength (T)	1.5 T and 3.0 T
Maximum Spatial Field Gradient	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR (W/kg)	2 W/kg (Normal Operating Mode)
Scan Duration	**1.5 Tesla** 2 W/kg whole-body average SAR for 10 minutes of continuous RF (a sequence or back to back series/ scan without breaks) followed by a wait time of 10 minutes if this limit is reached, for the total scanning session duration of up to 1 hour (or 60 minutes). **3.0 Tesla** 2 W/kg whole-body average SAR for 15 minutes of continuous RF (a sequence or back to back series/ scan without breaks) followed by a wait time of 6 minutes if this limit is reached, for the total scanning session duration of up to 1 hour (or 60 minutes).
MR Image Artifact	The presence of this implant produced an image artifact of approximately 21 mm from the VariAx 2 MIS Calcaneus when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.
Additional instructions	**⚠ 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 VariAx 2 MIS Calcaneus, this could result in additional MRI effects and the information provided above may not apply.

Implants

Plates

The MIS Calcaneal Plates are interchangeable between the left and right calcanei and have the features shown in Figure A on both sides.

K-wires should not be placed in the Connecting Pin or Targeting Guide/Plate Inserter attachment locations; otherwise, the K-wires must be removed prior to attaching the Connecting Pin and Targeting Guide or Plate Inserter.

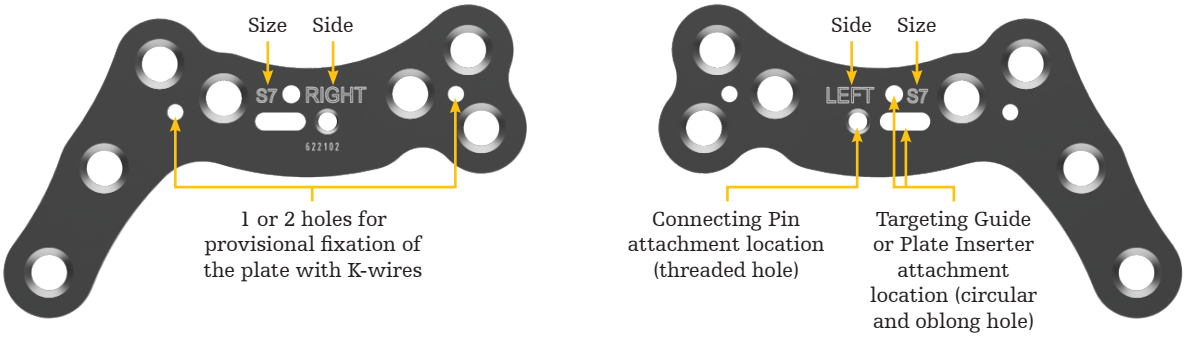


Figure A

Screws

Color coding

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

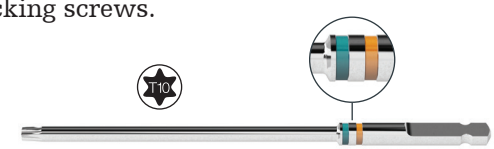
The drill bits and screws are also color coded.

Locking and non-locking screws

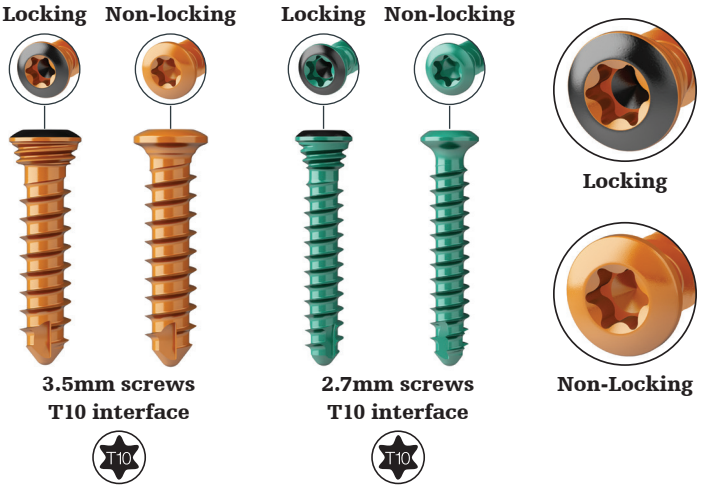
Locking and non-locking screws are available in 2.7mm and 3.5mm diameters. All holes in the MIS Calcaneal Plates provide an option for locking and non-locking screws.

NOTICE

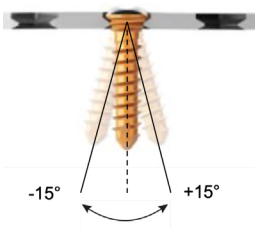
Locking screws are laser marked with a 'dot' and 'ring' marking on the screw head to differentiate them from non-locking screws.



Screwdriver blade



Screw type	Lengths	Plate hole size
2.7mm screws ●	8-70mm	T10
3.5mm screws ●	8-70mm	



Instrumentation

K-wires

K-wires are provided for provisional fixation of the plate and the fracture.

- Length: 150mm
- Diameter: Ø1.4mm and Ø2.0mm

Unthreaded K-wire Ø1.4mm x 150mm (705233)

Unthreaded K-wire Ø2.0mm x 150mm (705234)

Reduction pins

Reduction Pins are provided for reducing the fracture.

- Length: 165mm
- Diameters: Ø5.0mm and Ø6.0mm
- Other: Self-drilling and self-tapping tip and Cancellous thread

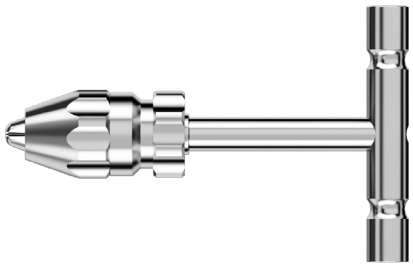
The Reduction Pins are inserted via a device with an AO quick-connect coupling, the T-handle, Cannulated Three-Jaw Chuck (705573), or by the T-handle with AO quick-chuck.

Reduction Pin, Cancellous Thread Ø5.0mm (705527)

Reduction Pin, Cancellous Thread Ø6.0mm (705528)

T-handle, cannulated three-jaw chuck

A T-handle with a cannulation of Ø5.0mm is provided to facilitate the reduction of the fracture. The three-jaw chuck accepts the Ø5.0mm (705527) and Ø6.0mm (705528) Reduction Pins.



T-handle, Cannulated Three-jaw Chuck (705573)

T-handle with AO quick-chuck

A T-handle with an AO coupling is provided to facilitate the reduction of the fracture. The T-handle with AO quick-chuck accepts the Ø5.0mm (705527) and Ø6.0mm (705528) Reduction Pins.

T-handle with AO quick-chuck (700367)

Elevator, osteotome curved tip

An Elevator is provided to facilitate the reduction of the fracture.

Elevator, Osteotome Curved Tip (705539)

Instrumentation (cont.)

Elevator, soft tissue

Elevator, soft tissue is used as a plate template and to facilitate dissection of soft tissue. The holes in the Elevators match the screw hole location in the corresponding plate.

The Elevator, soft tissue instruments are interchangeable between the left and right calcanei and have the features shown in Figure B on both sides.

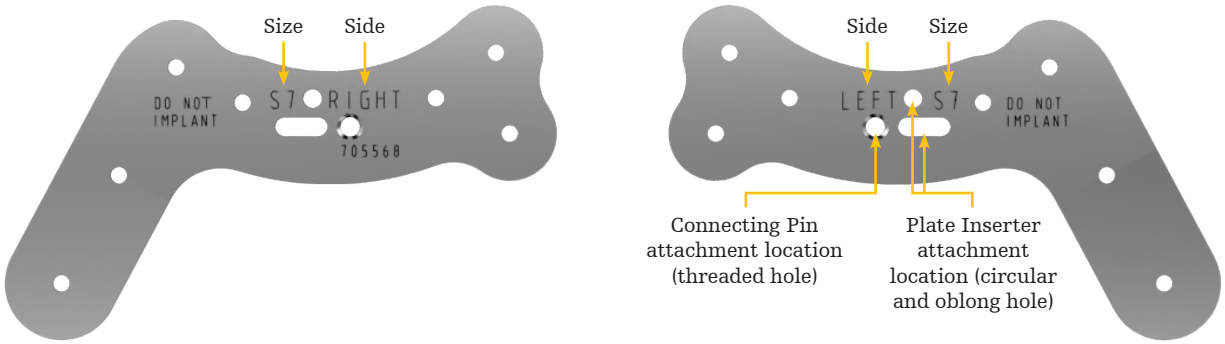


Figure B

MIS Calcaneal Plate, S7, 7 holes (622102)

MIS Calcaneal Plate, M8, 8 holes (622104)

MIS Calcaneal Plate, L9, 9 holes (622106)

Elevator, Soft Tissue, S7 (705568)

Elevator, Soft Tissue, M8 (705569)

Elevator, Soft Tissue, L9 (705570)

Instrumentation (cont.)

Plate positioning and insertion

The plates are placed into position via one of three options:

- Joystick
- Targeting Guide
- Plate Inserter

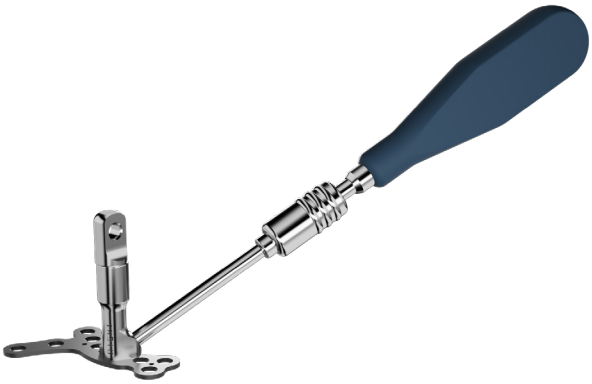
Joystick
The Joystick for T10 screw holes (703928) can be used to aid in plate positioning. Additionally, the Joystick can be used to temporarily fix the plate to the bone by inserting a K-wire with a diameter up to 1.6mm through the cannulation of the Joystick.

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, 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.

Targeting Guide
The MIS Calcaneal Plate can be inserted by hand while holding onto the Targeting Guide. Once in position, confirmed by fluoroscopy imaging, K-wires may be used to provisionally fix the MIS Calcaneal Plate to the bone.

Plate Inserter
The Teardrop-handle small with AO Quick Coupling (702428) is connected to the AO shaft on the Plate Inserter. This facilities the plate insertion and may help keep the surgeon's hand away from the fluoroscopy image.



Instrumentation (cont.)

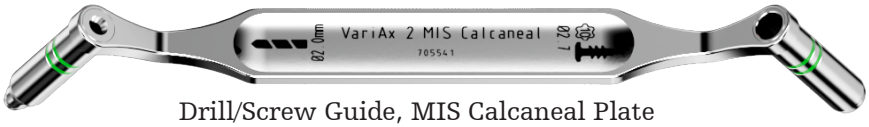
Drill/screw guides

The Drill/Screw Guide has two sides:

- A Drill Guide to protect the soft tissues when drilling a pilot hole for either a non-locking or locking screw
- A Screw Guide to protect the soft tissues during insertion of the screw into the plate via the Targeting Guide

Drill guide

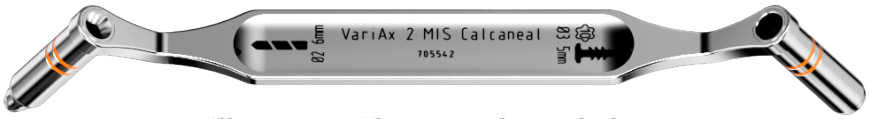
Screw color coding	Screw diameters	Drill guides	Interface	Drill bits diameter
Turquoise ●	2.7mm	2.0mm	T10	2.0mm
Orange ●	3.5mm	2.6mm	T10	2.6mm



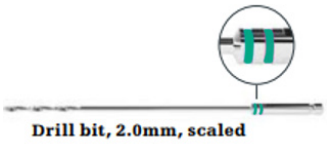
Drill/Screw Guide, MIS Calcaneal Plate
Ø2.0mm x Ø2.7mm (T10) (705541)

Drill guide

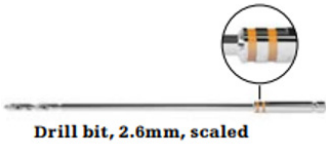
Screw guide



Drill/Screw Guide, MIS Calcaneal Plate
Ø2.6mm x Ø3.5mm (T10) (705542)



Drill Bit, AO,
Dia 2.0 ×135mm,
scaled (703690)



Drill Bit, AO,
Dia 2.6 ×135mm,
scaled (703691)

⚠ 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.

Screw guide

Screw color coding	Screw diameters	Screw guide
Turquoise ●	2.7mm	2.7mm
Orange ●	3.5mm	3.5mm

⚠ WARNING

Always match the screw anodization color with at least one of the color ring instrument markings.

Instrumentation (cont.)

Depth measurement options

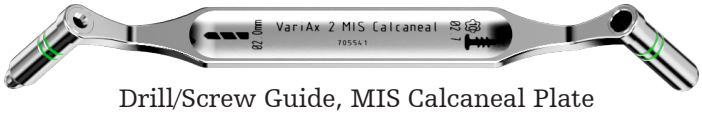
Drilled holes are measured via one of the two options:

- Depth Gauge
- Drill Guide and Drill

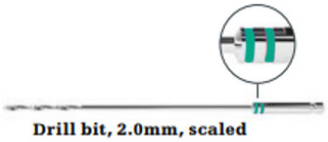
Depth gauge, MIS calcaneal plate
The Depth Gauge (705540) is used on any circular screw hole within the VariAx 2 MIS Calcaneal Plates, including use with the Targeting Guide (705571 or 705572).

Depth Gauge, MIS Calcaneal Plate (705540)

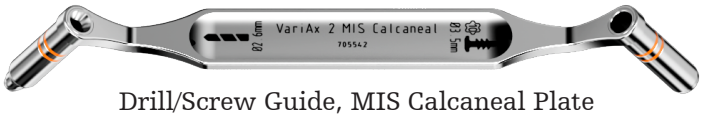
Drill/screw guide, MIS calcaneal plate
The drills are scaled to allow for estimating the correct screw length when used in conjunction with its corresponding Drill/Screw Guide, MIS Calcaneal Plate (705541 or 705542). This combination is used on any circular screw hole within the VariAx 2 MIS Calcaneal Plates, including use with the Targeting Guide (705571 or 705572).



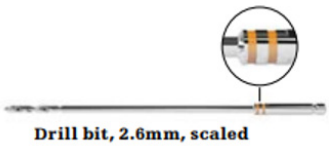
Drill/Screw Guide, MIS Calcaneal Plate Ø2.0mm x Ø2.7mm (T10) (705541)



Drill Bit, AO, Dia 2.0 ×135mm, scaled (703690)



Drill/Screw Guide, MIS Calcaneal Plate Ø2.6mm x Ø3.5mm (T10) (705542)



Drill Bit, AO, Dia 2.6 ×135mm, scaled (703691)

Instrumentation (cont.)

Assembly and disassembly of targeting guide to plate

The Targeting Guide (705571 or 705572) is secured to the MIS Calcaneal Plate with the Connecting Pin (705549) and Locking Nut (705550).

NOTICE

Targeting Guide or Plate Inserter cannot be used with plates that have been contoured or bent in the following locations:

- Posterior tuberosity tab
- Connecting Pin attachment location (threaded hole)
- Targeting Guide or Plate Inserter attachment location (circular and oblong hole)

NOTICE

Connecting Pin and Locking Nut should not be overly tightened as this may damage the threads on the Connecting Pin or Locking Nut. Only moderate effort is needed. (Finger tighten only)

Assembly

Step 1: Insert the M2.5mm thread on the Connecting Pin (705549) into the attachment location on the MIS Calcaneal Plate by rotating the Connecting Pin clockwise until secure.

Step 2: Slide the Targeting Guide (705571 or 705572) over the Connecting Pin (705549), aligning the circular pin and oblong tab on the Targeting Guide into the attachment location on the MIS Calcaneal Plate.

Step 3: Slide the Locking Nut (705550) over the Connecting Pin (705549) and secure the Targeting Guide (705571 or 705572) by rotating the Locking Nut clockwise until secure. The Locking Nut will first engage the threads on the Targeting Guide then disengage those threads. The Locking Nut will then engage the threads on the Connecting Pin.

Intra Operative Disassembly and Assembly

The Targeting Guide (705571 or 705572) may be removed intra-operatively while retaining the Locking Nut (705550).

Step 1: Rotate the Locking Nut counter-clockwise until it disengages the Connecting Pin (705549) but not the Targeting Guide.

Step 2: Slide the Targeting Guide, along with the Locking Nut, off the Connecting Pin.

Step 3: Assemble the Targeting Guide, along with the Locking Nut, back onto the device by sliding the Targeting Guide over the Connecting Pin.

Step 4: Rotate the Locking Nut clockwise to engage the Connecting Pin until secure.

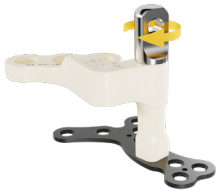
Disassembly

Step 1: Rotate the Locking Nut (705550) counter-clockwise until it fully disengages both the Connecting Pin (705549) and Targeting Guide (705571 or 705572).

Step 2: Slide the Targeting Guide off the Connecting Pin.

Step 3: Rotate the Connecting Pin counter-clockwise until it fully disengages the MIS Calcaneal Plate.

The Locking Nut has a cross hole to facilitate in the disassembly in case the Locking Nut can not be untightened by hand.

	Step 1	Step 2	Step 3	Step 4
Assembly				N/A
Intra operative disassembly and assembly				
Disassembly				N/A

Instrumentation (cont.)

Assembly and disassembly of plate inserter to plate or elevator, soft tissue

The Plate Inserter (705552 or 705553) is secured to the MIS Calcaneal Plate or Elevator, Soft Tissue (705568, 705569, or 705570) with the Connecting Pin (705549) and Locking Nut (705550).

NOTICE

Targeting Guide or Plate Inserter cannot be used with plates that have been contoured or bent in the following locations:

- Posterior tuberosity tab
- Connecting Pin attachment location (threaded hole)
- Targeting Guide or Plate Inserter attachment location (circular and oblong hole)

NOTICE

Connecting Pin and Locking Nut should not be overly tightened as this may damage the threads on the Connecting Pin or Locking Nut. Only moderate effort is needed. (Finger tighten only)

Assembly

Step 1: Insert the M2.5mm thread on the Connecting Pin (705549) into the attachment location on the MIS Calcaneal Plate or Elevator, Soft Tissue (705568, 705569, or 705570) by rotating the Connecting Pin clockwise until secure.

Step 2: Slide the Plate Inserter (705552 or 705553) over the Connecting Pin, aligning the circular pin and oblong tab on the Plate Inserter into the attachment location on the MIS Calcaneal Plate or Elevator, Soft Tissue.

Step 3: Slide the Locking Nut (705550) over the Connecting Pin and secure the Plate Inserter by rotating the Locking Nut clockwise until secure. The Locking Nut will first engage the threads on the Plate Inserter then disengage those threads. The Locking Nut will then engage the threads on the Connecting Pin.

Intra Operative Disassembly and Assembly

The Plate Inserter (705552 or 705553) may be removed intra-operatively while retaining the Locking Nut (705550).

Step 1: Rotate the Locking Nut counter-clockwise until it disengages the Connecting Pin (705549) but not the Plate Inserter.

Step 2: Slide the Plate Inserter, along with the Locking Nut, off the Connecting Pin.

Step 3: Assemble the Plate Inserter, along with the Locking Nut, back onto the device by sliding the Plate Inserter over the Connecting Pin.

Step 4: Rotate the Locking Nut clockwise to engage the Connecting Pin until secure.

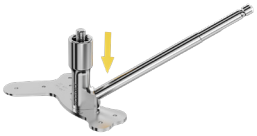
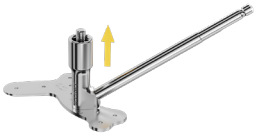
Disassembly

Step 1: Rotate the Locking Nut (705550) counter-clockwise until it fully disengages both the Connecting Pin (705549) and Plate Inserter (705552 or 705553).

Step 2: Slide the Plate Inserter off the Connecting Pin

Step 3: Rotate the Connecting Pin counter-clockwise until it fully disengages the MIS Calcaneal Plate or Elevator, Soft Tissue (705568, 705569, or 705570).

The Locking Nut has a cross hole to facilitate in the disassembly in case the Locking Nut can not be untightened by hand.

	Step 1	Step 2	Step 3	Step 4
Assembly (example shown with Plate Inserter and Elevator, Soft Tissue)				N/A
Intra operative disassembly and assembly (example shown with Plate Inserter and Elevator, Soft Tissue)				
Disassembly (example shown with Plate Inserter and Elevator, Soft Tissue)				N/A

Pre-operative planning

Back table layout

Other items needed:

- Power system (that accepts AO Adapters)
- Pin Driver/Drill
- AO Adapter

Either one of the following VariAx trays can be used for the remaining VariAx T10 instruments for implanting the plate and screws, as well as the VariAx Ø2.7mm or Ø3.5mm screws.

- VariAx 2 F&A Tray
- VariAx 2 Small Frag Core Tray

Before the patient is in the operating room, check the VariAx 2 MIS Calcaneus as well as any other supporting VariAx set to be sure all required instruments and implants are available.

Preoperative evaluation

It is recommended to obtain appropriate x-rays and CT scans with reconstruction to make a preoperative assessment of the fracture.

Position of patient

Place the patient in the lateral position with the operative extremity facing up on a radiolucent table. Obtain axial, lateral views, and Broden's views (to see all aspects of posterior facet from front to back of the calcaneus with an intraoperative fluoro C-arm or portable device of choice.

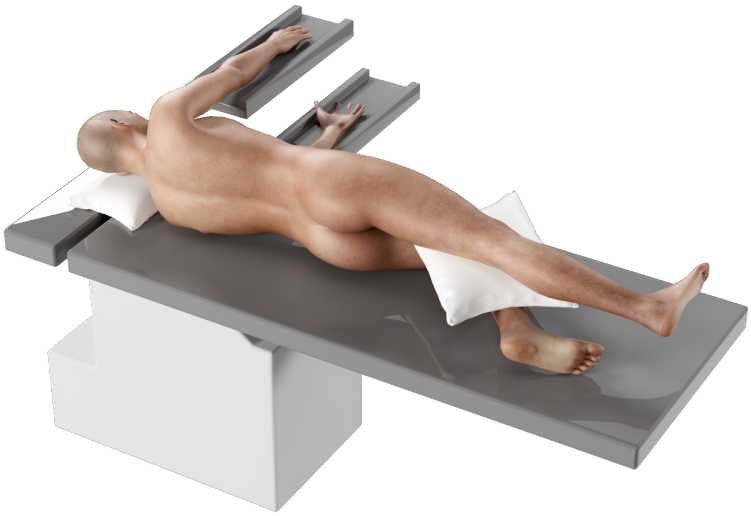


Plate selection

The Elevator, Soft Tissue (705568, 705569, or 705570) may be used to estimate which plate will be used. This can be done in two ways.

Place an appropriate Elevator, Soft Tissue instrument on the skin and obtain fluoroscopy views to verify size.

During the dissection using the Elevator, Soft Tissue, obtain fluoroscopy views to verify size.

Operative technique

Step 1

Dissection and plate selection

⚠ WARNING

Care must be taken to avoid the sural nerve.

1.1 Approach

Once extremity has been prepped per OR protocol, an incision is made on the lateral side of the operative foot beginning at the distal tip of the fibula extending up to 5cm towards the base of the fourth metatarsal. Keep incision dorsal to the peroneal tendons. Be sure the incision size is appropriate to avoid excessive soft tissue irritation or damage.

1.2 Dissection

After blunt dissection, select the appropriate Elevator, Soft Tissue (705568, 705569, or 705570) and assemble it to the Plate Inserter (705552 or 705553). Refer to Pages 14 and 15 for the assembly and disassembly of the Plate Inserter to the Elevator, Soft Tissue. Insert the selected Elevator, Soft Tissue through the incision to dissect the soft tissues off the lateral wall of the calcaneus.

1.3 Plate Selection

The Elevator, Soft Tissue (705568, 705569, or 705570) can also be used as an implant template under fluoroscopy imaging. The holes shown in Figures 1, 2, and 3, align with the corresponding screw holes in MIS Calcaneal Plate.

Select the appropriate MIS Calcaneal Plate based on the patients anatomy and the fracture pattern. The utility plates (622098 and 622100) are used for less comminuted fractures not involving the posterior tuberosity of the calcaneus; whereas, MIS Calcaneal Plates (622102, 622104, and 622106) are used with a fracture across the posterior tuberosity.

Figure 1

Figure 2

Figure 3

Step 2

Reduction

Provisional fixation of the fractured fragments is achieved with k-wires. Take care to ensure that k-wire positioning does not interfere with plate positioning. A Reduction Pin (705527 or 705528) is used to perform a standard reduction technique to restore the fractured fragment to the anatomic alignment prior to plate placement.

Reduction Pins are inserted under Stryker power system or the T-handle, see Sections A, B, and C.

Figure 4

A. Stryker Power

Connect the AO coupling on the Reduction Pin to the standard Stryker Power AO coupling adaptor.

B. T-handle, Cannulated Three-jaw Chuck (700573)

Rotate the conical housing counter-clockwise to open the three-jaw chuck. Slide the T-handle, Cannulated Three-jaw Chuck over the Reduction Pin to the desired position. Rotate the conical housing clockwise to secure the T-handle, Cannulated Three-jaw Chuck to the Reduction Pin.

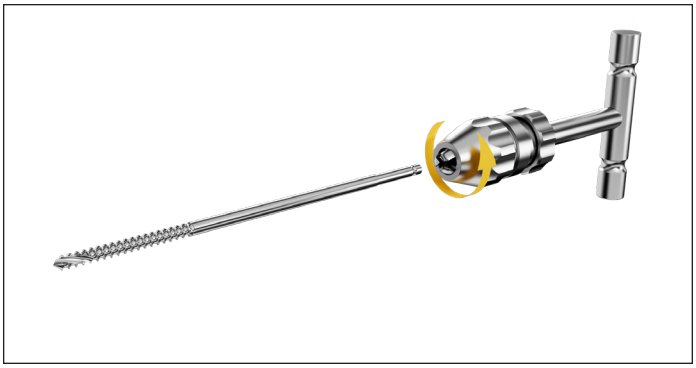


Figure 5

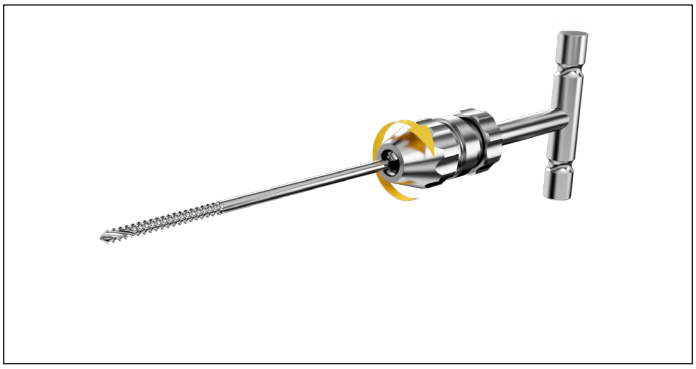


Figure 6

C. T-Handle with AO quick-chuck (700367)

Connect the AO coupling on the Reduction Pin to the AO coupling on the T-handle with AO quick-chuck.

Step 3

Plate insertion and plate bending

3.1 Plate Insertion

Once the applicable MIS Calcaneal Plate has been selected and the fracture reduced, the MIS Calcaneal Plate is inserted through the incision and into position by one of the three ways listed below.

A. Plate Inserter technique

Once the Plate Inserter is assembled to the MIS Calcaneal Plate, attach the Teardrop-handle small with AO Quick Coupling (702428) to the AO connection on the Plate Inserter.

Insert the posterior end of the plate through the incision, directing it posteriorly until the plate is in the desired position over the fractured calcaneus. Obtain fluoroscopy images to determine positioning of the plate and once confirmed, provisional fixation of the MIS Calcaneal Plate is provided by inserting Ø1.4mm K-wires (705233) into the identified holes on Page 6.

Figure 7

Figure 8

B. Targeting Guide technique

Insert the MIS Calcaneal Plate attached to the Targeting Guide through the incision and once the desired position is achieved, confirmed with fluoroscopy images, k-wires can be used for provisional fixation of the plate to the calcaneus.

Insert the posterior end of the plate through the incision, directing it posteriorly until the plate is in the desired position over the fractured calcaneus. Obtain x-ray images to determine positioning of the plate and once confirmed, provisional fixation of the MIS Calcaneal Plate is provided by inserting Ø1.4mm K-wires (705233) into the identified holes on Page 6.

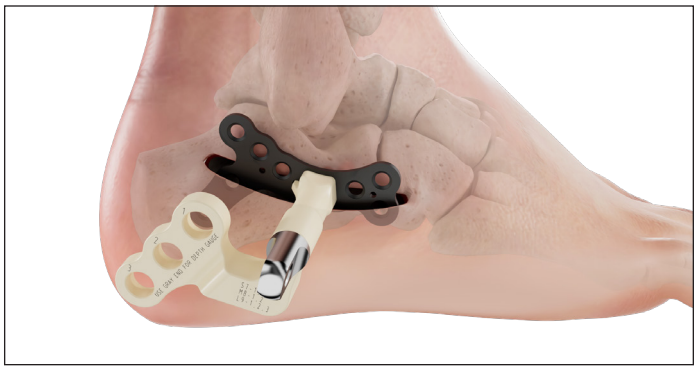


Figure 9

Figure 10

C. Joystick technique

Insert the MIS Calcaneal Plate attached to the Joystick through the incision and once the desired position is achieved, confirmed with x-ray images, k-wires may be used for provisional fixation of the plate to the calcaneus.

Insert the posterior end of the plate through the incision, directing it posteriorly until the plate is in the desired position over the fractured calcaneus. Obtain x-ray images to determine positioning of the plate and once confirmed, provisional fixation of the MIS Calcaneal Plate is provided by inserting Ø1.4mm K-wires (705233) into the identified holes on Page 6.

Figure 11

Figure 12

3.2 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.

Bending can only be performed when the Bending Pliers are engaged in two adjacent circular screw holes, in the portions of the plate as shown in Figure 13.

⚠ 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 or 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).

- If the adaptation holes are deformed, there may be potential for a screw to pass through the hole upon insertion
- If contouring of the plate is necessary and Targeting Guide is used to place screws, bending is only allowed in designated screw holes.

⚠ CAUTION

- The plate bending pliers are designed to be used only in circular holes
- Always attach the bending pliers to two adjacent holes to prevent deformation of the screw holes

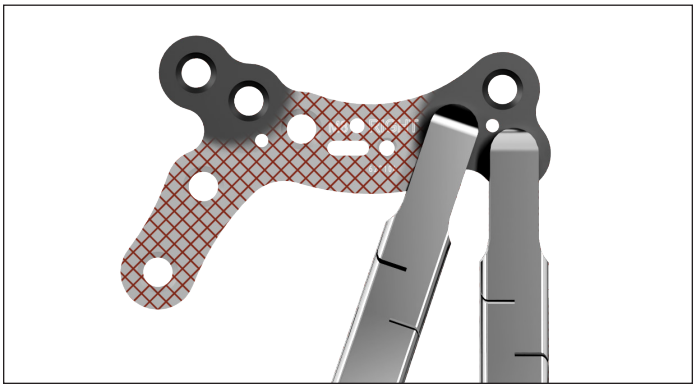


Figure 13
Example of the Bending Pliers (45-80010) engaged in two adjacent circular screw holes.

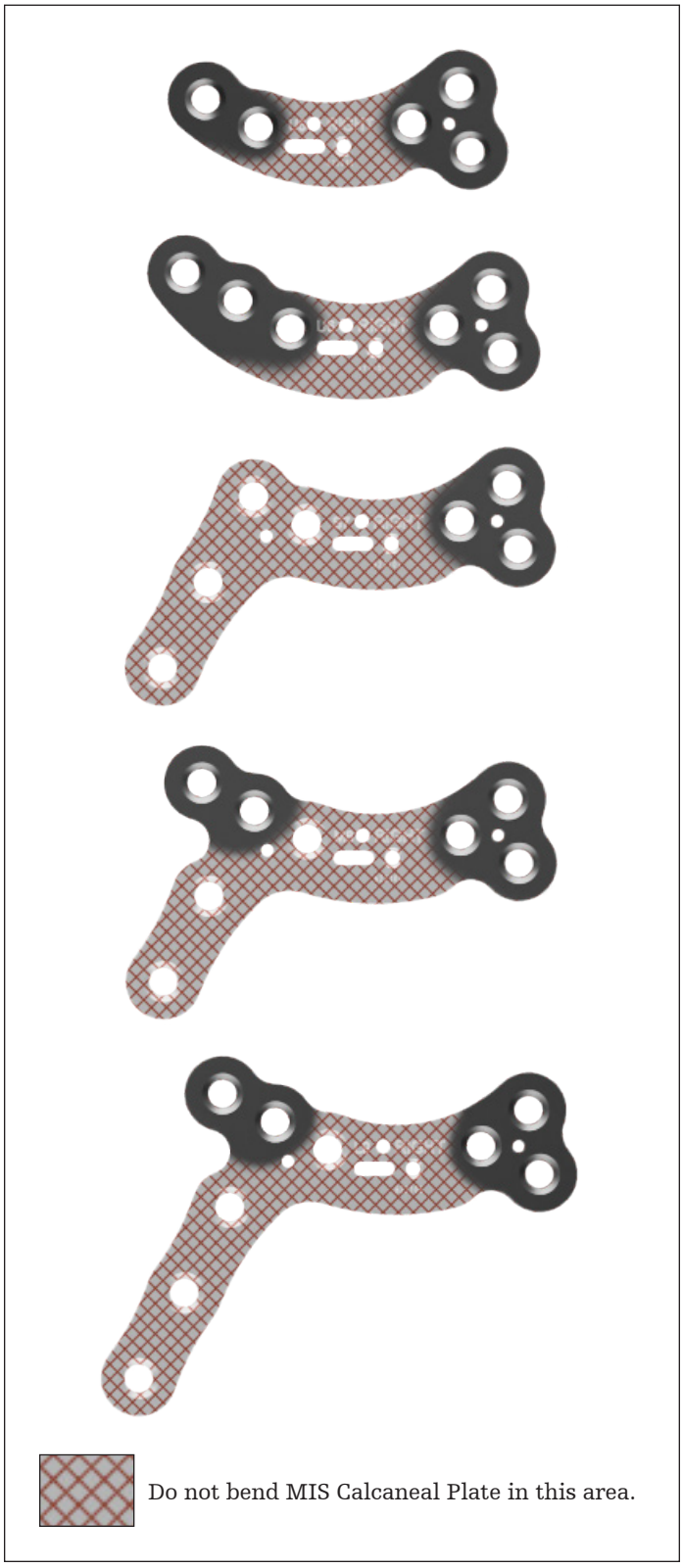


Figure 14
Where MIS Calcaneal Plates can and cannot be bent.

Step 4

Screw selection and insertion

4.1 Screw Selection

Choose the desired screw from the available system options:

- Ø2.7mm locking or non-locking
- Ø3.5mm locking or non-locking

Always insert all non-locking screws in the bone before using locking screws.

4.2 Drill

Select the appropriate Drill (703690 or 703691) and Drill/Screw Guide (705541 or 705542), refer to Page 10, based on the screw choice selected. The Drill Guide portion of the Drill/Screw Guide must first be placed into a corresponding circular screw hole in the plate prior to pre-drilling a pilot hole. Drill up to the far cortex or preferred depth using the appropriate drill bit.

⚠ CAUTION

First fully engage the drill guide in the hole and then aim the drill in the desired direction.

Figure 15

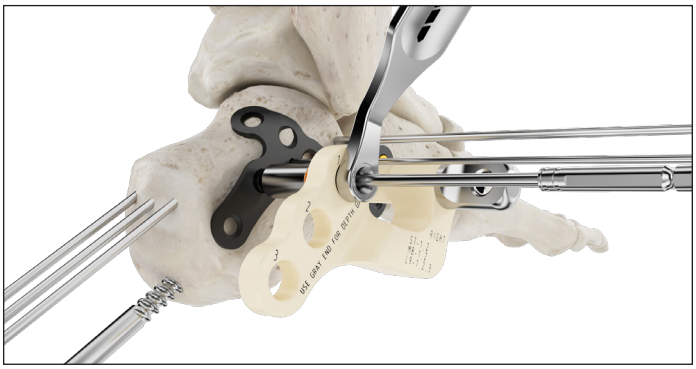


Figure 16

4.3 Tapping

Tapping is optional as the screws are self-tapping. Tap, if desired, using the appropriate tap.

- Tap, AO, for 2.7mm screws (703899)
- Tap, AO, for 3.5mm screws (703898)

4.4 Measure

The appropriate screw length can be measured off the drill or with the Depth Gauge (705540).

Appropriate screw length selection is important for the stability of the fixation. Measurements follow the principle of "what you read is what you get." This means that the measured value in millimeters on the drill or Depth Gauge (705540) is the exact value of the screw selected.

When measuring through the Targeting Guide (705571 or 705572) ensure the Drill Guide of the Drill/Screw Guide (705541 or 705542) or Depth Gauge (705540) is engaged with the appropriate hole of the Targeting Guide and screw hole of the MIS Calcaneal Plate.

A. Drill

Ensure the Drill Guide of the Drill/Screw Guide (705541 or 705542) is fully engaged in the screw hole of the plate and at the desired angle. Once the drill is at the desired depth, read the corresponding scale on the drill.

B. Depth Gauge

Ensure the gray end of the Depth Gauge (705540) is fully engaged in the screw hole of the plate. Insert the tip through the hole and locate the far cortex, read the corresponding scale on the Depth Gauge.

⚠ CAUTION

The tip of the depth gauge should be inserted through the pilot hole until it locates the opposite cortex.

⚠ WARNING

The Depth Gauge (705170) shall not be used to measure the screw length through the Targeting Guide (705571 or 705572), as an incorrect measurement will be obtained.

Depth Gauge (705170)

Figure 17

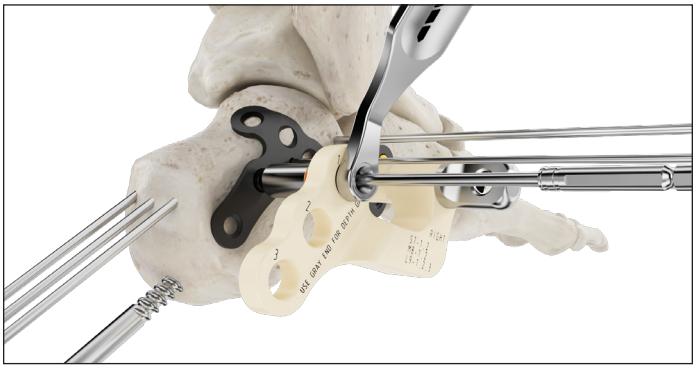


Figure 18

Figure 19

Figure 20

Depth Gauge (705540)

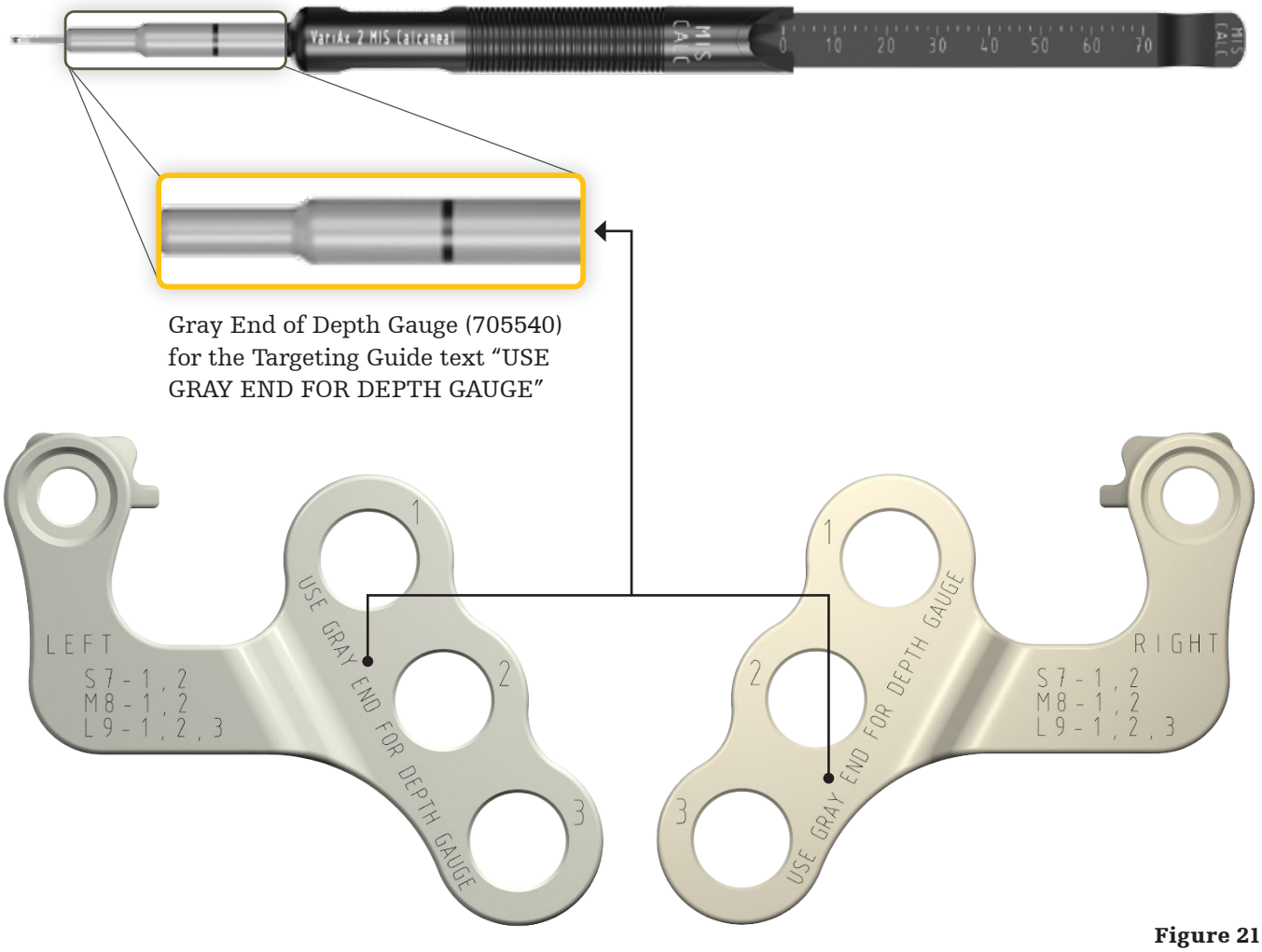


Figure 21

4.5 Screw Insertion

Insert the screw with Handle (703920 or 703921), Ratcheting Insert (703922) and Screw Driver Blade, AO, T10, self retaining (703880) into the pre-drilled hole. Final tightening is not recommended until all desired screws have been provisionally inserted into a plate.

When inserting a screw through the Targeting Guide (705571 or 705572) always use the appropriate Screw Guide on the Drill/Screw Guide (705541 or 705542) to protect the soft tissues during screw insertion.

Fluoroscopy is required to ensure correct length and angulation.

⚠ CAUTION

When final tightening of the locking screw occurs, take care not to over-torque the screw. Excessive torque may damage the locking mechanism, the screw and/or the screwdriver blade.

⚠ CAUTION

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

NOTICE

To avoid disengagement of the screwdriver blade from the screw during insertion, axial pressure is recommended.

Figure 22

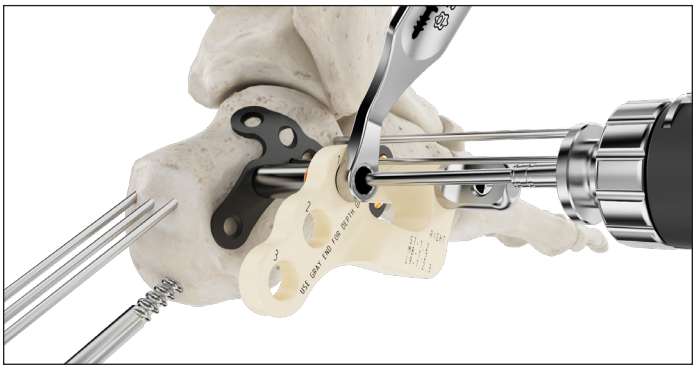


Figure 23

Step 5

Removal of instruments

Disassemble Targeting Guide (705571 or 705572), refer to Pages 12 to 13, and remove any other instruments.

Figure 24

Step 6

Wound closure

Verify reduction and screw placement under fluoroscopy. Close wound in layers per standard technique.

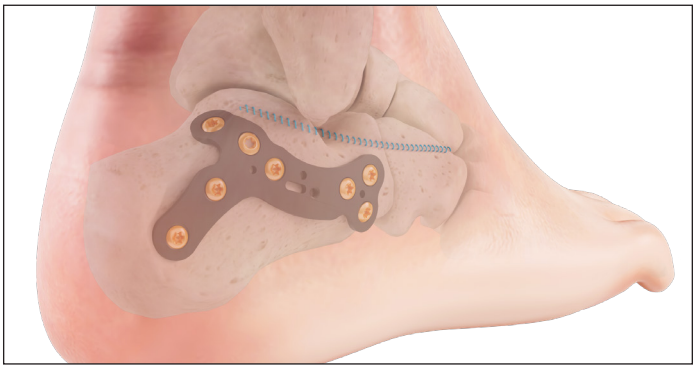


Figure 25

Reference numbers

Non-sterile Set Content (Full set)

Ref #	Description	Qty
622098	MIS Calcaneal Plate U5, 5 Holes	2
622100	MIS Calcaneal Plate U6, 6 Holes	2
622102	MIS Calcaneal Plate S7, 7 Holes	2
622104	MIS Calcaneal Plate M8, 8 Holes	2
622106	MIS Calcaneal Plate L9, 9 Holes	2
705233	Wire without thread D1.4/150mm	8
705234	Wire without thread D2.0/150mm	8
705527	Reduction Pin, Cancellous Thread Ø5.0mm	2
705528	Reduction Pin, Cancellous Thread Ø6.0mm	2
705573*	T-handle, Cannulated Three-jaw Chuck	1
705568	Elevator, Soft Tissue, S7	1
705569	Elevator, Soft Tissue, M8	1
705570	Elevator, Soft Tissue, L9	1
705539	Elevator, Osteotome Curved Tip	1
705540	Depth Gauge, MIS Calcaneal Plate	1
705541	Drill/Screw Guide, MIS Calcaneal Plate Ø2.0mm x Ø2.7mm (T10)	1
705542	Drill/Screw Guide, MIS Calcaneal Plate Ø2.6mm x Ø3.5mm (T10)	1
705571	Targeting Guide, MIS Calc Plates, Right	1
705572	Targeting Guide, MIS Calc Plates, Left	1
705549	Connecting Pin	2
705550	Locking Nut	2
705552	Plate Inserter, MIS Calc Plates, Right	1
705553	Plate Inserter, MIS Calc Plates, Left	1
702428	Teardrop-handle small with AO Quick Coupling	1
940630	VariAx 2 MIS Calcaneus – Tray	1
940577**	VariAx 2 MIS Calcaneus – Tray Base	1
1500-0042**	Spare Part 1/2 Lid	1
940576**	VariAx 2 MIS Calcaneus – Tray Insert	1

Sterile SKUs (not in non-sterile set)

Ref #	Description
622098S	MIS Calcaneal Plate U5, 5 Holes
622100S	MIS Calcaneal Plate U6, 6 Holes
622102S	MIS Calcaneal Plate S7, 7 Holes
622104S	MIS Calcaneal Plate M8, 8 Holes
622106S	MIS Calcaneal Plate L9, 9 Holes
705233S	Wire without thread D1.4/150mm
705234S	Wire without thread D2.0/150mm
705527S	Reduction Pin, Cancellous Thread Sterile Ø5.0mm
705528S	Reduction Pin, Cancellous Thread Sterile Ø6.0mm

*Ref # 700367 is an alternate T-handle for use.
**These reference numbers are included within the assembly of Ref # 940630.

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Foot & Ankle

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