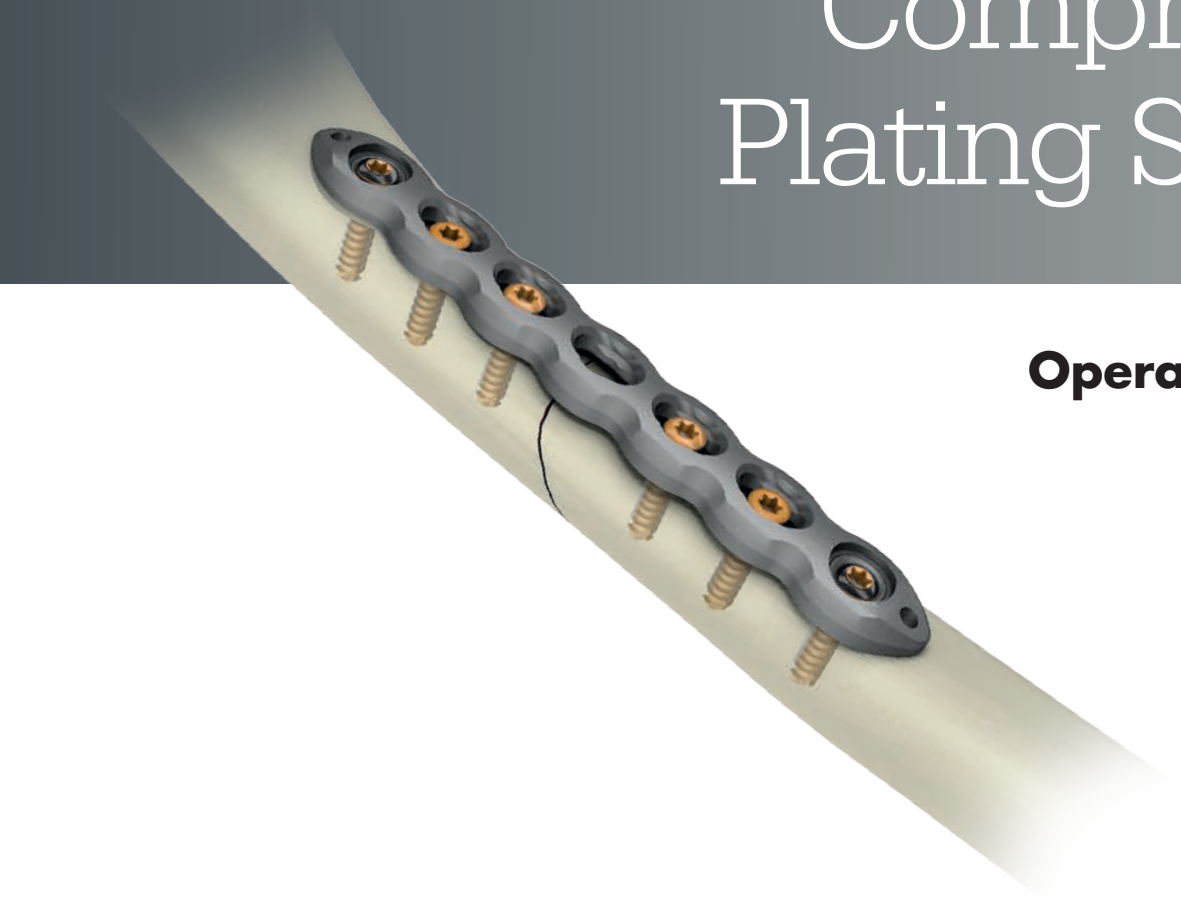
stryker

VariAx® 2 Compression Plating System



Operative technique

VariAx 2
Compression Plating System

Contents

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 first surgery.

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

See Instructions for Use (V15011 and V15013) 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.

Introduction

The VariAx 2 Compression Plating System is indicated to treat a variety of small fragment midshaft fractures. These locking compression plates come in a variety of lengths, shapes, and widths, which offer the ability to compress, neutralize, or bridge a fracture depending on the fracture pattern and the surgeon's fixation preference.

The VariAx 2 SmartLock[1] technology allows the surgeon to lock a screw in any of the circular holes in the plate in a variable angle of 30°.

Finally, made of titanium alloy (Ti6Al4V) and treated with a Type II anodization, these plates are designed to carry the loads that are required of them.

This operative technique explains the three main fracture fixation techniques, compression, neutralization, and bridge, as well as demonstrates the proper usage of the VariAx 2 instrumentation.

Straight broad plate

Straight narrow plate

Curved broad plate

[1] The SmartLock Technology is patented by Professor Dietmar Wolter, Hamburg Germany

Indications, contraindications & MRI safety information

Indications

The Stryker VariAx 2 Compression Plating System is indicated for internal fixation of fractures in the radius, ulna, humerus, clavicle, and distal fibula, in patients with normal bone density and osteopenic bone, for the following indications:

- Osteotomies, mal-unions and non-unions
- Single, segmental and comminuted fractures

NOTICE

The VariAx 2 Compression Plating System is only compatible with T10 3.5mm and T10 2.7mm screws.

Contraindications

The physician's education, training and professional judgment 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 around the affected area
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices
- Material sensitivity, documented or suspected
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself
- Patients having inadequate tissue coverage over the operative site
- Implant utilization that would interfere with anatomical structures or physiological performance
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery

MRI safety information

Non-clinical testing has demonstrated the VariAx 2 Compression Plate construct 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 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (normal operating mode)
- Scan time restriction
    - for 1.5 T: maximum 6 minutes of continuous scanning
    - for 3.0 T: maximum 15 minutes of continuous scanning

1.5 Tesla
Under the scan conditions defined above, the VariAx 2 Compression Plate construct is expected to produce a maximum temperature rise of less than 7.5°C after 6 minutes of continuous scanning at 1.5 T.

3.0 Tesla
Under the scan conditions defined above, the VariAx 2 Compression plate construct is expected to produce a maximum temperature rise of less than 5.8°C after 15 minutes of continuous scanning at 3.0 T.

In non-clinical testing, the image artifact caused by the device extends approximately 27.4mm from the VariAx 2 Compression plate 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 VariAx 2 Compression Plating System, this could result in additional MRI effects and the information provided above may not apply.

Operative technique

Operative technique

The VariAx 2 Compression Plating System is indicated for a variety of anatomic structures, but the main indications are radius and ulna fractures. The operative technique will demonstrate the surgical steps using these bones. It will also describe the three common plating principles of compression, neutralization, and bridge fixation.

Compression technique

Fracture reduction is performed in the usual manner. There are a variety of bone holding forceps, retractors, and K-wires in the system to facilitate reduction.

Implant choice

The VariAx 2 Compression Plating System offers narrow straight plates from 3 holes to 22 holes. The broad plates are offered in a straight design from 3 holes to 22 holes and a radial curved design from 9 holes to 20 holes with 2 holes steps from 12 to 20.

Also, specific 7-hole plates are designed with additional locking holes in which the surgeon can insert more locking screws if desired.

Ensure that there are sufficient amount of holes proximal and distal to the fracture to ensure proper fixation. Plate trials may be provided to determine the proper length of the plate to be implanted. This may be particularly useful when using sterile–packed plates.

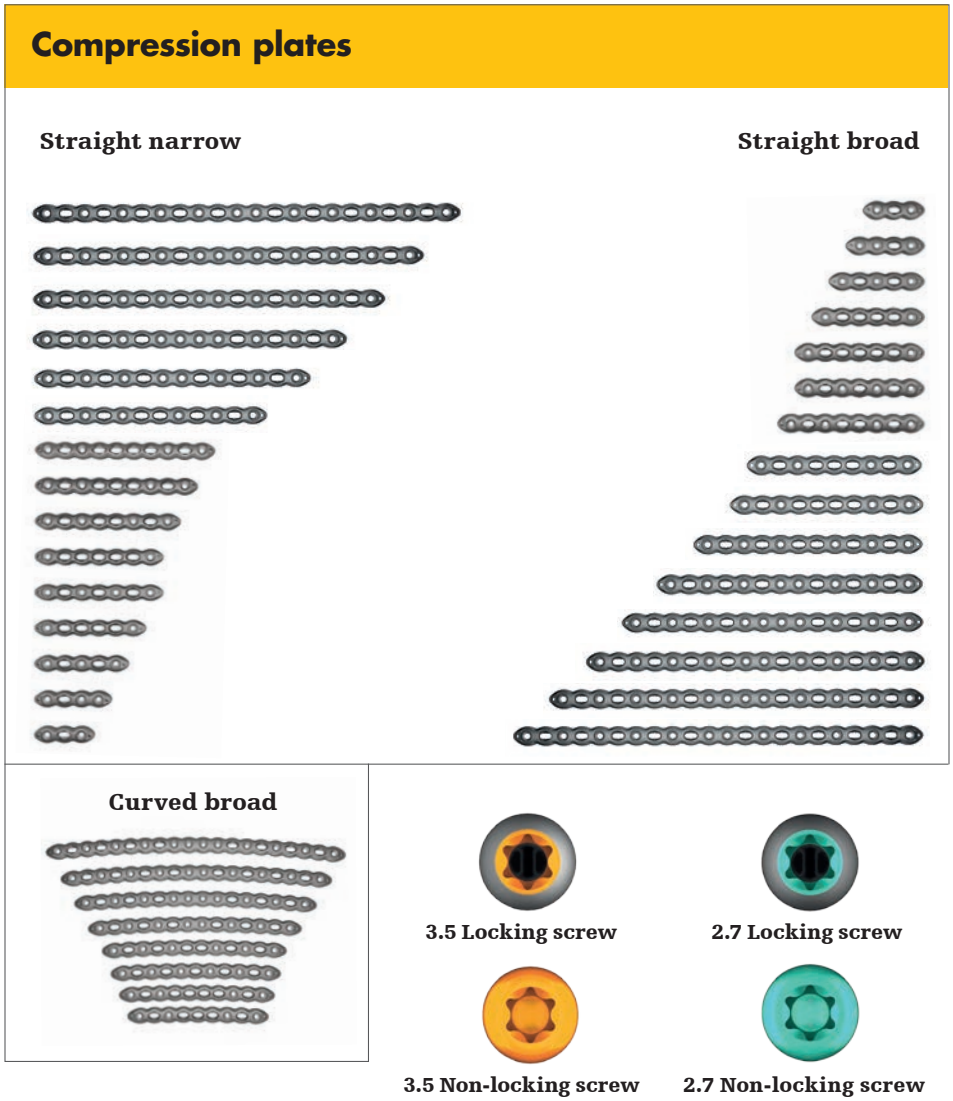
Locking or non–locking screws

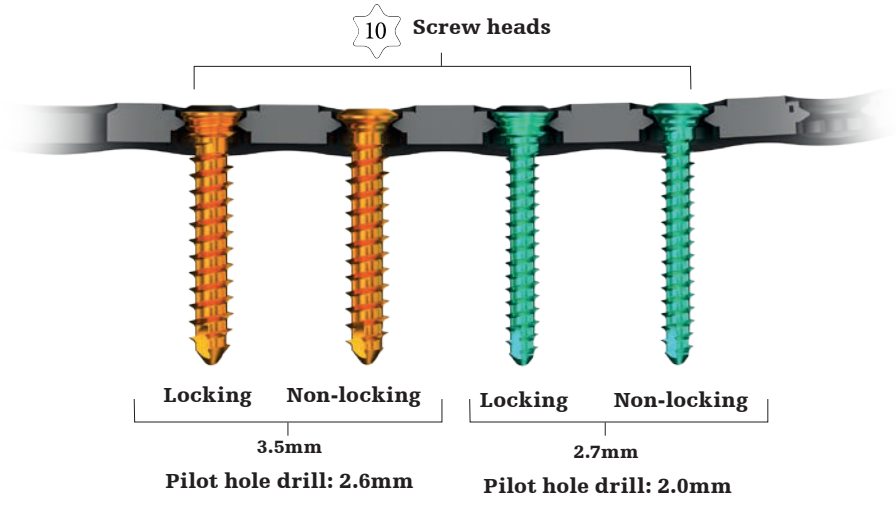
The circular holes in the plates provide an option for locking and non–locking. **The oblong compression holes are designed to work with non-locking screws.**

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.

3.5mm or 2.7mm screws

The VariAx 2 Compression 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.

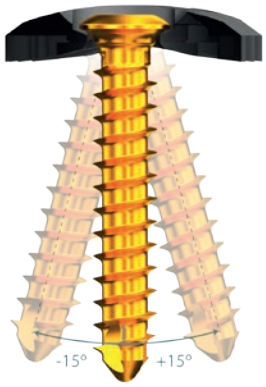


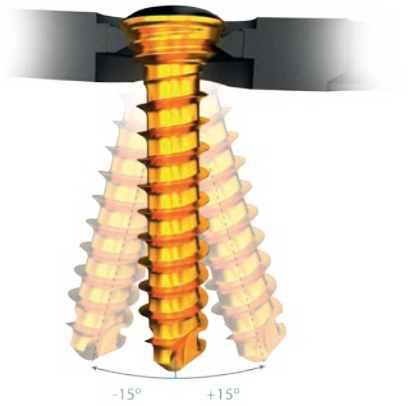


Operative technique

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 (703882 for 3.5mm screws and 703883 for 2.7mm screws) when drilling.



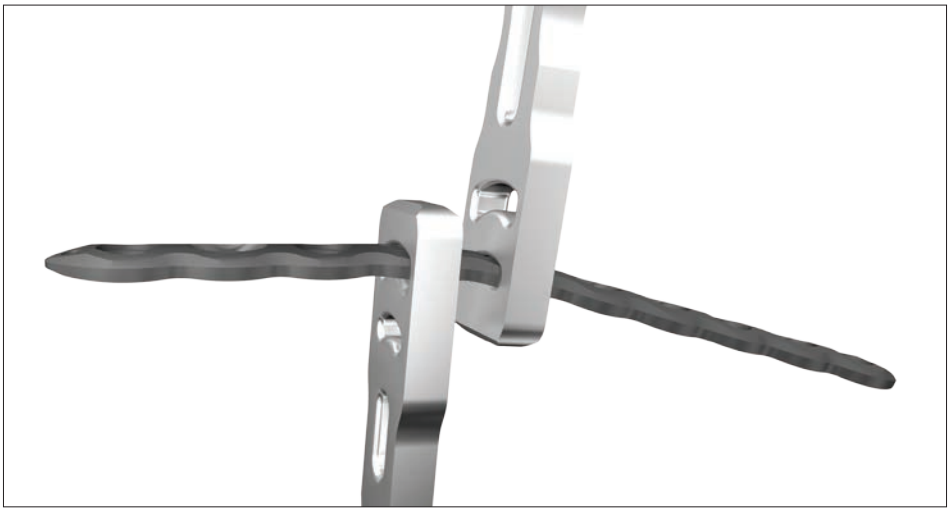


NOTICE

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.

Plate contouring

The longer broad plates are pre–contoured to fit the anatomy of the radius. Although not always necessary, all of the plates may be contoured to adapt to individual patient anatomy or fracture fixation technique.



⚠ WARNING

Avoid sharp bends, reverse bends or bending the device at a screw hole.

A locking plate which can be adjusted intra–operatively to precisely fit the bony anatomy without damaging the locking mechanism may be useful.

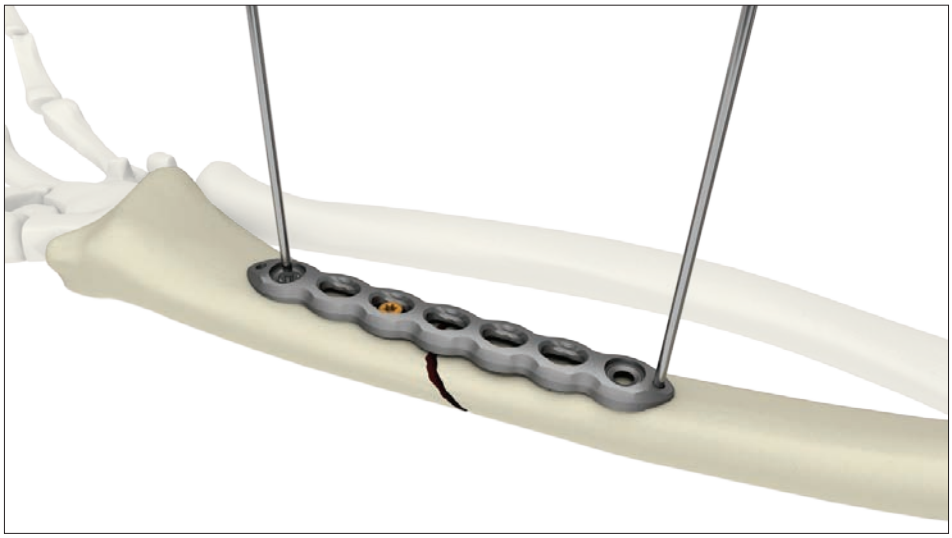
Operative technique

Compression technique

Plate fixation/screw insertion

The plate is centered over the fracture site. Temporary plate fixation can be performed using a K-wire through the K-wire holes in the plate or by using a K-wire with stop (703818) through a circular hole.

The technique shown here uses the ORANGE 3.5mm screws and instruments. A neutral non-locking screw is placed in the plate using the appropriate drill guide and drill. A SpeedGuide may also be used for drilling. This can either be in an oblong hole or a circular hole. If more than one compression step is needed, the oblong hole should be used.

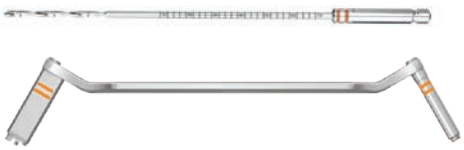


⚠ CAUTION

Do not use a K-wire in a screw hole on the compression side of the fracture if compression is needed.

Once the screw hole is drilled, measure the depth using the depth gauge, a scaled drill, or the gauge on the SpeedGuide. For further information on the SpeedGuide, please refer to the SpeedGuide operative technique. Insert the screw obtaining bi-cortical purchase and fix the plate to the bone.

Depth gauge (705170)



Scaled drill (703691) and drill guide (703882)

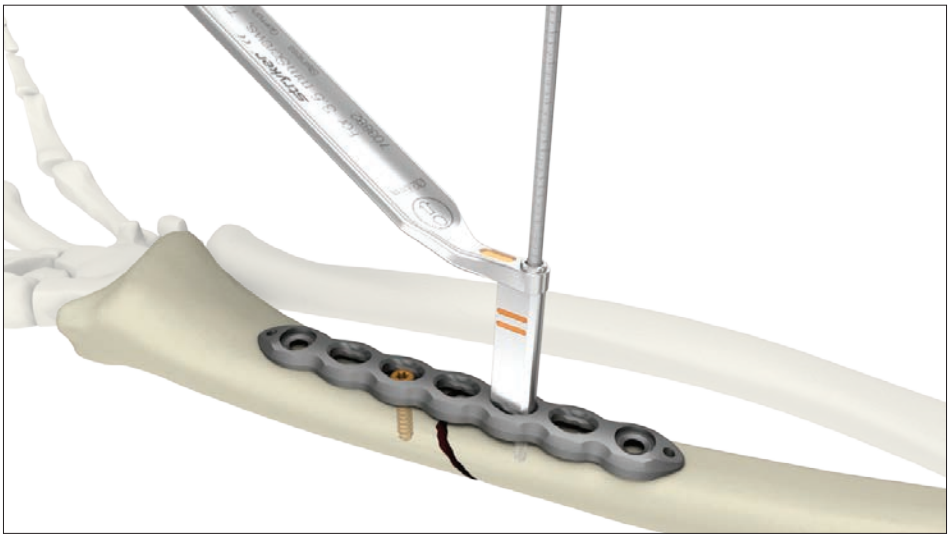
SpeedGuide (703886 guide and 703894 drill)

Depth measurement options for 3.5mm screws

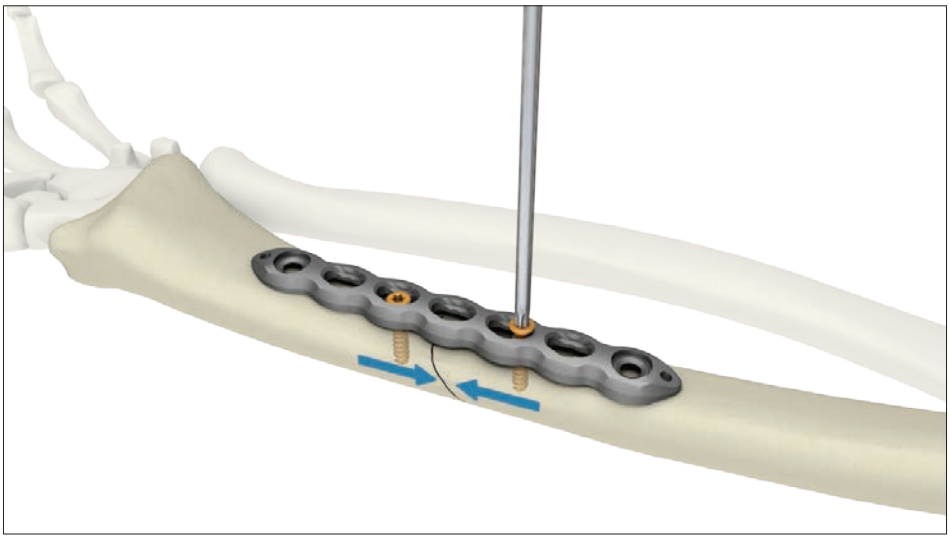
Operative technique

Compression technique

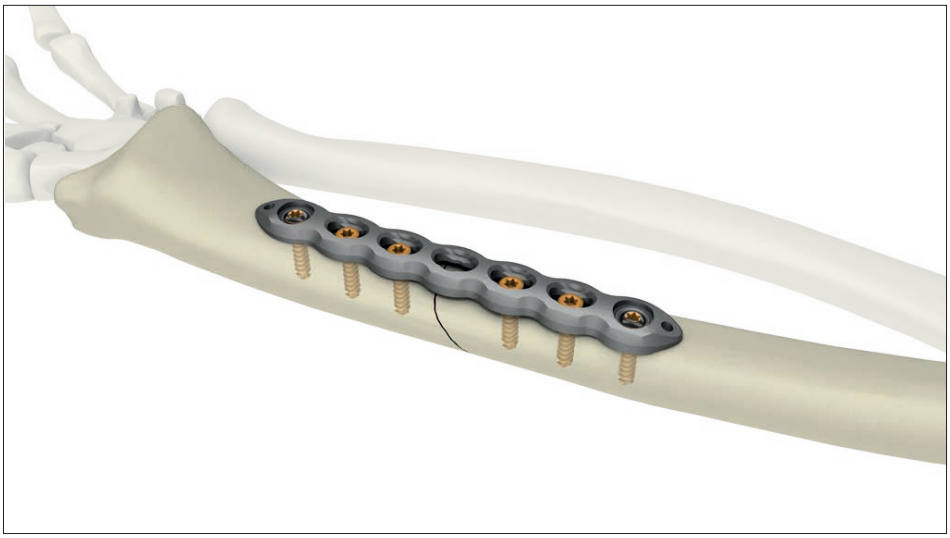
Choose an oblong hole on the opposite side of the fracture to obtain compression. The chosen hole is normally the one closest to the fracture. Use the appropriate compression drill guide (703882 for 3.5mm screws and 703883 for 2.7mm screws), which correctly places the drill hole in the eccentric position. An arrow is etched onto the compression drill guide. This arrow must be aiming toward the fracture line to correctly drill the hole. Measure the screw depth and insert the non-locking screw until fully seated, but prior to firmly tightening the screw, remove any provisional plate fixation on this side to allow for sliding of the plate in relationship to the bone. Then, firmly tighten the screw. The maximum shift per compression hole is approximately 1mm.



If further compression is desired, a compression hole may be used on the initial neutral side of the fracture provided that the initial neutral screw is untightened from the plate before finally seating the final compression screw.



After compression is achieved, the remaining holes of the plate are filled in the neutral position. If desired, locking screws may be filled in the circular holes.



Operative technique

Lag screw and neutralization plating

In addition to the standard drills and drill guides, a number of instruments are also available to perform a lag screw technique both through a plate and independently.

Dedicated overdrills (703694 for 3.5mm screws and 703695 for 2.7mm screws) for each screw size are available for overdrilling the near cortex when placing a lag screw, either through the plate or independently. In addition to being marked with the actual drill diameter on the AO coupling, these overdrills are also marked with a single color ring corresponding to the desired screw diameter. This marking matches the marking on the corresponding side of the lagging drill guide.

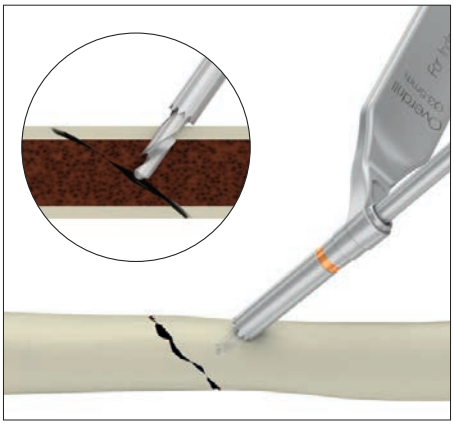
⚠ CAUTION

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.

In order to insert a lag screw independently of a plate, the independent lag screw drill guides (703686 for 3.5mm screws and 703687 for 2.7mm screws) should be used. First, the near cortex should be overdrilled using the side of the drill guide marked with a single color ring to create a gliding hole (Step 1).

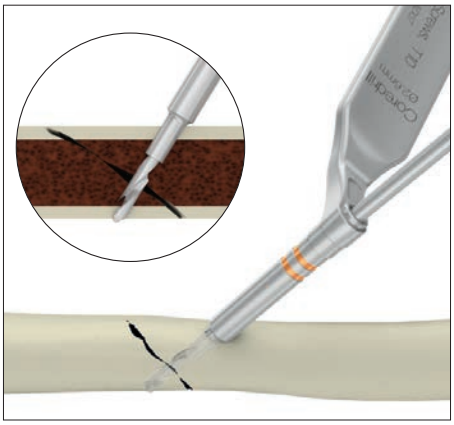
In order to perform a lag screw technique through a T10 plate hole, first use an overdrill and guide to drill the first cortex.

The pilot hole in the second cortex can then be performed with the standard polyaxial drill guide or the 'top–hat' end of the independent lag screw drill guide. Upon screw insertion, this technique will serve to lag the far cortex towards the plate and the near cortex, hence applying compression.



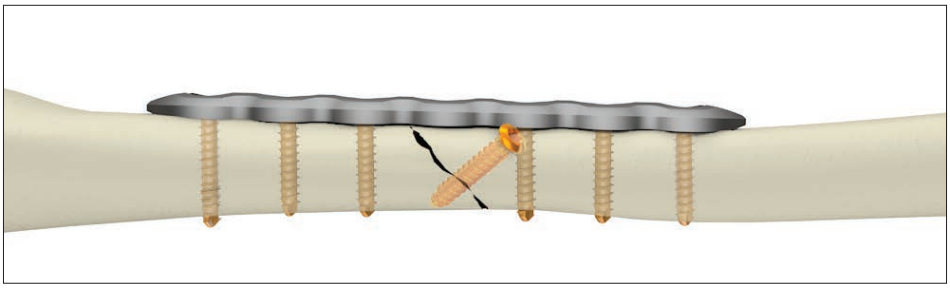
Step 1

3.5mm Overdrill



Step 2

2.6mm Pilot drill

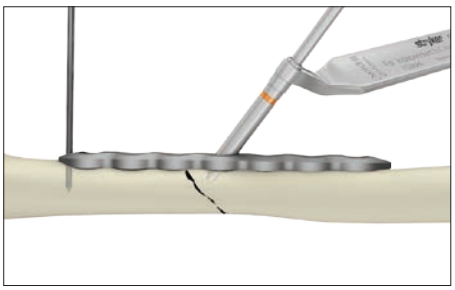


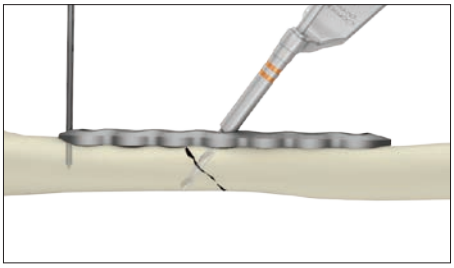
⚠ CAUTION

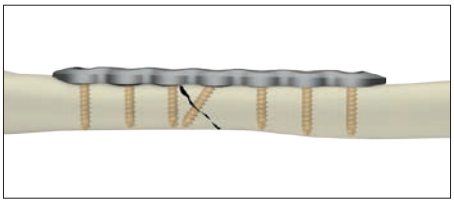
Take care when using the Independent lag screw drill guide for overdrilling through a plate hole as the drill guide's tip or overdrill could damage the plate hole.

The other side of the drill guide can then be used (marked with two color rings) by inserting the 'top–hat' end in the already drilled gliding hole and using the standard drill bit through it to drill through the second cortex (Step 2).

This standard drill is scaled in order to evaluate the appropriate screw length. Upon screw insertion, this technique will serve to lag the far cortex towards the near cortex, hence applying compression.







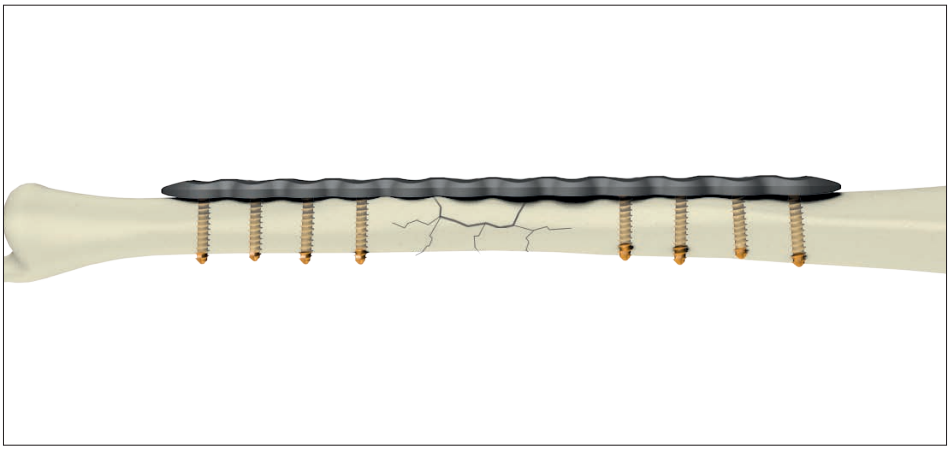
Operative technique

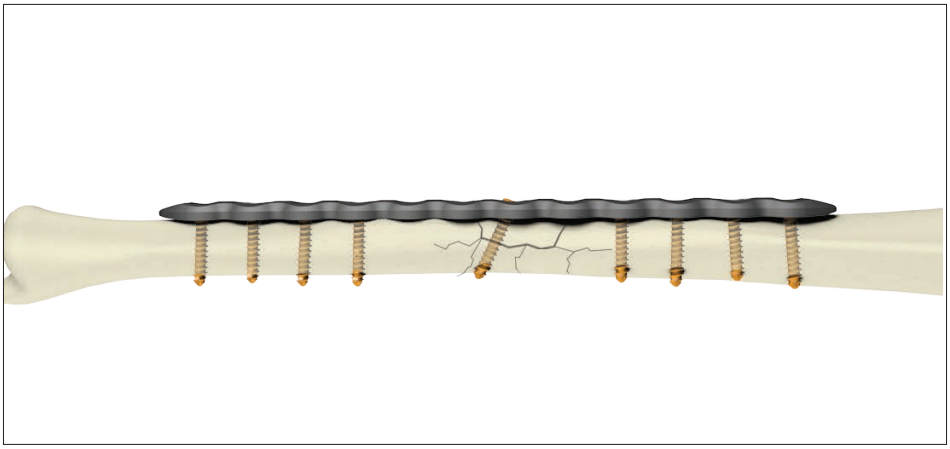
Bridge plating in comminuted fractures

When the fracture is not amenable to compression or lag screws due to a zone of comminution at the fracture site, the bridging technique may be used. Contrary to compression and lag screw techniques which rely on absolute fracture reduction and compression, bridge plating in effect splints the fracture. Length, alignment, and rotation are controlled by the plate, and secondary bone healing consolidates the fracture. In general, longer plates are used in these cases so that proper bridging of the fracture can occur.

Non-locking screws or locking screws may be used or a combination of both. If both screw types are used, ensure that the non-locking screws are inserted before any locking screws.

Normally, the zone of comminution is left undisturbed; however, a surgeon may choose to fixate a larger fragment within the zone to provide more relative stability. Care is taken not to disrupt blood supply.





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.

⚠ CAUTION

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 (703880) to choose from. The self–retaining blade is identified with a 10 symbol and has the word "RETAINING" on the AO coupling interface. Its conical tip helps ensure a friction fit connection with the screw head.

⚠ CAUTION

If power insertion is used, it must be used at low speed. Final tightening of the screw should be performed by hand to avoid damaging the screw-plate interface.

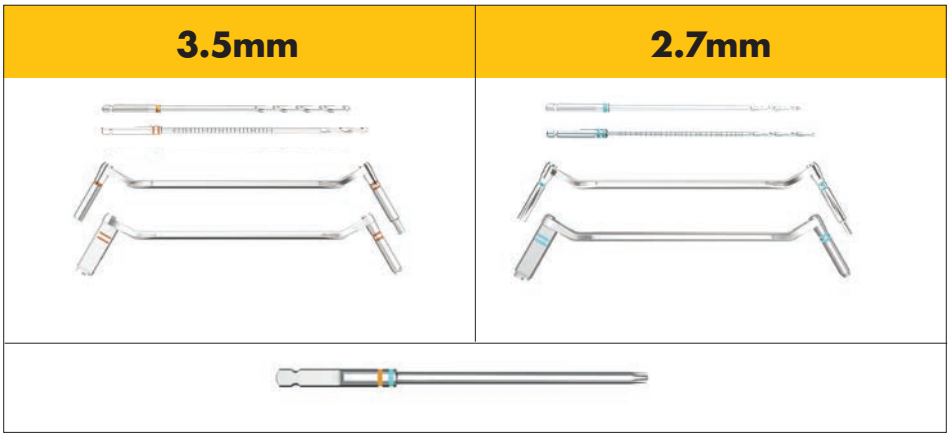
NOTICE

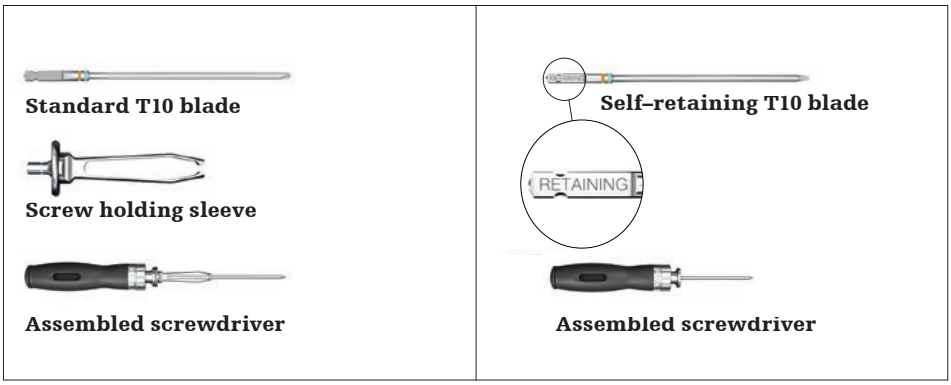
The self–retaining blade cannot be used with the screw holding sleeve.

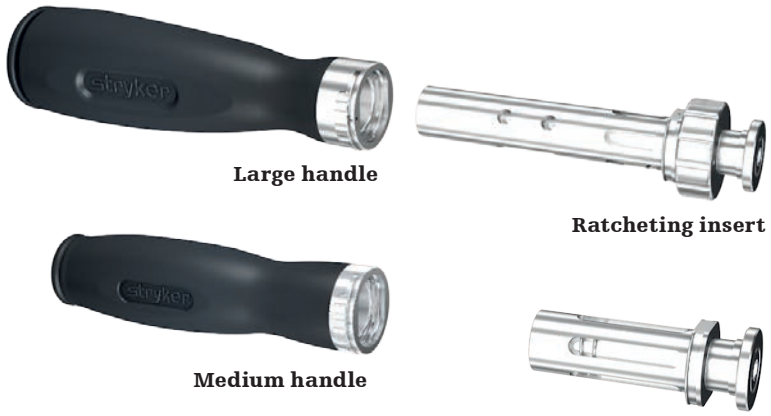
Modular handle

VariAx 2 offers a modular handle system. This is composed of a medium handle grip (703921) and a large handle grip (703920) that can be interchanged with either a bi-directional ratcheting AO-coupling insert (703922) or a standard AO-coupling insert (703923).

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, counterclockwise ratcheting or neutral. To switch between the different modes, simply twist the distal part of the insert to the desired driving direction.

NOTICE

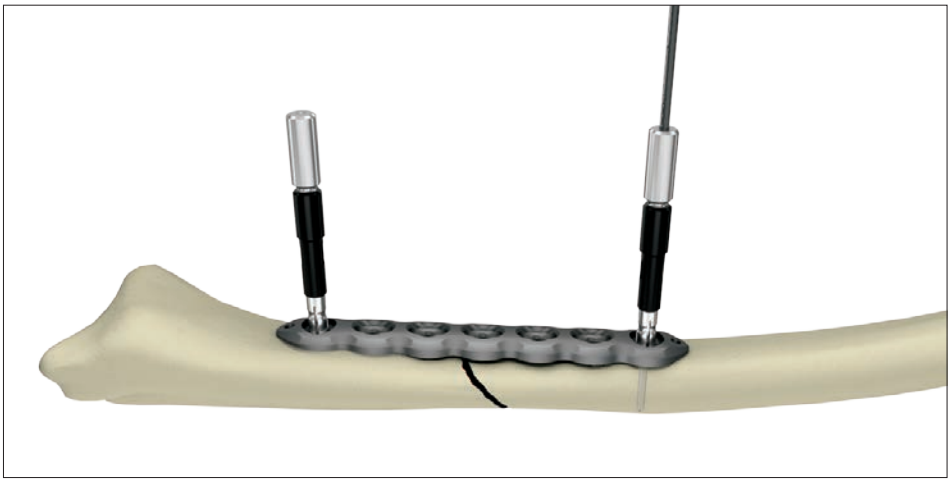
To ensure appropriate ratcheting function, perform appropriate maintenance on the insert by applying medical-grade lubricant oil through the marked cut-outs.

Operative technique

VariAx 2 instrumentation usage

Joystick for plate position & temporary fixation

The joystick for T10 holes (703928) can be used in any circular hole to aid in plate positioning. Additionally, it 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.

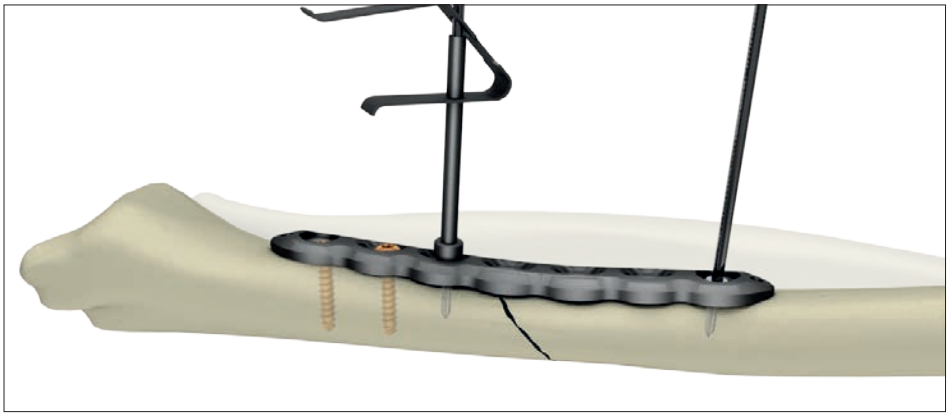
To remove the joystick, simply remove any K-wire and turn the knob counter–clockwise to disengage the tip from the hole.

⚠ CAUTION

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

K-wire with stop and K-wire clamp

The K-wire with stop (703818) can be used in any screw hole or K-wire hole in order to temporarily fix the plate to the bone. The optional K-wire clamp (703716) can be used to additionally secure a plate to the bone by sliding it over a smooth K-wire.



⚠ CAUTION

Do not use a K-wire in a screw hole on the compression side of the fracture if compression is needed.

Operative technique

VariAx 2 instrumentation usage

Depth measurement options

VariAx 2 offers various options to evaluate the screw length. As previously mentioned, all drills are scaled so that the surgeon may evaluate the screw length when using the drill through the dedicated drill guides.

A SpeedGuide is also offered that 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.

Lastly, a standard depth gauge may be used either independently or through a plate hole.

Drill & drill guides

Drill diameter	Drill bit	Drill guide
2.0	703690	703883
2.6	703691	703882

Scaled drill and drill guide

SpeedGuides up to 30mm

Drill diameter	Drill bit	SpeedGuide
2.0	703892	703887
2.6	703894	703886

SpeedGuides

Depth gauge

Taps & countersink

2.7mm and 3.5mm taps (703899 for 2.7mm screws / 703898 for 3.5mm screws) are available in the system.

⚠ CAUTION

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

A countersink (45-80040) is also available for reducing the screw head prominence when the screw is used independently of a plate.

Tap for 3.5mm screws

Countersink

VariAx 2 instrumentation usage

Reduction clamps

The plate holding clamp (703821) helps secure the plate to the bone. The fine toothed portion of the clamp grips the bone surface while the pivoting portion of the clamp holds the plate surface.

The straight reduction clamp (703822) allows the surgeon to apply apposition/compression forces to the fracture on one bone surface while placing the plate on another surface. As seen in the image here, the surgeon drills a 2.0mm hole on either side of the fracture, places the clamp in the drill holes, and then applies the necessary reduction force.

Then, the plate is placed in the usual manner, and the clamp does not interfere with the plate placement.

Plate holding clamp

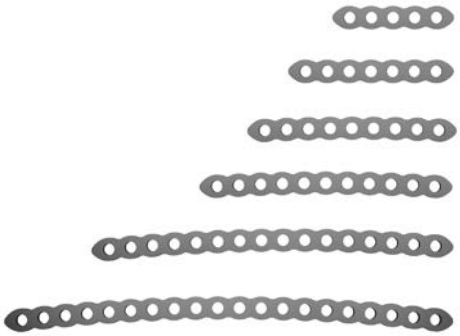
Straight reduction clamp

Lobster & lane bone holding forceps

These forceps (702932 and 703939) are used in the usual manner to reduce the fracture.

Plate trials

Six different lengths of plate trials are offered in order to determine the proper length. The trials come in 5, 7, 9, 11, 16 and 20 hole options. Also, the length in millimeters is marked on each trial as well as each plate and its sterile packaging. The trial design is based on the curved plates; the trials are also used for straight plates.



Trial	Length
5 hole	67mm
7 hole	91mm
9 hole	115mm
11 hole	139mm
16 hole	198mm
20 hole	246mm

Notes:

Notes:

stryker

Trauma & Extremities

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

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

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Manufacturer:

Stryker GmbH
Bohnackerweg 1
2545 Selzach
Switzerland

stryker.com