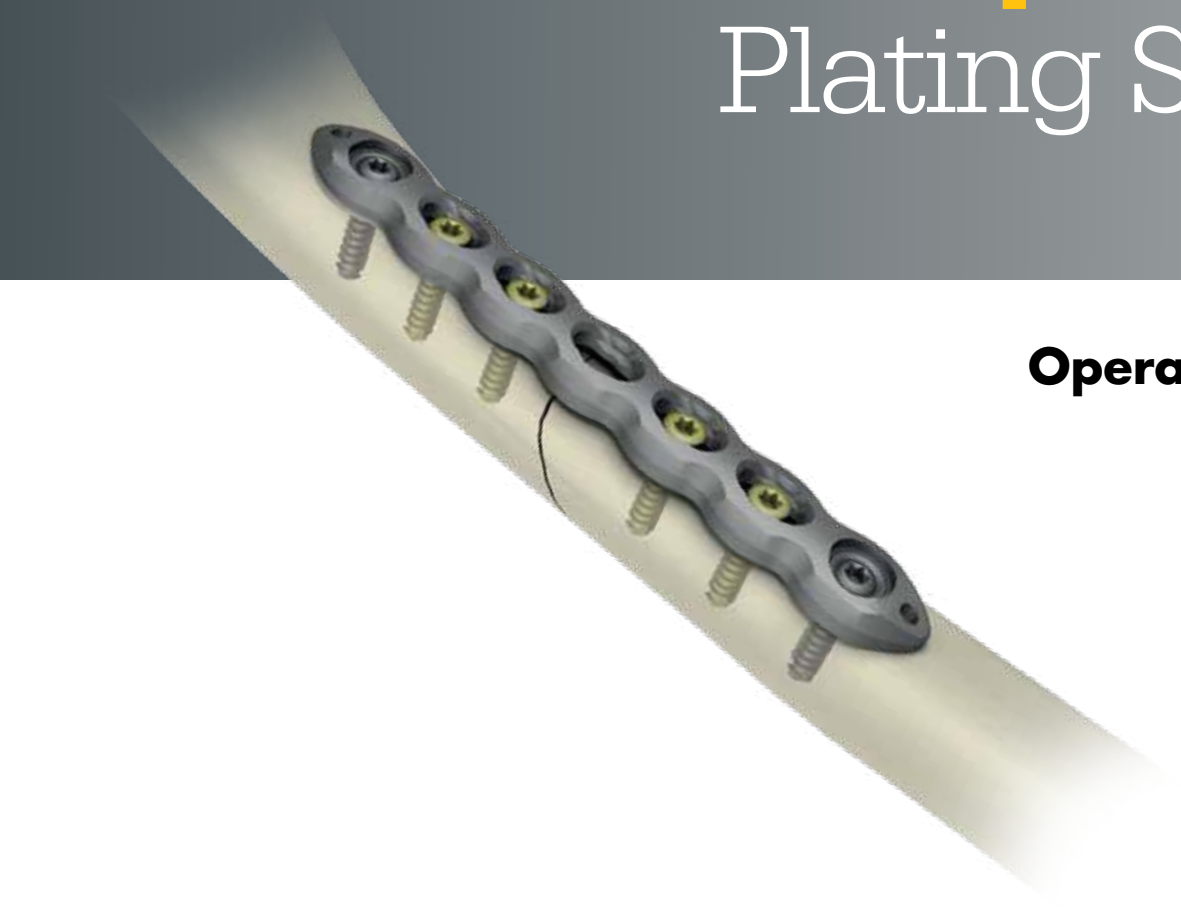
stryker

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.

⚠ 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.

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 SmartLock technology allows the surgeon to lock a screw in any of the circular holes in the plate in a variable angle of 30 degrees.

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

The VariAx 2 Compression Plating System is compatible with the existing VariAx elbow and clavicle systems, which use 3.5 and 2.7mm locking and non-locking screws.

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

Straight Broad Plate

Straight Narrow Plate

Curved Broad Plate

Indications and Contraindications

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 are 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 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 post-operative care
- Other medical or surgical conditions which would preclude the potential benefit of surgery

MRI safety information

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

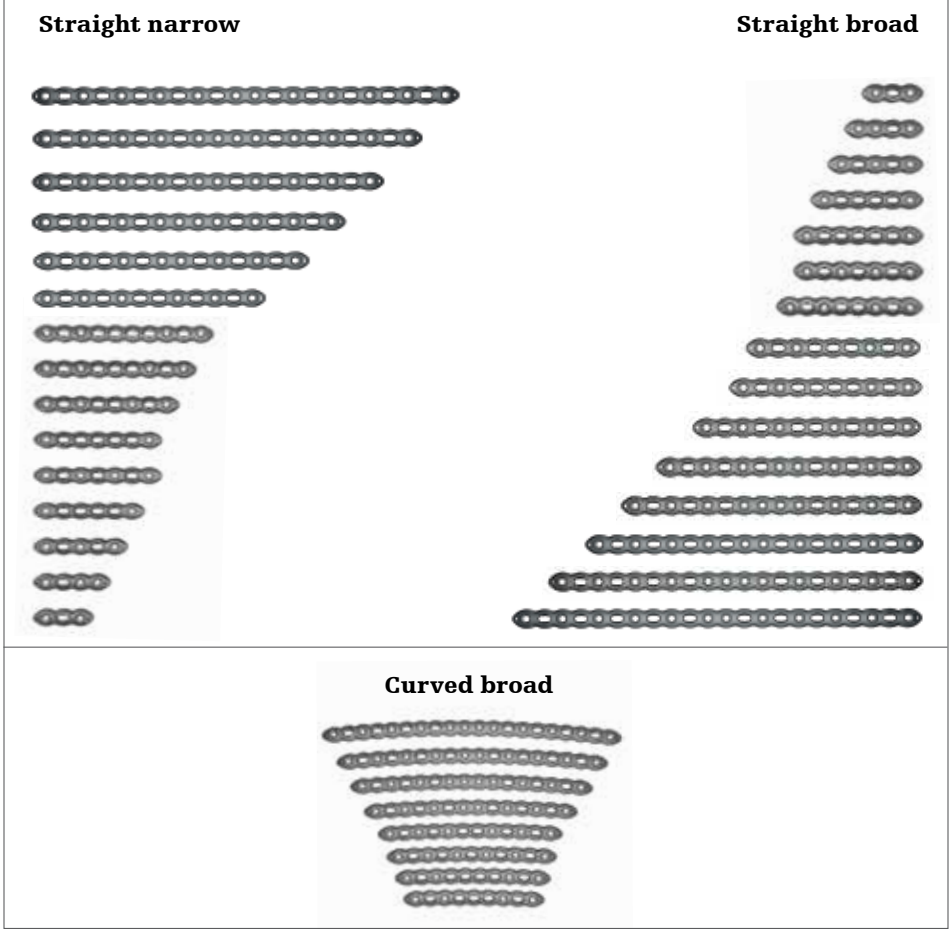
The VariAx 2 Compression Plating System offers narrow straight plates from 3 holes to 22 holes. The broad plates are offered in a straight design from 3 holes to 22 holes and a radial curved design from 9 holes to 20 holes with 2 holes steps from 12 to 20. Also, specific 7-hole plates are designed with additional locking holes in which the surgeon can insert more locking screws if desired.

⚠ CAUTION

Ensure that there are sufficient amount of holes proximal and distal to the fracture to ensure proper fixation.

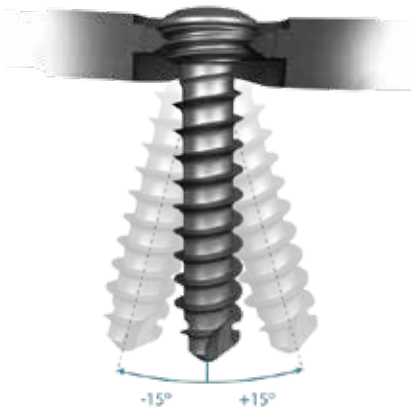
Plate Trials are supplied in order to properly determine the correct length of the plate to be implanted. This is useful when working with sterile packed plates.

Compression plates



SmartLock technology

The polyaxial locking technology works by using two different grades of titanium. When a screw is driven into a plate hole, the locking threads on the underside of the screw engage the circular 'lip' in the hole. This technology allows the surgeon to aim and lock the screw within a 30 degree cone.



Operative technique

Locking or non–locking screws

The circular holes in the locking plates offer an option for locking and non–locking screws.

CAUTION

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

Locking screws are colored silver while non-locking screws are colored gold.

3.5mm or 2.7mm screws

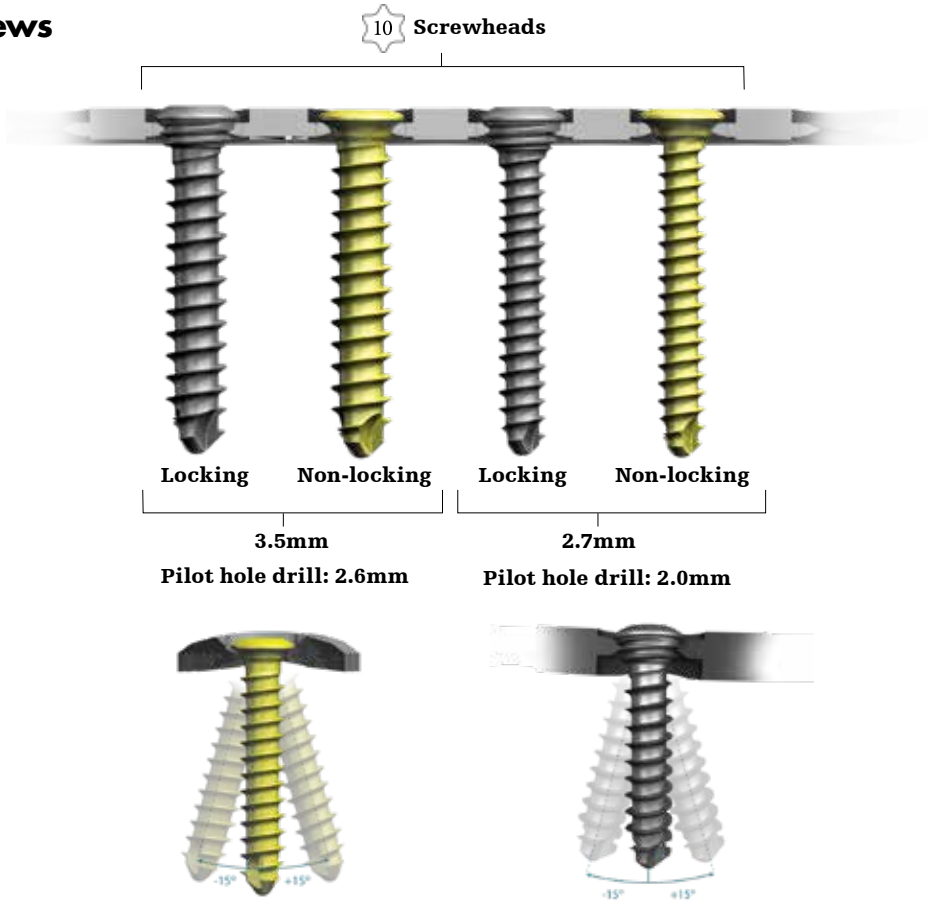
The plates are used with either 3.5mm or 2.7mm screws, giving the choice of screws size based on the anatomy and fracture pattern. Additionally, all screws in the system are inserted with the same T10 screwdriver for ease-of-use.

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.

CAUTION

These angles are controlled by using the appropriate polyaxial drill guide when drilling.



CAUTION

- During bone screw insertion in an oblong hole, the surgeon should rely on tactile feedback to prevent excessive torque which may result in thread/bone stripping, screw damage/pull through, or screwdriver damage.
- Proper observation of bone quality, screw size, and 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.

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

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).

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 through a circular hole.

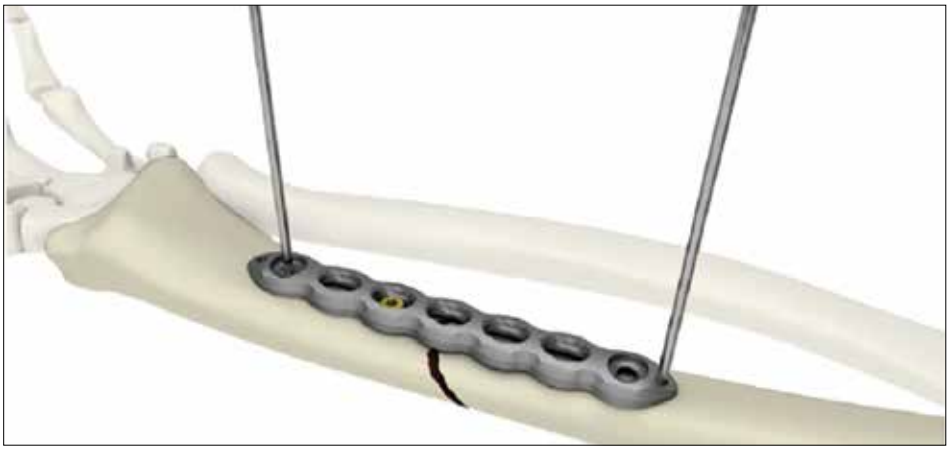
A neutral non-locking screw is placed in the plate using the appropriate drill guide and drill. A SpeedGuide may also be used for drilling. This can either be in an oblong hole or a circular hole. If more than one compression step is needed, the oblong hole should be used.

⚠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 fixing the plate to the bone.

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. A pair of eccentric circles are etched on the compression guide. These circles represent a drill in a hole. The drill guide must be placed in the compression holes so the smaller circle (representing the drill) is furthest away from the fracture line. 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.

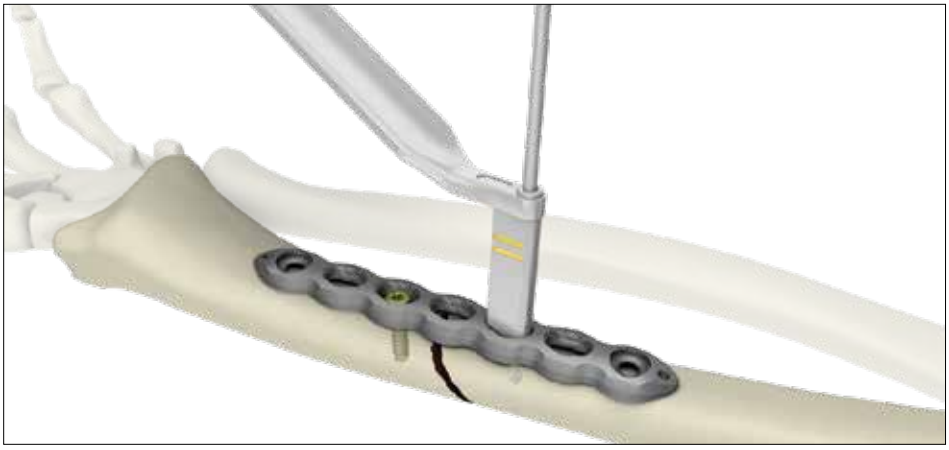


Depth measurement options

Depth gauge

Scaled drill and drill guide

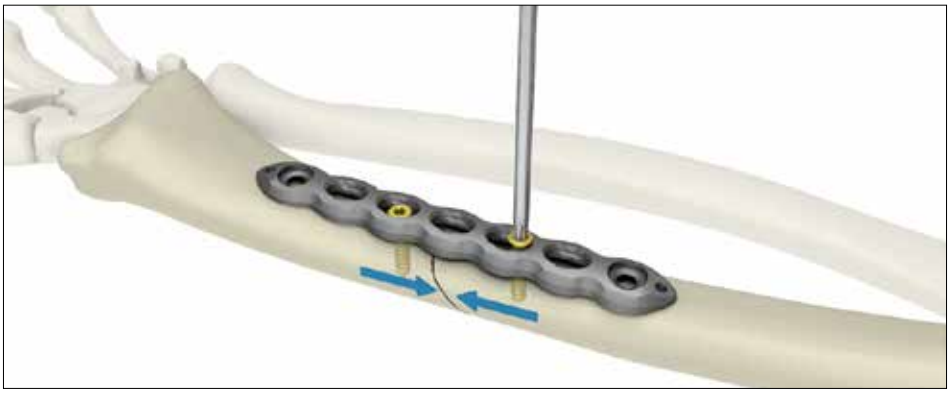
SpeedGuide



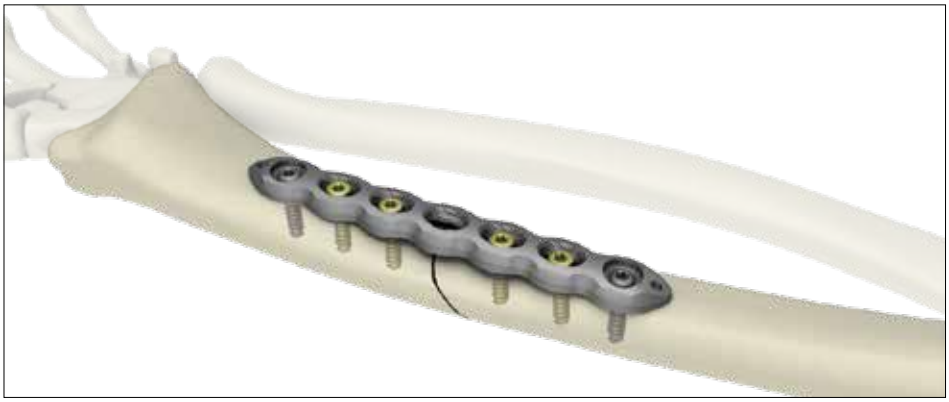
Operative technique

Compression technique

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.



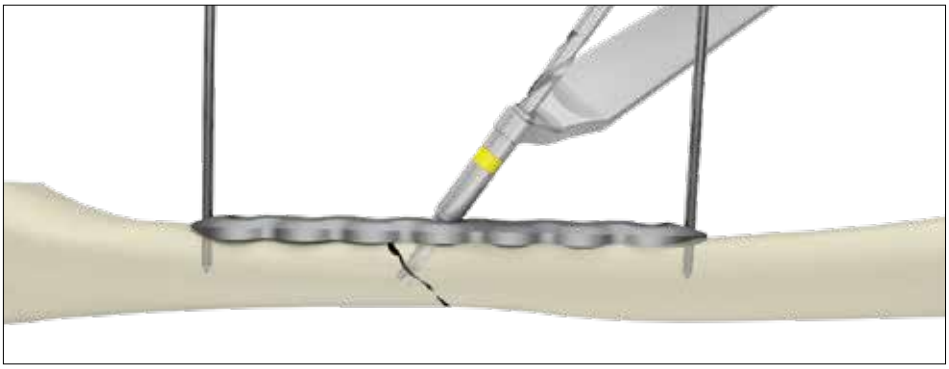
Operative technique

Lag screw and neutralization plating

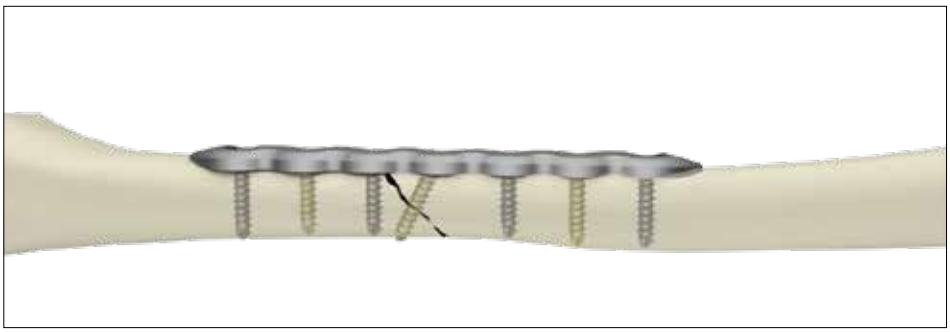
It is an option to place a lag screw across the fracture line if the fracture is amenable to interfragmentary compression. This is usually the case with oblique or spiral fractures. The plate in these cases acts in a neutralization or protection mode since the lag screw or screws alone normally cannot withstand a high degree of axial load.

Depending on the fracture pattern and approach, the lag screw can be placed either independent of the plate or through one of the plate holes near the fracture line. The lag screw may either be placed 90 degrees to the fracture line or placed at the midpoint between perpendicular to the fracture line and perpendicular to the long axis of the bone.

Use the appropriate drill guide for overdrill and pilot hole drilling depending on the screw diameter to be inserted.



Lagging through the plate



⚠ CAUTION

Always match the color ring marking on the drill bit with the color marking on the drill guide.

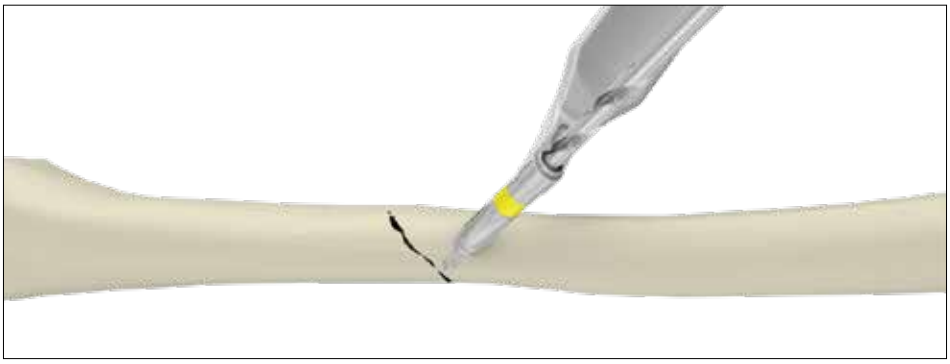
⚠ CAUTION

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

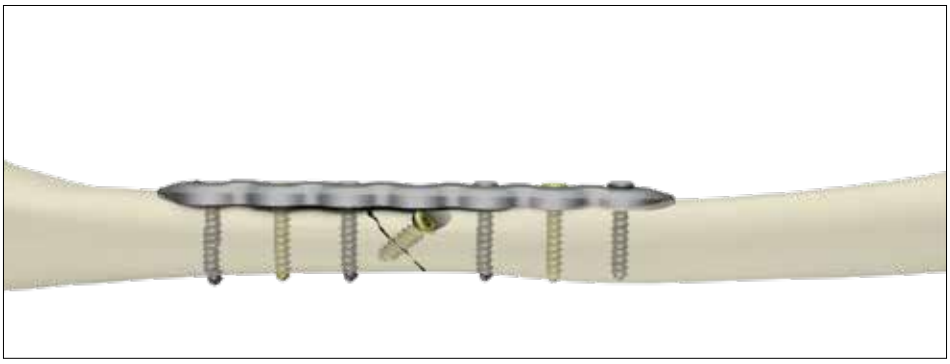
Operative technique

Lag screw and neutralization plating

After the lag screw is seated and compression is achieved, the plate in this case acts to neutralize the axial forces acting upon the fracture. The compression mode of the plate is no longer needed. The plate may be fixed with non-locking and locking screws if desired.



Lagging outside the plate



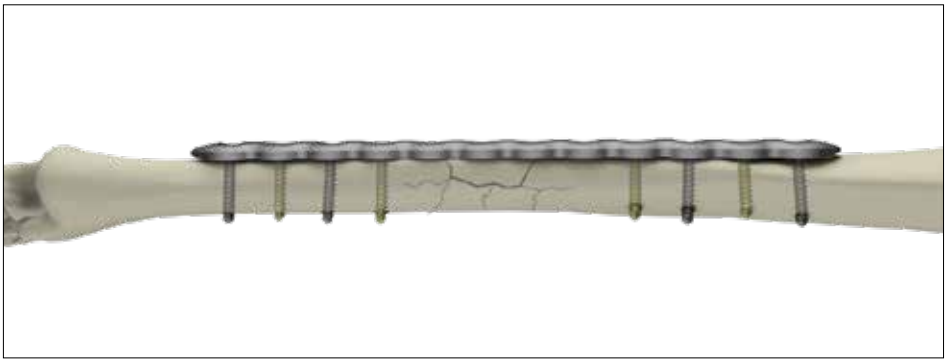
Operative technique

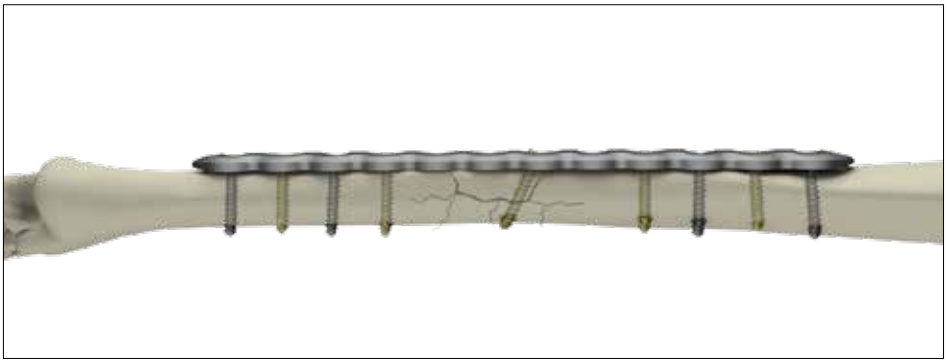
Bridge plating in comminuted fractures

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 to allow for proper bridging of the fracture.

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 instrumentation usage

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

NOTICE

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

The optional cylindrical blade is identified by the yellow and black color code. Its cylindrical tip does not allow friction fit self-retention of the screw. This is designed for surgeons who prefer to use a screw holding sleeve. The screw holding sleeve is also coded with yellow and black.

All blades come with an AO adapter. Also, it is important to insert the screws until the head is properly seated in the hole.

⚠ CAUTION

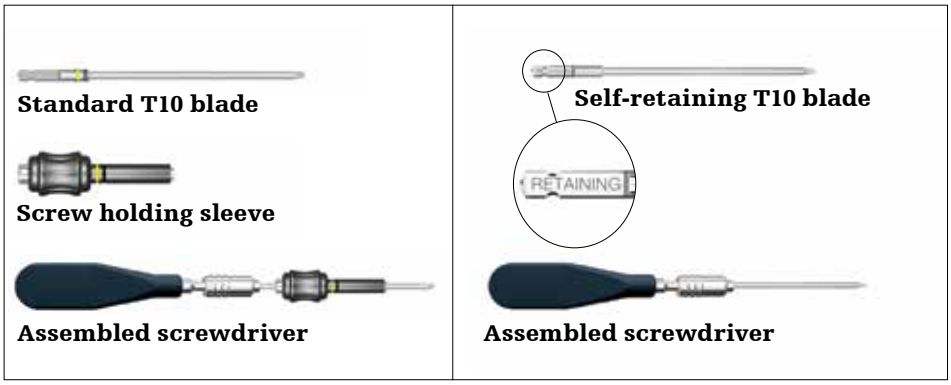
- With the use of variable speed power systems, the surgeon should initially reduce the power to the lowest setting.
- The power level may then be increased until appropriate cutting performance is achieved.
- Final tightening of the screw should be performed by hand to avoid damaging the screw-plate interface.

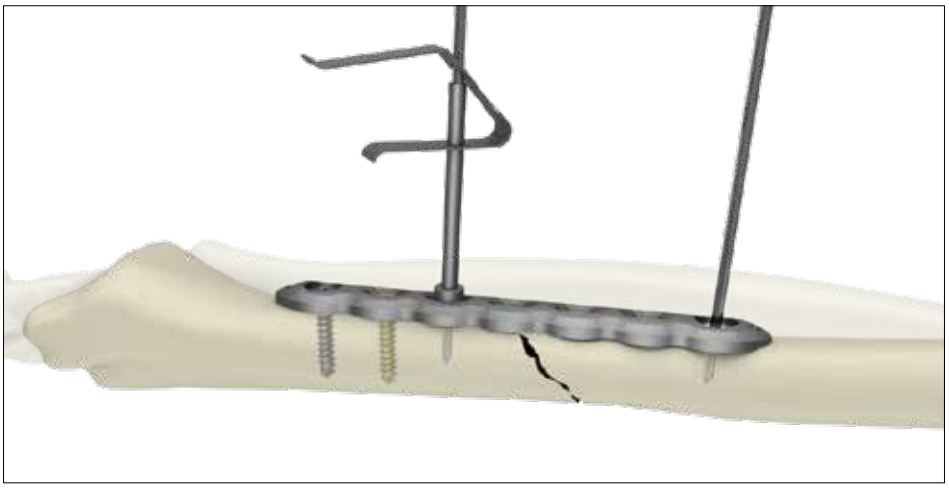
K-wire with stop and K-wire clamp

The K-wire with stop 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 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.



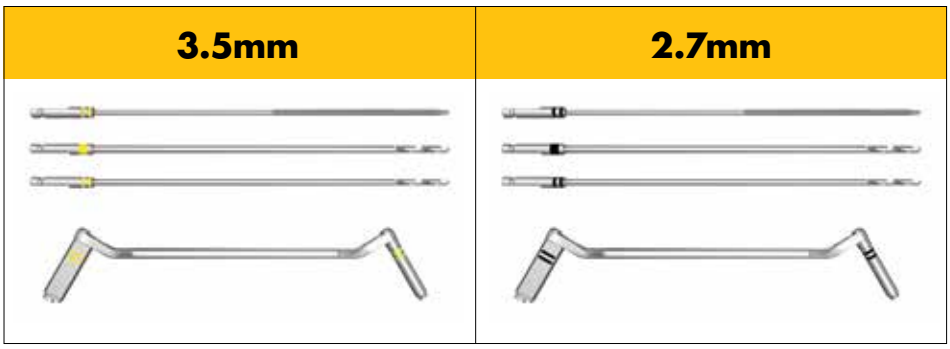


Color coding system

Color coding of the screws and appropriate instruments helps identify the components during surgery.

⚠ CAUTION

Always match the color ring marking on the drill bit with the color marking on the drill guide.



Operative technique

Taps & countersink

2.7mm and 3.5mm taps 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 is also available for reducing the screw head prominence when the screw is used independently of a plate.

Countersink for T8/T10 screws

Tap for 3.5mm screws

Tap for 2.7mm screws

Reduction clamps

The plate holding clamp 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 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 bone holding forceps

These forceps are used in the usual manner to reduce the fracture.

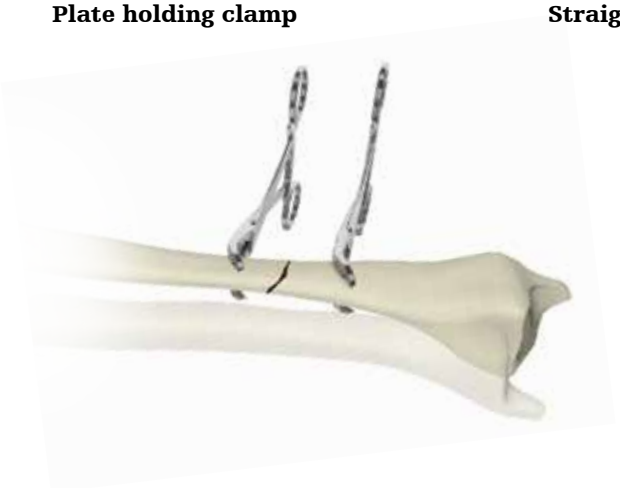


Plate trials

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

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 product label and/or Instructions for Use, including the instructions for Cleaning and Sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The Instructions for Use, Operative Techniques, Instructions for Cleaning, Sterilization, Inspection and Maintenance (OT-RG-1), Patient Information Leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com.

If saving the Instructions for Use, Operative Techniques and the Instructions for Cleaning, Sterilization, Inspection and Maintenance from the above mentioned websites, please make sure you always have the most up to date version prior to use.

This document is applicable to US and Canada.

Content ID: VAX-ST-6_Rev-6, 02-2022

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