



stryker®

Trauma & Extremities

VariAx® 2 Wrist Fusion

Locking Plate System

Operative Technique

- Wrist Fusion Plates
- Locking and Non-Locking Screws
- VariAx 2 Instrumentation

Stryker Plating



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 (L24002000). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling.

See 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.

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Introduction

Although wrist fusion is a relatively rare indication, it may be an effective treatment for chronic wrist joint pain. The VariAx 2 Wrist Fusion System is a range of titanium plates which are contoured to bridge the radius and metacarpal bones to allow for stable fixation during fusion osteosynthesis. The plating system uses the VariAx 2 screws and instrumentation platform which includes variable-angled locking and non-locking screws. Made of titanium and treated with a Type II anodization, these plates are designed to carry the loads that are required of them while remaining low profile.

The following pages contain a step by step operative technique which illustrates this locking plate system including the system instrumentation.



Indications, Contraindications & Precautions

Indications

The Stryker VariAx 2 Wrist Fusion System is indicated for wrist arthrodesis and fixation of fractures in patients with wrist arthritis or fractures of other small bones of the carpus.

Specific indications include:

- Post-traumatic arthritis of the joints of the wrist
- Rheumatoid wrist deformities requiring restoration
- Complex carpal instability
- Post-septic arthritis of the wrist
- Severe unremitting wrist pain related to motion
- Brachial plexus nerve palsies
- Tumor resection
- Spastic deformities

Precautions

Stryker systems have not been evaluated for safety and compatibility in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

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 about the affected area
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and/or fixation of the devices
- Material sensitivity, documented or suspected
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself
- Patients having inadequate tissue coverage over the operative site
- Implant utilization that would interfere with anatomical structures or physiological performance
- 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

Operative Technique

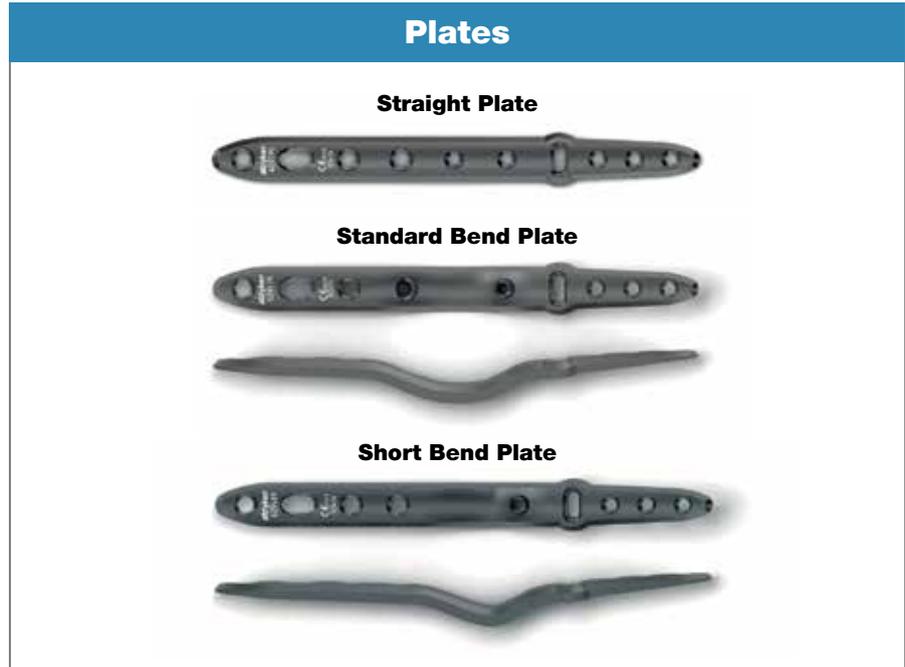
Plate Choice

The VariAx 2 Wrist Fusion System offers 3 types of plates from which to choose: Standard Bend Plate, Short Bend Plate, and Straight Plate.

The bended plates contain 4 proximal holes for distal radius fixation and 4 distal holes for metacarpal fixation. Within the bend of the plate, there is an additional hole for capitate fixation.

The straight plate is also designed with 4 proximal and distal holes; however, there are 2 additional holes located centrally for carpal fixation.

Plate Trials may be provided to determine the proper plate to be implanted. This may be particularly useful when using sterile-packed plates.



Screw Choice

For all plates, the distal radius holes are to be filled with 3.5mm (Orange). For the carpal and metacarpal holes, 2.7mm (Purple) or 2.4mm (Blue) screws are to be used.

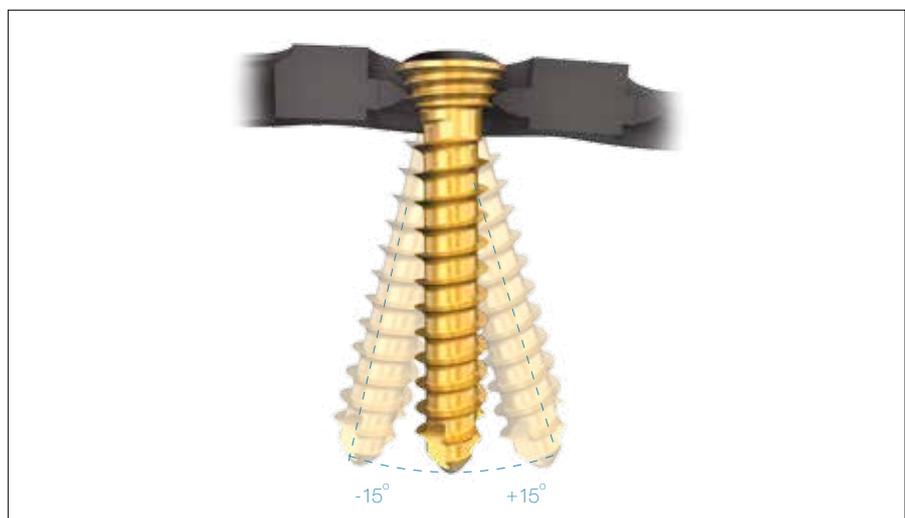
The circular holes in the plates provide an option for locking and non-locking. In order to distinguish a locking screw from a non-locking screw, the top of the locking screw heads are laser marked with a black circular ring and inner dot as shown here.



SmartLock Locking Technology¹

The polyaxial locking technology works by using two different grades of titanium. Locking screws are made of titanium alloy (Ti6Al4V) which is stronger than the pure titanium plate. When a screw is driven into a plate hole, the locking threads on the underside of the screw head engage the circular 'lip' in the hole.

This technology allows the surgeon to aim and lock the screw within a 30° cone.



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

Operative Technique

Temporary Plate Fixation

The fusion site is prepared using the surgeon's technique of choice. The T10 Joystick (703928) may be placed on the proximal locking hole to help aid in the placement of the plate. As the joystick is cannulated, a 1.6mm K-Wire (390164) may be inserted through the joystick to temporarily fixate the plate to the bone. Alternatively, a 2.0mm K-Wire with Stop (703818) may be placed in a locking hole to achieve temporary plate fixation.



Initial Proximal Screw Fixation

The proximal oblong hole is filled with a non-locking 3.5mm screw. The screw may be placed either in the compression mode or neutral mode by using the appropriate end of the T10 Compression/Polyaxial 2.6mm Drill Guide (703882) and 2.6mm scaled drill bit (703691). After drilling, the hole is measured, and the appropriate screw length is chosen. At this step of the procedure, the screw is not fully seated if the screw is placed in the compression mode.



Distal Screw Fixation

The distal oblong hole is drilled in the neutral position using the T8 2.0mm Compression/Polyaxial Drill Guide (703684) and 2.0mm scaled drill bit (703896). After drilling, the hole is measured, and the appropriate screw length is chosen. A non-locking screw is inserted, but not fully seated. At this point the hand may be rotated for proper alignment. Once proper plate/ bone alignment is achieved, the screw is fully seated and the remaining distal screws are inserted.



Operative Technique

Final Proximal Screw Fixation

If the proximal screw in the oblong hole has been placed in the compression mode, axial compression may now be achieved by fully seating the screw in the plate.

After final tightening of the screw in the oblong hole is completed, the remaining proximal screw holes are filled.



Carpal Fixation Screw

After fixation of the distal and proximal screws is completed, the carpal screw in the plate may be filled. The contoured plates are designed with 1 carpal screw hole, while the straight plate is designed with 2 carpal holes. Once fixation is achieved, the construct is complete.



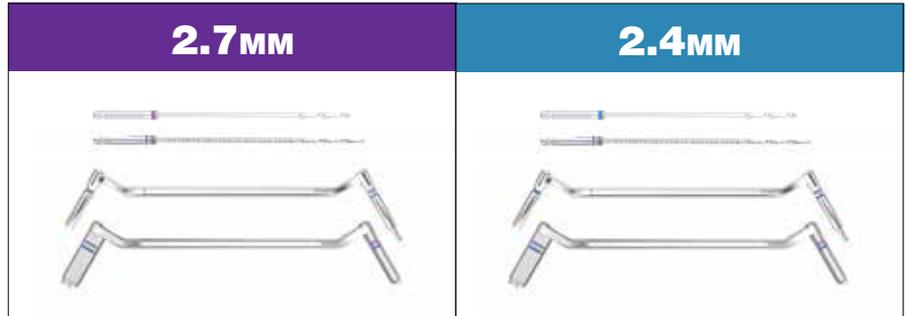
VariAx 2 Instrumentation

Color Coding System

Color coding of the screws and appropriate instruments may help identify the components during surgery as the color identifies the screw diameter. All instruments having the Orange color code are used with the T10 3.5mm screws, all of the Purple/Blue colored instruments are used with the T8 2.7mm and 2.4mm screws. Additionally, all drills are laser marked with the corresponding drill diameter.

Note:

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



Modular Handle

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

Both handle sizes are equipped with a spin-cap to allow insertion using a two-finger technique. In order to disengage the insert from the handle, push down on the button on the distal part of the handle and pull the insert away from the handle.

Note:

The inserts must be removed from the handles before cleaning.

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



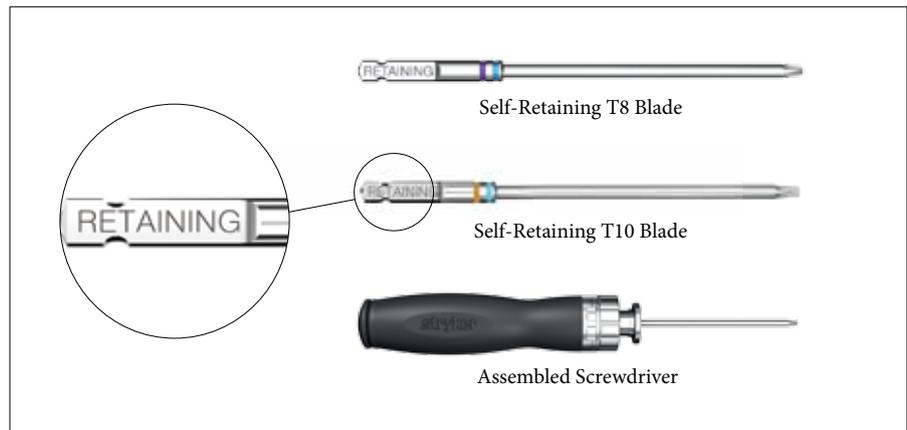
Note:

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

VariAx 2 Instrumentation Usage

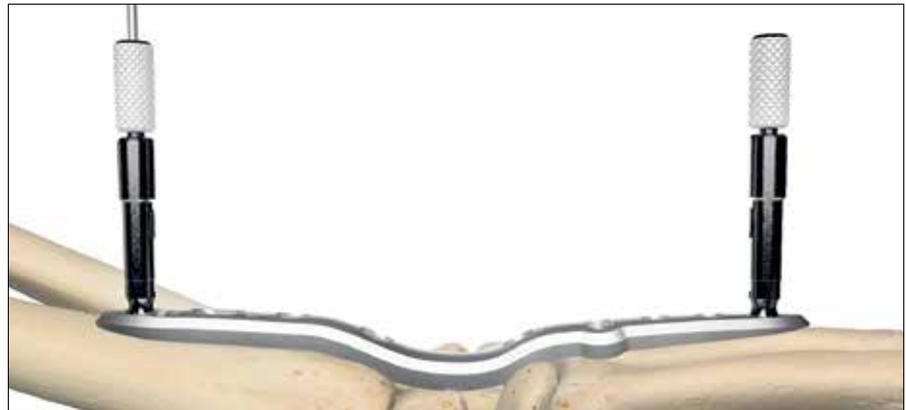
Self-Retaining Screwdriver Blades

The system also has self-retaining screwdriver blades. The self-retaining blade is identified with a symbol and has the word “RETAINING” on the AO coupling interface. Its conical tip helps ensure a friction fit connection with the screw head.



Joystick for Plate Position & Temporary Fixation

The Joystick is available for either T10 or T8 holes. They may be used in any respective T10 or T8 circular hole to aid in plate positioning. Additionally, they may 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.



Note:

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

Plate Contouring

The VariAx 2 plates are precontoured to assist in the placement of the plate to the fusion site.

The plates are pre-contoured to fit to a range of anatomies. Although not usually necessary, the plates may be contoured to adapt to individual patient anatomy.

Design requirements are strict when it comes to shaping a plate. For example, the surgeon should avoid sharp bends, reverse bends or bending the device at a screw hole as this may weaken the plate.



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 (705170) may be used either independently or through a plate hole.

Drill & Drill Guides

Drill Diameter	Drill Bit	Drill Guide
2.0	703896	703684
2.6	703691	703882



Scaled Drill and Drill Guide

SpeedGuides up to 30mm

Drill Diameter	Drill Bit	SpeedGuide
2.0	703891	703888
2.6	703894	703886



SpeedGuides



Depth Gauge

VariAx 2 Instrumentation Usage

Taps & Countersink

2.4mm (703900), 2.7mm (703899) and 3.5mm (703898) taps are available in the system. Although all screws are self-tapping, it is recommended to use a tap if excessive resistance is felt during screw insertion or if the bone is dense.

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

Notes

Notes

Notes

Reconstructive

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Manufactured by:

Stryker GmbH
Bohnackerweg 1
2545 Selzach
Switzerland

www.stryker.com