

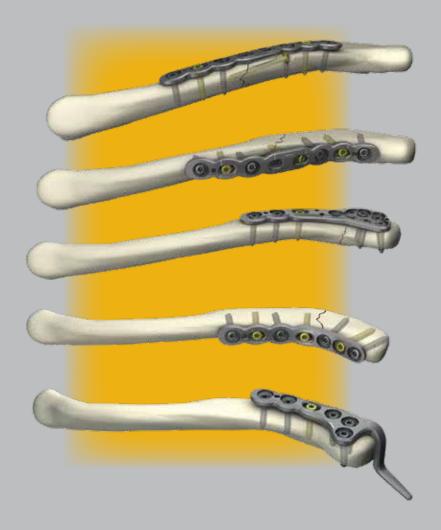


Trauma & Extremities

VariAx[®] Clavicle Locking Plate System

Operative Technique

- Superior Midshaft Plates
- Anterior Midshaft Plates
- Superior Lateral Plates
- Anterior Lateral Plates
- Lateral Hook Plates



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This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

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

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.

- 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.

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

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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.

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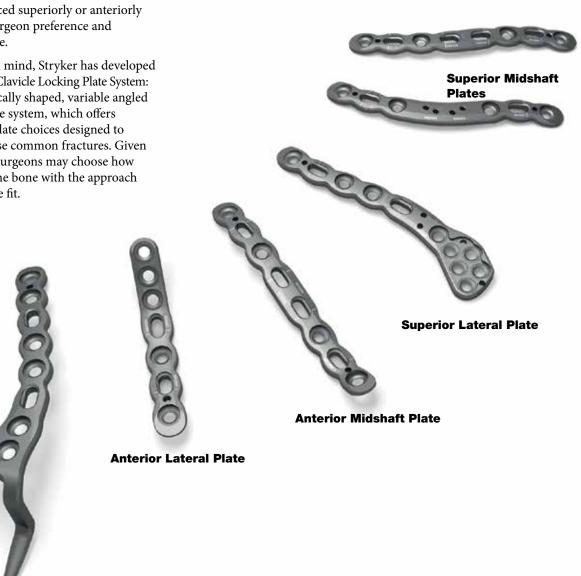
Introduction

Clavicle fractures have long been treated non-operatively. However, studies have shown that fractures with comminution and/or significant displacement may be better served with surgical intervention¹. Nevertheless, the distinct anatomic shape of the clavicle poses difficulties for stable fixation and anatomic fit with conventional plating systems including midshaft and lateral fractures, malunions, and non-unions. Also, the clavicle may be stabilized either with fixation placed superiorly or anteriorly based on surgeon preference and fracture type.

With this in mind, Stryker has developed the VariAx Clavicle Locking Plate System: an anatomically shaped, variable angled locking plate system, which offers a range of plate choices designed to address these common fractures. Given this range, surgeons may choose how best to fix the bone with the approach that they see fit.

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 while remaining low profile. Additionally, if locking is required, the 3.5mm and 2.7mm locking screws can be locked within a 30° cone in any circular plate hole.

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



Lateral Hook Plate

1. Nonoperative Treatment Compared with Plate Fixation of Displaced Midshaft Clavicular Fractures. A Multicenter, Randomized Clinical Trial Canadian Orthopaedic Trauma Society J Bone Joint Surg Am. 2007;89:1-10. doi:10.2106/JBJS.F.00020

Indications and Contraindications

Indications

Superior Midshaft & Lateral Plates and Anterior Midshaft & Lateral Plates

Indicated for fixation of single, segmental, and comminuted fractures, osteotomies, mal-unions, and non-unions of the clavicle.

Lateral Hook Plates

Indicated for fixation of lateral clavicle fractures, osteotomies, mal-unions, non-unions and dislocations of the acromioclavicular joint.

Contraindications

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.

The VariAx Clavicle Locking Plate System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the VariAx Clavicle Locking Plate System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

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.

System Overview

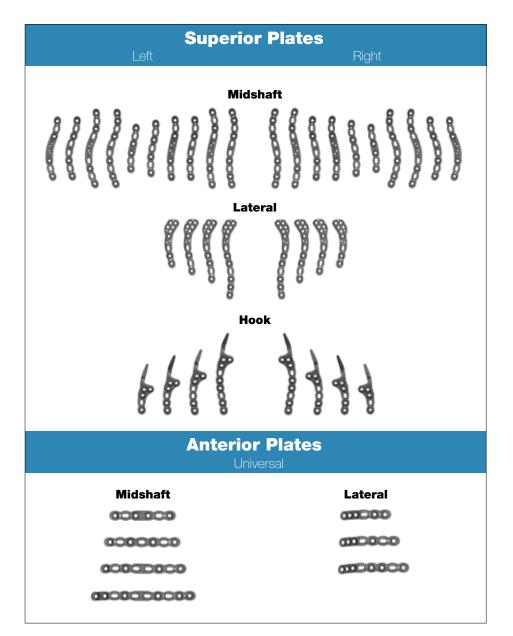
Implant Choice

Surgeons may choose to treat clavicle fractures with plates either with a superior approach or an anterior approach.

The VariAx Clavicle System offers a range of midshaft and lateral plates which are anatomically contoured to the superior or anterior surface of the bone. Additionally, the surgeon has a choice of different plate curvatures designed to fit various anatomies. Finally, these plates accept either 3.5mm or 2.7mm nonlocking or locking screws.

Implant Shape

The 3-dimensional anatomy of the clavicle is complex and varies from person to person. Stryker uses a CT Scan Database of clavicles of different size, gender, and ethnicity to design plates which are 3-dimensionally contoured.

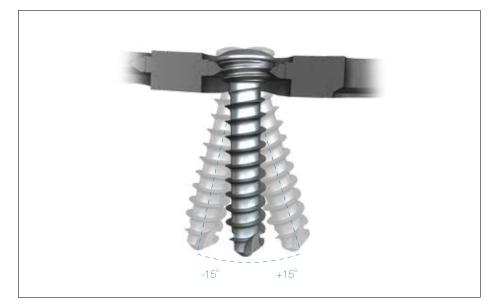


System Overview

SmartLock Locking Technology

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 holes. 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° cone. For example, this may be helpful for fixation using the superior lateral plates, where the screw trajectory in the expanded lateral clavicle fragment can be chosen.



Type II Anodization

The plates are processed with a Type II Anodization treatment.

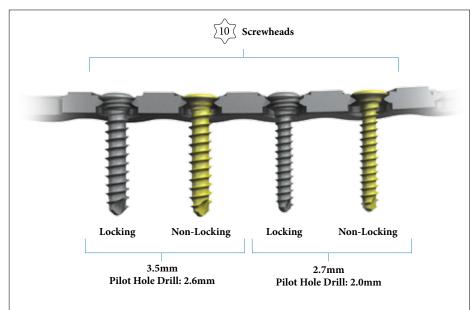
Locking or Non Locking Screws

The circular holes in the locking plates provide an option for locking and non-locking screws.

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.



Operative Technique²

Examination, imaging, and patient positioning is done in the same manner for both superior and anterior plating as well as for midshaft and lateral fractures.

Examination/Imaging

The overlying skin and soft tissues are examined for deficits, old scars, or previous incisions. The length of the injured clavicle is measured from the sternoclavicular joint to the acromioclavicular joint, and compared to the opposite uninjured side both clinically and radiographically.

A carefully documented neurovascular examination of the upper extremity is performed to document any preoperative injury. Anteroposterior and 20° cephalad upshot views of the clavicle are obtained to assess fracture configuration.

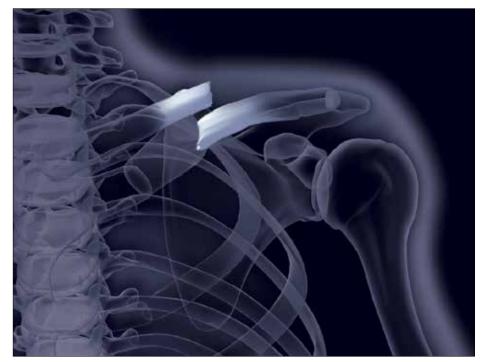
After implantation, final radiographs are taken to ensure accurate fracture reduction and screw/plate placement.

Patient Positioning

Use of a general anesthetic is preferred. The patient is placed in the beach chair position using a footboard to support the weight of the body and cushioned safety straps over the knees to prevent knee flexion. A small bump is placed under the posteromedial aspect of the shoulder girdle. The clavicle is prepared and draped using a laparotomy drape with the arm at the side. The operative arm may be free draped, but this is not typically necessary.

A bump under the shoulder girdle will aid in fracture reduction, as it allows the shoulder and lateral fragment to lateralize or "fall away" from the fracture site.

Positioning the head and endotracheal tube away from the operative site will allow greater access to the clavicle in the case of midshaft fractures. Tape across the forehead may be used to further stabilize the head position.



An anteroposterior radiograph of a completely displaced midshaft clavicle fracture with significant displacement and rotation at the fracture site

For an anterior approach, an alternative position may be used. The patient is placed supine on a radiolucent table.

A small towel bump is placed between the scapulas to provide length to the clavicles.

The clavicle and involved extremity are prepped and draped using split sheets. An impervious stockinet is used the wrap the involved extremity. An arm board is placed on the side of the bed to support the arm.

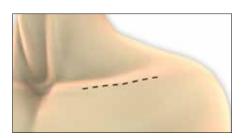
2. Portions of this operative technique are referenced from the following: Hall JA, McKee MD, Open reduction and plate fixation of displaced clavicle fractures, in "Orthopaedic Trauma Surgery: Operative Techniques", Schemitsch EH, McKee MD, eds, Chapter 1, pp 3-11, Saunders/ Elsevier, 2010, Philadelphia

Superior Midshaft Technique³

Portals/Exposures

The clavicle is exposed along the anterosuperior subcutaneous border. A 5 to 10cm incision is centered over the fracture site. As surgeons' experience improves, smaller incisions may be possible and preferred.

If noted, superficial branches of the intermediate supraclavicular nerve are identified and protected.



Implant Choice/Fracture Reduction

The VariAx system offers plates and screws in various shapes and sizes. The chart here shows the plate contours, lengths, and hole configurations as well as the screw diameters and types.

6 and 8 Hole Bridge Plates as well as standard 8 and 10 Hole Plates are designed in two different contours: decreased and increased curvature to accommodate different medial to lateral curvatures. All superior plates are curved to adapt to the AP bow of the clavicle.

The Bridge Plates are designed with suture holes which may be used to help reduce and hold comminuted fracture fragments.

All superior midshaft plates are marked with "Lat" and "Med" to indicate the standard fit of the plate. However, the surgeon may turn the plate 180° as needed for proper plate/bone fit.

Last, the system offers 3.5mm and 2.7mm locking and non-locking screws. Both screw diameters have the same screwhead diameter, which allows the surgeon to place either screw in the same plate hole.

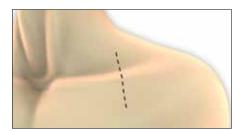
The skin edges are undermined in the subcutaneous plane to facilitate a mobile window of exposure. The fascia and periosteum are often disrupted, and this defect is extended medially and laterally to create anterior and posterior soft tissue flaps for fracture visualization.

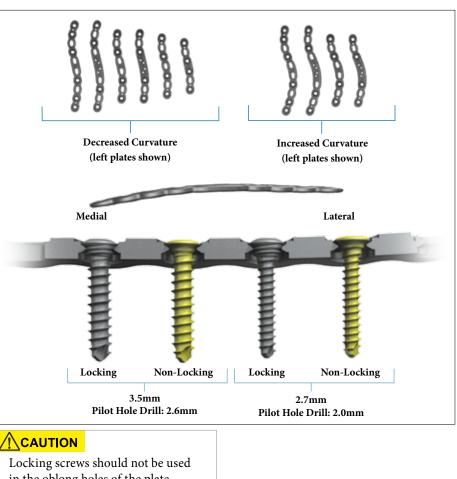
Any dissection that is required inferior to the clavicle must be done very carefully due to the proximity of the neurovascular structures.

A superior subcutaneous approach to the clavicle allows for fracture visualization without significant soft tissue dissection.

A two-layer exposure allows for a two-layer closure, providing greater soft tissue coverage of the hardware and fracture.

An alternative to this transverse incision is a vertical incision over the fracture site along Langer's lines.





in the oblong holes of the plate.

3. The superior midshaft technique was written with guidance from Professors Michael McKee and Emil Schemitsch

Superior Midshaft Technique

Implant Choice/Fracture Reduction

The fracture ends are exposed and debrided of interposed hematoma and soft tissues. The fracture is reduced and may be held in place with Kirschner wires and/ or reduction instruments with reduction techniques of the surgeon's choice. A lag screw may be placed perpendicular to the fracture plane (if possible). The system includes a countersink (45-80040) if required. If axial compression using the plate is desired, do not use an independent lag screw in this step.

Plate Fixation and Optional Compression

After the plate is positioned centrally over the fracture site, the plate is fixed to the bone in the usual manner. K-Wire holes are designed in the plate to facilitate this fixation. The oblong holes can act as adaptation holes to help with plate positioning or they can act as compression holes.

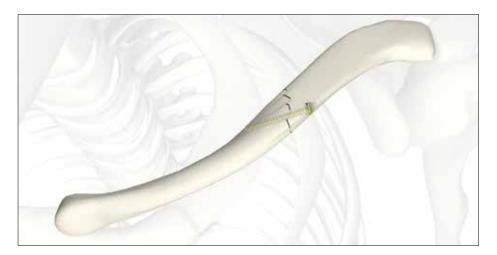
It is important that any nonlocking screw is inserted before any locking screw.

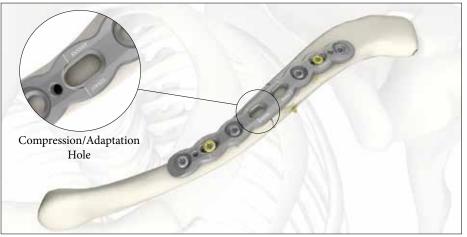
Furthermore, an independent lag screw should not be used prior to axial compression.

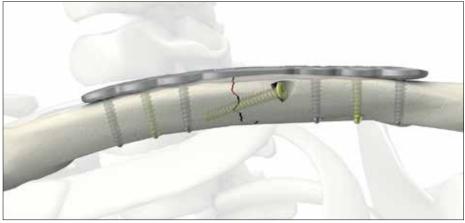
Compression is performed by placing a screw in the compression region of the plate. This is facilitated by using the Drill Guide for Compression (703826 for a 3.5mm screw or 703820 for a 2.7mm screw).

Each uni-directional compression hole is marked with a line where the compression initiates. Bi-directional compression holes have no directional laser markings.

Also of note, any non-locking screws or lag screws must be placed in the plate before any locking screws are placed.







The circular holes in the plate can accept either locking or non-locking screws based on surgeon preference and fracture fixation.

Make sure to use the proper drill guide which corresponds to the screw to be used.

Last, it is recommended to have at least 3 screws on either side of the fracture which are placed bi-cortically.

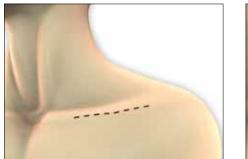
Anterior Midshaft Technique⁴

Portals/Exposures

The clavicle is exposed along the anterosuperior subcutaneous border. A 5 to 10cm incision is centered over the fracture site. As surgeons' experience improves, smaller incisions may be possible and preferred.

If noted, superficial branches of the intermediate supraclavicular nerves are identified and protected.

The fascia and periosteum are often disrupted, and this defect is extended medially and laterally to expose the fracture site. The pectoralis major and deltoid origins on the anterioinferior portion of the clavicle may need to be elevated to expose the plating surface. After the plating procedure, the muscle may be reattached over the plate. An alternative to this transverse incision is a vertical incision over the fracture site along Langer's lines.



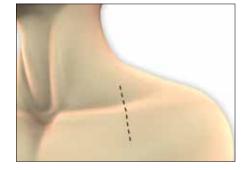


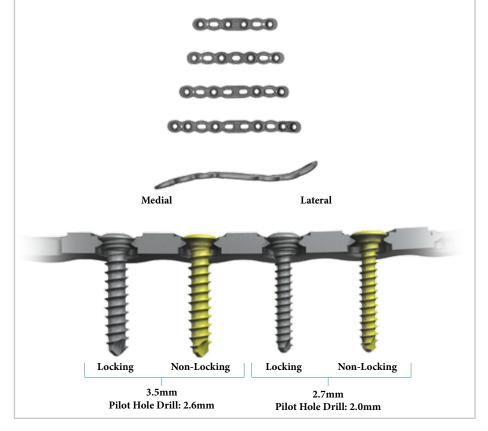
The VariAx system offers plates and screws in various shapes and sizes. The chart to the right shows the plate range, lengths, and hole configurations as well as the screw diameters and types.

Also, the system offers 3.5mm and 2.7mm locking and non-locking screws. Both screw diameters have the same screwhead diameter, which allows the surgeon to place either screw in the same plate hole.

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







4. The anterior midshaft technique was written with guidance from Dr. Howard Richter

Anterior Midshaft Technique

Implant Choice/Fracture Reduction

The fractured ends are exposed and debrided of interposed hematoma and soft tissues. The fracture is reduced and may be held in place with Kirschner wires and/or reduction instruments with reduction techniques of the surgeon's choice. A lag screw may be placed perpendicular to the fracture plane (if possible). This may be done anteriorly through one of the plate holes or in an independent interfragmentary manner. The system includes a countersink (45-80040) if required. If axial compression using the plate is desired, do not use an independent lag screw in this step.

Take care when using the Lag Screw Drill Guide (703710) for overdrilling through a plate hole as the drill guide's tip or overdrill could be damaged or could damage the plate hole.

Plate Fixation and Optional Compression

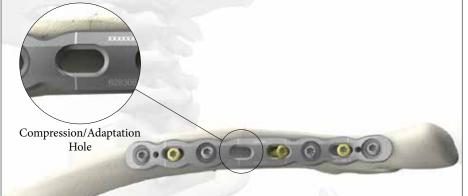
After the plate is positioned centrally over the fracture site, the plate is fixed to the bone in the usual manner. The oblong holes can act as adaption holes to help with plate positioning or they can act as compression holes.

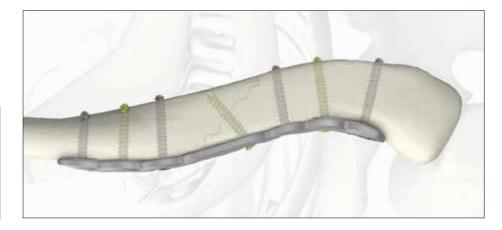
It is important to note that if axial compression is desired, non-locking screws should be used in the oblong holes before any circular holes on the same side of the fracture are filled.

Furthermore, an independent lag screw should not be used prior to axial compression.

Compression is performed by placing a screw in the compression region of the plate. This is facilitated by using the Drill Guide for Compression (703826 for a 3.5mm screw or 703820 for a 2.7mm screw).







Each uni-directional compression hole is marked with a line where the compression initiates. Bi-directional compression holes have no directional laser markings.

It is important that any nonlocking screw is inserted before any locking screw.

The circular holes in the plate can accept either locking or non-locking screws based on surgeon preference and fracture fixation. Ensure to use the proper drill guide which corresponds to the screw to be used.

Last, it is recommended to have at least 3 screws on either side of the fracture which are placed bi-cortically.

Superior Lateral Technique⁵

Portals/Exposures

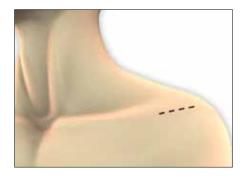
The clavicle is exposed along the anterosuperior subcutaneous border. A 3 to 5cm incision is centered over the fracture site ending just lateral to the AC joint.

If noted, superficial branches of the lateral supraclavicular nerve are identified and protected.

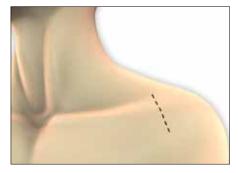
The skin edges are undermined in the subcutaneous plane to facilitate a mobile window of exposure.

The fascia and periosteum are often disrupted, and this defect is extended medially and laterally to create anterior and posterior soft tissue flaps for fracture visualization. A superior subcutaneous approach to the clavicle allows for fracture visualization without significant soft tissue dissection. A two-layer exposure allows for a twolayer closure, providing greater soft tissue coverage of the hardware and fracture.

An alternative to this transverse incision is a vertical incision over the fracture site along Langer's lines.







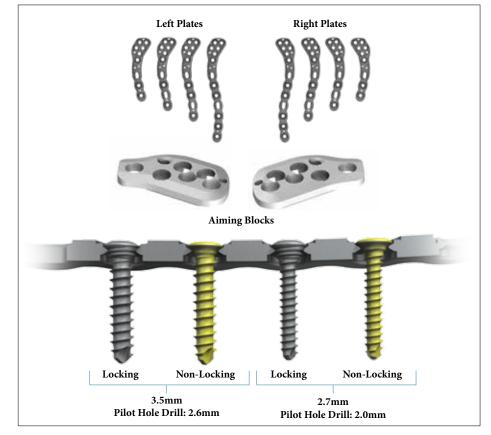
Implant Choice/Fracture Reduction

The VariAx system offers plates and screws in various shapes and lengths. The chart shows the plate contours, lengths, and hole configurations as well as the screw diameters and types.

The circular holes in the plate can accept either 2.7mm or 3.5mm locking or non-locking screws based on surgeon preference and fracture fixation.

Make sure to use the proper drill guide which corresponds to the screw to be used.

Additionally, the system offers an optional fixed-angled aiming block (703816 for Left plates or 703817 for Right plates) which may be used to help guide the surgeon in placing screws in a reproducible divergent screw pattern.



5. The superior lateral technique was written with guidance from Professors Michael McKee and Emil Schemitsch

Superior Lateral Technique

Implant Choice/Fracture Reduction

The fracture is exposed and debrided of interposed hematoma and soft tissues. The fracture is reduced and the AC joint is identified. This may be done using a small diameter needle.

Also, the use of a K-Wire into the distal clavicle through the most lateral K-Wire hole can help ensure that the screws will not be placed in the AC joint.

The plate is placed medial to the AC Joint. Then, the most lateral oblong hole may be used as an adaptation hole to determine the proper placement of the plate and to give primary fixation.

Plate Fixation and Optional Compression

It is important that any nonlocking screw is inserted before any locking screw.

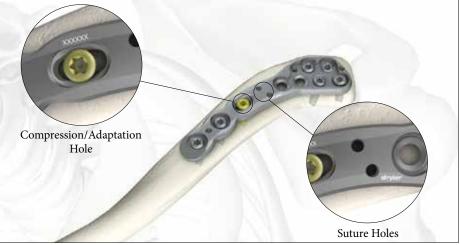
Compression is performed by placing a screw in the compression region of the plate. This is facilitated by using the Drill Guide for Compression (703826 for a 3.5mm screw or 703820 for a 2.7mm screw).

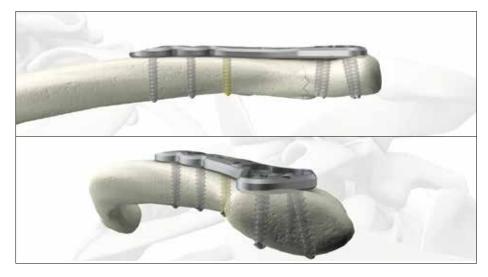
If an oblong hole has been used as an adaptation hole it cannot be used as a compression hole. Bi-directional compression holes have no directional laser markings.

The superior lateral plates are designed with suture holes laterally which may be used to reattach the coraco-clavicular ligaments if they have been ruptured. If sutures are used, it is recommended to place the knot anterior to the plate as not to cause possible irritation superiorly.

After proper lateral fixation ensuring there are no intra-articular placement of the screws in the AC joint, the remaining medial screws are inserted in the usual manner. Last, it is recommended to have at least 3 screws on either side of the fracture which are placed bi-cortically.







It is important that any nonlocking screw is inserted before any locking screw.

Anterior Lateral Technique⁶

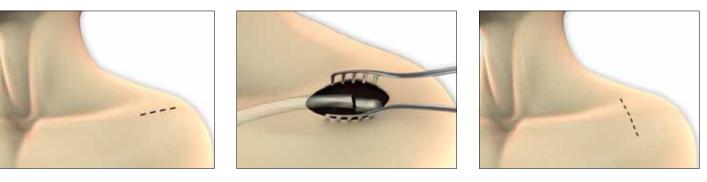
Portals/Exposures

The clavicle is exposed along the anterosuperior subcutaneous border. A 4 to 7cm incision is centered over the fracture site ending lateral to the AC joint.

If noted, superficial branches of the intermediate supraclavicular nerves are identified and protected.

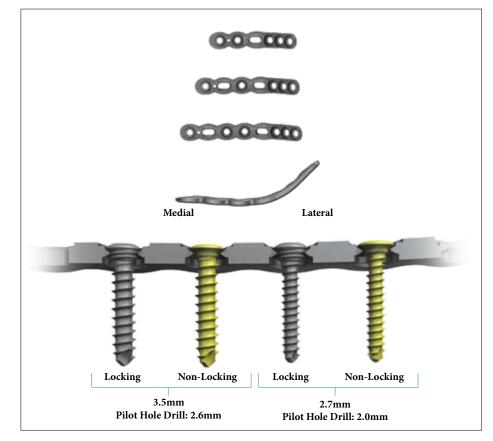
The fascia and periosteum are often disrupted, and this defect is extended medially and laterally to expose the fracture site.

The pectoralis major and deltoid origins on the anterioinferior portion of the clavicle may need to be elevated to expose the plating surface. After the plating procedure, the muscle may be reattached over the plate. An alternative to this transverse incision is a vertical incision over the fracture site along Langer's lines.



Implant Choice/Fracture Reduction

The VariAx system offers plates and screws in various lengths. The chart to the right shows the plate contours, lengths, and hole configurations as well as the screw diameters and types.



6. The anterior lateral technique was written with guidance from Dr. Howard Richter

Anterior Lateral Technique

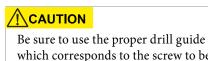
Implant Choice/Fracture Reduction

The fracture is exposed and debrided of interposed hematoma and soft tissues. The fracture is reduced and the AC joint is identified.

The plate is placed medial to the AC Joint. Then, the most lateral oblong hole may be used as an adaptation hole to determine the proper placement of the plate and to give primary fixation.

Plate Fixation and Optional Compression

The circular holes in the plate can accept either 2.7mm or 3.5mm locking or non-locking screws based on surgeon preference and fracture fixation.



which corresponds to the screw to be used.

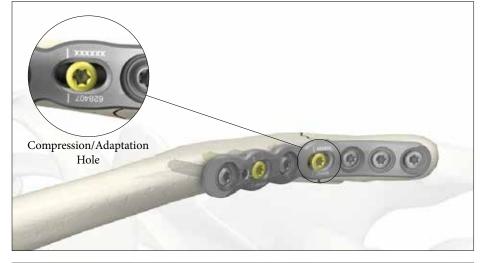
It is important that any nonlocking screw is inserted before any locking screw.

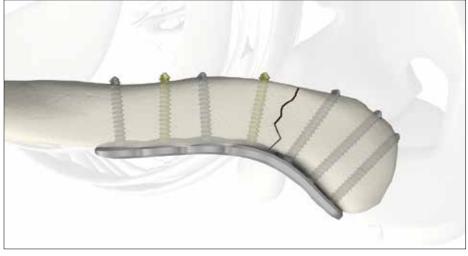
Compression is performed by placing a screw in the marked compression region of the plate. This is facilitated by using the Drill Guide for Compression (703826 for a 3.5mm screw or 703820 for a 2.7mm screw).

If an oblong hole has been used as an adaptation hole it cannot be used as a compression hole.

It is important that any nonlocking screw is inserted before any locking screw.







After proper lateral fixation, the remaining medial screws are inserted in the usual manner.

Last, it is recommended to have at least 3 screws on either side of the fracture which are placed bi-cortically.

Lateral Hook Technique⁷

Portals/Exposures

The clavicle and AC joint is exposed along the anterosuperior subcutaneous border. A 3 to 5cm incision is centered over the fracture site ending just lateral to the AC joint.

If noted, superficial branches of the lateral supraclavicular nerve are identified and protected.

If noted, superficial branches of the lateral supraclavicular nerve are identified and protected.

The skin edges are undermined in the subcutaneous plane to facilitate a mobile window of exposure. The fascia and periosteum are often disrupted, and this defect is extended medially and laterally to create anterior and posterior soft tissue flaps for fracture visualization. A two-layer exposure allows for a two-layer closure, providing greater soft tissue overage of the hardware and fracture. An alternative to this transverse incision is a vertical incision over the fracture site along Langer's lines.

Fracture/Dislocation Reduction

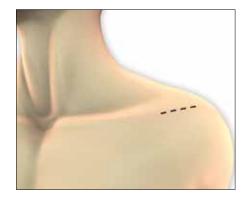
In the case of fracture, the fracture is exposed and debrided of interposed hematoma and soft tissues. The fracture is reduced and the AC joint is identified.

In the case of dislocation, re-align the AC Joint by manipulation, and temporarily fixate the joint with a K Wire if preferred.

Implant Choice

The VariAx system offers plates and screws in various shapes and sizes. The chart here shows the plate contours, lengths, and hole configurations as well as the screw diameters and types. The hook is anatomically pre-contoured to fit the inferior aspect of the acromion. This may help reduce impingement and point loading on the bone surface.

7. The lateral hook technique was written with guidance from Professors Michael McKee and Emil Schemitsch







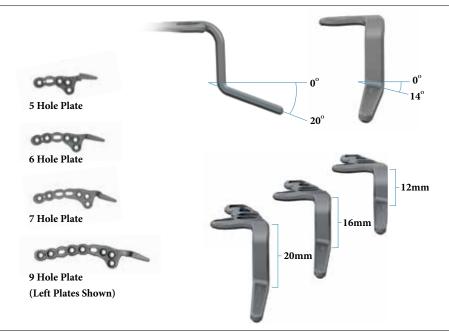
Lateral clavicle fracture



AC joint dislocation



Fracture Reduction



Lateral Hook Technique

Implant Choice /Plate 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. The plate is offered with hook depths of 12, 16, and 20mm. Start with the hook size that seems appropriate for the anatomy.

To determine the proper length of the plate shaft, use the plate trial ruler.

Note that the over reduction of the medial clavicle segment may lead to postoperative discomfort. On the other hand, a hook depth which is too deep may cause impingement in the shoulder joint.

To avoid over or under reduction, it is helpful to obtain a pre-operative radiograph of the contralateral AC joint to better understand the patient's intrinsic anatomy, which can be quite variable.

An important radiographic image to observe is an AP view of the acromion with a 20° superior tilt while the plate trial is in place. This will confirm if the proper depth has been obtained. The surgeon should notice a flush fit of the hook to the inferior aspect of the acromion while still having a proper anatomic distance between the clavicle and coracoid.

As an option in some cases, especially in chronic cases or those with pre-existing arthritis, the surgeon may excise the lateral clavicle ridge in order to provide a better fit of the plate to the clavicle. Ensure this is done before trialing of the Hook Plate as the proper depth will need to be adapted.

The most lateral oblong hole may be used as an adaptation hole to determine the proper placement of the plate and to give primary fixation.



Under reduction of medial clavicle segment



Over reduction of medial clavicle segment



Correct reduction

After the final position of the hook is determined the remaining holes can be filled as necessary. It is recommended to place a minimum of 3 screws bi-cortically which are medial to the fracture or AC separation.

In the case of fracture, fixation can be augmented with screws in the lateral fragment.

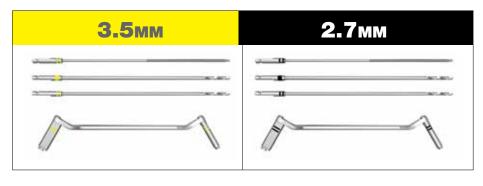
The circular holes in the plate can accept either 2.7mm or 3.5mm locking or non- locking screws based on surgeon preference and fracture fixation. Ensure to use the proper drill guide which corresponds to the screw to be used.

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

VariAx Instrumentation Usage

Color Code System

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



Drill Guides, Drills and Lateral Aiming Block

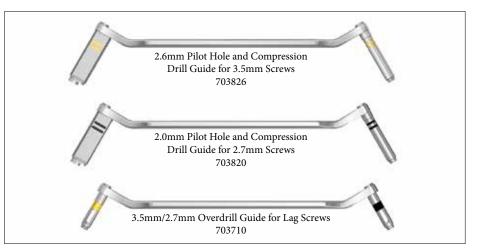
The VariAx Clavicle system offers 3 different types of drill guides: a 2.0mm drill guide, a 2.6mm drill guide and a 2.7/3.5mm overdrill guide.

The 2.0mm drill guide facilitates drilling a 2.0mm pilot hole for a 2.7mm screw either centric for locking/non locking screws or eccentric for use in a compression hole. The centric hole trajectory is +/- 15 degrees.

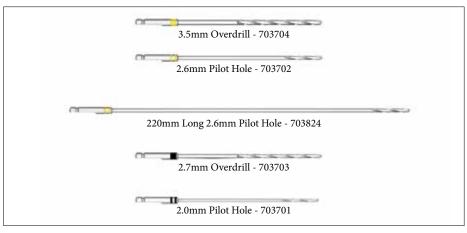
The 2.6mm drill guide facilitates drilling a 2.6mm pilot hole for a 3.5mm screw either centric or eccentric for use in a compression hole.

There are a variety of drills offered in the system. The 2.0mm and 2.6mm drills are used to drill the pilot hole for the 2.7mm and 3.5mm screws respectively. The 2.7mm and 3.5mm drills are used to overdrill the first cortex when placing a lag screw either through the plate or independently.

The long 2.6mm drill, which is 220mm in length, can be used when drilling pilot holes on the medial side of a superior plate in order to avoid power tool contact with the head.









VariAx Instrumentation Usage

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.

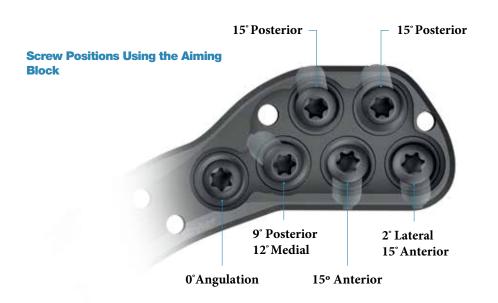
SpeedGuides up to 30mm				
Drill Diameter	Drill Bit	SpeedGuide		
2.0	703933	703931		
2.6	703934	703930		
3 IIIIIIIIIIIII				
	augusta and a second second	-		

SpeedGuides

The superior lateral plates are offered with optional aiming blocks (703816 for Left Plates / 703817 for Right Plates), which allow the surgeon to drill divergent drill holes in the lateral position of the plate. The joystick for the aiming block (703823) is designed to facilitate plate insertion and may act to manipulate plate positioning and fracture reduction.

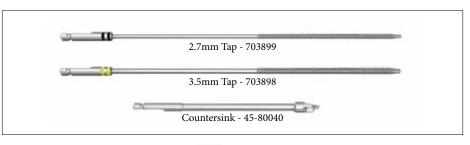


Aiming Blocks and Joystick



Taps and Countersink

2.7mm and 3.5mm taps are available in the system. Although the screws are self tapping, it is recommended to use a tap if excessive resistance is felt during insertion or if the bone is dense.



VariAx Instrumentation Usage

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 K-Wire Clamp (703716) can be used to additionally secure a plate to the bone by sliding it over a smooth K-Wire.

T10 Screwdriver Blades and Handle

The screwdriver handle (703714) has two driving options. Position 1(towards the blade) allows a rotating 2 finger technique, while position 2 (towards the handle) sets the driver to a standard 1 piece handle. The VariAx Clavicle has a variety of different blades 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 ensures a friction fit connection with the screwhead.

NOTICE

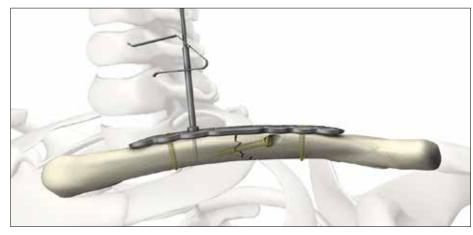
This blade cannot be used with the screw holding sleeve.

The standard blade is identified by the yellow and black color code. Its cylindrical tip does not allow friction fit. This is designed for surgeons who prefer to use a screw holding sleeve. The screw holding sleeve is also coded with yellow and black. The long self-retaining blade is used specifically in conjunction with superior plates which lie on the medial aspect of the clavicle. The long blade facilitates screw insertion while avoiding the patient's head.

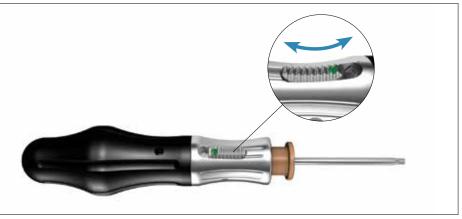
All blades come with an AO adapter.

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.

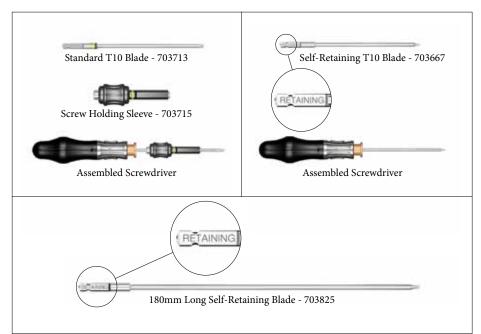
Also, it is important to insert the screws until the head is properly seated in the hole.



K-Wire Clamp



Screwdriver Blade and Handle



VariAx Instrumentation Usage

Reduction Clamps

The Plate Holding Clamp is designed to secure the plate to the bone superiorly. The fine toothed portion of the clamp grips the inferior clavicle 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 surface of the clavicle 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 compression. Then, the plate is placed in the usual manner, and the clamp does not interfere with the plate placement. The Repositioning Forceps are designed to reduce a fracture, and then allow a plate to be placed between its jaws while retaining the reduction. This may be especially helpful in short oblique or transverse fractures. The Repositioning Forceps and Small Reduction Clamp are used in the usual manner to reduce and hold the fracture. The Periosteal Elevator and Ball Spike is used in the usual manner to elevate soft tissue and help reduce the fracture.

Plate Contouring

All of the VariAx 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.

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).

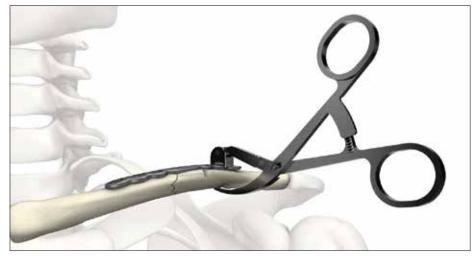


Plate Holding Clamp - 703821



Straight Reduction Clamp - 703822



Hohmann Retractor

The Hohmann Retractor 15mm (700667)may be placed under the clavicle to protect the neurovascular structure inferior to the clavicle while drilling from the superior side.

The Hohmann blade must be aligned with the hole being drilled.

Plate Trials

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. For Hook Plates, trials are provided in the three depths: 12mm, 16mm, and 20mm corresponding to the different depths of the implants.

A ruler for the hook plate shaft is provided to determine the length of the plate on the clavicle. Trials are especially useful when working with sterile packed plates.

The trials are color coded. BLUE indicates LEFT plates. GREEN indicates RIGHT plates and GREY indicates non-sided (universal) plates.





7 Hole Plate

Notes

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

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