stryker

VariAx® 2
Mini Fragment System

Operative technique

VariAx 2

Mini Fragment System

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This publication sets forth detailed recommended procedures for using Stryker's 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, V15013, V15247, V15246, 90-01961, and 90-01972) 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.

Indications and contraindications

Indications

The VariAx 2 Mini-Fragment System is indicated for fracture fixation, reconstruction, replantation, stabilization, reduction, fusions, osteotomies, mal-unions, and non-unions of small bones and small bone fragments including normal and osteopenic bones in adult and adolescent (12 – 21 years) patients. The system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones.

Compatibility with other systems

Components from this system may be used with the following systems:

- VariAx® 2 System

Precautions

See package insert for warnings, precautions, adverse effects and other essential product information.

Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity, unless used with a compatible system that may also be used in obese patients. 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.

MRI safety information

Non-clinical testing has demonstrated the VariAx 2 Mini Fragment System 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 or 3.0 T
- Maximum spatial field gradient of 3000 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: maximum 6 minutes of continuous scanning

Under the scan conditions defined above, the VariAx 2 Mini Fragment System is expected to produce a maximum temperature rise of less than 8.9 °C after 6 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 28 mm from the VariAx 2 Mini Fragment System 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 Mini Fragment System, this could result in additional MRI effects and the information provided above may not apply.

System overview
Instrumentation

Reduction instruments

These tools facilitate fracture reduction

Termite forceps (705151)

Straight Reduction Clamp, Broad (705297)

Straight Reduction Clamp (703822)

Repositioning forceps (702932)

Sharp Hook (700151)

Ball Spike (700153)

Hohmann Retractor 6mm (700664)

Hohmann Retractor 15mm (700667)

System overview

Plate positioning

To aid in plate positioning, the joystick for T8 holes (703927) can be used in any circular hole in the 2.4mm and/or 2.7mm plates and the joystick for T6 holes (705140) can be used in any circular hole in the 2.0mm plates. Additionally, they 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.

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 insert a K-wire through a joystick on the compression side of the fracture if compression is needed**
- **Do not use the engaged joystick to apply bending to the plate as this may damage the plate or joystick**

System overview

Plate contouring and cutting

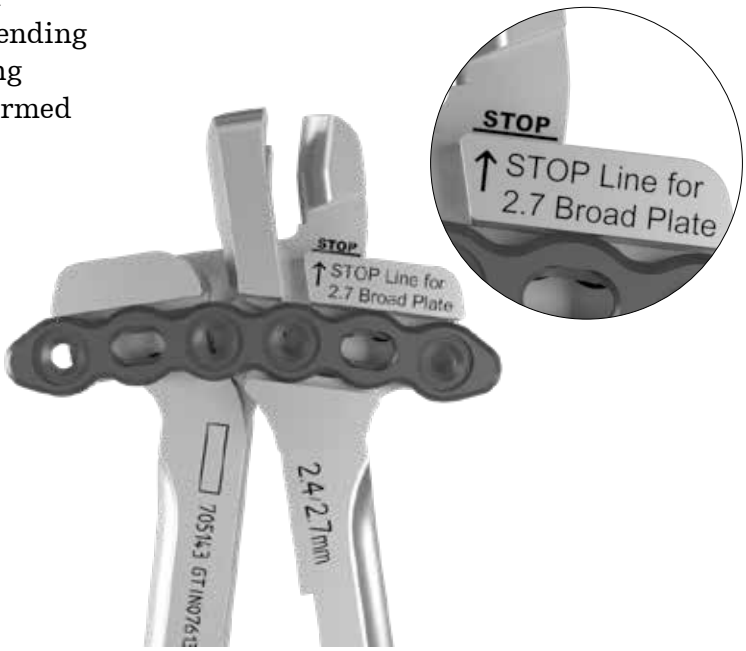
Cutting of all profile and narrow locking plates as well as 2.0mm broad locking plates is possible using the plate cutter (702951). 2.4mm and 2.7mm broad locking plates come in increments of 2 holes.

Additional contouring of all plates is possible using the Plate Bender (705143). The multiple-use plate bender can be used for both in-plane and out-of-plane bending for all plate sizes.

Both sides of the bender have a laser etching identifying which plate size may be contoured on that respective side.

Bending options are shown in the figures on the right.

The stop line laser engraved on the plate bender indicates the maximum allowable in-plane bend for the 2.7mm broad locking plates. In-plane bending of the 2.7mm broad locking plates should not be performed past this stop line.



Stop markings

In-plane bending

Out of plane bending

System overview
Plate contouring

In addition, contouring of narrow locking and profile plates as well as the 2.0mm broad locking plates is also possible using the Plate Bending Pliers (45-80010) when required based on local patient factors or anatomy.

Furthermore, the plates can be twisted by using a Plate bending plier (45-80010) in combination with the Plate Bender (705143).

In order to reduce the likelihood of a stress riser effect and avoid reducing the fatigue properties of the implant in load bearing situations and for treating comminuted fractures, care should be taken to only moderately bend the plate in between holes.

⚠ WARNING

- **Only moderate bending is recommended**
- **Excessive plate bending may lead to failure of the plate or the locking mechanism and should be avoided. Do not re-bend plates or bend plates at a screw hole**
- **The plate bending pliers are designed to be used only in circular holes**
- **If the oblong compression holes are deformed, there may be potential for a screw to pass through the hole upon insertion**
- **Always attach the bending pliers to two adjacent holes to prevent deformation of the screw holes**

System overview
Instrumentation

Modular self-ratcheting and fixed handles

The VariAx 2 System offers modular handle options. Medium Handles can be interchanged with either a bi-directional ratcheting AO-coupling insert (703922) or an optional standard fixed AO-coupling insert (703923).

⚠ CAUTION

The insert must be removed from the handle before cleaning.

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

The medium sized handle is 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.

A small elastosil handle is also available.

Medium handle (703921)

Ratcheting insert (703922)

AO Coupling insert (703923)

Elastosil handle, cannulated, AO coupling (45-90200)

⚠ CAUTION

To limit torque transmission of 2.0mm screws, use the small elastosil handle.

NOTICE

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

System overview
Instrumentation

Depth measuring options

Drills and K-wire Drills are scaled to allow for estimated correct screw length when used with the dedicated drill guides.

Additionally, a standard Depth Gauge (705141) can be used either independently or through a plate hole.

Drill bit (705134) for 2.4 and 2.7mm screws

Drill bit (705133) for 2.0mm screws

Depth Gauge (705141)

Taps and countersink

A countersink (706200) is available for reducing the screw head prominence when the screw is used independently of a plate. It can be used for all screw types of this system.

All screws are self-tapping. Taps are available in 2.0mm (706201), 2.4mm (703900) and 2.7mm (703899).

Tap

Countersink (706200) for 2.0 – 2.7mm screws

⚠ CAUTION

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

System overview
Instrumentation

Drill bits and guides

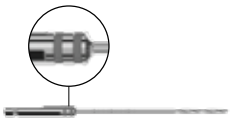
Screw color coding	Screw diameters	Drill guides	Interface	Drill bits diameter	Overdrill for screw diameter
Grey	**2.0mm**	**1.6mm**	T6	**1.6mm**	**2.0mm**
Blue	**2.4mm**	**2.0mm**	T8	**2.0mm**	**2.4mm**
Purple	**2.7mm**	**2.0mm**	T8	**2.0mm**	**2.7mm**

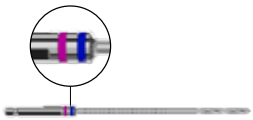
The drill guides facilitate drilling of pilot hole for either a non-locking or locking screw. Furthermore, the opposite side of the guide facilitates fixed angle drilling for use in a compression hole when compression is desired.

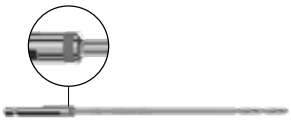
The standard drill bits allow for drilling a pilot hole until 30mm for 2.0mm screws and 40mm or 70mm for 2.4mm and 2.7mm screws. Overdrills and drill guides for interfragmentary lagging technique are available for all screw sizes.

⚠ 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.

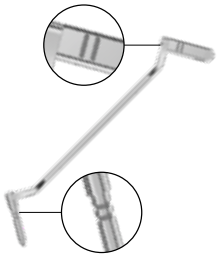

Drill bit, 1.6mm scaled

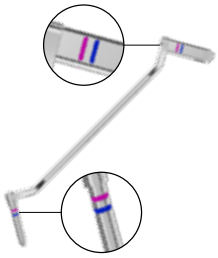

Drill bit, 2.0mm scaled

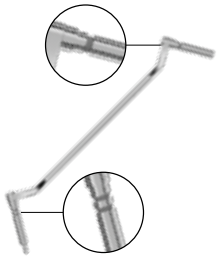

2.0mm overdrill

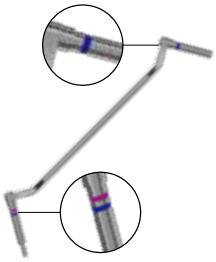

2.4mm overdrill

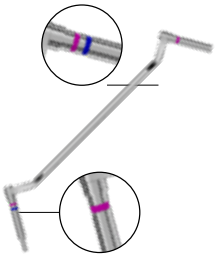

2.7mm overdrill


Drill Guide for 2.0mm screws, compression and polyaxial


Drill Guide for 2.4mm/2.7mm screws, compression and polyaxial


Drill guide for 2.0mm independent lag screw


Drill guide for 2.4mm independent lag screw


Drill guide for 2.7mm independent lag screw

⚠ CAUTION

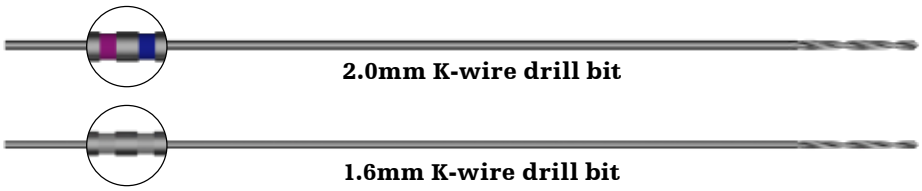
When a compression hole is used in neutral mode, use the polyaxial drill guide for soft tissue protection. When using a compression hole in compression mode, the compression drill guide must be used. It must be inserted perpendicularly into the compression hole and cannot be angulated. Please make sure the arrow marked on the compression side of the drill guide is pointing toward the fracture line/ osteotomy site.

When angulating the compression drill guide or using the wrong instrument, there is a risk that the screw will not properly sit in the plate.

System overview
Instrumentation

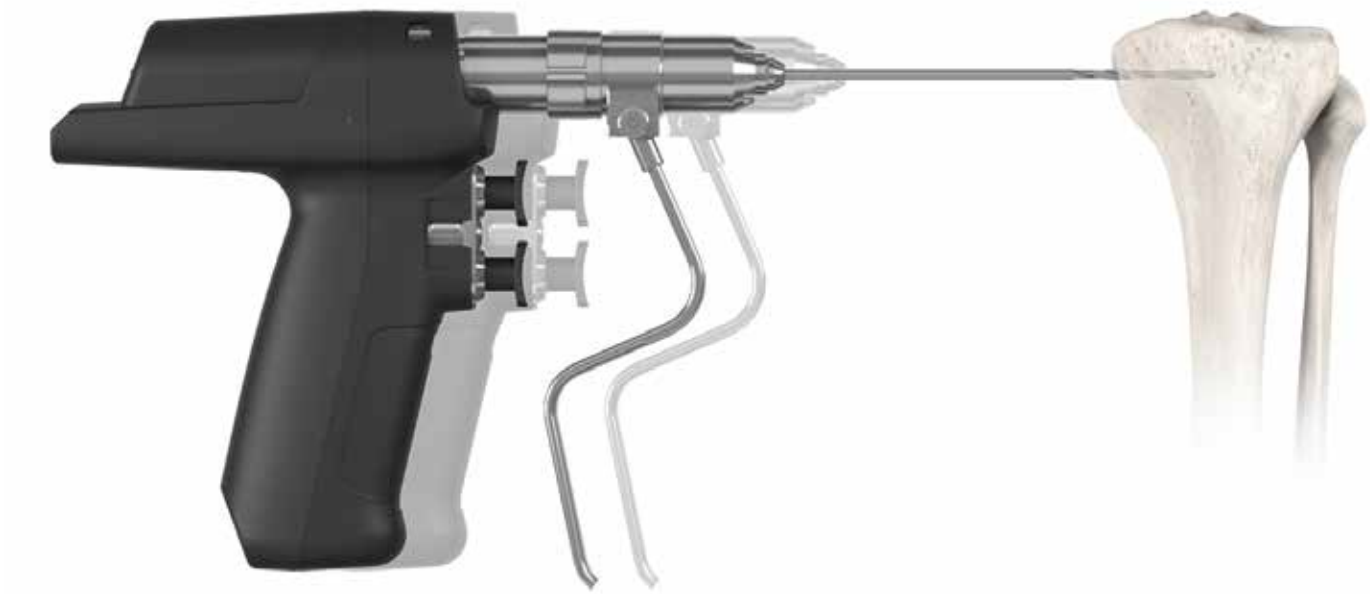
K-wire drill bits

For screws longer than 30mm for 2.0mm screws and 70mm for 2.4mm and 2.7mm screws, use a K-wire Drill Bit (705136 for 2.0mm screws and 705135 for 2.4mm and 2.7mm screws). Begin with a short overhanging length of K-wire Drill bit and increase the length step by step.



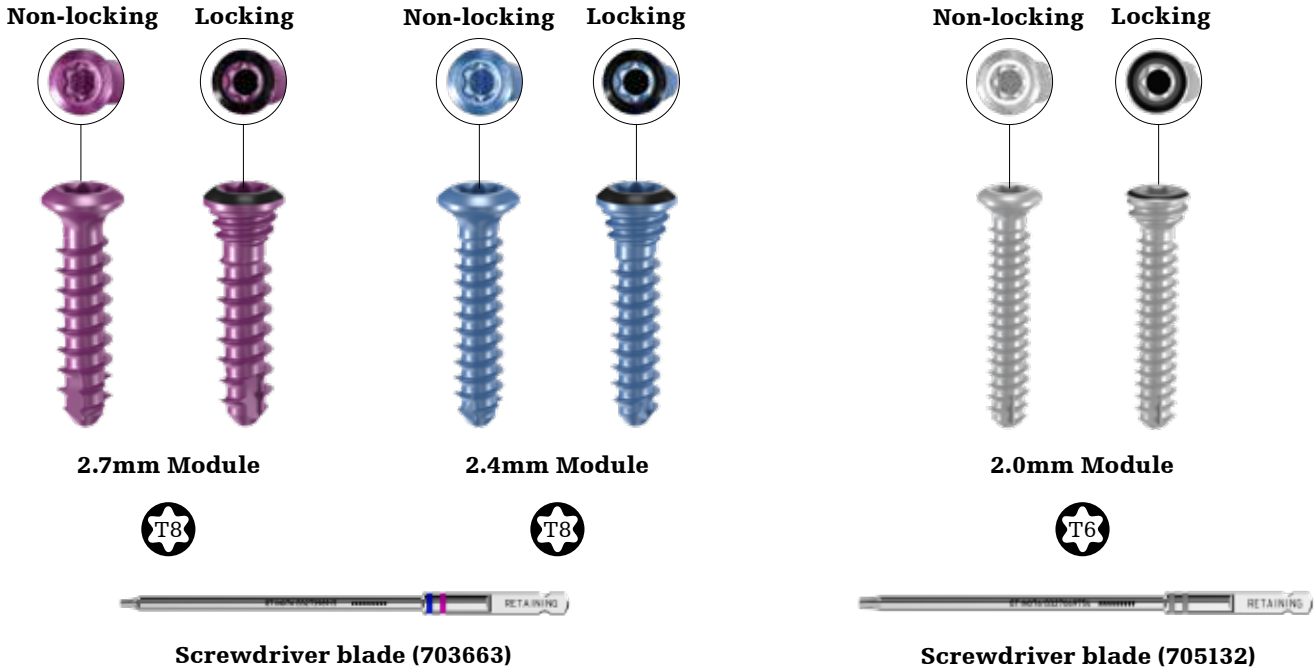
2.0mm K-wire drill bit

1.6mm K-wire drill bit



System overview
Implants: screw platform

VariAx2 screw platform



Screwdriver blade (703663)

Screwdriver blade (705132)

Color coding

The VariAx 2 screws and instruments follow a standardized color-coding scheme whereby the screw color matches the corresponding instrument's color. This color coding scheme helps identify the components needed during surgery based on the screw diameter.

Screw type	Lengths	Interface
2.0mm screws	**6-40mm**	T6
2.4mm screws	**6-80mm**	T8
2.7mm screws	**6-80mm**	T8

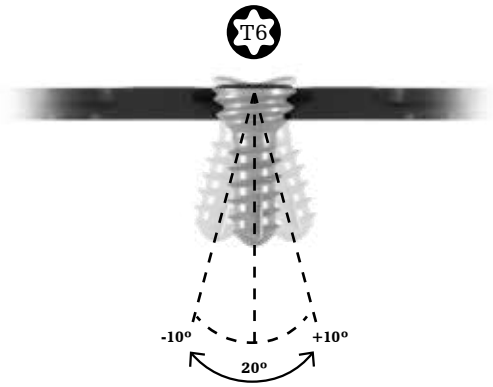
⚠ CAUTION

It is not recommended to use power for insertion. If power insertion is used, it must be used at low speed. Insertion and final tightening of the screw should be performed by hand to avoid over-torquing or damaging the screw-plate interface.

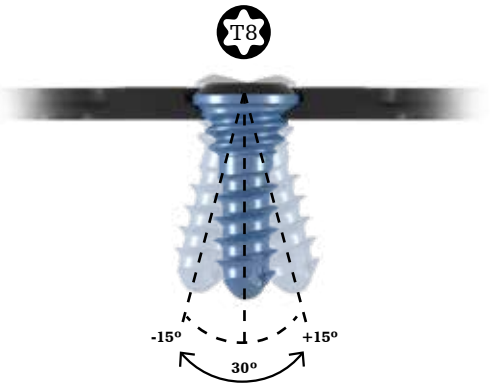
System overview
Implants: screw platform

SmartLock* technology

SmartLock technology permits polyaxial screw placement. 2.0mm locking screws can be angled up to 10° in each direction for a total range of 20°. 2.4mm and 2.7mm locking screws can be angled up to 15° in each direction for a total range of 30°.



2.0mm locking screw



2.4/2.7mm locking screw

Locking and non-locking screws

All circular holes in the dark grey 2.0mm, 2.4mm, and 2.7mm Narrow and Broad Locking Plates provide an option for both polyaxial locking and non-locking screws. The circular holes in the light silver 2.0mm and 2.4mm Profile Plates provide an option for non-locking screws only. The Hybrid LC Holes in the Narrow Locking Plates accept non-locking screws when used in compression mode, and locking or non-locking screws when used in neutral mode.

The oblong compression holes in the Broad Locking Plates provide an option for non-locking screws only.

Depending on the anatomy and fracture pattern, T8 2.4mm and 2.7mm polyaxial locking and non-locking screws are interchangeable with the 2.4mm and 2.7mm plates, due to the same screw head geometry. Locking screws are laser marked with a 'dot' and 'ring' marking on the screw head to differentiate them from non-locking screws.

Locking

Non-locking

Washers

Washers are available for all screw sizes when non-locking screws are used indepedently.

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

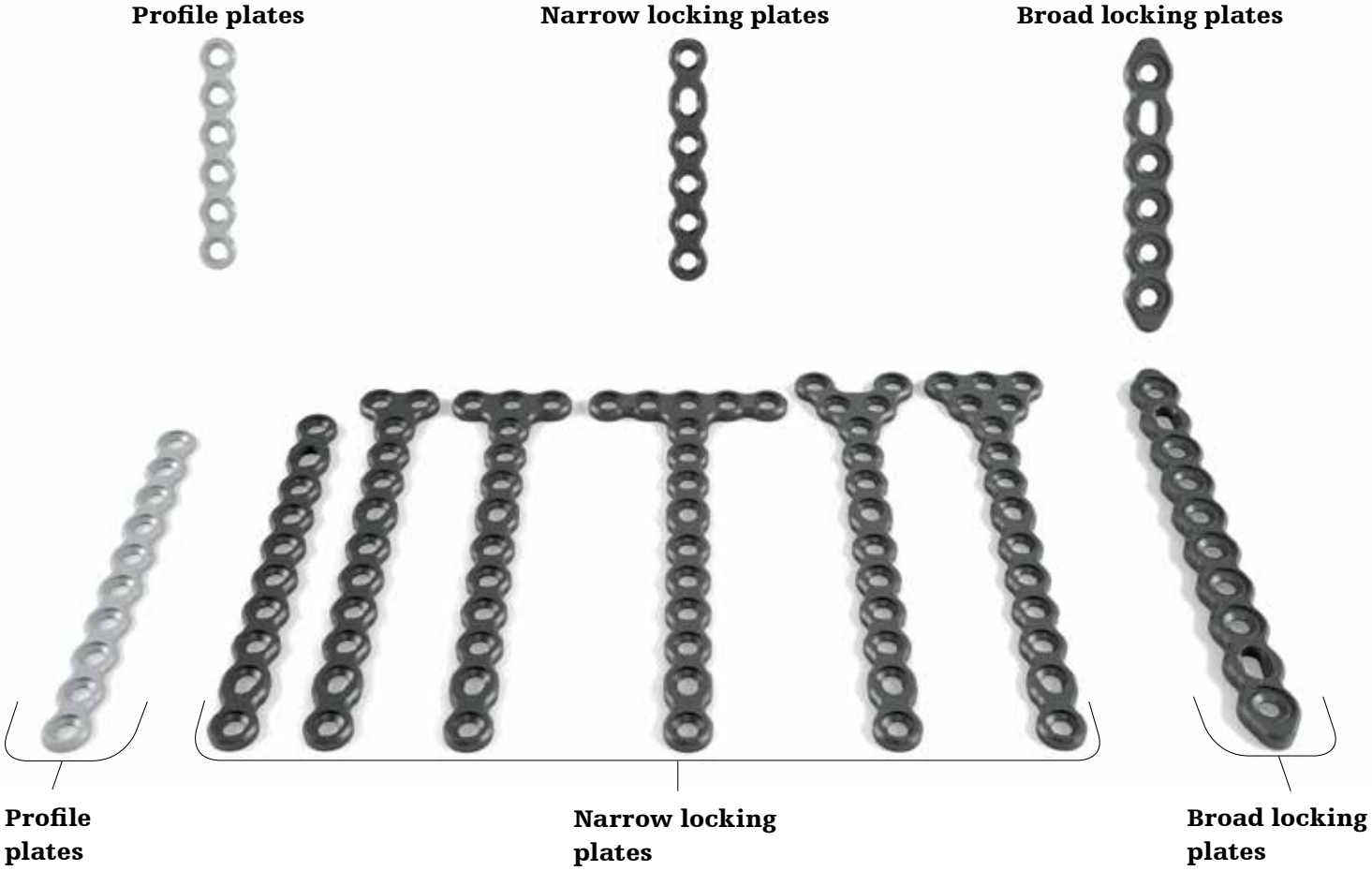
System overview
Implants: plate platform

VariAx 2 Mini Fragment plates

The VariAx 2 Mini Fragment System offers Profile, Narrow Locking, and Broad Locking plates. The Broad Locking plates are designed to provide a stronger option compared to the Narrow Locking plates.

Profile and Broad Locking plates are offered as straight plates only, ranging from 4 – 20-hole lengths. Narrow Locking plates are offered in straight, T, Y, and triangle plate options.

T-plates are offered in 5 and 10-holes lengths, and Y and Triangle plates are offered in 10-hole options. The top side of the plates always feature a circumferential chamfer.



System overview
Implants: plate platform

Plate module	Plate type	Number holes	Screw size	Color code	Interface
2.0	Profile plate	4, 6, 8, 10, 20	2.0mm		T6
	Narrow locking plate	4, 6, 8, 10, 20			
	Narrow locking T-plate	2x5, 2x10, 3x5, 3x10, 5x10			
	Broad locking plate	4, 6, 8, 10, 20			
2.4	Profile plate	4, 6, 8, 10, 20	2.4mm		T8
	Narrow locking plate	4, 6, 8, 10, 20			
	Narrow locking T-plate	2x5, 2x10, 3x5, 3x10, 5x10			
	Narrow locking Y-plate	10			
	Narrow locking triangle plate	10			
	Broad locking plate	4, 6, 8, 10, 12			
2.7	Narrow locking plate	4, 6, 8, 10, 20	2.7mm		T8
	Narrow locking T-plate	2x5, 2x10, 3x5, 3x10, 5x10			
	Narrow locking Y-plate	10			
	Narrow locking triangle plate	10			
	Broad locking plate	4, 6, 8, 10, 12, 14			

⚠ CAUTION

Profile plates and compression holes in the Broad Locking Plates are only compatible with non-locking screws.

System overview

Implants: plate platform – compression options

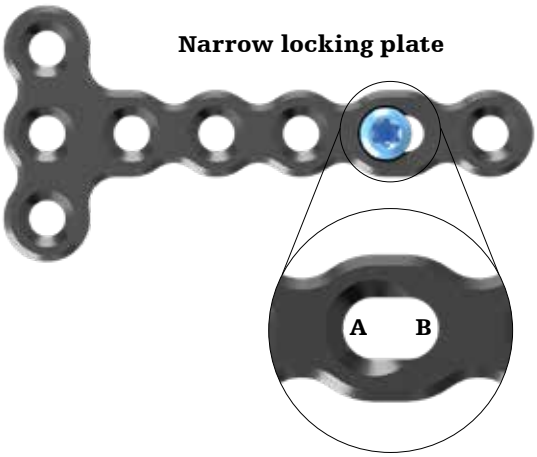
Compression holes

The Narrow Locking Plates include Hybrid LC Holes, while the Broad Locking Plates include standard compression holes. Hybrid LC Holes allow for either active compression with the use of a non-locking screw, or variable angle locking with the use of a locking screw in the round section of the hole. Standard compression holes only accept non-locking screws.

Narrow Locking Plates

Narrow locking plates include one or two **uni-directional** Hybrid LC Holes. These holes can be used as a compression hole by placing a non-locking screw eccentrically in the oblong hole.

They can also be used as a variable angle locking hole by placing a locking screw in the round section of the hole. Locking strength may be limited compared to a standard locking hole. A non-locking screw can also be used in the round section of the hole if locking or compression is not desired.



Narrow locking plate

Hybrid LC Holes

A: Screw placement for locking/non-locking

B: Initial screw placement for compression

Broad Locking Plates

Broad locking plates include multiple bi-directional compression holes allowing for compression in either direction along the plate. The bi-directional compression holes can only be used in conjunction with non-locking screws.

Broad locking plate

Operative technique
Plate fixation

⚠ WARNING

When a VariAx 2 Mini Fragment plate and/or screw is used on a long bone for non-load bearing stabilization and/or reduction, it is required that the plate and/or screw be used only in conjunction with separate, definitive fixation.

Examples of such definitive fixation include, but are not limited to, large and small fragment periarticular or periprosthetic plating systems, intramedullary nailing systems, external fixation systems, and total joint replacement systems.

Step 1

Select an appropriate sized implant. Cut and/or contour the plate if necessary.

Step 2

Position the plate on the fracture

Joystick for T6 (705140) or T8 holes (703927) can be used in any circular hole of the respective T6 or T8 plate 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. Furthermore, temporary plate fixation can be performed using a K-wire with stop (705150) through a circular hole.

Operative technique
Plate fixation

Step 3

Place the appropriate drill guide in the hole of the plate and aim the appropriate drill in the desired position. The polyaxial drill guide must be used in locking holes and can also be used in compression holes when used in neutral mode. The compression drill guides must be used in compression hole in compression mode. The polyaxial drill guide will not allow for drilling past +/-10 degrees for 2.0mm screws and +/-15 degrees for 2.4 and 2.7mm screws.

Step 4

Once the screw hole is drilled, measure the depth using the depth gauge or a scaled drill.

⚠ CAUTION

The sleeve of the depth gauge must be fully inserted into the respective plate hole prior to measuring.

Step 5

Select the VariAx 2 screw of appropriate length and diameter and verify length after pick-up from screw rack with the VariAx 2 screw rack lid.

Operative technique
Plate fixation

Step 6

Insert the screw, and fixate the plate to the bone.

Insert any additional screws as needed.

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.

⚠ CAUTION

Fluoroscopy is required to ensure correct length and angulation.

Operative technique

Compression technique – Hybrid LC Holes (uni-directional)

Step 1

To obtain compression, insert the appropriate drill guide (703684 for 2.4mm/2.7mm T8 screws and 705138 for 2.0mm T6 screws) in the oblong hole closest to the fracture on the opposite of the stabilizing screw. The etched arrow on the drill guide must be aiming towards the fracture line to obtain compression.
A mismatch between the drill guide and the plate hole indicates that the wrong dimension drill guide has been chosen. If using a locking or non-locking screw in the round side of the hole when compression is not desired, use the standard variable angle drill guide.

⚠ CAUTION

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

Step 2

Choose the appropriate screw length and insert the non-locking screw until fully seated. Remove any provisional plate fixation on this side before tightening the screw firmly.

Operative technique

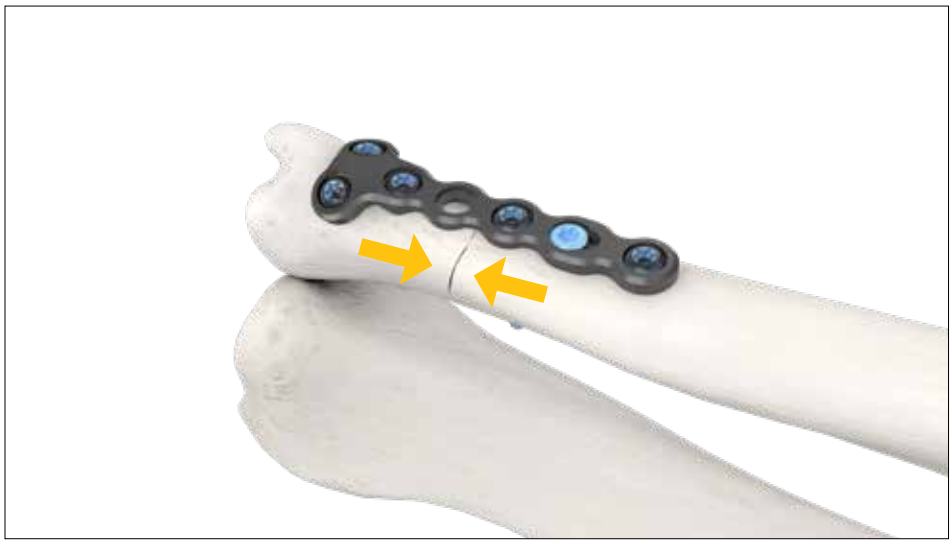
Compression technique – Hybrid LC Holes (uni-directional)

Step 3

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

⚠ CAUTION

Fluoroscopy is required to ensure correct length and angulation.



Operative technique

Compression technique – compression hole (bi-directional)

Step 1

To obtain compression, insert the appropriate drill guide (703684 for 2.4mm/2.7mm T8 screws and 705138 for 2.0mm T6 screws) in the oblong hole closest to the fracture on the opposite of the stabilizing screw. The etched arrow on the drill guide must be aiming towards the fracture line to obtain compression.
A mismatch between the drill guide and the plate hole indicates that the wrong dimension drill guide has been chosen.

⚠ CAUTION

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

Step 2

Choose the appropriate screw length and insert the non-locking screw until fully seated. Remove any provisional plate fixation on this side before tightening the screw firmly.

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.

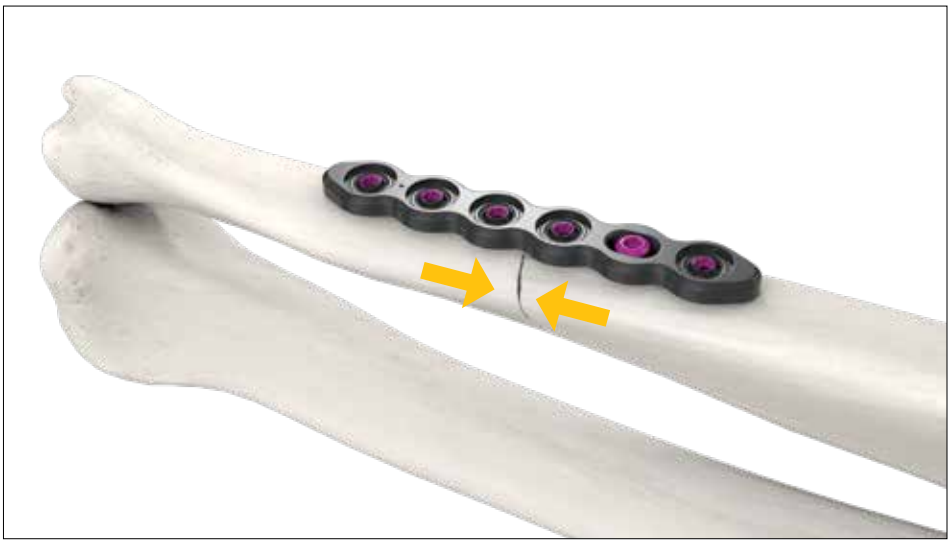
Operative technique

Compression technique – compression hole (bi-directional)

Step 3

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

The compression technique can be applied with mono-directional and bi-directional compression holes which are included in all narrow and broad locking plates.



⚠ CAUTION

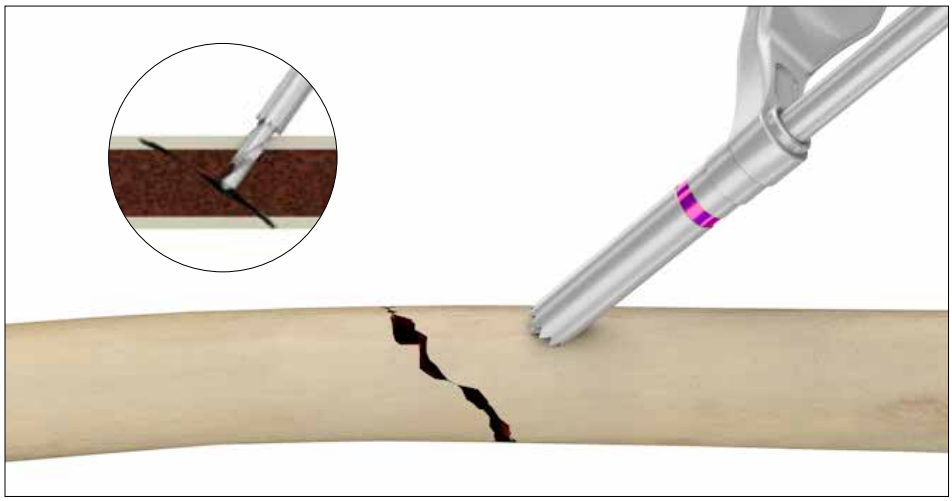
Fluoroscopy is required to ensure correct length and angulation.

Operative technique

Lag screw technique

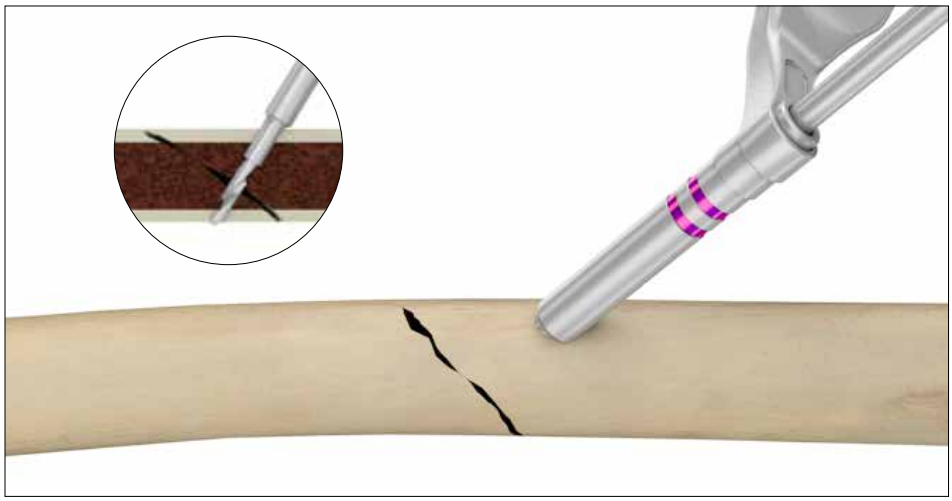
Step 1

Use the appropriate overdrill (705137 for 2.0mm T6 screws, 703696 for 2.4mm T8 and 703897 for 2.7mm T8 screws) to create a gliding hole in the near cortex using the “overdrill sleeve” of the independent lag screw drill guide (703884 for 2.7mm T8 screws, 703688 for 2.4mm T8 screws and 705139 for 2.0mm T6 screws) marked with a single color ring.



⚠ 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.

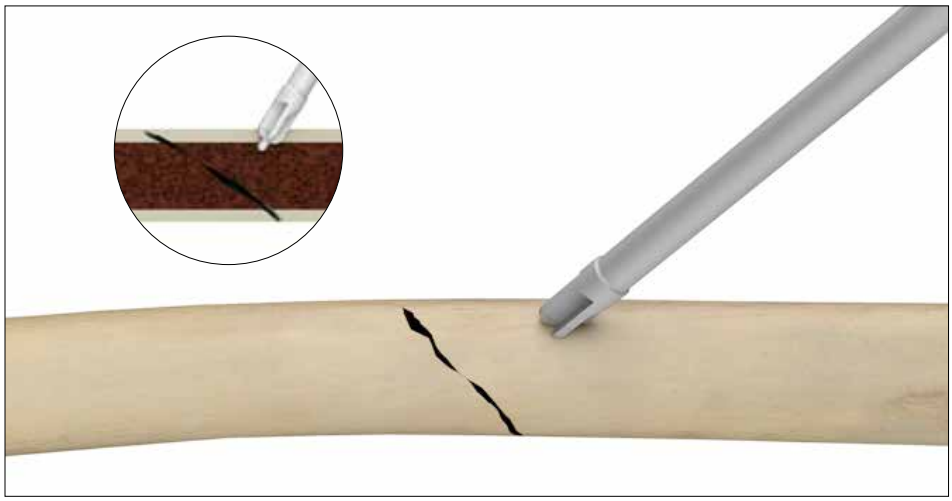


Step 2

Insert the “core drill sleeve” at the other side of the lag screw drill guide (marked with two color rings) in the gliding hole. Use the standard drill bit to drill through the second cortex.

Step 3

Countersink (706200) the gliding hole or apply a washer. Choose the appropriate screw length and fully insert the bone screw.



Operative technique

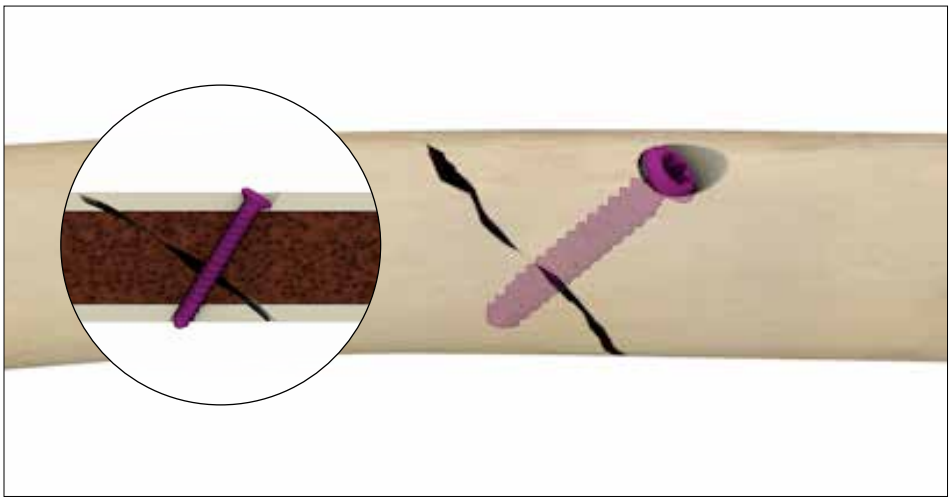
Lag screw technique

Step 4

Final implanted screw.

⚠ CAUTION

Fluoroscopy is required to ensure correct length and angulation.



Notes

Notes

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