stryker

VariAx® 2
Distal Ulna Locking Plates

Operative technique

VariAx 2 Distal Ulna Hook Plates

VariAx 2 Distal Ulna Base Plates

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.

MRI Safety Information

MRI safety information A patient with the Variax 2 Distal Ulna implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.	
Device name	VariAx 2 Distal Ulna
Static magnetic field strength (T)	1.5 T and 3.0 T
Maximum spatial field gradient	30 T/m (3000 gauss/cm)
RF excitation	Circularly Polarized (CP)
RF transmit coil type	Integrated Whole Body Transmit Coil
Operating mode	Normal Operating Mode
Maximum whole-body SAR (W/kg)	2 W/kg (Normal Operating Mode)
Scan duration	2 W/kg whole-body average SAR for 15 minutes of continuous RF (a sequence or back to back series/scan without breaks) followed by a wait time of 15 minutes if this limit is reached, for the total scanning session duration of up to 1 hour (or 60 minutes).
MR image artifact	The presence of this implant produced an image artifact of approximately 32 mm from the VariAx 2 Distal Ulna implant when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.
Additional instructions	**⚠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 Distal Ulna implant, this could result in additional MRI effects and the information provided above may not apply.

VariAx 2

Distal Ulna Locking Plates

Contents

Indications and Contraindications

VariAx 2 Distal Ulna

The devices are non-active implants intended to provide temporary stabilization for bones or bone fragments.

Indications for use

The VariAx 2 Distal Ulna implants are indicated for the treatment of fractures, non-unions, malunions and deformities of the distal ulna.

Contraindications

The licensed healthcare professional's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment.

They should warn patients about these contraindications and limitations when appropriate.

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.
- 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.

Overview

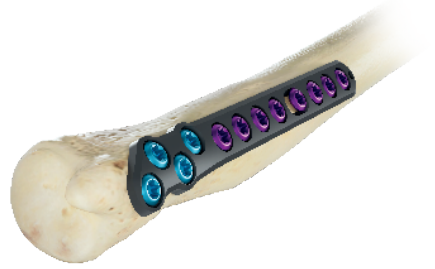
Implants: plate & screw platform

VariAx 2 Distal Ulna Plates

The DU Hook Plate may be used for DU fractures with a fractured or displaced ulnar styloid in order to apply compression on the fracture site.

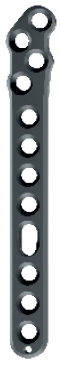
The DU Base Plate may be used for DU neck fractures and neck fractures that are extending into the shaft of the ulna.

DU Hook Plate



DU Base Plate

DU Base Plate Long, Right



DU Base Plate Short, Right

DU Hook Plate Short

DU Hook Plate Long

DU Base Plate Short, Left

DU Base Plate Long, Left

Color Coding and Screw/Peg Options

⚠CAUTION

When final tightening of the locking screw occurs, take care not to over-torque the screw. Excessive torque may damage the locking mechanism, the screw and /or the screwdriver blade.

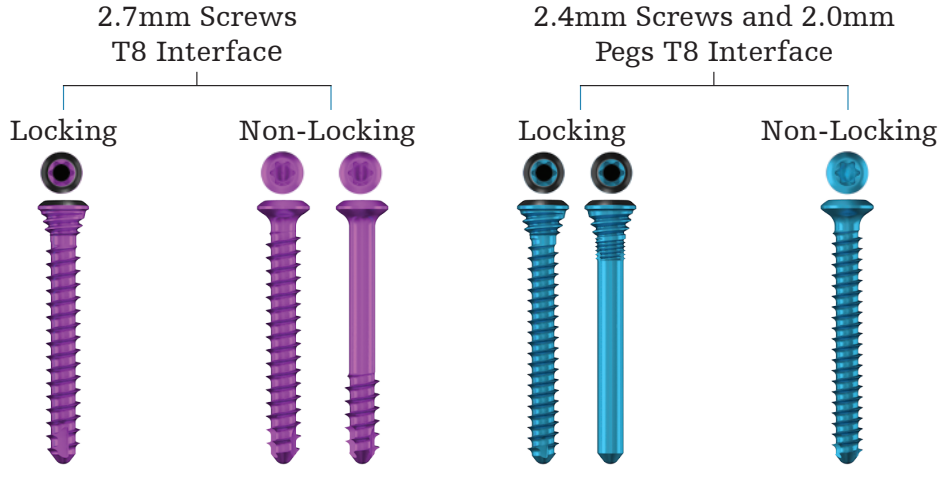
Locking and non-locking screws can be used in any round hole.

Locking screws are laser marked with a 'dot' and 'ring' marking on the screw head to differentiate them from non-locking screws.

Pre-Angled Distal Screw Holes

The distal screw holes are angled to give a predetermined screw pattern in the distal bone block.

When drilling at a 0° angle relative to the plate hole, the screw trajectories relative to the plate surface will be achieved.



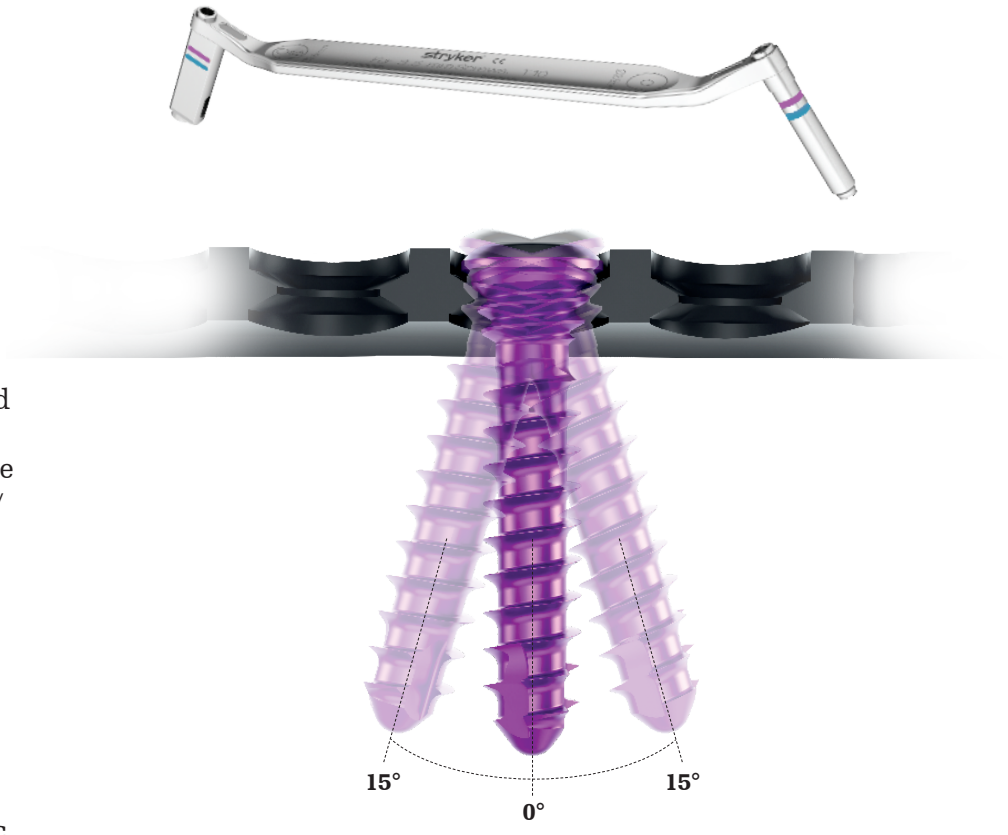
Overview

Instrumentation

SmartLock Polyaxial / Compression Drill Guide

Allows for ±15 degrees of angulation. A lip on the drill sleeve will engage and allow toggling in the hole. The range in which the drill guide toggles will create a 30-degree cone and every angle in this range will be a locking position. This may allow the surgeon to aim where the screw/peg should be placed. Also, depending on the placement of the plate, there may be a need to angle a screw/peg out of the fracture line.

The 2.0mm drill guide for T8 Screws (703684) facilitates drilling a 2.0mm pilot hole for a 2.4 or 2.7mm T8 screw or a 2.0mm peg centrically for locking or non-locking screws. Additionally, the opposite side of the guide facilitates eccentric drilling for use in a compression hole when compression is desired.



⚠ CAUTION

- When drilling eccentrically in a compression hole, the arrow marked on the compression side of the drill guide should be pointing towards the fracture line.
- The VariAx 2 compression drill guide (703684) should be use when drilling compression holes. Ensure compression drill guide is placed perpendicular to the compression hole.
- Using one of the provided drill guides for screw hole preparation is mandatory. Not using a drill guide may lead to drilling out of specified locking range and compromise the locking capabilities.
- First fully engage the drill guide in the hole and then aim the drill in the desired direction.
- Make sure to drill perpendicular to oblong holes.
- Verify proper placement of screws and pegs by use of fluoroscopy to ensure that they do not penetrate the joint and are of appropriate length.

Overview
Instrumentation

Drills & drill guides for lagging

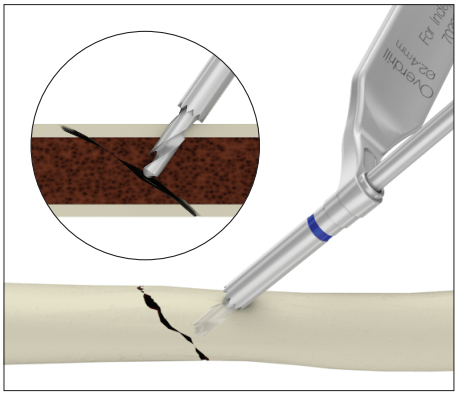
In addition to the standard Drills and Drill guides, a number of solutions are also available to perform a lag screw technique independently.

Dedicated overdrills for each screw size are available for overdrilling the near cortex when placing a lag screw independently. In addition to being marked with the actual drill diameter on the AO Coupling, these overdrills are also marked with a single color ring corresponding to the desired screw diameter. This marking matches the marking on the correct side of the lagging drill guide.

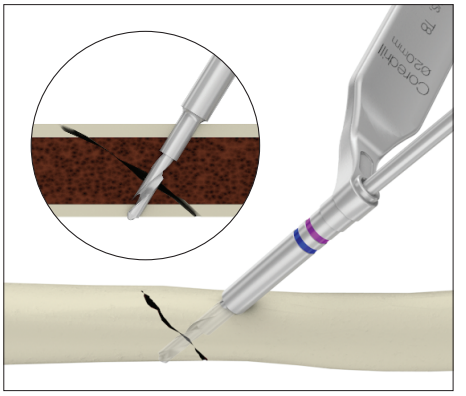
⚠ CAUTION

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

In order to insert a lag screw independently of a plate, the Independent Lag Screw Drill Guides (703688 for 2.4mm screws and 703884 for 2.7mm screws) should be used. First, the near cortex should be overdrilled using the side of the drill guide marked with a single color ring to create a gliding hole (Step #1).



Step 1



Step 2

The other side of the drill guide can then be used (marked with two color rings) by inserting the 'top-hat' end in the already drilled gliding hole and using the standard drill bit through it to drill through the second cortex (Step #2). This standard drill is scaled in order to evaluate the appropriate screw length. Upon screw insertion, this technique will serve to lag the far cortex towards the near cortex, hence applying compression.

⚠ CAUTION

Take care when using the Independent Lag Screw Drill Guide for overdrilling through a plate hole as the drill guide's tip could damage the plate hole.

Overview
Instrumentation

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.

⚠CAUTION

The inserts must be removed from the handles before cleaning.

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

NOTICE

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

Large Handle (703920)

Ratcheting Insert (703922)

Medium Handle (703921)

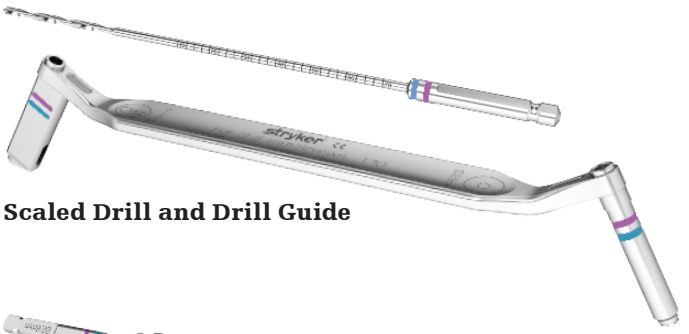
AO Coupling Insert (703923)

Overview
Instrumentation

Depth Measurement Options

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

A SpeedGuide (703891 for 2.0 Drill Bit and 703888 for the Speed Guide Sleeve) 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.



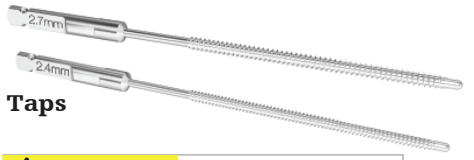
Scaled Drill and Drill Guide

SpeedGuides

Depth Gauge

Taps

2.4mm and 2.7mm taps (703900 for 2.4mm screws and 703889 for 2.7mm screws) are available in the system.



Taps

⚠CAUTION

Although all screws are self-tapping, it is recommended to use a tap if excessive resistance is felt during insertion or if the bone is dense.

⚠CAUTION

Screw length may need to be changed after plate is fully seated on bone.

Joystick for plate positioning and temporary fixation

The joystick for T8 holes can be used in any VariAx circular hole to aid in plate positioning. 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.

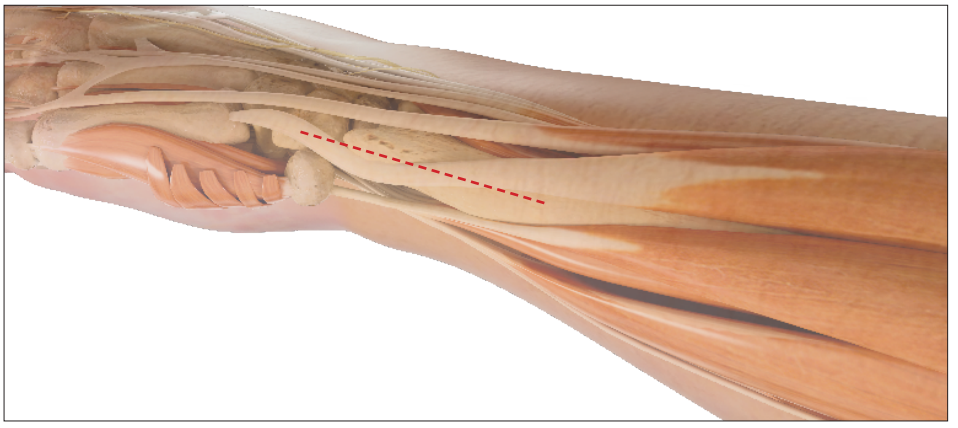
Operative technique

DU Hook Plates

A longitudinal incision is made over the palpable ulna.

⚠WARNING

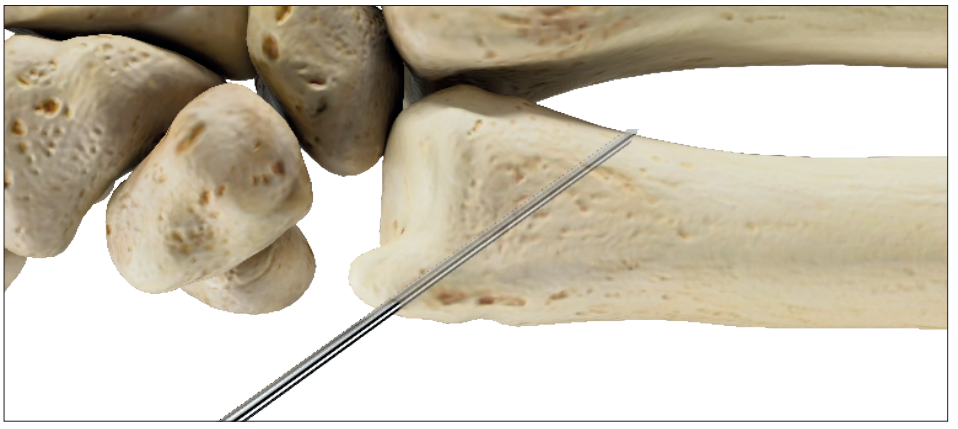
Care must be taken to avoid the dorsal sensory branch of the ulnar nerve.



Expose the distal ulna in the region between the tendons of the flexor carpi ulnaris and extensor carpi ulnaris toward the ulnar styloid. Fracture fragments can be visualized and reduced. The fractured ulna styloid should be reduced and temporarily stabilized with a K-wire.

⚠WARNING

Care is taken to protect the superficial radial and dorsal ulnar nerve branches.



The plate is slipped over the K-wire (07-40281) and placed along the medial aspect of the ulna, ensuring the distal hook is secured around the ulnar styloid. Plate placement can be adjusted by sliding the plate along the K-wire through the K-wire slot.

⚠WARNING

- The plate bending pliers are designed to be used only in circular holes.
- Always attach the bending pliers to two adjacent holes to prevent deformation of the screw holes.
- Do not re-bend plates.

NOTICE

The distal lateral aspect of the plate can be bent along the groove with bending pliers to better match patient anatomy.

Operative technique

DU Hook Plates

A non-locking screw placed in a circular shaft hole will compress the plate to the bone. If compression of the fracture site is desired, the oblong compression hole can be used.

Two distal screws are placed in the distal screw holes with locking unicortical screws.

⚠CAUTION

- Avoid bicortical screws to prevent injury to the distal radioulnar joint.
- Only use non-locking bone screws with compression hole.
- Only use non-locking bone screws in oblong holes.

Fill the remaining distal and proximal screw holes with either locking or non-locking screws, as necessary.

Temporary K-wires may now be removed.

Close the incision.

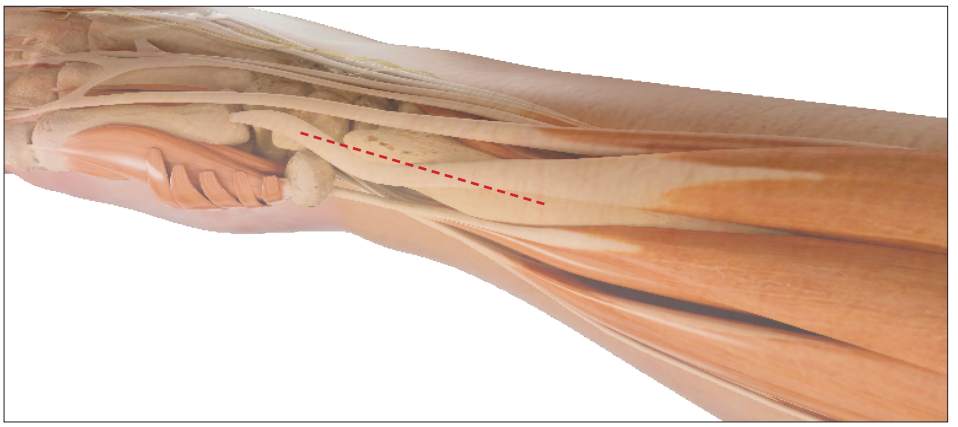
Operative technique

DU Base Plates

A longitudinal incision is made over the palpable ulna.

⚠WARNING

Care must be taken to avoid the dorsal sensory branch of the ulnar nerve.



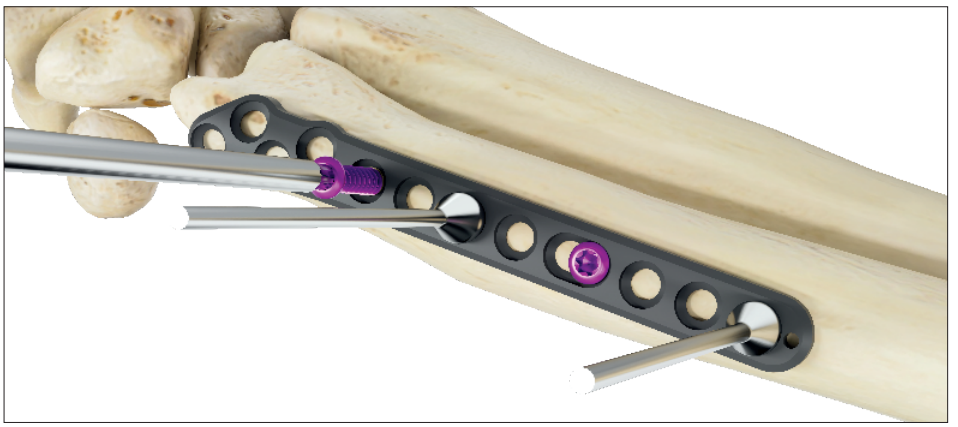
Expose the distal ulna in the region between the tendons of the flexor carpi ulnaris and extensor carpi ulnaris toward the ulnar styloid. Fracture fragments can be visualized and reduced.

Longitudinal traction may be used to reduce the fracture.

Place the plate on the medial aspect of the ulna. Temporary plate fixation can be achieved by inserting a K-wire (07-40281) through the proximal K-wire hole or by placing an olive-stop K-wire (56-400281) through two of the screw holes.

A non-locking screw placed in a circular shaft hole will compress the plate to the bone.

If compression of the fracture site is desired, the oblong compression hole can be used.



⚠WARNING

- The plate bending pliers are designed to be used only in circular holes.
- Always attach the bending pliers to two adjacent holes to prevent deformation of the screw holes.
- Do not re-bend plates.

NOTICE

The distal lateral aspect of the plate can be bent along the groove with bending pliers to better match patient anatomy.

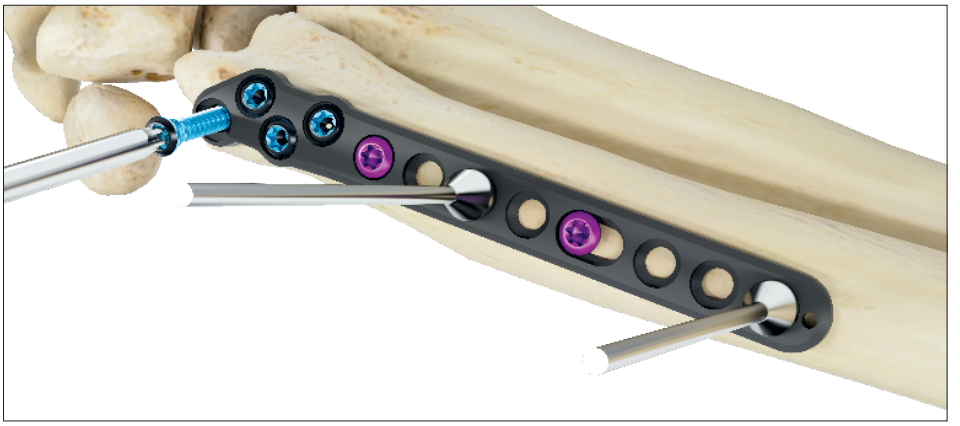
Operative technique

DU Base Plates

The 4 distal screws holes are designed to provide a diverging screw pattern. Fill the 4 distal screw holes with locking unicortical screws.

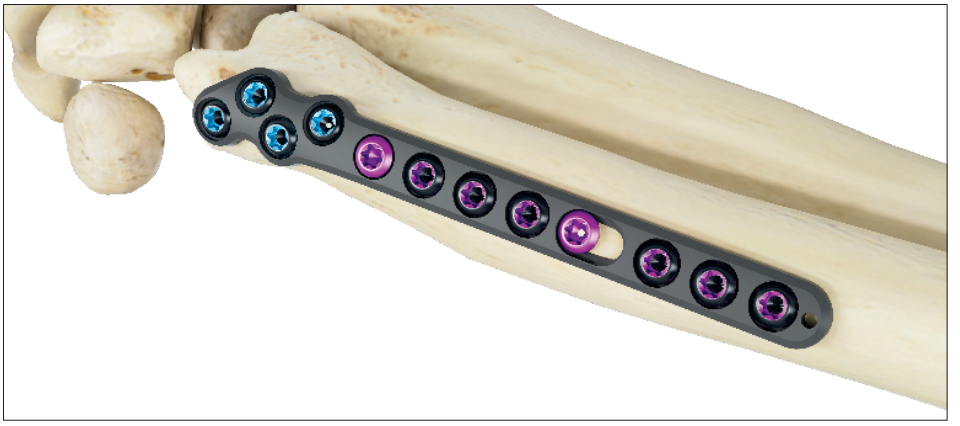
⚠CAUTION

Avoid bicortical screws to prevent injury to the distal radioulnar joint.

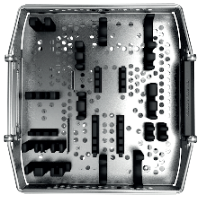


Fill the remaining proximal screw holes with either locking or non-locking screws, as necessary.

Close the incision.



System Components
VariAx 2 Dedicated Wrist Tray
Top Level & 4-Level Tray Frame
consisting of:

Ref #	Description
940213	Upper Tray Wrist
1500-0006	Lower Part, 2 Level, Detachable
940347	Wrist Tray Top Layer Clip

Instruments

Ref #	Description
703921	Handle, Medium
703920	Handle, Large
703923	Handle Insert, AO, cannulated
703922	Handle Insert, AO, Ratchet, cannulated
703885	Depth Gauge for Distal Radius
703664	Screwdriver blade T8 AO
45-80040	Countersink For Screws 02.7/3.5mm AO Fitting
703663	Screwdriver Blade, AO, T8, self retaining
703675	Universal Holding sleeve
703927	Joystick for T8 screw holes
703684	Drill Guide, 2.0mm Drill, Comp/Polyaxial (T8)
703884	Drill Guide, For 2.7mm independent lag screw (T8)
703688	Drill Guide, For 2.4mm independent lag screw (T8)
703902	Drill Guide, 1.1 K-wire, Fixed Angled T8 2.0mm Drill
703896	Drill Bit, AO, Ø2.0mm x 135mm, Scaled *new
703897	Overdrill, AO, Ø2.7mm x 122mm*new
703696	Overdrill, AO, Ø2.4mm x 122mm
703899	Tap, AO, For 2.7mm Screws
703900	Tap, 2.4mm for AO screws
703888	SpeedGuide™, For 2.4/2.7 mm Screws, T8 (L = 30mm)*new
703891	SpeedGuide™ Drill, AO, Ø2.0mm (L = 30mm)

- All non-sterile screws and drills may be ordered sterile by placing an "S" at the end of the REF Number.

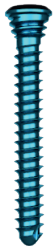
VariAx 2 Dedicated Wrist Tray

Drawer 1

8 2.4mm and 2.7mm screws & volar plates consisting of:

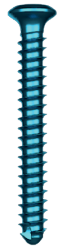
Ref #	Description
1500-0005	Drawer For Modules & Screw Racks
940348	Wrist Tray Screw Drawer Clip
940234	Screw Rack for 2.7mm Screws, T8
940235	Screw Rack for 2.4mm Screws, T8

2.4mm Locking Screw 8



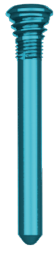
Titanium Ref #	Length mm
656008	8
656010	10
656012	12
656014	14
656016	16
656018	18
656020	20
656022	22
656024	24
656026	26
656028	28
656030	30
656032	32
656034	34
656036	36
656038	38

2.4 Non Locking Screws 8



Titanium Ref #	Length mm
656108	8
656110	10
656112	12
656114	14
656116	16
656118	18
656120	20
656122	22
656124	24
656126	26
656128	28
656130	30
656132	32
656134	34
656136	36
656138	38

2.0 mm Locking Pegs 8



Titanium Ref #	Length mm
656616	16
656618	18
656620	20
656622	22
656624	24
656626	26

VariAx 2 Dedicated Wrist Tray

2.7mm Locking Screws

Titanium Ref #	Length mm
656308	8
656310	10
656312	12
656314	14
656316	16
656318	18
656320	20
656322	22
656324	24
656326	26
656328	28
656330	30
656332	32
656334	34
656336	36
656338	38
656340	40
656345	45
656350	50

2.7mm Non Locking Screws

Titanium Ref #	Length mm
656408	8
656410	10
656412	12
656414	14
656416	16
656418	18
656420	20
656422	22
656424	24
656426	26
656428	28
656430	30
656432	32
656434	34
656436	36
656438	38
656440	40
656445	45
656450	50

2.7mm Non Locking Partially Threaded Screws

Titanium Ref #	Length mm
656516	16
656518	18
656520	20
656522	22
656524	24
656526	26

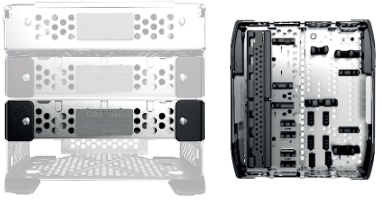
Washer

Ref #	Description
619920	Washer

VariAx 2 Dedicated Wrist Tray

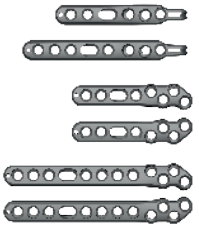
Drawer 2

Tray Content: Anatomical Dorsal, DR Fragment Specific, Wrist Spanning, Distal Ulna plates and instruments



Ref #	Description
1500-0005	Drawer For Modules & Screw Racks
940459	Wrist Tray Clip DR DU & Spanning Plates
940458	Wrist Add-on Clip DR & DU Spanning Plates
940199	Insert DU Plates & Frag Spec Instruments
940198	Insert DR & Wrist Spanning Plates

Anatomic Distal Ulna Plates



Ref #	Description	Length mm	Profile Height mm
625102	Distal Ulna Hook Plate, Short	47	1.5
625104	Distal Ulna Hook Plate, Long	58	1.5
625110	Distal Ulna Base Plate, Short, Right	43	1.7
625111	Distal Ulna Base Plate, Short, Left	43	1.7
625112	Distal Ulna Base Plate, Long, Right	67	1.7
625113	Distal Ulna Base Plate, Long, Left	67	1.7

Anatomical Distal Ulna Plates Trials

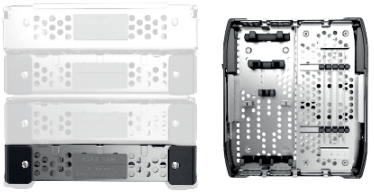
Ref #	Description	Length mm
705902	DU Hook Plate Trial, Short	47
705910	DU Base Plate Trial, Right, Short	43
705911	DU Base Plate Trial, Left, Short	43

- All non-sterile screws and drills may be ordered sterile by placing an "S" at the end of the REF Number.

VariAx 2 Dedicated Wrist Tray

Drawer 3

Reduction Instruments, consisting of:



Ref #	Description
1500-0005	Drawer For Modules & Screw Racks
940333	Labeling Clip Core Tray Reduction
940250	Reduction Instruments 1 Insert
940251	Reduction Instruments 2 Insert
940252	Reduction Instruments 3 Insert
940350	Wrist Tray Reduction Instrument Clip

Reduction Instruments

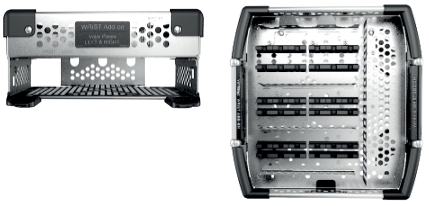
Ref #	Description
705297	Straight Reduction Clamp, Broad
703822	Straight Reduction Clamp
702926	Repositioning forceps L130mm
702932	Repositioning forceps L143mm (Lobster Claw)
705294	Periosteal Elevator, Round Edge 6mm
705295	Periosteal Elevator, Flat Blade 13mm
705293	Periosteal Elevator, Straight Edge 6mm (optional)
705296	Periosteal Elevator, Curved Blade 13mm (optional)
45-80010	Plate Bending Pliers
700151	Hook
700664	6mm Hohmann Retractor
700665	8mm Hohmann Retractor
700667	15mm Hohmann Retractor
703938	Bending Iron for VariAx Plates
700153	Ballspike
703818	K-Wire with Stop 2mm (pack of 5)
390192	K-Wire 2.0mm, x 150mm (pack of 10)
390164	K-Wire 1.6 x 150mm (pack of 10)
390157	K-Wire 1.25mm, x 150mm (pack of 10)

System Components

VariAx 2 Wrist Add–On Tray

Top Level & 2-Level Tray Frame

consisting of:



Ref #	Description
940221	Upper Tray Wrist Add-on, 2 Level

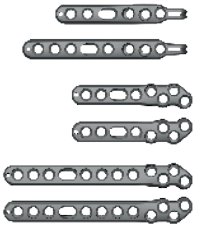
VariAx 2 Wrist Add–On Tray

Drawer 1

Tray Content: Anatomical Dorsal, DR Fragment Specific, Wrist Spanning, Distal Ulna plates and instruments

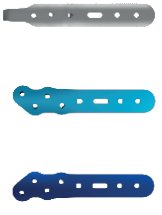
Ref #	Description
1500-0005	Drawer For Modules & Screw Racks
940459	Wrist Tray Clip DR DU & Spanning Plates
940458	Wrist Add-on Clip DR DU & Spanning Plates
940199	Insert DU Plates & Frag Spec Instruments
940198	Insert DR & Wrist Spanning Plates

Anatomic Distal Ulna Plates



Ref #	Description	Length mm	Profile Height mm
625102	Distal Ulna Hook Plate, Short	47	1.5
625104	Distal Ulna Hook Plate, Long	58	1.5
625110	Distal Ulna Base Plate, Short, Right	43	1.7
625111	Distal Ulna Base Plate, Short, Left	43	1.7
625112	Distal Ulna Base Plate, Long, Right	67	1.7
625113	Distal Ulna Base Plate, Long, Left	67	1.7

Anatomical Distal Ulna Plates Trials



Ref #	Description	Length mm
705902	DU Hook Plate Trial, Short	47
705910	DU Base Plate Trial, Right, Short	43
705911	DU Base Plate Trial, Left, Short	43

- All non-sterile screws and drills may be ordered sterile by placing an "S" at the end of the REF Number.

Notes

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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