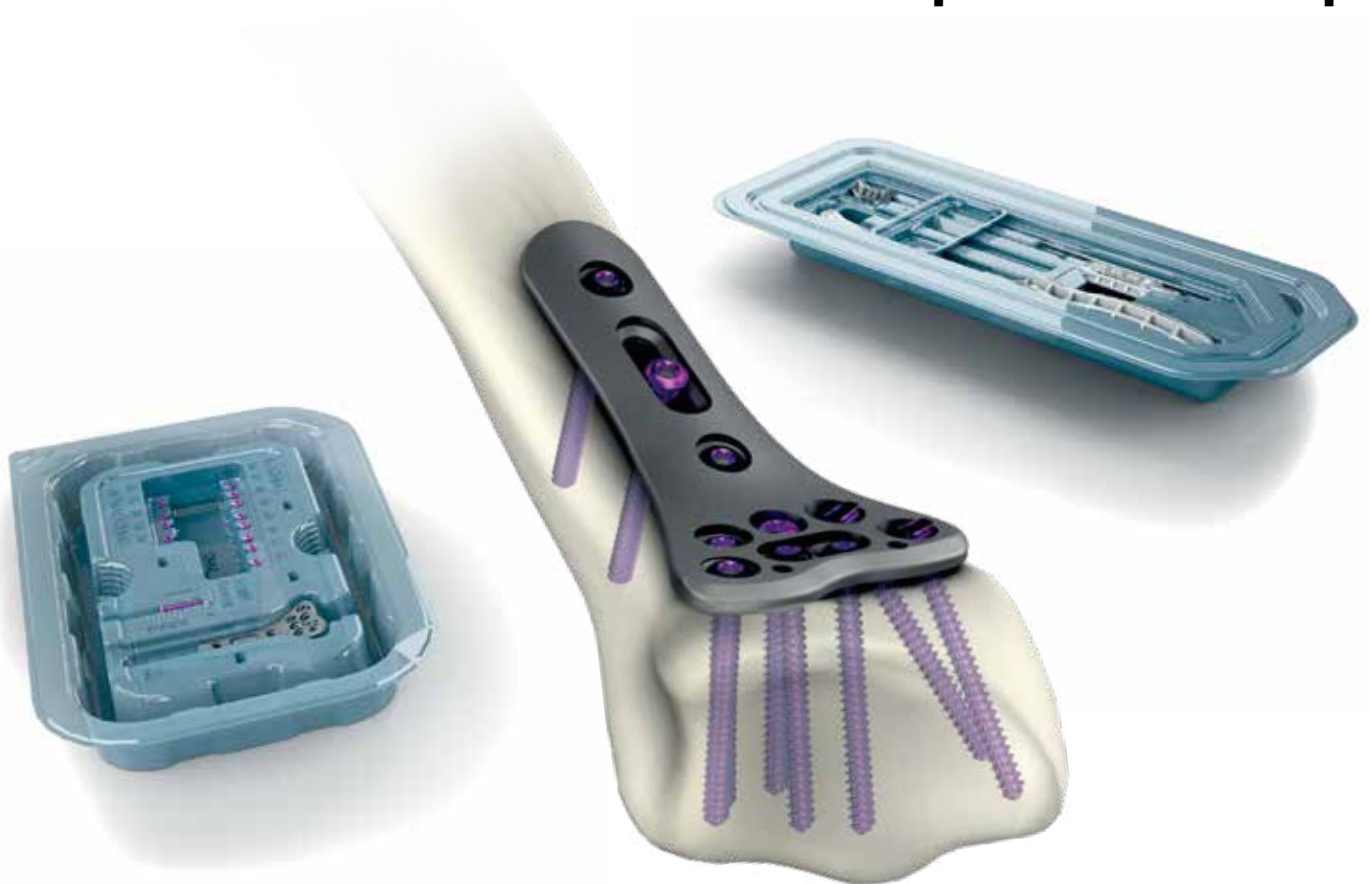


VariAx[®] 2 Xpress

Distal Radius Locking System

Operative technique



VariAx 2 Xpress

Distal Radius Locking System

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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.

WARNING

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

WARNING

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

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

Consult Instructions for Use (www.ifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.

The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.

WARNING

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future due to medical reasons.

WARNING

In the event of contamination, or expiration of shelf life or in the case of products supplied non-sterile, the product must be subjected to an appropriate cleaning process and sterilized by means of a validated sterilization procedure before use, unless specified otherwise in the product labeling or respective product technical guides.

WARNING

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

Indications and contraindications

Contraindications

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

The following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that can not provide adequate support and / or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

VariAx Distal Radius Locking System Indications:

The VariAx Distal Radius Locking System including the XXL Volar Distal Radius Plates is intended for

internal fixation of small bone fractures, primarily including distal radius fractures.

Indications include:

- Compression fractures.
- Intra-articular and extra-articular fractures.
- Displaced fractures.

Following additional indications apply only for the XXL Volar Distal Radius Plates:

Osteotomies, non-unions and malunions.

VariAx 2 Indications

The VariAx 2 System is indicated for adult and pediatric patients, where the implant would not cross open growth plates, for the treatment of normal or osteopenic bone for the following conditions or procedures:

- Fracture fixation , including single, segmental, and comminuted fractures.
- Revision, including nonunion and malunion.
- Intra- and extra-articular fractures.
- Compression fracture.
- Displaced fracture.
- Reconstruction.
- Replantation.
- Arthrodesis.
- Osteotomy.

T8 2.4mm screws and T8 2.0mm locking pegs:

For use in small bones, primarily including the distal radius, in the treatment of:

- Compression fractures;
- Intra-articular and extra-articular fractures;
- Displaced fractures;
- Reconstruction procedures.

Indications and contraindications

T8 2.7mm screws:

For use in small bones, including the distal radius as well as the fore, mid- and hind foot and ankle, in the treatment of:

- Intra-articular and extra-articular fractures of the distal radius.
- Displaced and compression fractures of the distal radius.
- Replantation, joint fusions or arthrodesis and corrective osteotomies in the foot and ankle.
- Reconstruction procedures in the foot and ankle and distal radius.

T10 3.5mm and T10 2.7mm screws:

For use in the radius, ulna, clavicle, humerus, foot and ankle, distal tibia and fibula, in the treatment of:

- Intra-articular and extra-articular fractures of the distal humerus and proximal ulna.
- Single, segmental and comminuted fractures.
- Replantation, joint fusions or arthrodesis and corrective osteotomies in the foot and ankle.
- Normal bone density or osteopenic bone.

NOTICE

Only the VariAx 2 T8 2.7mm diameter screws are included in the VariAx 2 Distal Radius Xpress Kit. These screws are only intended for use in the distal radius when packaged in the VariAx 2 Distal Radius Locking System Xpress Kit.

CAUTION

The Stryker VariAx 2 Xpress Distal Radius Locking 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 VariAx 2 Xpress Distal Radius Locking 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.

System overview

The VariAx 2 Xpress Distal Radius Locking Plate System is a single-use, disposable instrument and implant system created to treat distal radius fractures. The system is comprised of kitted anatomic volar plates and self-tapping screws, both locking and non-locking.

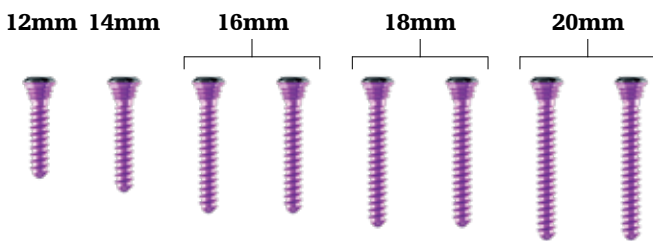
Narrow distal radius kits Available for left and right



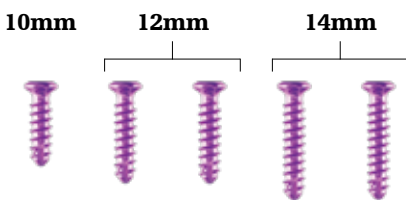
NOTICE
Long plate implant kits only available in select international markets.

T8 2.7mm screw range

8 locking screws



5 non-locking screws



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

The implant kits contain one VariAx Distal Radius Anatomical Volar Plate as shown below and a variety of 2.7mm screws to build the appropriate plate/screw construct. The following is an overview of the different implant kits.

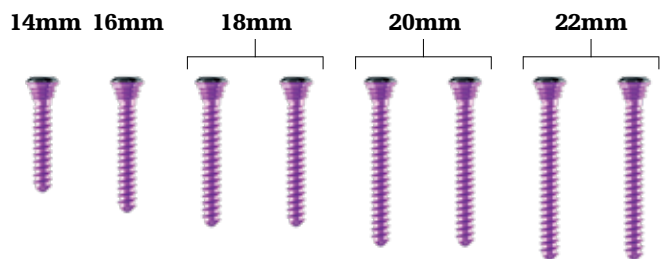
Intermediate distal radius kits Available for left and right



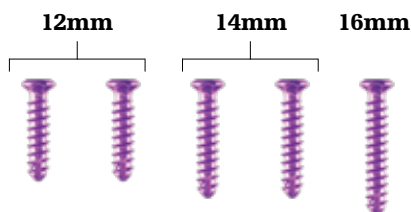
NOTICE
Long plate implant kits only available in select international markets.

T8 2.7mm screw range

8 locking screws



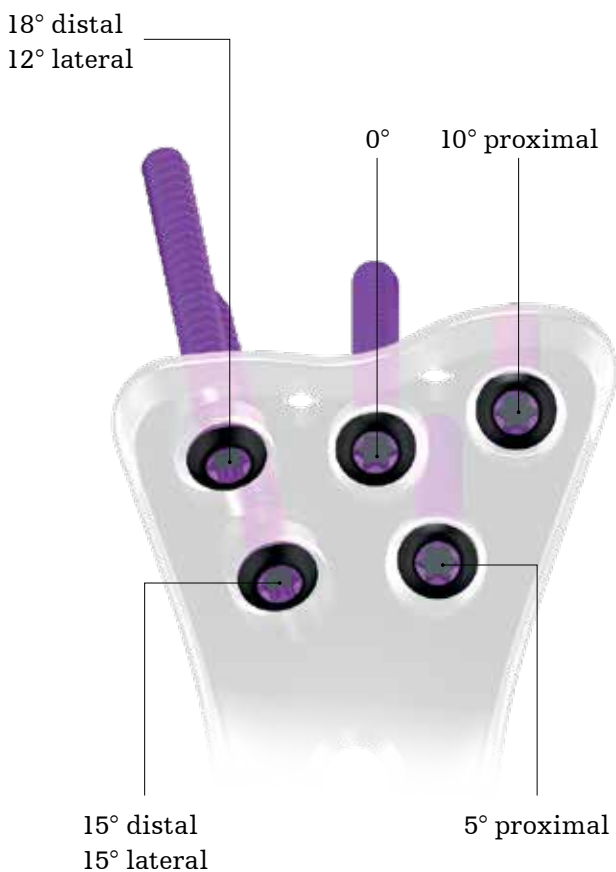
5 non-locking screws



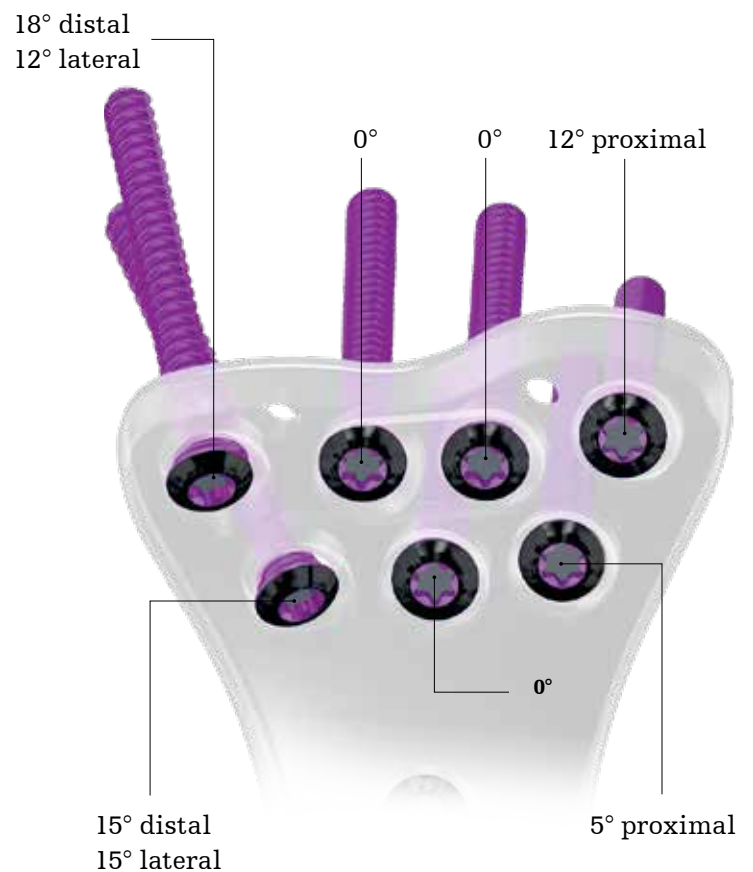
System overview

The distal screw holes in the anatomic plates are angled to give a predetermined screw pattern in the distal bone block. The image here shows the various trajectories. When drilling at a 0° angle relative to the plate hole, the screw trajectories shown here relative to the plate surface can be achieved.

Narrow plate (Plate width: 22mm) Screw trajectory



Intermediate plate (Plate width: 25mm) Screw trajectory



SmartLock technology

Allows for $\pm 15^\circ$ 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° cone and every angle in this range will be a locking position.

This may allow the surgeon to aim where the screw should be placed. Also, depending on the placement of the plate, there may be a need to angle a screw out of the fracture line.

System overview

VariAx 2 Xpress Sterile Instrument Kit T8

The system also includes a dedicated instrument kit which is used with any of the implant kits. The following is an overview of the instruments in the kit.

T8 screwdriver

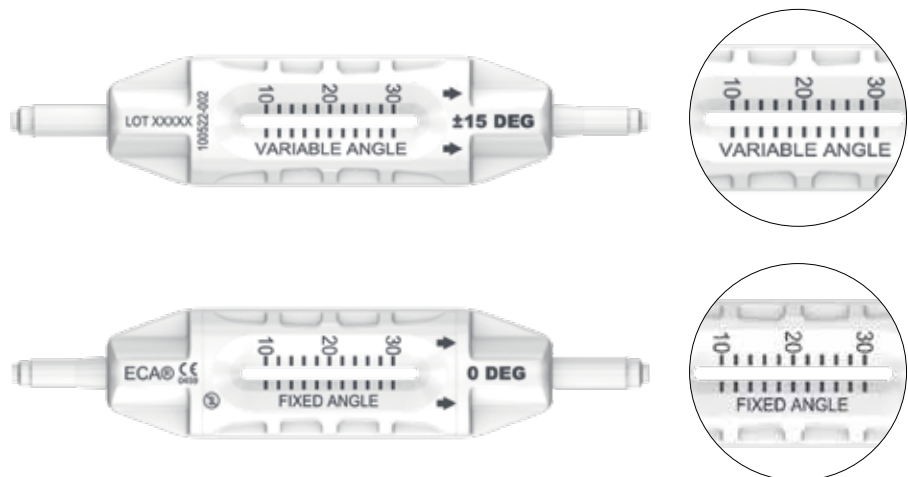
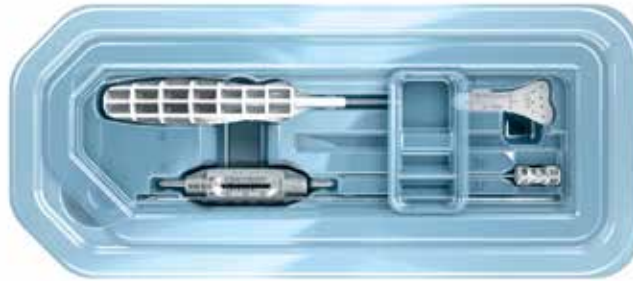
The T8 screwdriver provides a self-retaining connection to the screw.

NOTICE

To avoid disengagement of the screwdriver blade from the screw during insertion, axial pressure is recommended.

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.



Drill guide / depth gauge

This is a 2-in-1 instrument designed to drill the pilot hole in the plate either with an angulation of $\pm 15^\circ$ or at fixed angle in the plate. Also, when used with the probe or drill, the device can act as a gauge to measure the appropriate screw length. Drilling/measuring in the fixed angle mode - please note that when drilling and measuring in the fixed angle mode, the 'FIXED ANGLE' marking on the instrument must be visible to the surgeon.

Drilling/measuring in the variable angle mode - please note that when drilling and measuring in the variable angle mode, the 'VARIABLE ANGLE' marking on the instrument must be visible to the surgeon.

For further details on the application of this instrument, please refer to Step 11 (page 13) of this operative technique.

System overview

Depth probe

The probe is laser marked and used in conjunction with the drill guide depth gauge to measure the screw length.



2.0mm drill

The drill is to be used with a standard pin collet driver. The drill bit working length can be reduced by sliding the hand piece to a length that permits appropriate screw hole depth to be drilled.



Also, the drill is laser marked in order that direct measure of the drill depth can be viewed in the drill guide.

Plate trial

The plate trial can be used to choose appropriate implant according to patient anatomy and fracture pattern.

If an extra short plate is indicated, the plate trial may be cut using scissors to shorten the trial.



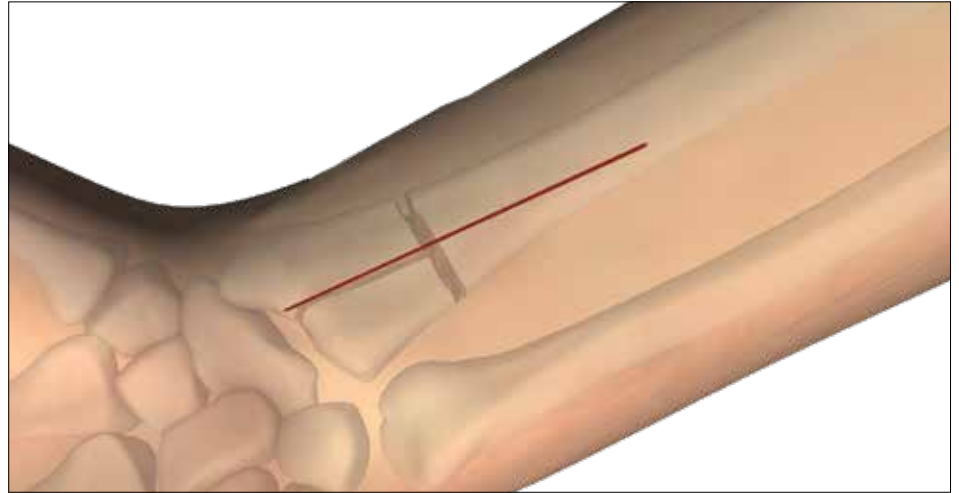
Operative technique

Step 1

⚠ CAUTION

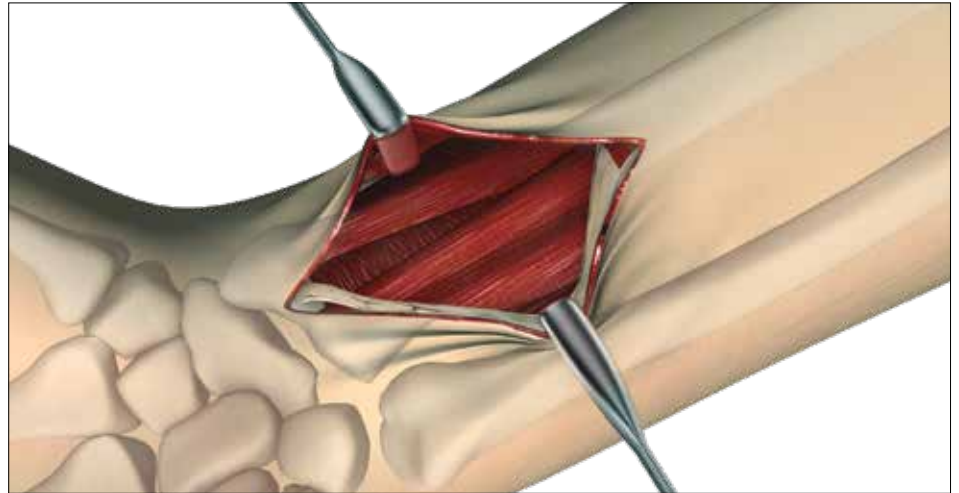
Ensure proper soft tissue protection by utilizing standard retraction instrumentation, especially if spinning of the outer sleeve occurs.

An incision is made approximately 5cm – 8cm long just radial to the FCR (Flexor Carpi Radialis) tendon. If more exposure is necessary, the incision can be extended radially at 45° along the wrist flexion creases.



Step 2

The FCR tendon is retracted ulnarly and dissection is carried down through the floor of the FCR sheath.

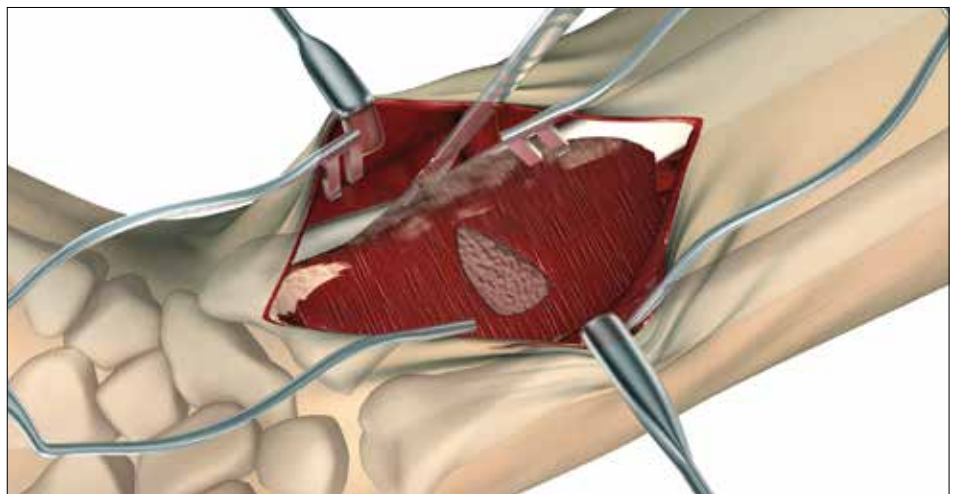


Step 3

The pronator quadratus muscle is identified and dissected in its entirety off of the volar surface of the radius as an ulnarly based flap.

Step 4

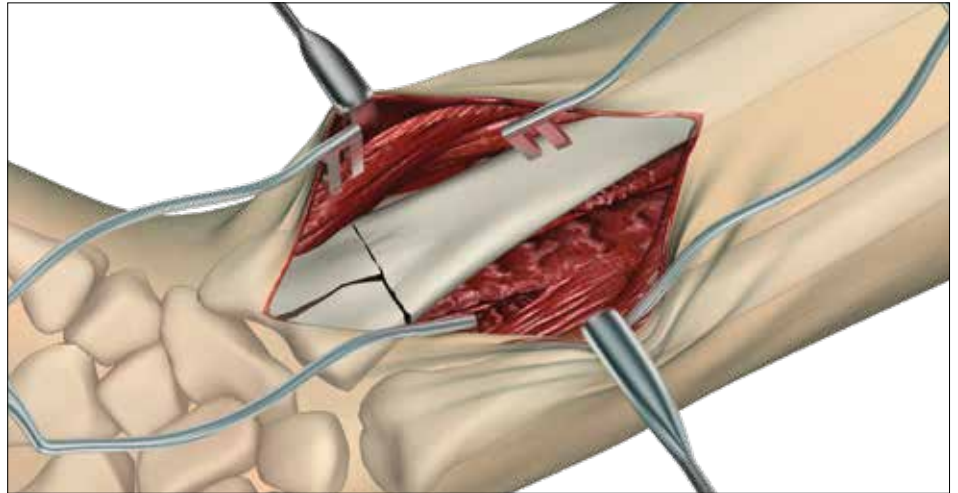
The insertion of the brachioradialis may be released.



Operative technique

Step 5

The fracture is visualized and reduced. The use of external traction, and/or the use of K-wires for temporary fixation may be helpful. The use of AP/Lateral fluoroscopy is helpful to determine correct fracture reduction and plate position.

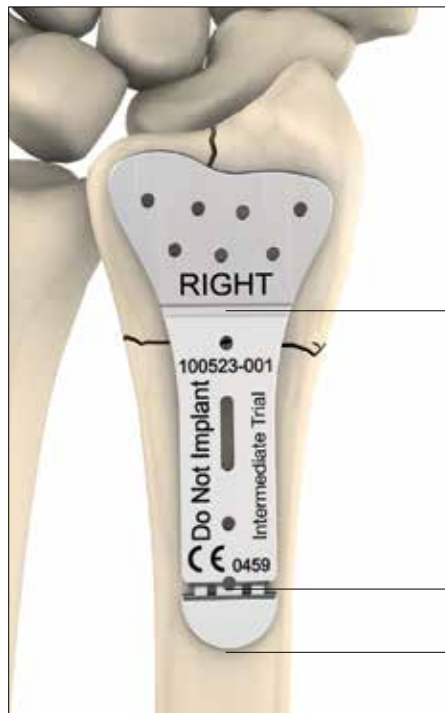


Step 6

The plate trial can be used to choose appropriate implant according to patient anatomy and fracture pattern. As the left and right distal radius plates mirror each other, the same trial may be used to trial the left or right distal radius by turning over to correct sided position.

The trial can be bent at the distal metaphyseal groove for the right or left anatomical side applications. The proximal end of the trial is perforated to indicate the difference in length between the extra short and short implant. If the fracture lies more proximal than the trial, a long plate is chosen. If the trial plate is to be shortened, the end should be cut off with scissors.

The trial matches the width of the intermediate distal radius plate. If the trial is too wide for the anatomy, the narrow distal radius plate can be chosen.



Metaphyseal groove

Extra short plate (trial may be cut with scissors to extra short length)

Short plate

Operative technique

Step 7

The plate should be placed proximal the distal rim of the radius to support the volar articular fracture fragments and also to avoid inserting screws into the joint. K-wires can be used for temporary fixation while evaluating the placement of the plate.



Step 8

The first pilot hole should be drilled in the oblong gliding hole using the 2.0mm drill and drill guide with the 'VARIABLE ANGLE' side of the drill guide visible to the surgeon.

To apply the variable angle mode of the drill guide, the 'VARIABLE ANGLE' and '±15 DEG' markings must be visible to the surgeon, with the drill guide tip engaged downwardly into the plate as indicated by the arrow markings on the instrument. Drilling and measuring may then be undertaken with the drill guide being held along its ribbed sides.

(For additional instructions regarding the application of the drill guide, please refer to Step 11 on page 13).



⚠ CAUTION

- First fully engage the drill guide in the hole and then aim the drill in the desired direction.

- When drilling locking holes, using the provided drill guide 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.

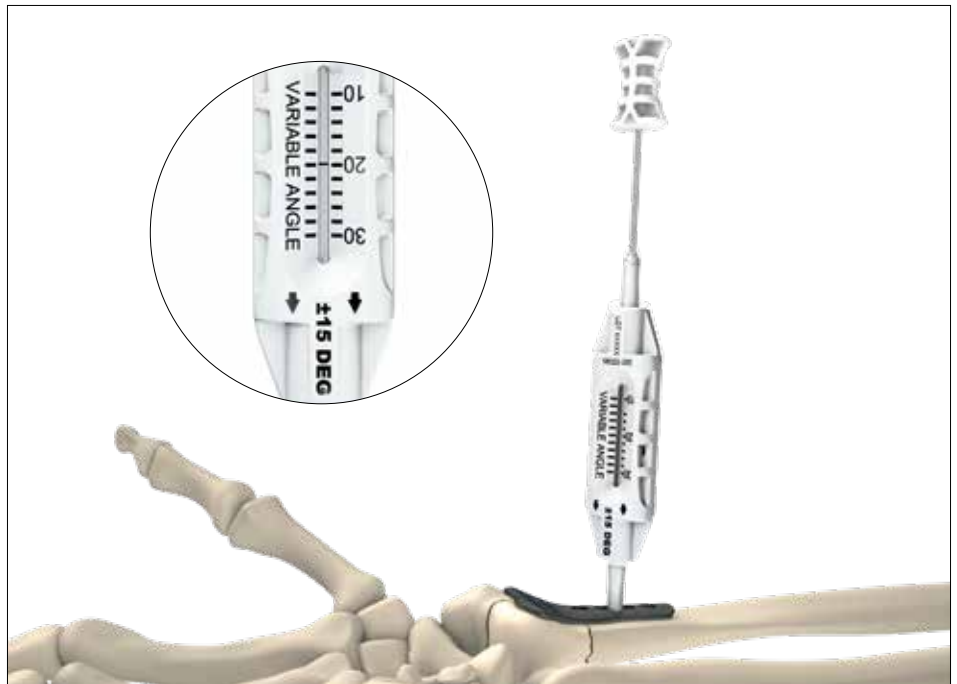
Operative technique

Step 9

Use the depth gauge probe in combination with drill guide to determine screw length. Alternatively, use the 2.0mm drill directly with the drill guide.

CAUTION

The tip of the depth gauge should be inserted through the pilot hole until it locates the opposite cortex.



Step 10

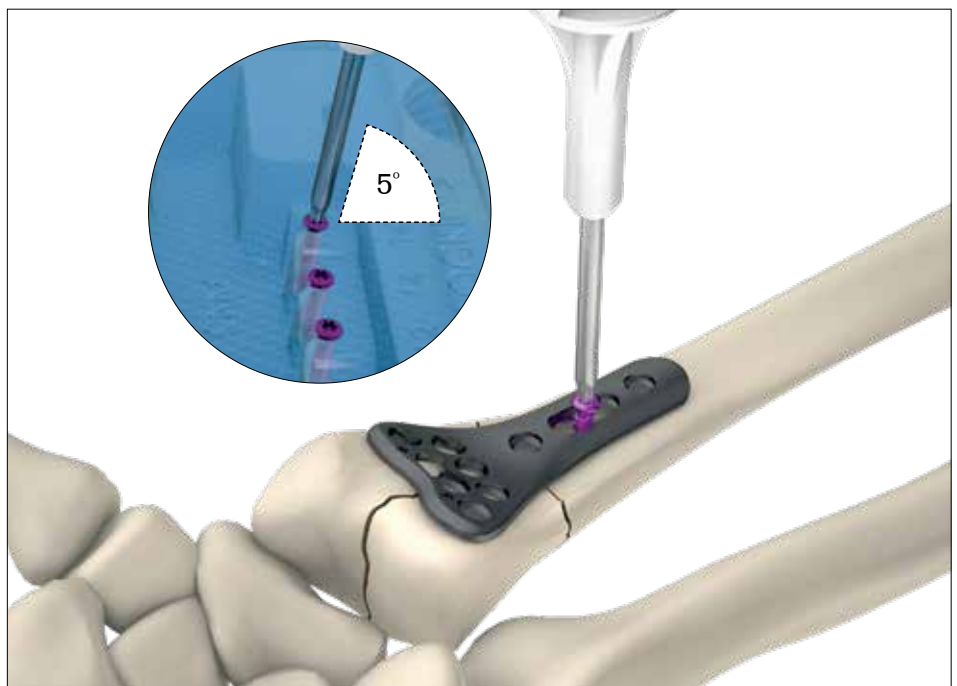
A non-locking screw is placed in the oblong gliding hole but not completely tightened to allow adjustment of the plate in distal or proximal directions. After confirmation of the correct positioning of the plate by use of fluoroscopy, tighten the screw.

CAUTION

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

While still in the implant kit tray, the screws are held at a 5° angle as illustrated by the image opposite.

Upon picking screws up from the tray using the screwdriver, position the screwdriver



at the same 5° angle as the screws, engage the blade in the screw head and withdraw the screw along the same axis.

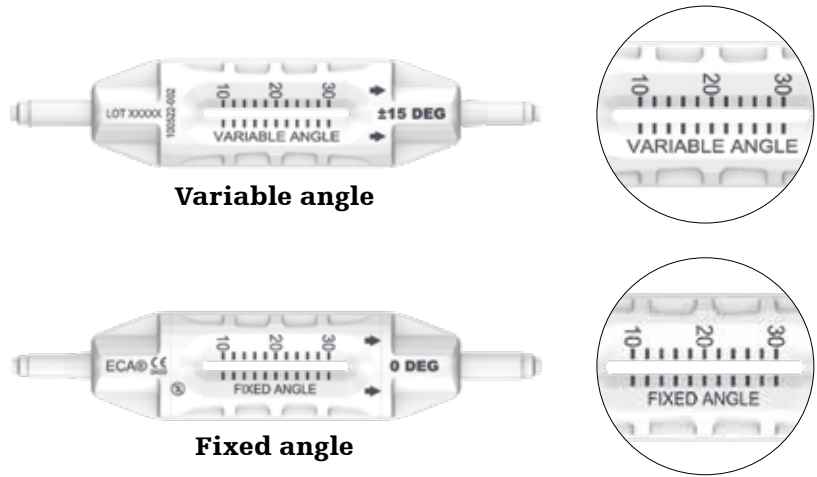
Operative technique

Step 11

Per surgeon preference, the metaphyseal holes may be drilled using the $\pm 15^\circ$ variable angled or fixed angled side of the drill guide. Each side is marked either with $\pm 15^\circ$ for variable angled drilling or 0° for fixed angled drilling. Using the desired drill guide tip, repeat drilling, measuring and placement of screws in the distal holes.

Please note that when drilling and measuring in the fixed angle mode, the 'FIXED ANGLE' and '0 DEG' markings on the instrument must be visible to the surgeon. The drill guide tip must then be engaged downwardly into the plate as indicated by the arrow markings on the instrument.

If variable angle mode is desired, the guide may be rotated 180° in order to make the 'VARIABLE ANGLE' and ' $\pm 15^\circ$ DEG' markings visible to the surgeon, with the drill guide tip engaged downwardly into the plate as indicated by the arrow markings on the instrument. Drilling and measuring may then be undertaken.



Operative technique

Step 12

Insert screws in the proximal end of the plate to complete the plate/screw construct. Verify proper alignment of screws by use of fluoroscopy to ensure that neither penetrate the joint.

Step 13

Close the incision.

⚠ WARNING

After the procedure check the proper positioning of all implants using the image intensifier.



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.

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

The Instructions for Use, Operative Techniques, Cleaning instructions, patient information leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com.

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

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