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austofix VRP 2.0+

DISTAL RADIUS PLATING SYSTEM

Surgical Technique

Australian Made • Australian Owned

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Contents

Disclaimer

This document is intended to be read by experienced orthopaedic surgeons familiar with plate fixation of the radius.

This document is intended as the recommended procedure for using the VRP 2.0+ distal radius fracture system. It offers guidance only. Each surgeon should consider the particular needs of the patient and make appropriate adjustments where necessary.

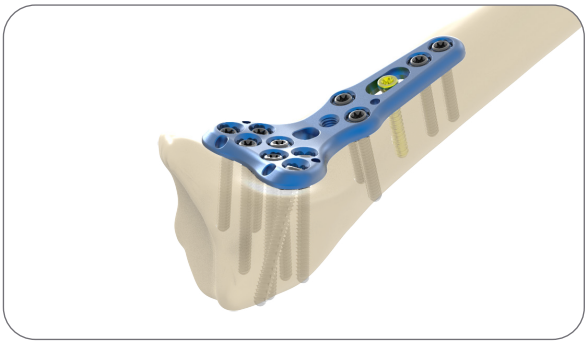
For further advice please contact your local Austofix representative.

Introduction

Austofix is an Australian medical device manufacturer and distributor specialising in orthopaedic medical devices. Since 1993, Austofix has designed, manufactured and distributed its range of implants throughout the world.

In collaboration with prominent Australian surgeons, Austofix has developed innovative, implant systems that improve patient outcomes whilst supporting safe and efficient operating procedures.

Austofix is dedicated to excellence in every aspect of medical device research and design, manufacture and product service.



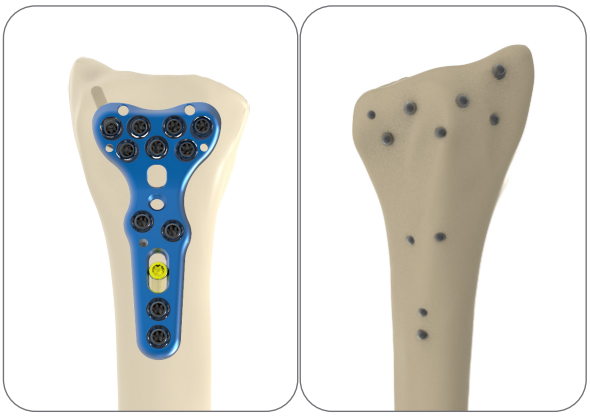
VRP 2.0+

The Austofix VRP 2.0+ is based on the successful VRP 1 with over 10 years clinical experience and post market surveillance. With extensive collaboration with Australia's prominent hand surgeons, Austofix have developed the VRP 2.0+. The key features of this innovative plate confirm the VRP 2.0+ as the market leader of volar radial plates.

Key features of the VRP 2.0+ include:

- VAST - Variable Angle Screw Technology design allows 30° conical screw angle.
- Lower profile and anatomically contoured plate to meet clinical requirements and improve patient outcomes.
- Universal plate design - for use on left or right wrist. Applicable in 80% of radius fractures.
- Increased plate range with corresponding fragment specific components.
- Specifically contoured to accommodate the FPL tendon.
- Smart Guide for intuitive navigation and rapid insertion of the fixed angle distal screws.
- Conformance to the anatomy of the radius, creating a template for fracture reduction.
- The distal screws offer support to dorsally displaced fractures preventing tendon irritation associated with dorsally implanted constructs.
- The distal screws are designed to be placed as close as possible to the subchondral bone of the articulating surface to maintain radial length.
- Harder medical grade Titanium Screws cut into the softer CP Titanium plate ensuring a solid construct.

The VRP 2.0 is supported by the comprehensive new and innovative instruments for efficient and safe surgical technique, including the innovative Ezy-Grip feature for secure screw handling.



Design Details

Plates

The Austofix VRP 2.0+ Volar Radius Plate incorporates locking screw technology with an anatomically designed plate to achieve angle stable fixation of most fractures of the distal radius.

- Innovative VAST - Variable Angle Screw Technology design, allowing 30° conical screw fixation angle.
- Lower profile to meet clinical and patient requirements.
- Universal plate design; for use on left or right wrist.
- Increased plate range with corresponding fragment specific components.
- Specifically contoured to accommodate the FPL tendon.

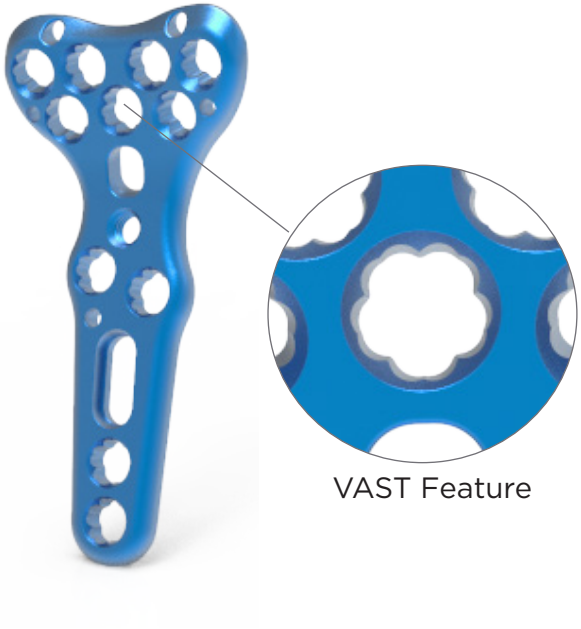
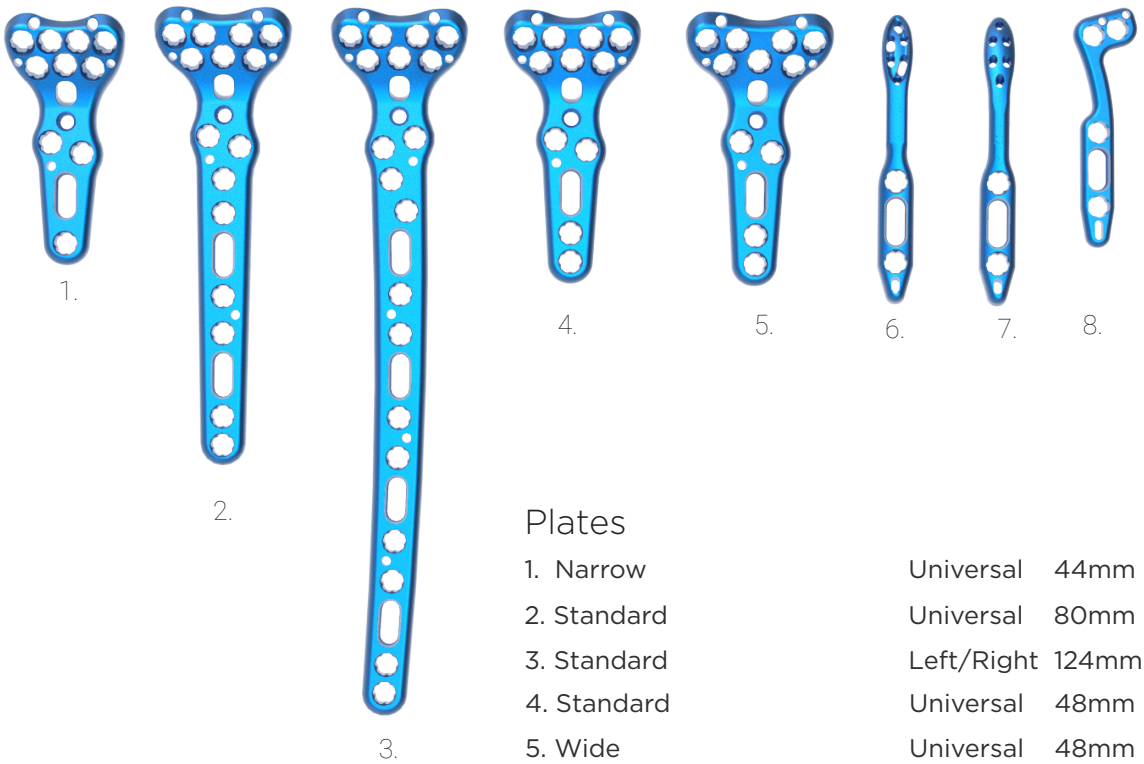


Plate Range

The Austofix VRP 2.0+ is available for different patient sizes. Plate selection is determined by the surgeon according to patient's anatomy and clinical requirements.



Plates

1. Narrow	Universal	44mm (L) x 20mm (W)
2. Standard	Universal	80mm (L) x 24mm (W)
3. Standard	Left/Right	124mm (L) x 24mm (W)
4. Standard	Universal	48mm (L) x 24mm (W)
5. Wide	Universal	48mm (L) x 26mm (W)
6. Radial Styloid slotted	Universal	52mm (L) x 6mm (W)
7. Radial Styloid low profile	Universal	52mm (L) x 6mm (W)
8. Dorsal	Left/Right	42mm (L) x 11mm (W)

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Screws

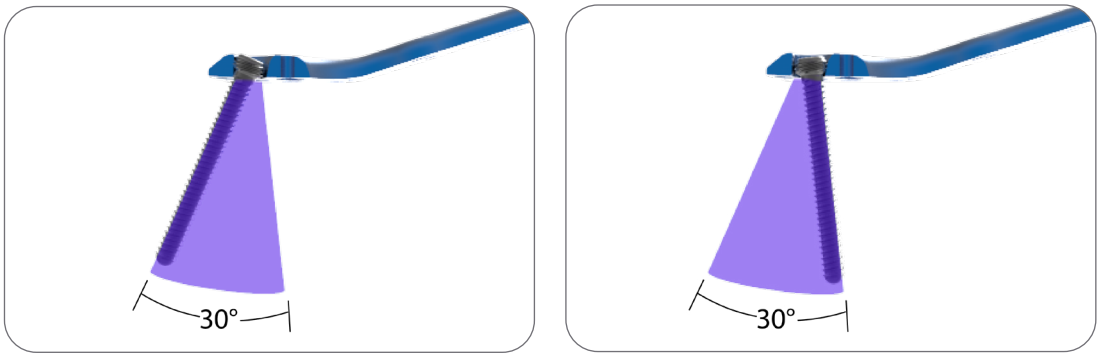
The VRP 2.0 screw range is made from medical grade Titanium Alloy. The Innovative screw design uses a Variable Angle Screw Technology (VAST) allowing 30° conical angle in VRP 2.0+ plates.

Locking screws have matched locking and cortical thread leads. This feature ensures minimal axial displacement of fragments during insertion and locking.

Locking, Non-locking Screws and Locking Pegs are available to provide options for fragment capture and reduction. This is particularly useful for dorsally displaced fragments. Features of the screws include:

- All screws use same drill size.
- Triple start head thread to maximise VAST stability when locked with the Locking Screw.
- Titanium Grade Locking Screw cuts into VAST feature when locked.
- Non-locking screw can be used in VAST as well as slots.
- Screw tips are rounded to reduce risk of soft tissue irritation in bi-cortical use.
- Pegs provide subchondral support in osteoperotic bone.

Warning
Only approved VRP 2.0 screws to be used with the VRP 2.0+ plating system.



Conical Screw Angle

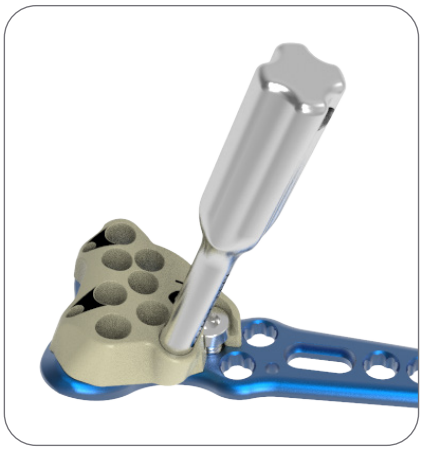
Smart Guide

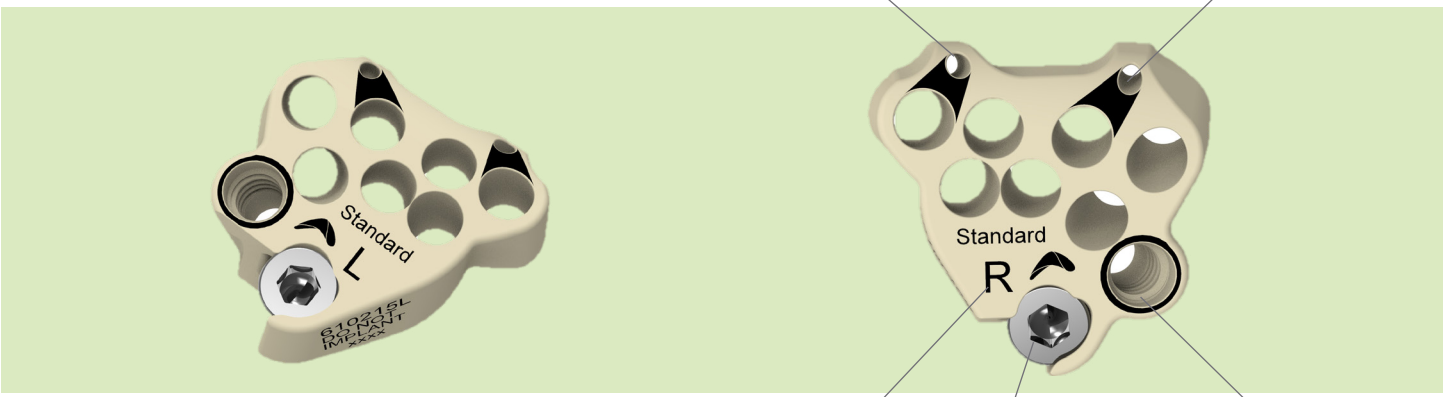
Smart Guide helps target screws in pre-set optimal angles.

- Simple screw on and off design allows for custom targeting for complex fractures.
- Specific design features providing visual and tactile feedback for accurate targeting and measurement.

By placing 2 distal K Wires behind the joint this will ensure no screws enter the articulating surface.

The Smart Guide Tool can be used for initial placement by locking it to the handle attachment hole in the smart guide.





Accurate Targeting and Measurement

Warnings

- Ensure the Smart Guide is removed prior to wound closure.
- Do not drill in Handle attachment hole.

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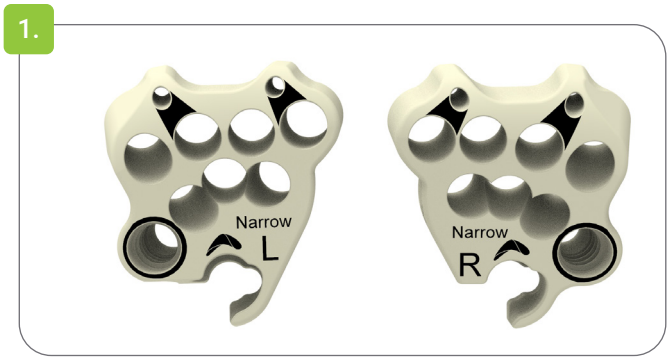
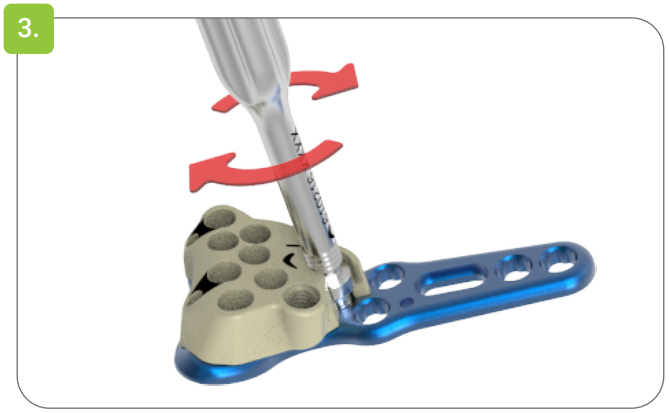
Reusable Smart Guide Placement

1. Choose the correct Smart Guide, corresponding to the patient's fracture site (L, left and R, right) and selected plate width.



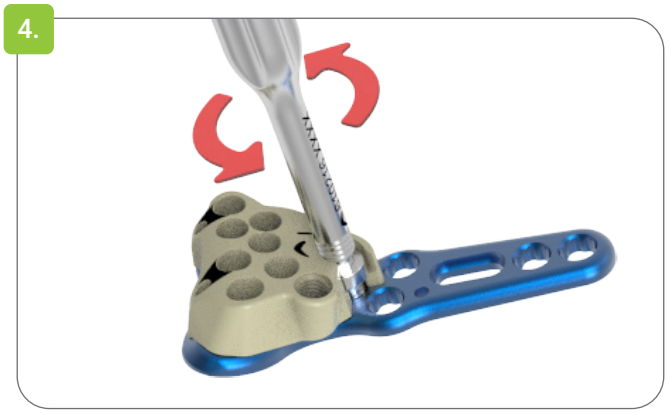
2. Locate the foot on the middle of the guide into the distal window in the plate. Ensuring the smart guide is flush to plate surface.

3. Using the Smart Guide Tool lock the guide to the plate with clockwise rotation.



Removal of reusable Smart Guide

4. Using the VRP 2.0 Smart Guide Tool unwind the smart guide screw with anti-clockwise rotation.



Warnings

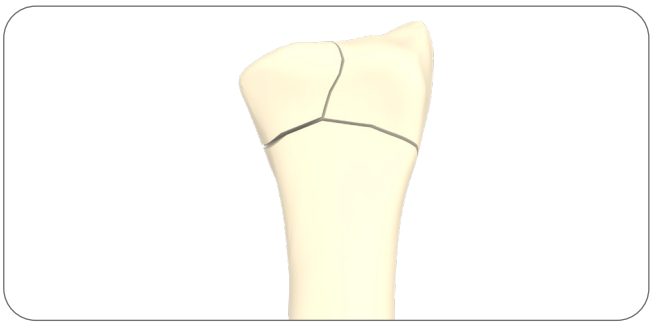
• Ensure the Smart Guide is removed prior to wound closure.

Indications & Pre-Operative Planning

VRP 2.0+ Volar Radius Plate

The Austofix VRP 2.0+ is indicated for the fixation of fractures, non-unions and osteotomies of the distal radius.

The Austofix VRP 2.0+ can be used to stabilise both dorsal and volar displaced fractures as well as intra-articular fractures.



Radial Styloid Plate

The primary indication for using the Radial Styloid Plate is an extra-articular or intra-articular fracture of the distal radius where a styloid fragment needs support.

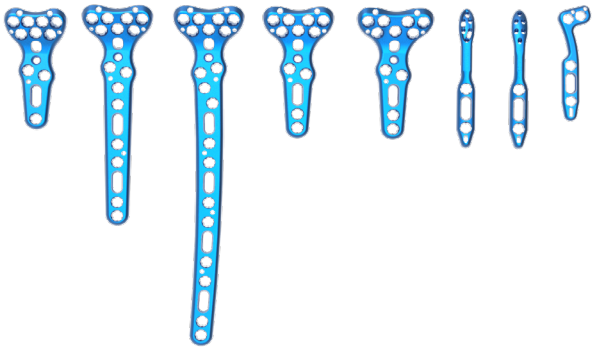
The Radial Styloid Plate is not recommended for use as the sole method of fixation other than for radial styloid fractures.

Dorsal Plate

The Austofix Distal radius Dorsal plates are intended for fixation of complex intra-articular fractures and osteotomies of the distal radius in adults.

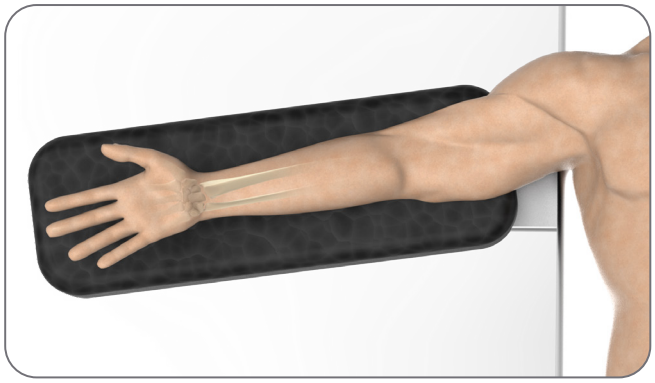
Plate Selection

The appropriate plate is selected by the surgeon after the patient's clinical requirements are assessed.



Patient Positioning

The patient lies supine with the hand extended to expose the surgical site. A radiolucent armboard or side table should be used to facilitate image intensification.



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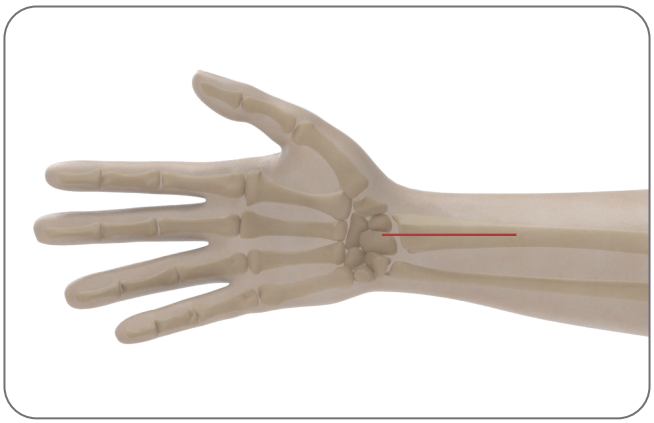
Surgical Approach

Incision



The incision for fixation of the distal radius from the volar aspect is through the distal extent of the Henry approach.

1. Make a 5 to 6cm incision longitudinally along the line of the flexor carpi radialis (FCR) tendon. Use a zigzag if crossing the wrist flexion crease.
2. Open the anterior sheath of the FCR tendon. Retract the tendon to the ulnar side and incise the posterior FCR sheath.
3. Retract the radial artery radially and develop the space between the FCR and the radial artery to expose the flexor pollicis longus muscle. Retract the FPL ulnarly.
4. The pronator quadratus muscle is exposed. It is often ruptured transversely at the fracture site. Incise the muscle along its radial and distal margins in an “L” shape. Elevate the pronator quadratus from radial to ulnar to expose the volar surface of the radius.
5. The fracture can now be visualised and assessed.
6. Depending on the fracture deformity and need for further exposure, the brachioradialis tendon may either be elevated from the radial styloid, release proximal to its insertion or incised in Z lengthening fashion for later repair.
7. Reduce the fracture and assess using image intensification.

Radial Styloid Plate

A lateral approach is recommended for effective Radial Styloid Plate placement and fixation.

Dorsal Plate

The Dorsal Plates are available as a left or right plate and used with a dorsal approach.

Screw Insertion Method

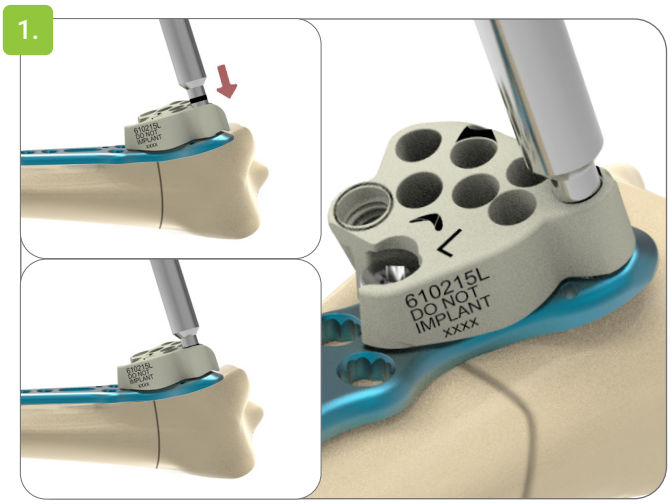
VRP 2.0+ system provides the option of a torque limiting handle or a fixed handle without a limiter. If a torque limiter does not sufficiently drive the screw into the plate, the fixed handle should be used to finish and lock the screw into position.

Only VRP 2.0+ screws to be used with the VRP 2.0+ plating system

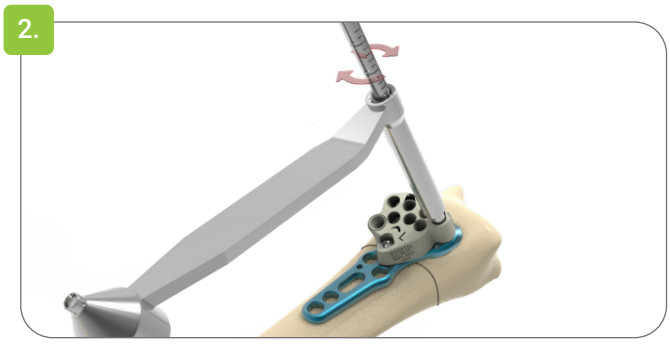
Using the Smart Guide

The Smart Guide helps target screws to the pre-set optimal angles in the distal portion. Both Locking and Non-locking screws can be used in the VAST holes.

1. Place the Drill Guide into the chosen hole of the Smart Guide. Ensure the laser marking on the Drill Guide is level with the surface of the Smart Guide.



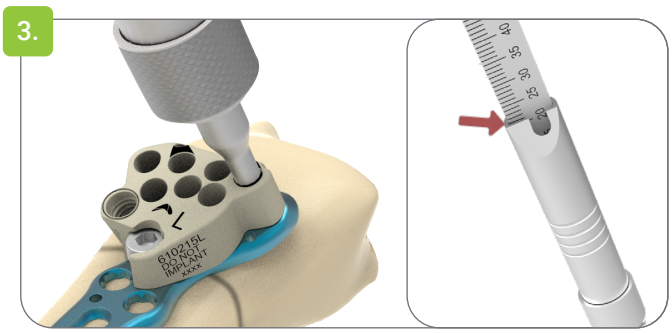
2. Use a 2.0mm Drill to drill through the radial bone. Graduations on the drill shaft give an indication of the drill depth.



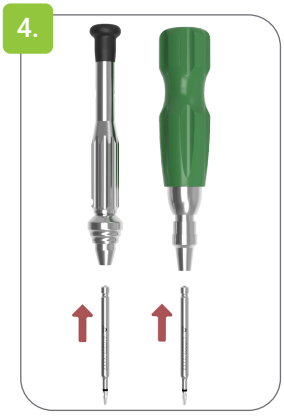
3. Remove the Drill Guide and replace with the Depth Gauge. Measurements marked on the Depth Gauge are used to determine the screw length.

   Insert the hook of the Depth Gauge to engage the dorsal cortex of the bone. Ensure the laser marked line of the Depth Gauge is level with the surface of the Smart Guide.

   Read the measurements from the barrel of the Depth Gauge. If the measurement is between graduations choose the smaller screw length.



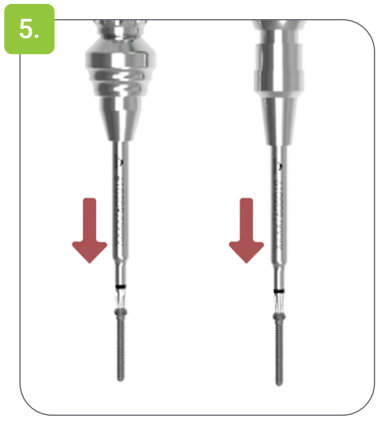
4. Assemble the Driver Tip into the Driver Handle.



5. Select the appropriate screw with the assembled Driver Tip and Handle.

   Note: The tapered Driver Tip engages the hexalobe head of the screw which form the Ezy-Grip function. The Driver Tip 'grips' the screw until placement.

   If the Driver Tip fails to capture the screw the Tip should be replaced.



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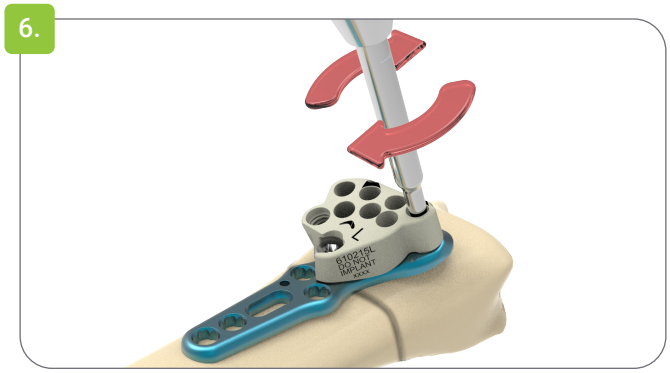
6. Insert the selected screw until the laser marking on the Driver Tip is flush with the Smart Guide.



Warning

The same screw can be re-inserted up to 2 times. A hole can have up to 4 attempts at screw insertion using a new screw after the second attempt.

Note: use steps 2-5 for required screws.

Variable Angle Screw Insertion

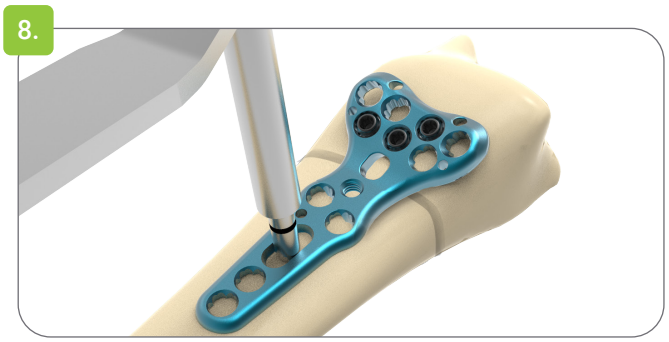
The VRP 2.0+ offers up to a 30° conical screw angle when using the VAST holes. The variable angle drill guide can be used in the distal portion after the Smart Guide has been removed. Both Locking and Non-locking screws can be used in the VAST holes.

7. Place the cone of the Drill Guide in the desired hole in the plate at the required angle using the cone. Ensure the cone is seated in the hole and not tilted. Drill to the required angle using the Drill Guide Cone, **do not** over angulate. When the cone is placed into the plate, **do not** rotate the handle or the locking hole may be damaged.

Dynamic Holes

The dynamic holes offer adjustment of the plate after the screw has been inserted. Only the Non-locking Screw can be inserted into this hole.

8. Place the Drill Guide in the proximal dynamic hole, perpendicular to the plate.



VRP 2.0+ Plate Fixation

The Austofix VRP 2.0+ may be implanted by fixating either the proximal or the distal end first.

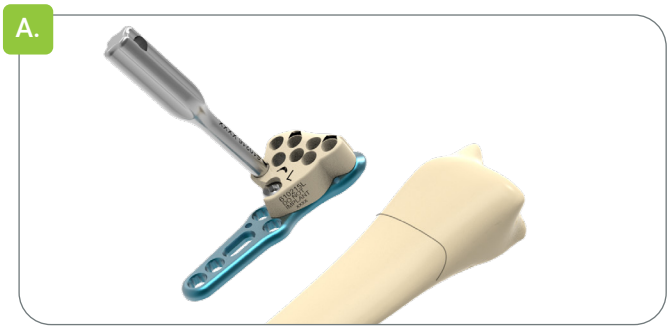
Note: It is recommended for a minimum of 6 distal screws to be inserted for optimal stability; 4 in the most distal row and 1 in each ulna and radial sided holes in the second row.

Proximal First

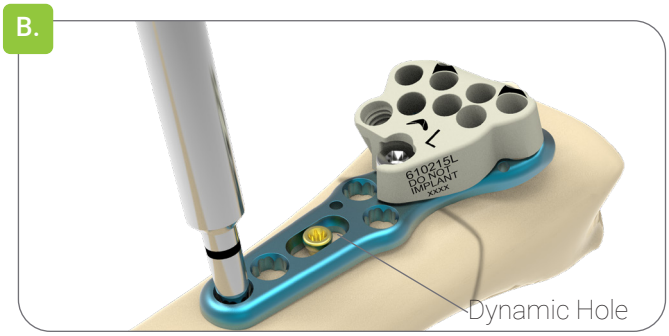
The correct spacing of the plate to the Distal Radioulnar Joint (DRUJ) must be ascertained with image intensification to prevent plate overhang before drilling and placing of non-locking screw.

Insert a 2.5mm Non-locking Screw using the 'Screw Insertion Technique' on page 11 (8) in the dynamic hole. Prior to fully seating the screw, check that the plate is correctly placed proximally and distally. Once optimal placement has been confirmed fully seat the screw. Insert the remaining screws required for a secure fixation.

A.



B.

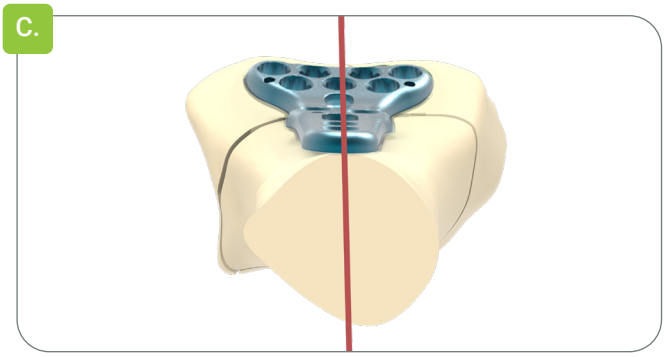


Proximal Shaft Alignment

Placement of the proximal shaft should be to the radial side to provide screw purchase in the thickest cross section of the radial shaft (C). Correct distal placement should be slightly proximal to the "watershed" line, below the distal edge of the radius to ensure the distal screws find optimal purchase in subchondral bone. This placement reduces potential contact with the flexor tendons.

The plate can also act as a buttress to assist in effective fracture reduction and subsequent fixation.

C.

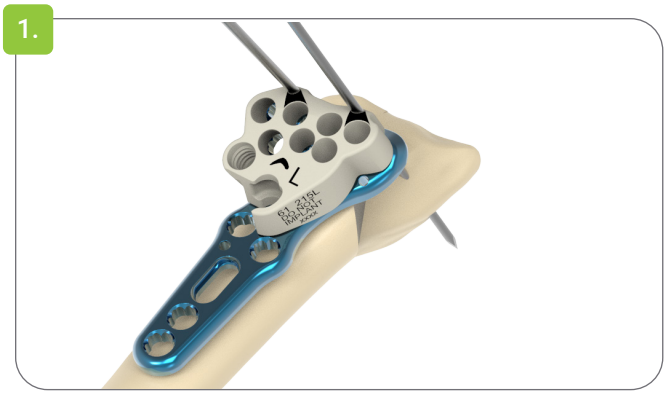


Distal First

This approach uses the plate to reduce dorsal tilt and return the radius to proper alignment. This technique is also applicable in the correction of radial malunion. The correct spacing of the plate to Distal Radioulnar Joint (DRUJ) must be ascertained with image intensification to prevent plate overhang before placing the K-wire.

1. Use the Smart guide tool and Smart Guide to position the Plate (A). Secure correct plate alignment with K-wires in the distal side of the fracture.

1.



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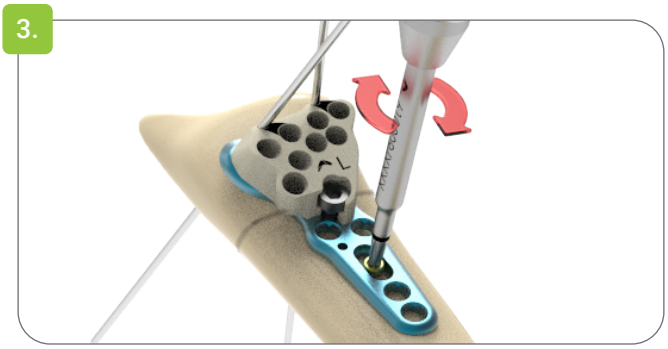
2. Insert 3 to 4 screws into any of the 7 available screw holes in the distal portion of the plate using the screw insertion technique on page 10.

Note: Depending on fracture displacement, different fracture reduction methods can be used.

2.

3. Reduce the fracture and ensure correct proximal shaft alignment, refer to image (C). Insert a Non-locking Screw into the dynamic hole.

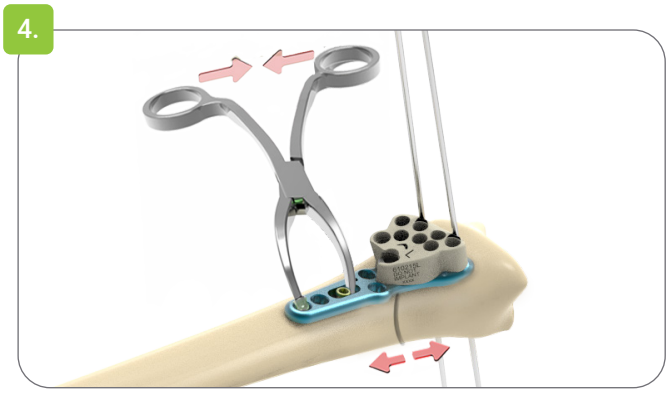
3.



4. If further fracture adjustment is required, particularly correction of radial displacement, loosen the proximal dynamic hole screw slightly and use the two manipulation forceps to provide distraction and then alignment. Release distraction and tighten the proximal screw to secure the plate.

Note: The pointed end of the forceps is designed to fit behind or into the head of the screw in the dynamic hole. Ensure correct alignment with imaging.

4.



5. Insert remaining required Proximal and Distal Screws.

Note: Reduction should be performed by manipulating the bone fragments as you would a closed reduction. Do not use the proximal plate as a lever as additional fragmentation of the distal fragments may occur.

Articular Reduction

Die Punch or Compression Fractures

The Articulating Probe is used to reduce a die punch or compression fracture of the lunate fossa. The Articulating Probe is designed to allow articular reduction from the inside of the bone and facilitate accurate pinning and screwing to hold the fragments in place.

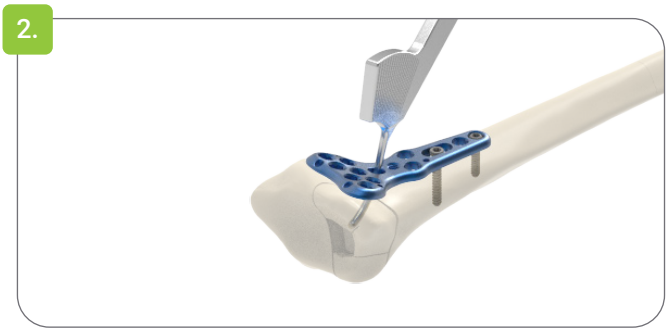
Ensure the plate has been partially secured before using the Articulating Probe.

1. Drill as per the 'Screw Insertion Method' on page 10 in the desired probing hole.
2. Feed the hook of the probe through the drilled distal hole and engage the loose fragment(s).
3. Use imaging to confirm correct bone fragment alignment.
4. Secure fragment(s) with a K-wire(s).
   Note: The markings align to the end of the probe. This can be used to target the proximal side of the displaced joint fragment.
5. If possible, secure with a Variable Angle Screw(s).

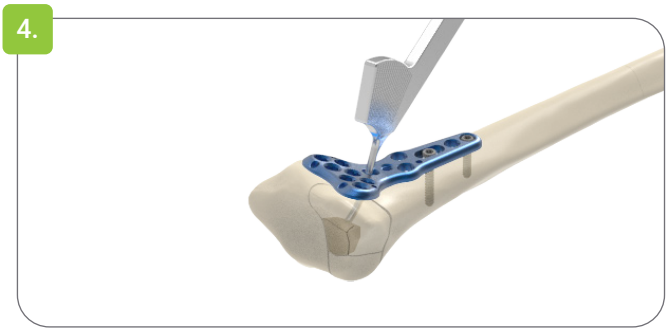
Articulating Probe

1.

2.



4.



Post Operative Management

Although post-operative management is at the surgeon's discretion it is recommended that the wrist be supported in a splint or plaster slab for 10-14 days, after which active motion should be encouraged. To ensure best final range of motion and function, the patient should begin hand therapy as soon as allowable.

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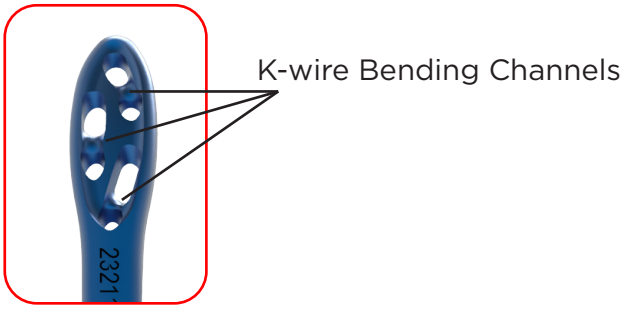
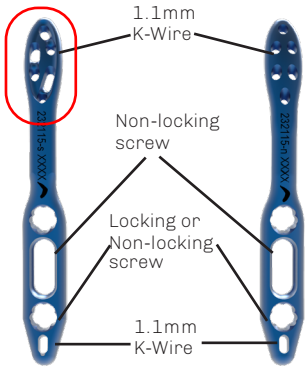
Radial styloid plate fixation

The plate is pre-contoured and designed to conform to underlying patient anatomy using screws and pins.

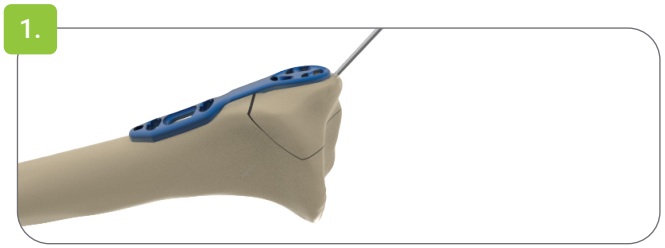




232115-s
Radial Styloid Plate Slotted

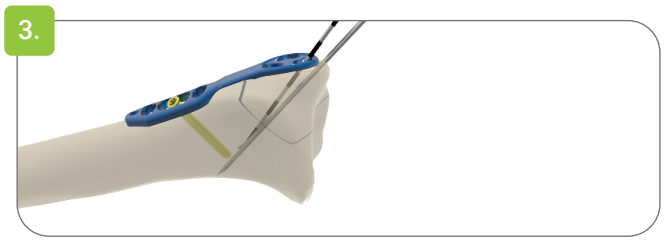
232115-n
Radial Styloid Plate Low profile

1. Reduce the fracture and insert a 1.4mm K-wire to stabilise the fragment. Slide the plate under the first dorsal compartment tendons. Ensure the shaft of the plate lies against the lateral surface of the radius.

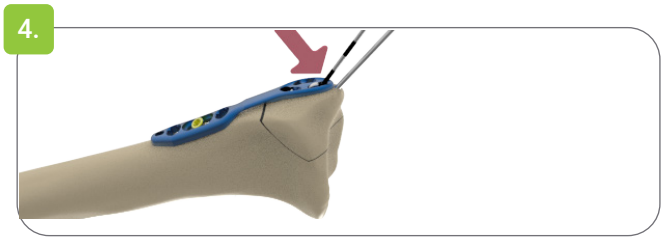


2. Insert a 1.1mm transtyloid K-wire across the fracture and exit the medial cortex.

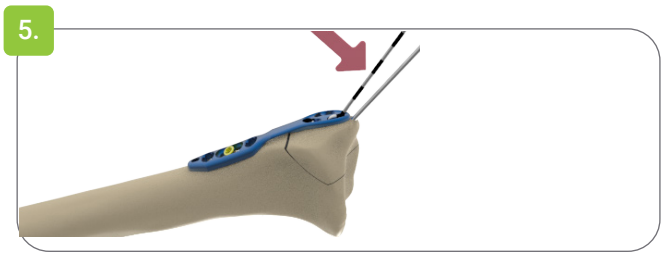
3. Ensure the plate is seated proximally against the bone and fix with a 2.5mm non-locking screw in the proximal dynamic hole.



4. To achieve an appropriate pin length, use the zebra pattern to mark a reference point where the K-wire and the plate intersect.



5. Withdraw the K-wire by at least one light and dark pattern (1cm) or more to a desired working distance.

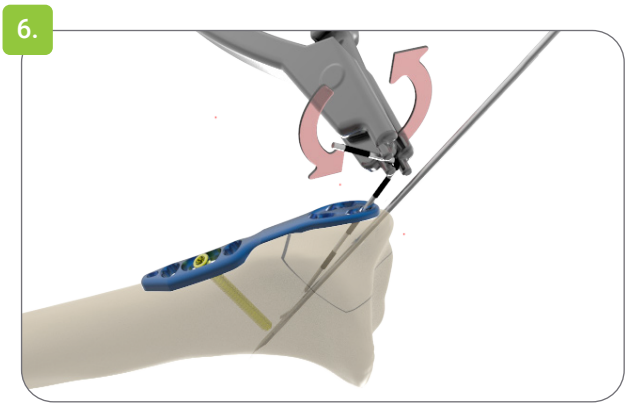


6. Remove the K-wire driver and then cut the K-wire at least 1cm from the reference point.

   Use the 3-point Wire bender to create a hook by simultaneously squeezing and rotating the Wire Bender in the direction of the bend.

   Slightly over-bending the hook will allow it to snap into the plate.

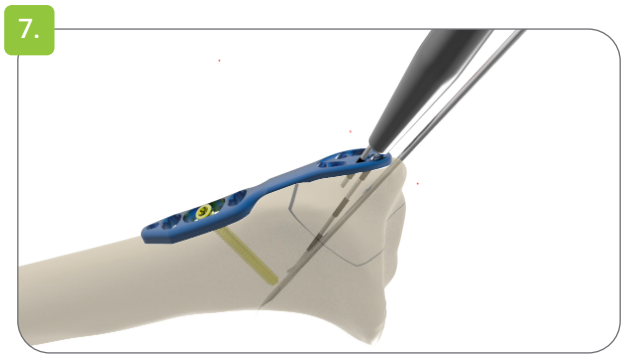
Warning: Make sure distal K Wires are positioned correctly before fully seating the K Wire in the plate. K Wires can be backed out by lifting proximal section of the plate off the bone.



7. Pre-drill a hole with a 1.1mm K-wire to receive the hook, in an adjacent pin hole over the edge of the plate.

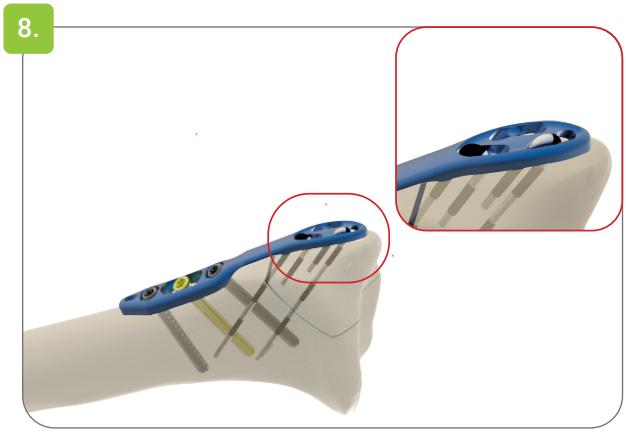
   With the Impactor, fully seat the pin against the plate.

   Repeat the procedure for the second 1.1mm K-wire.



8. Insert the second and the third Zebra K-wires and repeat step 2-7. Complete fixation with remaining proximal screws. (With the specially-designed channel, the K-wire is only about 0.4mm higher than the plate)

Note: All instruments and screws required are in the VRP 2.0+ Instrument Set and the Complex Wrist Set.



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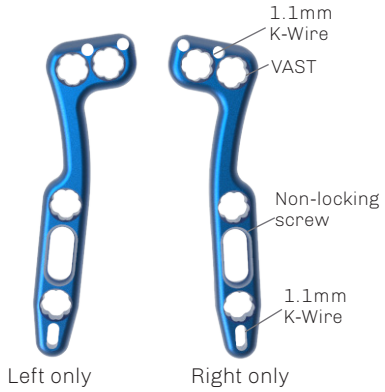
Dorsal Plate Fixation

The Dorsal Plates are supplied flat and can be used on the radial side of the bone without contouring.



1. If required to be used on the ulna side, use the two supplied bending pliers to form the plate.

   The spherical feature on the pliers locate into the locking holes in the plate.

Warning: Do not bend across locking features, and only form to a maximum twist of 20° in the neck. Repeatedly bending the plate will cause a mechanical failure of the plate.

Use the Drill Guide and 2.0mm Drill supplied to prepare holes for fixation.

Use VRP 2.0+ locking and non-locking screws in the circular VAST holes and non-locking screw in the dynamic hole for compression.

Where possible, final fixation should use all locking screw holes and 1 non-locking screw in dynamic hole.

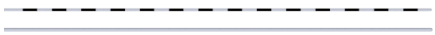
Note: Screws should be targeted perpendicular to the plate to minimise tendon irritation.

Product Codes

VRP 2.0+ Sterile Packed	
Product Code	Description
233305	VRP 2.0+ Standard Universal 5cm
233108	VRP 2.0+ Standard Universal 8cm
231113	VRP 2.0+ Standard RIGHT 13cm
232113	VRP 2.0+ Standard LEFT 13cm
233505	VRP 2.0+ Narrow Universal 4cm
233206	VRP 2.0+ Wide Universal 5cm
241104	VRP 2.0+ Dorsal Plate Right
242104	VRP 2.0+ Dorsal Plate Left
232115-n	VRP 2.0+ Radial Styloid Low profile
232115-s	VRP 2.0+ Radial Styloid Plate Slotted

Smart Guides	
Product Code	Description
610215L	Smart Guide - Left
610215R	Smart Guide - Right
610217L	Narrow Smart Guide - Left
610217R	Narrow Smart Guide - Right
610218L	Wide Smart Guide - Left
610218R	Wide Smart Guide - Right

K-Wire	
Product Code	Description
511115	1.1 x 150mm K-wire
511415	1.4 x 150mm K-wire



Drill	
Product Code	Description
522010	2.0 x 130mm Drill

2.5mm Locking Screw	
Product Code	Screw Length
262508	8
262510	10
262512	12
262514	14
262516	16
262518	18
262520	20
262522	22
262524	24
262526	26
262528	28
262530	30
262532	32
262534	34

2.5mm Non-Locking Screw	
Product Code	Screw Length
252510	10
252512	12
252514	14
252516	16
252518	18
252520	20
252522	22
252524	24
252526	26
252528	28
252530	30

2.0mm Locking Peg	
Product Code	Screw Length
272014	14
272016	16
272018	18
272020	20
272022	22
272024	24
272026	26
272028	28
272030	30

Instrument Codes

Mini Fragment Screwdriver Handle	610204	
T7 Driver Tip	610209	
2.0 VA Depth Gauge	610210	
2.0 Fixed Angle Guide and VA Drill Guide	610211	
Manipulation Forceps	600206L (Left) 600207R (Right)	
VRP 2.0+ Articular Probe	610212	
Periosteal Elevator (6mm)	600202	
Hohmann Retractor	600201	
Reduction Forceps with Points	600203	
Reduction Forceps with Teeth	600204	
Self-Retaining Retractor	600205	
Sharp Hook	610213	
0.6Nm Torque Limiter	610207	

Torque Limiter Driver Handle	610214	
VRP 2.0+ Standard Left Reusable Smart Guide	610215L	
VRP 2.0+ Standard Right Reusable Smart Guide	610215R	
VRP 2.0+ Narrow Left Reusable Smart Guide	610217L	
VRP 2.0+ Narrow Right Reusable Smart Guide	610217R	
VRP 2.0+ Wide Left Reusable Smart Guide	610218L	
VRP 2.0+ Wide Right Reusable Smart Guide	610218R	
VRP 2.0+ Universal Trial Plate	600222	
Radial Styloid Trial Plate	600226	
Dorsal Trial Plate	600225	
VRP 2.0 Smart Guide Tool	610216	

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Instrument Codes Complex Wrist

Plate Bending Pliers	600230	
K Wire Benders	600233	
K Wire Cutters	600231	
K Wire Clamp	600234	
K Wire Impactor	600232	
Mini Mallet	600235	

MRI Safety

Austofix has not evaluated its devices for safety and compatibility in a Magnetic Resonance (MR) environment. However, the materials used in their manufacture are known to have minimal ferromagnetism, with minimal risk to patients in strong magnetic fields.

Austofix has performed a review of published, peer-reviewed data, which confirms that only minor rises in MRI-related heating are observed from devices manufactured from the same titanium and stainless-steel materials. Trauma devices are considered unlikely to produce injury to patients, including in the worst-case 3.0T systems.

The devices and materials observed in the literature experience forces too weak to cause significant displacement; the risk being further mitigated by their implantation in bone. Risks of imaging artifacts are known to MRI operators, and can be reduced by choosing appropriate pulse sequences and optimizing scanning parameters by using a large bandwidth, small field-of-view and appropriate echo train length.

Average temperature changes have been observed in studies at 0.48oC in titanium and 0.74oC in stainless-steel. Rises in temperature in clinical situations may depend on individual patient factors. It should be recommended that patients be thoroughly monitored when undergoing MR scanning, and that impaired patient thermoregulation be considered a contraindication for MRI procedures.

Sources:

Chen CA, Chen W, Goodman SB, et al. New MR Imaging Methods for Metallic Implants in the Knee: Artifact Correction and Clinical Impact. 2011, 1121-1127.

Gill A, Shellock FG. Assessment of MRI issues at 3-Tesla for metallic surgical implants: findings applied to 61 additional skin closure staples and vessel ligation clips. J Cardiovasc Magn Reson. 2012, 14(1):3.

Shellock FG. Biomedical Implants and Devices: Assessment of Magnetic Field Interactions With a 3 . 0-Tesla MR System. 2002, 721-732.

Zou Y, Chu B, Wang C, Hu Z. Evaluation of MR issues for the latest standard brands of orthopedic metal implants, Plates and screws. Eur J Radiol. 2015, 84(3):450-457.

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Notes

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