austofix Distal Ulna

2.0mm L&C Hook Plate

Surgical Technique

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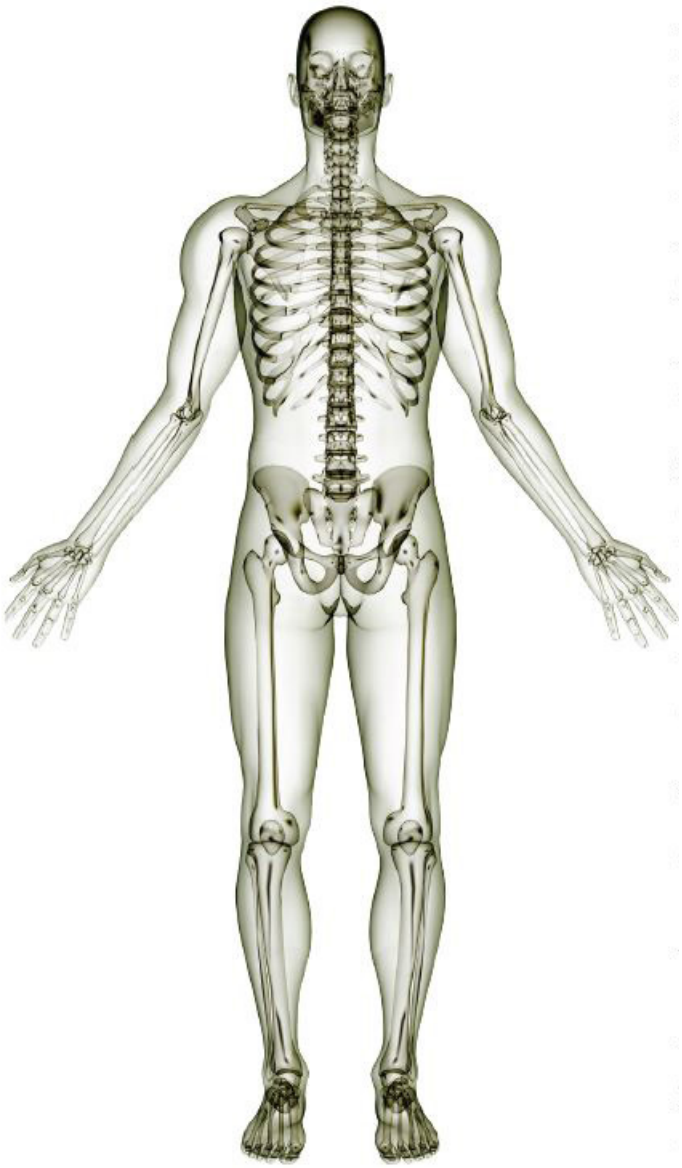
Contents



Austofix is a leading manufacturer and designer of orthopaedic trauma medical devices with a particular focus on innovation, excellence and patient safety. Austofix has the expertise and experience in developing a new device from concept to a fully commercialised product with regulatory approval for world-wide distribution.

Throughout its 20+ years Austofix has gathered a team of world-class research and development specialists. Together with orthopaedic surgeons, our specialists identify emerging techniques and innovations in the field of orthopaedic trauma and develop world-class solutions.

Austofix is now one of Australia's key contributors to the world-wide medical technology industry. By focusing on specific market needs we can leverage our staff expertise to develop effective solutions and successfully compete on the world stage.

We understand that accidents don't wait to happen, so we ensure that our equipment and devices are ready when needed. With a dedicated 24 hour, seven day a week customer service and sales team, Austofix products are ready when you are.

With our focus on trauma we understand the specific needs of trauma surgeons. Our product specialists actively support the surgeon by being on call to support procedures and offer advice.

Austofix products and innovations assist the surgeon in performing accurate, efficient and safe procedures that result in better health outcomes for the patient.

The measurement of our success is seen through our excellent clinical results and positive surgeon feedback. We understand the need for efficiency during operations and that this is key in improving patient outcomes. Our products and tools are designed to minimise time spent in theatre. Furthermore, all clinical feedback of our products is promptly addressed to ensure product refinements reflect all surgical concerns.

For further information, updates and contact details visit austofix.com.au and follow us on LinkedIn.

Disclaimer

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

This document is intended as the recommended procedure for using the Mini Fragment Plates 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.

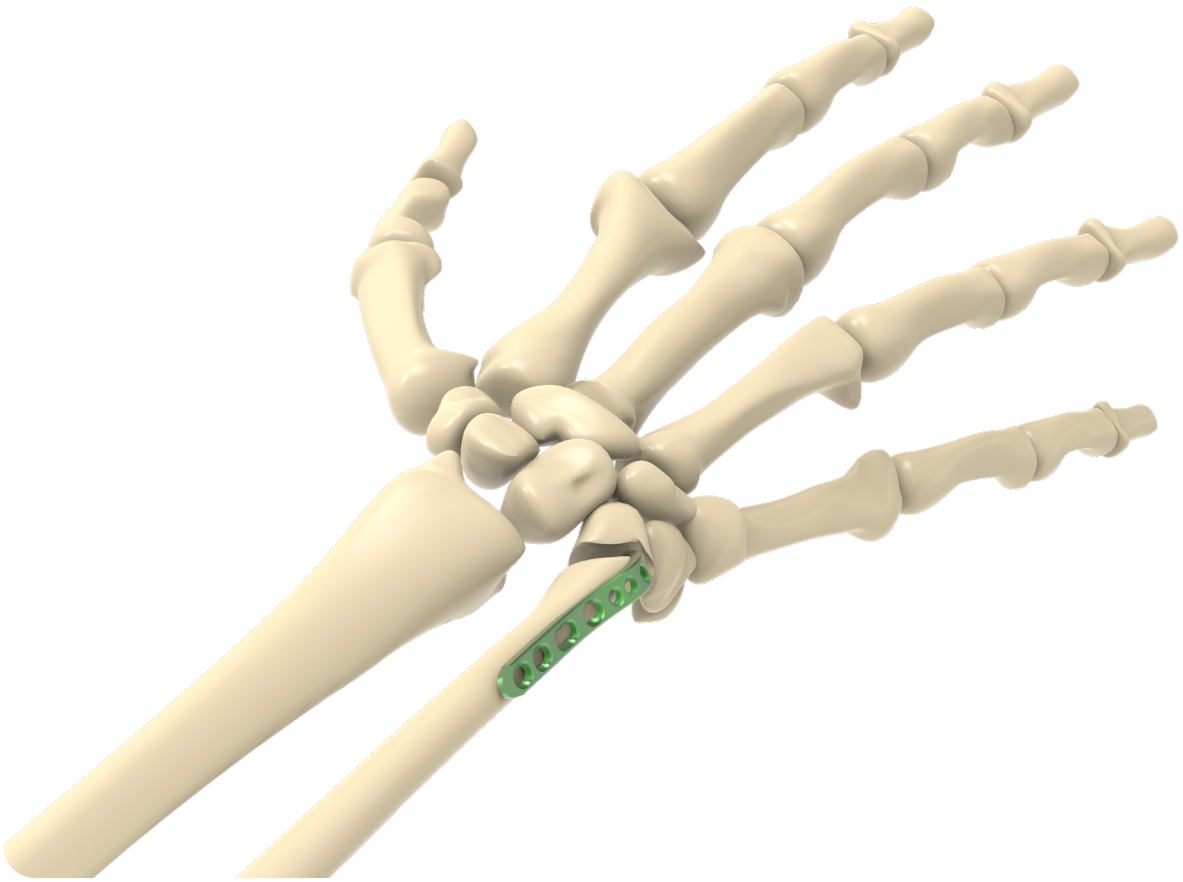
austofix Distal Ulna

2.0mm L&C Hook Plate

The Austofix Distal Ulna Hook Locking Plates are designed to fit the special anatomical characters of the distal ulna. The plates provide a complete fixation system for the many complex fracture patterns found in the distal ulna.

The titanium plates and screws incorporate significant design advantages, facilitating surgical accuracy and efficiency and delivering better patient outcomes.

Austofix understands the importance of proven, high quality medical devices and instruments. The Distal Ulna Hook Locking Plates adhere to these principles and will provide the surgeon with a comprehensive distal ulna fixation solution.



Implant Features

Plates

Combi Hole

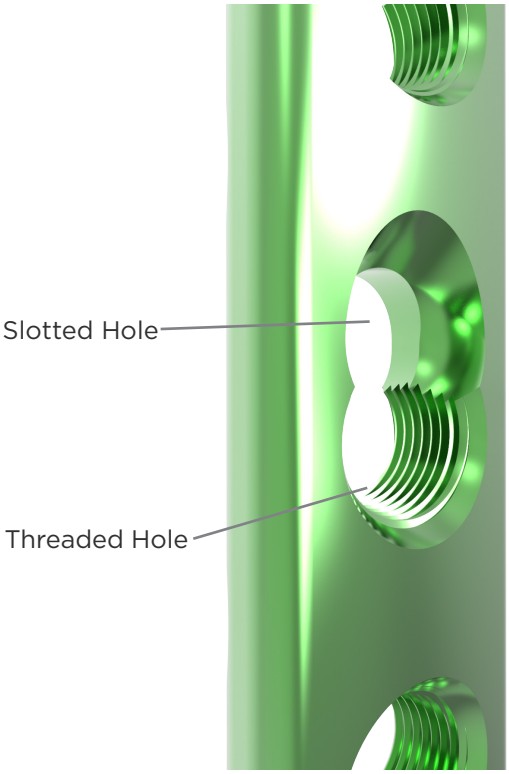
The Combi Hole allows for a range of plate fixation options. The holes accommodate both Compression and Locking Screws.

Slotted Hole - Cortex Screws

Cortex Screws used in the slotted hole for plate-to-bone compression increases stability.

Threaded Hole - Locking Screws

Locking Screws link with the threads in the Threaded Hole, keeping the Screw at a fixed angle.



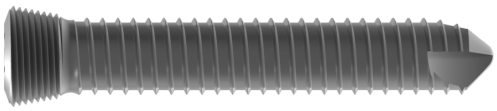
Tapered End

Tapered end assists in submuscular plate insertion and helps to minimise tissue trauma.

Screws

Locking Screw

- Self-Tapping
- Reduced Screw Backout
- Unicortical or Bicortical Fixation



Cortex (Cortical) Screw

- Dynamic compression
- Compression

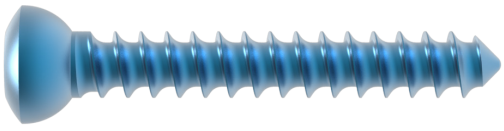


Plate Features

Anatomical Fit

» Pre-contoured design

» Tapered end assists in submuscular plate insertion and helps to minimise tissue trauma

» Plate can be further contoured for a more suitable anatomical fit

Distal Locking

» Distal locking holes provide superior support for the ulnar head with multiple points of fixation

» Recesses for head of screws ensure low-profile construct

Plate Fixation

» Combi-Holes along shaft of the Plate allow Locking Screw fixation for angular stability or Cortex/Cancellous Screws for dynamic compression

» Gliding Combi-Holes with elongated slotted holes facilitate plate repositioning and axial compression flexibility

» Plate shaft has increased thickness for additional strength

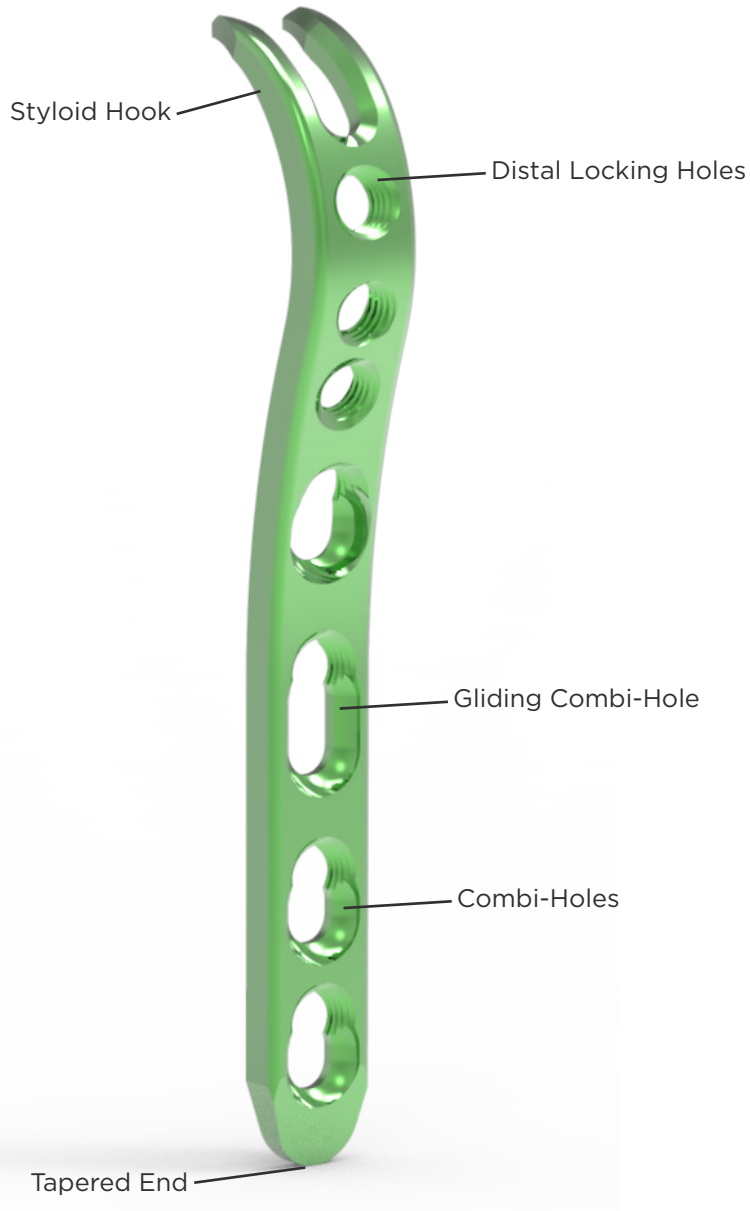
» Distal hook for styloid process facilitates unique position, size and shape of the distal ulna

Clinical Indications

» Designed to address complex fractures of the distal ulna

» Can be utilised for osteotomies and nonunions of the distal ulna

» Particularly beneficial for patients with osteopenic bone



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Surgical Technique

Preparation & Plate Length Selection

Preoperative radiographic assessment is required to determine plate length. Additionally, the Plate can be contoured to mould to the bone (see Contouring section below).

Patient Positioning

The patient should be positioned supine with the affected forearm place onto a hand table. Surgical access is made easier by abducting the shoulder, with appropriate positioning to allow imaging in the frontal and sagittal plane of the distal radius.

Incision

The standard location for incision lies toward the ulnar styloid between the flexor carpi ulnaris and extensor carpi ulnaris tendons. A longitudinal incision should be made over the ulna. Complete exposure of the ulnar head should be avoided as essential soft tissue stabilisers will detach.

Warning: Take care not to damage the dorsal sensory branch of the ulnar nerve and retract prior to plate insertion.

Contouring (Optional)

If contouring of the Plate is required is required, make sure to secure the Flat Pliers (111210012) over two consecutive holes to avoid distortion of the Threaded Holes.

Note: Bending of the plate can alter Locking Screw trajectory. Screw trajectories should be confirmed using an image intensifier and K-Wires. 0.8mm (081.010) and 1.1mm (114500001/2) K-Wires are available.

Note: If there is limited space available for Plate bending, the LCP Plate Benders (111210031) may be used. They can be threaded into Locking Screw holes to prevent deformation of the holes while contouring.

Warning: Do NOT bend the plate beyond what is required to contour with the bone. Reverse bending, over bending, using the incorrect instrumentation for bending or bending at the level of the holes may lead to plate failure.

Reduce the Fracture

Reduce the fracture using the image intensifier, Ø1.1mm K-Wires (114500001/2) and/or Reduction Forceps (111110008/9). Ensure that the reduction instrumentation will not interfere with plate placement.

Note: Ø0.8mm (081.010) K-Wires are available for fracture reduction.

Warning: Take care when using the Pointed Reduction Forceps (111110008) as the force applied from the instrument may cause further comminution of the fracture.

Compression Screws

Cannulated Compression Screws (Ø3.0 - Ø7.3mm) are available for interfragmentary compression and fracture fixation.

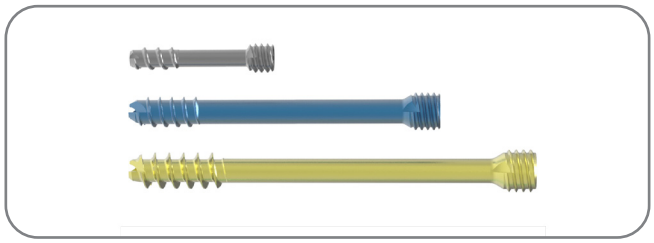
Please refer to the Austofix Cannulated Compression Screws Surgical Technique.

Note: The Cannulated Compression Screw instrument set (SET-INS-CAN) is required for this approach.

Headless Cannulated Screws are also available for fixation of intra-articular and extra-articular fractures, and non-unions of small bones.

Please refer to the Austofix Headless Cannulated Screws Surgical Technique.

Note: The Headless Cannulated Screw instrument set (SET-INS-HLCANN) is required for this approach.

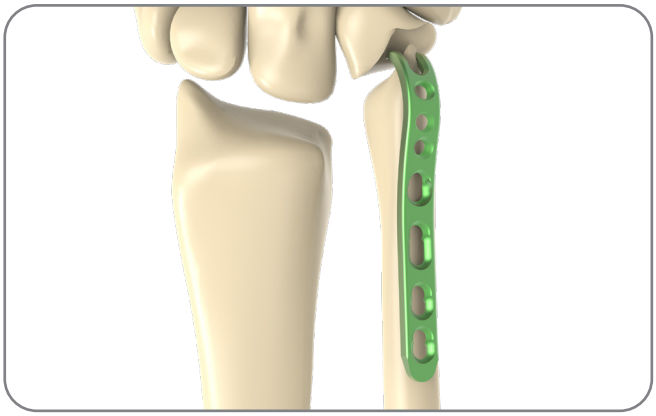


Position the Plate.

Place the selected Plate on the fractured bone and in a suitable position. If axial dynamic compression will be used ensure the middle of the plate is above the line of the fracture. The plate can be temporarily held in place using plate holding forceps.

Temporary stabilisation of the fracture may be necessary and can be achieved with the use of a Ø1.1mm transstyloid K-Wire inserted between the distal styloid hooks of the plate.

Following plate positioning, a preliminary Cortex Screw should be inserted through the elongated slotted hole of the Gliding Combi-Hole.



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Pre-Drilling

Determine whether Cortex Screws, Locking Screws, or a combination of Screws will be used.

Use the table to determine which combination of Drill and Drill Sleeve is required for the desired Screw.

Use the laser markings colour guide to assist with instrument identification.

● = Green (1.5mm instruments)

● = Blue (2.0mm instruments)

Note: The 0.4Nm Torque Limiter contains a **red** laser marking.

Note: The Yellow ● (2.4mm instruments) are not used for this surgical procedure.

If a combination of Screws are used, a Cortex Screw should be inserted first to pull the plate to the bone. If a Locking Screw is used first, care should be taken to ensure that the plate is securely held to the bone to avoid spinning of the plate about the bone as the Locking Screw is tightened to the plate.

Screw	1.5mm Cortex (Optional) ●	2.0mm Cortex ●	2.0mm Locking ●
Drill	Ø1.1mm Drill (111210036)	Ø1.5mm Drill (111210004)	Ø1.5mm Drill (111210004)
Drill Sleeve/ Guide	Ø1.1/1.5mm Drill Sleeve (111210035)	Ø1.5mm Drill Sleeve (111210003)	Ø1.5mm Drill Sleeve (111210002)
Driver	T4 Screwdriver (111210039)*	T6 Screwdriver (112300007)	T6 Screwdriver (112100007)
Torque Limiter	-	-	Torque Limiter 0.4Nm (111210014) ●

***Note:** Long T4 Screwdriver (111210038) also available.

Note: Screwdrivers do not contain a coloured laser marking band. Use the product code as a reference when selecting the appropriate driver tip.

Drilling

Using the Spring-Loaded Drill Sleeve for Neutral & Dynamic Compression

Neutral Screw Position

Advance the spring-loaded Drill Sleeve (111210003) through the Dynamic Compression slot of the plate. Press the Drill Guide against the bone, allowing the inner sleeve to retract. This will guide the rounded end of the outer sleeve to the **neutral** drilling position.

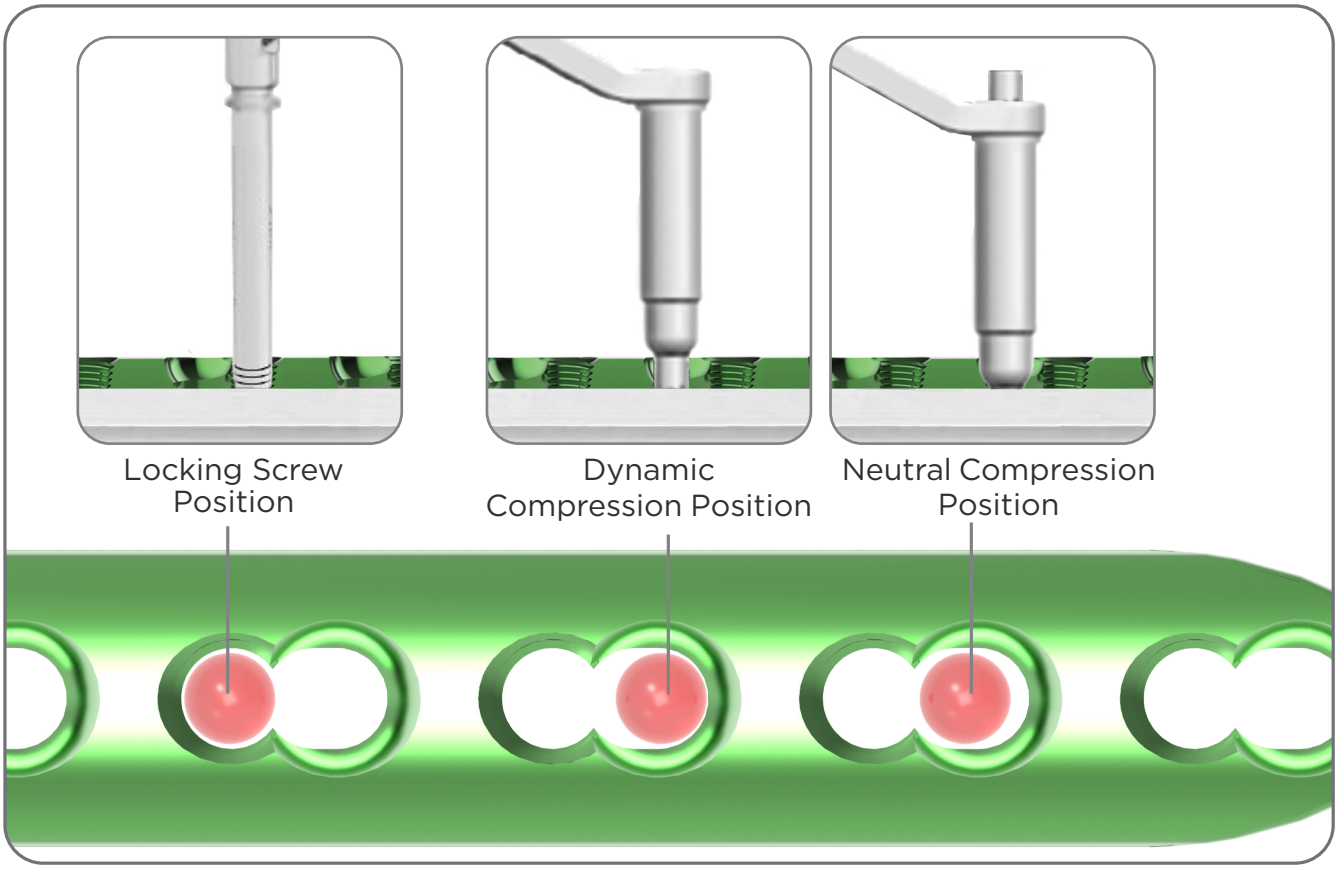
Dynamic Screw Position

Place the inner sleeve of the against the edge of the Dynamic Compression slot of the plate. Without exerting pressure on the Drill Sleeve, the inner sleeve will **remain in the dynamic** position. Dynamic Compression will occur once the Cortex Screws are tightened.

Using the Locking Sleeves for Locking Screw Position

Insert the threaded Locking Drill Sleeve (111210002) into the threaded hole. Carefully drill the Locking Screw hole using the appropriate drill.

Note: Refer back to the table on page 9 for instrument selection.



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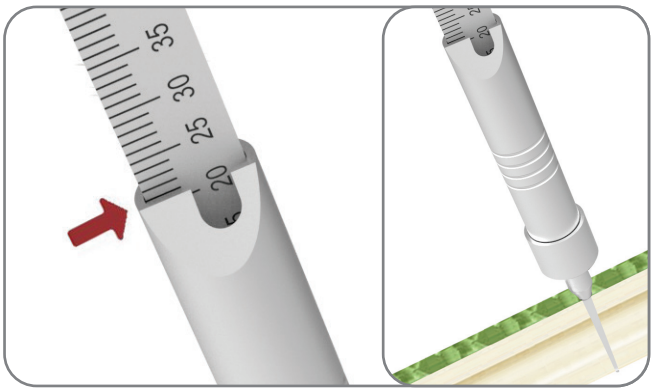
Determine Screw Length.

The Depth Gauge 2.0 & 2.4mm (112300008) can be inserted through the Drill Sleeve/Guide and through the hole in the bone. 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.

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



Screw Insertion

Select the appropriate Screw with the assembled Driver Tip and Handle. Use the table on page 9 to determine which Driver and Handle to use.

Screw Patterns

Screw Pattern 1:

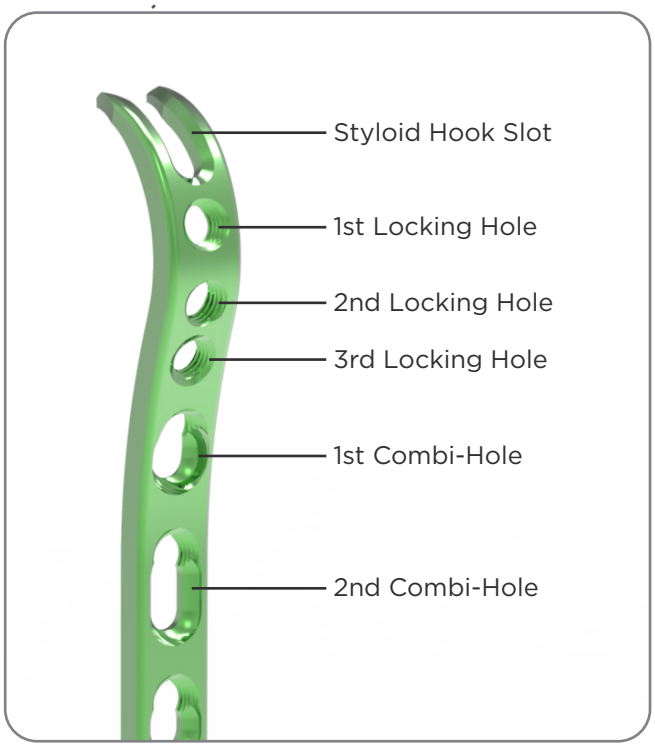
For fractures requiring length adjustment, one or two Locking Screws are used through the 2nd and 3rd Locking Holes to fixate the ulnar head. A Cortex Screw is inserted into the 2nd Combi-Hole (Gliding Combi-Hole). A combination of Cortex and Locking Screws can then be used to further stabilise the fracture.

Screw Pattern 2:

For unstable fractures of the ulnar styloid base, Locking Screws are inserted into the 1st, 2nd, and 3rd Locking Holes. A Cortex Screw is inserted into the 2nd Combi-Hole (Gliding Combi-Hole) where a combination of Cortex and Locking Screws can then be used to further stabilise the fracture.

Screw Pattern 3:

It may be necessary to stabilise the tip of the styloid process. Leaving the 1st Locking Hole empty, remove any K-Wires used for temporary fixation from the Styloid Hook slot and Drill the near fragment to the outer diameter of the Ø1.5mm Cortex Screw using the Ø1.5mm Drill (111210004). The remaining length is drilled using the Ø1.1mm Drill (111210036) through the 1.5mm sleeve of the Drill Sleeve 1.1/1.5mm (111210035). A Ø1.5mm Cortex Screw can then be inserted into the Styloid Hook Slot to function as a lag screw.



Locking Screw Insertion

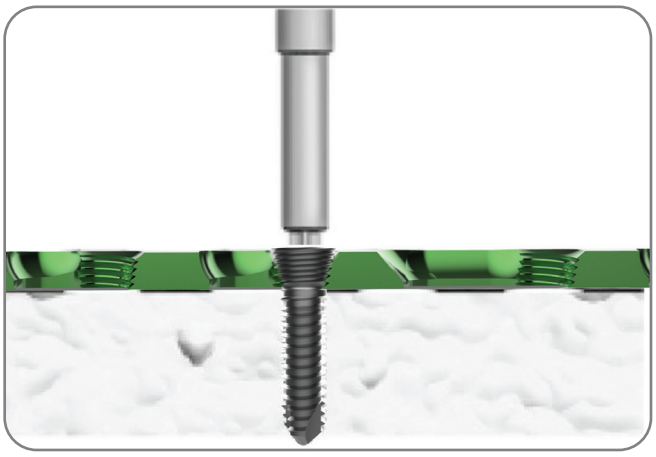
Before the insertion of the Locking Screw ensure the fracture is reduced as this cannot be done after the Screw has been inserted.

Ensure the Screw is concentric to the Plate's threaded hole. Insert the Screw and tighten with the appropriate Screwdriver*, Torque Limiter* and T-Handle with Quick Coupling (112300011). Tighten until the threaded Locking Screw head engages and is secure to the plate.

Warning: If using power to insert Locking Screws, always use a torque limiting attachment. This reduces the risk of the threads stripping from the head of the screw.

*__Note:__ Refer to table on page 9.

If a Locking Screw is used first ensure the plate is securely held to the bone to avoid the plate moving.

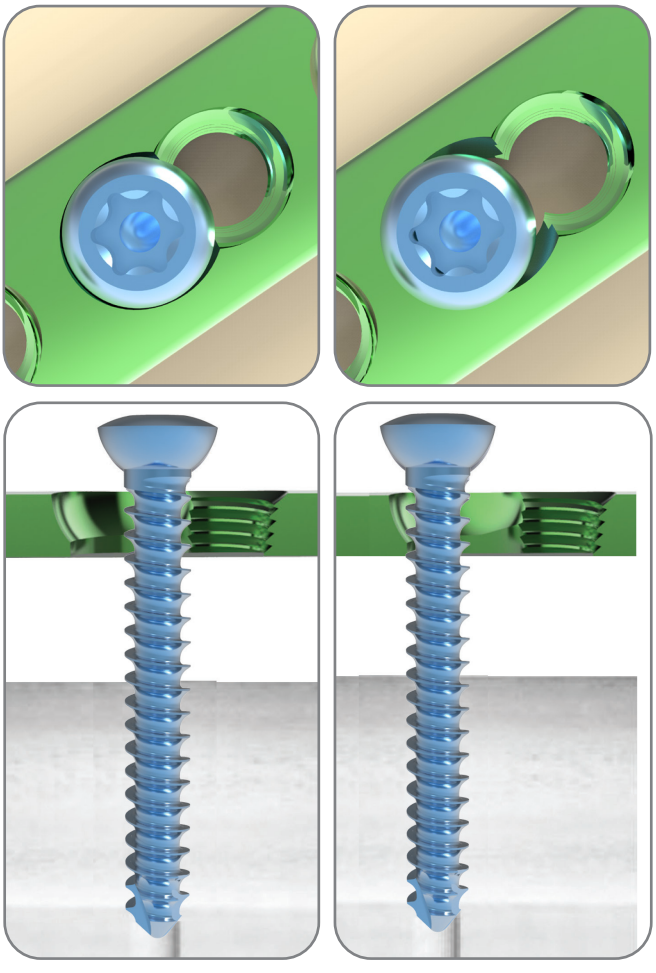


Cortex Screw Insertion

Use the appropriate Driver Tip (refer to table on page 9) with the Straight Handle with Quick Coupling (112300004) to insert Cortex Screw to appropriate depth.

For dynamic compression, ensure compression has been achieved before continuing.

Warning: If using power to insert Cortex Screws, complete Screw insertion by hand to avoid compromising the integrity of the plate and screw construct, and to avoid damage to patient soft tissue.



Neutral screw position

Dynamic compression position

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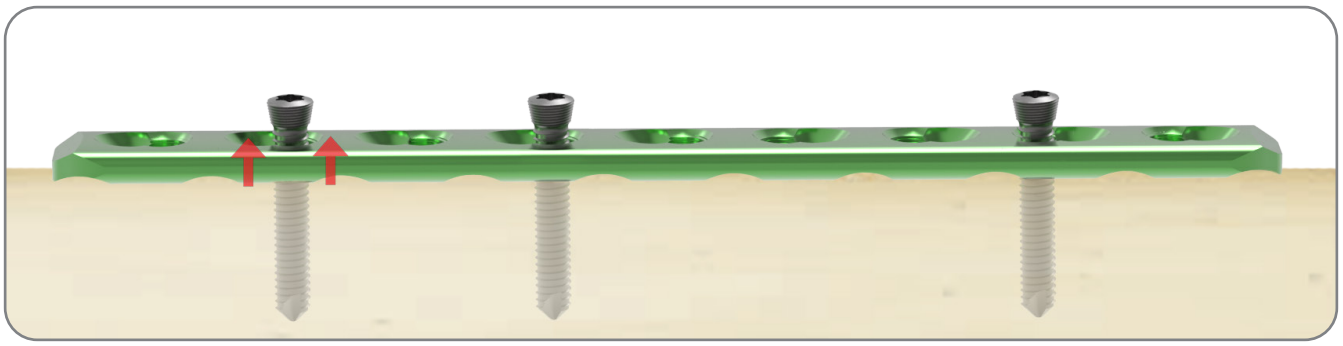
Screw Assessment

Imaging should be used to assess Screw alignment and positioning, ensuring that no Screws interfere with the distal radioulnar or ulnocarpal joints.

Removal of Plate

To remove the plate, unlock all the Screws first using the appropriate Star Screwdriver for Cortex Screws and Locking Screws respectively. Remove the Screws from the bone. This method prevents the simultaneous rotation of the plate when unlocking the final Locking Screw.



Implants - Plates

L&C Distal Ulna Hook Plate	
Product Code	Number of Holes
2058-00-07046	7

Compatible Screw: 2.0mm Locking Screw, 1.5 & 2.0mm Cortex Screw

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Implants - Screws

Locking Screw - Self-tapping	
Length	2.0mm
6	1016-01-20006
7	1016-01-20007
8	1016-01-20008
9	1016-01-20009
10	1016-01-20010
11	1016-01-20011
12	1016-01-20012
13	1016-01-20013
14	1016-01-20014
16	1016-01-20016
18	1016-01-20018
20	1016-01-20020
22	1016-01-20022
24	1016-01-20024
26	1016-01-20026
28	1016-01-20028
30	1016-01-20030

Cortex Screw - Self-tapping		
Length	1.5mm	2.0mm
6	1014-01-15006	1062-00-20006
7	1014-01-15007	1062-00-20007
8	1014-01-15008	1062-00-20008
9	1014-01-15009	1062-00-20009
10	1014-01-15010	1062-00-20010
11	1014-01-15011	1062-00-20011
12	1014-01-15012	1062-00-20012
13	1014-01-15013	1062-00-20013
14	1014-01-15014	1062-00-20014
15	1014-01-15015	-
16	1014-01-15016	1062-00-20016
17	1014-01-15017	-
18	1014-01-15018	1062-00-20018
19	1014-01-15019	-
20	1014-01-15020	1062-00-20020
22	-	1062-00-20022
24	-	1062-00-20024
26	-	1062-00-20026
28	-	1062-00-20028
30	-	1062-00-20030
32	-	1062-00-20032
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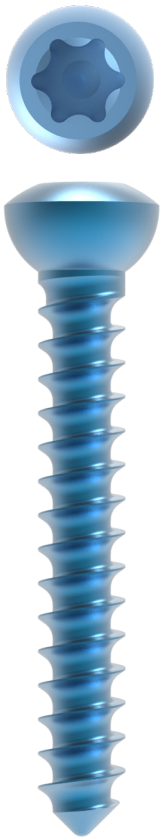
36	-	1062-00-20036
38	-	1062-00-20038



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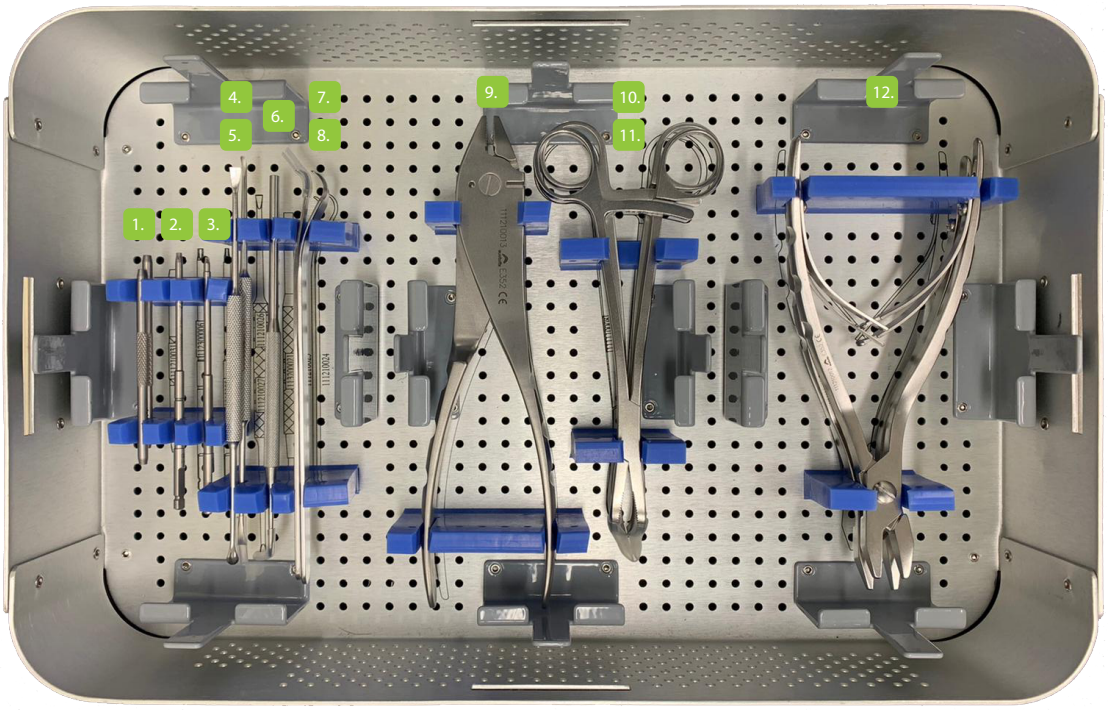
Instruments

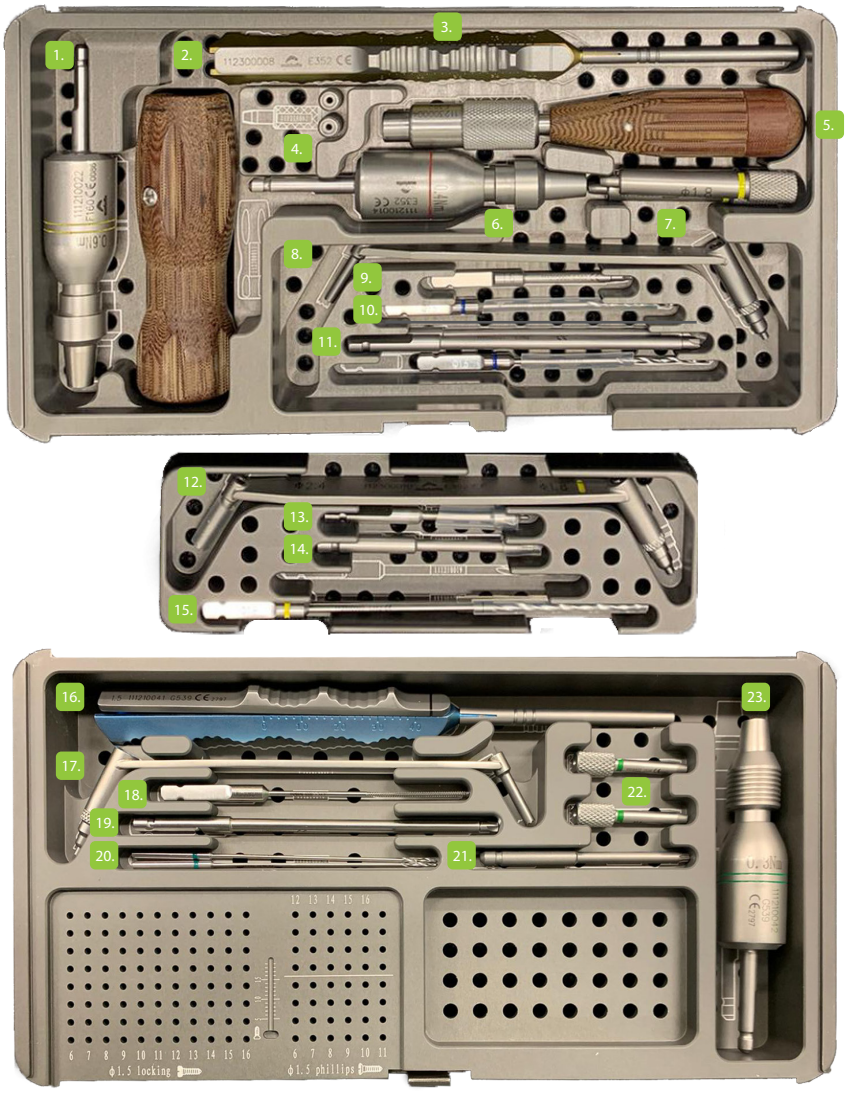


Instruments			
#	Code	Description	Qty
1	111210031	LCP Plate Bender	2
2	112300006	Screwdriver, Long 4.5 x 105mm (Star)	1
3	111210008	Screwdriver Shaft 2.0 x 105mm (Star)	1
4	111210026	Periosteal Elevator (Small)	1
5	111210027	Periosteal Elevator (Large)	1
6	113200021	Sharp Hook	1
7	111210023	Retractor (Small)	1
8	111210024	Retractor (Large)	1
9	111210013	Cutting Pliers	1
10	111110008	Reduction Forceps (Point)	1
11	111110009	Reduction Forceps (Serrated)	1
12	111210012	Flat Pliers	2

Instrument Set	
Code	Description
SET-INS-MINI	Full Mini Frag Instrument Set

1.5 Optional Instrument Set	
Code	Description
SET-INS-1.5M	Full 1.5 instrument Set

Instruments



Instruments							
#	Code	Description	Qty	#	Code	Description	Qty
1	111210022	Torque Limiter 0.6Nm	1	13	111210006	Mini Frag Countersink 4.5mm	1
2	112300011	T-Handle with Quick Coupling	1	14	112300005	Screwdriver, Short 4.5 x 55mm (Star)	1
3	112300008	Depth Gauge 2.0 & 2.4mm	1	15	112300002	Drill Bit 1.8mm	2
4	111210002	L&C Drill Sleeve Ø2.0mm	2	16	111210041	Mini Frag Depth Gauge 1.5mm	1
5	112300004	Straight Handle with Quick Coupling	1	17	111210035	Drill Sleeve 1.1/1.5mm	1
6	111210014	Torque Limiter 0.4Nm	1	18	111210040	Tap 4.5 x 80mm	1
7	112300009	L&C Drill Sleeve Ø1.8mm	2	19	111210038	Screwdriver Long 4.5 x 95mm (Star)	1
8	111210003	Drill Sleeve 2.0mm	1	20	111210036	Drill Bit 1.1mm	2
9	111210007	T6 Screwdriver 2.0 x 55 (Star)	1	21	111210039	Screwdriver Short 4.5 x 55mm (Star)	1
10	111210004	Drill Bit 1.5mm	2	22	111210037	Drill Sleeve 1.1mm	2
11	111110007	Screwdriver Shaft 4.5 x 95mm (Phillips)	1	23	111210042	Torque Limiter 0.3Nm	1
12	112300010	Universal Drill Guide	1				

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Instrument Trays

Instrument Trays	
Code	**Description**
111219600	Mini Frag Instrument Tray (Empty)
111219400	Special Instrument Tray 2.0 & 2.4
111219800	Special Instrument Tray 1.5

Single Use Items

Recommended K-Wires		
Code	**Description**	**Qty**
081.010	0.8 x 100mm K-Wire	2
611.112	1.1 x 120mm K-Wire	2

Optional K-Wires		
Code	**Description**	**Qty**
113210001	2.5 x 280mm K-Wire	2
522015	2.0 x 150mm K-Wire	2
511415	1.4 x 150mm K-Wire	2

Drill		
Code	**Description**	**Qty**
111210036	Drill Bit 1.1mm	2
111210004	Drill Bit 1.5mm	2
112300002	Drill Bit 1.8mm	2

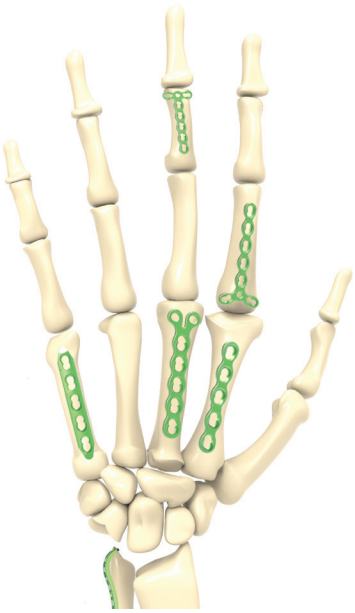
austofix Mini Fragment Range
1.5, 2.0, 2.4mm L&C Plates

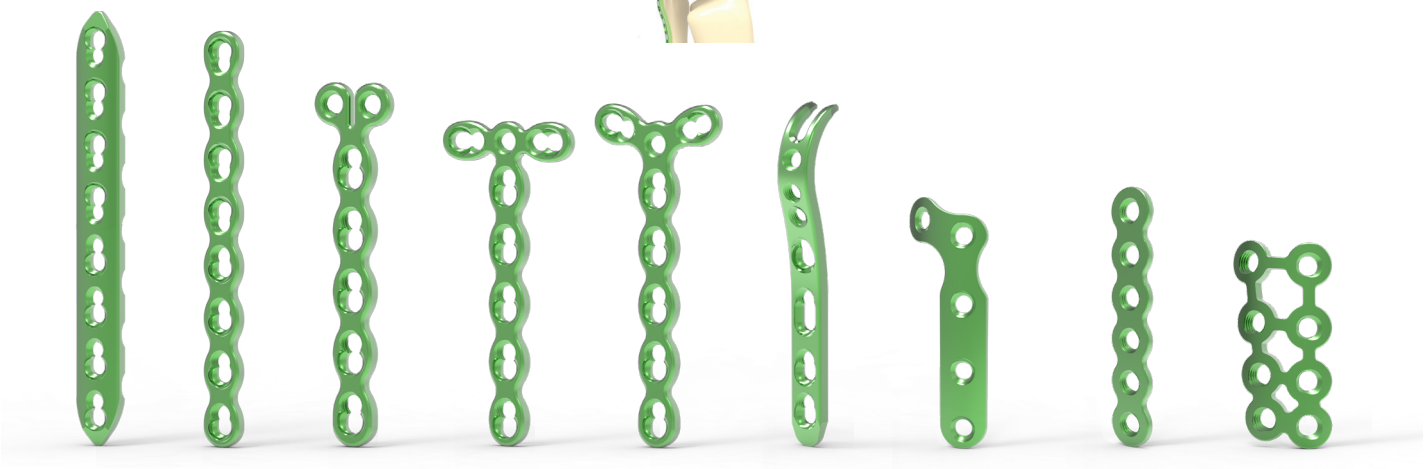
The Austofix Mini Fragment System provides surgeons with a complete fixation solution for a vast range of fracture patterns predominantly in small bones. The plates are designed to offer an innovative surgical solution through their adaptability to a wide range of anatomical conditions and trauma presentations.

The Mini Fragment System is a comprehensive collection of implant plates and screws essential for a small bone fixation solution.

The Austofix Mini Fragment Instrument Set and the Austofix Universal Trauma Set are compatible with the entire Austofix Mini Fragment range of plates shown below.

For more information on the usage and technique of these plates or for product codes, see the relevant plate-specific Surgical Technique.





L&C Locking Plate

L&C Adaption Locking Plate

L&C Condylar Locking Plate

L&C Locking T-Plate

L&C Locking Y-Plate

L&C Distal Ulna Hook Locking Plate

2.0mm L-Plate Oblique

1.5mm Phalangeal Metacarpal Locking Plate

1.5mm Locking Support Plate

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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 0.48°C in titanium and 0.74°C 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.

Notes

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Notes

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