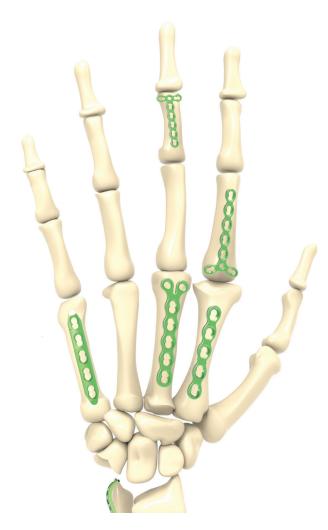


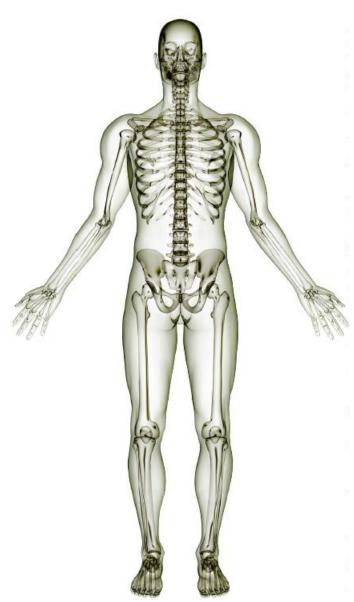
austofix Mini Fragment 1.5, 2.0, 2.4mm L&C Plates

Surgical Technique



Contents

Implant Features	5
Screws	
Plate Range	
L&C Locking Plate	
L&C Mini Locking Plate (Y-shape)	6
Screw Range	6
L&C Condylar Plate	
2.0mm L-Plate Oblique	6
Locking Screw	6
Adaption Locking Plate	6
L&C Mini Locking Plate (T-shape)	6
1.5mm Phalangeal Metacarpal Locking Plate	6
1.5mm Locking Support Plate	6
Cortex Screw	6
Surgical Technique	7
Plate Selection	
Reduce the Fracture.	7
Position the Plate.	7
Contouring	7
Pre-Drilling	8
Drilling	9
Determine Screw Length	10
Screw Selection.	10
Cortex Screw Insertion	11
Locking Screws	11
Removal of Plate	12
Implants - Plates	13
Instruments	21
Single Use Items	23
MRI Safety	
Notes	26



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. © This document is copyright to Austofix and may not be reproduced in whole or part without permission.

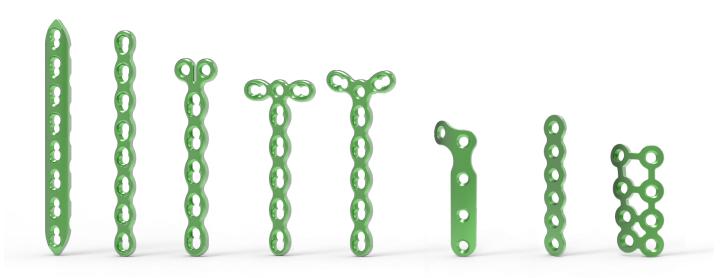
austofix Mini Fragment 1.5, 2.0, 2.4mm L&C Plates

The Austofix Mini Fragment System provides surgeons with a complete fixation solution for a vast range of fracture patterns predominantly in small bones.

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

The plates are designed to offer an innovative surgical solution through their adaptability to a wide range of anatomical conditions and trauma presentations.

These titanium plates and screws incorporate significant benefits: lightweight, high strength and bio-compatible.



Implant Features

Plates

Combi Hole

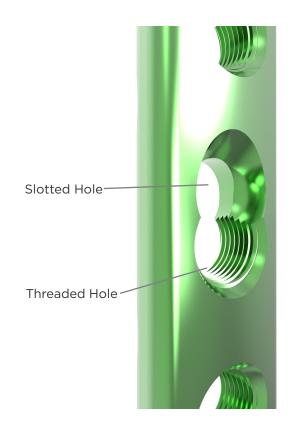
The Combi Hole allows for a range of plate fixation options. The holes accommodate both Compression and Locking Screws.

Slotted Hole - Cortex Screws

Cortex Screws used in the slotted hole for plateto-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 Range

This surgical technique applies to the following locking compression plates. Plate selection is determined by surgeon.



Adaption Locking Plate



1.5mm 2.0mm & 2.4mm

2.0mm & 2.4mm



1.5mm 2.0mm & 2.4mm

L&C Mini Locking Plate (T-shape)



1.5mm 2.0mm & 2.4mm



1.5mm 2.0mm & 2.4mm

1.5mm Locking Support Plate



1.5mm

2.0mm L-Plate Oblique



1.5mm Phalangeal Metacarpal Locking Plate



2.0mm 1.5mm

Screw Range



Cortex Screw

Surgical Technique

This Surgical Technique applies to the 1.5mm, 2.0mm, 2.4mm Mini Fragment Locking Compression Plates System.

Plate Selection

Select the appropriate Plate to treat the fracture. Determine the length of the Plate required. The Plate can also be bent to mould to the bone using the supplied Flat Pliers (111210012) or LCP Plate Benders (111210031).

Reduce the Fracture.

Perform an appropriate incision to treat the fracture.

Reduce the fracture if required using the image intensifier, Ø0.8mm K-Wires (081.010) and/or Reduction Forceps (111110008/9).

Note: Ø1.1mm K-Wires are also available for fracture reduction.

Position the Plate.

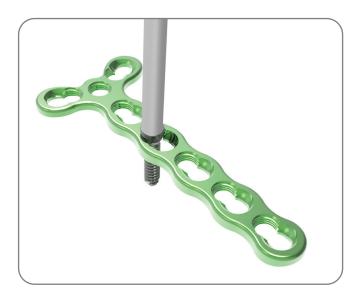
Place the selected Plate on the fractured bone and in a suitable position. If axial dynamic compression will be used ensure the middle of the plate is above the line of the fracture. The plate can be temporarily held in place using plate holding forceps.

Contouring

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: 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.



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/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)
- = Yellow (2.4mm instruments)

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

Position the Drill Sleeve as shown in the image on page 9 as required for compression or Locking. Drill.

Note: If a combination of Screws is 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	2.0mm	2.4mm	1.5mm	2.0mm	2.4mm
	Cortex	Cortex	Cortex	Locking	Locking	Locking
Drill	Ø1.1mm Drill	Ø1.5mm Drill	Ø1.8mm Drill	Ø1.1mm Drill	Ø1.5mm Drill	Ø1.8mm Drill
	(111210036)	(111210004)	(112300002)	(111210036)	(111210004)	(112300002)
Drill Sleeve/ Guide	Ø1.1/1.5mm Drill Sleeve (111210035)	Ø1.5mm Drill Sleeve (111210003)	Ø1.8mm Universal Drill Guide (112300010)	Ø1.1mm Drill Sleeve (111210037)	Ø1.5mm Drill Sleeve (111210002)	Ø1.8mm L&C Drill Sleeve (112300009)
Driver	T4	T6	T8	T4	T6	T8
	Screwdriver	Screwdriver	Screwdriver	Screwdriver	Screwdriver	Screwdriver
	(212000530)*	(112300007)	(112300005)	(212000530)*	(112100007)	(112300005)
Torque Limiter	-	-	-	Torque Limiter 0.3Nm (111210042)	Torque Limiter 0.4Nm (111210014)	Torque Limiter 0.6Nm (111210022)

*Note: Long T4 Screwdriver (212000531) 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 Sleeves for Neutral & Dynamic Compression

Neutral Screw Position

Advance the spring-loaded Drill Sleeve 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.

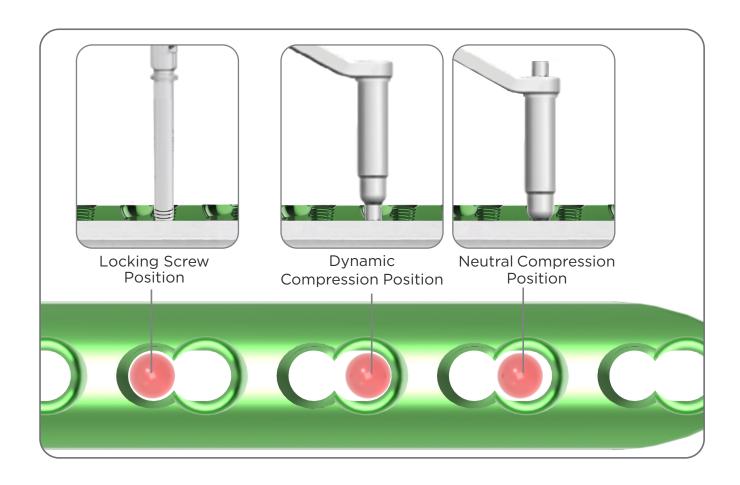
Dynamic Screw Position

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 (page 11).

Using the Locking Sleeves & Locking Screw Position

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

Note: Refer back to the table on page 8 for instrument selection.



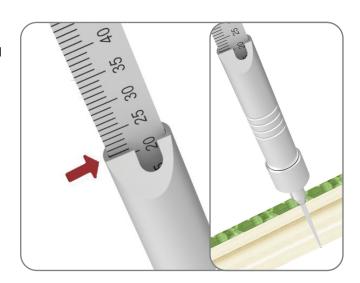
Determine Screw Length.

The Depth Gauge* 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.

*Note: For Ø1.5mm Screws use the 1.5mm Mini Frag Depth Gauge (111210041). Otherwise for Ø2.0 and Ø2.4mm Screws, use the 2.0 & 2.4mm Depth Gauge (112300008).



Screw Selection.

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

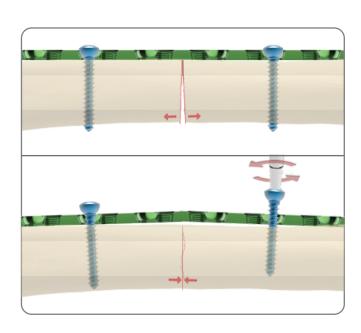


Far Cortical Deviation Correction

Dynamic screw insertion may result in a slight separation of the bone in the far cortical region due to the Cortex Screws initially creating compression in the near cortex.

This can be avoided by slightly bending the plate about the fracture line using the LCP Plate Benders (111210031) or Flat Pliers (111210012) followed by incremental screw insertion.

For optimal compression without loss of reduction, the Screws should be tightened sequentially in increments to fully compress the bone across its entire fracture.



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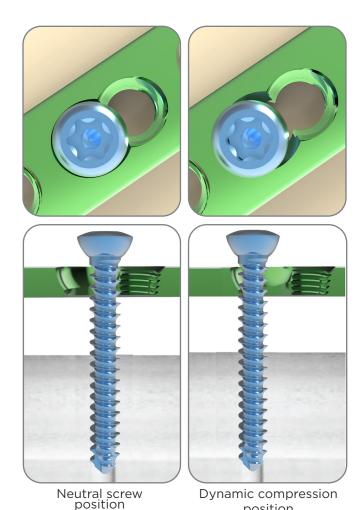
Cortex Screw Insertion

Note: If a combination of Cortex and Locking Screws are to be used then the Cortex Screw should be inserted first to generate interfragmentary compression.

Use the appropriate Driver Tip (refer to table on page 8) 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.



Locking Screws

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

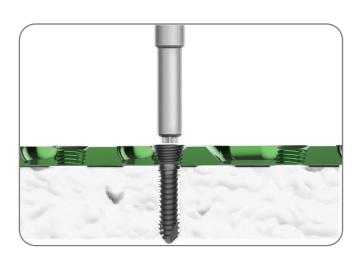
Ensure the desired Screw is concentric to the plate's threaded hole. Insert the Screw and tighten with the appropriate Screwdriver*, Torque Limiter* and T-Handle with Quick Coupling (112300011). Screw it down until the threaded screw head engages and is secure to the plate.

Warning: If using power to insert Locking Screws, always use a torque limiting attachment*. The Locking Screws should always be tightened to the final position by hand. This reduces the risk of the threads stripping from the head of the screw.

*Note: Refer to table on page 8.

If a Locking Screw is used first ensure the plate is securely held to the bone to avoid the plate moving. Depending on the clinical requirements no compression or dynamic compression will be generated.

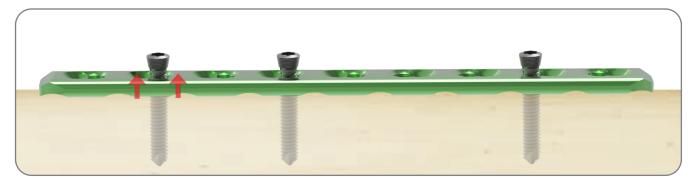
The number of screws and screw insertion configuration is to be determined by the surgeon.



position

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

1.5mm L&C Locking Plate			
Product Code	Number of Holes		
1170-00-04025	4		
1170-00-05031	5		
1170-00-06038	6		
1170-00-07044	7		
1170-00-08051	8		
1170-00-10064	10		

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

2.0mm L&C Locking Plate			
Product Code	Number of Holes		
2026-01-04031	4		
2026-01-05038	5		
2026-01-06045	6		
2026-01-07052	7		
2026-01-08059	8		
2026-01-10073	10		

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

2.4mm L&C Locking Plate			
Product Code	Number of Holes		
2032-01-04031	4		
2032-01-05038	5		
2032-01-06045	6		
2032-01-07052	7		
2032-01-08059	8		
2032-01-10073	10		

Compatible Screw: 2.4mm Locking Screw, 2.4mm Cortex Screw



1.5mm L&C Condylar Plate			
Product Code	Number of Holes		
1167-00-04027	4		
1167-00-05032	5		
1167-00-06037	6		
1167-00-07042	7		
1167-00-08047	8		

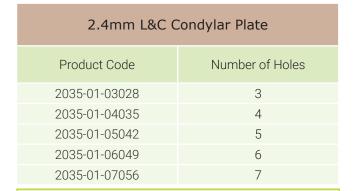
Compatible Screw: 1.5mm Locking Screw, 1.5mm

Cortex Screw

2.0mm L&C Condylar Plate			
Product Code	Number of Holes		
2029-01-03028	3		
2029-01-04035	4		
2029-01-05042	5		
2029-01-06049	6		
2029-01-07056	7		

Compatible Screw: 2.0mm Locking Screw, 2.0mm

Cortex Screw



Compatible Screw: 2.4mm Locking Screw, 2.4mm Cortex Screw



1.5mm L&C T-Plate		
Product Code	Number of Holes	
1165-00-04026	4	
1165-00-05031	5	
1165-00-06036	6	
1165-00-07041	7	
1165-00-08046	8	

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

2.0mm L&C T-Plate		
Product Code	Number of Holes	
2030-01-04033	4	
2030-01-05040	5	
2030-01-06047	6	
2030-01-07054	7	

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

2.4mm L&C Mini T Plate		
Product Code	Number of Holes	
2036-01-04033	4	
2036-01-05040	5	
2036-01-06047	6	
2036-01-07054	7	

Compatible Screw: 2.4mm Locking Screw, 2.4mm Cortex Screw



1.5mm Locking Support Plate		
Product Code	Number of Holes	
1168-00-08023L	8	
1168-00-08023R	8	



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

2.0mm L&C Adaption Locking Plate		
Product Code	Number of Holes	
2027-01-12085	12	

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

2.4mm L&C Adaption Locking Plate		
Product Code	Number of Holes	
2033-01-12085	12	

Compatible Screw: 2.4mm Locking Screw, 2.4mm Cortex Screw



1.5mm Locking Y-Plate			
Product Code	Number of Holes		
1166-00-04027	4		
1166-00-05032	5		
1166-00-06037	6		
1166-00-07042	7		
1166-00-08047	8		

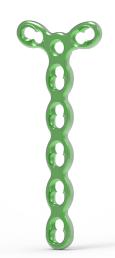
Compatible Screw: 1.5mm Locking Screw, 1.5mm Cortex Screw

2.0mm L&C Y-Plate			
Product Code	Number of Holes		
2031-01-04035	4		
2031-01-05042	5		
2031-01-06049	6		
2031-01-07056	7		

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

2.4mm L&C Mini Y Plate			
Product Code	Number of Holes		
2037-01-04035	4		
2037-01-05042	5		
2037-01-06049	6		
2037-01-07056	7		

Compatible Screw: 2.4mm Locking Screw, 2.4mm Cortex Screw



1.5mm Phalangeal Metacarpal Locking Plate			
Product Code Number of Ho			
1169-00-06030	6		
1169-00-12060	12		

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



2.0mm L-Plate Oblique			
Product Code	Number of Holes		
2180-00-04019L	4		
2180-00-05025L	5		
2180-00-04019R	4		
2180-00-05025R	5		

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



Implants - Screws

Locking Screw - Self-tapping					
Length	1.5mm	2.0mm	2.4mm		
6	1016-01-15006	1016-01-20006	1016-01-24006		
7	1016-01-15007	1016-01-20007	-		
8	1016-01-15008	1016-01-20008	1016-01-24008		
9	1016-01-15009	1016-01-20009	-		
10	1016-01-15010	1016-01-20010	1016-01-24010		
11	1016-01-15011	1016-01-20011	-		
12	1016-01-15012	1016-01-20012	1016-01-24012		
13	1016-01-15013	1016-01-20013	-		
14	1016-01-15014	1016-01-20014	1016-01-24014		
15	1016-01-15015	-	-		
16	1016-01-15016	1016-01-20016	1016-01-24016		
17	1016-01-15017	-	-		
18	1016-01-15018	1016-01-20018	1016-01-24018		
19	1016-01-15019	-	-		
20	1016-01-15020	1016-01-20020	1016-01-24020		
22	-	1016-01-20022	1016-01-24022		
24	-	1016-01-20024	1016-01-24024		
26	-	1016-01-20026	1016-01-24026		
28	-	1016-01-20028	1016-01-24028		
30	-	1016-01-20030	1016-01-24030		





Cortex Screw - Self-tapping					
Length	1.5mm	2.0mm	2.4mm		
6	1014-01-15006	1062-00-20006	1062-00-24006		
7	1014-01-15007	1062-00-20007	-		
8	1014-01-15008	1062-00-20008	1062-00-24008		
9	1014-01-15009	1062-00-20009	-		
10	1014-01-15010	1062-00-20010	1062-00-24010		
11	1014-01-15011	1062-00-20011	1062-00-24011		
12	1014-01-15012	1062-00-20012	1062-00-24012		
13	1014-01-15013	1062-00-20013	1062-00-24013		
14	1014-01-15014	1062-00-20014	1062-00-24014		
15	1014-01-15015	-	-		
16	1014-01-15016	1062-00-20016	1062-00-24016		
17	1014-01-15017	-	-		
18	1014-01-15018	1062-00-20018	1062-00-24018		
19	1014-01-15019	-	-		
20	1014-01-15020	1062-00-20020	1062-00-24020		
22	-	1062-00-20022	1062-00-24022		
24	-	1062-00-20024	1062-00-24024		
26	-	1062-00-20026	1062-00-24026		
28	-	1062-00-20028	1062-00-24028		
30	-	1062-00-20030	1062-00-24030		
32	-	1062-00-20032	1062-00-24032		
34	-	1062-00-20034	1062-00-24034		
36	-	1062-00-20036	1062-00-24036		
38	-	1062-00-20038	1062-00-24038		
40	-	-	1062-00-24040		
60	-	-	1062-00-24060		





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	212000531	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	212000530	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				

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		



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.

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Shellock FG. Biomedical Implants and Devices: Assessment of Magnetic Field Interactions With a 3. O-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.

24 | **Austofix** T | 1300 727 075 F | 1300 727 380 | sales@austofix.com.au | www.austofix.com.au | www.austofix.com.au

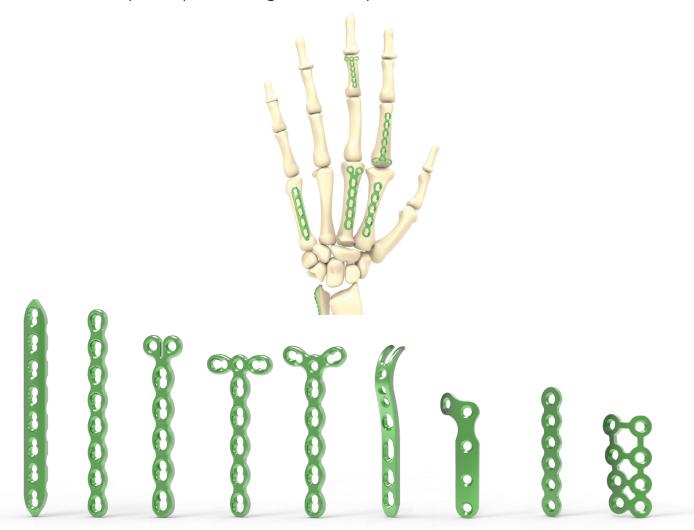
austofix Mini Fragment Range 1.5, 2.0, 2.4mm L&C Plates

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

Notes

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