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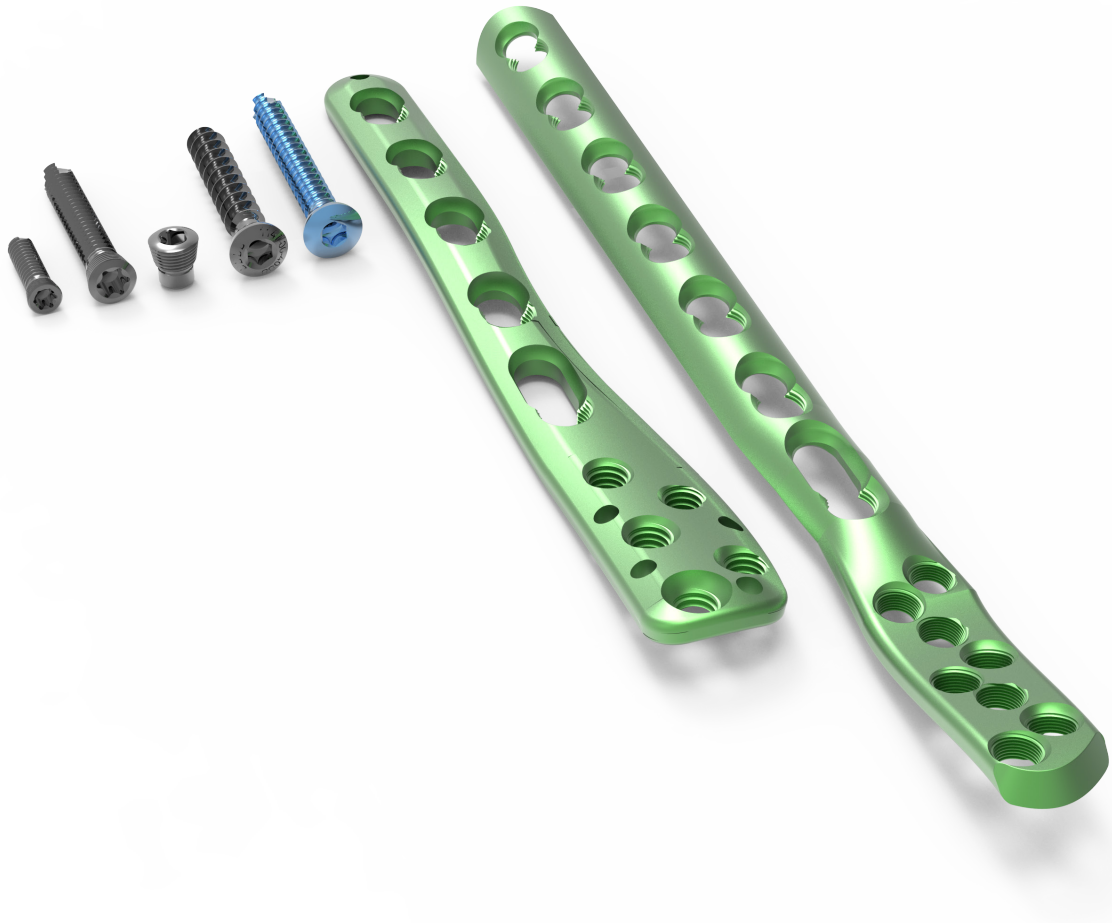
austofix Distal Fibula

2.7, 3.5mm L&C Plates

Surgical Technique



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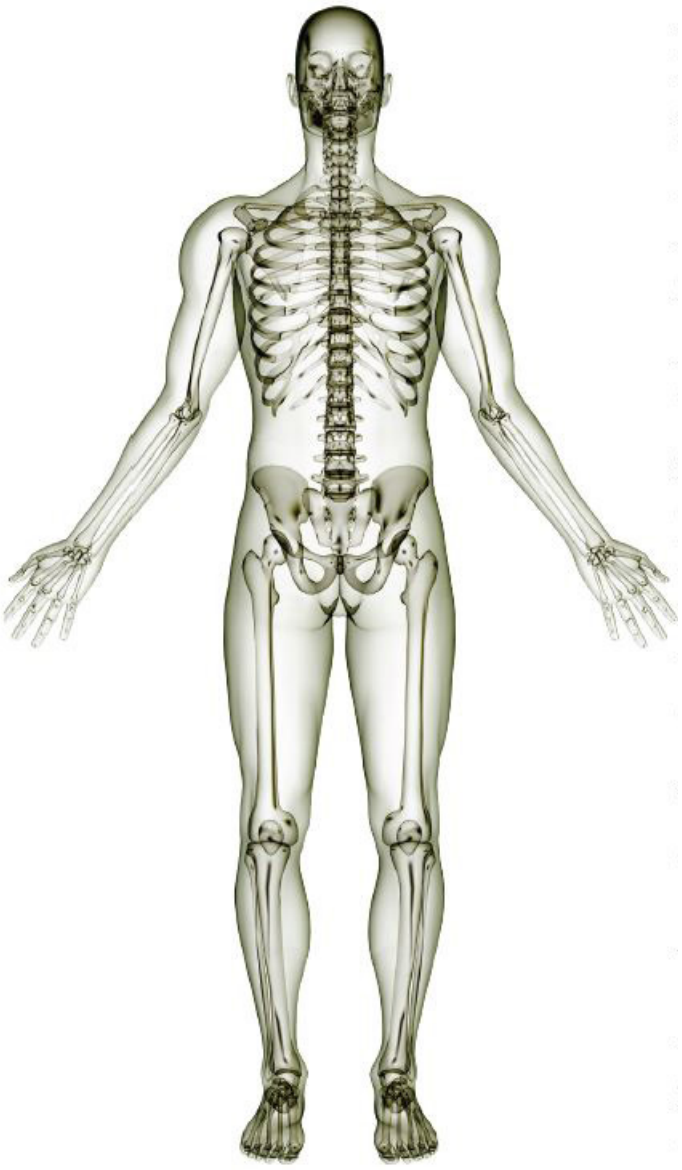

Austofix is a leading manufacturer and designer of orthopaedic trauma medical devices with a particular focus on innovation, excellence and patient safety. Austofix has the expertise and experience in developing a new device from concept to a fully Commercialised product with regulatory approval for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

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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 Small 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 Fibula

2.7, 3.5mm L&C Plates

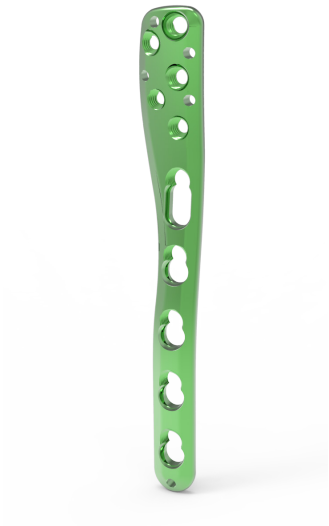
The Austofix Distal Fibula Plates provide surgeons with a complete fixation system for the many complex fracture patterns found in the distal fibula.

Implant grade Titanium Plates and Screws incorporate significant benefits: lightweight, high strength and biocompatible.

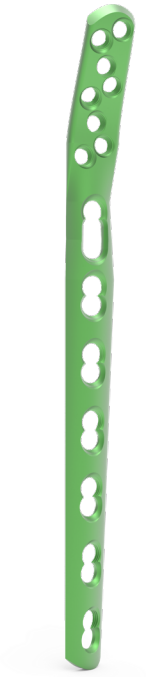
The use of Locking Screws allows for fixed-angle construction providing particular advantages in osteopenic bone or in multifragmentary fractures near the joints.

Austofix understands the importance of proven, high quality medical devices and instruments. The Distal Fibula L&C Plates adhere to these principles and will provide the surgeon with a comprehensive distal fibula fixation solution.

L&C Distal Lateral Fibula Locking Plate



L&C Distal Posterior Lateral Fibula Locking Plate



Screws

Implant Features

Plates

Combi Hole

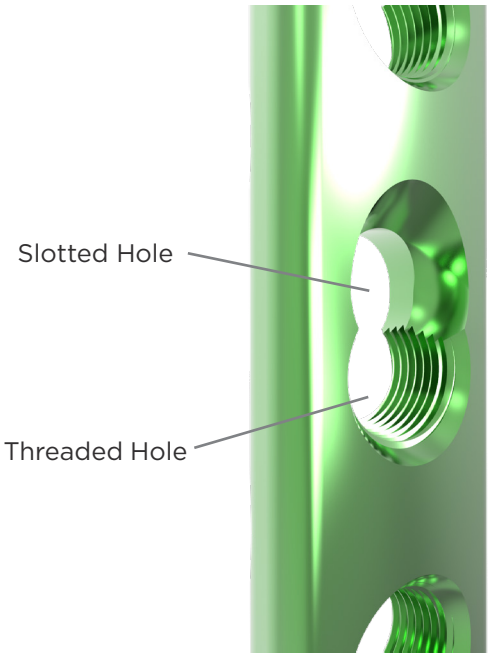
The Combi Hole allows for a range of plate fixation options. The holes accommodate both Compression and Locking screws.

Slotted Hole - Cortex Screws/Cancellous Screws

Cortex or Cancellous 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.



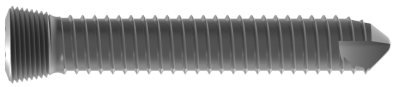
Tapered End

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

Screws

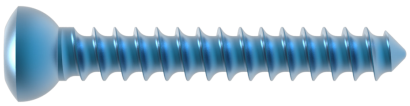
Locking Screw

- Self-Tapping
- Reduced Screw Back-out
- Unicortical or Bicortical Fixation



Cortex(Cortical) Screw

- Dynamic Compression
- Compression



Cancellous Screw

- Dynamic Compression
- Interfragmentary compression (Partially Threaded)
- Compression

Spacer

- Reduce Plate-To-Bone Contact
- Minimises Disruption of Periosteal Blood Supply

Plate Features

Anatomical Fit

» Pre-contoured design for left and right fibula

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

» Plate can be further contoured with Plate Benders (112100002/3) for a more suitable anatomical fit

Distal Locking

» Distal locking holes provide flexibility in Locking Screw fixation

» Multiple points of fixation for superior support

» Recesses for head of screws ensure low-profile construct

Note: Distal holes accept Ø2.4 Cortex and Ø2.7 Locking Screws

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

Clinical Indications

» Designed to address complex fractures of the metaphysis and diaphysis of the distal fibula

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

» Particularly beneficial for patients with osteopenic bone

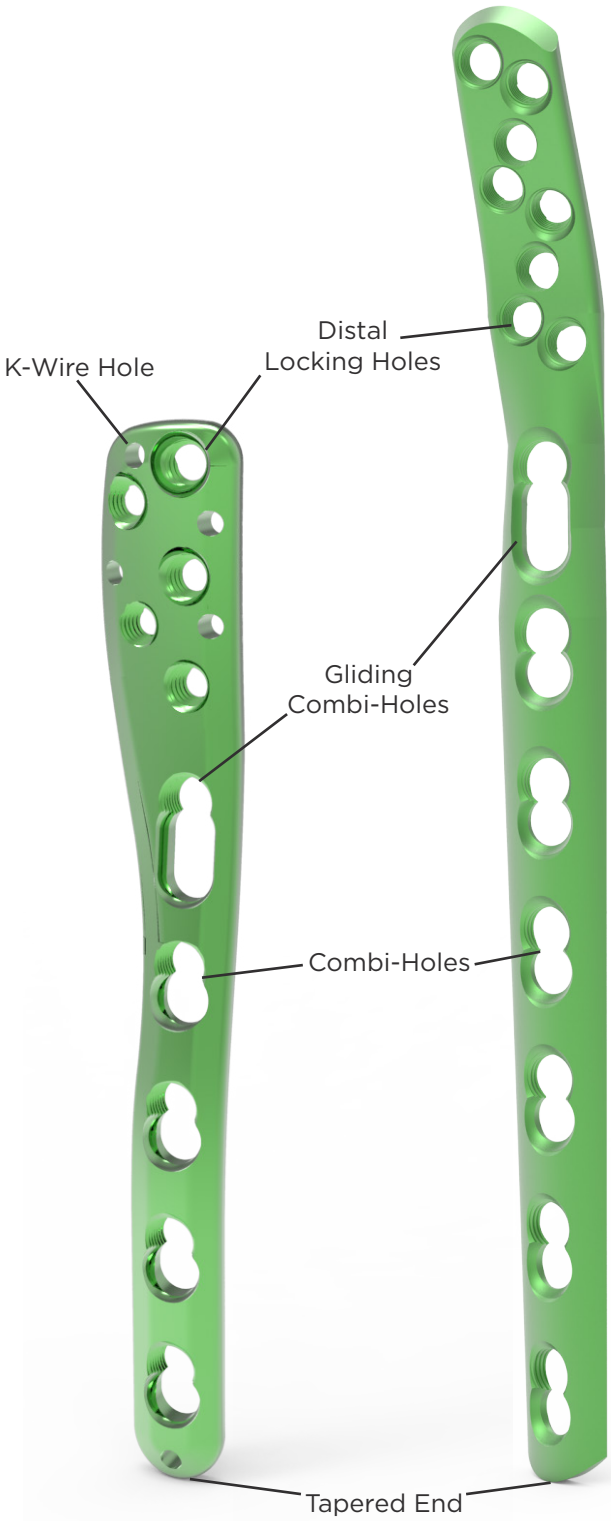


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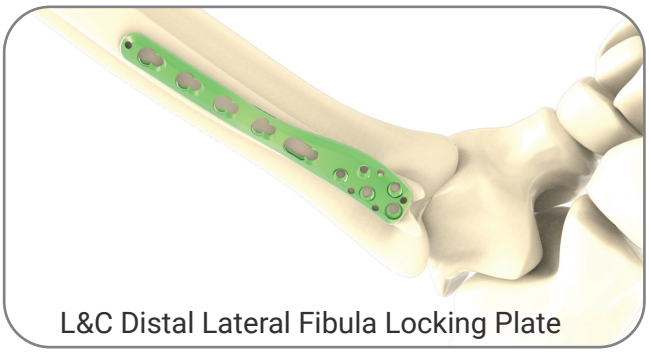
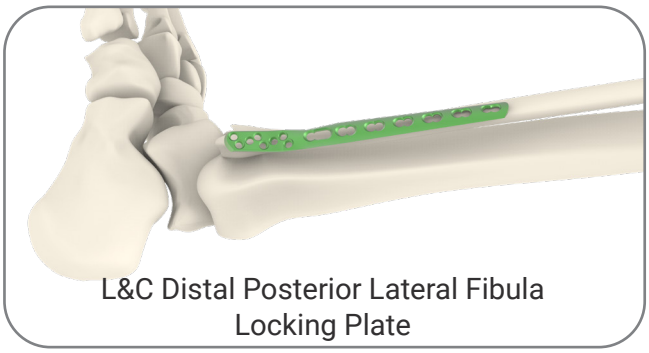
Plate Range

This surgical technique applies to the following Locking Compression Plates. Plate selection is determined by surgeon.



L&C Distal Lateral Fibula Locking Plate



L&C Distal Posterior Lateral Fibula Locking Plate

*__Note:__ Ø2.4 Cortex Screws and Ø2.7mm Locking Screws required for distal fixation. 2.4/2.7mm Instrument Set (SET-INS-2.4/2.7) is required.

Screw Range

Locking Screw

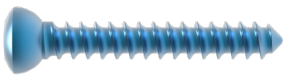
Spacer

Cancellous Screw

Fully Threaded

Partially Threaded

Cortex Screw



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 using the supplied Plate Benders (112100002/3).

Note: Bending of the plate can alter Locking Screw trajectory. Screw trajectories should be confirmed using an image intensifier and K-Wires. 1.4mm (511415) and 2.0mm (522015) K-Wires are available.

Patient Positioning

The patient should be positioned supine with support placed under the buttock of the affected side allowing the foot to lie neutral without external rotation of the leg. The leg should also be elevated with the knee slightly flexed.

Incision

The standard location for incision lies directly over the distal fibula, where a straight lateral or posterolateral incision should be made to expose the fracture site, distal fibula, and the diaphysis of the fibula.

Alternatively, an incision can be made along the posterolateral border of the fibula where improved soft tissue coverage is found. An extraperiosteal approach proximal to the fracture site is recommended.

Warning: Take care not to damage the superficial peroneal nerve or the sural nerve, located proximally and posteriorly respectively.

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Reduce the Fracture

Perform an appropriate incision to treat the fracture.

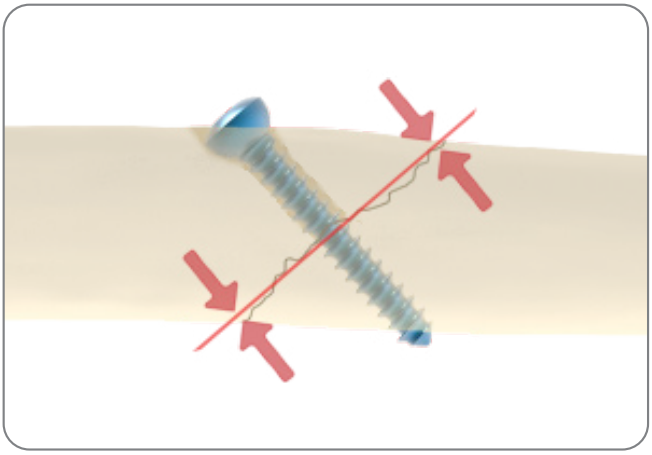
Reduce the fracture using the image intensifier, K-Wires* and/or Reduction Forceps (112100011/3). K-Wire bending can be achieved using the supplied K-Wire Bender (112200010). Ensure that the reduction instrumentation will not interfere with plate placement.

***Note:** The 1.1mm K-Wires (112300013) supplied with the Ø2.4/2.7mm Instrument Set can be used for fracture reduction. 1.4mm (511415) and 2.0mm (522015) K-Wires are also available.

Reduction Using Lag Screws

Depending on the fracture pattern, independent lag Screws may be required before the plate is fixed. 4.5mm Cortex Screws should be used as lag Screws.

1. Reduce the fracture and use the 3.5mm Drill Bit (112100015) with the 3.5mm sleeve of the Universal 3.5/2.5mm Drill Guide (112100005) to drill perpendicularly to the fracture line, taking care not to drill beyond the fracture line.
2. Use the 2.5mm sleeve of the Universal 3.5/2.5mm Drill Guide (112100005) to drill the far cortex using the 2.5mm Drill (112100016).
3. The Countersink (112100014) should then be used to improve bone load transfer.
4. Measurement for Screw length can then be obtained using the Depth Gauge (112100001).
5. Insert Ø3.5mm Cortex Screw of appropriate length to provide interfragmentary compression.



Compression Screws

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

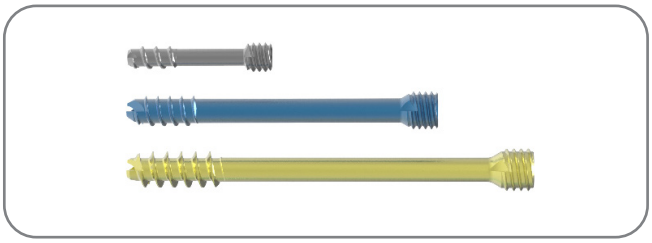
Please refer to the Austofix Cannulated Compression Screws Surgical Technique.

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.

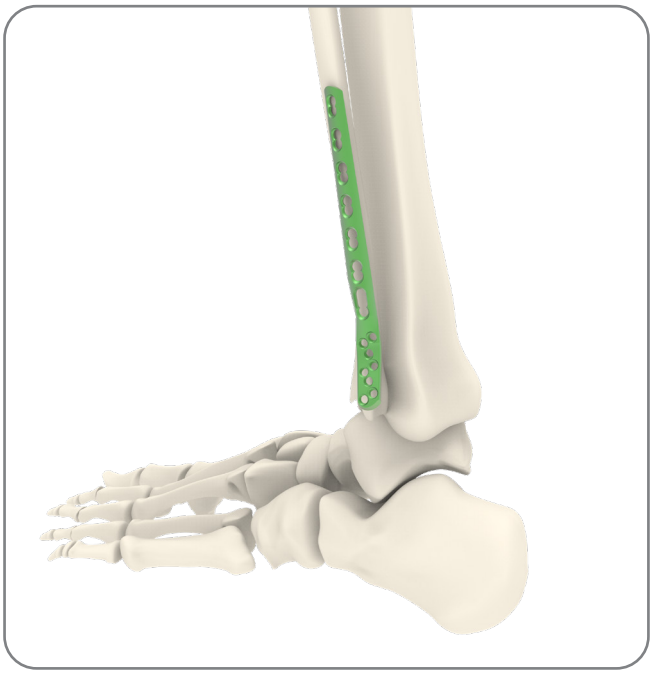


Contouring

If contouring is required, make sure to place the Plate Benders (112100002/3) on two consecutive holes to avoid distortion of the Threaded Holes. Bending Templates (Large: 112100008 & Small: 112100009) are included if desired.

Note: Contouring of the plate can alter Locking Screw trajectory. If contouring of the plate is required, screw trajectories should be verified using an image intensifier and K-Wires. 1.4mm (511415) and 2.0mm (522015) K-Wires are available.

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.



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. If a K-Wire hole is present, use a 2.0mm K-Wire (522015) to assist with determining the optimal position of the plate.

Pre-Drilling

Determine whether Cortex Screws, Cancellous Screws or Locking Screws will be used. A combination may be used.

Note: Following plate positioning, a preliminary Cortex Screw should be inserted first to pull the plate to the bone. The Screw should be inserted through the elongated slotted hole of the Gliding Combi-Hole.

Note: 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.

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

Screw	2.4mm Cortex*	3.5mm Cortex	4.0mm Cancellous	2.4mm Locking*	2.7mm Locking*	3.5mm Locking
Drill	Ø1.8mm Drill (112300002)	Ø2.5mm Drill (112100016)	Ø2.5mm Drill (112100016)	Ø1.8mm Drill (112300002)	Ø2.0mm Drill (112300003/ 112300015)	Ø2.8mm Drill (112200004)
Drill Sleeve/ Guide	1.8mm Drill Sleeve (112300010)	2.5mm Drill Guide (112100020)	2.5mm Drill Guide (112100020)	1.8mm Drill Sleeve (L&C) (112300009)	2.0mm Drill Sleeve (L&C) (112300014)	2.8mm Threaded Drill Sleeve (112200002)
Driver	T8 Star Screwdriver (112300005/6)	SW2.5 Hex Screwdriver (112100022)	SW2.5 Hex Screwdriver (112100022)	T8 Star Screwdriver (112300005/6)	T8 Star Screwdriver (112300005/6)	T15 Star Screwdriver (112200009)
Torque Limiter	-	-	-	0.8Nm Torque Limiter (112300012)	0.8Nm Torque Limiter (112300012)	1.5Nm Torque Limiter (112200001)

Note: The 2.8mm Threaded Drill Sleeve and the Ø2.8mm Drill has a **blue** laser marking for easy identification. The 1.8mm L&C Drill Sleeve and the Ø1.8mm Drill has a **yellow** laser marking for easy identification.

*__Note:__ 2.4/2.7mm Instrument Set (SET-INS-2.4/2.7) required.

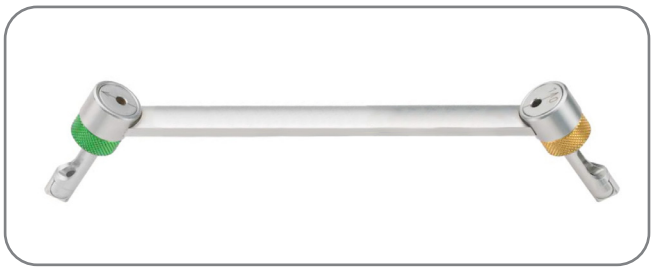
Drill Guides

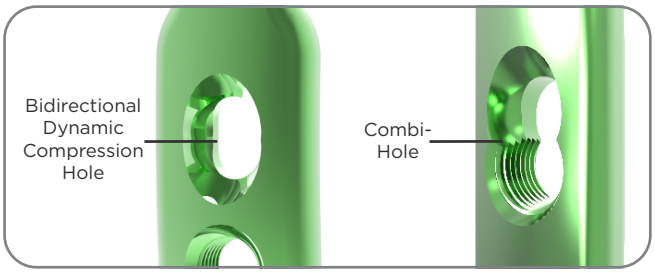
The Small Frag Instrument Set contains four different drill guides. Please follow the guide below to ensure the drill guides are used appropriately.

Drill Guide, LC-L&C 2.5/3.5mm (112100004)

The Limited Contact Locking & Compression (LC-L&C) Drill Guide is only used with plates with limited contact features and bidirectional **Dynamic Compression Holes**. The sleeve tips are designed to seat precisely within the hole to allow accurate neutral or compression drilling.

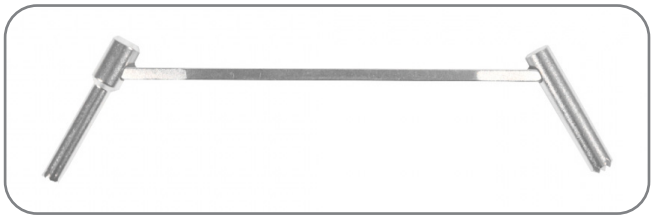
Warning: The LC-L&C Drill Guide 2.5/3.5 (112100004) is **not** suitable for use with the L&C Distal Fibula Plates listed in this Surgical Technique as no **bidirectional Dynamic Compression** Holes are present. Please use the Universal Drill Guide 3.5/2.5mm (112100020) to drill through **Combi-Holes**.





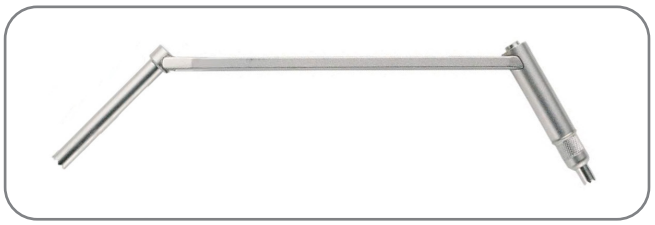
Drill Sleeve, Double 2.5/3.5mm (112100005)

The Double Drill Sleeve is a standard drill sleeve used predominantly for inserting Screws outside of the plate to capture fragments. The larger diameter drill sleeve can additionally be used as a tap sleeve.



Drill Guide, Universal 3.5/2.5mm (112100020) & 1.8/2.4mm (112300010)

The Universal Drill Guide can be used for insertion of Cortex and Cancellous Screws (**not** Locking Screws) through all holes including **Combi-Holes** found in the Small Fragment plating range. The spring-loaded tip allows for greater control over Screw angle within the plate hole. The drill guide also contains a larger diameter tap sleeve if tapping is required. Please refer to the Drilling section (page 12) for more information on using this drill guide.



Drill Sleeve, Threaded 2.8mm (112200002), 2.0mm (112300014), & 1.8mm (112300009)

The Threaded Drill Sleeve is used within the threaded portion of the **Combi-Holes** and the threaded **Locking Holes** for perpendicular insertion of Locking Screws for angular stability.

Drilling

Using the Universal Drill Guide 3.5/2.5mm

Neutral Screw Position

Advance the spring-loaded Universal Drill Guide 3.5/2.5mm (112100020) 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 Universal Drill Guide 3.5/2.5mm (112100020) against the edge of the Dynamic Compression slot of the plate. Without exerting pressure on the Drill Guide, the inner sleeve will remain in the Dynamic position. Dynamic Compression will occur once the Cortex/Cancellous Screws are tightened (page 13).

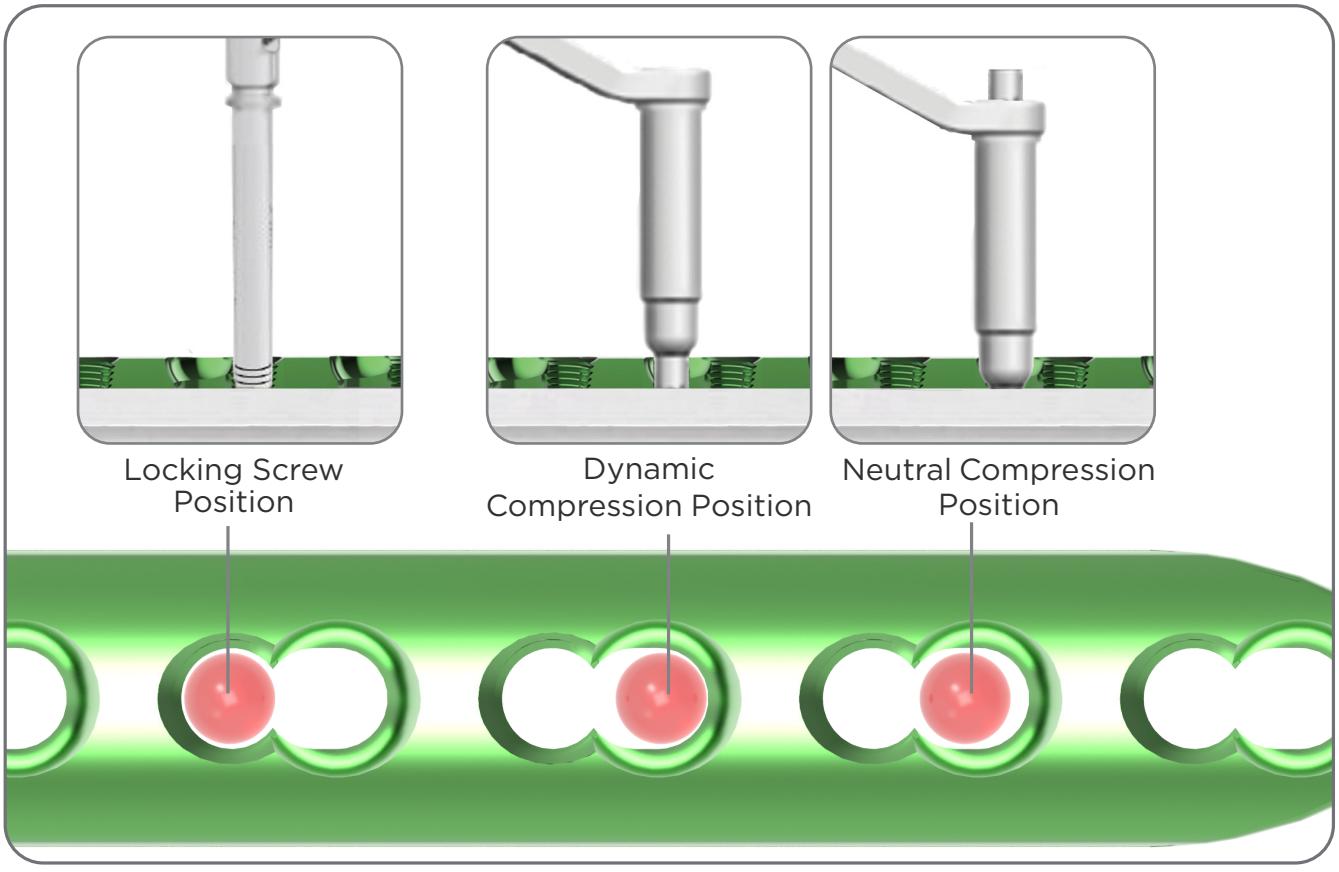
Note: The 1.8mm Drill Sleeve is required for Ø2.4mm Cortex Screws.

Locking Sleeve & Locking Screw Position

Insert the 2.8mm Threaded Drill Sleeve (112200002) into threaded hole. Carefully drill the Locking Screw hole using the 2.8mm Drill (112200004).

Note: The 2.0mm Drill Sleeve (L&C) is required for Ø2.7mm Locking Screws.

Note: The 2.8mm Threaded Drill Sleeve and the Ø2.8mm Drill have a **blue** laser marking for easy identification.



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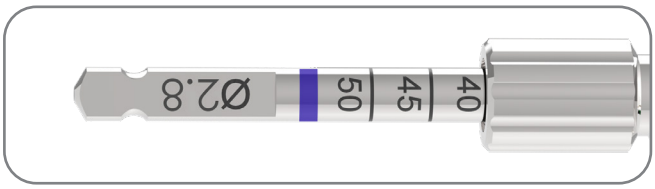
Determine Screw Length

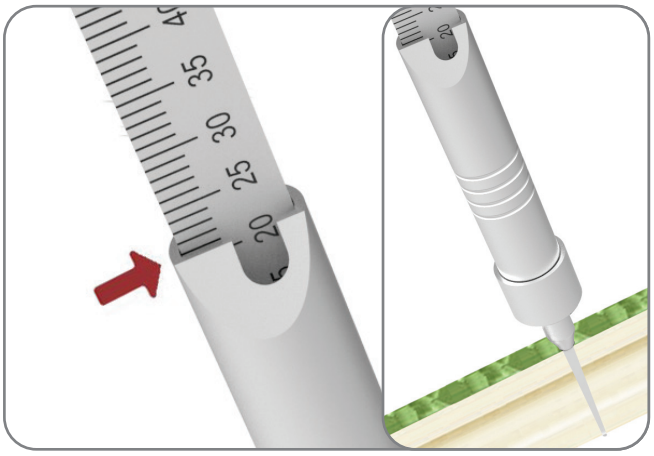
For Ø3.5mm Locking Screws, Screw length can be determined by reading the depth measurement directly from the calibrated Ø2.8mm Drill (112200004).



The 2.5/4.0mm Depth Gauge (112100001) is required to determine Cortex and Cancellous Screw length. The Depth Gauge can be inserted directly into the hole in the bone. Measurements marked on the Depth Gauge are used to determine the Screw length. The Depth Gauge can also be used as an alternative to determining Locking 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: Use the 2.0/2.4mm Depth Gauge (112300008) to determine Ø2.4 Cortex, Ø2.4 Locking, and Ø2.7mm Locking Screw length.

Screw Insertion

Use the table on page 10 to determine which Driver and Handle to use. If a combination of Cortex and Locking Screws are to be used then the Cortex Screw should be inserted first to generate interfragmentary compression.

Cortex/Cancellous Screws

Neutral Screw Position

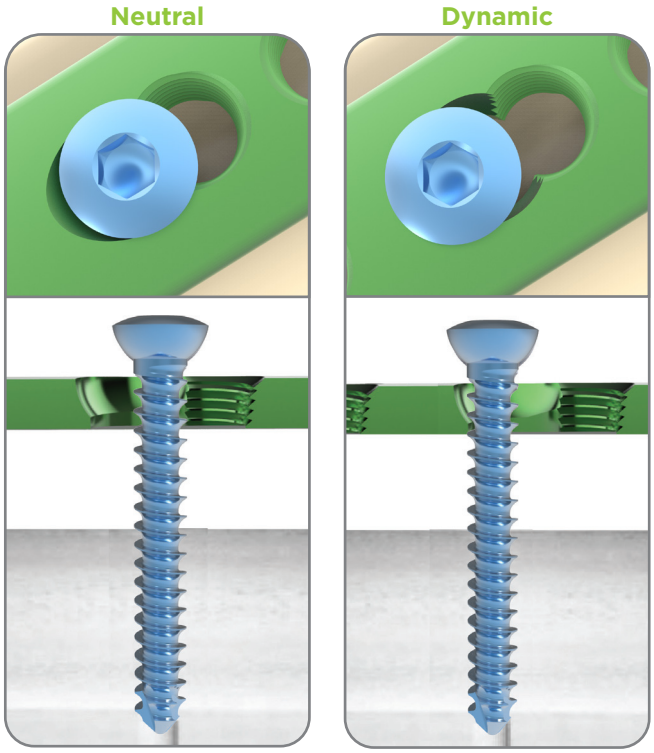
Use the Hex Screwdriver (112100022) to insert Cortex/Cancellous Screw to appropriate depth.

Alternatively, a Power Screwdriver (112100017) can be used.

Dynamic Screw Position

Use the Hex Screwdriver (112100022) or Power Screwdriver (112100017) to insert Cortex/Cancellous Screw to appropriate depth. The Screwdriver's Holding Sleeve can be used to assist in Screw insertion. Ensure Dynamic Compression has been achieved.

Note: For Ø2.4mm Cortex Screws, use either the short or long T8 Star Screwdriver (112300005/6).



Partially Threaded vs Fully Threaded Cancellous Screws

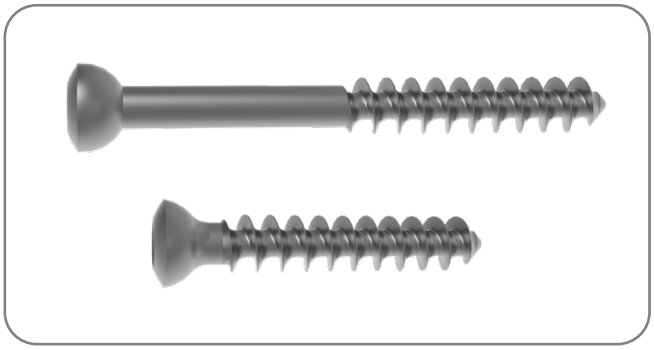
Partially Threaded

- Used to compress the Plate to the bone and can be used to provide interfragmentary compression

Fully Threaded

- Used to compress the Plate to the bone

Note: A Countersink (112100014) is available if Screws are being used to capture fragments outside of the Plate.

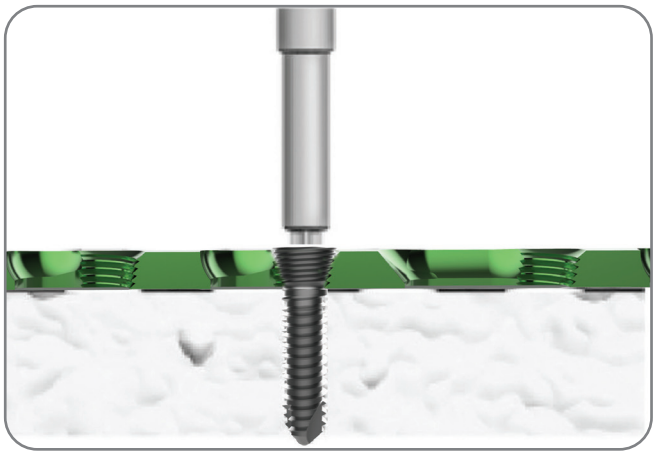


Locking Screw Insertion

Locking Position

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 1.5Nm Torque Limiter Screwdriver (112200001). Screw it down until the threaded screw head engages and is secure to the plate.



Note: For Ø2.4 & Ø2.7mm Locking Screws, use either the short T8 Star Screwdriver (112300005) with the 0.8Nm Torque Limiter (112300012) and T-Handle with Quick Coupling (112300011), or use the long T8 Star Screwdriver (112300006) with the Holding Sleeve (112300007) and Straight Handle With Quick Coupling (112300004).

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. The Star Screwdriver Shaft (112200003) can be used for insertion using power.

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.

Spacer

If minimal contact between the plate and bone is desired, a 3.5mm Spacer can be inserted using the SW2.5 Hex Driver (112100022). The Spacer ensures a distance of 2mm between the plate and bone when the Screws are later inserted. The Spacer can be removed after setting the Locking Screws.

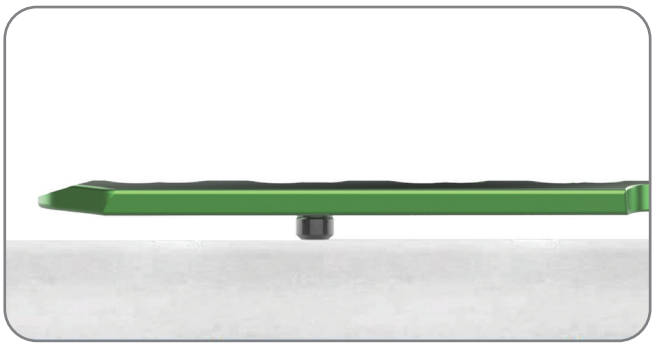
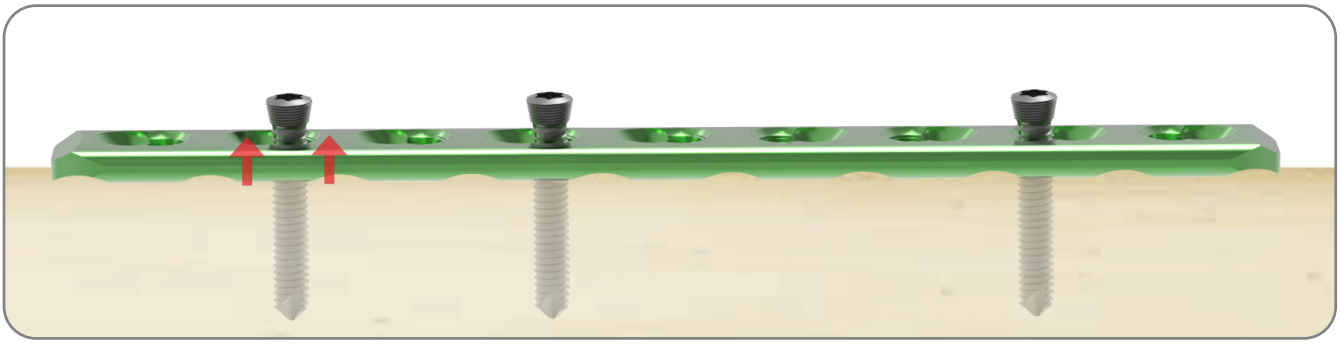


Plate Removal

To remove the Plate, unlock all the Screws first using the appropriate Hex (112100022) or Star (112200009) Screwdriver for Cortex/Cancellous 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.

Note: The Easyout (112200005) can be used with the T-Handle with Quick Coupling (112100024) or a Power Drill if there are difficulties in the removal of Screws.



Implants

Plates

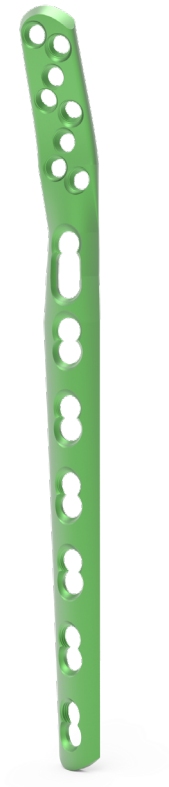
L&C Distal Lateral Fibula Locking Plate		
Product Code	Number of Holes	Left/Right
4149-00-03073L	3	L
4149-00-04086L	4	L
4149-00-05099L	5	L
4149-00-06112L	6	L
4149-00-07125L	7	L
4149-00-03073R	3	R
4149-00-04086R	4	R
4149-00-05099R	5	R
4149-00-06112R	6	R
4149-00-07125R	7	R

Compatible Screw: 2.4 & 3.5mm Cortex Screw, 4.0mm Cancellous Screw, 2.4, 2.7mm & 3.5mm Locking Screw, 3.5mm Spacer

Compatible K-Wire: 2.0mm

L&C Distal Posterior Lateral Fibula Locking Plate		
Product Code	Number of Holes	Left/Right
4178-00-03077L	3	L
4178-00-04090L	4	L
4178-00-05103L	5	L
4178-00-06116L	6	L
4178-00-07129L	7	L
4178-00-03077R	3	R
4178-00-04090R	4	R
4178-00-05103R	5	R
4178-00-06116R	6	R
4178-00-07129R	7	R

Compatible Screw: 2.4 & 3.5mm Cortex Screw, 4.0mm Cancellous Screw, 2.4, 2.7mm & 3.5mm Locking Screw, 3.5mm Spacer



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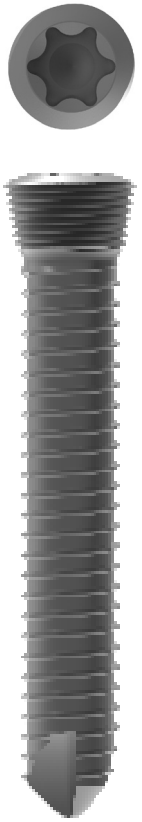
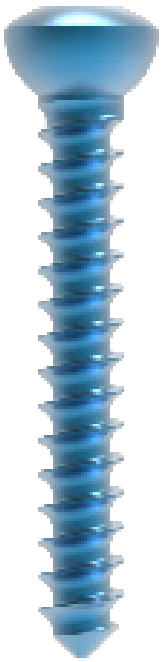
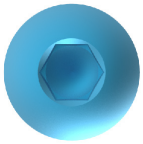
Screws

Locking Screw - Self-tapping			
Length	2.4mm	2.7mm	3.5mm
6	1016-01-24006	-	-
8	1016-01-24008	1059-00-27008	-
10	1016-01-24010	1059-00-27010	1061-00-35010
12	1016-01-24012	1059-00-27012	1061-00-35012
14	1016-01-24014	1059-00-27014	1061-00-35014
16	1016-01-24016	1059-00-27016	1061-00-35016
18	1016-01-24018	1059-00-27018	1061-00-35018
20	1016-01-24020	1059-00-27020	1061-00-35020
22	1016-01-24022	1059-00-27022	1061-00-35022
24	1016-01-24024	1059-00-27024	1061-00-35024
26	1016-01-24026	1059-00-27026	1061-00-35026
28	1016-01-24028	1059-00-27028	1061-00-35028
30	1016-01-24030	1059-00-27030	1061-00-35030
32	-	-	1061-00-35032
34	-	-	1061-00-35034
35	-	1059-00-27035	1061-00-35035
36	-	-	1061-00-35036
38	-	-	1061-00-35038
40	-	1059-00-27040	1061-00-35040
42	-	-	1061-00-35042
44	-	-	1061-00-35044
45	-	1059-00-27045	1061-00-35045
46	-	-	1061-00-35046
48	-	-	1061-00-35048
50	-	1059-00-27050	1061-00-35050
55	-	1059-00-27055	1061-00-35055
60	-	1059-00-27060	1061-00-35060
65	-	-	1061-00-35065
70	-	-	1061-00-35070
75	-	-	1061-00-35075
80	-	-	1061-00-35080
85	-	-	1061-00-35085
90	-	-	1061-00-35090



Cortex Screw - Self-tapping		
Length	2.4mm	3.5mm
6	1062-00-24006	-
8	1062-00-24008	-
10	1062-00-24010	1145-00-35010
11	1062-00-24011	-
12	1062-00-24012	1145-00-35012
13	1062-00-24013	-
14	1062-00-24014	1145-00-35014
16	1062-00-24016	1145-00-35016
18	1062-00-24018	1145-00-35018
20	1062-00-24020	1145-00-35020
22	1062-00-24022	1145-00-35022
24	1062-00-24024	1145-00-35024
26	1062-00-24026	1145-00-35026
28	1062-00-24028	1145-00-35028
30	1062-00-24030	1145-00-35030
32	1062-00-24032	1145-00-35032
34	1062-00-24034	1145-00-35034
36	1062-00-24036	1145-00-35036
38	1062-00-24038	1145-00-35038
40	1062-00-24040	1145-00-35040
42	-	1145-00-35042
44	-	1145-00-35044
46	-	1145-00-35046
48	-	1145-00-35048
50	-	1145-00-35050
60	1062-00-24060	-





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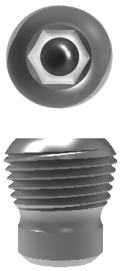
Cancellous Screw - Partially-threaded	
Length	4.0mm
20	1146-00-40020
22	1146-00-40022
24	1146-00-40024
26	1146-00-40026
28	1146-00-40028
30	1146-00-40030
32	1146-00-40032
34	1146-00-40034
36	1146-00-40036
38	1146-00-40038
40	1146-00-40040
42	1146-00-40042
44	1146-00-40044
46	1146-00-40046
48	1146-00-40048
50	1146-00-40050
52	1146-00-40052
54	1146-00-40054
56	1146-00-40056
58	1146-00-40058
60	1146-00-40060

Cancellous Screw - Fully-threaded	
Length	4.0mm
12	1147-00-40012
14	1147-00-40014
16	1147-00-40016
18	1147-00-40018
20	1147-00-40020
22	1147-00-40022
24	1147-00-40024
26	1147-00-40026
28	1147-00-40028
30	1147-00-40030
32	1147-00-40032
34	1147-00-40034
36	1147-00-40036
38	1147-00-40038
40	1147-00-40040
42	1147-00-40042
44	1147-00-40044
46	1147-00-40046
48	1147-00-40048
50	1147-00-40050
52	1147-00-40052
54	1147-00-40054
56	1147-00-40056
58	1147-00-40058
60	1147-00-40060

Spacer	
Length	3.5mm
2	1060-00-35002



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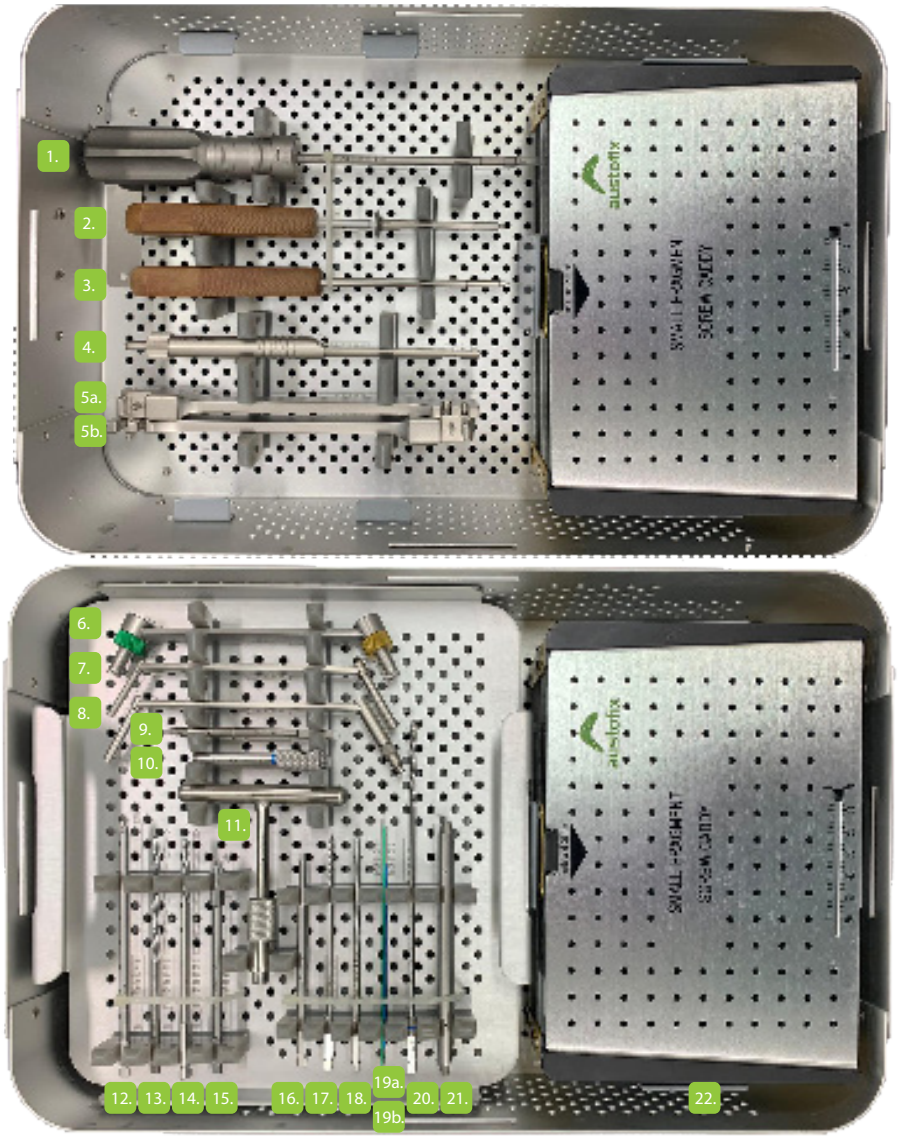
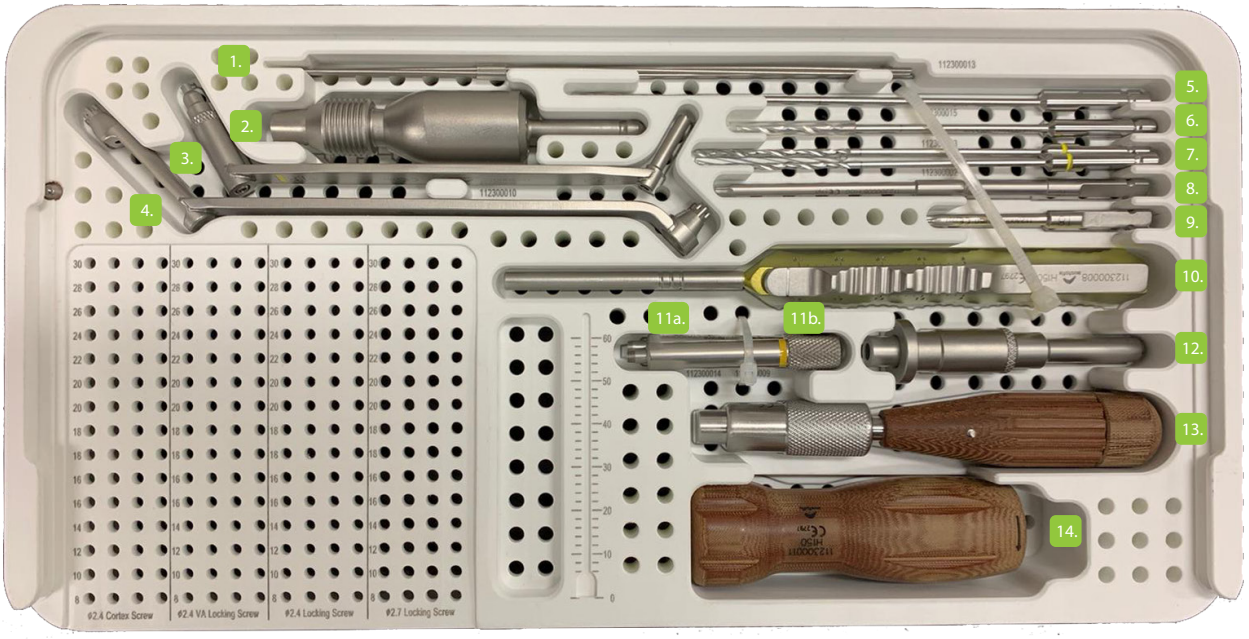
Instruments



Instruments							
#	Code	Description	Qty	#	Code	Description	Qty
1	112200001	Torque Limiter 1.5Nm	1	12	112200003	Screwdriver Shaft, 120mm (Star)	1
2	112100022	Screwdriver (Hex) with Holding Sleeve	1	13	112100015	Drill Bit 3.5mm	1
3	112200009	Screwdriver, 200mm (Star)	1	14	112100016	Drill Bit 2.5mm	2
4	112100001	Depth Gauge 2.5/4.0mm	1	15	112100014	Countersink, 100mm	1
5a.	112100002	Plate Bender (Left), 190mm	1	16	112100017	Screwdriver Shaft 100mm (Hex)	1
5b.	112100003	Plate Bender (Right), 190mm	1	17	112100018	Tap for Cortex Screw 3.5mm	1
6	112100004	Drill Guide, LC-L&C 2.5/3.5mm	1	18	112100019	Tap for Cancellous Bone Screw 4.0mm	1
7	112100005	Drill Sleeve, Double 2.5/3.5mm	1	19a.	112100008	Bending Template (Large) 10 x 118mm	1
8	112100020	Drill Guide, Universal 3.5/2.5mm	1	19b.	112100009	Bending Template (Small) 10 x 92mm	1
9	112200005	Easyout, 80mm	1	20	112200004	Drill Bit 2.8mm	2
10	112200002	Drill Sleeve, Threaded, 2.8mm (for 3.5)	2	21	112200010	K-Wire Bender	1
11	112100024	T-Handle with Quick Coupling, 90mm	1	22	112127000	Small Frag Screw Tray	1

Ø2.4/2.7mm Screw Set



Instruments			
#	Code	Description	Qty
1	112300013	Guide Wire 1.1 x 150mm	4
2	112300012	Torque Limiter 0.8Nm	1
3	112300010	Drill Guide, Universal 1.8/2.4mm	1
4	112300001	Drill Sleeve 1.8 - 2.4mm	1
5.	112300015	Drill Bit 2.0 x 140mm	1
6	112300003	Drill Bit 2.0 x 100mm	1
7	112300002	Drill Bit 1.8mm	2
8	112300006	Screwdriver, Long 4.5 x 105mm (Star)	1
9	112300005	Screwdriver, Short 4.5 x 55mm (Star)	1
10	112300008	Depth Gauge 2.0 & 2.4mm	1
11a	112300014	Drill Sleeve (L&C) 2.0mm	1
11b	112300009	Drill Sleeve (L&C) 1.8mm	1
12	112300007	Holding Sleeve	1
13	112300004	Straight Handle with Quick Coupling	1
14	112300011	T-Handle with Quick Coupling	1
15	112308000	Instrument Tray	1

Instrument Set		
Code	Description	Qty
SET-INS-2.4/2.7	Full Small Frag Instrument Set	-

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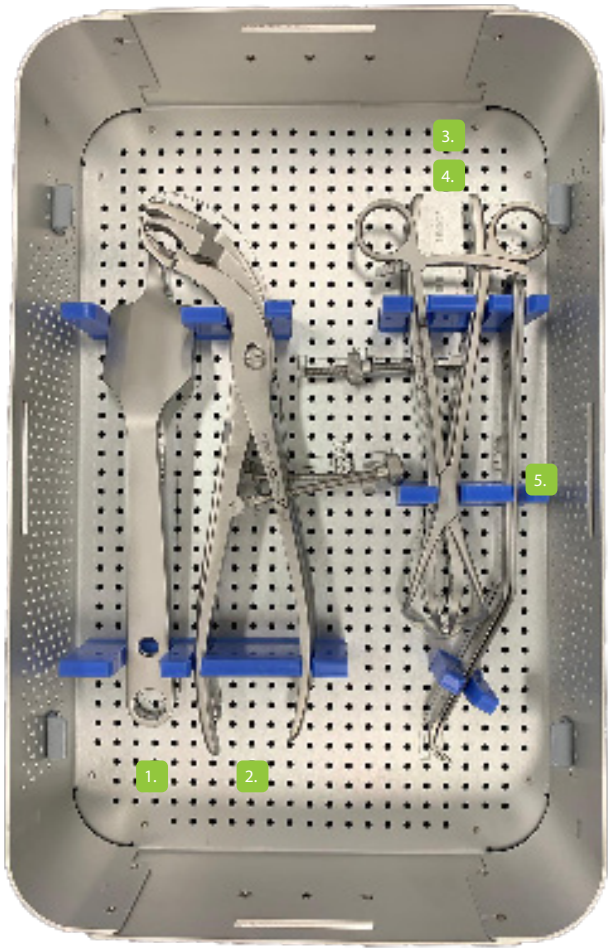
Optional Set

Universal Trauma Set



Instruments			
#	**Code**	**Description**	**Qty**
1	113100017	Hohmann Retractor (Large) 43.5 x 267mm	2
2	113100019	Self-Centering Bone Holding Forceps (Speed Lock) 266mm	1
3	113100021	Reduction Forceps (Serrated Jaws) 220mm	2
4	113100022	Reduction Forceps (Point) 207mm	1
5.	113100018	Hohmann Retractor (Small) 16 x 267mm	1
6	112100010	Self-Centering Bone Holding Forceps (Speed Lock) 191.8mm	2
7	112200012	Self-Centering Bone Holding Forceps (Compression)	1
8	112100011	Reduction Forceps (Serrated Jaws) 158mm	1
9	112100013	Reduction Forceps (Points) 182mm	1
10	112100006	Hohmann Retractor (Large) 15.5 x 159mm	2
11	112100007	Hohmann Retractor (Small) 10.5 x 170mm	2
12	113100016	Periosteal Elevator (Large)191mm	1
13	112100012	Periosteal Elevator (Small) 190mm	1

Instrument Trays & Sets

Instrument Tray		
Code	**Description**	**Qty**
112128000	Small Frag Instrument Tray PPSU (Empty)	1
113122000	Universal Trauma Instrument Tray (Empty)	1
112308000	2.4 / 2.7 Instruments Tray (Empty)	1

Instrument Set		
Code	**Description**	**Qty**
SET-INS-SML	Full Small Frag Instrument Set	-
SET-INS-UTRA	Full Universal Trauma Instrument Set	-
SET-INS-2.4/2.7	Full 2.4 / 2.7 Instrument Set	-

Single Use Items

Recommended K-Wires		
Code	**Description**	**Qty**
522015	2.0 x 150mm K-Wire	2
511415	1.4 x 150mm K-Wire	2

Optional K-Wires		
Code	**Description**	**Qty**
113210001	2.5 x 280mm K-Wire	2
611.112	1.1 x 120mm K-Wire	2
081.010	0.8 x 100mm K-Wire	2

Drill		
Code	**Description**	**Qty**
112300002	Drill Bit 1.8mm	1
112300003	Drill Bit 2.0 x 100mm	1
112300015	Drill Bit 2.0 x 140mm	1
112100016	Drill Bit 2.5mm (for 3.5mm Cortex & 4.0mm Cancellous Screws)	1
112200004	Drill Bit 2.8mm (for 3.5mm Locking Screws)	1
112100015	Drill Bit 3.5mm	1

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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.

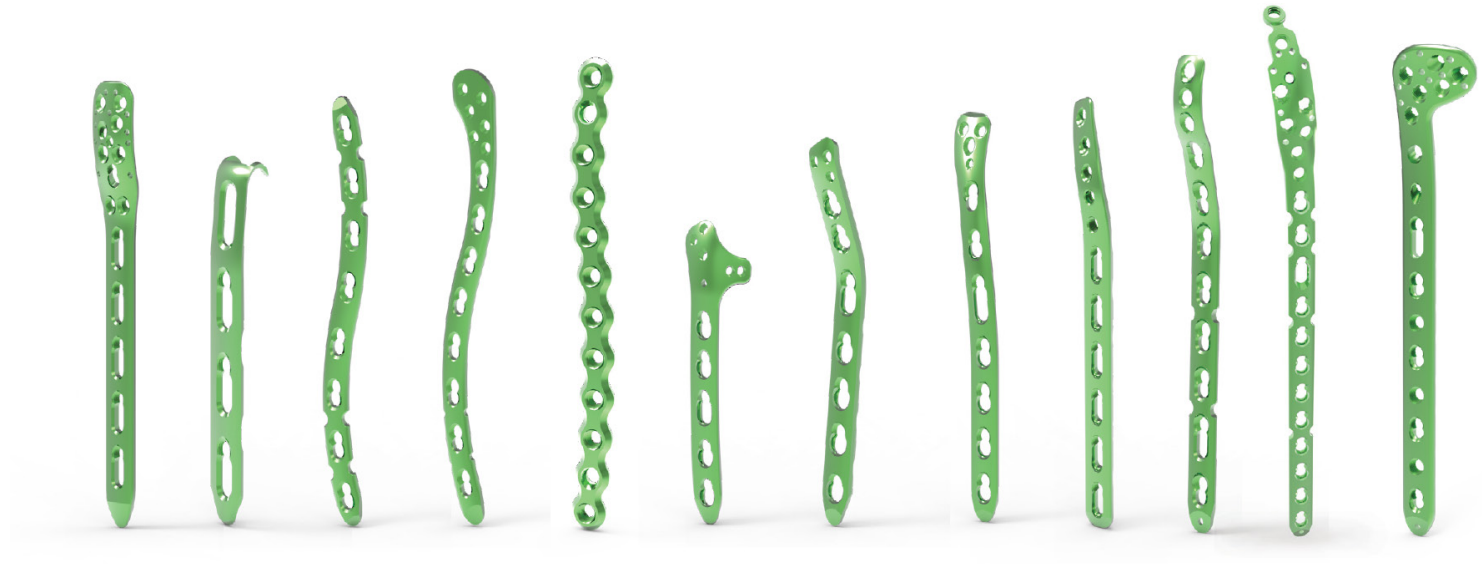
Shellock FG. Biomedical Implants and Devices: Assessment of Magnetic Field Interactions With a 3. 0-Tesla MR System. 2002, 721-732.

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.

Austofix Small Fragment Range

The Austofix Small Fragment Instrument Set and the Austofix Universal Trauma Set are compatible with the entire Austofix Small Fragment range of plates listed 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 Proximal Humeral Locking Plate
- L&C Hook Locking Plate
- L&C Superior Anterior Clavicle Locking Plate
- L&C Superior Anterior Clavicle Lateral Extension Locking Plate
- Clavicle Reconstruction Locking Plate
- L&C Distal Lateral Dorsal Humeral Locking Plate (Buttress)
- L&C Distal Medial Humeral Locking Plate
- L&C Distal Lateral Dorsal Humeral Locking Plate
- L&C Distal Humeral Extra-Articular Locking Plate
- L&C Distal Humeral Middle Metaphyseal Locking Plate
- L&C Olecranon Locking Plate
- Proximal Humeral Greater Tubercle Locking Plate

Continued

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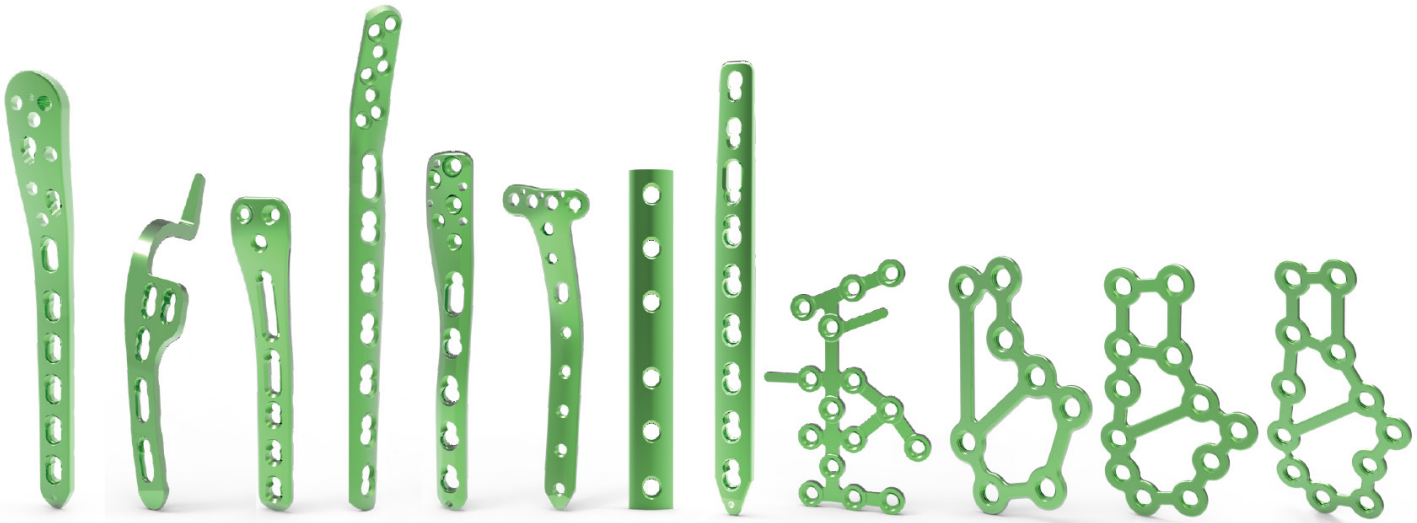

L&C Distal Medial Tibial Locking Plate

L&C Clavicle Hook Locking Plate

L&C Proximal Posterior Tibial Locking Plate

L&C Distal Posterior Lateral Fibula Locking Plate

L&C Distal Lateral Fibula Locking Plate

L&C Proximal Medial Tibial Locking T-Plate

1/3 Tubular Locking Plate

3.5mm L&C Metaphysis Locking Plate

Calcaneal Locking Plate I

Calcaneal Locking Plate II (53mm)

Calcaneal Locking Plate II (60mm)

Calcaneal Locking Plate II (68mm)

3.5mm L&C Reconstruction Locking Plate (Straight)

3.5mm LC-L&C Locking Plate (Narrow)

3.5mm L&C Locking T-Plate Right-Angle (Head 4 Hole)

3.5mm L&C Locking T-Plate Oblique-Angle (Head 3 Hole)

Clavicle Anterior Reconstruction Locking Plate

3.5mm L&C T-Plate Right-Angle (Head 3 Hole)

L&C Proximal Radius Arch Rising Locking Plate

L&C Proximal Radius Arch Cupped Locking Plate

L&C Anterolateral Distal Tibial Locking Plate

3.5mm L&C Distal Medial Tibial Locking Plate

L&C Proximal Lateral Tibial Locking Plate I

L&C Proximal Lateral Tibial Locking Plate

austofix

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