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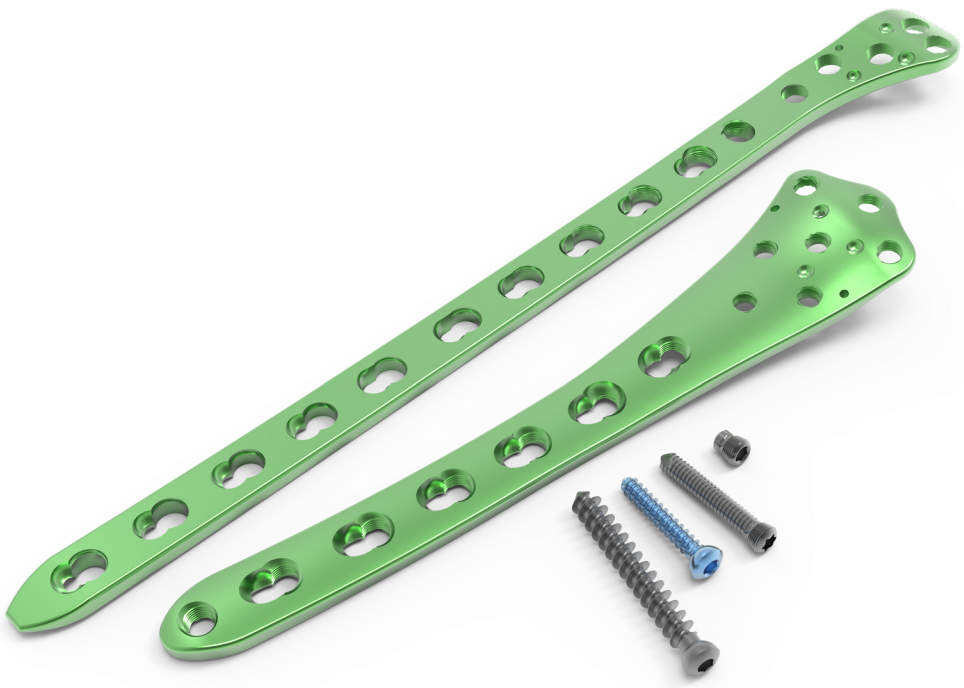
5.0mm Minimally Invasive L&C Plates

Surgical Technique



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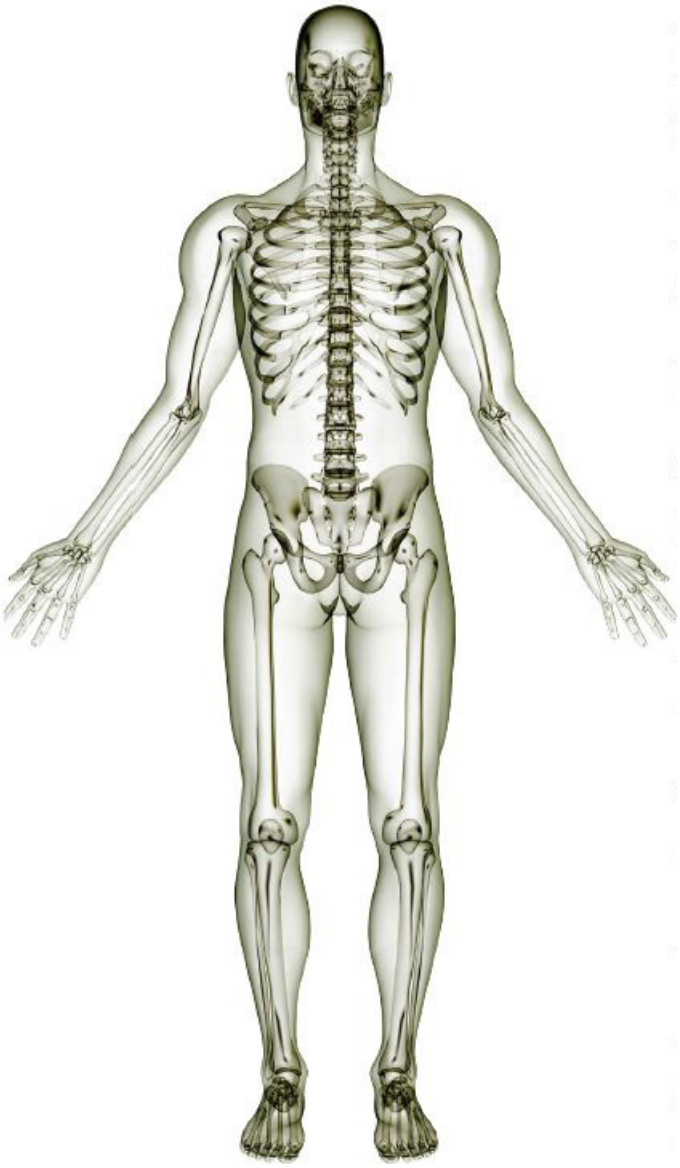

Austofix is a leading manufacturer and designer of orthopaedic trauma medical devices with a particular focus on innovation, excellence and patient safety. Austofix has the expertise and experience in developing a new device from concept to a fully commercialised product with regulatory approval for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

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 publication is intended as the recommended procedure for using the MI Plates and Screws 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.

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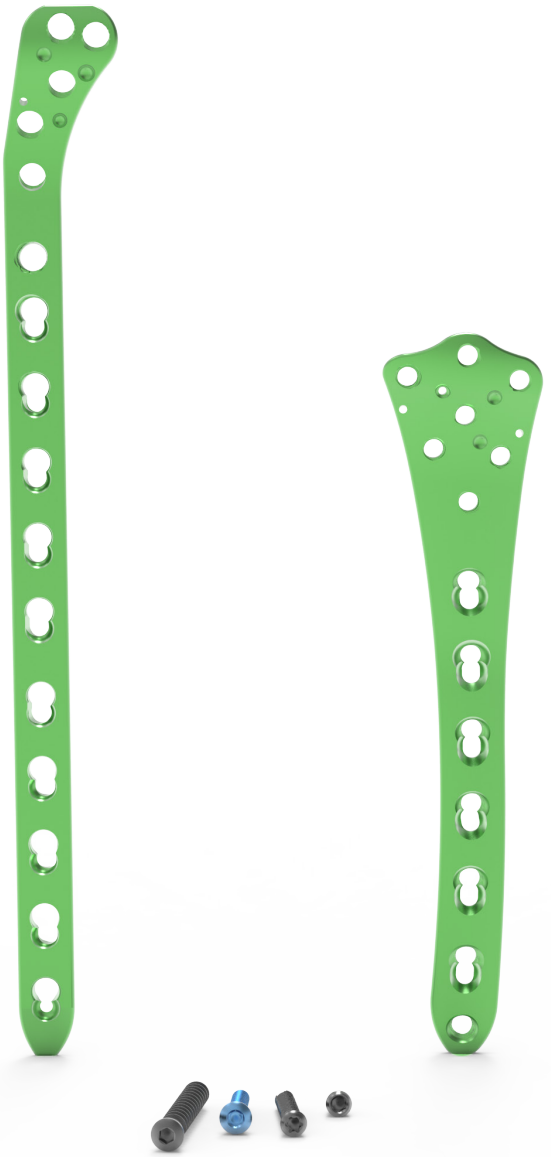
5.0mm Minimally Invasive L&C Plates

The Austofix Minimally Invasive System provides surgeons with a complete fixation solution for the many complex fracture patterns found in the distal femur and proximal tibia.

The Minimally Invasive System is a modern and extensive collection of plates and screws, providing surgeons with an effective array of flexible surgical solutions.

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 Minimally Invasive System adheres to these principles and will provide the surgeon with a comprehensive fixation solution.



Implant Features

Combi Hole

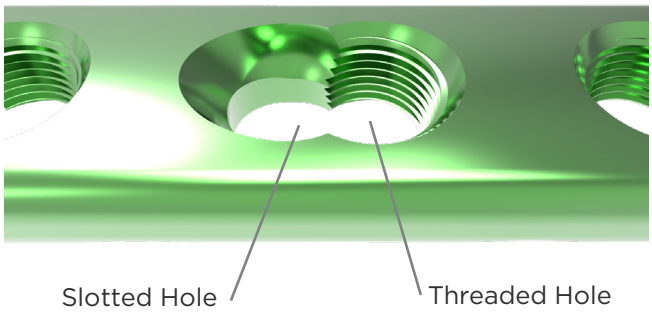
The Combi Hole allows for a range of plate fixation options. The holes accommodate both Compression and Locking screws.

Threaded Hole - Locking Screws

Locking Screws link with the threads in the threaded hole, keeping the screw at a fixed angle.

Slotted Hole - Cortex Screws*

Cortex Screws are used in the slotted hole for plate-to-bone compression and increases stability. Slotted holes are available on MI plates to provide surgeons with a more invasive dynamic compression option.



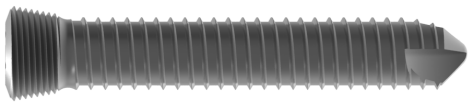
Tapered End

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

Screws

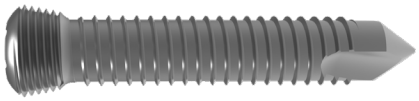
Self-Tapping Locking Screw

- Self-Tapping
- Reduced Screw Backout
- Unicortical or Bicortical Fixation in Metaphysis
- Precise Screw Length Measurement Required



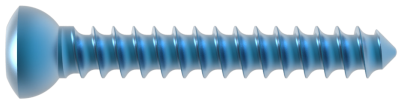
Self-Drilling / Self-Tapping Locking Screw

- Self-Drilling
- Self-Tapping
- Reduced Screw Backout
- Unicortical Fixation in Diaphysis



Cortex (Cortical) Screw*

- Dynamic compression
- Compression



Periprosthetic Screw

- Self-Tapping
- For Periprosthetic Fractures

Spacer

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

*Large Frag Instrument Set (SET-INS-LGE) required.

Plate Features

Anatomical Fit

- Tapered end assists in submuscular plate insertion and helps to minimise tissue trauma
- Rounded low-profile plate & screw construct minimises the risk of soft tissue irritation
- No need for plate contouring due to anatomically precontoured design
- Optimal anatomical screw positions

Plate Fixation & Dynamic Compression

- Multiple points of fixation for superior angular stability, preventing screw loosening and secondary loss of reduction
- Combi-Holes along shaft of the Plate allow Locking Screws and dynamic compression using Cortex Screws
- Provides stable fracture fixation while preserving vascularisation to the periosteum to accelerate bone healing
- Limited-contact shaft design
- Plate shaft has increased thickness for additional strength
- Threaded Locking Holes provide flexibility in Locking Screw fixation for multiple fracture patterns
- Threaded Locking Holes in the head of the plates allow Cortex Screw insertion to create compression

Minimally Invasive

- Radiolucent Insertion Guide facilitates plate placement and percutaneous screw insertion
- Minimally Invasive instrumentation available for left and right anatomy

Clinical Indications

- *MI L&C Distal Lateral Femoral Locking Plate* designed to address distal shaft, supracondylar, intra-articular and periprosthetic fractures of the distal femur
- *MI L&C Proximal Lateral Tibial Locking Plate* designed to address proximal shaft, metaphyseal, intra-articular and periprosthetic fractures of the proximal tibia
- Can be utilised for fixation of nonunions, malunions, and osteotomies
- Allows early mobilisation and function

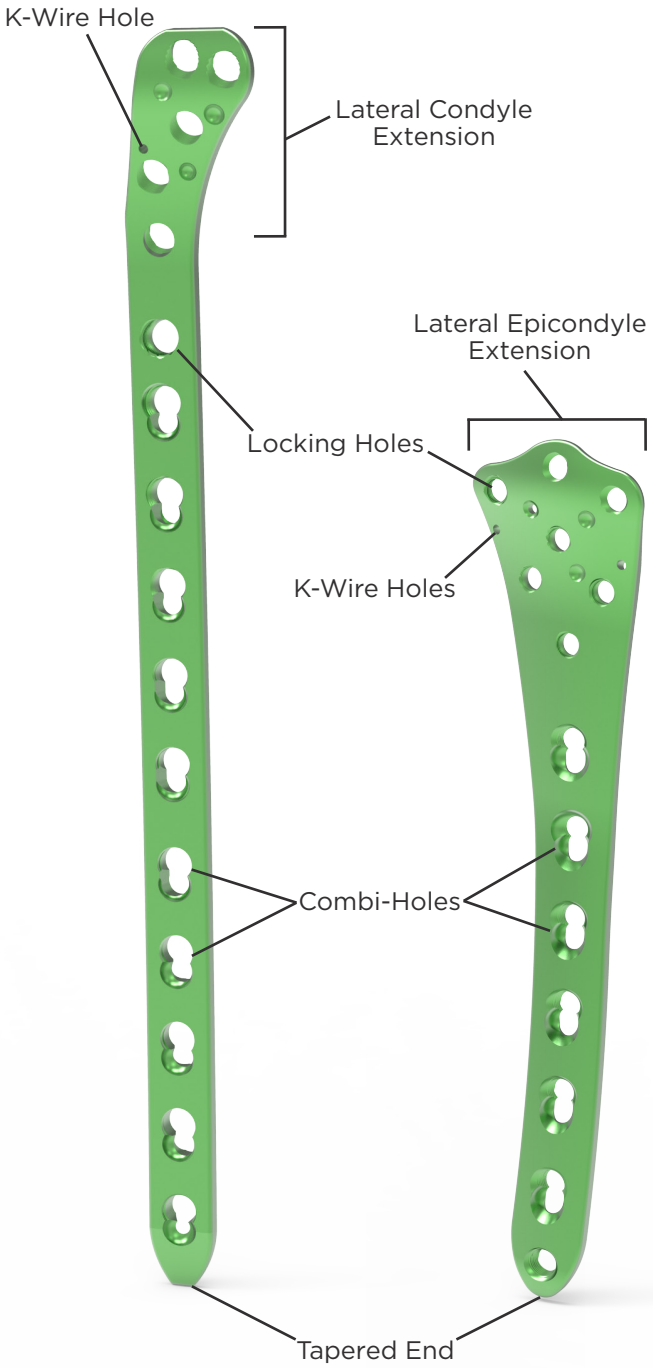


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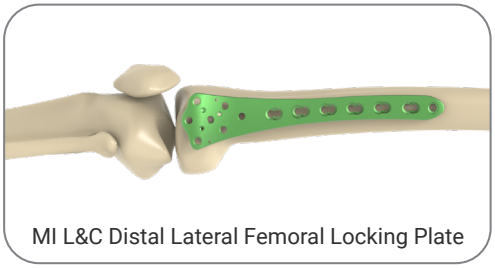
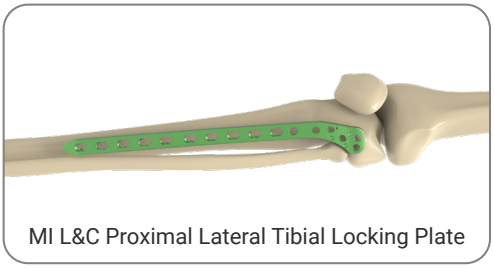
Plate Range

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



MI L&C Distal Lateral Femoral Locking Plate



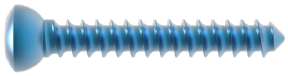
MI L&C Proximal Lateral Tibial Locking Plate

Screw Range

Self-Tapping Locking Screw

Self-Drilling/Self-Tapping Locking Screw

Cortex Screw



Periprosthetic Screw

Spacer

Surgical Technique

Pre-Drilling

Determine the number of Locking and Cortex Screws* to be used.

Cortex Screws can be used in the Threaded Locking Holes in the head of the plates to create compression, or in the slotted hole of the Combi-Holes for plate-to-bone compression and increased stability. Slotted holes are available on MI plates to provide surgeons with a more invasive dynamic compression option.

Note: Cortex Screws are only recommended when compression is needed or when independent lag screw fracture reduction is not possible. Screw selection should be based on patient history and overall bone quality.

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

Screw	Drill	Drill Sleeve/ Guide	Depth Gauge	Driver	Torque Limiting Driver
5.0mm Locking	Ø4.3mm Drill (113400001)	Threaded (113400002)	K-Wire Measuring Instrument (113400017)	Torx (Star) (113200009)	4.5Nm (113200038)
4.5mm Cortex*	Ø3.2mm Drill (113100002)	Ø3.2mm Drill Guide (113100014)	Depth Gauge (113400020)	Hex (113100001)	-

Contouring

Caution: Contouring of Minimally Invasive plates is not recommended as this can compromise the functionality of the Insertion Guide and may weaken the plate-screw interface.

In cases where it becomes clinically necessary to contour the plate, ensure that the plate is bent incrementally using the Large Fragment Plate Benders (113100008)* between consecutive screw holes to avoid distortion of the Threaded Holes.

Note: 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.

*Large Frag Instrument Set (SET-INS-LGE) required.

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Using the Universal Drill Guide 3.2/4.5mm*

Neutral Screw Position

Advance the spring-loaded Universal Drill Guide 3.2/4.5mm (113100014) 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.

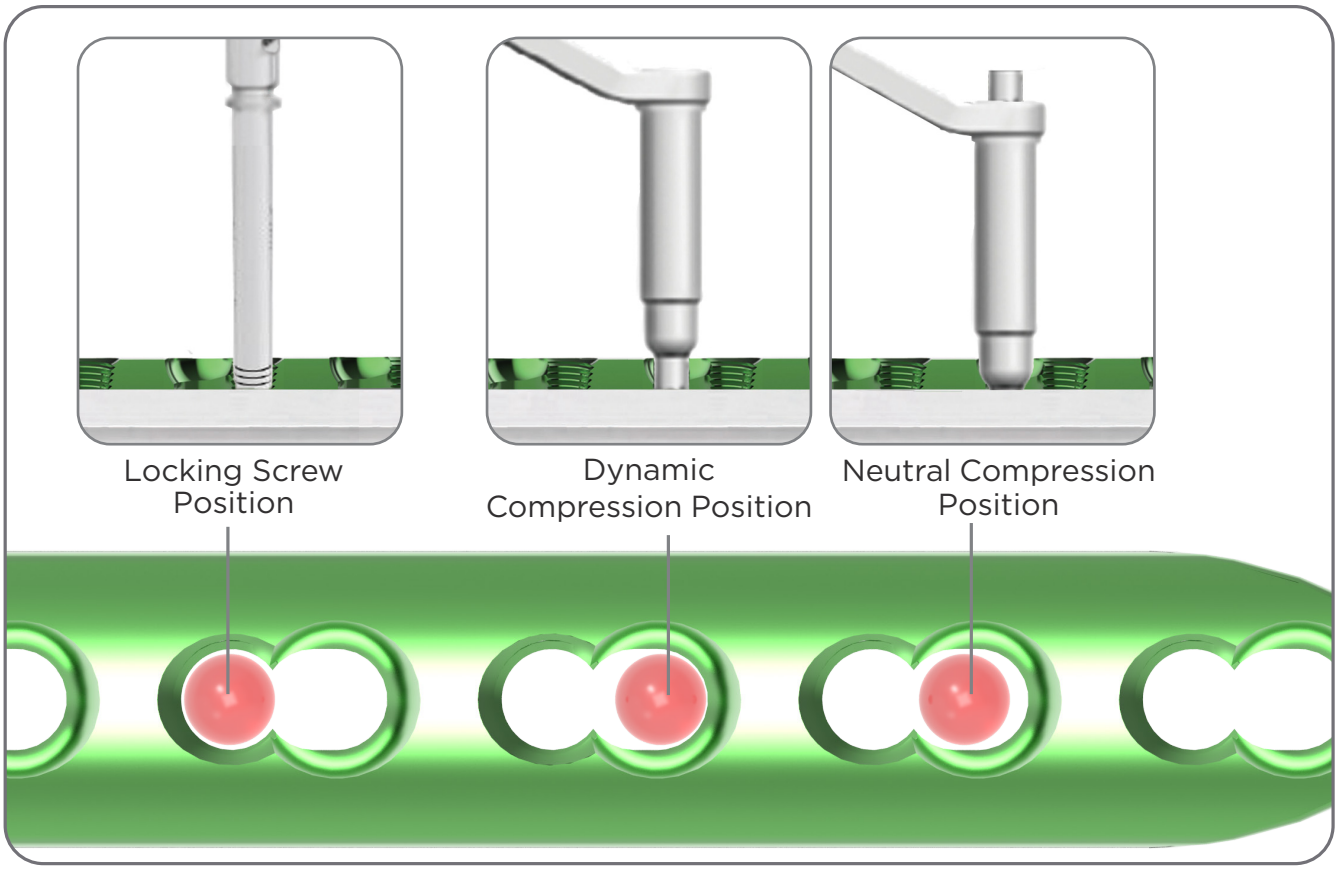
Dynamic Screw Position

Place the inner sleeve of the Universal Drill Guide 3.2/4.5mm (113100014) 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).

Locking Screw Position

Refer to Locking Screw Insertion section on pages 16 or 24 for Distal Lateral Femur or Proximal Tibia respectively.

Note: The Universal Drill Guide 3.2/4.5mm is designed to be used with the slotted holes of the Combi-Holes found within the shaft of the plates providing surgeons with a more invasive dynamic compression option using 4.5mm Cortex Screws.



*Large Frag Instrument Set (SET-INS-LGE) required.

Surgical Technique - Distal Femur

Plate & Screw Length Selection

Select the proper plate length using X-Ray radiographs.

Screw length can be determined with the use of an AP radiograph in conjunction with the supplied 50mm X-Ray Calibrator (113400015).

1. Place the X-Ray Calibrator either medially or laterally at the height of the relevant condyle.
2. Take an AP radiograph of the distal femur and measure the width of the X-Ray Calibrator on the radiograph.
3. Measure the maximum width of the condyle on the radiograph.
4. The real condyle width can then be determined using the following formula:

$$\text{Real Condyle Width} = \frac{50}{\text{X-Ray Calibrator Width}} \times \text{Maximum Condyle Width}$$

5. Screw lengths can then be acquired from the table below based on the Real Condyle Width.

Note: The plate must be placed correctly on the condyle to ensure correct screw length.

Real Condyle Width (mm)	Locking Screw Length (mm)						
	Hole A	Hole B	Hole C	Hole D	Hole E	Hole F	Hole G
60-80	65	40	40	55	65	65	55
81-87	75	40	55	65	75	75	65
88-95	75	55	65	65	75	75	75
96-110	85	65	75	75	75	85	85

Screw positions A to G are laser-marked onto the Distal Lateral Femur Insertion Guide (113400018/9) (see right).

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Patient Positioning

Place the patient in the supine position. The leg should remain freely moveable. The knee should be placed slightly distal to the hinged part of the table allowing flexion of the knee during the operation.

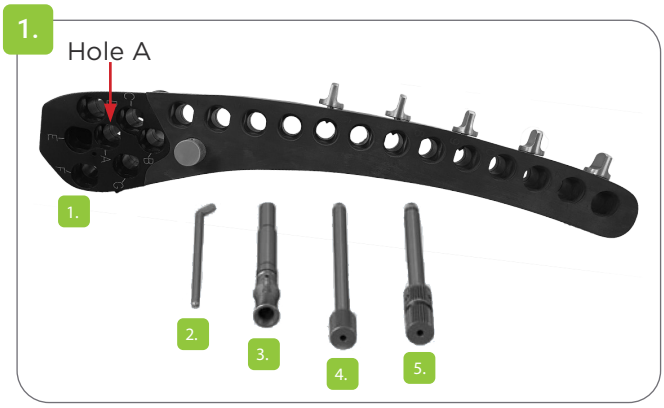
The lower leg should be flexed to approximately 60°, reducing traction force of the gastrocnemius muscle.

Caution: Full extension of the knee may cause the gastrocnemius muscle to draw the distal fragment into recurvatum, potentially causing damage to the popliteal artery and vein.

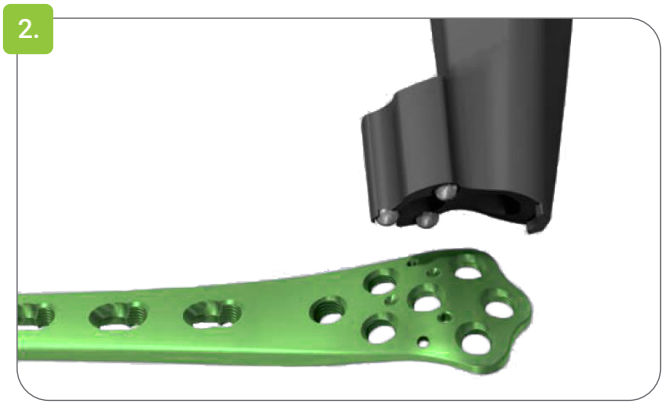
Instruments		
#	**Code**	**Description**
1	113400018/9	Insertion Guide - Dist Lat Femur LH/RH (Carbon Fibre)
2	113400008	Wrench Shaft
3	113400002	Drill Sleeve, Threaded
4	113400012	Stabilization Bolt
5	113400011	Fixation Bolt

Instrument Assembly

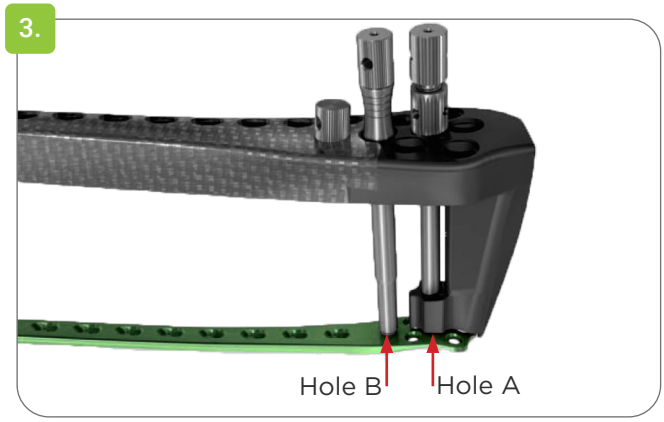
1. Insert the Fixation Bolt (113400011) into Hole A of the Distal Lateral Femur Insertion Guide (113400018/9).



2. Align the three-pronged locking mechanism onto the plate and tighten the Fixation Bolt onto the plate. The nut of the Fixation Bolt should then be tightened with the Wrench Shaft (113400008).



3. For greater stability, the Stabilization Bolt (113400012) with a Threaded Drill Sleeve (113400002) can be inserted into Hole B of the Insertion Guide and fixed to the plate.



Reduce the Fracture

Reduce the fracture using the image intensifier, Ø2.0 x 280mm K-Wires (113400016) and/or Reduction Forceps (112100011/3).

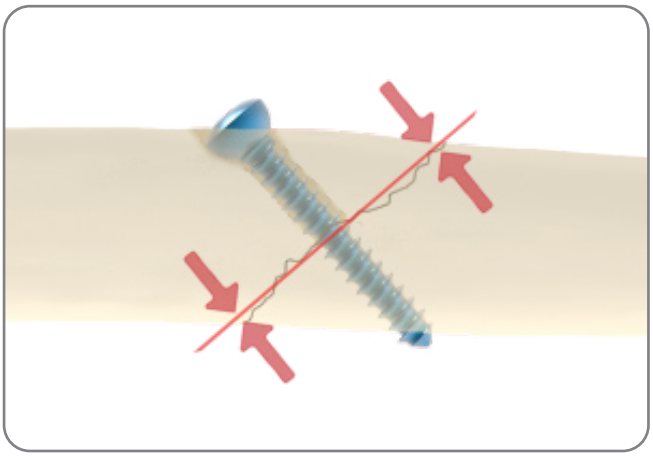
Note: Ø2.0 x 150mm (522015) and Ø2.5 x 280mm (113210001) K-Wires are also available.

Note: The fracture may be aligned by traction using a distractor or a temporary knee-bridging external fixator.

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. Large Frag Instrument Set (SET-INS-LGE) required.

1. Reduce the fracture and use the 4.5mm Drill Bit (113100003) with the 4.5mm sleeve of the Universal 3.2/4.5mm Drill Guide (113100014) to drill perpendicularly to and not beyond the fracture line.
2. Use the 3.2mm slot of the Universal 3.2/6.5mm Drill Guide (113100015) to drill the far cortex using the 3.2mm Drill (113100002).
3. The Countersink (113100020) should then be used to improve bone load transfer.
4. Measurement for Screw length can then be obtained using the Depth Gauge (113100007).
5. Insert Ø4.5mm 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.

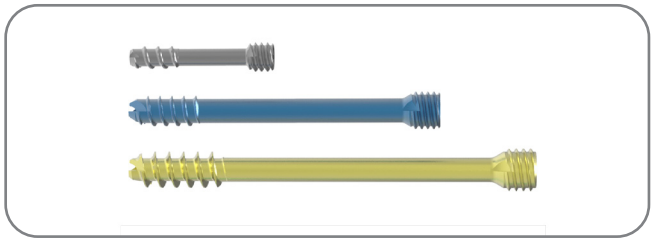
Note: The Cannulated Compression Screw instrument set (SET-INS-CAN) is required for this approach.

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.

Caution: Ensure any additional screws do not interfere with Locking Screw trajectory.



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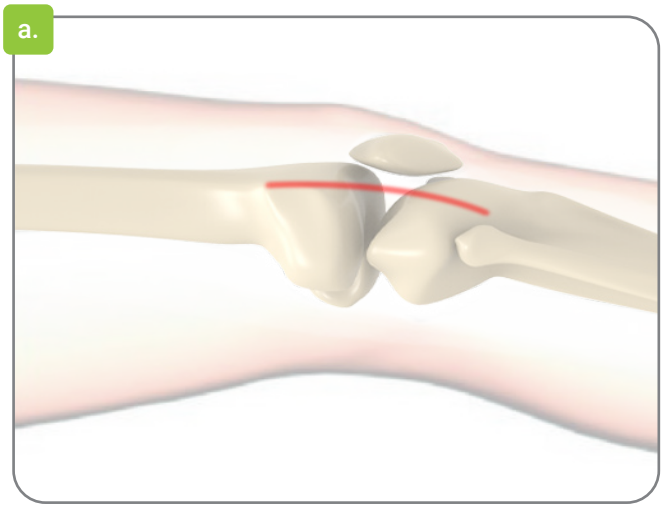
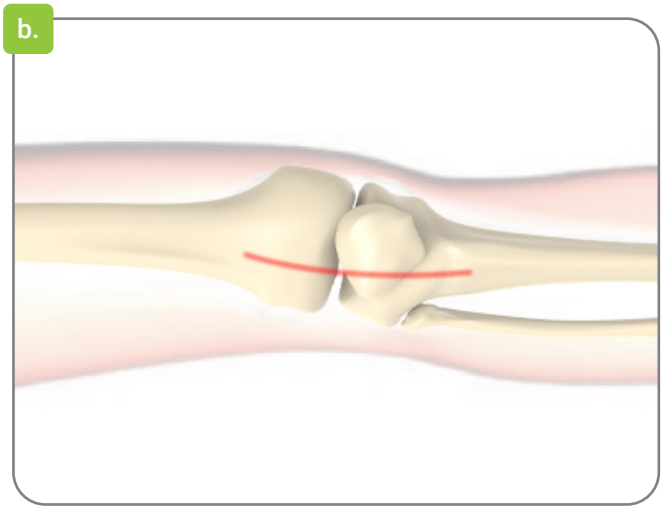
Incision

a. For extra-articular fractures or supracondylar fracture, a lateral incision should be made starting the incision at Gerdy's Tubercle, advancing proximally about 80mm. The iliotibial tract should be split following fibre direction before opening the space between the vastus lateralis and periosteum. The plate can then be inserted in the space between the periosteum and the muscle.



b. For a complex intra-articular fractures, a lateral parapatellar incision is recommended. An anterolateral arthrotomy of the knee provides good reduction control and allows subsequent insertion of the plate as well as medial lag screw insertion. This incision is performed between the vastus lateralis muscle and the periosteum.



Note: Extension of the incision may be necessary to improve visualisation in cases where it is not appropriate to use minimally invasive and closed reduction techniques.

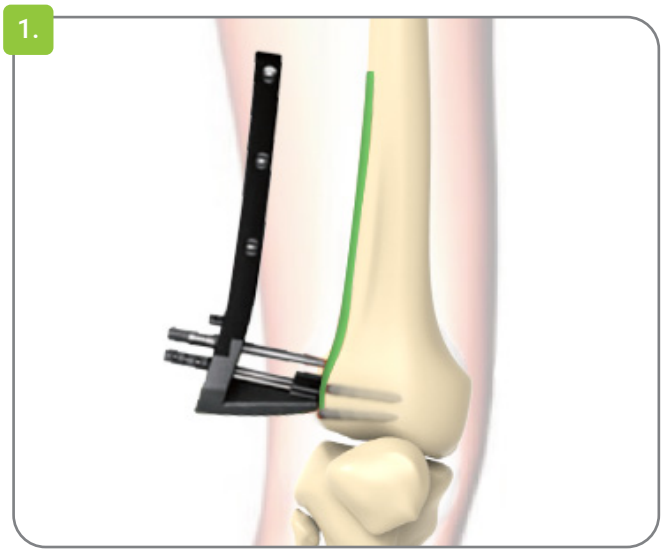
Plate Insertion

1. Insert the plate using the Distal Lateral Femur Insertion Guide (113400018/9) between the vastus lateralis muscle and the periosteum in a proximal orientation. Ensure the proximal section is in constant contact with the bone and the distal section is placed flat against the lateral condyle. The radiolucent proximal shaft of the Insertion Guide can be removed if it impairs plate insertion.

   Note: The Insertion Guide may rotate dorsally due to the weight of the Guide creating a lack contact between the plate and the lateral condyle. There are two ways to confirm that the plate is in the correct position:

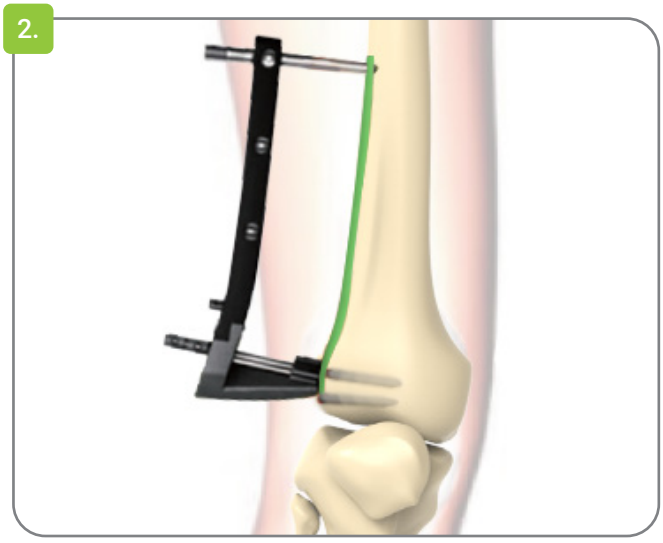
   1. The Fixation Bolt runs parallel to the patello-femoral joint.

   2. The plate is at about 10° of internal rotation.

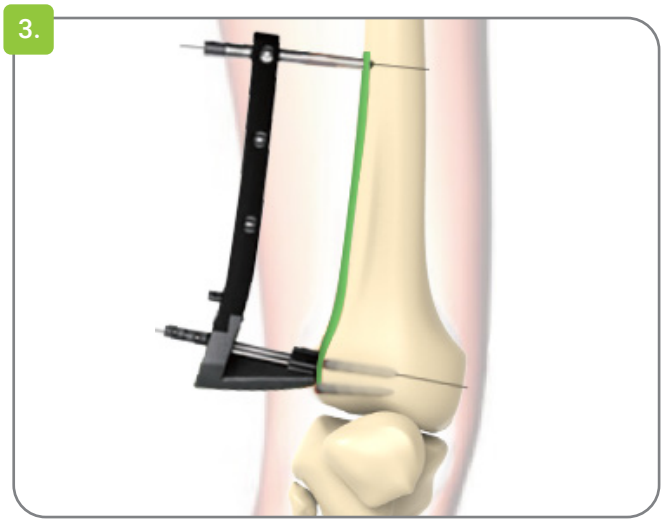


2. Once the plate is properly aligned remove the Threaded Drill Sleeve and Stabilization Bolt. Insert the Threaded Drill Sleeve with the Trocar (113400007) into the Insertion Guide for the most proximal hole in the plate. A stab incision is to be performed to advance the instruments further down to the plate. Check positioning of the proximal end of the plate using imagine intensification before securing the Drill Sleeve with the corresponding nut on the Insertion Guide. Remove the Trocar and thread a Stabilization Bolt in.

   Caution: Once this Stabilization Bolt has been inserted it will become difficult to change the position of the plate and Insertion Guide.



3. A Ø2.0mm K-wire (113400016) can be used to check correct positioning of the proximal end of the plate. For preliminary fixation of the plate, insert a Ø2.0mm K-Wire into the centre of both the Fixation Bolt and the Stabilization Bolt. Once the plate is in the correct position and the reduction is completed, the Locking Screws can be inserted.



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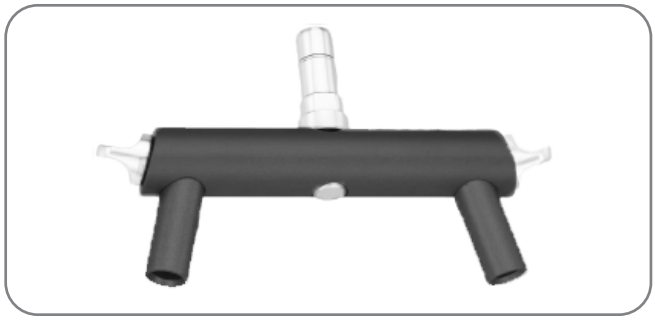
K-Wire Aiming Attachment

Ø2.0mm K-Wires (113400016) can be used in conjunction with the K-Wire Aiming Attachment (113400013) and two K-Wire Insertion Sleeves II (113400010) for preliminary fixation along the full length of the plate. The K-Wire Aiming Attachment is used from Hole 3 to Hole 13.



1. Insert two Ø2.0mm K-Wires against the ventral and dorsal aspects of the plate using the K-Wire Aiming Attachment.

   Note: The distance between the femur and the plate should remain minimal during K-Wire insertion.

   Caution: After insertion of the K-Wires, the distance between the plate and the femur can no longer be reduced.

2. Remove the K-Wire Insertion Sleeves II and the K-Wire Aiming Attachment to adjust proximal/distal displacement and position of the plate.

   Note: The Ø2.0mm K-Wires prevent sagittal migration of the plate.

3. Once the correct plate positioning has been achieved, the plate can be temporarily fixed with a Ø2.0mm K-Wire through the Fixation Bolt.

Locking Screw Insertion

Locking Screw placement depends on the type of clinical indication. Locking Screw positions should be selected based on established biomechanical principles of internal fracture fixation.

Note:

- Locking Screw insertion into the main fragments defines bone length and rotation.
- Locking Screws should be inserted close to and remote from the main fracture line.
- Self-Drilling/Self-Tapping Locking Screws are used for unicortical fixation in the diaphysis.
- Self-Tapping Locking Screws are used for unicortical or bicortical fixation in the metaphysis.
- The screws should be at the centre of the bone shaft to provide adequate purchase in bone.
- At least four Locking Screws should be used per fracture side.
- The first Locking Screw should be inserted into the distal fragment.
- The distal Locking Screws should be inserted parallel to the knee joint.

Note: 4.5mm Cortex Screws can be inserted into the head of the plate through the Insertion Guide if required, however they cannot be used with the Insertion Sleeve (113400005).

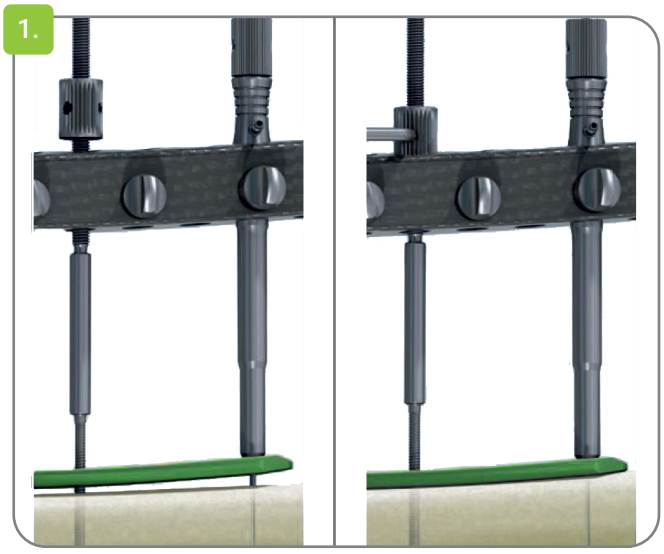
Pull Reduction Instrument

Before the first Locking Screw is inserted, the Pull Reduction Instrument (113400009) is recommended to minimise bone fragment movement. This instrument can be used in the presence of dense cortices or when there is a lack of stabilisation. It may also be utilised for translational adjustments.

1. Make a stab incision and insert an Insertion Sleeve (113400005) into the adjacent hole to the hole used for the first Locking Screw. Use a power tool to drill and insert the Pull Reduction Instrument. Rotate the corresponding nut under the image intensifier to achieve the desired reduction.

   Note: The Pull Reduction Instrument has a smaller diameter (Ø4.0mm) than that of Locking Screws (Ø5.0mm), ensuring Locking Screws insertion still achieves good bone purchase with no loss of stabilisation.

   Caution: Stop the power tool before the Pull Reduction Instrument is seated onto the plate as failure to do so may result in stripping the thread in the bone.



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Self-Drilling, Self-Tapping Locking Screw Insertion

1. Determine the length of Locking Screw to be inserted. This can be done using the method described on Page 9, or with the use of the K-Wire Measuring Instrument (113400017).

2. To use the K-Wire Measuring Instrument, make a stab incision and insert an Insertion Sleeve (113400005) with the 161mm K-Wire Insertion Sleeve (113400006) into the corresponding hole. Insert a Ø2.0mm K-Wire (113400016) to the desired depth, leaving at least 5mm between the tip of the K-Wire and the medial cortex. Use image intensifier to confirm depth.

2.

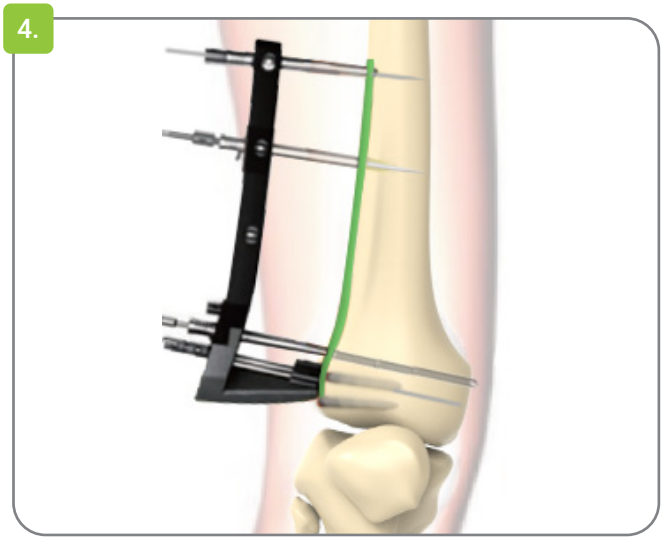
3. Measure Locking Screw length over the K-Wire using the K-Wire Measuring Instrument, rounding down to the nearest screw length, preventing protrusion of Locking Screws through the medial cortex. Following measurement, remove the Ø2.0mm K-Wire, K-Wire Measuring Instrument and 161mm K-Wire Insertion Sleeve.

4. Insert the Trocar through the Insertion Sleeve and remove prior to Locking Screw insertion. When using power, use the Ø4.5mm Drill Shaft (113400003) to insert Locking Screw through the Insertion Sleeve, beginning with slow insertion and increasing speed before the screw is fully tightened where speed should again be reduced. Advance the Locking Screw into the bone until the notch in the Drill Shaft sits entirely within the Insertion Sleeve. For the final tightening, use the 4.5Nm Torque Limiter (113200038) to manually tighten the screw. Repeat step 1-4 for all Locking Screw insertion.

   Note: 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 Locking Screws are tightened to the plate.

   Warning: Always use a torque-limiting attachment when inserting Locking Screws with power. This reduces the risk of the threads stripping from the head of the screw. If a Locking Screw needs to be removed and reinserted, do not use power and use the Torque Limiter 4.5Nm (113200038) driver instead.

4.



Note: In the case of dense cortex, pre-drilling using the Ø4.3mm Drill Bit (113400001) is recommended. Use irrigation and cooling while drilling to minimise thermal necrosis.

Self-Tapping Locking Screw Insertion

1. Make a stab incision and insert the Trocar through the Insertion Sleeve (113400005). Replace the Trocar with the Threaded Drill Sleeve (113400002) and thread the Drill Sleeve into the plate. Carefully drill the screw hole using the Ø4.3mm Drill Bit (113400001).

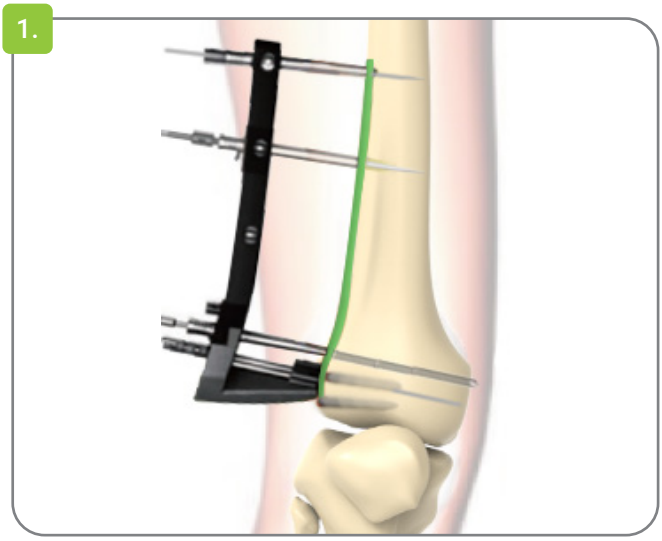
2. Determine the length of Locking Screw to be inserted. This can be done using the method described on Page 9, or by reading directly from the calibrated Ø4.3mm Drill Bit.

3. Remove the Drill Bit and Threaded Drill Sleeve. When using power, use the Ø4.5mm Drill Shaft (113400003) to insert Locking Screw through the Insertion Sleeve, beginning with slow insertion and increasing speed before the screw is fully tightened where speed should again be reduced. Advance the Locking Screw into the bone until the notch in the Drill Shaft sits entirely within the Insertion Sleeve. For the final tightening, use the 4.5Nm Torque Limiter (113200038) to manually tighten the screw. Repeat step 1-3 for all Locking Screw insertion.

   Note: 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 Locking Screws are tightened to the plate.

   Warning: Always use a torque-limiting attachment when inserting Locking Screws with power. This reduces the risk of the threads stripping from the head of the screw. If a Locking Screw needs to be removed and reinserted, do not use power and use the Torque Limiter 4.5Nm (113200038) driver instead.

1.



Note: In the case of dense cortex, pre-drilling using the Ø4.3mm Drill Bit (113400001) is recommended. Use irrigation and cooling while drilling to minimise thermal necrosis.

Manual Locking Screw Insertion

Manual insertion of both Self-Tapping and Self-Drilling/Self-Tapping Locking Screws is optional if no torque limiting attachment for power insertion is available.

Use the 4.5Nm Torque Limiter (113200038) driver through the Threaded Drill sleeve (113400002) to insert and lock the screw.

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Surgical Technique - Proximal Tibia

Patient Positioning

Place the patient in the supine position. The leg should remain freely moveable. The knee should be placed slightly distal to the hinged part of the table allowing flexion of the knee during the operation.

The lower leg should be flexed to approximately 60°, reducing traction force of the gastrocnemius muscle.

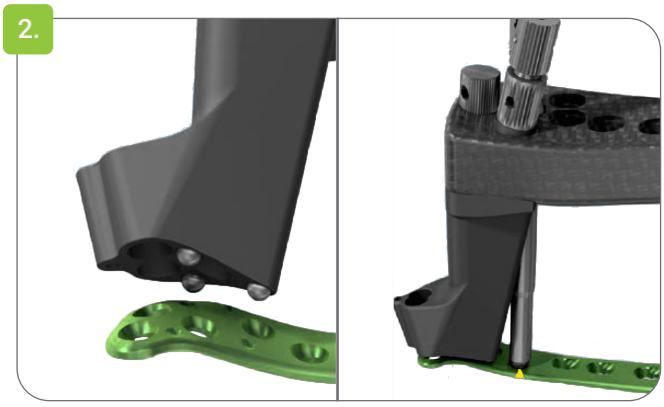
Caution: Full extension of the knee may cause the gastrocnemius muscle to draw the distal fragment into recurvatum, potentially causing damage to the popliteal artery and vein.

Instruments		
#	**Code**	**Description**
1	113400022/3	Insertion Guide - Prox Tib LH/RH (Carbon Fibre)
2	113400011	Fixation Bolt
3	113400012	Stabilization Bolt
4	113400002	Drill Sleeve, Threaded
5	113400008	Wrench Shaft

Instrument Assembly

1. Insert the Fixation Bolt (113400011) into Hole A of the Proximal Tibia Insertion Guide (113400022/3).

2. Align the three-pronged locking mechanism onto the plate and tighten the Fixation Bolt onto the plate. The nut of the Fixation Bolt should then be tightened with the Wrench Shaft (113400008). For greater stability, the Stabilization Bolt (113400012) with a Threaded Drill Sleeve (113400002) can be inserted into Hole C of the Insertion Guide and fixed to the plate.



Reduce the Fracture

Reduce the fracture using the image intensifier, Ø2.0 x 280mm K-Wires (113400016) and/or Reduction Forceps (112100011/3).

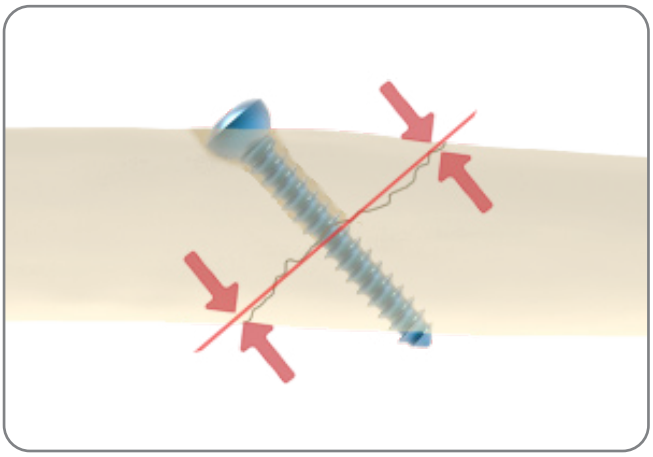
Note: Ø2.0 x 150mm (522015) and Ø2.5 x 280mm (113210001) K-Wires are also available.

Note: The fracture may be aligned by traction using a distractor or a temporary knee-bridging external fixator.

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. Large Frag Instrument Set (SET-INS-LGE) required.

1. Reduce the fracture and use the 4.5mm Drill Bit (113100003) with the 4.5mm sleeve of the Universal 3.2/4.5mm Drill Guide (113100014) to drill perpendicularly to and not beyond the fracture line.
2. Use the 3.2mm slot of the Universal 3.2/6.5mm Drill Guide (113100015) to drill the far cortex using the 3.2mm Drill (113100002).
3. The Countersink (113100020) should then be used to improve bone load transfer.
4. Measurement for Screw length can then be obtained using the Depth Gauge (113100007).
5. Insert Ø4.5mm 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.

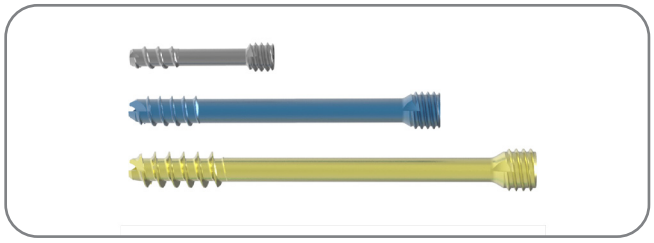
Note: The Cannulated Compression Screw instrument set (SET-INS-CAN) is required for this approach.

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.

Caution: Ensure any additional screws do not interfere with Locking Screw trajectory.



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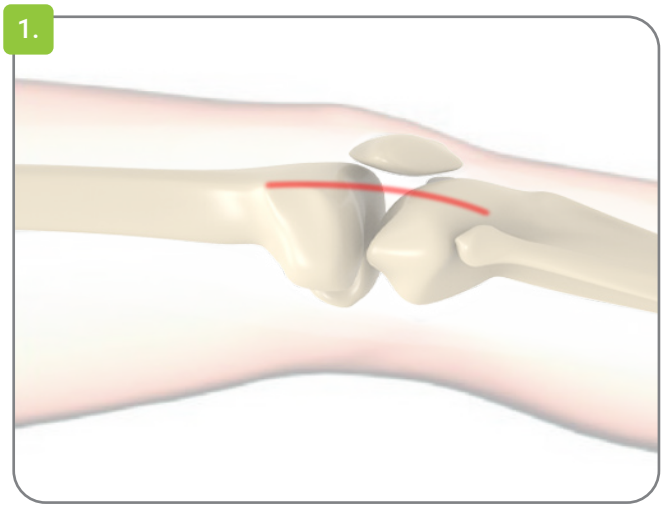
Incision

1. Either a straight or curved (shown) skin incision can be made from Gerdy's tubercle to about 50mm in a distal direction.



2. The anterior tibial muscle can be detached approximately half a centimetre from the tibial ridge and retracted to allow the plate to be inserted in the space between the periosteum and the muscle.

Note: For a complex intra-articular fractures, a lateral parapatellar incision is recommended. An anterolateral arthrotomy of the knee provides good reduction control and allows subsequent insertion of the plate.

Plate Insertion

1. Insert the plate using the Proximal Tibia Insertion Guide (113400022/3) between the anterior tibial muscle and the periosteum in a distal direction. Ensure the distal section is in constant contact with the bone and the proximal section is placed flat against the lateral condyle. The radiolucent distal shaft of the Insertion Guide can be removed if it impairs plate insertion.

   Note: The Insertion Guide may rotate dorsally due to the weight of the Guide creating a lack contact between the plate and the lateral condyle. There are two ways to confirm that the plate is in the correct position:

   1. The distal shaft is positioned on the anterolateral side of the tibia.

   2. The proximal head of the plate is positioned on the lateral condyle.

   Warning: Excessive internal rotation of the Insertion Guide must be avoided as screw placement in Hole D can compromise the popliteal artery.

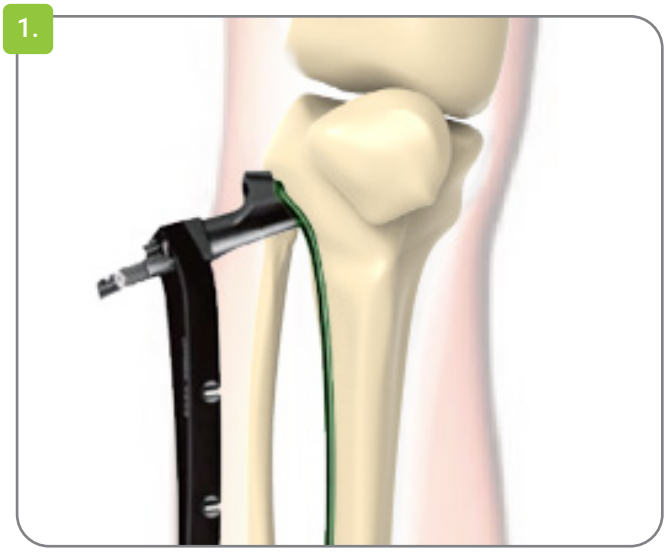
2. Once the plate is properly aligned remove the Threaded Drill Sleeve and Stabilization Bolt. Insert the Trocar (113400007) and a Threaded Drill Sleeve into the Insertion Guide for the most distal hole in the plate. A stab incision is to be performed to advance the instruments further down to the plate. Check positioning of the distal end of the plate using imagine intensification before securing the Drill Sleeve with the corresponding nut on the Insertion Guide. Remove the Trocar and thread the Stabilization Bolt in.

   Note: When using a 13 hole plate (4161-00-13301L/R), a soft tissue dissection down to the plate for holes 10 to 13 can be made in order to expose the superficial peroneal nerve.

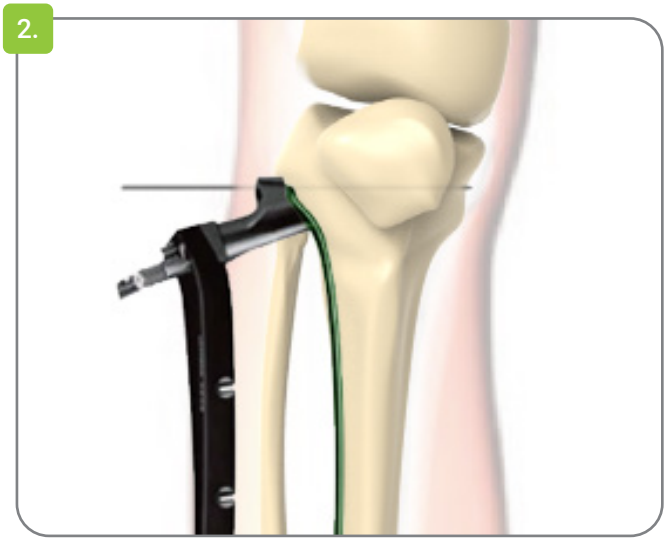
   Caution: Once this Stabilization Bolt has been inserted it will become difficult to change the position of the plate and Insertion Guide.

3. A Ø2.0mm K-wire (113400016) can be used for preliminary fixation of the plate. Insert a Ø2.0mm K-Wire into the most proximal K-Wire hole of the Insertion Guide and through the Stabilization Bolt. Once the plate is in the correct position and the reduction is completed, the Locking Screws can be inserted.

1.



2.



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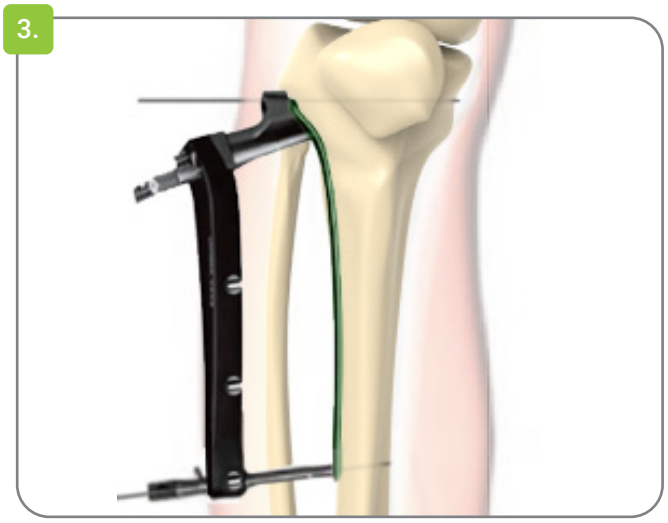

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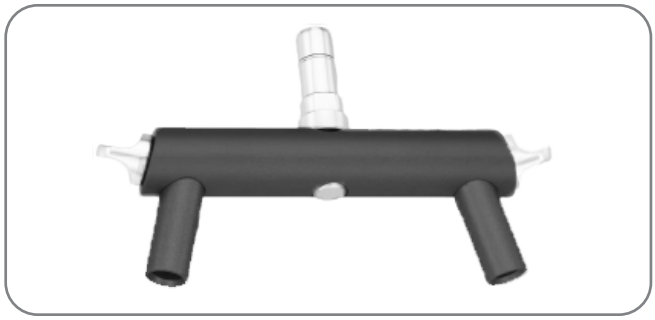
K-Wire Aiming Attachment

Ø2.0mm K-Wires (113400016) can be used in conjunction with the K-Wire Aiming Attachment (113400013) and two K-Wire Insertion Sleeves II (113400010) for preliminary fixation along the full length of the plate. The K-Wire Aiming Attachment is used from Hole 3 to Hole 13.



1. Insert two Ø2.0mm K-Wires against the ventral and dorsal aspects of the plate using the K-Wire Aiming Attachment.

   Note: The distance between the tibia and the plate should remain minimal during K-Wire insertion.

   Caution: After insertion of the K-Wires, the distance between the plate and the tibia can no longer be reduced.

2. Remove the K-Wire Insertion Sleeves II and the K-Wire Aiming Attachment to adjust proximal/distal displacement and position of the plate.

   Note: The Ø2.0mm K-Wires prevent sagittal migration of the plate.

3. Once the correct plate positioning has been achieved, the plate can be temporarily fixed with a Ø2.0mm K-Wire through the Fixation Bolt.

Locking Screw Insertion

Locking Screw placement depends on the type of clinical indication. Locking Screw positions should be selected based on established biomechanical principles of internal fracture fixation.

Note:

- Locking Screw insertion into the main fragments defines bone length and rotation.
- Locking Screws should be inserted close to and remote from the main fracture line.
- Self-Drilling/Self-Tapping Locking Screws are used for unicortical fixation in the diaphysis.
- Self-Tapping Locking Screws are used for unicortical or bicortical fixation in the metaphysis.
- The screws should be at the centre of the bone shaft to provide adequate purchase in bone.
- At least four Locking Screws should be used per fracture side.
- The first Locking Screw should be inserted into the proximal fragment.

Note: 4.5mm Cortex Screws can be inserted into the head of the plate through the Insertion Guide if required, however they cannot be used with the Insertion Sleeve (113400005).

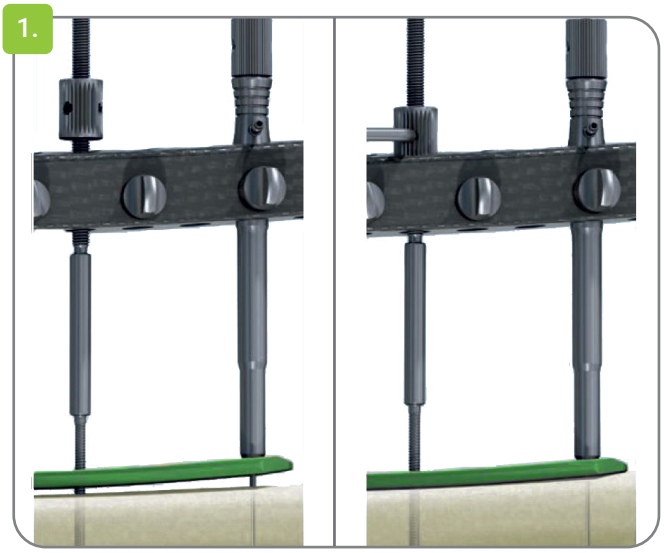
Pull Reduction Instrument

Before the first Locking Screw is inserted, the Pull Reduction Instrument (113400009) is recommended to minimise bone fragment movement. This instrument can be used in the presence of dense cortices or when there is a lack of stabilisation. It may also be utilised for translational adjustments.

1. Make a stab incision and insert an Insertion Sleeve (113400005) into the adjacent hole to the hole used for the first Locking Screw. Use a power tool to drill and insert the Pull Reduction Instrument. Rotate the corresponding nut under the image intensifier to achieve the desired reduction.

   Note: The Pull Reduction Instrument has a smaller diameter (Ø4.0mm) than that of Locking Screws (Ø5.0mm), ensuring Locking Screws insertion still achieves good bone purchase with no loss of stabilisation.

   Caution: Stop the power tool before the Pull Reduction Instrument is seated onto the plate as failure to do so may result in stripping the thread in the bone.



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Self-Drilling, Self-Tapping Locking Screw Insertion

1. Determine the length of Locking Screw using the K-Wire Measuring Instrument (113400017). Make a stab incision and insert an Insertion Sleeve (113400005) with the 161mm K-Wire Insertion Sleeve (113400006) into the corresponding hole. Insert a Ø2.0mm K-Wire (113400016) to the desired depth, leaving at least 5mm between the tip of the K-Wire and the medial cortex. Use image intensifier to confirm depth.

2. Measure Locking Screw length over the K-Wire using the K-Wire Measuring Instrument, rounding down to the nearest screw length, preventing protrusion of Locking Screws through the medial cortex. Following measurement, remove the Ø2.0mm K-Wire, K-Wire Measuring Instrument and 161mm K-Wire Insertion Sleeve.

3. Insert the Trocar through the Insertion Sleeve and remove prior to Locking Screw insertion. When using power, use the Ø4.5mm Drill Shaft (113400003) to insert Locking Screw through the Insertion Sleeve, beginning with slow insertion and increasing speed before the screw is fully tightened where speed should again be reduced. Advance the Locking Screw into the bone until the notch in the Drill Shaft sits entirely within the Insertion Sleeve. Ensure that the plate is securely held to the bone to avoid spinning of the plate about the bone as Locking Screws are tightened to the plate. For the final tightening, use the 4.5Nm Torque Limiter (113200038) to manually tighten the screw. Repeat step 1-3 for all Locking Screw insertion.

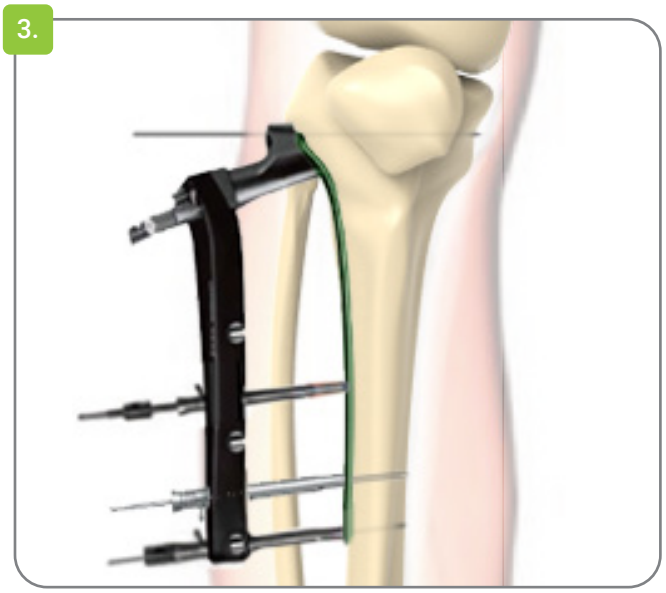
   Warning: Always use a torque-limiting attachment when inserting Locking Screws with power. This reduces the risk of the threads stripping from the head of the screw. If a Locking Screw needs to be removed and reinserted, do not use power and use the Torque Limiter 4.5Nm (113200038) driver instead.

Note: If improved visualisation of the condyle is desired, the Threaded Drill Sleeves for Holes D and E are to be guided through the aluminium foot part of the Insertion Guide only without being threaded into the plate. To avoid rotation of the Drill Sleeve, hold the Sleeve with two fingers during insertion and removal of the K-Wires and two most proximal Locking Screws.

Note: In the case of dense cortex, pre-drilling using the Ø4.3mm Drill Bit (113400001) is recommended. Use irrigation and cooling while drilling to minimise thermal necrosis.

1.

3.



Self-Tapping Locking Screw Insertion

1. Make a stab incision and insert the Trocar through the Insertion Sleeve (113400005). Replace the Trocar with the Threaded Drill Sleeve (113400002) and thread the Drill Sleeve into the plate. Carefully drill the screw hole using the Ø4.3mm Drill Bit (113400001).

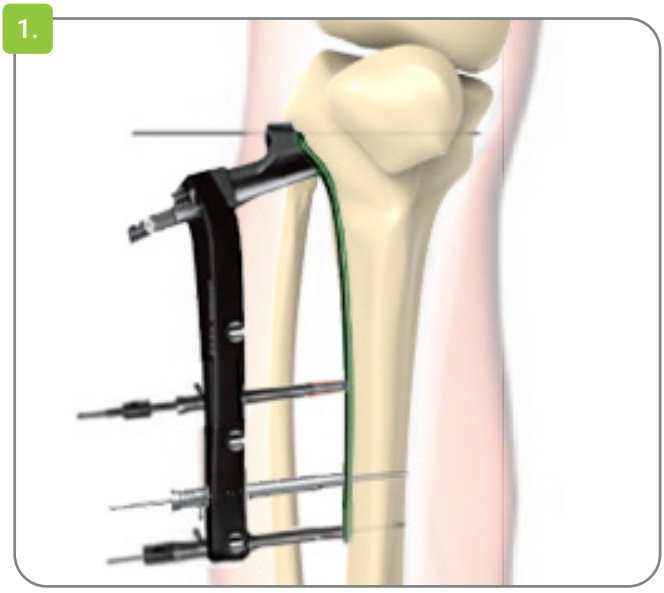
2. Determine the length of Locking Screw to be inserted. This can be done by reading directly from the calibrated Ø4.3mm Drill Bit.

3. Remove the Drill Bit and Threaded Drill Sleeve. When using power, use the Ø4.5mm Drill Shaft (113400003) to insert Locking Screw through the Insertion Sleeve, beginning with slow insertion and increasing speed before the screw is fully tightened where speed should again be reduced. Advance the Locking Screw into the bone until the notch in the Drill Shaft sits entirely within the Insertion Sleeve. For the final tightening, use the 4.5Nm Torque Limiter (113200038) to manually tighten the screw. Repeat step 1-3 for all Locking Screw insertion.

   Note: 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 Locking Screws are tightened to the plate.

   Warning: Always use a torque-limiting attachment when inserting Locking Screws with power. This reduces the risk of the threads stripping from the head of the screw. If a Locking Screw needs to be removed and reinserted, do not use power and use the Torque Limiter 4.5Nm (113200038) driver instead.

1.



Note: In the case of dense cortex, pre-drilling using the Ø4.3mm Drill Bit (113400001) is recommended. Use irrigation and cooling while drilling to minimise thermal necrosis.

Manual Locking Screw Insertion

Manual insertion of both Self-Tapping and Self-Drilling/Self-Tapping Locking Screws is optional if no torque limiting attachment for power insertion is available.

Use the 4.5Nm Torque Limiter (113200038) driver through the Threaded Drill sleeve (113400002) to insert and lock the screw.

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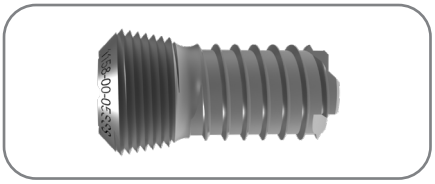
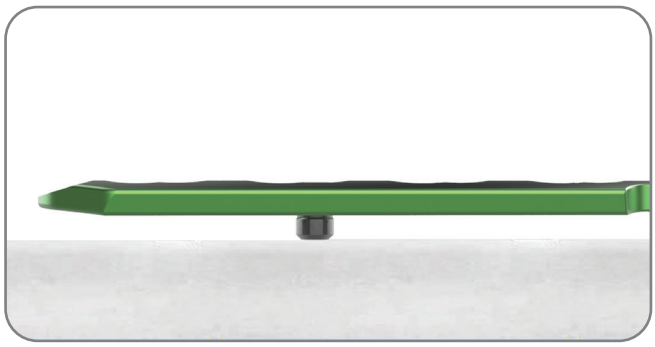
Periprosthetic Screws

Blunt tip self-tapping Periprosthetic Screws are used to provide unicortical fixation of fractures when the patient presents with an intramedullary implant.



Spacer

If minimal contact between the plate and bone is desired, an L&C spacer can be inserted using a Hex Driver (113100001/114110015) . 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.



Implant Removal

Implant removal follows a reversal of implantation.

1. Make an incision for the relevant Insertion Guide following the scar of the old incision and mount the Insertion Guide to the plate.
2. Make stab incisions to manually unlock Locking Screws with the use of the 4.5Nm Torque Limiter (113200038) driver.
3. Once all Locking Screws have been unlocked, a power tool using the Drill Shaft (113400003) can be used to remove the screws.

Note: When removing a 13 hole plate, a soft-tissue dissection down to the plate for holes 10 and 13 can be made before insertion the Trocar and Threaded Drill Sleeve. This will assist in visualisation of the superficial peroneal nerve.

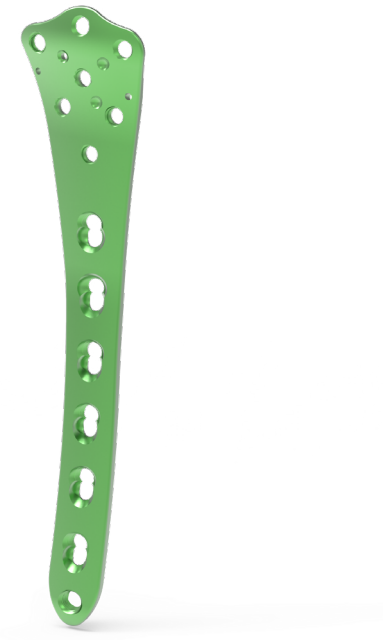
Note: Screw heads are susceptible to ingrowth and may be cleaned prior to removal. The Cleaning Instrument for Screw Head (113400014) can be used through a Threaded Drill Sleeve (113400002) to help clean the Locking Screw head recess.

Implants - Plates

MI L&C Distal Lateral Femoral Locking Plate		
Product Code	Number of Holes	Left/Right
3160-00-05155L	5	L
3160-00-07195L	7	L
3160-00-09235L	9	L
3160-00-11275L	11	L
3160-00-13315L	13	L
3160-00-05155R	5	R
3160-00-07195R	7	R
3160-00-09235R	9	R
3160-00-11275R	11	R
3160-00-13315R	13	R

Compatible Screw: 4.5mm Cortex Screw, 5.0mm Locking Screw, 5.0mm Spacer
Compatible K-wire: 2.0mm

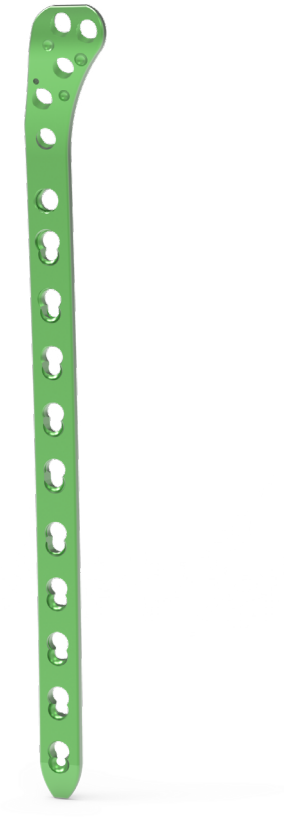
Sterile	Non-Sterile



MI L&C Proximal Lateral Tibial Locking Plate		
Product Code	Number of Holes	Left/Right
4161-00-05141L	5	L
4161-00-07181L	7	L
4161-00-09221L	9	L
4161-00-11261L	11	L
4161-00-13301L	13	L
4161-00-05141R	5	R
4161-00-07181R	7	R
4161-00-09221R	9	R
4161-00-11261R	11	R
4161-00-13301R	13	R

Compatible Screw: 4.5mm Cortex Screw, 5.0mm Locking Screw, 5.0mm Spacer
Compatible K-wire: 2.0mm

Sterile	Non-Sterile



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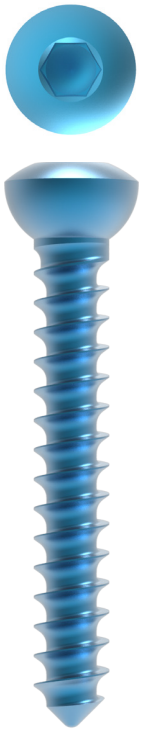
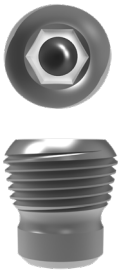
Implants - Screws

Locking Screw		
5.0mm		Length
Self-Drilling	Self-Drilling & Self-Tapping	
1059-00-50014	-	14
1059-00-50016	-	16
1059-00-50018	1162-00-05018	18
1059-00-50020	1162-00-05020	20
1059-00-50022	1162-00-05022	22
1059-00-50024	1162-00-05024	24
1059-00-50026	1162-00-05026	26
1059-00-50028	1162-00-05028	28
1059-00-50030	1162-00-05030	30
1059-00-50032	1162-00-05032	32
1059-00-50034	1162-00-05034	34
1059-00-50036	1162-00-05036	36
1059-00-50038	1162-00-05038	38
1059-00-50040	1162-00-05040	40
1059-00-50042	1162-00-05042	42
1059-00-50044	1162-00-05044	44
1059-00-50045	1162-00-05045	45
1059-00-50046	1162-00-05046	46
1059-00-50048	1162-00-05048	48
1059-00-50050	1162-00-05050	50
1059-00-50055	1162-00-05055	55
1059-00-50060	1162-00-05060	60
1059-00-50065	1162-00-05065	65
1059-00-50070	1162-00-05070	70
1059-00-50075	1162-00-05075	75
1059-00-50080	1162-00-05080	80
1059-00-50085	1162-00-05085	85
1059-00-50090	1162-00-05090	90
1059-00-50095	1162-00-05095	95
1059-00-50100	1162-00-05100	100

Cortex Screw - Self-tapping	
4.5mm	Length
1145-00-45016	16
1145-00-45018	18
1145-00-45020	20
1145-00-45022	22
1145-00-45024	24
1145-00-45026	26
1145-00-45028	28
1145-00-45030	30
1145-00-45032	32
1145-00-45034	34
1145-00-45036	36
1145-00-45038	38
1145-00-45040	40
1145-00-45042	42
1145-00-45044	44
1145-00-45046	46
1145-00-45048	48
1145-00-45050	50
1145-00-45052	52
1145-00-45054	54
1145-00-45056	56
1145-00-45058	58
1145-00-45060	60



5mm Spacer	
Product Code	Length
1060-00-50002	2



5mm Periprosthetic Screw	
Product Code	Length
1158-00-05014	14
1158-00-05018	18

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Instruments

MI Instrument Set

Instruments							
#	Code	Description	Qty	#	Code	Description	Qty
1	113400016	K-Wire with Threaded Tip 2.0 x 280mm	4	11	113400002	Drill Sleeve, Threaded	2
2	113400020	Depth Gauge	1	12	113400012	Stabilization Bolt	2
3	113200009	Screwdriver 248mm (Star)	1	13	113400005	Insertion Sleeve	3
4	113200038	Torque Limiter 4.5Nm	1	14	113400011	Fixation Bolt	1
5	113400009	Pull Reduction Instrument	1	15	113400006	K-Wire Insertion Sleeve 161mm	1
6	113400007	Trocar 164mm	1	16	113400004	Hole Stopper	10
7	113400014	Cleaning Instrument for Screw Head	1	17	113400013	K-Wire Aiming Attachment	1
8	113400003	Drill Shaft 4.5 x 180mm	1	18	113400015	X-Ray Calibrator	2
9	113400001	Drill Bit 4.3mm	2	19	113400008	Wrench Shaft 4.3 x 120mm	1
10	113400010	K-Wire Insertion Sleeve II, 184mm	2	20	113400017	K-Wire Measuring Instrument	1

Instruments

MI Insertion Guides

21.

22.

Insertion Guides			
#	**Code**	**Description**	**Qty**
21	113400018	Insertion Guide - Dist Lat Femur - RH (Carbon Fibre)	1
	113400019	Insertion Guide - Dist Lat Femur - LH (Carbon Fibre)	1
22	113400022	Insertion Guide - Prox Tibia - RH (Carbon Fibre)	1
	113400023	Insertion Guide - Prox Tibia - LH (Carbon Fibre)	1

Note: 113400019 & 113400023 shown.

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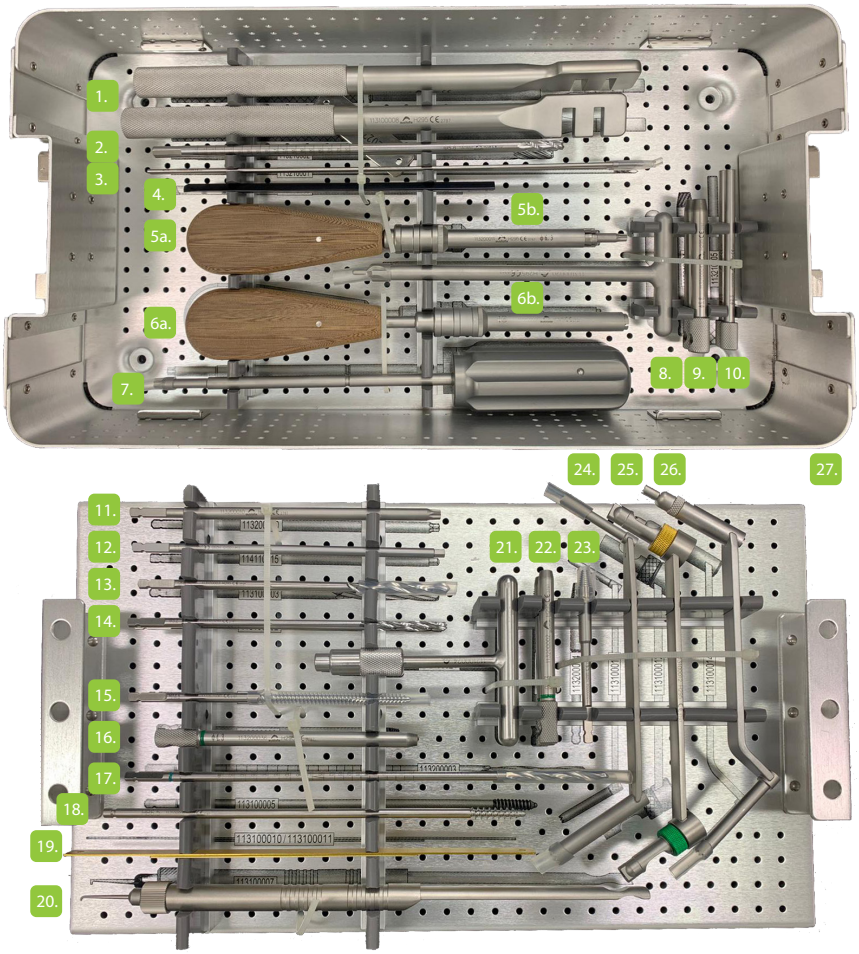
Instruments

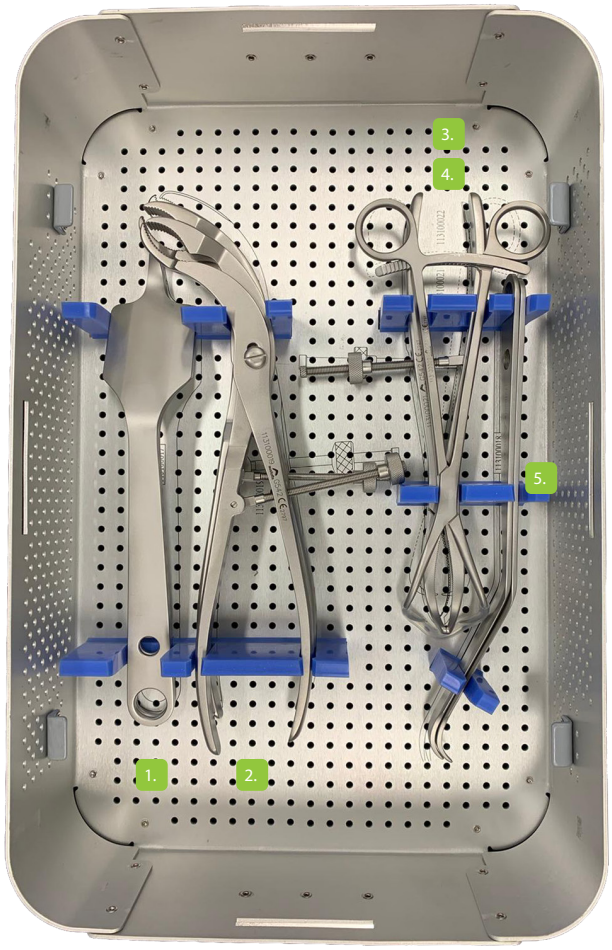
Large Frag Instrument Set



Instruments							
#	Code	Description	Qty	#	Code	Description	Qty
1	113100008	Plate Bender, 285mm	2	14	113100002	Drill Bit 3.2mm	1
2	113210002	Drill Bit, Cannulated 5.8mm	2	15	113100006	Tap for Ø4.5mm Cortex Screw	1
3	113210001	K-Wire Ø2.5mm	3	16	113200036	Drill Sleeve, Threaded 4.3mm (Long)	1
4	113200005	Direct Measuring Device	1	17	113200003	Drill Bit 4.3mm	2
5a.	113200009	Screwdriver 248mm (Star)	1	18	113100005	Tap for Ø6.5mm Cancellous Bone Screw	1
5b.	113200011	Holding Sleeve Ø6.3mm	1				
6a.	113100001	Screwdriver 248mm (Hex)	1	19a.	113100010	Bending Template (Large)	1
6b.	114400007	Holding Sleeve Ø8.0mm	1	19b.	113100011	Bending Template (Small)	1
7	113200038	Torque Limiter 4.5Nm	1	20	113100007	Depth Gauge for Screws 4.5/6.5mm, 110mm	1
8	113100020	Countersink	1	21	112100024	T-Handle with Quick Coupling, 90mm	1
9	113210004	Drill Sleeve, Cannulated 5.8mm	2	22	113200002	Drill Sleeve, Threaded 4.3mm	2
10	113210005	Guide for Ø2.5mm K-Wire	2	23	113200004	Easyout	1
11	113200010	Screwdriver T25 Shaft 145mm (Star)	1	24	113100015	Drill Guide, Universal 3.2/6.5mm	1
12	114110015	Screwdriver with Quick Coupling 3.5 x 100mm (Hex)	1	25	113100012	Drill Guide, Double 3.2mm	1
				26	113100014	Drill Guide, Universal 3.2/4.5mm	1
13	113100003	Drill Bit 4.5mm	1	27	113127000	Large Frag Instrument Tray (Empty)	1

Optional Sets

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

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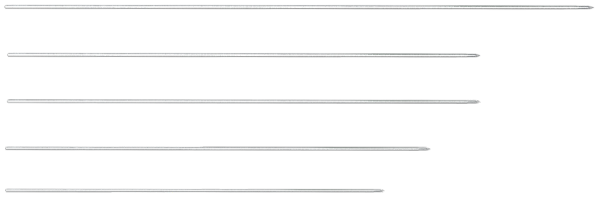
Single Use Items

Required K-Wires		
Code	**Description**	**Qty**
113400016	K-Wire with Threaded Tip 2.0 x 280mm	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
611.112	1.1 x 120mm K-Wire	2
081.010	0.8 x 100mm K-Wire	2



Drills		
Code	**Description**	**Qty**
113400001	Drill Bit 4.3mm	1
113100002	Drill Bit 3.2mm	1

Instrument Trays & Sets

Instrument Trays		
Code	**Description**	**Qty**
113403000	MI Instrument Tray (Empty)	1
113127000	Large Frag Instrument Tray (Empty)	1
113122000	Universal Trauma Instrument Tray (Empty)	1

Instrument Set		
Code	**Description**	**Qty**
SET-INS-MI	Full MI Instrument Set	-
SET-INS-LGE	Full Large Frag Instrument Set	-
SET-INS-UTRA	Full Universal Trauma Instrument Set	-

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.

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Notes

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Notes

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