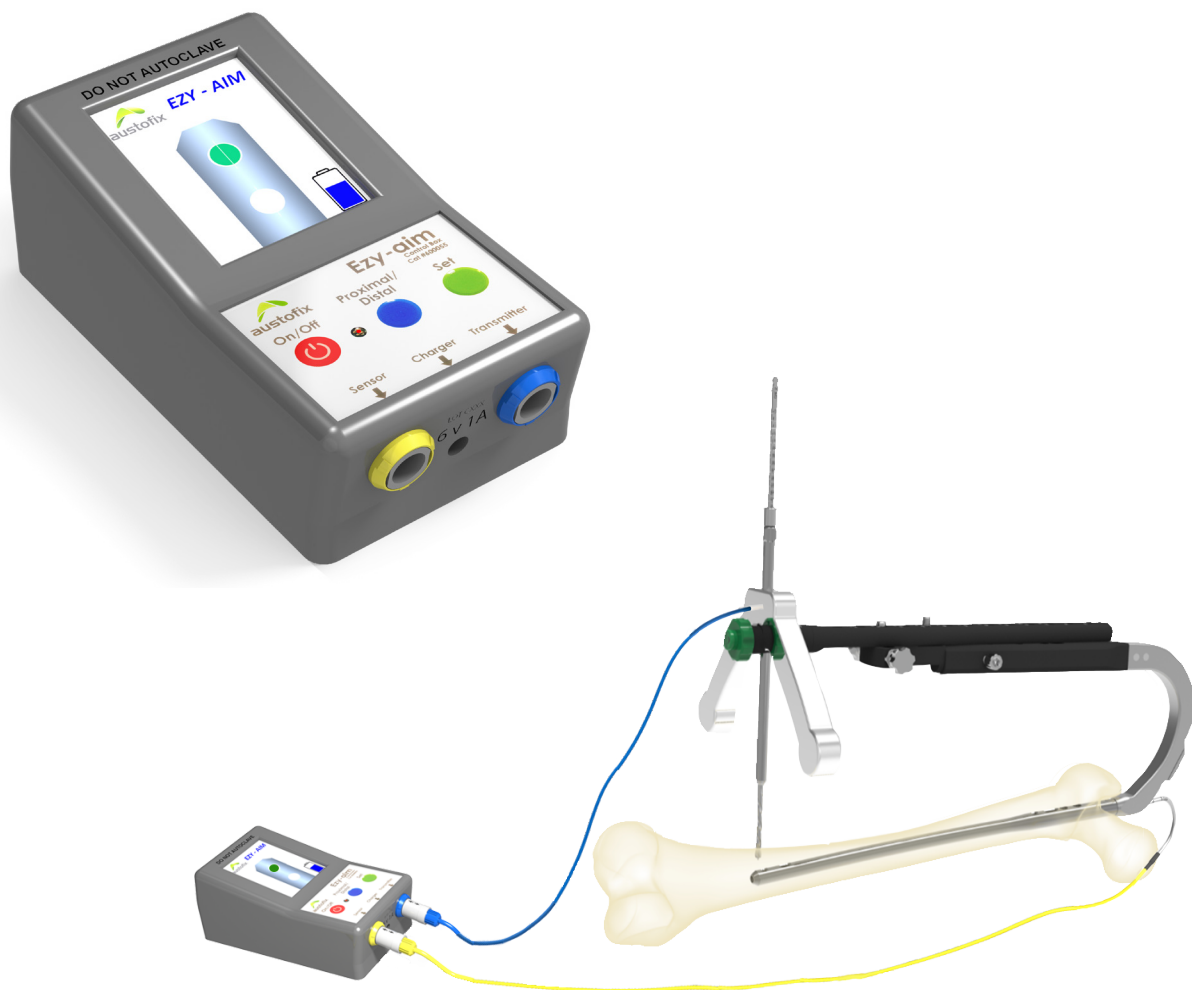


austofix EZY-AIM

ELECTRONIC DISTAL TARGETING

Surgical Technique



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Disclaimer

This document is intended to be read by experienced orthopaedic trauma surgeons familiar with I.M. Nailing of the long bones.

This publication is intended as the recommended procedure for using the Austofix nailing 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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Introduction

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

In collaboration with Australian surgeons, Austofix has introduced innovative, cost-effective implant systems that improve patient outcomes whilst supporting safe and efficient operating procedures. Austofix continues to develop its range of products through collaboration with new expertise, technologies and partnerships with surgeons and scientific institutions.

Austofix products are distributed globally from our offices based in Thebarton, Australia. Our well-trained product specialists and customer service staff are available for all customer enquiries and product support and understand the needs of the orthopaedic market.

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

EZY-AIM

The Austofix Ezy-aim Electronic Distal Targeting System provides an accurate and effective method for surgeons to perform distal screw hole targeting in an intramedullary nail (IM). This method reduces fluoroscopy use and the concomitant exposure to radiation. The system is used in conjunction with the Austofix IM cannulated nails.

The system consists of two electronic transmitting coils mounted on a distal targeting arm. These send a signal that is detected by the sensor placed within the nail. The two coils are equidistant from the drill guide. When the sensor receives equal signals from the transmitter the drill guide is directed to the centre of the nail.

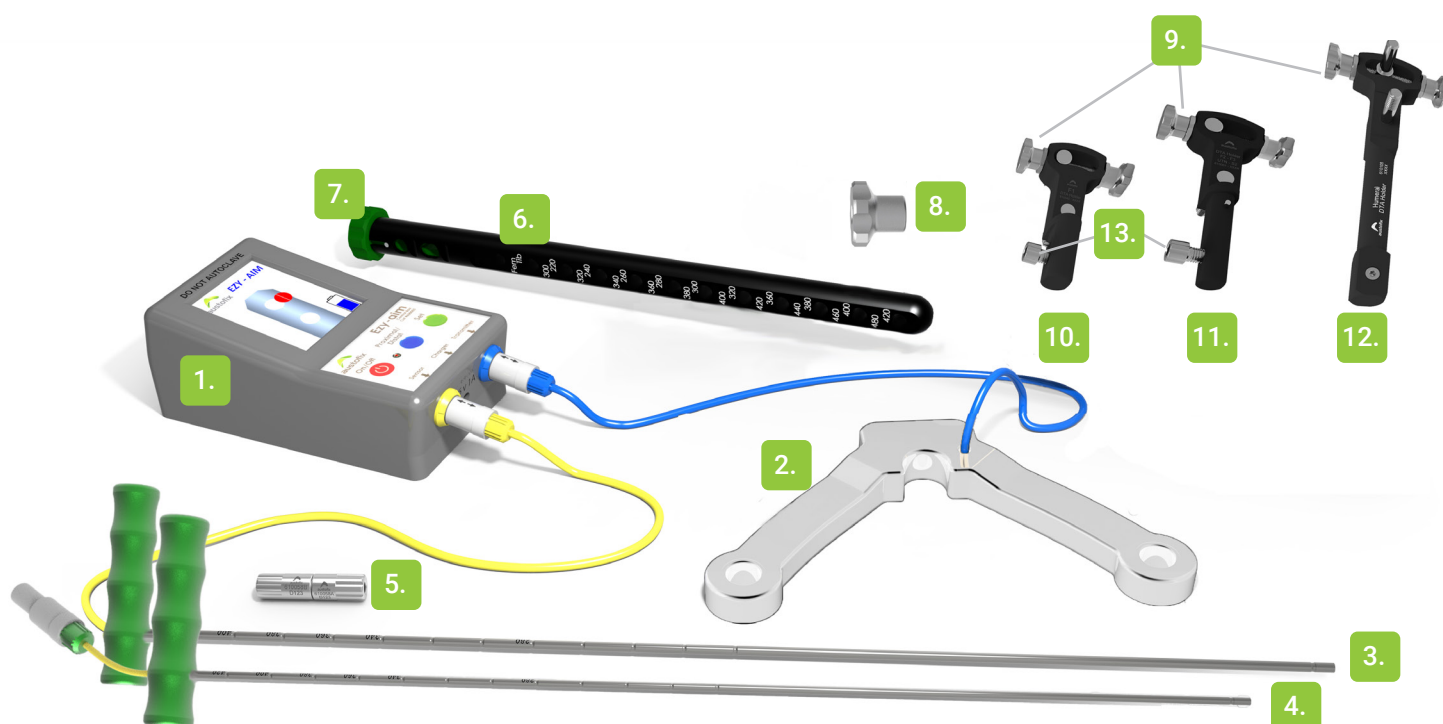
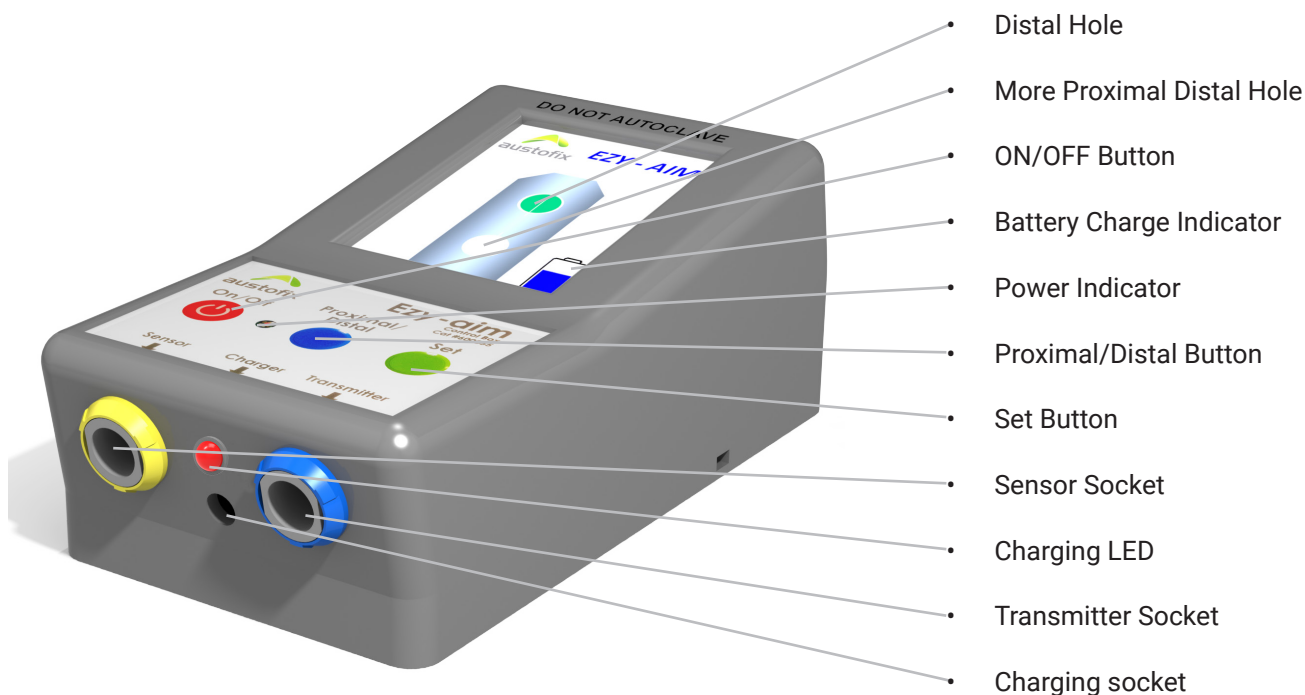
The graphic display simulates the aiming position of the drill guide.

The instruments are assembled prior to nail insertion and adjusted to aim at the hole in the nail. The instruments can be positioned to aim at either the Distal or the more Proximal (Dynamic) Distal hole.

All instruments besides the Control Box are autoclavable. The cables are attached to the unsterilised Control Box which is placed on an adjacent unsterilised side table. All the targeting instruments are re-usable.

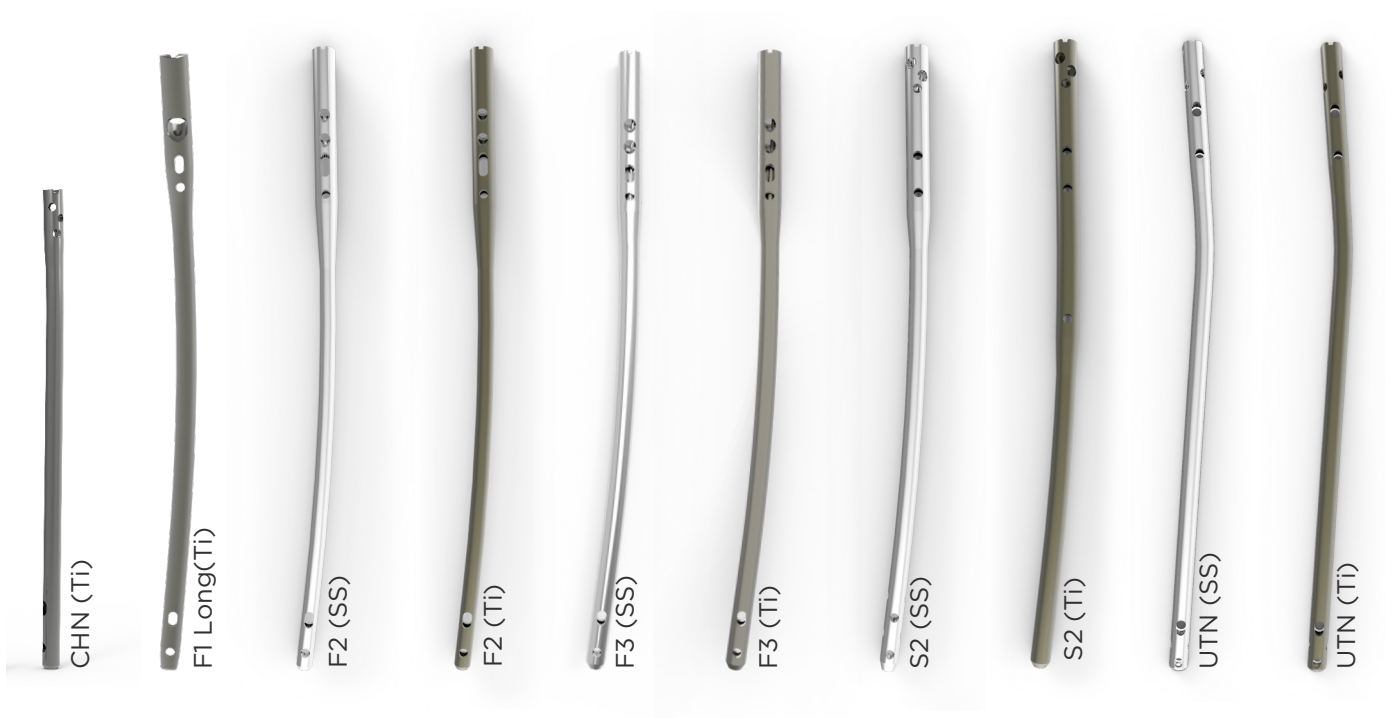
The Austofix Ezy-aim embodies precision, reliability and immediacy to provide the surgeon full control during fracture repair.

Instrument Overview



- | | | |
|---|---|---|
| 1. Ezy-aim Control Box (610055) | 6. Distal Targeting Arm (DTA) (610046A) | 11. Combo DTA Holder (F2, F3, UTN & S2) (610061) |
| 2. Ezy-aim Transmitter (610056) | 7. DTA Locking Sleeve (610046B) | 12. Humeral DTA Holder (610105) |
| 3. Ezy-aim Sensor (610057) | 8. Locking Knob (610050) | 13. M8 Mounting Screw (632007) |
| 4. Ezy-aim Small Sensor (610059) | 9. Adjuster Knobs | |
| 5. Ezy-aim Sensor Length Stop (Inner and Outer) (610058A/B) | 10. F1 DTA Holder (610045) | |

Austofix Nails Used With Ezy-aim System



* Stainless Steel (SS) Titanium (Ti)

Control Box

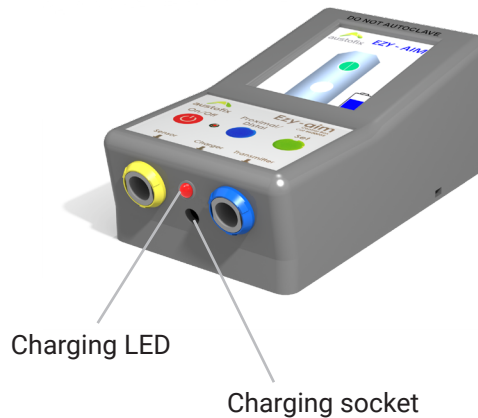
Battery Management

The Ezy-aim Control Box (610055) contains 4xAA cell 2000mAh NiMH rechargeable battery pack. When fully charged the device will operate for 3-4 hours. To preserve power the device will turn off after 30 minutes of non-use. The battery symbol indicates the amount of charge remaining. In normal use the device will be on for 10-15 minutes per procedure.

Charging is done with the AC/DC 9V plug-pack supplied by Austofix. When charging a red indicator light comes on. This switches itself off when charging is complete.

Total charge will take approximately 2 hours.

Note: the device cannot be switched on while connected to the charger.



Battery Level

To check the battery level on the Ezy-aim Control Box, switch on and wait 1-2 minutes for it to initialise. If the battery is at half charge there is sufficient power for one procedure.

If the charge is less than half and is required for one procedure, charge the unit for at least 15 minutes. To preserve power turn the unit off until needed.

Note: short charging as described above is only recommended for emergency procedures.



Warning

Do not autoclave Control Box.

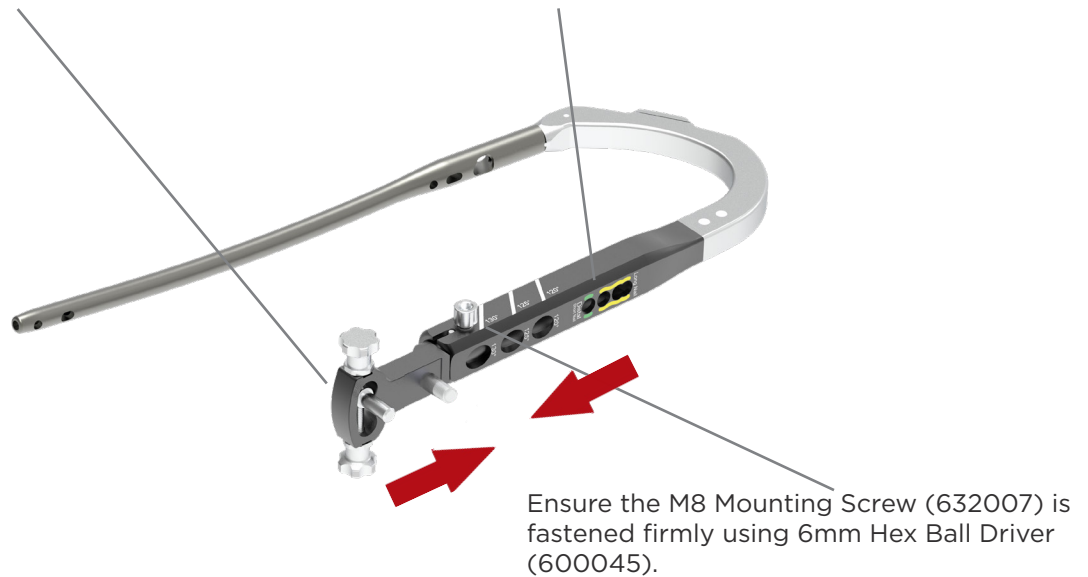
Assembly of Ezy-aim System

Nail, Nail Holder, DTA Holder

Assemble the Nail with the appropriate Nail Holder as per the relevant Nail Surgical Technique.

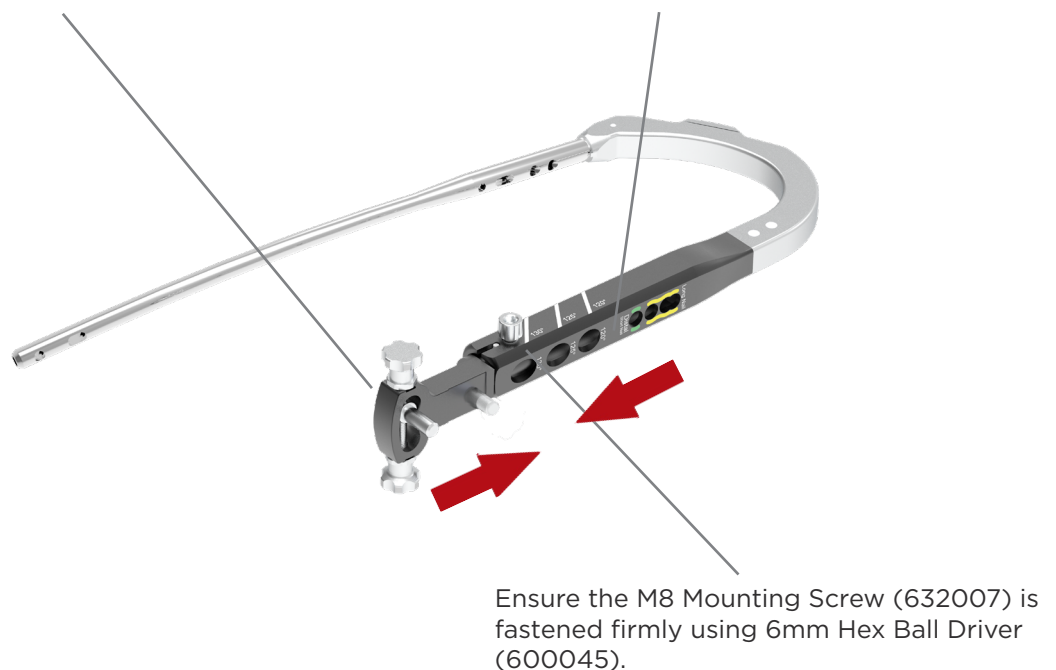
F1 FEMORAL NAIL

Attach the F1 DTA Holder (610045) to the F1 Proximal Screw Guide (600094).



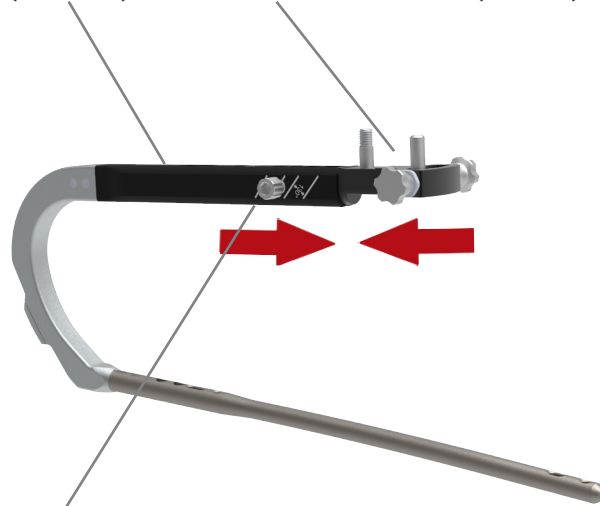
F2 FEMORAL NAIL

Attach the Combo DTA Holder (610061) to the F2 Proximal Screw Guide (600071).



F3 FEMORAL NAIL

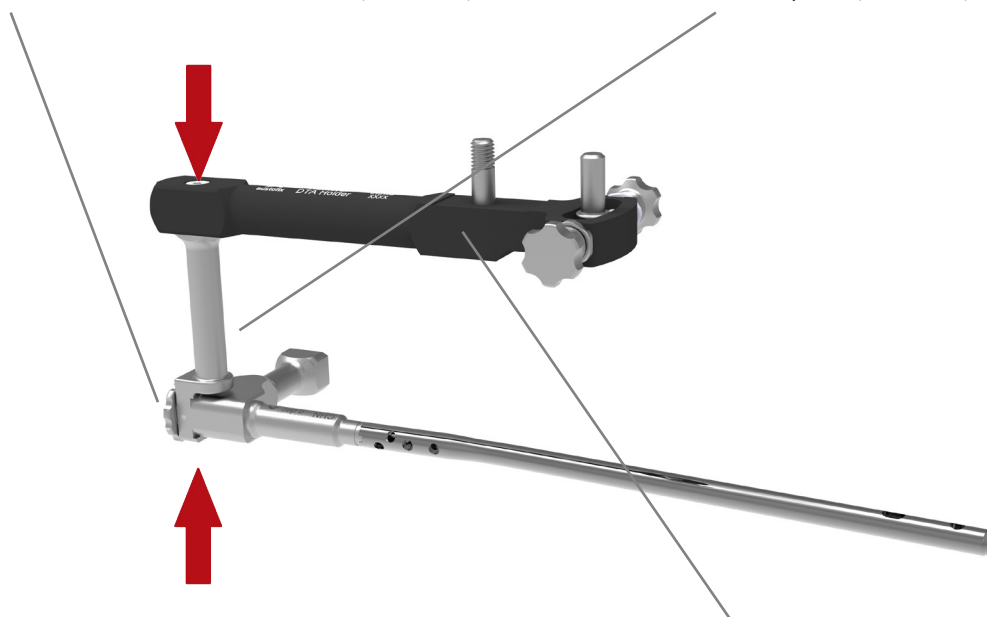
Attach the F3 Nail Holder (600062) to the Combo DTA Holder (610061).



Ensure the M8 Mounting Screw (632007) is fastened firmly using 6mm Hex Ball Driver (600045).

CANNULATED HUMERAL NAIL

Attach the Cannulated Humeral Nail Holder (600075) to the Humeral DTA Adaptor (600077).

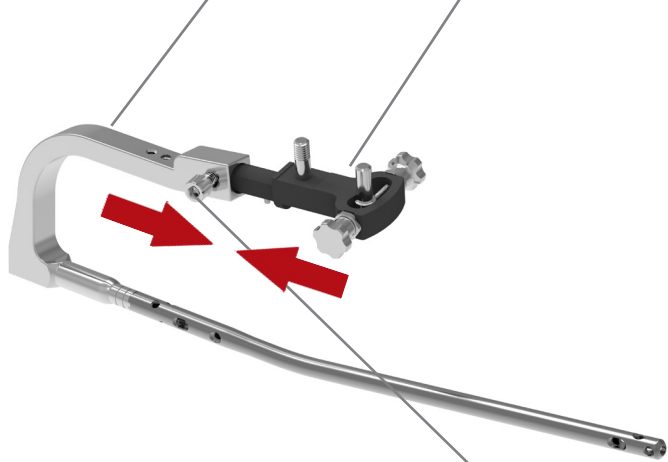


Then attach the Humeral DTA Adaptor (600077) to the Humeral DTA Holder (610105).
Secure the Humeral DTA Holder (610105) using 3.5 Hex 250mm Screwdriver (610067).

UNIVERSAL TIBIAL NAIL

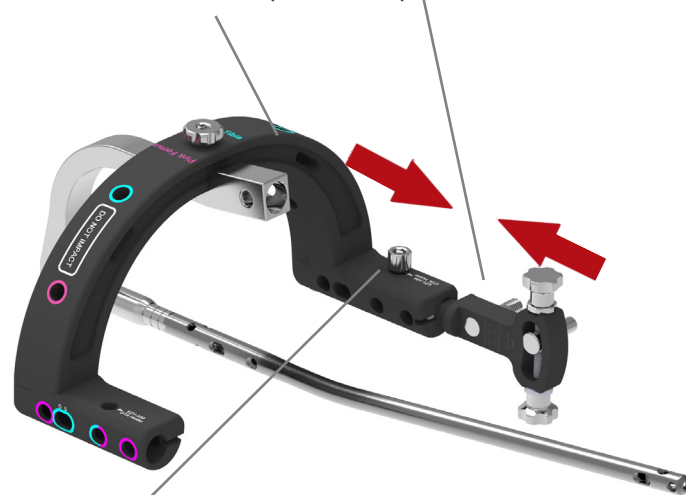
ANTERIOR-POSTERIOR ENTRY

Attach the Combo DTA Holder (610061) to the UTN & S2 Nail Holder (600083).



MEDIAL-LATERAL ENTRY

Attach the Combo DTA Holder (610061) to the Anterior Screw Guide (600084A).

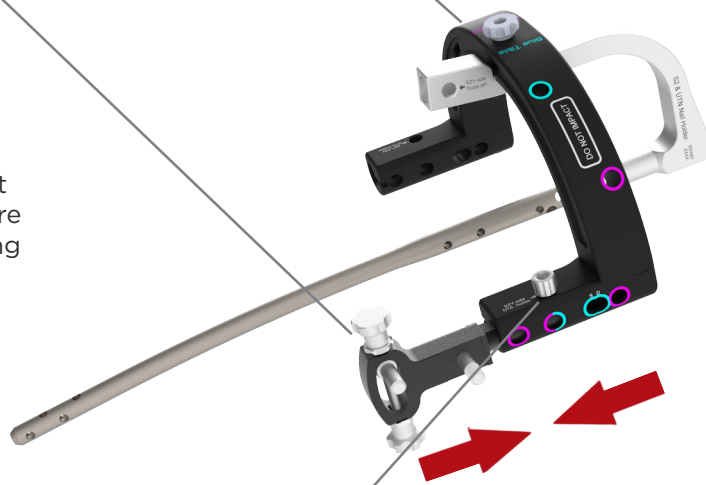


Ensure the M8 Mounting Screw (632007) is fastened firmly using 6mm Hex Ball Driver (600045).

S2 SUPRACONDYLAR NAIL

Attach the Combo DTA Holder (610061) to the Anterior Screw Guide (600084A).

Note: The S2 A-P holes are not accessible by Ezy-Aim. They are only used in free hand targeting

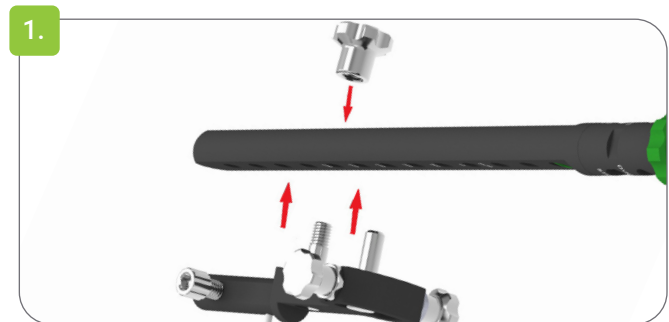


Ensure the M8 Mounting Screw (632007) is fastened firmly using 6mm Hex Ball Driver (600045).

Distal Targeting Arm (DTA)

To assemble the DTA and its attachments see below.

1. Place the DTA (610046A) onto the DTA Holder with the length of the nail type facing out.

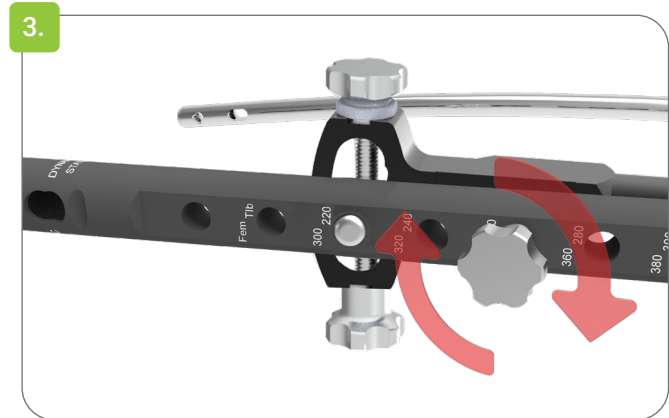


2. Place the DTA onto the pivot point at the appropriate nail length.

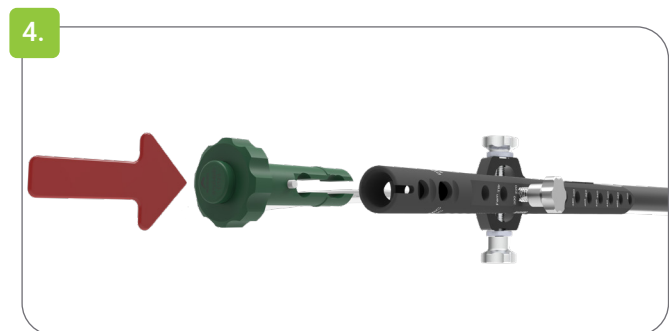
Note: Setting for 340mm Femoral Nail shown.
For S2 Nails, use the lengths marked for Tibia.



3. Engage the Locking Knob (610050) on the DTA Holder and lightly tighten.



4. Depending on surgeon's preference, insert Static DTA Locking Sleeve (610046B-S) or Dynamic DTA Locking Sleeve (610046B-D) into the DTA ensuring the pin lines up. Set the semi-assembled unit aside.



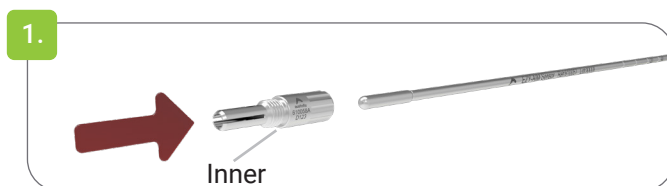
For Femoral nails: The Ezy-aim System must be calibrated for both the more proximal distal hole and distal nail holes **before** inserting the nail into the bone. The more proximal distal nail hole should be calibrated first, with the Sensor Length Stop (610058) set 20mm shorter than the length of the nail being used. For example, for a 340mm nail set the sensor length stop to 320mm

For Humeral nails: The Ezy-aim System must be calibrated for only the more proximal hole **before** inserting the nail into the bone.

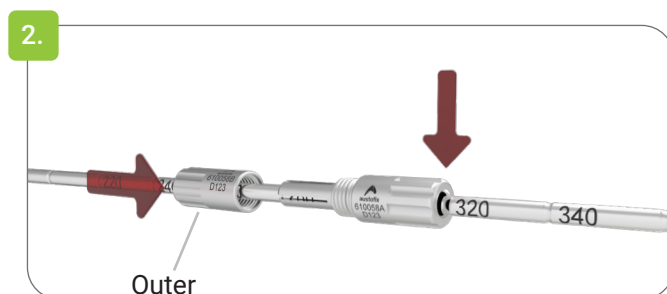
For Tibial nails: The M-L holes only require calibration of the more proximal hole. The A-P hole is only used for very distal fractures and is calibrated separately, using the Proximal “Static” hole in the DTA and the “Distal” setting in the Control Box. Both are calibrated **before** inserting the nail into the bone.

Setting the Sensor Length Stop

1. Slide the Inner Sensor Length Stop (610058A) onto the sensor as shown.



2. Place the end of the Inner Sensor Length Stop onto the sensor notch marked with the measurement 20mm shorter than the length of the nail. Slide on the Outer Sensor Length Stop (610058B) onto the sensor leading with the threads.

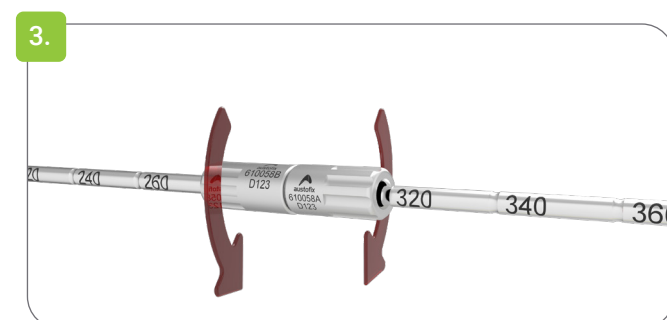


Note: The Ezy-Aim Small Sensor (610059) will be required for the following nails:

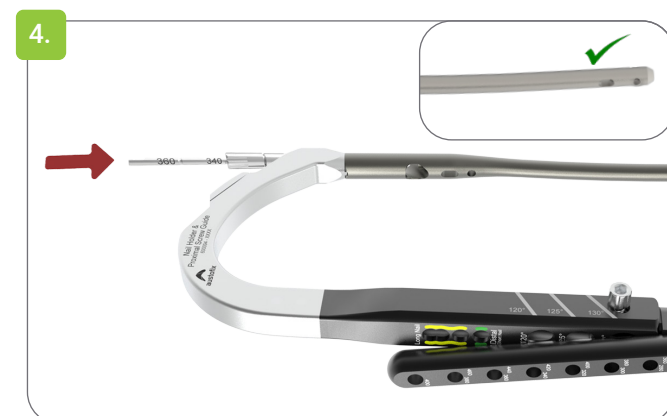
- 8mm Universal Tibial Nail
- 7, 8 & 9mm Cannulated Humeral Nails

Warning: When using the Small Sensor, do not shorten by 20mm. Use actual marked nail length.

3. Tighten the Outer Sensor Length Stop while maintaining alignment of the Inner Sensor Length Stop with the notch closest to the measurement required. Once tightened ensure it cannot slide off the notch.

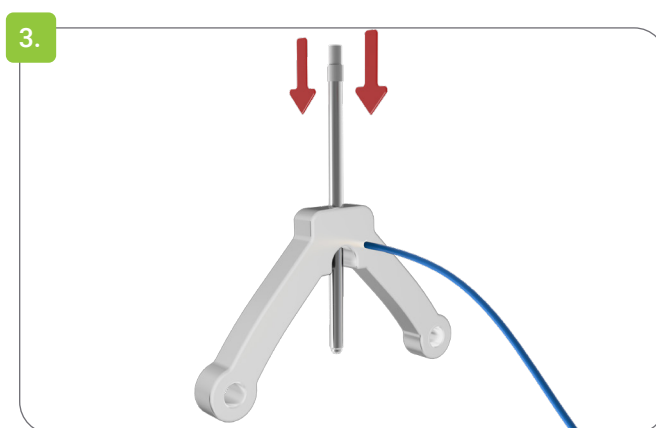
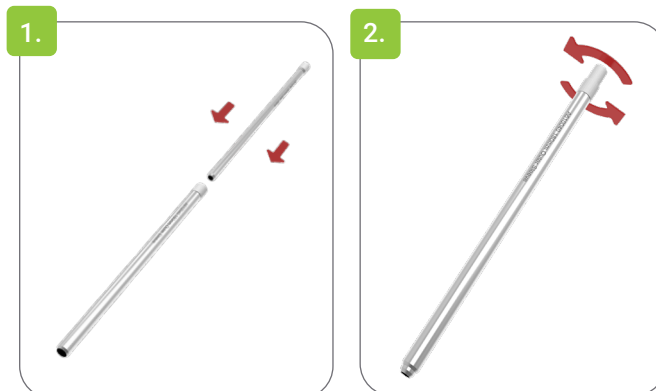


4. Insert the Ezy-aim Sensor (610057) through the Nail Holder and into the Nail until the Sensor Length Stop engages the Cannulated Nail Holding Screw (600029). Look through the nail's more proximal distal hole to ensure the sensor is not visible. Place unit onto a sterile table.

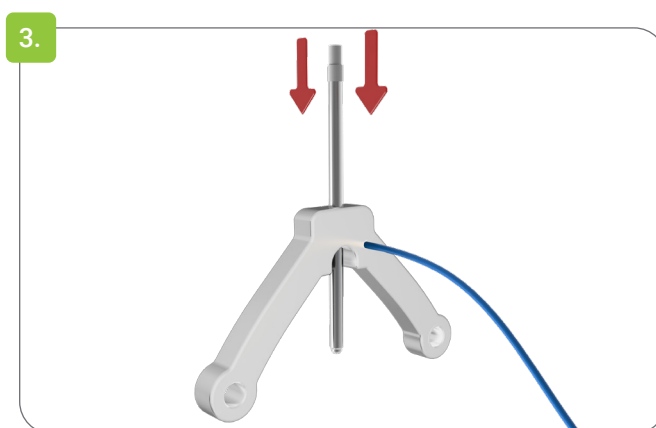


Attaching the Transmitter

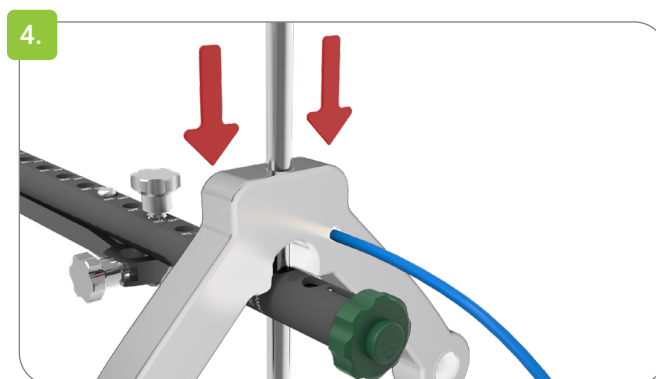
1. Insert the Drill Sleeve (610064) into the Outer Sleeve (610065).
2. Lock the two Sleeves together by twisting the Drill Sleeve.



3. Insert the Sleeves through the hole on the top of the Ezy-aim Transmitter (610056) to the approximate depth as shown in the image.

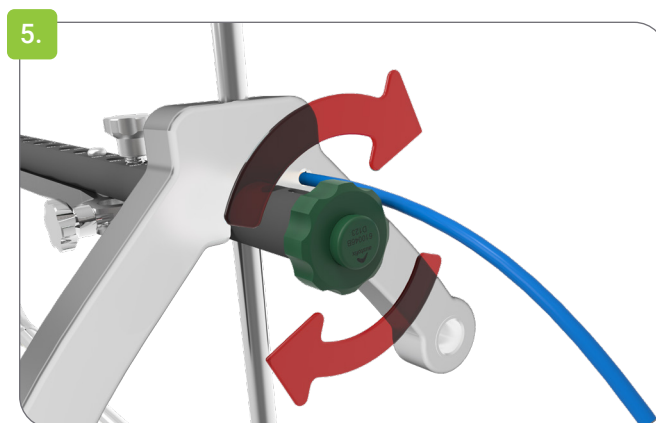


4. Pass the Sleeves through the 'Dynamic' or 'Static' hole on the DTA (610046), depending on surgeon's preference. Then push the Transmitter firmly onto the DTA until it snaps on. The side of the transmitter marked 'Proximal Side' must be facing the nail holder.



Note: The Dynamic slot is chosen if dynamisation is required.

5. Tighten the DTA Locking Sleeve Nut (610046B) to secure the Sleeves and Transmitter in position.



Calibration

Calibrating the more Proximal Distal Hole

1. Place the Ezy-aim Control Box (610055) near the surgeon but outside the sterile zone. Pass the ends of the Transmitter and Sensor cables to an unsterile person to attach to the Control Box. The cables are colour coded: yellow for Sensor and blue for Transmitter.
- Turn on the Ezy-aim Control Box. Press 'Proximal/Distal' to select the Proximal hole.
2. Pass the 4.5x340mm Drill (514534) through the Drill Sleeves and use the adjustment knobs on the DTA Holder (610060) to align the drill with the more proximal distal hole in the nail.
3. Make sure the Drill is able to pass through the proximal hole in the nail freely.
4. Press 'Set' to Calibrate the Ezy-aim to the proximal hole.

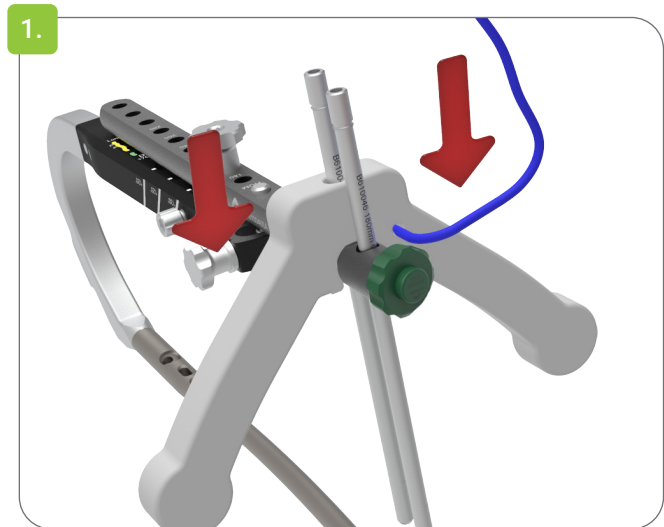


Caution!

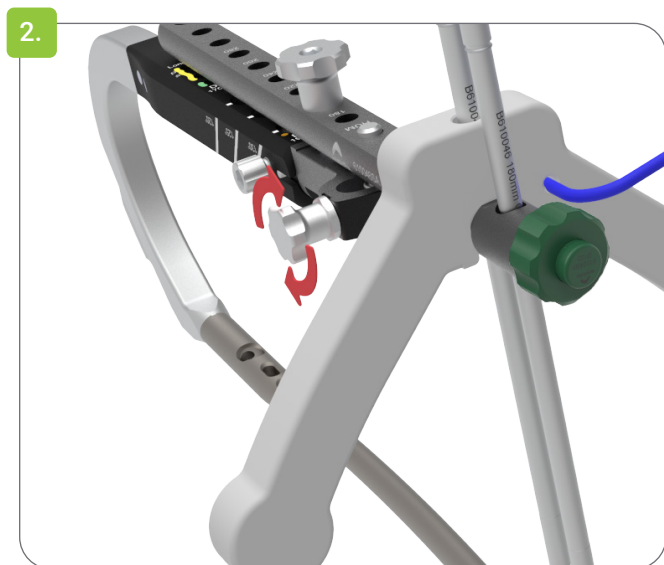
To avoid interference from other instruments and equipment when setting, hold the instrument assembly so that the Ezy-aim Transmitter (610056) is up above the table, and more than 100mm from any other metal objects.

Calibrating the Most Distal Hole

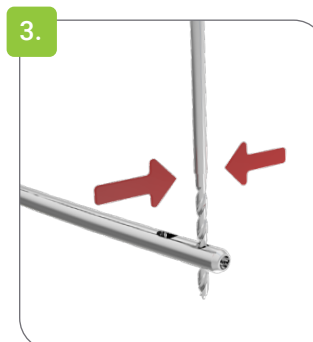
1. Keep the Sleeves and Transmitter in position over the more proximal hole and pass a second sleeve assembly through the distal hole of the DTA.



2. Use the Adjustment Knobs on the DTA Holder and drill to align the Drill Sleeves with the Distal hole in the Nail. Normally no adjustment is needed for tibial and humeral nails, but a small adjustment may be needed for femoral nails.



3. Make sure the drill is able to pass through the distal hole in the nail freely.
 4. Press 'Proximal/Distal' on the Ezy-aim Control Box (610055) to select the Distal hole. Press 'Set' to calibrate the Distal hole.
- Turn off the Ezy-aim Control Box.



The system is now calibrated to the Proximal and Distal Nail holes. It will need to be partially disassembled to insert into the patient.

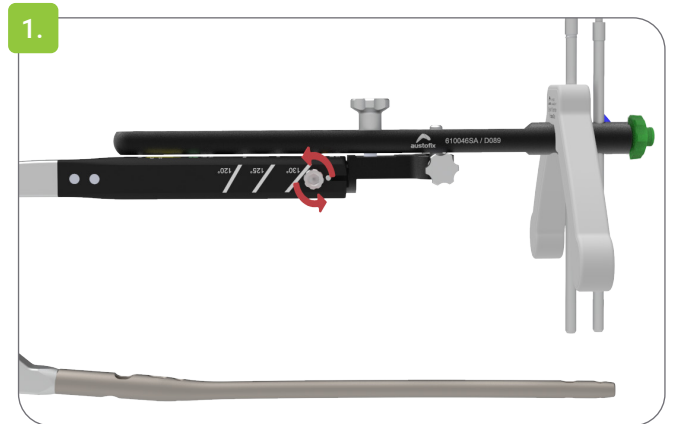
Caution!

To avoid interference from other instruments and equipment when setting, hold the instrument assembly so that the Transmitter is up above the table, and more than 100mm from any other metal objects.

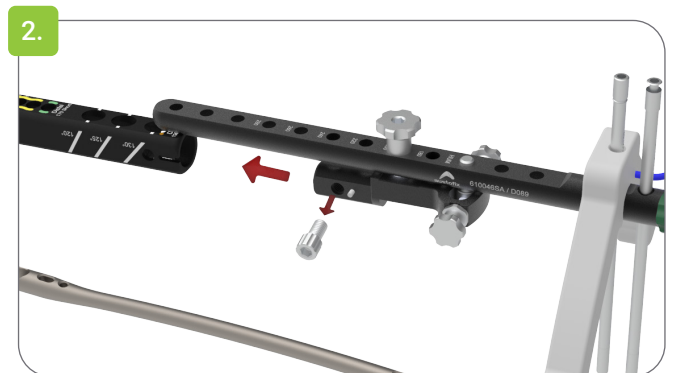
Disassemble

Preparation for Nail Targeting

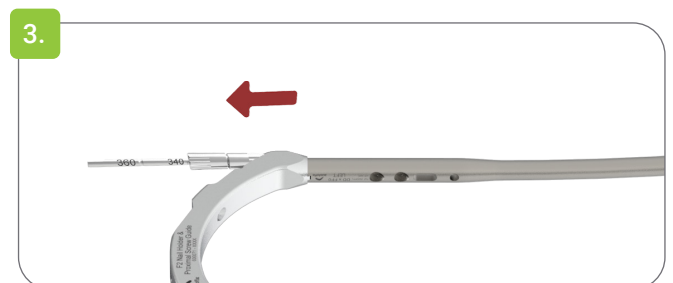
1. Unscrew the M8 Mounting Screw (632007) from the Nail Holder.



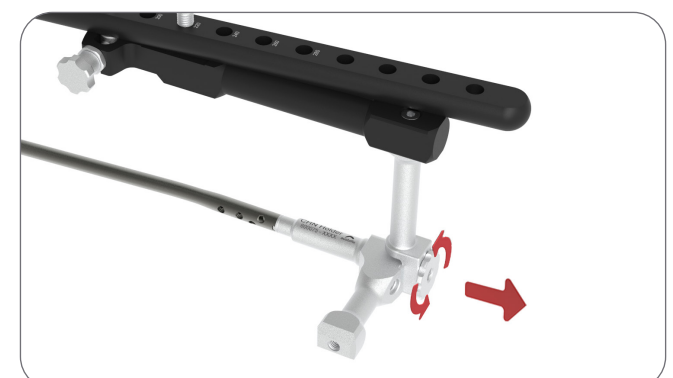
2. Separate the DTA assembly from the Nail Holder, keeping the rest of the assembly intact.



3. Remove the Ezy-aim Sensor (610057) from the Nail.



Note: For CHN Long procedures, the Ezy-Aim assembly including the Cannulated Humeral Nail DTA Adaptor (600077) must be removed following calibration and prior to nail insertion. The assembly can then be reattached once distal targeting is required after the nail has been inserted.

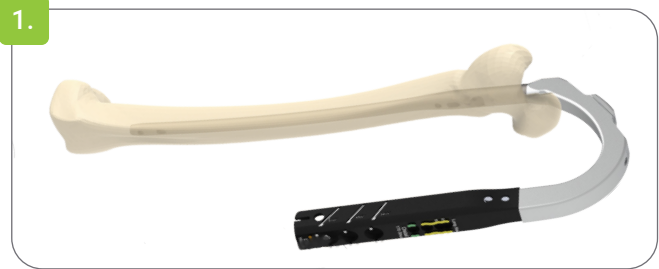


Nail Targeting

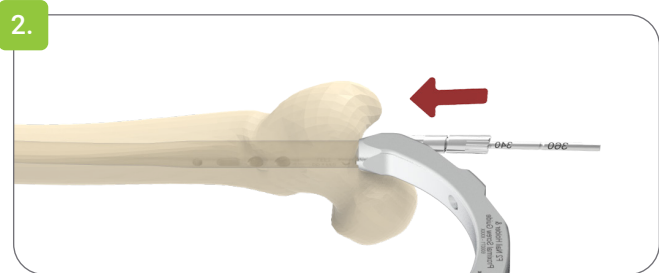
Nail Insertion

1. Insert Nail as per relevant Surgical Technique.

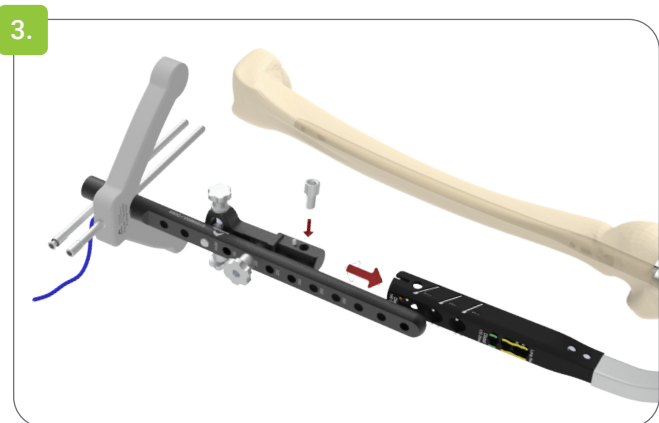
Note: The setup must exclude any other metal objects within 100mm of the area of the distal screws. A traction table is preferred. If this is not used, the limb may need to be lifted up from the operating table when setting the Ezy-aim.



2. Insert Ezy-aim Sensor (610057) until Sensor Stop (610058) engages the Cannulated Nail Holding Screw. The Sensor Stop is kept set to the more proximal distal hole.

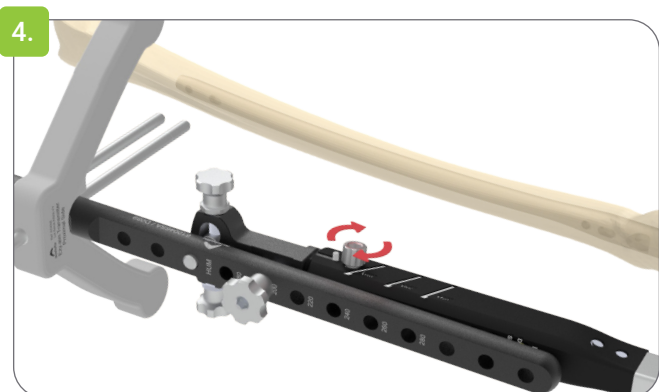


3. Re-attach the assembled DTA and the Ezy-aim Transmitter (610056).



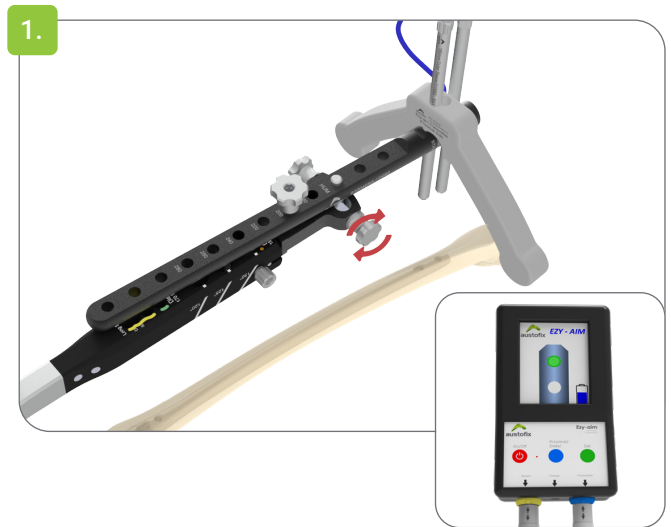
4. Tighten M8 Mounting Screw (632007) until firm. This can be done either by hand or with a 6mm Hex Ball Driver (600045).

Note: Check that no other metal objects are within 100mm of the targeting area. Also check that the Transmitter is free from contact with any other objects which might affect its alignment.



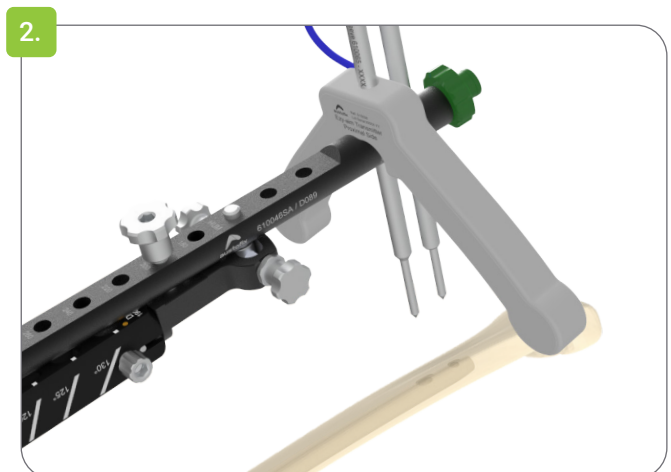
Targeting the most Distal Hole

1. Switch on the Ezy-aim Control Box (610055). Set proximal/distal display to 'distal'. Turn adjustment knob to realign the Drill Sleeves with the distal nail hole until the dot on the graphic display is centred and turns green. The distal hole of the nail is now aligned with the DTA (610046) and Drill Sleeves.



2. Make a 1cm stab incision and advance the Trocar (610063) through the Inner and Outer Sleeve assembly. Loosen the DTA Locking Sleeve Nut (610046B) allowing the Sleeve assembly and Trocar to advance through the incision to the bone. Lock this position using the Locking Nut on the DTA Locking Sleeve. Recheck alignment on the Ezy-aim graphic display and adjust as necessary.

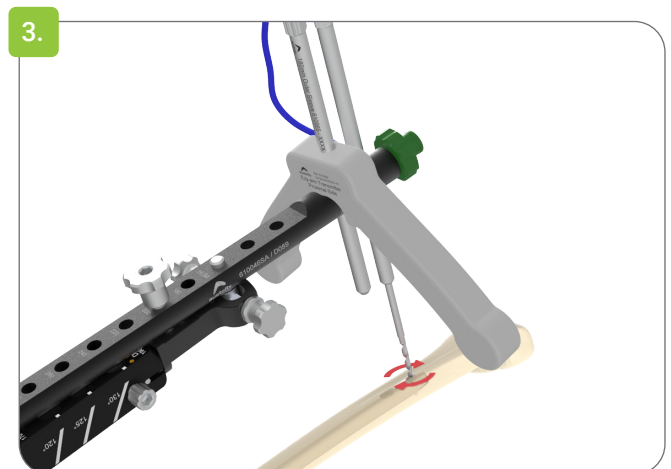
Note: Inadvertent movement of the Locking Knob will affect the alignment. Please check display regularly and adjust as required.



3. The system is now ready for drilling of the distal hole. While drilling the hole, care must be taken to keep the targeting position aligned by maintaining the green dot in the distal hole in the graphic display.

To check that the drill has passed through the Nail correctly, partially withdraw the Ezy-aim Sensor (610057), unlock the Ezy-aim Sensor Length Stop (610058), and advance the Ezy-aim Sensor until it is felt to hit the drill.

Remove the Drill and Drill Sleeves and insert the screw following the relevant Austofix Nail Surgical Technique.



Targeting the More Proximal Hole

If a second fixation screw is needed:

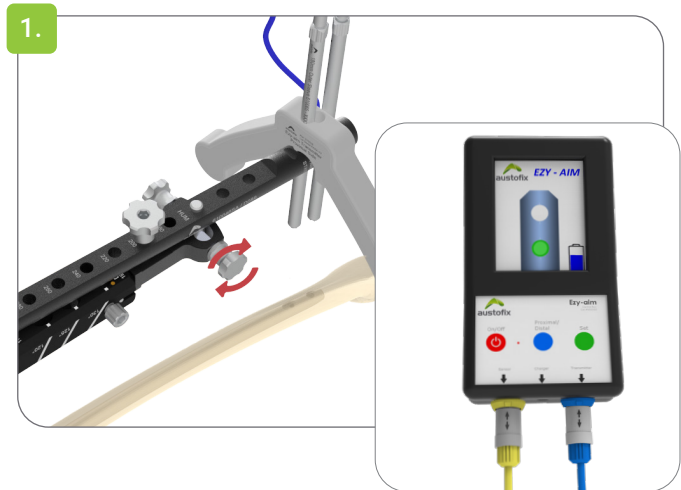
1. Turn on the Ezy-aim Control Box (610055)

Press “Proximal/Distal” on the Ezy-aim Control Box to select the Proximal hole.

Use the Adjustment Knobs to realign the dot on the graphic display until it appears green and centered in Proximal hole. The system is now ready for drilling and screw insertion of the Proximal hole.

While drilling the hole care must be taken to keep the targeting position aligned by maintaining the green dot in the Proximal hole in the graphic display.

Note: To check that the drill has passed through the Nail correctly, partially withdraw the Ezy-aim Sensor, unlock the Ezy-aim Sensor Length Stop (610058), and advance the Ezy-aim Sensor until it is felt to hit the drill. Remove the Drill and Drill Sleeves and insert the screw following the relevant Austofix Nail Surgical Technique.



Final Disassembly

Some operations are performed in reverse as described in the assembly.

1. Remove the Drill from the Sleeve assembly.
2. Remove the Sleeves by loosening the DTA Locking Sleeve (610046B-D or 610046B-S) and unscrew the Drill Sleeve (610064) from the Outer Sleeve (610065).
3. Remove the Ezy-aim Sensor (610057) from the Nail. Then unscrew the Inner and Outer Length Sensor Stop and remove.
4. Detach the Nail from the Nail Holder by unscrewing the Cannulated Nail Holding Screw (600029) with the Cannulated 6mm Hex Ball Driver (600045).
5. Remove the Ezy-aim Transmitter (610056) from the DTA (610046).
6. Unscrew the Locking Knob (610050) on the DTA Holder and remove the DTA.
7. Unscrew the DTA Locking Sleeve (610046B) at the end of the thread for optimal cleaning.
8. Unscrew the M8 Mounting Screw (632007) to remove the DTA Holder from the Nail Holder.

If the Humeral DTA Holder (610105) is being used, unscrew the DTA Holder using 3.5mm Hex Screwdriver (610067).
9. Detach the Ezy-aim Sensor and Ezy-aim Transmitter Plugs from the Ezy-aim Control Box (610055). Pull on the grey part of the plug marked with a double arrow as this releases the lock in the plug.
10. Place the disassembled instruments into their designated places in the Ezy-aim Instrument Tray.

Warning

Do not autoclave the Control Box.

Sterilisation

Perform sterilisation as per “Instructions for Cleaning, Sterilisation, Inspection and Maintenance of Austofix Reusable Instruments”.

Troubleshooting

Setup

- Check the charger plug is not connected.
- Check the battery is charged.
- Check the cables are connected appropriately to the Ezy-aim Control Box (610055).
- Check the Ezy-aim Sensor (610057) is inserted until the Sensor Stop (610058) has engaged.
- Check the 'Proximal' side of the Ezy-aim Transmitter (610056) is placed facing the Nail Holder.
- Check the instruments were assembled correctly.
- Check there were no metal objects close to the Ezy-aim Transmitter when calibrating.

Targeting

- Check the Ezy-aim Control Box is on. To conserve battery power the device automatically switches off when inactive for 30 minutes.
- Check for any metal objects near the Ezy-aim Transmitter.
- To maintain alignment, the Transmitter must be free of contact with other objects such as parts of the operating table or its accessories.
- Check the Ezy-aim Sensor and Sensor Stop are inserted to the correct length for the appropriate hole being targeted.
- Check the 'Proximal' side of the Ezy-aim Transmitter is placed facing the Nail Holder.
- Once calibration has been set ensure that the 'Set' button is not pressed during the procedure.

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.

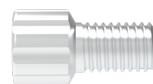
Gill A, Shellock FG. Assessment of MRI issues at 3-Tesla for metallic surgical implants: findings applied to 61 additional skin closure staples and vessel ligation clips. J Cardiovasc Magn Reson. 2012, 14(1):3.

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.

Product Codes

M8 Mounting Screw 632007



F1 DTA Holder 610045



F2, F3, UTN & S2 DTA Holder 610061



Humeral DTA Holder 610105



Distal Targeting Arm (DTA) 610046A



Dymanic DTA Locking Sleeve 610046B-D



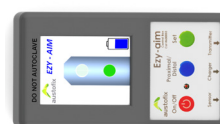
Static DTA Locking Sleeve 610046B-S



Locking Knob 610050



Ezy-Aim Control Box 610055



Ezy-Aim Transmitter 610056



Ezy-Aim Sensor 610057

Ezy-Aim Small Sensor 610059



Ezy-Aim Sensor Length Stop Inner 610058A

Ezy-Aim Sensor Length Stop Outer 610058B



Ezy-aim Distal Targeting Tray (Empty) 621100



Notes



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