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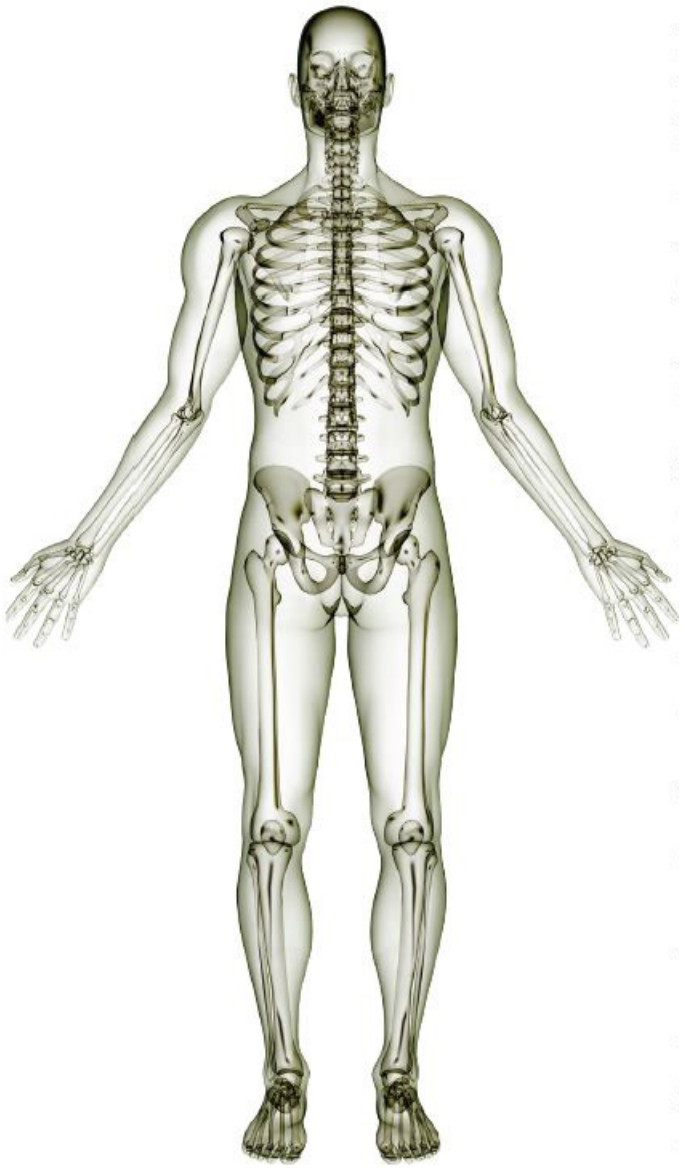
austofix JUNIOR
ELASTIC NAILS

Surgical Technique

Contents



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

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

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

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

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

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

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

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

Disclaimer

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

This document is intended as the recommended procedure for using the 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.

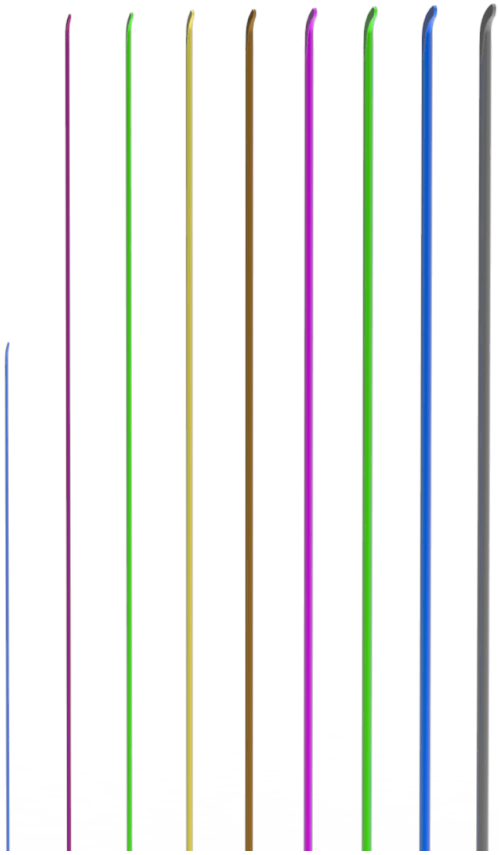
austofix JUNIOR
ELASTIC NAILS

The Austofix JUNIOR Elastic Nail range is designed to fix a wide range of bone fractures in children, where the canal is narrow or the implant needs to be flexible.

The titanium elastic nails 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 JUNIOR Elastic Nails adhere to these principles and will provide the surgeon with a comprehensive paediatric femoral fixation solution.

Nails



End Caps

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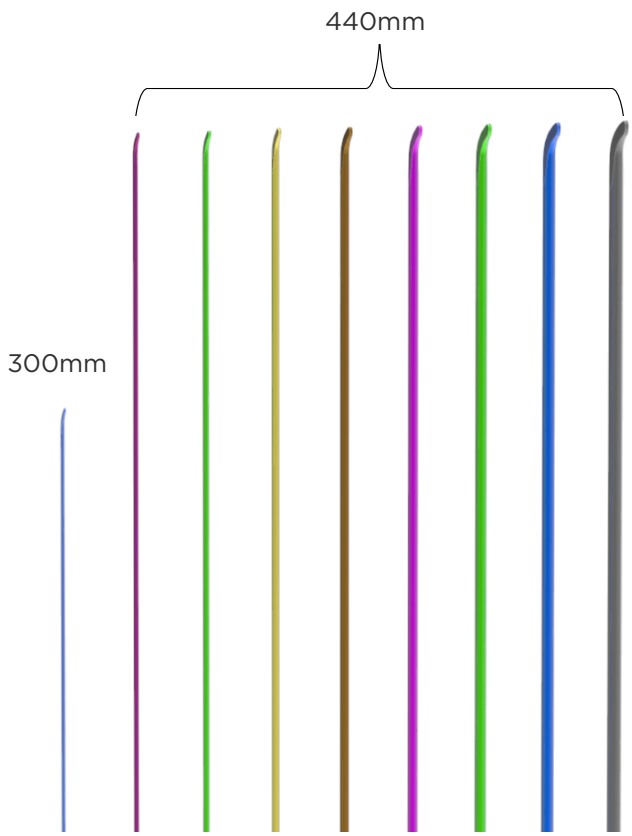
Implant Features

Nails

The JUNIOR Elastic Nail is made with Ti6Al4V ELI to provide better ductility for bending nails to match the anatomy of the patient.



Nail Diameter

A range of options available for nail diameter to encompass multiple bone fractures and patient anatomy.

- Nine diameters, ranging from Ø1.5 mm to Ø5.5 mm with Ø0.5 mm increments

Nail Length

A range of options for nail length is available on request to ensure customizability.

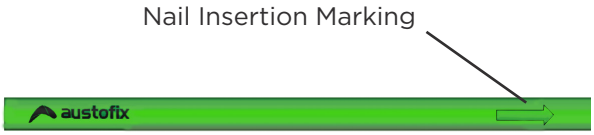
- 300 mm option is compatible with a nail diameter of Ø1.5 mm
- 440 mm option is compatible with a nail diameter of Ø2.0 mm to Ø5.5 mm

Nail Tip

- Facilitates nail insertion and sliding along the medullary canal

Nail Insertion Marking

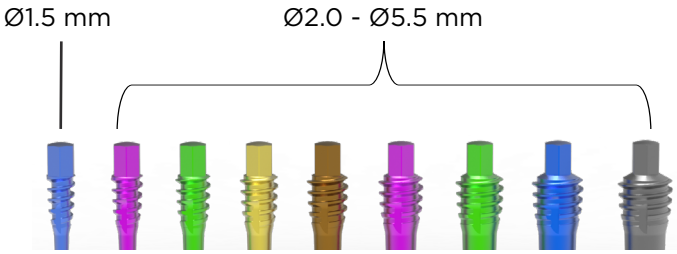
- Allows for direct visual feedback of the insertion and alignment of the nail in the medullary canal



End Caps

End Caps

- Nine end caps are available for each nail size to ensure perfect-fitting
- Sharp self-cutting thread for fixation in bone
- Reduces the risk of nail back-out
- Reduces the risk of soft-tissue irritation
- Facilitates implant removal



Nail Features

Materials

- The JUNIOR Elastic Nail is Titanium (Ti6Al4V ELI) with anodized finish
- Laser marking for clear and easy identification of the nail length, diameter as well as its appropriate orientation of the nail in the intramedullary canal

Diameters

- Austofix provides extensive range of nail diameters for optimal patient treatment
- Diameters: Ø1.5mm with 300mm nail length
- Diameters: Ø2.0; Ø2.5; Ø3.0; Ø3.5; Ø4.0; Ø4.5; Ø5.0; Ø5.5 mm with 440mm nail length

Curved Tip

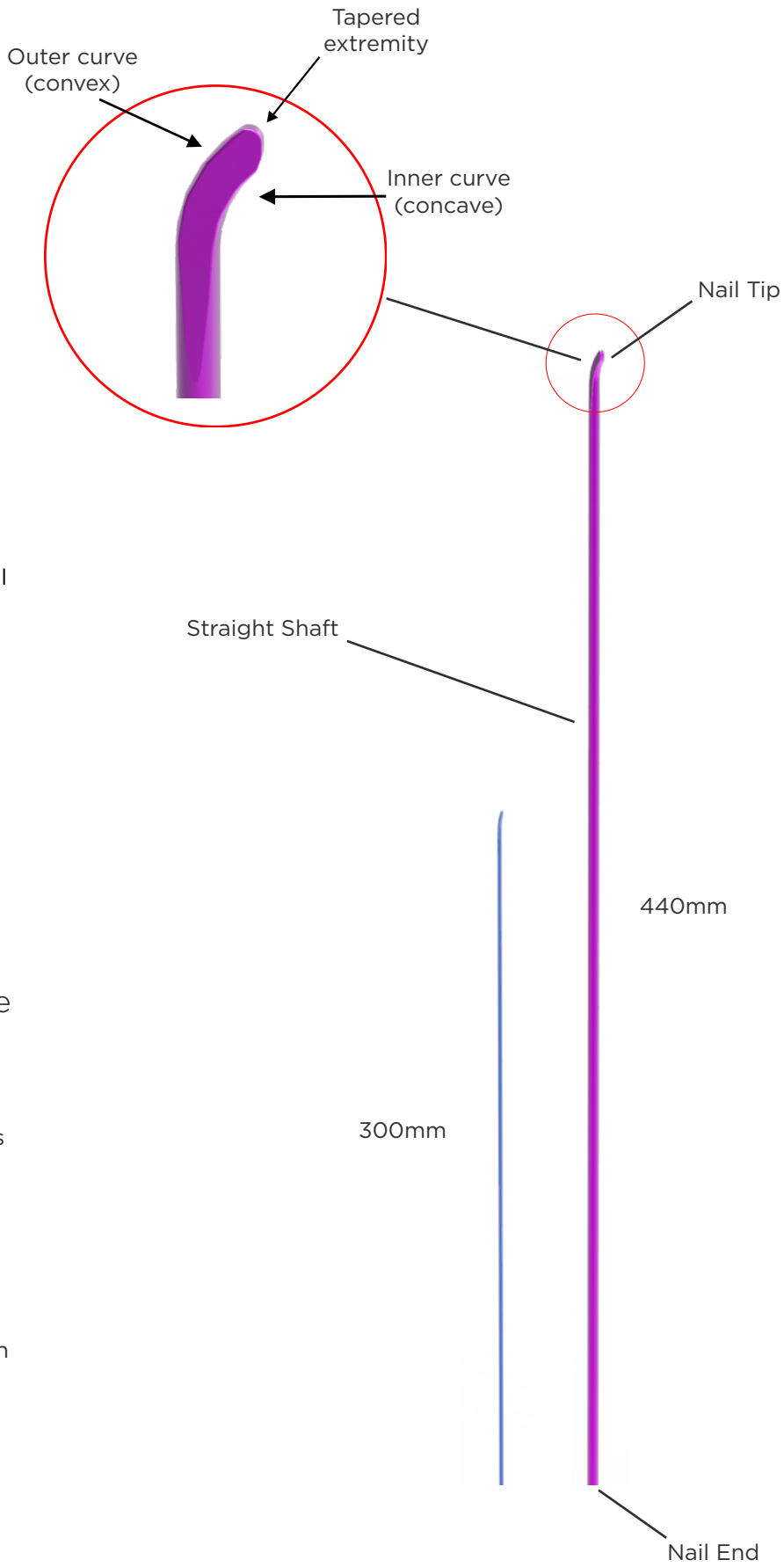
- Curved nail tip with optimized length ensures maximal guidance without hindering the pathway of intramedullary canal

Tapered Tip and Concave Side

- Tapered tip of the nail allows for facilitated insertion and fracture reduction
- Concave (inner) side of the nail tip is for anchoring in metaphyseal bone and capturing fracture fragments

Convex Side

- Convex (outer) side of the nail improves gliding during nail insertion into intramedullary canal and helps prevent second cortex penetration



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Indications & Contraindications

Austofix JUNIOR Elastic Nail range is indicated for the management of diaphyseal and certain metaphyseal fractures of long bones in children as well as in adults.

Paediatric and Adolescent Patients

- Diaphyseal fractures of long bones
- Certain metaphyseal fractures of humerus
- Complex clavicular fractures (significant dislocation)
- Bone shortening, “floating shoulder,” exceeding 2cm
- Multiple Fractures

Adult Patients

- Clavicular Shaft fractures
- Upper extremity shaft fractures

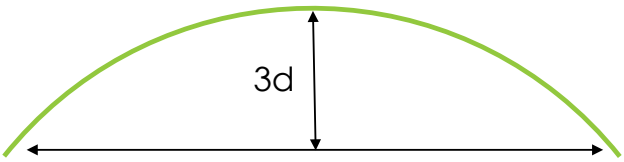
Contraindications

- Low or inadequate bone quality,
- Allergic reactions to implant material
- Acute localized inflammation
- Insufficient blood flow
- Physical or mental inconsistencies
- Instruments should not be used for anything other than their intended use.

Biomechanical Principle of Elastic Stable Intramedullary Nailing (ESIN)

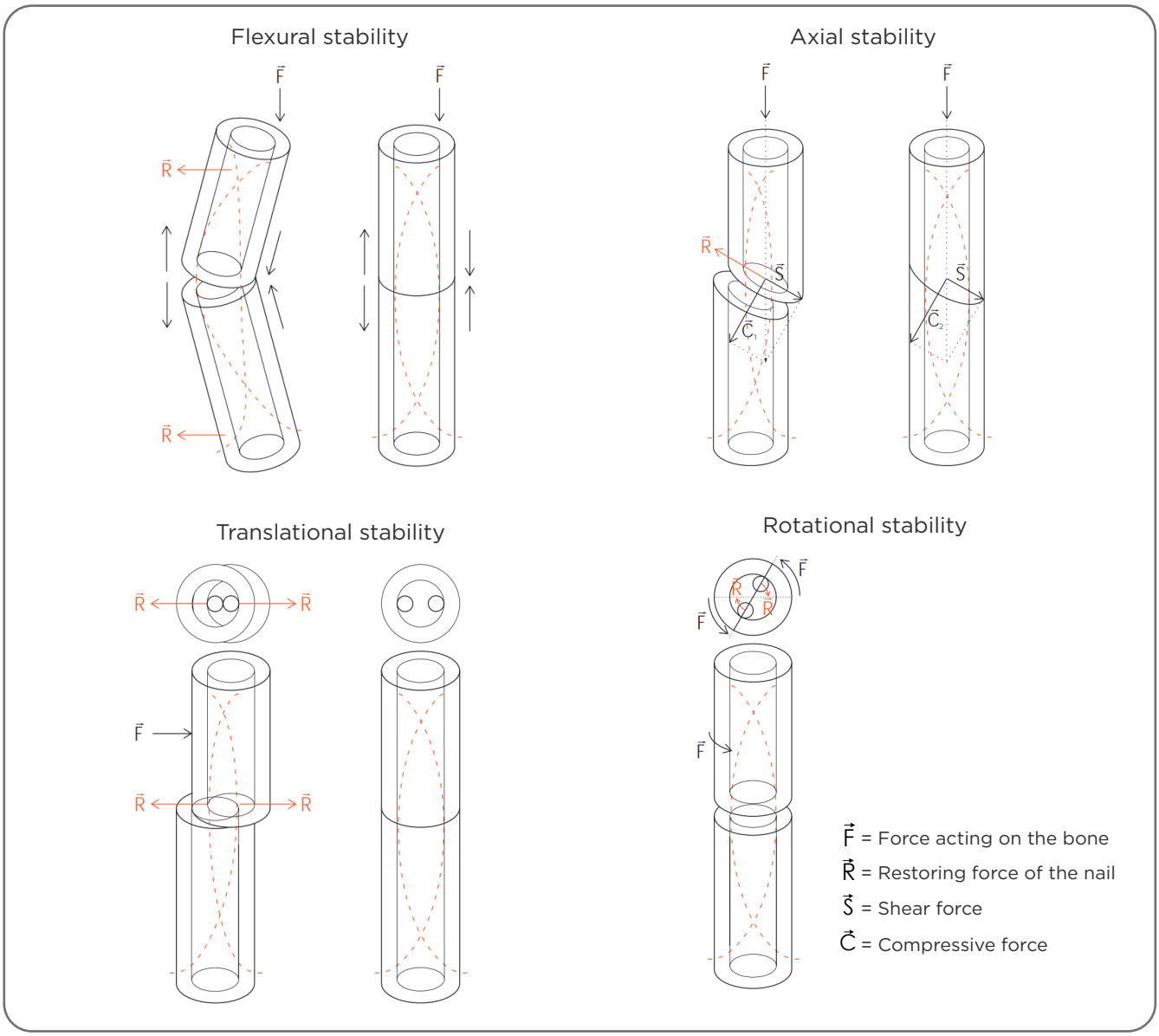
Nail Bending

The biomechanical principle of ESIN is based on the symmetrical bracing action of elastic flexible nails that are inserted into the medullary canal, where each nail is inserted to achieve 3-point fixation of the bone. To achieve this fixation, the nails are pre-bent to three times the diameter of the isthmus with maximum bend at the level of the fracture.



Such bending produces the following biomechanical properties shown below: flexural stability, axial stability, translational stability, and rotational stability.

Note: In the majority of cases, two nails are used, identically pre-curved and inserted opposite each other to produce a perfectly balanced construct that maintains alignment.



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Biological Principle of Elastic Stable Intramedullary Nailing (ESIN)

Bone Healing

ESIN is a minimally invasive technique for paediatric fractures with the aim to achieve rapid bone healing by approximating the physiological healing process of bone without opening the fracture site.

In children, osteoblasts in the inner cellular layer of periosteum are able to build new bone more rapidly. With age, the layer of periosteum becomes thinner; thus the bone-healing process is prolong in line with the patient's age.

The ESIN technique ensures the preservation of periosteum, allowing for rapid bone healing in children.

Double-Frame Model

The principle of the ESIN technique can be described by the double-frame model that highlights the importance of two frames in function to provide sufficient stability and reduce and maintain fracture reduction.

The inner frame consists of the medullary canal containing the elastic nails and the bone, and outer frame consists of muscles on the anterior/posterior, medial/lateral sides.

Exceptions

Due to missing outer frame, and the muscle coverage on both the medial and lateral sides of tibia, the application of ESIN is more demanding.

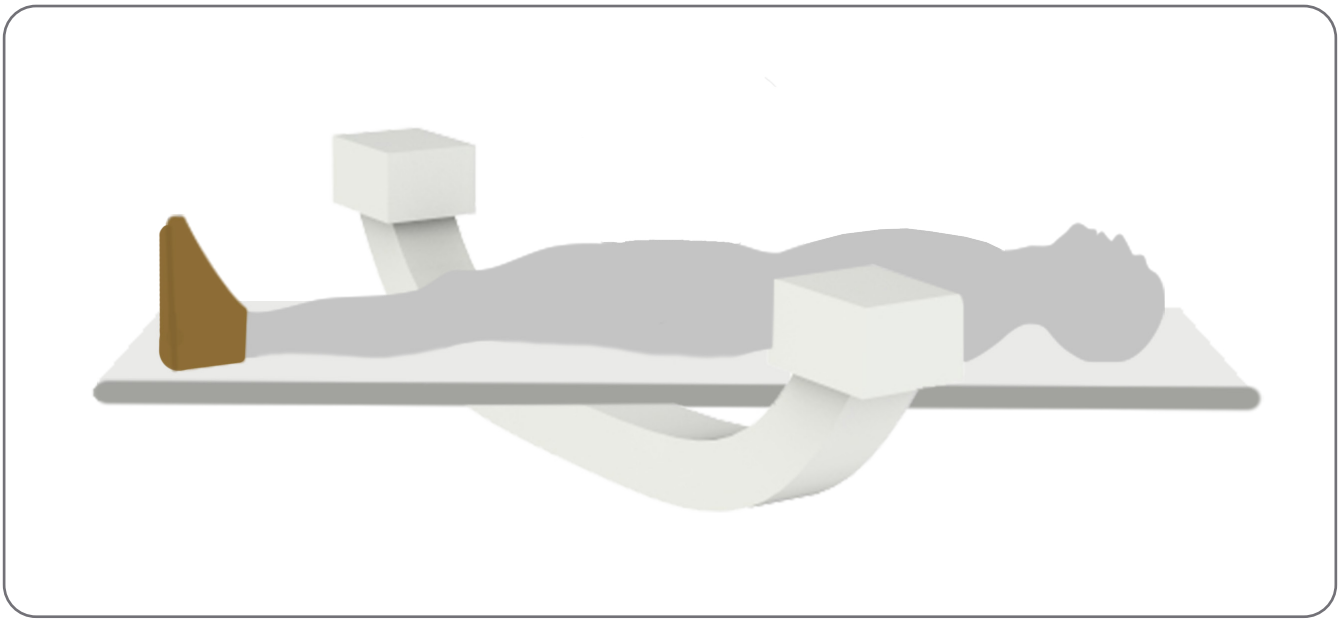
There is no standard ESIN technique for clavicle fractures due to the specificity of the anatomical features of the clavicle.

Surgical Technique (Femur - paediatrics only)

Patient Positioning

Place the patient in a supine position on a radio-translucent operating table or on a traction using traction boot. Although any standard femoral nailing position can be applied, the Austofix Instrument have been developed using the supine position with traction applied by the boot or distal femoral pin. This position is useful for checking the entry hole for the nail. Also, free positioning allows better control of the nail position and rotation.

Position the image intensifier so that AP and lateral x-rays can be recorded the full length of the femur.



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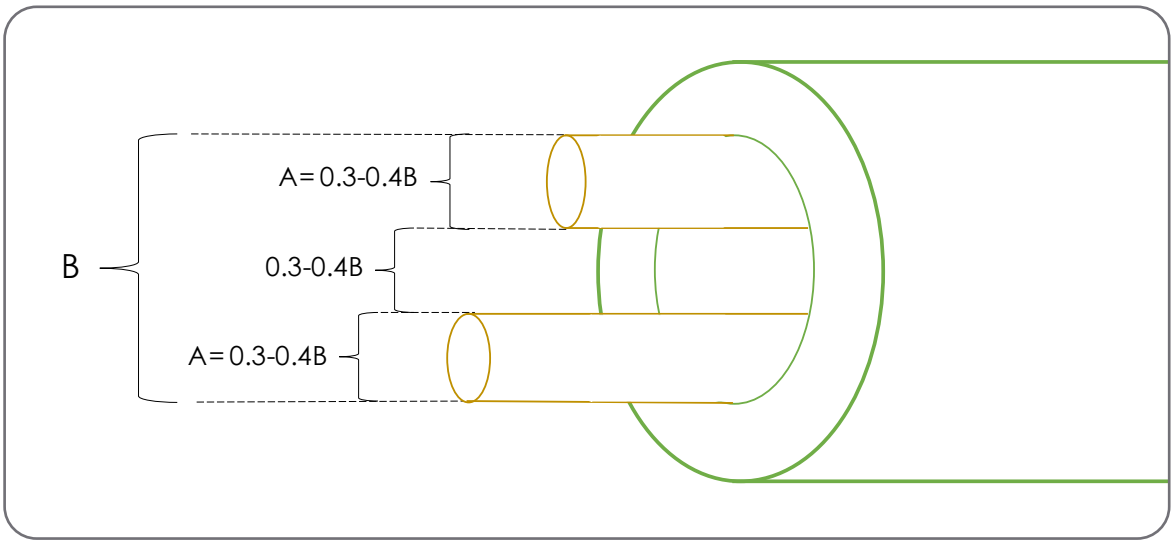
Nail Diameter Determination

Determine the diameter of the nail by measuring the isthmus of the medullary canal on the x-ray image. The diameter of individual nail (A) should be 30-40% of the narrowest diameter of the medullary canal (B).



Select two nails with identical diameter and corresponding end caps noted by the same colour.

Such selection is to ensure that the opposing bending forces are equally distributed, avoiding possible malalignment with varus or valgus malpositioning.

The following sizes are typically used as a rough guideline in selecting the most appropriate nail diameter for different age group.

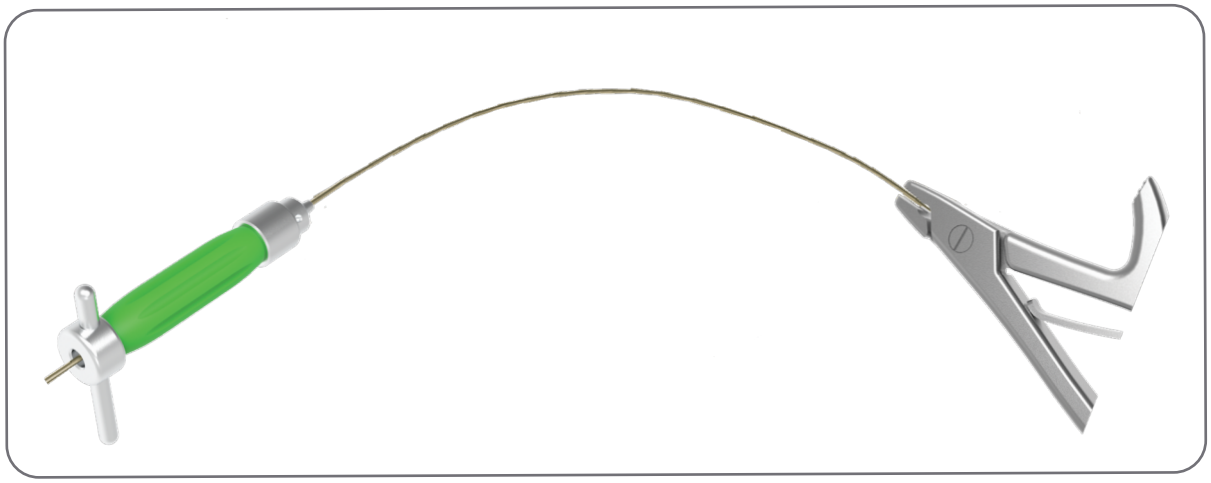
Patient's Age	Nail Diameter (mm)	Colour of Ti version
6 - 8	Ø1.5mm	Yellow Anodize
9 -11	Ø2.0mm	Gold Anodize
12 - 14	Ø2.5mm	Pink Anodize

Pre-bend Nail

Pre-bending the nail is highly recommended to achieve a good three-point contact with the inner side of the cortex. With regard to biomechanical properties, the nail is pre-bent three times the diameter of the medullary canal. The nails can be bent by hand or by using an Introducer Handle with Chuck (640008) and Locking Pliers (640005). In following the latter method, fix the tip of the nail with the introducer, and contour the nail with the locking pliers.

Note: It is important to pre-contour the nail in the plane of the tip. The vertex of the arch should be located at the level of the fracture zone. Both nails should be symmetrically pre-contoured.

Caution: AVOID creating a sharp bend that may reduce the effectiveness of the nail.



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Incision & Bone Preparation

1. Incision and Nail Entry Points

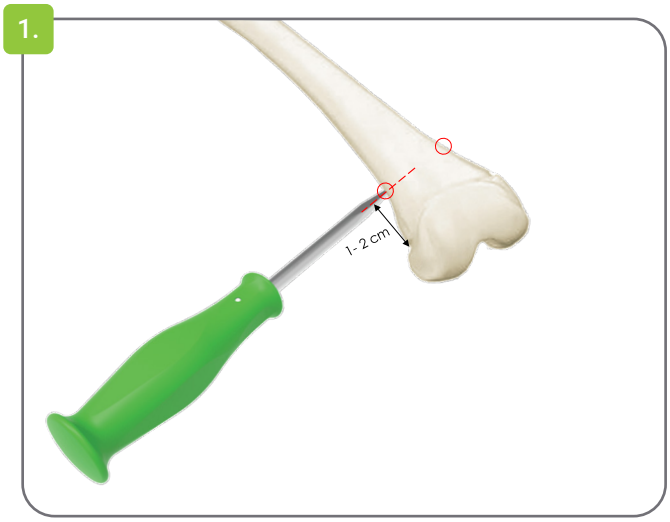
Make an appropriate incision to access the surgical site. This incision is made on the lateral and medial aspects of distal femur.

Use the Straight Awl (640006) to make an entry point into the nearest cortex. The insertion point is recommend to be 1 to 2 cm proximal to the distal physis.

Note: Ensuring the precisely matched openings of medullary canal on both sides is crucial for optimal symmetrical bracing.

Caution: When creating an entry point on the medial side, be careful NOT to let the Awl slip posteriorly in the region of the femoral artery.

1.



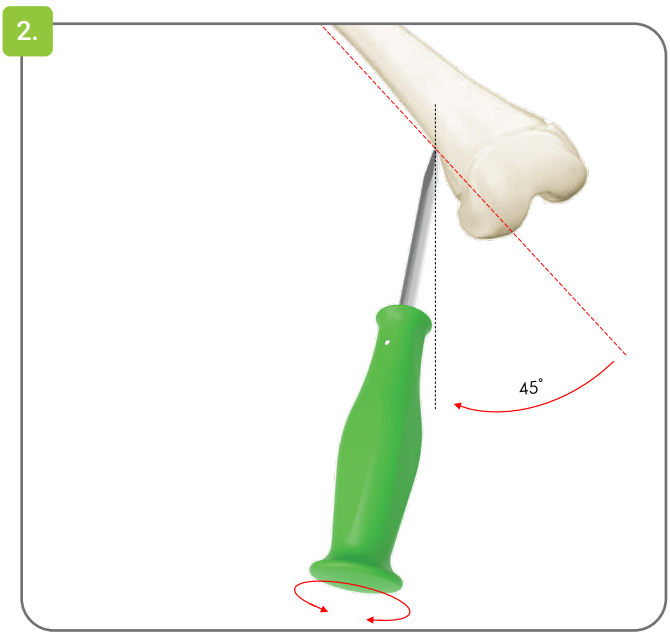
2. Medullary Canal Opening

Insert the Straight Awl at the upper end of the incision perpendicular to the bone. Create a central mark by rotating the awl.

Lower the awl to an angle of 45° in respect to the shaft axis indicated by black dotted line. Continue perforating the bone at an upward angle.

Note: The opening at the bone should be slightly larger than the selected nail diameter. When using the end caps, make sure that the holes correspond to the core-diameter of the end cap.

2.



3a. Nail Insertion

Ensure the appropriate Elastic Nail size has been selected according to pre-operative measure and assessment. Load the first nail in the Introducer Handle with Chuck (640008) by aligning the laser marking on the nail end with the guide marking on the introducer.

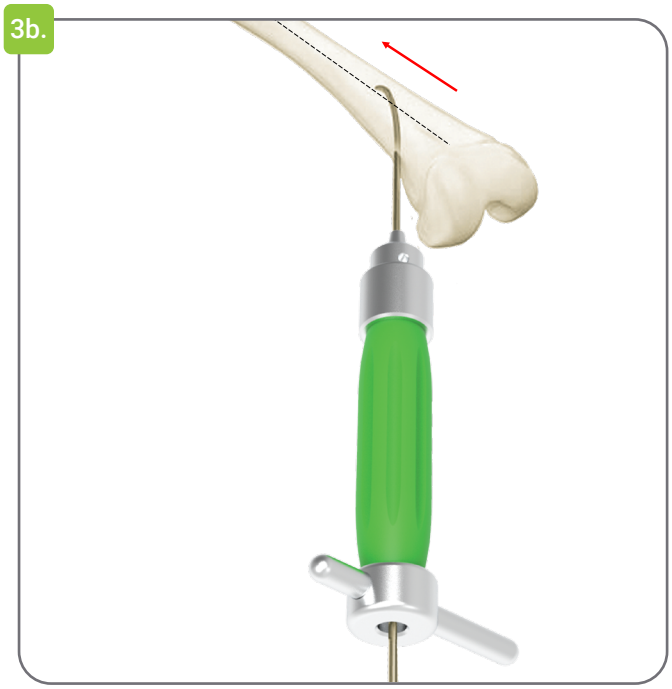
Insert the nail into the medullary canal using the Introducer with the nail tip at right angles to the bone shaft. Once the insertion has been made, rotate the nail about 180° with the Introducer

3a.

3b. Nail Alignment

While rotating about 180° with the Introducer, make sure that the nail tip is aligned with the axis of the medullary canal. The laser marking on the end of nail indicates the nail tip alignment. This facilitates nail insertion, helps reduce x-ray exposure frequency, and prevents excessive crossover with the nails.

Note: If necessary, check the nail tip position when inserted under the image intensifier.



4. Nail Advancement

Once the nail has been positioned correctly along the axis of medullary canal, advance the nail manually up to the fracture site by following methods:

- Create oscillating movements with the Introducer
- Apply gentle taps onto the impaction surface of the introducer using the Combined Hammer (640013). For facilitation, insert the Hammer Guide (640012) firmly into the Introducer

Note: Ensure to drive the first nail to the level of the fracture, and that the convex side of the nail slides along the inner side of the cortex. If necessary, monitor the advancement of the nail under the image intensifier.

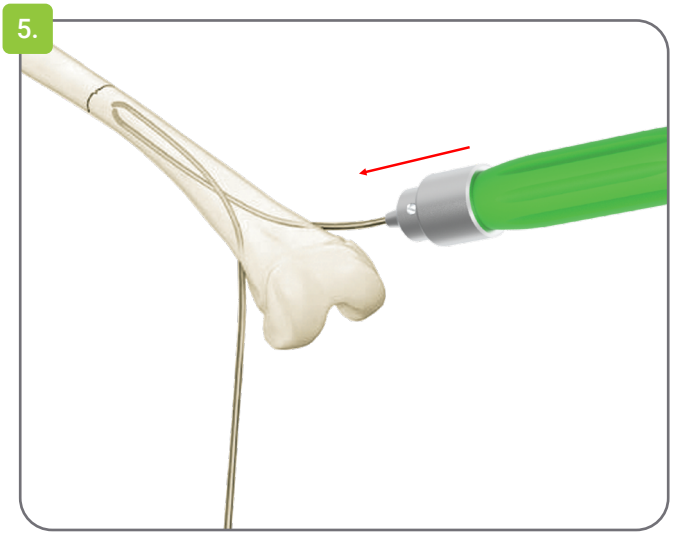
Caution: AVOID striking the arms of the Introducer directly as it may result in damage to the Introducer.

5. Second Nail Insertion

Repeat steps 1 through 5 to insert the second nail on the opposite side. Create an entry point on the medullary canal and pre-bend the nail of identical diameter in the same manner. The two nails should diverge in opposite directions for rotational stability.

Note: Consider the following options in a case of limited advancement of nail with repetitive hammer strikes:

- Ensure that the nail is properly oriented and aligned
- Increase the bending of the anterior side of the nail
- Advance the first nail across the fracture site to stabilize the proximal fragment

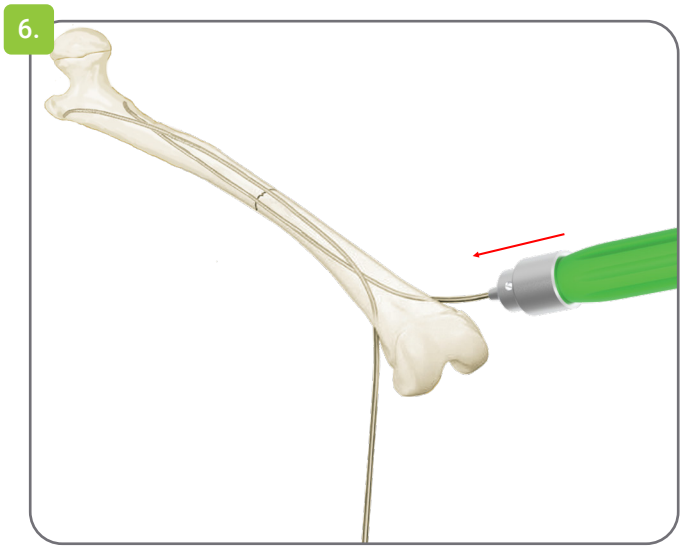


6. Crossing the Fracture

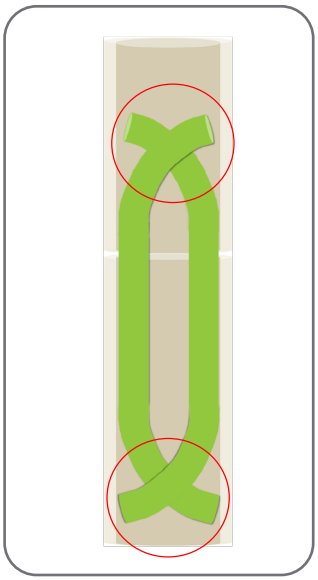
Once the nails have been inserted and aligned correctly, advance each nail alternately by gently tapping the impaction site of the Introducer or oscillating far enough across the fracture site. Make sure that the main fragments are held firmly. Following this, advance the nails as far as the metaphysis.

Note: Check the stability and rotation of the fragments. Once the nails are fixed in and placed in the metaphysis, it should no longer be possible to adjust the rotation.

Caution: Ensure that the second nail is either in front (or behind) the first nail both distally and proximally. DO NOT rotate the nail more than 180° about its own axis. This will result in "corkscrew effect," which is more than two nail crossover points.



Corkscrew Effect



7. Cutting the Nails to Length

Shorten the nails to the required length with the Cannulated Cutter if the nail tips in the proximal fragment are correctly located.

The Cannulated Cutter Base (640004) and Cannulated Cutter Handle (640003) can be assembled to cut the nails in close proximity to the bone cortex.

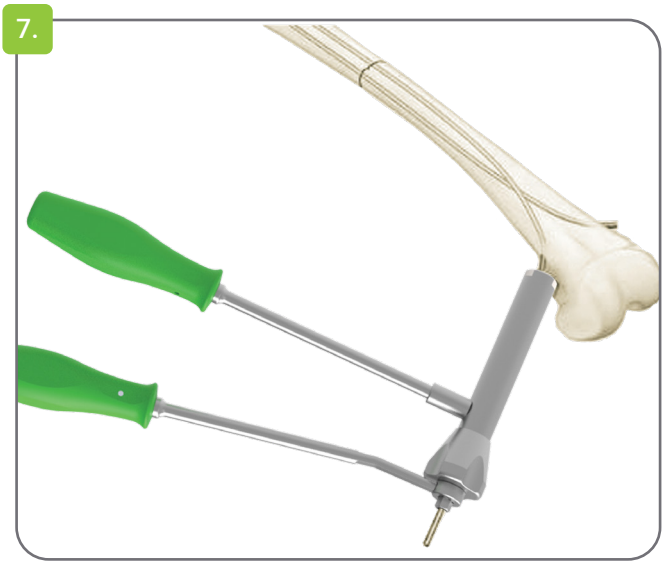
To perform the cut, move the handles toward each other in one fluid motion. The point at which the nail is cut is indicated by a black ring on the Cannulated Cutter Base.

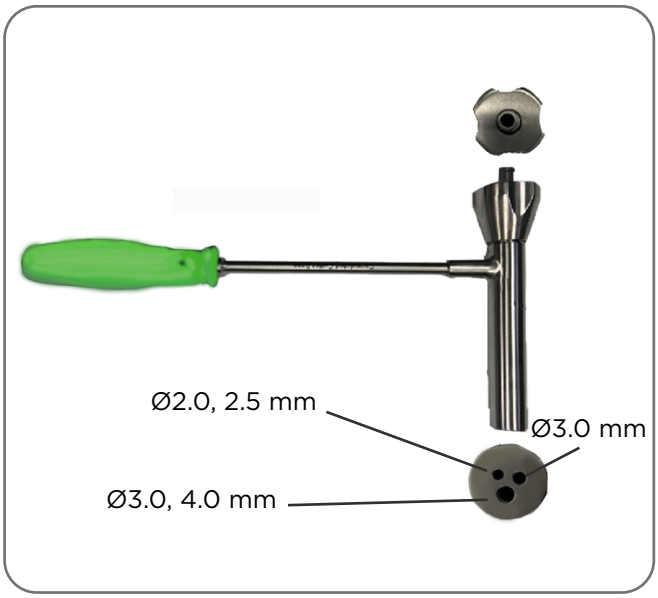
Note: If the end caps for nails with diameter of Ø3.0, 3.5, 4.0 are used, use the Bevelled Impactor (640011) to ensure that the nail end lengths protruding from the cortex does not exceed 10 mm.

Caution: Exceptionally long nail ends can result in pseudo bursa formation, and hinders free-flexion of the knee. Also, they may cause skin perforation, possibly causing infection.

When using the elastic nail end cap, the nail end must NOT be bent away from the cortex

7.





8. Nail Positioning

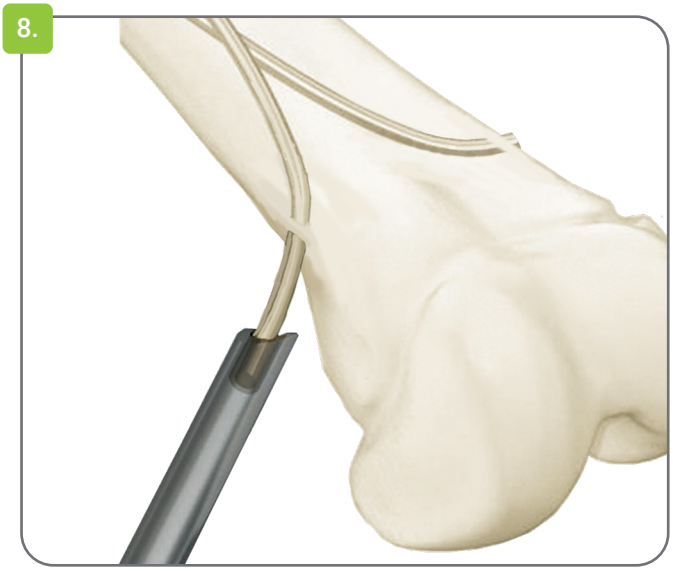
Once the nails have been positioned correctly inside of the canal, and their lengths have been finalized, use the Bevelled Impactor to guide the nails into their planned anchorage position in the proximal metaphysis.

During this process, the bevelled side of the Impactor must reach the cortical bone. This ensures a protection of about 8 - 10 mm.

Note: If the nails are over-inserted into the bone, use the Locking Pliers (640005) to retract the nails. To facilitate the extraction of the nails, bend the remaining tip of the nails.

Note: If end caps are used, use the Bevelled Impactor to ensure that the protruding length of the nail end is correct.

8.



9. End Caps Insertion

Use the End Cap Introducer (640009) to insert the correct end cap that corresponds to the diameter of the nails. The end cap is inserted over the correctly cut end of the nail and threaded into the metaphysis obliquely.

Mount the end cap by inserting the 'Hexagonal' end into the end of the Introducer's shaft.

Note: The dimension of the 'Hexagonal' end is universal for all end caps.

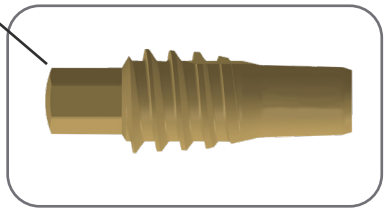
Place the end cap over the nail end and thread it clockwise into the entry site of the bone. The End Cap has a self tapping thread that allows it to be inserted directly into the bone.

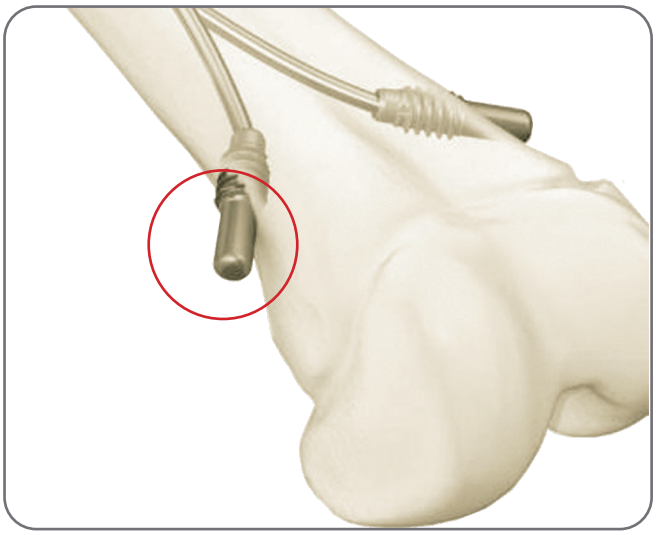
Note: The threaded portion of the end cap directed toward the bone must be fully inserted.

The usage of end caps indicate the instability of the fractures, e.g. long oblique, spiral, and comminuted fractures.

9.

"Hexagonal" end





Post-Operative Care

The expected anatomical reduction of a child can be observed by post-operative radiographic images. The nails should be placed correctly with distal and proximal anchorage.

Depending on the age of the child, either the immediate passive motion by a physiotherapist or continuous passive motion (CPM) should be initiated on the first day after the operation.

The first clinical and x-ray checks are usually performed with in 4-5 weeks of post-operative period. Weight-bearing may begin once the patients regain their quadriceps function. The full weight-bearing may be started depending on the callus formation.

Note: It usually takes approximately four weeks to be able to straight leg raise.

Normal activities and school sports are recommended to be resumed after 6 - 8 weeks.

Once the bone healing is controlled after 4 - 6 months, nails can be removed within 6 - 8 months.

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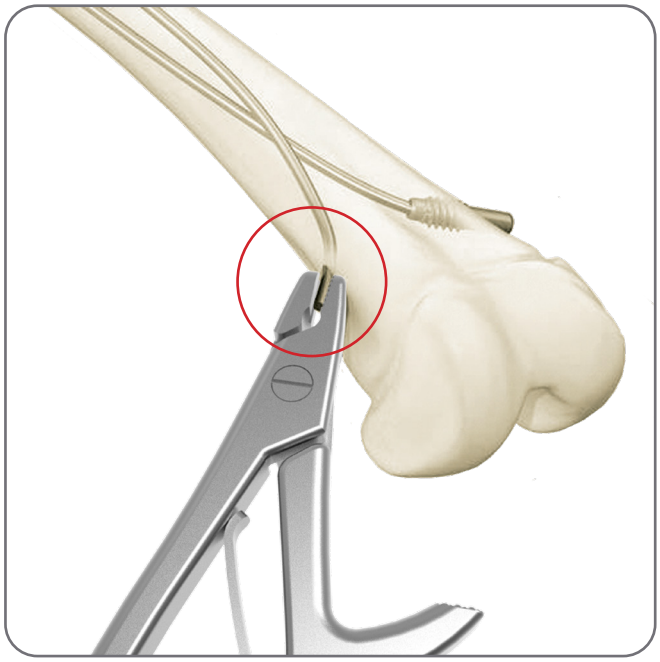
Implants Removal

1. Make an appropriate incision to access the End Cap. The end cap should be cleaned with a curette
2. Use the same End Cap Introducer (640009) that was used in insertion of the end cap to remove the End Cap by mounting the 'Hexagonal" end of the end cap into the Introducer.
3. Once the end caps are properly mounted onto the introducer, thread it counter-clockwise, away from the bone entry site.
4. Once the end caps have been removed, use the Locking Pliers (640005) to first, bend the ends of the nails so that they are offset from formed callus. Next, firmly hold the nails and gently pull along the axis of the canal, away from the bone.

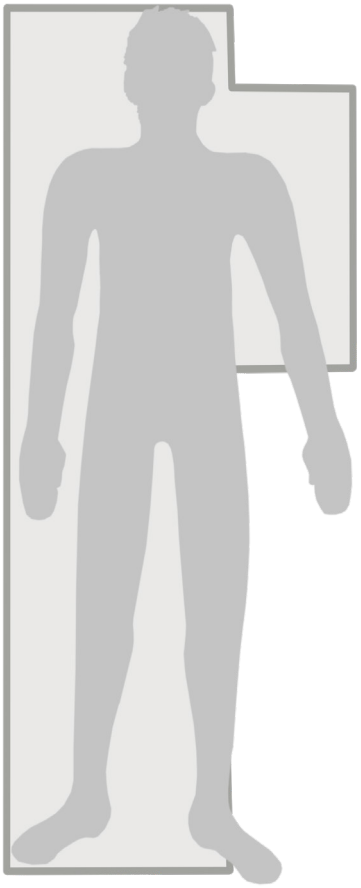


Surgical Technique (Humerus)

Patient Positioning

Place the patient in a supine position on the operating table with the shoulder and arm lying on a radio-translucent board. This position is useful for checking the entry hole for the nail.

Position the image intensifier so that AP and lateral x-rays can be recorded the full length of the femur.



Nail Diameter Determination

The nail diameter determination procedure is identical to that described in technique for femoral fractures (see page 11).

Pre-bend Nail

Pre-bending nail technique for all unilateral nail insertions is identical to that described in technique for femoral fractures (see page 12).

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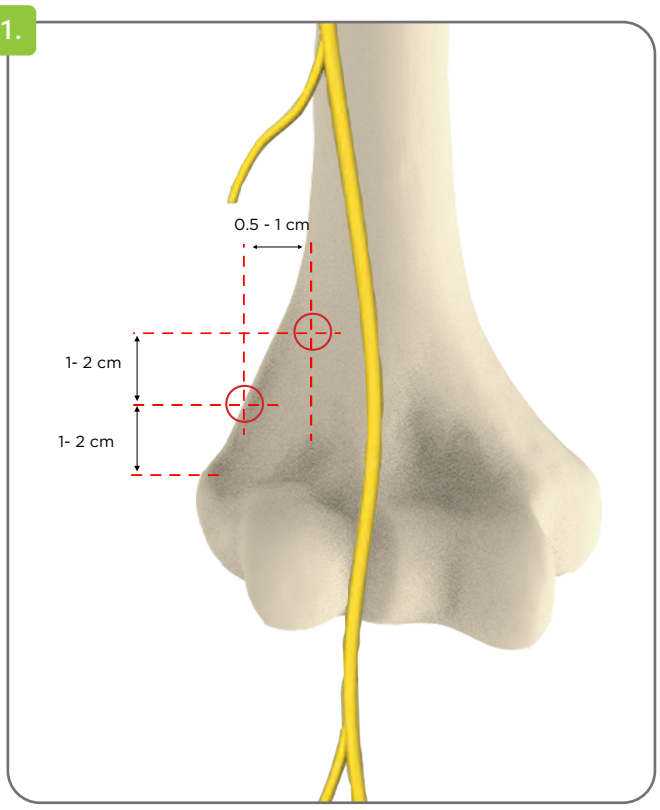
1. Incision and Nail Entry Points

Make an appropriate incision to access the surgical site by using the Straight Awl (640006), as mentioned previously at the nearest cortex.

The insertion point is recommend to be 0.5 -1 cm above the palpable prominence of the lateral epicondyle and progresses, and 3-4 cm proximally up the lateral side of the humerus.

Note: It is recommend to prepare the ventral aspect of the distal, and lateral humerus to visualize the bone and the entry points.

1.



2. Nail Insertion

The preparation of nail insertion is identical to that of the technique used in femoral fractures.

The nail insertion points are located on the supracondylar lateral ventral aspect, outside the capsule.

Note: It is recommend to prepare the ventral aspect of the distal, and lateral humerus to visualize the bone and the entry points.

Caution: When creating an entry point on the medial side, be aware of the position of the radial nerve in relation to the fracture.

Use the same End Cap Introducer (640009) from the femoral technique to insert the end caps that corresponds to the diameter of the nails.

2.

Surgical Technique (Clavicle)

Patient Positioning

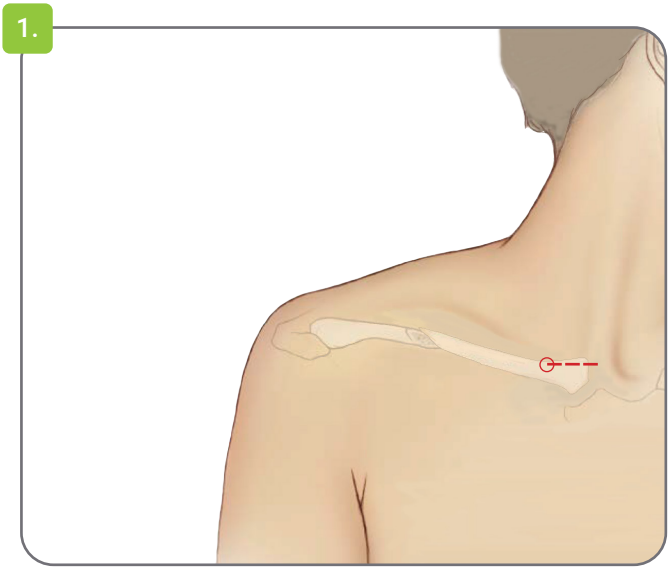
A beach-chair or supine position is recommended with the head of the patient facing away from the operating side, providing access to the clavicle. Support should be placed between the scapulae to allow retraction of the shoulders. Avoid prolonged and excessive extension of the neck.

1. Incision

The standard location for incision lies horizontally over the superior or inferior clavicle as per the stabilisation required.

Create a 1 - 1.5 cm long incision along the anatomical skin-line of the medial clavicle end using a scalpel.

1.



2. Nail Insertion

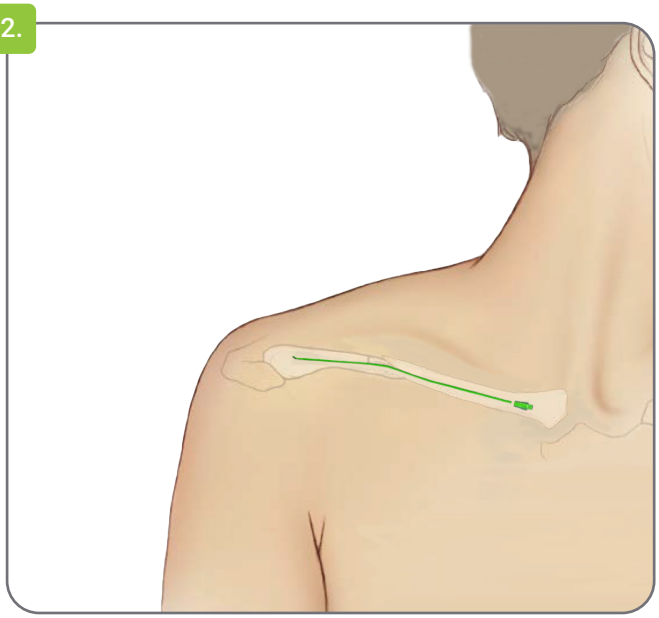
Usually only one nail is inserted through the medial side of the clavicle, where the incision was made, and towards the lateral side.

The nail entry is 1 -2 cm distal to the sterno-clavicular joint in the centre of the proximal clavicle in the anterior quadrant.

Note: The insertion through medial side of the clavicle allows better identification and easier handling compared to that of lateral approach. This method also minimizes the risk of damaging the central vessels.

Use the same End Cap Introducer (640009) from the femoral technique to insert the end caps that corresponds to the diameter of the nails.

2.



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Implants

Nails

Elastic Nail			
Product Code	Nail Diameter (mm)	Nail Length (mm)	Colour of Ti version
3158-03-15300	Ø1.5mm	300mm	Blue Anodize
3158-03-20440	Ø2.0mm	440mm	Pink Anodize
3158-03-25440	Ø2.5mm	440mm	Green Anodize
3158-03-30440	Ø3.0mm	440mm	Yellow Anodize
3158-03-35440	Ø3.5mm	440mm	Gold Anodize
3158-03-40440	Ø4.0mm	440mm	Pink Anodize
3158-03-45440	Ø4.5mm	440mm	Green Anodize
3158-03-50440	Ø5.0mm	440mm	Blue Anodize
3158-03-55440	Ø5.5mm	440mm	Grey Anodize

End Caps

End Cap		
Product Code	Diameter	Colour of Ti version
3159-03-00015	Ø1.5mm	Blue Anodize
3159-03-00020	Ø2.0mm	Pink Anodize
3159-03-00025	Ø2.5mm	Green Anodize
3159-03-00030	Ø3.0mm	Yellow Anodize
3159-03-00035	Ø3.5mm	Gold Anodize
3159-03-00040	Ø4.0mm	Pink Anodize
3159-03-00045	Ø4.5mm	Green Anodize
3159-03-00050	Ø5.0mm	Blue Anodize
3159-03-00055	Ø5.5mm	Grey Anodize

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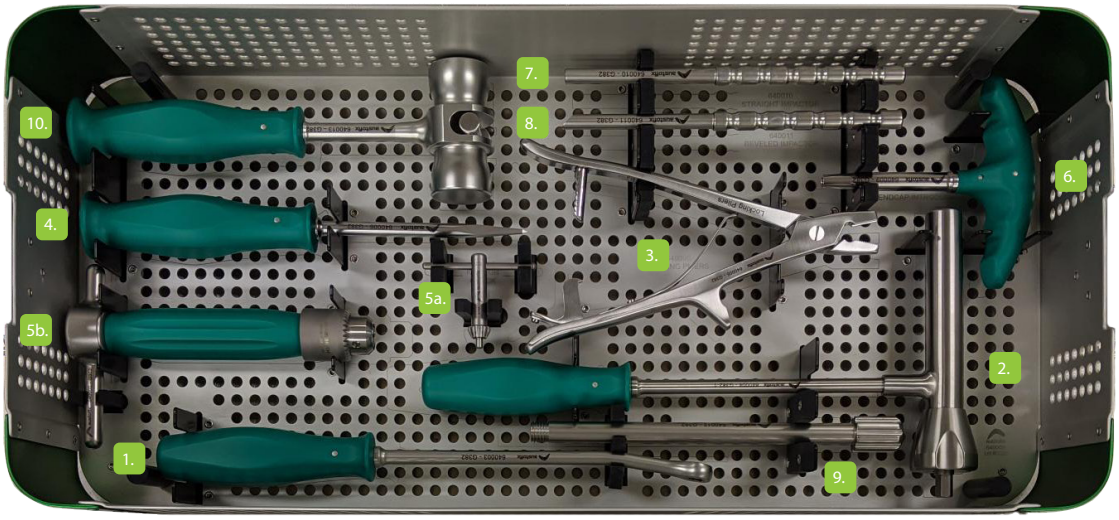
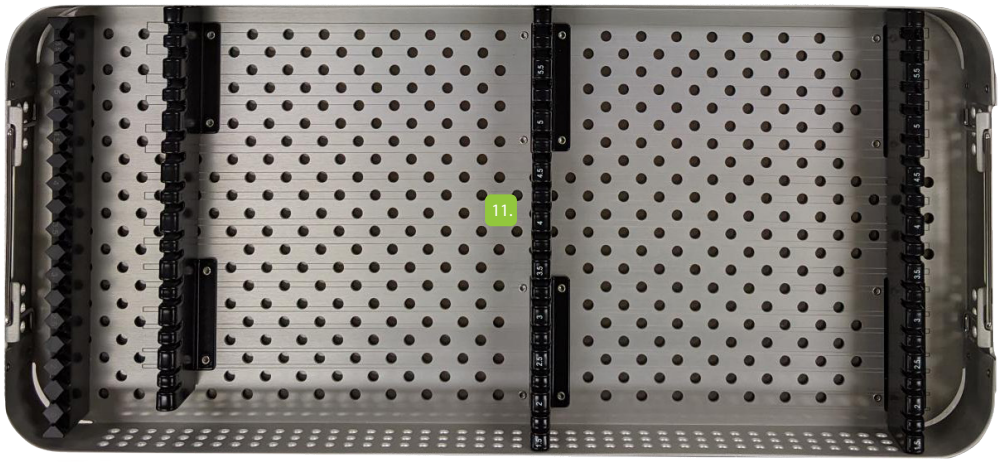
Instruments

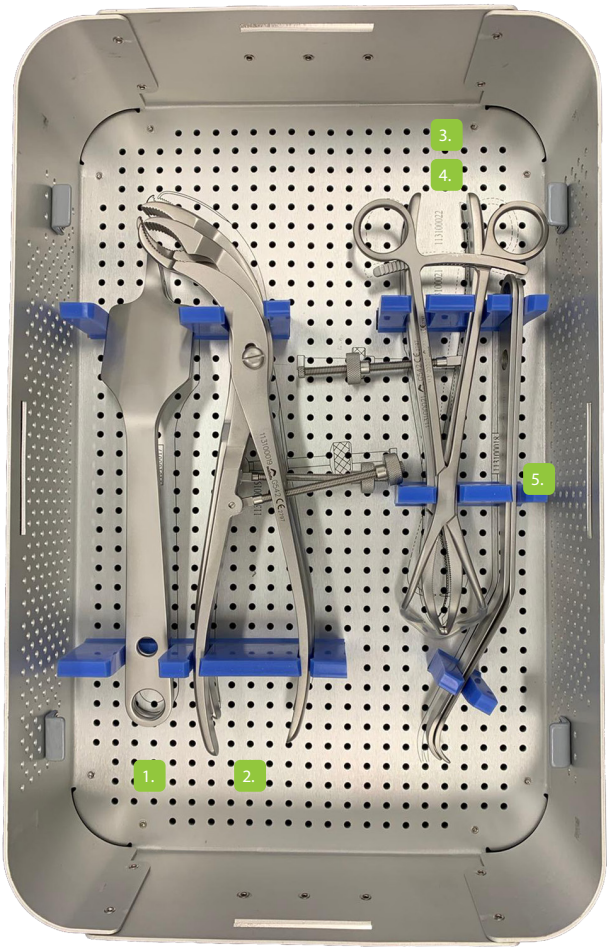




Instruments			
#	Code	Description	Qty
1	640003	Cannulated Cutter Handle	1
2	640004	Cannulated Cutter Base	1
3	640005	Locking Pliers	1
4	640006	Straight Awl	1
5a.	640007	Key For Chuck	1
5b.	640008	Introducer Handle With Chuck	1
6	640009	End cap Introducer	1
7	640010	Straight Impactor	1
8	640011	Bevelled Impactor	1
9	640012	Hammer Guide	1
10	640013	Combined Hammer	1
11	640002	Elastic Nail Instrument & Implants-Case (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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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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