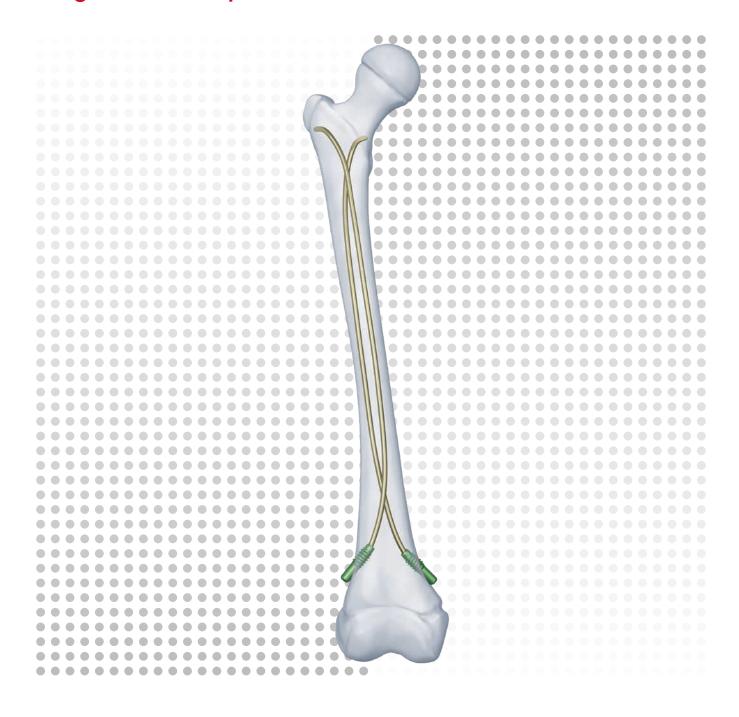
Titanium/Stainless Steel Elastic Nail System

For Elastic Stable Intramedullary Nailing (ESIN)

Surgical Technique









(Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance For general information about reprocessing, care and maintenance of DePuy Synthes reusable devices, instrument trays and cases, as well as processing of DePuy Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to: http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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TEN/STEN System

For Elastic Stable Intramedullary Nailing

Implants For Stable Fixation

Nail diameters

- Six nail diameters
- Available in titanium alloy (Ti-6Al-7Nb) or stainless steel

Nail marking

• Allows visual control of the alignment of the nail tip

TEN end caps

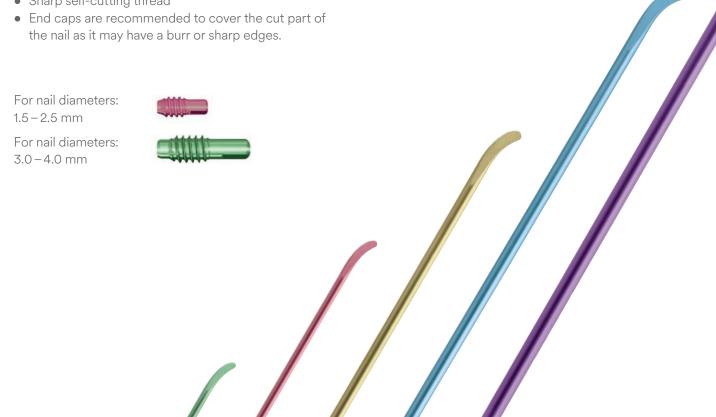
1.5 mm

• Two sizes of end caps to cover the nail diameters

2.5 mm

3.0 mm

• Sharp self-cutting thread



Awl for TEN

• Sharp tips facilitate entry to the medullary canal



Inserter for TEN

Hammer guide allows insertion of nail through the inserter



Extraction pliers for TEN

• Secure grasping hold of the nails with the tip of the pliers

• Hammer guide use facilitates nail extraction



Cutter for TEN

- Allows cutting of the nail
- Can be used close to the skin



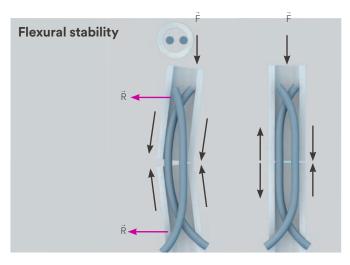
Impactor for TEN

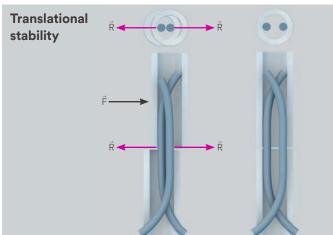
- End placement of elastic nail due to the specific depths of the holes at the tips of the corresponding impactors
- Facilitates positioning and fixation of end caps
- Bevelled (large/small) or straight impactors are available

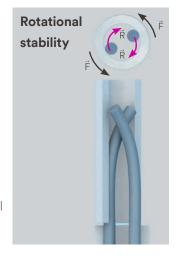
Intended Use, Indications and Contraindications can be found in the corresponding system Instructions for Use.

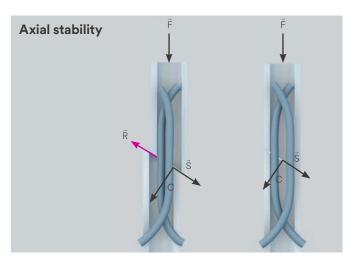
Biomechanical Principle of Elastic Stable Intramedullary Nailing (ESIN)

The elastic flexible nails are bent and inserted into the medullary canal. This elastic deformation within the medullary canal creates a bending moment within the long bone that is not rigid, but that is stable enough to reduce and fix the fracture.









 \vec{F} = force acting on the bone \vec{R} = restoring force of the nail

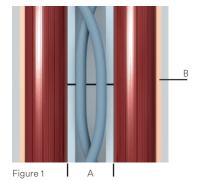
 \ddot{S} = shear force

C = compressive force

Biological Aspects of Elastic Stable Intramedullary Nailing (ESIN)

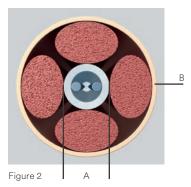
Bone healing

The development of the ESIN technique is based on the aim of achieving bone healing, while taking into account all the child-specific bone-healing properties. In children, osteo-blasts in the inner cellular layer of the thick periosteum are able to build new bone. Later in life, as the periosteum becomes thinner, the bone-healing process is prolonged in line with the patient's age. This method thus preserves the periosteum allowing for bone healing in children.



Double-frame model

The double-frame model illustrates the principle of the ESIN technique. The inner frame consists of the medulary canal containing the elastic flexible nails and the bone (A in fig. 1 and 2), whereas the muscles on the anterior/posterior, medial/lateral sides form the outer frame (B in fig. 1 and 2). Both frames have to be functional in order to provide sufficient stability for reducing and maintaining fracture reduction.



Exceptions

In the tibia, the application of the principle of ESIN is demanding because of the missing outer frame, and muscle coverage on the medial and lateral sides. In the clavicle, the elastic nails are used to treat certain fractures.

Surgical Technique for Standard Indications

The following section describes the principally used surgical techniques. In general, careful preoperative planning, correct choice of implant and a precise rotational check on the basis of the non-operated extremity are all crucial for a successful clinical result.

Femur – Ascending Technique (pediatrics only)

Femoral fractures in children are typically stabilized with two nails of identical diameter, inserted in a retrograde manner from medial and lateral entry points above the distal physis. Antegrade nailing, with a lateral entry point for both nails, is normally reserved for very distal femoral fractures.

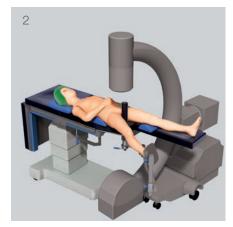
This technique guide describes the common retrograde technique in detail. For femoral fractures in children of average stature, use of 3.0 mm, 3.5 mm or 4.0 mm diameter nails is recommended according to the patient anatomy.

1. Position the patient

Place the child in a supine position on a radiolucent operating table (1). The fracture table (2) can be used for larger children.

Secure small children to the operating table. The assistant extends the injured extremity. Free positioning allows control of the nail position and rotation. Position the image intensifier so that AP and lateral x-rays can be recorded over the full length of the femur.

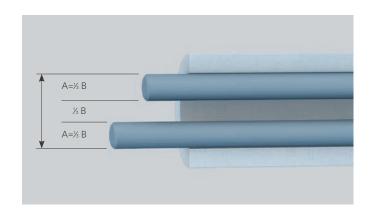




2. Determine the nail diameter

Measure the isthmus of the medullary canal on the x-ray image. The diameter of the individual nail (A) should be 30–40% of the narrowest diameter of the medullary canal (B). Choose nails with identical diameter (indicated by the same color), so that the opposing bending forces are equal, avoiding malalignment with varus or valgus malpositioning.

For femoral nailing of children with average stature, use the following rough guideline for age-matched selection of the nail diameter:

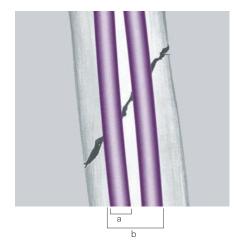


Age (years)	Nail size (mm)
6-8	3.0
9-11	3.5
12-14	4.0



■ Note:

Nail diameter (a) should be no more than 40% of the width of the medullary canal at the narrowest point (b).



3. Pre-bend nail

Instrument

359.219 Inserter for TEN

Regarding the biomechanical properties, a good contact of the nail with the inner side of the cortex is essential. Pre-bending in this case is therefore highly recommended.

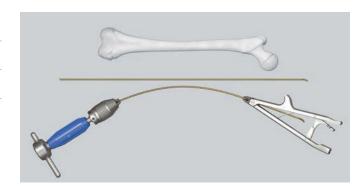
To achieve a three point contact of the elastic nail in the femur, it is recommended to pre-bend the nail over the length of the bone three times the diameter of the medullary canal. The nails can be pre-bent either by hand or using the inserter and pliers. For this fix the tip of the nail in the inserter and contour the nail by hand or with the pliers; it is important to precontour 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 pre-contoured in the same way.

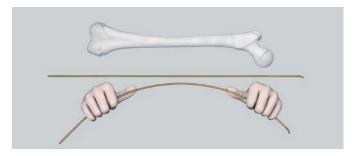


Avoid creating a sharp bend which may reduce the effectiveness of the nail.

■ Note:

A stainless steel elastic nail is approximately twice as rigid as a comparable titanium elastic nail, and therefore care should be taken when contouring and inserting the stainless steel elastic nail.





4. Determine the nail entry point

Incision

Make one incision in each case on the lateral and medial aspects of the distal femur, starting at the planned entry point, and extend distally for 2-4 cm depending on the child's size.

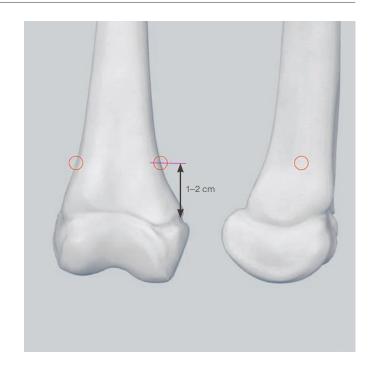
Nail entry points

The insertion points on the femur should be 1 to 2 cm proximal to the distal physis. In children, this is about one fingerbreadth proximal to the upper pole of the patella.

■ Note:

Precisely matched openings of the medullary canal on both sides are essential for optimal symmetrical bracing.

If necessary, check the intended insertion points under the image intensifier.



5. Open medullary canal

Instrument

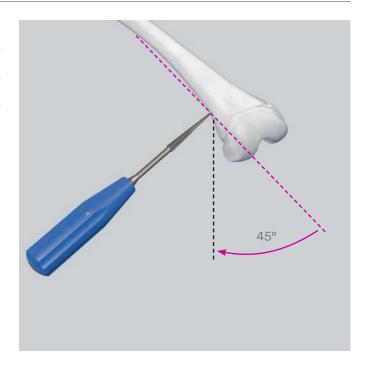
359.213 Awl for TEN

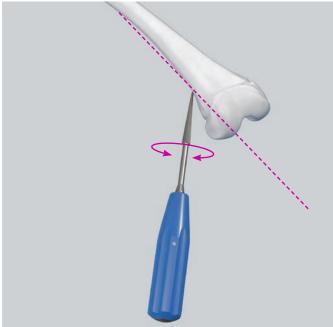
Divide the fascia lata over a sufficient length. Insert the awl at the upper end of the incision perpendicular to the bone. With rotating movements make a central mark.

Lower the awl to an angle of 45° in relation to the shaft axis and continue perforating the bone at an upward angle. The opening should be slightly larger than the selected nail diameter.*

When using end caps for the nails, make sure that the holes correspond to the core-diameter of the end cap.

Check the position and insertion depth of the awl with the image intensifier.





^{*} Identical approach on the medial side.

Alternative technique

Instruments	;
312.460	Double Drill Guide 4.5/3.2
315.280	Drill Bit Ø 2.7 mm, length 125/100 mm, 3-flute, for Quick Coupling
315.290	Drill Bit Ø 3.2 mm, length 195/170 mm, 3-flute, for Quick Coupling
315.480	Drill Bit Ø 4.5 mm, length 195/170 mm, 3-flute, for Quick Coupling

If the cortical bone is very hard, open up the medullary canal with the corresponding drill bit and the double drill guide 4.5/3.2. The drill bit may be lowered by 45° only while the drill is running, otherwise the bit could break.

Check the position and insertion depth of the drill bit un- der the image intensifier.

▲ Precautions:

- When opening the medial side, be careful not to let the drill bit slip posteriorly into the region of the femoral artery.
- The drill must be running when angling the drill bit or drill bit breakage may result

6. Insert the nail

Instruments	
359.219	Inserter for TEN
321.170	Pin Wrench Ø 4.5 mm, length 120 mm
321.250	Spanner Wrench

Load the first nail in the inserter. Align the laser marking on the straight nail end with one of the guide markings on the inserter. Tighten the nail in the inserter in the desired position using the pin wrench or the spanner wrench.

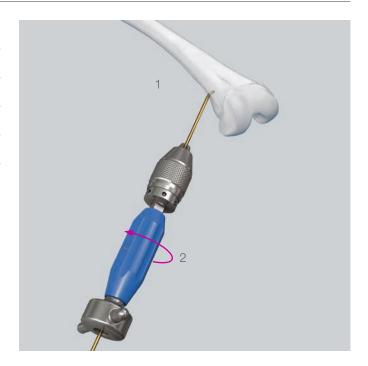
Insert the nail into the medullary canal with the nail tip at right angles to the bone shaft (1). Rotate the nail through 180° (2) with the inserter and align the nail tip with the axis of the medullary canal (3).

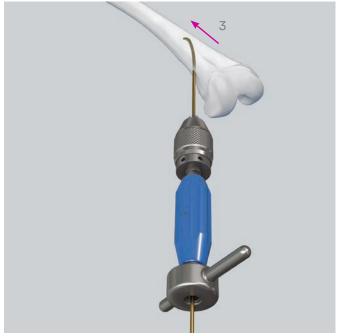
If necessary, check the position of the nail tip under the image intensifier.

The laser marking on the nail end indicates the nail tip alignment. This facilitates nail insertion and the marking supports the user to prevent crossover of the nail.

■ Note:

A stainless steel elastic nail is approximately twice as rigid as a comparable titanium elastic nail, and therefore care should be taken when contouring and inserting the stainless steel elastic nail.





7. Advance the nail

Instruments	
359.219	Inserter for TEN
359.221	Combined Hammer for TEN
359.218	Hammer Guide for TEN
321.170	Pin Wrench Ø 4.5 mm, length 120 mm

Advance the nail manually up to the fracture site, using oscillating movements or with gentle blows to the impaction surface of the inserter using the slotted part of the combined hammer. This step can be facilitated by using of the hammer guide for TEN. Drive the first nail to the level of the fracture.

▲ Precautions:

- Avoid hitting the T-piece of the inserter directly as this may result in damage to the inserter.
- Never rotate the nail more than 180°.
- Monitor the advancement of the nail under the image intensifier. Ensure that the convex side of the nail tip slides along the inner side of the cortex. The nail will bend as it progresses up the canal.



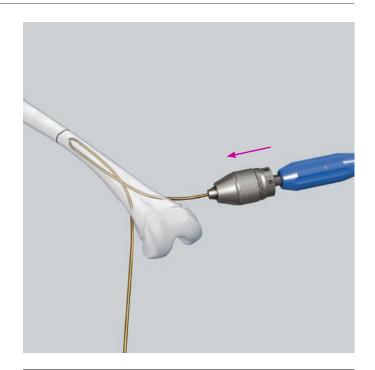
At the insertion point on the opposite side, open the medullary canal in the same manner. Pre-bend a nail of identical diameter (same color) in the same way, insert into the metaphysis and advance up to the fracture zone.

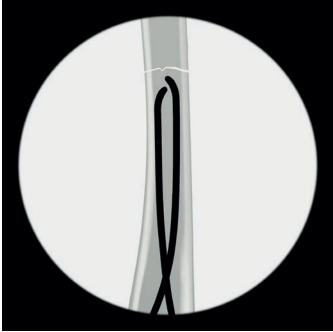
■ Note:

If it is very difficult to advance the nail with repeated hammer blows, consider the following options:

- Ensure that the nail is properly oriented or aligned.
- Increase the bending of the anterior part of the nail.
- Change to the next smaller nail diameter.

In some cases it is advisable to advance the first nail across the fracture zone to stabilize the proximal fragment.





8. Reduce the fracture

Instrument	
359.209	F-Tool for Reduction, small



■ Note:

It is helpful to make a preliminary reduction before sterile draping of the leg, especially when the fracture table is used.

The proximal fragment can be manipulated and reduction can be achieved by means of protruding nails using the so called "joystick" technique.

If this maneuver does not result in an acceptable reduction, intraoperative closed reduction can be facilitated by the use of the F-tool for reduction. The two arms of the F-tool should lie as close together as possible.

To assemble the small F-Tool:

- 1. Thread one threaded rod at the end of the bar.
- 2. Thread the second rod into the bar so the rods just fit across the leg.
- 3. Thread the third rod into the opposite end of the bar.

■ Note:

If a closed reduction is not possible within 20 – 30 min or after several attempts, a short incision and an open reduction are recommended.

9. Cross the fracture with the nails

Instruments		
359.219	Inserter for TEN	
359.218	Hammer Guide for TEN	
359.221	Combined Hammer for TEN	

When the cavities are aligned correctly, advance the nails alternately with gentle hammer blows or oscillating movements far enough across the fracture zone to ensure that the main fragments are held firmly. Then advance the nails as far as the metaphysis. The tips of the nails in the proximal fragment must be correctly aligned in the frontal plane. At this point check the stability and rotation. Once the nails are fixed in the metaphysis it is no longer possible to adjust the rotation.



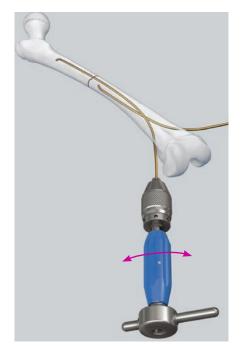
■ Notes:

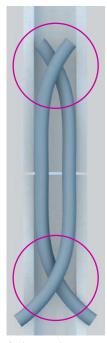
• If a nail has to be rotated 180° to cross the fracture line, twist the nail back afterward. Orientation of the nail is facilitated by marks on the inserter.

Example: Start 0 ->1 -> 2

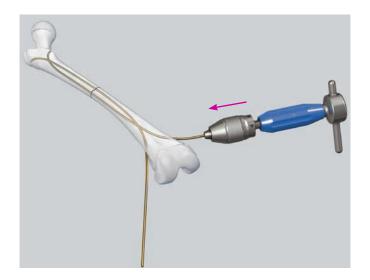
Back 2 -> 1 -> 0

• Ensure that the second nail is in front of (or behind) the first nail distally and proximally; otherwise it will not be possible to align the nails properly. Avoid the "corkscrew phenomenon".





Corkscrew phenomenon



10. Cut the nails to length

Instrument

359.217

Cutter for TEN

If the nail tips in the proximal fragment are correctly located, then the nails can be shortened to the required length with the cutter for TEN, which allows the nails to be cut very close to the bone cortex.

If end caps for TEN \varnothing 3.0 to 4.0 mm (475.900) are used, the nail end lengths protruding from the cortex should not exceed 10 mm, which can be achieved by using of the bevelled impactor (359.206).

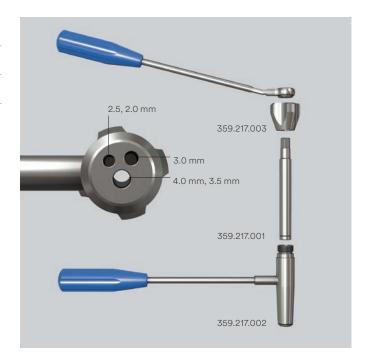
Assemble the cutter for TEN according to the picture and make sure that the stop nut (359.217.003) is tightened. Rotate the cutting bolt (359.217.001) to the fully open position. In the fully open position, the lettering "TOP" is aligned both on the cutting bolt and cutting sleeve (359.217.002).

Slide the nail through the appropriate marked opening cutter sleeve. The black ring on the cutting sleeve indicates the point at which the nail will be cut.

Place the handle on the cutting bolt. With a firm grip, move handles toward each other in one fluid motion to cut the nail. The trimmed portion of the nail is captured within the cutter.

▲ Precautions:

- Excessively long nail ends result in pseudobursa formation and prevent free flexion of the knee. They can also perforate the skin and cause infections.
- The nail end must not be bent away from the cortex if using an elastic nail end cap.





Alternative Technique

Instrument

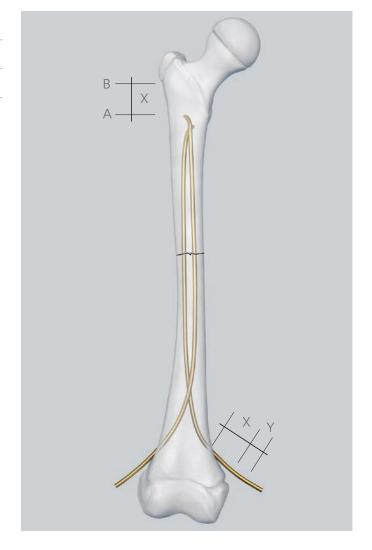
388.720 Bolt Cutter

If the specific cutter for TEN is not available, then the following procedure should be considered.

Estimate the distance (X) between the current position of the nail tips (A) and the definitive anchoring position (B) in the proximal part on the image intensifier. This distance plus an extraction length of 10 mm (Y) produces the distance from the bone to the cutting point.

■ Note:

If end caps are used, the correct length of the nail end has to be considered.



11. Final nail positioning

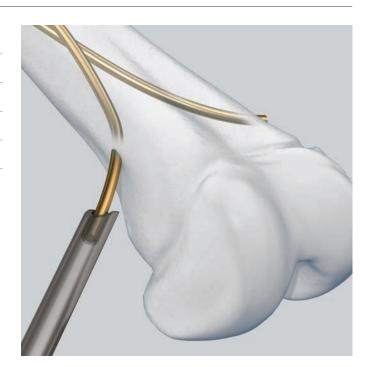
Instruments		
359.206	Impactor for TEN, bevelled	
359.221	Combined Hammer for TEN	
359.215	Extraction Pliers for TEN	

After the nails have been inserted and its length adapted, the corresponding bevelled impactor for TEN brings the nails into their planned anchorage position in the proximal metaphysis with gentle hammer blows.

In this process the bevelled part of the impactor must reach the cortical bone. This position provides a protection of about 8–10 mm.

■ Notes:

- If the nail has been over-inserted, use the extraction pliers to grip and retract the nail. Slight bending of the remaining nail tip will facilitate later removal.
- If end caps are used, always use the bevelled impactor to ensure that the protruding length of nail end is correct.





12. Insertion of TEN end caps

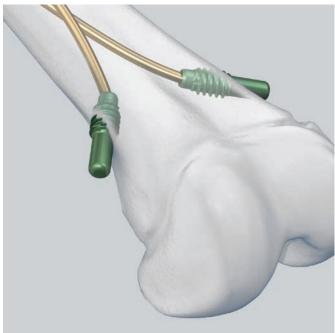
Instruments	
359.219	Inserter for TEN
359.222	Screwdriver Shaft for End Cap for TEN Ø 3.0 to 4.0 mm (No. 475.900)
321.170	Pin Wrench Ø 4.5 mm, length 120 mm

The end cap (475.900) is inserted over the correctly cut end of the nail and threaded into the metaphysis obliquely.

Insert the screwdriver shaft into the inserter and tighten it with the pin wrench. Mount the end cap on the screwdriver by aligning the "D" flats. Place the end cap over the nail end and thread it clockwise into the bone at the entry site. The threaded portion of the end cap directed toward the bone must be fully inserted.

Check the correct position of the end cap under the image intensifier.





Femur – Ascending Technique (pediatrics only)

13. Post-operative care

Post-operative radiograph images should show an anatomical reduction that would be expected in a Pediatric Patient. The nails should be positioned correctly with good distal and proximal anchorage.

Depending on the age of the child, immediate passive motion by a physiotherapist or continuous passive motion (CPM) should be started on the first day after the operation. On the second day, mobilization on crutches with toe contact may be possible depending on the pain. The patient is usually discharged after 3 to 5 days.

First clinical and x-ray checks are usually performed 4–5 weeks post-operatively. Full weight-bearing may be started depending on the callus formation.

Normal activities and school sport can usually be resumed after 6 – 8 weeks.

Bone healing is controlled after 4–6 months, and nail removal can usually be scheduled for months 6–8.

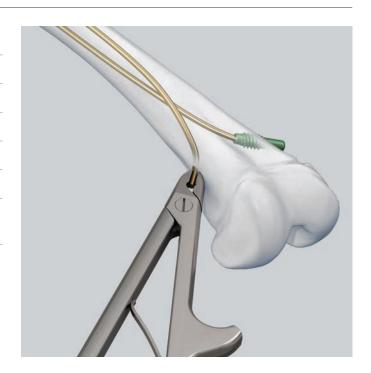
14. Removal of the implants

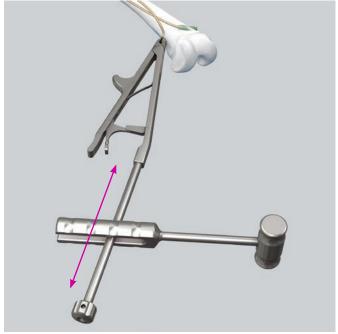
Instruments	;
359.215	Extraction Pliers for TEN
359.218	Hammer Guide for TEN
359.219	Inserter for TEN
359.221	Combined Hammer for TEN
359.222	Screwdriver Shaft for End Cap for TEN ∅ 3.0 to 4.0 mm (No. 475.900)

If end caps were used, the end caps are removed using the corresponding screwdriver shaft mounted on the inserter for TEN.

Open the old incisions and expose the ends of the nails. Use the extraction pliers for TEN to first bend the ends of the nails so that they are lifted clear of the formed callus.

With the hammer guide for TEN firmly screwed onto the extraction pliers for TEN, the nails can be removed with strong axial blows along the guide with the combined hammer for TEN.





Femur – Descending Technique (pediatrics only)

This so called monolateral descending technique is preferable for fractures of the distal third of the femur or the distal metaphysis. The descending technique in femur requires a different procedure because both nails are inserted laterally.

To achieve the correct biomechanical configuration for stabilization of the nail tips and the metaphyseal fragment, one nail must be contoured and twisted in a different way.

Incision

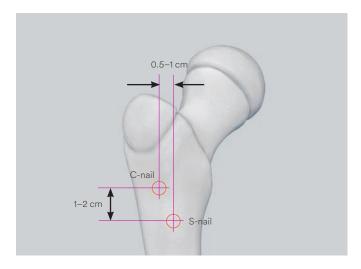
The incisions should start just below the greater trochanter and extend distally for 3 – 4 cm long, just below the lesser trochanter. It needs to be long enough to expose a sufficient length of proximal shaft to accommodate the two separate nail entry points.

Nail insertion points

The insertion point for the C-shaped nail is located laterally, whereas the insertion point for the S-shaped nail lies antero-laterally in the subtrochanteric area, as shown in the picture. The points are separated from each other vertically by approx. 1–2 cm and horizontally by 0.5–1 cm. If the insertion points are placed too close to each other, the bone may split during nail insertion.

Pre-bend nails

To ensure correct internal bracing, i.e. with 3-point contact, bend one of the nails in the standard way. This nail subsequently forms the C-shape.







Nail insertion

Introduce the first C-shaped pre-bent nail through the more proximal lateral entry point, reduce the fracture with the nail and achieve primary stabilization.

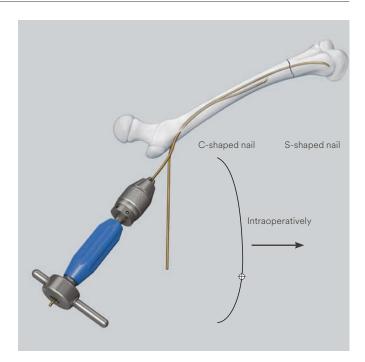
Insert the second C-shaped nail, with only the first third being pre-bent, through the more distal / anterior hole until it has good contact with the medial cortex along its length of curvature. This is when the nail has been advanced two-thirds distally. In this position rotate the nail 180° clockwise or counter-clock wise. The external part of the nail is then bent in a distal direction by almost 90°, creating an S-shape.

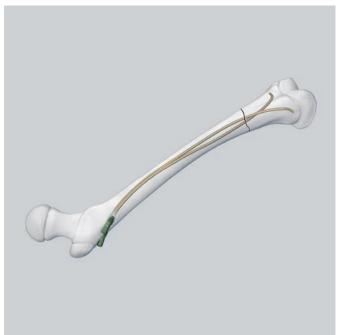
Final positioning and anchoring of the nails

Once the fracture is reduced, advance the nail into the distal fragment and align the nail tips so that they diverge from each other.

■ Note:

End caps can also be used in the descending technique.





Tibia – Descending Technique (pediatrics only)

The descending technique should always be used for tibial fractures. Tibial fractures in children typically require two nails inserted from medial and lateral entry points at the proximal tibia. The nail diameters are determined by the diameter of the isthmus of the medullary canal as previously described and are normally between 2.5 mm and 4.0 mm, depending on the patient's age and bone size.

Pre-bending is recommended and performed as shown in the standard femoral technique.

Incision

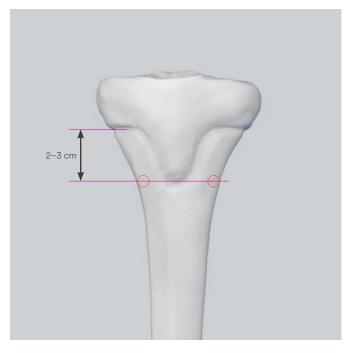
The symmetrical skin incisions are made on the same level on the medial and lateral sides of the tibial tuberosity. These are 2-3 cm in length proximal to the planned entry points.

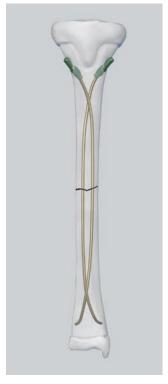
Nail insertion

The entry points are situated anteriorly on the proximal medial and proximal lateral metaphyseal cortices, 2 cm distal to the proximal physis, next to the tibial tuberosity.

■ Note:

Due to the asymmetrical placement of the tibia in relation to the muscle coat, its triangular form and its wide proximal metaphysis, special biomechanical problems arise regarding stability. Therefore, these special problems must be taken into account.







Due to the triangular shape of the tibial medullary canal, both nails tend to lie dorsally, which would result in recurvation. Therefore, before hammering the nails in their final position in the distal metaphysis turn the tips of both nails slightly posteriorly in order to achieve the physiological antecurvation of the tibia.

Compress the fracture to prevent fixation in distraction and cut the nails to length. The nail ends should be kept short and not bent upward in view of minimal soft-tissue cover.

■ Note:

Since tibial fractures, especially oblique and spiral fractures, have a great tendency to shorten, the use of end caps is recommended in these cases.

Forearm

If stabilization of an adult forearm fracture with the ESIN technique is indicated, it is important to follow the correct procedure. In this situation the technique for pediatric and adult fractures is similar. However, in pediatrics the penetration of the physis must be avoided at all costs.

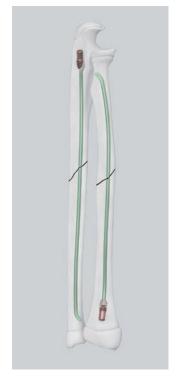
Forearm fractures typically require a single nail inserted in each bone since the radius and ulna form a single unit together with the interosseous membrane.

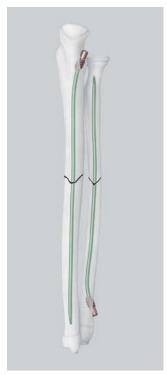
Nails may be used either antegrade or retrograde, depending on the fracture location and the surgeon preference.

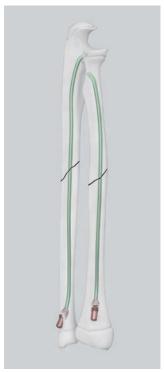
In this surgical technique guide, it is recommended that the nail is always placed in a retrograde approach in the radius to avoid the risk of damage of the deep branch of the radial nerve. By contrast, in the ulna the nail can be inserted via an antegrade or retrograde approach.

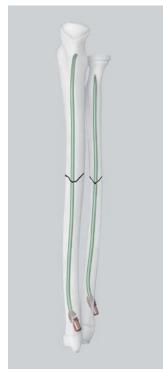
End caps are recommended to cover the cut part of the nail as it may have a burr or sharp edges.

The following section describes the technique for pediatric and adult fractures.









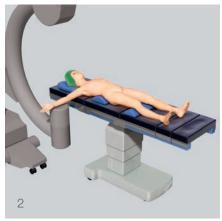
1. Position the patient

Position the patient more on the lateral side of the operating table in the supine position with the affected arm placed on a radiolucent arm table (1). The image intensifier is positioned in such a manner that it does not interfere with the surgical field.

■ Note:

Positioning the arm directly under the image intensifier (2) provides a better x-ray image quality, reduces exposure time to radiation and produces a bigger, more focused, image of the fracture site.





2. Determine the nail diameter

The nail diameters are about two thirds of the medullary isthmus of each bone. Nails that are identically precurved are chosen and inserted opposite to each other to produce a balanced construct that maintains alignment.

For forearm fractures a nail diameter of 1.5, 2.0 and 2.5 mm is usually used in pediatrics, whereas 3.0 mm nails may also be used in adults.





3. Determine nail entry point in the radius

Incision

There are two different approaches for generating the distal radial insertion point: the old traditional approach with a distal lateral insertion and the dorsal approach over Lister's tubercle.

In regards to the direction of the incision, a longitudinal skin incision is traditionally made. Alternatively a transverse skin cut can be performed, taking account of cosmetic and comfort aspects.

■ Note:

An open dissection is recommended to prevent tendon damage.

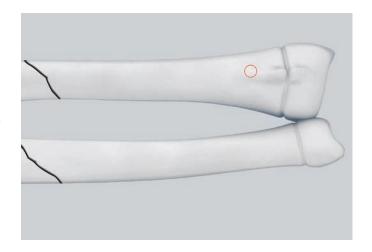
Entry point

In the radius, the insertion point is approx. 2 cm proximal to the distal physis; in adults 4 cm proximal to the joint line.

The following surgical technique steps and pictures describe the dorsal approach.

▲ Precaution:

Be aware of the extensor tendons and superficial radial nerve.



4. Create the nail entry point in the radius

Instrument

359.213 Awl for TEN

Alternative instrument

359.214 Awl, curved, length 180 mm, for Clavicular Fractures

Place the awl directly on Lister's tubercle under visual control. Insert the awl in the original way as described.

▲ Precaution:

Take care not to penetrate the contralateral cortex.

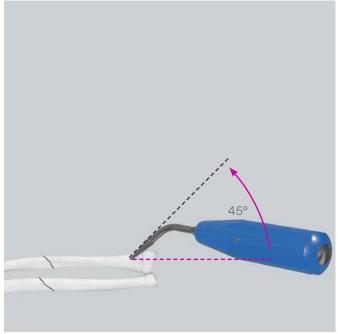
Insert the awl at the upper end of the incision perpendicular to the bone. With rotating movements make a central mark. Lower the awl to an angle of 45° in relation to the shaft axis and then continue perforating the bone at an upward angle. The opening should be slightly larger than the selected nail diameter.*

When using end caps for the nails, make sure that the holes correspond to the core-diameter of the end cap (475.905).

■ Note:

When using TEN end caps, make sure that the small TEN end caps (475.905) are used.





^{*} Identical approach on the ulna.

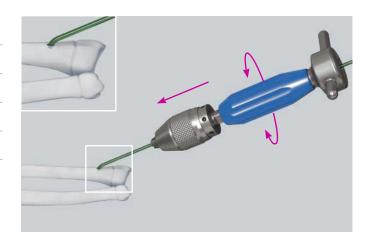
5. Insert nail in the radius

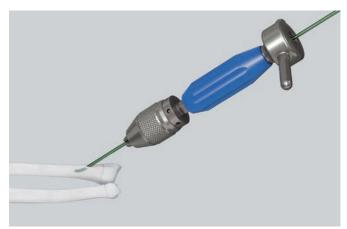
Instruments	
359.219	Inserter for TEN
321.170	Pin Wrench Ø 4.5 mm, length 120 mm
321.250	Spanner Wrench

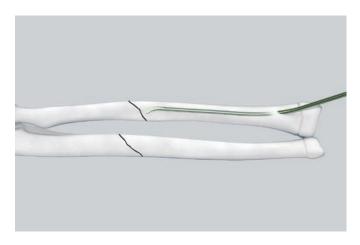
Because the radius is often more difficult to reduce, it should be splinted first. Insert the radial nail manually with the inserter for TEN into the medullary canal, with the nail tip at right angles to the bone shaft. Then rotate the nail through 180° with the inserter and align the nail tip with the axis of the medullary canal. Advance the nail up to the fracture site with oscillating movements.

▲ Precaution:

The use of a hammer is not recommended since hammering may produce further fracture fragments.







6. Determine nail entry point in the ulna

Two different techniques can be used for nailing of the ulna:

- 1. antegrade approach from the lateral cortex of the proximal metaphysis;
- 2. retrograde approach from the medial cortex of the distal metaphysis.

Incision

For the antegrade technique perform the longitudinal skin incision on the dorso-radial side, of the proximal ulna, 3 cm distal to the apophysis.

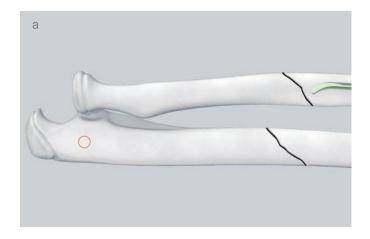
For the retrograde technique, make a 2-3 cm incision over the distal ulna starting 3 cm proximal to the palpable ulnar styloid.

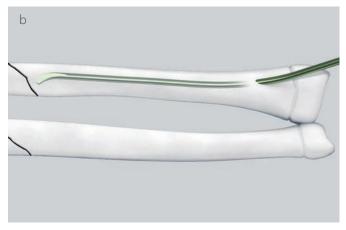
Entry point

For the antegrade technique, the nail entry point is on the antero-lateral side of the proximal metaphysis, approx. 2 cm distal to the apophyseal plate in the proximal ulna.

For the retrograde technique, the nail entry point is on the antero-lateral side of the distal metaphysis, approx. 2 cm from the joint line.

The following text describes the surgical technique for the retrograde approach with both nails inserted retrograde.



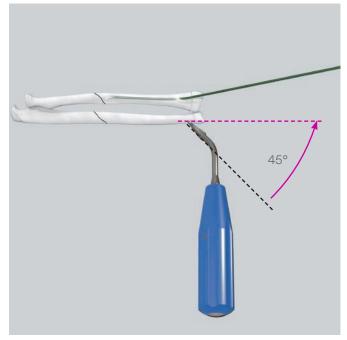


7. Create the nail entry point in the ulna

Instrument	s
359.213	Awl for TEN
359.219	Inserter for TEN
321.170	Pin Wrench Ø 4.5 mm, length 120 mm
321.250	Spanner Wrench
Alternative	instrument
359.214	Awl, curved, length 180 mm, for Clavicular Fractures

At the determined nail entry point, first place the awl perpendicular to the cortex and then gradually widening the angle to enter the medullary canal with rotating movements as previously described for the radius (step 4).

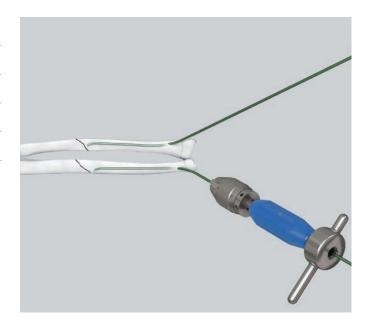




8. Insert the nail into the ulna

Instruments	
359.219	Inserter for TEN
321.170	Pin Wrench \varnothing 4.5 mm, length 120 mm
321.250	Spanner Wrench

Manually insert and advance the ulna nail up to the fracture site using the inserter for TEN.



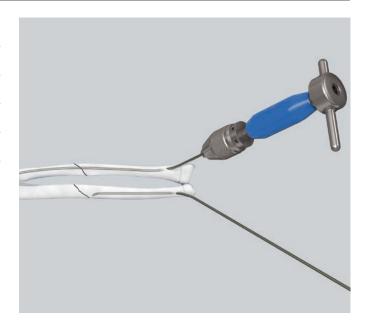
9. Reduce and fix the radius

Instrument	
359.219	Inserter for TEN
321.170	Pin Wrench Ø 4.5 mm, length 120 mm
321.250	Spanner Wrench

Align the radial nail tip with the medullary canal of the proximal fragment. Then, manually advance the nail with smooth oscillating movements until the tip reaches the proximal fragment at the level of the olecranon.

■ Note:

If reduction cannot be achieved with this method, then open reduction needs to be performed. A small incision at the fracture level should be done and the fragments aligned using small reduction clamps. The radial nail is able to cross the fracture line and to be advanced into the proximal fragment.



10. Reduce and fix the ulna

Instruments				
359.205	Impactor for TEN, straight			
359.215	Extraction Pliers for TEN			
359.219	Inserter for TEN			
321.170	Pin Wrench Ø 4.5 mm, length 120 mm			
321.250	Spanner Wrench			

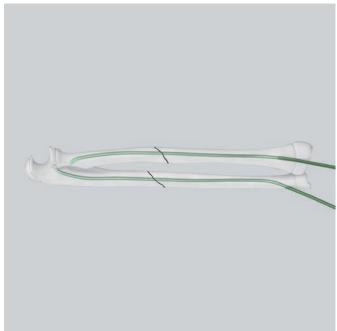
The ulna usually reduces spontaneously after radius reduction.

Advance the ulna nail with the inserter for TEN across the fracture line into the proximal metaphysis.

■ Note:

Independently of the technique (radius retrograde/ulna antegrade or radius retrograde/ulna retrograde), at the end both nail tips should be rotated towards the interosseous membrane for maximal spread.





11. Cut the nails to length and finalize nail position

Instruments			
359.217	Cutter for TEN		
359.205	Impactor for TEN, straight		
359.220	Impactor, bevelled, small, for TEN \varnothing 1.5 to 3.0 mm		

When the nails are correctly positioned in the opposite metaphysis, cut the protruding nail ends approximately 1 cm from the bone.

Using the impactor for TEN (359.205 or 359.220), push the nails in both bones into their final position. Be careful not to over-insert the nail, 5 mm of nail end should protrude beyond the cortex. If the nails are over-inserted, use the extraction pliers for TEN (359.215) to retract the nails.

End caps are recommended to cover the cut part of the nail as it may have a burr or sharp edges. In addition the threads of the end cap anchor the nail into the bone. Since nail diameters of 1.5 to 2.5 mm are usually employed for forearm fractures, the corresponding end caps for TEN \emptyset 1.5 to 2.5 mm (475.905) are used.

The protruding nail end lengths should not exceed 5 mm otherwise the end cap will not be sufficiently screwed into the bone. Use of the impactor ensures the correct protruding length of nail end.

Alternatively:

If TEN end caps are not used, the radial nail end should be left longer and placed sufficiently far outside the tendon compartment to reduce constant friction and tendon rupture.







12. Insertion of TEN End Caps

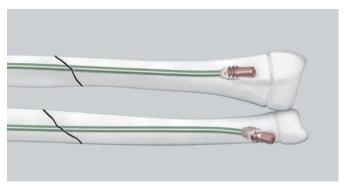
Instruments	
Ilistruments	
321.170	Pin Wrench Ø 4.5 mm, length 120 mm
359.219	Inserter for TEN
359.226	Screwdriver Shaft for End Cap for TEN Ø 1.5 to 2.5 mm (No. 475.905)
359.205	Impactor for TEN, straight
359.220	Impactor, bevelled, small, for TEN \varnothing 1.5 to 3.0 mm

Insert the screwdriver shaft into the inserter and tighten it with the pin wrench. Mount the end cap (475.905) on the screw driver by aligning the "D" flats. Place the end cap over the nail end and thread it clockwise into the bone at the entry site. The threaded portion of the end cap directed toward the bone must be fully inserted.

■ Note:

When using end caps, it is recommended to position the nails with the impactor for TEN (359.205 or 359.220).







13. Post-operative care

No post-operative immobilization is required, active motion can commence as soon as it is tolerated.

The removal of the nails is usually recommended after 4 to 6 months depending on the fully circumferential complete bone remodeling (woven bone) at the fracture site. The bone healing time is dependent on multiple factors.

Humerus - Ascending Technique

The ascending, monolateral nail technique is used to treat fractures of the proximal humerus and the humeral shaft. In the ascending technique two nails are inserted retrograde from the lateral (radial) ventral aspect of the distal humerus. An ulnar approach risks damaging the ulnar nerve and must be avoided.

Position the patient supine with the injured extremity on the arm table. With subcapital fractures the shoulder needs to be positioned inside the table to prevent the metal edge of the table interfering with the image.

The nail diameters are determined as previously described in the standard femoral technique.

For all unilateral nail insertions the technique for bending the nails is identical to that described in the femoral descending technique.

Incision

Start the skin incision 1 cm above the palpable prominence of the lateral epicondyle and progresses 3-4 cm proximally up the lateral aspect of the humerus.

It is recommended to prepare the ventral aspect of the distal, lateral humerus by sub-periosteal preparation to visualize the bone and the entry points.

Nail insertion

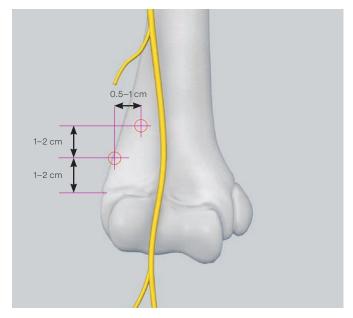
The nail insertion points are located on the supracondylar lateral ventral aspect, outside the capsule.

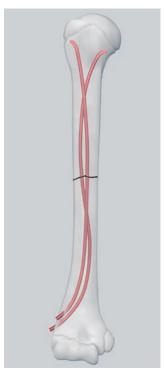
▲ Precaution:

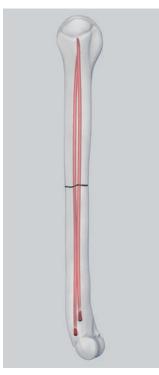
Be aware of the position of the radial nerve in relation to the fracture.

■ Note:

In unstable or comminuted fractures, we recommend the use of the corresponding end cap (for surgical technique, please refer to the standard femoral technique, step 12).







Humerus – Descending Technique

The descending monolateral technique is used for adult and pediatric fractures of the distal humerus, including supracondylar humerus fractures.

The nail diameters are determined as previously described in the standard femoral technique.

Incision

Make a 3-4 cm skin incision in children and a 4-5 cm skin incision in adults, proximal to the planned insertion point. Then expose the humerus subperiostally.

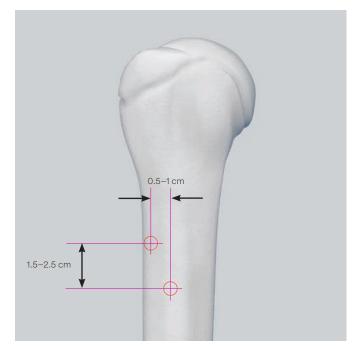
Nail insertion

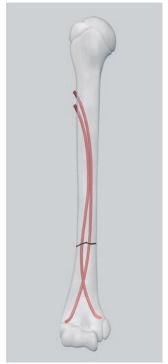
The insertion points are located laterally and distal to the insertion of the deltoid muscle. A more distal entry point could cause injury to the radial nerve.

The nail insertion points are separated from each other vertically by 1.5-2.5 cm and horizontally by 0.5-1 cm.

▲ Precaution:

Be aware of the position of the radial nerve in relation to the fracture.







Surgical Technique for Extended Indications Proximal Radius: Radial Neck

Because of its flexibility, the nail is very suitable for the closed reduction and fixation of radial neck fracture as well as Salter-Harris (SH) I and II fractures of the proximal radius.

The nail diameter is determined as previously described in the technique for the forearm. A nail diameter of 2.0 or 2.5 mm is usually used for radial neck and SH I and II fractures.

Incision and Nail Entry Point

The skin incision and nail entry point are identical to those described in the forearm technique.

Reduction

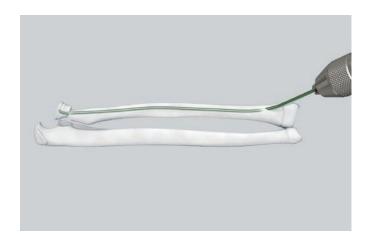
Align the well bent tip of the nail with the dislocated radial head in the most dislocated view on the image intensifier. Advance the tip across the fracture in the radial neck or head. Decompaction of the fracture can be achieved by applying slight axial pressure or slight hammering to the nail. Then reduce the fracture by rotating the nail through 180°.

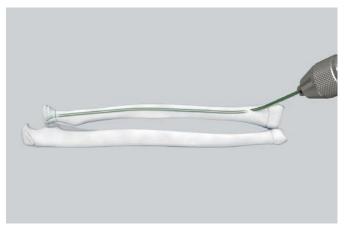
In cases of complete or severe dislocation, apply external pressure to the head of the radius to place it in front of the nail tip.

A severely dislocated head of radius can be moved toward the nail and reduced with the aid of a 1.2 or 1.6 mm Kirschner wire (joystick method).

■ Notes:

- If indicated in adults, the same technique as described for pediatric patients can be followed.
- In this technique the nail is primarily used as a reduction device and secondly as an implant.





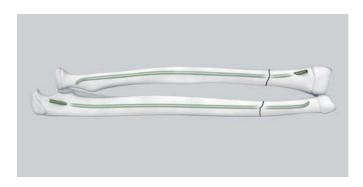
Distal Radius and Ulna Diaphyseal – Metaphyseal, Displaced Fractures

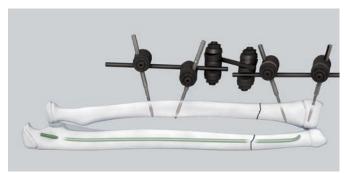
The standard technique for forearm fractures can be employed for these kinds of fractures. However one major difference should be considered. Whereas the nails are not pre-bent in the forearm surgical technique, the nails have to be pre-bent for these fracture patterns.

Before the radial nail crosses the fracture site, the nail should be bent to resist the tendency of the fracture to drift into valgus malalignment. The apex of the bent nail should be at the level of the fracture site.

■ Notes:

- Sufficient stability can be achieved only if there is good contact between the nail and the distal fragment.
- If fracture reduction cannot be obtained with the ESIN, an alternative technique should be used, e.g. using the small external fixator (186.430).





Clavicle

Because of their elasticity, Titanium Elastic Nails are used to treat fractures of the clavicle.

Usually one elastic nail is inserted through the medial portion of the clavicle towards the lateral side.

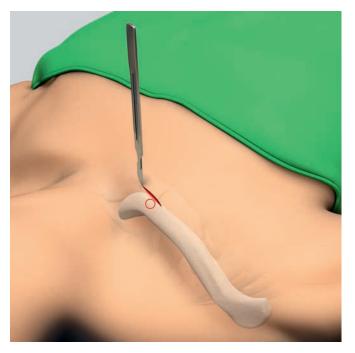
Incision

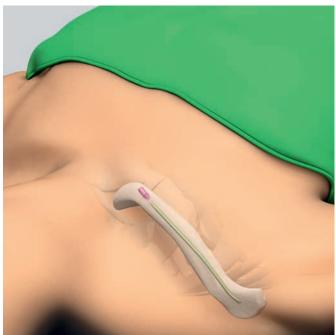
Make a 1-1.5 cm long skin along the anatomical skin-line of the medial clavicle end.

Nail insertion

The nail entry point is 1 to 2 cm distal to the sternoclavicular joint in the center of the proximal clavicle in the anterior quadrant. This is a region of low cortical thickness.

The use of the small end caps (475.905) with the impactor (359.205 or 359.220) for these indications is recommended, because the end caps are covering the cut part of the nail as it may have a burr or sharp edges and the threads of the end cap anchor the nail into the bone.





Product Information

The Titanium/Stainless Steel Elastic Nail (TEN/STEN) System was developed for elastic stable intramedullary nailing (ESIN).

- Nails are available in diameters of 1.5 mm to 4.0 mm and can be adjusted to length.
- The tip of the nail facilitates insertion and sliding.
- Marks on the end of the nail provide appropriate orientation of the nail in the intramedullary canal.
- End caps are available for all nail diameters.

Implants

STEN/TEN					
Stainless Steel	Titanium	Nail diameter	Length (mm)	Color of Ti version	
275.915	475.915	1.5	300	purple	
275.920	475.920	2.0	440	green	
275.925	475.925	2.5	440	rose red	
275.930	475.930	3.0	440	gold	
275.935	475.935	3.5	440	light blue	
275.940	475.940	4.0	440	purple	

STEN/TEN End Caps

Stainless steel	Titanium	For Nail Diame	eters Color of Ti version	
275.900	475.900	3.0 – 4.0	green	
275.905	475.905	1.5 – 2.5	rose red	

Titanium Implants and End Caps are available nonsterile or sterile packed. Add suffix "S" to article number to order sterile product.

Stainless Steel Nails are only available nonsterile.

Instruments

321.170	Pin Wrench Ø 4.5 mm, length 120 mm	
359.205	Impactor for TEN, straight	
359.206	Impactor for TEN, bevelled	
359.220	Impactor, bevelled, small, for TEN ∅ 1.5 to 3.0 mm	
359.213	Awl for TEN	
359.215	Extraction Pliers for TEN	
359.217	Cutter for TEN	
359.218	Hammer Guide for TEN	-
359.219	Inserter for TEN	
359.221	Combined Hammer for TEN	
359.222	Screwdriver Shaft for End Cap for TEN Ø 3.0 to 4.0 mm (No. 475.900)	
359.226	Screwdriver Shaft for End Cap for TEN Ø 1.5 to 2.5 mm (No. 475.905)	

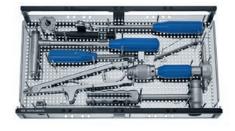
Optional instruments

312.460	Double Drill Guide 4.5/3.2
315.280	Drill Bit ∅ 2.7 mm, length 125/100 mm, 3-flute, for Quick Coupling
315.290	Drill Bit ∅ 3.2 mm, length 195/170 mm, 3-flute, for Quick Coupling
315.480	Drill Bit Ø 4.5 mm, length 195/170 mm, 3-flute, for Quick Coupling
321.250	Spanner Wrench
359.204	Pliers, flat-nosed, for TEN
359.209	F-Tool for Reduction, small
359.214	Awl, curved, length 180 mm, for Clavicular Fractures
388.720	Bolt Cutter

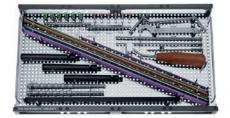
Setlist Modular Trays TEN System

Modular trays for TEN instruments and implants

without Contents
1
1
1
1
1
1



01.009.012	Modular TEN Instrument and Implant Tray, size 1/1, with Contents			
68.009.002	Modular Tray, size 1/1, for TEN Instruments and Implants, without Contents			
359.222	Screwdriver Shaft for End Cap for TEN \varnothing 3.0 to 4.0 mm (No. 475.900)	1		
359.226	Screwdriver Shaft for End Cap for TEN \varnothing 1.5 to 2.5 mm (No. 475.905)	1		
475.900*	End Cap for TEN \varnothing 3.0 to 4.0 mm, Titanium Alloy (TAN)	6		
475.905*	End Cap for TEN \varnothing 1.5 to 2.5 mm, Titanium Alloy (TAN)	6		
475.915*	TEN - Titanium Elastic Nail \varnothing 1.5 mm, length 300 mm, Titanium Alloy (TAN), violet	6		
475.920*	TEN - Titanium Elastic Nail \varnothing 2.0 mm, length 440 mm, Titanium Alloy (TAN), green	6		
475.925*	TEN - Titanium Elastic Nail \varnothing 2.5 mm, length 440 mm, Titanium Alloy (TAN), pink	6		
475.930*	TEN - Titanium Elastic Nail \varnothing 3.0 mm, length 440 mm, Titanium Alloy (TAN), gold	6		
475.935*	TEN - Titanium Elastic Nail \varnothing 3.5 mm, length 440 mm, Titanium Alloy (TAN), light blue	6		
475.940*	TEN - Titanium Elastic Nail Ø 4.0 mm, length 440 mm, Titanium Alloy (TAN), violet	6		
359.205	Impactor for TEN, straight	1		
359.206	Impactor for TEN, bevelled	4		



Optional storage		
68.009.003	Labelling Clip for Modular TEN Instrument Tray	
68.009.004	Labelling Clip for Modular TEN Instrument and Implant Tray	
68.000.101	Lid for Modular Tray, size 1/1	
689.511	Vario Case, Framing, size 1/1, height 126 mm	
689.507	Lid (Stainless Steel), size 1/1, for Vario Case	

^{*}also available as stainless steel

Optional instruments

312.460	Double Drill Guide 4.5/3.2			
315.280	Drill Bit \varnothing 2.7 mm, length 125/100 mm, 3-flute, for Quick Coupling	1		
315.290	Drill Bit \varnothing 3.2 mm, length 195/170 mm, 3-flute, for Quick Coupling	1		
315.480	Drill Bit \varnothing 4.5 mm, length 195/170 mm, 3-flute, for Quick Coupling	1		
321.250	Spanner Wrench	1		
359.214	Awl, curved, length 180 mm, for Clavicular Fractures	1		
359.209	F-Tool for Reduction, small	1		
359.220	Impactor, bevelled, small, for TEN \varnothing 1.5 to 3.0 mm			
388.720	Bolt Cutter			

Modular tray for implant removal

01.009.015	Modular TEN Extraction Instrument Tray (with contents)		
68.009.005	Modular Tray, size 1/1, for TEN Extraction Instruments, without Contents	1	
359.219	Inserter for TEN	1	
359.215	Extraction Pliers for TEN	1	
359.221	Combined Hammer for TEN	1	
359.218	Hammer Guide for TEN	1	
321.170	Pin Wrench ∅ 4.5 mm, length 120 mm	1	
359.222	Screwdriver Shaft for End Cap for TEN Ø 3.0 to 4.0 mm (No. 475.900)	1	
359.226	Screwdriver Shaft for End Cap for TEN Ø 1.5 to 2.5 mm (No. 475.905)	1	



Optional storage			
68.009.006	Labelling Clip for Modular TEN Extraction Instrument Tray		
68.000.101	Lid for Modular Tray, size 1/1		
689.507	Lid (Stainless Steel), size 1/1, for Vario Case		
689.508	Vario Case, Framing, size 1/1, height 45 mm		

Optional instruments			
321.250	Spanner Wrench	1	
359.204	Pliers, flat-nosed for TEN	1	
395.380	T-Handle for Steinmann Pins and Schanz Screws		

MRI Information

Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F2119-07

Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.

Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a

Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]).

▲ Precautions:

The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:

- It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations.
- Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures.
- Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible.
- Using the ventilation system may further contribute to reduce temperature increase in the body.

Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

Intended use, Indications and Contraindications can be found in the corresponding system Instructions for Use.

All Surgical Techniques are available as PDF files at www.depuysynthes.com/ifu





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