For Fixation of Fractures Where the Medullary Canal Is Narrow or Flexibility of the Implant Is Paramount.

Titanium Elastic Nail System

Surgical Technique



Introduction	Elastic Nails	2
	Indications	3
	Clinical Cases	4
Surgical Technique	Nail Selection	
	Femoral Nail Insertion	9
	Tibial Nail Technique	21
	Humeral Nail Technique	22
	Forearm Nail Technique	23
	Implant Removal	24
	Care and Maintenance	26
Product Information	Implants	28
	Instruments	30
	Set List	34

MR Information

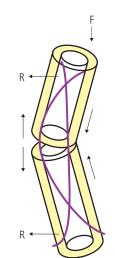
The Elastic Nail System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the Elastic Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

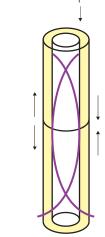
Image intensifier control

The aim of this biological, minimally invasive fracture treatment is to achieve a level of reduction and stabilization that is appropriate to the age of the child.

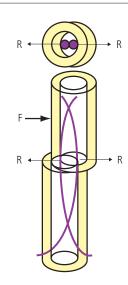
The biomechanical principle of the elastic nail is based on the symmetrical bracing action of two elastic nails inserted into the metaphysis, each of which bears against the inner bone at three points. This produces the following four properties: flexural stability, axial stability, translational stability and rotational stability. All four are essential for achieving optimal results.¹

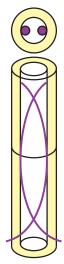
- F = force acting on the bone
- R = restoring force of the nail
- S = shear force
- C = compressive force





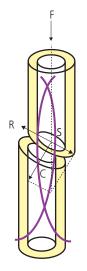
R

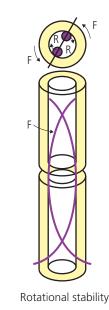




Flexural stability

Translational stability





Axial stability

 Dietz, H.G. et al., Intramedulläre Osteosynthese im Wachstumsalter. Urban and Schwarzenberg; München 1997.

Indications

The Synthes Titanium Elastic Nail (TEN) and Stainless Steel Elastic Nail are intended for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is paramount.

This includes:

- lower extremity fractures in pediatric and small-statured patients
- upper extremity fractures in all patients

This system is also intended to treat metaphyseal and epiphyseal fractures, such as radial neck fractures, and is intended for fixation of small long bones, such as carpal and tarsal bones. In pediatric applications, the flexibility of the elastic nail allows it to be inserted at a point which avoids disruption of the bone growth plate.



Clinical Cases

Case 1 Pediatric femur—standard technique





Postoperative



Follow-up

Case 2 Pediatric femur—descending technique



Preoperative



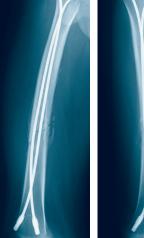
Postoperative

*Results from case studies are not predictive of results in other cases. Results in other cases may vary.

Case 3 Pediatric femur with end cap









Preoperative

Intraoperative

Postoperative

Follow-up

Case 4 Pediatric tibia



Preoperative



Postoperative

Follow-up

Case 5 Pediatric humerus—ascending technique





Postoperative

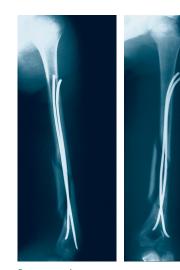


Follow-up

Case 6 Pediatric humerus — descending technique



Preoperative



Postoperative



Follow-up

Case 7 Pediatric radius and ulna



Preoperative



Postoperative



Follow-up

Titanium elastic nails are available in six diameters: 1.5 mm, 2.0 mm, 2.5 mm, 3.0 mm, 3.5 mm and 4.0 mm. The 1.5 mm diameter nail is 300 mm long. The 2.0 mm through 4.0 mm diameter nails are 440 mm long. The nails are color-coded for easy identification.*

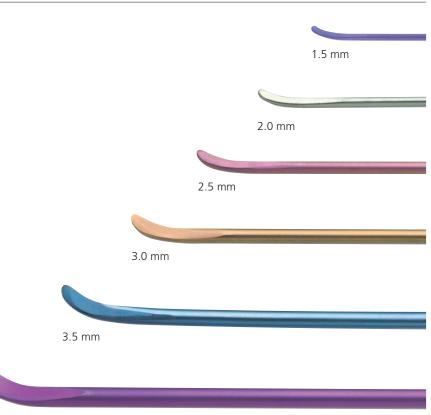
Measure the narrowest diameter of the medullary canal with a ruler. The proper nail diameter is no more than forty percent of the width of the canal.

The following guidelines for femoral nailing are sizes typically used for children of average stature and are dependent on patient anatomy:

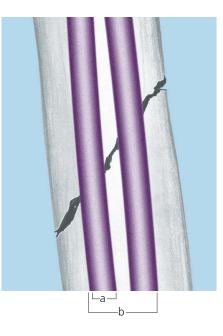
Age (years)	Nail size (mm)
6-8	3.0
9–11	3.5
12–14	4.0

Select two nails of the same diameter so the opposing bending forces are equal, avoiding malalignment.

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



4.0 mm



* Also available in stainless steel

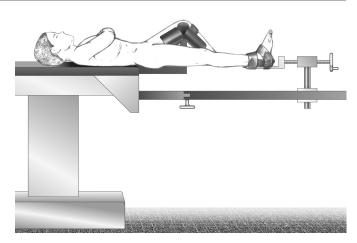
Femoral fractures in children are typically stabilized with two nails inserted in a retrograde manner from medial and lateral entry points above the distal physis. Antegrade nailing, with a lateral entry point, is normally reserved for very distal femoral fractures.

This technique guide describes the more common retrograde technique in detail. For femoral fractures in average-statured children, 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

Position the patient supine in a free position or on a fracture table with a traction boot. If fracture reduction can be accomplished with manual reduction (usually only in small patients), a standard table may be used. Position the image intensifier on the lateral side of the affected femur for AP and lateral views of the leg from knee to hip. The setup must allow the surgeon access to both the lateral and medial aspects of the distal femur. Reduce the fracture and confirm alignment with fluoroscopy in both the AP and lateral views. Prep and drape the leg from hip to knee for reduction and intraoperative imaging.



Contour nail

Optional sets		
105.954H	Small Battery Drive with 14.4 V Battery Pack Set, with Hudson Reduction Drive Unit	
105.957	Power Drive Set	
150.16	ComPact Air Drive II Set	

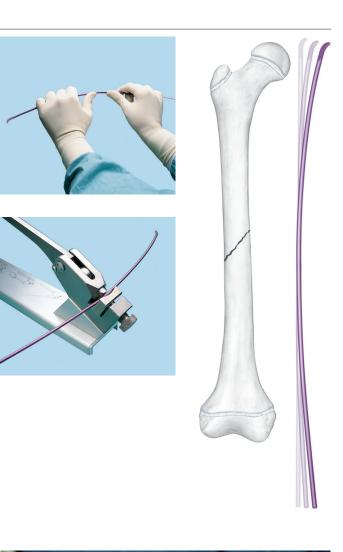
Optional instrument

329.30 [°] Plate-Bending Press	Press	Plate-Bending	329.30*
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Contour both nails into a bow shape with the nail tip pointing to the concave side of the bowed nail. The etched line on the nail will provide a reference for the nail tip during insertion and should follow the same plane as the bow. Contouring may be done by hand or with the tabletop plate-bending press. The apex of the bow should be at the level of the fracture. This shape allows the nail to generate optimal resistance to malaligning forces. The bow in each nail should be similar for a balanced effect.

Precaution: 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.





* Also available

3 Create nail entry point

Instruments	
312.46	4.5 mm/3.2 mm Double Drill Sleeve
315.28	2.7 mm Three-Fluted Drill Bit 125 mm, quick coupling
315.29	3.2 mm Three-Fluted Drill Bit 195 mm, quick coupling
315.48	4.5 mm Three-Fluted Drill Bit 195 mm, quick coupling

Make an incision on the lateral or medial aspect of the distal femur, starting 3 cm above the physis and extending distally for 2.5 cm. The entry point for the nail should be 2.5 cm to 3.0 cm proximal to the physis.

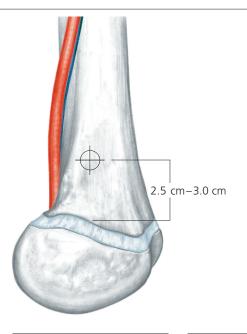
Precaution: When opening the medial side, be careful not to let the drill bit slip posteriorly in the region of the femoral artery.

Select the next largest drill bit relative to the diameter of the nail. Use the 4.5 mm/3.2 mm double drill sleeve to protect the soft tissues. Start the drill bit perpendicular to the bone surface, 2.5 cm-3.0 cm proximal to the physis. Check the drill bit position with fluoroscopy.

Penetrate the near cortex with the drill bit. With the drill bit rotating, but not advancing, slowly lower the drill to a 45° angle relative to the shaft axis. Now advance the drill bit at this angle until it reaches the medullary canal.

Precaution: The drill must be running when angling the drill bit or drill bit breakage may result.

Note: Finding the drilled entry hole can be difficult in pediatric patients since the periosteum may close over it. Have the contoured nail ready to introduce before removing the drill bit.









Create nail entry point continued

Optional instrument

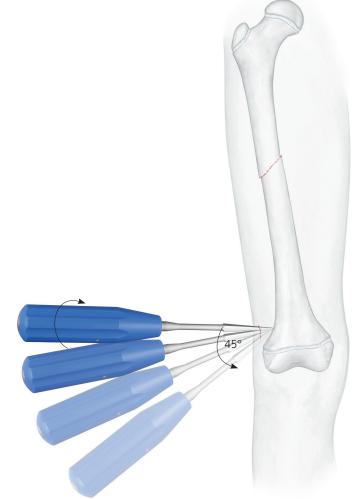
359.213 Awl

Alternative technique

The awl can be used to penetrate the near cortex. Vertically insert the awl down to the bone. With rotating motion, lower the awl to a 45° angle relative to the shaft axis and continue to penetrate the cortical bone at an upward angle.

Optional technique—end caps

If the operative plan includes use of an end cap for elastic nail, the awl must be inserted fully into the entry site before nail insertion and rotated at least 180° to ensure the end cap fit.

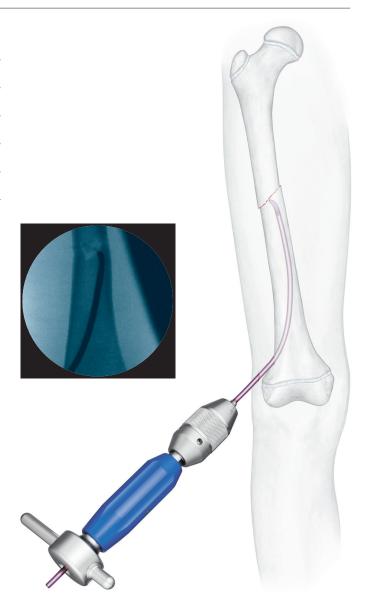


Insert nail

Instruments	
321.25	Spanner Wrench
359.218	Hammer Guide
359.219	Inserter, for Titanium Elastic Nails
359.225	Locking Slide Hammer

Locate and maintain the entry hole with a fingertip while withdrawing the drill bit and introducing the nail. Using fluoroscopy, align the nail tip so the convex side will glance off the far cortex. Advance the nail through the drilled entry hole by hand as far as possible.

Attach the hammer guide to the inserter. Attach the inserter onto the nail with a length of about 150 mm of nail between the Inserter and entry point. The longer this distance, the more difficult hammering will be since the nail will dampen the impact force. Tighten the inserter using the spanner wrench.



Insert nail continued

Attach the locking slide hammer to the shaft of the hammer guide. Use controlled blows to drive the nail up the medullary canal.

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 nail advancement with fluoroscopy. Ensure that the convex side of the nail tip is glancing off the far cortex and is advancing with each blow. The nail will bend as it progresses up the canal. This part of the procedure requires the greatest insertion force.

Note:

- If it is very difficult to advance the nail with repeated hammer blows, consider the following options:
 - 1. ensure that the nail is properly oriented;
 - 2. increase the contour near the tip of the nail; or
 - 3. change to the next-smaller diameter nail.

Drive the first nail to the level of the fracture. In a similar manner to that previously described, open the femur on the opposite side and insert the second nail up to the level of the fracture.

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.



5 Reduce fracture

Instruments	
359.207	Bar, for Small F-Tool
359.208	Threaded Rod, for Small F-Tool

Use the small F-tool to provide reduction forces on either side of the fracture gap.

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.

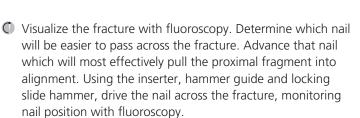
The small F-tool is placed on the leg at the level of the fracture so that both rods provide force on the opposing fragments to aid reduction.





Cross f	racture
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Instruments	
321.25	Spanner Wrench
359.218	Hammer Guide
359.219	Inserter, for Titanium Elastic Nails
359.225	Locking Slide Hammer

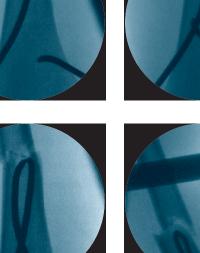


The nail can be rotated to manipulate the curved tip across the fracture. Rotation is easiest while the nail is being advanced or retracted.

Care should be taken not to twist the nails more than 90°. Otherwise, a "corkscrew phenomenon" may be created and stability will be lost. Rotating the nail while it is stationary may loosen the inserter.

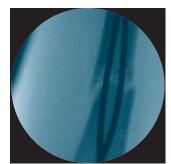
Note: The locking slide hammer is essential at this stage since it is often necessary to advance and retract the nail repeatedly when attempting to cross the fracture. The locking slide hammer allows the inserter and nail to be retracted easily and then advanced again.

Advance the nail into the proximal fragment only enough to ensure reduction will be maintained. Further advancement may cause displacement of the proximal fragment making it more difficult to pass the second nail. Confirm nail position in both the AP and lateral views.









Using the inserter, hammer guide, and locking slide hammer, drive the second nail across the fracture and into the proximal fragment. Continue advancing this nail until it is just distal to the proximal physis. Advance the other nail to the same level. The two nails should diverge in opposite directions, both medial and lateral, for optimal rotational stability. If the fracture is distracted, release traction and impact the patient's heel.

7

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Cut nails to length	
Instruments	
359.205	Standard Tamp
359.206	Beveled Tamp
359.217*	Cutter
359.224	Locking Pliers, long
359.225	Locking Slide Hammer

Before cutting the nails to length, verify the position of the nails in relation to the rotation of the leg. Once the nail is inserted to its final position, mark the nail with a pen or clamp at the planned cutoff point. The cutoff point should be 10 mm-20 mm outside of the cortex (only 10 mm if using the end cap). Retract the nail far enough to access the cutoff point from outside of the incision (usually 25 mm-50 mm).

The nail end can be bent away from the bone to deform it slightly (approximately $10^{\circ}-15^{\circ}$ of permanent deflection). This will allow the protruding nail end to sit slightly off of the cortex for easy removal while remaining low profile to help minimize soft tissue irritation.

Precaution: The nail end must not be bent away from the cortex if using an elastic nail end cap.

* Also available

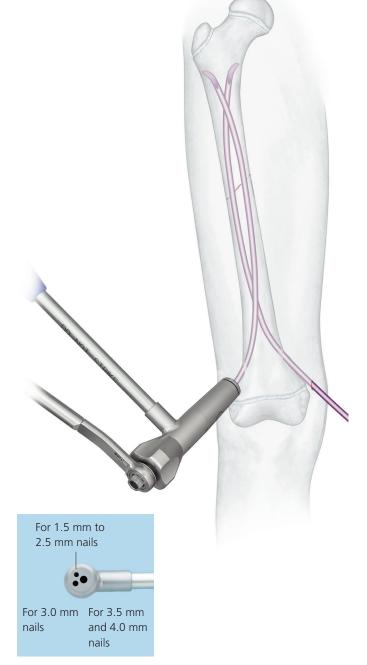
7 Cut nails to length continued

To use the cutter, rotate the cutting bolt to the fully open position. In the fully open position, the lettering "TOP" is aligned both on the cutting bolt and cutting sleeve.

Slide the nail through the appropriate opening on the cutting 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 the handles toward each other, in one fluid motion, to cut the nail. The trimmed portion of the nail is captured within the cutter.

Precaution: Excessively long nail ends result in pseudobursa formation and prevent free flexion of the knee. They can also perforate the skin and cause infections.



Reinsert the nail with either the standard tamp or the beveled tamp and the flat side of the locking slide hammer. The standard tamp captures 2 mm of nail tip.

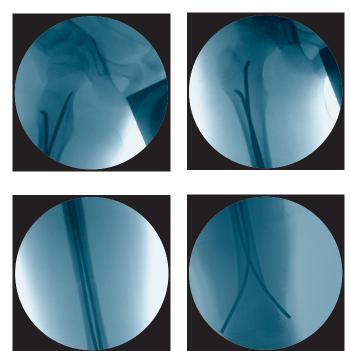
The beveled tamp captures 6 mm of nail tip and will leave approximately 10 mm of nail protruding from the cortex when the tamp is driven flush to the periosteum. Keep the etched line aligned with the long axis of the bone to keep the beveled surface in proper orientation. In order to prevent distraction of the fracture, a slight blow on the knee is recommended.

Confirm final nail position and fracture reduction with fluoroscopy. In its final position, the end of the nail should protrude 10 mm-20 mm outside the cortex at an angle approximately 10°-15° above the bone. If the nail has been overinserted, use the locking pliers to grip and retract the nail.

Note: If using the end cap for elastic nail 3.0 mm-4.0 mm diameters, the nail should only protrude 10 mm.



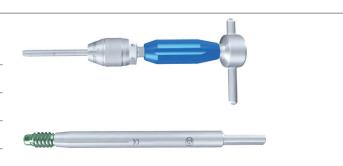




Insert end caps

Instruments

321.25	Spanner Wrench
359.213	Awl
359.219	Inserter, for Titanium Elastic Nails
359.222	Inserter, for Titanium Elastic Nail End Cap
359.226*	Inserter, for Titanium Elastic Nail End Cap, small

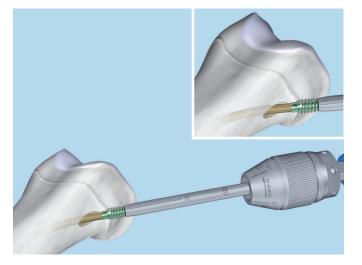


The end cap is inserted over the external portion of the elastic nail and threaded into the cortical bone in an oblique orientation. This is to prevent nail migration and soft tissue irritation. Use of the end cap also facilitates extraction of the nail.

Attach the end cap inserter to the nail inserter and tighten with the spanner wrench.

Connect an end cap to the end cap inserter by aligning the "D" flats.

Place the end cap over the elastic nail 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.



Tibial fractures in children typically require two nails inserted with an antegrade technique from medial and lateral entry points. The nail diameters are normally between 2.5 mm and 4.0 mm, depending upon patient anatomy. Position the patient supine on a standard or fracture table. Prep and drape the entire lower leg.

The entry points are a few centimeters distal to the physis at anterolateral and anteromedial locations, to minimize soft tissue irritation.

Before fully inserting the nails into the distal metaphysis, verify rotational and angular limb alignment. Alignment can be adjusted by rotating the nails or modifying their curvature. Once alignment is satisfactory, the nails can be fully inserted to achieve the best anchorage in the metaphysis. Before cutting the nails to length, release traction and impact the heel, if necessary.





Follow-up





Humeral Nail Technique

Humeral fractures in both children and adults typically require two nails inserted with a retrograde technique from a posterior insertion site. The nail diameters are normally between 2.5 mm and 3.5 mm, depending upon patient anatomy.

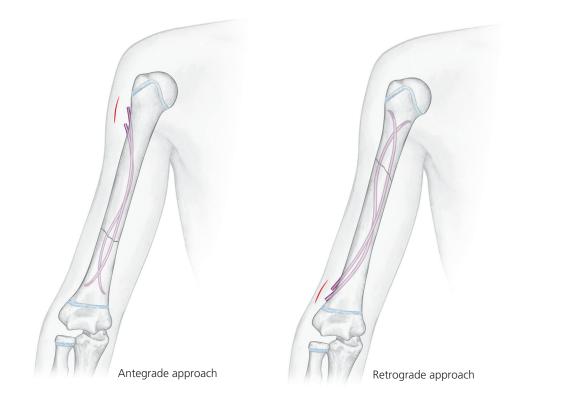
The entry point for each nail is posterolateral off the lateral supracondylar ridge, one hole above the other, angled upwards.

Alternatively, two nails can be inserted with an antegrade technique. The entry point for antegrade technique is located on the lateral humerus, level with the attachment point of the deltoid muscle.

Position the patient supine without a tourniquet. The arm may be placed on a radiolucent arm table or suspended vertically in traction. Prep and drape the arm from elbow to shoulder.

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







Follow-up

Instrument

393.10* Universal Chuck with T-Handle

Forearm fractures typically require a single nail inserted in each bone. Nails may be used either antegrade or retrograde, depending on fracture location and surgeon preference. It is recommended that the nail be placed in the radius from a distal approach and the nail be placed in the ulna from a proximal approach. The nail diameters are normally between 2.0 mm and 3.0 mm, depending upon patient anatomy.

In forearm indications where hammering is not required for nail insertion, the lighter weight universal chuck with T-handle may be used in place of the inserter, for more delicate control.

Position the patient supine with the affected arm placed on a radiolucent arm table. The image intensifier is positioned perpendicular to the arm, entering from the foot of the table.

For diaphyseal fractures the entry point in the radius is either just proximal to the radial styloid or through Lister's tubercle.

For radial head fractures the nail is inserted retrograde, allowing the nail tip to capture the proximal fragment. Using a percutaneous probe, partial reduction can be obtained. Reduction can be completed using rotation of the curved tip of the nail.

Precautions:

- Be aware of the extensor tendons and superficial radial nerve.
- Take care not to penetrate the contralateral cortex.
- The use of a hammer is not recommended since hammering may produce further fracture fragments.

The antegrade entry point in the ulna can be either at the posterior aspect of the olecranon or a lateral approach through the proximal metaphysis. The retrograde entry point in the ulna is through the distal metaphysis.





Follow-up

* Also available

End cap removal

Instruments	
321.25	Spanner Wrench
359.213	Awl
359.219	Inserter, for Titanium Elastic Nails
359.222	Inserter, for Titanium Elastic Nail End Cap
359.226*	Inserter, for Titanium Elastic Nail End Cap, small

Palpate over the end cap, make an incision in the skin and bluntly dissect to expose the end cap. Fluoroscopy may be needed to find the end cap.

Attach the end cap inserter to the nail inserter and tighten with the spanner wrench. Remove possible bone overgrowth with the awl or a rasp and place the inserter over the end cap (light hammer blows may be necessary). Turn counterclockwise to remove the end cap.

* Also available

2 Nail removal

Instruments	
359.218	Hammer Guide
359.224	Locking Pliers, long
359.225	Locking Slide Hammer

For nail removal, the end cap must be removed first.

Once the nail end is exposed, attach the long locking pliers. The pliers require only a few millimeters of engagement with the nail for removal in most cases.

If capturing the nail is difficult, the lower jaw of the pliers can be driven under the nail end with light hammer blows. Use care to protect the physis from damage.

To remove the nail, use the flat on the hammer to strike the pliers on the "horn." Alternatively, the hammer guide can be threaded into the end of the pliers, and the hammer can be used to back out the nail. Once the nail is retracted a few millimeters, removal can usually be completed by hand. If the nail is still difficult to remove, the inserter and slide hammer can be used to complete removal.





After each use, all instruments should be cleaned. Instruments with removable parts should be dismantled prior to cleaning. Steel brushes must not be used to clean the instruments. Cannulated instruments must be thoroughly cleaned and opened prior to washing and disinfection. Standard proprietary detergents and disinfectants can be used in accordance with the manufacturer's recommendations.

Prior to autoclaving, instruments should be checked for cleanliness. Instruments with moving parts must be lubricated with Synthes Autoclavable Oil (519.97).*

Clean the inserter after every use. Use a soft brush and neutral pH detergent to wash debris from the inserter chuck and 6 mm cannulation.

It is essential to lubricate the inserter periodically with autoclavable oil to maintain smooth operation of the chuck. After cleaning, apply a single drop of oil to the three chuck jaws and rear chuck bushing.

Open and close the chuck several times then wipe away the excess oil with a dry towel. Wash and sterilize the inserter before use.





* Also available

The cutter has movable parts. To disassemble the cutter, unscrew the stop nut and remove the cutting bolt from the cutting sleeve.

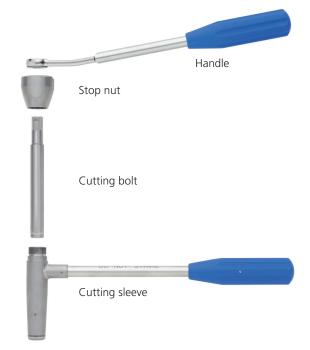
Following cleaning, and before autoclaving, lubricate the cutting bolt with DePuy Synthes autoclavable oil. The cutting bolt must be adequately lubricated to ensure smooth cutting.

After autoclaving, to reassemble the cutter, insert the cutting bolt into the cutting sleeve. Screw the stop nut onto the assembly.

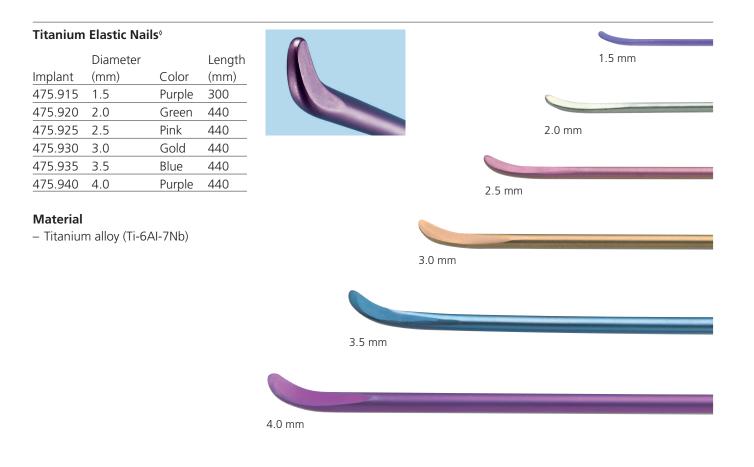








Implants



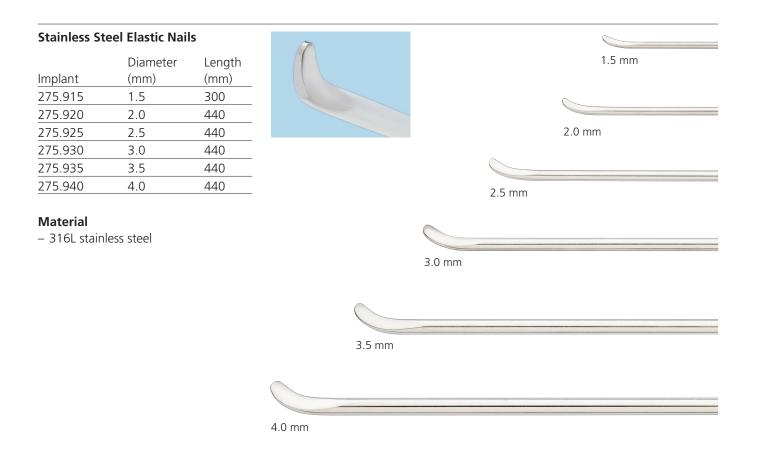
Titanium End Caps[°], for Titanium Elastic Nails

	For Nail Diameter	
Implant	(mm)	Color
475.900	3.0-4.0	Green
475.905	1.5–2.5	Pink

Material

– Titanium alloy (Ti-6Al-7nb)

These implants are available nonsterile or sterile-packed. Add "S" to product number to order sterile product.



Stainless Steel End Caps [°] , for Stainless Steel Elastic Nails		
Implant	For Nail Diameter (mm)	
275.900	3.0-4.0	_

Material – 316L Stainless Steel

1.5-2.5

275.905

All stainless steel elastic nail implants are available nonsterile only.

Instruments

312.46	4.5 mm/3.2 mm Double Drill Sleeve	
315.28	2.7 mm Three-Fluted Drill Bit, 125 mm	
315.29	3.2 mm Three-Fluted Drill Bit, 195 mm	
315.48	4.5 mm Three-Fluted Drill Bit, 195 mm	<u>66660</u>
321.25	Spanner Wrench	
359.205	Standard Tamp	
359.206	Beveled Tamp	

359.207	Bar, for Small F-Tool*		
359.208	Threaded Rod, for Small F-Tool*		
		8 8	
		_	
359.213	Awl, for use with Titanium Elastic Nails		
		_	
359.218	Hammer Guide, for Titanium Elastic Nails		
359.219	Inserter, for Titanium Elastic Nails	_	

*Small F-Tool (359.209) consists of Bar (359.207) and three Threaded Rods (359.208).

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SMISS

359.222 Inserter, for Titanium Elastic Nail End Cap

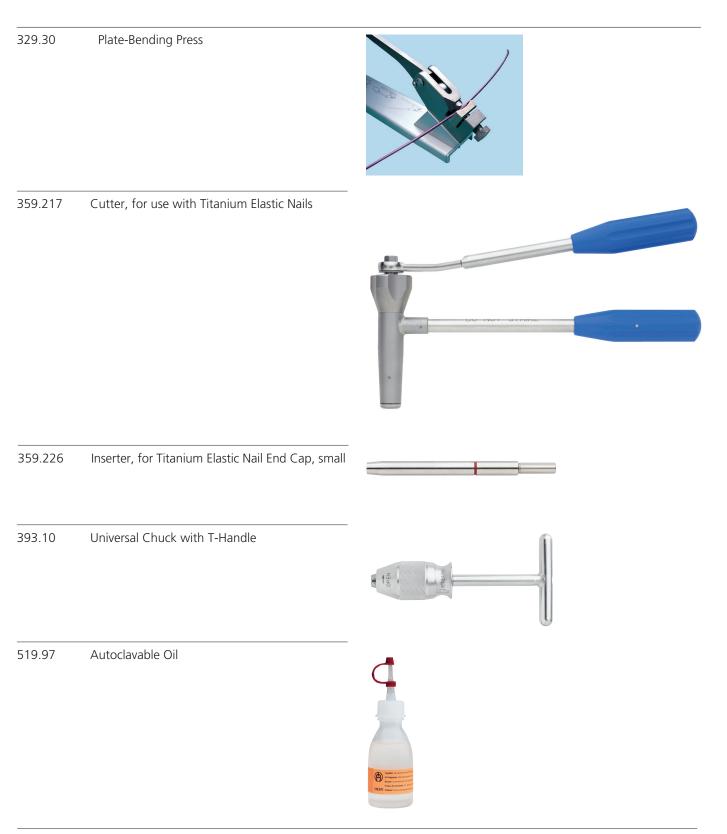
359.224Locking Pliers, long



359.225Locking Slide Hammer, 400 grams



Also Available Instruments



Graphic Case

690.109	Titanium Elastic Nail System Graphic Case	
Instruments		
312.46	4.5 mm/3.2 mm Double Drill Sleeve	
315.28	2.7 mm Three-Fluted Drill Bit, quick coupling, 125 mm	
215 20	. 20	
315.29	3.2 mm Three-Fluted Drill Bit, quick coupling, 195 mm	
315.48	4.5 mm Three-Fluted Drill Bit, quick coupling,	
	195 mm	
321.25	Spanner Wrench	
359.205	Standard Tamp	
359.206	Beveled Tamp	
359.207	Bar, for Small F-Tool	
359.208	Threaded Rod, for Small F-Tool, 3 ea.	
359.213	Awl, for use with Titanium Elastic Nails	
359.218	Hammer Guide, for Titanium Elastic Nails	
359.219	Inserter, for Titanium Elastic Nails	
359.222	Inserter, for Titanium Elastic Nail End Cap	
359.224	Locking Pliers, long	
359.225	Locking Slide Hammer, 400 grams	

Implants

475.900	Titanium End Cap for Titanium Elastic Nail,
	3.0 mm-4.0 mm diameters, 10 ea.
475.905	Titanium End Cap for Titanium Elastic Nail,
	1.5 mm–2.5 mm diameters, 4 ea.

Titanium Elastic Nails, 6 ea.

	Diameter (mm)	Length (mm)
475.915	1.5	300
475.920	2.0	440
475.925	2.5	440
475.930	3.0	440
475.935	3.5	440
475.940	4.0	440



Stainless Steel Elastic Nail Implant Set (105.708)

690.112 Stainless Steel Elastic Nail Implant Graphic Case

Implants in set 105.708

275.900	Stainless Steel End Cap for Stainless Steel
	Elastic Nail, 3.0 mm-4.0 mm diameters, 4 ea.
275.905	Stainless Steel End Cap for Stainless Steel
	Elastic Nail, 1.5 mm–2.5 mm diameters, 4 ea.

Stainless Steel Elastic Nails, 6 ea.

	Diameter (mm)	Length (mm)
275.915	1.5	300
275.920	2.0	440
275.925	2.5	440
275.930	3.0	440
275.935	3.5	440
275.940	4.0	440



Note: For additional information, please refer to the package insert or <u>www.e-ifu.com</u>.

For detailed cleaning and sterilization instructions, please refer to www.depuysynthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.

Power Equipment

Small Battery Drive with 14.4 V
Battery Pack Set
Small Battery Drive
Small Battery Drive Battery Casing, for
12 V Battery
Quick Coupling for Drill Bits



105.957	Power Drive Set
530.100	Power Drive
530.280	Battery Casing, for Power Drive
511.75	Quick Coupling, for Drill Bits





150.16	ComPact Air Drive II Set
511.701	ComPact Air Drive II
519.515	Double Air Hose, Schrader Stem
511.75	Quick Coupling, for Drill Bits





36 DePuy Synthes Titanium Elastic Nail System Surgical Technique

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Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information. CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

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