



# SURGICAL TECHNIQUE

## ELASTIC NAIL SYSTEM






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## SYSTEM OVERVIEW

PLATES	
<p>Elastic Nail 40 cm</p> <ul style="list-style-type: none"> <li>• Catalogue Number: Stainless Steel: SS 223 Titanium: TT 223</li> <li>• Available in Stainless Steel 316L and Titanium Grade 5</li> <li>• 4 TO 14 holes</li> <li>• Length: 40 cm</li> <li>• Diameter : <math>\phi</math> 2.0 mm, <math>\phi</math> 2.5 mm, <math>\phi</math> 3.0 mm, <math>\phi</math> 3.5 mm, <math>\phi</math> 4.0 mm, <math>\phi</math> 4.5 mm</li> </ul>	
<p>Elastic Nail 44 cm</p> <ul style="list-style-type: none"> <li>• Catalogue Number: Stainless Steel: SS 223 Titanium: TT 223</li> <li>• Available in Stainless Steel 316L and Titanium Grade 5</li> <li>• 4 TO 14 holes</li> <li>• Length: 40 cm</li> <li>• Diameter : <math>\phi</math> 2.0 mm, <math>\phi</math> 2.5 mm, <math>\phi</math> 3.0 mm, <math>\phi</math> 3.5 mm, <math>\phi</math> 4.0 mm, <math>\phi</math> 4.5 mm</li> </ul>	
INSTRUMENT SET	
<p><b>SIS 115 Elastic Nail Instruments Set</b></p> <p>SIS 115-001 Impactor for Elastic Nail, Straight</p> <p>SIS 115-002 Impactor for Elastic Nail, Bevelled</p> <p>SIS 115-003 Insertor for Elastic Nail</p> <p>SIS 115-004 Extraction Plier for Elastic Nail</p> <p>SIS 115-005 Hammer Guide for Elastic Nail</p> <p>SIS 115-006 Pin Wrench Dia. 4.5mm, Length 120mm</p> <p>SIS 115-007 F-Tool for Reduction - Small</p> <p>SIS 115-008 Double Drill Guide 4.5/3.2mm</p> <p>SIS 115-009 Hammer 500gms</p> <p>SIS 115-010 Slide Hammer 400gms</p> <p>SIS 115-011 Awl Curved Length 180mm, for Clavicular Fractures</p> <p>SIS 115-012 Bolt Cutter</p> <p>SIS 115-013 Stainless Steel Box for Elastic Nail Instrument Set</p>	  

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## INDICATIONS:

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Elastic Intramedullary Nail System is indicated for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is important. This includes upper extremity fractures in all patients and lower extremity fractures in paediatric or small-stature 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.

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

## INDICATIONS IN ADULTS:

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In adult patients, TEN is used for the osteosynthesis of clavicle, forearm and humerus fractures.

As follows:

- Diaphyseal fractures of long bone fractures in upper extremity
- Clavicle shaft fractures

## CONTRAINDICATIONS:

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1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

## PRECAUTIONS:

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An implant shall never be reused. Previous stresses may have created imperfections which can lead to device failure. Instruments shall be inspected for wear or damage prior to usage. Protect implant appliances against scratching and nicking. Such stress concentrations can lead to failure.

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**Single Brand Usage:** Implant components from one manufacture should not be used with those of another. Implants from each manufacture may have metal, dimensions and design differences so that the use in conjunction with different brands of devices may lead to inadequate fixation or adverse performances of the devices.

#### ADVERSE EVENTS:

- Clinical failure (i.e. pain or injury) due to bending, loosening, breakage of implant, loose fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant.
- Primary and/or secondary infections.
- Allergic reactions to implant material.
- Necrosis of bone or decrease of bone density.
- Injury to vessels, nerves and organs.
- Elevated fibrotic tissue reaction around the surgical area.

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## SURGICAL TECHNIQUE:

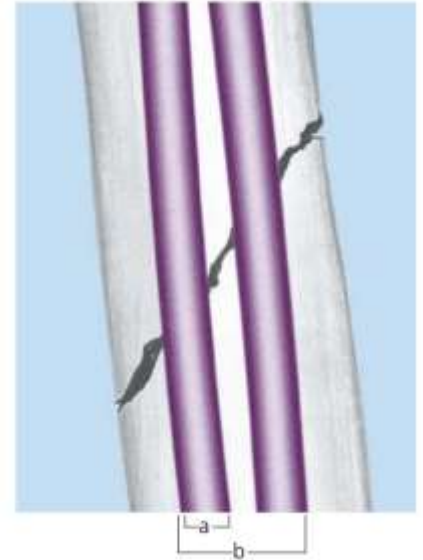
### NAIL SELECTION

**Elastic Nails are available in six diameters:**  $\phi$  2.0 mm,  $\phi$  2.5 mm,  $\phi$  3.0 mm,  $\phi$  3.5 mm,  $\phi$  4.0 mm,  $\phi$  4.5 mm. The nails are color coded for easy identification.

Measure the narrowest diameter (point b) of the medullary canal with a ruler. The proper nail diameter (point a) 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	3.0mm
9-11	3.5mm
12-14	4.0mm

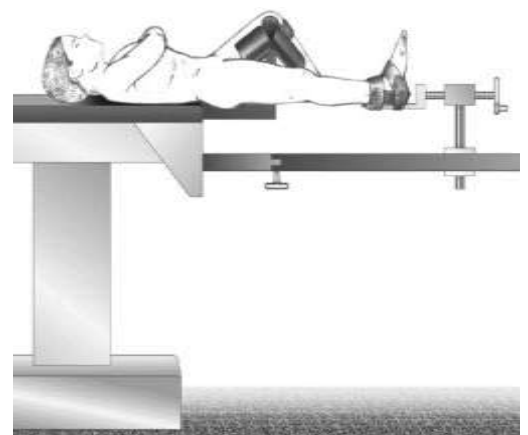


**Note:** Select two nails of the same diameter so the opposing bending forces are equal, avoiding malalignment.

**FEMORAL NAIL INSERTION:** 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





## 2. Contour the nail:

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 table-top 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 mal-aligning 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:** SS316L Elastic Nail is approximately twice as rigid as a comparable Titanium Grade 5 Elastic Nail, and therefore care should be taken when contouring and inserting the SS 316L elastic nail.

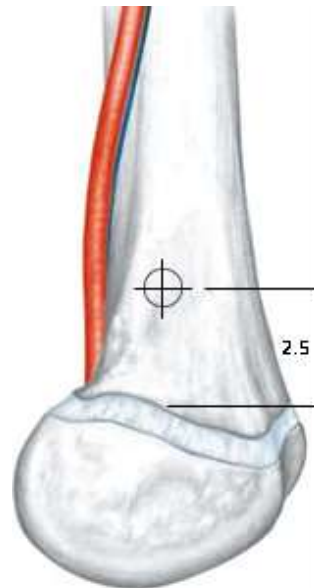
## 3. Create nail entry point:

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 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 leakage may result.

### **Note:**

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

#### 4. Insert nail:

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.

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.

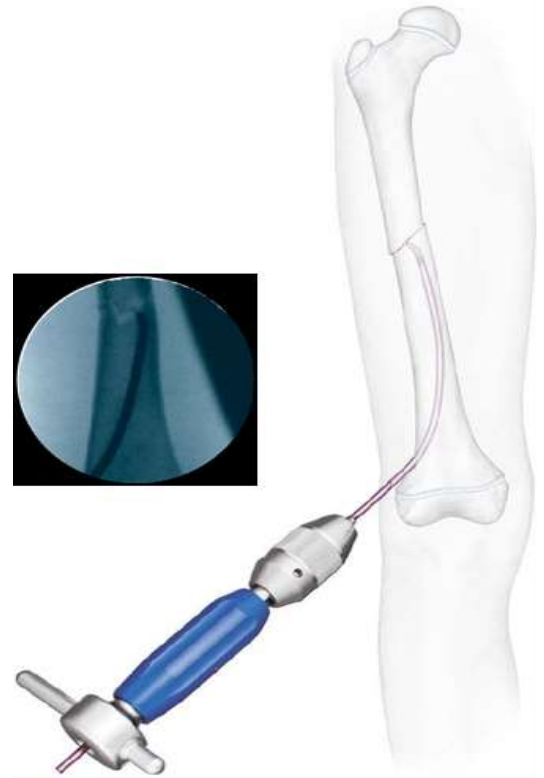
Ensure that the convex side of the nail tip is glancing off the far cortex and is advancing with each blow. The nail will bend as it progresses up the canal. This part of the procedure requires the greatest insertion force.

#### Note:

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.
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.



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### 5. Reduce fracture:

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



### 6. Cross fracture:

Visualize the fracture with fluoroscopy. Determine which nail will be easier to pass across the fracture. Advance that nail which will most effectively pull the proximal fragment into alignment. Using the inserter, hammer guide and locking slide hammer, drive the nail across the fracture, monitoring nail position with fluoroscopy.

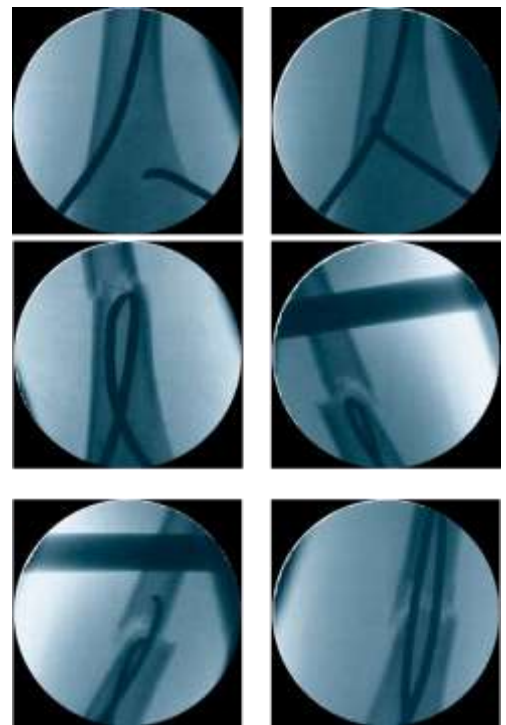
The nail can be rotated to manipulate the curved tip across the fracture. Rotation is easiest while the nail is being advanced or retracted.

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



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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. Cut nails to length:

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 cut-off point. The cut-off 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 cut-off 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°– 15° 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 cap.

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.



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

The bevelled 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 bevelled 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 over-inserted, use the locking pliers to grip and retract the nail.

**Note:**

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

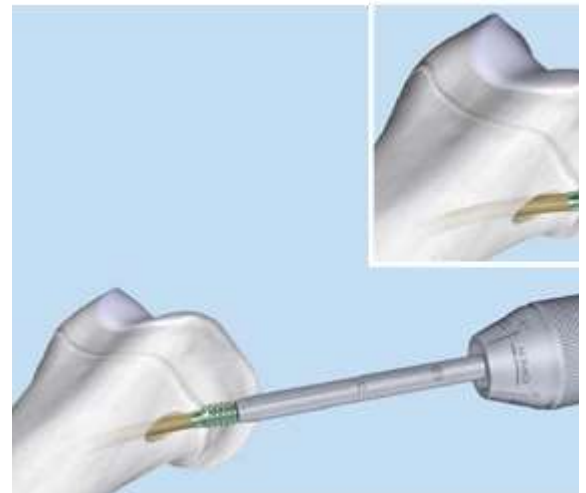
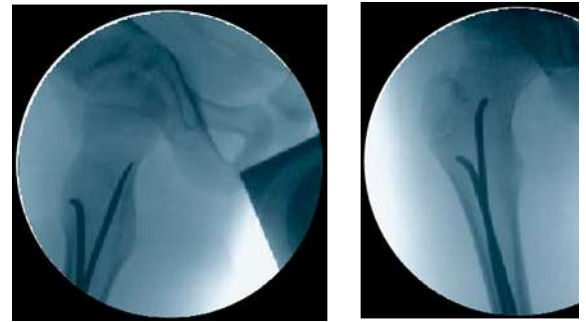
**8. Insert end cap:**

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.





## TIBIA NAIL TECHNIQUE

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 2.5mm and 4.0mm, 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 centimetres 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 achieved the best anchorage in the metaphysis. Before cutting the nails to length, release traction and impact the heel, if necessary.



Follow-up



Lateral view



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## HUMERAL NAIL TECHNIQUE

Humeral fracture in both children and adults typically required two nails inserted with a retrograde technique from a posterior insertion site. The nail diameters are normally between 2.5mm and 3.5mm, 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.



Follow-up

### Precaution:

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

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## FOREARM NAIL TECHNIQUE

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 diameter are normally between 2.0mm to 3.0mm, depending upon the patient anatomy.

In the 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 radius 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

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### **END CAP REMOVAL:**

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 counter clockwise to remove the end cap.

### **NAIL REMOVAL:**

For nail removal, the end cap must be removed.

### **VARIATIONS ON THE FEMORAL TECHNIQUE FOR FOREARM INSERTIONS:**

#### **RADIAL INSERTION:**

**Skin Marking and Identification Of Insertion Site:** A skin mark is made at the physis. A second mark is made at the insertion point metaphyseal / diaphyseal junction. The position of each mark is confirmed by fluoroscopy directly overlying the radial border.

**Incision:** An incision is made connecting the two marks. Blunt dissection protects the soft tissues and the prominence of the distal radial metaphysis is visualized.

**Nail Insertion:** The nail should be inserted just proximal to the Radial Styloid and directed towards it. This will allow the bow of the nail to recreate the natural bow of the radius.

#### **ULNAR INSERTION:**

**Skin Marking and Identification Of Insertion Site:** A small stab wound is made over the olecranon and an entry hole is made through the olecranon cortex.

**Contour The Nail:** No nail contouring is necessary.

**Insert The Nail:** The nail is placed through the ulnar canal to the level of the fracture. The fracture is reduced, the nail inserted across the fracture site and brought to the distal ulna.

### **CAUTION:**

**USED IMPLANTS:** Used implants which appear un-damaged may have internal and/or external defects. It is possible that individual stress analysis of each part fail to reveal the accumulated stress on the metals as a result of use within the body. This may lead ultimately to implant failure after certain point of time due to metal fatigue. Therefore reuses of implants are strictly not recommended.

**MRI Safety Information:** Samay Surgicals Pvt. Ltd. implants are manufactured from Titanium Gr.2, SS316L, SS316LVM material and both are non-magnetic material, hence it

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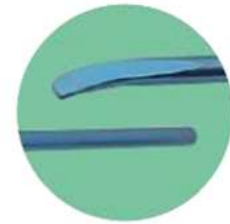
do not pose any safety risk. Patients should be directed to seek a medical opinion before entering potentially adverse environments that could affect the performance of the implants, such as electromagnetic or magnetic field or including a magnetic resonance environment. - Doctor shall conduct a Risk Benefit Analysis before directing the patient to enter electromagnetic or magnetic fields or including a magnetic resonance environment.

SamaySurgicals Pvt. Ltd. implants has not been evaluated for safety and compatibility in the MR environment but on the basis of literature study below mentioned points can be taken care during MRI The minimum recommended time after the implantation that allows patients to safely undergo MRI examination or allowing the patient or an individual to enter the MRI environment is 6 (six) weeks. The maximum recommended time limit for MRI examination in patients implanted with the evaluated device is 30 min with a scanner operating at 1.5T (Tesla) or less.

**DISPOSAL OF USED IMPLANTS:** Every used or removed implant must be discarded after use and must never be re- used. It should be bent or scratched & then disposed of properly so that it becomes unfit for reuse. While disposing it off, it should be ensured that the discarded implant does not pose any threat to children, stray animals and environment. Dispose of the implants as per applicable medical practices and local, state and country specific regulatory requirement of Bio Medical Waste rules.

**PACKAGING MATERIAL DISPOSAL:** The packaging material of this device is made of LDPE and therefore if swallowed, may cause choking Hazards. Therefore, it should be disposed of in such ways that keep out of reach of children and stray animals.

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### Elastic Nail

Code No. S.S. 316L	Code No. Titanium	Dia	Length
SS 223-325	TT 223-325	2.5mm	44cm
SS 223-330	TT 223-330	3.0mm	44cm
SS 223-335	TT 223-335	3.5mm	44cm
SS 223-340	TT 223-340	4.0mm	44cm
SS 223-345	TT 223-345	4.5mm	44cm
SS 223-350	TT 223-350	5.0mm	44cm





Implants Certified by: **CE**  
**XXXX**

Instruments Certified by Self Declaration : **CE**



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