

# SURGICAL TECHNIQUE

## INTERLOCKING FEMORAL NAIL

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## SYSTEM OVERVIEW

NAILS	
<p>INTER-LOCKING FEMORAL NAIL (9.0 mm)</p> <ul style="list-style-type: none"> <li>• Catalogue Number: Stainless Steel: SS 202 Titanium: TT 202</li> <li>• Available in Stainless Steel 316L and Titanium Grade 5</li> <li>• Length: 34cm to 48cm</li> <li>• Diameter: 9mm</li> </ul>	
<p>INTER-LOCKING FEMORAL NAIL (10.0 mm)</p> <ul style="list-style-type: none"> <li>• Catalogue Number: Stainless Steel: SS 202 Titanium: TT 202</li> <li>• Available in Stainless Steel 316L and Titanium Grade 5</li> <li>• Length: 34cm to 48cm</li> <li>• Diameter: 10mm</li> </ul>	
<p>INTER-LOCKING FEMORAL NAIL (11.0 mm)</p> <ul style="list-style-type: none"> <li>• Catalogue Number: Stainless Steel: SS 202 Titanium: TT 202</li> <li>• Available in Stainless Steel 316L and Titanium Grade 5</li> <li>• Length: 34cm to 48cm</li> <li>• Diameter: 11mm</li> </ul>	
<p>INTER-LOCKING FEMORAL NAIL (12.0 mm)</p> <ul style="list-style-type: none"> <li>• Catalogue Number: Stainless Steel: SS 202 Titanium: TT 202</li> <li>• Available in Stainless Steel 316L and Titanium Grade 5</li> <li>• Length: 34cm to 48cm</li> <li>• Diameter: 12mm</li> </ul>	
<p>CAP FOR FEMUR NAIL</p> <ul style="list-style-type: none"> <li>• Catalogue Number: Stainless Steel: SS 200-003 Titanium: TT 200-003</li> </ul>	

<p><b>3.9 mm INTER-LOCKING SCREW</b></p> <ul style="list-style-type: none"> <li>• Catalogue Number: Stainless Steel: SS 213 Titanium: TT 213</li> <li>• Available in Stainless Steel 316L and Titanium Grade 5</li> <li>• Length: 16mm to 50mm</li> <li>• Diameter: 3.9mm</li> </ul>	
<p><b>4.9 mm INTER-LOCKING SCREW</b></p> <ul style="list-style-type: none"> <li>• Catalogue Number: Stainless Steel: SS 214 Titanium: TT 214</li> <li>• Available in Stainless Steel 316L and Titanium Grade 5</li> <li>• Length: 20mm to 90mm</li> <li>• Diameter: 4.9mm</li> </ul>	
<p><b>GUIDE WIRE</b></p> <ul style="list-style-type: none"> <li>• Catalogue number- Stainless Steel 316L: SS 291 Available in Stainless Steel 316L</li> </ul>	
<p><b>INSTRUMENT SET DETAILS</b></p>	
<p><b>SIS 119 Tibia &amp; Femur Nail Instruments Set</b></p> <ul style="list-style-type: none"> <li>SIS 119-001 Bone Awl</li> <li>SIS 119-002 Conical Bolt for Tibia Nail</li> <li>SIS 119-003 Conical Bolt for Femur Nail</li> <li>SIS 119-004 Depth Guage</li> <li>SIS 119-005 Distal Device for Tibia Nail</li> <li>SIS 119-006 Distal Device for Femur Nail</li> <li>SIS 119-007 Distal Device Bolt</li> <li>SIS 119-008 Drill Bit, 4.0 mm</li> <li>SIS 119-009 Drill Bit, 3.2 mm</li> <li>SIS 119-010 Drill Sleeve, 8 X 4.0 mm</li> <li>SIS 119-011 Drill Sleeve, 8 X 3.2 mm</li> <li>SIS 119-012 Guide Wire Pusher</li> <li>SIS 119-013 Guide Wire (Simple)</li> <li>SIS 119-014 Guide Wire (Bullet Tip)</li> <li>SIS 119-015 Hammer</li> <li>SIS 119-016 Hammering Bolt</li> <li>SIS 119-017 Impactor Extractor</li> <li>SIS 119-018 Main Sleeve 10 X 8 mm</li> <li>SIS 119-019 ProgzialZig Tibia Nail</li> <li>SIS 119-020 ProgzialZig Femur Nail</li> <li>SIS 119-021 Screw Driver</li> <li>SIS 119-022 Spanner</li> <li>SIS 119-023 Teflon Sleeve</li> <li>SIS 119-024 Tissue Protector</li> <li>SIS 119-025 Trocar</li> <li>SIS 119-026 Box - for Int. System</li> </ul>	  

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## INDICATIONS:

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The interlocking femoral nail is indicated for use in long or rotationally unstable diaphyseal fracture, Segmental fracture, comminuted fracture, fracture with bone loss and rotationally unstable proximal and distal fractures.

## CONTRAINDICATIONS:

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- Isolated femoral neckfractures
- Supracondylar fractures
- Intertrochanteric fractures
- Pertrochanteric fractures

## ADVERSE REACTIONS:

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- 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

## 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.

### 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.

## SURGICAL TECHNIQUE:

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### PREOPERATIVE PLANNING:

#### 1. Selection of nail:

Although definitive nail length and diameter are determined intra operatively, nail selection should be part of the preoperative plan.

An approximate nail length is determined by measuring the patient from the tip of the greater trochanter to the knee joint space and subtracting 2 cm.

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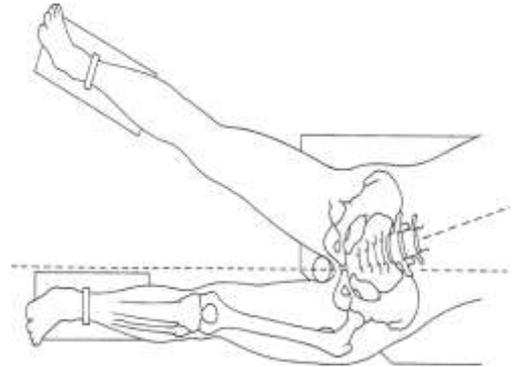
An approximate nail diameter is determined by measuring the isthmus of the affected medullary canal from an X-ray. If the isthmus is obliterated by the fracture pattern, a measurement is made from the contralateral side.

The Radiographic Ruler, available separately may also be used to determine approximate nail size. The ruler depicts the nails 15 % larger than actual size, to compensate for the magnification which occurs when taking an X-ray at the standard tube-to-film distance of one meter. Placing the ruler directly over the preoperative X-ray of the uninjured leg provides an estimation of nail length and diameter.

Based on these measurements, a minimum of three diameters of nails in three lengths should be available for surgery.

**2. Patient positioning:**

Position the patient supine on a fracture or radiolucent operating table. Place the contralateral leg on a leg support, and orient it intraoperatively. Position the C-arm of the image intensifier in such a way that true AP and lateral views of the proximal femur are possible, and check it pre-operatively. To ensure unimpeded access to the medullary cavity, abduct the upper body approximately 10–15° to the contralateral side (or abduct the affected leg by 10–15°). When selecting the nail size, consider canal diameter, fracture pattern, patient anatomy and post-operative protocol.



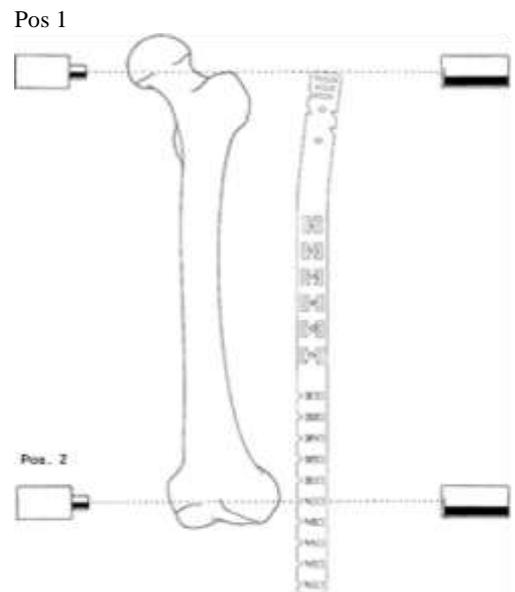
**3. Fracture reduction on the fracture table**

If possible, carry out a closed preoperative reduction of the fracture under image intensifier control. Exact reduction and secure fixation of the patient to the operating table are essential for easy handling and a good surgical result.

**4. Determine nail length:**

Measure with the measuring device under image intensification. Position the image intensifier for an AP view of the proximal femur (position 1). Use long forceps to hold the Measuring Device alongside the lateral aspect of the thigh parallel to and at the same level as the femur. Adjust the C-arm of the image intensifier so that the beam is centred between the femur and the measuring device; this will prevent magnification errors. Adjust the measuring device until its proximal end is level with the tip of the greater trochanter.

Mark the skin at the top of the measuring device. Move the image intensifier to the distal femur end (position 2), replace the proximal end of the measuring device at the skin mark and take an AP image of the distal femur. Verify the fracture reduction.

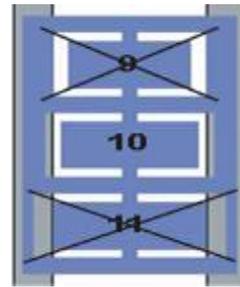


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Read the nail length directly from the image of the measuring device, selecting the measurement at or just proximal to the epiphyseal scar, or at the chosen insertion depth.

**5. Determine nail diameter**

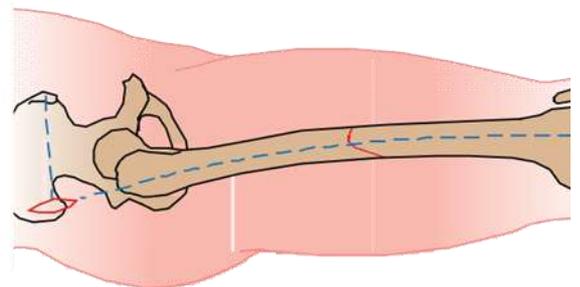
Determine the distal nail diameter by placing the AO/ASIF planning template on an AP image over the isthmus



**OPENING OF THE MEDULLARY CANAL**

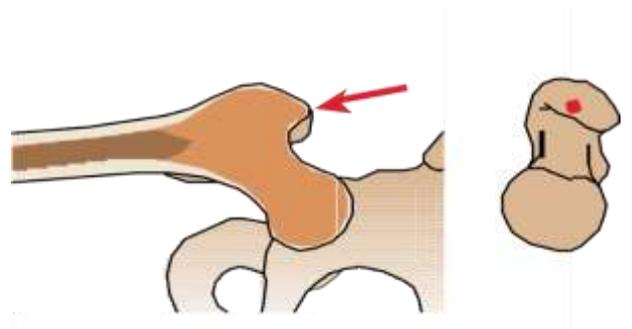
**1. Incision of the skin**

Extending the femoral shaft axis about 70mm proximal to the tip of the trochanter, a longitudinal incision of about 40mm is made. The fascia is split longitudinally in the direction of the tip of the trochanter, so that the greater trochanter can be palpated with the fingertip.



**2. Entry point of the nail**

The entry point of the intramedullary nail lies transversely in the extension of the axis of the medullary canal, directly lateral to the tip of the greater trochanter



**3. Insertion of the guide rod**

Under image intensification, insert the 2.5mm Guide wire into the canal, across the fracture site, and into the distal metaphysis. The Chuck with T-Handle may be used to facilitate insertion.

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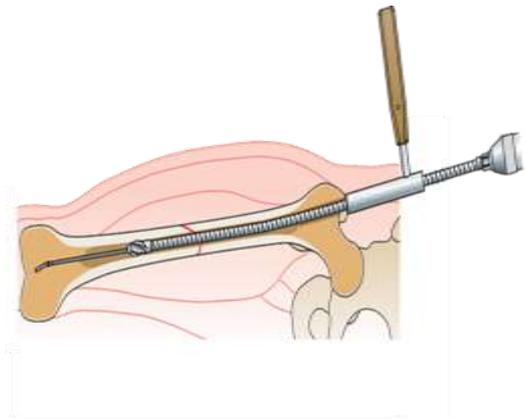
#### 4. Reaming the Medullary Canal

Use the Fixed Cannulated Reamer or Flexible Shaft with the front-cutting 8mm Reamer Head to begin reaming.

To protect the soft tissue, place the Tissue Protector medial to the Reamer shaft.

Reaming progresses in 1mm in case of fixed reamer and 0.5mm increments using the flexible interchangeable Medullary Reamer Heads.

The diameter of the nail to be used will match the diameter of the last reamer used. Over reaming the medullary canal by 0.5 mm–1.0 mm facilitates nail insertion but is not absolutely necessary.



#### 5. Measuring for the Nail

Determine the appropriate nail length by subtracting the exposed length of the Guide Wire from its overall length of 92cm. Confirm the diameter of the selected nail with the Measuring Gauge

#### PROXIMAL JIG ASSEMBLY

1. Slide the femoral nail over the 2.5 mm Guide Wire. Manually insert the nail into the medullary canal as far as possible.
2. Put the proximal jig on femoral nail, match the slot and Screw the nail holding bolt into the proximal end of the nail. The proximal jig should be oriented laterally.
3. Using the proximal jig handle to control nail rotation, tighten the nail holding bolt with the socket wrench with T handle.
4. Fix the impactor head on nail holding bolt and screw it onto the end of the bolt.



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## NAIL INSERTION:

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### 1. Inserting the Nail:

With controlled blows of the hammer, insert the nail into the canal. Image intensification should be used to monitor the passage of the nail across the fracture. Control rotation of the nail using the Jig Handle.

The nail should advance in the medullary canal with each blow of the hammer. If resistance is encountered, remove the nail and ream the canal to an additional 0.5mm to 1 mm.

When the nail is fully seated, remove the Impactor head and guide wire. If the nail needs to be locked, the Proximal jig assembly shall remain on the nail



### 2. Confirmation of the final position of the intramedullary nail for femur

The final position of the intramedullary nail must be checked in both planes with the image intensifier. In particular, the correct rotation of the extremity must be checked at this time.

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## DISTAL LOCKING

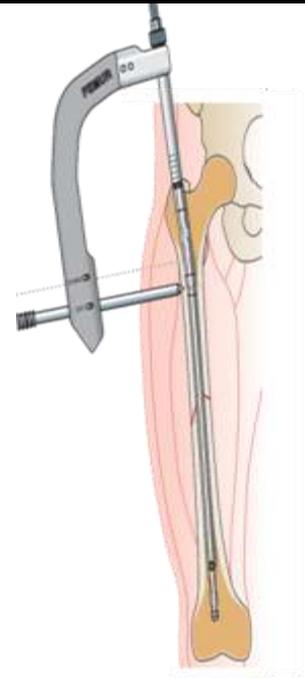
Use the image intensifier for AP and axial control.

Under image intensification, place a scalpel or Steinman pin on the skin with the tip of the blade or point of pin over the center of the hole to determine the stab incision point and make a stab incision. Insert the 4 mm x10" Drill Bit into the stab incision point. Under image intensification, place the tip of the drill bit oblique to the X-ray beam, into the stab incision and onto the femur, until the tip of the drill bit is centered in the locking hole.

Tilt the beam until the drill bit is in line with the X-ray beam and appears in the center of the hole. The drill bit will nearly fill in the locking hole. Hold the drill firmly in this position and drill through both cortices. Use image intensification to keep the drill bit centered.

Measure the hole with the Long Depth Gauge 4.9mm for Interlocking screws. Add 2 mm to this reading to ensure that the interlocking screw will engage the far cortex.

Insert the Interlocking screw and tighten with the long hexagonal screwdriver 4.9mm.



## PROXIMAL LOCKING:

Decide the first hole to be locked and based on selection of holes DC or Static, Insert the Protection Sleeve, with Trocar inserted, through the appropriate drill hole in the Proximal Jig. The Jig shows marking of DC or ST holes. Make a stab incision through the skin at the point where the trocar touches the skin. Pass the protection sleeve with trocar through the incision and onto the bone.

Remove the trocar. The protection sleeve remains in place until the Interlocking screw is completely inserted.

Insert the 4 mm Drill Sleeve through the protection sleeve and Drill through both cortices using the 4 mm Drill Bit.

Remove the drill sleeve. Using the long Depth Gauge for 4.9mm, measure for the proper length 4.9 mm Interlocking screw. Add 2 mm to the measurement to ensure engagement of the far cortex.

Insert the Interlocking screw through the Protection Sleeve. If an additional proximal Interlocking screw is to be placed, repeat steps.

Remove the remaining proximal jig instruments



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## REMOVING THE NAIL

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The Interlocking Femoral Nails' threaded proximal ends greatly simplify removal. The thread provides a secure connection with the nail holding bolt for smooth and accurate transmission of forces during nail extraction.

Selection of the appropriate nail holding bolt is critical to avoid complications or damage to the nail during extraction. The Interlocking Femoral Nail uses one nail holding bolt for all nail diameters, simplifying removal.

Interlocking screws must be removed prior to nail extraction. Make a short incision over the heads of the Interlocking screw. Use a curette and sharp hook to remove tissue in growth in the hex recess. Using the Long Hexagonal Screwdriver 4.9mm, insert the screwdriver into the hexagonal recess of the Interlocking screw and Remove the Interlocking screws.

**Note:** The final decision of removing the Nail shall be taken by the operating surgeon only. It is recommended that the implant used as an aid for healing should be removed once its service is over after proper consultation and examination by the operating surgeon in final follow up, particularly in younger and more active patient.

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## CAUTION:

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### 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.

### 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.

## MRI Safety Information:

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Samay Surgical implants are manufactured from Titanium Gr.5 and S316L material for Nails. Titanium Gr.5 and SS316L material and are non-magnetic material, hence it 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.

Samay Surgical 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.

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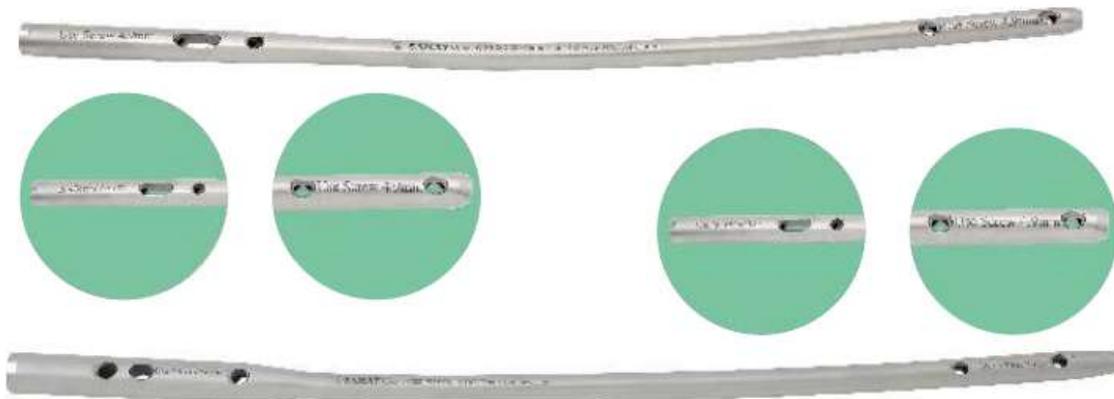
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## Inter-Locking Femoral Nail

Note : Define Code for S.S. 316L/SS 202, Titanium/TT 202, S.S. 316LVM/LM 202  
Screw Places : 4.9mm/3.9mm

Code No. S.S. 316L	Code No. S.S. 316L	Code No. S.S. 316L	Code No. S.S. 316L	Length
Dia. (9.0mm)	Dia. (10.0mm)	Dia. (11.0mm)	Dia. (12.0mm)	
SS 202-034	SS 202-134	SS 202-234	SS 202-334	34cm
SS 202-036	SS 202-136	SS 202-236	SS 202-336	36cm
SS 202-038	SS 202-138	SS 202-238	SS 202-338	38cm
SS 202-040	SS 202-140	SS 202-240	SS 202-340	40cm
SS 202-042	SS 202-142	SS 202-242	SS 202-342	42cm
SS 202-044	SS 202-144	SS 202-244	SS 202-344	44cm



### Inter-Locking Femoral Nail (New Design)

Note : Define Code for S.S. 316L/SS 202, Titanium/TT 202, S.S. 316LVM/LM 202  
Screw Places : 4.9mm

Code No. S.S. 316L	Code No. S.S. 316L	Code No. S.S. 316L	Code No. S.S. 316L	Length
Dia. (9.0mm)	Dia. (10.0mm)	Dia. (11.0mm)	Dia. (12.0mm)	
SS 202-034	SS 202-134	SS 202-234	SS 202-334	34cm
SS 202-036	SS 202-136	SS 202-236	SS 202-336	36cm
SS 202-038	SS 202-138	SS 202-238	SS 202-338	38cm
SS 202-040	SS 202-140	SS 202-240	SS 202-340	40cm
SS 202-042	SS 202-142	SS 202-242	SS 202-342	42cm
SS 202-044	SS 202-144	SS 202-244	SS 202-344	44cm



### 4.9mm Inter-Locking Screw

Code No. S.S. 316L	Code No. Titanium	Length
SS 214-020	TT 214-020	20mm
SS 214-022	TT 214-022	22mm
SS 214-024	TT 214-024	24mm
SS 214-026	TT 214-026	26mm
SS 214-028	TT 214-028	28mm
SS 214-030	TT 214-030	30mm
SS 214-032	TT 214-032	32mm
SS 214-034	TT 214-034	34mm
SS 214-036	TT 214-036	36mm
SS 214-038	TT 214-038	38mm
SS 214-040	TT 214-040	40mm
SS 214-042	TT 214-042	42mm
SS 214-044	TT 214-044	44mm
SS 214-046	TT 214-046	46mm
SS 214-048	TT 214-048	48mm
SS 214-050	TT 214-050	50mm
SS 214-052	TT 214-052	52mm
SS 214-054	TT 214-054	54mm
SS 214-056	TT 214-056	56mm
SS 214-058	TT 214-058	58mm
SS 214-060	TT 214-060	60mm
SS 214-062	TT 214-062	62mm
SS 214-064	TT 214-064	64mm
SS 214-066	TT 214-066	66mm
SS 214-068	TT 214-068	68mm
SS 214-070	TT 214-070	70mm
SS 214-075	TT 214-075	75mm
SS 214-080	TT 214-080	80mm



### 3.9mm Inter-Locking Screw

Code No. S.S. 316L	Code No. Titanium	Length
SS 213-018	TT 213-018	18mm
SS 213-020	TT 213-020	20mm
SS 213-022	TT 213-022	22mm
SS 213-024	TT 213-024	24mm
SS 213-026	TT 213-026	26mm
SS 213-028	TT 213-028	28mm
SS 213-030	TT 213-030	30mm
SS 213-032	TT 213-032	32mm
SS 213-034	TT 213-034	34mm
SS 213-036	TT 213-036	36mm
SS 213-038	TT 213-038	38mm
SS 213-040	TT 213-040	40mm
SS 213-042	TT 213-042	42mm
SS 213-044	TT 213-044	44mm
SS 213-046	TT 213-046	46mm
SS 213-048	TT 213-048	48mm
SS 213-050	TT 213-050	50mm



### Guide wire (Simple)

Code No. S.S. 316L	Dia	Length
SS 291-010	1.0mm	225mm
SS 291-012	1.2mm	225mm
SS 291-015	1.5mm	225mm
SS 291-018	1.8mm	225mm
SS 291-020	2.0mm	225mm
SS 291-025	2.5mm	225mm

Implants Certified by :   
XXXX

Instruments Certified by Self Declaration : 



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