SURGICAL TECHNIQUE

INTERLOCKING HUMERUS NAIL

NAILS	
INTER-LOCKING HUMERUS NAIL (SOLID) (6.0 mm) • Catalogue Number: Stainless Steel: SS 203 Titanium: TT 203 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 20cm to 30cm • Diameter: 6mm	
INTER-LOCKING HUMERUS NAIL (SOLID) (7.0 mm) • Catalogue Number: Stainless Steel: SS 203 Titanium: TT 203 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 20cm to 30cm • Diameter: 7mm	
INTER-LOCKING HUMERUS NAIL (CANNULATED) (6.0 mm) • Catalogue Number: Stainless Steel: SS 204 Titanium: TT 204 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 20cm to 30cm • Diameter: 6mm	
INTER-LOCKING HUMERUS NAIL (CANNULATED) (7.0 mm) • Catalogue Number: Stainless Steel: SS 204 Titanium: TT 204 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 20cm to 30cm • Diameter: 7mm	

INTER-LOCKING HUMERUS NAIL (CANNULATED) (8.0 mm) • Catalogue Number: Stainless Steel: SS 204 Titanium: TT 204 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 20cm to 30cm • Diameter: 8 mm	
CAP FOR HUMERUS NAIL • Catalogue Number: Stainless Steel: SS 200-01 Titanium: TT 200-01	
2.9 mm INTER-LOCKING SCREW • Catalogue Number: Stainless Steel: SS 212 Titanium: TT 212 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 16mm to 50mm • Diameter: 2.9mm	
3.4 mm INTER-LOCKING SCREW • Catalogue Number: Stainless Steel: SS 212 Titanium: TT 212 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 16mm to 50mm • Diameter: 3.4mm	
3.9 mm INTER-LOCKING SCREW • Catalogue Number: Stainless Steel: SS 213 Titanium: TT 213 • Available in Stainless Steel 316L and Titanium Grade 5 • Length: 16mm to 50mm • Diameter: 3.9mm	

GUIDE WIRE (SIMPLE)

- Catalogue number-
  Stainless Steel 316L: SS 291-018
- Available in Stainless Steel 316L
- Diameter: 1.8mm

INSTRUMENT SET DETAILS

SIS 117	**Humuras Nail Instruments**
SIS 117-001	ProgzimalZig
SIS 117-002	Conical Bolt
SIS 117-003	Main Sleeve
SIS 117-004	Drill Sleeve 2.7mm
SIS 117-005	Extractor Bolt
SIS 117-006	Distal Device
SIS 117-007	Device Locking Bolt
SIS 117-008	Compression Device
SIS 117-009	Compression Screw
SIS 117-010	Troccar
SIS 117-011	Bone Awl
SIS 117-012	Spanner
SIS 117-013	Depth Gauge
SIS 117-014	Hammer
SIS 117-015	Hammering Bolt
SIS 117-016	Impactor / Extractor
SIS 117-017	Screw Driver (3.4 mm)
SIS 117-018	Guid Wire 1.8mm X 20"
SIS 117-019	Drill Bit Dia. 2.7 mm X 10"
SIS 117-020	Box - for Int. system - Humuras Nail

DEVICE DESCRIPTION:

TheHumerus Nail System consists of all implants and instruments necessary for Humerus fracture fixation.

Screw places: 3.9mm/3.4mm/ 2.9mm

INDICATIONS:

The interlocking humerus nail can be used for an antegrade or retrograde insertion in the humeral shaft, and can be employed universally for the left and right humeri.

CONTRAINDICATIONS:

- Any active or suspected latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.

PRECAUTIONS:

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.

ADVERSE REACTIONS:

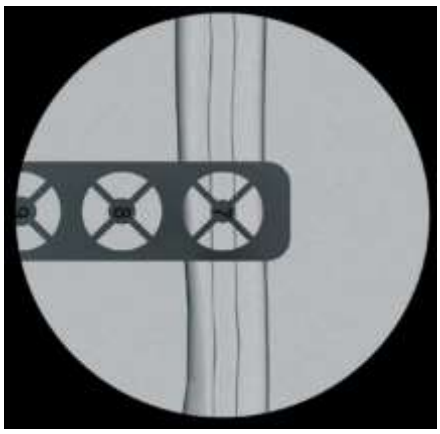
- Clinical failure (i.e. pain or injury) due to bending, loosening, breakage of implant, loose fixation, dislocation and/or migration
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant.
- Primary and/or secondary infections.
- Allergic reactions to implant material.
- Necrosis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

SURGICAL TECHNIQUE:

Patient positioning: Place the patient in a modified lateral position. Use an OR table that is completely radiolucent. The table setup should permit full C-arm visualization of the entire Humerus in the AP and lateral view. Place the C-arm opposite the surgeon and orient it perpendicular to the longitudinal axis of the Humerus shaft in the AP view. Obtain the scapular "Y" lateral view by bringing the C-arm through a 90° arc and projecting the beam directly at the glenoid.

Confirm nail length:
The approximate nail length can be determined preoperatively. Measure the length of the unfracturedhumerus from its head to the olecranon fossa and deduct 3–5 cm from the measured distance

Confirm nail diameter: Position the image intensifier for a lateromedial view of the humerus. Hold the radiographic medullary canal estimator over the humerus with the diameter gauge centered over the medullary canal at the narrowest part that will contain the nail. Read the diameter measurement on the circular indicator that fills the canal.



Determine entry point: Make the initial incision anterolateral to the acromion process and split the deltoid muscle longitudinally. Palpate the greater tuberosity, identify – but do not expose – the supraspinatus tendon and split the mid-section lengthwise. Avoid any additional injury to the rotator cuff at all costs. The arm can be adducted across the chest in order to gain better access to the proximal humerus. The antegrade insertion point for the Expert Humeral Nail is located on the extended axis of the central humeral shaft in the lateral view and at the bone-cartilage transition of the humeral head in the AP view and not on the greater tuberosity, otherwise the tendon attachment of the supraspinatus will be affected. With the humeral head correctly positioned, the point is located just in front of, or below, the tip of the acromion process. Find this position under the image intensifier using a 1.8 mm Kirschner wire.

Insert Kirschner wire

Using the small universal chuck with T-Handle, insert a 1.8 mm Kirschner wire at the appropriate insertion point in the proximal humerus and advance it in the medullary canal. Check the position of the Kirschner wire under the image intensifier in both the frontal and sagittal planes.

Open medullary canal:

Place the cannulatedawl over the Kirshner wire to the bone. Use a twisting motion to advance the awl. Remove the awl and the Kirshner wire.

Caution: Do not reuse the k wire

Assemble the Nail Holder/Proximal Jig instruments:

Insert the Nail holding bolt into Nail Holder/Jig and manually turn the appropriate length or Proximal Humerus Nail onto the Nail Holding Bolt. Connect the nail to the Nail Holder/Jig, apex of the nail bend pointing away from the Nail Holder/Jig. Thread the nail holding bolt fully into the nail and secure the assembly with the hexagonal T spanner

Insert the nail:

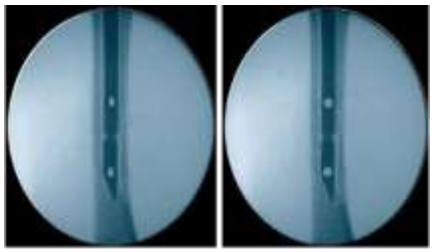
Insert the nail into the Humerus using a twisting hand motion. Verify fracture reduction and monitor nail passage across the fracture under image intensification. Use the nail as a reduction tool while keeping the patient's elbow steady to counter any distraction forces. If needed, thread the Impactor Head on to the nail holding bolt. Use light, controlled blows of the Hammer to seat the nail. Insert the nail until the proximal end is slightly countersunk beneath the superior surface of the proximal Humerus.

Use the hammer to seat the nail.

PROXIMAL LOCKING

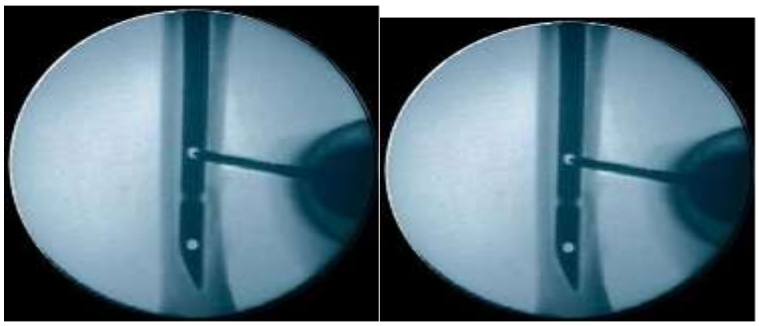
Confirm fracture reduction, keeping the Nail holder/jig oriented laterally. Determine the proximal locking configuration for the Humerus Nail. Place the arm in neutral rotation to minimize tension on the axillary nerve .Consider an open approach to help avoid injury to the surrounding neurovascular structures and soft tissues. Insert the Protection Sleeve and Trocar through the "STATIC" or "OBLIQUE" hole in the Nail Holder/Jig.

Remove the insertion assembly and insert an End Cap if required
Insert the Interlocking Screw 3.5mm
A second transverse Interlocking Screw may be inserted through the Static hole



DISTAL LOCKING- FREE HAND:

While maintaining fracture reduction, orient the image intensifier for an AP view of the distal Humerus and make a longitudinal skin incision over the superior distal locking hole being targeted. Bluntly dissect through the biceps muscle to the bone. Confirm reduction. Align the image intensifier with the hole in the nail until a perfect circle is visible in the center of the screen. Place a scalpel blade on the skin to determine the incision point and make an incision using open technique. Under image intensification, insert the tip of the 2.2 mm Drill Bit for 6mm & 7mm Nail and 2.7mm Drill bit for 8mm Nail through the incision. Place the drill bit oblique to the X -ray beam until the tip is centered in the locking hole. Be sure to use a sharp drill bit to prevent slippage and ensure accuracy.

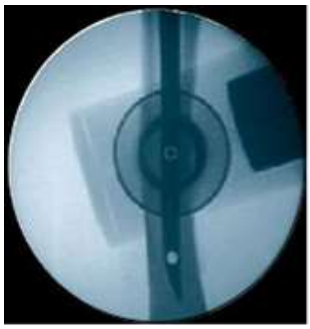


Incorrect (oblique hole) Correct (round hole)

Determine incision point. Position the 2.2/2.7mmDrill Bit.

DISTAL LOCKING- FREE HAND

Tilt the drill chuck handle until the drill bit is in line with the beam and appears as a radiopaque solid circle in the center. The drill bit will nearly all the locking hole image. Hold the drill in this position and drill through both cortices. Measure for Interlocking Screw length using the Long Depth Gauge. Pressing the sleeve to the bone, grasp the far cortex with the hook of the Long Depth Gauge. Read the scale against the top of the depth gauge to determine the appropriate Interlocking Screw length. Insert the Interlocking Screw in a freehand fashion using the Long Hexagonal Screwdriver of 3.5mm .Option of using hexagonal screw driver with Quick coupling sleeve 3.5mm is also available to hold the interlocking screw firmly. Verify Interlocking Screw length under image intensification. If needed (e .g osteopenia, short distal fragment), a second distal Interlocking Screw may be inserted using the same technique

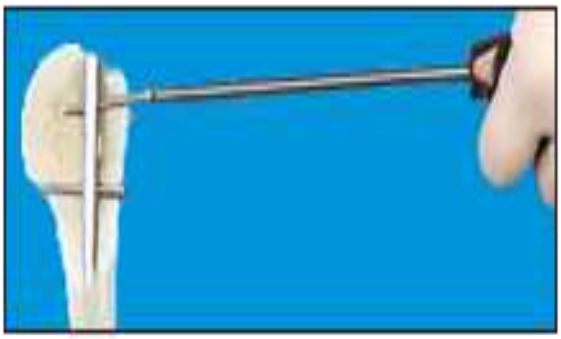


NAIL REMOVAL TECHNIQUE:

1. Remove the Interlocking Screws Connect the Nail holding bolt and Nail Holder/Jig to the nail before removing the last Interlocking Screw. This will prevent the nail from rotating in the medullary canal during assembly of the Extractor instruments to the nail. Use the Long Hexagonal Screwdriver 3.5mm or Screw Driver with quick coupling sleeve 3.5m to remove the Interlocking Screws. Remove the nail:

2. Thread the Extractor Rod onto the end of the Nail Holding Bolt. Remove the nail using the Slide Hammer with Ram. Remove the Locking Screw and Nail.

Note: The final decision of removing the implants 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 patients



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.

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.

MRI SAFETY INFORMATION:

Samay Surgicalimplants are manufactured from Titanium Grade 5 and SS 316L material and both 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.

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.

PRODUCT NAME	SS316L CATALOG NO.	TITANIUM CATALOG NO,	LENGTH	DIAMETER
Inter-Locking Humerus Nail (Solid) (6.0 mm)	SS 203-020	TT 203-020	20 cm	ø 6.0
	SS 203-022	TT 203-022	22 cm	ø 6.0
	SS 203-024	TT 203-024	24 cm	ø 6.0
	SS 203-026	TT 203-026	26 cm	ø 6.0
	SS 203-028	TT 203-028	28 cm	ø 6.0
	SS 203-030	TT 203-030	30 cm	ø 6.0
Inter-Locking Humerus Nail (Solid) (7.0 mm)	SS 203-120	TT 203-120	20 cm	ø 7.0
	SS 203-122	TT 203-122	22 cm	ø 7.0
	SS 203-124	TT 203-124	24 cm	ø 7.0
	SS 203-126	TT 203-126	26 cm	ø 7.0
	SS 203-128	TT 203-128	28 cm	ø 7.0
	SS 203-130	TT 203-130	30 cm	ø 7.0
Inter-Locking Humerus Nail (Solid) (8.0 mm)	SS 203-220	TT 203-220	20 cm	ø 8.0
	SS 203-222	TT 203-222	22 cm	ø 8.0
	SS 203-224	TT 203-224	24 cm	ø 8.0
	SS 203-226	TT 203-226	26 cm	ø 8.0
	SS 203-228	TT 203-228	28 cm	ø 8.0
	SS 203-230	TT 203-230	30 cm	ø 8.0
Inter-Locking Humerus Nail (Cannulated) (6.0 mm)	SS 204-020	TT 204-020	20 cm	ø 6.0
	SS 204-022	TT 204-022	22 cm	ø 6.0
	SS 204-024	TT 204-024	24 cm	ø 6.0
	SS 204-026	TT 204-026	26 cm	ø 6.0
	SS 204-028	TT 204-028	28 cm	ø 6.0
	SS 204-030	TT 204-030	30 cm	ø 6.0
Inter-Locking Humerus Nail (Cannulated) (7.0 mm)	SS 204-120	TT 204-120	20 cm	ø 7.0
	SS 204-122	TT 204-122	22 cm	ø 7.0
	SS 204-124	TT 204-124	24 cm	ø 7.0
	SS 204-126	TT 204-126	26 cm	ø 7.0
	SS 204-128	TT 204-128	28 cm	ø 7.0
	SS 204-130	TT 204-130	30 cm	ø 7.0
Inter-Locking Humerus Nail (Cannulated) (8.0 mm)	SS 204-220	TT 204-220	20 cm	ø 8.0
	SS 204-222	TT 204-222	22 cm	ø 8.0
	SS 204-224	TT 204-224	24 cm	ø 8.0
	SS 204-226	TT 204-226	26 cm	ø 8.0
	SS 204-228	TT 204-228	28 cm	ø 8.0
	SS 204-230	TT 204-230	30 cm	ø 8.0

2.9mm Inter-Locking Screw

Code No. S.S. 316L	Code No. Titanium	Length
SS 212-118	TT 212-118	18mm
SS 212-120	TT 212-120	20mm
SS 212-122	TT 212-122	22mm
SS 212-124	TT 212-124	24mm
SS 212-126	TT 212-126	26mm
SS 212-128	TT 212-128	28mm
SS 212-130	TT 212-130	30mm
SS 212-132	TT 212-132	32mm
SS 212-134	TT 212-134	34mm
SS 212-136	TT 212-136	36mm
SS 212-138	TT 212-138	38mm
SS 212-140	TT 212-140	40mm
SS 212-142	TT 212-142	42mm
SS 212-144	TT 212-144	44mm
SS 212-146	TT 212-146	46mm
SS 212-148	TT 212-148	48mm
SS 212-150	TT 212-150	50mm

3.4mm Inter-Locking Screw

Code No. S.S. 316L	Code No. Titanium	Length
SS 212-018	TT 212-018	18mm
SS 212-020	TT 212-020	20mm
SS 212-022	TT 212-022	22mm
SS 212-024	TT 212-024	24mm
SS 212-026	TT 212-026	26mm
SS 212-028	TT 212-028	28mm
SS 212-030	TT 212-030	30mm
SS 212-032	TT 212-032	32mm
SS 212-034	TT 212-034	34mm
SS 212-036	TT 212-036	36mm
SS 212-038	TT 212-038	38mm
SS 212-040	TT 212-040	40mm
SS 212-042	TT 212-042	42mm
SS 212-044	TT 212-044	44mm
SS 212-046	TT 212-046	46mm
SS 212-048	TT 212-048	48mm
SS 212-050	TT 212-050	50mm

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

Implants Certified by : CE XXXX

Instruments Certified by Self Declaration : CE

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