

INTERLOCKING NAILING SYSTEM FOR HUMERUS SURGICAL TECHNIQUE

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INTERLOCKING NAILING SYSTEM FOR HUMERUS SURGICAL TECHNIQUE



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INDICATIONS:

- Diaphyseal fractures of the Humerus shaft
- Fractures of the proximal Humerus
- Proximal Humerus fractures with diaphyseal extension
- Impending pathologic fractures

CONTRAINDICATIONS:

There are no specific contraindications but do not use the Nail in cases of:

- Inadequate bone quantity and/or bone quality
- Hypersensitivity to metal or allergic reaction
- Patients with limited blood supply
- Patient within whom co-operation or mental competence is lacking, thereby reducing patient compliance

ADVERSE REACTIONS

- Adverse reactions may include but are not limited to:
- 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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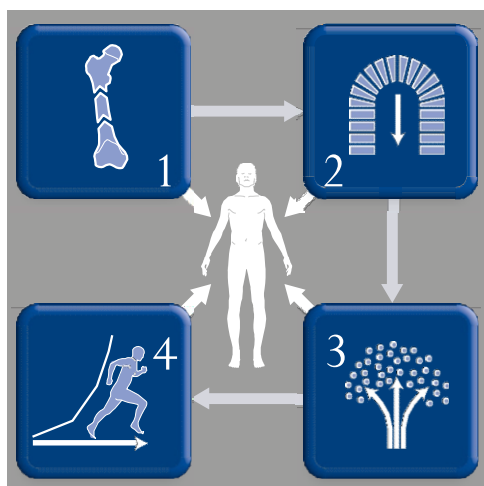
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AO PRINCIPLES

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.

Anatomic reduction

Fracture reduction and fixation to restore anatomical relationships.



Early, active mobilization Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

Stable fixation

Fracture fixation providing absolute or relative stability, as required by the patient, the injury, and the personality of the fracture.

Preservation of blood supply Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.

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Humerus Nail



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

Features and Benefits

- Universal design for right or left Humerus.
- Cannulated for easy insertion on guide wire
- Conventional and compression locking options
- Dia. 6mm, 7mm, 8mm x Lengths from 20cm to 30cm
- Proximal locking holes (one slot and two holes) accept a 3.5 mm

Interlocking Screw

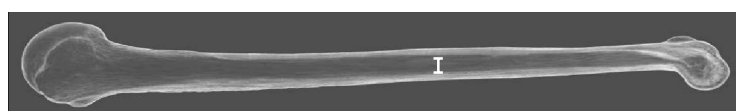
- Distal locking holes (3 holes) accept 2.7 mm Interlocking Screws

Nail Insertion Humerus Nails

Preoperative implant selection

To estimate nail length preoperatively, place the Radiographic ruler on the AP X-ray of the uninjured humerus and select a nail length that is 1 cm distal to the superior edge of the articular surface and at least 2.5 cm proximal to the superior edge of the olecranon fossa.

To determine nail diameter preoperatively, place the Radiographic ruler on the AP X-ray of the uninjured Humerus and measure the diameter at the narrowest part of the medullary canal that will contain the nail. When selecting nail size, consider medullary canal size, fracture pattern and postoperative protocol.

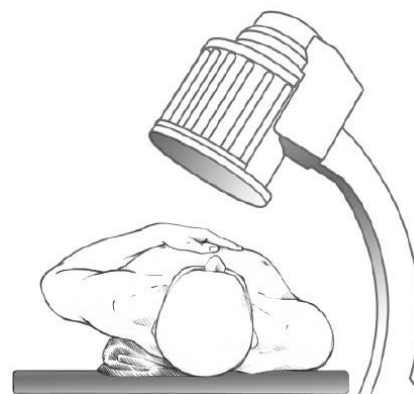


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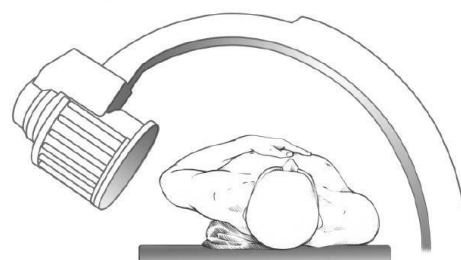
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PATIENT POSITIONING

- 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.



C-arm in position for AP view



C-arm in position for scapular “Y” lateral view

Open the proximal Humerus

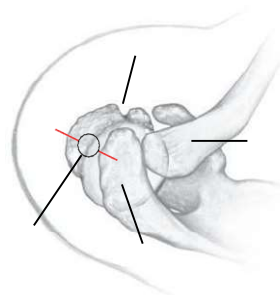
The surgical approach to the proximal Humerus should be considered carefully. The anterior acromial approach is recommended to minimize damage to the rotator cuff. The more traditional lateral acromial site is not suggested because it may transect the infraspinatus and teres minor. The lateral acromial approach will also position the entry site poster lateral resulting in varus displacement of a proximal fragment and the possible fracture of the entry site if the fracture is more distal. Access the entry site through the raphe separating the anterior and middle third of the deltoid.

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Incision Entry

Bicipital Groove

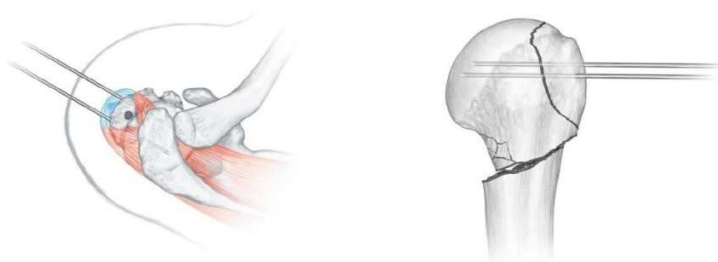


Clavicle

Insert 2mm K -wires into the Humerus head to enable manipulation. The head is maneuvered, using radiographic control, until the sulcus (cephalic notch) between the greater tuberosity and the margin of the articular cartilage is recognized.

Portal Acromion

Anterior acromial approach is recommended.



Manipulate the head fragment with the K-wires.

Humerus Nail Insertion

Open the Proximal Humerus

The insertion point is in line with the medullary canal in the lateral view and at the margin of the articular surface in the AP view. After the entry site has been verified, incise the supraspinatus longitudinally and tag the margins with sutures. These sutures will help retract the edges of the supraspinatus during the procedure and assist in reapproximating the supraspinatus during final closure.

Insert 1.8mm guide wire through the sulcus and into the medullary canal.

Mobilize the greater tuberosity fragment and perforate it with a tuberosity punch or

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other suitable instrument. Secure the greater tuberosity fragment with heavy non-absorbable suture and/or K-wires positioned to reapproximating the fragment. For a four-part fracture, a delto-pectoral approach may be more useful.

Use the Bone Awl and use a twisting hand motion to create the portal into the medullary canal.



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.



Asymmetric nail Holder/Jig couple with the nail only one orientation, ensuring correct

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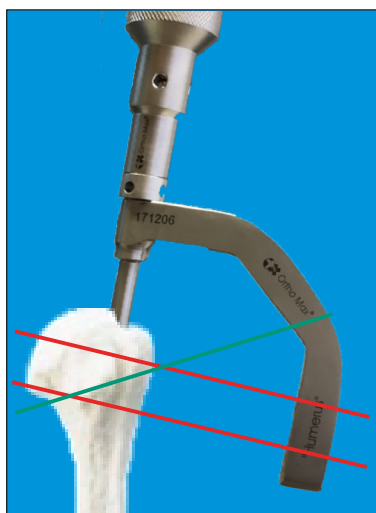
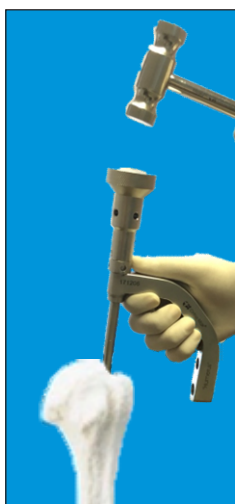
assembly.

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.

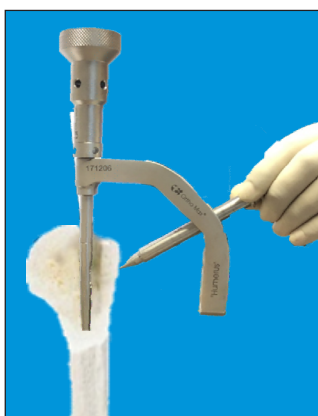
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Proximal Locking

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.



Note: Insertion of the oblique Inter Locking Screw prohibits insertion of a second, transverse proximal Screw.



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Proximal Locking

Replace the trocar with the 2.7 mm Drill Sleeve and drill through both cortices with the 2.7mm Drill Bit, stopping the drill immediately after penetrating the far cortex. Careful attention to drill bit and Interlocking Screw length is important to prevent Neuro-vascular injury.

Monitor the drill bit insertion radio-graphically because the position of the drill bit tip directly represents Interlocking Screw tip position in the bone. To avoid measurement errors, press the drill sleeve armly to the cortex.

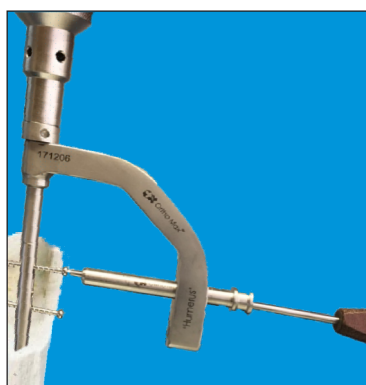
Use the Long Depth Gauge 3.5mm. Remove the drill sleeve from the protection sleeve. Insert the Tip of the depth gauge through the protection sleeve. The hook of the Long Depth Gauge grasps the far cortex of the bone. Read the scale against the edge of the protection sleeve to determine the appropriate Interlocking screw length.

Drill through both cortices with the
2.7 mm Drill Bit

Proximal Locking

Insert the Interlocking Screw through the protection sleeve using the Long Hexagonal Screwdriver 3.5mm. If a transverse Interlocking Screw is used, a second transverse Interlocking Screw may be inserted by repeating this procedure through the hole of the Nail holder/Jig

Remove the insertion assembly and insert an End Cap if required.

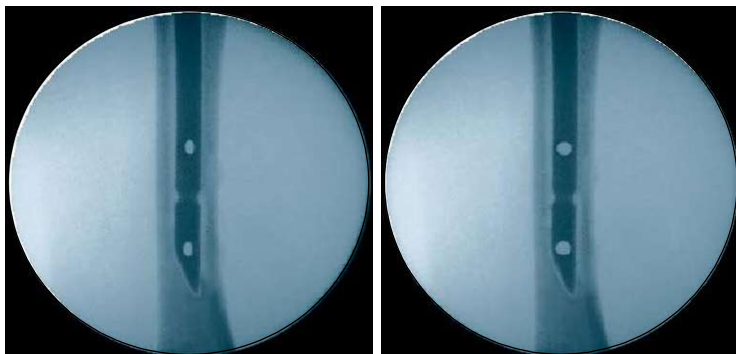


Insert the Interlocking Screw 3.5mm.

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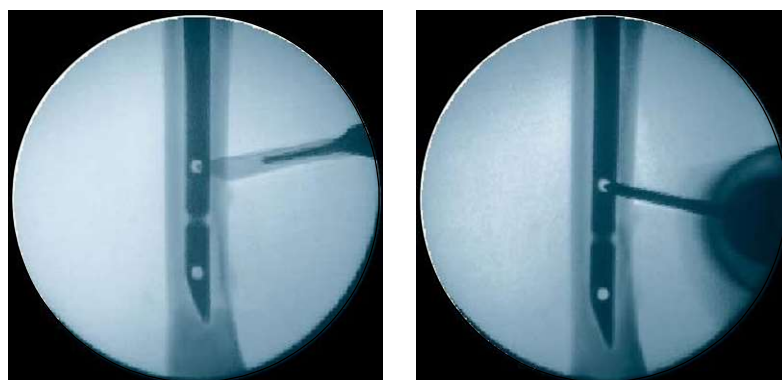
A second transverse Interlocking Screw may be inserted through the Static hole



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 2.2/2.7mm Drill Bit.

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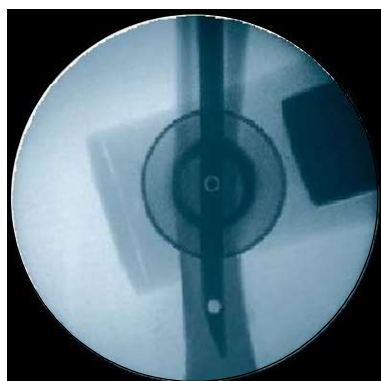
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Distal Locking- Free Hand

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 fill 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.

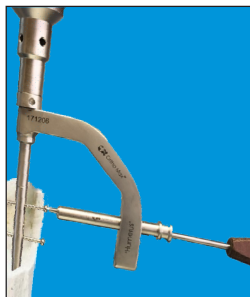


Hold the drill in this position and drill through both cortices.

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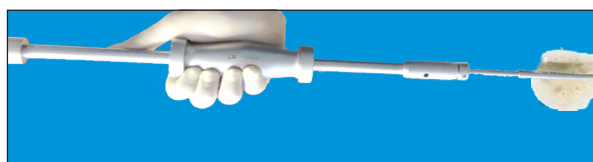
Nail Removal Technique:



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:



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.

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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.

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.

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.

MRI SAFETY INFORMATION

- Ortho Max Mfg. Co Pvt. Ltd. implants are manufactured from Titanium Gr.2, SS316L, SS316LVM material for Bone Plate & Titanium Gr.5, SS316L, SS316LVM material for Bone Screw, Pins & Wires, 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

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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.
- The Ortho Max Mfg. Co 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.

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Product Details:

HUMERUS

Implants
Humerus Interlocking Nails System


Interlocking Nail For Humerus
Cannulated



Intended Use	For Intramedullary Fixation & Locking of Humerus Fracture
Profile	For 6mm & 7mm Proximal Hole Dia. 3.5mm -Distal Hole Dia. 2.7mm For 8mm Proximal & Distal Hole Dia. 3.5mm
Nail Diameter	6mm, 7mm & 8mm Cannulated
Size	20cm To 30cm - 1 cm diff.

Material	Reference
SS 316L	170.1620 To 170.1830
* Titanium	170.T1620 To 170.T1830


Interlocking Screws



Intended Use	For Intramedullary Fixation & Locking of Humerus Nail
Profile	Core Dia 2.2mm for 2.7mm & 2.7mm for 3.5mm screw
Screw Diameter & Size	2.7mm x 18mm To 30mm - 2mm diff. 3.5mm x 18mm To 50mm - 2mm diff.

Material	Reference
SS 316L	184.2718 To 184.3550
* Titanium	184.T2718 To 184.T3550


Interlocking Nail's Cap



For Humerus

Material	Reference
SS 316L	185.003
* Titanium	239.003


Bone Awl - Small



Reference
659.001

Instruments


Guide Wire - Short



1.8mm x 20"


Reference
940.1820

Nail Holder / Proximal Jig




Reference
725.001

Hexagonal Spanner with T Handle




Reference
937.001

Protection Sleeve




Reference
725.003

Nail Holding Bolt




Reference
725.002

Drill Sleeve - 2.7mm














Reference
725.004

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Humerus Interlocking Nails System		Instruments
Trocar  <div>Reference 725.005</div>	Depth Gauge - Long  3.5mm <div>Reference 561.335</div>	
Hexagonal Long Screw Driver  3.5mm <div>Reference 569.235</div>		
Drill Bits  2.2 mm x 6" <div>Reference 552.226</div>  2.7 mm x 10" <div>Reference 552.2710</div>	Tommy Bar  <div>Reference 942.001</div> Impactor Head  <div>Reference 938.001</div>	
Extractor Set  Rod <div>Reference 939.001</div>  Head <div>Reference 939.002</div>  Ram <div>Reference 939.003</div>	Humerus Nail Set Container With 2 Trays  <div>Reference 800.002</div>	

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Humerus Interlocking Nails System Set

Humerus Nail's Jig Assembly



Contents :

Implants :-	Qty
Interlocking Nail for Humerus - Cannulated	
- 6, 7, 8mm x 20 cm To 30cm - 1 each (2cm diff)	18 Nos
Interlocking Screws	
- 2.7mm x 18mm To 30mm - 2 each (2mm diff)	14 Nos
- 3.5mm (6mm Head) x 18mm To 46mm - 2 each (2mm diff)	30 Nos
Instruments :-	
- Bone Awl - Small	01 No
- Guide Wire 1.8mm x 20"	02 Nos
- Nail Holder / Proximal Jig	01 No
- Nail Holding Bolt	01 No
- Hexagonal Spanner with T Handle	01 No
- Protection Sleeve	01 No
- Drill Sleeve 2.7mm	01 No
- Trocar	01 No
- Tommy Bar	01 No
- Depth Gauge - Long - 3.5mm	01 No
- Hexagonal Long Screw Driver - 3.5mm	01 No
- Drill Bits 2.2mm x 6" (For Interlocking 2.7mm)	02 Nos
- Drill Bits 2.7mm x 10" (For Interlocking 3.5mm)	02 Nos
- Impactor Head	01 No
- Extractor Set with Bolt	01 Set
- Humerus Nail Set Container with 2 Tray	01 No

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Implants Certified by ITC : 

Instruments Certified by Self Declaration : 



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