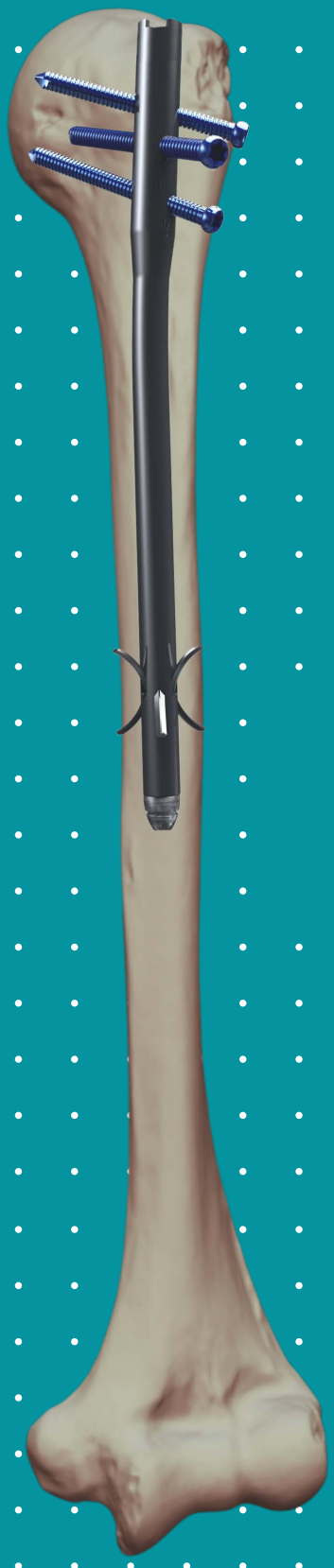


NUNA Humeral Nail

Surgical Technique

Dunitech

get better

About Us

We were established in 2012 to serve the healthcare industry by innovative technologies, superior quality materials and top-notch customer and after-sales services. Today, OLIGA is a medical technology company that engineers, designs, manufactures and markets osteosynthesis systems with 15 years of experience in orthopaedics.

Thanks to our dynamic, solution-oriented and expert staff, our pursuit for serving the best service possible approach helps us to contribute to orthopaedic community every single day. We provide high-quality products and services with prompt action at competitive costs.

For those who opt for Oliga; Success is a Choice

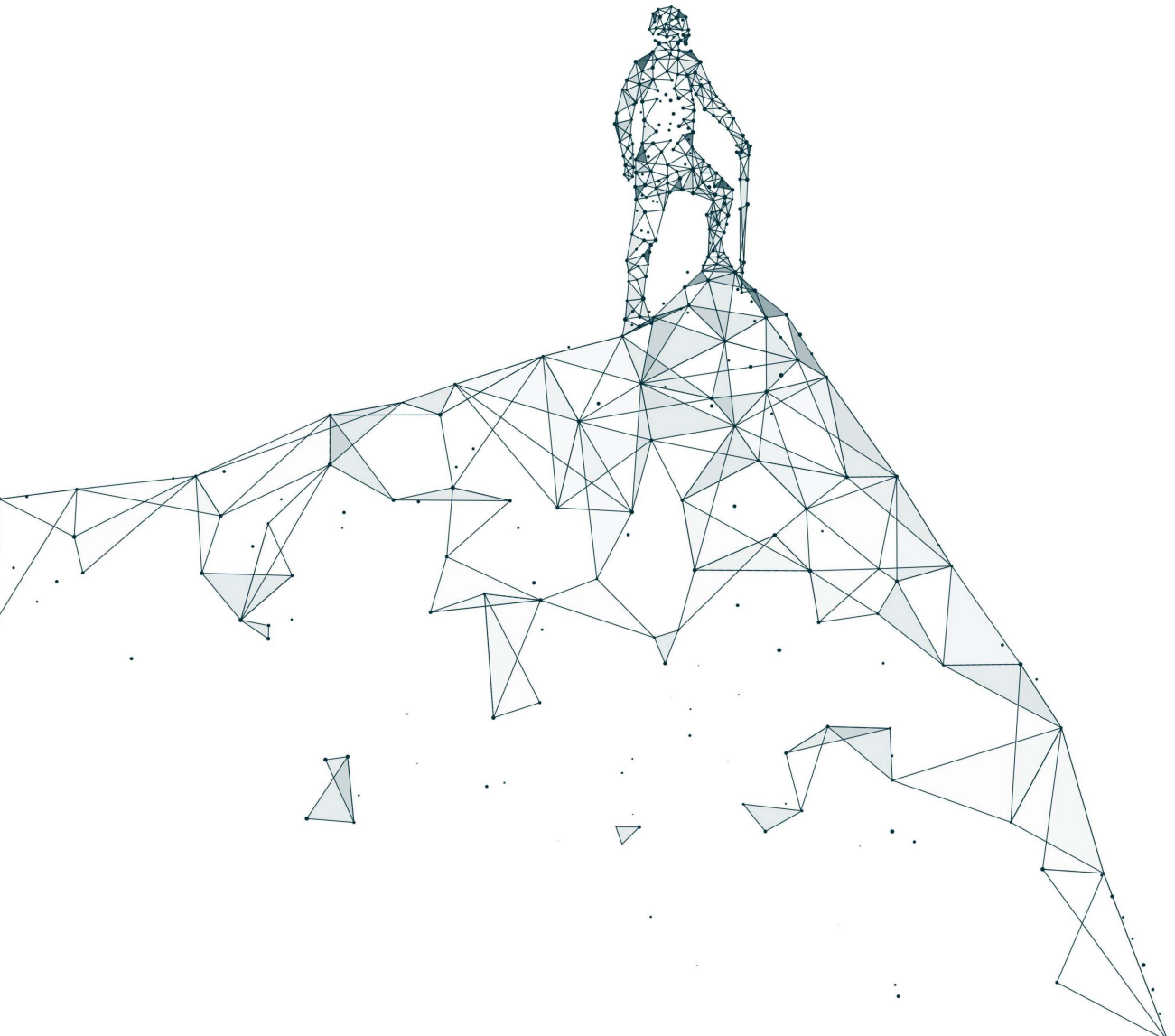


TABLE OF CONTENTS

Nuna Humeral Nail

INTRODUCTION

SURGICAL TECHNIQUE

MISCELLANEOUS

Note: This publication is provided to set forth a suggested surgical procedure. The physician should tailor this procedure to the specific needs of the patient.

NUNA Humeral Nail System

Nails

- Proximal Head Diameter: 10mm
- Shaft Diameters: 8, 9, 10mm
- Lengths: 165mm-315mm
  (15mm increments)
- Proximal Bend: 4 Degrees
  Maximum Claw Span: 22mm
- Universal Design

Cortical Screws

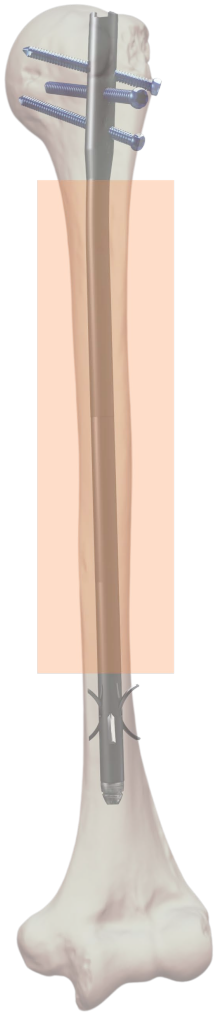
- Head Diameter: 6 mm
- Thread Diameter: 4mm
- Core Diameter: 3.2mm
- Lengths: 18mm-80mm
  (2mm until 60, 5 after 60 increments)
- Self-tapping design
- T25 Drive

End Caps

- Lengths: Flush, +5mm, +10mm, +15mm
- Lead-in section aligns end cap with head of nail
- Internal thread secures cap to 5mm Hex Driver
- Locking version available

ALL CLAWS ARE FULLY RETRACTABLE

Indications



The Nuna Humeral Nail System is indicated to aid in the alignment and stabilization of humeral fractures, including:

- Diaphyseal fractures of the humeral shaft
- Proximal humeral fractures with diaphyseal extension
- Impending pathologic fractures

Relative Contraindications

The following conditions may present an increased risk of implant failure. It is not meant to be comprehensive. Physicians should use their clinical judgment when determining the appropriate implant and approach for a given patient.

- Active local infection
- Material sensitivity
- Loss of bone stock/insufficient bone quality to support the device
- Cognitive and/or physical impairment that would lead to unacceptable risk of fixation failure

Special Considerations

- Claws perform best when deployed into the cortical bone of the humeral shaft. Care should be taken to avoid deploying Claws through the cortex near the radial/ulnar nerves and other soft tissue considerations.
- The Nuna Humeral Nail System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.
- Screws Warning: The cortical screws are not approved for screw attachment or fixation to the posterior element (pedicles) of the cervical, thoracic or lumbar spine.

Patient Positioning

The patient is placed in a semireclined “beach chair position” or supine on a radiolucent table. Patient positioning should be checked to ensure that imaging and access to the entry site are possible without excessive manipulation of the affected extremity (Fig. 4-1). The image intensifier is placed at the legside of the patient; the surgeon is positioned at the headside.

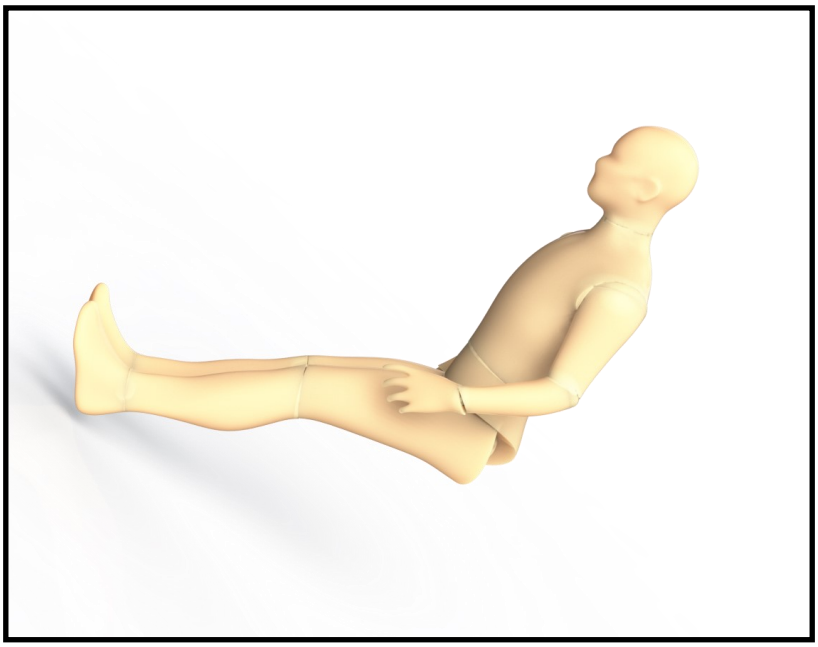


Fig. 4-1

Opening the Proximal Humerus

A small incision is made in line with the fibers of the deltoid muscle anterolateral to the acromion. The deltoid is split to expose the subdeltoid bursa. Palpate to identify the anterior and posterior margins of the greater tuberosity and supraspinatus tendon. The supraspinatus tendon is then incised in line with its fibers (Fig. 4-2).

It is recommended to localize the entry point under image intensifier control, also palpating the bicipital groove, the portal is about 10mm posterior to the biceps tendon. This will make the entry portal concentric to the medullary canal.

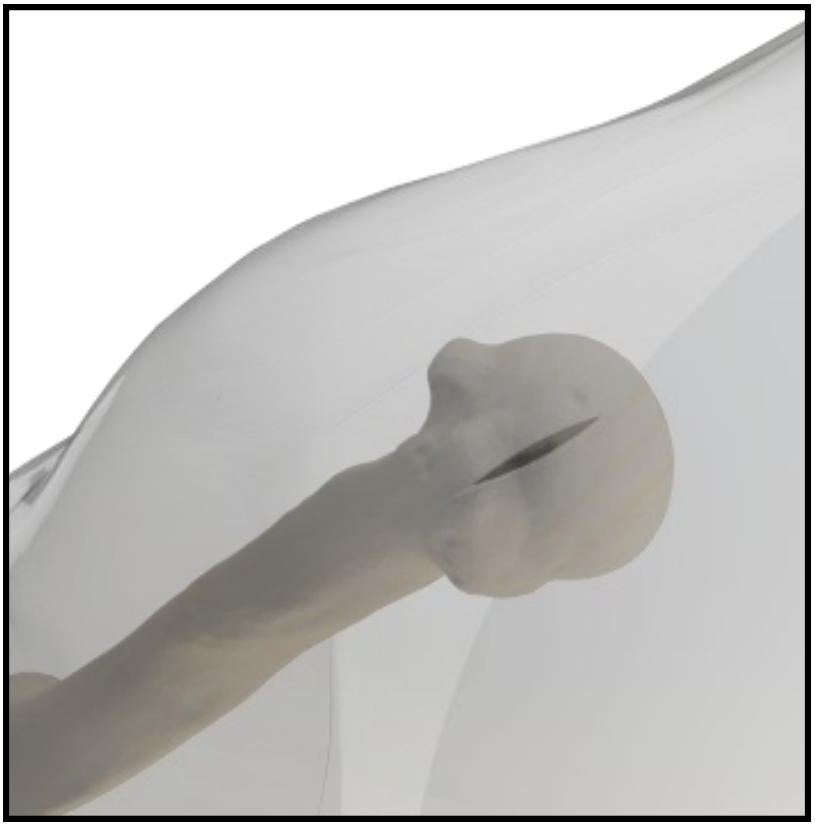


Fig. 4-2

The entry point for the Nuna Humeral Nail is in line with the medullary canal in the lateral view. In the AP view, the 4° lateral bend of the proximal nail pushes the entry point slightly lateral towards the greater tubercle (Fig. 5-1).

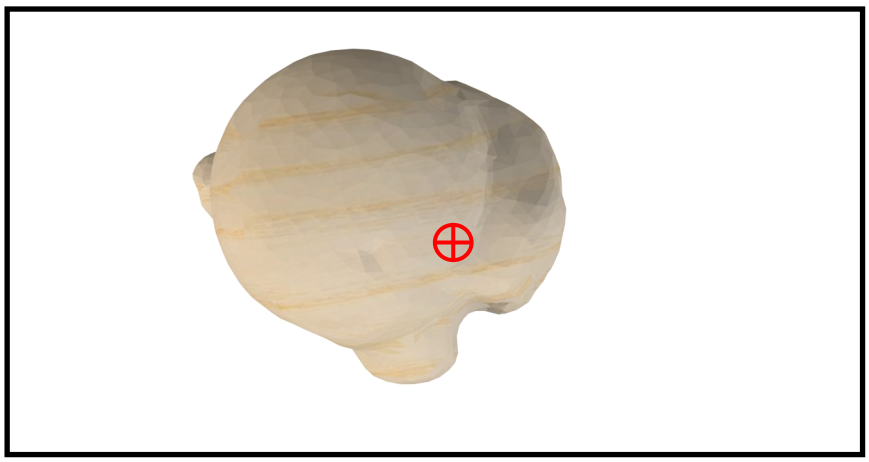


Fig. 5-1

Method One: Standard Method

Advance the 2.5mm x 280mm Trocar Tip Guide Wire through the starting point with a powered driver. Confirm its position in the AP (Fig. 5-2) and lateral (Fig. 5-3) planes. Proper position is critical. Withdraw wire and reposition as necessary.

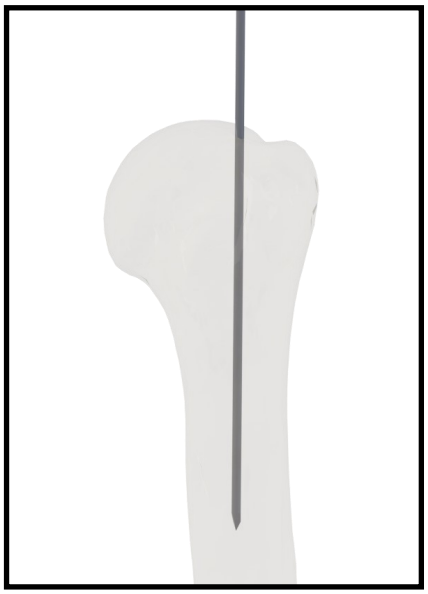


Fig. 5-2

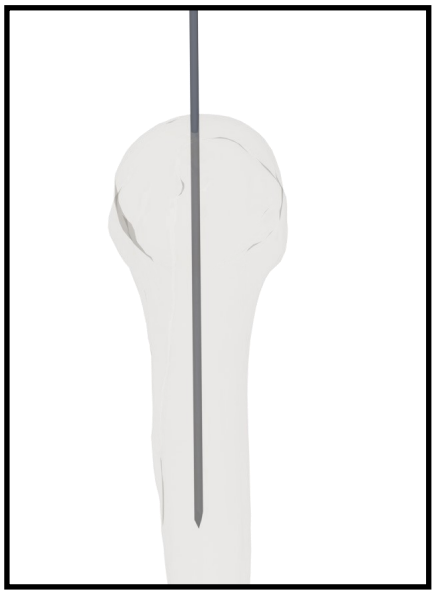


Fig. 5-3

Method Two: Awl Method

Insert the Curved Entry Awl (N07-0150) through the incision and down to the bone (Fig. 5-4). Rotate the awl back and forth to penetrate the bone, then pass a Ball Tip Dia 2mm 600mm Guide Wire through the awl. If the trajectory of the wire is not correct, withdraw it and reposition as necessary.

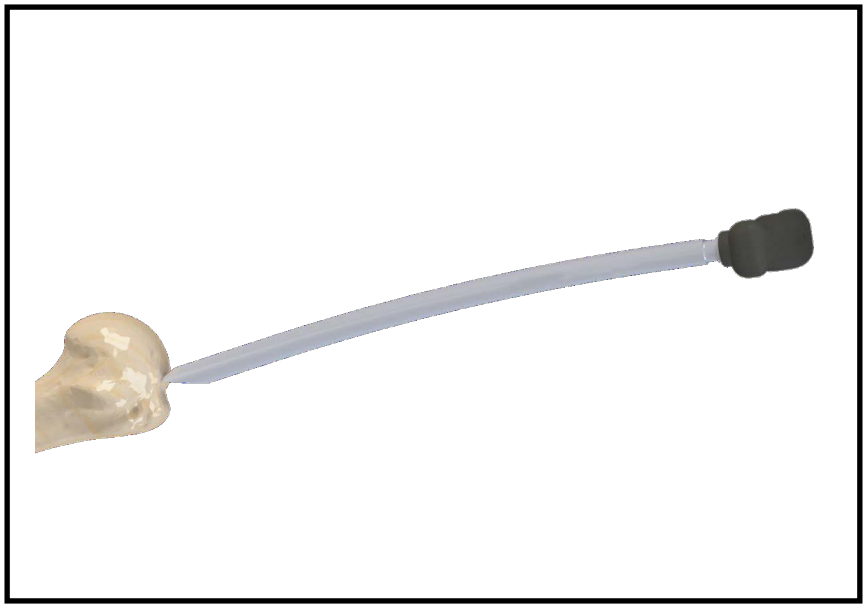


Fig. 5-4

Pass the Nuna Entry Reamer (N07-0110) and Nuna Tissue Protector (N07-0140) over the guide wire to the level of the bone. Use a powered driver to advance the entry reamer into the proximal humerus (Fig. 6-1).

Monitor the reaming depth via the image intensifier. Grooves on the cutter head indicate depth. The grooves on the cutter head can be read radiographically as they pass into the humeral head (Fig. 6-1). These grooves correspond to the four End Cap sizes—flush, +5, +10 and +15.

If the Trocar Tip Wire was used to access the medullary canal, it should now be exchanged for the Ball Tip Guide Wire. Advance the wire down the humeral canal and across the fracture site.

Enlarge the medullary canal through distal reaming. It is recommended that the canal be reamed 1mm greater than the diameter of the desired nail.

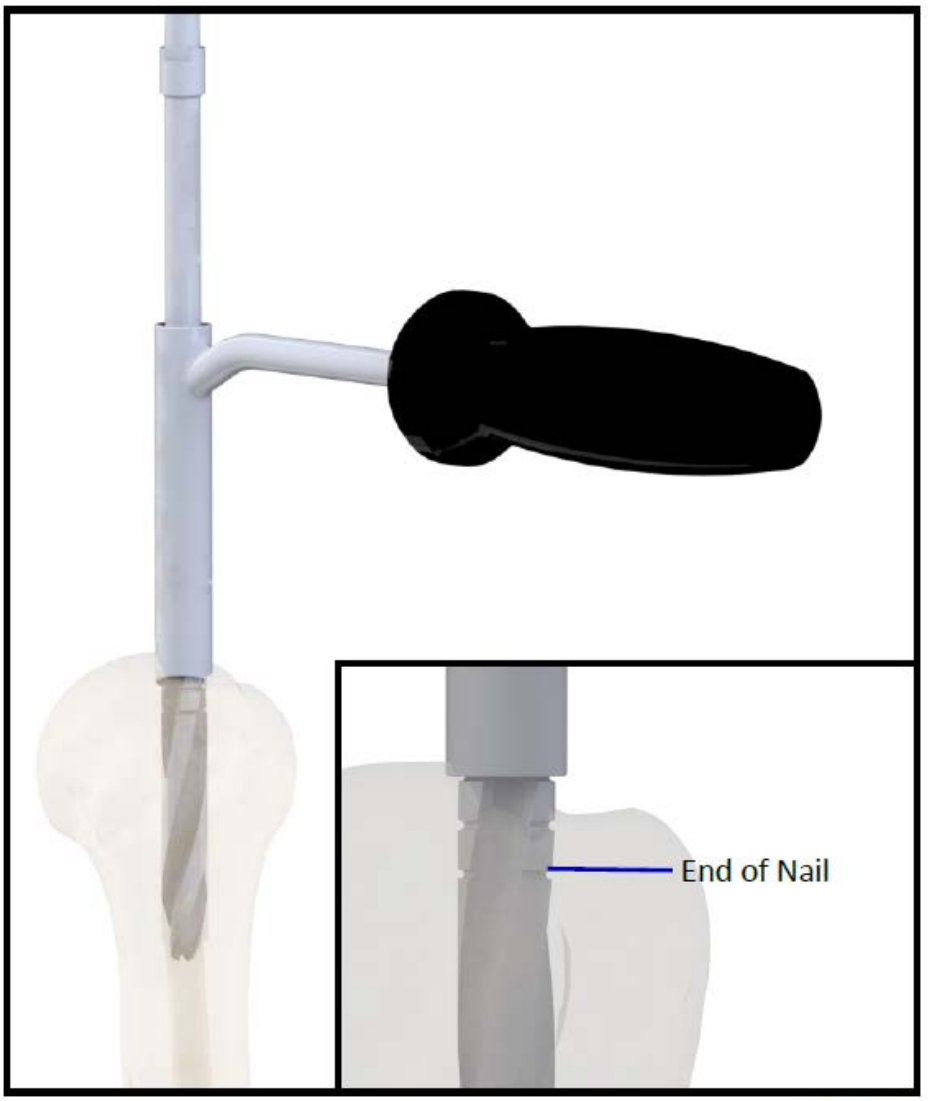


Fig. 6-1

Nail Length

Nail length can be determined via — measuring off the guide wire.

Measuring the Wire

Open the Nuna Guide Wire Ruler (N07-0130) and pass it over the guide wire noting that the end of the Guide Wire Ruler is the measurement reference.

Adjust the guide wire until its tip is at the desired level of the distal end of the implant (Fig. 7-2). Read the suggested nail length off the back of the wire (Fig. 7-3).

Note that this measurement is a direct reading to the distal tip of the guide wire. A fracture that is not properly reduced may result in an artificially high or low measurement. Actual nail length is determined by the surgeon.

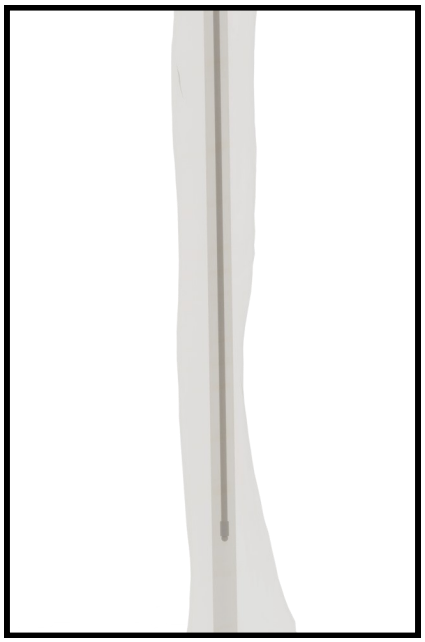


Fig. 7-2

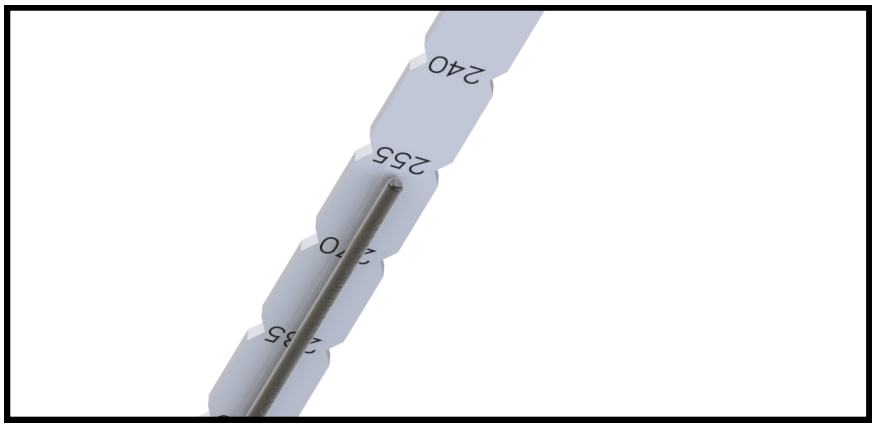


Fig. 7-3

Nail Insertion

Mate the chosen nail with the Nuna Guide Handle (N07-0010). Take care to align the reference mark on the nail head with the appropriate corresponding mark on the handle (Fig. 9-1).

Secure the nail to the handle with the Nail -Handle Connector Screw (N07-0020) using the 5mm Hex Driver (N07-0180) (Fig. 9-2). Ensure the screw is tightly secured by turning the handle.

Pass the nail over the wire and into the humerus. Apply steady pressure and use small oscillating motions to advance the nail (Fig. 9-3). Monitor passage of the nail across the fracture site radiographically. Rings on the guide handle indicate insertion depth. Insert the nail to the depth noted during nail selection.

An Impactor (N07-0120) can be used to aid in seating the nail (Fig. 9-4). Extract shaft (N07-0190) and slide hammer (N07-0200) should be used together with implactor (N07-0120).

Never strike the guide handle directly. If significant resistance is encountered, remove the nail, and further enlarge the medullary canal through reaming.

Once the nail is fully seated, confirm the reduction of the fracture in both the AP and lateral planes. If satisfied, remove the guide wire.

Fig. 9-1

Fig. 9-2

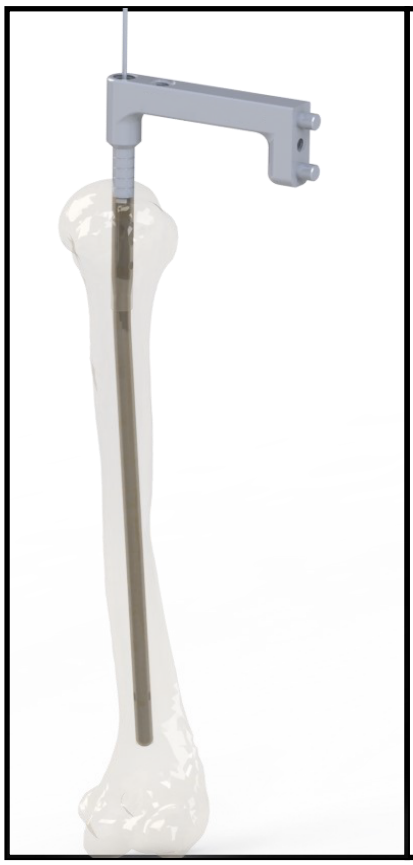


Fig. 9-3

Fig. 9-4

Claw Deployment

Attach the Claw Driver (N07-0020) to the Torque Limiting Handle (N07-0160) and pass the driver down the cannulation of the nail. Turn the driver clockwise to deploy the Claws (Fig. 10-1).

A consistent low resistance/torque should be felt during deployment until the cortex is reached. A sudden increase in resistance/torque marks cortical contact. Monitor the deployment progress in the distal humerus once cortical contact is made. Continue deploying until the torque-limiting handle trips or you are radiographically indicated to stop. If necessary, retract the Talons by turning the driver counterclockwise. Talons are shown fully deployed in Fig. 10-2 as an example.

NOTE: TALONS NEED NOT BE FULLY DEPLOYED. AT SURGEON'S DISCRETION, DEPLOYMENT CAN BE STOPPED AT ANY TIME. TALONS ARE DESIGNED TO PENETRATE THE CORTICAL BONE. CARE SHOULD BE TAKEN TO AVOID EXCESSIVE PERFORATION *THROUGH* THE CORTICAL BONE AND INTO SOFT TISSUE.

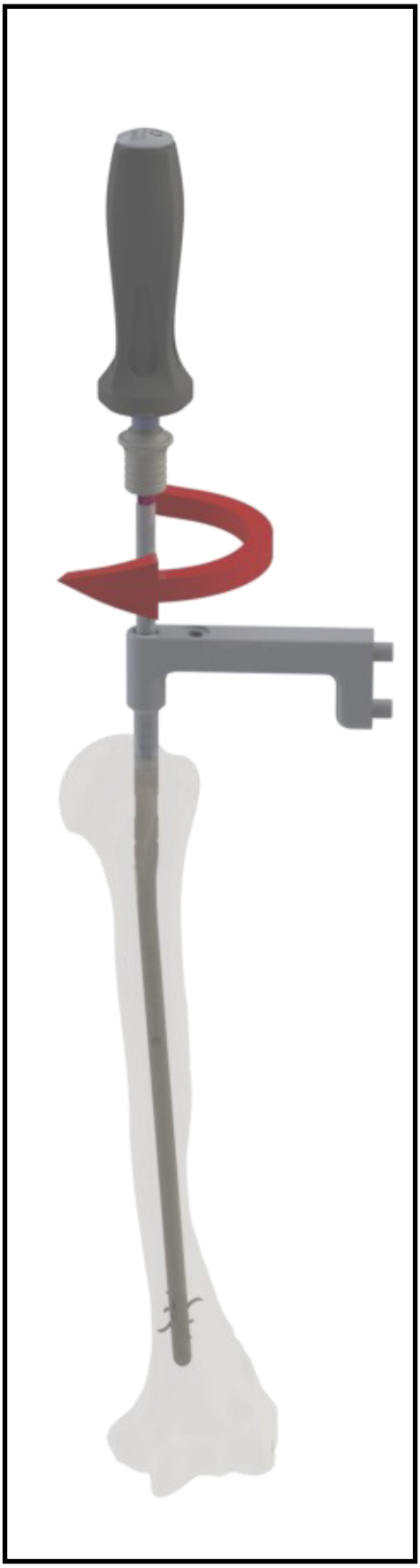


Fig. 10-1 **Fig. 10-2**

`CLAWS SHOULD NEVER BE DEPLOYED USING A POWERED DRIVER.

Attach the Guide Handle (N07-0010) to the Guide Arm (N07-0030) and tighten the Handle-Arm Connector Screw (N07-0070) (Fig. 11-1). The technique for placing cortical screws is identical for all screw hole positions.

Insert the triple sleeve assembly—Screw Sleeve (N07-0040), Drill Sleeve (N07-0050), and Trocar (N07-0060)—through the hole in the Guide Arm. Make a small incision in the skin and advance the sleeves to the cortical surface (Fig. 11 -2). Apply pressure with the Trocar to create a dimple in the lateral cortex.

Remove the Trocar and pass the calibrated 3.2mm Cortical Drill (N07-0090) through the Drill Sleeve and drill to desired depth (Fig. 11-3).

Read the drilled depth directly from the graduations on the drill (Fig. 11-4). Apply pressure to the Drill Sleeve to ensure it is in contact with the cortex. Graduations are calibrated to the tip of the drill and coincide with the available screw lengths. If using the Drill Depth Gauge (N07-0210), seat it on the Drill Sleeve, allowing the cortical drill to rest in the channel. Take measurement from the back of the cortical drill.

Fig. 11-1

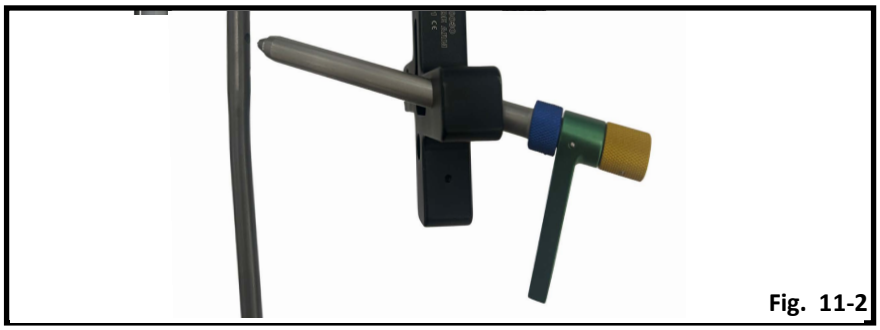


Fig. 11-2

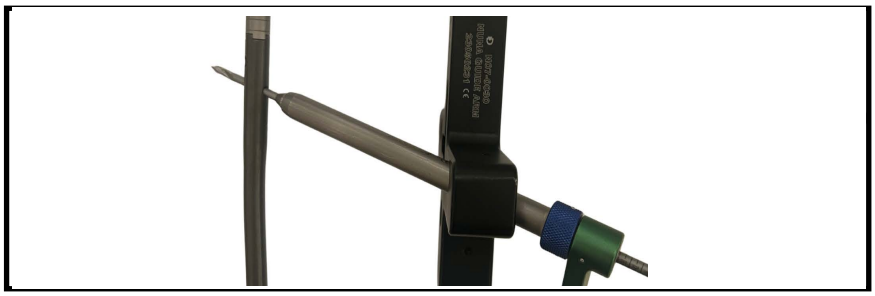


Fig. 11-4

SURGICAL TECHNIQUE

Mate the chosen cortical screw with the T25 Hex Driver held by the Axial Handle (N07-0170) (Fig. 12-1). Note: Cortical screw length can be verified using cortical screw block measurement inlay.

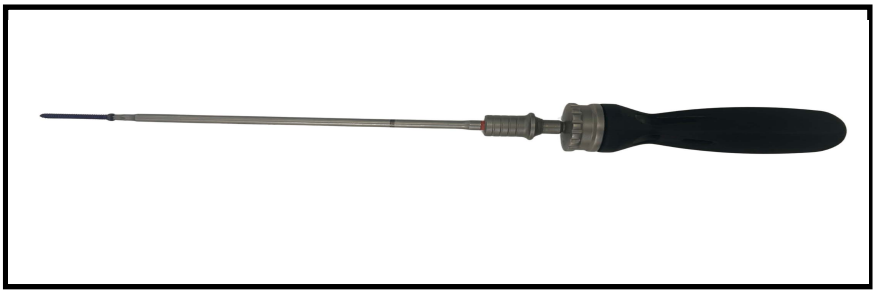


Fig. 12-1

Remove the Drill Sleeve and pass the cortical screw/driver assembly through the Screw Sleeve and into the bone (Fig. 12-2). Advance the screw until the screw head is seated against the lateral cortex. Do not over tighten as this may lead to the screw stripping. Remove the Screw Sleeve from the Guide Arm. Note: The T25 Driver may have a reference line indicating screw head position in reference to cortical sleeve.

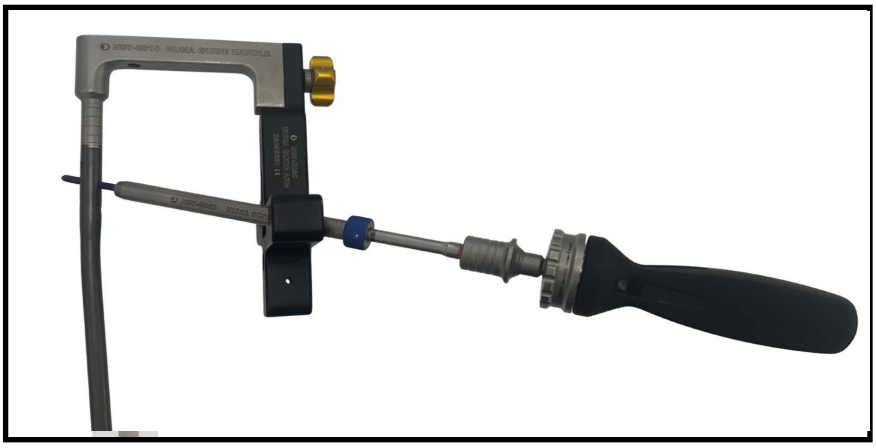
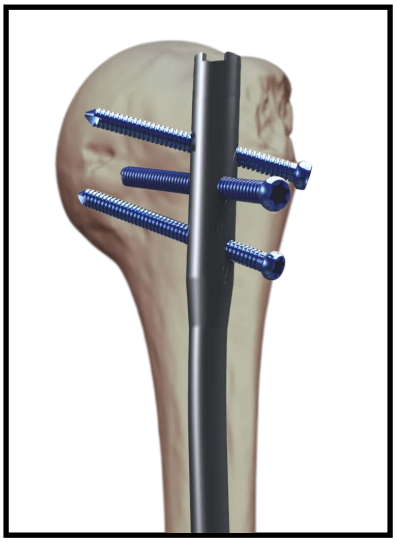


Fig. 12-2

Lock in the rest of the screws in similar process.



End Cap Selection and Placement

Note the proximal position of the nail after cortical screw placement (Fig. 14-1). **Final position should be 3-5mm below subcondylar bone**. The depth of the nail may have changed if compression was applied.

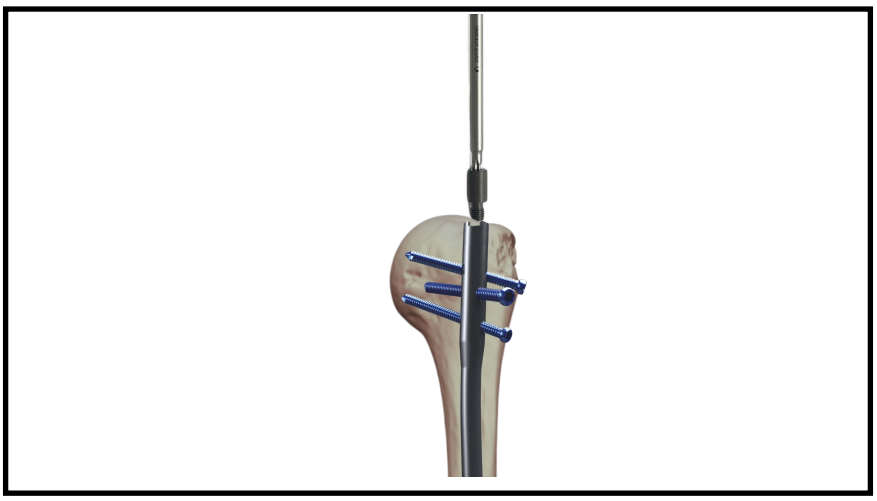


Fig. 14-1

Confirm the final implant position—proximally and distally—with the image intensifier in both the AP and lateral planes. If satisfied, use the 5mm Hex Driver to loosen the Nail-Handle Connector Screw (N07-0020) and remove the Guide Handle (N07-0010).

Mate the chosen end cap with the 5mm Hex Driver (N07-0180) (Fig. 14-2).

Fig. 14-2

Bring the end cap to the head of the nail—the lead-in segment should help orient the end cap with the head of the nail. Turn the driver clockwise to engage the cap (Fig. 14-3).

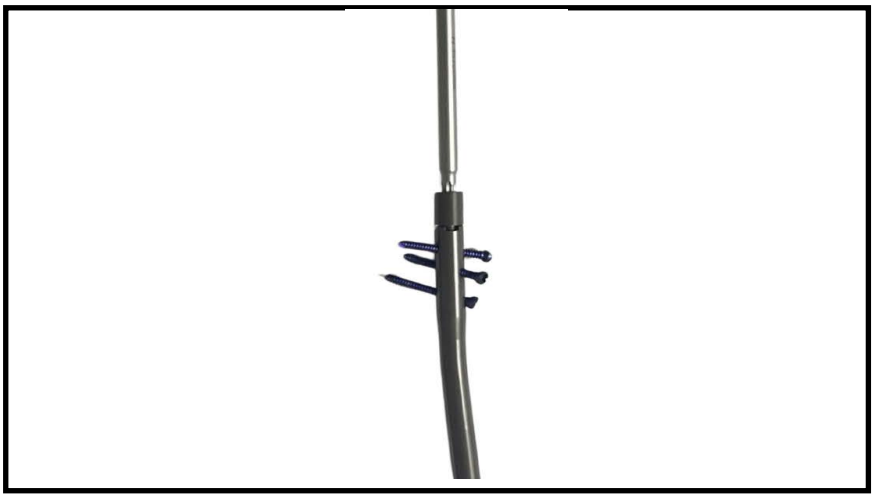


Fig. 14-3

Implant Removal—Optional

Implant removal is an elective procedure. Clear any blockage that may have grown into the hex socket of the end cap. Remove the end cap with the 5mm Hex Driver (Fig. 16-1).

Clear any debris that may have grown into the 5mm Hex socket of the cortical screws. Remove cortical screws with the 5mm Hex Driver (Fig. 16-2).

Be sure to remove all screws before proceeding (Fig. 16-3).

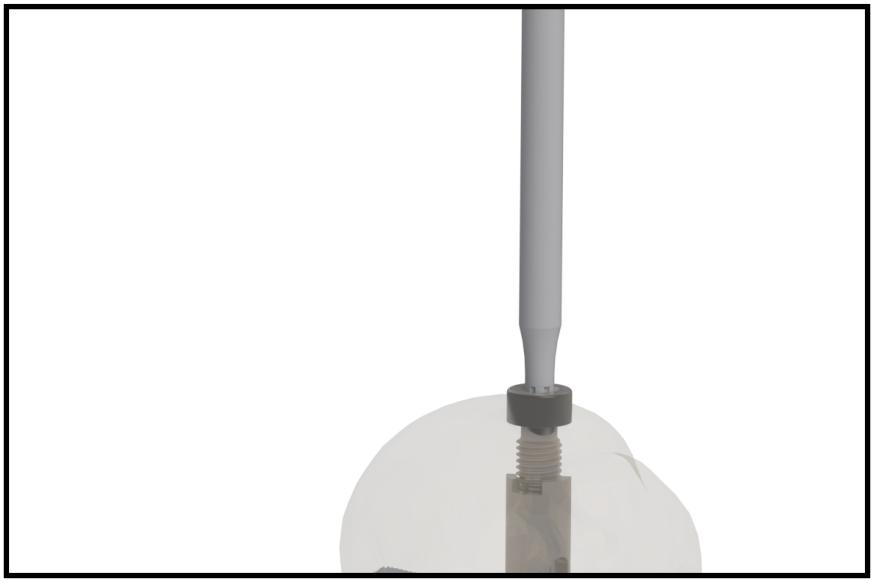


Fig. 16-1

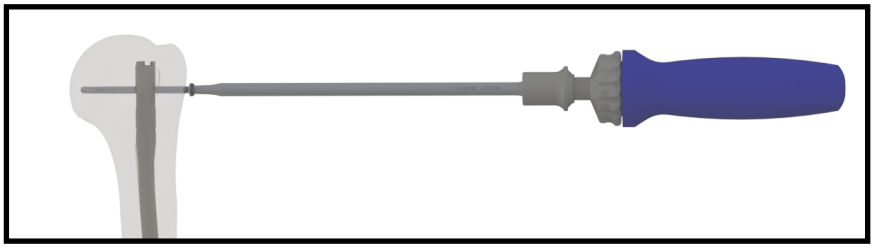


Fig. 16-2

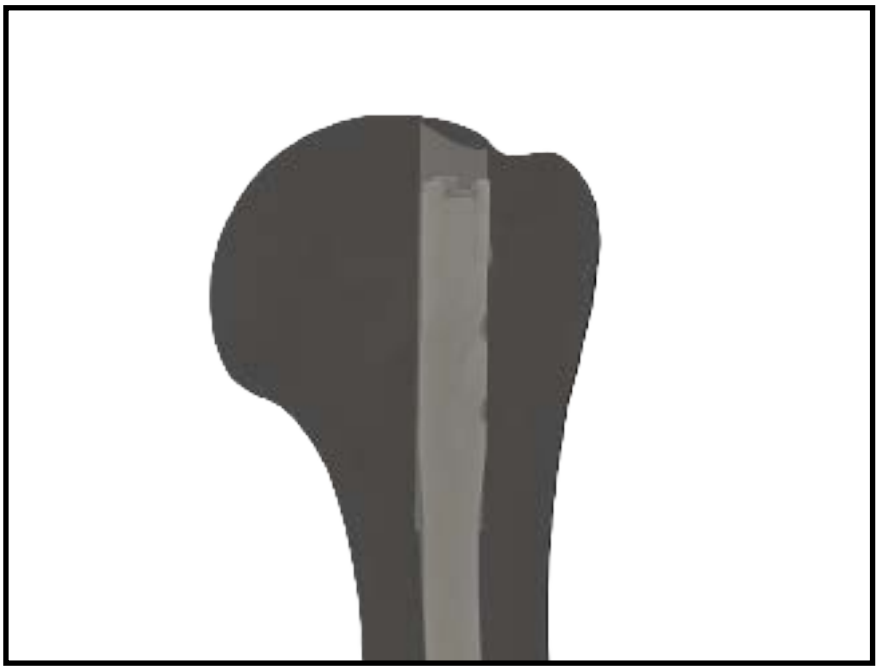


Fig. 16-3

Connect the Claw Driver (N04-0020) to the Torque-Limiting Handle (N07-0160). Pass the driver down the nail and engage the Claw mechanism. Ensure the driver is fully seated in the mechanism before turning. Turn counterclockwise to retract the Talons (Fig. 17-1).

Confirm radiographically that the Talons are fully retracted (Fig. 17-2). Remove the Claw Driver.

Pass the Extractor Shaft (N07-0190) through the Slide Hammer (N07-0200) and connect the Extractor to the head of the nail. Extract the nail via gentle blows of the Slide Hammer against the Extractor (Fig. 17-3).

Note: Countertorque may be required to fully retract the claws. If required, the Guide Handle (N07-0010) may be used to provide contertorque. Secure the nail to the handle with the Nail-Handle Connector Screw (N07-0020) using the 5mm Hex Driver (Fig. 17-4). Ensure the screw is tightly secured before applying countertorque to handle.

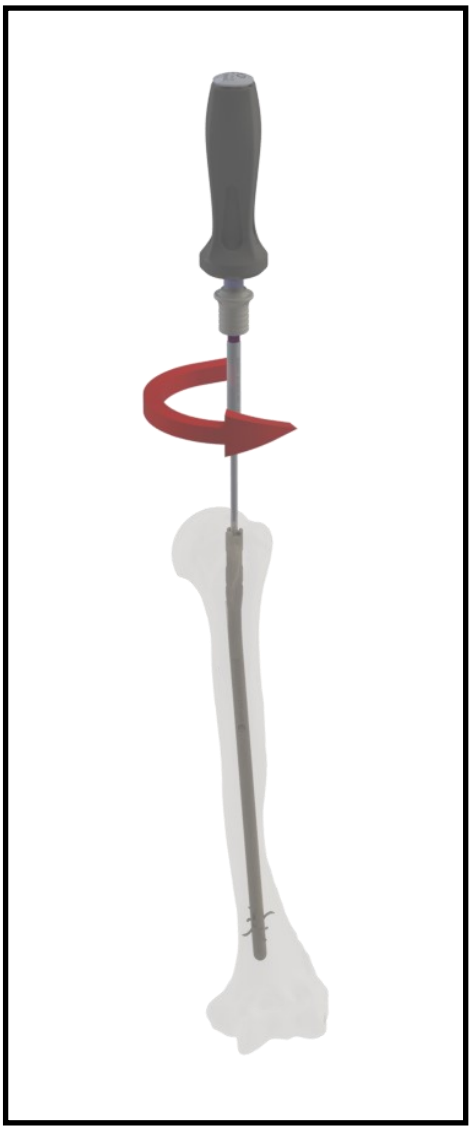


Fig. 17-1

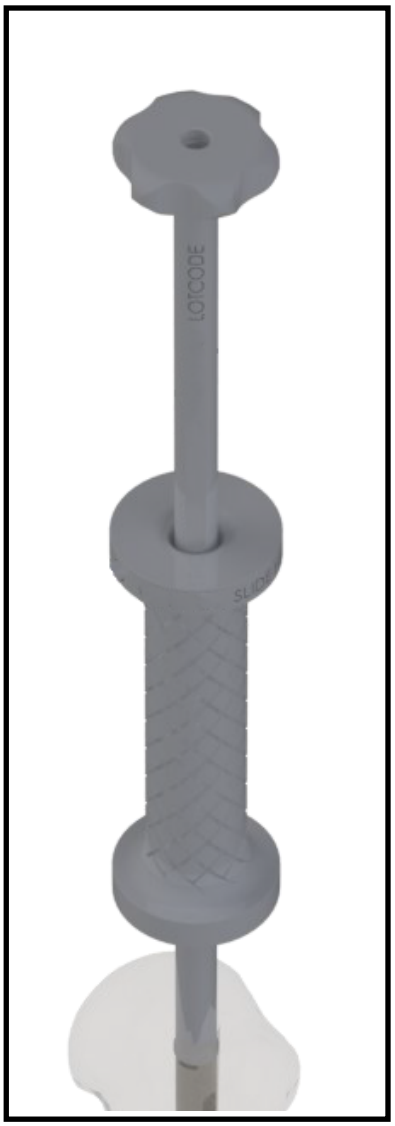


Fig. 17-3

Fig. 17-2

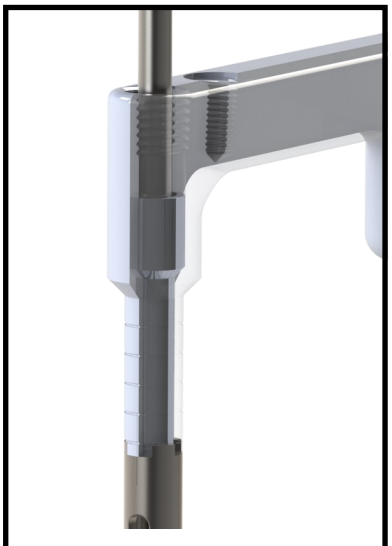


Fig. 17-4

MISCELLANEOUS

Implant Catalog

Nails

Length (mm)	8mm DIAMETER
165	NUNA-08-165
180	NUNA-08-180
195	NUNA-08-195
210	NUNA-08-210
225	NUNA-08-225
240	NUNA-08-240
255	NUNA-08-255
270	NUNA-08-270
285	NUNA-08-285
300	NUNA-08-300
315	NUNA-08-315

Length (mm)	9mm DIAMETER
165	NUNA-09-165
180	NUNA-09-180
195	NUNA-09-195
210	NUNA-09-210
225	NUNA-09-225
240	NUNA-09-240
255	NUNA-09-255
270	NUNA-09-270
285	NUNA-09-285
300	NUNA-09-300
315	NUNA-09-315

Length (mm)	10mm DIAMETER
165	NUNA-10-165
180	NUNA-10-180
195	NUNA-10-195
210	NUNA-10-210
225	NUNA-10-225
240	NUNA-10-240
255	NUNA-10-255
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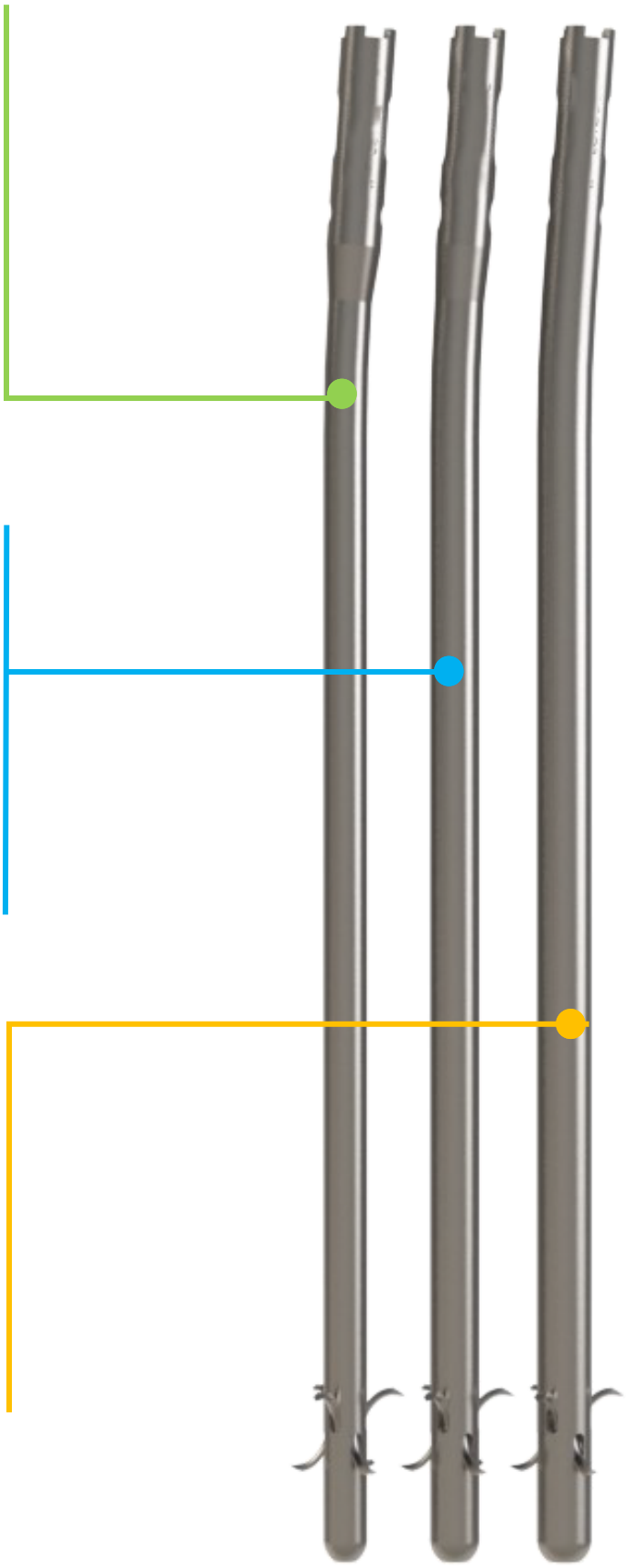
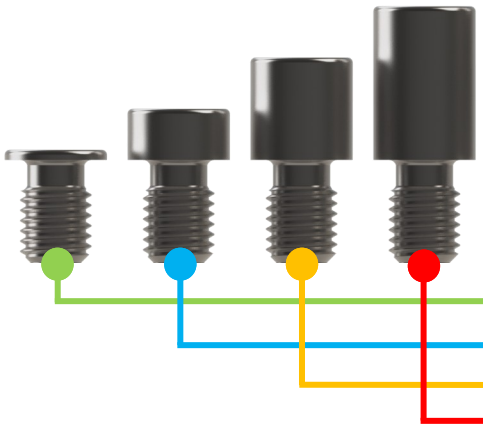
315	NUNA-10-315

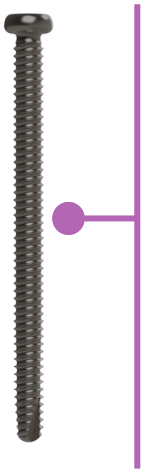




End Caps

Length (mm)	10mm DIAMETER
1	NUNA-10-000
5	NUNA-10-005
10	NUNA-10-010
15	NUNA-10-015

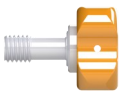
Cortical Screws



Length (mm)	4mm DIAMETER		4mm DIAMETER		4mm DIAMETER
18	CORS-04-018	40	CORS-04-40	65	CORS-04-065
20	CORS-04-020	42	CORS-04-42	70	CORS-04-070
22	CORS-04-022	44	CORS-04-44	75	CORS-04-075
24	CORS-04-024	46	CORS-04-46	80	CORS-04-080
26	CORS-04-026	48	CORS-04-48		
28	CORS-04-028	50	CORS-04-50		
30	CORS-04-030	52	CORS-04-52		
32	CORS-04-032	54	CORS-04-54		
34	CORS-04-034	56	CORS-04-56		
36	CORS-04-036	58	CORS-04-58		
38	CORS-04-038	60	CORS-04-60		

Instrument Catalog

MISCELLANEOUS

N07-0010	Nuna Guide Handle	
N07-0020	Nuna Nail-Handle Connector Screw	
N07-0030	Nuna Guide Arm	
N07-0040	Nuna Screw Sleeve	
N07-0050	Drill Sleeve	
N07-0060	Trocar	
N07-0070	Handle-Arm Screw	
N07-0080	T25 Driver	
N07-0090	Nuna 3.4mm Cortical Drill	
N07-0100	External Compressor	

N07-0110	Nuna Entry Reamer	
N07-0120	Nuna Impactor	
N07-0130	Nuna Guide Wire Ruler	
N04-0020	Claw Driver	
N07-0140	Nuna Tissue Protector	
N07-0150	Curved Entry Awl	
N07-0160	Torque Limiting Handle (5 Nm)	
N07-0170	Ratcheting 1/4 SQ Cannulated Handle	
N07-0180	Nuna 5mm Hex Driver	

Instrument Catalog

N07-0190	Extractor Shaft	
N07-0200	Slide Hammer	
N07-0210	Nuna Dill Depth Gauge	
N07-0000	Instrument Tray	

Ball Tip Guide Wire 2mm x 600mm

Trocar Tip Guide Wire 2.5mm x 280mm

Important Medical Information

The use of surgical implants provides the orthopedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as an aid to normal healing, and are not intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions, in the presence of load bearing or weight bearing, might eventually cause the implant to break, due to metal fatigue. All metal surgical implants are subject to repeated stress in use, which can result in metal fatigue.

1. NO PARTIAL WEIGHT BEARING OR NONWEIGHT BEARING DEVICE CAN BE EXPECTED TO WITHSTAND THE UNSUPPORTED STRESSES OF FULL WEIGHT BEARING. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities which would place stress upon the implant or allow movement at the fracture site and delay healing.
   Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses, which are transmitted by the body to any temporary internal fixation device, prior to the healing of the fracture. Due to normal metal fatigue, these stresses can cause eventual bending or breakage of the device. Therefore, it is important that immobilization of the fracture is maintained until firm bony union (confirmed by clinical and roentgenographic examination) is established.
   Special precautions are necessary if a temporary internal fixation device is used to treat an unstable fracture. These fractures are more difficult to reduce and result in unusually strong unbalanced muscle forces, which cause greater stress to be transmitted to the temporary internal fixation device than with other types of humeral fractures. These stresses increase the possibility of implant bending or breakage.
   NOTE: Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instruction could lead to breakage of the implant, requiring revision surgery to remove the device.
2. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for success in fracture fixation is increased by the selection of the proper size, shape and design of the implants. The size and shape of the human bone presents limiting restrictions on the size and strength of the implants.
3. Preoperative and operative procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implant are important considerations in the successful utilization of temporary internal fixation devices. See the specific surgical technique for surgical procedure.
4. In evaluating patients for orthopedic appliance application, the patient's weight, occupation, activity level, mental condition, foreign body sensitivity, and any degenerative diseases are of extreme importance to the eventual success of the procedure. These conditions must be evaluated as part of the preoperative planning.
5. CORRECT HANDLING OF IMPLANTS IS EXTREMELY IMPORTANT. The device should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce defects in the surface finish and internal stress concentrations, which may become the focal point for eventual failure of the appliance.
   If metal screws, wire bands or other metallic devices are to be used together with a particular temporary internal fixation device, all such devices should be manufactured from materials having similar composition, to avoid the possibility of galvanic corrosion or other metallic reactions.
6. NO METALLIC SURGICAL IMPLANT SHOULD BE REUSED. Any metal implant, once used, should be discarded. Even though it appears undamaged, stresses from prior use may create small defects and internal stress patterns which may lead to fatigue failure.
7. Detailed written instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending or breakage of the device are complications which may occur as a result of weight bearing or muscle activity. An active patient, debilitated or demented patient, who cannot properly use weight support devices, may be particularly at risk during postoperative rehabilitation.
8. SCREWS WARNING. This device is not approved for screw attachment or fixation to the posterior element (pedicles) of the cervical, thoracic, or lumbar spine.
9. Implants that are provided sterile should be stored unopened in their protective packaging. Inspect packages for damage prior to surgery. Products not labeled as sterile are non-sterile.

Method	Cycle	Temperature	Exposure Time	Minimum Dry Time*
Steam	Gravity	120°C	30 minutes	30 minutes
Steam	Gravity	130°C	15 minutes	30 minutes
Steam	Prevacuum	130°C	10 minutes	30 minutes

Note: Any cycle should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

*Refers to in chamber dry time. Please note that dry times may vary due to differences in the user's packaging materials, environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. It is the user's responsibility to validate the appropriate drying time with the sterilization equipment and sterilization load used.

NOTES

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