AOS Advanced orthopaedic solutions

Advanced Orthopaedic Solutions 3203 Kashiwa Street Torrance, CA 90505

T: 310.533.9966 F: 310.533.9876 www.aosortho.com Follow us @



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Humeral Nail System

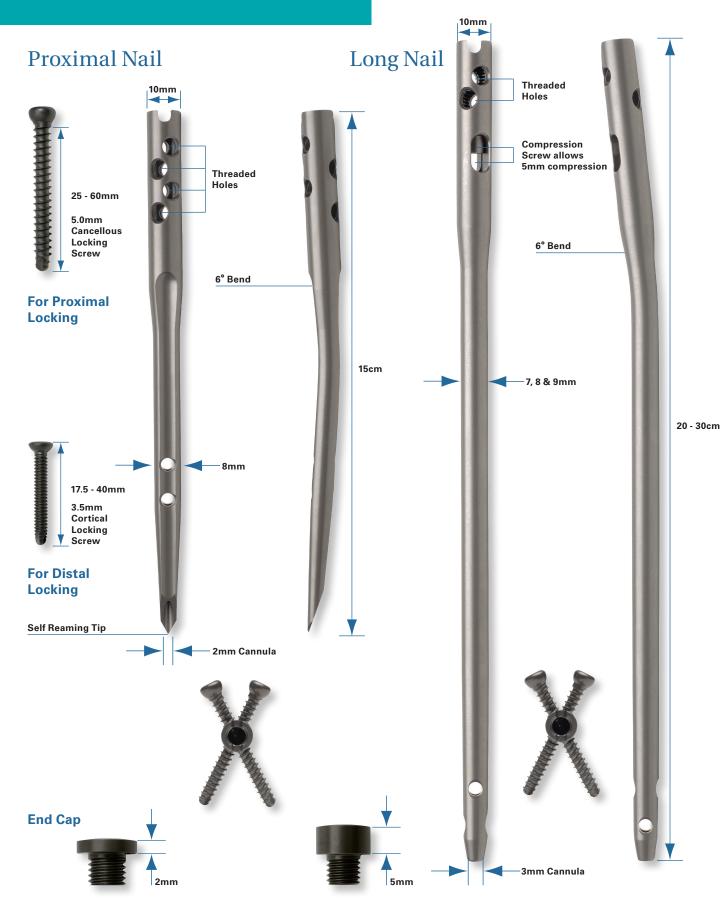
Surgical Technique

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This Surgical Technique sets forth detailed recommended procedures for using AOS devices and instruments. It offers guidance, but as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. Surgeons must always rely on their own professional clinical judgement when deciding which products and surgical treatments to use with their patients. Refer to package insert for information on indications, warnings, precautions and contraindications.

Implant Features



Humeral Nail System Surgical Technique

1. Indications

The AOS Humeral Nail is intended to treat stable and unstable proximal fractures of the humerus including two and three, and in some cases, four part humerus fractures. The Humeral Nail is also intended to treat proximal and distal one third fractures, midshaft fractures and pathological fractures.

2. Pre-operative Planning

Thorough evaluation of pre-operative radiographs of Technical Tip: Closed reduction by "Joystickthe affected upper arm and shoulder is critical. Careful technique" with 3.2mm Guide Pins to manipulate radiographic examination of the humeral head region may fragments can be used. prevent intra-operative complications. Templating the fracture will estimate the diameter and length of implant for humeral shaft fractures. Fig. 1



U.S. Patent 7,232,442



3. Patient Positioning & Fracture Reduction

The patient is placed semi-reclined in a "beach chair position" or supine on a radiolucent table. In the "beach chair position" the C-arm is placed above the head of the table (Fig. 1). The arm can then be extended to establish a proper entry point. If a supine position is used lateralize the patient on a radiolucent table to allow the arm to be extended. A "Bump" placed under or between the scapula can aid in extending the arm to establish a proper starting point.

4. Incision

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 sub-deltoid bursa. The supraspinatus tendon is then incised in line with its fibers.

5. Entry Point

To indicate the exact entry point before incising the supraspinatus tendon, a **3.2mm Guide Pin (0100)** can be placed through the tendon into the bone at the expected entry point. Confirmation should be made with the image intensifier, in both lateral and A/P views (**Fig. 2**).

The Humeral Nail is designed to be inserted either through a lateral or a central entry point. The lateral entry point is located just inside the greater tuberosity (as seen on the lateral view). Verify with the image intensifier. The central entry point is located at the very top of the humeral head, in the articular surface, in line with the humeral axis (in both A/P and lateral views).

Note: Care should be taken to avoid too lateral a starting point to help prevent lateral "cutout" of the nail.

Technical Tip: For difficult proximal fractures place a finger through the incision along the lateral cortex interiorly from the greater tuberosity palpating the surgical neck fracture. Take care to protect the

Fig. 2

axillary nerve. Insert the nail at the proper starting point up to the fracture site. Manipulate the arm "feeling" the cortices align then advance the humeral nail under C-arm guidance. Patient positioning should be checked to ensure that imaging and access to the entry site are possible without excessive manipulation of the affected extremity.

The entry point is made with the **Cannulated Straight Awl** (0218) (Fig. 3). Image intensification is required to identify the correct entry point. The proximal metaphysis may be reamed with the 10.5mm Cannulated Entry Reamer (0221) (Fig. 4).





Alternatively, the Proximal Humeral Nail may be used over the **2.0mm Trochar Tip Guide Wire (0102)** for entry portal preparation in poor bone quality. A **Guide Wire Gripper (0419)** is used for Guide Wire placement (Fig. 5).

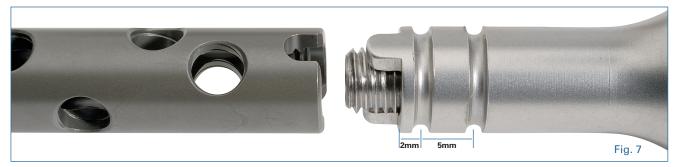


er al **r** The bayonet trochar tip and fluted nail design may be used as a self entry implant to prepare the proximal metaphysis. Further reaming is not necessary with the Proximal Humeral Nail. The nail may be inserted directly **(Fig. 6)**.



6. Proximal Nail Insertion

The Proximal Humeral Nail is available in 8mm diameter and 15cm length.



The selected nail is attached to the **Insertion Guide (1230)** locating its two keys into the corresponding keyway slots of the Nail (**Fig. 7**). The captured **Locking Bolt (1231)** is tightened securely with the **Hex Driver (0407)** and **T-Handle** (**0411)** to avoid loosening during Nail insertion.

Technical Tip: Two circumferential grooves are located on the Insertion Guide at 2mm and 7mm from the driving end of the nail. Depth of insertion may be visualized with the aid of fluoroscopy.

The **Targeting Module (1228)** is assembled onto the Insertion Guide using the thumb wheel **(Fig. 8)**.



Targeting Module Hole Identification (Fig. 9).

The AOS Humeral Nail System is comprised of two nail types; the Short Proximal Nail and the Long Nail. The Short Proximal Nail (S) and Long Nail (L) have different proximal screw locations. One **Targeting Module (P/N 1228)** is provided for both nail types. Therefore, the Targeting Module holes are laser marked with an "S" or/and "L" to identify type of nail with respect to the proximal hole locking options. In addition, the Long Nail has a dynamic hole option at one location.



il	S/L	_	Short or Long Nail static locking hole
	0/2	-	Short of Long Nan Static locking hold
rt	S	=	Short Nail only static locking hole
al	L-DYN	=	Long Nail only dynamic locking hole
;)			
g			
0			
g			
n			

Note: Prior to insertion verify the correct assembly with a Drill through the required holes.

The nail is ready for insertion. Advance it through the entry point. Gentle rotation of the nail may be necessary for nail insertion (Fig. 10).



The nail should be advanced with manual pressure. Aggressiveness can result in additional fractures or fragment displacements. If the nail does not advance easily, use the image intensifier to identify the problem.

Note: The nail should be inserted at least up to the first circumferential groove on the Insertion Guide but not deeper than up to the second groove. Alternatively, a 3.2mm Guide Pin may be inserted through a hole in the Targeting Module indicating the proximal end of the nail.

7. Proximal Locking

Prior to proximal locking the Targeting Module must be firmly tightened to the Insertion Guide using the thumb wheel.

The Screw Sheath (0601) together with the Trochar (0607) are inserted into the Targeting Module (Fig. 11). The Trochar is removed and replaced with the gold colored 3.5mm Drill Guide (0309). The 3.5mm Calibrated Drill (0220) is advanced under C-arm guidance to the subchondral bone of the humeral head (Fig. 12). The appropriate screw length may be read directly off of the Drill at the end of the Drill Guide.





When the Drill Guide is removed, the correct 5.0mm Fully Threaded Cancellous Locking Screw is inserted through the Screw Sheath using the 3.5mm Hex Screw Driver (0417) with the T-Handle (Fig. 13).

Technical Tip: In order to optimize screw insertion in the threaded screw hole, push the Cancellous Locking Screw without rotating through the first cortex until it



- is in contact with nail. Then start turning the Locking
- Screw with gentle axial pressure to engage the internal
- thread of the nail. C-arm guidance is useful to avoid articular surface penetration.
- Repeat the locking procedure for all lateral Proximal Locking Screws.

8. Distal Guided Locking For Proximal Nail

The Screw Sheath together with the Trochar are inserted into the Targeting Module in the distal hole location. A small skin incision is made and the assembly is pushed through until it is in contact with the lateral cortex. The Trochar is removed from the Sheath and replaced with the green colored 2.5mm Drill Guide (0307). After drilling both cortices with the

2.5mm Calibrated Drill (0217), the screw length may be read directly off of the Calibrated Drill at the end of the Drill Guide (Fig. 14).

Alternatively, after removal of the Drill Guide, the Hook Tip Depth Gauge (0513) can be used for screw length measurement.

The 3.5mm Cortical Locking Screw is inserted with the 2.5mm Hex Screw Driver (0416) and T-Handle (Fig. 15). For the second distal Locking Screw, routine Screw insertion is employed using the same procedure.

In dense bone a 3.5mm Cortical Tap (0226) may be utilized. Alternatively, a blue colored 3.0mm Drill Guide (0314) may be used with a 3.0mm Calibrated Drill (0230).





Fig. 15

9. Long Nail Selection

For entry point preparation refer to steps described in previous section 5.



The Long Humeral Nail is available in 7, 8 and 9mm diameter and 20, 22.5, 25, 27.5 & 30cm lengths for humeral shaft fractures.

For humeral shaft fractures the **Fracture Reduction Tool** (0807) may be utilized followed by placement of the **2.0mm Ball Nose Guide Wire (0103-600) (Fig. 16)**.



Ream the humeral shaft 1mm greater than the diameter of the selected nail using the **Flexible Shaft (0222)** and **Reamer Heads (0223) (Fig. 17)**. Reaming should be done in increments of 0.5mm. Nail length is determined by



sliding the **Guide Wire Depth Gauge (0515)** over the guide wire and reading the appropriate length directly from the calibrated line on the guide wire **(Fig. 18)**.



10. Long Nail Insertion

The selected nail is attached to the Insertion Guide locating its two keys into the corresponding keyway slots of the Nail. The captured Locking Bolt is tightened securely with the Hex Driver and T-Handle to avoid loosening during Nail insertion.

Technical Tip: Two circumferential grooves are located on the Insertion Guide at 2mm and 7mm from the driving end of the nail. Depth of insertion may be visualized with the aid of fluoroscopy.

The Targeting Module is assembled onto the Insertion Guide using the thumb wheel.

Note: Prior to insertion verify the correct assembly with a Drill through the required holes.

The nail is ready for insertion. Advance it through the entry point. Gentle rotation of the nail may be necessary for nail insertion. The nail should be advanced with manual pressure. The **Impactor Pad (0808)** should be used if impaction is necessary and is threaded into the Insertion Guide. Aggressiveness can result in additional fractures or fragment displacements. If the nail does not advance easily, use the image intensifier to identify the problem.

Note: The nail should be inserted at least up to the first circumferential groove on the Insertion Guide but not deeper than up to the second groove. Alternatively, a 3.2mm Guide Pin may be inserted through a hole in the Targeting Module indicating the proximal end of the nail.

11. Proximal Locking For Long Nail

Prior to proximal locking the Targeting Module must be **firmly** tightened to the Insertion Guide using the thumb wheel.

The Screw Sheath together with the Trochar are inserted into the Targeting Module.

For the Long Humeral Nail the proximal dynamic screw may be placed first. The dynamic mode will allow for fracture compression following distal locking. The remainder of the proximal screws can then be applied following compression of the fracture.

The Trochar is removed and replaced with the gold colored 3.5mm Drill Guide. The 3.5mm Calibrated Drill is advanced under C-arm guidance to the subchonral bone of the humeral head (Fig. 19).

The appropriate screw length may be read directly off of the Drill at the end of the Drill Guide.



When the Drill Guide is removed, the correct 5.0mm Fully Threaded Cancellous Locking Screw is inserted through the Screw Sheath using the 3.5mm Hex Screw Driver with the T-Handle.





12. Fracture Reduction for Long Nail

The Long Humeral Nail can be pre-assembled with a Compression Screw. The Compression Screw may be used to reduce the fracture if the fracture is displaced after distal locking. A Proximal Locking Screw is first inserted in the dynamic hole. The Compression Screw is then adjusted using the **3.5mm Flexible Hex Driver (0418)** and T-Handle **(Fig. 20)**. This will provide up to 5mm of compression **(Fig. 21)**.

Repeat the locking procedure for all lateral Proximal Locking Screws (Fig. 22).



13. Distal Locking For Long Nail

The freehand technique is used to insert Locking Screws into both A/P and M/L holes. A small incision is made. A **2.9mm Short Drill (0224)** and **2.9mm Drill Guide (0604)** are utilized for the freehand technique. The **Hook Tip Depth Gauge (0513)** may be placed through the **Distal Sheath (0602)** for screw length measurement.

14. End Cap Insertion

After removal of the Insertion Guide, an End Cap may be inserted. The End Cap is inserted with the 3.5mm Hex Screw Driver and T-Handle. Fully seat the End Cap to minimize the risk of loosening.

Note: To avoid impingement, carefully select the length of the End Cap.

15. Nail Extraction

Nail removal is an elective procedure. The End Cap, if used, and the most proximal Locking Screws are removed with the 3.5mm Hex Screw Driver Shaft and T-Handle.

Note: Attaching the Extractor to the nail before removal of all other Locking Screws, will prevent nail migration.

The **Extractor (0803**) is inserted into the driving end of the nail. All remaining Distal Locking Screws are removed with the 2.5mm Hex Screw Driver and T-Handle.

The nail can then be extracted.