

THE SMITH & NEPHEW HUMERAL INTERLOCKING NAIL



S U R G I C A L T E C H N I Q U E

THE SMITH & NEPHEW HUMERAL INTERLOCKING NAIL

by

David G. LaVelle, M.D., Thomas A. Russell, M.D.,
and John Charles Taylor, M.D., Memphis, Tennessee;
James N. Powell, M.D., Toronto, Ontario;
and Kevin Christiansen, M.D., Honolulu, Hawaii

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Nota Bene: The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

The Smith & Nephew Interlocking Nail System was designed with two overall goals for the healing of long bone fractures. The first was to improve the clinical success of previously available interlocking nails by reducing complications. The second overall goal was to design an interlocking nail system that would be more acceptable for treating complex fractures of the femur (including ipsilateral neck/shaft, subtrochanteric, and pathologic fractures) as well as complex fractures of the tibia and humerus.

The primary feature of the Interlocking Nail is the “non-slotted” or closed section design. This is different from the first widely accepted design for an IM nail which contained a longitudinal slot beginning at the distal end and proceeding proximally either the full length of the nail or to within a few centimeters of the proximal end.

The closed section design of the Interlocking Nail overcomes the biomechanical shortcomings of a slotted nail and, therefore, inherently answers some of the overall design goals. The elimination of the slot reduces complications by:

1. Decreasing torsional shear post-operatively in the healing bone,
2. Increasing the amount of material around the screw holes,
3. Reducing torsional rotation during insertion of the nail, and,
4. Easing distal targeting.

Another equally important area in the design of the interlocking nail concerned the bending strength. This was especially critical in light of the second overall design goal of the Interlocking Nail

System: for the interlocking nail to be more acceptable for treating complex fractures of the femur (including ipsilateral neck/shaft, subtrochanteric and pathologic fractures), as well as complex fractures of the tibia and humerus. It was felt that smaller nails could be very useful in the treatment of open fractures and in treating small boned patients. However, before this could become a reality, “unreamed” interlocking nails would have to be stronger than their historical counterparts which were reported to have higher breakage rates in nails of less than 13 mm in diameter.^{1,2,3}

The practical manifestation of the attention to strength requirements can be seen in the Interlocking DELTA® nails and the DELTA II nails. These nails have increased wall thickness in smaller diameters in order to maintain strength while avoiding the clinical problems of an overly stiff nail. Clinically, these smaller diameter interlocking nails have been very effective in the treatment of open fractures where they could be used without reaming. They have also been used as the nail of choice in patients with small canals that could not have easily withstood the excessive amount of reaming necessary to insert a standard diameter intramedullary nail.

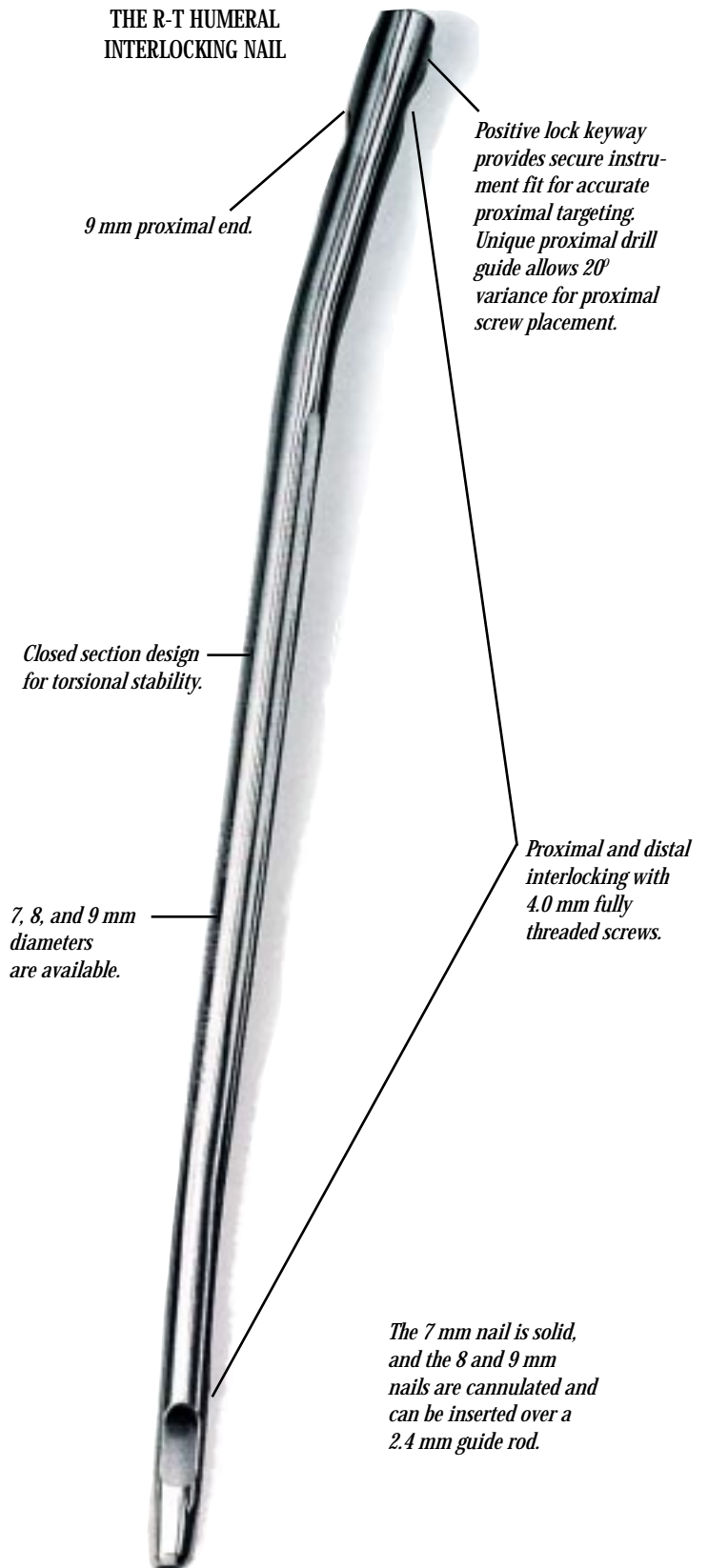
REFERENCES

- ¹ Kyle, R. F.; and Latta, L. L.: *Mechanics of Femoral Intramedullary Nailing*, AAOS Committee of Biomechanical Engineering, Las Vegas, 1985.
- ² Franklin, J. L.; Winquist, R. A.; Benirschke, S. K.; and Hansen, S. T. Jr.: *Broken Intramedullary Nails*, *J. Bone and Joint Surg.*, 70-A: 1463-1471, 1988.
- ³ Bucholz, R. W.: *Dilemmas and Controversies in Intramedullary Nailing in The Science and Practice of Intramedullary Nailing*. Ed by Browner, Bruce D. and Edwards, Charles C., Lea and Febiger, 1987, Philadelphia, pg. 85-89.

DESIGN FEATURES

The Russell-Taylor® (R-T) Humeral Nail is available in shaft diameters of 7, 8, and 9 mm. The proximal end is tapered to 9 mm. The 8 and 9 mm nails are cannulated and can be inserted over a 2.4 mm Guide Rod. The 7 mm nail is solid. Proximally and distally, the R-T Humeral Nail uses 4.0 mm fully threaded, self-tapping bone screws. They allow for bi-cortical fixation to reduce the possibility of screw backout, and can be used to help maintain length and prevent rotation. The R-T Humeral Nail has a unique Proximal Drill Guide which allows 20° variance for proximal screw insertion. Designed to address the widening spectrum of indications for fractures of the humerus, the R-T Humeral Nail allows for intramedullary fixation of humeral shaft fractures, including those that are segmental or severely comminuted. It is useful for the treatment of fractures, nonunions, and pathologic fractures of the humeral shaft, from 3 cm superior to the olecranon fossa, to within 2 cm of the surgical neck of the humerus.

The R-T Humeral Nail is designed for reamed or non-reamed application and can be inserted antegrade or retrograde.



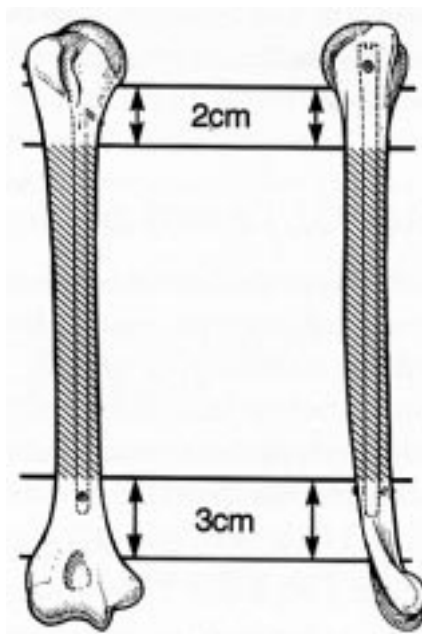
PREOPERATIVE PLANNING

Preoperative radiographs of the uninjured humerus may be used to estimate proper nail diameter, expected amount of reaming (if necessary), and final nail length for severely comminuted fractures. (X-ray templates for the R-T Humeral Nail are available for preoperative planning.)

Proper length and alignment must be obtained with traction before initiating closed antegrade intramedullary nailing. In late displaced fractures, open reduction may be required to prevent brachial plexus palsies. Ideally, the nail selected would be inserted just medial to the tip of the greater tuberosity, approximately a half centimeter posterior to the bicipital groove (to minimize damage to the rotator cuff), and should be templated to be buried in the bone proximally, to minimize subacromial impingement. It is important that the entry portal be in line with the midplane of the humerus. The nail length and diameter should take into account the distal narrowing of the humerus. The nail should end approximately 1-2 cm proximal to the olecranon fossa. In comminuted fractures, care should be taken that the humerus is not lengthened, as this may lead to delayed healing. Due to the circular cross section of the humerus in the proximal two-thirds and the narrowing and flattening of the medullary canal distally, it is difficult to obtain true interference fit. Therefore, static interlocking should be strongly considered in the treatment of these fractures.

The nail size used depends on the size of the patient and the extent of humeral comminution. It should be noted, however, that a small but consistent percentage of complications due to nail fatigue failure remain. Therefore, it is always recommended that the largest implant suitable for the patient be used.

NOTE: Intramedullary nails are not intended to carry significant loads for extended periods of time. All patients should be cautioned against significant weight bearing such as walking with the use of crutches, canes, or walkers prior to good callus formation. Lifting heavy weights beyond knee level and excessive rotation of the elbow should also be avoided. For this reason, patients who are noncompliant, as well as patients who could be predisposed to delayed or nonunions, must have external support.



Fractures situated in the shaded area can be treated with an R-T Humeral Nail.

PATIENT POSITIONING

In the supine position, turn the patient's head to the contralateral side to maximize exposure of the shoulder. Traction may be applied through a skeletal traction pin in the olecranon attached to a traction bow. Obtain rotational alignment by placing the shoulder in an anatomic position and rotating the distal fragment such that the arm and hand are pointing toward the ceiling with the elbow flexed 90° (*Figure 1*). Operating on a radiolucent table top will aid in radiographic imaging during the case.

PATIENT PREPARATION

Scrub and prepare the patient to include the proximal shoulder proximally to the line of the nipple, midline of the chest to the nape of the neck, and the entire extremity to the fingers. Sterile towels sutured or clipped to the skin will prevent their movement in the area of the axilla. Cover the image intensifier arm with a sterile isolation drape.

SURGICAL TECHNIQUE

Make a longitudinal skin incision from the most lateral point of the acromion. Extend it distally, centered over the tip of the greater tuberosity. Incise the fascia of the deltoid and palpate the greater tuberosity. Take care not to extend the incision more than 4-5 cm in the deltoid muscle to avoid damage to the axillary nerve.

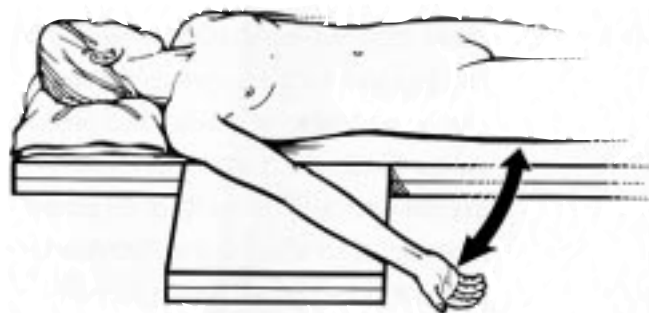


Figure 1

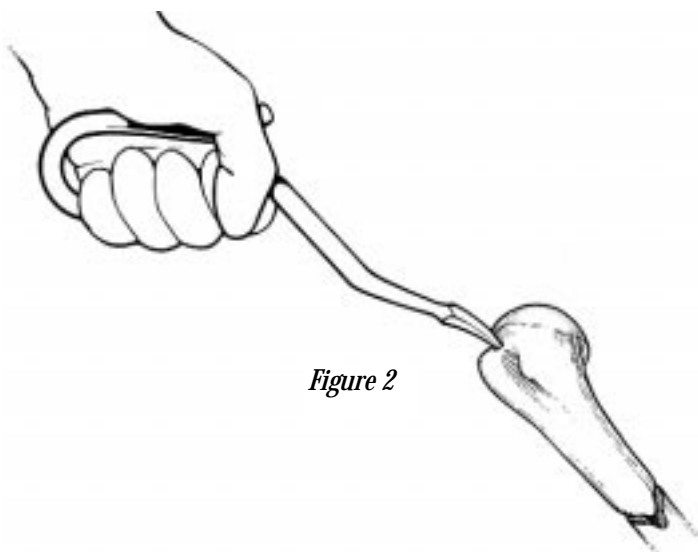


Figure 2

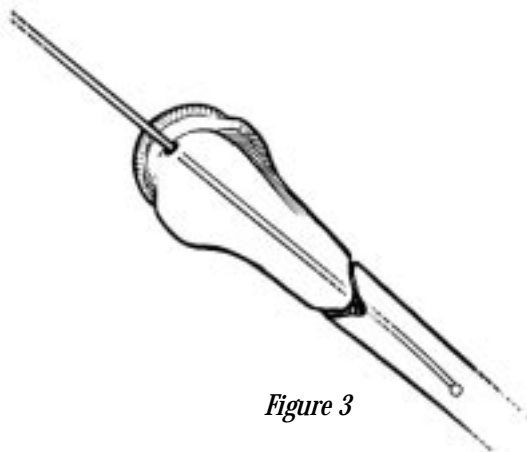


Figure 3

HUMERAL PREPARATION

Using the Curved Awl, establish the entry portal site just medial to the tip of the greater tuberosity and confirm this with image intensification (*Figure 2*). Advance the Curved Awl until it is seated within the humeral head and rotate the humerus internally and externally to confirm containment of the Curved Awl by image intensification. The entry portal should be centered on both views such that the nail will be in the midplate of the humerus.



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GUIDE ROD INSERTION

Withdraw the Curved Awl and insert the 2.0 mm Ball Tipped Reamer Guide Rod (*Figure 3*). Bending the tip of the Guide Rod may aid in reduction. Advance it down the medullary canal. By internally and externally rotating the arm, image intensification will confirm containment of the Guide Rod. Advance the Guide Rod into the center of the distal fragment until the tip is 1-2 cm proximal to the olecranon fossa. Containment of the guide rod distally is confirmed by internal and external rotation of the humerus while avoiding distraction and shortening.



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HUMERAL NAIL LENGTH DETERMINATION

Verification of the proper nail length may be determined by two separate methods:

Guide Rod Method — With the distal end of the Guide Rod 1-2 cm proximal to the olecranon fossa, overlap a second Guide Rod extending proximally from the humeral entry portal. Subtract the length

(X mm) of the overlapped Guide Rod from 700 mm to determine nail length (*Figure 4*).

Nail Length Gauge — Position the Nail Length Gauge anterior to the humerus (unaffected humerus preoperatively; affected humerus intraoperatively), with its distal end 1-2 cm proximal to the olecranon fossa. Move the C-arm to the proximal end of the humerus and use the image intensifier to read the correct nail length directly from the stamped measurements on the Nail Length Gauge (*Figure 5*).

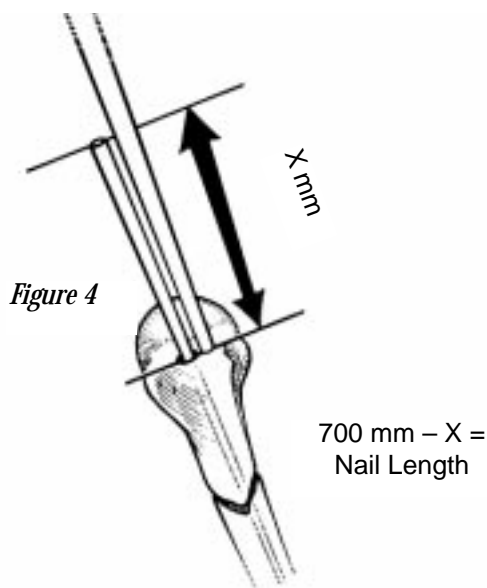


Figure 4

700 mm - X =
Nail Length

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REAMED TECHNIQUE

For a reamed technique, ream the entire humerus over the 2.0 mm Ball Tipped Reamer Guide Rod in 0.5 mm increments, until the desired diameter is achieved (*Figure 6*). Gently ream the distal end 1-2 cm proximal to the olecranon fossa. Exercise caution, as the cortical thickness of the humerus is much less than that of the tibia and femur and the procedure is often performed in osteoporotic bone. If the entry portal is too lateral, the lateral wall of the proximal humerus may be reamed out or fractured during nail insertion. Pushing the reamer shaft medially may prevent this complication. The final reamer diameter should be verified with the Reamer Template. It is essential to ream 0.5-1 mm over the selected nail diameter. **Never insert a nail that has a larger diameter than the last reamer used.**

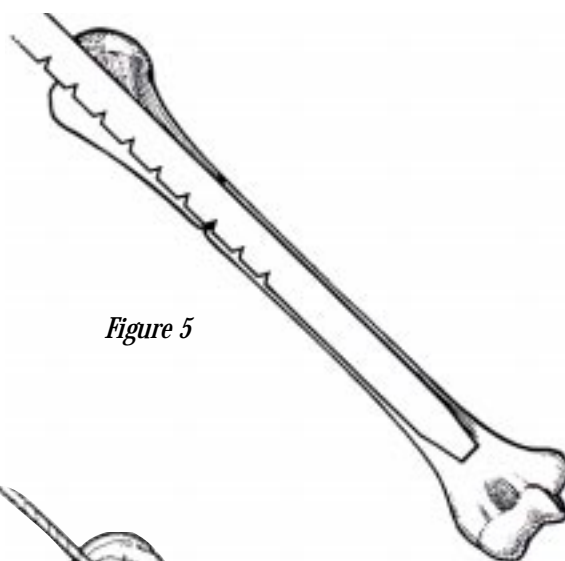


Figure 5

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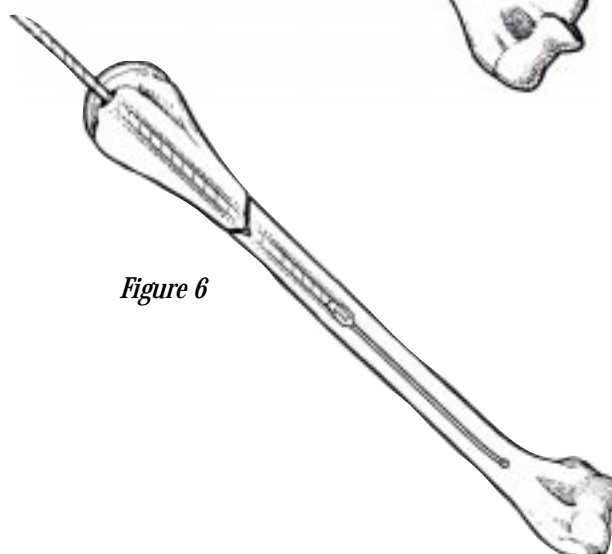


Figure 6

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Use the Medullary Exchange Tube over the 2.0 mm Ball Tipped Reamer Guide Rod to maintain fracture reduction. Replace the 2.0 mm Ball Tipped Reamer Guide Rod with a 2.4 mm Nail Guide Rod. Remove the Medullary Exchange Tube.

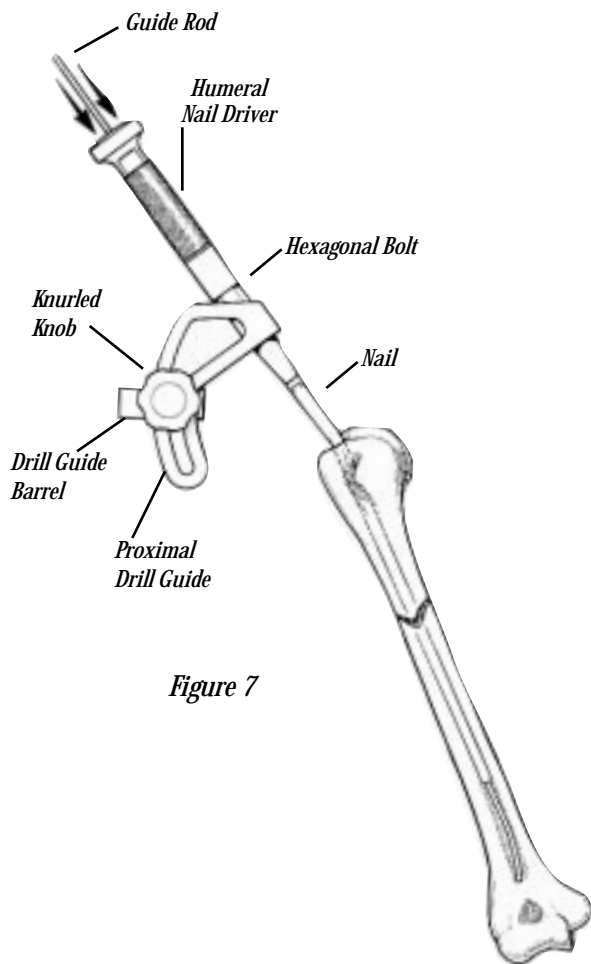


Figure 7

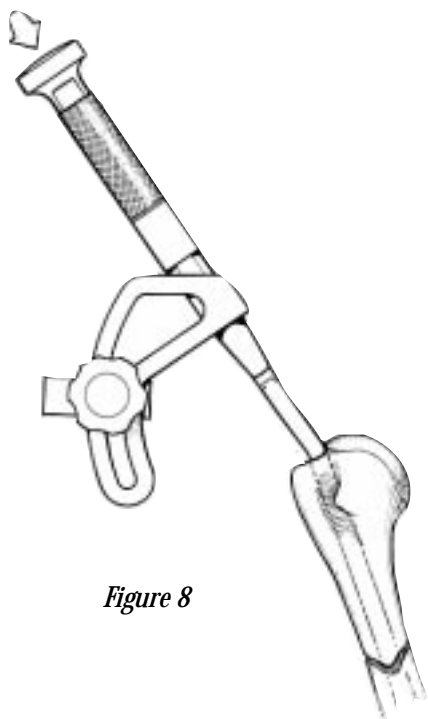


Figure 8

UNREAMED TECHNIQUE

For the unreamed technique, Interchangeable Sounds can be used to determine the diameter of the canal and proper nail size prior to insertion of the nail. In this situation, the proximal metaphysis of the humerus should be reamed to a diameter of 10 mm approximately 4 cm in length to open the medullary canal. The sounds are inserted over the Guide Rod. The sounds must be inserted manually, NOT DRIVEN. If resistance is encountered, STOP, and withdraw the sound. The largest diameter sound that can pass easily through the isthmus is the correct diameter for the nail. Preoperative estimates of canal diameter should be obtained as confirmation of the correct nail diameter.



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NAIL INSERTION

NOTE: The 7 mm Humeral Nail is not cannulated, therefore, the Guide Rod must be removed and the 7 mm nail inserted under radiographic control, without a Guide Rod. Attach the selected nail to the Proximal Drill Guide. Hold the Proximal Drill Guide with the handle pointed away from the patient and the proximal curvature of the nail pointed laterally. The Hexagonal Bolt should be tightened onto the nail with the 9/16" Wrench. The drill guide barrel is attached to the humeral outrigger with the knurled knob. Attach the Humeral Nail Driver to the hexagonal bolt on the proximal drill guide.



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Using the Proximal Drill Guide Assembly to control rotation, insert the nail. If a Guide Rod is used, the nail should be driven gently over the Guide Rod to the fracture site.

At this point, fracture reduction should be confirmed and the nail gently passed across the fracture site to avoid comminution (Figure 7). Remove the Guide Rod after the nail has entered the distal fragment. Advance the nail distally until it is 1-2 cm proximal to the olecranon fossa (Figure 8). Take care to

avoid splitting the distal humerus or developing a supracondylar fracture from wedging the tip of the nail too close to the olecranon fossa. However, when the nail reaches the fracture site, reduction is maintained manually and the nail is advanced gently across the fracture site and confirmed on A-P and lateral views by rotating the arm internally and externally until nail containment in the distal fragment is confirmed. Seat the nail so that the proximal end of the nail is beneath the bone to avoid subacromial impingement.

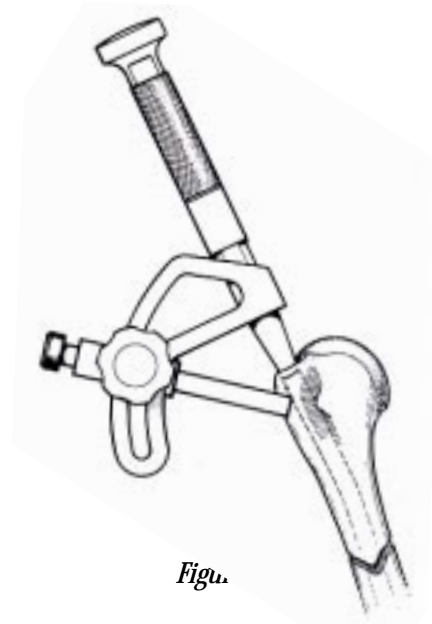


Fig. 9

PROXIMAL INTERLOCKING

Proximal and distal interlocking involves the use of 4.0 mm locking screws, 2.7 mm Drill Bit, 8 mm Brown Drill Sleeve, and 2.7 mm Green Drill Sleeve.

It is important, at this point, that the arm be adducted to prevent damaging the brachial artery with the drill. The Proximal Drill Guide allows adjustment of the interlocking screw angle by 20°. This maximizes the surgeon's ability to engage the best cortical bone on the medial surface of the humeral metaphysis. After the correct angle is selected, make a stab wound through the skin. Introduce the 8 mm Brown Drill Sleeve through the barrel of the Proximal Drill Guide and push it to bone (Figure 9). Introduce the humeral 2.7 mm Green Drill Sleeve through the 8 mm Brown Drill Sleeve. Attach the 2.7 mm Trocar to the T-Handle Jacob's Chuck and use it to dimple the cortex (Figure 10). Use the 2.7 mm Drill Bit to drill from the lateral cortex into

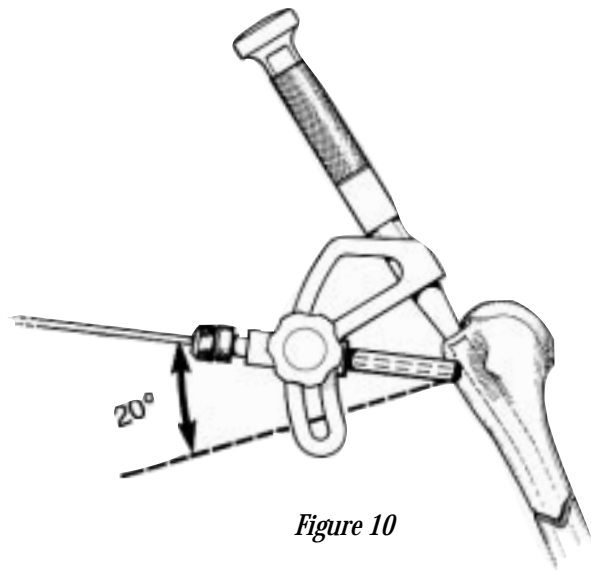


Figure 10



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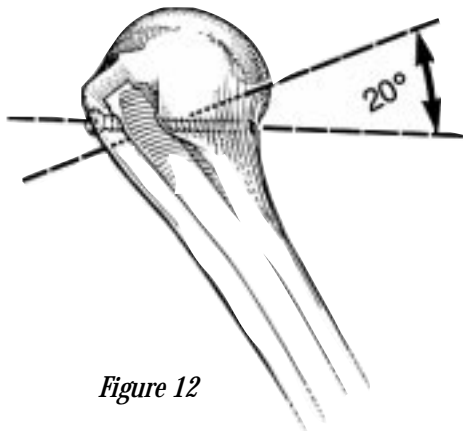
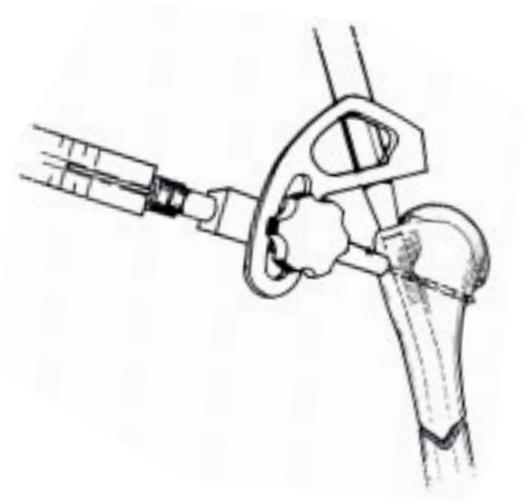


Figure 12

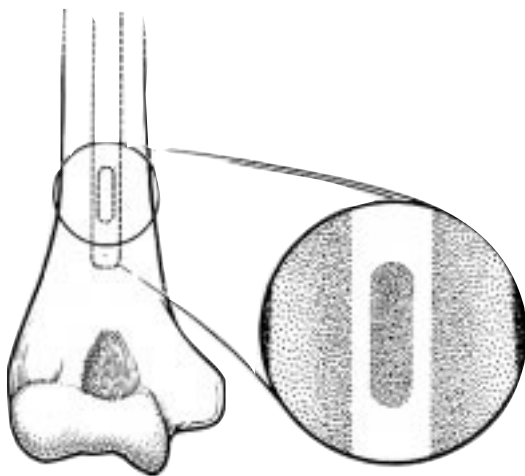


Figure 13

the medial cortex of the humerus. Use the image intensifier to avoid overpenetration of the medial humeral cortex. To confirm screw length using the Humeral Direct Measurement Gauge, slide the gauge against the Drill Bit and down to the Green Drill Sleeve and read the correct screw length (*Figure 11*). Insert the selected 4.0 mm fully threaded Humeral Locking Screw through the 8 mm Brown Drill Sleeve with the DELTA Tibial/Humeral Hexdriver (*Figure 12*). In osteoporotic bone, it may be necessary to put a washer on the screw to prevent it from being countersunk. Confirmation of the interlocking screw within the nail is made by introducing the 2.4 mm Guide Rod through the proximal end of the nail.

DISTAL INTERLOCKING

With an anterior-posterior orientation of the oval distal screw hole, make either an anterior or posterior insertion portal for distal interlocking. The anterior approach is preferred, which involves a percutaneous incision through the biceps muscle distally. Advance the image intensifier over the distal humerus until the oval slot is viewed (*Figure 13*). Make a 1 cm transverse skin incision, centered over the slot of the nail. Use a hemostat to spread through the biceps muscle. Attach a 2.7 mm Trocar to the T-Handle Jacob's Chuck and use it to localize the starting portal in the freehand technique. First introduce the tip of the 2.7 mm Trocar percutaneously through the biceps muscle to the anterior cortex and locate the tip in the slot, first from a lateral to medial plane, and then from a proximal to distal plane. Ideally, the 4.0 mm locking screw will be placed distally in the



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oval hole to allow axial compression during postoperative care. Rotate the 2.7 mm Trocar upward until it is parallel with the image beam. **Gently tap the Trocar into the anterior cortex of the humerus.** Take care to avoid a supracondylar fracture with this step. Remove the T-Handle Jacob's Chuck and confirm the placement of the pin within the slot of the nail with image intensification. With this pilot hole established, insert the 2.7 mm Green Drill Sleeve into the 8.0 mm Hand-Held Drill Sleeve. Insert the 2.7 mm Drill Bit into the Green Drill Sleeve and advance it through the anterior and posterior cortices of the humerus (*Figure 14*). Remove the drill sleeves and confirm containment of the 2.7 mm Drill within the slot of the Humeral Nail with image intensification. Replace the Drill Sleeves. Using the Humeral Direct Measurement Gauge, slide the Gauge against the drill bit and down to the Green Drill Sleeve and read the correct screw length (*Figure 15*).



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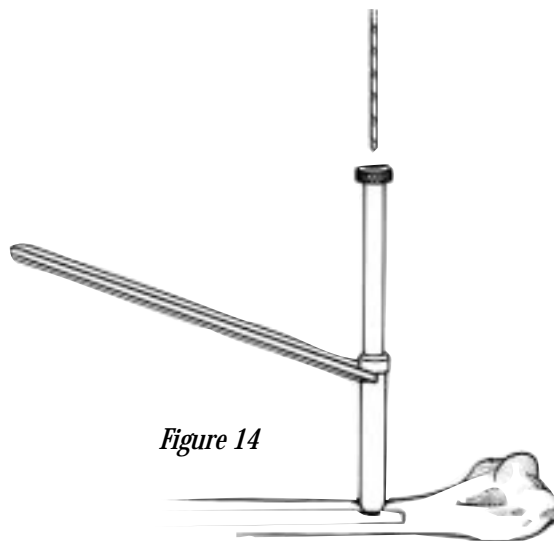


Figure 14

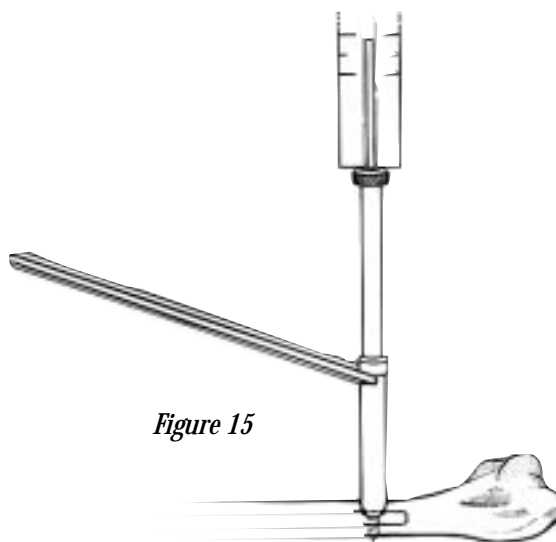


Figure 15

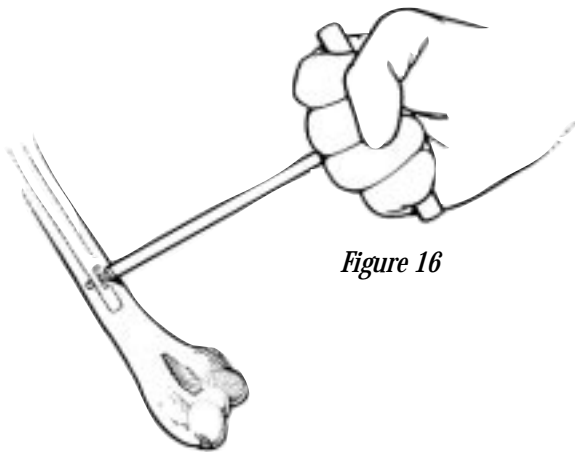


Figure 16



Figure 17

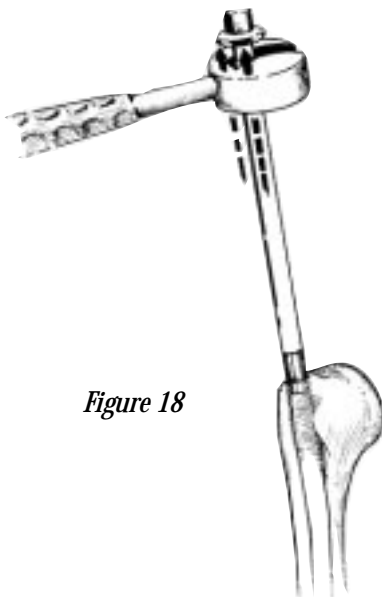


Figure 18

Insert the selected 4.0 mm fully threaded humeral locking screw with the DELTA Tibial/Humeral Hexdriver (*Figure 16*). In osteoporotic bone, it may be necessary to put a washer on the screw to prevent it from being countersunk. After completion of successful distal interlocking, the humerus should be visualized in full length views, A-P and lateral, with image intensification (*Figure 17*). Remove the Humeral Nail Driver and Proximal Drill Guide. Irrigate both proximal and distal incisions with saline. Insert a drain through the skin if necessary and close the wound in layers.



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POSTOPERATIVE

Postoperatively, the patient is placed in a long-arm posterior plaster splint and collar and cuff. After two to three days, patients are put in a cast brace if there is concern of stability. Active range of motion exercises can begin at four to seven days.

EXTRACTION TECHNIQUE HUMERAL NAIL

Extract the R-T Humeral Nail by first applying the Extraction Bolt to the proximal end of the nail. Then remove the interlocking screws through percutaneous incisions. Finally, attach the Driver/Extractor tube and drive the nail out with the slotted hammer (*Figure 18*).



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PREOPERATIVE PLANNING

Preoperative radiographs of the uninjured humerus may be used to estimate proper nail diameter, expected amount of reaming (if necessary), and final nail length for severely comminuted fractures. (X-ray templates for the R-T Humeral Nail are available for preoperative planning.)

Proper length and alignment must be attained with traction before initiating closed retrograde intramedullary nailing. If fixed traction is used, it should be intermittent to prevent brachial plexus palsies.

The Retrograde Humeral Interlocking Nailing Technique may be used in patients with proximal third or mid-shaft humeral fractures without disturbing the rotator cuff or the subacromial space. The retrograde technique is contraindicated in patients who have fractures in the distal third of the humerus, or in patients whose bone is osteopenic, which would make distal insertion difficult. Patients whose medullary canals are less than 10 mm in diameter should have an antegrade nailing. In comminuted fractures, take care not to lengthen the humerus while locking proximally and distally.

The nail size used depends on the size of the patient and the extent of humeral comminution. It should be noted, however, that a small but consistent percentage of complications due to nail fatigue failure remain. Therefore, it is always recommended that the largest implant suitable for the patient be used.

NOTE: Intramedullary nails are not intended to carry significant loads for extended periods of time. All patients should be cautioned against significant weight bearing such as walking with the use of crutches, canes, or walkers prior to good callus formation. Lifting heavy weights beyond knee level and excessive rotation of the elbow should also be avoided. For this reason, patients who are noncompliant, as well as patients who could be predisposed to delayed or nonunions, must have external support.



Figure 1

PATIENT POSITIONING

The patient may be placed either prone or in the lateral decubitus position for the retrograde nailing. If the patient is prone, support the fractured extremity by a radiolucent armboard (*Figure 1*). In the lateral decubitus position, suspend the fractured extremity, but take care not to distract the fracture site, as this could lead to neurovascular compromise. Suspension may be aided by an olecranon pin (*Figure 2*).

PATIENT PREPARATION

Scrub and prepare the patient to include the region of the distal clavicle, the acromion, and the medial scapula. The scrub and prep should include all of the arm, the forearm, and the hand. Cover the image intensifier arm with a sterile isolation drape.

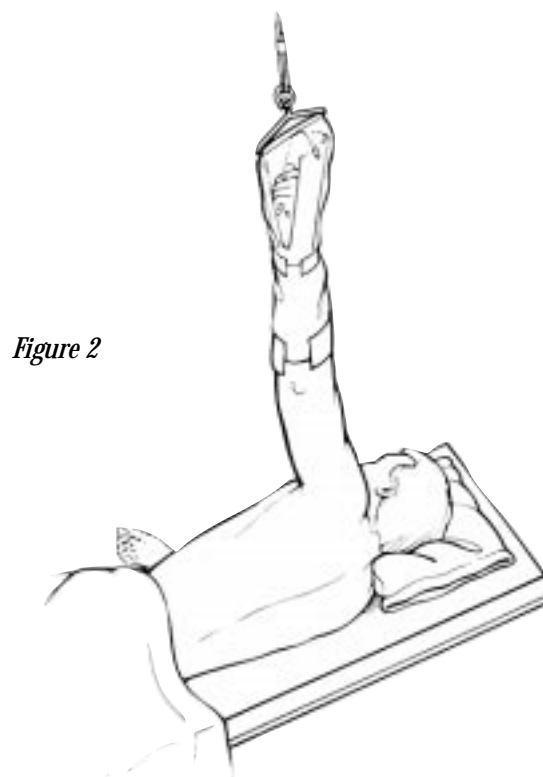


Figure 2

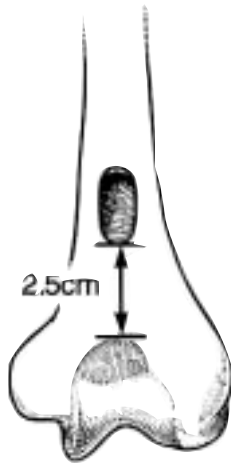


Figure 3

SURGICAL TECHNIQUE

Make a longitudinal skin incision, beginning at the tip of the olecranon and extend it proximally about 6 cm. Continue the incision through the triceps, splitting it in line with its fibers. Identify and expose the olecranon fossa in the posterior humerus and the region just proximal to the olecranon fossa.



21-6600

HUMERAL PREPARATION

Using a drill, open the posterior humeral cortex about 2.5 cm proximal to the proximal-most extent of the olecranon fossa (Figure 3). Enlarge this hole with a Curved Awl or a rongeur to 10 mm wide and 20 mm long.

GUIDE ROD INSERTION

Withdraw the Curved Awl and insert the 2.0 mm Ball Tipped Reamer Guide Rod. Bending the tip of the Guide Rod may aid in reduction. Advance it down the medullary canal. Using image visualization, reduce the fracture and pass the Guide Rod across the fracture site. Confirm presence of the Guide Rod in the proximal fragment of the humerus by rotating the image intensifier and the arm internally and externally. Once the Guide Rod has been confirmed to be located in the medullary canal of the proximal fragment, pass the Guide Rod into the humeral head (Figure 4).

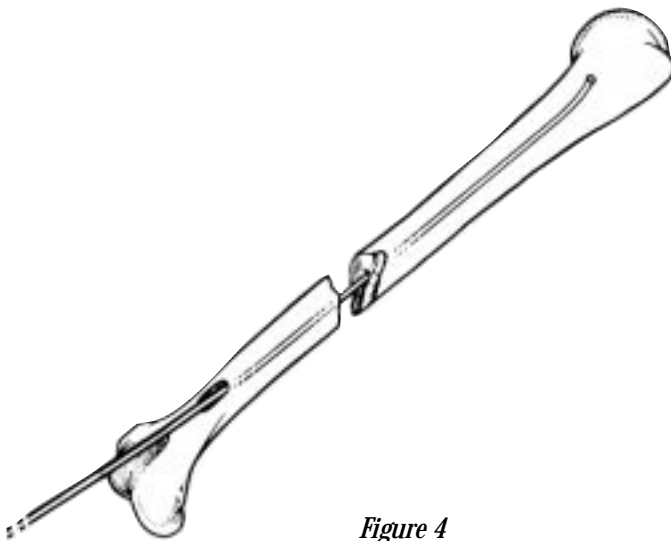


Figure 4

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HUMERAL NAIL LENGTH DETERMINATION

Verification of the proper nail length may be determined by two separate methods.

Guide Rod Method — With the proximal end of the Guide Rod in the humeral head, overlap a second Guide Rod extending distally from the humeral entry portal. Subtract the length (X mm) of the overlapped Guide Rod from 700 mm to determine nail length (*Figure 5*).

Nail Length Gauge — Position the Nail Length Gauge anterior to the humerus (unaffected humerus preoperatively; affected humerus intraoperatively) with its proximal end centered in the humeral head. Move the C-arm to the distal end of the humerus and use the image intensifier to read the correct nail length directly from the stamped measurements on the Nail Length Gauge (*Figure 6*).

REAMED TECHNIQUE

For a reamed technique, ream the entire humerus over the 2.0 mm Ball Tipped Reamer Guide Rod in 0.5 mm increments until the desired diameter is achieved (*Figure 7*). The entry portal and 4 cm into the canal should be reamed to at least 11-12 mm diameter, if adequate bone stock is available. Take care not to penetrate the anterior cortex when first passing the reamer into the entry portal and the medullary canal of the distal fragment. Ream the diaphysis of the humerus 0.5 to 1.0 mm over the selected nail diameter. **Never insert a nail that has a larger diameter than the last reamer used.**

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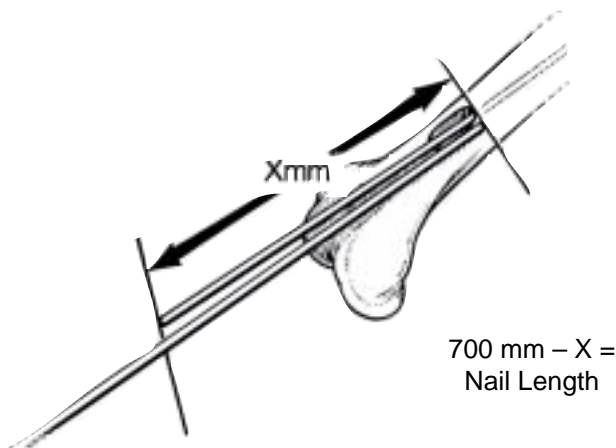


Figure 5

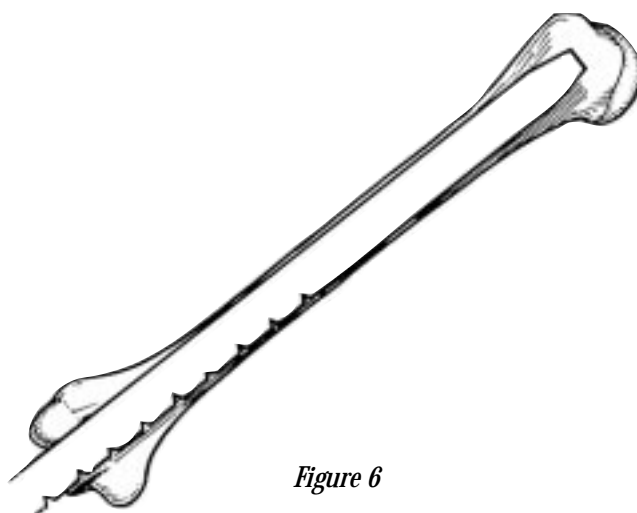


Figure 6

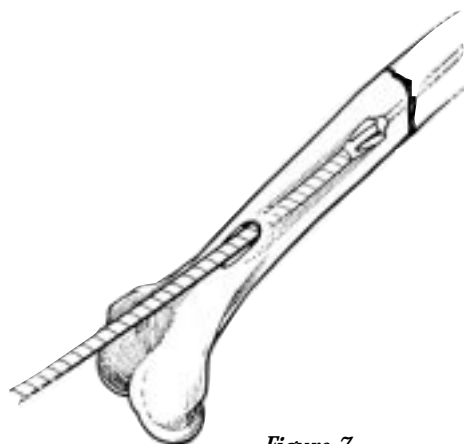


Figure 7

Use the Medullary Exchange Tube over the 2.0 mm Ball Tipped Reamer Guide Rod to maintain fracture reduction. Replace the 2.0 mm Ball Tipped Reamer Guide Rod with a 2.4 mm Nail Guide Rod. Remove the Medullary Exchange Tube.



11-5115

UNREAMED TECHNIQUE

For the unreamed technique, Interchangeable Sounds can be used to determine the diameter of the canal and proper nail size prior to insertion of the nail. In this situation, enlarge the distal metaphysis of the humerus to 10 mm to open up the medullary canal. Sounds should be used primarily in open fractures. They are inserted at the fracture site rather than the entry portal. The sounds are inserted over the Guide Rod. The sounds must be inserted manually and NOT DRIVEN. If resistance is encountered, STOP, and withdraw the sound. The largest diameter sound that can pass easily through the isthmus is the correct diameter for the nail.

11-5123

NAIL INSERTION

The 7 mm Humeral Nail is not cannulated, therefore, the Guide Rod must be removed and the 7 mm nail should be inserted under radiographic control without a Guide Rod. Extreme caution must be exercised when inserting the nail, as propagation of the entry portal proximally, or driving the nail out through the anterior cortex of the humerus is possible, particularly in osteopenic bone. If necessary, withdraw the nail and ream the entry portal and distal canal 1 or 2 mm more, if adequate bone stock is available.



11-8190
11-8192
11-8194
11-8196
11-8198
11-8200



11-5116



11-5113



11-0566



11-5125



11-5122



11-5121

Attach the nail to the Proximal Drill Guide. The Proximal Bolt should be tightened onto the nail with the 9/16" Wrench. Attach the Humeral Nail Driver to the proximal bolt. Using the outrigger to control rotation, insert the nail (*Figure 8*). If a Guide Rod is used, gently drive the nail over the Guide Rod to the fracture site (*Figure 9*). At that point, confirm fracture reduction and gently pass the nail across the fracture site to avoid comminution. Remove the Guide Rod after the nail has crossed into the proximal fragment. Confirm containment of the nail within the proximal fragment by rotating the arm and the image beam. Drive the nail until its curve, which is facing anteriorly, is buried in the medullary canal of the humerus. The distal end of the nail should be prominent no more than 1 cm outside of the medullary canal. The proximal end of the nail should end no closer than 2 cm to the subchondral bone, as closer placement would place the proximal interlocking screw in a position where it may impinge in the subacromial space.

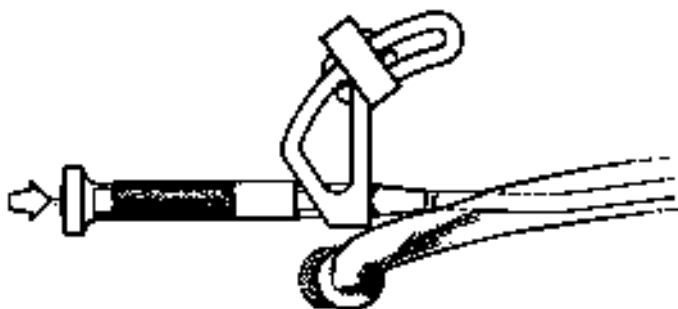


Figure 8

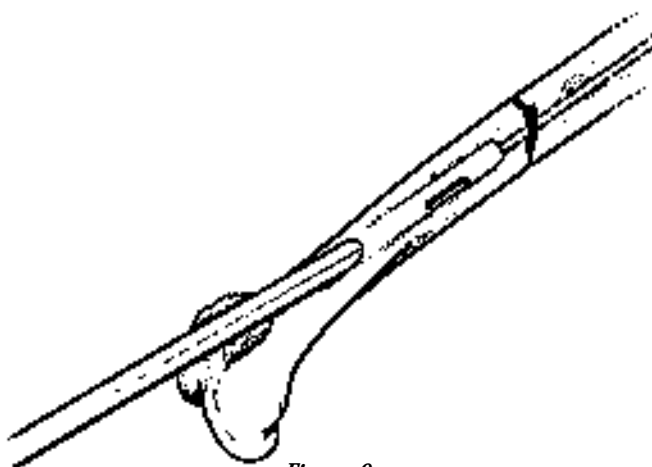


Figure 9

DISTAL INTERLOCKING

The R-T Humeral Nail is designed so that, with the retrograde technique, the distal screw is inserted from posterior to anterior and the proximal screw is inserted from lateral to medial. The distal screw is placed using direct vision of the bone (*Figure 10*). Introduce the 8.0 mm Brown Drill Sleeve and the 2.7 mm Green Drill Sleeve through the barrel of the Proximal Drill Guide and

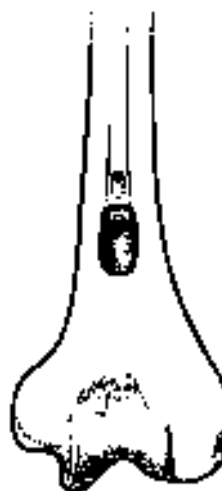


Figure 10

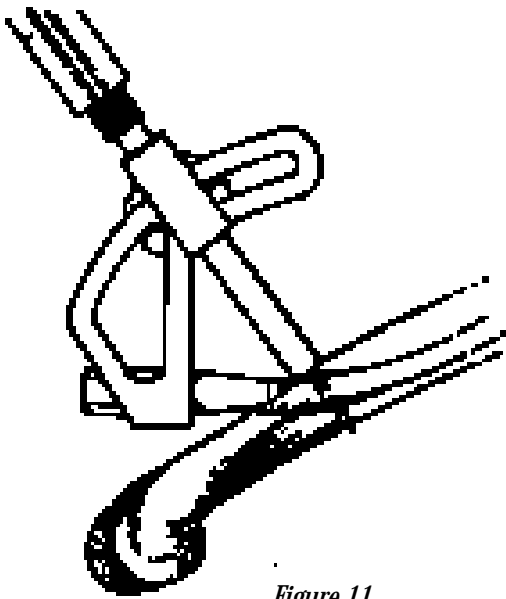


Figure 11

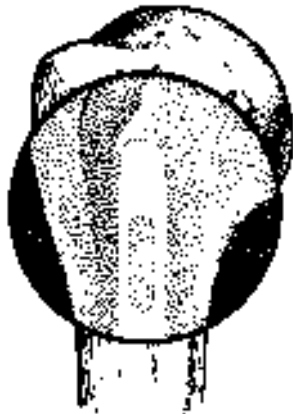


Figure 12

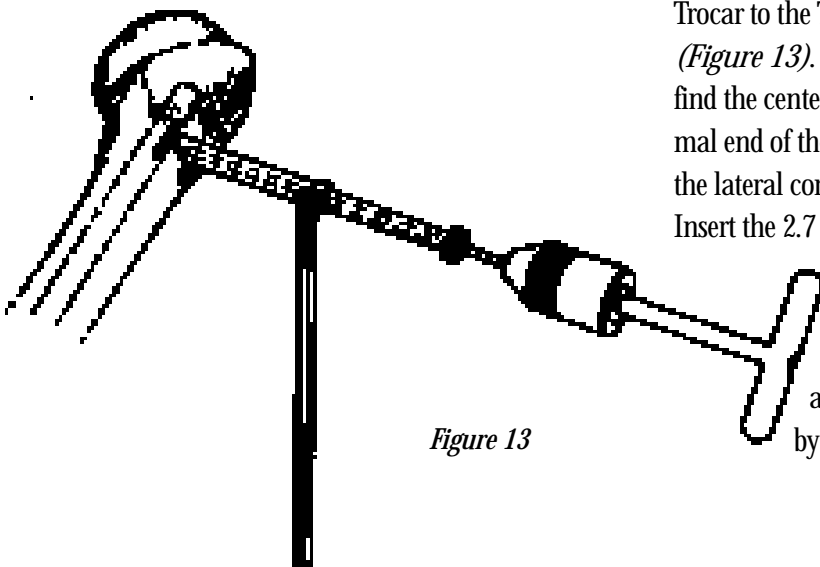


Figure 13

push it to bone. Attach the 2.7 mm Trocar to the T-Handle Jacob's Chuck and use it to dimple the cortex. Use the 2.7 mm Drill Bit to drill from the posterior cortex into the anterior cortex of the humerus (Figure 11). Use the image intensifier to avoid overpenetration of the anterior humeral cortex. To confirm screw length using the Humeral Direct Measurement Gauge, slide the gauge against the Drill Bit and down to the Green Drill Sleeve and read the correct screw length. Remove the Green Drill Sleeve and insert the selected 4.0 mm fully threaded Humeral Locking Screw through the 8.0 mm Brown Drill Sleeve with the DELTA Tibial/Humeral Hexdriver. In osteoporotic bone, it may be necessary to put a washer on the screw to prevent it from being countersunk. Confirmation of the interlocking screw within the nail is made by introducing the 2.4 mm Guide Rod through the distal end of the nail.

PROXIMAL INTERLOCKING

Using the image intensification, identify the oval hole in the proximal end of the nail (Figure 12). Make an incision laterally over the proximal humerus and use blunt dissection down to bone. Attach a 2.7 mm Trocar to the T-Handled Jacob's Chuck (Figure 13). Use the tip of the Trocar to find the center of the oval hole of the proximal end of the nail. Use the Trocar to open the lateral cortex of the proximal humerus. Insert the 2.7 mm Drill Bit through the 2.7 mm Green Drill Sleeve and 8.0 mm Hand-Held Drill Sleeve, and insert this assembly into the hole made by the Trocar.



11-5117



11-0257



11-5130



11-5118



11-2096



11-5129

Drill parallel to the beam of the image through the oval hole in the proximal end of the nail (*Figure 14*). Take care not to drill through articular cartilage in the humeral head. Use the Humeral Direct Measurement Gauge to measure the length of the screw.

Insert the 4.0 mm fully threaded humeral screw through the 8 mm Hand-Held Drill Sleeve, and through the oval hole in the proximal end of the nail (*Figure 15*). Confirm containment of this screw within the nail, using image intensification (*Figure 16*). Irrigate both proximal and distal incisions with saline. Insert a drain through the skin if necessary and close the wound in layers.

POSTOPERATIVE

Postoperatively, place the patient in a long-arm posterior plaster splint and collar and cuff. After two to three days, patients are put in a cast brace if there is concern about stability. Active range of motion exercises can begin at four to seven days.

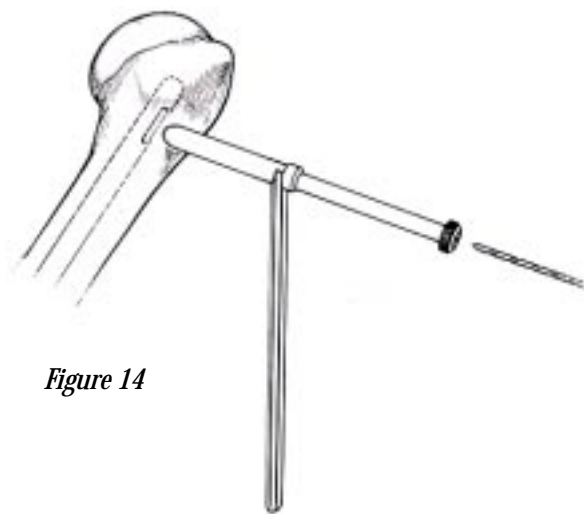


Figure 14

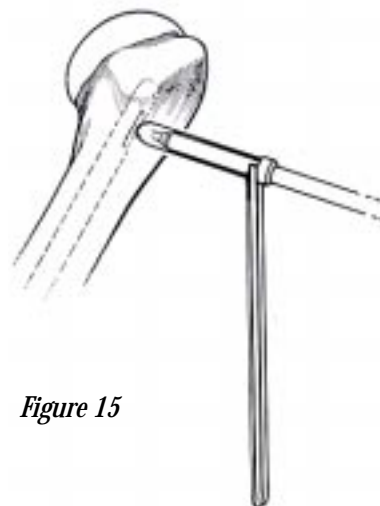


Figure 15

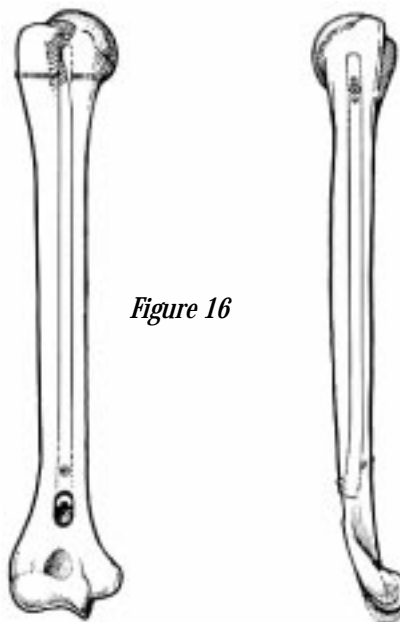


Figure 16

EXTRACTION TECHNIQUE HUMERAL NAIL

Extract the R-T Humeral Nail by first applying the Extraction Bolt to the proximal end of the nail. Then remove the interlocking screws through percutaneous incisions. Finally, attach the Driver/Extractor tube and drive the nail out with the slotted hammer.



11-5127



11-5126



11-5175

R-T HUMERAL INTERLOCKING NAILS

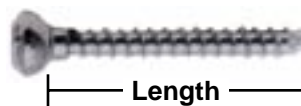


Cat. No.	Size
12-2450	7 mm x 18 cm
12-2451	7 mm x 20 cm
12-2452	7 mm x 22 cm
12-2453	7 mm x 24 cm
12-2454	7 mm x 26 cm
12-2455	7 mm x 28 cm
12-2456	7 mm x 30 cm
12-2460	8 mm x 18 cm
12-2461	8 mm x 20 cm
12-2462	8 mm x 22 cm
12-2463	8 mm x 24 cm
12-2464	8 mm x 26 cm
12-2465	8 mm x 28 cm
12-2466	8 mm x 30 cm
12-2470	9 mm x 18 cm
12-2471	9 mm x 20 cm
12-2472	9 mm x 22 cm
12-2473	9 mm x 24 cm
12-2474	9 mm x 26 cm
12-2475	9 mm x 28 cm
12-2476	9 mm x 30 cm



4.0 MM LOCKING SCREW

Cat. No.	Length
12-2912	12 mm
12-2914	14 mm
12-2916	16 mm
12-2918	18 mm
12-2920	20 mm
12-2922	22 mm
12-2924	24 mm
12-2926	26 mm
12-2928	28 mm
12-2930	30 mm
12-2932	32 mm
12-2934	34 mm
12-2936	36 mm
12-2938	38 mm
12-2940	40 mm
12-2942	42 mm
12-2944	44 mm
12-2946	46 mm
12-2948	48 mm
12-2950	50 mm
12-2952	52 mm
12-2954	54 mm
12-2956	56 mm
12-2958	58 mm
12-2960	60 mm





Nail Length Gauge

Cat. No. 11-2058



Curved Awl

Cat. No. 21-6600



Tip Threaded Guide Wire

3.2 mm x 305 mm

Cat. No. 11-2057



Cannulated Reamer

9.0 mm

Cat. No. 11-2003



Pseudarthrosis Chisel

5.6 mm

Cat. No. 11-5128



T-Handle Jacob's Chuck

Cat. No. 11-0257

Key for T-Handle Jacob's Chuck

Cat. No. 7111-0258

(not shown)

Interchangeable Sounds

Cat. No.	Size
11-8190	7 mm
11-8192	8 mm
11-8194	9 mm
11-8196	10 mm
11-8198	11 mm
11-8200	12 mm



T-Handled Shaft for Interchangeable Sounds

Cat. No. 11-8180



Humeral Screw Length Gauge

Cat. No. 11-5124

INSTRUMENTS

Ball Tipped Reamer Guide Rod

2.0 mm x 700 mm (for 6.0-7.5 reamers)
 Cat. No. 11-5120



Reamer Template

Cat. No. 11-2023



Skin Protector

Cat. No. 41-5330



Humeral Medullary Exchange Tube

Cat. No. 11-5115



Nail Guide Rod

2.4 mm x 700 mm
 Cat. No. 11-5123



Humeral Proximal Drill Guide

Cat. No. 11-5116



Replacement Bolt for Proximal Drill Guide

Cat. No. 11-5113



Open End Wrench

9/16" (2 included in set)
 Cat. No. 11-0566





Humeral Nail Driver
Cat. No. 11-5125



Slotted Hammer
Cat. No. 11-5175



8.0 mm Brown Drill Sleeve
Cat. No. 11-5122



2.7 mm Green Drill Sleeve
Cat. No. 11-5121



Trocar
2.7 mm x 216 mm
Cat. No. 11-5117



Drill Bit
2.7 mm x 216 mm
Cat. No. 11-5118



Hexdriver Shaft for 4.0/4.5 mm Screws
Cat. No. 11-2096



Drill Sleeve with Handle
8.0 mm
Cat. No. 11-5129

**Humeral Direct
Measurement Gauge**
Cat. No. 11-5130



Self-Holding Attachment
(for 4.0, 4.5, and 5.0 mm
Locking Screws)
Cat. No. 11-2076



Humeral Extractor Bolt
(Replacement Bolt for Humeral Guide)
Cat. No. 11-5127



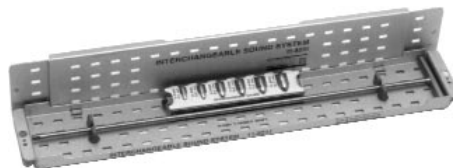
Humeral Driver/Extractor Tube
Cat. No. 11-5126



Quick Release T-Handle
Cat. No. 11-6011



Interchangeable Sound System
Cat. No. 11-2146



Universal Socket Wrench
Cat. No. 7111-1650



R-T Humeral Sterilization Case
Cat. No. 7111-2140



Instrument Tray

Cat. No. 7111-2140

Will hold the following:

Cat. No.	Description	Qty.
11-0257	T-Handle Jacob's Chuck	1
11-0566	9/16" Open End Wrench	2
11-2003	9.0 mm Cannulated Reamer	1
11-2023	Reamer Template	1
11-2058	R-T Nail Length Gauge	1
11-2076	Self-Holding Attachment F/Locking Screw	1
11-2096	Hex Driver for 4.0/4.5 mm Locking Screws	1
11-5115	R-T Humeral Medullary Exchange Tube	1
11-5116	R-T Humeral Proximal Drill Guide (Includes Bolt)	1
11-5121	2.7 mm Drill Sleeve (Green)	1
11-5122	8.0 mm Drill Sleeve (Brown)	1
11-5124	R-T Humeral Screw Length Gauge	1
11-5125	R-T Humeral Nail Driver	1
11-5126	R-T Humeral Driver/Extractor Tube	1
11-5127	R-T Humeral Extractor Bolt	1
11-5128	5.6 mm Pseudarthrosis Chisel	1
11-5129	R-T 8.0 mm Drill Sleeve W/Handle	1
11-5130	R-T Humeral Direct Measuring Gauge	1
11-5175	Slotted Hammer	1
21-6600	Curved Awl	1
41-5330	Skin Protector	1
11-6011	Quick Release T-Handle	1
11-2146	Interchangeable Sound System	1
7111-1650	Universal Socket Wrench	1



Humeral Instrument Set

Cat. No. 11-2141

(Not Shown)

Includes the following:

Cat. No.	Description	Qty.
11-0257	T-Handle Jacob's Chuck	1
11-0566	9/16" Open End Wrench	2
11-2003	9.0 mm Cannulated Reamer	1
11-2023	Reamer Template	1
11-2058	R-T Nail Length Gauge	1
11-2076	Self-Holding Attachment F/Locking Screw	1
11-2096	Hexdriver Shaft for 4.0/4.5 mm Locking Screws	1
11-5116	R-T Humeral Proximal Drill Guide (Includes Bolt)	1
11-5121	2.7 mm Drill Sleeve (Green)	1
11-5122	8.0 mm Drill Sleeve (Brown)	1
11-5124	R-T Humeral Screw Length Gauge	1
11-5125	R-T Humeral Nail Driver	1
11-5126	R-T Humeral Driver/Extractor Tube	1
11-5127	R-T Humeral Extractor Bolt	1
11-5128	5.6 mm Pseudarthrosis Chisel	1
11-5129	R-T 8.0 mm Drill Sleeve W/Handle	1
11-5130	R-T Humeral Direct Measuring Gauge	1
11-5175	Slotted Hammer	1
21-6600	Curved Awl	1
41-5330	Skin Protector	1
11-2146	Interchangeable Sound System	1
11-6011	Quick Release T-Handle	1
7111-1650	9/16" Universal Socket Wrench	1
7111-2140	R-T Humeral Sterilization Case	1

IMPORTANT MEDICAL INFORMATION

Warnings and Precautions

RICHARDS INTRAMEDULLARY NAIL SYSTEM

IMPORTANT NOTE

Intramedullary nails provide an alternative to open reduction and fixation of a variety of fractures. The objective of this closed technique as compared to open techniques is to provide fixation with minimal trauma, reduced risk of infection, and reduced blood loss. As with all orthopedic devices, success varies with the patient; even in the less difficult case there is a risk of complications. The surgeon is cautioned that any of the circumstances listed under categories below may reduce the chances of a successful outcome.

BASIC STRUCTURE

The Richards Intramedullary Nail System consists of interlocking intramedullary nails, interlocking reconstruction nails, and intramedullary hip screw systems. All of these systems listed previously accept locking screws. The locking screws reduce the likelihood of shortening and rotation of femoral shaft fractures. All nails are available in a variety of diameters and lengths. All implantable devices are for single use only.

Intramedullary interlocking nails and femoral/recon nails are curved or straight nails that contain holes proximally and distally to accept locking screws.

Interlocking reconstruction nails are curved nails that contain holes proximally to accept screws which thread into the femoral head for compression and rotational stability; distally there are two holes to accept locking screws. Interlocking reconstruction nails are available in a variety of diameters and lengths in left and right models, as proximal screw holes are anteverted 8° with respect to the plane containing the curve of the nail.

Intramedullary hip screw systems contain a pre-bent nail containing holes proximally and distally to accept a lag screw and locking screws, respectively. Intramedullary hip screws are available in a variety of diameters, lengths and neck/shaft angles.

The **ReVision™ Nail** consists of an intramedullary nail with holes at each end to accept 5.0 mm locking screws. The locking screws reduce the likelihood of shortening and rotation of the fusion site.

Interlocking retrograde nails have proximal and distal holes for locking screws.

MATERIALS

Intramedullary nails, locking screws, sleeves, draw bolts, set screws, and lag screws are manufactured from stainless steel (ASTM F 138 and ISO 5832/1).

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

General

The general principles of patient selection and sound surgical judgment apply to the intramedullary nailing procedure. The size and shape of the long bones present limiting restrictions on the size and strength of implants.

Indications for **interlocking intramedullary nails** include severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; and bone lengthening/shortening. Femoral interlocking nails include the indication for proximal, middle and distal third femoral shaft fractures. Tibial interlocking nails also include the same indications for tibial shaft fractures.

Humeral interlocking intramedullary nails are indicated for humeral shaft fractures, including severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions, proximal, middle and distal third shaft fractures; polytrauma and/or multiple fractures; humerus reconstruction, following tumor resection and grafting; and prophylactic nailing of impending pathologic fractures.

Forearm interlocking intramedullary nails are indicated for radial and ulnar shaft fractures, including severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; proximal middle and distal third shaft fractures; polytrauma and/or multiple fractures.

Interlocking reconstruction nails are indicated for the following: Subtrochanteric fractures with lesser trochanteric involvement; ipsilateral femoral shaft/neck fractures; severely comminuted shaft fractures; femur reconstruction following tumor resection and grafting; bone shortening/lengthening; and prophylactic nailing of impending pathologic fractures.

Femoral/recon antegrade nails are indicated for shaft fractures including severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; bone lengthening/shortening; femur reconstruction following tumor resection and grafting; fractures in osteoporotic bone; severely comminuted shaft fractures; pathologic fractures, pseudoarthrosis, failed osteosynthesis; closed supracondylar fractures; and prophylactic nailing of impending pathologic fractures. Additional indi-

cations for the femoral/recon antegrade include: subtrochanteric fractures with lesser trochanteric involvement; ipsilateral femoral shaft/neck fractures.

Retrograde nails are indicated for shaft fractures including severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; bone lengthening/shortening; femur reconstruction following tumor resection and grafting; fractures in osteoporotic bone; severely comminuted shaft fractures; pathologic fractures, pseudoarthrosis, failed osteosynthesis; closed supracondylar fractures; and prophylactic nailing of impending pathologic fractures. Additional indications for retrograde nails include: severely comminuted supracondylar fractures with or without difficult intra-articular extension, fractures that require opening the knee joint to stabilize the femoral condylar segment. Also, fractures above total knee implants.

Intramedullary hip screw systems are indicated for intertrochanteric and high subtrochanteric fractures, femoral neck fractures, and subcapital fractures. Indications limited to the intramedullary hip screw long stem device only are comminuted neck and shaft fractures, femur reconstruction following tumor resection, prophylactic nailing of impending pathologic fractures, and leg length discrepancies secondary to femoral fracture.

Indications for the **ReVision Nail** include the following: degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations in the hindfoot: tibio-calcaneal arthrodesis; combined arthrodesis of the ankle and sub-talar joints; avascular necrosis of the talus following trauma; failed total ankle replacement with sub-talar intrusion; failed ankle arthrodesis with insufficient talar body; rheumatoid arthritis; severe deformity secondary to untreated talipes equinovarus or neuromuscular disease; and severe pilon fractures with trauma to the sub-talar joint.

Contraindications

1. These systems should not be used in crossing open epiphyseal plates.
2. Insufficient quantity or quality of bone, obliterated medullary canal or conditions which tend to retard healing, also, blood supply limitations, previous infections, etc.
3. Foreign body sensitivity; where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Active infection.
5. Conditions which tend to impair the patient's ability or willingness to restrict activities or to follow directions during the healing period.
6. The forearm nail should not be used in children who have not reached skeletal maturity.

In addition to the contraindications listed above, reconstruction nails are also not recommended for any fracture which can be suitably fixed with a standard interlocking intramedullary nail.

In addition to the contraindications listed above, intramedullary hip screw systems are also contraindicated for a severe bow or gross distortion of the femur.

Possible Adverse Effects

1. Loosening, bending, cracking or fracture of the nails or screws, or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures or one or more of the factors listed in Contraindications above and/or Warnings and Precautions, below.
2. Loss of anatomic position with nonunion or malunion with rotation or angulation.
3. Infections, both deep and superficial.
4. Allergies and other reactions to device materials.
5. Irritational injury of soft tissues, including impingement syndrome.
6. Supracondylar fractures from retrograde nailing.

WARNINGS AND PRECAUTIONS

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Preoperative

1. Use care in handling and storage of implant components. Cutting, sharply bending or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or noninert stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instrument components or implants have been damaged during storage or prior procedures.

2. Patient conditions and/or predispositions, such as those addressed in Contraindications, above, should be avoided.
3. An adequate inventory of implant sizes should be available at the time of surgery.
4. Allergies and other reactions to device materials, although infrequent should be considered, tested for (if appropriate), and ruled out preoperatively.
5. Certain special surgical instruments are required to perform this surgery including an image intensifier and an appropriate fracture table. Review of the use and handling of these instruments is recommended.
6. Before the initial experience, we recommend that the surgeon acquaint himself with the device and attend a technique seminar. Surgical technique brochures are available upon request at no charge, and should be reviewed by the surgeon prior to initial surgery. Skill in the use of this technique should be acquired on less complicated fractures before attempting its use in unstable, difficult fractures. The surgical technique provides reaming information for each nail.
7. The patient should be advised that a second more minor procedure for the removal of implants is usually necessary.

Operative

1. Please refer to the surgical technique for the specific nail for important reaming directions and modular nail assembly techniques.
2. Selection of the proper nail length and diameter is extremely important; the patient's age, weight and cortical bone quantity must be evaluated for the proper implant selection. It should be noted that a small but consistent percentage of complications due to nail fatigue failure remain. Therefore, it is always recommended that the largest implant suitable for the patient be used.
3. Care should be taken not to scratch, bend sharply, or cut metal components during surgery for the reasons stated in number one of the preoperative section of Warnings and Precautions. Once removed from the patient, implants should never be reused since internal stresses (in the implant) that are not visible may lead to early bending or fracture.
4. A stable construct should be achieved and verified under image intensification.
5. For femoral interlocking intramedullary nails, the trochanteric entrance hole should be in line with the femoral medullary canal in the lateral aspect of the trochanteric fossa and *not* at the tip of the trochanter. An excessive lateral placement of the entrance hole may result in eccentric reaming and comminution of the medial cortex of the proximal fragment at the fracture site.
6. For tibial interlocking intramedullary nails, the entrance hole of the tibia should be proximal to the tibia tubercle in the midline behind or slightly medial to the patellar ligament. An excessive distal placement of the entrance hole may result in entering the inner distal cortex at a steep angle and splitting the bone.
7. The use of Locking Screws is necessary for strength and compatibility. Please refer to the surgical technique or product catalogue for information on the correct size of screws for each nail.
8. For retrograde insertion of humeral interlocking intramedullary nails, nails are inserted through a hole 1 cm wide by 2 cm long starting 2-3 cm proximal to the olecranon fossa. The entry portal is in the lateral aspect of the greater tuberosity for antegrade insertion. An incorrect entry portal will increase the chance of breaking the humeral cortex during nail insertion.
9. For interlocking reconstruction nails, the proper sized proximal screws are necessary. Both proximal screws should be used where possible for better fixation of the femoral head.
10. In certain cases a bone graft may be appropriate.
11. For intramedullary hip screw systems, the intramedullary nail uses the Richards standard lag screw proximally in conjunction with an intramedullary hip screw sleeve and set screw.
12. For the ReVision Nail, the inner diameter of bone must be 1.0-1.5 mm larger than the inserted nail whether reamed or not. Nail diameter "sounds" are available to determine inner bone diameter.

Postoperative

1. **Intramedullary nails are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time.**

Postoperative directions and warnings to patients by physicians and appropriate nursing care are extremely important, particularly those admonitions that concern early weight bearing or active use of the extremities. These activities substantially increase the stress on implants that can lead to complications. For this reason patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed or nonunion, must have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries.

2. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of the nail's screw hole, as this situation places greater stress on the nail at the location of the transverse screw hole.
3. Supplemental support may be necessary for those patients using external devices for ambulatory assistance.
4. Periodic X-ray examinations for at least the first six (6) months postoperatively are recommended for close comparison with postoperative conditions to detect changes in position, nonunion, loosening, bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and early revision considered.
5. While the surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not suggested.
6. Even after full healing, the patient should be cautioned that refracture is more likely with the implant in place and soon after its removal, rather than later, when voids in the bone left by implant removal have been filled in completely.
7. Patients should be cautioned against unassisted activity that requires walking or lifting.
8. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident.

PACKAGING AND LABELING

All implants are provided sterile and should be accepted only if the factory packaging and labeling arrive intact. If the sterile barrier has been broken, refer to the Resterilization section below for additional instructions.

STERILIZATION

Metal components have been sterilized by a minimum of 25 kilo Grays of gamma irradiation. Inspect packaging for punctures or other damage prior to surgery.

RESTERILIZATION

Metal components may be resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all the original packaging and labeling. Protect prosthesis, particularly mating surfaces, from contact with metal or other hard objects. The following process parameters are recommended for these devices:

Table 2:	Sterilization Information - Pulsing Vacuum Cycle
Temperature	270° - 275° F
Pulse 1:	Steam to 12 psig, vacuum to approximately 5"Hg.
Pulse 2:	Steam to 12 psig, vacuum to approximately 20"Hg.
Pulse 3:	Steam to 12 psig, vacuum to approximately 25"Hg.
Pulse 4:	Steam 27-30 psig, exposure time 4.0 min. ± 5 sec., post vacuum ≥ 25"Hg.

INFORMATION

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Smith+Nephew

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The following statement is required by the U.S. FDA.

WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.