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COMPRESSION HIP SCREW PLATES AND NAILS



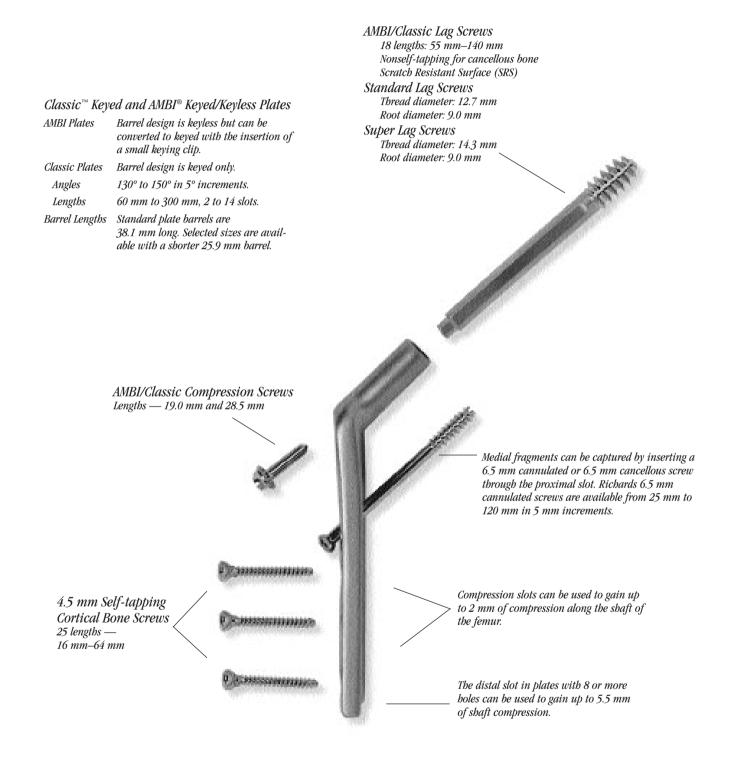
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COMPRESSION HIP SCREW PLATES

by Michael R. Baumgaertner, M.D. Associate Professor Chief, Orthopaedic Trauma Service Yale University School of Medicine Department of Orthopaedics and Rehabilitation New Haven, Connecticut

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

DESIGN FEATURES



PREOPERATIVE PLANNING

Adequate preoperative assessment of the patient who has sustained a proximal femur fracture requires (at the minimum) a thorough history, a careful physical exam, and adequate radiographic studies. The ambulatory status of the patient, as well as previous lower extremity fractures and surgeries must be known. The physical exam should pay particular attention to the presence of hip and knee flexion contractures and the range of motion of the contralateral hip. Note any skin compromise.

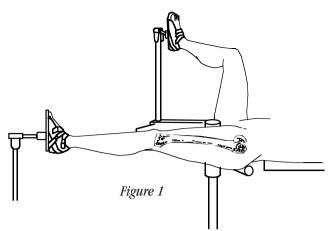
An anteroposterior pelvic radiograph and a "cross table" lateral view of the involved hip are required. Preferably, radiographs should be obtained with the extremity in neutral rotation and with gentle longitudinal traction applied to allow for an appreciation of the extent and stability of the fracture pattern.

PATIENT POSITIONING AND PREPARATION

Open reduction and internal fixation of proximal femur fractures are usually carried out with the patient on a fracture table, using the image intensifier. Following the induction of regional or general anesthesia, move the patient onto the fracture table, stabilize the pelvis against the perineal post, and apply a safety strap around the torso. Carefully secure the involved extremity to the foot holder so that adequate traction and rotational forces can be transmitted to the fracture. The unaffected leg is usually flexed at the hip and knee, and then abducted and slightly internally rotated *(Figure 1)*. This position has the advantage of allowing full freedom to position the fractured extremity and complete fluoroscopic visualization of the fracture, but it can allow the pelvis to tilt and rotate if strong traction is applied. Alternative positions for the unaffected hip include wide abduction or extension ("heel to toe"). These positions maintain a stable pelvis but may compromise C-arm imaging.

Depending on the fracture pattern, a closed reduction can usually be achieved. Stable intertrochanteric fractures usually reduce with traction and mild internal rotation. Unstable fractures may require slight external rotation, abduction, and anterior translation of the femoral shaft in addition to traction.

Prior to the preparation and draping of the field, scrutinize the C-arm images, particularly in the lateral view. The surgeon must be able to visualize the proximal shaft, the fracture zone, the femoral neck, and the complete circumference of the femoral head on the A-P and lateral fluoroscopic images. Only when the images are judged adequate should the quality of the closed reduction be evaluated based on fragment displacement, neck/shaft angle, anteversion, and femoral shaft "sag." Be certain to clinically confirm anatomic rotational alignment.



The closed reduction should then be accepted, modified or, if necessary, abandoned in favor of a formal open reduction. Adequate fracture reduction and radiographic visualization are critical to facilitate appropriate implant placement and a successful clinical outcome.

Routine preparation and draping usually involve applying a sterile plastic curtain to separate the surgical field from the unscrubbed assistant and the image intensifier.

SURGICAL APPROACH

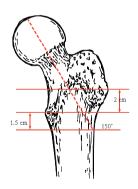
Make a straight lateral incision extending distally from the palpable vastus lateralis ridge on the greater trochanter. The length of the incision depends on the length of the sideplate used. Incise the fascia lata in line with the skin incision, just posterior to the tensor muscle, exposing the vastus fascia. Release the vastus fascia in line with its fibers approximately two centimeters anterior to its posterior attachment to the linea aspera and elevate the muscle to expose the lateral shaft of the femur. If desired, release the vastus origin sharply from the vastus ridge to facilitate atraumatic anterior retraction of the muscle.

INSERTING THE GUIDE PIN

The level of insertion of the guide pin varies with the angle of the plate used. The proximal aspect of the osseous insertion of gluteus maximus and the tip of the lesser trochanter, which are approximately 2 cm below the vastus lateralis ridge, help demonstrate the level of entry for a 135° angle plate. If a higher angle sideplate is used, move the entrance site 5 mm distally for each 5° increase in barrel angle *(Figure 2)*.



Proper Guide Pin entry point for a 135° femoral neck.



Proper Guide Pin entry point for a 150° femoral neck.

Attach the 3.2 mm Tip Threaded Guide Pin to the power source using the Quick Connect Adaptor *(Figure 3)*. If the plate angle was determined prior to guide pin insertion, place the appropriate Fixed Angle Guide midway on the lateral cortex such that the guide pin enters at the designated level. Be certain that the guide is flush and parallel with the lateral cortex to ensure an accurate angle *(Figure 4)*.

Tip Threaded Guide Pin







Fixed Angle Guide





Adjustable Angle Guide

Aim the guide pin toward the apex of the femoral head, the point where a line parallel to, and in the center of, the femoral neck intersects the subchondral bone. Be certain to confirm central placement in the lateral view as well. Avoid peripheral placement, in any direction, because only with the pin directed centrally in both views can the lag screw be safely advanced to *within* 10 mm of the joint line without risking joint penetration. (In neck fractures, where the surgeon intends to place a cannulated screw just proximal to the CHS, the guide pin can be placed 5 mm inferior to the apex).

Some surgeons may prefer to insert the guide pin freely. In this case, the Perforation Drill can be used to make an opening in the lateral cortex allowing for easy insertion of the guide pin. After confirming appropriate tip position of the guide pin on both the A-P and lateral views, verify the appropriate plate angle using the Adjustable Angle Guide *(Figure 5)*.

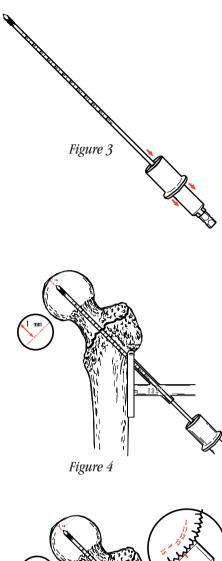




Figure 5

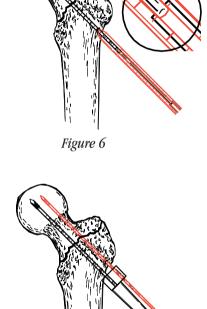
Central and deep placement allows screw purchase in the best bone available and allows maximal collapse of the screw without the threads impinging on the barrel. These factors greatly reduce the risk of mechanical failure of fixation. Carefully assess the C-arm images to identify the position of the guide pin relative to the apex of the femoral head on both views. Peripheral or shallow position on either view should not be accepted. Rather, the reduction should be reassessed, and the guide pin redirected.

When the guide pin is positioned satisfactorily, use the Percutaneous Direct Measuring Gauge to determine the appropriate lag screw length and reaming distance *(Figure 6)*. For an average size adult, using a plate with an angle of 135°, the length of the guide pin inside the femur is usually 95 mm.

The Guide Pin Placement Instrument can be used to insert a parallel 3.2 mm guide pin 13 mm proximal to the primary guide pin *(Figure 7)*. This step is especially useful in providing temporary stability for unstable fractures, where the reduction can be lost if the guide pin backs out after reaming, and for neck fractures, where the head could rotate during screw insertion. This instrument also accommodates a 2.4 mm guide pin, should the surgeon wish to insert a 6.5 mm Cannulated Screw for definitive rotational stability.



Guide Pin Placement Instrument



NOTE: Remaining illustrations are shown without the stabilizing guide pin for clarity.

Figure 7

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REAMING THE FEMUR

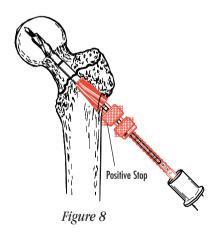
Occasionally, the guide pin will pull out of position upon removal of the reamer. To minimize the occurrence of guide pin pullout, it is important to avoid reaming over the threaded portion of the guide pin. This can be achieved in two ways:

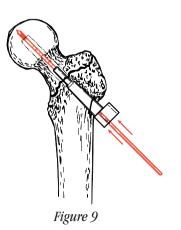
Option 1: Once the guide pin is inserted and measured, advance it an additional 5 mm into the subchondral bone and ream according to the exact lag screw length measurement. Choose a lag screw that matches the length measurement.

or

Option 2: Insert the guide pin into the subchondral bone, measure, and set the reamer 5 mm shorter than the length measured. Choose a lag screw that matches the length that was reamed.

In this technique, option 1 will be used. Set the Power Combination Reamer to the lag screw length indicated by the Measuring Gauge and ream until the distal aspect of the positive stop reaches the lateral cortex (Figure 8). Ream coaxially to the guide pin to avoid binding the guide pin and use "spot" image intensification to confirm that the guide pin is not advancing into the pelvis or being withdrawn at the conclusion of reaming. Should the guide pin be inadvertently withdrawn, reverse the Guide Pin Placement Instrument, insert it into the femur, and reinsert the guide pin (Figure 9).







Reamer

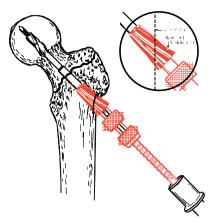


Figure 10

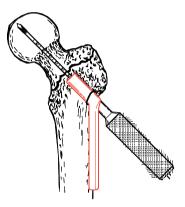


Figure 11

If a Richards CHS short barrel plate is being used, add 5 mm to the lag screw length setting on the Power Combination Reamer. Be careful to stop reaming when the short barrel notch indicator on the barrel reamer reaches the lateral cortex to avoid over penetration *(Figure 10)*.

If desired, confirm the proper plate angle using the Trial Plates and the Trial Handle *(Figure 11)*. The trials are especially useful if the guide pin has been freely inserted because freehanded angles will likely fall between standard plate angle sizes. In these cases, the trials let the surgeon choose the angle that fits best.



Trial Plate



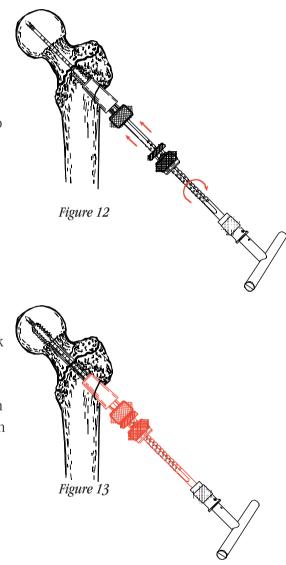
TAPPING THE FEMORAL HEAD

Generally, screws inserted into osteoporotic bone do not require tapping. In younger patients, or abnormally sclerotic bone, tapping is indicated to avoid excessive torque on the insertion wrench and to minimize the chance of inadvertently malrotating the head fragment during final seating of the screw.

Attach the Quick Connect T-Handle to the Lag Screw Tap and set it for the appropriate lag screw length. Insert the Lag Screw Tap into the reamed portion and slide the cortex guide into the lateral cortex of the femur *(Figure 12).* Tap until the advancing portion of the positive stop rests against the cortex guide *(Figure 13).*

SELECTING THE LAG SCREW

A fully inserted lag screw that equals the length determined by the Direct Measuring Gauge will allow for 5 mm of compression when the compressing screw is used, or 5 mm of fracture collapse before the shaft of the screw begins to back out of the barrel. If more than 5 mm of compression is desired (or significant telescoping of the implant is expected), a shorter lag screw can be used. A 5 mm shorter lag screw will permit an additional 5 mm of compression. When using a lag screw that is shorter than the length indicated by the Direct Measuring Gauge, it should be advanced the full distance as required by the measurement.



Quick Connect T-Handle



Lag Screw Tap

If a shorter screw is chosen, it must be retracted into the barrel with a compression screw or the fracture should be manually impacted following the release of traction. Do not use a screw that is more than 10 mm shorter than indicated by the Direct Measuring Gauge, otherwise there may be insufficient coverage of the screw within the barrel. This could inhibit the screw from sliding within the barrel or, if the compression screw was not left in place, increase the possibility of disengagement between the screw shaft and barrel. For the same reason, do not use screws that are shorter than determined by the Direct Measuring Gauge when using a short barrel plate.

INSERTING THE PLATE AND LAG SCREW (Options A, B, & C):

Option A:

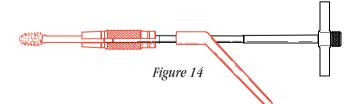
Richards Classic Plate with the Classic Insertion Wrench (Figures 14–17)

Assemble the appropriate Classic plate and lag screw onto the Classic Insertion Wrench. Screw the Lag Screw Retaining Rod into the distal end of the lag screw until a firm connection is obtained. Slip the AMBI/Classic Centering Sleeve onto the Classic Insertion Wrench (Figure 14). Place the entire assembly over the guide pin and introduce it into the reamed hole. DO NOT USE THE WRENCH AS A LEVER.



Lag Screw **Retaining Rod**

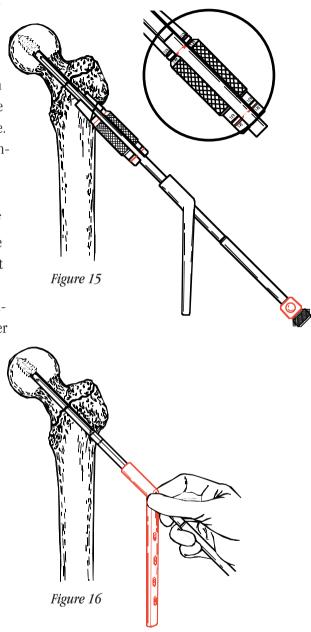
AMBI/Classic **Centering Sleeve**



Advance the lag screw into the proximal femur to the predetermined level and verify using image intensification. As a guide, when using a 135° sideplate, the lag screw should be advanced until the rings on the Classic Insertion Wrench are aligned with the 135° marks on the AMBI/ Classic Centering Sleeve. If a 150° sideplate is selected, advance the lag screw until the rings on the Classic Insertion Wrench are aligned with the 150° marks on the AMBI/Classic Centering Sleeve. Other angled plates should be inserted proportionally between the marks (*Figure 15*).

A 180° turn represents a 1.5 mm advancement of the lag screw. Verify the position and depth of the screw via image intensification in both planes. At the conclusion of screw insertion, the handle of the Classic Insertion Wrench must be perpendicular to the axis of the femoral shaft to allow proper keying of the lag screw to the plate barrel *(Figure 15)*.

Remove the AMBI/Classic Centering Sleeve and advance the sideplate onto the lag screw shaft *(Figure 16)*.



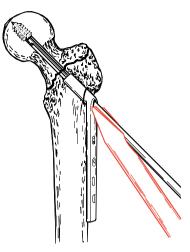


Figure 17



Figure 18

Figure 19

The Plate Tamper should be used to fully seat the plate *(Figure 17)*. Unscrew the Lag Screw Retaining Rod and remove the Classic Insertion Wrench from the back of the lag screw. Then, remove the 3.2 mm Tip Threaded Guide Pin.

Option B:

Richards AMBI Plate with the AMBI Insertion Wrench (Figures 18–22)

Press the tips of the AMBI Clip together *(Figure 18)*. Assemble the AMBI Clip, plate and lag screw onto the AMBI Insertion Wrench. For a keyless system, the AMBI Clip may be omitted. Screw the Lag Screw Retaining Rod into the distal end of the lag screw until a firm connection is obtained. Slip the AMBI/Classic Centering Sleeve onto the AMBI Insertion Wrench *(Figure 19)*. Place the entire assembly over the guide pin and introduce it into the reamed hole. DO NOT USE THE WRENCH AS A LEVER.

Advance the lag screw into the proximal femur to the predetermined level and verify using image intensification. As a guide, when using a 135° sideplate, the lag screw should be advanced until the rings on the AMBI Insertion Wrench

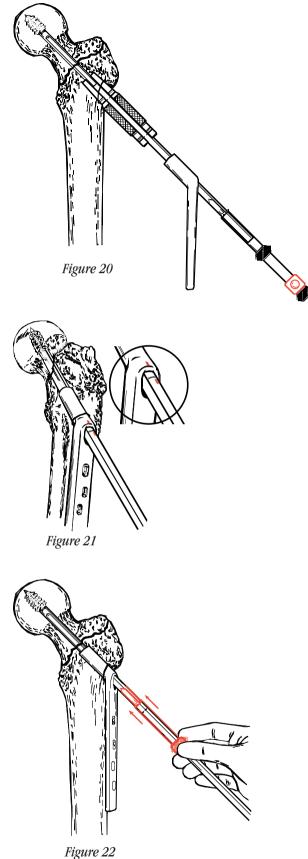
are aligned with the 135° marks on the AMBI/ Classic Centering Sleeve. If a 150° sideplate is selected, advance the lag screw until the rings on the AMBI Insertion Wrench are aligned with the 150° marks on the AMBI/Classic Centering Sleeve. Other angled plates should be inserted proportionally between the marks *(see inset Figure 15)*. Plate Tamper



AMBI Insertion Wrench with Lag Screw Retaining Rod and Clip Inserter The handle of the AMBI Insertion Wrench must be perpendicular to the axis of the femoral shaft to ensure proper keying of the lag screw and plate barrel if the AMBI Clip is being used *(Figure 20).*

A 180° turn represents a 1.5 mm advancement of the lag screw. Verify the position and depth of the screw using image intensification in both planes. Remove the AMBI/Classic Centering Sleeve and advance the sideplate onto the lag screw shaft.

If the keyed technique is selected, align the longitudinal line on the barrel and the longitudinal line on the AMBI Insertion Wrench (see inset, *Figure 21*). This alignment allows the AMBI Clip to enter the plate. Finger pressure should be used to introduce the Clip into the barrel. If difficulty is encountered, a slight readjustment of the screw-barrel relationship should allow easy insertion. Next, push the cylindrical AMBI Clip Inserter down the shaft of the AMBI Insertion Wrench to fully seat the Clip (*Figure 22*). This should be accomplished by a firm tap using fingers until the Clip snaps into place. Using an instrument or a mallet to accomplish the last task may result in destruction of the Clip and will not help to seat it.



The Plate Tamper should be used to fully seat the plate *(see Figure 17, page 14)*. Unscrew the Lag Screw Retaining Rod and remove the AMBI Insertion Wrench from the back of the lag screw. Then, remove the 3.2 mm Tip Threaded Guide Pin.

Option C:

Richards Classic or AMBI Plate with the Insertion/Removal Wrench and Cannulated Barrel Guide (Figures 23-27)

Insert the threaded portion of the Cannulated Barrel Guide into the cannulated portion so that it emerges at the end with flats *(Figure 23)*. Screw the assembled Cannulated Barrel Guide into the distal end of the appropriate lag screw. Slide the Centering Sleeve onto the Insertion/ Removal Wrench. Next, insert the entire Cannulated Barrel Guide assembly into the Insertion/Removal Wrench until the connection point between the lag screw and the Cannulated Barrel Guide is flush with the end of the Wrench *(Figure 24)*.

Place the entire assembly over the guide pin and introduce it into the reamed hole. DO NOT USE THE WRENCH AS A LEVER.

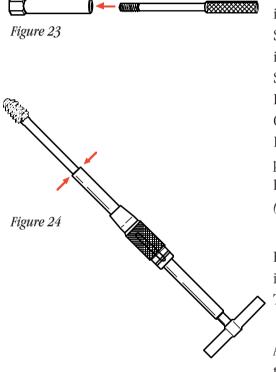
Advance the lag screw into the proximal femur to the level desired by image intensification. As a guide, when using a 135° sideplate, the lag screw may be advanced until the ring on the Insertion/Removal Wrench is aligned with the 135° mark on the more proximal end of the Centering Sleeve.





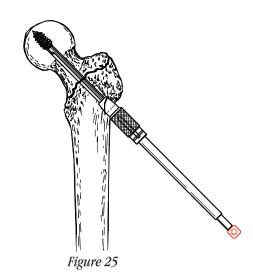


Insertion/Removal Wrench



If a 150° sideplate is selected, advance the lag screw until the ring on the Insertion/Removal Wrench is aligned with the 150° mark on the Centering Sleeve. Other angled plates should be inserted proportionally between the two marks. Caution should be used not to advance the Insertion/Removal Wrench past this point, otherwise penetration of the head or lack of coverage of the screw within the barrel may occur. When using a keyed application, the handle of the Insertion/Removal Wrench must be perpendicular to the axis of the femoral shaft to ensure proper alignment of the lag screw and plate barrel *(Figure 25)*.

Remove the Insertion/Removal Wrench and Centering Sleeve and insert the appropriate plate over the guide pin and Cannulated Barrel Guide *(Figure 26)*. The Cannulated Plate Tamper should be used to fully seat the plate *(Figure 27)*. Unscrew the Cannulated Barrel Guide and remove. Then, remove the 3.2 mm Tip Threaded Guide Pin.



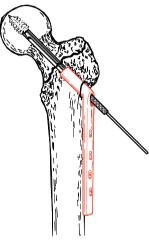
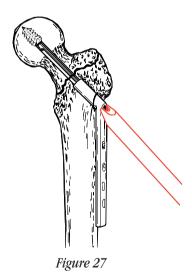


Figure 26



Cannulated Plate Tamper

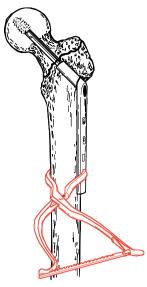


Figure 28

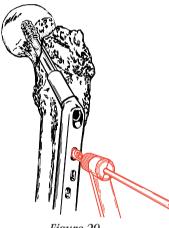
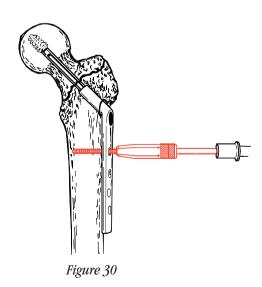


Figure 29

ATTACHING THE PLATE

Use the Plate Clamp to secure the plate to the shaft *(Figure 28).* Consider releasing traction and manually impacting the fracture fragments at this point, particularly in well aligned but unstable fractures. This will ensure some initial loading of the medial cortex. The Plate Clamp should be readjusted during this process.

Use the 3.5 mm Twist Drill through the green (neutral) end of the Combination Drill Guide to drill the bone screw holes *(Figure 29)*. Determine appropriate cortical screw length using the Bone Screw Length Gauge. Insert the screw using the Self-Holding Hex Screwdriver *(Figure 30)*. This Screwdriver will attach directly to a power source or to one of the two Quick Connect Adaptors for quick initial insertion. Final tightening can be achieved manually with the Hex Screwdriver. A 4.5 mm Bone Screw Tap is available, but only necessary in extremely hard cortical bone.



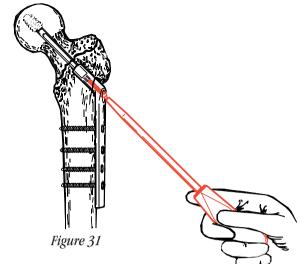


When all screws are inserted and tightened, and all traction is released, fracture compression can be accomplished by means of the compression screw. The 19 mm compression screw is usually used. If deeper seating of the lag screw was used to allow the potential for more compression, use the longer 28.5 mm compression screw initially, and then replace it with the standard 19 mm compression screw using the Hex Screwdriver *(Figure 31)*.

Caution should be used when carrying out the compression. The compression screw exerts a powerful force that must be correlated with the quality of bone. Placement of the compression screw should be considered mandatory when a short barrel plate is used. This will help prevent potential disengagement of the screw-plate assembly.

SPECIAL FEATURES OF THE PLATE

The oval "autocompression" holes of the plate will allow for up to 2 mm of fracture line compression for subtrochanteric fractures or osteotomies. To achieve compression, place the eccentric gold end of the Combination Drill Guide in the first compression slot distal to the fracture with the arrow pointing toward the fracture and drill through the guide using a 3.5 mm Twist Drill *(Figure 32)*.



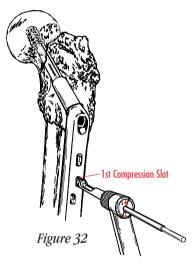




Figure 33

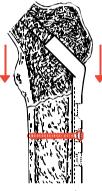


Figure 34

Place a 4.5 mm self-tapping cortical screw in the slot. The screw will engage through the distal part of the slot, away from the fracture (Figure 33). As the screw is seated, it abuts the inclined distal aspect of the slot, forcing the plate and the attached proximal fragment slightly distally until resisted by fracture compression (Figure 34). The insertion of this first bone screw will produce approximately 1 mm of compression. For an additional 1 mm of compression, repeat this step in the compression slot distal to the first one. Slightly loosen the first eccentrically placed screw after the second screw abuts the slot, but before it is fully seated to allow the additional compression. Following seating of the second screw, retighten the first screw. Drill for the remaining screws with the green neutral end of the Combination Drill Guide.

When using plates with eight or more slots (typical for subtrochanteric fractures), the most distal slot can be used to achieve even greater compression. An eccentrically placed screw in this last slot will allow compression of nearly 5.5 mm.

CAPTURING LESSER TROCHANTER AND POSTERIOR-MEDIAL FRAGMENTS

The geometry of the most proximal slot in the sideplate allows for the insertion of a 6.5 mm Cancellous Screw or Universal Cannulated Screw. These screws can be used to capture the lesser trochanteric or a large posterior-medial fragment. The slot allows up to 45° of proximal and 26° of distal angulation in the coronal plane and 14° of anterior or posterior angulation in the sagittal plane.



Pin Guide





Retaining Rod for Wrench

To insert a cannulated screw, snap the 2.4 mm Pin Guide into the Combination Drill Guide handle. Place the Pin Guide into the proximal slot and insert a 2.4 mm Guide Pin toward the fragment (Figure 35). Use the instruments from the Cannulated Screw Set to implant the appropriate 6.5 mm Cannulated Screw (Figure 36). (Refer to Richards 6.5 mm Cannulated Screw Surgical Technique, Cat. No. 62-17541.)

CLOSING THE WOUND

Closure of the wound is done in layers, closing separately the fascia of the vastus lateralis muscle and the facia lata. Carefully reapproximate the subcutaneous tissue and the skin to facilitate prompt healing of the wound.

REMOVING THE HIP SCREW

The most important step in the removal of the hip screw is the determination of the manufacturer who produced that particular implant. Although hip screws of different manufacturers may look similar, most instruments for insertion and removal are not interchangeable.

Open the original incision in the manner previously described. Remove the compression screw, then the cortical screws. Lift the plate from the femoral shaft and disengage it from the lag screw. Use the Lag Screw Trephine to remove the tissue and bone formed behind the distal portion of the lag screw (Figure 37). Connect the Insertion/Removal Wrench to the base of the lag screw. Attach it by means of the Retaining Rod for the Insertion/Removal Wrench. Use a counterclockwise motion combined with a pulling motion to accomplish the removal of the lag screw.

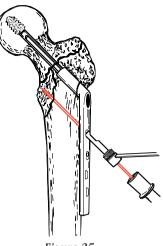


Figure 35

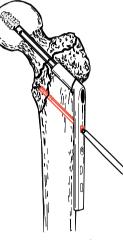


Figure 36

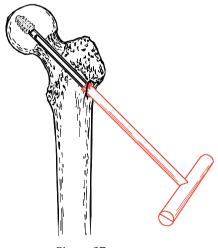


Figure 37

by Michael R. Baumgaertner, M.D. Associate Professor Chief, Orthopaedic Trauma Service Yale University School of Medicine Department of Orthopaedics and Rehabilitation New Haven, Connecticut

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

SUPRACONDYLAR FRACTURES AND FRACTURES OF THE LOWER THIRD OF THE FEMUR

The Richards Classic and AMBI Compression Screw with a 90° or 95° angled plate are excellent alternatives to the use of an angled blade plate in the fixation of supracondylar/ intracondylar femur fractures. The use of a cannulated lag screw over a guide pin allows for precise and controlled positioning of the implant.

Unlike the single piece blade plate, where insertion requires simultaneous three dimensional alignment control, the screw and sideplate design allows flexion/extension alignment to be "dialed in" after the implant is seated, as the plate can be rotated on the screw in the sagittal plane. Finally, the compression screw itself allows for interfragmentary compression of the intercondylar component of the fracture.

PREOPERATIVE PLANNING

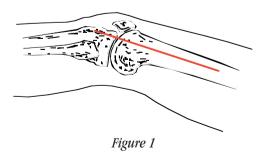
Quality anteroposterior and lateral radiographs taken with the extremity in gentle traction are mandatory to assess the fracture. Frequently, oblique views and X-rays of the normal side are helpful to plan fracture reconstruction. Occasionally, a CT scan is necessary to adequately define intra-articular fracture planes. An intracondylar coronal fracture, which requires sagitally directed lag screws and can compromise or prevent placement of the compression screw, is a strong relative contraindication to the use of a compression screw and plate. Careful preoperative assessment of a complex distal femoral fracture will help assure that the appropriate implant inventory is available at the time of surgery. Also, a thorough understanding of the fracture anatomy will minimize unnecessary soft tissue stripping and allow fracture stabilization to proceed in an organized fashion.

PATIENT POSITIONING AND PREPARATION

Place the patient in the supine position on a fluoroscopically compatible table. It is helpful to place a sandbag under the ipsilateral hip to resist the tendency toward external rotation of the extremity. Use of a sterile tourniquet allows a bloodless field during the intra-articular reconstruction with free access to the shaft during supracondylar fixation.

SURGICAL APPROACH

With the knee flexed 20°, extend a straight lateral incision along the distal thigh anteriorly to the tibial tubercle. Incise the iliotibial band, release the vastus lateralis off the linea aspera, and elevate it from the lateral shaft; controlling any perforating vessels. Minimize exposure of the anterior and medial cortices to avoid devitalizing the fracture zone. Make a lateral parapatellar arthrotomy, avoiding injury to the lateral meniscus *(Figure 1)*. An adequate arthrotomy is required to reduce and fix the intercondylar fracture and to appreciate the alignment of the patellofemoral and tibiofemoral joints when inserting the guide pin.



If an intercondylar component of the fracture exists, reduce and temporarily fix it with Kirschner wires or guide pins and pointed bone holding clamps. Exchange the bone clamps and K-wires for cancellous lag screws to achieve interfragmentary compression. Position the screws so that they do not interfere with the subsequent placement of the compression screw and sideplate.

INSERTING THE GUIDE PIN

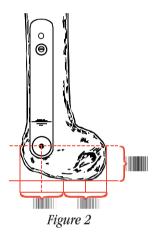
Identification of the correct location and direction of the guide pin is the most important step in reconstructing an anatomically aligned extremity following distal femoral fractures. Since the condyles project posteriorly to the femoral shaft, the guide pin must be inserted in the center of the anterior half of the lateral condyle in order for the plate to align with the shaft in the anteroposterior plane. The entrance site should be no more than 2.0 cm from the tibiofemoral articular surface (*Figure 2*).

Supracondylar Pin Guide





Use the 90° or 95° Supracondylar Pin Guide with the Quick Connect T-Handle to direct the 3.2 mm Tip Threaded Guide Pin for high supracondylar fractures, or simple fractures where an anatomic reduction can be achieved directly and held with guide pins. Attach the Quick Connect T-Handle to the Supracondylar Pin Guide and place it against the lateral condyle and the distal femoral shaft. Insert the guide pin *(Figure 3)*.



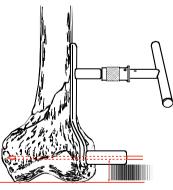
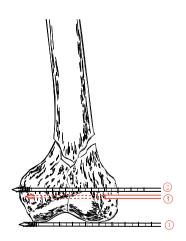


Figure 3

NOTE: Bone screws typically used to hold an intracondylar fracture together have been omitted for clarity.



Figure 4



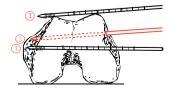


Figure 5

For many supracondylar fractures, particularly low fractures and fractures with metaphyseal comminution, it is necessary to apply the plate to the condylar fragment before reducing the supracondylar fracture. In these situations, the reconstructed joint surfaces serve as guides for the direction of the guide pin. The 95° angled plate applied with the screw parallel to the joint line will reestablish appropriate valgus alignment of the knee.

Place one guide pin (1) across the distal tibiofemoral joint line and a second guide pin (2) to mark the slope of the patellofemoral joint *(Figure 4)*. With the guide pin located at the proper entrance site, align the third guide pin parallel to the first guide pin in the A-P plane and parallel to the second guide pin (3) in the transverse plane and drill it across the condyles *(Figure 5)*. The position and direction of the guide pin should be confirmed radiographically before reaming and inserting the screw. Because the widest part of the medial condyle is posterior to the path of the guide pin, a pin that is at the medial cortex will appear 5 to 10 mm short on an A-P radiograph (Figure 6). Palpate the tip of the guide pin to confirm proper penetration, and determine the lag screw length with the Percutaneous Direct Measuring Gauge (Figure 7).

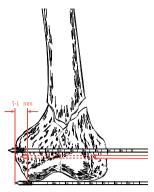


Figure 6

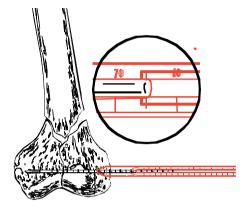


Figure 7

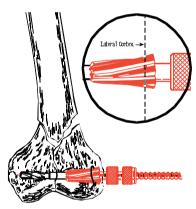
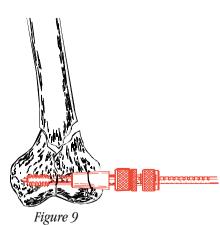


Figure 8



Percutaneous Direct Measuring Gauge







Lag Screw Tap

REAMING AND TAPPING THE CONDYLES

The 90° and 95° supracondylar plates have barrels that are 5 mm shorter than the standard barrels. Therefore, when preparing the Power Combination Reamer, 5 mm should be added to the length setting indicated on the Percutaneous Direct Measuring Gauge. Reaming should be stopped when the notch indicators on the barrel reamer for the CHS short barrel/supracondylar plates reach the lateral cortex (Figure 8).

Adding 5 mm to the length setting ensures proper reaming for the entire length of the lag screw while stopping at the short barrel notch indicator prevents over-reaming for the plate barrel. However, the lag screw should match the length determined by the Percutaneous Direct Measuring Gauge.

If desired, prior to lag screw insertion, the Lag Screw Tap can be used in younger individuals (*Figure 9*).

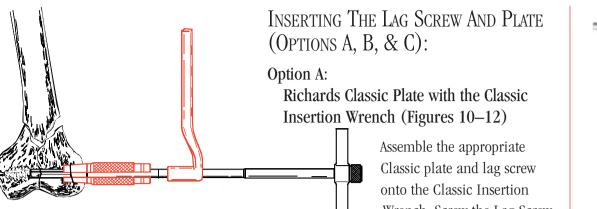


Figure 10

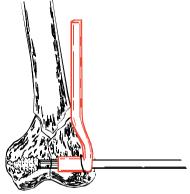


Figure 11

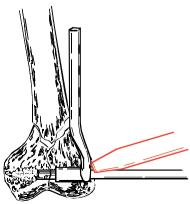


Figure 12

Wrench. Screw the Lag Screw

Retaining Rod into the distal end of the lag screw until a firm connection is obtained. Slip the AMBI/Classic Centering Sleeve onto the Classic Insertion Wrench. Place the entire assembly over the guide pin and introduce it into the reamed hole (Figure 10). DO NOT USE THE WRENCH AS A LEVER.

Use image intensification to advance the lag screw into the cancellous bone of the femoral condyle. In osteoporotic bone, it is beneficial to engage one thread of the lag screw in the cortical bone of the medial condyle. Be aware of the slope of the medial condyle so as not to overpenetrate.

The handle of the Classic Insertion Wrench must be perpendicular to the position of the femur to ensure proper keying of the lag screw and plate barrel. Verify the position of the screw and its depth using image intensification in both planes. Remove the AMBI/Classic Centering Sleeve and advance the sideplate onto the lag screw shaft (Figure 11).

The Plate Tamper should be used to fully seat the plate (Figure 12). Unscrew the Lag Screw Retaining Rod and remove the Classic Insertion Wrench from the back of the lag screw. Then, remove the 3.2 mm Tip Threaded Guide Pin.



Retaining Rod

AMBI/Classic **Centering Sleeve**





AMBI Insertion Wrench with Lag Screw Retaining Rod and Clip Inserter

Option B: Richards AMBI Plate with the AMBI Insertion Wrench (Figures 13-16)

Press the tips of the AMBI Clip together (*Figure 13*). Assemble the AMBI Clip, plate, and lag screw onto the AMBI Insertion Wrench. For a keyless system, the AMBI Clip may be omitted. Screw the Lag Screw Retaining Rod into the distal end of the lag screw until a firm connection is obtained. Slip the AMBI/Classic Centering Sleeve onto the AMBI Insertion Wrench. Place the entire assembly over the guide pin and introduce it into the reamed hole (*Figure 14*). DO NOT USE THE WRENCH AS A LEVER.

Use image instensification to advance the lag screw into the cancellous bone of the femoral condyle. Also, the handle of the AMBI Insertion Wrench must be perpendicular to the position of the femur to ensure proper keying of the lag screw and plate barrel if the AMBI keyed application is being used.

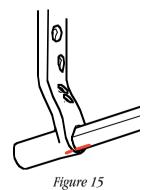
In osteoporotic bone, it is beneficial to engage one thread of the lag screw in the cortical bone of the medial condyle. Be aware of the slope of the medial condyle so as not to overpenetrate. Remove the AMBI/Classic Centering Sleeve and advance the sideplate onto the lag screw shaft.

If the keyed technique is selected, align the longitudinal line on the barrel and the longitudinal line on the AMBI Insertion Wrench *(Figure 15)*. This alignment allows the AMBI Clip to enter the plate. Finger pressure should be used to introduce the Clip into the barrel. If difficulty in introducing the Clip is encountered, a slight



Figure 13

Figure 14



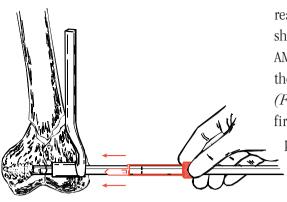


Figure 16

Figure 17

Figure 18

readjustment of the screw-barrel relationship should allow easy insertion. Push the cylindrical AMBI Clip Inserter manually down the shaft of the AMBI Insertion Wrench to fully seat the Clip *(Figure 16)*. This should be accomplished by a firm tap using fingers until the Clip snaps into place. Using an instrument or a mallet to
 accomplish the last task may result in destruction of the Clip and will not help to seat it.

The Plate Tamper should be used to fully seat the plate *(see Figure 12, page 27)*. Unscrew the Lag Screw Retaining Rod and remove the AMBI Insertion Wrench from the back of the lag screw. Then, remove the 3.2 mm Tip Threaded Guide Pin.

Option C:

Richards Classic or AMBI Plate with the Insertion/Removal Wrench & Cannulated Barrel Guide (Figures 17–21)

Insert the threaded portion of the Cannulated Barrel Guide into the cannulated portion so that it emerges at the end with flats *(Figure 17)*. Screw the assembled Cannulated Barrel Guide into the distal end of the appropriate lag screw. Slide the Centering Sleeve onto the Insertion/ Removal Wrench. Next, insert the entire Cannulated Barrel Guide assembly into the Insertion/Removal Wrench until the connection point between the lag screw and the Cannulated Barrel Guide is flush with the end of the Wrench *(Figure 18)*. Place the entire assembly over the guide wire and introduce it into the reamed hole. DO NOT USE THE WRENCH AS A LEVER.



Cannulated Barrel Guide





Use image intensification to advance the lag screw into the cancellous bone of the femoral condyle. In osteoporotic bone, it is beneficial to engage one thread of the lag screw in the cortical bone of the medial condyle. Be aware of the slope of the medial condyle so as not to overpenetrate. Also, when using a keyed application, the handle of the Insertion/Removal Wrench must be perpendicular to the position of the femur to ensure proper alignment of the plate and lag screw *(Figure 19)*.

0

Figure 19

Remove the Insertion/Removal Wrench and Centering Sleeve and insert the appropriate plate over the guide pin and Cannulated Barrel Guide *(Figure 20)*. The Cannulated Plate Tamper should be used to fully seat the plate *(Figure 21)*. Unscrew the Cannulated Barrel Guide and remove. Then, remove the 3.2 mm Tip Threaded Guide Pin.

ATTACHING THE PLATE

At this point, if the supracondylar fracture has not yet been fully reduced, rotate the plate to align it properly to the condyles in the sagittal (flexion/extension) plane. Fluoroscopy can be used to confirm appropriate plate position and exclude a flexion or hyperextension malalignment *(Figure 22)*. Occasionally, a small notch has to be made just proximal to the barrel in the femoral condyle to allow the plate to lie flush with the anterolateral face of the bone.

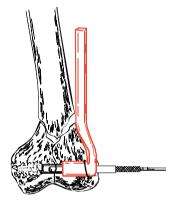


Figure 20

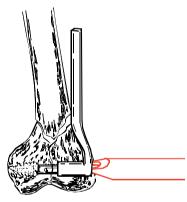


Figure 21

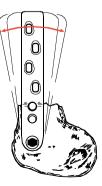
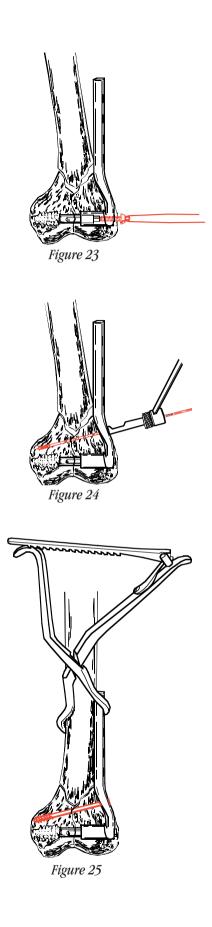


Figure 22





Intercondylar fracture compression can be accomplished by means of the Compression Screw. The standard 19 mm screw is usually used *(Figure 23)*.

Caution should be used when carrying out the compression. The compressing screw exerts a powerful force that must be correlated with the quality of bone. Placement of the compressing screw should be considered mandatory when a supracondylar plate is used. This will help prevent potential disengagement of the screw-plate assembly.

The most distal hole in the 90° and 95° plates is designed to accept a 6.5 mm Cancellous Screw or a 6.5 mm Cannulated Screw for purchase into the metaphyseal bone of the distal femur. Inserting the most distal screw in the plate prevents subsequent plate flexion/extension, and definitively fixes in all three planes the relationship between the distal articular block and the plate.

To insert a cannulated screw, snap the black 2.4 mm Pin Guide into the Combination Drill Guide. Place the Pin Guide into the distal slot and insert a 2.4 mm Guide Pin toward the fragment *(Figure 24)*. Use the instruments from the Cannulated Screw Set to implant the appropriate 6.5 mm Cannulated Screw. *(Refer to Richards 6.5 mm Cannulated Screw Surgical Technique, 62-17541.)*

If the guide pin was inserted at the appropriate position and parallel to the joint surfaces, reducing the plate and attached condyles to the intact shaft will restore anatomic alignment to flexion/ extension and varus/valgus even in the most complex fracture patterns. Confirm appropriate rotational reduction before clamping the Plate Clamp to the shaft (*Figure 25*).



2.4 mm Pin Guide



2.4 mm Guide Pin



Plate Clamp

SPECIAL FEATURES OF THE PLATE

The oval "autocompression" holes of the plate will allow for up to 2 mm of compression of the supracondylar fracture. To achieve compression, place the eccentric gold end of the Combination Drill Guide in the first compression slot proximal to the fracture with the arrow pointing toward the fracture and drill through the guide using a 3.5 mm Twist Drill *(Figure 26)*. Determine the appropriate cortical bone screw length using the Bone Screw Length Gauge *(Figure 27)*.

Place a 4.5 mm self-tapping cortical screw in the slot. The screw will engage through the proximal part of the slot, away from the fracture (Figure 28). As the screw is seated, it abuts the inclined sides of the slot, forcing the plate, and the attached distal fragment, slightly proximally until resisted by the compressed fracture (Figure 29). The insertion of this first bone screw will produce approximately 1 mm of compression. For an additional 1 mm of compression, repeat this step in the compression slot proximal to the first one. Slightly loosen the first eccentrically placed screw after the second screw abuts the slot, but before it is fully seated to allow the additional compression. Following seating of the second screw, retighten the first screw.

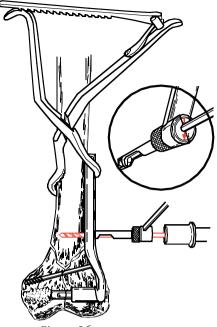
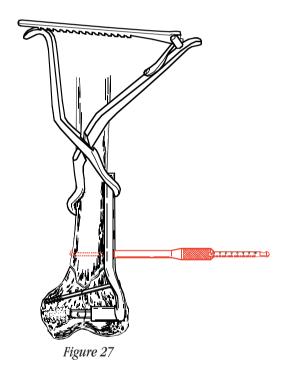


Figure 26



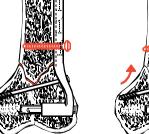


Figure 28

Figure 29

3.5 mm Twist Drill



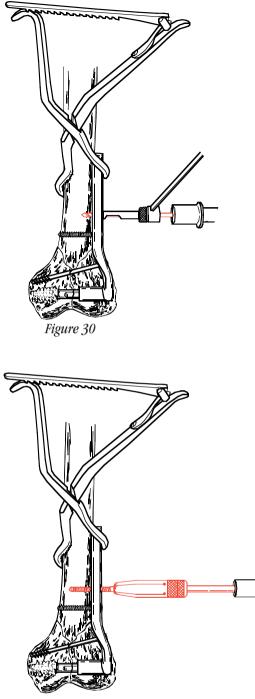


Figure 31

When using plates with eight or more slots typical for supracondylar fractures, the geometry of the most proximal slot allows compression of nearly 5.5 mm.

Drill for the remaining screws using the green (neutral) end of the Combination Drill Guide *(Figure 30)*. Determine appropriate cortical screw length using the Bone Screw Length Gauge. Insert the screw using the Self-Holding Hex Screwdriver *(Figure 31)*. This Screwdriver will attach directly to a power source or one of the two Quick Connect Adaptors for quick initial insertion. Final tightening can be achieved manually with the Hex Screwdriver. A 4.5 mm Bone Screw Tap is available, but only necessary in extremely hard cortical bone.

CLOSURE

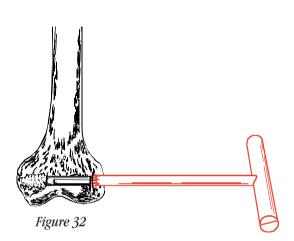
Obtain final X-rays to confirm appropriate screw length and position. Consider placing a large wound suction drain. Lay the vastus lateralis back into its anatomic position and carefully repair the fascia lata and joint capsule. Following routine closure and dressings, briefly immobilize the knee in flexion before initiating early motion.



REMOVING THE IMPLANTS

The most important step in the removal of a compression hip or supracondylar screw is the determination of the manufacturer who produced that particular implant. Although constructs from different manufacturers may look similar, most instruments for insertion and removal are not interchangeable.

Open the original incision in the manner previously described. Remove the compression screw, then the cortical screws. Lift the plate from the femoral shaft and disengage it from the lag screw. Use the Lag Screw Trephine to remove the tissue and bone formed behind the distal portion of the lag screw *(Figure 32)*. Connect the Insertion/Removal Wrench to the base of the lag screw. Attach it by means of the Retaining Rod for the Insertion/Removal Wrench. Use a counterclockwise motion combined with a pulling motion to accomplish the removal of the lag screw.





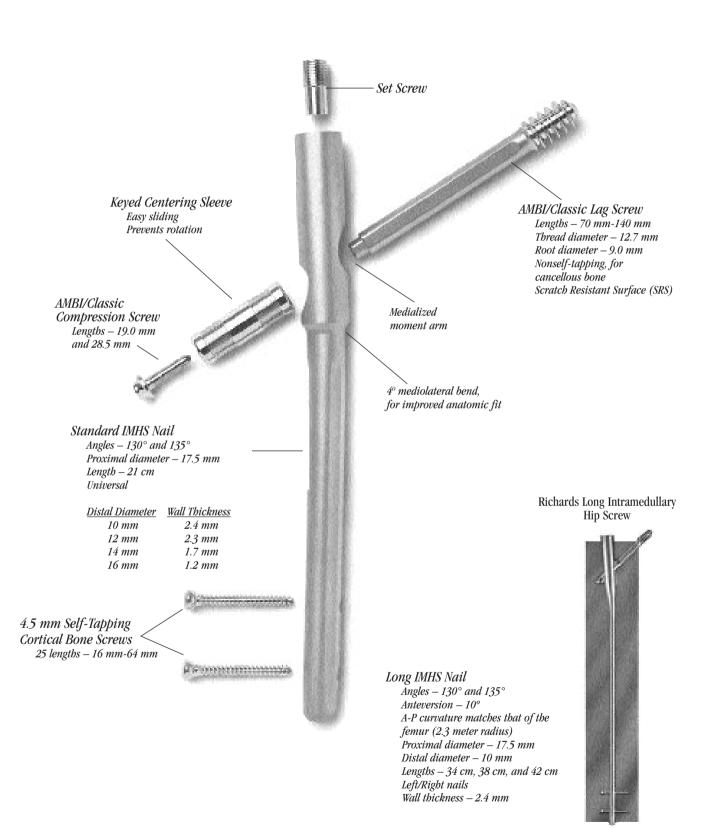
Retaining Rod for Insertion/ Removal Wrench

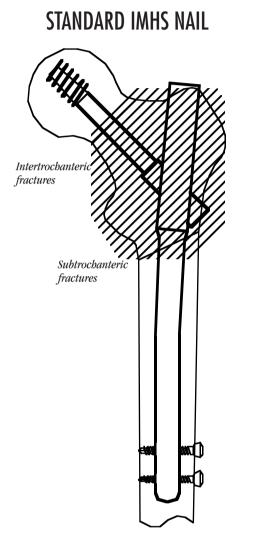
COMPRESSION HIP SCREW NAILS

by Mr. John S. Albert, B.Sc., M.B., F.R.C.S. The Orthopaedic Department Norfolk & Norwich Hospital Brunswick Road Norwich, England

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

DESIGN FEATURES





Richards CHS nails, known as Intramedullary Hip Screws (IMHS), provide an intramedullary approach to fractures of the proximal femur and are particularly suited to unstable peritrochanteric fractures, reverse obliguity fractures, and subtrochanteric fractures. IMHS features a cannulated intramedullary nail with a 4° mediolateral bend to allow for insertion through the greater trochanter. The nail is used with a standard Richards AMBI/Classic Lag Screw (1/2" thread diameter), compression screw, and 4.5 mm locking screws. A sleeve, which is held by a set screw, passes through the intramedullary nail and over the lag screw. The sleeve helps prevent rotation, while allowing the lag screw to slide. The Standard IMHS nail is available in two angles — 130° and 135° and in four diameters — 10 mm, 12 mm, 14 mm, and 16 mm, to allow a proper fit within the femoral canal. The Standard IMHS nails are all 21 cm in length. IMHS is locked using one or two 4.5 mm locking screws.

The Long IMHS nail is designed for subtrochanteric fractures, comminuted neck and shaft fractures, femur reconstruction following tumor resection, prophylactic nailing of impending pathologic fractures, and leg length discrepancies secondary to femoral fracture. It has a distal diameter of 10 mm and is available in lengths of 34 cm, 38 cm, and 42 cm. 130° and 135° angles are available as with the Standard IMHS. The Long IMHS nail has a 2.3 meter radius to conform with the natural bow of the femoral shaft and 10° of anteversion to match the angle of the femoral head in relation to the shaft of the femur. Distal locking is carried out using 4.5 mm locking screws.

Both types of IMHS nails have a proximal diameter of 17.5 mm.

PREOPERATIVE PLANNING

The operation is performed on a standard fracture table and requires the use of an image intensifier which will produce images in two planes. Apart from standard surgical instruments, a power drill with reaming capability is required.

Before embarking upon the procedure, obtain anteroposterior and lateral views of the proximal one half of the femur, either fluoroscopically at the time of the operation or on a preoperative roentgenogram. Severe deformities of the femoral canal or excessive anterior bowing may preclude the use of an intramedullary device.

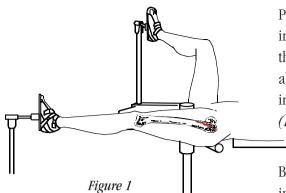
Radiographic templates are available. These allow preoperative estimation of the nail's diameter and angle and the lag screw's length.

PATIENT POSITIONING AND PREPARATION

In general, the position used for the Intramedullary Hip Screw is similar to that employed for all supine intramedullary nailings of the femur.

Place the patient supine on a standard fracture table. Both feet may rest in a padded foot holder. Use a padded perineal post.

The pelvis must lie in the horizontal position. Adduct the affected femur to allow access to the trochanteric region. With the patient in a supine position, abduct the unaffected limb while adducting the trunk and affected extremity. Tilt the trunk away from the fracture and strap the arm on the same side across the chest of the patient. This is particularly important in obese patients.



Place the uninjured leg either adjacent to the injured side (in the "heel-to-toe" position with the uninjured side lower), or flexed and abducted to allow unimpeded access of the image intensifier between the legs *(Figure 1).*

Before the start of the operative procedure, it is important to achieve reduction of the fracture. Peritrochanteric fractures are usually reduced with internal rotation of the femur and traction. Most subtrochanteric fractures are commonly reduced by a small degree of external rotation. Avoid excessive traction of the affected limb. It is especially important to ensure that the head fragment of the femur is reduced to the shaft fragment in the lateral position. In the majority of cases, a satisfactory reduction should be achieved before beginning the operative procedure. If closed reduction is impossible, perform a more extensive operative incision and an open reduction of the fracture.

A successful outcome is unlikely if the implant is inserted into an unreduced fracture. Comminuted peritrochanteric fractures, with loss of the medial cortical buttress including the lesser trochanter, are more likely to result in failure of fixation. In such cases, an intramedullary device may reduce the risk of failure.

It is very important to obtain satisfactory images of the fracture and the upper femur, in both the A-P and lateral planes, before beginning the operation. Prepare the operative field in the usual manner. The sterile field extends from just above the iliac crest to the knee and from beyond the midline anteriorly to the midline posteriorly. Draping is comparable to that of conventional internal fixation of hip fractures. A vertical "sail-type" plastic drape is commonly used because it allows the operative field to be separated from the image intensifier and any unscrubbed personnel.

SURGICAL APPROACH

Make a lateral approach, similar to all intramedullary procedures of the femur. Extend the skin incision from the tip of the trochanter proximally for 3-8 cm depending on the size or obesity of the patient *(Figure 2)*. Split the aponeurosis of the gluteus maximus in line with its fibers, from the tip of the trochanter proximally for 5 cm. This brings into view a small fat pad which lies between the tip of the trochanter and the piriformis fossa. Then, split the gluteus medius in the line of its fibers.

The eventual size of the surgical incision depends on both the obesity of the patient and whether the fracture has been adequately reduced. In the majority of cases, a satisfactory reduction is achieved before the operative procedure is started. If an open reduction is necessary, extend the surgical approach distally to allow an anterior approach to the hip capsule and fracture. Check the adequacy of the open reduction radiographically. It is critical that the head fragment is reduced on the shaft fragment in the lateral plane.

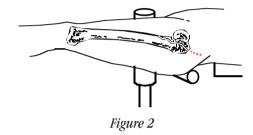


Figure 3

Figure 4

FEMORAL PREPARATION

Unlike the standard entry point for femoral nails in the piriformis fossa, insert the IMHS through the tip of the greater trochanter. The 4° bend allows this without encroachment of the femoral neck, which may be fractured.

NOTE: The red numbered delta symbols match the numbering system in the sterilization trays. All instruments are numbered in order of use, providing guidance to the O.R. staff in anticipating the surgeon's instrumentation needs.

Following adequate exposure of the tip of the trochanter with the Curved Awl (1, (Figure 3)) position the Tissue Protector (2, 0) on the tip of the trochanter and insert a 3.2 mm Tip Threaded Guide Pin (3, 1) through the Tissue Protector's guide pin centering sleeve (*Figure 4*). Advance the pin down the femoral canal well beyond the subtrochanteric region. Check the position of the pin radiographically in the A-P and lateral planes.





3.2 mm Tip Threaded Guide Pin



Proximal Reamer

Remove the guide pin centering sleeve from the Tissue Protector. Use the Proximal Reamer 4 to open the proximal portion of the femur to 18 mm to accommodate the proximal portion of the nail (17.5 mm). The minimum length of femur that requires reaming is 7 cm. The proximal reamer's positive stop has 3 settings. The "7" setting will ream to 7 cm, the "7.5" setting will ream to 7.5 cm, and the "8" setting will ream to 8.0 cm. Once the positive stop is set, guide the Proximal Reamer over the Guide Pin and through the Tissue Protector and ream until the positive stop meets the outer portion of the Tissue Protector (Figure 5).

In elderly patients with peritrochanteric fractures, the bone of the proximal femur, and in particular the fractured greater trochanter, is often very soft. The tip of the greater trochanter may be opened with the Curved Awl and checked radiographically in the A-P and lateral planes. Then, ream the proximal femur to 18 mm using the Proximal Reamer without the use of a Ball Tipped Guide Pin. Reaming over a 3.2 mm Tip Threaded Guide Pin is optional. If the trochanteric region is very osteoporotic, proximal reaming may be unnecessary.

The IMHS nail is available in four diameters and two angles — 130° and 135° . Using the templates on the preoperative radiograph, estimate the appropriate diameter of the nail and the ideal angle and length for the lag screw. The final decision on the lag screw angle is a matter of experience. The majority of cases will require an angle of 130°.



Trial Handle

Trial

Use one of the four Trials \triangle to verify the appropriate nail diameter. Place the appropriate diameter trial on either the Trial Handle Δ or the Drill Guide \bigwedge . Insert the Trial through the prepared proximal femur to ensure that the implant will fit in the medullary canal. It is preferable to use a smaller diameter implant than one which is tight within the canal.

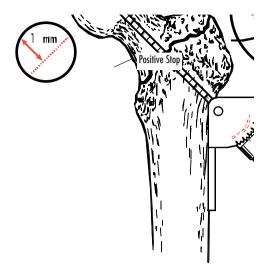


Figure 5

Using the Drill Guide and the appropriate Angle Guide Attachment \bigwedge , insert a guide pin into the femoral head to verify the angle. Refer to the Proximal Targeting section for the proper technique. Always remove the guide pin before removing the trial.

NOTE: There is no trial for the Long IMHS implant. If the canal is narrow and will not accommodate a 10 mm nail, then standard intramedullary reaming should be carried out over a Ball Tipped Guide Rod. The femur should be reamed to 1 mm larger than the nail's diameter. Special attention should be paid to the anterior bow to ensure that a nail of the correct length and orientation, left or right, is used.

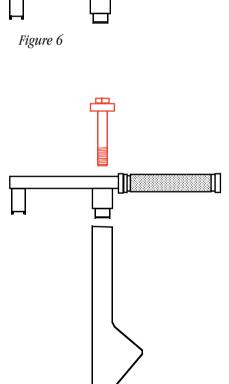
DRILL GUIDE AND NAIL ASSEMBLY

The assembly of the Drill Guide with the chosen nail and the corresponding Angle Guide Attachment is critical. If the Angle Guide Attachment and nail are incorrectly matched, it will be impossible to insert the lag screw. For this reason, it is recommended that you assemble the Angle Guide Attachment to the Drill Guide prior to insertion of the Intramedullary Hip Screw.

First, assemble the Drill Guide to the Drill Guide Handle *(Figure 6)*. Secure the selected Angle Guide Attachment to the Drill Guide with the Angle Guide Attachment Bolt and tighten using the 11/16" Universal Socket Wrench (Figure 7).















Next, attach the appropriate nail to the drill guide assembly with the Drill Guide Bolt *(Figure 8)*. Tighten the bolt using the 11/16" Universal Socket Wrench 200. Then, attach the Driver 200 to the Drill Guide and tighten using the 9/16" Open End Wrench 200 *(Figure 9)*.

Confirm correct assembly by passing the Sleeve Reamer \bigwedge through the Silver Drill Sleeve \bigwedge and the proximal hole of the IMHS nail *(Figure 10)*.

NOTE: When using the Long IMHS nail, make sure the bow is anterior.

NAIL INSERTION

In most cases, the IMHS can be inserted without the use of a guide rod. Insert the tip of the nail into the prepared proximal femur and push it down the shaft. Carry this out under fluoroscopic control. **Under no circumstances should** the nail and driver assembly be hammered down the femur. If the nail will not pass easily down the canal with simple, gentle twisting movements of the driver assembly, it should be removed and the canal reamed by 1 or 2 mm before reinsertion.

Remove the Driver since this part of the assembly is no longer needed. If the Driver has tightened during nail insertion, the 9/16" Open End Wrench can be used to loosen it. The remainder of the insertion apparatus does not obscure the femoral head on the lateral radiograph.

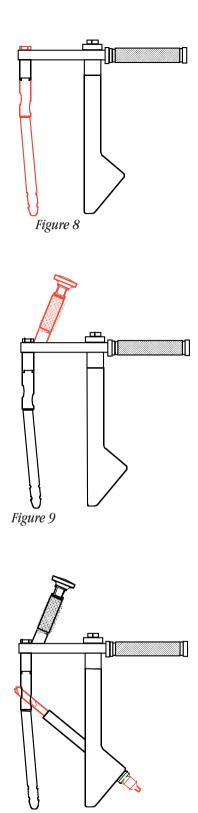


Figure 10

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PROXIMAL TARGETING

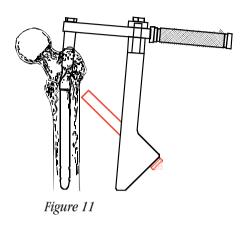
Correct positioning of the nail is critical to ensure that the lag screw will be placed in the center of the femoral head in both A-P and lateral planes.

Two Silver Drill Sleeves are available for use with the Angle Guide Attachment, lengths 14 cm and 16 cm. When the nail is in the correct position, thread the appropriate Drill Sleeve into the Angle Guide Attachment.

Make an incision in the skin to allow the selected size Silver Drill Sleeve to be screwed in until it is flush with the Angle Guide Attachment *(Figure 11)*. Choose the sleeve that comes closest to the lateral cortex without impeding its ability to be completely screwed into the Angle Guide Attachment. Insert the Guide Pin Sleeve $\widehat{}$ until it rests on the lateral cortex of the femur *(Figure 12)*. It is important that the sleeve fit flush against the femur to reduce the likelihood of the guide pin "walking." Using A-P fluoroscopy, estimate the approximate position of the lag screw.

Insert a 3.2 mm Tip Threaded Guide Pin A through the Guide Pin Sleeve and into the femoral neck and head. The position of the guide pin, and thus the ultimate position of the lag screw, can now be determined both on A-P and lateral radiographic screening. If any fine adjustments in the nail depth need to be made, withdraw the guide pin and slightly insert or withdraw the IMHS nail until the correct final position is achieved.

The perfect position of the guide pin is in the exact center of the femoral neck and head on both the A-P and lateral views. The pin should certainly lie within the central third of the femoral neck and head on both radiographic views. When the correct position of the guide pin is achieved in both planes, advance it to within 5 mm of the articular surface of the femoral head *(Figure 13).*



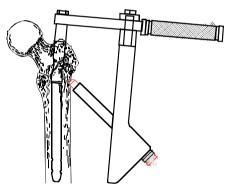


Figure 12

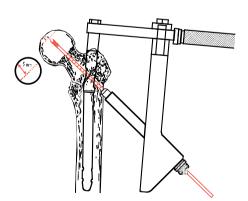


Figure 13

Guide Pin Sleeve

3.2 mm Tip Threaded Guide Pin



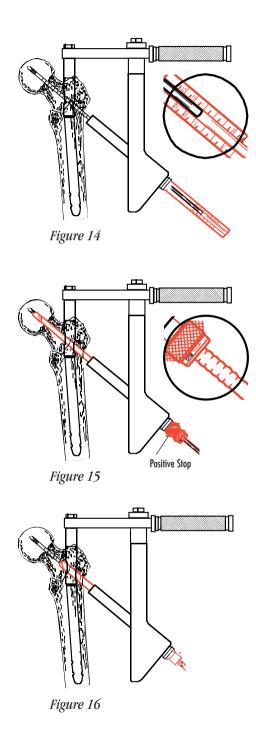
Sleeve Reamer

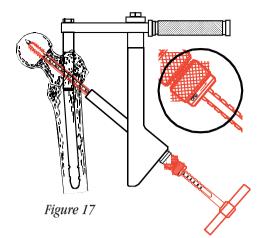
SELECTING THE LAG SCREW

After insertion of the guide pin, remove the Guide Pin Sleeve from the Silver Drill Sleeve so that the lag screw length measurement can be correctly determined. Position the Lag Screw Length Gauge f so that it rests against the guide pin and is flush with the Silver Drill Sleeve. Read the length of the lag screw directly from the guide pin (*Figure 14*).

REAMING FOR THE LAG SCREW

Use the Lag Screw Shaft Reamer <u>6</u> to prepare the femoral neck for the lag screw. The correct depth for reaming is 5 mm less than the length of the guide pin, as previously measured. This will reduce the likelihood of the guide pin being removed with the Reamer. Set the Lag Screw Shaft Reamer to the correct length and advance it through the Silver Drill Sleeve and into the femoral head until the positive stop makes contact with the Silver Drill Sleeve (Figure 15). (If the guide pin is removed with the reamer, reinsert the Guide Pin Sleeve and reintroduce the guide pin without moving the external jig.) Check the position radiographically and remove the Lag Screw Shaft Reamer. Insert the Sleeve Reamer not to ream the lateral cortex and metaphysis until the positive stop makes contact with the Silver Drill Sleeve (Figure 16). Remove the Sleeve Reamer.





TAPPING FOR THE LAG SCREW

In an osteoporotic femur, tapping is unnecessary. In younger individuals, tapping the femoral neck to prepare for the lag screw is preferred. Otherwise, there may be a tendency for the femoral neck and head fragment to rotate during the insertion of the lag screw. Set the Lag Screw Tap $\widehat{}$ for the same length as the Lag Screw Shaft Reamer (5 mm less than the guide pin measurement) and insert it through the Silver Drill Sleeve *(Figure 17)*.

SELECTION OF THE LAG SCREW

Use a standard Richards AMBI/Classic Lag Screw. The tip of the lag screw should lie within 5-10 mm of the articular surface of the femoral head, since the bone in this region is denser than in the center of the head. This will make screw cut-out less likely. The length given by the measurement already allows for 5 mm of compression. In most peritrochanteric fractures, compression is only temporarily effective, and is not regarded as necessary.

Note: Do not use Richards AMBI/Classic Super Lag Screws. The Super Lag Screws will not pass through the IMHS nail.





INSERTION OF LAG SCREW, SLEEVE, AND SET SCREW

Assemble an IMHS Centering Sleeve (HN-1200) onto the Lag Screw Insertion Wrench (*Figure 18*). Attach the appropriate Lag Screw to the Wrench and tighten the Lag Screw Retaining Rod (*Figure 19*). Snap the Insertion Wrench Handle over the Lag Screw Retaining Rod and onto the shaft of the Wrench (*Figure 20*).

Insert the entire assembly over the guide pin and through the Silver Drill Sleeve. Advance the lag screw into the proximal femur to the desired level using radiographic control. When the notch on the Wrench's shaft is flush with the edge of the Silver Drill Sleeve, the screw is correctly positioned for 5 mm of compression *(Figure 21).*

The handle of the Insertion Wrench must be perpendicular to the axis of the femoral shaft to ensure maximum strength of the lag screw in-situ.

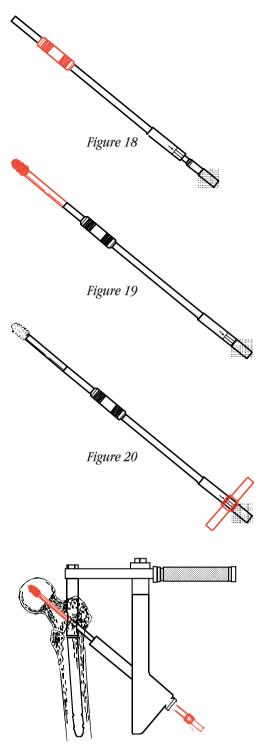
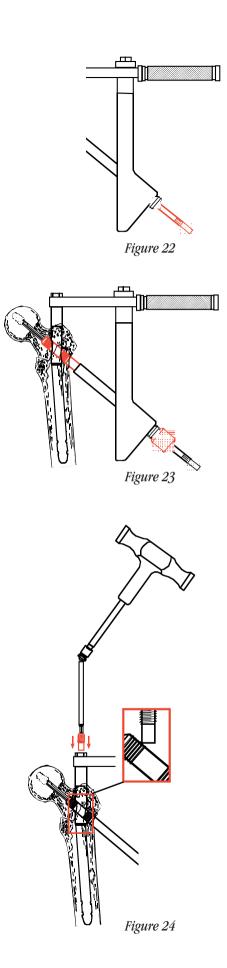


Figure 21



When the lag screw has been inserted to the correct depth, remove the Insertion Wrench Handle, leaving the Wrench Shaft and Lag Screw Retaining Rod attached to the lag screw *(Figure 22)*. Slide the Sleeve Inserter over the Wrench Shaft and up through the Silver Drill Sleeve. Use it to push the Centering Sleeve through the lateral cortex of the femur and into the nail. The sleeve inserter may be tapped with the Slotted Hammer on until it contacts the Silver Drill Sleeve *(Figure 23)*. An A-P view with the image intensifier will confirm that the Centering Sleeve is centered within the nail.

Use the Universal Set Screwdriver 22 with the 75 in./lb. Torque Wrench 23 to insert a Set Screw (HN-1202) through the Drill Guide Bolt and into the top of the nail (*Figure 24*). The set screw will lock into a groove of the Centering Sleeve (*Figure 24 Inset*). When an audible snap is heard while turning the Torque Wrench, the set screw is firmly secured against the Centering Sleeve. For optimal results, the Torque Wrench and the Universal Set Screwdriver should be in line with the nail as closely as possible. Also, a retorque after a one minute pause ensures maintenance of optimal torque.

















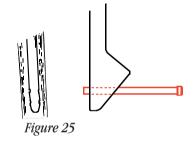
Once the Centering Sleeve is secured by the Set Screw, the lag screw will no longer rotate, but it will be able to slide. The Sleeve Inserter, Lag Screw Insertion Wrench, and Silver Drill Sleeve may now be removed.

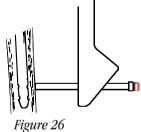
Polyethylene Nail Caps are available for use in preventing tissue ingrowth in the proximal portion of the nail. After the Set Screw is in place, manually screw the Nail Cap into place.

DISTAL TARGETING FOR THE STANDARD IMHS

Place the 8.0 mm Green Drill Sleeve through the superior distal hole in the Angle Guide Attachment and push it down to the skin (Figure 25). Make a small incision through the skin, down to the bone, to allow the Green Drill Sleeve to pass through the soft tissue and rest against the femoral shaft. Insert the 3.5 mm Black Drill Sleeve A through the Green Drill Sleeve and down to the bone (Figure 26).

It is important to prevent "walking" of the Drill Tip on the curved femoral cortex. The risk of this is reduced by dimpling the lateral cortex and by using a new drill bit for every case. It is also important that the drill sleeves are flush with the femoral cortex. Using the T-Handle Jacob's Chuck 26 to hold a 3.5 mm Trocar 26, insert the Trocar through the Black Drill Sleeve to dimple the lateral cortex. Through the Black Drill Sleeve, drill a hole into the femoral shaft with a 3.5 mm Twist Drill 2 (*Figure 27*). Once the drill has passed through the lateral femoral





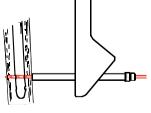
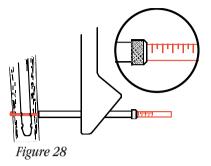
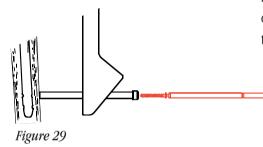


Figure 27





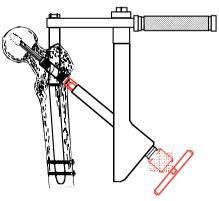


Figure 30

cortex, the nail, and the medial femoral cortex, determine bone screw length by measuring directly from the 3.5 mm Twist Drill and the Black Drill Sleeve, or remove the 3.5 mm Twist Drill and the Black Drill Sleeve and insert the Bone Screw Length Gauge from through the Green Drill Sleeve. Read the appropriate screw length off the edge of the sleeve (*Figure 28*).

Choose the appropriate 4.5 mm self-tapping bone screw with the Screw Pickup A. Insert the appropriate screw through the Green Drill Sleeve using the Hexdriver A. (*Figure 29*). Advance the screw until the second groove of the Hexdriver reaches the end of the Green Drill Sleeve. Once the screw has been inserted, check the position by lateral radiograph, using the image intensifier to ensure that the screw has passed through the nail.

Repeat the procedure for the inferior distal screw.

INSERTION OF THE COMPRESSION SCREW

Release the traction on the injured leg. If desired, compression of the lag screw may now be carried out. Reinsert the Silver Drill Sleeve and Sleeve Inserter in the Drill Guide. Insert the AMBI/Classic Compressing Screw (12-1116) into the lag screw with the Hexdriver and compress it against the Centering Sleeve (*Figure 30*).

The insertion of the implant is now complete. After final radiographic checking, loosen the Drill Guide Bolt using the 11/16" Universal Socket Wrench. Remove the Drill Guide Assembly.

NOTE: The Angle Guide Attachment is not used for distal targeting the 10 mm long nail. Attempting to drill through the Angle Guide Attachment could result in damage to the nail. Distal targeting the 10 mm nail is accomplished using the freehand technique or by using the Cole Radiolucent Drill technique.







DISTAL TARGETING FOR THE LONG IMHS NAIL: FREEHAND TECHNIQUE

Described by Robert F. Hall, Jr., M.D. Chairman, Division of Orthopaedic Surgery Cook County Hospital, Chicago, Illinois

The Long IMHS has 10° anteversion built into the proximal Lag Screw hole, thus allowing distal targeting to take place with the image intensifier in a true lateral position. With the image intensifier in the lateral position, scan the distal femur. Adjust the position of the intensifier until the screw holes are perfectly circular. The position of the image intensifier and the rotation of the leg can be adjusted to obtain a true lateral image of the nail.

When the holes are completely circular, center a ring forceps over the proximal hole on the lateral side of the leg. Then introduce a 10 blade within the confines of the ring forceps; make a longitudinal incision along the midline axis of the leg, carrying the incision down to bone. Repeat the procedure on the distal screw hole. Connect the two incisions with an approximately 3 cm long incision, which is carried down to the bone.

Attach the T-Handle Jacob's Chuck to the 3.5 mm Trocar and insert it through the Black Drill Sleeve to dimple the lateral cortex. The risk of the Twist Drill "walking" is reduced by dimpling the lateral cortex and using a new drill bit for each case.

Using the image intensifier, adjust the trocar until the point is centered over the screw hole. Return the image intensifier to the anteriorposterior view and maintain constant pressure on the trocar to prevent skidding. Swing the trocar perpendicular to the axis of the bone. Adjust the angle on the A-P image so that the trocar will be driven towards the hole in the nail. Now the trocar is lined up both in the lateral and the A-P planes. Using a mallet, drive the trocar to the lateral side of the nail. Remove the T-handled chuck from the trocar and obtain a lateral image of the femur. The trocar should point directly to the center of the hole within the rod. If this is not the case, make adjustments as necessary.

Once proper alignment has been obtained, withdraw the trocar; place the drill in the previously made hole and drill through the rod and opposite cortex. Determine the length of the screw using the Screw Length Gauge. Place the screw in its proper position. Repeat the procedure on the distal screw hole. The last image should be a lateral view, confirming satisfactory placement of the screws.

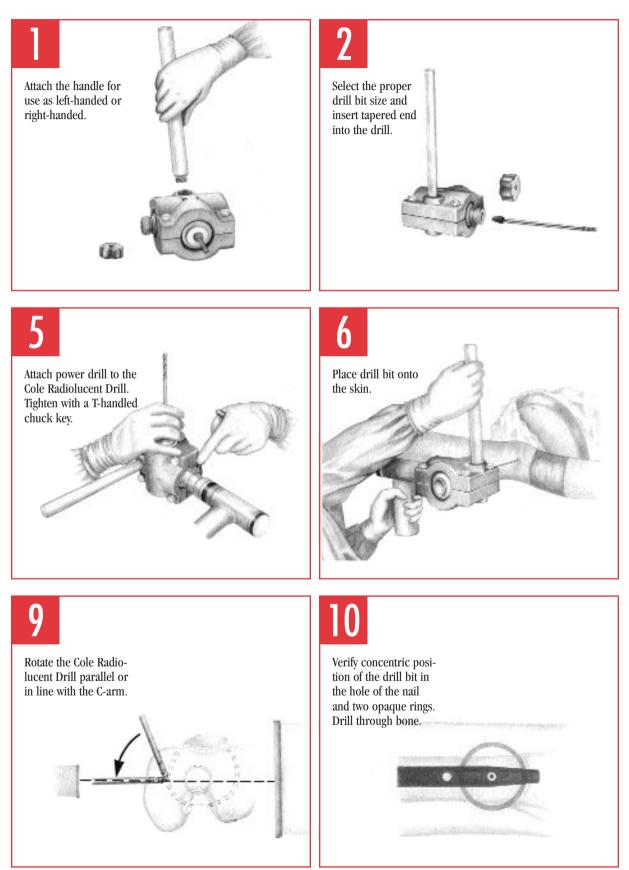
CLOSURE

Close the proximal operative wound over a suction drain. The fibers of gluteus medius may be carefully approximated and the gluteus maximus aponeurosis closed with a continuous suture. The distal wounds require skin closure only. Finally, apply an impermeable dressing.

POSTOPERATIVE INSTRUCTIONS

In peritrochanteric fractures with a stable configuration (i.e., where the medial cortical buttress and lesser trochanter remain intact), early full weight bearing is permitted. Mobilize the patient after the removal of the drain, at 24-48 hours, and allow weight bearing as tolerated. In unstable fracture configurations, it is recommended that full weight bearing be deferred for a period of six weeks if possible.

COLE RADIOLUCENT DRILL — ABBREVIATED TECHNIQUE



3

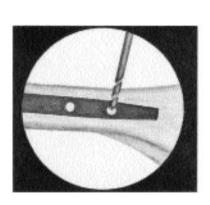
Place the locking cap over the drill bit with one hand while preventing rotation of the hollow tube with the other hand.



Use the T-handled chuck key over the chuck end of the Cole Radiolucent Drill to prevent the shaft from rotating. Tighten the locking cap. Remove T-handled chuck key.

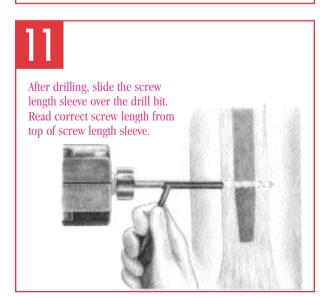


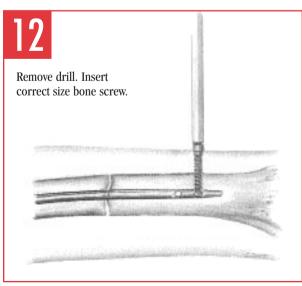
Use image intensification to verify placement in the center of the perfect circle.





After making an incision to bone and placing the drill bit on bone, center bit within the perfect circle with long axis of bit perpendicular





IMHS REMOVAL INSTRUCTIONS

- 1. Remove both the 4.5 mm distal locking screws with the Hexdriver.
- 2. Loosen the Set Screw (HN-1202), using the 75 in./lb. Torque Wrench and Universal Set Screwdriver enough so that the sleeve and lag screw can pass through the nail's hole. The set screw does not have to be fully removed.
- 3. Remove the Compressing Screw (12-1116) from the end of the lag screw with the Hexdriver.
- Attach the Lag Screw Insertion Wrench onto the lag screw and engage the Stabilizer Bar. The centering sleeve (HN-1200) will come out with the lag screw. Note: If difficulty is expected, use the Richards Round T-Wrench (11-0048) instead of the Insertion Wrench.
- 5. Attach the Removal Bolt 2 to the proximal end of the nail using the 11/16" Universal Socket Wrench.
- 6. Screw the Driver/Extractor Tube into the end of the Removal Bolt. Use the Slotted Hammer to remove the nail. Note: For difficult cases, attach the R-T Slide Hammer (11-2011) to the removal bolt instead of the Driver/ Extractor Tube.





Richards Classic Compression Hip Screw Standard Barrel Plates

	ngth: 1.5" (38.		11 E.O
Cat. No.	Description	Length	Angle
12-4120	2 Slot	60 mm	130°
12-4121	2 Slot	60 mm	135°
12-4122	2 Slot	60 mm	140°
12-4123	2 Slot	60 mm	145°
12-4124	2 Slot	60 mm	150°
12-4125	3 Slot	80 mm	130°
12-4126	3 Slot	80 mm	135°
12-4127	3 Slot	80 mm	140°
12-4128	3 Slot	80 mm	145°
12-4129	3 Slot	80 mm	150°
12-4130	4 Slot	100 mm	130°
12-4131	4 Slot	100 mm	135°
12-4132	4 Slot	100 mm	140°
12-4133	4 Slot	100 mm	145°
12-4134	4 Slot	100 mm	150°
12-4135	5 Slot	120 mm	130°
12-4136	5 Slot	120 mm	135°
12-4137	5 Slot	120 mm	140°
12-4138 12-4139	5 Slot 5 Slot	120 mm 120 mm	145° 150°
12-4140 12-4141	6 Slot 6 Slot	140 mm 140 mm	130° 135°
12-4141	6 Slot	140 mm	135 140°
12-11-12	6 Slot	140 mm	145°
12-4144	6 Slot	140 mm	150°
12-4145	8 Slot	180 mm	130°
12-4146	8 Slot	180 mm	135°
12-4147	8 Slot	180 mm	140°
12-4148	8 Slot	180 mm	145°
12-4149	8 Slot	180 mm	150°
12-4150	10 Slot	220 mm	130°
12-4151	10 Slot	220 mm	135°
12-4152	10 Slot	220 mm	140°
12-4153	10 Slot	220 mm	145°
12-4154	10 Slot	220 mm	150°
12-4155	12 Slot	260 mm	130°
12-4156	12 Slot	260 mm	135°
12-4157	12 Slot	260 mm	140°
12-4158 12-4159	12 Slot 12 Slot	260 mm 260 mm	145°
			150°
12-4160	14 Slot	300 mm	130°
12-4161 12-4162	14 Slot 14 Slot	300 mm	135° 140°
12-4162	14 Slot 14 Slot	300 mm 300 mm	140° 145°
12-4105	14 Slot 14 Slot	300 mm	145 150°
14 1101	110101	J00 IIIII	1,00



RICHARDS CLASSIC COMPRESSION HIP SCREW SHORT BARREL PLATES

Barrel Length: 1.0" (25.9 mm)			
Cat. No.	Description	Length	Angle
12-4176	4 Slot	100 mm	130°
12-4177	4 Slot	100 mm	135°
12-4178	4 Slot	100 mm	140°
12-4179	4 Slot	100 mm	145°
12-4180	4 Slot	100 mm	150°
12-4165	5 Slot	120 mm	130°
12-4166	5 Slot	120 mm	135°
12-4167	5 Slot	120 mm	140°
12-4168	5 Slot	120 mm	145°
12-4169	5 Slot	120 mm	150°



RICHARDS CLASSIC Compression Hip Screw Supracondylar Plates

Barrel Length: 1.0" (25.4 mm)			
Cat. No.	Description	Length	Angle
12-4181	6 Slot	124 mm	90°
12-4182	6 Slot	124 mm	95°
12-4170	8 Slot	164 mm	90°
12-4173	8 Slot	164 mm	95°
12-4171	10 Slot	204 mm	90°
12-4174	10 Slot	204 mm	95°
12-4172	12 Slot	244 mm	90°
12-4175	12 Slot	244 mm	95°



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AMBI Compression Hip Screw Standard Barrel Plates

Barrel Lei	ngth: 1.5" (38.	1 mm)	
Cat. No.	Description	Length	Angle
12-1120	2 Slot	60 mm	130°
12-1121	2 Slot	60 mm	135°
12-1122	2 Slot	60 mm	140°
12-1123	2 Slot	60 mm	145°
12-1124	2 Slot	60 mm	150°
12-1125	3 Slot	80 mm	130°
12-1126	3 Slot	80 mm	135°
12-1127	3 Slot	80 mm	140°
12-1128	3 Slot	80 mm	145°
12-1129	3 Slot	80 mm	150°
12-1130	4 Slot	100 mm	130°
12-1131	4 Slot	100 mm	135°
12-1132	4 Slot	100 mm	140°
12-1133	4 Slot	100 mm	145°
12-1134	4 Slot	100 mm	150°
12-1135	5 Slot	120 mm	130°
12-1136	5 Slot	120 mm	135°
12-1137	5 Slot	120 mm	140°
12-1138	5 Slot 5 Slot	120 mm 120 mm	145°
12-1139	-		150°
12-1140	6 Slot	140 mm	130°
12-1141	6 Slot 6 Slot	140 mm	135° 140°
12-1142 12-1143	6 Slot	140 mm 140 mm	140° 145°
12-1145	6 Slot	140 mm	149 150°
12-1145 12-1146	8 Slot 8 Slot	180 mm 180 mm	130° 135°
12-1140	8 Slot	180 mm	135 140°
12-114/	8 Slot	180 mm	140 145°
12-1149	8 Slot	180 mm	150°
12-1150	10 Slot	220 mm	130°
12-1150	10 Slot	220 mm	135°
12-1152	10 Slot	220 mm	140°
12-1153	10 Slot	220 mm	145°
12-1154	10 Slot	220 mm	150°
12-1155	12 Slot	260 mm	130°
12-1156	12 Slot	260 mm	135°
12-1157	12 Slot	260 mm	140°
12-1158	12 Slot	260 mm	145°
12-1159	12 Slot	260 mm	150°
12-1160	14 Slot	300 mm	130°
12-1161	14 Slot	300 mm	135°
12-1162	14 Slot	300 mm	140°
12-1163	14 Slot	300 mm	145°
12-1164	14 Slot	300 mm	150°

AMBI Compression Hip Screw Short Barrel Plates

Barrel Length: 1.0" (25.4 mm) Cat. No. Description Length

Cat. No.	Description	Length	Angle
12-1198	4 Slot	100 mm	130°
12-1199	4 Slot	100 mm	135°
12-1200	4 Slot	100 mm	140°
12-1201	4 Slot	100 mm	145°
12-1202	4 Slot	100 mm	150°
12-1165	5 Slot	120 mm	130°
12-1166	5 Slot	120 mm	135°
12-1167	5 Slot	120 mm	140°
12-1168	5 Slot	120 mm	145°
12-1169	5 Slot	120 mm	150°

AMBI Compression Hip Screw Supracondylar Plates

Barrel Length: 1.0" (25.4 mm)

Cat. No.	Description	Length	Angle
12-1203	6 Slot	124 mm	90°
12-1204	6 Slot	124 mm	95°
12-1170	8 Slot	164 mm	90°
12-1173	8 Slot	164 mm	95°
12-1171	10 Slot	204 mm	90°
12-1174	10 Slot	204 mm	95°
12-1172	12 Slot	244 mm	90°
12-1175	12 Slot	244 mm	95°

AMBI/CLASSIC/IMHS STANDARD LAG SCREWS

Thread Diameter: 1/2" (12.7 mm) Thread Length: 21.0 mm Root Diameter: 9.0 mm

Cat. No.	Length	Cat. No.	Length
12-1100	55 mm	12-1109	100 mm
12-1101	60 mm	12-1110	105 mm
12-1102	65 mm	12-1111	110 mm
12-1103	70 mm	12-1112	115 mm
12-1104	75 mm	12-1113	120 mm
12-1105	80 mm	12-1114	125 mm
12-1106	85 mm	12-1176	130 mm
12-1107	90 mm	12-1177	135 mm
12-1108	95 mm	12-1178	140 mm
		, 60, or 65 mm lag screws v	with IMHS.

NOTE: Do not use AMBI/Classic 55, 60, or 65 mm lag screws with If These sizes are too short to work effectively with this device.

Ambi Clip

Cat. No. 12-1115



.











AMBI/Classic Super Lag Screws

Thread Diameter: 9/16" (14.3 mm) Thread Length: 21.0 mm Root Diameter: 9.0 mm

	,		
Cat. No.	Length	Cat. No.	Length
12-1180	55 mm	12-1189	100 mm
12-1181	60 mm	12-1190	105 mm
12-1182	65 mm	12-1191	110 mm
12-1183	70 mm	12-1192	115 mm
12-1184	75 mm	12-1193	120 mm
12-1185	80 mm	12-1194	125 mm
12-1186	85 mm	12-1195	130 mm
12-1187	90 mm	12-1196	135 mm
12-1188	95 mm	12-1197	140 mm

6.5 MM CANNULATED SCREWS

-			
Cat. No.	Length	Cat. No.	Length
12-1625	25 mm	12-1635	75 mm
12-1626	30 mm	12-1636	80 mm
12-1627	35 mm	12-1637	85 mm
12-1628	40 mm	12-1638	90 mm
12-1629	45 mm	12-1639	95 mm
12-1630	50 mm	12-1640	100 mm
12-1631	55 mm	12-1641	105 mm
12-1632	60 mm	12-1642	110 mm
12-1633	65 mm	12-1643	115 mm
12-1634	70 mm	12-1644	120 mm

COMPRESSION SCREWS

Cat. No.	Length	Cat. No.	Length
12-1116	19 mm	12-1117	28.5 mm

4.5 mm Self-Tapping Cortical Bone Screws

Head Diameter: 8.0 mm Major Thread Diameter: 4.5 mm Root Diameter: 3.2 mm

noot bituin	0.001. 9.12 11111		
Cat. No.	Length	Cat. No.	Length
12-7016	16 mm	12-7042	42 mm
12-7018	18 mm	12-7044	44 mm
12-7020	20 mm	12-7046	46 mm
12-7022	22 mm	12-7048	48 mm
12-7024	24 mm	12-7050	50 mm
12-7026	26 mm	12-7052	52 mm
12-7028	28 mm	12-7054	54 mm
12-7030	30 mm	12-7056	56 mm
12-7032	32 mm	12-7058	58 mm
12-7034	34 mm	12-7060	60 mm
12-7036	36 mm	12-7062	62 mm
12-7038	38 mm	12-7064	64 mm
12-7040	40 mm		

IMHS COMPRESSION HIP SCREW NAILS

Standard Nails

Cat. No.	Size
7116-3010	10 mm x 21 cm x 130°
7116-3510	10 mm x 21 cm x 135°
HN-3012	12 mm x 21 cm x 130°
HN-3512	12 mm x 21 cm x 135°
HN-3014	14 mm x 21 cm x 130°
HN-3514	14 mm x 21 cm x 135°
HN-3016	16 mm x 21 cm x 130°
HN-3516	16 mm x 21 cm x 135°

Long Nails

Cat. No.	Size
7116-3034R	10 mm x 34 cm x 130°
7116-3034L	10 mm x 34 cm x 130°
7116-3038R	10 mm x 38 cm x 130°
7116-3038L	10 mm x 38 cm x 130°
7116-3042R	10 mm x 42 cm x 130°
7116-3042L	10 mm x 42 cm x 130°
7116-3534R	10 mm x 34 cm x 135°
7116-3534L	10 mm x 34 cm x 135°
7116-3538R	10 mm x 38 cm x 135°
7116-3538L	10 mm x 38 cm x 135°
7116-3542R	10 mm x 42 cm x 135°
7116-3542L	10 mm x 42 cm x 135°
(R and L after Cat	. No. indicates right or left.)

IMHS CENTERING SLEEVE & SET SCREW

Cat. No.	Description
HN-1200	Centering Sleeve

HN-1202 Set Screw

IMHS NAIL CAP

Cat. No. 12-2672







Tip Threaded Guide Pin, 3.2 mm

Cat. No.Description7111-0056Sterile Package, Single11-0016Nonsterile Package, Single





Quick Connect Adaptor (for use with Hall, Jacobs, or Stryker power) Cat. No. 7111-0136

Quick-Connect Adaptor

(for use with Synthes power) Cat. No. 7111-0236

Perforation Drill

Cat. No. 11-0021







Fixed Angle Guide

Cat. No.	Angle
11-5037	130°
11-5038	135°
11-5039	140°
11-5041	145°
11-5042	150°

Quick Connect T-Handle 7111-5045

Adjustable Angle Guide 11-0925

Percutaneous Direct Measuring Gauge 11-0026

Guide Pin Placement Instrument 11-5036



Power Combination Reamer 11-0023

Trial Handle 11-0047



Trial Plates

Cat. No.	Angle
11-0042	130°
11-0043	135°
11-0044	140°
11-0045	145°
11-0046	150°





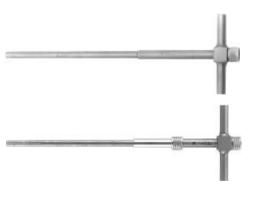


Classic Insertion Wrench Cat. No. 11-0054

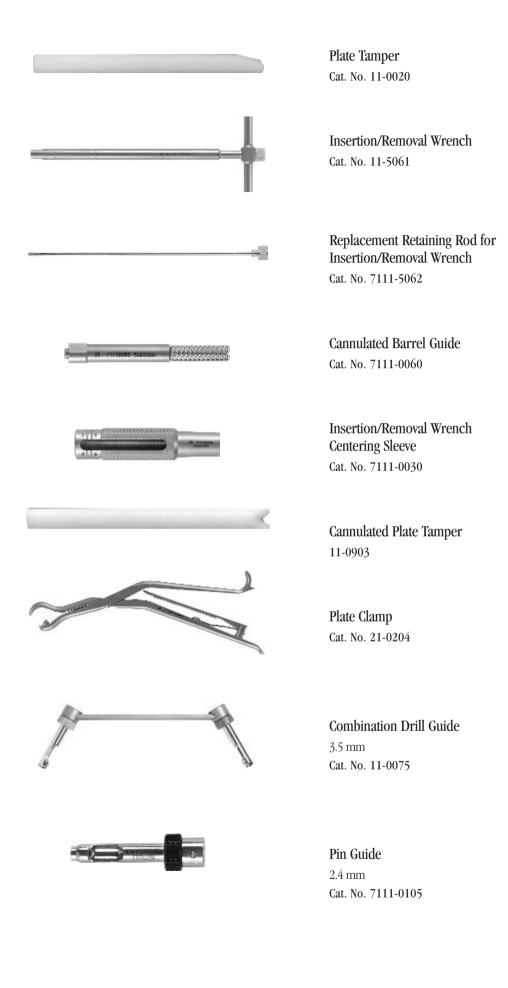
AMBI Insertion Wrench Cat. No. 11-0022

Replacement Retaining Rod for AMBI/Classic Insertion Wrenches Cat. No. 7111-0024

AMBI/Classic Wrench Centering Sleeve Cat. No. 11-0029







Guide Pin 2.4 mm Cat. No. 41-0236

Twist Drill

3.5 mm Cat. No. 7111-0045

Bone Screw Tap for 4.5 mm Self-Tapping Screws Cat. No. 11-0077

Bone Screw Tap for 4.5 mm Nonself-Tapping Screws Cat. No. 7111-0070

Bone Screw Length Gauge Cat. No. 41-3500

Screw Pickup Cat. No. 7111-5085



1000

Self-Holding Hex Screwdriver Cat. No. 7111-0026



Hex Screwdriver Cat. No. 11-5035



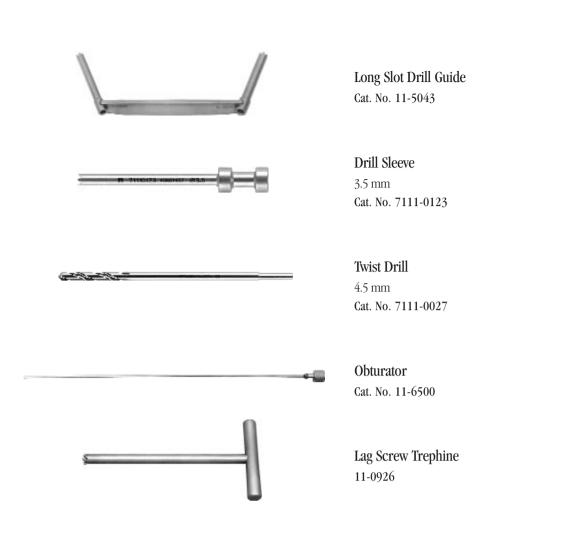
 Supracondylar Pin Guides

 Cat. No.
 Angle

 11-0018
 90°

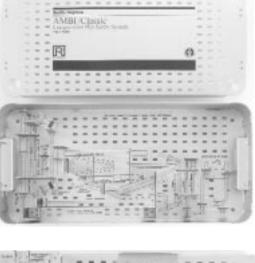
 11-0019
 95°

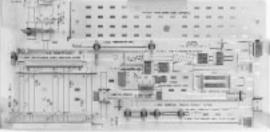




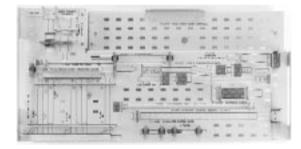
STERILIZATION TRAYS

Sterilization Tray Cat. No. 7111-5090





Standard Tray Insert Cat. No. 7111-5070







Basic Tray Insert Cat. No. 7111-5080

Bone Screw Caddy (optional) Cat. No. 7111-0137

Trial Tray (optional) Cat. No. 7111-5032

AMBI Comprehensive Instrument Set

Cat. No. 7111-5055 (Not Shown)

Set includes:

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Cat. No.	Description
7111-5090	Sterilization Tray
7111-5070	AMBI/Classic Standard Tray Insert
11-0021	Perforation Drill
11-0016	Tip Threaded Guide Pin—3.2 mm (6/Box)
11-0026	Percutaneous Direct Measuring Gauge
11-5036	Guide Pin Placement Instrument
11-5037	130° Fixed Angle Guide
11-5038	135° Fixed Angle Guide
11-5039	140° Fixed Angle Guide
11-5041	145° Fixed Angle Guide
11-5042	150° Fixed Angle Guide
11-0925	Adjustable Angle Guide
7111-5045	Quick Connect T-Handle
11-0023	Power Combination Reamer
7111-0014	Lag Screw Tap
11-0029	Centering Sleeve (For use with Classic or
	AMBI Insertion Wrench)
7111-0060	Cannulated Barrel Guide (Two Pieces)
11-0022	AMBI Insertion Wrench
11-5061	Insertion/Removal Wrench (Two Pieces)
41-3500	Depth Gauge
11-0075	Combination Drill Guide—3.5 mm
7111-0105	Pin Guide—2.4 mm
11-0077	Bone Screw Tap—4.5 mm
	(For Self-Tapping Screws)
7111-0045	Twist Drill—3.5 mm
7111-0027	Twist Drill—4.5 mm
11-0926	Lag Screw Trephine
11-5035	Hex Screwdriver
7111-0026	Self-Holding Hex Screwdriver
21-0204	Plate Clamp
11-0020	Plate Tamper
11-6500	Obturator
11-5043	Long Slot Drill Guide
7111-0123	Drill Sleeve—3.5 mm
	90° Supracondylar Pin Guide
11-0018	90° Supracondylar Pill Guide

Classic Comprehensive Instrument Set

Cat. No. 7111-5060

(Not Shown)

Set includes:

Cat. No.	Description
7111-5090	Sterilization Tray
7111-5070	AMBI/Classic Standard Tray Insert
11-0021	Perforation Drill
11-0016	Tip Threaded Guide Pin—3.2 mm
	(6/Box)
11-0026	Percutaneous Direct Measuring Gauge
11-5036	Guide Pin Placement Instrument
11-5037	130° Fixed Angle Guide
11-5038	135° Fixed Angle Guide
11-5039	140° Fixed Angle Guide
11-5041	145° Fixed Angle Guide
11-5042	150° Fixed Angle Guide
11-0925	Adjustable Angle Guide
7111-5045	Quick Connect T-Handle
11-0023	Power Combination Reamer
7111-0014	Lag Screw Tap
11-0029	Centering Sleeve (For use with Classic
	or AMBI Insertion Wrench)
7111-0060	Cannulated Barrel Guide (Two Pieces)
11-0054	Classic Insertion Wrench
11-5061	Insertion/Removal Wrench (Two Pieces)
41-3500	Depth Gauge
11-0075	Combination Drill Guide—3.5 mm
7111-0105	Pin Guide—2.4 mm
11-0077	Bone Screw Tap—4.5 mm
	(For Self-Tapping Screws)
7111-0045	Twist Drill—3.5 mm
7111-0027	Twist Drill—4.5 mm
11-0926	Lag Screw Trephine
11-5035	Hex Screwdriver
7111-0026	Self-Holding Hex Screwdriver
21-0204	Plate Clamp
11-0020	Plate Tamper
11-6500	Obturator
11-5043	Long Slot Drill Guide
7111-0123	Drill Sleeve—3.5 mm
11-0018	90° Supracondylar Pin Guide
11-0019	95° Supracondylar Pin Guide

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AMBI/Classic Basic Technique Set

Cat. No. 7111-5065

(Not Shown)

Set includes:

Cat. No.	Description
7111-5090	Sterilization Tray
7111-5080	AMBI/Classic Basic Tray Insert
11-0021	Perforation Drill
11-0016	Tip Threaded Guide Pin—3.2 mm (6/Box)
11-0026	Percutaneous Direct Measuring Gauge
11-5036	Guide Pin Placement Instrument
11-5037	130° Fixed Angle Guide
11-5038	135° Fixed Angle Guide
11-5039	140° Fixed Angle Guide
11-5041	145° Fixed Angle Guide
11-5042	150° Fixed Angle Guide
7111-5045	Quick Connect T-Handle
11-0023	Power Combination Reamer
7111-0014	Lag Screw Tap
7111-0030	Centering Sleeve
7111-0060	Cannulated Barrel Guide (Two Pieces)
11-0022	AMBI Insertion Wrench
11-5061	Insertion/Removal Wrench (Two Pieces)
41-3500	Depth Gauge
11-0075	Combination Drill Guide—3.5 mm
7111-0105	Pin Guide—2.4 mm
11-0077	Bone Screw Tap—4.5 mm (For Self-Tapping Screws)
7111-0045	Twist Drill—3.5 mm
7111-0027	Twist Drill—4.5 mm
11-0926	Lag Screw Trephine
11-5035	Hex Screwdriver
7111-0026	Self-Holding Hex Screwdriver
21-0204	Plate Clamp
11-0903	Cannulated Plate Tamper
11-6500	Obturator
11-5043	Long Slot Drill Guide
7111-0123	Drill Sleeve—3.5 mm
11-0018	90° Supracondylar Pin Guide
11-0019	95° Supracondylar Pin Guide

OPTIONAL SETS

Bone Screw Caddy Set for 4.5 mm Bone Screws

Cat. No. 7111-0135 (Not Shown)

Set includes:

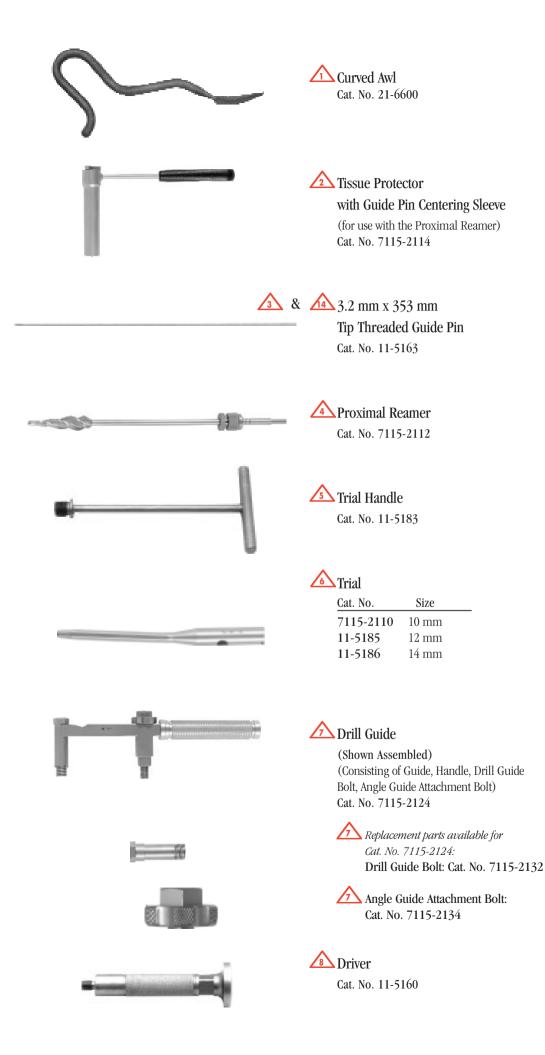
Cat. No.	Description
7111-0137	Bone Screw Caddy—4.5 mm
7111-5085	Screw Pickup (Replacement Part for Caddy)

Trial Set

Cat. No. 7111-5030 (Not Shown)

Set includes:

Cat. No.	Description	
7111-5032	Trial Tray	
11-0047	Trial Handle	
11-0042	130° Trial Plate	
11-0043	135° Trial Plate	
11-0044	140° Trial Plate	
11-0045	145° Trial Plate	
11-0050	150° Trial Plate	



Angle Guide Attachment

Cat. No.	Angle
11-5170	130°
11-5171	135°

11/16" Universal Socket Wrench Cat. No. 11-5177

9/16" Open End Wrench Cat. No. 11-0566





Silver Drill Sleeve

Cat. No.	Size
11-5161	14 cm
7115-2116	16 cm

▲ Guide Pin Sleeve

Cat. No. 11-5164

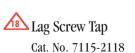
3.2 mm x 353 mm Tip Threaded Guide Pin Cat. No. 11-5163

> Lag Screw Length Gauge Cat. No. 11-5162



Lag Screw Shaft Reamer Cat. No. 11-5166

Cat. No. 11-5182





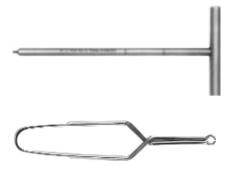


3.5 mm Twist Drill Cat. No. 7115-2128

Bone Screw Length Gauge Cat. No. 7115-2126

Hexdriver Cat. No. 11-2088

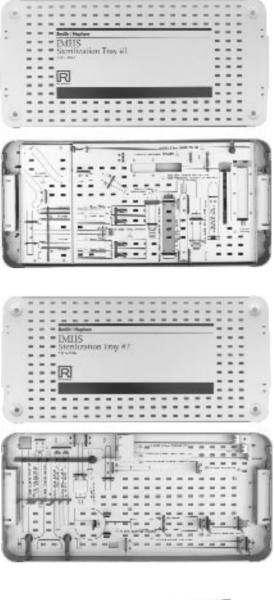
Screw Pickup Cat. No. 7111-5085



Removal Bolt Cat. No. 11-5174

Driver/Extractor Tube Cat. No. 11-2008

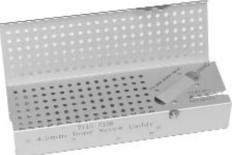




IMHS Instrument Sterilizing Case #1 (with Tray Lid and Insert) Cat. No. 7115-2102

IMHS Instrument Sterilizing Case #2

(with Tray Lid) Cat. No. 7115-2106



4.5 mm Bone Screw Caddy

NOTE: This caddy holds 6 each of the most widely used bone screw sizes. They are 20–48 mm in 2 mm increments. Cat. No. 7115-2108

IMHS Instrument Set

(Not Shown)

Cat. No. 7115-2100

Includes one each of the following:

Cat. No.	Description
7115-2102	Sterilization Tray #1 (with Lid)
7115-2106	Sterilization Tray #2 (with Lid)
21-6600	Curved Awl
7115-2114	Tissue Protector for use with Proximal Reamer
11-5163	3.2 mm Tip Threaded Guide Pin
7115-2112	Proximal Reamer
11-5183	Trial Handle
7115-2110	10 mm Trial
11-5185	12 mm Trial
11-5186	14 mm Trial
7115-2124	Drill Guide
11-5160	Driver
11-5170	130° Angle Attachment
11-5171	135° Angle Attachment
11-0566	9/16" Open End Wrench
11-5177	11/16" Universal Socket Wrench
11-5161	14 cm Silver Drill Sleeve
7115-2116	16 cm Silver Drill Sleeve
11-5164	Guide Pin Sleeve
11-5162	Lag Screw Length Gauge
11-5166	Lag Screw Shaft Reamer
11-5182	Sleeve Reamer
7115-2118	Lag Screw Tap (includes Tap & Removable Handle)
11-5176	Lag Screw Insertion Wrench Assembly
11-5165	Sleeve Inserter
11-5175	Slotted Hammer
11-5188	75 in./lb. Torque Wrench
7115-2122	Universal Set Screwdriver
11-2086	3.5 mm Black Drill Sleeve
11-2012	8.0 mm Green Drill Sleeve
11-0257	T-Handle Jacob's Chuck
11-2085	3.5 mm Trocar
7115-2128	3.5 mm Twist Drill
7115-2126	Bone Screw Length Gauge
11-2088	Hexdriver
7111-5085	Screw Pickup
7115-2108	4.5 mm Bone Screw Caddy
11-5174	Removal Bolt
11-2008	Extractor Tube

Standard IMHS Templates Cat. No. 7118-0342

(Not Shown)

Long IMHS Templates

Cat. No. 7118-0298 (Not Shown)

IMHS Implant Set

(Not Shown)

Includes the following:					
Cat. No.	Description				
HN-1200	Centering Sleeve 12.7				
HN-1202	Set Screw				
7116-3010	IM Hip Screw 10 mm				
7116-3510	IM Hip Screw 10 mm				

0	Description	Quy.
HN-1200	Centering Sleeve 12.7 mm x 38.1 mm	4
HN-1202	Set Screw	4
7116-3010	IM Hip Screw 10 mm x 21 cm x 130° (Universal)	1
7116-3510	IM Hip Screw 10 mm x 21 cm x 135° (Universal)	1
HN-3012	IM Hip Screw 12 mm x 21 cm x 130° (Universal)	1
HN-3512	IM Hip Screw 12 mm x 21 cm x 135° (Universal)	1
HN-3014	IM Hip Screw 14 mm x 21 cm x 130° (Universal)	1
HN-3514	IM Hip Screw 14 mm x 21 cm x 135° (Universal)	1
7116-3034R	IM Hip Screw 10 mm x 34 cm x 130° (Right)	1
7116-3038R	IM Hip Screw 10 mm x 38 cm x 130° (Right)	1
7116-3042R	IM Hip Screw 10 mm x 42 cm x 130° (Right)	1
7116-3534R	IM Hip Screw 10 mm x 34 cm x 135° (Right)	1
7116-3538R	IM Hip Screw 10 mm x 38 cm x 135° (Right)	1
7116-3542R	IM Hip Screw 10 mm x 42 cm x 135° (Right)	1
7116-3034L	IM Hip Screw 10 mm x 34 cm x 130° (Left)	1
7116-3038L	IM Hip Screw 10 mm x 38 cm x 130° (Left)	1
7116-3042L	IM Hip Screw 10 mm x 42 cm x 130° (Left)	1
7116-3534L	IM Hip Screw 10 mm x 34 cm x 135° (Left)	1
7116-3538L	IM Hip Screw 10 mm x 38 cm x 135° (Left)	1
7116-3542L	IM Hip Screw 10 mm x 42 cm x 135° (Left)	1
12-1116	Compression Screw 19 mm	6
12-1106	Richards CHS Lag Screw 85 mm	4
12-1107	Richards CHS Lag Screw 90 mm	4
12-1108	Richards CHS Lag Screw 95 mm	4
12-1109	Richards CHS Lag Screw 100 mm	4
12-7022	Bone Screw 4.5 mm x 22 mm	6
12-7024	Bone Screw 4.5 mm x 24 mm	6
12-7026	Bone Screw 4.5 mm x 26 mm	6
12-7028	Bone Screw 4.5 mm x 28 mm	6
12-7030	Bone Screw 4.5 mm x 30 mm	6
12-7032	Bone Screw 4.5 mm x 32 mm	6
12-7034	Bone Screw 4.5 mm x 34 mm	6
12-7036	Bone Screw 4.5 mm x 36 mm	6
12-7038	Bone Screw 4.5 mm x 38 mm	6
12-7040	Bone Screw 4.5 mm x 40 mm	6
12-7042	Bone Screw 4.5 mm x 42 mm	6
12-7044	Bone Screw 4.5 mm x 44 mm	6
12-7046	Bone Screw 4.5 mm x 46 mm	6
12-7048	Bone Screw 4.5 mm x 48 mm	6

Qty.

IMPORTANT MEDICAL INFORMATION SMITH & NEPHEW COMPRESSION HIP SCREWS CANNULATED/BONE SCREWS BONE PLATES, PINS, WIRES FRACTURE FIXATION DEVICES

SPECIAL NOTE

Fracture fixation devices are used only as an aid to healing, they are not a substitute for normal intact tissue or bone. The anatomy of human bones presents limitations with respect to the size or thickness of bone screws or barrel plates and thus the strength of implants is limited. Full weight bearing prior to complete bone healing is contraindicated. With repeated stress in patients with delayed healing or nonunion, the appliance will inevitably bend, break or pull out of bone.

Fracture fixation devices are available in many styles and sizes and are made from various types of metals. The component material is provided on the outside carton label. Use only components made from the same material together. Do not mix dissimilar metals or components from different manufacturers. All implantable devices are designed for single use only.

INDICATIONS

Bone Plates, Screws, Pins and Wires

Bone plates, screws, pins and wires are indicated for pelvic, small and long bone fracture fixation. Refer to medical or manufacturer literature for specific product applications.

Compression Hip Screws/IMHS

- Intracapsular fractures of the femoral neck. (For high subcapsular fractures it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of a nonunion or avascular necrosis of the femoral head.)
- 2. Trochanteric or subtrochanteric fractures with appropriate additional postoperative precautions about weight bearing and more than sedentary activity.
- 3. Osteotomies for patients with diseases or deformities of the hip.
- 4. Hip arthrodesis.
- 5. Supracondylar fractures and distal femoral fractures using a supracondylar plate.

6. Ipsilateral femoral shaft/neck fractures (long IMHS only).

- Pediatric and Intermediate Compression Hip Screws
- 1. Congenital coxa vara.
- 2. Congenital dislocation of the hip.
- Subluxation or dislocation secondary to neurologic disorders such as cerebral palsy, myelomenigocele, poliomyelitis, etc. Usually valgus-anteversion deformities.
- Coxa plana (Legg-Calve-Perthes disease) for containment of the head completely within the acetabulum.

CONTRAINDICATIONS

 Physical conditions that would preclude adequate implant support or retard healing) such as, blood supply impairment, insufficient bone quality or quantity, previous infection, obesity, severe bow or; gross distortion of the femur.

2. Mental conditions that preclude cooperation with the rehabilitation regimen.

Additional Contraindications for Pediatric and Intermediate Compression Hip Screws

- Fracture of the neck of the femur. The capital femoral epiphysis or trochanteric epiphysis should not be violated by the lag screw. Cessation of growth may take place.
- 2 Slipped upper epiphysis. The bones in the trochanteric area and in the center of the femoral neck are so dense and the target area in the head of the femur so small that other techniques are preferable.
- The Pediatric Compression Hip Screw is also contraindicated for patients under the age of 2 or over the age of 6 years.

WARNINGS

- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.
- 3. Because of unbalanced muscle forces, subtrochanteric fractures and osteotomies place extreme loads on implants, substantially reducing the chance of fracture healing with bending or breaking implant components. Additional precautions and internal or external supports should be utilized to enhance the stability of the fracture and to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph. Supplementary procedures such as bone graft or medial displacement osteotomy may also be considered.
- 4. Subtrochanteric and comminuted trochanteric fractures and osteotomies place increased stresses on bone plates. Plate length should be increased to provide maximal fixation. The highest angle plate is recommended. Length of plate must allow engagement of the maximum number of cortical screws in the intact femoral shaft distal to the fracture line. The length of time for non- or limited weight bearing should be correspondingly increased until solid bony union occurs.

- 5. The threads of an implanted lag screw should not engage the fracture line. The screw threads should be firmly fixed in bone and the screw should be long enough to permit telescopic sliding in the event of resorption of the fracture surface.
- Do not mix dissimilar metals. Use only stainless steel screws with stainless steel devices, Ti-6A-4V screws with Ti-6A-4V devices, and Ti-13Nb-13Zr screws with Ti-13Nb-13Zr devices.

PRECAUTIONS

- Use extreme care in handling and storing implant components. Cutting, bending or scratching the surface of metal components can cause internal stresses which significantly reduce the strength and fatigue resistance.
- 2. Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact.
- 3. While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished.
- Surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.

ADVERSE EFFECTS

- 1. Loosening, bending, cracking or fracture of implant components.
- 2. Loss of anatomic position with malunion may occur
- 3. Infections, both deep and superficial, have been reported.
- 4. Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis of the femoral head may result from the surgery and concomitant use of internal fixation devices.
- 5. Leg length discrepancies and subsequent patient limp may occur.
- 6. Screw cutting through the femoral head (usually associated with osteoporotic bone), penetration of the joint by a lag screw with or without chondrolysis, and failure of a lag screw to slide in the barrel, especially with low angle plates and/or improper screw plate assembly have been reported.
- 7. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
- 8. Penetration of a guide wire/screw into the pelvis can occur.
- 9. Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.
- 10. Damage to the femoral capital epiphysis due to trauma during surgery or improper position or length of compression screws and guide wires.

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION/RESTERILIZATION

Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

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

- Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 15 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants.

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.

IMPORTANT MEDICAL INFORMATION Warnings and Precautions INTRAMEDULLARY NAIL SYSTEM

SPECIAL NOTE

The Intramedullary Nail System consists of interlocking intramedullary nails and interlocking fusion nails and pins. Intramedullary nails contain holes proximally and distally to accept locking screws. Components are available in many styles and sizes and are manufactured from various types of metals. The component material is provided on the outside carton label. Use only components made from the same material together. Do not mix dissimilar metals or components from different manufacturers. Refer to manufacturer literature for specific product information. All implantable devices are designed for single use only.

Intramedullary Interlocking Nails are provided with a variety of screw placement options based on surgical approach, antegrade or retrograde, and indications.

Interlocking Fusion Nails indicated for joint arthrodesis have screw holes for locking on either side of the joint being fused. The locking screws reduce the likelihood of shortening and rotation of the fusion site.

INDICATIONS

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 simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; poly-trauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability are indicated for the following: subtrochanteric fractures with lesser trochanteric involvement; ipsilateral femoral shaft/neck fractures; and intertrochanteric fractures.

In addition to the indications for interlocking intramedullary nails, devices that utilize a retrograde femoral surgical approach are indicated for the following: severely comminuted supracondylar fractures with or without difficult intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants.

Indications for the **ReVision Nail** include the following: degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations in the hindfoot; tibiocalcaneal arthrodesis; combined arthrodesis of the ankle and subtalar joints; avascular necrosis of the ankle and subtalar joints; failed total ankle replacement with subtalar 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 subtalar joint.

Knee Fusion Nails are intended for intramedullary knee arthrodesis.

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. Active infection.
- 4. The presence of a previously inserted fracture fixation device.
- 5. Preexisting bone deformity.
- 6. Hypovolemia, hypothermia and coagulopathy.
- 7. Mental conditions that preclude cooperation with the rehabilitation regimen.
- The forearm nail should not be used in children who have not reached skeletal maturity.

WARNINGS

- This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- 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.
- The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.
- Do not mix dissimilar metals. Use only stainless steel screws with stainless steel devices, and Ti-6AI-4V screws with Ti-6AI-4V devices.

PRECAUTIONS

 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 noninternal stresses that could lead to fracture of the implants.

- Surgical technique information is available upon request. The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.
- The use of locking screws is necessary for strength and compatibility. Please refer to the surgical technique or product catalog for information on the correct size of screws for each nail.
- The patient should be advised that a second, more minor procedure for the removal of implants is usually necessary.
- 5. While the surgeon must make the final decision regarding implant removal, wherever 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. Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact. Patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed or non-union, must have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries.
- 7. 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.
- 8. Patients should be cautioned against unassisted activity that requires walking or lifting.
- Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident.
- 10. 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.

POSSIBLE ADVERSE EFFECTS

- 1. Loosening, bending, cracking or fracture of the implant components.
- Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation may occur.
- 3. Infections, both deep and superficial, have been reported.
- 4. Irritational injury of soft tissues, including impingement syndrome.
- 5. Supracondylar fractures from retrograde nailing.
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants.
- Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION/RESTERILIZATION

Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to 25 kiloGrays of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

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

- Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig [2.8 bars] & Minimum = 10.0 inHg [339 millibars]) with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 15 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants.

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.

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Smith & Nephew, Inc. • 1450 Brooks Road • Memphis, TN 38116 U.S.A. (901) 396-2121 • For information: 1-800-821-5700 • For orders and order inquiries: 1-800-238-7538

The following statement is required by the U.S. FDA: WARNING: This device is not approved for screw attachment or screw fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.