Technique Manual
of
SIGN IM Nail & Interlocking Screw System
Insertion & Extraction Guide

www.sign-post.org

Revision # TM-2011.07.01

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Lewis G. Zirkle, M.D.
President & Founder

Dear SIGN Partner:

SIGN implants are made from stainless steel that satisfies ASTM implant-grade material specifications acceptable to the U.S. FDA. Our orthopaedic hardware manufacturing operation is being conducted in accordance with national good manufacturing practices and quality assurance standards. The SIGN IM Nail is a legally distributed device in the United States.

Features of the SIGN nail

- Interlocking can be accomplished without C-arm
- Stainless steel-less adherence of biofilm than titanium alloy, easier to remove stainless steel nail than titanium
- Solid-stronger with less bending than hollow nails. Less infection as less area for biofilm to adhere
- Slots-allow for compression and distraction of fracture site to accelerate healing
- 9º bend in proximal nail
- 1-1/2º bend in distal end for easier insertion

The SIGN Surgical Database was implemented in August 2003 to record SIGN surgeries. We request that each SIGN surgery be recorded in the database, photos of pre and post op x-rays are requested to accompany each report. Follow-up x-rays are appreciated. We will answer your questions or comments in the comment section.

We value your comments on any aspect of SIGN. It is a team effort. We can be reached by e-mail, fax, or telephone.

The SIGN technique manual is updated frequently. For updates please visit our website at www.sign-post.org and click on manual, username **sign** and password **03signtech**. Please read this manual several times before your first SIGN surgery. Refer to it for each step in the OR as you do your first surgeries.

Sincerely,

Lewis G. Zirkle, M.D.
SIGN Founder & President

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

SIGN STANDARD IM NAILS AND FIN NAILS

DESCRIPTION: SIGN intramedullary rods, fin nails and screws are designed to provide fixation of tibial, femoral and humeral fractures while they heal.

INFORMATION FOR USE: The surgeon must select the type and size that best meets the patient's requirements for close adaptation and firm seating with adequate support.

INDICATIONS: The SIGN IM Nail is indicated for internal fixation of diaphyseal tibial fractures and distal femur fractures including transverse fractures, oblique and spiral fractures, comminuted fractures, fractures with bone loss, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, nonunions, malunions and fractures of the proximal femur. The SIGN Fin nail is indicated for internal fixation of stable fractures in the femur and humerus.

CONTRAINDICATIONS: Active or latent infection. Wounds should be closed and dry. Osteoporosis, insufficient quantity or quality of bone/soft tissue. Material sensitivity. If suspected, tests are to be performed prior to implantation. Patients who are unwilling or incapable of following postoperative care instructions.

WARNINGS: For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, the method of application, instruments, and the recommended surgical technique for this device. Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening and migration. The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant including the possibility of the device failing as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail.

PRECAUTIONS: An implant shall never be reused. Previous stresses may have created imperfections which can lead to device failure. Instruments shall be inspected for wear or damage prior to usage. Protect implant appliances against scratching and nicking. Such stress concentrations can lead to failure.

ADVERSE EFFECTS: Fracture of the implant due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material. Pain, discomfort, or abnormal sensations due to the presence of an implant. Nerve damage resulting from surgical trauma. Necrosis of bone or bone resorption. Necrosis of tissue or inadequate healing may occur with any fracture.

STERILITY: All Implants and Instruments are provided *non-sterile*. Sterilization must be performed prior to surgery, using one of the following methods. For a gravity displacement autoclave, set at 250ºF (121ºC) for 30 min., allow drying time of 45 min. For a prevacuum autoclave, set at 270ºF (132ºC) for 4 min., allow drying time of 30 min. or at 273ºF-279ºF (134ºC to 137ºC) for 3

min., allow drying time of 16 min. Please consider your equipment manufacturer's written instructions for the specific sterilizer and load configuration being used and current AORN standards and recommended practices. **NOTE:** these parameters are for full loads using wrapped sets, rigid containers and /or peel pouches.

STORAGE INSTRUCTIONS: Store in a cool dry place, and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering, damage, or water contamination. Use oldest lots first.

SIGN INSTRUMENTS: SIGN instruments are reusable; however, they have a limited life span. Prior to and after each use, the instruments must be inspected where applicable for sharpness, wear, damage, proper cleaning, corrosion and integrity of the connecting mechanisms. Notify SIGN if they should be replaced. Instrument breakage or damage can occur when an instrument is subjected to excessive loads, speeds, or dense bone. Striking the cutting surfaces with other metal will cause these surfaces to become dull.

CLEANING: SIGN instruments and accessories must be thoroughly cleaned before reuse. Decontamination of reusable instruments should occur immediately after completion of the surgical procedure. Excess blood or debris should be wiped off to prevent it from drying onto the surface. Use an enzymatic-cleaning product such as Enzol.

NOTE: Even surgical instruments manufactured from high-grade stainless steel must be dried thoroughly to prevent rust formation. All devices must be inspected for cleanliness of surface and joints, proper function, and wear and tear prior to sterilization.

SHARPENING: The drill bits become dull if they are dinged by hitting the nail or other metal. They should be protected during surgery, cleaning and sterilization. They are also dulled by pushing drill bits into bone when they are not advancing. The drill bit heats up and becomes dull.

INDICATIONS FOR SIGN NAIL

FRACTURE TYPE

a. Closed at time of injury

Fractures that cannot be reduced or lose reduction.

b. Open-acute

Fractures that are Gustilo grade I, II, III a, debrided and closed within 24 hours of injury may have immediate SIGN nail insertion. Sometimes this time limit is impossible, so we must study the elapsed time between injury and surgery if antibiotics are given within 6 hours from injury. If closure is delayed, the surgeon should determine when the SIGN nail is placed at wound closure.

c. Open-delayed closure

Debrided and covered by skin, muscle or free flap, with no drainage, may have SIGN nail insertion.

d. Fractures treated by external fixation

Risk of infection is increased if external fixation pins are present for over 10 days but we are studying this as closure at 10 days may not be indicated.

e. Non-unions

PATIENT PREPARATION

Patient must have no infected areas or injuries that preclude surgery. Patient should be told about risks, benefits of surgery and agree to insertion of SIGN nail. Please check the patient's skin the night before surgery. If possible, washing the patient's leg should be done the night before. The cast may be removed for washing.

Check list for the night before surgery

1. Any infections? Where? – Surgery should be postponed.
2. Skin of extremity washed well.
3. Range of motion of knee? – need 60° flexion to do retrograde femur approach.
4. Template X-rays to estimate size of nail, screws.
5. X-rays to be in OR.
6. Check appropriate lab work.

SURGEON PREPARATION

Read the technique manual and /or watch the technique CD. Be contemplative surgeons.

X-RAYS

X-rays should include knee and ankle on the same film to measure the nail. X-rays should be present in OR during surgery. Look carefully for fracture comminution.

ANTIBIOTICS

Antibiotics are started 1 hour before surgery.

OPERATING ROOM EQUIPMENT

These materials, which are not part of the SIGN set, should be present in the operating room: drill; chuck key; mallet; bone holding forceps; knife; forceps; clamps; cautery; suction; towel clips; needle holders; sutures; retractors, bone reamer, curved awl and periosteal elevator.

All personnel must wear masks, hats, and cover as much skin as possible. Bacteria spread to the wound on skin cells from people in the operating room. Traffic in the OR should be minimal.

(SIGN) EQUIPMENT NECESSARY FOR USE OF SIGN NAIL:

- L-handle
- Locking Bolt - (2) one is extra
- Target Arm (Long Proximal Target Arm, Distal Target Arm)
- Short Target Arm (for use with nails shorter than 280mm)
- Distal Cap Screws - (4) two are extra
- Shoulder Cap Screw - (2) one is extra
- Combination Hex Wrench - (2) one end fits the Locking Bolt, Shoulder Cap Screw and Distal Cap Screws. The other end fits the interlocking screws.
- Cannula
- Alignment Pin - (2)
- Drill Guides - (2) (one large for large drill bits) (one small for small drill bits)
- Drill Bits
    - Large (2) (6.3mm) for near cortex
    - Small (2) (3.5mm) for both near & far cortex
- Screw Caddy and SIGN Interlocking screw assortment
- SIGN IM nail assortment

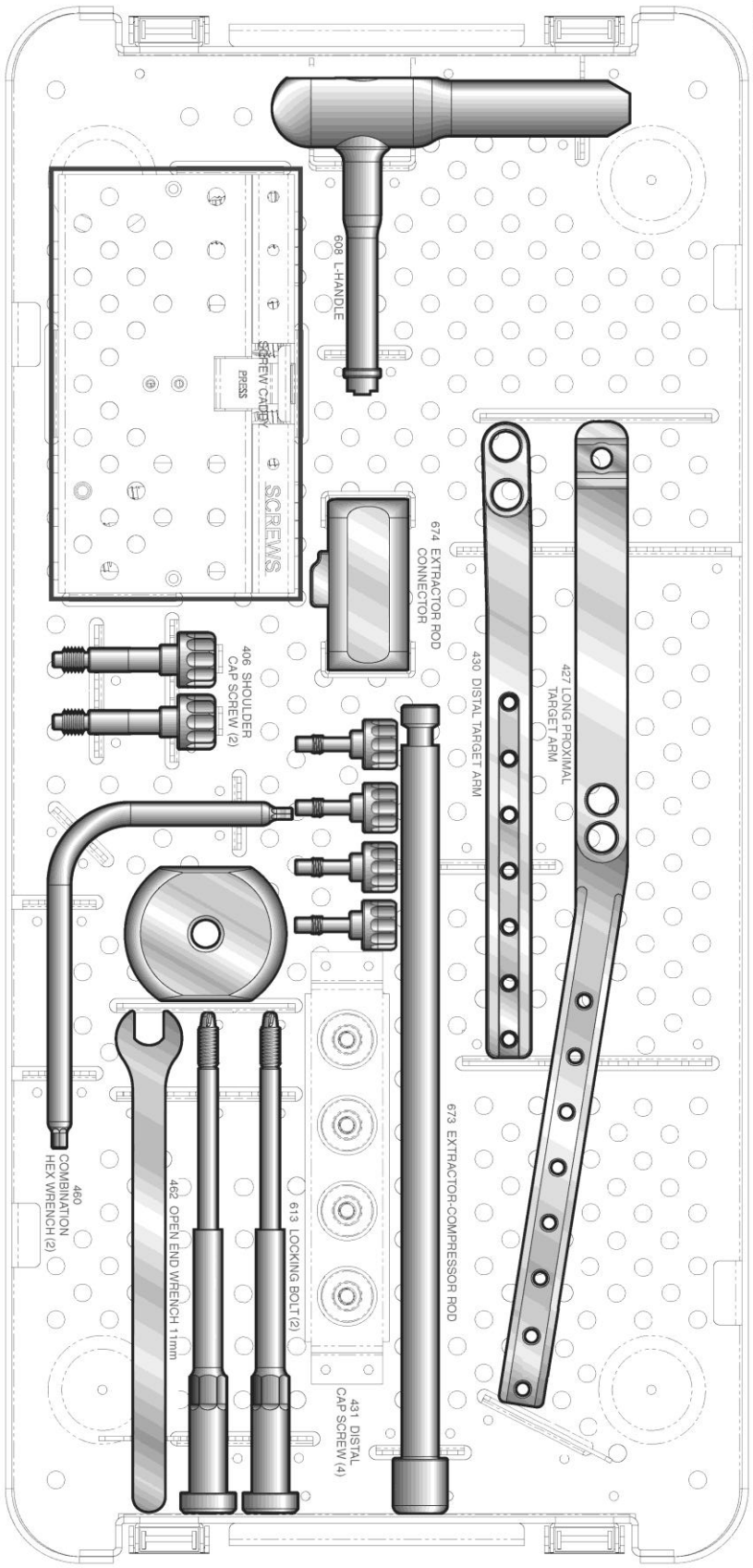
> Be sure an assortment of sizes are sterilized.

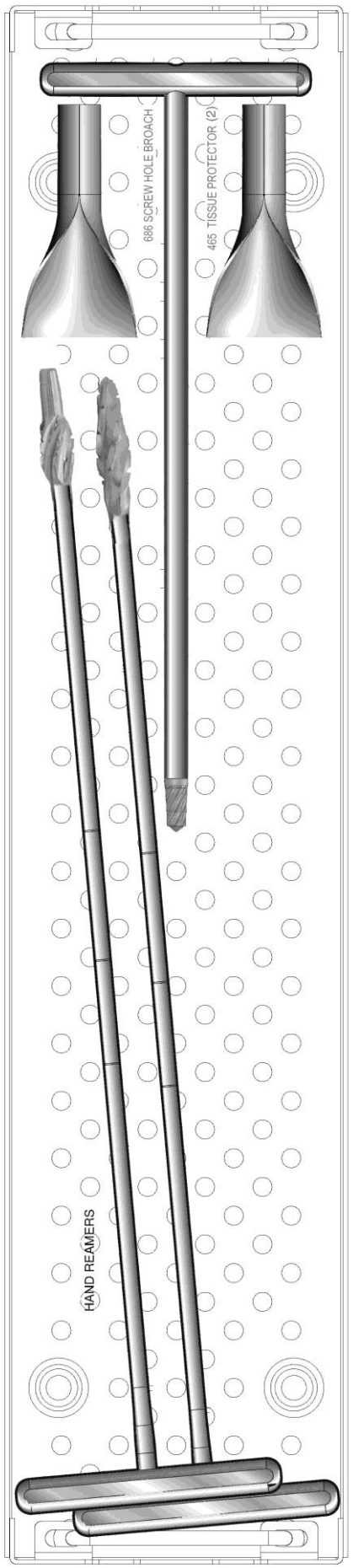
- Hex Driver (3.5mm)
- Extractor/Compressor Set
    - Extractor Rod Connector
    - Extractor-Compressor Rod
    - Slap Hammer Weight
- Slot Finders: Cannulated, Solid and Curved (one of each)
- 11mm Wrench
- Tissue Protector - (2) one is extra (**these are reusable**)
- Depth Gauge
- Step Drill
- Screw Hole Broach

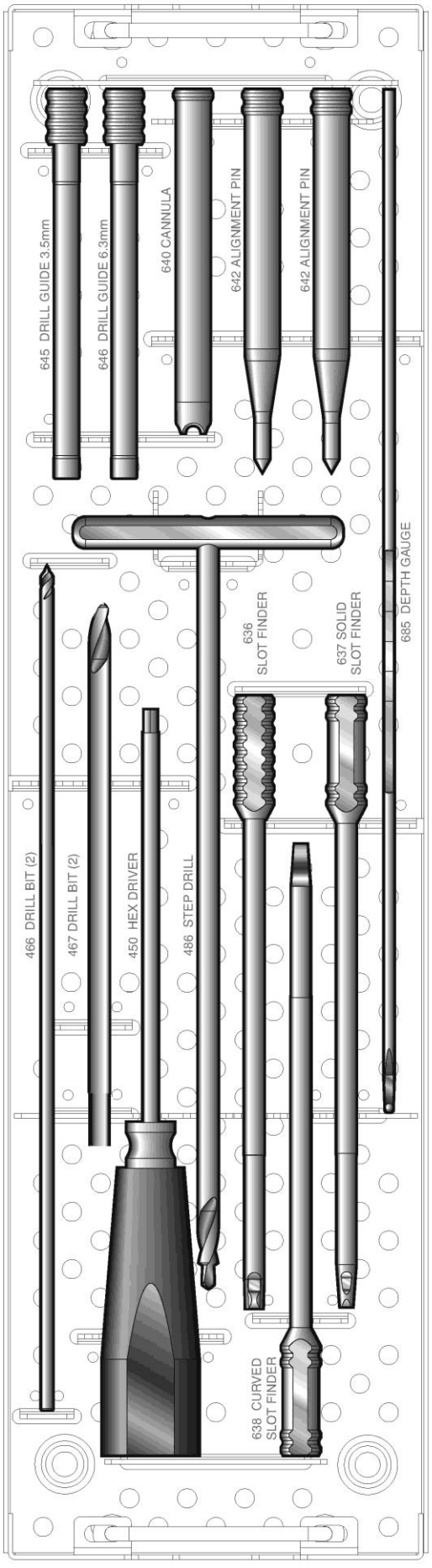
Care of SIGN Equipment:

It is essential that the equipment be well maintained as described on Page 4. Sometimes during the surgery the cannula and drill bits become bloody. They should be washed off before the next interlock, as they may stick due to the close fit. This also applies to the threads of caps screws.

NOTE: Please protect the drill bits, reamers and step drill from striking metal objects during surgery and cleaning.


608 L-HANDLE
SCREW CADDY
PRESS
SCREWS
674 EXTRACTOR ROD CONNECTOR
406 SHOULDER CAP SCREW (2)
430 DISTAL TARGET ARM
427 LONG PROXIMAL TARGET ARM
673 EXTRACTOR-COMPRESSOR ROD
460 COMBINATION HEX WRENCH (2)
462 OPEN END WRENCH 11mm
613 LOCKING BOLT (2)
431 DISTAL CAP SCREW (4)


HAND REAMERS
686 SCREW HOLE BROACH
465 TISSUE PROTECTOR (2)

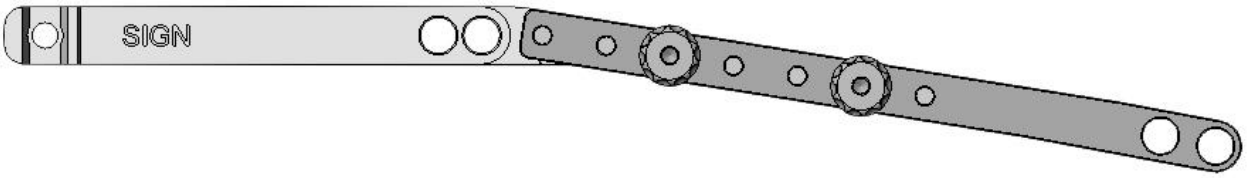

645 DRILL GUIDE 3.5mm
646 DRILL GUIDE 6.3mm
640 CANNULA
642 ALIGNMENT PIN
642 ALIGNMENT PIN
685 DEPTH GAUGE
636 SLOT FINDER
637 SOLID SLOT FINDER
466 DRILL BIT (2)
467 DRILL BIT (2)
450 HEX DRIVER
486 STEP DRILL
638 CURVED SLOT FINDER

SIGN NAILS

Standard Length – Tibia/Femur
Diameter = 8mm, 9mm, 10mm, 11mm and 12mm
Length = 280mm, 300mm, 320mm, 340mm, 360mm, 380mm, 400mm and 420mm

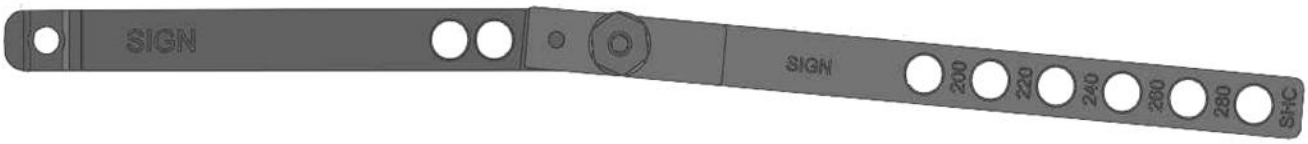
A solid nail decreases the risk of infection. The 9º proximal bend can be used in tibia, femur and humerus. The 1.5º bend makes canal penetration less likely during insertion.

Standard Target Arm



Short Length to be used with the Short Target Arm
Diameter = 8mm, 9mm, 10mm
Length = 220mm, 240mm and 260mm

Short Target Arm for Fin, Hip and Pediatric Nails



Technique for fractures in <u>all</u> locations

Patient Preparation

Check for open wounds

Check the patient the night before the operation for open wound. Remove cast the night before to check skin condition. Cancel surgery if open wound is present. Wash the extremity the night before to decrease skin bacteria.

Antibiotic prophylaxis

Start IV antibiotics 1 hour before surgery. Patients with open fractures should be given antibiotics as soon after surgery as possible. Antibiotic should be given to patients with closed fractures one hour prior to incision.

Pre-op scrub for surgeon and patient, Hexachlorophene is best, Betadine is less effective.

Soft tissue evaluation

If the fracture is open, the wound should be debrided, irrigated and evaluated as to whether wound closure can be done. Factors that must be considered are contamination by virulent bacteria, high energy vs. low energy trauma, foreign bodies. Virulent bacteria occur from "barnyard injuries" or areas where bacteria are prevalent. The degree of injury is also determined by the forces that cause the injury. These forces may destroy large amounts of muscle which leaves a dead space after debridement. This dead space must be closed before the nail can be inserted. Therefore, the wound classification is divided into wounds that can be closed without risk of infection, and those that can't. Whenever a wound can be closed without risk of infection, a nail can be inserted.

Reduction of closed fracture

Closed reduction can often be accomplished if the fracture is less than 7-10 days old. If closed reduction is attempted, check stability in all planes prior to the reduction so you can test and compare the stability after the reamer or nail is inserted. The reamers are passed into both fragments followed by the nail.

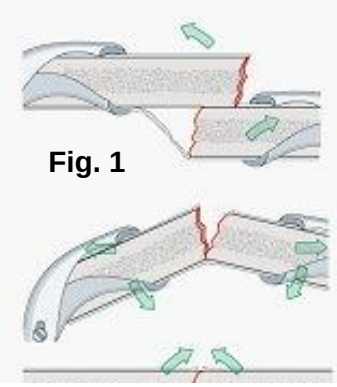
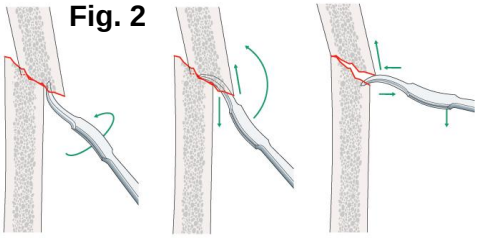


Fig. 1

Open reduction is necessary if the fracture is beginning to heal. Transverse fractures can be reduced after both ends have been freed from soft tissue. Figure 1 demonstrates one method. Allow the tissues to slowly elongate during reduction. Figure 2 demonstrates reduction of oblique fractures. Before reduction is accomplished, ream both sides of the fracture site. Stop reaming at the metaphysis.

Fig. 2



The reamer should be turned 360º in clockwise direction **both** during insertion and removal of the reamer from the canal. The cutting edges of the reamer are damaged by reaming counterclockwise or to-fro reaming. Save the bone in a bone cup. Do not place on a sponge or in saline. Use gradual distraction and allow time for the tissues to stretch.

Nail Preparation

Assemble the Nail

Insert the locking bolt through the hollow stem of the L-handle, figure 6.

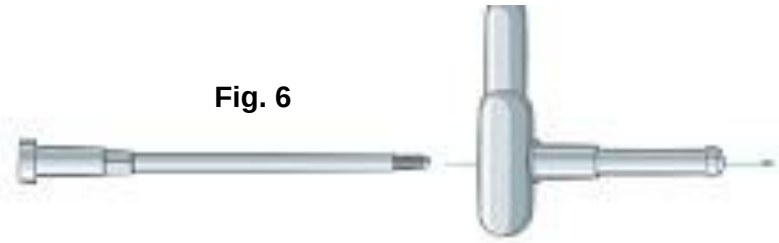


Fig. 6

Align the notches in the nail to the corresponding protrusions on the stem tube of the L-handle, figure 6. Be sure the L-handle rests on the side for proper interlock.

NOTE: Be sure the locking bolt rests as far down the stem tube as possible, figure 7.

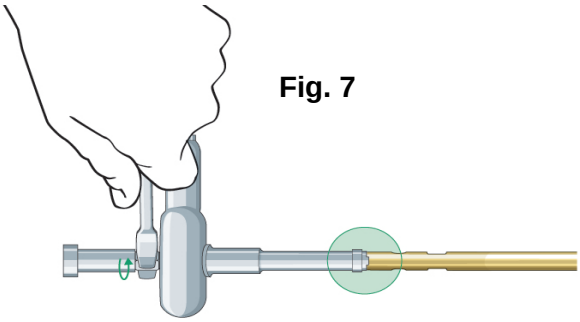


Fig. 7

Tighten the bolt into the nail, figure 7. If the locking is not progressing easily through the L-handle and into the nail, unscrew the locking bolt and reorient the locking bolt so that it enters the canal of the nail easily.

Attach target arm

Attach the assembled L-handle and nail to the proximal target arm using the shoulder cap screw, figure 8. Place the screw on the preferred side of the L-handle for interlocking. Push the shoulder cap screw in and carefully tighten by hand. Use the hex wrench to secure the target arm to the L-handle. If the shoulder cap screw does not turn easily, adjust the junction between the L-handle and the target arm.

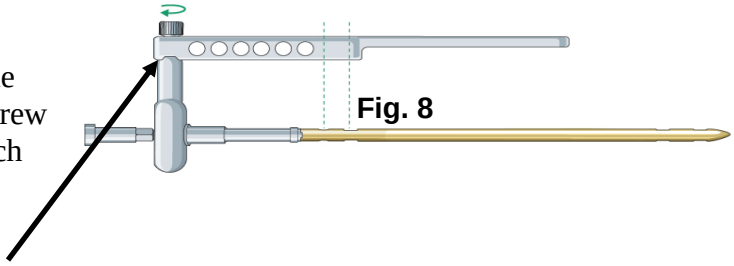


Fig. 8

Attach distal target arm to proximal target arm

Place the alignment pin through the end hole in the distal target arm and distal slot in the nail, figure 9. The distal cap screws are now placed to connect the proximal and distal target arms. Leave 2 holes between the two distal cap screws for stability. Withdraw the alignment pin so only the tip is in the slot to check alignment of the target arm as the distal cap screws are hand tightened. Use progressive alternative tightening; tighten one screw a little and then the other a little at a time, final tightening by hex wrench. Recheck alignment of alignment pin to the slot.

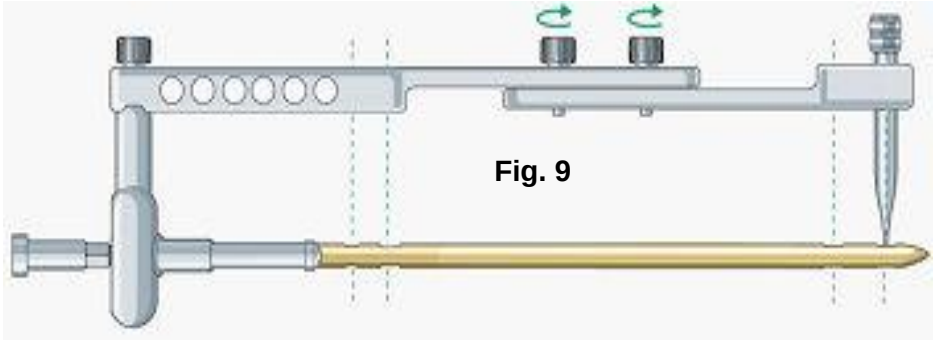


Fig. 9

Pearl: Insert caps screws downwards
The shoulder and distal cap screws are inserted easier if they are inserted in a downward direction so the target arm is parallel to the floor and the cap screws are perpendicular to the floor. Removal is the reverse. This avoids stripping the cap screw threads.

Remove the target arm
Remove the target arm from the L-handle, leaving the L-handle attached to the nail, figure 10.

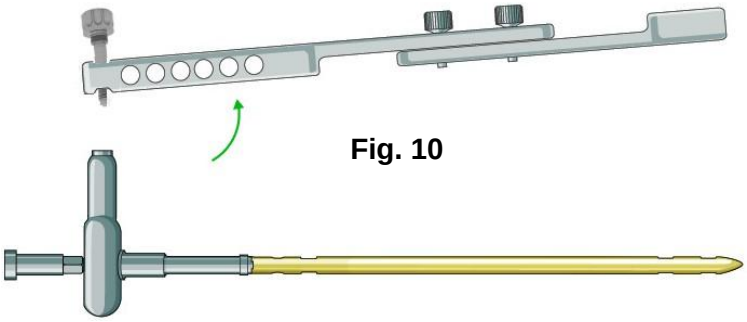


Fig. 10

Nail Insertion

Use the tissue protector to prevent the nail from touching the skin. Push the nail into the canal as far as possible. Many surgeons do not use a mallet to insert the nail. If you decide to use a mallet, use small taps and rotate the nail 10º as it proceeds down the canal, figure 11. Apply counter pressure to allow advance. If the nail does not advance with the small taps, consider using a smaller diameter nail or reaming more. Hitting the nail forcibly will bend the nail and make interlock more difficult.

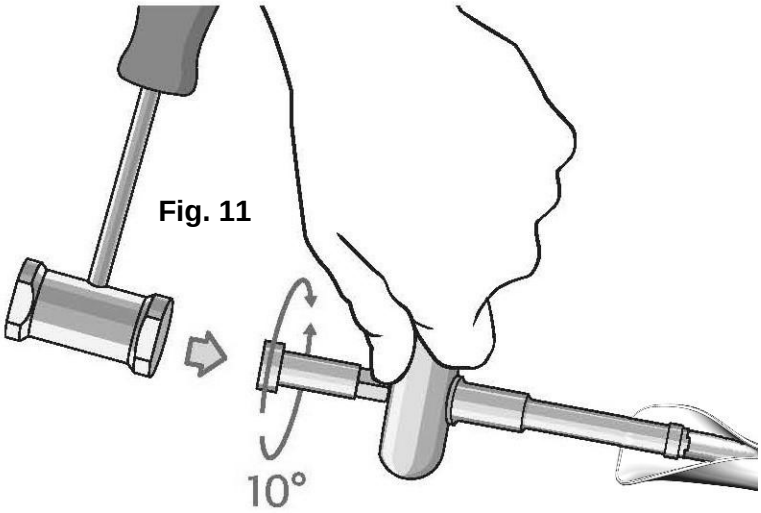


Fig. 11

Leave the proximal 3mm of the nail above the cortical bone to provide additional stability. Remember the ring on the stem tube is 3mm above the nail, figure 12.

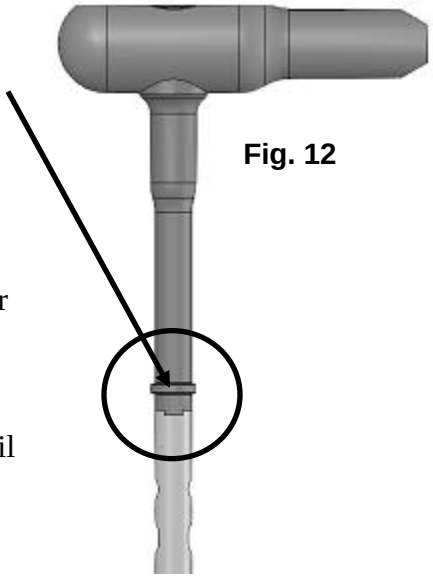


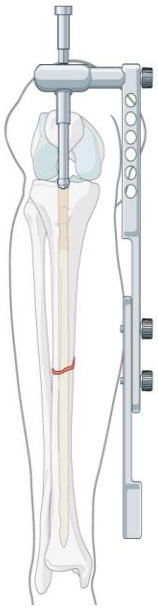
Fig. 12

Distal Interlock

If you follow this technique, distal interlock without C-arm is successful quickly in approximately 80% of your surgeries. Further techniques to obtain distal interlock are listed after this technique. Please send us your ideas.

The distal interlock is done before the proximal interlock so the nail can be rotated to find the slot in the nail.

Fig. 13



Reattach the target arm to the L-handle, figure 13. Be sure the locking bolt is tight.
Decide whether you will use 1 or 2 interlocking screws. If one interlocking screw is sufficient, place the screw in the hole nearest the fracture. Use the alignment pin to mark the location for the skin incision. Be sure the skin incision is large enough to place the cannula and your finger on the bone. This finger is used to identify the location of the cannula on the bone. If the cannula is directed by the target arm so it does not hit the bone, loosen the distal cap screws and adjust the target arm so the cannula will direct the hole into the cortex. You will find slot in nail for interlock by rotation of the nail. Champher the hole with the screw hole broach toward the bone.

Incise the fascia but use the periosteal elevator to spread the muscle down to the bone. Insert the cannula on the bone, figure 14. Use a curved clamp to remove soft tissue between the cannula and the bone. Be sure no fascial bands are pushing the cannula. Tap cannula lightly with a mallet to secure to the bone.

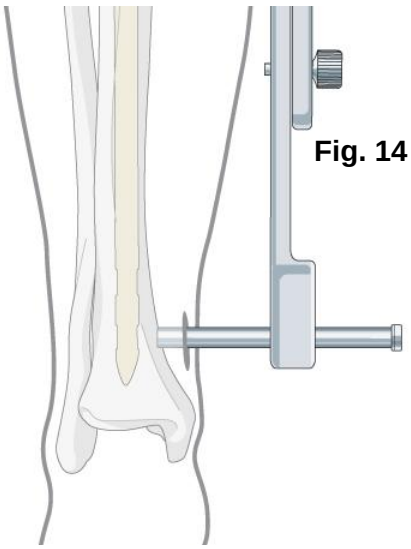


Fig. 14

Insert the small drill guide into the cannula and use a small drill bit to drill a hole through the near cortex. Avoid hitting the nail with the drill bit or it will become dull.

Insert the large drill guide and use the step drill or large drill bit to enlarge the pilot hole. Be sure the step drill tip engages the pilot hole, figure 15.

Stop rotating the step drill or drill bit when it stops suddenly after engaging in the slot of the nail. Further twisting will break the step drill. If the step drill does not progress, use the large drill bit.

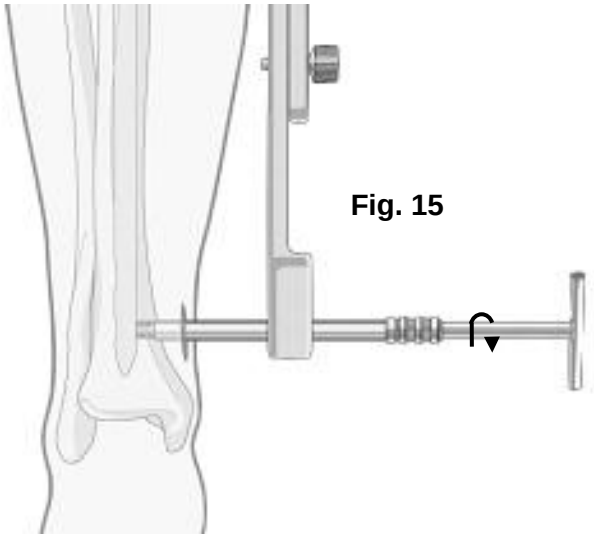


Fig. 15

Insert the solid slot finder through the hole in the near cortex, figure 16. In hard bone the screw hole broach inserted through the cannula must be used to enlarge the hole to allow the slot finders to enter the canal.

See figure 17 for comparison of screw hole broach and step drill.

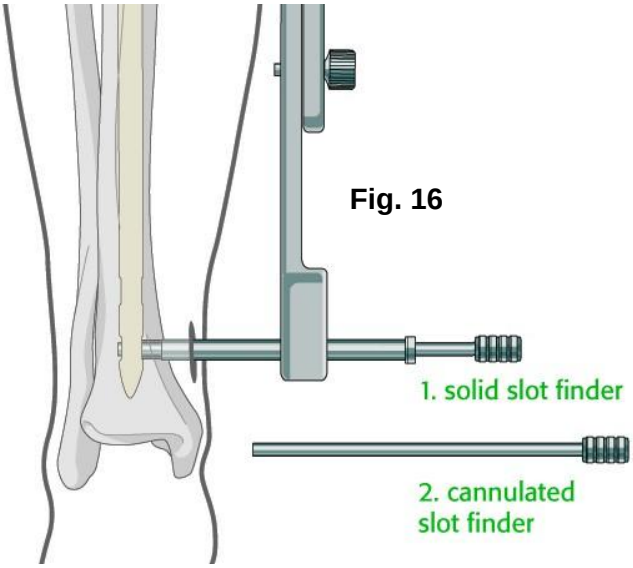


Fig. 16

Push the solid slot finder with the flats in the plane of the target arm. Rotation is not used to place the slot finder. Push the slot finder in. If the slot finder engages the slot in the nail, 10-15º of rotation with a sharp stop to the rotation will occur. This is the "SIGN feel." If the slot finder rotates 360º, it is not in the slot or stuck in the hole in the cortex. Rotate the nail to orient the slot in the nail parallel to the hole in the near cortex. If the solid slot finder enters the slot and the "SIGN feel" is felt, place the cannulated slot finder. Test again for "SIGN feel."

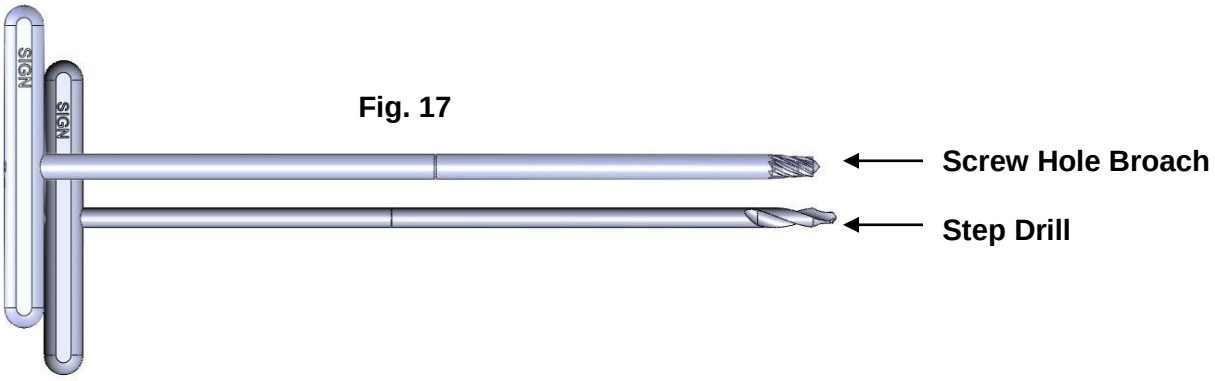


Fig. 17

Sometimes the cannulated slot finder will not proceed through the hole in the near cortex because it is wider than the solid slot finder. Use the screw hole broach to enlarge the hole if this occurs.

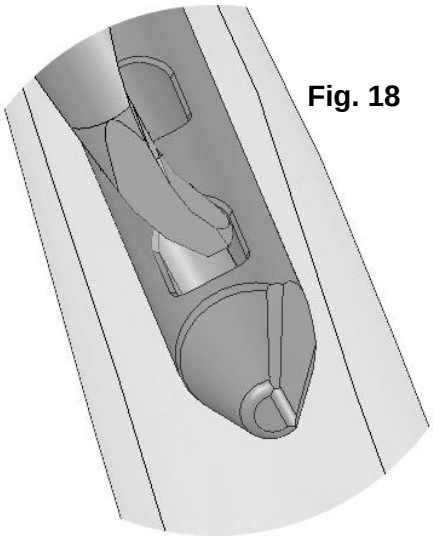


Fig. 18

If either slot finder does not enter the slot in the nail after rotation of the nail, **remove the target arm**; use the curved slot finder, figure 18, to locate the slot in the nail. Find the slot in the nail by combination of rotation of the nail by rotating the L-handle and slight pressure to push in the curved slot finder. The surgeon should both rotate the L-handle and manipulate the curved slot finder. Once the slot in the nail has been discovered by "SIGN feel," insert the cannulated slot finder and drill the hole in the far cortex.

If rotating the cannulated slot finder results in the "SIGN feel," place the small drill bit through the cannulated slot finder to drill a hole in the far cortex, figure 19.

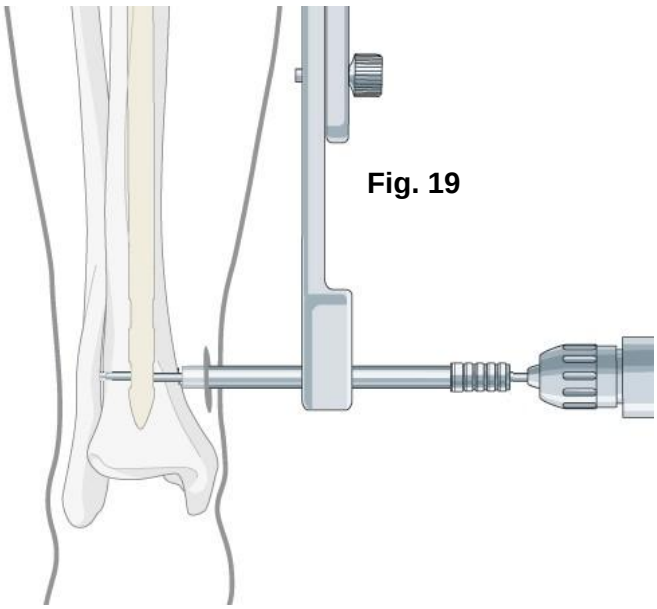


Fig. 19

Measure the proper length of the screw by placing the depth gauge through the cannulated slot finder. Do not bend the depth gauge. The depth gauge marks the hole. Remove the cannulated slot finder and measure the depth of the screw using the cannula and depth gauge, figures 20a and 20b.

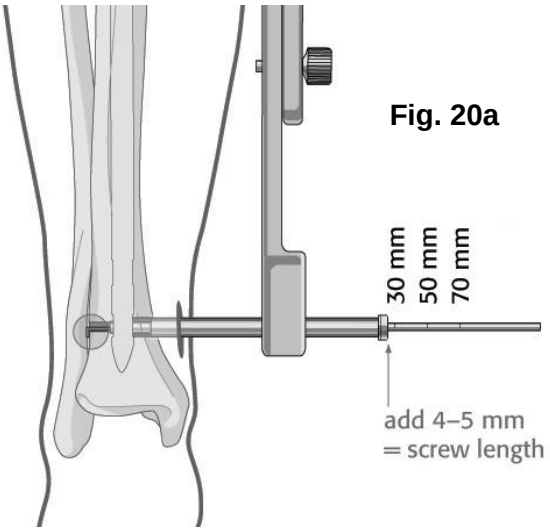


Fig. 20a

Add 5mm to the measurement so 2 threads can be inserted through the far hole and the head of the screw is 3mm prominent on the near cortex. This will make screw removal much easier should it be necessary.

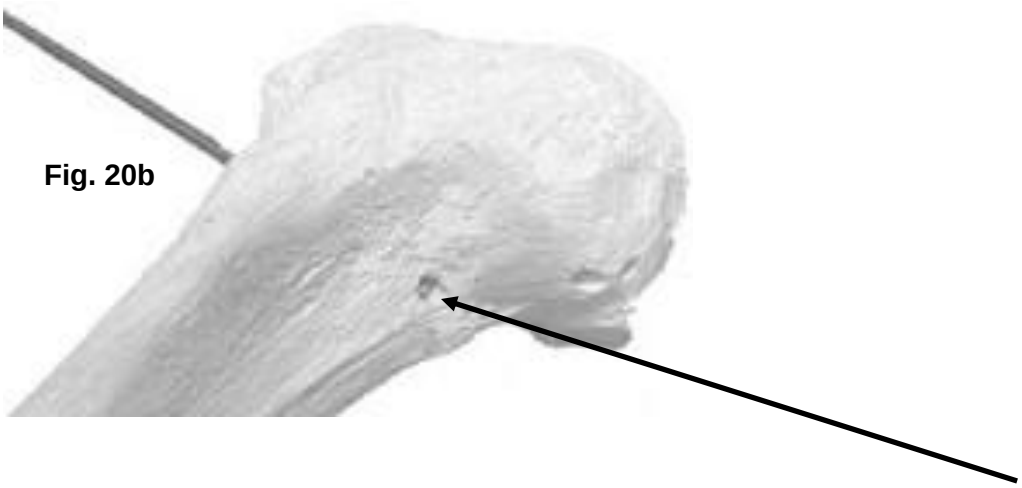


Fig. 20b

Use your gentle tactile sense to determine when the tip is caught on edge of the hole.

Insert the screw through the holes in the cortex and slot of the nail. Raise the cannula so the screw head can be visualized in order not to insert the screw too deeply, figure 21. Rotate the L-handle to be sure the screw is in the slot after the screw has been inserted.

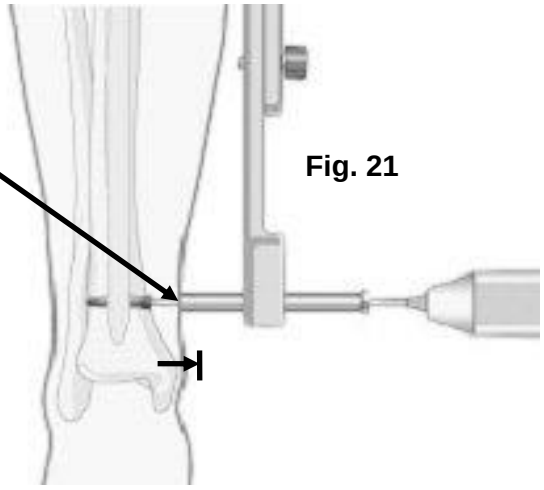


Fig. 21

Compress the fracture as needed after the first interlocking screw has been placed, see page 21.

Tips for interlocking
If either slot finder will not rotate after being placed into the hole in the near cortex, enlarge the hole with the screw hole broach. Often bone will remain in the hole even though the step drill enters the slot in the nail.

If the slot finder does not enter the slot in the nail, remove the target arm and use the curved slot finder. This step is necessary approximately 20% of the time. Place the curved slot finder through the hole in the near cortex and find the nail by tapping on it. Rotate the nail so the slot in the nail is parallel with the hole in the cortex. If the curved slot finder partially enters the slot, rotate the nail to allow it to fully enter the slot. Confirm location of the slot by using the solid slot finder and then the cannulated slot finder. Once the cannulated slot finder has been placed and confirmed by the "SIGN feel," drill the hole in the far cortex. Measure and place the screw.

If the curved slot finder does not enter the slot, check the longitudinal orientation. Be sure the reduction has not slipped. This will misalign the longitudinal orientation of the hole in the cortex and slot of the nail. Correct this misalignment and place the slot finder. Check to be sure the nail has not migrated proximally or distally which will also misalign the hole and slot in the longitudinal plane.

After placing the target arm on the L-handle, sometimes the cannula directs the small drill guide so it is not in contact with the bone cortex. If this occurs, loosen the distal cap screws and adjust the target arm so the pilot hole is directed through the cortex. In the femur this occurs in the anterior plane and in the tibia the posterior plane. Proceed with enlarging the hole in the near cortex and use the curved slot finder to find the slot in the nail. Sometimes it is necessary to champher the hole with the screw hole broach to allow slot finder to enter slot in nail. Rotate the nail by rotating L-handle to position slot in nail parallel with hole in near cortex.

EXTRACTION - EXTRACTOR/COMPRESSOR

If the fracture needs compression, place the extractor-compressor on the locking bolt and attach the compressor rod with the slap hammer attached. Back slap the fracture.

1. First, make sure the locking bolt is connected tightly to the nail through the L-handle, figure 22.

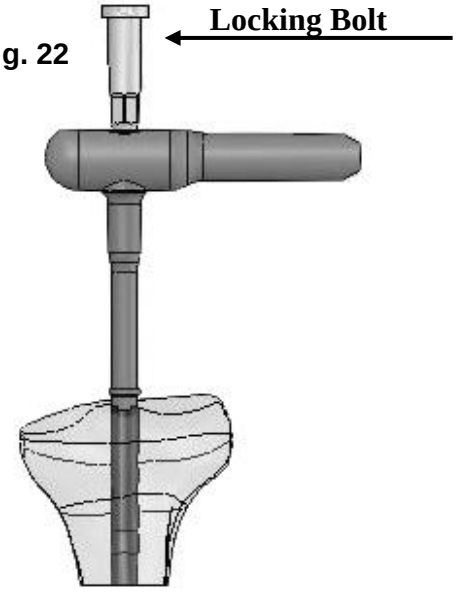


Fig. 22

2. Place the connector on the locking bolt by sliding the head of the bolt into the base of the connector, figure 23.

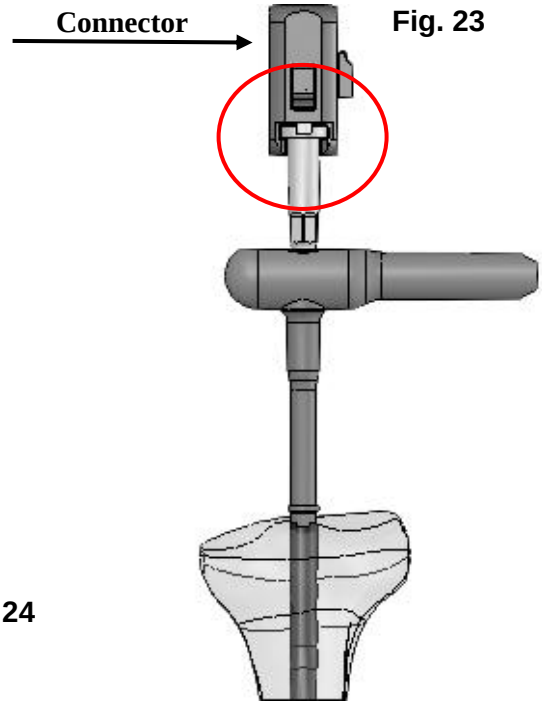


Fig. 23

3. Place the slap hammer weight on the connector rod, figure 24.

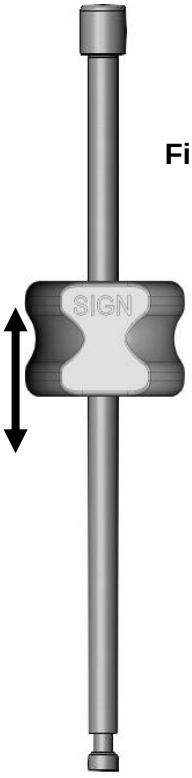


Fig. 24

4. Attach the connector rod to the connector. The extractor-compressor can now be used to extract the nail or compress the fracture figure, 25.

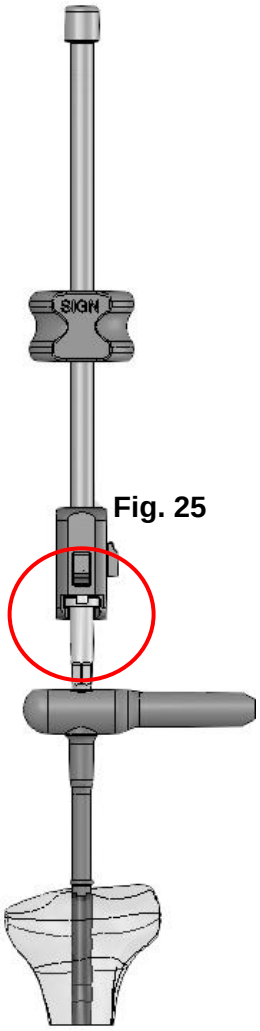


Fig. 25

Placement of the second distal interlocking screw
The second distal interlocking screw is used for additional stability.

Place the alignment pin in the hex of the head of the screw which has been inserted, figure 26. An assistant should be assigned to be sure this alignment pin remains in the hex. Rotate the L- handle and leave it in the center of the rotation.

The initial incision should be large enough to insert the second interlocking screw. Use the same procedure as the first distal interlocking screw.

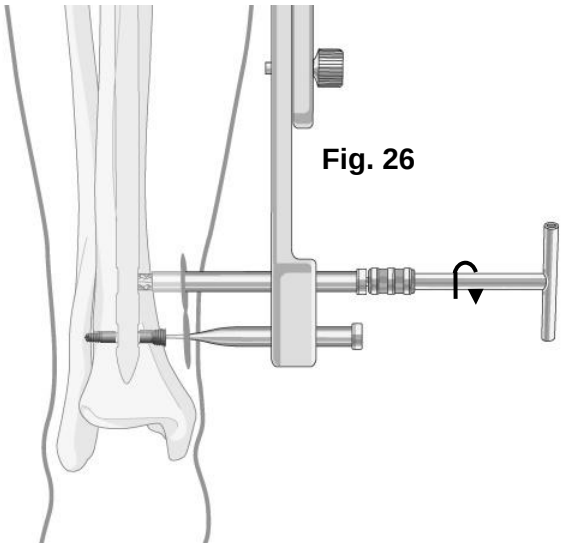


Fig. 26

Proximal interlocking screw fixation
Remove the alignment pin resting in the screw head of a distal interlocking screw. This is **not** necessary for the proximal interlocking.

Finding the slot and hole in the proximal nail does **not** require slot finder. The cannula and small drill guide are placed through the target arm and the hole is drilled through **both** near and far cortex. The hole is enlarged in the near cortex. The depth gauge is used to measure the length of the screw using the cannula and the proximal interlocking screws are placed. Remember the proximal apertures in the nail are a slot and a hole, figure 27.

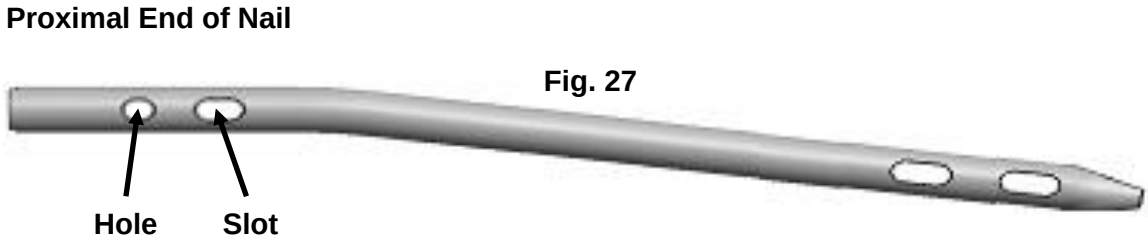


Fig. 27

Retrograde Approach to FEMUR

SIGN technique that is used in all bones is recorded beginning on page 11.

Indications distal
Fractures in the distal femur should be treated with retrograde approach. This is surgeon preference. If manipulation of the knee is done after the nail insertion and interlocking and range of motion exercises follow postoperatively, full range of motion usually is achieved and maintained.

Position of the patient
Supine position with a sterile bump or triangle under the knee. 60º of knee flexion is desirable. Knee extension and flexion allows better visualization of the femoral shaft.

Reduction of the closed fracture
Closed reduction can be done without C-arm in fresh fractures. Open reduction is accomplished by the mini incision technique dissecting through the muscle fibers without cutting them.

Skin incision
Some surgeons make a medial parapatellar incision for larger exposure. The median parapatellar attachments can be released and the patella subluxed slightly. This allows visualization of the femoral notch. After more experience, the surgeon makes the incision through the patellar tendon. This is done by flexing the knee so the patellar tendon can be palpated, incising the patellar tendon and removing a window in the fat pad to see the medial aspect of the femoral notch. See figure 32 in the tibia section on page 24.

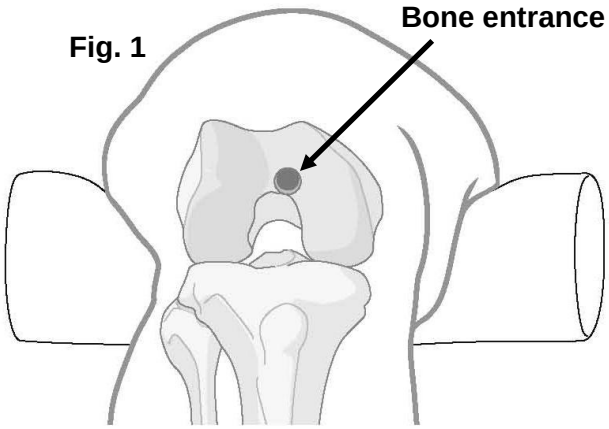


Fig. 1

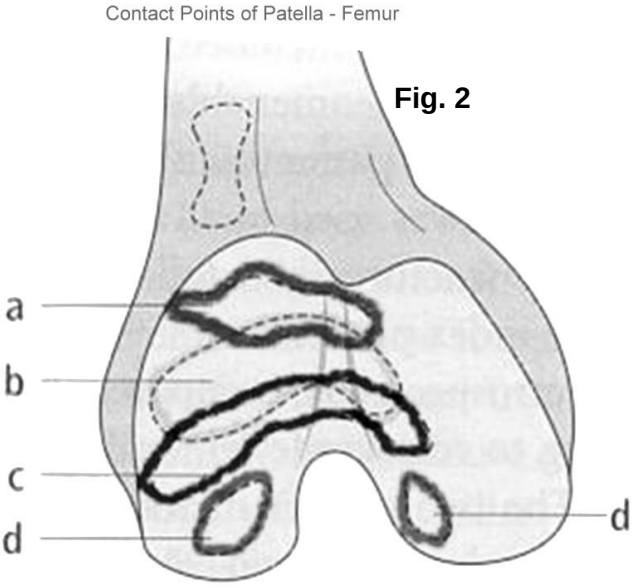


Fig. 2

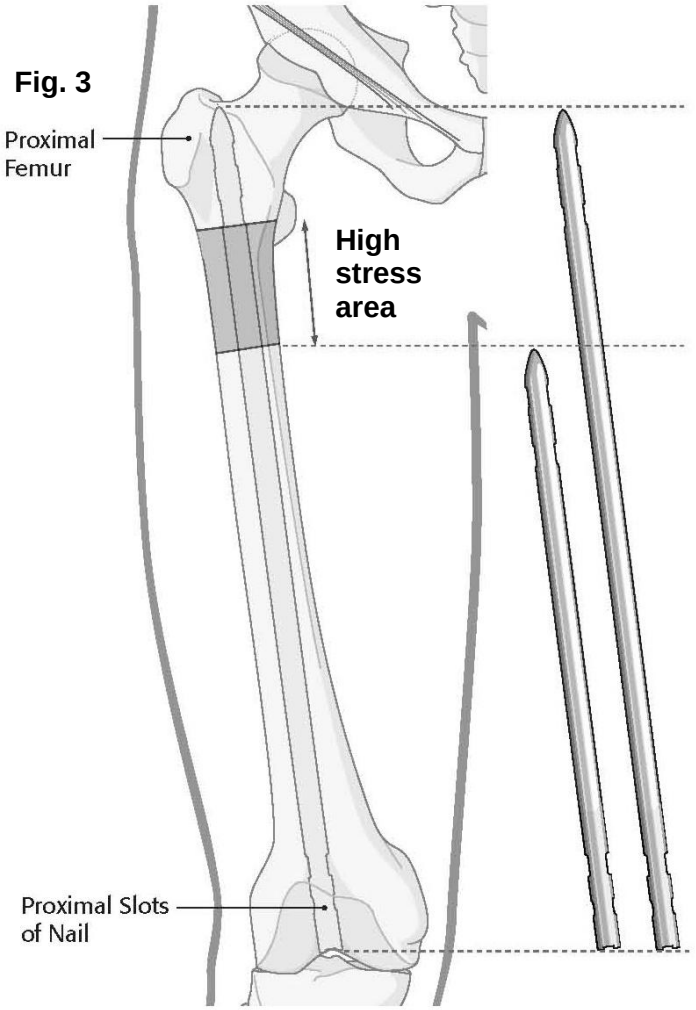
Bone entrance
Use curved awl to make entrance hole in the medial aspect of the femoral notch above the posterior cruciate ligament at junction of articular surface, figure 1.

If the entrance is placed too far posteriorly, the posterior cruciate blood supply will be compromised. The patella does not articulate with the articular surface in the area of the entrance hole, figure 2. Stabilize the distal femoral fragment as the bony entrance and reaming take place. Look at the fracture site to see the direction of the awl and subsequent reamers.

Reaming
Introduce the reamers after the bone entrance has been made using the awl. The reamers are rotated 360º in a clockwise manner. This is important to preserve the cutting edges which go only one way. Look at the distal femur fragment if the fracture site is exposed to direct the reamer. Save the bone from the flutes of the reamer in a bone cup for use as a bone graft. Do not place in sponge or saline. Diameter of the nail is determined by noting the size of the reamer that creates chatter in the isthmus of the femoral canal. Use a nail whose diameter is 2mm smaller than the reamer that created the chatter.

Nail insertion
The bend of the nail is angled apex **anteriorly**. The nail should not end at or less than 6cm below the lesser trochanter, figure 3. The nail may end short of this high stress area or extend past it. We are studying benefits of each length.

Fig. 3



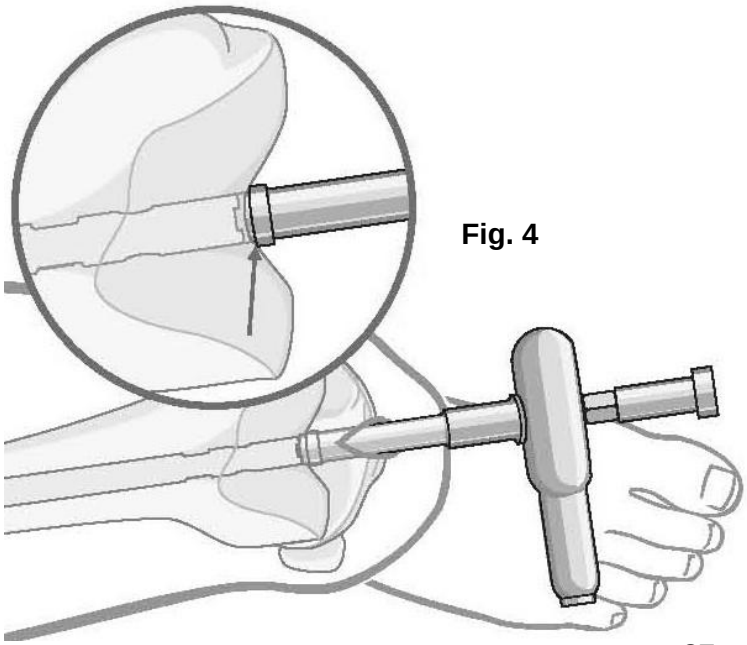


Fig. 4

Stop advancing the nail when the ring touches the articular cartilage on the medial femoral condyle, figure 4. Check the tightness of the locking bolt to the nail. The nail should be inserted so the ring rests on the articular surface of the medial femoral condyle. The nail will then be just below the articular surface, figure 4.

Distal interlock

The final location of the slots in the distal nail depends on the curve of the femur and the force necessary to insert the nail. SIGN nail is a straight nail. If it is inserted into the canal without a great deal of force, it will end up in the anterior portion of the femur, figure 5. The longer the nail, the more anterior the distal tip will be. Adjust the target arm (page 20) if the cannula rests too far anterior.

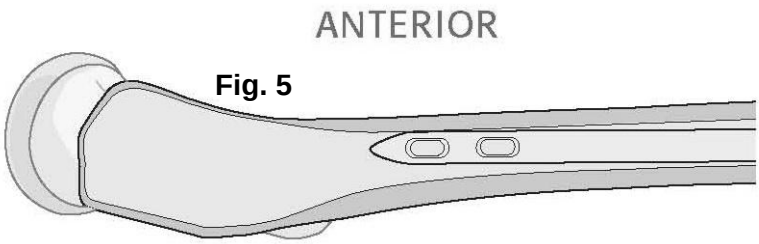


Fig. 5

If the nail is exerted with force it will bend and be more centrally located in the canal, figure 6. If the slots are in a narrow part of the femur, they will be more central in the canal, figure 6. The target arm may have to be adjusted to accommodate for bending of the nail. Loosen the distal cap screws and adjust the distal target arm.

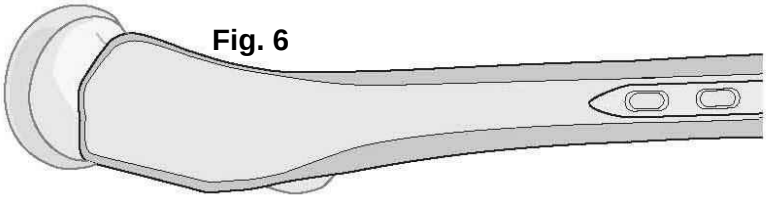


Fig. 6

Figure 7 and figure 8 illustrate the effect rotation has on the orientation of the slots. Rotation of the nail will place the slots in parallel with the hole in the near cortex. This is especially important with a curved slot finder.

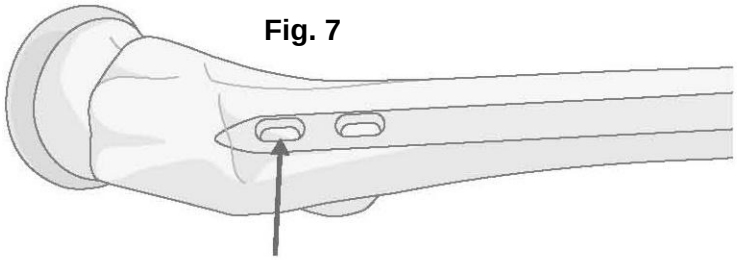


Fig. 7

Insert the solid slot finder. Keep the flat of the handle in line with the nail. Push it in the slot.

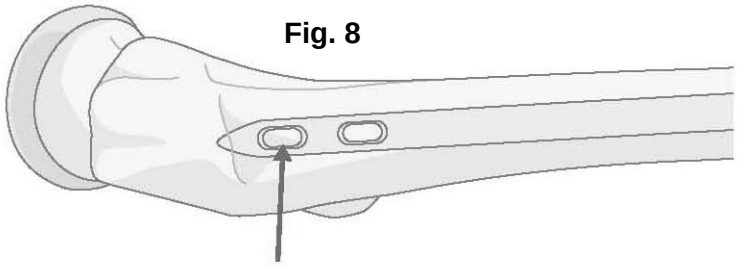


Fig. 8

The second "SIGN feel" is rotating the slot finder 10º when it is in the slot. If it does not rotate, it may be stuck in the bone hole or obliquely in the slot, figure 7. Sometimes the L-handle must be rotated to orient the slot to the hole, figure 7 and figure 8, or the screw hole broach needed to enlarge the hole.

NOTE: See technique used in all approaches on page 11.

If either slot finder cannot be placed, remove the target arm and use the **curved** slot finder. Be sure the fracture has not shifted or the hole will not be in longitudinal orientation to the slot. Rotate the nail to orient the slot to the hole. Practice this using the nail when not in the bone or use a sawbones.

After compression of fracture site

Some rotation is still possible if the proximal interlocking screw has been placed to impact the fracture, page 29. Use the usual technique for finding the distal slot in the nail. If more rotation is needed, the proximal screw closest to the knee may be removed to allow rotation. After the distal interlock has been accomplished, place the proximal interlock. See figure 9 on page 29.

NOTE: Distal and proximal refers to the nail rather than the bone, figure 9.

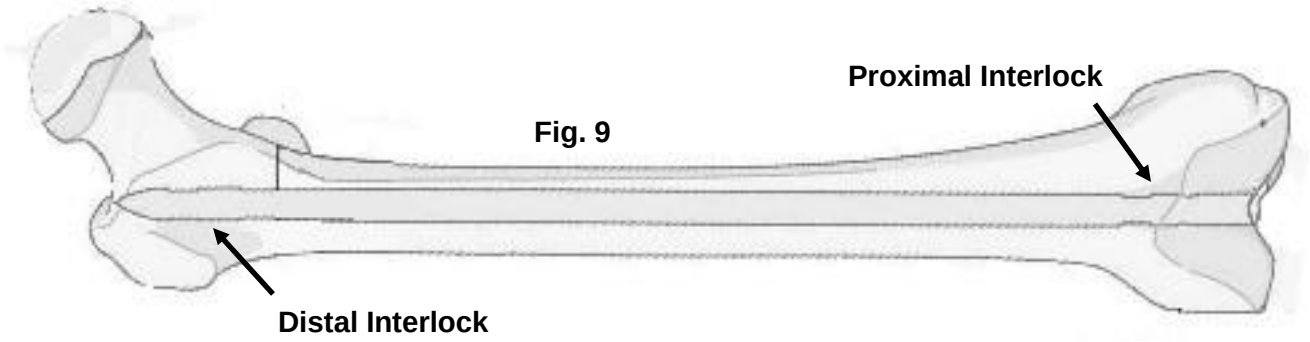


Fig. 9

NOTE: If you wish to compress the fracture site, place one interlocking screw in the nail hole nearest the knee. The locking bolt is struck to move the distal fracture fragment toward the proximal fragment, figure 10. **Different** from the antegrade approach.

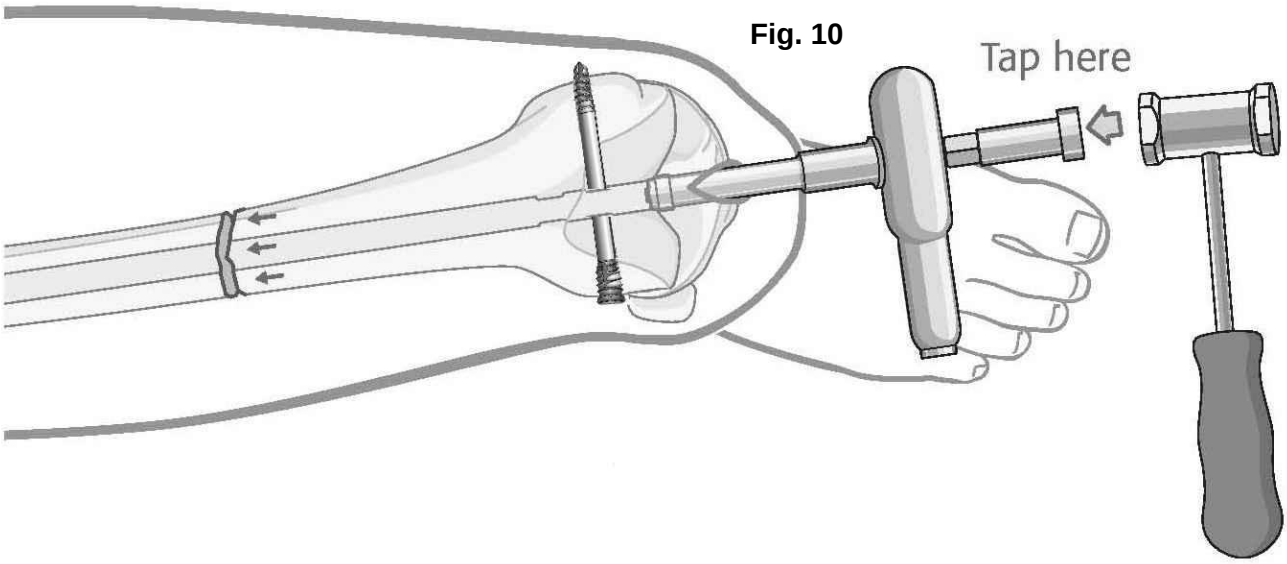


Fig. 10

Proximal interlock

NOTE: See technique used in all approaches on page 11.

Manipulate the knee into flexion and extension after the nail insertion and interlock has been accomplished. Continue range of motion and strengthening exercises after the surgery. If the fracture is stable, we advise weight-bearing as tolerated.

Antegrade Approach to FEMUR

Position of patient
Supine or lateral. Lateral is best for open reductions. Technique for lateral position will be described. Patient must be stabilized in the lateral position to prevent shifting during surgery.

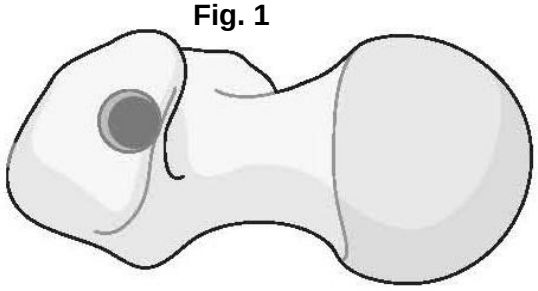
Reduction
If open reduction is indicated, perform this prior to skin incision for nail insertion. Incision should be as short as possible. Identify the proximal fragment by abducting the leg. Incise the skin and fascia over the end of this fragment. Dissect through muscle with your finger to identify the fracture site. You can then extend the incision as needed. Free up each of the main fragments by removing soft tissue attachments. Save the callus for bone graft. Ream each fragment from the fracture site. Do not penetrate the metaphysis at either end of the bone. Save the bone from the flutes of the reamer for bone graft. Secure the reduction with clamps and proceed to preparation for nail insertion.

Variations in reductions
If the fracture is comminuted over a long segment, free up only the 2 main fragments and do not devascularize the fragments in the middle of the fracture. Pass the nail from the proximal fragment into the distal fragment without disturbing the fragments within the fracture site.
If the fracture occurred within the past week, closed reduction may be attempted. If the reamers do not pass immediately into the distal fragment, plan a mini open reduction and guide the reamers and the nail into the distal fragment with a clamp or bone hook.

Skin incision
Extend from the superior greater trochanter posteriorly in the direction of the gluteus maximus fibers. Dissect down to the greater trochanter in the region between the posterior and middle one third junction. Dissect through muscle fibers with finger or periosteal elevator.

Bone entrance
Entrance should be placed in a junction between the posterior and middle one third of the greater trochanter, figure 1. We do **not** recommend placing the entrance through the piriformis fossa. Hoop stresses are generated when the bend passes through the piriformis fossa. If you doubt this, place a nail into a sawbones and note the hoop stresses. Use a curved awl to make the entrance. If possible visualize the fracture site to determine the direction of the awl. Sink the awl to the hilt by rotation.

Fig. 1



Reaming
Start with the smaller reamers and increase reamer sizes until chatter is heard. Be sure you can feel the reamer rotating through a 360º arc to know the reamer is in the canal. Once chatter is felt for 4-6cm, over ream the proximal 6cm to allow room for the bend of the nail. Be aware of the reduction during reaming. Nail diameter is 2mm smaller than the reamer which caused chatter.

Preparation of the nail

NOTE: See technique used in all approaches on page 11.

Insertion of the nail

Use tissue protector to keep the nail off the skin. Push the nail in as far as it will go. If the nail stops, tap the locking bolt with small taps. Rotate the nail 10º after 4 taps, figure 2. The 1-1/2º bend at the end of the nail helps keep the nail from being caught in the canal. If the nail does not advance with light taps, it is not in the canal or it is too large. Never hit the nail with heavy blows. This will cause the nail to bend and make interlocking difficult. **Never hit the L-handle** or you will ruin the L-handle for interlocking. Check reduction as the nail advances.

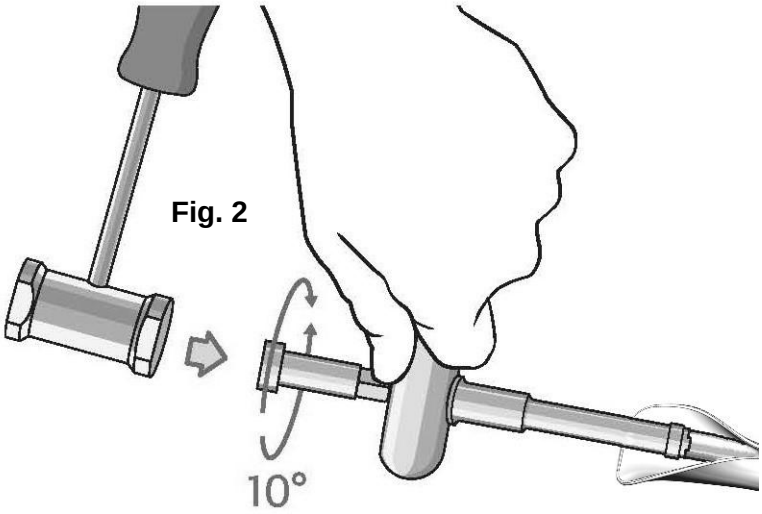


Fig. 2

Allow the nail to rotate as the bend in the nail slides into the canal, never force rotation. Leave nail 2mm prominent above bone cortex, figures 3 and 4.

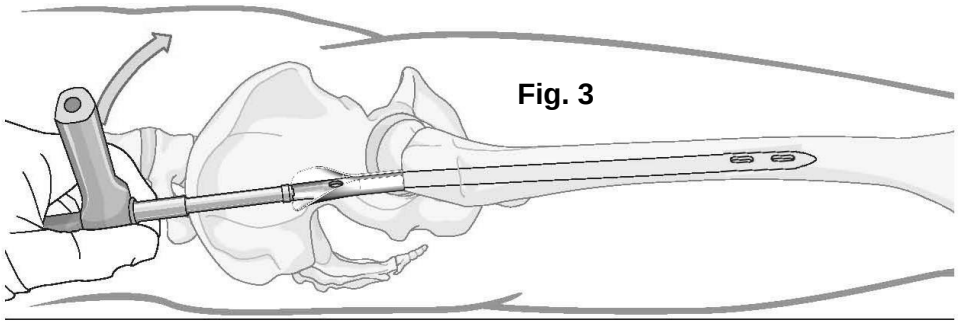


Fig. 3

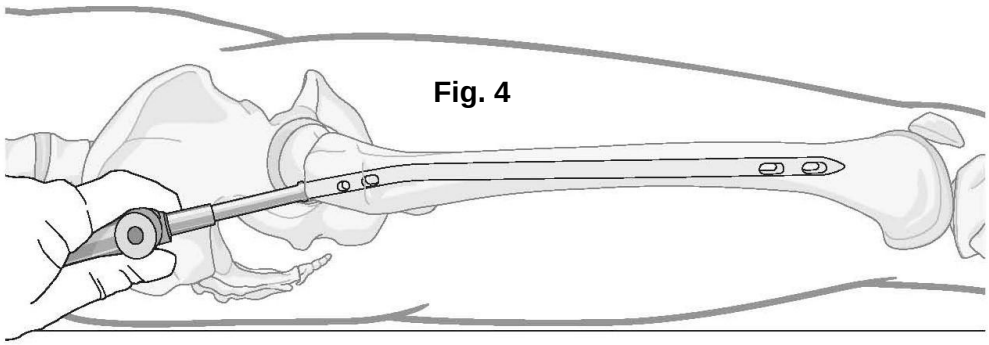


Fig. 4

Note the difference in orientation of slots, figures 3 and 4. Both directions allow stable interlock.

Proximal interlock can be done through lateral to medial or anterior to posterior direction, figure 5. They are equally stable.

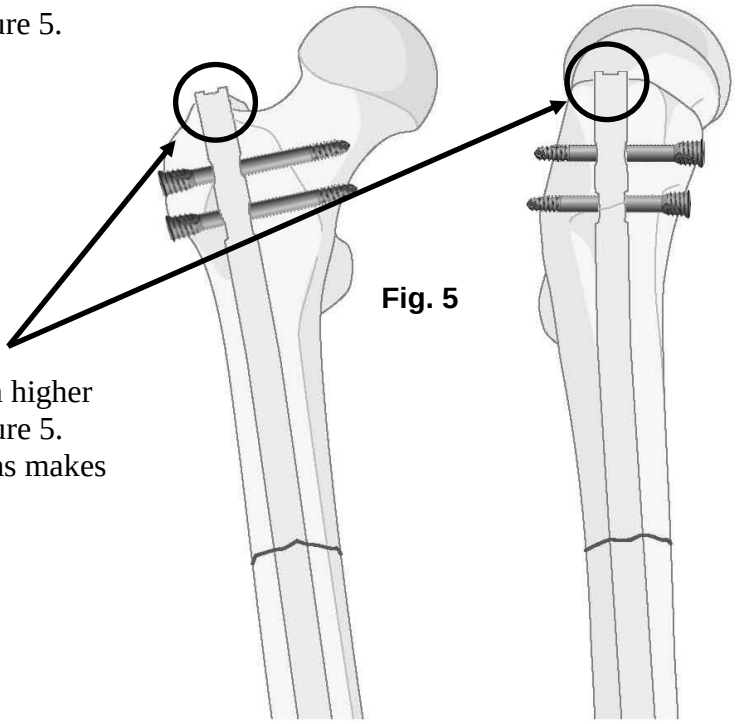


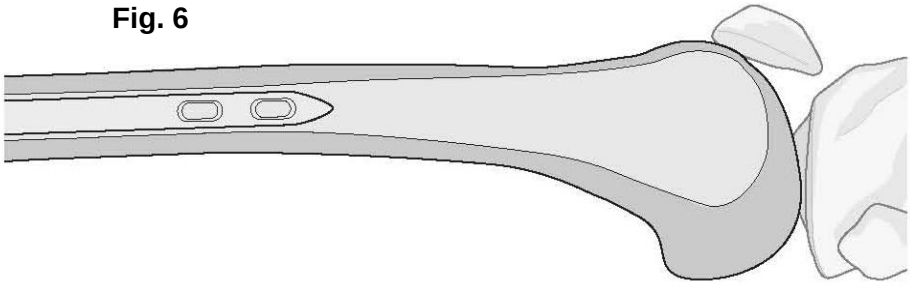
Fig. 5

The proximal end of the nail should be 3mm higher than the cortex of the greater trochanter, figure 5. This adds to the stability of the nail as well as makes removal easier.

Distal interlock

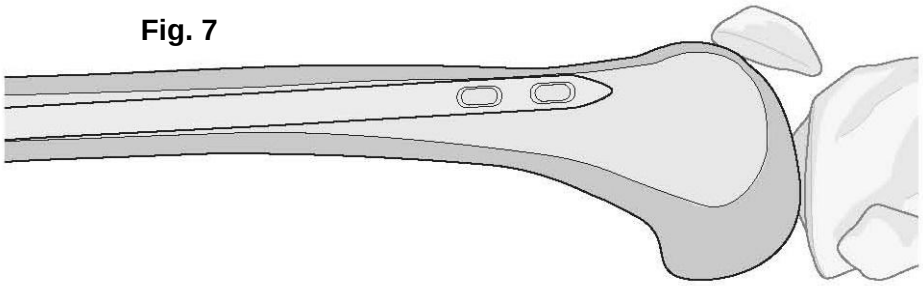
The final location of the slots will vary depending on their location in the canal. If the end of the nail is in the narrow part of the canal, the slots will be central, figure 6.

Fig. 6



If nail ends in the wide part of the canal, the slots will be anterior, figure 7. The SIGN nail does not have an arc of radius and the femur is curved. Recognizing this difference will determine where the pilot hole is made. The pilot hole would be made in the center of the femur if the slots are in the narrow part of the canal and anteriorly in the wide part of the canal. The incision for interlocking should be large enough so you can feel the cannula on the bone to determine its location. Sometimes the target arm must be adjusted to account for this. Loosen the distal cap screws to make this adjustment rather than bending the target arm.

Fig. 7



NOTE: See page 20 for tips on interlocking.

Compression of fracture
After the first distal interlocking screw is placed, the fracture site may be impacted, figure 8.

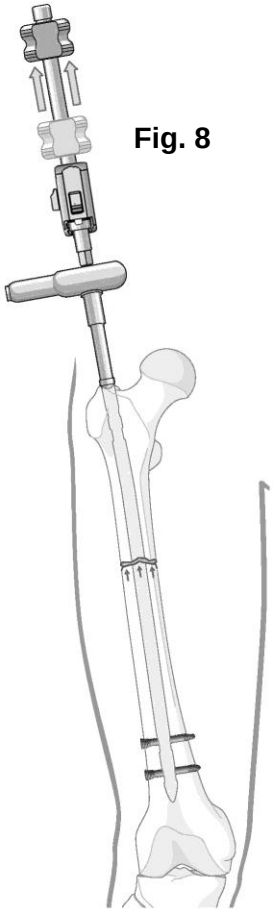


Fig. 8

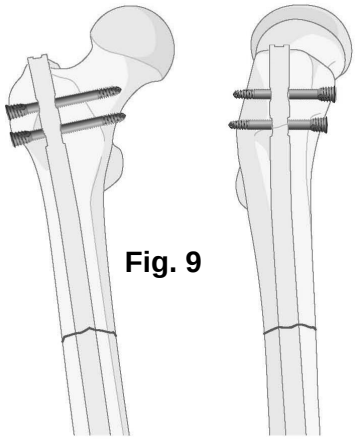


Fig. 9

Proximal interlock
This may be directed from lateral to medial or anterior to posterior, figure 9. We are studying the stability of these interlocks. Mechanism of interlock is the same as tibia. in retrograde approach.

Manipulate the knee to full flexion.

Removal of Broken Nail

1. It is important to leave the proximal end of the nail and the screws prominent. Many times I see that the nail has been placed inside the bone and I am concerned about removal later on. It is much easier to find the interlocking screws if they are left prominent.
2. Try to use the same distal holes for interlocking in the replacement nail if the broken nail is SIGN. Use the same length of nail, but a wider width. Four holes in the femur provide a stress concentrator which may result in a fracture at the distal interlocking area. If the broken nail is not SIGN try to line up at least one hole to SIGN slot.
3. Leave one screw present until the nail can be adequately secured and pulled out. Sometimes after the distal interlocking screws have been removed a screw driver or other instrument can be left in the slots of the nail so it does not slide down. We were also able to push the nail up using this method.
4. The advantage of using stainless steel nails over titanium becomes manifest because the bone does not grow into stainless steel as it does into titanium.
5. Reaming results in bone graft. Don't irrigate the hematoma because this contains a great deal of BMP.

ADDITIONAL NOTES

- Save bone from reaming or take bone from the entrance hole for bone grafting.
- Sometimes casting or splinting after SIGN nail insertion is necessary for unstable fractures.
- Weight bearing is encouraged in stable fractures. Crutches are used depending on patient's pain.
- Fracture healing is a race between bone healing and implant failure. Therefore, if healing is delayed past 3 months, consider bone grafting.
- Implant removal should be delayed for 24 months. If the nail is removed, protect the bone by crutch for 6 to 8 weeks after removal.
- If you have a comment, problem or something to share with SIGN surgeons around the world, please e-mail or place it in the comment section of the database.
- Reaming the middle fragment of a segmental fracture. There is a great decrease in vascularity after power reaming. I don't know if hand reaming also causes a decrease. Inserting a smaller diameter nail without reaming is an option.

Keep your sharp instruments sharp

Our drill bits have been tested and will drill a hole 300 times without becoming dull. If the drill bit hits another metal object and a nick is formed, the drill bit will become rapidly dull. No food or drink should be allowed in the cleaning and sterilizing process area.

Step drills will become dull if they engage the slot in the nail.

Reamers will become dull if they are not rotated clockwise. The cutting edge only goes one way.

The threads on the locking bolts and cap screws will become dull if they're forced into the hole. Always thread using gravity.

Changes of SIGN interlocking procedure

Vietnam has soft bone. We used a hand drill and large drill bits to make the hole in the near cortex. The bone was soft and the drill did not walk along the bone.

Bangladesh has hard bone. The large drill bit in the hand drill walked along the bone during the attempt to drill a hole in the near cortex. We made a pilot hole and used a step drill to enlarge it. We improved step drills in many ways. No matter how we improve them they become dull.

SIGN surgeons began to use a commercial drill which allowed them to drill faster and more accurately. We were not satisfied with the sterility of the drill. A drill cover placed over the drill with a chuck extension has allowed us to use commercial drills in a sterile manner.

We can use power so we are modifying our drill bits to enable the interlock holes to be drilled quicker.

The slot finders have also changed. The curved slot finder has become very helpful. If the longitudinal alignment has been maintained, the slot in the nail can always be found.