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

www.signfracturecare.org

Revision # TM-002-03

Dear SIGN Fracture Care International Partner:

The SIGN technique and instruments described here have progressively improved since SIGN began in 1999. The 5000 SIGN surgeons and SIGN staff all work together to provide optimum treatment of fractures. We share ideas and results through email, the database, and conferences throughout the world. Our technique video and animated video shows SIGN surgery from the inside of the femoral canal. Please view both videos and give us your ideas for improvement. We welcome your participation.

Features of all SIGN IM nails:

- Adaptability—The basic designs of the SIGN implants and instruments are used for tibia, humerus, and retrograde and antegrade approach to the femur. The nail is manufactured so that there are no right or left SIGN nails.
- No radiation exposure—C-arm is not needed to place interlocking screws. Tactile sense rather than visual sense is used in the SIGN technique.
- Solid—Stronger and less surface for biofilm
- No arc of radius – Allows three point fixation within the femoral canal

Standard Nail Features:

- Slots instead of holes – Allows for compression and distraction of fracture fragments to accelerate healing
- 9° proximal bend—Provides rotational stability
- 1.5° distal bend – Facilitates insertion and extraction

Fin Nail Features:

- No distal slots, fixation is achieved via three point fixation

SIGN database - Reports of SIGN surgery on the SIGN Database have validated results equivalent to other IM nail interlocking screw systems used with C-arm. The percentage of follow-up reports submitted to the SIGN Database continues to increase.

Sincerely,

Lewis G. Zirkle M.D.

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Founder & President
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CHAPTER 1: PATIENT PREPARATION

Patient Preparation

The patient and family must be counseled about the nature of the surgery, including risks and benefits. The patient must agree in writing to insertion of the SIGN IM Nail. The surgeon should instruct the patient and family about patient activity, exercises both stretching and strengthening after the surgery.

The patient's skin should be checked for open wounds which would preclude surgery. The cast, if present, should be removed. The patient's skin should be washed the night before and the morning of surgery. Shaving or clipping is not necessary before surgery. Sterile towels should cover the incision area. X-rays of the fracture including the joint above and below should be evaluated and present during surgery. Templating, if necessary, should be performed the night before.

The surgeon and anesthesia team should evaluate the general condition and laboratory work the night before surgery.

Hospital Equipment

The following equipment is supplied by the hospital and should be available in the operating room: Curved awl, drill, chuck key (drill cover, quick release and sterile chuck if a hardware drill is used), bone holders, mallet, knife, forceps, clamps, cautery, suction, towel clips, needle holders, retractors, periosteal elevators and disposables such as suture and dressings.

SIGN Implants

Please refer to the SIGN Product Catalog. The standard set includes the Standard SIGN Nail Interlocking Screw System, Fin Nails, and FX Plates. Additional implants such as pediatric nails, and SHC are provided based on number of surgeries, number of follow-up reports submitted to the SIGN database, and training.

CHAPTER 2: SIGN TECHNIQUES FOR ALL FRACTURES

Open Fractures

The indications for the SIGN Nail in open fractures are decided by each operating surgeon. As more reports of open fractures that include follow-up reports are evaluated on the SIGN Database, guidelines will become apparent. Debridement and irrigation are critical. Dead space must be filled. A general rule is that if the wound is clean enough to close, the SIGN Nail can be inserted.

Fractures That Have Been Treated With External Fixation

External fixators may be removed if the pin tracks are clean and the SIGN Nail inserted during the same surgery. If the pin tracks appear to be infected, remove the pin, over drill the pin hole and place a new pin in another location for continued external fixation.

Checklist

We strongly advise using the checklist as suggested by Dr. Gawande (reference at end). The checklist will decrease possibility of complications. A list of nail and screw sizes available should be posted on a paper and taped to the wall if the full SIGN inventory is not available.

Reduction

- **Closed reduction** of the tibia is routinely accomplished without C-arm if the patient has surgery within 10 days of injury. This will be discussed in Chapter 5. We are seeing increasing numbers of closed reduction of distal femur performed without C-arm using retrograde approach.

- **Open reduction** with minimal incision may be accomplished quickly and accurately. The fracture site is identified by moving the leg at the fracture site. The proximal fragment does not migrate distally, but the distal fragment migrates proximally. The fracture site therefore is distal to the skin movement when the leg is abducted.

The surgeon should emphasize atraumatic surgery without damaging the blood supply to the fragments. If a muscle such as the vastus lateralis must be traversed for reduction, use a periosteal elevator to spread the muscle fibers rather than a knife or cutting cautery. Perforators are identified, clamped, and cauterized as the fibers are spread.

Reduction (cont.)

Each fragment is then freed from surrounding soft tissues and immature callus. The callus is saved because it can be used to fill the dead space. Once a main fracture fragment has been freed of soft tissue, ream through the fracture site. A 4 cm length of bone on either side of the fracture site is overreamed to remove the bone that has grown into the canal. This will allow the canals of the two fragments to line up during nail insertion. Do not ream into the metaphysis of either bone fragment. Save the bone and blood from the flutes of the reamers in a bone cup. Place this material around the fracture site at the end of the procedure.

If the fracture is comminuted over 4 cm or more, expose the proximal and distal fragments only and allow the reamer and nail to pass through the comminuted fracture without exposing the fragments.

The fracture fragments are then reduced. One method is to flex the fracture site and connect the cortex of each fragment. The fracture is then slowly extended. It is very important to slowly extend the fracture fragments in order to stretch the tissues rather than rupture them or fracture the bone fragments (Figure 1).

A Hohman retractor or a periosteal elevator can be placed between the two fragments and used to stretch the soft tissues (Figure 2).

Fig. 1

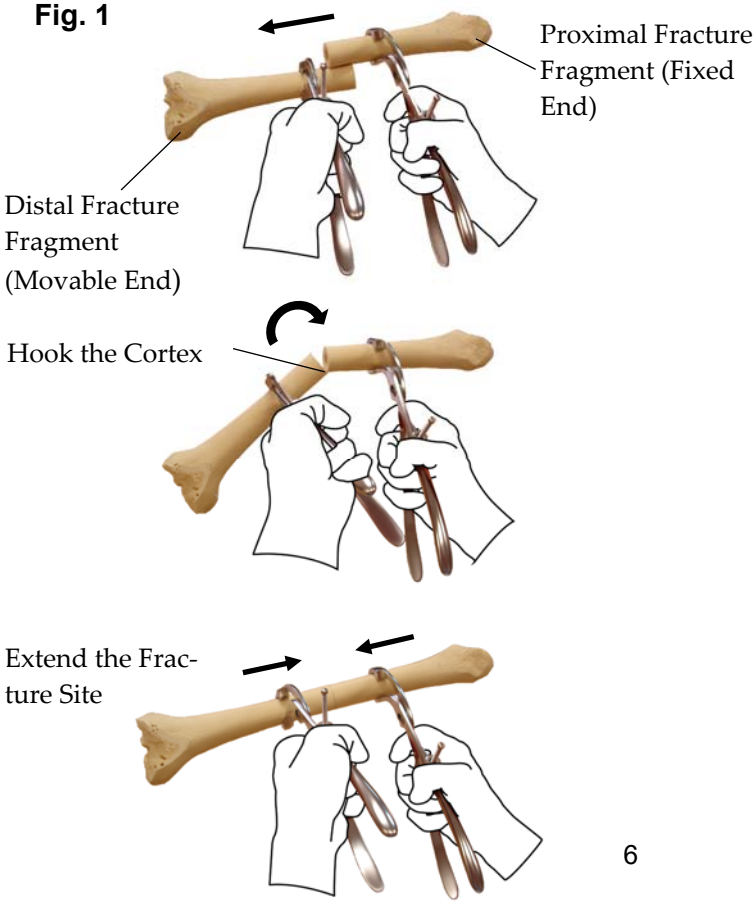
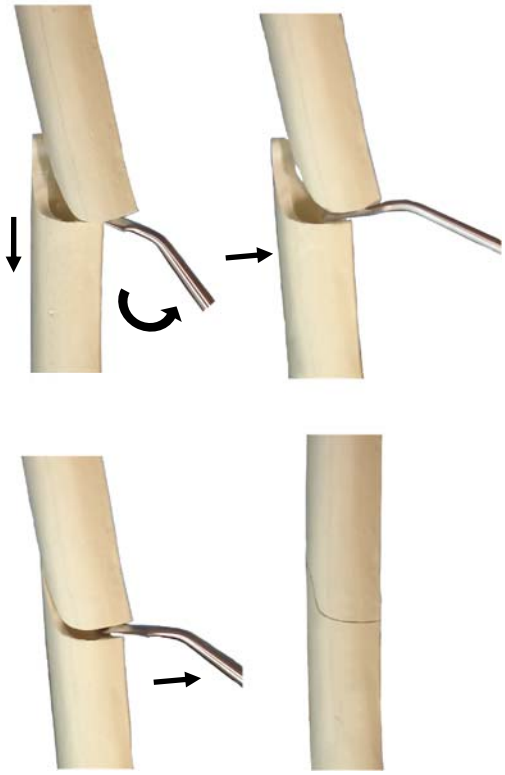


Fig. 2



Reduction (cont.)

Distractor

The Distractor may be used, if available, to slowly achieve reduction. Be sure the fracture fragments are parallel when the distractor is placed over the bone clamps (Figure 3).

There is one movable arm of the distractor and one stationary arm. Attach the stationary arm to the clamp holding the proximal fragment and attach the movable arm to the clamp holding the distal fragment (Figure 3).

Move the ratchet slowly and stop periodically to stretch the soft tissues. Relocate the clamps when they are separated 3 inches. The clamps are brought closer together and distraction is resumed. Be sure proper rotational alignment is maintained.

Fig. 3

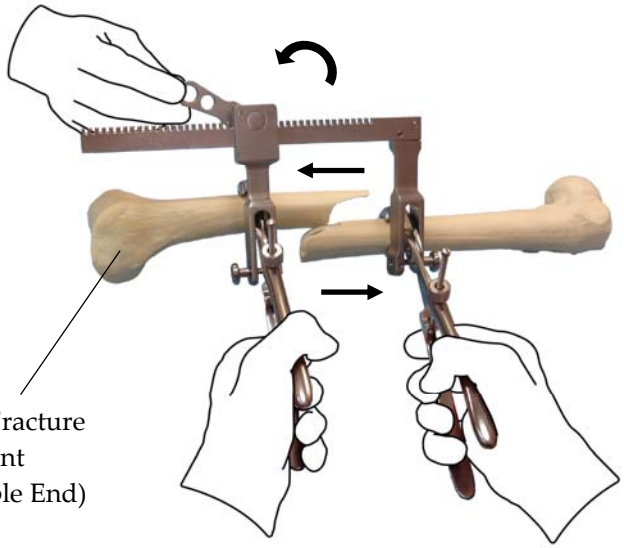


Fig. 4

The distractor can be purchased from Innomed, Inc.

CHAPTER 2: SIGN TECHNIQUES FOR ALL FRACTURES

Reaming from the Bone Entrance

The Curved Awl is used to make the entrance hole. The pointed 7, 8 and 9 mm reamers progressively enlarge a track from the bone entrance down the canal. The blunt tip reamers, sizes 10, 11, 12, 13, 14 mm are used progressively until chatter is detected over 4 cm.

Use the Tissue Protector to keep the reamer off of the skin. Rotate the reamer in a **clockwise** direction during insertion and removal of the reamer. The cutting flutes go only one way. The reamer will become dull if you oscillate or reverse the direction of rotation.

Counter pressure should be applied to the limb during reaming. If the reamer does not advance, rotate it out of the bone entrance, save the bone from the flutes and place the reamer again. Reaming with the blunt reamers (10-14mm) should be repeated to obtain more bone for use at the fracture site. If you are uncertain that the reamer is in the canal, push the reamer to see if there is a stop. If there is **no** stop, the reamer is not in the canal.

Once chatter is felt for 4 cm distance through the canal, the diameter of this reamer is noted and the diameter of the nail chosen is 2 mm less for the femur and 1 or 2 mm less for tibia fractures.

See Chapter 7 for Fin Nail instructions.

CHAPTER 2: SIGN TECHNIQUES FOR ALL FRACTURES

Attach Nail to the Target Arm

- Insert the Locking Bolt through the hollow stem of the L-Handle (Figure 5).
- Align the tabs in the nail with the tabs on the L-Handle. Consider the direction of the proximal nail bend and the side of the bone used for interlocking when orienting the tabs. Once the Locking Bolt has been tightened by hand, use the 11mm wrench to further tighten the Locking Bolt into the nail (Figure 6).

Fig. 5

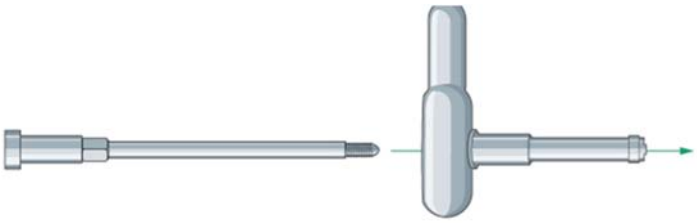
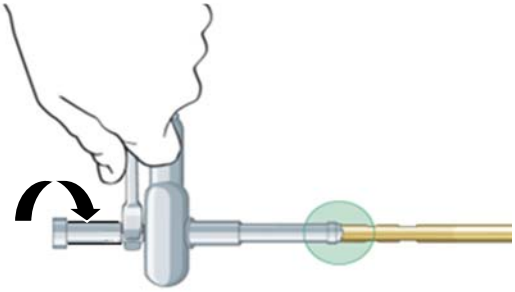


Fig. 6



Standard Target Arm (pg. 9-10)

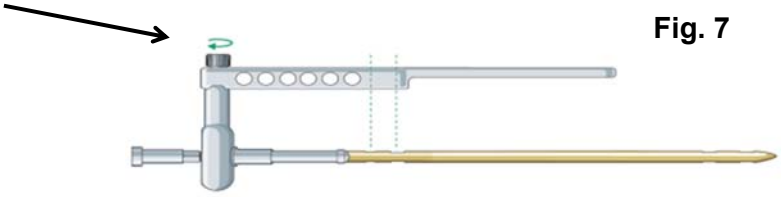
Adjustable Arm for All SIGN Systems (pg. 11-15)

Standard Target Arm

1. Attach the Target Arm to the L-Handle

- Attach the assembled L-Handle and nail to the Proximal Target Arm using the Shoulder Cap Screw (Figure 7).
- If the Shoulder Cap Screw does not turn easily, adjust the junction between the L-Handle and the Target Arm.
- Use the Combination Hex Wrench to secure the Target Arm to the L-Handle.

Fig. 7



Attach Nail to the Target Arm (cont.)

Standard Target Arm

2. Attach Distal Target Arm to Proximal Target Arm

- Place the tongue of the Distal Target Arm in the groove of the Proximal Target Arm.
- Place the Alignment Pin into distal nail slot (Figure 8).
- Align the holes in the Distal and Proximal Target Arms.
- Be sure the two sides of Target Arm are approximated before screwing in Distal Cap Screws, which are placed two holes apart.
- Tighten each Distal Cap Screw a bit and then tighten the other while the Alignment Pin is held above the slot in the nail.
- Final tightening of the Distal Cap Screws is done with the Combination Hex Wrench.
- Remove the Target Arm (Figure 9).
- If you have a different Target Arm, the description follows on the next page.

Fig. 8

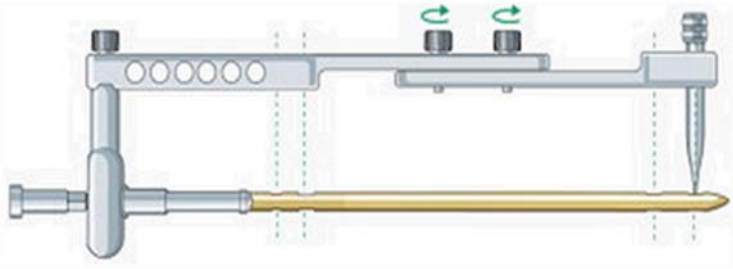
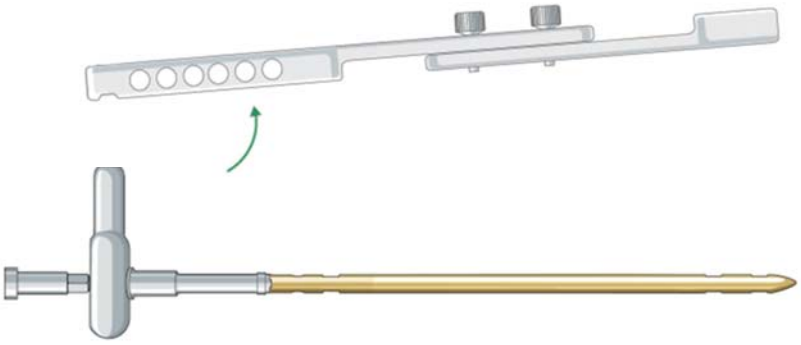


Fig. 9



Attach Nail to the Target Arm (cont.)

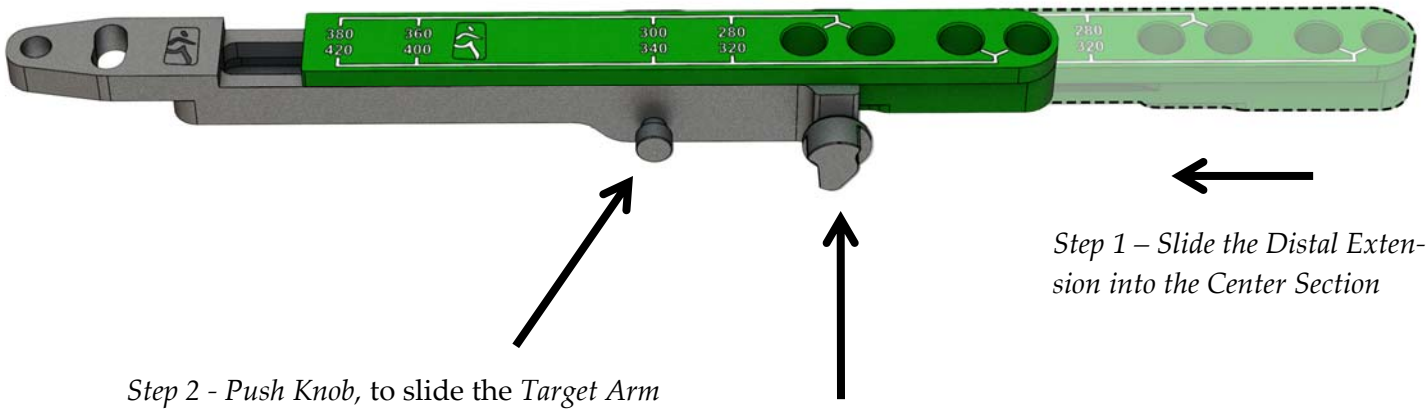
Adjustable Target Arm for all SIGN systems

1. Slide the Distal Extension 280mm - 420mm into the Center Section (Figure 10).

2. Adjust for Nail Length

Change the setting of the Distal Extension 280mm - 420mm by pushing the knob to allow the Distal Extension 280mm - 420mm to slide into the Center Section. To secure, tighten the thumb screw by hand only (Figure 10). (**DO NOT** USE ANY TYPE OF WRENCH TO TIGHTEN THE THUMB SCREW.) See Figure 13 for adjusting the target arm to specific nail lengths.

Fig. 10



Step 1 – Slide the Distal Extension into the Center Section

Step 2 - Push Knob, to slide the *Target Arm Extension* to specific Nail length

Step 3 – Tighten Thumb Screw
Hand Tighten Only

Attach Nail to the Target Arm (cont.)

Adjustable Target Arm for all SIGN systems

3. Attach Proximal Target Arm to L-Handle

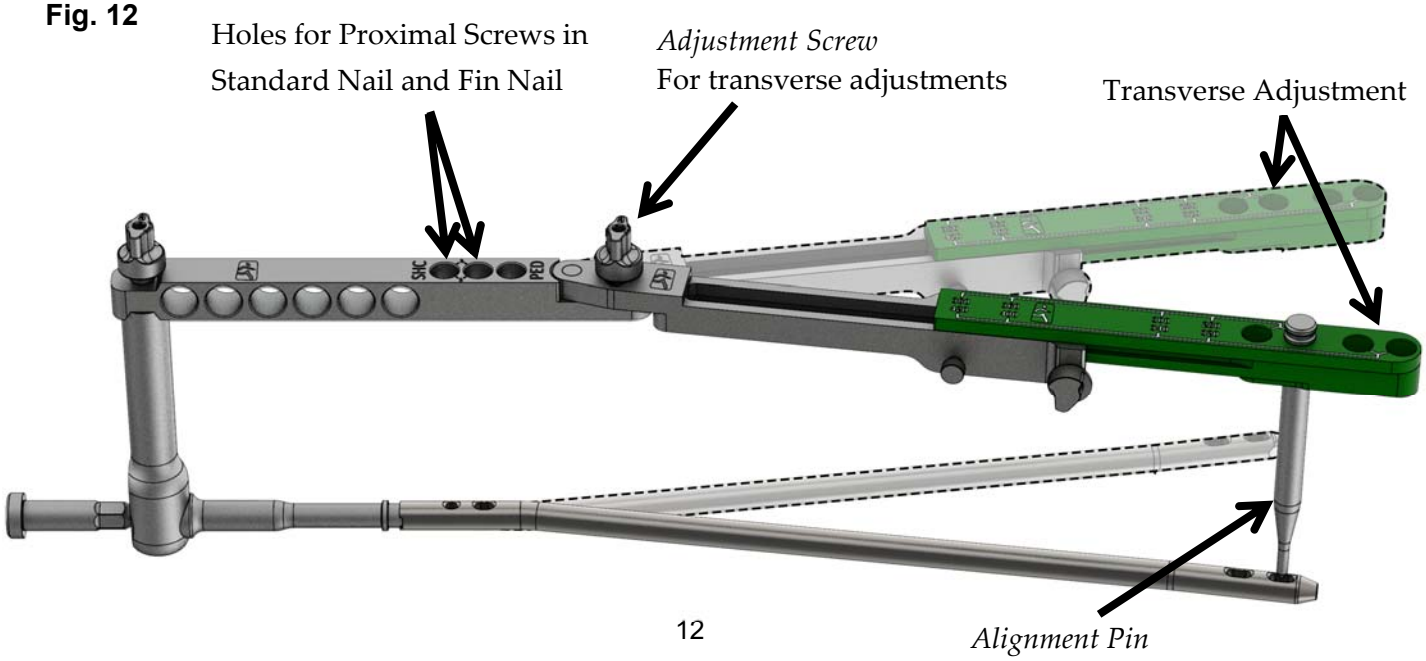
- Attach the Proximal Target Arm to the L-Handle using the Shoulder Cap Screw (Figure 11).
- If the Shoulder Cap Screw does not turn easily, adjust the junction between the L-Handle and the Target Arm.
- Use the Combination Hex Wrench to tighten the Shoulder Cap Screw.

Fig. 11

4. Attach Center Section to the Proximal Target Arm (Figure 12).

- Use the Alignment Pin to position the distal hole of the Target Arm in line with the center of the distal slot of the Nail.
- With the Alignment Pin in place, tighten the Adjustment Screw. Usually the Combo Hex Wrench is necessary for tightening.

Fig. 12

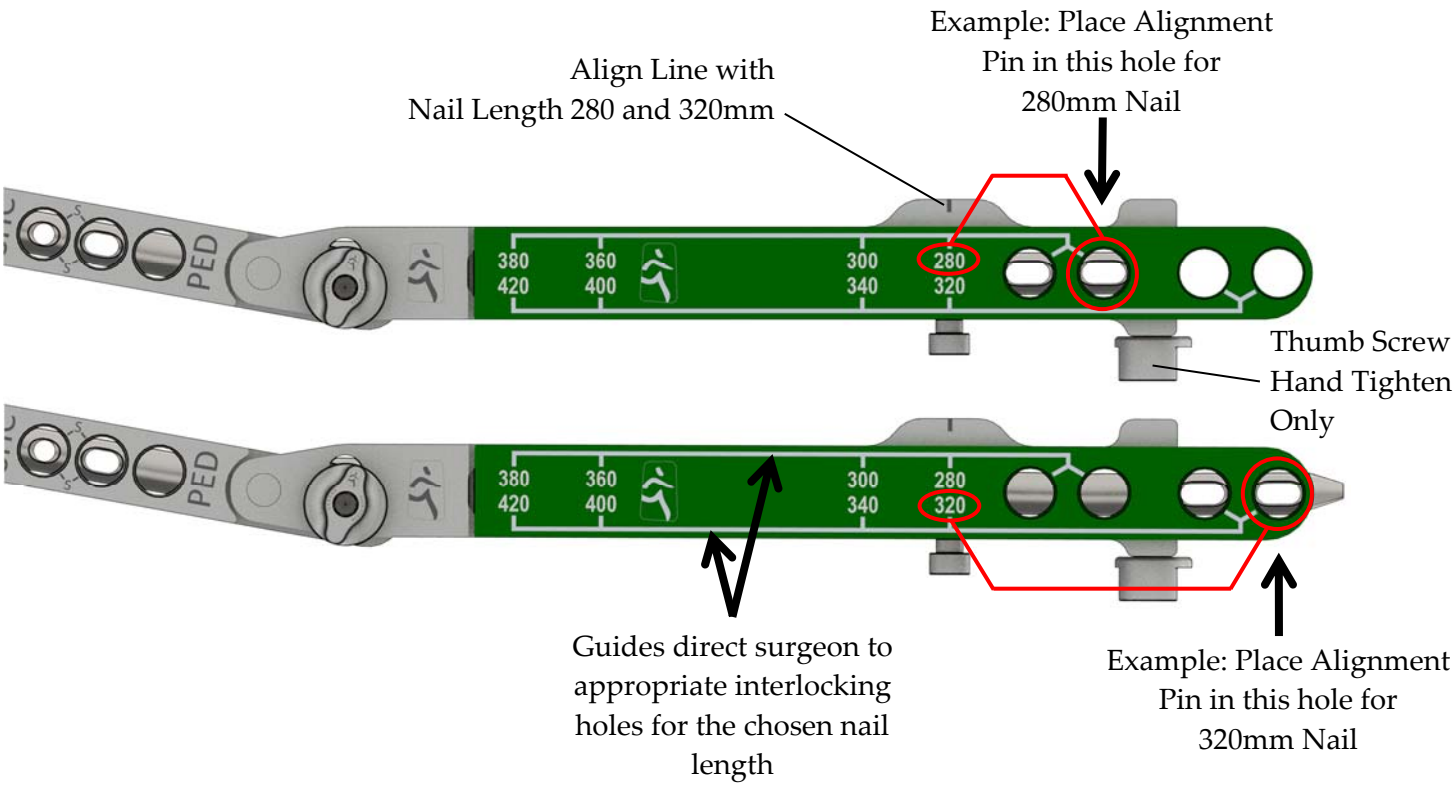


Attach Nail to the Target Arm (cont.)

Adjustable Target Arm for all SIGN systems

5. Adjusting Examples (Figure 13).

Fig. 13



NOTE: Distal Extension 280mm-420mm can also be used for the 280mm SHC Nail and MUST be used for the 320mm SHC nail.

Attach Nail to the Target Arm (cont.)

Adjustable Target Arm for all SIGN systems

6. For short nails, 200-260 mm and the 280mm SHC Nail, the Distal Extension 200mm-260mm is connected to the Proximal Target Arm using the Adjustment Screw. The nail lengths are labeled between the two holes that match the distal slots of the corresponding nail. The Alignment Pin should be placed into the most distal hole when making transverse adjustments to align the Target Arm (Figures 14 and 15).

Fig. 14

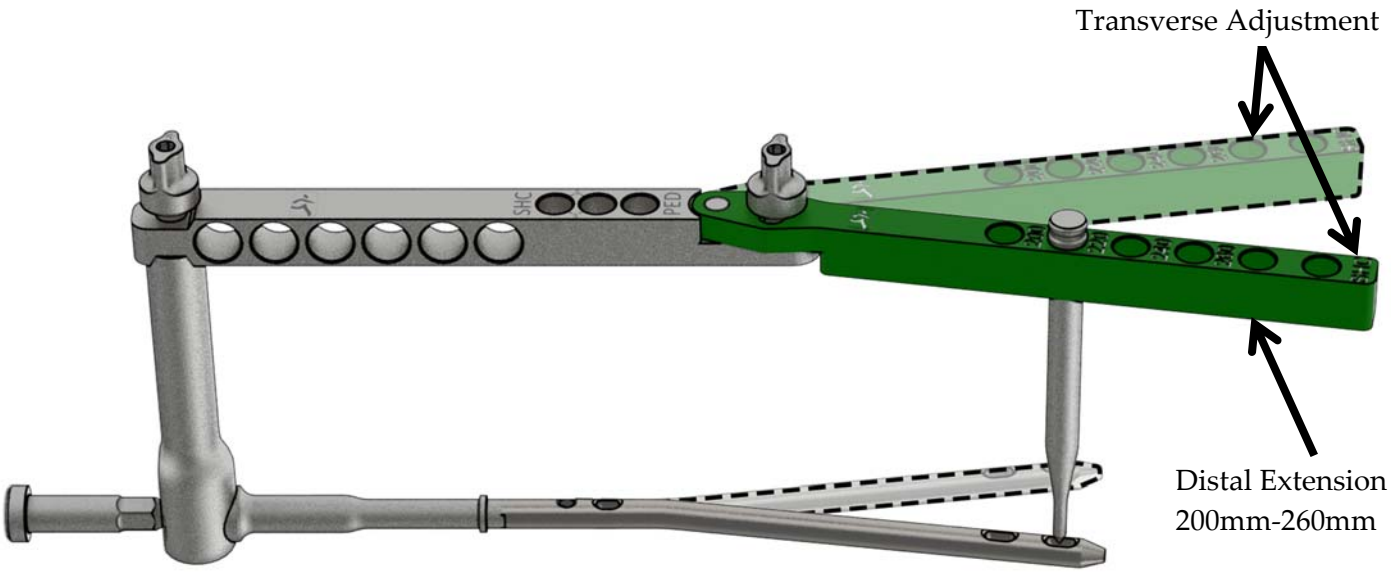
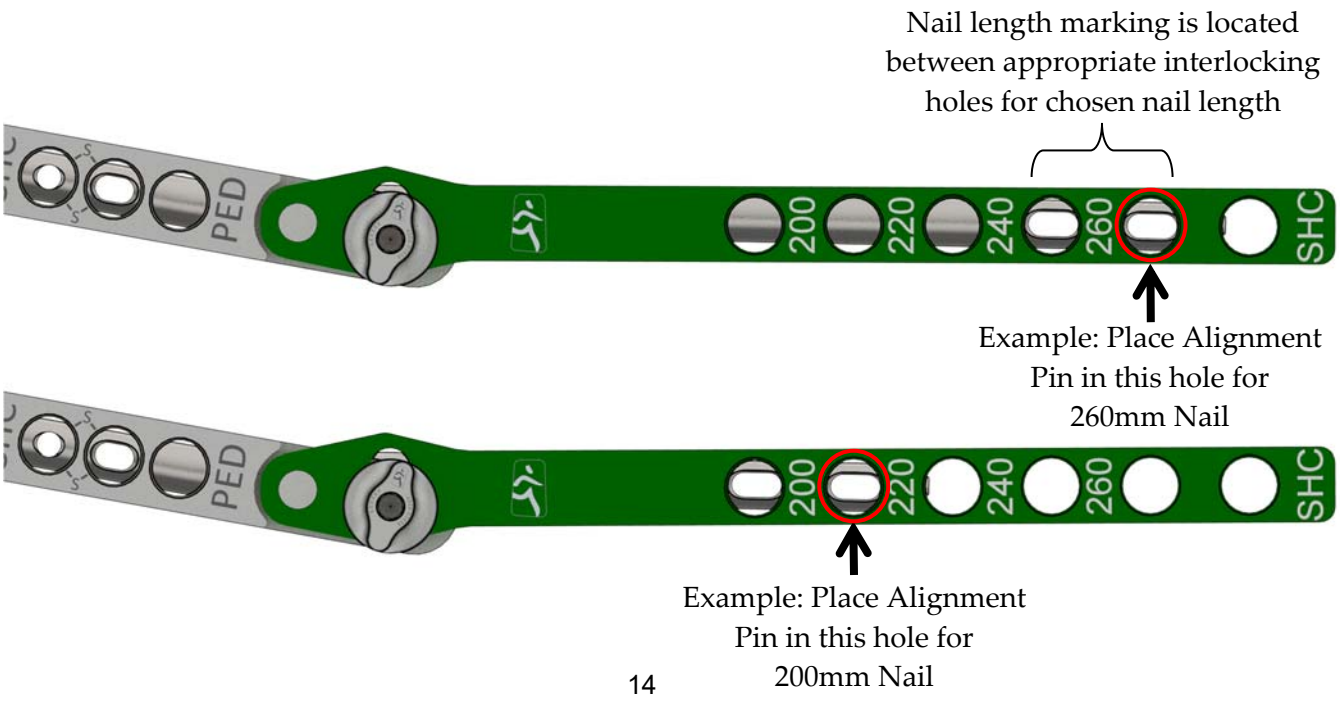


Fig. 15



Attach Nail to the Target Arm (cont.)

NOTE: The Locking Bolt, Shoulder Cap Screw and Adjustment Screw must remain tight when the Target Arm is in use. Loose screws will affect the alignment of the drilled hole with the distal slot in the nail. See figures 16 and 17.

Fig. 16

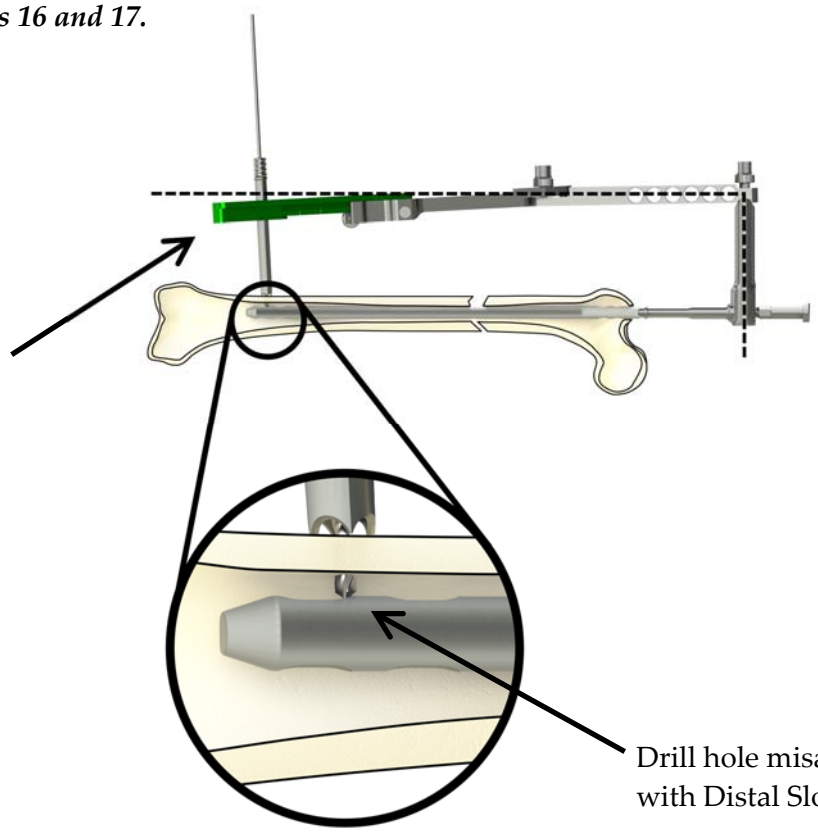
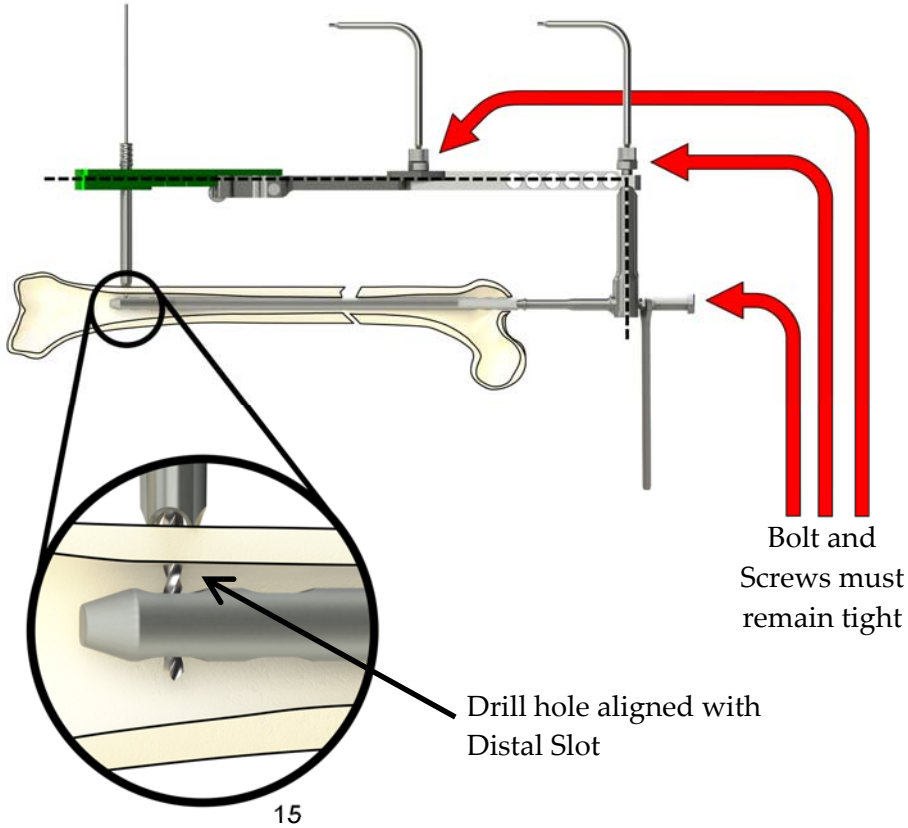


Fig. 17



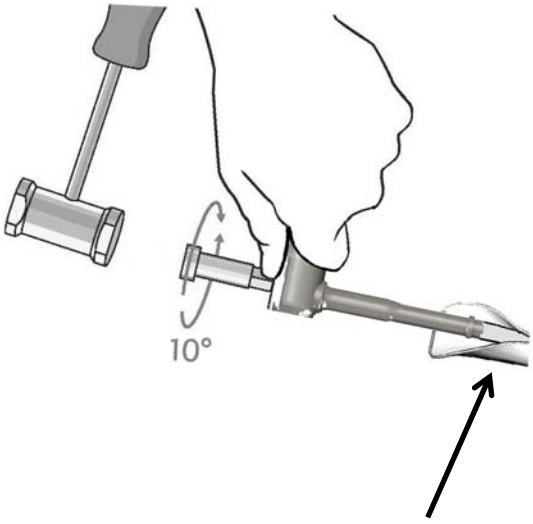
Nail Insertion

- Remove the Target Arm from the L-Handle and place the Shoulder Cap Screw and Target Arm in a secure and sterile place.
- Use the Tissue Protector to keep the nail from touching the skin. The skin of the patient and the surgical team are covered with bacteria. The Tissue Protector can be reused many times. It is **not** designed to be disposable.
- Many surgeons do not use a mallet to insert the nail. There is an **optimal balance** between ease of the nail insertion and the largest diameter nail possible. If the nail does not advance by pushing, use small taps and rotate the nail 10° as it proceeds down the canal (Figure 18).
- Apply counter pressure to the limb to allow the nail to advance.

  If the nail does not advance with rotation and small taps, ream the canal with a larger reamer. Hitting the nail forcibly will bend the nail and make interlock more difficult

  Check the reduction periodically.

Fig. 18



Nail Insertion

- The end of the nail is positioned differently depending on proximity to the joint (Figure 19). Reference chapters 3 to 6 for details on end of nail position relative to specific approaches.
    - In the antegrade approach to the humerus and tibia, and the retrograde approach to the femur, the end of the nail should be flush with the cortical bone surface.
    - In the antegrade approach to the femur, leave the proximal end of the nail 3mm above the cortical bone to provide additional stability. The ring on the L-Handle is 3mm above the nail (Figure 20).
- Note the height of the ring above the cortex after the nail has been inserted.

  If this changes, it indicates that the nail slipped after insertion and is an important clue when addressing challenges in finding the distal slot.

Fig. 19

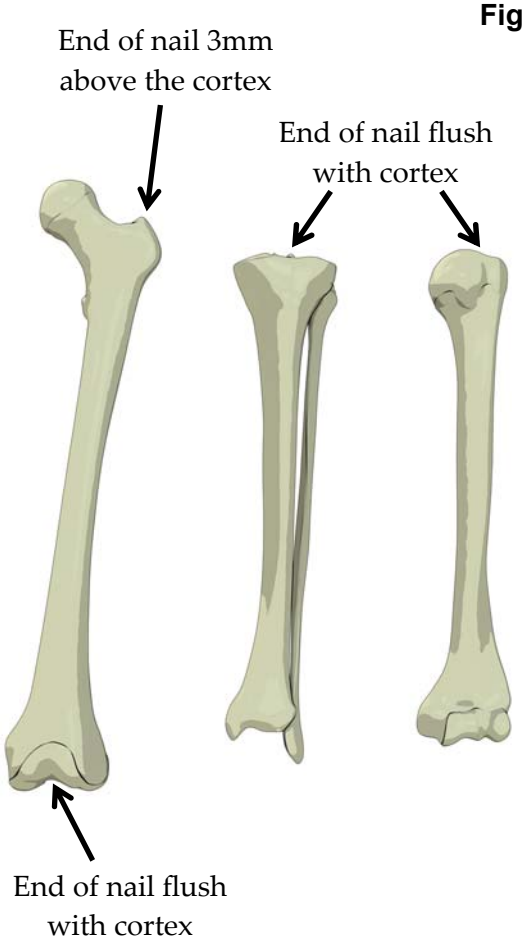
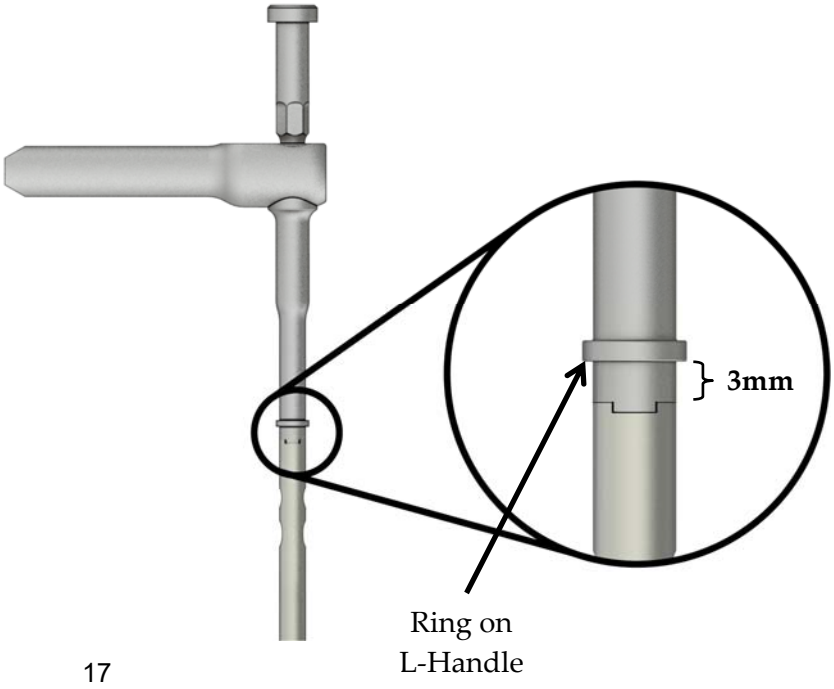


Fig. 20



Distal Interlock

This first sequence will describe placing the distal interlocking screw without difficulty.

- Decide if one screw or two screws are necessary. This depends on comminution of the fracture and how far the end of the nail is from the fracture site. If one screw is decided upon, place that screw in the slot of the nail nearest the fracture.

- Attach the Target Arm to the L-Handle using the Shoulder Cap Screw. If two screws are necessary, use the Alignment Pin to indent the skin in two places. If one screw is decided upon, place the screw in the slot nearest to the fracture. The incision should be large enough to put the Cannula and one finger of the assistant or surgeon through the incision down to the bone.
- Make incision for distal interlock. Spread the muscle rather than cut with a knife or cauterizing the tract to the bone. Use the Periosteal Elevator to remove all soft tissue from the bone.
- Place the Cannula on the bone. Do **not** hammer the Cannula (Figure 22).

Fig. 21

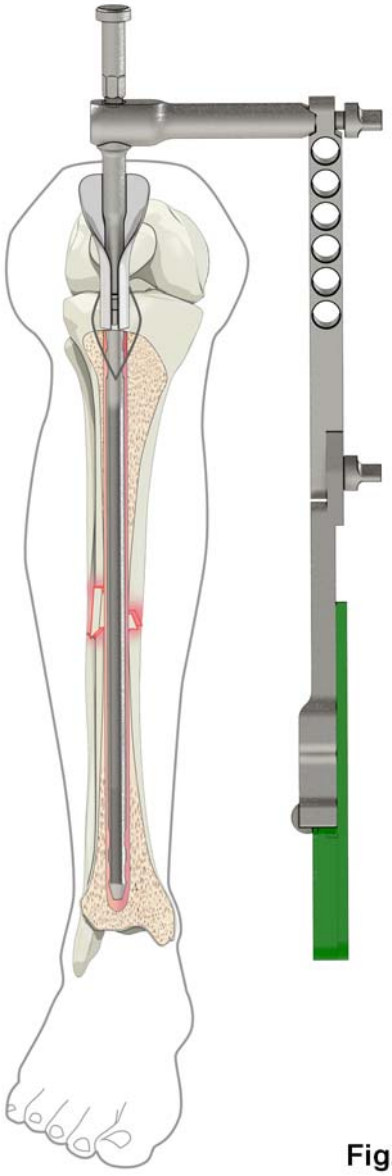


Fig. 22

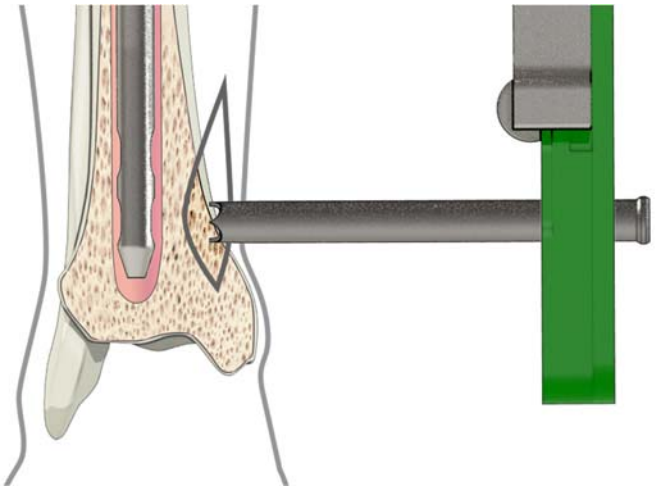
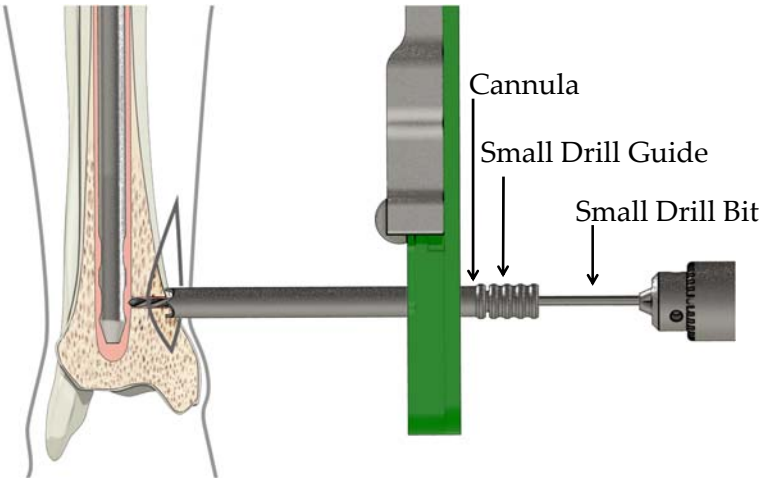


Fig. 23



Distal Interlock (cont.)

Drilling hole in near cortex:

- Use the Small Drill Guide to direct the drill bit through the near cortex (Figure 23). Hold the drill steady and centered in Target Arm (Figure 24). The assistant's finger will steady the Cannula and keep it from sliding during drilling of the holes in the cortex.

NOTE: When entering and exiting the bone, use the drill bits in a clockwise (forward) direction only . The drill will become dull if you reverse direction of rotation.

Fig. 24

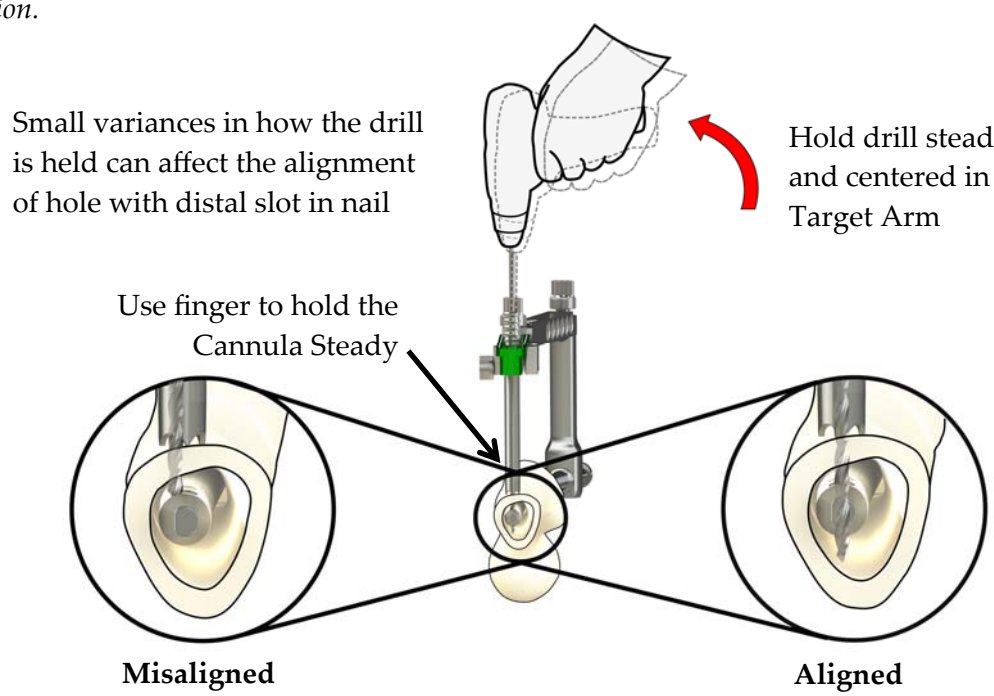
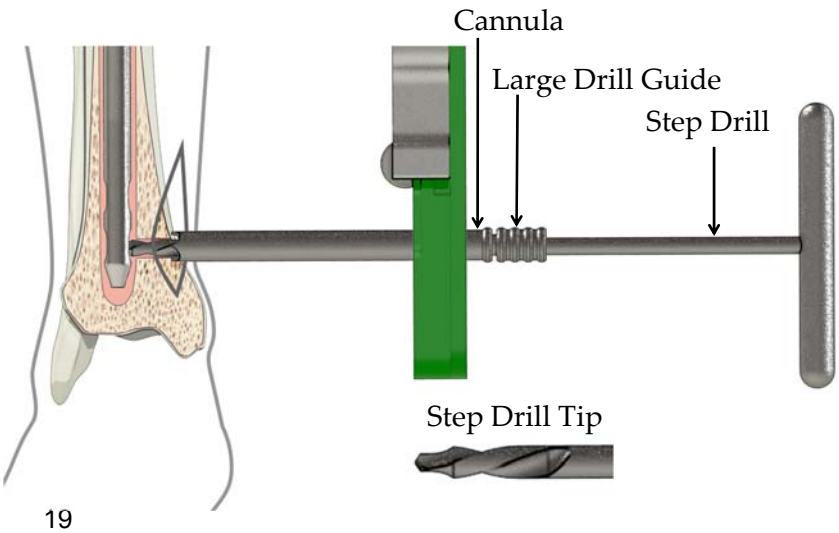


Fig. 25

- Replace the Small Drill Guide with the Large Drill Guide and use the Step Drill to enlarge the pilot hole. (Figure 25).

- The anatomy of the Step Drill is such that the narrow point will follow the pilot hole. If the Step Drill enters the slot of the nail, rotation of the Step Drill stops abruptly. Do not force. Do not use the Step Drill to find the slot in the nail. The cutting edges will be made dull by hitting the nail which will make it more difficult to use the next time.

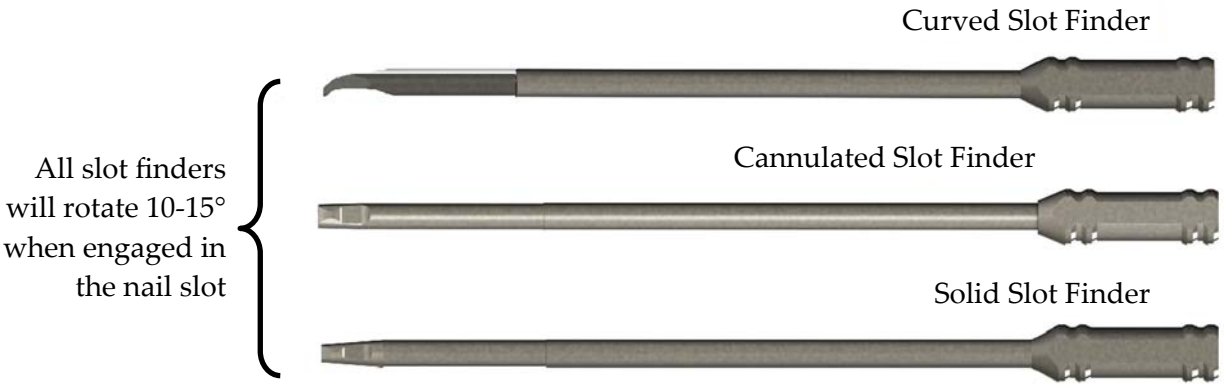


Distal Interlock (cont.)

Different Slot Finders for Different Uses

Note: Refer to SIGN Catalog for Slot Finder part numbers and detailed pictures.

Fig. 26



- Remove the Step Drill and place the Solid Slot Finder into the hole (Figure 26). Orient the flats of the Slot Finder to the direction of the nail. (Figure 27).
- Figure 28 shows the Solid Slot Finder entering the slot in the nail. If the Solid Slot Finder can be rotated 10 – 15°, it rests in the slot of the nail. **This is the SIGN feel.**
- If the Solid Slot Finder does not enter the slot, use the Curved Slot Finder. If the Curved Slot Finder does not enter the slot, turn the Curved Slot Finder 180° and try again. If the SIGN feel is not achieved, proceed to the section for Technique for Curved Slot Finder (pages 25-30).

Fig. 27

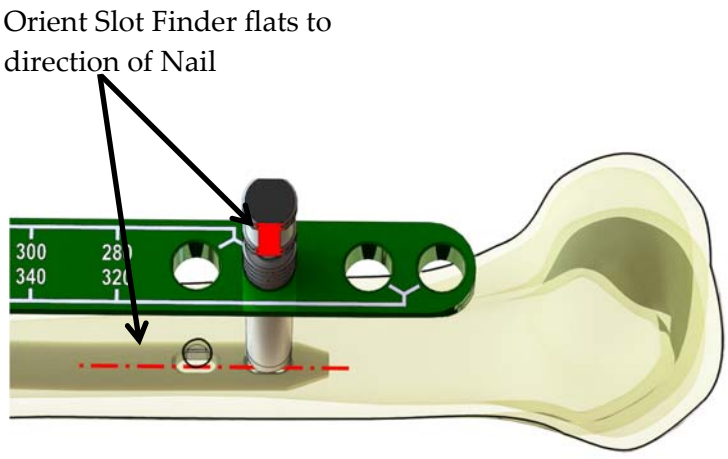
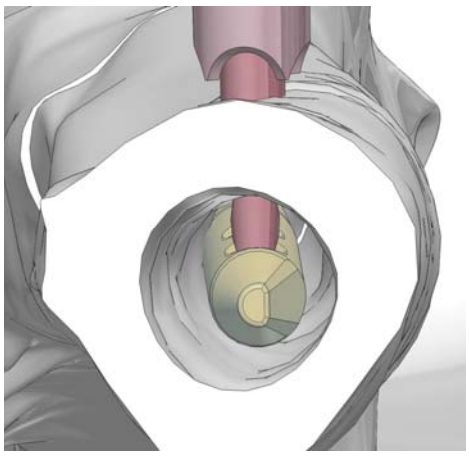


Fig. 28



Distal Interlock (cont.)

- Replace the Solid Slot Finder with the Cannulated Slot Finder.
- Figure 29 shows insertion of the Cannulated Slot Finder and drilling of the hole in the far cortex. The Solid Slot Finder diameter is smaller than the Cannulated Slot Finder. If the Cannulated Slot Finder does not rotate, it is caught in the hole in the near cortex. Use the Screw Hole Broach to enlarge the hole (Figure 30).

NOTE: Use the Screw Hole Broach sparingly because enlarging the hole reduces the thread/bone interface in the near cortex (Figure 37).

Use the Screw Hole Broach in a clockwise direction only. The Screw Hole Broach will become dull if you reverse direction.

Fig. 29

Please note the difference between the Screw Hole Broach and the Step Drill geometry.

Fig. 30

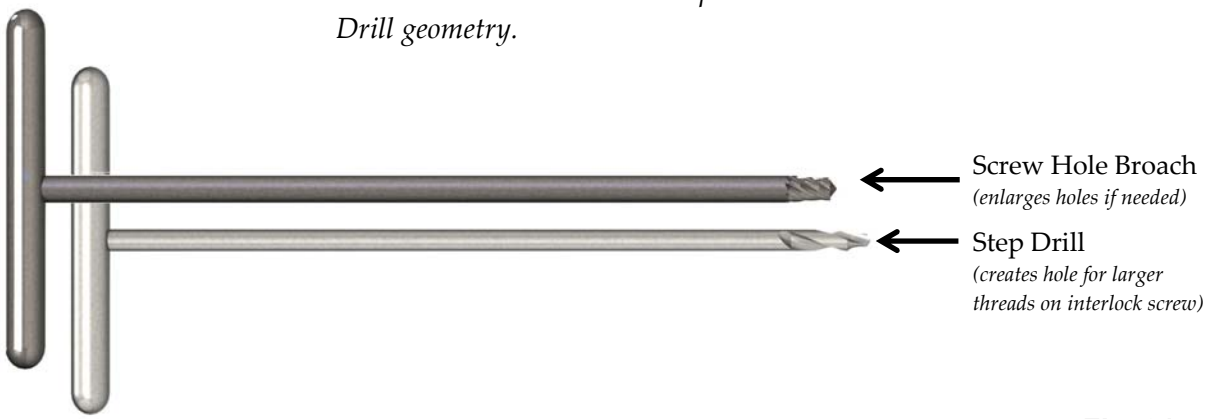


Fig. 31

- **DO NOT** rotate nail or probe for slot with Cannulated Slot Finder as this will damage the instrument (Figure 31). Always check for alignment with Solid Slot Finder first.

Damage from misuse of Cannulated Slot Finder

Distal Interlock (cont.)

Drill hole in far cortex and measure for length of screw

- After the Cannulated Slot Finder has been placed, drill the hole in the far cortex (Figure 32).
- Place the Depth Gauge through the Cannulated Slot Finder to hook the far cortex (Figure 33) and remove the Cannulated Slot Finder and Large Drill Guide.

Fig. 32

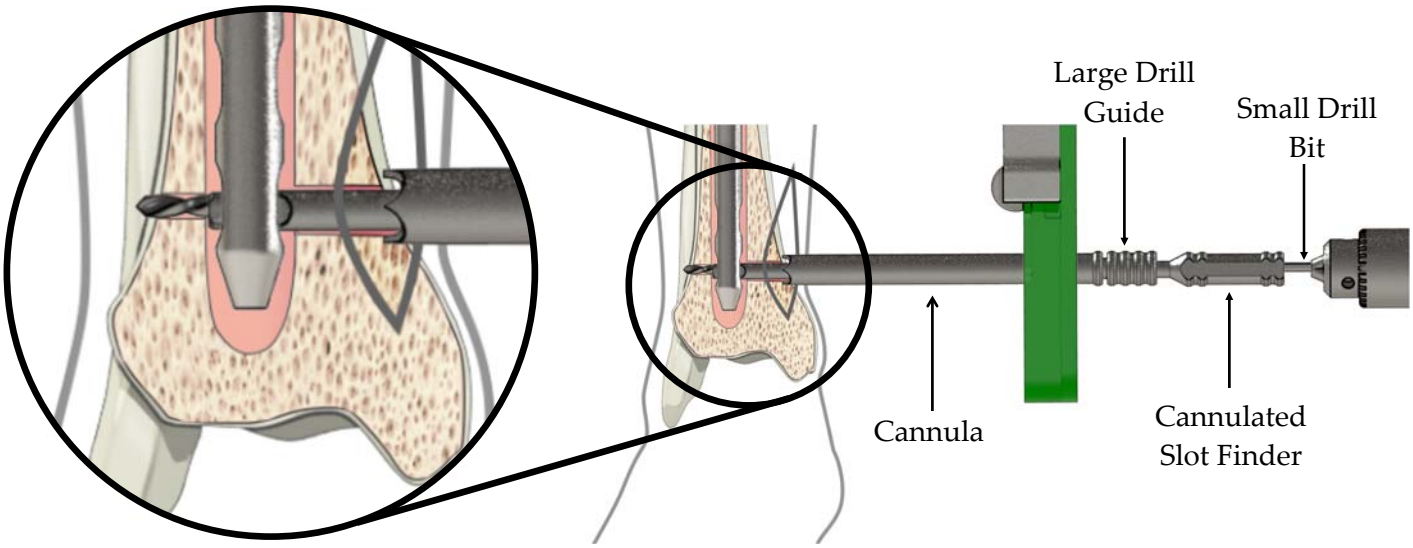
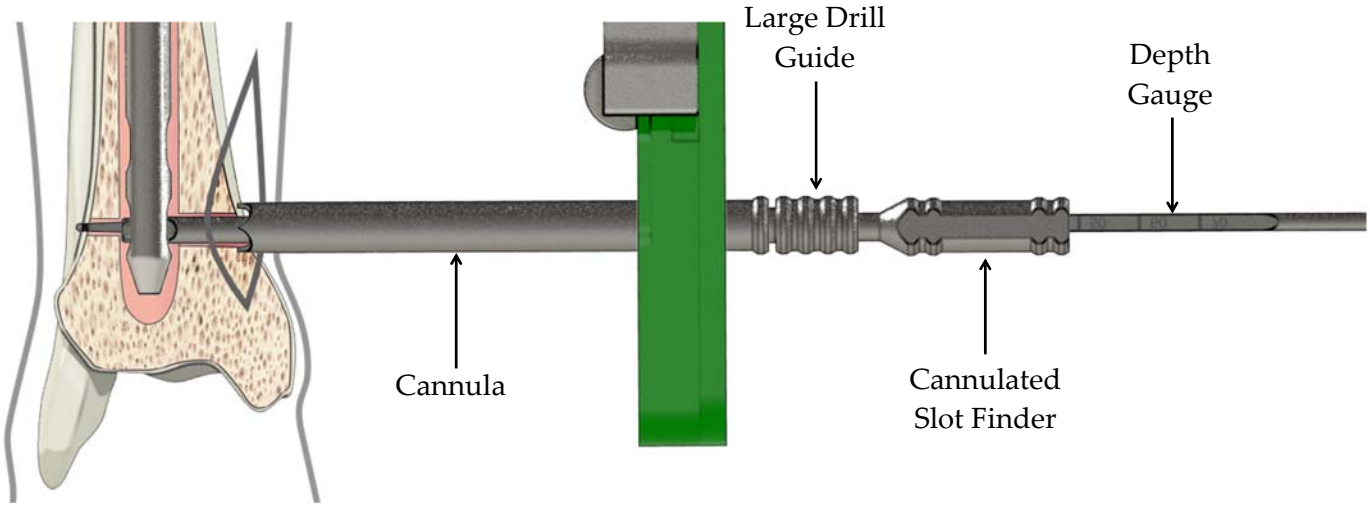


Fig. 33



Distal Interlock (cont.)

- Use the Depth Gauge to measure the bone to determine the length of the screw. Take the reading against the Cannula opening. Rotate the Depth Gauge to measure on two sides of the hole (Figure 34).

Fig. 34

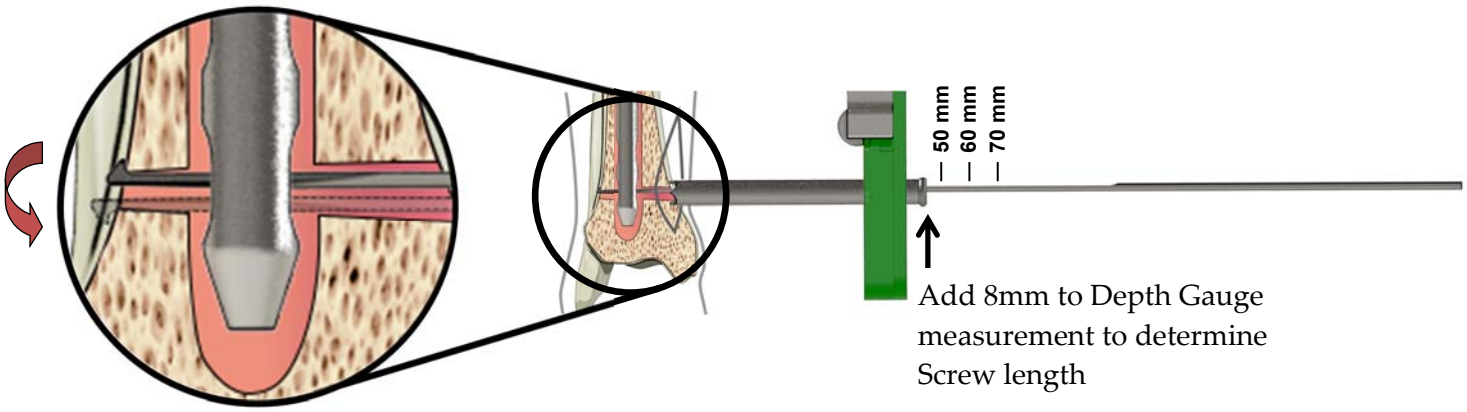
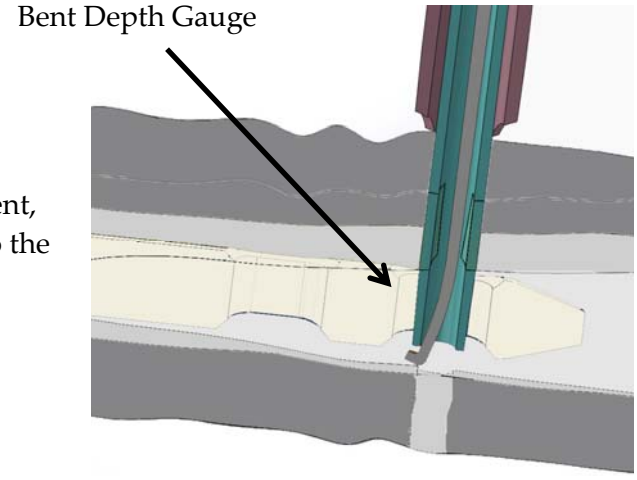


Fig. 35



- Do not bend the Depth Gauge. If the Depth Gauge is bent, it will not pass through the Cannulated Slot Finder into the hole of the distal cortex (Figure 35).

Distal Interlock (cont.)

- Add 8 mm to the measurement to determine the screw length so that the threads of the interlock screw will be fully engaged with the near and far cortex (Figure 37). This will also make removal of the screw much easier if necessary.
- Place the screw through the holes in the cortex and slot of the nail. Raise the Cannula during screw insertion so the screw head can be visualized in order not to insert the screw too deeply (Figure 36).
- Check the placement of the screw in the slot of the nail by gently rotating the nail with the L-Handle.
- The Alignment Pin is placed in the head of the distal interlocking screw (Figure 38).
- The second distal interlocking screw is then placed using the same technique as the first distal screw.

Fig. 36

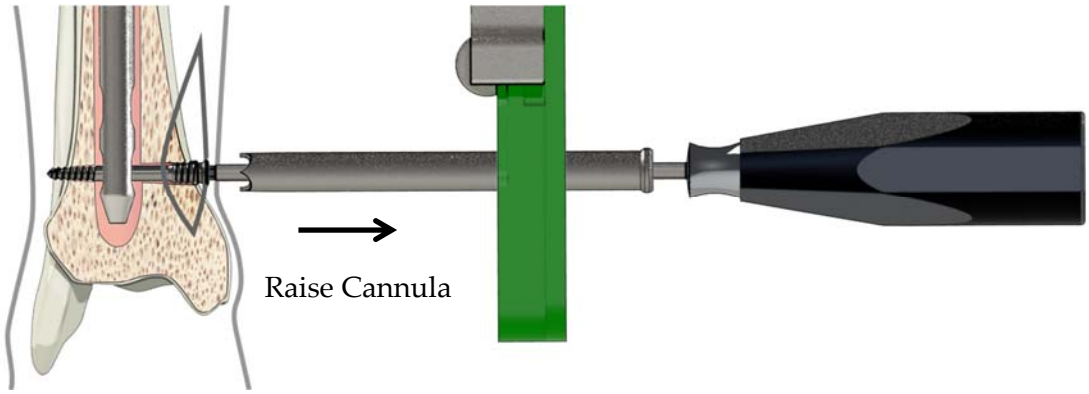


Fig. 37

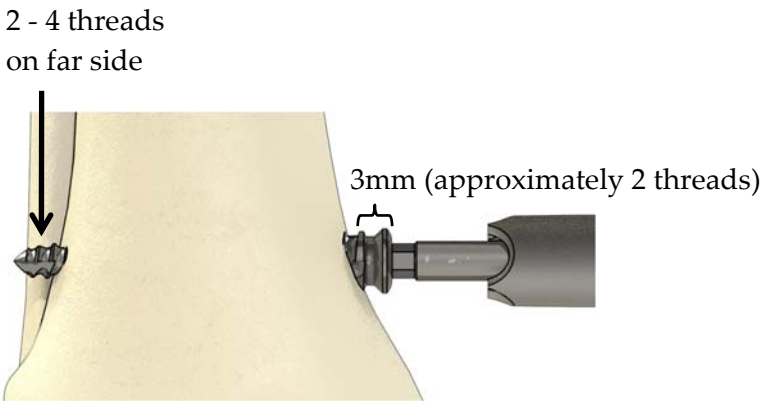
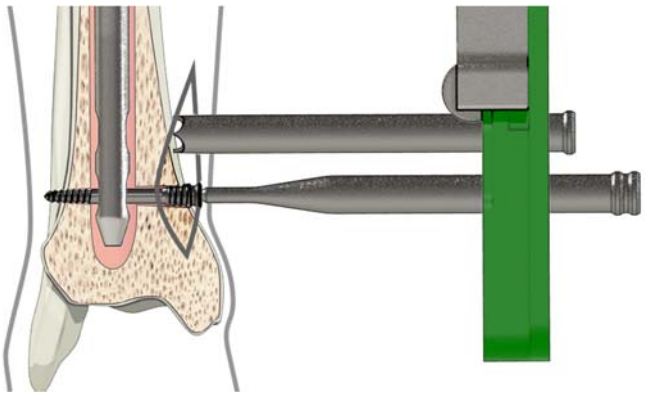


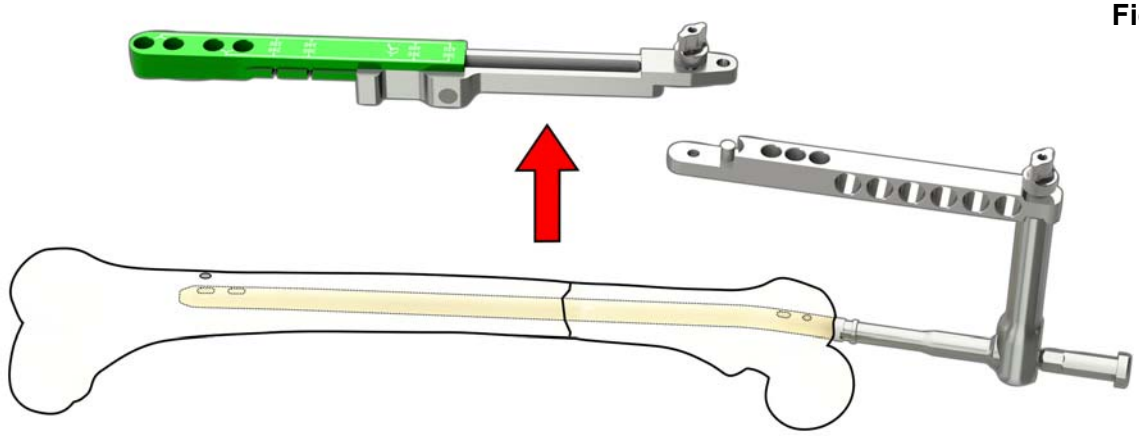
Fig. 38



Technique for Curved Slot Finder

- If the Solid Slot Finder does not enter the slot, remove the Solid Slot Finder and the distal Target Arm. (Figure 39). Removing the Target Arm will allow a wider arc of movement for the Curved Slot Finder.

Fig. 39

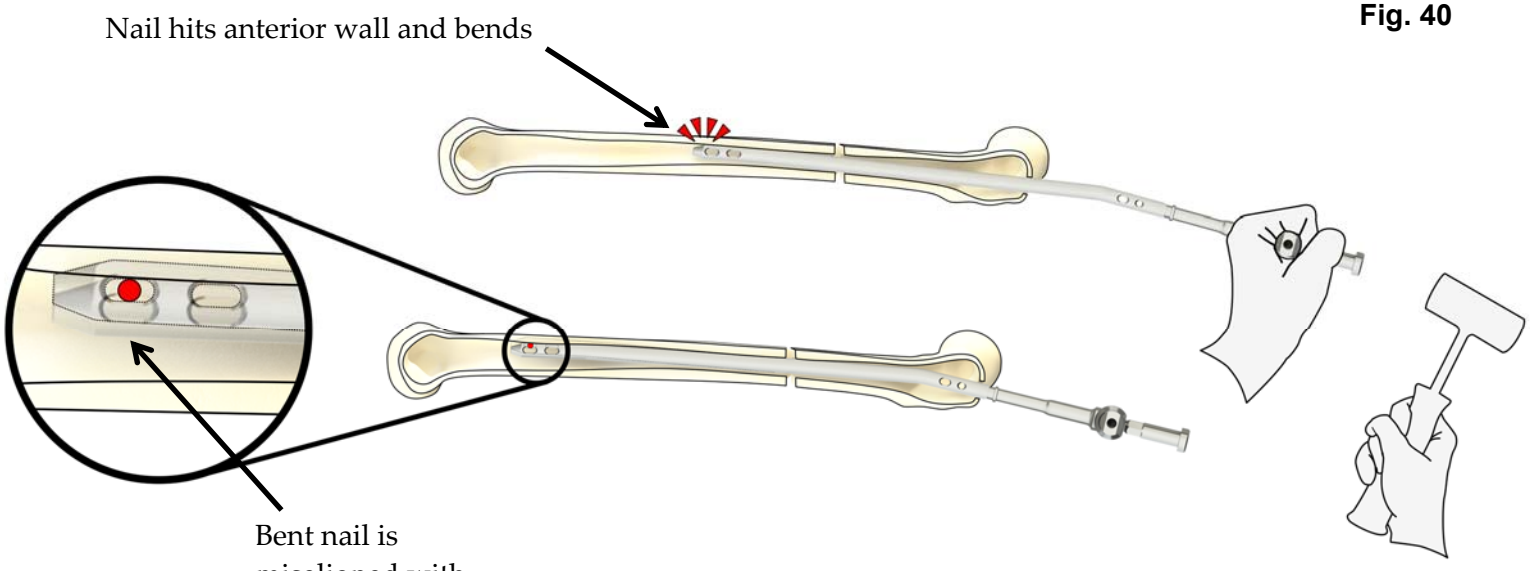


Rotational Malalignment

- Determine if the difficulty is due to rotational malalignment by observing the height of the ring on the L-Handle above the cortex. If the position of the ring on the L-Handle hasn't changed and the fracture site has not shifted, rotational malalignment should be addressed.

Causes of Rotational Malalignment	How to Prevent Rotational Malalignment
The nail hits anterior wall and bends during insertion (Figure 40)	Do not use excessive force during nail insertion.
The nail rotates after the hole is drilled in the near cortex.	Hold the L-Handle steady throughout the procedure.
One or more of the screws on the Target Arm loosened during nail insertion or drilling.	Periodically check that the screws on the Target Arm remain tight.

Fig. 40

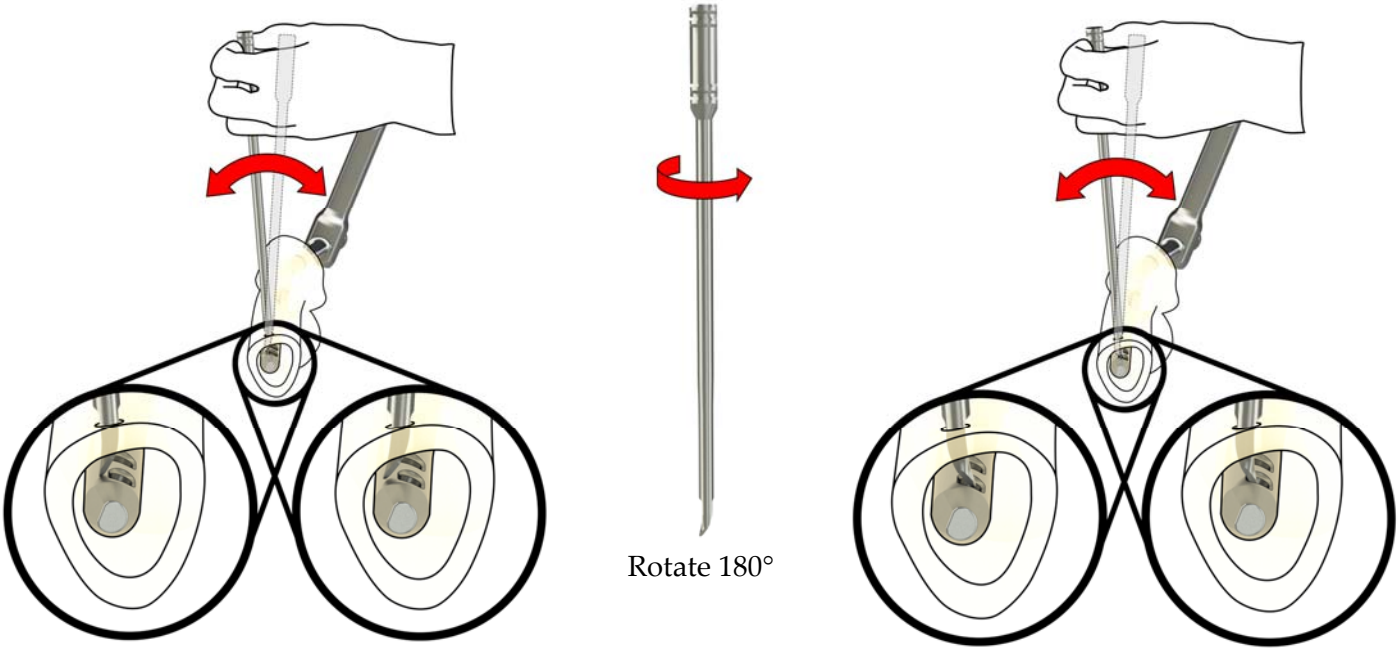


Technique for Curved Slot Finder (continued)

Rotational Malalignment

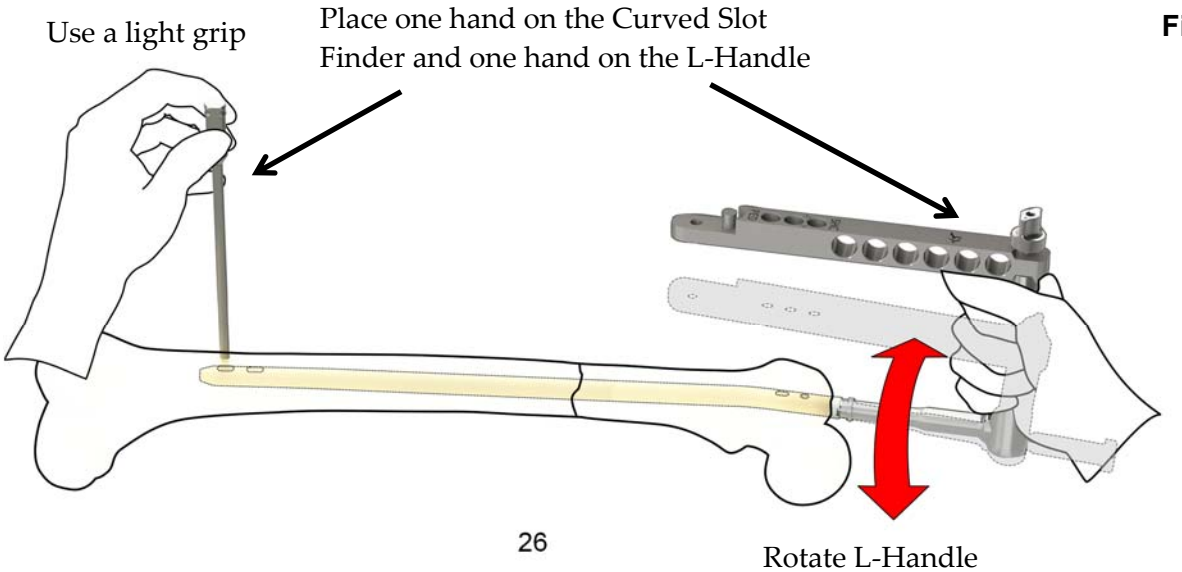
- When this occurs, adjust rotational nail position to find the nail slot.
    - Place the Curved Slot Finder through the hole in the near cortex.
    - Once the Curved Slot Finder touches the nail, search for the slot by moving the slot finder back and forth while gently tapping the nail with the slot finder. If the slot is not detected, rotate the Curved Slot Finder 180° and search again (Figure 41).

Fig. 41



    - Rotate the nail by gently turning the L-Handle while feeling for the slot with the Curved Slot Finder (Figures 42-44).

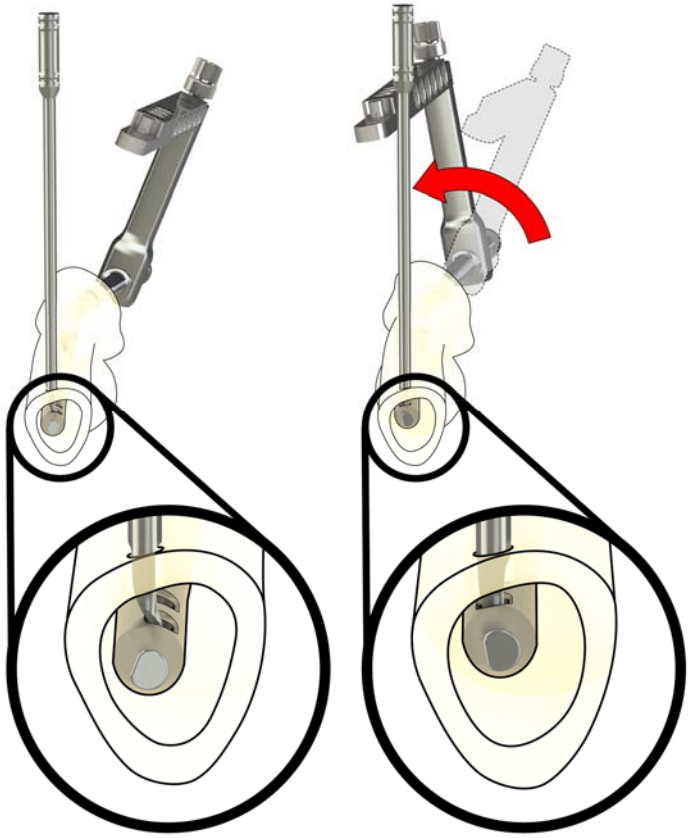
Fig. 42



Technique for Curved Slot Finder (continued)

Rotational Malalignment

Fig. 43

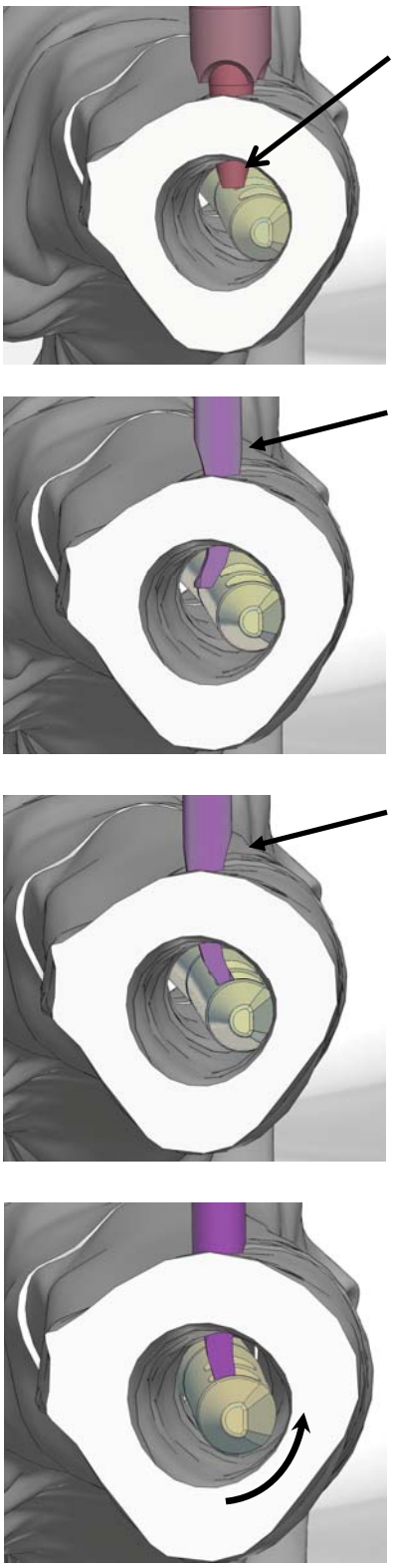


- Make sure that the flats on the Curved Slot Finder handle are in-line with the direction of the nail. Continue until the Curved Slot Finder enters the slot and you can detect the SIGN Feel.
- With the Curved Slot Finder in the slot, adjust the L-Handle so that it is perpendicular to drilled hole. Hold the L-Handle stationary and replace the Curved Slot Finder with the Cannulated Slot Finder.

To summarize:

- Hold the Curved Slot Finder with a light grip and probe for the distal interlock. Rotate the Curved Slot Finder 180° as needed.
- Use the L-Handle to gently rotate the nail and adjust the rotational position of the nail until the slot finder enters the nail slot.
- Check the animated video for further illustration.

Fig. 44



Use the L-Handle to rotate the Nail, allowing Curved Slot Finder to engage the slot

Technique for Curved Slot Finder (continued)

Longitudinal Malalignment

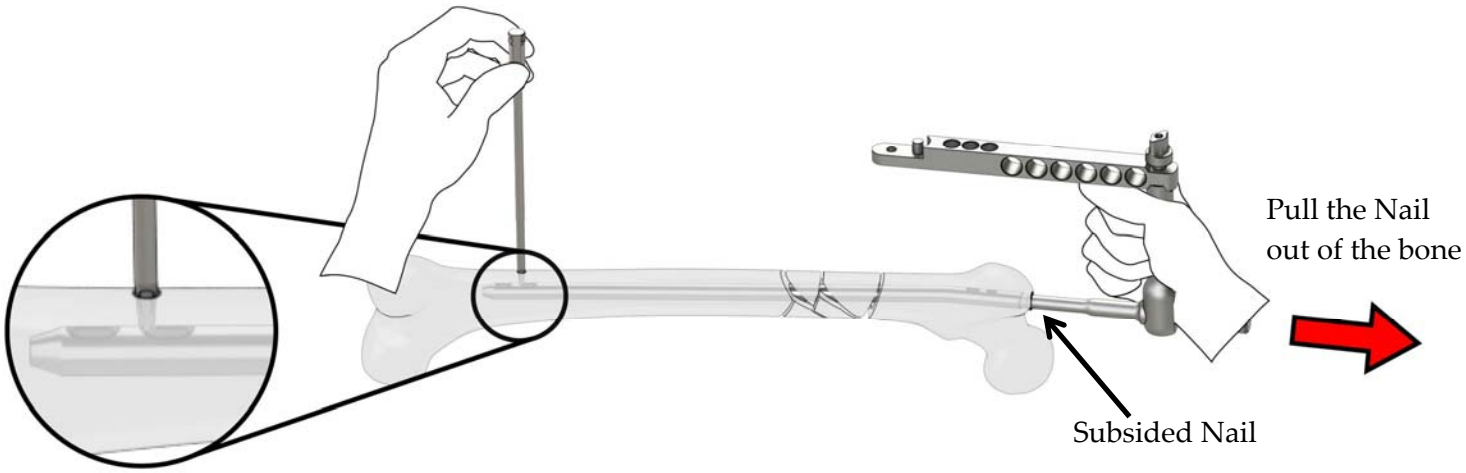
- Determine if the difficulty is due to longitudinal malalignment by observing the height of the ring on the L-Handle above the cortex. If the nail has subsided into the bone or if the nail end is more prominent above the bone, the longitudinal position of the nail must be adjusted. If the fracture has slipped, the fracture site must be corrected.

Causes of Longitudinal Malalignment	How to Prevent Longitudinal Malalignment
The nail slips after the hole is drilled in the near cortex	Hold the L-Handle steady to be sure the nail does not move after the near cortex is drilled.
The fracture site changes after the hole is drilled in the near cortex	An assistant should watch the fracture site during the distal interlocking procedure to be sure it does not shift.

NOTE: When probing for the slot, the surgeon should have one hand on the L-Handle and one hand on the Curved Slot Finder. Hold the Curved Slot Finder with a light grip to improve the sensitivity of touch.

- Adjust longitudinal nail position to find the slot
    - If the nail has subsided into the bone, slowly extract the nail out of bone while searching for the slot with the Curved Slot Finder. (Figure 45)

Fig. 45



Technique for Curved Slot Finder (continued)

Longitudinal Malalignment

- If the nail is more prominent, slowly push the nail further into the bone while searching with the Curved Slot Finder. (Figure 46)
- If the nail has not moved and the fracture site has slipped, the fracture site must be corrected. (Figure 47)

Fig. 46

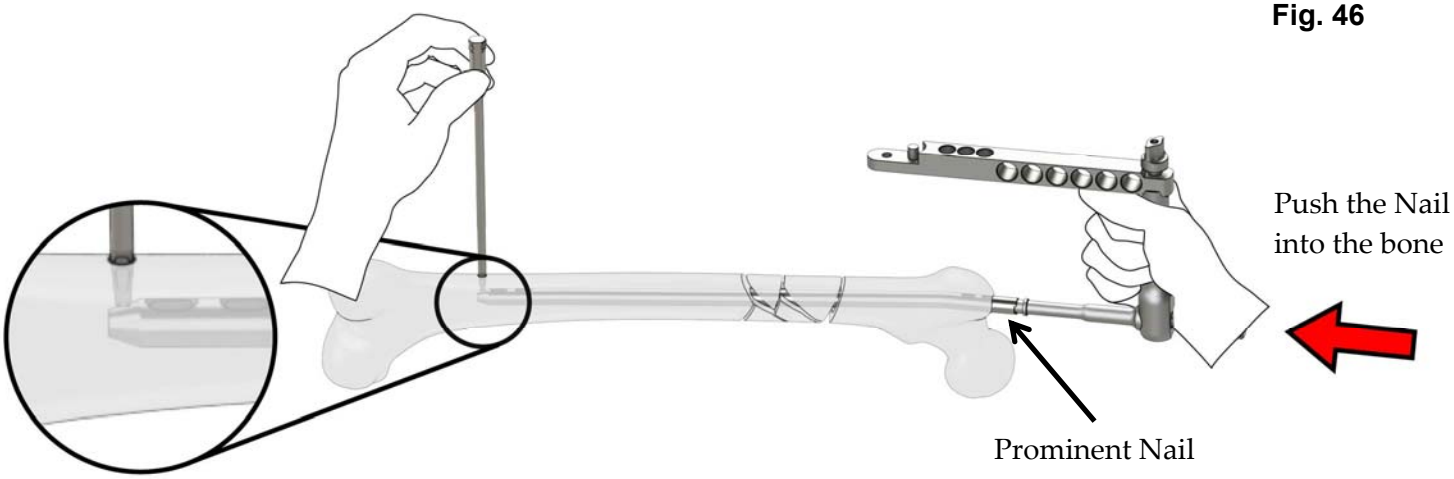
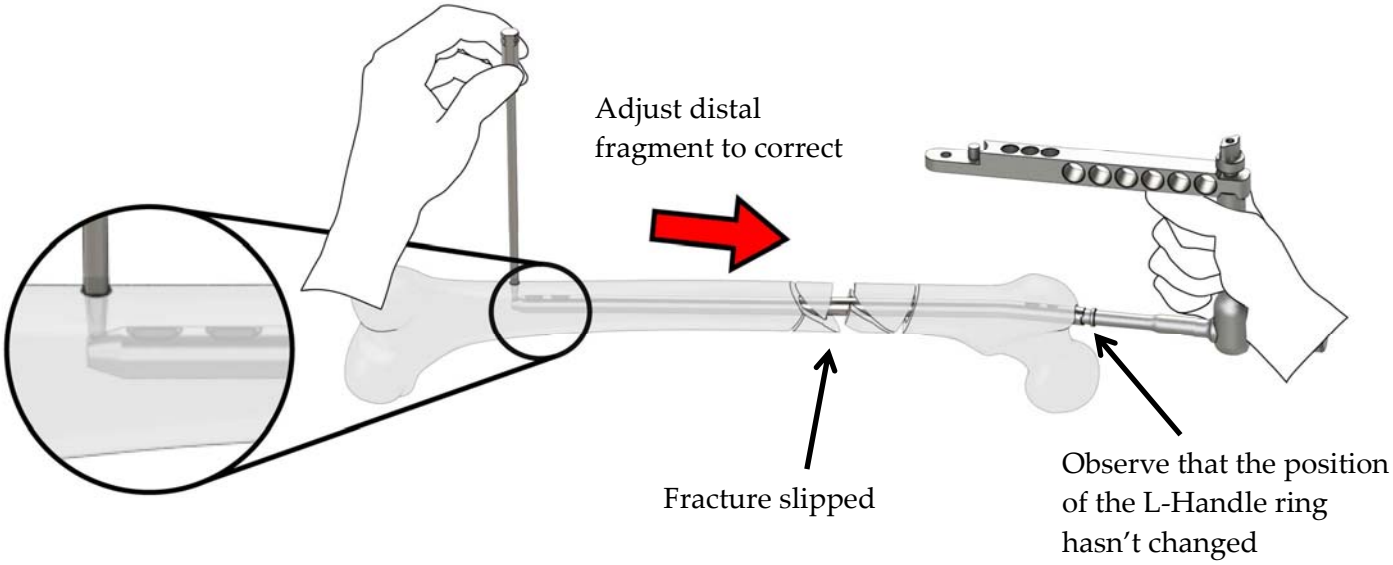


Fig. 47



Technique for Curved Slot Finder (continued)

Drilling Through the Far Cortex without Distal Target Arm

- After the Cannulated Slot Finder enters the slot, drill the far cortex, insert the Depth Gauge through the Cannulated Slot Finder and hook the far cortex. Replace the Cannulated Slot Finder with the Cannula, then take Depth Gauge reading against the Cannula opening.
- The screw can be inserted through the Cannula or after the Cannula has been removed. The surgeon will feel the screw passing through the slot of the nail into the hole in the far cortex.
- If using two distal interlock screws, reattach the Target Arm and use the Alignment Pin in the head of the interlocking screw to position the Target Arm for drilling the second hole. (Figure 38)

Compress the Fracture Site

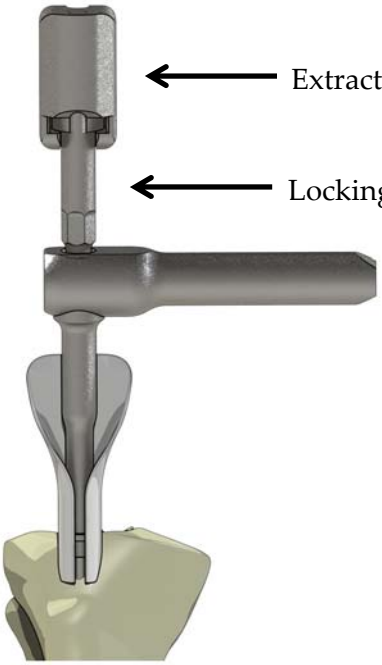
The fracture may need compression after the nail and the first interlocking screw has been placed.

1. First, make sure the Locking Bolt is connected tightly to the nail through the L-Handle (Figure 48).

Fig. 48

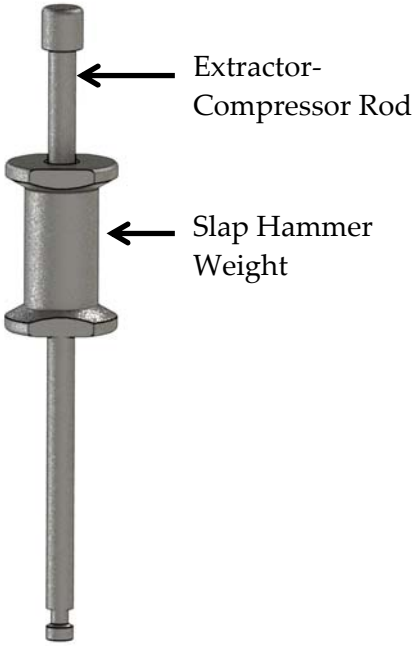
2. Place the Extractor Rod Connector on the Locking Bolt by sliding the base of the Connector onto the head of the Locking Bolt (Figure 49).

Fig. 49



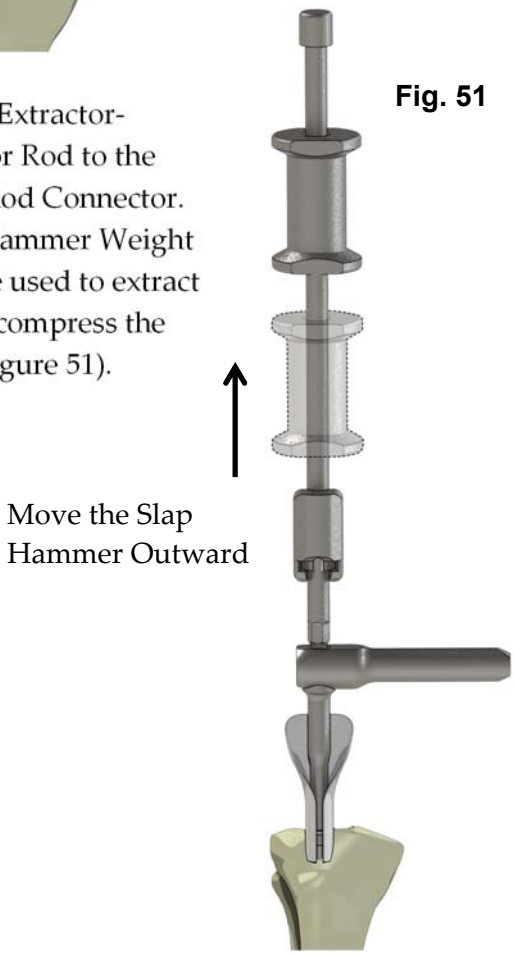
3. Place the Slap Hammer Weight on the Extractor-Compressor Rod (Figure 50).

Fig. 50



4. Attach the Extractor-Compressor Rod to the Extractor Rod Connector. The Slap Hammer Weight can now be used to extract the nail or compress the fracture (Figure 51).

Fig. 51



Proximal Interlocking Screw Fixation

Fig. 52

- Note that the proximal aperture in the nail is a hole, not a slot (Figure 52).
- Remove the Alignment Pin resting in the screw head of the distal interlocking screw. This is **not** necessary for proximal interlocking.
- Placement of the proximal interlocking screws is done by drilling holes in both cortices without stopping (Figure 53). The slot finders are not necessary to find the proximal hole or slot in the nail.
- The large 6.3mm Drill Guide and Step Drill are used to enlarge the hole (Figure 54). The screw length is measured by using the Depth Gauge and the Cannula and choosing a screw 8 mm longer than the Depth Gauge reading.
- As the screw is being placed, raise the Cannula to be sure the screw is not placed too far into the bone. Usually two screws are used in the proximal fragment.

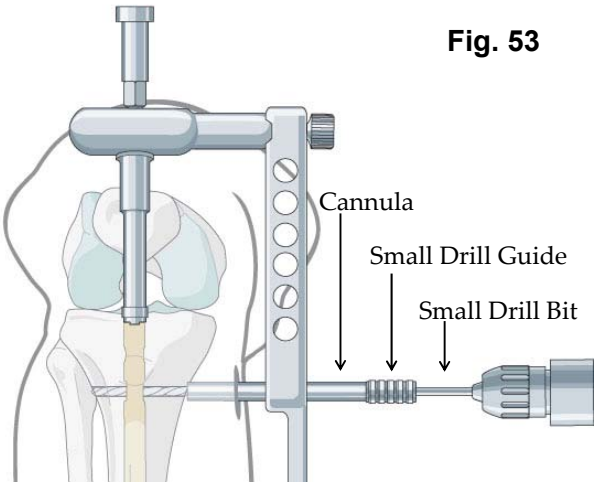


Fig. 53

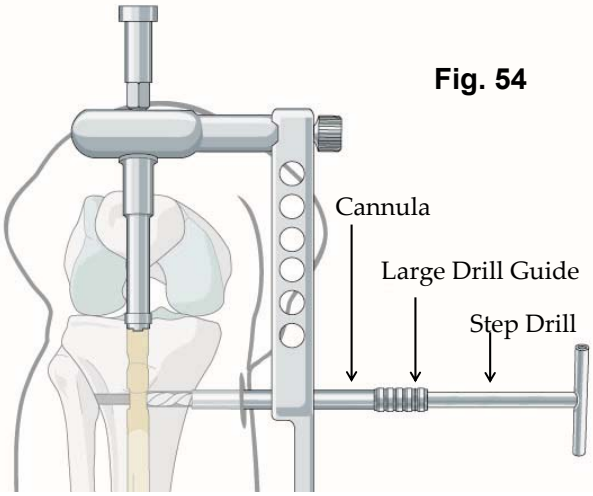


Fig. 54

Closure

- Suture of the muscle is not necessary. The fascia is closed over the open reduction in the femur, but fascia is not closed over the tibia.
- Manipulate the knee slowly at the end of every procedure

CHAPTER 3: ANTEGRADE APPROACH TO FEMUR

Position

The lateral position provides better access for open reduction and approach to greater trochanter. The supine position can be used also.

Reduction

The fracture site is identified as described in SIGN technique for all fractures. Many times there will be a rupture in the vastus lateralis which will lead the surgeon to the fracture.

Once the main bone fragments are free, they are reamed from the fracture site as described.

We recommend the trochanteric approach, which accommodates the proximal bend of the nail. The piriformis fossa entry is used for straight nails. Nails that have a proximal bend, such as the SIGN Nail, may cause increased hoop stresses in the femoral neck when forced into the piriformis fossa because there is not enough room for the bend. These increased hoop stresses may result in fracture of the femoral neck.

Skin Incision For the Entrance

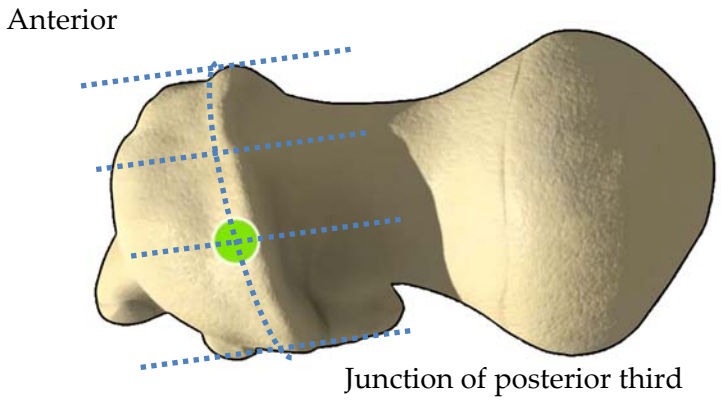
The skin incision is made posterior superior to the greater trochanter in the direction of the fibers of the gluteus maximus. Spread the muscle fibers using your fingers or the Periosteal Elevator. The abductor fascia is incised down to the bone over the greater trochanter at the junction between the posterior third and the middle third of the trochanteric ridge.

Bone Entrance

The Curved Awl is used to penetrate the greater trochanter. Direct the awl toward the fracture site (Figure 55).

Introduce the 7 or 8mm sharp reamer to make a track through the cancellous bone between the bone entrance and the femoral canal. The reamers should always be rotated clockwise during insertion and removal. The cutting edge only goes one way, and reversing the rotation makes the reamer cutting edge dull. The same principle applies for the Step Drill and drill bits.

Fig. 55



CHAPTER 3: ANTEGRADE APPROACH TO FEMUR

Reaming

Hand reaming has many advantages:

- Not dependent on electricity
- Bone can be saved from the flutes of the reamers using a gloved hand and collected in a cup of saline.
- The canal is straightened as the reamer sizes increase progressively.

Use the Tissue Protector to keep the reamer from touching the skin.

Once chatter is felt along 4 cm length in the isthmus, note the diameter of the reamer causing the chatter and select a nail 2 mm smaller in diameter. The length of the nail to be used is determined by X-ray, with consideration for the location and comminution of the fracture site.

Attach the nail to the L-Handle using the Locking Bolt. Orient the tabs of the nail and L-Handle so the proximal bend in the nail is oriented anteriorly. Be sure the Locking Bolt is kept tight throughout nail insertion. We recognize that when the proximal bend of the nail is inserted, spontaneous rotation of the nail may change the direction of the interlocking screws. The nail should be allowed to rotate freely to conform to the canal.

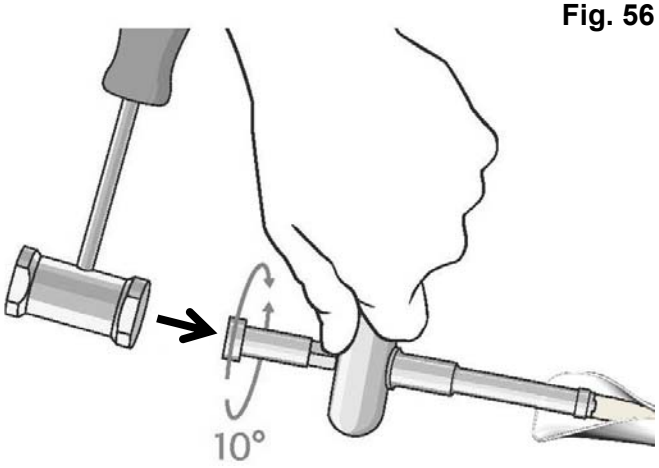
Remove the Target Arm from the L-Handle before inserting the SIGN Nail.

Preparation of the Nail

NOTE: See technique used in all approaches in Chapter 2.

The nail is attached to the L-Handle so that the proximal bend is either anterior or medial (Figures 57 and 58).

Fig. 56



Insertion of the Nail

Use the **Tissue Protector** to keep the nail from touching the skin. The Tissue Protector is reusable. The nail should be pushed in manually as far as it will go. Rotate the nail 10° each way as the nail is progressing down the canal. The one and half degree distal bend in the Standard Nail will enlarge the track if the nail is rotated. If more force is needed, use the mallet to provide light taps, but continue to rotate the L-Handle after each two taps (Figure 56). Never strike the nail with heavy blows. **If the nail will not advance, remove the nail and ream with the last reamer used or a larger reamer and reintroduce the nail**. Check the reduction as the nail advances.

When the proximal bend of the nail enters the bone entrance, the L-Handle will spontaneously rotate. The surgeon should allow this rotation as the proximal bend is entering the helical bend in the proximal femur (Figure 57 and 58).

Fig. 57

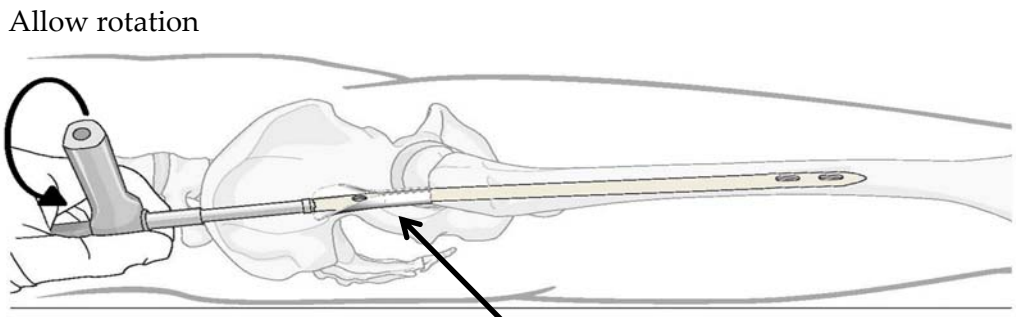
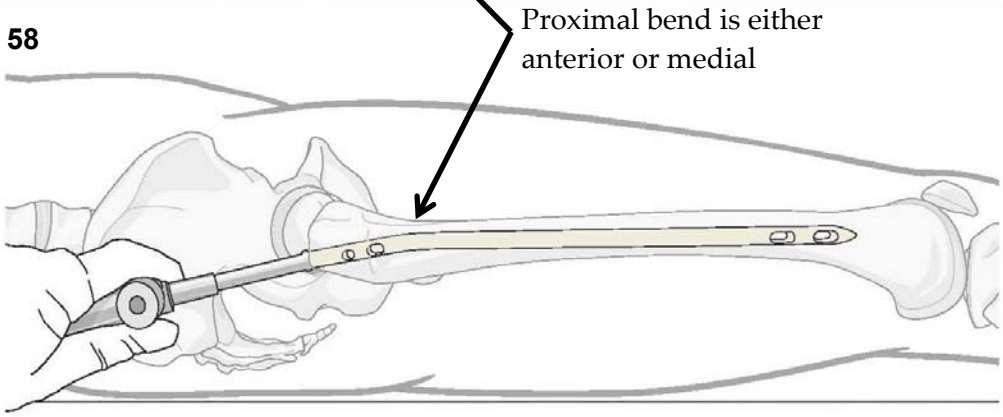


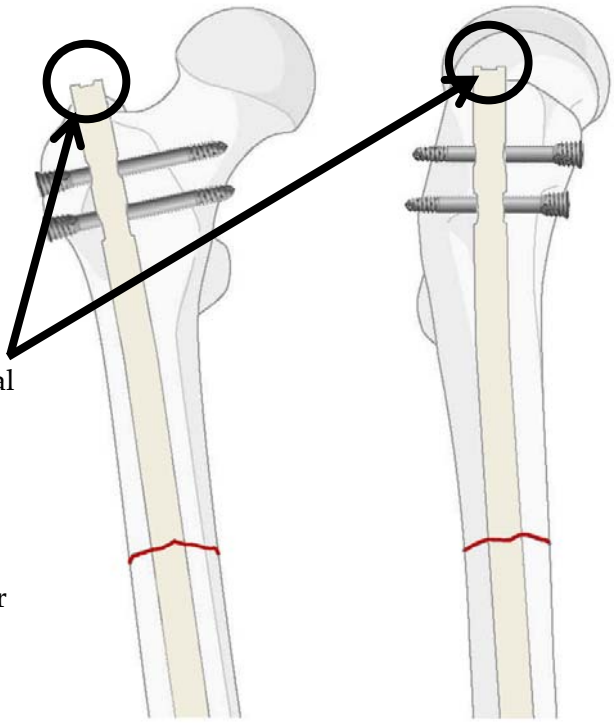
Fig. 58



Insertion of the Nail (cont.)

Interlocking is stable if the screws are placed either anterior-posterior or lateral-medial direction (Figures 59 and 60).

Fig. 59 Fig. 60



Leave the nail 3 mm prominent because the surrounding cortical bone provides more stability to the nail. Nail removal will be easier if the nail is left prominent.

Placing the Distal Interlocking Screws

Placing the distal interlocking screws is described in Chapter 2 and in the animated video.

CHAPTER 3: ANTEGRADE APPROACH TO FEMUR

Compress the Fracture Site

The decision to compress the fracture site depends on comminution and stability of the fracture site. The fracture site in nonunion exchange nailing should be compressed. This is described in Chapter 2 and shown in Figure 61.

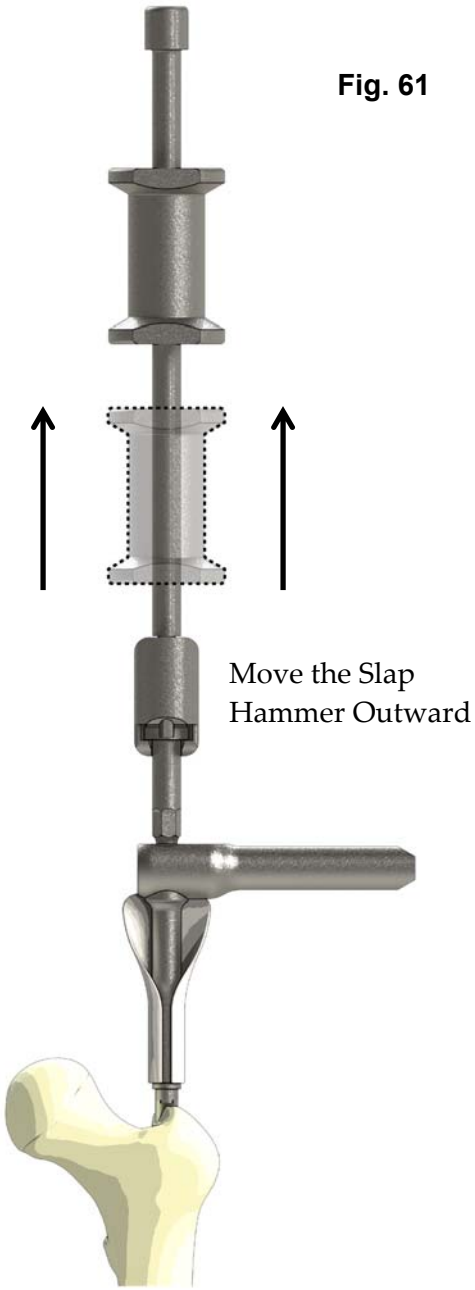


Fig. 61

Proximal Interlock

The pilot hole is drilled through both cortexes or into the femoral head, depending on nail orientation. The hole is enlarged with the Step Drill and appropriate drill guides. Measurement of the screw size is made by the Depth Gauge reading on the Cannula. The measurement is increased by 8 mm so the screw threads will fully engage both the near and far cortex.

Lift the Cannula to observe the depth of the screw as it is being introduced. Use two screws in the proximal femur because the bone cortex is not as thick as the diaphysis where the distal interlocking screws are placed.

Closure

- If open reduction is done, the tensor fascia lata is closed using a running suture. The muscle is not sutured. The question of leaving a drain is up to the surgeon. It depends on hemostasis of the wound.
- Manipulate the knee slowly at the end of every procedure.

CHAPTER 4: RETROGRADE APPROACH TO FEMUR

NOTE: See technique used in all approaches in Chapter 2.

The retrograde approach is chosen if the fracture is in the distal femur or if there are systemic or anesthetic reasons for using the supine position. 60° of knee flexion is optimal. Flexion of the knee may be increased by manipulation of the knee prior to surgery. Another maneuver is to incise the medial one-third of the patella tendon and detach this segment from the tibia tubercle. This is reattached at the end of the procedure.

Reduction

Closed reduction can be accomplished without C-arm. Open reduction is accomplished through a lateral incision.

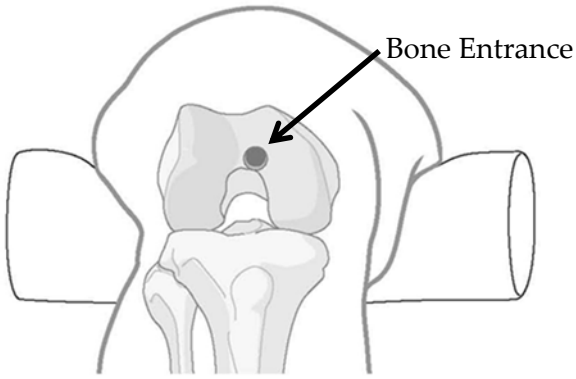
The usual approach, if there are no intra-articular fractures, is to make an incision medial to the patellar tendon or through it.

A window must be made in the fat pad. This can be done with a knife or cutting cautery.

Flex and extend the knee to improve visualization of the femoral notch.

The Curved Awl is used to penetrate the femoral notch just medial to the femoral groove (Figure 62).

Fig. 62



Be sure the fracture remains reduced to provide counter traction for reaming and nail insertion

If **intra-articular** fracture is present, a straight skin incision beginning 3 cm proximal to the patella and extended to the tibial tubercle is done. The quadriceps tendon is incised and one half is detached from the patella, as this incision is extended to a medium parapatellar incision. This incision extends medial to the patellar tendon. A window is made in the fat pad and the patella can be dislocated laterally to completely expose the femoral articular surface for reduction and stabilization. The nail is placed while the intra-articular fractures are held reduced by a clamp. Transverse screws are placed to stabilize the fracture after interlocking. Sometimes supplemental transverse screws are needed for stability.

CHAPTER 4: RETROGRADE APPROACH TO FEMUR

Reaming

Direct the reamers by observing the fracture site during reaming. The size of the Standard Nail should be 2-3 mm smaller than the reamer that caused chatter. The size of the Fin Nail should be 1 mm larger than the reamer that caused chatter (see Chapter 7 for special instructions of reaming for a Fin Nail). The Standard Nail should not end between the lesser trochanter or 4 cm below the lesser trochanter. This is the high stress area of the femur (Figure 63). Subsequent trauma may result in a fracture through the holes for interlocking or at the end of the nail if the nail ends in the high stress area. Place the end of the nail either below or above this high stress area or use a SIGN Fin Nail. We suggest using a Fin Nail whenever possible.

The nail is attached to the L-Handle so the proximal bend is anterior (Figure 64). Interlocking is from the lateral side. This is described in Chapter 2.

The nail is then introduced with minimal force until the L-Handle ring rests on the articular surface of the medial femoral condyle (Figure 65).

Fig. 63

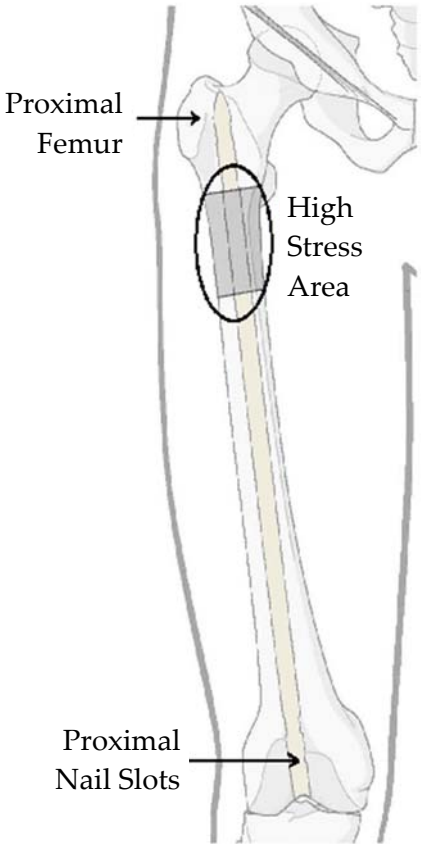


Fig. 64

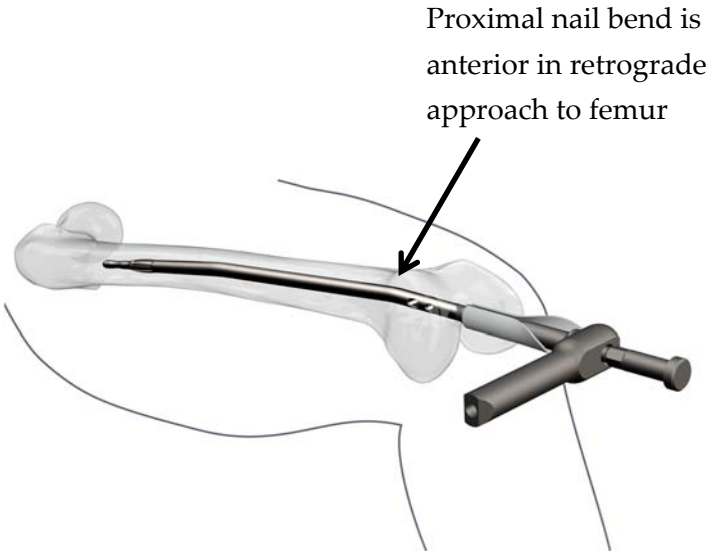
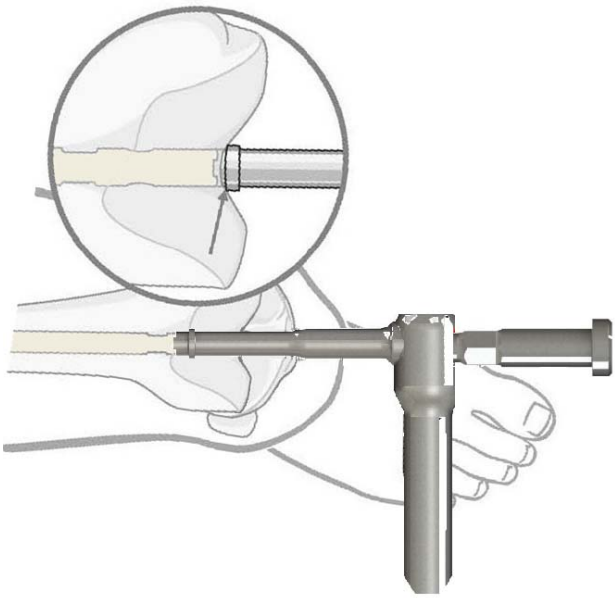


Fig. 65



CHAPTER 4: RETROGRADE APPROACH TO FEMUR

Distal Interlocking Screws—in the end nearest the hip

The distal interlocking screws are placed as described in chapter 2.

If the nail end is in the isthmus, the hole in the near cortex should be placed in the center of the isthmus (Figure 66). If the nail is placed above the lesser trochanter, the end of the nail will be located as described in Chapter 2 (Figure 67).

Fig. 66

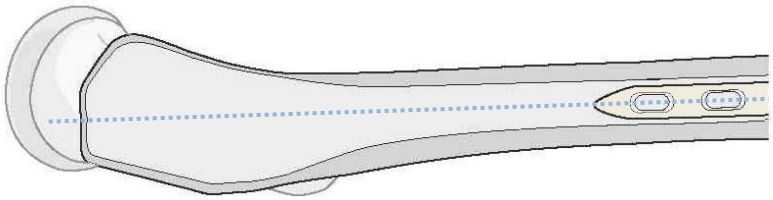
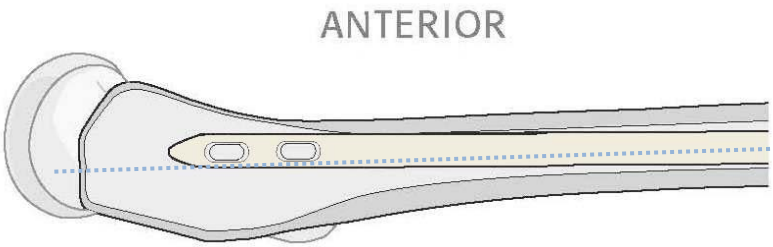


Fig. 67



Proximal Interlocking Screws

We suggest two screws be placed through the slots nearest the knee because the bone cortex is not as thick as the cortex in diaphyseal bone.

CHAPTER 5: SIGN TECHNIQUE FOR THE TIBIA

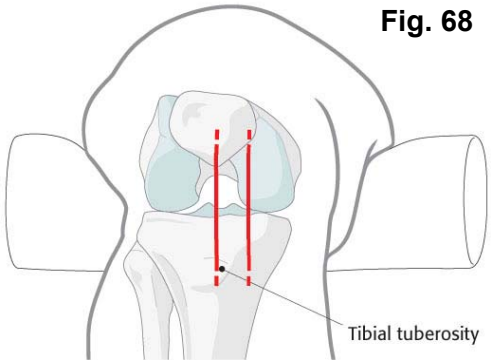
Position of Patient for Proximal Tibia Fractures

The tibia is stabilized with the patient in the supine position. The position used for the reduction depends on the location of the fracture.

Bone Entrance

The bone entrance is guided by the incision through the patella tendon. The bone entrance is anterior to the fat pad and the intermeniscal ligaments. Shape the hole anteriorly.

Fig. 68



Reaming and Placement of the Nail

- The incision used for reaming and nail insertion can be a longitudinal incision in the patellar tendon or an incision medial to the patellar tendon. The fat pad is not violated (Figure 68).
- 110° of knee flexion is necessary to keep the reamer and nail from striking the patella (Figure 69).
- The diameter of the nail is determined by chatter. The length of the nail can be determined by placing a blunt reamer down to the subchondral bone and measuring the length (Figure 70).
- Assemble the Target Arm so that the proximal bend in the nail is posterior (Figure 71).
- The nail is introduced with minimal force until the L-Handle ring rests on the intercondylar surface.

Fig. 69

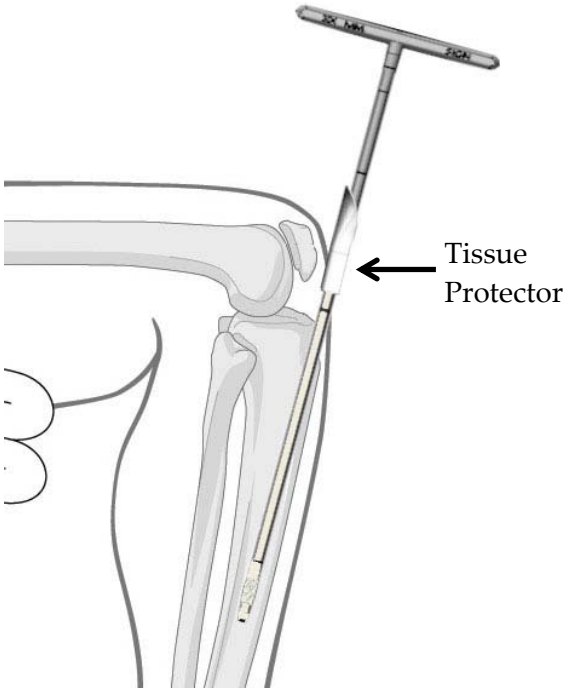


Fig. 70

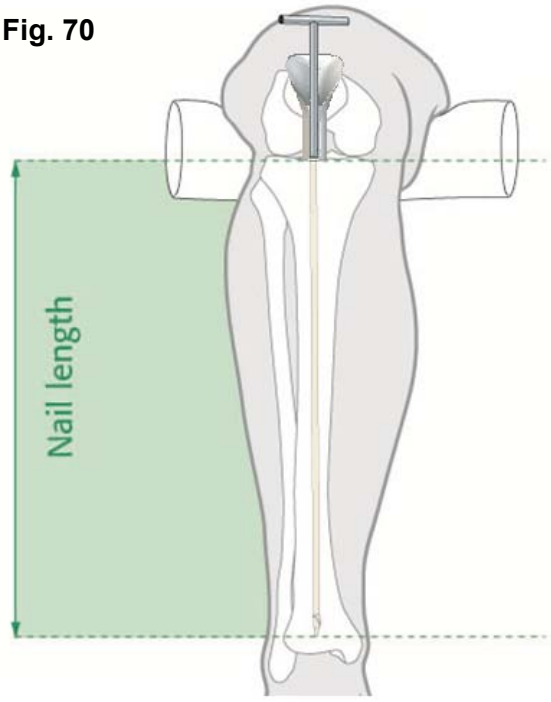
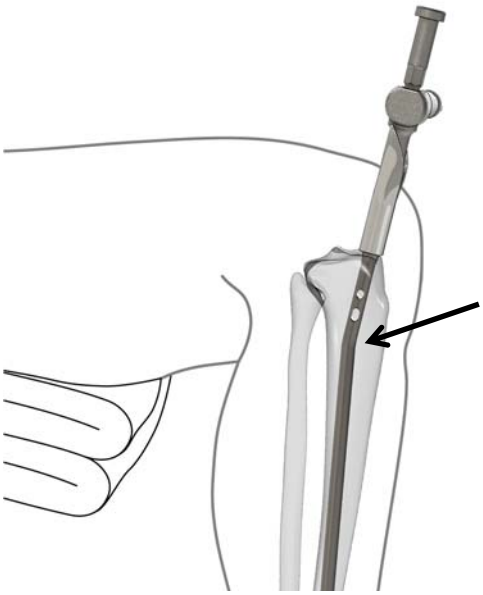


Fig. 71



CHAPTER 5: SIGN TECHNIQUE FOR THE TIBIA

Reduction

Tibia fractures can be reduced closed if surgery is within 10-14 days from injury. The surgeon and assistant can try closed reduction if the reamers pass through the fracture site. The reamers will stop if pushed when they are in the canal.

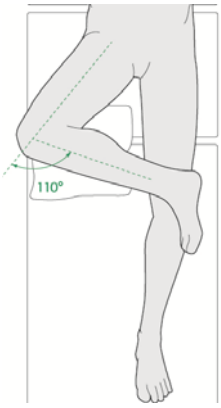
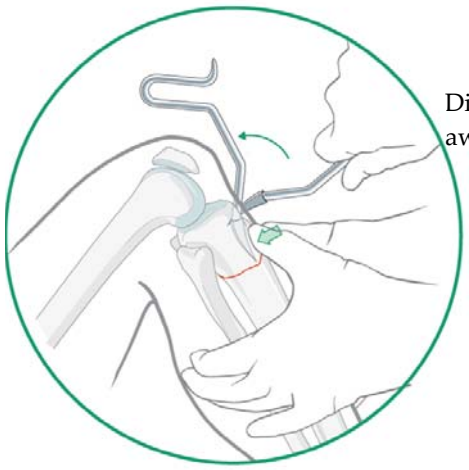


Figure 4 Position

Proximal fracture – The Figure 4 position facilitates reduction and placement of the nails (Figure 72). Determine if the proximal fragment is displaced anterior to the distal fragment. If so, the **proximal** fragment is pushed into reduction in the Figure 4 position. Sometimes distraction is necessary to free up the fragments. It is important that the pressure be placed on the proximal fragment rather than distal to the fracture. Pressure on the proximal fragment is facilitated by Figure 4 position. The knee must be flexed at least 110°.

Fig. 72


Direct curved awl anteriorly.

Midshaft and distal – Gravity is necessary for reduction and therefore the knee is suspended on a triangle or the leg is suspended off the end of the table or the side of the table. The surgeon who is manipulating the fracture site must first determine stability and instability in all directions. Sometimes if the fibula is intact, the reamer placed alongside the distal fragment gives the appearance of stability and reduction. The reamer is definitely in the distal fragment if there is a stop to progression of reaming at the same level as the other reamers.

Be sure no pressure is placed on the popliteal vessels (Figure 73 and 74).

Fig. 73

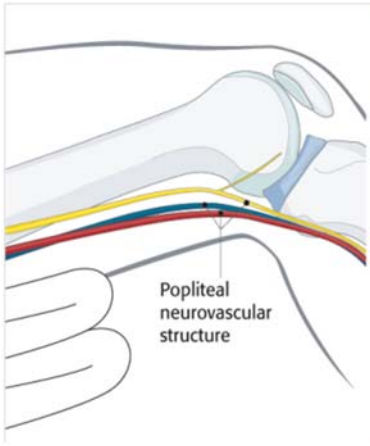
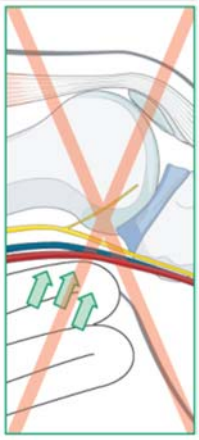


Fig. 74



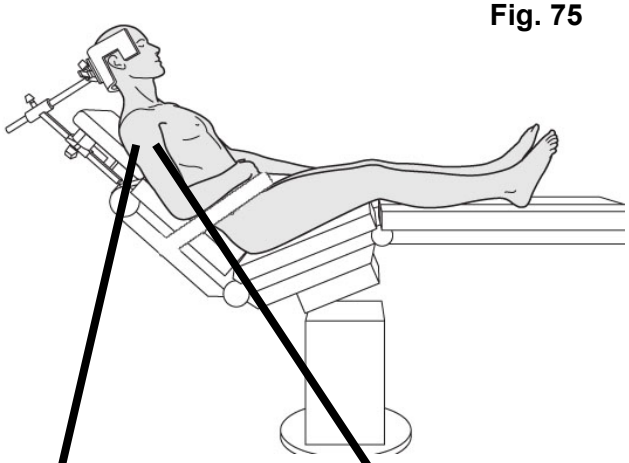
CHAPTER 6: HUMERUS

Position of Patient

The patient is placed in a beach chair position on the operating table (Figure 75).

All prominences must be padded especially the radial nerve.

Fig. 75



Reduction

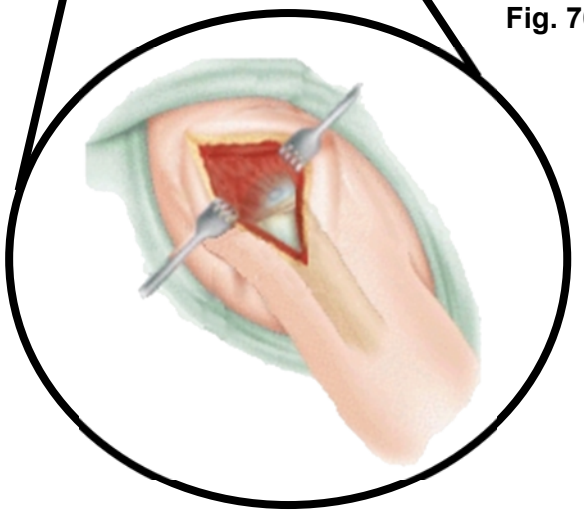
If open reduction is done first, avoid damage to the radial nerve.

Skin Incision

Palpate the bicipital groove and make the incision posterior to the groove (Figure 76) in the greater tuberosity.

Use the Periosteal Elevator to dissect through the fibers of the deltoid muscle. Split the rotator cuff so it can be repaired. **Repair is very important.**

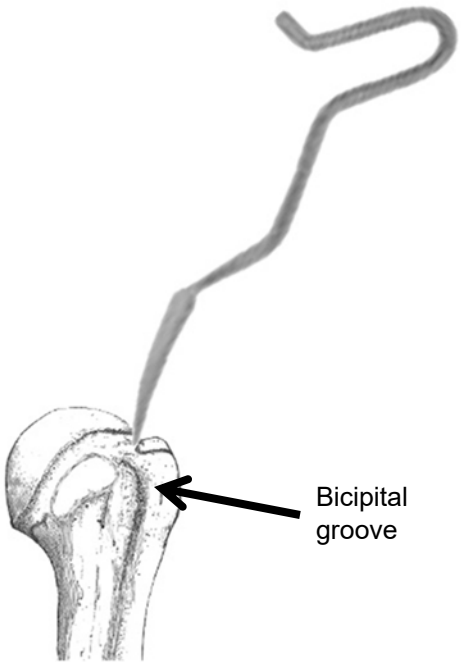
Fig. 76



Bony Entrance

The hole should be placed in the greater tuberosity at the junction of the articular surface. Use the Curved Awl (Figure 77).

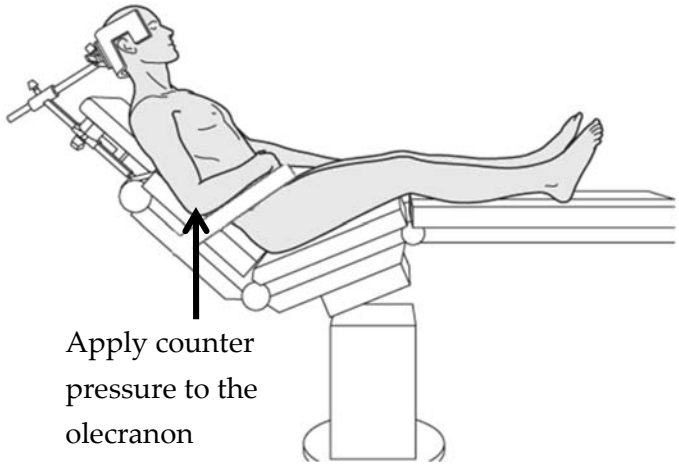
Fig. 77



Reaming

Be sure the fracture site is not distracted during reaming. The elbow should be placed on the bed for counter pressure (Figure 78).

Fig. 78



Apply counter pressure to the olecranon during insertion of nail into distal fragment.

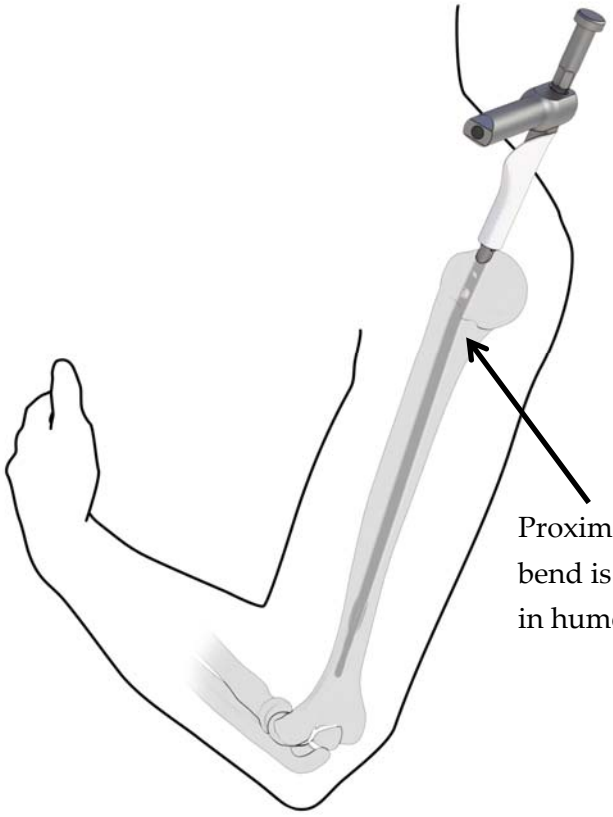
Nail Insertion

The SIGN Nail diameter is chosen as described in reaming instructions.

Assemble the Target Arm so that the proximal bend in the nail is anterior (Figure 79).

Be sure the fracture site is not distracted during placement of the nail.
The nail should be flush with the entrance hole. Place bone wax over the end of the nail after the L-handle is removed.

Fig. 79



Proximal nail bend is anterior in humerus

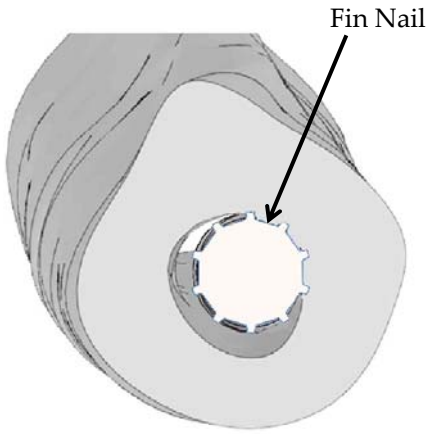
Proximal Interlocking

Interlocking is done as described in Chapter 2. The difference in the proximal interlock is that the screw must not penetrate the joint space. Make the pilot hole and enlarge using the Step Drill.

CHAPTER 7: FIN NAIL

Description

Fig. 80



Cross section of fins seated in bony canal

The SIGN Fin Nail is designed so that the fin takes the place of the distal interlocking screw (Figure 80).

Proper technique, especially reaming for the Fin Nail, will optimize the fixation.

Please note the femoral canal is oval distal to the isthmus. On one view of the post-op X-ray, the Fin Nail appears to be surrounded by bone, and on the other X-ray, there is a gap between the canal and the Fin Nail on one side.

Fig. 81 Fin Nail

Double Bend Fin Nail

	7mm	8mm	9mm	10mm	11mm	12mm
190mm	***1003-07190***	***1003-08190***	***1003-09190***	***1003-10190***		
240mm	***1003-07240***	***1003-08240***	***1003-09240***	***1003-10240***	***1003-11240***	***1003-12240***
260mm	***1003-07260***	***1003-08260***	***1003-09260***			
280mm		***1003-08280***	***1003-09280***	***1003-10280***	***1003-11280***	***1003-12280***
300mm			***1003-09300***	***1003-10300***	***1003-11300***	***1003-12300***
320mm		***1003-08320***	***1003-09320***	***1003-10320***	***1003-11320***	***1003-12320***
340mm			***1003-09340***	***1003-10340***	***1003-11340***	***1003-12340***
360mm			***1003-09360***	***1003-10360***	***1003-11360***	***1003-12360***

NOTE: ***The Fin Nail length refers to the distance between the nail notch (at the proximal end of nail) and the end of the flutes as shown above. (Figure 81)***

CHAPTER 7: FIN NAIL

Indications

SIGN suggests using the Fin Nail for all retrograde approaches to the femur if the fracture is not too comminuted. The fin takes the place of the distal interlocking screws.

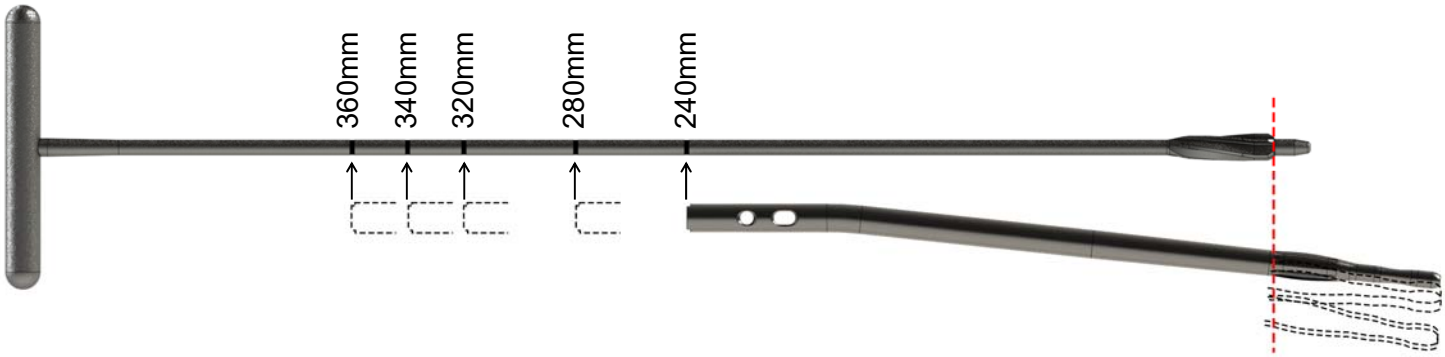
First Ream

- Ream until chatter is felt for 4 to 6cm of the canal. The diameter of the Fin Nail will be 1mm larger than this reamer.

Second Ream

- Ream with the next larger size reamer but stop at the mark pertaining to the length of the Fin Nail selected. (Figure 82)

Fig. 82



The nail diameter chosen corresponds to the size of the *LAST* reamer used.

Proximal Interlocking

Follow the procedure for proximal interlocking outlined in chapter 2.

Instruments

The short section of the Target Arm that attached to the L-Handle is used for the proximal interlocking (Figure 83).

Fig. 83

CHAPTER 8: ACCESSORIES- PLATING

Description:

When additional fracture stability is needed a plate can be used with the SIGN IM Nail for proximal femur fractures. There are two SIGN plate designs available– the FX Plates and the HV Plates. The FX Plates are applied using a Series V Step Screw in the large aperture, which also interlocks the SIGN IM Nail. The remaining apertures are suitable for FDA cleared 3.5mm bone screws.

The HV Plates are thicker and have apertures that are all suitable for SIGN Series V Step Screws. A Series V Step Screw can be used in the first hole of the HV Plate for interlocking of the SIGN IM Nail. At the surgeon's discretion and when this would benefit the patient, FDA cleared 3.5mm bone screws with washers can be used with the HV Large Plate instead of 4.5mm screws, except when interlocking with the SIGN IM Nail when 4.5mm screws must be used. See Figure 84 below for examples of plate application.

At a minimum, two screws above and two screws distal to the fracture should be used through the plate apertures. Use the appropriate screw length for bi-cortical or intra-cortical screw fixation. Care should be taken when drilling and installing the non interlocking screws to avoid the IM Nail.

Intended Use:

The FX Plate or HV Large Plate may be used in conjunction with the SIGM IM Nail for Subtrochanteric Fractures of the proximal femur.

Fig. 84

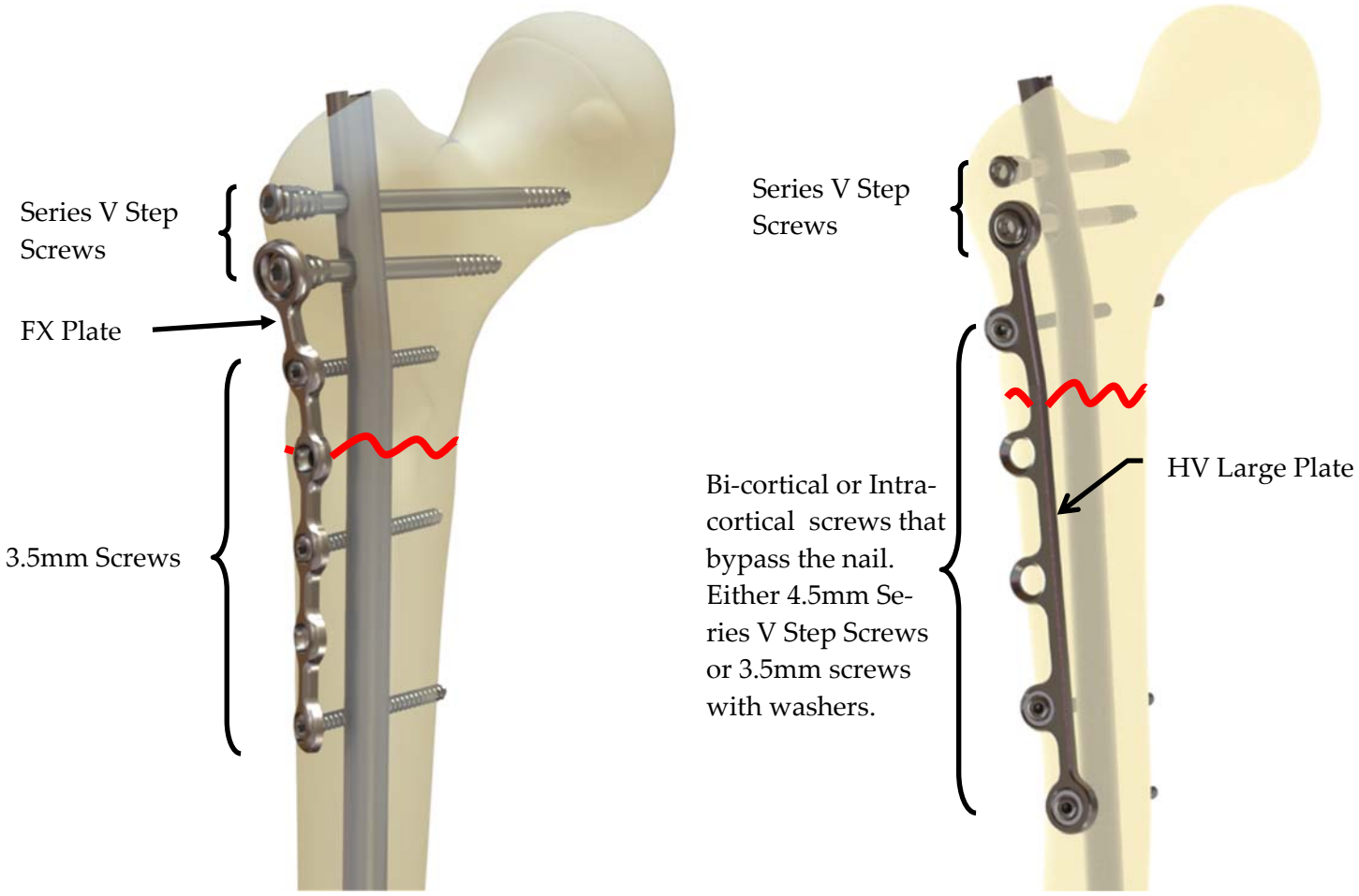


Plate Bending

If required, plates can be bent using the SIGN Plate Benders. Bending can be done before or during surgery.

Warning: Repeated bending may cause the plate to weaken or break. Do not bend the same area of the plate more than twice.

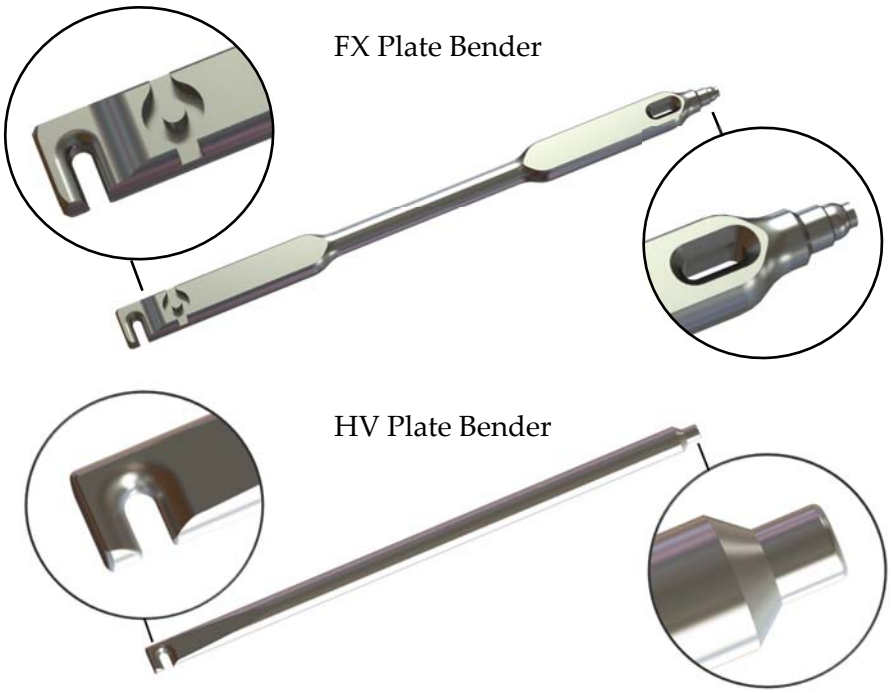
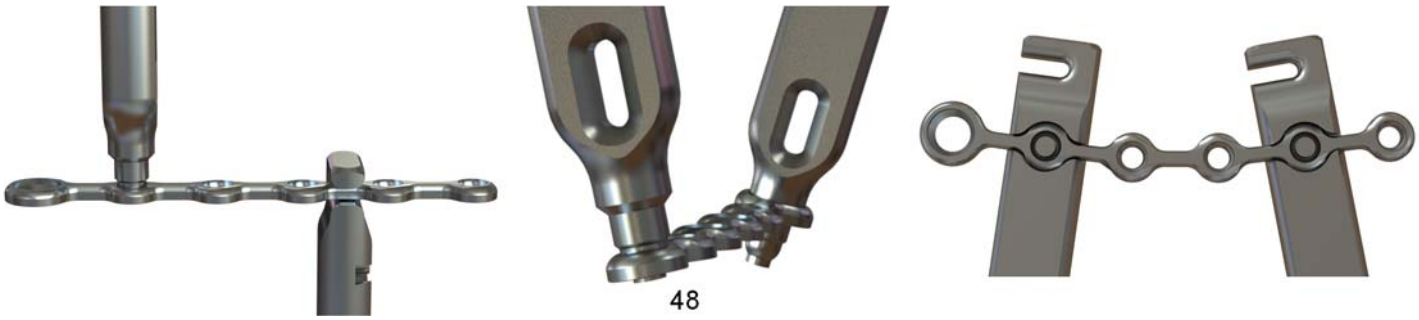


Fig. 85

Each Plate Bender has a different tool on each end. The post end can be placed inside a screw hole, while the notched end is placed between screw holes along the shaft of the plate. The recess profiles of the FX Plate Benders can be used to bend plates in-plane.

Plates can be curved, bent or twisted in any direction.



CHAPTER 9: REMOVAL OF BROKEN NAIL

Nail Removal

1. It is important to leave the proximal end of the nail and the screws prominent whenever possible. Many times we see that the nail has been placed inside the bone and we are concerned about removal later on. It is much easier to find the interlocking screws and nail if they are left prominent.
2. 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. Try to use the same distal holes for interlocking in the replacement nail if the broken nail is a SIGN Nail.
3. If the SIGN extraction set is not available, the Winquist Universal Extraction System can be used. Winquist Catalog No. WIN4 for the 1/4-20 extractor size and a 3.5mm Hex Driver.

CHAPTER 10: STIPULATIONS

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

SIGN Standard IM Nails

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

INFORMATION FOR USE: Physiological dimensions limit the sizes of implant appliances. 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.

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

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, 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.

CHAPTER 10: STIPULATIONS

STERILITY: All Implants and Instruments are provided non-sterile. Sterilization must be performed prior to surgery, using one of the following methods. For a prevacuum autoclave, set at 270°F (132°C) for 4 minutes, allow drying time of 30 minutes **(acceptable for use in the United States).** The following is **only recommended for use outside of the United States**. A prevacuum autoclave, set at 273°F-279°F (134°C to 137°C) for 3 minutes, allow drying time of 16 minutes. For a gravity displacement autoclave, set at 250°F (121°C) for 30 minutes, allow drying time of 45 minutes. 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 (FDA cleared wraps) 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.

CAUTION: Federal Law (USA) restricts this product to sale by or on the order of a physician or hospital.

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

WARNING: The SIGN Standard IM Nail has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SIGN Standard IM Nail in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 (info@signfracturecare.org) if instruments should be replaced. Instrument breakage or damage can occur when an instrument is subjected to excessive loads, speeds, or dense bone. Striking the cutting edges with other hard surfaces will cause these cutting edges 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 and reamers 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. Pulse the drill to help reduce heat.

CHAPTER 10: STIPULATIONS

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

SIGN Fin Nails

DESCRIPTION: SIGN Fin Nails and screws are designed to provide fixation of 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 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. 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, 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: Nerve damage resulting from surgical trauma. Necrosis of bone or bone resorption. Necrosis of tissue or inadequate healing may occur with any fracture.

CHAPTER 10: STIPULATIONS

STERILITY: All Implants and Instruments are provided non-sterile. Sterilization must be performed prior to surgery, using one of the following methods. For a prevacuum autoclave, set at 270°F (132°C) for 4 minutes, allow drying time of 30 minutes **(acceptable for use in the United States).** The following is **only recommended for use outside of the United States.** A prevacuum autoclave, set at 273°F-279°F (134°C to 137°C) for 3 minutes, allow drying time of 16 minutes. For a gravity displacement autoclave, set at 250°F (121°C) for 30 minutes, allow drying time of 45 minutes. Please consider your equipment manufacturer's written instructions for the specific sterilizer and load configuration being used and current AORN standards and recommended practices.

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WARNING: The SIGN Fin Nail has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SIGN Fin Nail in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 (info@signfracturecare.org) if instruments should be replaced. Instrument breakage or damage can occur when an instrument is subjected to excessive loads, speeds, or dense bone. Striking the cutting edges with other hard surfaces will cause these cutting edges 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 and reamers 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. Pulse the drill to help reduce heat.

Processing SIGN Non-sterile Implants and Instruments

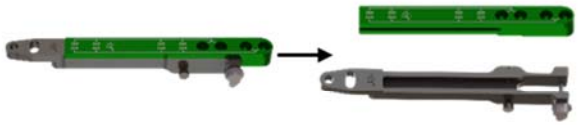
NOTES: Even surgical instruments manufactured from high-grade stainless steel must be dried thoroughly to prevent rust formation. All devices must be inspected for cleanliness of surface, joints, proper function, and wear and tear prior to sterilization.
After disinfecting and rinsing, un-magnified visual inspection under good light conditions is generally sufficient. All parts of the devices should be checked for visible soil and/or corrosion.

Cleaning Overview

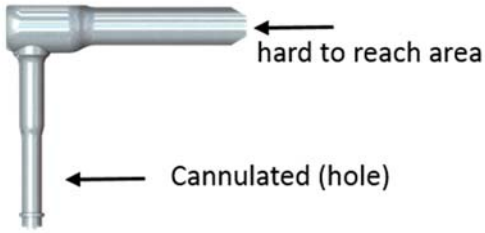
1. Disassemble where possible
2. Prepare an enzymatic cleaning solution following the manufacturer's recommendations.
3. Completely submerge the device in the enzymatic solution for a minimum of 20 minutes.
4. Carefully scrub the device for a minimum of three (3) minutes with a soft bristled brush, removing all visible soil.
5. If an ultrasonic unit is available, fully submerge the device in the ultrasonic unit with a cleaning solution. Sonicate for a minimum of ten (10) minutes.
6. Rinse the device in deionized water for a minimum of three (3) minutes or until all signs of blood or soil are absent from the rinse.
7. Inspect the device for visible soil. If soil is seen, repeat steps 3-6.
8. Dry the device using a clean, non-shedding wipe.

Notes

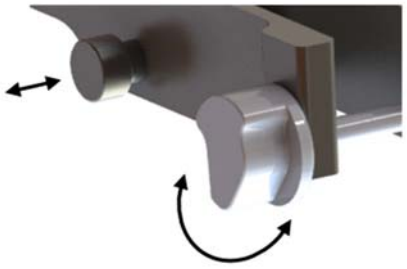
- Distal Extension should be removed from center section for cleaning



- Pay special attention to cannulated devices, crevices, and hard to reach areas.



- If there are any moving parts, articulate the parts and scrub all surfaces possible.



CHAPTER 10: STIPULATIONS

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.

Processing SIGN Non-sterile Implants and Instruments

Warnings and Precautions

- **Use caution when handling devices with sharp points or cutting edges.**
- **Do not use metal brushes or scouring pads during the cleaning process.**
- **Anodized aluminum must not come in contact with certain solutions, or the anodization layer may dissolve. Avoid strong alkaline cleaners or solutions containing iodine, chlorine or certain metal salts as well as any solution with a pH value above 11.**
- **Do not allow the contaminated device to dry prior to cleaning.**
- **Any contaminated device should be processed according to hospital protocol.**
- **There are limits to reprocessing. Implants should be inspected for damage such as corrosion, scratches and residues. Damaged devices should be discarded.**
- **Refer to the appropriate instructions for use (IFU) for sterility requirements.**
- **Users should wear appropriate personal protective equipment (PPE) when processing devices.**
- **All users should be qualified personnel with documented evidence of training and competency. Training should be inclusive of current applicable guidelines, standards and hospital practices.**

Manual Cleaning / Disinfecting Instructions

1. Disassemble where possible.
2. Prepare an enzymatic cleaning solution following the manufacturer's recommendations, paying close attention to the correct concentration and temperature. Fresh solutions should be prepared when existing solutions become unacceptably contaminated.
3. Completely submerge the device in the enzymatic solution for a minimum of 20 minutes.
4. Carefully scrub the device for a minimum of three (3) minutes with a soft bristled brush, removing all visible soil. Pay special attention to cannulated devices, crevices, and hard to reach areas. If there are any moving parts, articulate the parts and scrub all surfaces possible.
5. If an ultrasonic unit is available, fully submerge the device in the ultrasonic unit with a cleaning solution. Sonicate for a minimum of ten (10) minutes.
6. Rinse the device in deionized water for a minimum of three (3) minutes or until all signs of blood or soil are absent from the rinse.
7. Inspect the device for visible soil. If soil is seen, repeat steps 3-5.
8. Dry the device using a clean, non-shedding wipe.

REFERENCES

Gawande, Atul. *The Checklist Manifesto.* New York, NY: Picador; 2009.

Young S, Lie SA, Hallan G, et al. Low infection rates after 34,361 intramedullary nail operations in 55 low- and middle-income countries. *Acta Orthopaedica* 2011;82(6):737-743.