Technique Manual of SIGN Pediatric Fin Nail Operative Guide

www.signfracturecare.org

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Dear SIGN Fracture Care International Partner:

The number of adolescent femur fractures in developing countries is increasing rapidly. The SIGN program managers asked us to design a method to stabilize these fractures. We have designed a trochanteric entry semi rigid nail using our fin concept for distal interlocking. This nail has provided excellent stabilization during bench testing and reports sent to our SIGN surgical database.

The shaft of the SIGN pediatric fin nail has a 4 mm shaft. The canals of adolescent patients in developing countries are quite wide and therefore we have added a 6 mm shaft for the surgeon to use in these patients with wider canals. The size of the fin is determined at the time of surgery during the reaming process.

The SIGN pediatric fin nail is made from stainless steel that satisfies ASTM implant-grade material specifications acceptable to the US FDA. Our orthopedic hardware manufacturing operations conducted in accordance with national good manufacturing practices in quality assurance standards. SIGN has received ISO 13485 certification.

We look forward to your initial and follow-up reports on the SIGN surgical database. Please send your comments in the comment section of the database.

Sincerely,

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SIGN Fracture Care International
Founder & President
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Patient Preparation

Patient must have no infected areas or injuries that preclude surgery. Patient and/or responsible adult should be told about risks, benefits of surgery and agree to insertion of the Pediatric Fin Nail. Please check the patient’s skin the night before surgery. Wash the patient’s femur in the area of surgery the **night before** surgery and **morning of** surgery and cover with a sterile towel.

Check list for the night before surgery:

- Any infections? Where?
- Skin of extremity washed well.
- Template X-Rays to estimate length and angle of all screws.
- X-rays to be in OR.
- Check appropriate lab work and medical condition
- Medical condition of the patient.

X-rays

X-rays should include the entire femur. X-rays should be present in OR during surgery. Look carefully for fracture comminution.

Antibiotics

Antibiotics are started one hour before surgery and continued for 24 hours if the fracture is a closed fracture. Antibiotics should be started as soon as possible following injury on open fractures.
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, curved awl and periosteal elevator.

All personnel in the operating room 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 designed for pediatric nail use
- Shoulder Cap Screw - (2) one is extra
- Combination Hex Wrench - (2) This fits the Shoulder Cap Screw, Distal Cap Screws and the other end fits the Interlocking Screws
- Cannula
- Alignment Pin - (2) One is extra
- Drill Guides - (2) (one large for large drill bits) (one small for small drill bits)
- Drill Bits
  - (2) (3.5mm) (2) (6.3mm) for both near & far cortex
- Hex Screw Driver (3.5 mm)
- 11 mm Wrench
- Tissue Protector - (2) one is extra
- Depth Gauge
- Step-Drill
- Screw Hole Broach
- Reamers – 6 mm and 7 mm with pediatric marking
- Pediatric Fin Nail Template
- Extractor-Compressor Rod
- Extractor Rod Connector
- Slap Hammer Weight
Pediatric Femur Fractures Discussion for the Surgeon

Need
We asked our SIGN program managers to assess the number of pediatric fractures they treated in their hospital. 24 hospitals reported 2973 pediatric femur fractures.

Treatment
The standard of care in United States is internal fixation of femur fractures between the ages of 10 and above. The regular SIGN fin nail can be used beginning approximately age 12 – 16 depending on the maturity of the child.

The 4 types of fixation for femur fractures include:
1. external fixation
2. flexible nails
3. rigid nail
4. plate

Note: Comparison of these treatments is discussed in The Journal of Bone and Joint Surgery. Time to union was quickest with rigid nails. Loss of reduction was 30% with external fixation and 0% when using rigid nails and plates: Flexible nails do not hold rotation properly. The conclusion is that fractures treated with rigid nails have fastest healing and least complications. The comminuted fractures in this series were treated with rigid nails and plates which skewed the study.

Preparation for Design

Question-Will placing a nail through the trochanteric apophysis cause growth disturbances?

A series of 30 patients ages 8-16 years old that had femoral osteotomies and immobilization with the Phillips intramedullary nail through the trochanteric apophysis. No osteonecrosis, growth disturbances of the femoral neck or leg length discrepancy were noted.2

25 patients age 9 and older did not have growth changes after a nail was placed through the greater trochanteric apophysis.3 Bone entrance should not be through piriformis fossa as this may cause damage to blood vessels of femoral head.

REFERENCES
The SIGN pediatric fin nail is designed to enter the femur through the greater trochanteric apophysis. The femoral apophysis does not contribute to longitudinal growth of the femur. It is very important to avoid entering the piriformis fossa due to potential damage to the vascular supply of the proximal femoral epiphysis and femoral head.

The proximal end of the SIGN pediatric fin nail is 8 mm with a 9 mm enlargement at the proximal end for attachment of the L. handle. This 9 mm enlargement does not enter the femur. The nail has a proximal bend of 6°. The 4 mm shaft is flexible and the 6 mm shaft is not.

**NOTE:** The 4 mm shaft is for patients 90 lbs (40.8 Kg) or less where the greater flexibility is appropriate. The 6 mm shaft is for patients over 90 lbs (40.8 Kg) where the greater strength is appropriate.

The role of the distal interlocking screws is replaced by the proven SIGN fin configuration. Please use a template to determine approximate size of the canal in order to determine shaft and fin size. The final determination will be made after reaming at the time of surgery.

The nail is composed of stainless steel alloy which can be removed easier than nails made from titanium alloy.

The proximal interlocking screw is placed using the same technique as the standard SIGN nail. The aperture for the interlock has been placed more distally in order to avoid damage to the femoral neck and head.
Standard Length and Diameter

Length: 140 mm, 170 mm, 200 mm, 240 mm

Diameter of fin: 6 mm, 7 mm, 8 mm

Diameter of shaft: 4 mm, 6 mm

SIGN Reamers are 6 and 7 mm marked for pediatric fin nails.

Marks on reamer are set from the distal end of the reamer fin.
Antegradel Approach

Template
Template the fracture using x-ray of femur of patient which is not fractured. This will determine the optimum length of the nail and diameter of shaft. Fin size is determined during surgery.

Position of Patient
Patient in lateral position with the usual precautions to prevent infection and pressure on prominences.

Reduction
Closed if possible.

Open reduction-incise the skin and tensor fascia lata at the level of the fracture. Dissect your finger down through or posterior to the posterior vastus lateralis to the fracture site. Extend the incision as necessary but limit dissection. Identify the fracture with your finger. Use a periosteal elevator to dissect through muscle. Do not cut the muscle or use cautery on the muscle. Reduce and hold the fracture.

Bone Entrance

The bone entrance-between the posterior and middle third of the tip of the lateral trochanter.

Use awl to penetrate tip of trochanter between posterior third and middle third of the trochanter. Do not enter the piriformis fossa.
CHAPTER 6: TECHNIQUE FOR PEDIATRIC FIN NAIL

Triple Ream

1. Ream until chatter in the narrow part of the canal (Figure 4). This means you can feel the reamer touching all around the canal wall. Do not ream vigorously. If there is no chatter while using 6 mm reamer, use 7 mm reamer and use 8 mm pediatric fin diameter. Select length, shaft size and fin diameter of nail. If there is still no chatter consider the SIGN fin nail.

2. After chatter occurs, use the next larger size reamer. It must stop at the mark on the reamer corresponding to the length of the nail. (Figure 5)

3. Ream progressively 1 or 2 mm more in the metaphysis. (Figure 6)

Nail Selection

The length of the nail is selected based on the location of the fracture and length of the femur. The fin should reside in the canal at least 6 cm distal to the fracture. The diameter of the fin is based on the triple ream described above.

The 4 mm shaft is used for patients weighing 90 lbs. (40.8 kg) or less. The 6 mm shaft is used for patients weighing over 90 lbs. (40.8 kg).

Insert the Nail

Gently tap the nail to insert it. If the nail does not progress, remove and use one size smaller fin diameter nail. Do not force rotation of the nail. Leave 3 mm of nail proximal to the bone cortex. (Figure 7)
**Proximal Interlock**

Proximal Interlock is done using the Target Arm Base. Use the distal hole. (Figure 8)

Interlocking screw may be directed lateral —> medial (Figure 9) or anterior —> posterior (Figure 10).

Both directions provide equal stabilization.

**Limited weight-bearing, limited to crutch walking until callus is seen on x-ray.**

**Note:** If the fin resides distal to the isthmus, the three-point fixation causes the fin to attach to the canal. We are studying follow-up x-rays of these patients and have not noted loss of reduction. We want to see follow-up x-rays until the end of growth. We do not recommend using the SIGN fin nail in retrograde approach to femur.
CHAPTER 7: STIPULATIONS

DESCRIPTION: SIGN Pediatric Fin Nails and screws are designed to provide fixation of femoral fractures while they heal.

INFORMATION FOR USE: The surgeon must select the type and size implant that best meets the patient’s requirements for close adaptation and firm seating with adequate support. The surgeon must also consider both age and body weight of the patient. The SIGN Pediatric Fin Nail is recommended for antegrade approach.

INDICATIONS FOR USE: The SIGN Pediatric Fin Nail is indicated for internal fixation of diaphyseal fractures of the femur, osteotomies, correction of malunions and nonunions on patients who are anatomically suited to receive the device.

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 in pediatric and small stature patients, instruments, and the recommended surgical technique for this device. The device is not designed to withstand the stress of immediate weight bearing, load bearing, or excessive activity. 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 and caregiver in the case of a child, 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: Nerve damage resulting from surgical trauma. Necrosis of bone or bone resorption. Necrosis of tissue or inadequate healing may occur with any fracture.
CHAPTER 7: 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, 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 Pediatric Fin Nail has not been evaluated for safety and compatibility in the MR environment. The SIGN Pediatric Fin Nail has not been tested for heating or migration in the MR environment.

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.

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, joints, and 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.
CHAPTER 7: 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.

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, joints, and proper function, and wear and tear prior to sterilization.

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.
Case A

A 10-year old boy from Mongolia fell from a horse and fractured his left femur. Picture shows him standing one day after surgery.

Case B

12-year old girl from Tanzania was run over and fractured her right femur. Picture shows her standing, at school, four weeks after surgery.
CHAPTER 9: SIGN INSTRUMENTS AND IMPLANTS

**Part numbers are in BOLD**

### PEDIATRIC FIN NAIL

<table>
<thead>
<tr>
<th>Length</th>
<th>6mm</th>
<th>7mm</th>
<th>8mm</th>
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<tbody>
<tr>
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<td>PF6X140</td>
<td>PF7X140</td>
<td>PF8X140</td>
</tr>
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<td>PF7X170</td>
<td>PF8X170</td>
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<td>PF6X200</td>
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<td>PF8X200</td>
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<tr>
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### SERIES IV SCREWS

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</tr>
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<tr>
<td>70mm x 4.5mm Screw</td>
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### L-Handle

608

### Locking Bolt

613

### 11mm Open End Wrench

462

### Combination Hex Wrench

460

### Shoulder Cap Screw

406
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<tr>
<th>PART NUMBER</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>433P</td>
<td>Target Arm Base 200mm</td>
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<tr>
<td>673</td>
<td>Extractor-Compressor Rod</td>
</tr>
<tr>
<td>472</td>
<td>Slap Hammer Weight</td>
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<tr>
<td>674</td>
<td>Extractor Rod Connector</td>
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<tr>
<td>642</td>
<td>Alignment Pin</td>
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<td>640</td>
<td>Cannula</td>
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<tr>
<td>645</td>
<td>Drill Guide 3.5mm</td>
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<tr>
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<td>Drill Guide 6.3mm</td>
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<tr>
<td>466</td>
<td>Drill Bit 3.5mm x 280mm</td>
</tr>
<tr>
<td>467</td>
<td>Drill Bit 6.3mm x 180mm</td>
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### CHAPTER 9: SIGN INSTRUMENTS AND IMPLANTS

Part numbers are in BOLD

| **Step Drill** | 486 |
| **Screw Hole Broach** | 686 |
| **Depth Gauge** | 685 |
| **Hex Wrench 3.5mm** | 450 |
| **Tissue Protector** | 465 |

**REAMERS**

| **Pediatric Fin Nail Reamer** |  |
| **Pilot Reamer 6mm** | 506 |
| **Pilot Reamer 7mm** | 507 |

| **Standard Fin Nail Reamer** |  |
| **Pilot Reamer 8mm** | 508 |
| **Pilot Reamer 9mm** | 509 |

**INSTRUMENT TRAYS**

| **Standard Instrument Tray System** | 692 |
| **Screw Caddy** | 693 |