Intramedullary Nail System

IMPORTANT MEDICAL INFORMATION

SUMMARY
1. Proper size, length, side and type selection as well as use of intramedullary nails is essential to safe and effective fracture treatment. See NOTES, INDICATIONS, CONTRAINDICATIONS, and PREOPERATIVE PLANNING below.
2. Intramedullary nails are NOT substitutes for skeletal healing, and proper follow-up care is essential to safe and effective use. See POSTOPERATIVE CARE and POSSIBLE ADVERSE EFFECTS below.
3. Metallic surgical implants are NEVER TO BE REUSED (single use).

NOTES
Metallic surgical implants are intended to be used as aids to normal fracture healing. Such implants are NOT replacements for skeletal structures. Healing of fractures treated with metallic surgical implants must be confirmed prior to permitting weight bearing on the bones. Weight bearing on bones that have failed to heal or healed partially or improperly can cause stress and fatigue in metallic surgical implants with consequent breakage or failure of the implants. Surgeons should consider the following information and SHOULD INFORM PATIENTS OF PERTINENT INFORMATION RELEVANT TO THE PATIENTS’ HEALTH AND SAFETY.

The Intramedullary Nail System consists of metallic implants including interlocking intramedullary nails, interlocking fusion nails, and nail caps. Intramedullary nails contain holes proximally and distally to accept locking screws.

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

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

ENDER™ Nails (pins) are flexible nails that do not use interlocking or screw fixation. ENDER Nails are small diameter nails that are used in multiples to provide three or four point fixation.

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

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

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/neck fractures.

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for the following: comminuted supracondylar fractures with or without intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (peri-prosthetic fractures).

Indications for the Short Knee Nail, REVISION® Nail and Hindfoot Fusion Nail (HFN) include the following: degeneration, deformity, or trauma of both the tibiotalar and talocalcaneal articulations of the hindfoot; tibiocalcaneal arthrodesis; combined arthrodesis of the ankle and sub-talar joints; avascular necrosis of the ankle and sub-talar joints; failed total ankle replacement with sub-talar intrusion; failed ankle arthrodesis with insufficient talar body; rheumatoid arthritis; severe deformity secondary to untreated talipes equinovarus or neuromuscular disease; and severe pilon fractures with trauma to the sub-talar joint.

Knee Fusion Nails are intended for intramedullary knee arthrodesis.

ENDER Nails are indicated as follows: fracture of the neck, trochanteric, and subtrochanteric region of the femur; distal femoral fractures with a distal fragment 10cm or longer; tibial shaft fractures; and proximal humeral fractures.

The TRIGEN® Humeral Nail System is indicated for proximal and/or diaphyseal fractures of the humerus, non-unions, malalignments, pathological humeral fractures, and impending pathological fractures.

The TRIGEN InterTAN nails are indicated for fractures of the femur including: simple shaft fractures, comminuted shaft fractures, spiral shaft fractures, long oblique shaft fractures and segmental shaft fractures; subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; intracapsular fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; bone lengthening and shortening.

SURESHOT® TAN Nails are indicated for fractures of the femur including simple long bone fractures, severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening; and for fixation of fractures that occur in and between the proximal third and distal fourth of the femur.

In addition, SURESHOT TAN Nails contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability and are indicated for the following: subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; and intracapsular fractures.

CONTRAINDICATIONS
1. These systems should not be used in crossing open epiphyseal plates.
2. Insufficient quantity or quality of bone, obliterated medullary canal or conditions which tend to retard healing, blood supply limitations, previous infections, etc.
3. Active infection.
4. Any hardware that would preclude use of nails.
5. Congenital or acquired bony deformity.
6. Hypovolemia, hypothermia and coagulopathy.
7. Mental conditions that preclude cooperation with the rehabilitation regimen.
8. The forearm nail should not be used in children who have not reached skeletal maturity.
9. The ENDER Nail is contraindicated for the younger and/or more active patient, where open reduction techniques provide firm fixation without a substantially increased risk of mortality or morbidity.
10. The Short Intertrochanteric Nail is contraindicated for complex intertrochanteric and femoral neck fractures.

PREOPERATIVE PLANNING

1. Surgical Technique. Correct surgical technique is essential to a successful outcome. Proper reduction of fractures and proper placement of implants are necessary to effectively treat patients using metallic surgical implants. Please review the surgical technique for effective surgical procedures.

2. Implant Selection. A proper type and size of implant must be selected to insure effective treatment of patients. The following factors should be considered:
   - A patient’s size, strength, skeletal characteristics, skeletal health, and general health. Overweight or musculoskeletally deficient or unhealthy patients may create greater loads on implants that may lead to breakage or other failure of the implants.
   - A patient’s activity level during the time the implant is in the patient’s body, including such factors as whether the patient’s occupation or typical activities include running, heavy lifting, impact loading, or the like.
   - Whether a patient has a degenerative or progressive disease that delays or prevents healing, and consequently decreases the effective life of the implant.
   - If a patient is suspected of having material or foreign body sensitivities, appropriate testing should be accomplished prior to implantation.
   - Mental conditions or substance abuse problems that may prevent a patient from understanding or following directions or observing precautions.

3. Implant Alterations. Unless an implant is designed to be physically altered, it should not be altered in any way. If the implant is designed to be altered, it should only be altered in accordance with manufacturer’s instructions. In no case should an implant be sharply or reverse bent, notched, gouged, reamed, scratched or cut.

4. Component Compatibility. Components such as intramedullary nails, screws, wires, pins, and the like are available in many styles and sizes and are manufactured from various types of metals. The component material is provided on the outside carton label. Use only components made from the same material together unless specifically approved by the manufacturer. Do not mix dissimilar metals or components from different manufacturers unless specifically approved by a manufacturer of the components. Refer to manufacturers’ literature for specific product information.

5. Implant Removal. The patient should be advised that a second procedure for the removal of implants may be necessary.
POSTOPERATIVE CARE

1. Care Prior to Bony Union. Immobilize and/or externally support skeletal structures that have been implanted with surgical metallic implants until skeletal union is observed. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact. Patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed or non-union, should have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the management of soft tissue injuries. PATIENTS AND NURSING CARE PROVIDERS SHOULD BE ADVISED OF THESE RISKS.

2. Care Subsequent to Bony Union. Even after bony union, the patient should be cautioned that a fracture is more likely with the implant in place and soon after its removal, rather than later, when voids in the bone left by implant removal have been filled in completely. Patients should be cautioned against unassisted activity that requires walking or lifting. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of the nail’s screw hole, as this places greater stress on the nail at the location of the transverse screw hole.

3. Implant Removal. The operating surgeon will make final recommendations regarding removal of implants, considering all facts and circumstances. Smith & Nephew suggests that whenever possible, and after bony union is observed, that implants be removed. Removal is particularly advisable for younger and more active patients. In the absence of a bursa or pain, removal of the implant in elderly or debilitated patients is not suggested.

4. Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY
Smith & Nephew, Inc. Intramedullary Nailing System devices have not been evaluated for safety and compatibility in the MR environment. Smith & Nephew Intramedullary Nailing System devices have not been tested for heating or migration in the MR environment.

NO REUSE
Metallic surgical implants are NEVER TO BE REUSED. Stresses and fractures, even though not noticeable by visual inspection, may have been created during implantation. Single use devices should not be reused due to risks of breakage, failure or patient infection.

POSSIBLE ADVERSE EFFECTS
1. Loosening, bending, cracking or fracture of the implant components.
2. Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation.
3. Infections, both deep and superficial.
4. Irritational injury of soft tissues, including impingement syndrome.
5. Supracondylar fractures from retrograde nailing.
6. Tissue reactions which include macrophage and foreign body reactions adjacent to implants.
7. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.
8. Restricted range of motion of the joint adjacent to the insertion point of the ENDER Nail, usually transitory due to protruding nails.

PACKAGING AND LABELING
Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

STERILIZATION
For components provided sterile, the sterilization method is noted on the label. Sterile implant components are supplied sterile to a Sterility Assurance Level (SAL) of $10^{-6}$. Sterile packaged components are supplied in protective sterile barrier packaging. Inspect packages for punctures or other damage prior to surgery. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

If not specifically labeled sterile, components are supplied non-sterile and must be cleaned and sterilized prior to surgery. For non-sterile trauma implants (i.e. plates, nails, and screws) remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization. Please see the document, “Recommendations for decontamination and sterilization of Smith & Nephew orthopaedic devices”, which is provided with Smith & Nephew instrument sets, for further information on cleaning instructions and validated sterilization procedures.

DO NOT REUSE implant components or single use disposable instruments.

Do not resterilize products with internal plastic bushings/sleeves because they can become damaged during resterilization. The labels on these products will be noted with the statement “CAN NOT BE RESTERILIZED”.

RECOMMENDED STEAM STERILIZATION CYCLE PARAMETERS

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132°C (270°F) for 4 minutes or 135°C (275°F) for 3 minutes and a minimum vacuum drying time of 30 minutes.
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 minutes and a minimum vacuum drying time of 30 minutes.
- Flash Steam Cycle (Reusable instruments only): Exposure temperature: 132°C (270°F) for 10 minutes in a Gravity Displacement Cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134°C for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010.)

Containment devices should be wrapped with an approved central supply wrap (CSR) or placed in an approved reusable rigid container for sterilization. All sterilization wraps may not be approved for all cycle types. Check with manufacturer for approvals.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS
The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant from damage during handling and shipment. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent spread of bloodborne pathogens.
If the implant will be returned to Smith & Nephew, Inc. for analysis, contact Customer Service using the phone numbers outlined in the Information section.

**INFORMATION**

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

**Manufacturing facilities and EC representative:**

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

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81068703 Rev. B 2010-02