OIC Intramedullary Nail System

IMPORTANT MEDICAL INFORMATION

INDICATIONS

The OIC Intramedullary Nail System is intended for surgical management of femoral and tibial fractures including open and closed fractures, pseudarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures, tumor resections, nonunions and malunions. The hip nails may be used for basilar neck, subtrochanteric and intertrochanteric fractures. The femoral nails may be used for fractures of the femur below the hip joint including ipsilateral femur fractures, fractures proximal to a total knee arthroplasty and supracondylar fractures, including those with intra-articular extension.

CONTRAINDICATIONS

1. These systems should not be used in crossing open epiphysial plates. Insufficient quantity or quality of bone, obliterated medullary canal or conditions which tend to retard healing, blood supply limitations, previous infections, etc.
2. Active infection.
3. Any hardware that would preclude use of nails.
4. Congenital or acquired bony deformity.
5. Hypovolemia, hypothermia and coagulopathy.
6. Mental conditions that preclude cooperation with the rehabilitation regimen.
7. 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 musculoskeletal deficiencies 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.

3. Implant Alternations. 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

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 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 implant subsequent to the management of soft tissue injuries.

PATIENTS AND NURSING CARE PROVIDERS SHOULD BE ADVISED OF THESE RISKS.

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 with callus. 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.

Implant Removal. The operating surgeon will make final recommendations regarding removal of implants, considering all facts and circumstances. The Orthopaedic Implant Company suggests that whenever possible, and after bony union is observed, 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.

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

The OIC Intramedullary Nail System 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 OIC Intramedullary Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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. Irritation 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 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 The Orthopaedic Implant Company.

STERILIZATION

For components provided sterile, Gamma radiation is the sterilization method used. Sterile packaged components are supplied in protective sterile barrier packaging. Inspect packages for punctures or other damage prior to surgery.
the sterile barrier has been broken, return the component to The Orthopaedic Implant Company.

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. New implants and instruments must be thoroughly cleaned before initial sterilization. Trained personnel must perform cleaning (manual and/or machine cleaning, ultrasound treatment, etc.) along with maintenance and mechanical inspection prior to initial sterilization. Exact compliance with the equipment manufacturers’ user instructions and recommendations for chemical detergents is required.

DO NOT REUSE implant components or single use disposable instruments.

LIMITS ON REPROCESSING:
Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on OIC implants and instruments. OIC implants and instruments should be inspected for damage such as corrosion, scratches, notches, debris, visible wear, discoloration or residue. Damaged implants and instruments should be discarded.

CLEANING OF INSTRUMENTS:
1. Within a maximum of two (2) hours after use, remove gross soil using absorbent paper wipes. Rinse with warm (<45°C) water for a minimum of two minutes. Use a soft bristled brush to remove soil, debris and orifices. Actuate joints, handles and other moveable device features to expose all areas to the detergent solution.
2. Ultrasonic Clean (if required) Add one (1) ounce of Enzol® (or equivalent) to one (1) gallon of water for a minimum of ten minutes. Follow detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
3. Rinse device thoroughly with cold (<45°C) tap water until all traces of cleaning solution are removed. Visually inspect for any remaining soil and repeat the above steps if necessary. Allow to dry, and then transfer to the cleaning step.
4. Automated Cleaning: Place instrument(s) in an automated washer (e.g. Steris Reliance® 444 Washer/Disinfector or equivalent). Load device(s) in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft bristled brush to remove soil and debris. Actuate joints, handles and other moveable device features to expose all areas to the detergent solution.
5. Rinse device thoroughly with cold (<45°C) deionized or high purity water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable devices.

Automated Cleaning Parameters

<table>
<thead>
<tr>
<th>Automated Cleaning Parameters</th>
<th>Time/Temp</th>
<th>Cleaning Agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step</td>
<td>Enzymatic Wash</td>
<td>04:00</td>
</tr>
<tr>
<td>Wash</td>
<td>02:00</td>
<td>65.5°C Tap Water</td>
</tr>
<tr>
<td>Rinse</td>
<td>02:00</td>
<td>70°C</td>
</tr>
<tr>
<td>Dry</td>
<td>15:00</td>
<td>80°C</td>
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Inspection
Visually inspect each instrument for evidence of organic matter. Repeat the cleaning process if necessary. If instruments are wet, use a lint-free wipe to dry.

STERILIZATION METHODS
Pre-vacuum autoclave Temperature: 270°F (132°C) for 4 minutes Dry Time: 30 minutes

- Please consider your sterilization equipment manufacturer’s written instructions for the specific sterilizer and load configuration used.
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- The devices should be sterilized using an FDA cleared wrap indicated for these sterilization cycles.

STORAGE INSTRUCTIONS: Store in a cool dry place and keep away from direct sunlight.

INFORMATION
For more information about products, please visit www.orthoimplantcompany.com or contact Customer Service at (800) 619-2797.

Manufactured and distributed by:

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