



IMPORTANT MEDICAL INFORMATION

INDICATIONS

The Ortemiz 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 epiphyseal 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 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

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.

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.

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 Ortemiz 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 Ortemiz 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. 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 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. If

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 Ortemiz implants and instruments. Ortemiz 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) tap water for two (2) minutes. Flush cannulated devices thoroughly to prevent the drying of soil and/or debris to the inside.
2. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
3. Disassemble device if possible prior to cleaning. Detailed instructions for assembling and disassembling the instruments are contained in the surgical technique guide.
4. Tap water used for cleaning and rinsing will meet the characteristics for potable water in AAMI TIR34. Deionized and high purity water will meet the characteristics listed in AAMI TIR34.

Manual Cleaning:

1. Rinse soiled device under running cold (<45°C) tap water for a minimum of two minutes. Use a soft bristled brush to assist in the removal of gross soil and debris
2. Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
3. Rinse device with cold (<45°C) tap water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.

4. Manually clean device for a minimum of five minutes 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:

1. Pre-Treatment is required for any instrument(s) heavily soiled and/or containing dried organic material: Add one (1) ounce of Enzol® (or equivalent) to one (1) gallon of cold (<45°C) tap water. Using a soft bristle brush, clean the instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process. Rinse in warm (>45°C) running 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.
2. Ultrasonic Clean (if required) Add one (1) ounce of Enzol (or equivalent) and one (1) gallon of warm (>45°C) tap water to an ultrasonic cleaner. Completely submerge instruments and sonicate for ten (10) minutes.
3. Ultrasonic Rinse To remove the detergent, thoroughly rinse each instrument with cold (<45°C) deionized water including all holes and cannulations. Inspect each instrument for evidence of organic matter. Repeat the sonication and rinse if needed.
4. Automated Washer Place instrument(s) in an automated washer (e.g. Steris Reliance® 444 Washer/Disinfector or equivalent). Load instruments such that contact is avoided and articulating instruments are in the open position.

Automated Cleaning Parameters

Step	Time mm:ss	Minimum Temp °C	Cleaning Agent
Enzymatic Wash	04:00	49 °C Tap Water	Steris Prolystica 2X Concentrate (or equivalent) (1/8 oz./gal)
Wash	02:00	65.5°C Tap Water	Steris Prolystica 2X Concentrate Alkaline Cleaner (or equivalent) (1/8 oz./gal)
Rinse	02:00	70°C	Deionized or High Purity water
Dry	15:00	80°C	Not Applicable

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.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: 2006 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities".
- 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.

CAUTION: When using the suprapatellar approach to implant a tibial nail use care to avoid damaging the patellofemoral cartilage. The cannula assembly must be used to protect the retropatellar space. When inserting the cannula into the knee joint the Guide Pin Entry Trocar (01-IMSE05) must be locked securely to the cannula (either 01-IMSE03 or 01-IMSE04) via the spring-loaded locking pin within the Cannula Handle (01-IMSE07).

INFORMATION

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

Manufactured and distributed by:

ortemiz

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