	Instructions for use for ATLAS° Tibial Fracture(TF) Nail	Doc. No.: IU/15 Rev. No.: 01 Rev. Date:10FEB2022

Important Information on ATLAS° Tibial Fracture Nail
For use by an Accredited Orthopaedic Surgeon only

Device Description:

The ATLAS° TFN (Tibial Fracture Nail) is designed to handle tibial fracture indications in diameters 8.5mm, 10mm, 11.5mm, and 13mm in length range from 26cm to 50cm. It consists of tibia nails in the preceding length and diameter sizes, distal locking screw, and nail cap screw. The ATLAS° TFN system includes implantable nails and screws, which are provided in a variety of lengths and types to accommodate the prescribed fixation technique. The system includes instrumentation trays, which house the instrument that are needed for installation and removal of the implantable assembly. The Atlas TF Nails, Screws and Caps are made from titanium-vanadium alloy Ti-6Al-4V material complying to ISO 5832-3.

Summary:

Operating surgeons should be aware of the following aspects related to the use of metallic implants.

1. Proper size, length, side and type selection, as well as proper handling and use of the TF nails are essential to safe and effective fracture treatment. See NOTES, INDICATIONS, CONTRAINDICATIONS, and PREOPERATIVE PLANNING below.
2. TF Nails are NOT substitutes for skeletal healing, and proper follow-up care is essential to safe and effective use. See WARNINGS, 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 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:

The ATLAS° TF Nail is indicated for shaft fractures between the proximal and distal third of the Tibia. This includes transverse, comminuted, spiral, oblique, and segmental fractures. It may also be used for nonunions, malunions, prophylactic nailing of impending pathological fractures.

Contraindications:

ATLAS° TF Nail should not be used in:

1. 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.

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.
2. Implant Selection: Selection of the proper size, shape and design of the complete set of Implants and Instruments is a crucial parameter for success of the operative procedure and to insure effective treatment of patients that must be ensured by the operative surgeon. All Implants, Instruments and its sub-assemblies should be checked for intact packaging on receipt. All implants and instruments must be carefully checked for completeness and should be carefully inspected for compatible dimensions.
3. 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.
4. 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.
5. Component Compatibility: Components such as nails, screws are available in many styles and sizes and are manufactured from various types of metals. 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.
6. Implant Removal: The patient should be advised that a second procedure for the removal of implants may be necessary.

Warnings:

1. The correct selection of device components is extremely important. The appropriate size should be selected for the patient. Failure to use largest possible components or improper positioning or the use of excessive forces during implantation may result in loosening, bending, cracking, or fracture of the device or bone or both.
2. The length of time for non or limited weight bearing should be correspondingly increased until solid bony union occurs.
3. The threads of an implanted screw should not engage the fracture line. The screw threads should be firmly fixed in bone and the screw should be long enough to permit telescopic sliding in the event of resorption of the fracture surface.
4. Do not mix dissimilar metals. Use only ATLAS® TF Titanium screws with ATLAS® TF Titanium Nails.
5. Implant guiding devices such as guide pins, guide wires etc. should not be re-used to prevent potential damage to the implants, inaccurate measurements and other possible errors.

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 of 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 any locking holes provided in the nail. This would typically include distal most proximal locking hole and the proximal most distal locking hole. Greater stress is placed on the nail at these hole locations in these situations.
3. 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.
4. Implant Removal: The operating surgeon will make final recommendations regarding removal of implants, considering all facts and circumstances. Adler 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 recommended. If the implant components are not removed subsequent to completion of their intended use, the following complications may ensue.

- Corrosion combined with localized pain or tissue reaction.
- Migration of position of the implant, resulting in injury.
- Bending, loosening or breakage of implant components, which may make removal more difficult or even impractical.
- Possibly increased risk of infection.
- Bone loss due to stress shielding.
- Pain, discomfort or abnormal sensations felt by the patient due to the presence of the device.

Magnetic Resonance Imaging (MRI) Safety:

ATLAS® TF Nail System has not been evaluated for safety and compatibility in the MR environment. This system has 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. Infections, both deep and superficial.
3. Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation.
4. Leg length discrepancies and subsequent patient limp may occur.
5. Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.
6. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.
7. Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas may result from the surgery and concomitant use of internal fixation devices.
8. Implant Migration related to loss of fixation or poor fracture reduction.
9. Screw Back-out.
10. Pain at the surgical site as a normal consequence of the operative procedure.

Packaging and Labeling:

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. Implant components supplied in non-sterile condition are packed in unwoven polyethylene and are indicated as 

on the label which must be properly sterilized by suitable method prior to surgery as indicated below. The set of instruments used for the surgery must be carefully checked for completeness and individual instruments must be inspected for functionality and absence of damage prior to surgery.

Cleaning:

Use deionized, or distilled, warm (room temperature) water for soaking, cleaning and rinsing. Disassemble as appropriate. Soak soiled products for a minimum of 10 minute. For non-ceramic coated components: immerse and hand wash with a neutral pH or mild detergent. Scrub with a soft bristle brush paying close attention to threads and hard to reach areas. If product is cannulated, insert a soft nylon brush into cannula. Rinse all components immediately and thoroughly after washing. Immediately dry product. Inspect all products prior to sterilization and storage.

Sterilization Instructions:

Remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization.

DO NOT REUSE implant components or single use disposable instruments.

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.

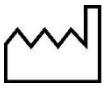
Storage Conditions:

Store in dry place. Protect devices from exposure to direct sunlight, radioactive sources and rains. Do not stack devices.

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.

Symbols Used in IFUs, Labels and Packaging Materials:

Symbol	Definition	Symbol	Definition	Symbol	Definition
	Single use (Do not re-use)		Batch Number		Non Sterile
	Date of Manufacture YYYY-MM-DD		Manufactured by		CE Logo conformity to MDD 93/42/EEC
	European Authorised Representative		Code Number / Part No.		
	Caution: check for specific warnings or precautions		Consult instructions for use		

Further information:

For further information concerning use of these devices, please check with Adler Customer Service at the address given herein or e-mail to **adler-customer.care@adler-healthcare.com**.