Shotel Ankle Arthrodesis Nail System Instructions for Use

Non-sterile Implants and Instruments

Caution: This device is restricted to use by or on the order of a physician.

DEVICE DESCRIPTION

The Shotel Ankle Arthrodesis Nail System consists of fusion nails offered in two configurations, (left and right), fixation bone screws offered in one diameter and nail caps in two configurations, (standard and plus 5 mm). All three implant components are manufactured from a titanium alloy.

INDICATIONS FOR USE

The Shotel Ankle Arthrodesis Nail System is intended for the following:

- Charcot Foot
- Avascular necrosis of the talus
- Failed total ankle arthroplasty
- Trauma (malunited tibial pilon fracture)
- Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Revision ankle arthrodesis
- Neuroarthropathy
- Rheumatoid arthritis
- Osteoarthritis
- Pseudoarthrosis
- Post-Traumatic arthrosis
- Previously infected arthrosis
- Severe end stage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis

CONTRAINDICATIONS

- Dysvascular limb
- Active infection
- Severe longitudinal deformity
- Insufficient plantar heel pad
- Where an isolated ankle or subtalar fusion can be performed
- Patient conditions including blood supply limitations and insufficient quantity and quality of bone
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device

POSSIBLE ADVERSE EFFECTS

- Loosening, bending, cracking, or fracture of the nail or screws or loss of fixation in bone attributable to nonunion.
- Loss of anatomic position with nonunion or malunion with rotation or angulation.
- Infection, both deep and superficial.
- Allergies and other reactions to the device material.
- Pain, discomfort, or abnormal sensations due to the presence of an implant.
- Nerve damage resulting from surgical trauma.
- Bone necrosis or bone resorption.

WARNINGS AND PRECAUTIONS

- No metallic surgical implant should be reused. Any metal implant, once used, should be discarded. Even though it appears undamaged, it may already have small defects and internal stress patterns which may lead to fatigue failure.
- Correct handling of implant is extremely important. Avoid contouring metallic implants whenever possible. The device should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce defects in the surface finish and internal stress concentrations, which may become the focal point for eventual failure of the appliance.
- If metal plates or other metallic devices are to be used together with the Shotel Ankle Arthrodesis Nail System, all such devices should be manufactured from a metal that has a similar composition to avert possibility of galvanic corrosion or other metallic reactions.
- Correct selection of the implant is extremely important. The potential for success in fracture fixation is increased by the selection of the proper diameter and length of the implants. The patient's anatomy and indication will determine the size of the Fusion nail and bone screws to be used.
- The size and shape of the human bones presents limiting restrictions on the size and strength of implants.
- Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to breakage of the implant requiring revision surgery to remove the device.
- The use of the Shotel Ankle Arthrodesis Nail System provides the surgeon a means of bone fixation and helps in the management of fractures and reconstructive surgeries. The implants are intended as a guide to normal healing and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or non-unions in the presence of load bearing or weight bearing might eventually

cause the implant to break due to metal fatigue. All metallic surgical implants are subject to repeated stress in use which can result in metal fatigue.

- Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device prior to the healing of the fracture. Due to normal metal fatigue, these stresses can cause eventual bending or breakage of the device. Therefore, it is important that immobilization of the fracture site is maintained until firm bony union (confirmed by clinical and roentgenographic examination) is established.
- No partial weight bearing or non-weight bearing device can be expected to withstand the unsupported stresses of full weight bearing. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities that would place stress upon the implant or allow movement at the fracture site and delay healing.
- Detailed written instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending or breakage of the device are complications that may occur as a result of the weight bearing or muscle activity. An active patient or a debilitated or demented patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation.
- While the surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger more active patients.

MR SAFETY INFORMATION
The Shotel Ankle Arthrodesis 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 Shotel Ankle Arthrodesis Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. Contact surgeon if a change in performance or pain level is noticed.

Sterilization Guidelines for Instrument Trays

These guidelines are intended to provide a better understanding of the care and handling of the Shotel Ankle Arthrodesis Nail System Instrumentation kit including the implants. These guidelines are not intended for use with electrical, pneumatic or other powered surgical instruments. Instruments and Implants are shipped in a NON-STERILE condition and must be cleaned and sterilized prior to use. All implants are SINGLE-USE.

General Care and Handling
Use instruments and implants only for their intended purpose, such as cutting, holding, retracting, torquing, etc. Avoid undue stress or strain when handling or cleaning. Always transport contaminated or soiled items in or on a cart. Tap water can contain many minerals that may discolor and stain surgical instruments; therefore, it is recommended that deionized water be used for the final rinsing to prevent spotting. For instruments contaminated with protein material, prevention of drying prior to cleaning will facilitate cleaning. Placing instruments in water until cleaning can prevent drying.

Cleaning: Follow these steps to thoroughly clean all instruments

1. Submerge instruments and implants in an enzymatic detergent. Prepare detergent according to the manufacturer's recommendations. Soak the instruments for ten (10) minutes in the protein solubilizing detergent.
2. Scrub the submerged instruments with a soft sponge and agitate.
3. Use a pipe cleaner or brush in any lumens and crevices.
4. Rinse in warm (38-49 degree C) tap water for one (1) minute.
5. Thoroughly flush all lumens and other difficult to reach areas.
6. Ultrasonically clean the instruments for ten (10) minutes in a neutral pH detergent (Neutrad or acceptable alternative). Prepare the detergent according to the manufacturer's recommendations.
7. Rinse the instruments and implants with clean tap water for at least one (1) minute, repeat twice.
8. Dry the instruments thoroughly with a clean, lint free cloth.
9. Visually Inspect instruments for any damage or remaining contaminates. Instruments should be visually clean.
10. Repeat cleaning procedure as necessary if contamination remains. The instruments must be thoroughly clean.
11. Contact BioPro if any instruments are damaged.

Sterilization
Following the cleaning process, place a sterilization indicator in each instrument tray along with the instruments. Instrument tray is to be wrapped in a double layer of CSR wrap. Steam sterilization is required with the following parameters:

For pre-vacuum cycle:
Wrapped items: 4 minutes exposure at a minimum temperature of 132° C (270° F), maximum temperature of 143° C (290°F), 4 pulses, 30 minutes dry time.

Examination Prior to Use
All instruments should be carefully examined for wear or damage by surgeons and staff in operating centers prior to surgery. The examination shall include a visual and functional inspection. It should also include verifying the cleanliness of the device, as well as the absence of any cracks, distortion, wear, corrosion, or other changes. Like any precision surgical device, all instruments should undergo regular checks by knowledgeable personnel to ensure that they remain in good condition and continue to act as intended.

Do not use any instrument or device that is damaged, incomplete, showing signs of excessive wear and tear, or that has been repaired outside the control of the manufacturer. If an implant shows any signs of use or contamination, do not place it back into the kit and contact BioPro immediately.

Warnings and Precautions

- Devices must only be used by surgeons who have been trained in the surgical technique and are familiar with the instruments provided.
- Use care in handling and storage. Some instruments are sharp and incorrect use or handling may result in puncture wounds.
- Improper use may result in breakage of the instrumentation during operation.
- Remove all broken instrument fragments. As a result of mechanical features required, the device is made of medical grade but not implant grade materials. Failure to remove broken instruments from the patient could result in patient complications and further intervention.
- Incorrect maintenance, cleaning or handling may render the instrument unsuitable for its intended use, cause corrosion, dismantling, distortion and/or instrument breakage or injury to the patient or operating staff. Potential complications include device breakage, leaching of debris, lack of component engagement, infection, and damage to tissue.

STORAGE AND HANDLING

Store at room temperature. Avoid storing the Shotel Ankle Arthrodesis Nail System at conditions of excessive heat or humidity. All components should be handled carefully to avoid damaging the device.

SURGICAL PROCEDURE

A Surgical Technique brochure is available which outlines the basic procedure for device implantation and use of the specialized surgical instrumentation. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

DISPOSAL PROCEDURES

Upon completion of the procedure, dispose of the other removed components per hospital procedure in accordance with clinical-internal, administrative and/or applicable legal regulations.

SYMBOL GLOSSARY

For a complete glossary of symbols, please visit www.bioproimplants.com/IFU. To receive a printed version within 5 business days, please contact orders@bioproimplants.com

Unique Device Identification (UDI)

All BioPro components can be identified by M209XXXXX, where “XXXXX = Item #”. For a complete listing of BioPro item numbers visit www.bioproimplants.com/udi

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