EN

ADVANCED ORTHOPAEDIC SOLUTIONS

AOS MODULAR FEMORAL NAIL SYSTEM

INSTRUCTIONS FOR USE

Federal Law restricts this device to sale by or on the order of a physician

DEVICE DESCRIPTION

The AOS MODULAR FEMORAL NAIL SYSTEM is used in intramedullary fixation of fractures of the femur. They have a chamber at the proximal end that is designed to receive one of five inserts with various screw hole configurations (antegrade, standard, standard, reconstruction, and supracondylar). The screw holes in the inserts are designed to receive either 5.0mm or 6.5mm screws. The nails are cannulated through their entire length with the distal end containing three screw holes designed to receive 5.0mm screws. Regardless of the diameter of the nails, the overall diameter of the proximal chamber is 13mm with working diameters of 9mm to 13mm. The nails are in lengths of 15cm to 46cm with the proximal end threaded to accept an end cap. Its unique screw configuration provides the surgeon with options to accommodate patient anatomy and optimize patient outcomes. Its innovative features offer superior solutions for the orthopedic advancement of hip fractures. All implants are made of titanium alloy. The system is provided in a dedicated sterilization tray and includes an accompanying set of instruments.

INDICATIONS FOR USE

The AOS MODULAR FEMORAL NAIL SYSTEM is intended to be used for fixations of fractures of the femur to include the following: open and closed femoral fractures, pseudoarthrosis and correction osteotomy, pathologic fractures, impending pathologic fractures and tumor resections, supracondylar fractures, including those with severe comminution and intra articular extension, ipsilateral femur fractures, bone lengthening, fractures proximal to a total knee arthroplasty or prosthesis, fractures distal to a hip joint, non-unions and malunions, and fractures resulting from osteoporosis. The AOS MODULAR FEMORAL NAIL is also indicated for use in fusion of the knee and in tibiotalocalcaneal fusions and treatment of trauma to the hindfoot and distal tibia.

CONTRAINDICATIONS

1. Patients with an active superficial infection.
2. Pediatric patients, or patients with skeletal immaturity.
3. Patients with a history of frequent infections.
4. Patients with known sensitivity or allergies to the implant materials.
5. Patients with neuromuscular deficiencies in the affected limb sufficient to render the procedure unwarranted.
6. Conditions that preclude cooperation with the rehabilitation regimen for postoperative care or impair the patient's ability to follow directions.
7. Physical conditions that would preclude adequate implant support or retard healing, such as blood supply impairment in the treated area, obliterated medullary canal, insufficient bone quality or quantity, previous infection, or obesity.

WARNINGS

The AOS MODULAR FEMORAL NAIL SYSTEM must be sterilized prior to use. Please refer to the section on STERILIZATION below.

The AOS MODULAR FEMORAL NAIL SYSTEM is intended for use by individuals with adequate training and familiarity with techniques associated with the orthopedic surgical procedure employed. For further information about techniques, complications, and hazards, consult the medical literature.

The implants of the AOS MODULAR FEMORAL NAIL SYSTEM are for single use only. Reuse of the devices is associated with risks for the transmission of infectious diseases and loss of mechanical strength. While the device may appear undamaged, previous stress may have created imperfections and internal stress patterns which could lead to implant failure.

Use care in storage and handling of devices. While in storage, device components should be protected from corrosive environments such as salt air, moisture, etc. While handling device components, do not apply excessive force to implants, as cutting, bending, or scratching the surface of device components can reduce their strength and fatigue resistance. Inspect all device components for damage prior to surgery. Replace damaged or worn components, as necessary.

The AOS MODULAR FEMORAL 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 AOS MODULAR FEMORAL NAIL in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

For proper care and handling of AOS REUSABLE INSTRUMENTS and AOS SINGLE USE INSTRUMENTS, please refer to their package insert (IFU-9000).

POSSIBLE ADVERSE EVENTS

1. Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue, or inadequate healing from surgical trauma or presence of implant.
2. Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis of the femoral head.
3. Metal sensitivity or histological or allergic reaction to device materials.
4. Irritation injury of soft tissues, including impingement syndrome.
5. Pain, discomfort, or abnormal sensations.
6. Infections, both deep and superficial.
7. Bone damage or refracture.

DIRECTIONS FOR USE

PREOPERATIVE

Inspect all AOS MODULAR FEMORAL NAIL SYSTEM implant components under adequate lighting prior to sterilization for wear or damage that would impact its performance. If wear or damage is identified, component parts should be discarded and replaced.

An image intensifier and an appropriate fracture table are required to perform this surgery.

Allergies and other reactions to device materials should be ruled out preoperatively.

INTEROPERATIVE

Select the most appropriate implant size suitable for the patient's age, weight, and bone quality. Use the largest implant suitable for the patient to prevent loosening, migration, bending, cracking, or fracture of the device or bone or both. A stable construct should be achieved and verified under image intensification.

IFU-9003 / D
February 2022

POSTOPERATIVE
The AOS MODULAR FEMORAL NAIL SYSTEM is not designed to withstand the stress of weight-bearing, load-bearing, or excessive activity. Caution patients against unassisted activity that requires walking, to reduce the likeliness of weight-bearing on the affected limb during treatment. Device breakage or damage can occur when the implant is subjected early weight-bearing or increased loading associated with delayed union, nonunion, or incomplete healing. Internal or external supports may be utilized to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph.

Periodic x-ray examinations for at least the first six (6) months postoperatively are recommended for close comparison with postoperative conditions to detect changes in position, nonunion, loosening, bending, or cracking of components.

Assure daily cleansing of pin-skin interface. Maintain meticulous daily pin site care management to prevent infection.

The AOS MODULAR FEMORAL NAIL may be removed after treatment. In the absence of pain, removal of the implant in elderly or debilitated patients is not suggested.

STERILIZATION
Inspected devices should be placed into their trays as provided. The total weight of tray with devices should not exceed 11.4kg/25 lbs. (other local limits below 11.4kg/25 lbs. may apply). Packaging should be completed utilizing a pouch or wrap which conforms to the recommended specifications for steam sterilization as outlined below. The wrap should be completed following AAMI double-wrap or equivalent guidelines with an appropriate wrap (cleared by the FDA or the local governing body). Bracketed positions designated for specific devices shall contain only devices intended for those areas. Devices should not be stacked or placed in close contact. Only AOS devices should be included in the trays. These validated instructions are not applicable to trays or cases that include devices not intended to be used with AOS trays.

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table below. Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

RECOMMENDED STEAM STERILIZATION PARAMETERS

Prevacuum Cycle Type	Exposure Temperature	Exposure Time	Minimum Drying Time[1]	Minimum Cooling Time[2]
US Cycle[3]	132 °C/270 °F	4 minutes	30 minutes	30 minutes
UK Cycle[3]	134 °C/273 °F	3 minutes	30 minutes	30 minutes
Prion Cycle[4]	134 °C/273 °F	18 minutes	30 minutes	30 minutes

[1]Drying times vary according to load size and should be increased for larger loads.

[2]Cooling times vary according to the sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

[3]For markets outside of the US, the cycle parameters listed for exposure time and temperature can be considered as minimum values.

[4]For markets outside of the US, reprocessing parameters recommended by the World Health Organization (WHO) where there is concern regarding TSE/CJD contamination.

INFORMATION
For further information please contact Advanced Orthopaedic Solutions at (310) 533-9966.

SYMBOL GLOSSARY

Part number (catalog number)

Lot number (batch code)

Quantity

Material


Caution


Consult instructions for use


Manufacturer


Date of manufacture


Expiration date


Do not reuse

Sterilized using irradiation

Do not resterilize

Non-sterile product

MR Conditional


Do not use if package is damaged

Authorized Representative in the European Community


Advanced Orthopaedic Solutions
3203 Kashiwa Street
Torrance, CA 90505
USA

Phone: (310) 533-9966
Email: ATI_Regulatory@arthrex.com

Arthrex GmbH
Erwin-Hielscher-Straße 9
81249 Munich
Germany

Phone: +49 89 90 90 05-0
Email: info@arthrex.de

IFU-9003 / D
February 2022