EN

ADVANCED ORTHOPAEDIC SOLUTIONS

AOS GALILEO® TROCHANTERIC NAIL SYSTEM

INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION

The AOS GALILEO® TROCHANTERIC NAIL SYSTEM includes the AOS GALILEO® TROCHANTERIC NAIL and the AOS ES™ TROCHANTERIC NAIL. These are open reduction and internal fixation device. The AOS TROCHANTERIC NAIL is available in 17cm, 20cm, 30cm, 33cm, 36cm, 39cm, 42cm and 45cm lengths, with proximal diameters ranging from 9mm to 14mm. All implants in the AOS GALILEO® TROCHANTERIC NAIL SYSTEM, including all nails, screws, and end caps, are made of titanium alloy.

The nails have a proximal bend of 5° and two proximal screw holes. The proximal screw holes in the long nails have 10° of anteversion. One of the proximal screw holes accepts a 10.5mm Solid Lag Screw, 10.5mm Solid Locking Lag Screw, side specific 10.5mm Galileo® Lag Screw, or side specific Galileo® CRT²™ Lag Screw, which are used to lag together fractures of the proximal femur. To help minimize lag screw back out, the Solid Locking Lag Screw, Galileo® Lag Screw, and Galileo® CRT²™ Lag Screw can be locked on to the nail intraoperatively. Both the AOS Galileo® Lag Screw and Galileo® CRT²™ Lag Screw allow the threads to collapse unidirectionally up to 10mm within the barrel with the exception of the 85mm length (7mm collapse) and 90mm length (9mm collapse). The other proximal screw hole accepts an optional 5.0mm anti-rotation screw.

The distal end of the nail has one slot and one hole to accept 5.0mm screws. The ES™ nails have a targeted hole in the proximal third which accepts the 5.0mm cortical screw. The proximal end of the nail is threaded to accept an end cap.

The system is provided in a dedicated sterilization tray and includes an accompanying set of instruments.

INDICATIONS FOR USE

The AOS GALILEO® TROCHANTERIC NAIL is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated for subtrochanteric fractures, pertochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revisions procedures.

The AOS ES™ TROCHANTERIC NAIL is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric, fractures and combinations of these fractures.

CONTRAINDICATIONS

1. Patients with an active superficial infection.
2. Pediatric patients, or patients with skeletal immaturity.
3. Patients with shaft fractures should not be treated with the AOS ES™ TROCHANTERIC NAIL.
4. Patients with a history of frequent infections.
5. Patients with known sensitivity or allergies to the implant materials.
6. Patients with neuromuscular deficiencies in the affected limb sufficient to render the procedure unwarranted.
7. Conditions that preclude cooperation with the rehabilitation regimen for postoperative care or impair the patient's ability to follow directions.
8. 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 GALILEO® TROCHANTERIC NAIL SYSTEM must be sterilized prior to use. Please refer to the section on STERILIZATION below.

The AOS GALILEO® TROCHANTERIC NAIL 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. Please refer to the Galileo® Trochanteric Nail System Surgical Technique (PN 9065) for additional information on the use of the AOS GALILEO® TROCHANTERIC NAIL SYSTEM.

The implants of the AOS GALILEO® TROCHANTERIC 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.

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

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that AOS GALILEO® TROCHANTERIC NAIL SYSTEM implants are MR Conditional. A patient with these devices can be safely scanned in an MR system meeting the following conditions:

1. Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
2. Maximum spatial field gradient of 2,670 G/cm (26.7 T/m).
3. When scanning in a 1.5 T scanner, patients can be scanned with a whole-body averaged SAR of 2.0 W/kg (Normal Operating Mode) when landmarked superior to the hip for a maximum scan time of 15 minutes. If scanning is performed between below the hip, the whole-body SAR needs to be limited to 1.0 W/kg or less for a maximum scan time of 15 minutes.
4. When scanning in a 3 T scanner, patients can be scanned with a whole-body averaged SAR of 2.0 W/kg (Normal Operating Mode) for all landmark location for a maximum scan time of 15 minutes.

The scanner SAR restrictions above apply to a circularly polarized whole-body RF coil. For other RF coil types (e.g., extremity, head, neck), appropriate whole-body SAR restrictions should be considered to ensure similar levels of localized SAR are achieved.

RF HEATING

Under the scan conditions defined above, AOS GALILEO® TROCHANTERIC NAIL SYSTEM implants are expected to produce a maximum temperature rise less than or equal to 5.4 ºC after 15 minutes of continuous scanning.

MR ARTIFACT

In non-clinical testing, the image artifact caused by AOS GALILEO® TROCHANTERIC NAIL SYSTEM implants extend radially approximately 4.1 cm from the device.

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 GALILEO® TROCHANTERIC 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.

The Trochanteric End Cap with Post implant should not be used with the AOS Solid Locking Lag Screw or Galileo® Telescoping Lag Screw, as it may cause damage to the locking feature of the screws.

The lockout spacer in the Galileo® Telescoping Lag Screw should always be removed after implantation of the screw. The telescoping feature only works properly if the lockout spacer is removed.

POSTOPERATIVE

The AOS GALILEO® TROCHANTERIC 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 GALILEO® TROCHANTERIC NAIL SYSTEM 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