INSTRUCTIONS FOR USE

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

IMPORTANT NOTE

Intramedullary nails provide an alternative to open reduction and fixation of a variety of fractures. The objective of intramedullary nailing as compared to open techniques is to provide stable fixation with minimal trauma, thus reducing blood loss and risk of infection. As with all orthopedic devices, success varies with the patient; even in the less difficult case there is a risk of complications. The implants are intended as a guide to healing and are not intended to replace a normal body structure. The surgeon is cautioned that any of the circumstances listed under categories below may reduce the chances of a successful outcome.

BASIC DESIGN

The Advanced Orthopaedic Solutions (AOS) Intramedullary Nails are intramedullary nails of varying length and diameters and with cross locking holes to accommodate varying sizes of locking screws. The intramedullary nails are manufactured from Titanium Alloy (Ti-6Al-4V ELI, ASTM F136).

AOS Antegrade Femoral Nails are intramedullary nails with three holes and a slot designed to allow for various screw hole configurations (Antegrade and Reconstruction). The screw holes are designed to receive a 6.5mm fully threaded cortical screw and a 6.0mm partially threaded cancellous screw, and the slot is designed to receive 5.0mm screws. The nails are cannulated through their entire length with the distal end containing two screw holes and a slot designed to receive 5.0mm cortical screws. Regardless of the diameter of the nails, the overall diameter of the proximal end is 13mm (14mm for the 14mm Nail) with working diameters of 9mm to 14mm. The nails are in lengths of 30cm to 46cm with the proximal end threaded to accept an end cap.

AOS Clavicle Intramedullary Devices are titanium cannulated intramedullary nails that are designed to enter the Clavicle through the posterolateral aspect of the acromioclavicular joint. The AOS Clavicle Intramedullary Device is available in three shaft diameters, 2.7mm, 3.5mm and 4.0mm, with 80, 90, 100, 110, and 120mm length options. The system includes a fully threaded 2.7mm cortical screw to interlock with the nail, prevent medial migration of the implant, and add rigid fixation.

AOS Humeral Nails are intramedullary nails designed to enter the humerus through the greater tuberosity. The nails are cannulated with a 6° proximal bend and a proximal diameter of 10mm. The proximal nails are produced in 15cm lengths, and the long nails are produced in 20cm, 22.5cm, 25cm, 27.5cm and 30cm lengths. The distal diameter of the proximal nail is 8mm, and the distal diameters of the long nails are 7mm, 8mm and 9mm. The proximal end of the proximal nail has four, six or eight holes to accept the 5.0mm cancellous screw. The proximal end of the long nail has two holes and one slot which also accept the 5.0mm cancellous screw. The proximal end of the nail is threaded to accept an end cap.

AOS Modular Femoral Nails are modular intramedullary nails with a chamber at the proximal end that is designed to receive an insert with various screw hole configurations (antegrade, retrograde/supracondylar and standard). The screw holes in the inserts are designed to receive 5.0mm screws (antegrade, retrograde, and standard) and 6.5mm screws (reconstruction). 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.

AOS Retrograde & ES™ Retrograde Femoral Nails are titanium intramedullary nails that are designed to enter the femur through the intercondylar notch. The system consists of intramedullary nails, fully threaded locking cortical and cancellous screws, partially threaded non-locking cancellous screws, spacers, condyle nuts, washers and end caps. The Femoral Nail is a cannulated nail with a distal diameter of 13mm and proximal diameters of 10mm to 13mm with increments of 1mm. The nails are manufactured in lengths 26cm to 50cm (ES) and 18 cm to 50 cm (Retrograde) in increments of 2cm. The distal end of the nail has a transverse threaded hole and slot, as well as two oblique threaded holes. The holes and slot all accept the 6.5mm Fully Threaded Cancellous Locking Screw, the 6.5mm Fully Threaded Cortical Locking Screw, or the 6.0mm Partially Threaded Cancellous Non-locking Screw. The ES™ screw hole accepts a 5.0mm Cortical Screw.

AOS Small Bone Nails are side specific intramedullary nails for three different long bones: the fibula, radius and ulna. The distal diameters and lengths of all nails range from 2.5mm to 5.0mm and from 110mm and 260mm respectively. The intramedullary nails (excluding the 2.5mm nail) feature a cannulation that is compatible with a 1.3mm Stainless Steel Guide Wire prior to inserting the device inside the intramedullary canal. All of the intramedullary nails have a 6.0mm proximal diameter with holes that allow for 3.5mm and 2.7mm locking screws that provide additional fixation to the proximal section of nail.

AOS Tibial Nails are intramedullary nails in lengths of 27cm to 39cm. For the nails with working diameters of 8mm, 9mm, 10mm, and 11mm, the proximal diameter is 11.5mm. For the 12mm and 13mm diameter nails, the diameter is throughout the length. The nails have a proximal bend of 10°, and the distal end has a 3° bend. The proximal portion has two holes and one slot designed to accept a 5.0mm cortical screw. The proximal end of the nail has three holes with the 9mm, 10mm, 11mm, 12mm, and 13mm diameter nails accepting 5.0mm cortical screws and the 8mm diameter nail accepting 4.2mm screws. The proximal end of the nail is threaded to accept an end cap and/or a static locking spacer.

AOS Trochanteric Nails are intramedullary nails in lengths of 17cm and 20cm (Short) and 30cm to 45cm (ES™ and Long) with a proximal diameter of 16.0mm and working diameters of 9mm to 14mm. The nails have a proximal bend of 5° and two proximal screw holes angled at 120°, 125°, 130° and 135°. One of the proximal screw holes accepts a 10.5mm Solid Lag Screw, 10.5mm Solid Locking Lag Screw, or 10.5mm Telescopying (Galileo™) Lag Screw. All three Lag Screws are used to lag together fractures of the proximal femur. The Solid Locking and Telescopying (Galileo™) Lag Screws also contain a locking sleeve that allows them to be locked to the nail intraoperatively to help minimize lag screw back out. The AOS Telescopying (Galileo™) Lag Screw allows the threads to collapse unidirectionally up to 10mm within the barrel. The other proximal screw hole accepts an optional 5.0mm anti-rotation screw. The proximal screw holes in the long nails have 10° of antversion. 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. All implants in the Trochanteric Nail System, including all nails, screws and end caps, are made of titanium alloy per ASTM F136.

See the surgical technique for the complete system description and uses.
INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EVENTS

General

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 restrictions on the size and strength of the implants.

The AOS Antegrade Femoral Nail is intended for use in intramedullary fixation of fractures of the femur to include the following: open and closed femoral fractures, pseudoarthrosis and correction osteotomy, pathologic fractures, impeding 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.

AOS Clavicle Intramedullary Device is intended to be used to repair an acute fracture, mal-union, or non-union of the clavicle.

The AOS Humeral Nail is intended to treat stable and unstable proximal fractures of the humerus including two and three, and in some cases four-part humerus fractures. The Humeral Nail is also intended to treat proximal and distal one third fractures, midshaft fractures and pathological fractures.

The AOS Modular Femoral Nail is intended for use in intramedullary fixation of fractures of the femur to include the following: Open and closed femoral fractures, pseudoarthrosis and correction osteotomy, Pathologic fractures, impeding 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 Femoral Modular 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.

The AOS Retrograde and ES™ Retrograde Femoral Nail is intended for use in intramedullary fixation of fractures of the femur to include the following: open and closed femoral fractures, pseudoarthrosis and correction osteotomy, pathologic fractures, impeding 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 Small Bone Nail is intended for fixation of fractures and osteotomies of the fibula, radius and ulna, including fractures where the medullary canal is narrow or flexibility of the implant is paramount.

The AOS Tibial Nail is intended to provide temporary stabilization of various types of fractures, malunions, and non-unions of the tibia. The AOS Tibial Nail System is indicated for long bone fracture fixation of tibial fractures, which may include the following: transverse, oblique, spiral, segmental and comminuted fractures; fractures with bone loss and bone transport; open and closed fractures, pathologic fractures; corrective osteotomies; pseudarthrosis of the tibial shaft; non-unions, malunions, metaphyseal and epiphyseal fractures.

AOS 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, pertrochanteric 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.

CONTRAINDICATIONS

As with all surgical procedures, the surgeon must rely on his/her expertise in evaluating the best treatment for his/her patient in a given set of circumstances. The following are given as possible contraindications to the use of this device:

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. Foreign body sensitivity; where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
4. Active infection
5. Conditions which tend to impair the patient’s ability or willingness to restrict activities or to follow directions during the healing period.
6. Skeletal immaturity
7. As the ES Nail is only intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures, it is contraindicated for all of the following fractures: transverse, oblique, spiral, segmental and comminuted fractures; fractures with bone loss and bone transport; open and closed fractures, pathologic fractures; corrective osteotomies; pseudarthrosis of the tibial shaft; non-unions, malunions, metaphyseal and epiphyseal fractures.

Due to higher complication rates with the use of reconstruction vs. standard antegrade mode of any femoral nail system, it is recommended that the reconstruction mode (transfixation screws into the femoral head) be used only when fracture pattern is not suitable to other intramedullary fixation means.

POSSIBLE ADVERSE EFFECTS

1. Loosening, bending, cracking or fracture of the nails or screws, or loss of fixation in bone attributable to non-union, osteoporosis, markedly unstable comminuted fractures or one or more of the factors listed in CONTRAINDICATIONS above and/or WARNINGS AND PRECAUTIONS below.
2. Loss of anatomic position with non-union or malunion with rotation or angulation.
3. Infections, both deep and superficial.
4. Allergies and other reactions to device materials.
5. Irritation injury of soft tissues, including impingement syndrome.
6. Subtrochanteric fractures from retrograde nailing.

WARNINGS AND PRECAUTIONS

Preoperative

1. Use care in handling and storage of implant components. Cutting, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or nonintelligent stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instrument components or implants have been damaged during storage or prior procedures.
2. Patient conditions and/or predispositions, such as those addressed in CONTRAINDICATIONS above should be avoided.
3. An adequate inventory of implant sizes should be available at the time of surgery.
4. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
5. Certain special surgical instruments, including an image intensifier and an appropriate fracture table, are required to perform this surgery.
6. Before the initial experience, we recommend that the surgeon acquaint himself/herself with the appropriate surgical technique.
7. The patient should be advised that a second more minor procedure for the removal of the implant may be necessary.

OPERATIVE
1. Please refer to the surgical technique for the specific nail for important reaming directions and nail assembly techniques.
2. Selection of the proper nail length and diameter is extremely important; the patient's age, weight, and cortical bone quantity must be evaluated for the proper implant selection. It should be noted that a small but consistent percentage of complications due to nail fatigue failure remain. Therefore, it is always recommended that the largest implant suitable for the patient be used.
3. Care should be taken not to scratch, bend sharply, or cut metal components during surgery for the reasons stated in number one of the preoperative section of WARNINGS AND PRECAUTIONS. Once removed from the patient, implants should never be reused since internal stresses (in the implant) that are not visible may lead to early bending or fracture.
4. A stable construct should be achieved and verified under image intensification.
5. For femoral interlocking intramedullary nails, the surgeon must be familiar with the surgical technique and the proper placement of the entry hole. This is especially important for the ES Trochanteric Nail, which is only indicated for head and neck fractures of the femur. The surgeon should not use with shaft fractures.
6. The use of Locking Screws is necessary for strength and compatibility. Please refer to the surgical technique for information on the correct size of screws for each nail.
7. For interlocking reconstruction nails, the proper sized proximal screws are necessary. Both proximal screws should be used where possible for better fixation of the femoral head.
8. In certain cases, a bone graft may be appropriate.
9. For the revision nail, the inner diameter of bone must be 1.0-1.5mm larger than the insert nail whether reamed or not.
10. 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.
11. The Trochanteric End Cap With Post implant should not be used in the AOS Solid Locking or Galileo™ Telescoping Lag Screws as these screws have locking features that lock the lag screw to the nail and may be damaged if used with the End Cap With Post.

Postoperative directions and warnings to patients by physicians and appropriate nursing care are extremely important; particularly those admonitions that concern early weight bearing or active use of the extremities. These activities substantially increase the stress on implants that can lead to complications. For this reason, patients who are obese and/or noncompliant, as well as patients who could be pre-disposed to delayed union or non-union, must have auxiliary support. The implant may be exchanged for a larger, stronger nail subsequent to the rearrangement of soft tissue injuries.

12. Intramedullary nails are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time.
13. Additional postoperative precautions should be taken when the fracture line occurs within 5cm of the nail’s screw hole, as this situation places greater stress on the nail at the location of the transverse screw hole.
14. Supplemental support may be necessary for those patients using external devices for ambulatory assistance.
15. 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, non-union, loosening, bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and early revision considered.
16. 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. In the absence of pain, removal of the implant in elderly or debilitated patients is not suggested.
17. Even after full healing, the patient should be cautioned that re-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 not been filled in completely.
18. Patients should be cautioned against unassisted activity that requires walking or lifting.
19. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. Intramedullary Nails are for single use only. Reuse of these 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.

MRI SAFETY INFORMATION
AOS Nail Systems have 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 AOS Nail Systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

CLEANING
To ensure the maximum effectiveness of the product, please refer to the following cleaning instructions below.

WARNINGS
Follow the instructions and warning issued by the supplier of any cleaning disinfecting agents and equipment used. Do not exceed 285 °F during the cleaning process. Highly alkaline or acidic conditions can damage parts; keep the pH within the 6 to 8 range. Complex parts, such as those with tubes, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Manual pre-cleaning of such device features is required before automated cleaning processing, with special attention to removing any debris, tissue, or bone fragments that may collect on the instrument.

CARE AT THE POINT OF USE
Clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible detergent solution or water to prevent drying and encrustation of surgical soil. Avoid prolonged exposure to saline to minimize the chance of corrosion.

MANUAL CLEANING
1. Prepare a fresh neutral-pH, enzymatic cleaning solution (i.e. Enzol) to the cleaning solution’s specification using warm 30 to 43 °C (86 to 109 °F) tap water. Soak for 20 minutes.
2. Using a soft-bristled brush, remove all traces of soil, paying close attention to crevices, mating surfaces, actuating parts, and any hard-to-reach areas.
3. Thoroughly rinse for at least 1 minute using warm 30 to 43 °C (86 to 109 °F) tap water, actuating any moveable parts 5 times.
4. Prepare a fresh, neutral-pH, enzymatic cleaning solution (i.e. Enzol) to the cleaning solution’s specification using warm 30 to 43 °C (86 to 109 °F) tap water. Sonicate for 20 minutes.
5. Thoroughly rinse for at least 1 minute using warm 30 to 43 °C (86 to 109 °F) tap water, actuating any moveable parts 5 times.
6. Thoroughly dry with a soft cloth saturated in 70% Isopropyl Alcohol (IPA). Dry with compressed air at least 20 psi.

Inspect each device for remaining debris (detergent or soil). If any is observed, repeat the cleaning procedure with freshly prepared cleaning solutions.

The above cleaning procedure has been validated in accordance with AAMI TIR30:2011.
STERILIZATION
Advanced Orthopaedic Solutions Nails must be sterilized by the following process parameters. All original packaging and labeling should be removed and the tray should be wrapped in an FDA cleared protective wrapping. The following process parameters have been validated for the sterilization of the AOS trays.

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270 °F (132 °C)</td>
<td>4 minutes</td>
</tr>
</tbody>
</table>

The recommended drying time for an AOS Nail is 30 minutes.

The above sterilization procedure has been validated to an SAL of 10^{-6} in accordance with AAMI TIR12:2010, ANSI/AAMI ST77:2013, and ISO 17665-1:2006 per the biological indicator overkill method per Annex D of ISO 17665-1:2006.

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

SYMBOL GLOSSARY
- **REF**: Part number (catalog number)
- **LOT**: Lot number (batch code)
- **QTY**: Quantity
- **MATL**: Material
- **Caution**: Consult instructions for use
- **Manufacturer**: Date of manufacture
- **Expiration date**: Expiration date
- **Do not reuse**: Do not use if package is damaged
- **STERILE**: Sterile product
- **Do not resterilize**: Non-sterile product
- **Non-sterile product**: Do not use if package is damaged
- **Authorized Representative in the European Community**: Authorized Representative in the European Community

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