BONE SCREWS

INSTRUCTIONS FOR USE

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

IMPORTANT NOTE

Fracture fixation devices are used only as an aid to healing: they are not a substitute for normal intact tissue or bone. The anatomy of human bones presents limitations with respect to the size or thickness of bone screws, and thus the strength of the implant is limited. Full weight bearing prior to complete bone healing is contraindicated. With repeated stress in patients with delayed healing or nonunion, the appliance will inevitably bend, break or pull out of bone.

BASIC DESIGN

The Advanced Orthopaedic Solutions (AOS) Bone Screws are titanium alloy (Ti-6Al-4V ELI, ASTM F136) self-tapping screws in diameters of 2.4mm, 2.7mm, 3.5mm, 4.0mm, 4.2mm, 5.0mm, 6.0mm, 6.5mm, 7.0mm and 10.5mm and range in length from 8mm to 150mm.

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EVENTS

General

Bone screws are indicated for fracture fixation, interlocking of intramedullary nails, and locking of plates. Refer to medical or manufacturer literature for specific product applications.

The AOS Cannulated Bone Screw System is intended for fracture fixation of small and long bones and of the pelvis. This system is not intended for spinal use.

CONTRAINDICATIONS

Physical conditions that would preclude adequate implant support or retard healing such as blood supply impairment, insufficient bone quality or quantity, previous infection, or obesity.

Mental conditions that preclude cooperation with the rehabilitation regimen.

POSSIBLE ADVERSE EFFECTS

1. Loosening, bending, cracking or fracture of implant components.
2. Loss of anatomic position with malunion may occur.
3. Infections, both deep and superficial, have been reported.
4. Vascular disorders including thrombophlebitis, pulmonary emboli, wound hematomas, and avascular necrosis of the femoral head may result from the surgery and concomitant use of internal fixation devices.
5. Leg length discrepancies and subsequent patient limp may occur.
6. Screw cutting through the femoral head (usually associated with osteoporotic bone), penetration of the joint by a lag screw with or without chondrolysis, and failure of a lag screw to slide, have been reported.
7. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
8. Penetration of a guide wire/screw into the pelvis can occur.
9. Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.

10. Damage to the femoral capital epiphysis due to trauma during surgery or improper position or length of compression screws and guide wires.

WARNINGS

The correct selection of device components is extremely important. The appropriate type and size should be selected for the patient. Failure to use the largest possible components or improper positioning may result in loosening, bending, cracking, or fracture of the device or bone or both.

Because of unbalanced muscle forces, subtrochanteric fractures and osteotomies place extreme loads on implants, substantially reducing the chance of fracture healing with bending or breaking implant components. Additional precautions and internal or external supports should be utilized to enhance the stability of the fracture and to minimize internal stress loading of the implant and broken bone until solid bony union is evident by radiograph. Supplementary procedures such as bone graft or medial displacement osteotomy may also be considered.

AOS Bone Screws 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.

PRECAUTIONS

Use extreme care in handling and storing implant components. Cutting, bending or scratching the surface of metal components can cause stresses which significantly reduce the strength and fatigue resistance.

Postoperative instructions to patients and appropriate nursing care are critical. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact.

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

The Trochanteric End Cap With Post implant should not be used with the AOS Solid Locking or Telescoping (Galileo™) 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.

While the surgeon must make the final decision regarding implant removal, wherever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished.

The surgeon should be familiar with the devices, instruments and surgical technique prior to surgery.

The AOS Bone Screws 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 Bone Screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

MRI SAFETY INFORMATION

AOS Cannulated Bone Screw System 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 Cannulated Bone Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
STERILIZATION
Advanced Orthopaedic Solutions Bone Screws 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>
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<tbody>
<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270 °F (132 °C)</td>
<td>4 minutes</td>
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The recommended drying time for an AOS Bone Screw 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**: Manufacturer
- **Date of manufacture**: Date of manufacture
- **Expiration date**: Expiration date
- **Do not reuse**: Do not reuse
- **STERILE**: Sterile product
- **Non-sterile product**: Do not re-sterilize
- **EC REP**: Non-sterile product
- **Do not use if package is damaged**: Authorized Representative in the European Community

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