SMALL FRAGMENT 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, and range in length from 10mm to 60mm.

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EVENTS
General
Bone screws in the systems are intended to be used for fixations of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, including osteopenic bone.

In conjunction with the plates, bone screws in the systems are intended to be used for fracture fixation, arthrodesis, reconstruction, reimplantation or reduction of small bones and small bone fragments. This system is also indicated for non-load bearing stabilization and reduction of bone fragments in long bones. Used for metaphyseal fragments that are non-committed and can be used in an anti-glide position.

The AOS Small Fragment Plating System, Lite System, and the AOS Calcaneal Plating System are ORIF device (open reduction and internal fixation) systems that consists of plates varying in design to accommodate the needs of the surgeon. All implants are made of Ti-6Al-4V (ELI). The plates and mating screws are designed for permanent implantation into human beings for general use. The system includes an accompanying set of instruments.

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. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
7. Tissue reactions which include macrophage and foreign body reactions adjacent to implants can occur.

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.

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.

MRI SAFETY INFORMATION
AOS Small Bone Fragment 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 Small Bone Fragment Screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

STERILIZATION
Advanced Orthopaedic Solutions Small Fragment 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 Small Fragment Bone Screws is 30 minutes.


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

mayı Manufacturer

📅 Date of manufacture
 срок Expiration date
⚠️ Do not reuse

STERILE Sterile product
⚠️ Do not resterilize

⚠️ Non-sterile product
⚠️ Do not use if package is damaged

EC REP Authorized Representative in the European Community

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