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.

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.

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

ADVERSE EFFECTS

- Loosening, bending, cracking or fracture of implant components.
- Loss of anatomic position with malunion may occur.
- Infections, both deep and superficial, have been reported.
- 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.
- Leg length discrepancies and subsequent patient limp may occur.
- Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
- Tissue reactions which include macrophage and foreign body...
reactions adjacent to implants can occur.

**MRI SAFETY INFORMATION**

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

**CLEANING**

Manual cleaning is required for all reprocessed instruments before sterilization. Manual cleaning is optional for new non-sterile instruments or implants.

Warning: Follow the instructions and warning issued by the supplier of any cleaning disinfecting agents and equipment used. Do not exceed 285 degrees Fahrenheit during the cleaning process. Highly alkaline or acidic conditions can damage parts; keep the pH within the 6-8 range.

**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:**

If available, it is recommended to use endotoxin free water (i.e. de-ionized or reverse osmosis) during all water soaks and rinses mentioned below:

1. Prepare a fresh neutral-pH, enzymatic cleaning solution (i.e. Enzol) to the cleaning solution’s specification using warm (30º-43º C/ 86-109º 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 (30º-43º C/ 86-109º 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 (30º-43º C/ 86-109º F) tap water. Sonicate for 20 minutes.
5. Thoroughly rinse for at least 1 minute using warm (30º-43º C/ 86-109º 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.
7. 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 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 (°F/°C)</th>
<th>Exposure Time (Min.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270/132</td>
<td>4</td>
</tr>
</tbody>
</table>

The recommended drying time for an AOS 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 +1 310.533.9966. *Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.*