SMALL FRAGMENT PLATING SYSTEM

INSTRUCTIONS FOR USE

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

IMPORTANT NOTE

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 chance of a successful outcome.

BASIC DESIGN

The AOS Small Fragment Plating System, System Lite, and the AOS Calcaneal Plating System are ORIF device (open reduction and internal fixation) systems that consist 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.

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EVENTS

The AOS Small Fragment Plating System is 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.

The AOS Small Fragment Plating System Lite is intended to be used for fracture fixation, arthrodesis, reconstruction, replantation 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-glise position.

The AOS Calcaneal Plating System is intended to be used for fixation of fractures, osteotomies, non-unions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone.

CONTRAINDICATIONS

1. Patients that have an active infection.
2. Disabled or non-compliant patients who cannot perform the necessary postoperative care.
3. Patients with fractures that will heal satisfactorily with conservative treatment.
4. Patients with known sensitivity and/or allergies to the materials in the internal fixation device model to be used.
5. Patients with histories of frequent infections.
6. Patients with neuromuscular deficiencies.
7. Patients with significant deficiency in bone quantity and quality.
8. Patients with inadequate or impaired blood flow in the body site(s) to be treated.
9. For skeletal immaturity.

POSSIBLE ADVERSE EFFECTS

Possible adverse effects are pain, discomfort, or abnormal sensations and nerve or soft tissue damage due to the presence of an implant or due to surgical trauma. Fracture of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing or excessive force exerted on the implant during insertion. Implant migration and/or loosening may occur. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

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

WARNINGS

AOS Plates are 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.

Device breakage or damage can occur when the implant is subjected to increased loading associated with delayed union, nonunion, or incomplete healing. Improper insertion of the device during implantation can increase the possibility of loosening or migration. The patient must be cautioned, preferably in writing, about the use limitations and possible adverse effects of this implant. These cautions include the possibility of the device or treatment failing as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the implant. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail. Inspect all devices and instrumentation prior to surgery. Replace when necessary.

The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity.

The implants of the AOS Plate Systems 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

An implant shall never be reused. Use utmost care in handling and storing of devices to prevent unintended cutting, bending or scratching of the device. Plates may only be bent in specific bend locations and only to the degree specified in the system’s surgical technique.

MRI SAFETY INFORMATION

AOS Plating 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 Plating 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

Following 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 Plates 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>
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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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</table>

The recommended drying time for an AOS Plate 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.

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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
- Do not reuse
- Sterile product
- Do not resterilize
- Non-sterile product
- Do not use if package is damaged
- Authorized Representative in the European Community

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