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

DEVICE DESCRIPTION
AOS REUSABLE INSTRUMENTS and AOS SINGLE-USE INSTRUMENTS are a collection of non-sterile, reusable instruments and non-sterile, single-use instruments, respectively, designed to assist in the surgical implantation of various AOS orthopedic implant systems. They require sterilization prior to use. AOS REUSABLE INSTRUMENTS, such as drill guides, wrenches, drill sheaths, obturators, adapters, and sterilization trays, are durable orthopedic instruments designed to undergo multiple uses and repeated sterilization cycles. AOS SINGLE-USE INSTRUMENTS, such as drills, reamers, taps, guide pins and wires, drivers, sheathes, extractors and templates, have intricate design features that cannot withstand repeated use, and must therefore be discarded after use.

INDICATIONS FOR USE
Drills and reamers are indicated for making holes in bone, by attachment to a surgical power drill. A tap is indicated to ease the insertion torque of screws through a pilot hole. A guide pin or wire is indicated for the entrance to a surgical power drill. A tap is indicated to ease the insertion torque of screws and bolts. A sheath is indicated for creating an unobstructed channel within the soft tissue through which a component may be inserted and/or implanted. An extractor is indicated for assisting with implant removal. A template is indicated for assisting with the contouring of orthopedic plates to bone profiles.

CONTRAINDICATIONS
There are no contraindications for the use of the AOS REUSABLE INSTRUMENTS or the use of the AOS SINGLE-USE INSTRUMENTS.

WARNINGS
AOS REUSABLE INSTRUMENTS and AOS SINGLE-USE INSTRUMENTS must be sterilized prior to use. Proper sterilization instructions are included in this package insert. Refer to section on STERILIZATION.

AOS REUSABLE INSTRUMENTS and AOS SINGLE-USE INSTRUMENTS have been designed and evaluated for use with their corresponding AOS orthopedic implant systems only. Do not use the AOS REUSABLE INSTRUMENTS or AOS SINGLE-USE INSTRUMENTS with any other orthopedic implant system other than the AOS system for which they were designed. Failure to use the AOS REUSABLE INSTRUMENTS and AOS SINGLE-USE INSTRUMENTS with any orthopedic implant system other than the indicated AOS system is considered off-label use, and could result in patient harm.

AOS REUSABLE INSTRUMENTS must be cleaned as soon as possible after use. Proper cleaning instructions are included in this package insert. Refer to section on MANUAL CLEANING for further information. 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. Follow the instructions and warning issued by the supplier of any cleaning disinfecting agents and equipment used.

PRECAUTIONS
Do not exceed 285 °F during the cleaning process for AOS REUSABLE INSTRUMENTS. 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.

AOS SINGLE-USE INSTRUMENTS must be discarded appropriately after use. Soiled surgical instruments should be disposed of in proper biohazardous waste receptacles. Sharp items should be placed in an appropriate sharps container labeled for biohazardous waste.

ADVERSE EVENTS
There are no adverse events associated with the use of the AOS REUSABLE INSTRUMENTS or the use of the AOS SINGLE-USE INSTRUMENTS.

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 REUSABLE INSTRUMENTS AND SINGLE-USE INSTRUMENTS 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**: Caution
- **Consult instructions for use**: Consult instructions for use
- **Manufacturer**: Manufacturer
- **Date of manufacture**: Date of manufacture
- **Expiration date**: Expiration date
- **Do not use if package is damaged**: Do not use if package is damaged
- **Authorized Representative in the European Community**: Authorized Representative in the European Community
- **STERILE**: Sterile product
- **Do not resterilize**: Do not resterilize
- **Non-sterile product**: Non-sterile product
- **Do not reuse**: Do not reuse

Advanced Orthopaedic Solutions, Inc.
3203 Kashiwa Street
Torrance, CA 90505
USA
Phone 310-533-9966
Email regaffairs@aosortho.com

ADVENA LTD
Tower Business Centre, 2nd Flr
Tower St, Swatar, BKR 4013
MALTA
Phone +44 (0) 1926 800 153
Email info@advenamedical.com