AOS REUSABLE INSTRUMENTS

AOS SINGLE-USE INSTRUMENTS

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 temporary fixation of bone fractures during the implant process, or planning the placement of a screw prior to use of a cannulated drill or cannulated screw. Drivers are indicated for tightening or loosening 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.

STERILIZATION

AOS REUSABLE INSTRUMENTS and AOS 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>
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</tbody>
</table>

The recommended drying time for AOS REUSABLE INSTRUMENTS and AOS SINGLE-USE INSTRUMENTS is 30 minutes.

The above sterilization procedure has been validated to a 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.

MANUAL CLEANING

To ensure the maximum cleanliness of the AOS REUSABLE INSTRUMENTS, please refer to the following cleaning instructions below.

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, actuating any moveable parts 5 times.
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 cleaning procedure has been validated in accordance with AAMI TIR30:2011.
SYMBOL GLOSSARY

REF Part number (catalog number)

LOT Lot number (batch code)

QTY Quantity

MATL Material

⚠️ Caution

📝 Consult instructions for use

 изготовлен

Date of manufacture

⏰ Expiration date

🚫 Do not reuse

STERILE Sterile product

🚫 Do not re-sterilize

⚠️ Non-sterile product

🚫 Do not use if package is damaged

EC REP Authorized Representative in the European Community

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