EN

ADVANCED ORTHOPAEDIC SOLUTIONS

AOS SINGLE USE NON-STERILE INSTRUMENTS

AOS REUSABLE INSTRUMENTS

INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION

AOS SINGLE USE NON-STERILE INSTRUMENTS are a collection of non-sterile, single use instruments, designed to assist in the surgical implantation of various AOS orthopedic implant systems. They require cleaning and sterilization prior to use. AOS SINGLE USE NON-STERILE INSTRUMENTS, such as drills, reamers, taps, guide pins and wires, drivers, sheaths, extractors, and templates, have intricate design features that cannot withstand repeated use, and must therefore be discarded after use.

AOS REUSABLE INSTRUMENTS are a collection of non-sterile, reusable instruments designed to assist in the surgical implantation of various AOS orthopedic implant systems. They require cleaning and 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 processing.

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.

A drill guide allows drills to precisely hit a trajectory through the bone cortices and nail. Wrenches are intended for the tightening or loosening of bolts. An obturator is intended to help advance a guide wire back into the bone canal as a shaft reamer is being pulled out of the patient. Adapters are intended for adapting and linking standard surgical equipment connections. Sterilization trays are intended for the transport, storage, and sterilization of implantable medical devices and surgical instruments for which they have been designed.

CONTRAINDICATIONS

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

WARNINGS

AOS SINGLE USE NON-STERILE INSTRUMENTS must be cleaned and sterilized prior to use. Refer to CLEANING AND DISINFECTION section for further information.

Single use instruments must be cleaned separately from soiled devices.

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

AOS REUSABLE INSTRUMENTS must be cleaned and sterilized prior to use or re-use. Refer to CLEANING AND DISINFECTION section for further information. It is recommended that soiled instruments are reprocessed within a maximum of 2 hours of use. At point of use, soiled instruments must be removed from trays and moistened to prevent debris from drying before transportation to the reprocessing area for cleaning procedures. Soaking in enzyme solutions facilitates cleaning, especially in devices with complex features and hard-to-reach areas (lumens, etc.). These enzyme solutions as well as enzymatic foam sprays break down protein matter and prevent blood and protein-based materials from drying on devices. Manufacturer's instructions for preparation and use of these solutions should be explicitly followed. Devices should be contained and transported in a closed, puncture-proof device to ensure safety. Do not clean soiled instruments while in cases or trays. Instrument cases and trays are considered reusable devices. Trays should be inspected for visible soil and must be cleaned prior to use.

Repeated processing has minimal effect on AOS REUSABLE INSTRUMENTS. End of life is normally determined by wear and damage due to the intended use. Refer to section on INSPECTION for further information. When disposing of AOS REUSABLE INSTRUMENTS, use proper biohazardous waste receptacles. Sharp items should be placed in an appropriate sharps container labeled for biohazardous waste.

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

AOS SINGLE USE NON-STERILE INSTRUMENTS and AOS REUSABLE INSTRUMENTS are intended for use in an operating room for the surgical implantation of AOS implantable medical devices only. They are not intended to be used during diagnostic testing and have not been validated for use in an MR environment.

ADVERSE EVENTS

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

CLEANING AND DISINFECTION

If possible, the MACHINE (AUTOMATED) CLEANING procedure (Washer-Disinfector) should be used for cleaning and disinfection of the instruments. The MANUAL CLEANING procedure should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of the MANUAL CLEANING procedure should be considered. Manual cleaning may require onsite validation by the healthcare facility and appropriate procedures should be in place to avoid human factor variability. The PRELIMINARY CLEANING steps are to be performed for either type of cleaning procedure for the AOS REUSABLE INSTRUMENTS. For cleaning of the AOS SINGLE USE NON-STERILE INSTRUMENTS, it is sufficient to use the MACHINE (AUTOMATED) CLEANING procedure without the need to perform preliminary cleaning steps.

DETERGENT SELECTION

Consider the following points during selection of the cleaning detergent:

- Suitability of the cleaning agent for ultrasonic cleaning (no foam development).
- Compatibility of the cleaning agent with the instruments. AOS recommends the use of neutral pH or enzymatic cleaning agents. Alkaline agents may be used to clean devices in countries where required by law or local ordinance, or where prion diseases such as Transmissible Spongiform Encephalopathy (TSE) or Creutzfeldt - Jakob disease (CJD) are a concern (applies only outside of the US). Advanced Orthopaedic Solutions does not recommend the use of a

specific brand of cleaning agent. Enzol® and neodisher® MediClean forte were utilized during the validation of these instructions. Pay attention to the instructions of the detergent manufacturer with respect to neutralization and post-rinsing.

Follow the instructions of the detergent manufacturer regarding use concentration and temperature for either manual or automated cleaning. Use only freshly prepared solutions as well as only purified/highly purified water at least for final rinse, and a soft, low-linting cloth and/or filtered medical grade air for drying, respectively.

PRELIMINARY CLEANING

1. Remove excess soil from devices, especially in areas such as joints and crevices, by cleaning the surfaces with a sponge or brush under cold running water or with a non-shedding disposable wipe for a minimum of 1 minute.
2. Rinse the devices at least 1 minute under running utility water (temperature < 35 °C/95 °F). Special attention should be given to lumens, joint, crevices, and other hard-to-reach areas.
3. Immerse the devices in cleaning solution inside an ultrasonic bath. While immersed in solution, brush the devices for 2 minutes using a soft-bristled brush. Special attention should be given to lumens, joints, crevices, and other hard-to-reach areas. Lumens should be brushed with appropriate diameter and length bristle sizes for the particular lumen. Actuate movable parts at least (5) times during soaking, as applicable.
4. After brushing, turn on ultrasonic power and soak and sonicate for 10 minutes at a minimum of 40±5 kHz. Ensure devices are in the open position and that lumens have complete contact with cleaning solution during soaking.
5. Remove the devices from the cleaning solution and rinse at least 1 minute with utility water. Thoroughly and aggressively rinse lumens, joints, crevices, and other hard-to-reach areas.
6. After the completion of preliminary cleaning, the end user has the option to perform either Manual Cleaning and Disinfection ***or*** Machine (Automated) Cleaning and Thermal Disinfection (preferred).

MACHINE (AUTOMATED) CLEANING AND THERMAL DISINFECTION
Considerations for the selection of the washer-disinfector:

- Capable of providing an approved program for thermal disinfection (appropriate exposure time and temperature according to A_0 concept)
- Final rinse completed with purified (critical, e.g., RO or DI) water and utilizes only filtered air for drying

CLEANING PROCEDURE

1. After preliminary cleaning is complete, load the devices in the washer-disinfector such that all design features of the device are accessible to cleaning and such that design features that might retain liquid can drain (for example, hinges should be open, and cannulations/holes positioned to drain).
2. If using alkaline cleaning agents, a neutralization step should be utilized as appropriate.
3. Run an automated wash cycle with fundamentally approved efficiency of the washer-disinfector (for example, CE marking according to ISO 15883 or FDA approval/clearance/registration).

The following minimum recommended wash cycle parameters were utilized during the validation of these instructions.

RECOMMENDED WASH CYCLE PARAMETERS

Phase	Recirculation Time	Temperature	Detergent
Pre-Wash	3 Minutes	Cold Water	N/A
Cleaning Wash	10 Minutes	Follow detergent manufacturer's recommendation	Enzymatic or alkaline detergent
Neutralization Rinse (optional)	Follow detergent manufacturer's recommendation	Follow detergent manufacturer's recommendation	Neutralizing agent (as needed)
Rinse	3 Minutes	Cold Water	N/A
Thermal Disinfection Rinse	5 Minutes	90°C (194°F)	N/A
Drying	Minimum 6 Minutes or until visibly dry	Minimum 100°C (212°F)	N/A

4. Remove the devices from the washer-disinfector following the completion of the program and check devices for visible soil. Repeat cleaning if soil is visible and re-inspect; otherwise, proceed to Inspection section.

MANUAL CLEANING AND DISINFECTION
Following preliminary cleaning, the instructions for Manual Cleaning and Disinfection may be followed as an alternative cleaning method to Machine (Automated) Cleaning and Thermal Disinfection if an automated procedure is not available.

1. After preliminary cleaning is complete, repeat steps 1-5 provided in the Preliminary Cleaning section of this IFU, including rinsing, immersion and sonication, and post-rinsing. Final rinsing should be completed with purified (critical, e.g., RO or DI) water.
2. Check devices for visible soil. Repeat cleaning if soil is visible and re-inspect.
3. Soak the devices for the given soaking time (provided by the disinfectant manufacturer) in disinfectant solution so that the devices are sufficiently covered. Make sure that there is no contact between the devices. Ensure that the device is in the open position during soaking. Actuate movable parts at least five times during disinfection, as applicable.
4. Remove the devices from the disinfectant solution and rinse per disinfectant manufacturer's instructions.
5. Dry devices thoroughly utilizing filtered medical grade air or a soft, clean, and low-linting cloth. Proceed to Inspection section.

INSPECTION
AOS REUSABLE INSTRUMENTS should be inspected under adequate lighting after cleaning and prior to sterilization for wear or damage that would impact its performance. AOS REUSABLE INSTRUMENTS should be discarded and replaced when any of the following are noticed during the visual inspection: breakage, cracks, bends, corrosion, rust, pitting, discoloration, excessive scratches, flaking, illegible markings (indecipherable part numbers, lot numbers, or UDI), dulled or damaged cutting edges, signs of residual foreign material following cleaning process (especially at mating surfaces, in cannulations, hinges, shafts, or recessed areas), improper function of mechanical features (such as impeded hinges, joints, couplings, handles, threads, or locking features), or reduced performance of flexible features.

STERILIZATION
Cleaned and inspected devices should be placed into their trays as provided. The total weight of tray with devices should not exceed 11.4kg/25 lbs. (other local limits below 11.4kg/25 lbs. may apply). Packaging should be completed utilizing a pouch or wrap which conforms to the recommended specifications for steam sterilization as outlined below. The wrap should be completed following AAMI double-wrap or equivalent guidelines with an appropriate wrap (cleared by the FDA or the local governing body). Positions designated for specific devices shall

contain only devices intended for those areas. Devices should not be stacked or placed in close contact. Only AOS devices should be included in the trays. These validated instructions are not applicable to trays or cases that include devices not intended to be used with AOS trays.

Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in the table below. Sterilizers vary in design and performance characteristics. Cycle parameters and the load configuration should always be verified against the sterilizer manufacturer's instructions.

RECOMMENDED STEAM STERILIZATION PARAMETERS

Prevacuum Cycle Type	Exposure Temperature	Exposure Time	Minimum Drying Time[1]	Minimum Cooling Time[2]
US Cycle[3]	132 °C/270 °F	4 minutes	30 minutes	30 minutes
UK Cycle[3]	134 °C/273 °F	3 minutes	30 minutes	30 minutes

[1]Drying times vary according to load size and should be increased for larger loads.

[2]Cooling times vary according to the sterilizer used, device design, temperature and humidity of ambient environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

[3]For markets outside of the US, the cycle parameters listed for exposure time and temperature can be considered as minimum values.

VALIDATION

Sterilization procedures have been validated in accordance with the requirements of ISO 17665-1 and demonstrate a sterility assurance level (SAL) of 10^{-6}.

Cleaning procedures have been validated in accordance with ISO 17664-1 and AAMI TIR30 requirements.

INFORMATION

For further information please contact Advanced Orthopaedic Solutions at (310) 533-9966.

SYMBOL GLOSSARY

Part number (catalog number)

Lot number (batch code)

Quantity

Material


Caution


Consult instructions for use


Manufacturer


Date of manufacture


Expiration date


Do not reuse

Sterilized using irradiation

Do not resterilize

Non-sterile product

MR Conditional


Do not use if package is damaged

Authorized Representative in the European Community

Advanced Orthopaedic Solutions
3203 Kashiwa Street
Torrance, CA 90505
USA

Phone: (310) 533-9966
Email: ATI_Regulatory@arthrex.com

Arthrex GmbH
Erwin-Hielscher-Straße 9
81249 Munich
Germany

Phone: +49 89 90 90 05-0
Email: info@arthrex.de

Emergo Consulting (UK) Limited
c/o Cr360 – UL International
Compass House
Vision Park Histon
Cambridge CB24 9BZ
United Kingdom

Phone: +44(0) 1223 772 671
Email: UKRPvigilance@ul.com

IFU-9000 / H
August 2022