



CAUTION:
Non-Sterile

INSTRUCTIONS FOR USE



Cleaning, Sterilization and Inspection of Reusable Ascension Instruments

1. DESCRIPTION AND INTENDED USE

Ascension Orthopedics' reusable surgical instrument sets consist of various configurations of orthopedic instruments in cases or trays. The sets are constructed from durable metal and plastic materials. The reusable surgical instruments are intended for use in orthopedic surgical procedures according to the Instructions for Use and surgical techniques that accompany Ascension implants. Instruments are to be cleaned, inspected, and sterilized between uses.

2. INSPECTION BEFORE USE

Reusable instruments can be used indefinitely if not damaged or worn. Instrument systems should be cleaned and then inspected between uses. **DO NOT** use broken or damaged instruments. Contact Ascension for repair or replacement of damaged items. If damage or malfunction is detected, the instrument should not be used.

3. MACHINE CLEANING

If possible, use automated equipment (washer-disinfectors) for instrument cleaning and disinfection, as machine processes are more consistent. Be sure to observe and follow the operating and loading instructions provided by the machine manufacturer. In addition, only the cleaning agents recommended by the manufacturer should be used. If needed, manual pre-cleaning can be done. Please note the following:

- Jointed instruments should be processed in open position.
Be sure to arrange the items so that the water can easily flow out of cannulations, blind holes, and cavities.
- Complex instruments should be disassembled as far as possible before cleaning.
- For instruments with long or narrow lumens, standard processing should be used only if the hot disinfectant can flow easily through the lumens and safe rinsing is guaranteed.
- The instrument trays used for cleaning must always be loaded correctly to ensure proper cleaning.
- After cleaning, check instruments for cleanliness (visible dirt). This especially applies to cannulated instruments or those with blind holes. If necessary, brush and pre-clean manually or repeat the cleaning cycle.
- Demineralized or distilled water should be used for the final rinse.

4. MANUAL CLEANING

It is best to disinfect and clean the instruments immediately after use in order to avoid instrument encrustations that make cleaning and disinfection more difficult.

The following should be observed in manual cleaning processes:

- The solutions used for manual cleaning must always be prepared in accordance with the manufacturer's instructions.
- Use a suitable brush for cleaning lumens, cannulations, blind holes, and cavities, making sure that every part of the inner surface can be properly accessed.
- Use a soft brush and a neutral or mildly alkaline detergent for removing blood and other residues.
- Never use metal brushes or metal sponges for manual cleaning.
- To ensure proper instrument functioning, verify that all movable parts have been thoroughly cleaned.
- Clean jointed instruments in closed as well as open positions.
- Disassemble instruments as far as possible before cleaning.
- Pay special attention to slots, ratchets, joints and box locks, narrow lumens, blind holes, and other areas that are hard to access.

4. INSPECTION AFTER CLEANING

Following cleaning, the instruments must be macroscopically clean, i.e. free from visible dirt or deposits. All movable parts, working tips and blades (scissors) should be inspected with particular care.

5. STERILIZATION

Ascension Orthopedics, Inc. has completed sterilization validations for our instrument sets. The validation protocols were performed in accordance with [*AAMI ST79:2006 Steam Sterilization and Sterility Assurance in Health Care Facilities*](#), and [*AAMI ST77:2006 Containment Devices for Reusable Medical Device Sterilization*](#). All testing was done using the overkill approach with *Geobacillus stearothermophilus* spores. The results confirmed a 10⁻⁶ Sterility Assurance Level (SAL) for the sets when using the recommended cycles.

In accordance with our validation results, the following cycles are recommended for wrapped goods:

- **Steam Pre-vacuum:** 4 minutes at 132°C (270°F)
- **Steam Gravity:** 15 minutes at 132°C (270°F) – **DO NOT USE THIS CYCLE FOR FILTERED STERILIZATION CONTAINERS**

A vacuum drying cycle of at least 30 minutes is also recommended.

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