

Tarsal Joint Distractor: Instruction for Cleaning, Processing and Sterilization

Tarsal Joint Distractor Instruction for Cleaning, Processing and Sterilization

These instructions are recommended for the care, cleaning, disinfection, maintenance and sterilization of the Tarsal Joints Distractor. New and used instruments **must** be thoroughly processed according to these instructions **prior to use**. The user/processor must comply with all local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this manual.

1. Processing Instructions

These processing instructions are intended to assist the hospital and central supply management in developing procedures to attain the above goals, both for hospital owned and for loaned Tarsal Joint Distractors. This information is based on testing, experience, material science, as well as widely accepted recommendations of the following organizations:

- American National Standards Institute (ANSI)
- American Society for Testing and Materials (ASTM)
- Association for the Advancement of Medical Instrumentation (AAMI)
- Association of Operating Room Nurses (AORN)
- Centers for Disease Control (CDC)
- German Instrument Working Group (AKI) Arbeitskreis Instrumenten-Aufbereitung
- International Standards Organization (ISO)
- International Association of Healthcare Central Service Material Management (IAHCSMM)
- National Health Service (NHS)
- Robert Koch Institute (RKI)
- Swissmedic
- World Health Organization (WHO)

A. Warnings and Precautions

- **Universal Precautions should be observed** by all hospital personnel that work with contaminated or potentially contaminated instruments. **Personal Protective Equipment** (gown, mask, goggles or face shield, gloves and shoe covers) **should be worn** when handling potentially contaminated instruments.
- **Metal brushes or scouring pads must not be used** during manual cleaning procedures.
- **Do not allow contaminated devices to dry prior to reprocessing.**
- Cleaning/disinfecting agents which contain aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and **should not** be used.
Do NOT place or soak the Tarsal Joint Distractor in Ringers Solution.
- Mineral oil or silicone lubricants **should not** be used.

B. Limitations and Restrictions

- Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning the Tarsal Joint Distractor. Alkaline agents with pH of 12 or less may be used in countries where required by law or local ordinance; or where prion diseases (Transmissible Spongiform Encephalopathy and Creutzfeldt-Jakob Disease) are a concern. **It is important to select enzymatic solutions intended specifically for the breakdown of blood, body fluids and tissues. It is critical that alkaline cleaning agents are completely and thoroughly neutralized and rinsed from the Tarsal Joints Distractor.**
- Automated cleaning using a washer/disinfector alone **may not** be effective for the Tarsal Joints Distractor because of the pin lumens, recesses, threads and other complex features. A thorough, manual or combination manual/automated cleaning process is recommended.
- **Steam/moist heat is the recommended sterilization method for the Tarsal Joints Distractor.**
- Ethylene Oxide (EO), Gas Plasma Sterilization and dry heat sterilization methods are not recommended for sterilization of the Tarsal Joints Distractor.
- Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on the Tarsal Joints Distractor.

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C. Point of Use Preparation for Reprocessing

- Remove excess body fluids and tissue from instruments with a disposable, lint-free wipe. Place the instrument in a basin of distilled water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.
- Instruments **should be** cleaned within 30 minutes of use. Do not dry the instrument prior to cleaning.
- Soaking in proteolytic enzyme solutions facilitate cleaning, especially hard-to-reach areas of the Tarsal Joint Distractor (e.g. pin holes, threads, recessed areas) Manufacturer's instructions for preparation and use of these solutions should be explicitly followed.
- Neutral pH enzymatic and cleaning agents with low foaming surfactants are preferred and recommended for use with the Tarsal Joint Distractor. Alkaline agents with pH of 12 or less may be used in countries where required by law or local ordinance. All alkaline agents must be followed with a neutralizer and thoroughly rinsed.

D. Manual Cleaning/Disinfecting Instructions

1. Completely submerge the instrument in enzyme solution and soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the instrument until all visible debris has been removed. Particular attention must be given to hard-to-reach areas of the Tarsal Joint Distractor (e.g. pin holes, threads, recessed areas). Hard-to-reach areas should be cleaned with a long, narrow, soft-bristled brush.
2. Remove the device from the enzyme solution and rinse in tap water for a minimum of 3 minutes.
3. Place prepared cleaning agents in a sonicator. Completely submerge the instrument in the cleaning solution and sonicate for 10 minutes at 45-50kHz.
4. Rinse the instrument in purified water for at least 3 minutes.
5. Repeat steps 2, 3, and 4 as described above.
6. Remove excess moisture from the instrument with a clean, absorbent and lint-free wipe.

E. Combination Manual/Automated Cleaning and Disinfecting Instructions

1. Completely submerge the instrument in enzyme solution and soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the instrument until all visible debris has been removed. Particular attention must be given to hard-to-reach areas of the Tarsal Joint Distractor (e.g. pin holes, threads, recessed areas). Hard-to-reach areas should be cleaned with a long, narrow, soft-bristled brush. Remove the instrument from the enzyme solution and rinse in purified water for a minimum of 1 minute.
2. Place the instrument in a suitable washer/disinfector basket and process through a standard instrument washer/ disinfector cleaning cycle.

F. Sterile Packaging

- Medical grade steam sterilization pouches may be used to double package an individual Tarsal Joint Distractor. Follow the manufacturer instructions. The package should be prepared using the AAMI double wrap or equivalent method. **Reusable wraps are not recommended.**

2. Sterilization Instructions

- **Moist heat/steam sterilization is the preferred and recommended method for the Tarsal Joint Distractor.** Sterilizer manufacturer recommendations should **always** be followed.
- See Table 1 for recommended minimum sterilization parameters.
- Ethylene oxide or gas plasma sterilization methods **should not** be used.
- Gravity displacement sterilization cycles are **not recommended.**

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Table 1. Recommended Steam Sterilization Parameters

Cycle Type	Minimum Temperature	⁶ Pressure	⁷ Minimum Exposure Time		¹¹ Minimum Dry Time
			^{8,9} Wrapped	¹⁰ Unwrapped	
^{1,3} UK Prevacuum/ Pulsating Vacuum	134°C 273°F	3bar 28.5 psi	3 min	3 min	30 minutes
^{2,3} Prevacuum/ Pulsating Vacuum	132°C 270°F	1.86bar 27 psi	4 min	4 min	
^{3,4} Prevacuum/ Pulsating Vacuum	134°C 273°F	3bar 28.5 psi	18 min	18 min	
⁵ Prevacuum/ Pulsating Vacuum	132°C 270°F	1.86bar 27 psi	8 min	8 min	

- 1 Minimum validated steam sterilization time required to achieve a 10⁻⁶ sterility assurance level.
- 2 Minimum validated steam sterilization temperature required to achieve a 10⁻⁶ sterility assurance level.
- 3 Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table.
- 4 Disinfection/steam sterilization parameters recommended by the World Health Organization (WHO) for reprocessing instruments where there is concern regarding TSE/CJD contamination.
- 5 For Universal Instrument Cases without defined load configurations.
- 6 Sea level
- 7 AAMI/AORN steam sterilization cycles with longer times than those listed are also acceptable.
- 8 Medical grade steam sterilization compatible wrap equivalent to four thicknesses of 140-thread-count muslin.
- 9 Rigid sterilization container that complies with ANSI/AAMI ST46.
- 10 Flash (unwrapped) sterilization by exposure at 132°C / 270°F should only be used as an emergency procedure. Instruments must be cleaned and disassembled.
- 11 Drying times vary according to load size and should be increased for larger loads.

References

1. AAMI TIR12, *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*
2. AAMI TIR13, *Principles of industrial moist heat sterilization*
3. AAMI TIR30, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*
4. ANSI/AAMI ST33, *Guidelines for the selection and use of reusable rigid container systems for ethylene oxide sterilization and steam sterilization in health care facilities*
5. ANSI/AAMI ST35, *Safe handling and biological decontamination of reusable medical devices in healthcare facilities and in nonclinical settings*
6. ANSI/AAMI ST37, *Flash sterilization – Steam sterilization of patient care items for immediate use*
7. ANSI/AAMI ST46, *Steam sterilization and sterility assurance in health care facilities*
8. ANSI/AAMI ST67, *Sterilization of health care products – Requirements for products labeled “Sterile”*
9. ANSI/AAMI ST81, *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*
10. ANSI/AAMI/ISO 15223 and Amendments 1 and 2, *Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied*
11. AORN, *Standards, Recommended Practices and Guidelines*
12. ASTM F 565, *Standard Practice for Care and Handling of Orthopedic Implants and Instruments*
13. German Instrument Working Group (AKI) Arbeitskreis Instrumenten-Aufbereitung, *Proper Maintenance of Instruments*, 8th Ed, 2004.
14. IAHCSMM, *Central Service Technical Manual*
15. ISO 15883, *Washer/Disinfectors: Requirements, definitions and Test Methods*
16. ISO 17664, *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*
17. Robert Koch Institute (RKI), *Hospital Supplies and Instrument Sterilization in Light of CJD Patients and Suspected CJD Cases*, Federal Health Gazette, 7/1998
18. UK Department of Health, Health Technical Memorandum (HTM) 2010, *Sterilization, Part 5 – Good Practice Guide*
19. UK Department of Health, Health Technical Memorandum (HTM) 2030, *Washer-Disinfectors – Validation and Verification*
20. World Health Organization (WHO), WHO/CDS/CSR/APH 200.3, *WHO Infection Control Guidelines for TSE*