HAYDEN MEDICAL

Instructions for Use (IFU) Plastic Sterilization Trays

The reprocessing instructions provided in this document were developed in accordance with ISO 17664 and are compatible with healthcare facility practices described in ISO 15883 (washer-disinfectors) and ISO 17665 (moist heat sterilization).

1. Device Description

Reusable plastic sterilization trays are designed to hold and protect surgical instruments during cleaning, sterilization, storage, and transport.

Trays are manufactured from high-performance medical-grade polymer materials and are intended to support sterilization processes while maintaining organization of instruments.

2. Intended Use

Sterilization trays are intended to contain and organize surgical instruments during reprocessing and sterilization procedures and to facilitate aseptic presentation at the point of use.

3. Contraindications

Do not use trays that are damaged, deformed, cracked, or otherwise compromised.

Do not use trays for applications outside of their intended use.

4. Warnings

- Do not use damaged trays. Use of damaged trays may compromise sterility or instrument protection.
- Always use an appropriate sterile barrier system to maintain sterility after processing.
- Improper loading may prevent effective sterilant penetration.
- Follow sterilizer manufacturer instructions at all times.
- If used on a patient with known or suspected Creutzfeldt-Jakob Disease (CJD), trays must be removed from service.

5. Precautions

- Do not overload trays.
- Ensure instruments are arranged to allow sterilant contact.
- Avoid mechanical damage during handling and transport.
- Use only compatible cleaning agents.

6. Inspection Before Use

- Inspect trays for cracks, warping, or discoloration.
- Ensure all components are intact and functional.
- Remove damaged trays from service.

7. Preparation and Pre-Cleaning

- Remove gross debris immediately after use.
- Rinse trays under cool or lukewarm water.
- Do not allow soil to dry on surfaces.

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8. Cleaning

- Use a neutral pH detergent (pH 6–8).
- Clean using a soft brush or cloth.
- Ensure all surfaces are thoroughly cleaned.
- Rinse thoroughly with deionized water.

Cleaning warnings:

- Do not use abrasive materials.
- Do not use bleach or chlorine-based cleaners.

9. Automated Cleaning

Automated cleaning may be performed using washer-disinfectors compliant with ISO 15883.

Follow equipment manufacturer instructions for cycle parameters.

10. Rinsing and Drying

- Rinse thoroughly with deionized water.
- Dry completely before sterilization.

11. Inspection and Preparation for Sterilization

- Verify cleanliness and integrity.
- Ensure trays are dry prior to sterilization.
- Arrange instruments to allow sterilant penetration.

12. Packaging for Sterilization

- Use an appropriate sterile barrier system.
- Ensure packaging is not under tension.
- Follow ISO 11607 requirements.

13. Sterilization

Sterilization must be performed using validated steam sterilization cycles in accordance with ISO 17665 and applicable national standards.

Healthcare facilities are responsible for validating their sterilization equipment and procedures.

Method	Temperature	Exposure Time
Gravity Steam (Wrapped)	121–123°C (250–254°F)	15–30 minutes
Gravity Steam (Wrapped)	132–135°C (270–275°F)	10–15 minutes
Pre-Vacuum Steam (Wrapped)	132–135°C (270–275°F)	3–4 minutes
Immediate Use Steam (IUSS)	132°C (270°F)	3–10 minutes

The above sterilization parameters are based on recognized steam sterilization practices in accordance with ISO 17665 and are compatible with healthcare facility sterilizers operating under applicable national standards.

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14. Storage

- Store in a clean, dry environment.
- Protect from damage and contamination.

15. Limitations on Reprocessing

Trays are designed to withstand repeated sterilization cycles.

When properly handled, trays may withstand over 1000 cycles.

End of life is determined by damage or loss of function.

16. Disposal

Dispose according to local regulations.

17. Warranty

Products are warranted against defects under normal use.

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