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MICROWASH

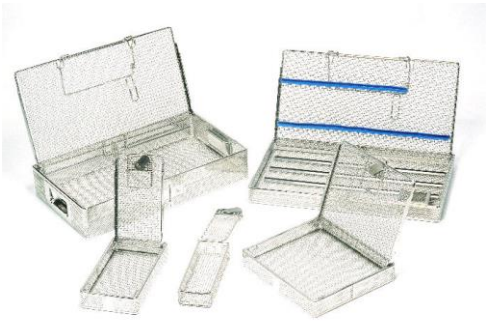
Non-sterile device

Read instructions for use (IFU)

CE marked

This is a medical devices

Instructions For Use



Microwash Trays	
Ref	Dimensions (Length x Width x Height)
A9104	195 x 70 x 40
A9106	220 x 125 x 40
A9110	250 x 220 x 40
A9111	340 x 250 x 40
A9112	440 x 250 x 40
A9113	340 x 250 x 80
A9114	440 x 250 x 80
A9118	460 x 320 x 80
Eco (Economy) Trays	
Ref	Dimensions (Length x Width x Height)
A9304	220 x 70 x 40
A9306	220 x 125 x 40
A9310	250 x 220 x 40
A9310D	250 x 220 x 80
A9311	340 x 250 x 40
A9312	440 x 250 x 40
A9313	340 x 250 x 80
A9314	440 x 250 x 80
A9315	510 x 250 x 40
Scope Trays	
Ref	Dimensions (Length x Width x Height)
A9312	290 x 80 x 50
A9314	460 x 80 x 50
75.99.003	670 x 80 x 50
75.99.007	460 x 160 x 80
75.99.070	640 x 160 x 80
75.99.0022	480 x 100 x 80
75.99.012	640 x 240 x 140
75.99.0161	750 x 125 x 50
Ring Trays	
Ref	Dimensions (Length x Width x Height)
75.99.80	510 x 254 x 60

These devices are made from Medical Grades of Stainless Steel and Silicone. They do not contain latex or phthalates. See also Altomed Reprocessing Reusable Stainless Steel and Titanium Devices ALT I013 IFUs available from Altomed.

The instructions provided below have been validated by Altomed as being capable of preparing a sample worst case tray load of medical device for re-use. **It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result.** This requires validation and routine monitoring of the process. Like-wise any deviation by the processor from any instructions provided by manufacturers of devices or the trays should be properly evaluated for effectiveness and potential adverse consequences.

1. Introduction:
Microwash Trays are designed to securely hold medical devices in place while they are processed through washers and sterilizers. See the Altomed "Stainless Steel and Titanium Instruments Care Sheet" for instructions for processing devices. These procedures should be used in conjunction with any existing Hospital Cleaning and Sterilization Procedures. These devices should only be used by suitably trained and qualified personnel under the facility approved quality management system. Follow facility approved, Department of Health, MHRA and NICE guidelines where applicable

2. Warnings:
Ensure all difficult to clean devices (for example cannulated instruments, closed tips, serrations etc) are cleaned following manufacturer guidelines before insertion into the trays. Follow facility approved, Department of Health, MHRA and NICE guidelines where applicable. Do not process rusty, damaged or iron devices together with good stainless steel or titanium ones. Do not reprocess single use devices. Any trays used for processing devices contaminated with mutated prions eg vCJD should be marked accordingly and segregated and processed following facility approved procedures. Always handle contaminated devices with PPE as specified by your facility.

3. Limitations on processing:
Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use, processing or handling. Exposure to strong acid or alkaline may reduce the working life of instruments.

4. Point of use (see also*):
Check trays prior to processing for any signs of physical damage such as split rubbers or incorrectly aligned or damaged lids and baskets. Ensure any difficult to clean devices are cleaned by following the manufacturers instructions for use as the trays are not designed to clean cannulated devices. Ensure all devices are placed into their correct location as specified on the Laminated Card. Do not allow contaminants to dry on the devices; Altomed recommends the use of a suitable Enzymatic preparation solution such as Ruhof Prepzyme XF to keep debris moist until processing. Care must be taken to prevent unwanted contamination. Follow facility approved procedures for transporting contaminated devices.

5. *Preparation for cleaning:
Prior to using the tray for the first time, it is recommended to put it through a cleaning cycle to remove any unwanted contaminants. Once the Tray has been cleaned and inspected fit all the instruments into their respective positions as shown on the Laminated Card. Ensure devices are securely in place. Ensure the lid is the correct way round then lock the lid.

6. Cleaning:
The Microwash Tray will withstand repeated exposures to Washer/Disinfectors and Ultrasonic Baths. When washing it is recommended to use a pH neutral endozymatic detergent such as Ruhof Endozyme Triple Plus. Strong alkaline detergents may be used however this may cosmetically discolour the finish of the tray and devices within over a period of time. Run a cycle that has been approved and validated by the hospital/facility. The initial rinse should be at or below 45°C, followed by a hot water disinfection rinse where the surface of the device should reach 90°C for a minimum of 1 minute (see also ISO 15883-1). Altomed have validated a cycle with the following parameters: 2 minute pre-wash at <45°C followed by an Endozyme wash at 65.5°C for 5 minutes, a 2 minute rinse in hot water and a thermal disinfection cycle of 90°C for 1 minute followed by a 15 minute drying cycle; however, it is recommended to follow Department of Health Guidance where applicable. Deionised water should preferably be used throughout the final machine rinsing stages to minimise impurities in the water. Ensure tray and devices are all thoroughly dry before passing for sterilization. See individual device instructions for any special care to be taken during processing. It is recommended to inspect trays after each cycle to ensure they are clean, if necessary, carefully remove instruments and wash trays separately, by hand if necessary.

7. Inspection and Maintenance:
Visually inspect devices for complete removal of debris and any physical damage. If devices are not visibly clean reprocess using manual cleaning is necessary. If unsure about the integrity of cannulated devices flush using deionised water to check the flow rate. Inspect devices further as specified by the instrument manufacturer where necessary. If specified by the manufacturer, instruments with moving joints (e.g. scissors etc) should then be lubricated with a water soluble lubricant (Altomed recommend Ruhof PreMix Slip). It is not recommended to use non-CE marked oil based lubricants. Department of Health guidelines should be followed were applicable. Inspect the tray before use for any signs of damage to the carcass and silicone strips; send to Altomed for repair if damaged (see 11 below).

8. Packaging:
Prior to sterilisation securely enclose the Microwash Tray in a facility approved wrap or pouch to current harmonised standards. Ensure traceability with the minimum of a Tray Description, LOT number and use by date.

9. Sterilization:
Use a hospital/facility approved and validated protocol and sterilize to current Harmonised Standards. Ensure all equipment and systems are controlled, maintained and calibrated, e.g. Department of Health Guidelines. The preferred sterilization cycle and one that has been validated by Altomed is a standard autoclave cycle operating between 134°C and 137°C with a 3 - 3½ minute holding time. See individual device instructions for any special care to be taken during processing.

10. Storage:
Stores should ensure optimum quality conditions are maintained. Processed trays should be kept away from floors, walls, and ceilings on a suitable storage unit (eg. cupboard or shelves). Store in a clean, dry well ventilated environment. Sterile devices should be clearly identified with use by dates and be segregated from non-sterile devices where appropriate. Keep sterile products out of direct sunlight at normal room temperature and humidity. Ensure all devices are dry before storage. Reject any devices in wet or damaged packing. NEVER STORE INSTRUMENTS WHEN WET OR CONTAMINATED ONES WITH CLEAN ONES.

11. Damaged Trays
If a tray is damaged, for example the silicone rubber strips are split or torn, the tray has been bent or buckled, fasteners, strips or pins have come loose, wires have snapped and are protruding etc. send to Altomed Repairs Department for evaluation along with a signed Decontamination Certificate for evaluation. If the tray is beyond repair then it should be decontaminated and wrapped to protect handlers from sharp edges. It should then be disposed of by following hospital/facility approved procedures. Only Altomed approved silicone strips or accessories should be used.