Instruction for Use

Organizational Trays

Intended Use

This product is intended for sterilizing devices contained inside with high-pressure steam.

CAUTION

Federal law restricts this device to sale by or on order of a physician.

This IFU applies to multiple types of Organizational Trays. Prior to use of this product, ensure the product is operated and used only by persons with the required training, knowledge and/or experience. Read, follow and retain these instructions and use the product only for its intended purpose. No additional training is required as Surgeons have an intimate knowledge of anatomy and physiology, and are trained in the use of similar devices as part of their surgical practice. Prior to use, remove its packaging, carefully clean either by hand or with the use of a machine prior to sterilization. If the product is found damaged or defective do not use.

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Before and after using this device, inspect for function and/or damage, wash and sterilize in accordance with these instructions. If any issues are found related to the device do not use and contact Mizuho America Representative.

Warning

- These are the risk of injury and/or failure of the product is not inspected prior and after use
- Product should be used according to these instructions and pay close attention to the safety of patients. Failure to follow these and/or the healthcare's requirements may cause harm to the patient and/or healthcare workers
- Do not reuse the device when it is used to support instruments that have been used on a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD) or variant CJD (vCJD).
- The device must be inspected and cleaned before being used to sterilize instruments.

Storage/Life

- Service of life of this device: 5 years
- Always inspect the devices between uses to confirm proper functioning
- Do not store this device in high temperatures or in areas with high humidity where the temperature has drastic variations.

Contraindication/Prohibition

- The improper use of this device during handling, surgical use or reprocessing, for which they are indicated, may result in damage or broken instrument(s).
- Keep stored ebonized devices separate from other stainless steel devices to avoid scratches to and removal of the ebonized coating.
- Use only medical detergents to clean this device. Washing with an improper detergent could result in discoloration or corrosion.
- This device is supplied non-sterile
- Materials: Plastic, Stainless Steel, Aluminum Alloy, Silicone

Sterilization

- Use a validated, properly maintained steam sterilizer. Always follow instructions of the machine manufacturer.
- Do not overload cases. Overloading may inhibit steam flow, cause excessive drying time, and make product too heavy to safely handle.
- Do not exceed 140°C (284°F) during sterilization cycle.
- Do not stack cases. For effective sterilization trays must have adequate steam circulation around all surfaces.
- For proper ventilation, do not place the product on its side or at vertical angles.
- The product should be wrapped in two layers of 1-ply polypropylene wrap (KC600) or hospital designated, FDA cleared sterilization wrapping materials. Always follow the sterilization wrap manufacturer's instruction prior to sterilization.
- Wrapping materials and the trays are designed to allow air removal, steam penetration/evacuation (drying) and maintain the sterility of the internal items.
- Effective sterilization can be achieved following the steam sterilization cycle recommended in the IFU of the particular set of instruments stored in the tray.

Maintenance

Decontamination

- Reprocess all devices as soon as they are reasonably practical following use.

- Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to decay, corrosion or damage to the product.
- Residues containing chlorine or chlorides (e.g. from surgical residues, drugs, saline solutions, and water for cleaning, disinfection, and sterilization) may cause corrosion and/or surface damage to stainless steel making the product(s) unusable or unrepairable.
- Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants, and cleaning agents used. Wherever possible avoid use of mineral acids or harsh, abrasive agents
- Do not use high acid (pH 4.0 or lower) or high alkaline (pH 10 or higher) products for disinfection. Neutral pH detergents 7.0-9.0 are preferred
- Remove gross contaminants with a soft bristled brush or steady stream of lukewarm/cool water, not to exceed 35°C (95°F). Rinse each device thoroughly. Do not use saline or chlorinated solutions. Only use distilled or deionized water.
- Do not soak devices in hot water, alcohol, disinfectants or antiseptics solution. Do not exceed 2 hours soaking in any solution.
- Do not use steel wool, wire brushes or abrasive detergents.

Cleaning & Drying: Automated

- Use only validated washer-disinfector machines and low-foaming, non-ionizing cleaning agents and detergents.
- Follow the manufacturer's instructions for use, which includes warnings, concentrations and recommended cycles.
- Load the devices carefully.
- Remove lids, caddies, inner trays and liners to wash with Neutral pH detergents (7.0-9.0 pH preferred).
- Place heavy devices on the bottom containers, taking care not to place on delicate devices or overload wash baskets.
- Ensure that soft, high purified water that is controlled for bacterial endotoxins is used in the final rinse stage.
- Devices must be thoroughly dried and all residual moisture must be removed before they are sterilized. Use a soft absorbent towel or cloth to dry external surfaces.

Inspection and Function Testing

- After cleaning, visually inspect all surfaces, for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the device for repeat decontamination.
- Visually inspect and check; all devices for damage and wear.
- Consider removing for repair or replacement any blunt, worn out, fractured, corroded, stained, discolored or damaged instruments.

Note: If the device is returned to the manufacturer or supplier, the device must be decontaminated and sterilized, otherwise a cleaning charge may apply and delay processing of the repair. Contact Mizuho America via phone (800) 699-CLIP (2547) or email customerservice@mizuho.com to obtain an RGA for return of any damaged instruments.

Packaging

All devices to be wrapped or packaged following local procedures, in ANSI/AAMI ST 46-1993.

Storage

Non-sterile devices or sterile wrapped devices should be stored in dry, clean conditions at an ambient room temperature

Name and address of manufacturer

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