

Instruction for Use

Trade Name: Evans Rotatable Instruments - Tray

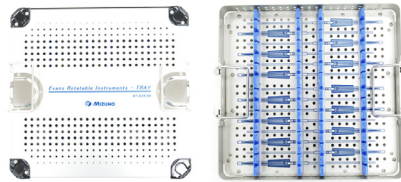
Warning

Please read these instructions carefully prior to using this product.
Product should be used according to these instructions and pay close attention to the safety of patients. Not doing so may give rise to serious problems or adverse events.

Symbol mark for labeling

MD : Medical Device

Specifications



Material: aluminum alloy, stainless steel, plastic

Code No.	Product Description
07-829-00	Evans Rotatable Instruments - Tray Ver.2

Intended purpose

The Evans Rotatable Instruments - Tray is a device intended to be used to enclose another medical device that is to be steam sterilized by a healthcare provider. By double wrapped in sterilization bag etc., it allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used.

Intended user

This product is to be used by health care professionals, including but not limited to surgeons, nurses and biomedical technicians.

Instructions for use

- These instructions provide information on how to set up, use, troubleshoot, and maintain the Evans Rotatable Instruments - Tray. For information about the product that is not covered in this document, contact your local distributor.
- Inspect, thoroughly clean, and rinse the device. Not properly preparing your Evans Rotatable Instruments - Tray may adversely affect the protective anodized finish.

General Precautions

- Pre-processing Instructions**
It is recommended that devices are reprocessed as soon as is reasonably practical following use. Devices should be transported via the institutions established transport procedure. Excess gross soil should be removed as soon as possible after use by rinsing or wiping the device. All lids of the devices must be removed.
- Cleaning and Processing**
Wash this product after each use. Wash with a correctly diluted enzyme detergent or neutral detergent. A neutral pH is defined as 7. The post-dilution pH level should not be below 5.5 or exceed 8.5.
Caution: A detergent with a highly acidic or highly alkaline pH could permanently damage the anodized finish of the device. Alcohol is not recommended for manual cleaning or wiping down. All cleaning agents should be thoroughly rinsed off prior to any sterilization process to remove all residual chemicals which could damage. Hard-to-clean area should be scrubbed with a soft brush.

3. Cleaning

- Use only properly diluted, neutral pH detergent solution recommended for safe use on anodized aluminum. Use of highly acidic or highly alkaline detergents could permanently damage the protective finish of the tray.
- All cleaning agents should be thoroughly rinsed off prior to any sterilization process to remove all residual chemicals which could damage the protective anodized finish.
- Do not use abrasive cleaners, abrasive cleaning pads, or metal brushes on device surfaces. Use of these abrasive materials will permanently damage the protective anodized finish of the device.
- Do not clean the anodized device in an ultrasonic washer.

4. Manual Cleaning

- Ensure all pre-processing instructions are followed prior to cleaning.
- Devices and accessories must be cleaned in the completely open and disassembled (i.e. taken-apart) configuration. Prepare the enzymatic / neutral pH detergent solution, utilizing potable/drinking water with a temperature range of 27°C to 44°C (81°F to 111°F), per manufacturer's instructions.
- Place devices in the open/relaxed position, and completely immerse in the detergent solution and allow device to soak for a minimum of 5 minutes. Actuate all movable parts during the initiation of the soak time.
- Using a soft bristled brush, remove all visible soil from the device. Actuate all movable parts of device while brushing, paying particular attention to hinges, crevices and other difficult to clean areas.
Note: It is recommended that the detergent solution is changed when it becomes grossly contaminated (bloody and/or turbid).
- Rinse the device by completely immersing in potable/drinking water with a temperature range of 27°C to 44°C (81°F to 111°F), for a minimum of 30 seconds to remove any residual detergent or debris.
- Dry the device with a clean, lint-free towel.
- Visually examine each device and accessory device for cleanliness.
- If visible soil remains, repeat cleaning procedure.

5. Automated Cleaning

If you wish to use automatic cleaning for these devices, you must follow the washer manufacturer's recommendations.

- Ensure all pre-processing instructions are followed prior to cleaning.
- Manipulate the devices and accessories to allow rinse water to drain.
- Visually examine each instrument for cleanliness.
- If visible soil remains, repeat cleaning procedure.
- If visible moisture is present dry the instrument with a clean, lint-free towel.

6. Sterilization

Device must be sterilized by users in accordance with validated sterilization procedures, such as an autoclave, that are regulated by medical organizations in each country or region.

7. Cooling

- Do not remove devices from the carrier until cool to touch. Proper cool down is necessary to prevent wet sets or re-condensation from forming.

7.2 Eliminate drastic temperature differences by keeping the devices away from cool ventilation ducts or cool drafts. Rapid cooling can cause wet sets.

7.3 Do not place processed devices into the sterile storage area until they reach room temperature

Product Return for Repair Information

1. Thoroughly clean and sterilize devices per these instructions for use before returning for service or repair.
2. Permission is required from MIZUHO Corporation in order to return the product for repair or to exchange the product under warranty. Please contact your local distributor.
3. Wrap accessories in protective foam before placing in the device to avoid internal shipping damage. Avoid contact between devices with cardboard dividers or similar protection.
4. Lock the lid to the tray bottom for shipment.
5. Place device in plastic bag. Use protective packaging such as packing paper or foam to cushion the bottom of the box. Gaps around devices should be protected with packing to avoid internal movement.

Maintenance and check by agents

For safety use of this instrument, conduct periodic checks by the manufacturer or the agent recognized by the manufacturer. Maintenance and check by other agents could cause the adverse events and the decrease of the performance and the function. To schedule the periodic check, contact your local distributor or the manufacturer.

Packing

1 piece per pack

Warranty

MIZUHO Corporation will repair defective parts of this product without charge for one year from the date of delivery/installment except for cases of damage caused by a third party's repair, act of nature, improper use or intentional damage. All other warranty terms and conditions are subject to regulations of MIZUHO Corporation.

Disposal

This device must be disposed of in accordance with local regulations. Please contact your local distributor for proper disposal.

Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in which the user and/or patient is established.



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