

ReNew Sterilization Tray Instructions For Use



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ReNew Sterilization Tray - Instructions For Use

INDICATIONS FOR USE

Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are intended to protect medical device instrumentation and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used.

ENGLISH

CONTRAINDICATIONS

The ReNew Sterilization Tray is not intended for use except as indicated.

COMPONENTS OF A RENEW STERILIZATION TRAY

The ReNew Sterilization Tray consists of:

1. One perforated Lid.
2. One perforated Base.
3. Silicone brackets.

PRE-CHECK INSTRUCTIONS

1. Carefully inspect the packaging to ensure that there are no signs of damage. If damage is visible, do not use the instrument.
2. Ensure that the device received is the ReNew Sterilization Tray and matches the supplied IFU.

DEVICE DESCRIPTION

The Microline Surgical ReNew Sterilization Tray intended purpose is to secure the ReNew Reusable Tips (Scissors, Graspers and Dissectors) during transportation, sterilization and storage purposes. The ReNew Sterilization Trays are available in two configurations. Catalog #3708 holds 18 device tips and catalog #3709 holds 9 device tips. The ReNew Sterilization Tray consists of a base, a lid and device holding brackets. The lid can be fastened to the base by means of a locking tab, designed as a part of the lid. The brackets are constructed from silicone. These brackets are used to secure the intended devices during transportation, sterilization and storage purposes. The Reusable Tips sterilized using the ReNew Sterilization Trays are all non-porous devices and include devices such as various graspers, dissectors and scissors. The ReNew Sterilization Tray lid and base are designed using polyphenylsulfone (Radel) material, which allows the trays to be reused after sterilization with a steam sterilization methods. To support steam sterilization, the tray and lid have an evenly distributed hole pattern in relation to its size.

PREPROCESSING INSTRUCTIONS

Prior to use, follow the guidelines below for proper cleaning and sterilization.

MANUAL CLEANING (minimum required steps)

1. Rinse with running tap water to remove gross soil.
2. Prepare enzymatic detergent solution in accordance to the manufacturer's recommendations.
3. Immerse in enzymatic solution; allow to soak for a minimum of five (5) minutes.
4. Clean the device of any visible signs of contamination using a soft brush.
5. Rinse with lukewarm tap water.
6. Rinse with deionized water. Repeat 3 times.
7. Wipe with a clean, soft, lint-free cloth.
8. Visually inspect to ensure all soil is removed.

AUTOMATED CLEANING

1. Rinse with running tap water to remove gross soil.
2. Load device(s) into automated washer. Load device(s) in the open position.
3. Automated wash cycle parameters as follows:
Instrument Cycle: High

| Phase | Time (Minutes) | Temperature | Detergent |
|------------|----------------|---------------|--------------------|
| Pre-Wash | 2:00 | Tap Water | N/A |
| Wash 1 | 2:00 | 65.5 °C | Alkaline Detergent |
| Rinse 1 | 00:15 | Hot Tap Water | N/A |
| PURW Rinse | 1:00 | 90 °C | N/A |
| Dry | 6:00 | 98.8 °C | N/A |

4. Visually inspect to ensure all soil is removed.
5. Package appropriately for sterilization.

STERILIZATION

| Sterilization Parameters | | | | |
|--------------------------|-------------|------------|------------|--|
| Sterilization Method | Temperature | Time | Dry Time | Sterilization Wrap |
| Pre-vacuum | 132 °C | 4 minutes | 30 minutes | Wrapped in two layers of 1-ply polypropylene wrap of appropriate basis weight to accommodate the weight of the sterilization tray. |
| Gravity | 121 °C | 30 minutes | 20 minutes | |
| Gravity | 132 °C | 15 minutes | 20 minutes | |

INSTRUCTIONS FOR USE

1. Clean and disinfect the used instruments, then secure each device in the brackets of the tray.
2. Cover the base with the lid and press down until the side tabs click shut, securing the lid.
3. Wrap the sterilization tray with 2 layers of FDA-approved 1-ply polypropylene wrap.
4. Sterilize the loaded wrapped tray in accordance with the instrument device manufacturer's guidelines for steam sterilization.
5. After sterilization, move wrapped tray to a sterile storage area for storage or transport to the point of use location.
6. Return tray to the sterile processing department after use.
7. The trays are reusable and should be cleaned and decontaminated prior to reuse.

STORAGE CONDITIONS

After sterilization, product should be stored in a clean, dry place.

ENVIRONMENTAL PROTECTION

To reduce contamination risks, the ReNew Sterilization Tray shall be disposed of in compliance with all applicable local, state and federal laws and regulations.

WARRANTY

Microline Surgical warrants that its instruments are free from any defects in both material and workmanship. Microline Surgical shall not be held liable for any incidental or consequential damage of any kind. Work performed on an instrument will void this warranty. Gross abuse or neglect of a Microline Surgical instrument will void this warranty.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

SYMBOL DEFINITION

Following are the graphical symbols and their descriptions used in the labeling of the ReNew Sterilization Tray:

Not made with natural rubber latex.

| | | | |
|--|--|---|--------------------------|
|  | Do not use if package is damaged. | REF | Catalog Number |
|  | Consult instructions for use | LOT | Lot Number |
|  | Manufacturer | SN | Serial Number |
|  | Refer to instruction manual/booklet |  | Non Sterile |
| RxOnly | Federal law (USA) restricts this device to sale by or on the order of a physician. |  | Date of Manufacture |
| Auto-clavable | Autoclavable | GTIN | Global Trade Item Number |



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