Product Manual

Instructions For Use (IFU)

Safety, Assurance, Innovation, and Quality,
Enabling perioperative professionals to achieve higher standards of performance and enhanced patient safety.

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Welcome to one tray®

Thank you for purchasing our ONE TRAY® Sealed Sterilization Container. ONE TRAY® Sealed Sterilization Containers are intended to be used to hold temperature tolerant medical devices during steam sterilization cycles.

After sterilization, the ONE TRAY® Sealed Sterilization Container provides for the safe storage, transport and assured delivery of the enclosed devices in a sealed container with tamper evident security and load record documentation.

ONE TRAY® containers are reusable devices consisting of a base, lid, filter covers and a deck plate constructed of anodized aluminum and stainless steel materials. With proper care and handling, ONE TRAY® will provide years of effective and reliable service.

The performance and intended use of the ONE TRAY® Sealed Sterilization Containers should utilize the:

- Device manufacturer’s sterilization exposure parameters
- Recommended practices/guidelines outlined by AAMI (Association for the Advancement of Medical Instrumentation) and AORN (Association of periOperative Registered Nurses)
Available Components and Configurations

### ONE TRAY® 21” Model

<table>
<thead>
<tr>
<th>Product #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M2104</td>
<td>21” (53.3cm) L x 12” (30.5cm) W 4” (10.2cm) working height</td>
</tr>
<tr>
<td>M2106</td>
<td>21” (53.3cm) L x 12” (30.5cm) W 6” (15.2cm) working height</td>
</tr>
<tr>
<td>M2108</td>
<td>21” (53.3cm) L x 12” (30.5cm) W 8” (20.3cm) working height</td>
</tr>
</tbody>
</table>

### ONE TRAY® 24” Model

<table>
<thead>
<tr>
<th>Product #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M2404</td>
<td>24” (61.0cm) L x 12” (30.5cm) W 4” (10.2cm) working height</td>
</tr>
<tr>
<td>M2406</td>
<td>24” (61.0cm) L x 12” (30.5cm) W 6” (15.2cm) working height</td>
</tr>
<tr>
<td>M2408</td>
<td>24” (61.0cm) L x 12” (30.5cm) W 8” (20.3cm) working height</td>
</tr>
</tbody>
</table>

### ONE TRAY® Accessories

<table>
<thead>
<tr>
<th>Product #</th>
<th>Description</th>
</tr>
</thead>
</table>
| OTK-210   | **ONE TRAY® Processing Kit**  
200 kits per case. Each kit contains:  
3 Single Use Filters  
2 load ID cards, 1 Type 5 Chemical Integrator  
2 Tamper Evident Locks w/Steam Sterilization Indicator dot |

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**Storage**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>15°C to 30°C</td>
<td>Keep away from direct exposure to sunlight and flourescent light</td>
</tr>
<tr>
<td>20% to 70% Relative Humidity</td>
<td>Keep Dry</td>
</tr>
<tr>
<td>Reference UDI device label attached to the <strong>ONE TRAY®</strong> processing kit box for expiration date</td>
<td></td>
</tr>
</tbody>
</table>

Keep away from hydrogen peroxide and other sterilants. Storage on top of or near a heat source should be avoided. Do not use after expiration date.
## Steam Sterilization Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Dynamic Air Removal/ Steam Sterilization Cycle</th>
<th>Gravity Steam Sterilization Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure Temperature</td>
<td>270°F (132°C)</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td>Exposure Time</td>
<td>4 minutes</td>
<td>34 minutes</td>
</tr>
<tr>
<td>Dry Time</td>
<td>Not required</td>
<td>Not required</td>
</tr>
<tr>
<td>Cycle Cool Time</td>
<td>Not required</td>
<td>Not required</td>
</tr>
<tr>
<td>Stacking</td>
<td>Not permitted in sterilization cycle</td>
<td>Not permitted in sterilization cycle</td>
</tr>
</tbody>
</table>
## ONE TRAY® Performance Testing Summary

<table>
<thead>
<tr>
<th>Contents/Configuration</th>
<th>Performance Testing conducted and reviewed by the FDA under 510k K052567</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Required Accessories</strong></td>
<td>ONE TRAY® components, filters and tamper evident locks</td>
</tr>
<tr>
<td><strong>Lumens</strong></td>
<td>Lumens 3mm in diameter or larger with lengths up to 400mm</td>
</tr>
<tr>
<td><strong>Shelf Life/Maintenance of Sterility</strong></td>
<td>2 Days</td>
</tr>
<tr>
<td><strong>Maximum Weight</strong></td>
<td>Challenge set weighing 25 lbs to support the use of a 25 lb load</td>
</tr>
<tr>
<td><strong>Device Types</strong></td>
<td>Instruments with hinges, knurled areas and lumens</td>
</tr>
</tbody>
</table>
| **Device Materials**   | **Metals:** Stainless Steel  
                          | **Aluminum Thermoplastics:** Polypropylene, Radel  
                          | **Thermosetting Polymers:** Silicone |

Performance testing of the **ONE TRAY®** was conducted by HIGHPOWER Labs, an ISO 17025 accredited laboratory. All testing was performed without the use of a dry time. The following performance testing/validations were conducted in accordance with the below listed recognized standards:

**Performance Testing/Validation:**
- Steam Lethality
- Sterilant Penetration
- Material Compatibility
- Shelf Life
- Biocompatibility
- Moisture Sterility
- Package Integrity
- Limit of Reuse

**Testing / Validation in accordance to:**
- ANSI/ AAMI ST77
- ANSI/ AAMI ST79
- ANSI/ AAMI ST8
- ANSI/ AAMI TIR12
- ANSI/ AAMI TIR30
- ANSI/ AAMI ST81
- AAMI 14161
- ANSI/ AAMI ST8
- ISO 10993
- ISO 11607
- ISO 17665
- ISO 19885
Preparation

1. Thoroughly inspect container for dents, loose components or damage that may affect performance.

2. Place container on stable and level surface at height that facilitates opening the lid safely.

3. Open the container by removing the lid according to the instructions illustrated in the table on the next page.

4. Confirm the rim of the base is free of burrs and dents.

5. Inspect to ensure lid gasket is free of cracks, tears, imperfections or defects and is completely seated in lid channel.

6. Confirm that the lid properly mounts on the base and seals in place.
Opening Method

1. Lid on base with latch mechanism in locked position.

2. Grasp the latch mechanisms at each end of container.

3. Simultaneously pull outward on the latching mechanisms on each end.

4. Locking lever is disengaged from mounting block on base as the latching mechanisms are raised.

5. Locking lever releases from the mounting block on the base as both latching mechanisms are raised.

6. Latching mechanisms are fully open and lid removed from base.
The validated performance of ONE TRAY® is in effect ONLY with the exclusive use of ONE TRAY® components, filters and tamper evident locks.

Filter Installation

1. A single disposable ONE TRAY® filter is required for each of the perforated areas (one in lid and two in the base).
2. Each disposable ONE TRAY® filter should be inspected to confirm the absence of imperfections or defects such as puncture holes or tears.
3. Insert the ONE TRAY® filter with the ONE TRAY® logos placed face up. The holes should be under the filter cover slide bar.
4. Each disposable ONE TRAY® filter must completely cover the grooved channel surrounding the perforated areas.
5. Confirm the notched end of the filter cover is properly oriented with the correct set of retention posts.
6. Insert the notched end of filter cover under retention posts.
7. Position “keyholes” in the filter cover slide-bar over an opposing set of retention posts.
8. Apply downward pressure on the outer edges of the belt loops on the filter cover and push the slide bar completely forward into a fully locked position under the retention posts.
9. All filters and filter covers are interchangeable

Filters are for single use only and must be discarded after each processing cycle. Do not use more than one filter in each area that requires a filter.
Filter Installation

1. Use ONE TRAY® Processing Kit.
2. Confirm lid seal and channel are clean and unobstructed.
3. Position the ONE TRAY® filter so that the holes align over the retention posts on the same side as the slide bar on the filter cover. The ONE TRAY® logos should be placed face up.
4. Insert notched end of filter cover under appropriate retention post.
5. Position “keyholes” in filter cover slide-bar over the retention posts on the opposite side.
6. Apply downward pressure on the filter cover and push the slide-bar into the locked position.
Loading the Container

1. Prevent contents from contacting the lid.
2. Avoid obstructing perforated areas and filter covers.
3. Chemical integrator should be used within each assembled content set. Facilities should follow their internal policies and procedures for integrator usage.
4. When loading the container, utilize the ONE TRAY® deck plate or equivalent size containment device for the direct placement of medical devices or instrument organizing trays.
5. Place the chemical integrator in the container per your facilities’ internal policy and procedures.

Medical Devices should be prepared and sterilized per the specified exposure time and at a specified temperature according to the manufacturer’s written instructions.
Container Assembly & Security

1. Inspect the rim of the base to confirm there are no dents or burrs.
2. Inspect the lid gasket to confirm there are no cracks, tears, imperfections, or defects.
3. Confirm that all filter covers are securely in place.
4. Place the lid on the base evenly and confirm proper fit.
5. Secure the lid by simultaneously pressing down to engage the latching mechanisms at each end.
6. Insert a **ONE TRAY**® tamper evident lock through the latching mechanisms at both ends of base.
7. Content I.D. cards are provided. Follow your facilities internal policies and procedures for content identification.

The validated performance of **ONE TRAY**® is in effect ONLY with the exclusive use of **ONE TRAY**® components, filters, and tamper evident locks.
Closing Method

1. Align the lid with the base.
2. Mount the lid properly onto the base.
3. Engage the latching mechanisms with the mounting block on the base and the locking levers are in the horizontal position.
4. Simultaneously push down on both locking levers.
5. Push down on both locking levers until latches are fully engaged and in the locked position.
6. Container is clasped and sealed when both cover latching mechanisms are in locked position.
Sterilization & Handling

1. Place a single ONE TRAY® container in a level horizontal position. Containers cannot be placed on their side.
2. Confirm that all perforated areas are not obstructed.

**DO NOT STACK ONE TRAY® CONTAINERS DURING STERILIZATION**

3. Follow your facilities’ internal policies and procedures for determining storage periods.
4. ONE TRAY® is cleared for steam sterilization for total gross weight (container plus contents) not to exceed 25lbs/11.3kg. ONE TRAY® is cleared for use in the following cycles:

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum</td>
<td>4 Minutes @ 270° F / 132° C</td>
</tr>
<tr>
<td>Gravity</td>
<td>34 Minutes @ 270° F / 132° C</td>
</tr>
</tbody>
</table>

Following sterilization, avoid unprotected contact with the hot container by using insulated handles and/or gloves to lift and transport.

5. Retained moisture is normal and expected and will vary by load composition. This moisture does not compromise the sterility of contents.
Tamper evident Lock Method

1. Insert narrow end of tamper evident lock in hole from the back side of latch before cam locking.

2. Partially lower latch while keeping locking lever up and insert 1 tamper evident lock.

3. Position locking lever between tamper evident lock and ensure indicator dot is facing outwards.

4. Cam actuate the locking lever then insert narrow end into flat side of tamper evident lock.

5. Push narrow end through opening until tamper evident locks are engaged.

6. Assure that tamper evident locks have been correctly placed and locked on both ends of the container.
Sterile Storage, Delivery & Presentation

1. Place container on stable and level surface at height that facilitates aseptic opening.
2. Follow your facilities’ internal policies and procedures for the release of sterilized medical devices.
3. Check to ensure tamper evident locks are intact by gently tugging on each lock and verify steam indicator dot color change.
4. Check to ensure the external indicator dot has turned the appropriate color. Upon exposure to high temperature steam, the indicator will transition from blue to dark. The transition color may vary depending on the load configuration, length and condition of exposure. A color transition from blue to a shade of black/grey provides indication of exposure to high temperature steam.
5. Before opening, inspect container and confirm presence of all three filters.
6. Break the tamper evident locks by twisting the lock until the lock breaks. Remove the lock.

Failing to follow ONE TRAY® lock breaking procedures could result in lock pieces transferring into the sterile field

7. Place thumbs on upper surface of lid above latching mechanisms.
8. Place fingers under lid locking lever at both ends of container.
9. Aseptically lift lid off the base of the container and inspect for proper placement of all filters and installation of filter covers. Ensure filter covers are securely in place.

ONE TRAY® Storage:

<table>
<thead>
<tr>
<th>Facility Follows</th>
<th>Course of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event Related Shelf Life</td>
<td>Follow Facility Policies and procedures</td>
</tr>
<tr>
<td>Expiratory Dating</td>
<td>Follow Facility Policies and procedures</td>
</tr>
</tbody>
</table>
Removing Sterile Contents

1. Before removing the contents within the container, properly trained personnel should verify internal sterilization indicators per facility policies and procedures.

2. Securely grasp the contents, or modular organizing tray handles and remove in an aseptic manner without touching the outside of the container.

3. Before placing contents on the sterile field, each disposable ONE TRAY® filter should be inspected to confirm the absence of imperfections or defects such as puncture holes or tears.

Inspection Check List

Contents should be considered non-sterile if any of the following conditions are present:

- A tamper evident lock is not intact or is missing from either latching mechanism.
- A filter cover is dislodged and not securely attached.
- A filter does not completely cover the channel around the vented area.
- Integrity of the filters has been compromised. Each disposable ONE TRAY® filter should be inspected to confirm the absence of imperfections or defects such as puncture holes or tears.
- Gasket is either damaged or separated from the lid channel.
- Sterilization cycle is interrupted or aborted (doesn’t complete required steam sterilization parameter).
- If you have questions about the proper functionality of the ONE TRAY® Sealed Container System, contact your ONE TRAY® representative.
Reprocessing Instructions

It is recommended that containers are reprocessed as soon as it is reasonably practical following use. Containers should be transported per facility’s policies and procedures.

Soil should be removed as soon as possible per facility’s policies and procedures utilizing AAMI TIR 34 compliant water.

All containers must be reprocessed in the completely open and disassembled configuration (i.e. taken-apart and all disposables removed).

Disassembly

1. Remove and discard all disposables (filters, load content cards, tamper evident locks).
2. Inspect the container lid and base for dents or damage that may affect performance.
3. Confirm the rim of the container base is free of burrs and dents.
4. Inspect to ensure the lid gasket is free of cracks, tears and is properly seated in the lid channel.
5. Confirm the lid properly interfaces and engages on container base.
Reprocessing

1. ONE TRAY® containers and components may be safely reprocessed in a mechanical washer/decontaminator, cart washer or processed manually.

2. Water quality and removal of reprocessing agents is an important consideration for the reprocessing of medical devices. AAMI TIR 34 provides guidelines to personnel involved in medical device reprocessing on the quality of water that should be used in various stages of medical device reprocessing.

   All reprocessing agents must be thoroughly rinsed off and facilities should utilize AAMI TIR 34 compliant water prior to sterilization.

3. Mechanical or automatic reprocessing should follow the directions of the equipment manufacturer.

4. The ONE TRAY® lid and base should be positioned to prevent water collection.

5. Use reprocessing agents with a neutral pH.

6. Alcohol based disinfecting wipes should not be used.

   Use of reprocessing agents below or above the recommended range could permanently damage the protective finish of the container. Use of reprocessing agents below or above the recommended range will result in warranty exclusion.

7. NEVER clean the container with abrasives or wire brushes.

   Use of abrasive materials will permanently damage the protective anodized finish of the container. Use of abrasive materials will result in warranty exclusion.

8. All components should be secured or enclosed inside a rack or basket with no protrusions to prevent damage during reprocessing.

9. Ensure container and contents are dry prior to sterilization. If necessary, dry container and components with a clean lint-free towel.
ONE TRAY® Sealed Sterilization Containers are guaranteed for the life of the product to be free of functional defects in workmanship and materials when used normally as recommended for their intended purpose in conjunction with ONE TRAY® filters, tamper evident locks, and deck plate.

ONE TRAY® containers should be inspected prior to each usage for signs of misuse or mishandling (i.e. dents, missing parts, damaged pieces, misalignment etc.) and sent in for warranty claims.

Any product determined to be defective after normal usage will be repaired or replaced with no charge to the customer at the sole discretion of Innovative Sterilization Technologies. A restocking fee will be charged on returns.

Used product may not be returned for credit (used is considered any box that has been cut opened). Any and all non-used returns must receive prior authorization from Innovative Sterilization Technologies.

This warranty is valid only to the original purchaser.

The following exclusions apply to this warranty that include, but are not limited to:
- Conditions resulting from: negligence, misuse and improper reprocessing, handling, closing or opening.
- Damage from excessive force or pressure.
- Use of abrasive reprocessing agents that are not neutral pH.
- Modification(s) to the container.
- Effects from fire, flood or other unpredictable event not under the control of Innovative Sterilization Technologies.

ONLY IST trained technicians are authorized to repair ONE TRAY® Sterilization Container System. Using a non-IST repair technician to repair containers will void the ONE TRAY® warranty on the container and will void any of the validation/performance testing associated with ONE TRAY® containers.

If you have questions regarding the ONE TRAY® warranty, contact: info@onetray.com or call 937.619.0138
DEFINITIONS

cleaning: Removal of contamination from an item to the extent necessary for further processing or for the intended use.

containment device: Instrument case, cassette, or organizing tray intended for use in healthcare facilities for the purpose of containing reusable medical devices for sterilization.

critical water: Water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process. This water is mainly used for the final rinse or steam generation.

cycle, steam sterilization, dynamic-air-removal type: One of two types of sterilization cycles in which air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure-pulse [SFPP] cycle).

exposure time: Period for which the process parameters are maintained within their specified tolerances. In a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

healthcare facility: Specialized facility where professionals deliver services utilizing medical devices.

instructions for use (IFU): Written recommendations provided by the manufacturer that provide instructions for operation and safe and effective use of its device defined within the Food Drug & Cosmetic Act.

medical device: as defined within the Food Drug & Cosmetic Act as “...an instrument, apparatus, implement, machine, contrivance, implant,
in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it’s primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

**packaging system**: Combination of the sterile barrier system and protective packaging.

**pH level**: Number denoting alkalinity or acidity. NOTE—The pH scale is logarithmic and runs from 0 to 14; the neutral point is 7. Numbers below 7.0 indicate acidity, and those above 7.0 indicate alkalinity.

**reprocess**: To prepare a device, instrument, or piece of equipment for reuse by any or a combination of the following processes: precleaning, cleaning, disinfection, sterilization, and rinsing at appropriate stages.

**rinsing**: Removal of any residue of cleaning agents and chemicals remaining after the cleaning process.

**steam quality**: Steam characteristic reflecting the dryness fraction (weight of dry steam present in a mixture of dry saturated steam and entrained water) and the level of noncondensable gas (air or other gas that will not condense under the conditions of temperature and pressure used during the sterilization process).

**sterile barrier system**: Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.
sterility assurance level (SAL): Probability of a single viable microorganism occurring on an item after sterilization. SAL is normally expressed as 10-n. A SAL of 10-6 means that there is less than or equal to one chance in a million that a single viable microorganism is present on a sterilized item.

sterilization: Validated process used to render a product free from viable microorganisms.

sterilization cycle: Defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber.

tray: Basket, with or without a lid, that has perforated sides or bottom, that holds instruments, and that is either enclosed in sterilization wrap or a pouch or placed inside a container for sterilization.

validation: Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

water quality: Descriptor of the levels of various impurities present in water.