Product Manual
User’s Guide

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

Innovative Sterilization Technologies
7625 Paragon Road, Suite A
Dayton, OH 45459
www.iststerilization.com

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Welcome to ONE TRAY®

Thank you for purchasing our ONE TRAY® Sealed Sterilization Container. You have purchased a state of the art rigid container system. 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 according to AAMI and AORN guidelines.

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 manufactures sterilization exposure parameters
- Recommended practices/guidelines outlined by AAMI (Association for the Advancement of Medical Instrumentation), AORN (Association of periOperative Registered Nurses)
# ONE TRAY® 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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## ONE TRAY® Steam Sterilization Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Dynamic Air Removal/Pre-Vacuum 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>Preconditioning Pulses</td>
<td>Minimum 3</td>
<td>n/a</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>

Although cleared under 510k K052567 for a 34-minute gravity cycle, IST does not recommend the use of a Gravity cycle. Unless the device manufacturer specifically recommends the use of Gravity cycle, Dynamic Air Removal (Pre-vacuum) cycles should be the cycle of choice. It is critical to refer to the device manufacturers’ instructions to determine the required sterilization cycle.
# ONE TRAY® Performance Testing Summary

<table>
<thead>
<tr>
<th>Contents/Configuration</th>
<th>Performance Testing conducted for 510k K052567</th>
<th>Additional Performance Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Required Accessories</td>
<td>ONE TRAY® components, filters and tamper locks</td>
<td>ONE TRAY® components, filters and tamper locks</td>
</tr>
<tr>
<td>Lumens</td>
<td>Lumens 3mm in diameter or larger with lengths up to 400mm</td>
<td>Lumens 1mm in diameter or larger with lengths up to 500mm</td>
</tr>
<tr>
<td>Shelf Life/Maintenance of Sterility</td>
<td>Test #1 - 2 Days</td>
<td>Test #2 - 30 days, Test #3 - 180 days, Test #4 - 365 days</td>
</tr>
<tr>
<td>Maximum Weight</td>
<td>Challenge set weighing 25lbs to support the use of a 25 lb load</td>
<td>Challenge set weighing 40 lbs to support the use of a 25 lb load</td>
</tr>
<tr>
<td>Device Types</td>
<td>Instruments with hinges, knurled areas and lumens</td>
<td>Conjoined/mated surfaces: forceps, clamps, bending pliers, ratchet handles, retractors Cannulated: drill bits, taps, guides, screwdrivers, cannulated screws</td>
</tr>
</tbody>
</table>

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. Performance testing included:

- Steam Lethality
- Sterilant Penetration
- Moisture Sterility
- Shelf Life
- Material Compatibility
- Biocompatibility
- Package Integrity
- Limit of Reuse

Additional labeling claims are supported by performance testing utilizing the original 510(k) protocols and have been documented internally by the company. Performance testing and additional labeling claims are consistent with FDA guidances.

Per industry practices/guidelines, facilities should follow internal policies and procedures for:

- Storage and transport for event-related maintenance of sterility practices.
- Sterilization and the release of sterilized medical devices.
- The use of contents of container systems that appear to have retained moisture
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 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® name placed face up. The name 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.

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.

Make sure filter does not overlap itself or become wrinkled or creased (folded over onto itself).
## 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®** name will align under the slide bar of the filter.

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 side-bar into the locked position
**Loading the Container**

1. Prevent contents from contacting the lid.
2. Avoid obstructing perforated areas and filter covers.
3. Per industry recommended practices/guidelines, a chemical integrator should be used within each assembled content set. Facilities should follow their internal policies for integrator usage.

Innovative Sterilization Technologies recommends the use of a Type 5 Chemical Integrator.

4. When loading the container, only the **ONE TRAY**® deck plate has been designed for the direct placement of medical devices or insertion of modular instrument organizing trays.
5. Place the chemical integrator in the container per your internal policy.

Medical Devices should be prepared and sterilized according to the manufacturers’ written instructions for steam sterilization exposure.
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. Facilities should follow their internal policies for content identification.

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

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Align the lid with the base</td>
</tr>
<tr>
<td>2</td>
<td>Mount the lid properly onto the base</td>
</tr>
<tr>
<td>3</td>
<td>Engage the latching mechanisms with the mounting block on the base and the locking levers are in the horizontal position</td>
</tr>
<tr>
<td>4</td>
<td>Simultaneously push down on both locking levers</td>
</tr>
<tr>
<td>5</td>
<td>Push down on both locking levers until latches are fully engaged and in the locked position</td>
</tr>
<tr>
<td>6</td>
<td>Container is clasped and sealed when both cover latching mechanisms are in locked position</td>
</tr>
</tbody>
</table>
### Sterilization & Handling

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

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

3. **ONE TRAY®** is validated for steam sterilization for total gross weight (container plus contents) not to exceed 25lbs/11.3kg. **ONE TRAY®** is validated for use in the following cycles:

- **Pre-vacuum**: 4 Minutes @ 270° F / 132° C
- **Gravity**: 34 Minutes @ 270° F / 132° C

Although cleared under 510k K052567 for a 34-minute gravity cycle, IST does not recommend the use of a Gravity cycle. Unless the device manufacturer specifically recommends the use of Gravity cycle, Dynamic Air Removal (pre-vacuum) cycles should be the cycle of choice. It is critical to refer to the device manufacturers’ instructions to determine the required sterilization cycle.

4. Retained moisture is normal and expected and will vary by load composition. This moisture does not compromise the sterility of contents. Per AAMI recommended practices/guidelines, IST recommends the user to develop a policy and procedure regarding the sterility and use of the contents of container systems that appear to have retained moisture.

Following sterilization, avoid unprotected contact with the hot container by using insulated handles to lift and transport.
Tamper Lock Method

1. Insert narrow end of tamper 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 lock.

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

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

5. Push narrow end through opening until tamper locks.

6. Tamper lock placed on latch at both ends of container.
Sterile Delivery & Presentation

1. Place container on stable and level surface at height that facilitates aseptic opening.
2. Facilities should follow their internal policies for the release of sterilized medical devices.
3. Check to ensure tamper evident locks are intact by gently tugging on each lock.
4. Before opening, inspect container and confirm presence of all three filters.
5. Break the tamper evident locks by twisting the lock until the lock breaks. Remove the lock.
6. Place thumbs on upper surface of lid above latching mechanisms.
7. Place fingers under lid locking lever at both ends of container.
8. 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.
9. Confirm filters are undamaged.

The validated performance of ONE TRAY® is in effect ONLY with the exclusive use of ONE TRAY® components, filters, and tamper locks.
Removing Sterile Contents

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

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, properly trained personnel must inspect the placement and security of all filter covers and integrity of each filter in regards to all three perforated areas.

4. After container is empty, replace the container lid and secure the latching mechanism to the container base using the latch handles.

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.
- 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 is reasonably practical following use. Containers should be transported per facility’s policies.

Soil should be removed as soon as possible per facility’s policies 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 utilizing 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®** cover and base should be positioned to prevent water collection.

5. For optimal reprocessing results, use reprocessing agents with a neutral pH.

   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.

6. 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.

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

8. Confirm that all components are cool before handling.

9. Ensure container and contents are dry prior to sterilization. If necessary, dry container and components with a clean lint-free towel.
Appendix

Manufacturer’s Warranty

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.

Used product may not be returned for credit. Any and all returns must receive prior authorization from Innovative Sterilization Technologies and include documentation that the returned product was properly cleaned and decontaminated.

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.
- Use of accessories (tamper evident locks, filters, etc.) not supplied by ONE TRAY®.
- 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.