ONE TRAY®

Sealed Sterilization Container

IFU K250029

15 MIN MINIMUM DRY TIME, 365 DAY STORAGE



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

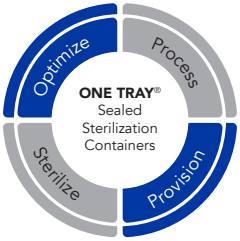
Innovative Sterilization Technologies
7625 Paragon Road, Suite A
Dayton, OH 45459
www.iststerilization.com

Proudly Made in the U.S.A.

When complying with IFU K250029 requirements, ORANGE locks should be used.

K250029 Condoc 712 Rev 01 021626

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Personnel training and competency is required to perform all phases of processing. Sterilizing equipment, water supply and quality, and practices within a facility all contribute to providing an effective reprocessing system and should be monitored by each facility.

WELCOME TO ONE TRAY®

Thank you for purchasing the ONE TRAY® Sealed Sterilization Container system.

INDICATIONS FOR USE

The ONE TRAY® Container is a reusable rigid sterilization container intended to be used to enclose reusable medical devices that are to be steam sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed devices and maintenance of sterility of the enclosed devices during storage, transport and until used. This container is compatible for use in the following sterilization modalities in the configuration listed below:

- Prevac Steam
- 270°F, 4 min exposure
- 15-minute minimum dry time

ONE TRAY® is validated to process a twenty five pound (25 lb) gross weight load (single container plus contents). This includes sterilization of lumens (Stainless Steel and Titanium) 1 mm in diameter or larger with lengths of up to 500 mm.

DO NOT STACK ONE TRAY® CONTAINERS DURING STERILIZATION

Examples of validated materials that can be processed within the ONE TRAY®- Metals: Stainless Steel, Titanium, Aluminum, Thermoplastics: PEEK, Polypropylene, Radel, Thermosetting Polymers: Silicone, Phenolic

The ONE TRAY® sealed sterilization container consists of a line of rigid reusable containers in listed in the table below.

Model	Model Description
M2104DT	(L) 20.142" x (H) 4.573" x (W) 11.616"
M2106DT	(L) 20.142" x (H) 6.573" x (W) 11.616"
M2108DT	(L) 20.142" x (H) 8.573" x (W) 11.616"
M2404DT	(L) 23.142" x (H) 4.573" x (W) 11.616"
M2406DT	(L) 23.142" x (H) 6.573" x (W) 11.616"
M2408DT	(L) 23.142" x (H) 8.573" x (W) 11.616"

Healthcare Facilities should follow steam sterilization cycle and storage guidelines as stated in AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

For device model numbers, sizes and product accessory information please go to **https://onetray.com/products/onetray/**for details.

ONE TRAY® SYSTEM RECOMMENDED USAGE & STERILIZATION GUIDELINES

ONE TRAY® is validated to process a twenty five pound (25 lb) gross weight load (single container plus contents) in the following parameters listed in Table 1. This includes sterilization of lumens 1 mm in diameter or larger with lengths of up to 500 mm.

Run loaded sterilizer according to the times and temperatures listed. The following parameters were established during validation testing of ONE TRAY® and performed in an AAMI ST08 compliant steam sterilizer.

ONE TRAY® is validated for use utilizing the following steam sterilization cycle parameters:

Dynamic Air Removal/Pre-Vacuum Steam Sterilization

Table 1

Parameter	K250029
Exposure Temperature	270°F (132°C)
Exposure Time	4 minutes
Dry Time	15 minutes minimum
Cool Time	Varies according to load
Event Related Shelf Life/Storage Period	365 days

ONE TRAY® containers have been validated to maintain the sterility of the contents for 365 day event related shelf life/storage period with a 15 minute minimum dry time.

ONE TRAY® 510K CLEARED PERFORMANCE TESTING SUMMARY

Contents/Configuration	Performance Testing conducted for 510k K250029
Required Accessories	ONE TRAY® container, filters and tamper evident locks
Lumens	Lumens 1mm in diameter or larger with lengths up to 500mm
Shelf Life	365 day event related shelf life/storage with a 15 minute minimum dry time
Maximum Weight	Total gross weight, container plus contents not to exceed 25lbs
Device Types	Instruments with hinges, knurled areas and lumens
Device Materials	Metals: Stainless Steel. *Aluminum Thermoplastics:* Polypropylene, Radel *Thermosetting Polymers*: Silicone



All clinical research and validation testing of ONE TRAY® was performed using the ONE TRAY® container, filters, and tamper evident locks.

Performance testing of the ONE TRAY® was conducted by HIGHPOWER Labs, an ISO 17025 accredited laboratory. 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
- Package Integrity
- Limit of Reuse

Testing / Validation in accordance to:

- ANSI/ AAMI ST77
- ANSI/ AAMI ST79
- ANSI/ AAMI ST8
- ANSI/ AAMI TIR12
- AAMI ST98
- AAMI/ISO 17664-1
- AAMI/ISO 11138-7
- AAMI ST108
- ISO 10993
- ISO 11607
- ISO 17665

PREPARATION

1. Thoroughly inspect the 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 all gaskets are free of cracks, tears, imperfections or defects and are completely seated in the applicable channel.
6. Confirm that the lid properly mounts on the base and seals in place.



OPENING METHOD

1		2	
	Lid on base with latch mechanism in locked position		Grasp the latch mechanisms at each end of container
3		4	
	Simultaneously pull outward on the latching mechanisms on each end		Locking lever is disengaged from mounting block on base as the latching mechanisms are raised
5		6	
	Locking lever releases from the mounting block on the base as both latching mechanisms are raised		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 the ONE TRAY® container, filters, and tamper evident locks.

DISPOSABLE ⊗ 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. Each disposable ⊗ ONE TRAY® filter **must** completely cover the grooved channel surrounding the perforated areas.
4. Confirm the notched end of the filter cover is properly oriented with the correct set of retention posts.
5. Insert the notched end of filter cover under retention posts.
6. Position "keyholes" in the filter cover slide-bar over an opposing set of retention posts.
7. 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.
8. Filters and filter covers are interchangeable.



Disposable⊗ filters are for single use only and must be discarded after each processing cycle. Do not use more than one filter in each perforated area that requires a filter.

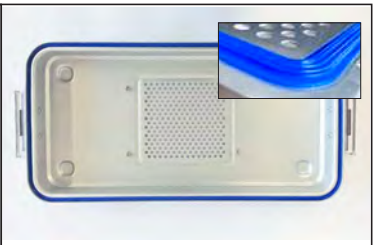
FILTER INSTALLATION

1



Use ONE TRAY® Processing Kit

2



Confirm filter cover seal and grooved channels are undamaged (cracks, tears, burrs, dents, discoloration) and clean

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.

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. A 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. Do not set anything directly on the filter covers.





Medical Devices should be prepared and sterilized according to the device manufacturer's written instructions for sterilization cycle exposure parameters **(time and temperature)**.

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 filters and 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. Confirm lock is fully engaged before processing. Only the following ONE TRAY® tamper evident locks have been validated for use with the ONE TRAY® Container System.

ONE TRAY® Container System Tamper Evident Locks

IST ONE TRAY™ Container System Tamper Evident Lock K250029					
Lock Color	**Indicator**	**Part #**	**Quantity/Pack**	**Pre Vac Steam w/ Dry Time**	**Pre Vac Steam w/o Dry Time**
Orange	Change[1] Blue to Dark	6-PPS02	400	Yes	--

1. 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



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

CLOSING METHOD

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

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

6



Tamper evident lock placed on latch at both ends of container

STERILIZATION & HANDLING

1. Place ONE TRAY® container(s) in a level position on the shelf of the sterilizer or sterilizer rack.
2. Confirm that all perforated areas are not obstructed.



DO NOT STACK ONE TRAY® CONTAINERS DURING STERILIZATION

3. ONE TRAY® is validated for processing a total gross weight (container plus contents) not to exceed 25 lbs. This includes sterilization of lumens of 1 mm in diameter or larger with lengths of up to 500 mm.
   ONE TRAY® is validated for use in the following sterilization cycle:

Pre-vacuum	Temperature 270°F (132°C), Exposure Time 4 minutest, 15 min minimum dry time.

4. Steam sterilization dry-time performance may vary by facility due to factors such as sterilizer performance, load configuration, and density, quantity and type of instruments, and water and steam quality.

   - There should be no visible condensation or pooling on the external surface of the containment device, and the contents of the container should be free of visible condensation.

   - Users should perform user verification in accordance with AAMI ST79, defined as documented procedures conducted in the user environment to obtain, record, and interpret results demonstrating that predetermined specifications have been met.



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



Items sterilized in a steam sterilization cycle: Temperature 270°F (132°C), Exposure Time 4 minutes, are validated for 365 day event-related shelf life/storage with a 15-minute minimum dry time.

STERILE DELIVERY & ASEPTIC PRESENTATION

1. Place container on stable and level surface at height that facilitates aseptic opening.
2. Check to ensure tamper evident locks are intact by gently tugging on each lock.
3. 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.
4. Before opening, inspect the container and confirm the presence of all three filters.
5. 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 onto the sterile field.

6. Place fingers under lid locking lever at both ends of container.
7. 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.

REMOVING STERILE CONTENTS

1. Before removing the contents within the container, trained personnel should verify internal sterilization integrator 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.



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

REPROCESSING INSTRUCTIONS

Follow facility's policies, procedures, and AAMI ST79 recommended guidelines for the transportation of soiled instruments and containers.

It is recommended that containers be reprocessed as soon as is reasonably practical following use. Containers should be reprocessed in the completely open and disassembled configuration.

Container, lids and baskets that may not be used or needed right away should be decontaminated and cleaned prior to storage.

The ONE TRAY® Container System should be stored neatly, either assembled or unassembled, in a dry, clean area.

DISASSEMBLY

1. Remove and discard all disposable components (filters, tamper evident locks).
2. Inspect the container lid and base for dents or damage that may affect performance. Confirm the rim of the container base is free of burrs and dents.
3. Inspect to ensure the lid gaskets are free of cracks, tears and is properly seated in the lid channels.
4. Inspect filter cover seal and grooved channels. Ensure these features are undamaged (cracks, tears, burrs, dents, discoloration) and clean.
5. Confirm the lid properly interfaces and engages on container base.

CLEANING

1. ONE TRAY® containers and components may be safely reprocessed in a mechanical washer.

2. Mechanical reprocessing should follow:
   - minimum parameters outlined in Table 2
   - operating directions of the equipment manufacturer

Table 2

Treatment	Time (mm:ss)	Temp	Cleaning Solution
Enzyme Wash	04:00	60°C	Steris Prolystica 2X Concentrate Enzymatic Cleaner 118 oz. per gallon (minimum effective concentration)
Wash	02:00	Hot Tap Water	Steris Prolystica 2X Concentrate Neutral De-tergent 118 oz. per gallon (minimum effective concentration)
Rinse	02:00	70°C	N/A
Dry	15:00	80°C	N/A

3. Use reprocessing agents within a pH range of 6.5 to 8.5.

   3.1 If white residue is observed within the container, this may have been caused by the use of reprocessing agents outside the recommended pH range.



Visually inspect for residual soil. If residual soil is visible on the device, repeat the cleaning process.



All reprocessing agents **must** be thoroughly rinsed off. AAMI ST108 compliant water is recommended for the final rinse to avoid discoloration or damage resulting from minerals found in utility water.



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

4. **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.

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

6. Confirm that all components are cool before handling.

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

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 must be inspected via the inspection checklist 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.

All products must be thoroughly decontaminated and cleaned before being returned for warranty claims.

Any product determined to be defective after normal usage will be repaired or replaced with no charge to the customer:

Non Return Policy

All products are sold under a No Return Policy.

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.
- Not using reprocessing agents within a pH range of 6.5 to 8.5
- 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.

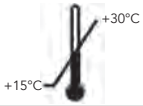
LIMITS OF USE

Repeated reprocessing has minimal effect on the ONE TRAY® device. The useful life depends on many factors including the method and duration of each use, and the handling between uses. Careful inspection before use is the best method of determining the end of serviceable life.

Do not use devices that show evidence of damage and wear. Evidence of damage and wear may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks.

Ref #	Symbol	Title of Symbol	Description of Symbol
5.1.1		Manufacturer	Indicates the medical device manufacturer.
5.4.2		Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.4.3		Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.
5.4.4		Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

ONE TRAY® PROCESSING KIT STORAGE REQUIREMENTS

	15°C to 30°C		Keep away from direct exposure to sunlight and flourescent light
	20% to 70% Relative Humidity		Keep Dry
	Reference UDI device label attached to the ONE TRAY® processing kit box for expiration date. Do not use after the labeled expiration date. Expired product is not eligible for return, credit, or exchange.		
	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.		

- Industry Definitions can be found on the ONE TRAY® Website at: *https://onetray.com/definitions*
- Vent to volume ratios for the ONE TRAY® container can be found on the ONE TRAY® website at: *https://onetray.com/onetrayspecs*

CONTACT

If you have questions regarding the **ONE TRAY®** warranty, contact

info@onetray.com or call 937.619.0138.