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CENTRAL STERILE
PROCESSING

Policy & Procedure

Subject: ONE TRAY - SEALED STERILIZATION CONTAINER SYSTEM

Effective Date: January 2015

Primary Responsibility:
CENTRAL STERILE STAFF

Review / Revision Dates:
2016

Policy Location:
CENTRAL STERILE DEPARTMENT

Purpose:
ONE TRAY® Sterilization Containers are intended for the terminal sterilization of surgical devices and supplies; including instrumentation with lumens of 1mm in diameter or larger, with lengths up to 400mm. In addition, ONE TRAY® complies with AAMI and AORN guidelines for the safe transport and assured delivery of the contents with tamper evident security in a sealed container. ONE TRAY® has a 365 Day Event Related Shelf Life.

Policy Statement:
ONE TRAY® is validated and FDA 510(k) cleared for the rapid processing of temperature tolerant surgical instrumentation by gravity or pre-vacuum sterilization cycles with a gross weight (container plus contents) of 25lbs/11.3kg, and validated up to 41lbs/18.6kg. This includes sterilization of lumens of 1mm in diameter, or larger; with lengths up to 500mm according to the times and temperatures listed below:

Pre-Vacuum

Temperature 270° F/132°C

Exposure Time 4 Minutes

Cycle Dry Time

Not Required

Cycle Cool Time

Not Required

IST is not responsible for the policy created or adopted by the organization.

Definitions:

Procedure:

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

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

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

4. Confirm the rim of container 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 channel.

6. Confirm that the cover properly mounts on container base and seals in

place. Cover on base with latch handles in locked position.

Grasp cover latch handles at each end of container

Clasp is disengaged from anchor on base as the cover latch handles are raised.

Simultaneously pull outward on cover latch handles on each end

Clasp releases from the anchor on the base as both cover latch handles are

raised Latch handles are fully open and cover removed from base.

The validated performance and 510(k) clearance of ONE TRAY® is in effect

ONLY with the exclusive ONE TRAY® Processing Kits and Deck Plate.

1. A single disposable ONE TRAY* filter element is required for each of the vented areas (one in container lid and two in container base).

2. Each disposable filter element should be inspected to confirm the absence of imperfections or defects such as puncture holes or tears, etc.

3. Each disposable filter element must completely cover the grooved channel surrounding the vented area.

4. Confirm the notched end of filter cover is properly oriented with either set of stand-off posts.

5. Insert notched end of filter cover under stand-off posts.

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6. Position “keyholes” in filter cover slide-bar over an opposing set of stand-off posts.
7. Apply downward pressure on filter cover and push the slide bar completely forward into a fully locked position under the standoff posts.

Use all of the items contained in the ONE TRAY® Processing Kit for each processing cycle.

USE ONE TRAY® Processing Kit

Confirm vent channel is clean and unobstructed.

Insert notched end of filter under appropriate stand-off post.

Centrally position filter between stand-off posts completely covering the vent gasket.

Apply downward pressure on the filter cover and push the side-bar into the locked position.

Position “keyholes" in filter cover slide-bar over the stand-off posts on the opposite side.

1. ALWAYS prevent contents from contacting the filter cover.
2. Avoid obstructing the vent and filter cover with pliable items.
3. Per AAMI guidelines, a chemical indicator or integrator should be used within each assembled set according to organizational policy.

ONE TRAY® recommends the use of a Class 5 Multi-Parameter Steam Sterilization Integrator with all rapid sterilization cycles.

4. When loading the container, only the ONE TRAY® deck plate has been specifically designed for the direct placement of items or insertion of modular instrument organizing trays.

Complex instruments should be prepared and sterilized according to the manufacturers written instructions for only sterilization time. Dry time will be 1 minute based on ONE TRAY® instructions.

1. Inspect rim of container to confirm there are no dents or burrs.
2. Inspect cover gasket to confirm there are no cracks, tears, imperfections, or defects.
3. Confirm that all filter covers are securely in place.
4. Place cover on container base evenly and confirm proper fit between cover and base.

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5. Secure cover by simultaneously pressing down to engage the latch at each end.

6. Properly complete both content I.D. cards and insert into slot on latch plate at each end of container.

7. Insert a ONE TRAY® tamper evident seal through the latch at both ends of container.

The validated performance and 510(k) clearance of ONE TRAY® is in effect ONLY with the exclusive use of ONE TRAY® Processing Kits and Deck Plate.

Insert narrow end of seal through the bracket

Position tagged end of seal in bracket

Grasp narrow end of seal

Insert narrow end of seal into flat side of seal

Push narrow end through opening on tag

Seal placed on bracket at both ends of container

1. Place ONE TRAY® container in a level horizontal position on each shelf within the sterilizer.

2. Confirm that all vented areas are not obstructed. DO NOT STACK DURING STERILIZATION.

3. ONE TRAY® is 510(k) cleared for rapid processing by pre-vacuum sterilization of total gross weight (container plus contents) not to exceed 25lbs/11.3kg and validated up to 41lbs/18.6kg. This includes sterilization of lumens of 1mm in diameter or larger with lengths of up to 500mm. ONE TRAY® is validated for use in the following cycle:

Pre-vacuum 4 Minutes @ 270° F / 132° C

CAUTION!

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

5. After each Sterilization Cycle, retain any Steam Integrators used.

6. Retained condensed moisture is normal and expected and will vary by load composition. This moisture does not compromise the sterility of contents.

Align the cover with base.

Mount the cover properly onto the base.

Engage the clasp with anchor on the base and the cover latch handles are in the horizontal position. Simultaneously push down on both cover latch handles.

Container is clasped and sealed when both cover latch handles are in locked position.

Push down on both cover latch handles until clasps are fully engaged and in the locked position.

1. Place container on stable and level surface at height that facilitates aseptic opening.
2. Check that external dot indicators have turned the appropriate color.
3. Inspect load content card(s) to verify identification of the correct instrument set.
4. Check to ensure tamper proof seals are intact by gently tugging on each seal.
5. Before opening, inspect container and confirm presence of filters in all three vents.
6. Place thumbs on upper surface of cover above latch handles.
7. Place fingers under lid latch handles at both ends of container.
8. Break the tamper evident seals by firmly and simultaneously pulling up on both lid latch handles.
9. Aseptically lift cover off the base of the container and inspect for proper placement of filter and Installation of filter cover on lid.
10. Remove lid filter cover and confirm filter is undamaged.

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1. Before touching the insert tray or contents of the container, properly trained personnel must check internal sterilization indicators following facility guidelines to verify acceptable results.

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 of both filter retention plates and integrity of each filter element on both vents in the floor of the container base.

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

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

. A tamper evident seal is not intact or is missing from either latch.

. A filter retention plate is dislodged.

. A filter does not completely cover the gasket around the vented area.

. Integrity of a filter element has been compromised (i.e. punctured, torn, etc.)

. Gasket is either damaged or separated from the cover.

1. Remove and discard all disposables (filters, load content cards, etc.)

2. Inspect container cover 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 that cover gasket is free of cracks, tears and is properly seated in channel on the cover.

5. Confirm that cover properly fits on container base.

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

2. Mechanical or automatic processing should follow the directions of the equipment manufacturer with ONE TRAY® cover and base positioned to prevent water collection.

3. For optimal cleaning results, use a neutral pH detergent.

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4. Never clean the container with abrasives or wire brushes.

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

6. Confirm that all components are cool before handling.

7. If necessary, dry container and components by wiping with a soft dry cloth.

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 seals, and deck plate.

The following exclusions apply to this warranty that include, but are not limited to:

. Conditions resulting from; negligence, misuse and improper cleaning, handling, closing or opening.

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

. Damage from excessive force or pressure.

. Use of abrasive cleaning agents or harsh detergents that are not neutral pH.

. Modification(s) to the container.

ONE TRAY® containers have been validated to perform for five hundred steam sterilization cycles. The Actual limits of reuse for the ONE TRAY® are based upon the proper handling, use, care and cleaning of the ONE TRAY®.

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References:
AAMI TIR 12:2010
ANSI/AAMI ST8: 2013ANSI/AAMI ST77:2013 ANSI/AAMI ST79:2010
Highpower Validation Testing & Lab Services Internal Standard Operating Procedures.
One Tray Product Manual
US Pharmacopeia.

Approved by: Review/Revision

Central Sterile: Date: _____