

Policy/ Procedure	Subject: Steam Sterilization of ONE TRAY for Sterile Processing Department			Number: XXXXXX
	Scope: ONE TRAY can terminally sterilize in a sealed container with no dry time or cool time creating efficiencies and patient safety for Sterile Processing Department.			Pages: X
	Revised: 05/09; 11/10; 04/13; 05/15 05/16	Reviewed By: 04/14	Approved By: [Redacted]	SUPERCEDES: XXXXXX EFFECTIVE: 12/1/2013

PURPOSE:

To provide guidance in the sterilization of items in the sterile processing department for terminal sterilization.

LEVEL: Interdependent

SUPPORTIVE DATA:

“ONE TRAY” is a FDA-cleared sealed terminal filtered vent sterilization container that uses a four (4) minute pre-vacuum cycle and no dry or cool times. ONE TRAY will be used according to manufacturer’s instructions. ONE TRAY is intended for sterilization of consignment/loaner/vendor sets/implants and can be stored as Event Related per our facilities policy # XXXXXX. This follows an Event Related Shelf Life with ONE TRAY as defined and stated in: AAMI ST79 8.9.3 and ST77-Rigid Container Guidelines-Sterility Maintenance Excerpt 4.4.4, The Joint Commission (2009), AORN (2010b).

ONE TRAY is also supported by AAMI, AORN, and HFAP as a means of terminal sterilization.

ONE TRAY (510K-K052567) indications for use state the containers are intended to hold temperature tolerant medical devices, single/multiple/or whole sets of instruments for sterilization. After sterilization, it provides safe transport & delivery for enclosed devices in a sealed container with tamper evident security and load record documentation according to AAMI and AORN guidelines.

ONE TRAY is validated for implants (cannulated and non-cannulated), 1mm in diameter lumen up to 500mm in length, and up to 41lbs. The efficiency of ONE TRAY in time combined with its terminal sterilization will eliminate the process of IUSS, Immediate Use Steam Sterilization (*formerly Flash*).

KEYPOINT:

- The results of the Terminal Sterilization biological integrators (3m Attest Packs) are available after one hour.

All steam sterilizers in the sterile processing department are PreVac and Gravity sterilizers. The recommended exposure times and temperature settings are listed below:

[Redacted]	[Redacted]
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[REDACTED]

[REDACTED]

XXXXXX

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

Preparation of items for Terminal Steam Sterilization

1. Only items that are approved for steam sterilization.
2. Items must be clean and free of bioburden.
3. Instruments should be unlocked and/or disassembled as indicated.
4. Instruments should be placed in a wire mesh tray or their original housing (case of the instruments) to allow for the passage of steam around all surfaces.
5. Instruments should be positioned to allow optimal contact with steam and to prevent air trapping.
6. A class 5 chemical integrator must be run with all instruments.
7. A biological indicator must be run with all implants.
8. Temperature and exposure times for must be available within the surgery department.
9. All Terminal Steam Sterilization load runs must be documented.
10. All Steam Sterilization printouts must also be completed and validated on printout with the patient name, initials of person loading, as well as verification parameters met and chemical integrator met after cycle completion by the person unloading with their initials.

Transportation of ONE TRAY closed container system:

“ONE TRAY” Terminal Sterilization

1. Decontaminate items/instruments for sterilization per AAMI/AORN guidelines. Reference- Instrument/Basins, Reusable, Decontamination and cleaning of #XXXXXXX.
2. Place ONE TRAY filters (3) into metal ONE TRAY pans. Secure.
3. Place items/instruments to be sterilized in ONE TRAY container system.
4. Place chemical integrator 2 per tier on opposite corners.
5. Place/secure lid on ONE TRAY system.
6. Secure with tamper resistant locks.
7. Label ONE TRAY with Load Cards provided in filter kit with contents-OR-Place sticker provided by computerized load tracking system for label and monitoring of load.
8. Place ONE TRAY in sterilizer and select PreVac Cycle. Run cycle for appropriate time.
9. If processing implantable items/instruments, place ATTEST/biological pack in front of ONE TRAY in sterilizer.
10. When cycle is complete, open the sterilizer.
11. Verify that all parameters of sterilization are within acceptable limits.
12. Complete the Daily Steam Sterilization Log for the appropriate sterilizer.
13. Deliver the instruments in the ONE TRAY pan to the appropriate operating room.
14. Remove sterilized instruments/supplies using aseptic technique.