Usage of ONE TRAY® Rigid Container System

Policy

It is the policy of this organization to use the ONE TRAY® rigid container system to process medical devices needed for surgical procedures.

Purpose

The ONE TRAY® rigid container system is intended to be used to hold temperature tolerant medical devices during steam sterilization cycles. The FDA definition of medical devices includes instruments and implants. The Device manufacturers' sterilization exposure parameters of time and temperature should be followed when considering the appropriate steam sterilization cycle.

After sterilization, the ONE TRAY® rigid container system 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.

Definitions

- **Sterilization** – validated process used to render a product free from viable microorganisms.
- **Type 5 Chemical Integrators** – chemical integrators designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in ISO 11138 series for BIs.
- **Immediacy,** rather than being defined according to a specific time frame, is established through the critical analysis and expert collaboration of the health care team.

Sterilization Procedure

- **Basic Principle**
  - Prior to any steam sterilization, all items are to be disassembled, decontaminated, cleaned and prepared according to manufacturers' instructions for use (IFU).
    (See department specific decontamination policy for more detail).

- **Sterilization Monitoring**
  - Commercially manufactured biological test pack or individual biological indicators may be used in accordance with manufacturers' instructions for use (IFU).
  - Biological Indicator or PCD (Process Challenge Device) - A BI PCD should be used at least weekly for all cycle types and for every load that contains an implant.
  - Bowie-Dick Test – performed daily on pre-vacuum steam sterilizers before the first load of the day.
  - Leak test – performed daily or weekly, frequency will be determined by equipment IFU.
  - A Type 1 process indicator should be clearly visible on the outside of every package to be sterilized.
  - Type 5 Chemical Integrator will be placed in packages or trays to be sterilized.
    (See department specific sterilization monitoring policy for more detail).

- **Sterilization Load Documentation**
  - All packaged items should be labeled with the sterilizer identification, the load number and the sterilization date. (See department specific sterilization load documentation policy for more detail).

- **Sterilization Maintenance**
  - Sterilization equipment preventative maintenance will be performed in accordance with the equipment manufacturers' instructions for use.

- **Sterilization & Handling**
  - Place a single ONE TRAY® container in a level horizontal position on each shelf within the sterilizer. Containers cannot be placed on their sides.
  - Confirm that all vented areas are not obstructed. (DO NOT STACK DURING STERILIZATION)
  - ONE TRAY® is validated for pre-vacuum sterilization cycles with sterilization parameters of 270°,4 minutes sterilization time and 0 dry time; total gross weight (container plus contents) should not exceed 25 lbs. Lumens of 3mm in diameter or larger with lengths of up to 400 mm have been validated in performance testing.
  - Following sterilization avoid unprotected contact with the hot sterilization container by using insulated handles and gloves to lift and transport.
  - Containers may be taken directly from the sterilizer and taken into an OR suite for use (not IUSS because the Tray has a shelf life) or placed on a case cart or stacked on the shelf for future use. Since event related sterility is followed in this organization, the sterilized container will be considered sterile until there is an event that renders the tray unsterile or compromised.
  - Retained condensed moisture is normal and expected and may vary by load composition. The presence of water in the tray does not compromise the sterility of contents.

- **Sterilizer Failures/recall**
  - In the event of a biological test or chemical integrator failure, the items in that load must be considered nonsterile and be reprocessed. All disposable items (filters, integrators and locks) must be discarded The equipment in question must be sent to decontamination and then reassembled for a sterilization cycle. (See department specific sterilization physical monitoring policy for more detail)

- **Personnel**
  - Sterile processing technicians, certified and non-certified; operating room personnel to include circulating nurses, surgical technologists, core personnel and supervisors.

- **Competencies**
  - All personnel responsible for aspects of preparation and assembling of these trays will be trained and completed competency measurements will be placed in the employees' files. (See department specific ONE TRAY® competency for more detail).

- **Considerations**

  Immediacy is defined in department sterilization policy.

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

  Retained moisture is normal and will vary by load composition. The use of the contents of the container system that have retained moisture is permissible only if the instructions for use have been followed and

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

parameters, device manufacturer for steam sterilization parameters, i.e., time and temperature and the packaging system (ONE TRAY®) for dry time and storage requirements.

Instruments that are hot should not come in contact with a patient. Use cooling method for instrumentation per department policy.

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.

Maintain onsite and always use the current IFUs as above of the Sterilizer, Medical Device Manufacturers and ONE TRAY®.