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

UNIT PROCEDURE: Central Sterile Processing Department

Title: One Tray Sterilization

Purpose: It is the policy of this organization to use the ONE TRAY® rigid container system to safely process medical devices needed for surgical procedures and to provide CSP and perioperative nursing staff safe guidelines for One Tray sterilization of reusable medical instrumentation in CSP and in the OR.

Definitions

The ONE TRAY® rigid container system is intended to be used to hold temperature tolerant medical devices during steam sterilization cycle. 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.

Qualifications

Central Sterile Processing Technician, OR Registered Nurse and Surgical Technologist that are trained and competent on the use of ONE TRAY®

Policy:

1. The creation and maintenance of an aseptic environment is a direct influence on the outcome of surgical intervention for the patient.
2. ONE TRAY® is validated for pre-vacuum sterilization cycles with sterilization parameters of 270° exposure time, 4 minutes' sterilization time and 0 dry time. Strict adherence to device manufacturer's instructions for use (IFU), proper cleaning, decontamination, sterilization are critical elements of ONE TRAY® sterilization.
3. Retained condensed moisture is normal, expected and will vary by load composition and tray density. The presence of water in the tray does not

4. compromise the sterility of contents because of its hydrophobic filter system.
5. XXX follows event related sterility and therefore the sterilized item inside the ONE TRAY® container will be considered sterile until there is an event that renders the tray unsterile or compromise its sterility.

Equipment

1. 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.
2. A ONE TRAY® rigid container must be obtained, inspected inside and out for dents or damage before use.
3. A ONE TRAY® single disposable filter should be used on each perforated vent.
4. 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.
5. Biological Indicator or PCD (Process Challenge Device) - A BI PCD should be used for all cycle types and for every load that contains an implant.
6. All packaged items processed in CSP must be labeled with the sterilizer identification number, the load number and the sterilization date while ONE TRAY® sterilized in the Operating room autoclaves must be documented in the sterilization logs.
7. The components necessary for sterilization to occur by this method are ONE TRAY® rigid container, steam, pressure, time, and temperature.

Procedure

Sterilization procedure adheres to basic principal steps that must be taken prior to any steam sterilization such as ensuring all items are disassembled, decontaminated, cleaned, assembled and prepared according to manufacturers' instructions for use (IFU).

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

References

ANSI/AAMI (Association for the Advancement of Medical Instrumentation) ANSI/AAMI ST79:2017

INNOVATIVE STERILIZATION TECHNOLOGIES: 2006

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DEVELOPED BY:

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REVISED BY:

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REVIEWED BY:

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APPROVED BY: xxxxxxxx