WVU IACUC Guidelines:
Autoclave Validation and Sterile Pack Processing

Purpose

The purpose of this document is to ensure that all instruments and supplies used for aseptic surgery and other procedures are properly sterilized. These guidelines follow those used by the Sterile Processing section of the WVU Medicine J.W. Ruby Memorial Hospital and are consistent with manufacturer recommendations, Centers for Disease Control infection control guidelines, hospital good practices and the scientific literature.

Definitions

Sterilization Pouch- Contains chemically impregnated indicators on the external and internal surfaces of the pouch that undergo a visual color change when exposed to appropriate temperature. [For example, Chex-All® Propper™ Sterilization Pouches, available from Fisher Scientific.]

Indicator Tape (a.k.a autoclave tape) or Chemical Indicator Strip- Impregnated with a chemical that undergoes a visual color change when exposed to a high temperature. The tape is placed on the outside of the item to be sterilized. Confirms temperature reached, not sterilization. [For example, 3M™ Autoclave Tape, available from Fisher Scientific.]

Chemical Integrator (integrator strip)- Contain a chemical that undergoes a visual color/physical change when all sterilization parameters (time, temperature, and steam penetration) have been met. They are placed inside of a surgical pack, prepared caging, or other items to be sterilized to ensure that the steam has penetrated to the inner layers of the pack/cage. [For example, 3M™ Comply™ (Thermalog™ or SteriGage™) Steam Chemical Integrators, available from many sources.]

Biological Indicator- These are the highest order of indicators. They monitor time, temperature, and steam penetration by confirming the killing of microbial spores of *Geobacillus stearothermophilus*, a thermophilic bacteria. This is the only method that actually verifies sterilization is occurring.

Surgical Pack Preparation and Storage

- Packs to be autoclaved should be wrapped in porous, temperature-safe materials that will allow steam penetration. Appropriate materials include paper, cloth, and *peel pouches*.
- Each autoclaved pack used in survival surgical procedures ***must*** use external (*autoclave tape*) and internal (*chemical integrator*) indicators with each pack.
- Internal indicators ***must*** be placed into the center of the pack to verify adequate steam penetration.
- BOTH INDICATORS ***MUST*** CHANGE in order for the pack to be used for survival surgical procedures.
- All items sterilized should be marked on the outside of the pack with the date of sterilization. Ideally, sterile items are autoclaved as close to the day of use as possible (e.g. the day before surgery).

- Items sterilized in plastic peel-down pouches and wrapped packs sealed in polyethylene overwraps are considered sterile for at least two years unless the packaging is broken, wet, soiled or otherwise damaged.
- Items sterilized in cloth wraps should be considered sterile for one year.
- If any of the following events occur the pack should be repackaged and sterilized prior to use:
  - Any tears or perforations in the wrapping, whether instruments are directly exposed or not.
  - Wetting of the surgical pack.
  - Dropping of packs onto the floor or excessive accumulation of dust on the outer surface.

Autoclave Validation and Documentation

- Validation uses biological indicators to evaluate the functional effectiveness of an autoclave.
- This testing ***must*** be performed and documented for any autoclave used to sterilize instruments for survival surgery.
- All autoclaves (laboratory/departmental/OLAR) used for the purpose of survival surgery equipment/instrument sterilization at WVU ***must*** be validated at a minimum frequency of every 6 months using biological indicators.
- Failure of any of these validation cycles indicates that autoclave settings ***must*** be adjusted, or the autoclave serviced. An autoclave that fails validation cannot be used again for sterilization of surgical instruments until it has passed a biological indicator test. The results of all tests, pass or fail, ***must*** be documented and available for review at the semi-annual IACUC inspections.
- Please email OLARhusbandrysupervisors@hsc.wvu.edu to arrange or confirm semi-annual bio-indicator testing of your autoclave. OLAR will coordinate the twice a year testing and provide results for each autoclave to all users.
- OLAR will provide a sticker to place on the autoclave machine to provide proof of validation for the next 6 months.

References

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