Subject: Autoclave Monitoring and Sterile Pack Storage Standards

BACKGROUND

This Standard Operating Procedure (SOP) describes standards to be followed to monitor the function of an autoclave as well as the safe storage time for sterile surgical packs.

The Guide for the Care and Use of Laboratory Animals states that “sterilization indicators should be used to validate that materials have been properly sterilized.” (p. 119)

NOTE: These validation and monitoring requirements are not sufficient when an autoclave is used to process hazardous biological materials. If biological hazards need to be autoclaved, the Biosafety Officer must be contacted.

IACUC Standard Operating Procedure:

Surgical Pack Preparation

- 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\(^1\). Foil is only appropriate for dry heat sterilization and cannot be used when steam autoclaving.
- Each autoclaved pack used in survival surgical procedures must have indicators that confirm minimum temperatures were achieved during the cycle.
- Both external (autoclave tape\(^2\)) and internal (chemical integrator\(^2\)) indicators must be used with each pack.
- Internal methods 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.

Autoclave Validation and Documentation

Validation uses biological indicators\(^4\) to evaluate the functional effectiveness of an autoclave. This testing must be periodically performed and documented for any autoclave used to sterilize instruments for survival surgery. Anyone using an autoclave for the purpose of survival surgery in animals at WSU is responsible for ensuring that validation is occurring as described in this document. This applies to both laboratory owned and centrally managed autoclaves. At a minimum, validation should occur 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.

Storage of Sterile Items

Ideally, sterile items are autoclaved as close to the day of use as possible (e.g. the day before surgery) and not stored for an extended period of time. All sterile packs must be labeled with the date of autoclaving. They should be stored in a closed cabinet and protected from moisture. As a general rule, packs wrapped in cloth or woven paper should be used within 1 month of autoclaving and sealed peel packs should be used within 1 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.

Definitions

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

2. **Indicator tape (a.k.a. autoclave tape)** – Tape 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.]

3. **Chemical integrator (a.k.a. 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.]

   NOTE: Chemical indicator strips are also available that, like autoclave tape, change color when a certain temperature is reached. Unlike integrators, these do not provide assurance that the pressure or duration needed for sterilization have been met. These are not an equivalent substitute of chemical integrators.

4. **Biological indicators** – 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. [For example, 3M™ Attest™ Biological Indicator, available from many sources or as a service by DLAR Veterinary Technical Services]