VERIFICATION AND VALIDATION OF STERILIZATION METHODS FOR INSTRUMENTS / EQUIPMENT USED IN SURVIVAL SURGERY

Overview/Purpose

In accordance with the Guide for the Care and Use of Laboratory Animals, “sterilization methods should be selected on the basis of physical characteristics of materials to be sterilized and sterilization indicators should be used to validate that materials have been properly sterilized.” Autoclaving or gas sterilization (such as Ethylene Oxide or Hydrogen Peroxide) are commonly used methods for sterilizing instruments and equipment prior to surgery. The purpose of this policy is to ensure verification and validation of the process used for sterilization of survival surgery equipment or instruments.

Definitions

1. **Verification** - Verification of sterilization function includes the use of chemical control indicators (e.g. chemical indicator tape or indicator test strips) to ensure the appropriate conditions have been reached during the cycle. Chemical control indicators are specific to the sterilization method being used and so care must be taken to select the appropriate indicator. Though chemical control indicators are useful to ensure adequate temperatures or gas exposures have been reached during the cycle, they cannot verify the length of time that the parameters were maintained and therefore validation is still required.

2. **Validation** - Validation of sterilization function includes the use of biological controls (e.g. Verify®, 3M™ Attest™) to confirm lack of microbial growth. Biological controls use heat resistant microorganisms to determine the effectiveness of steam or chemical sterilization. Biological controls are sensitive and accurate and require a period of incubation to validate the effectiveness of the cycle. Similar to the chemical indicators, specific biological indicators are available for each sterilization method. Validation is not required when cold sterilants are used according to manufacturer's instructions.

Requirements

1. A chemical control indicator must be used for verification of all items being sterilized for survival procedures or surgeries. Chemical control indicators provide instant notification of failures to reach the required cycle parameters.
   a. A chemical control indicator must be present on the outside package of all items being sterilized. Most surgical peel pouches have a built-in chemical control indicator.
   b. An additional chemical control indicator must be present on the inside of surgical packs prior to sterilizing to ensure adequate steam / gas penetration.
   c. The sterilization date must be present on the outside package or pouch.
   d. Unused items must be resterilized within 1 year from the date of initial sterilization, or if the outer covering is compromised.
   e. If chemical control indicators fail or if sterilization cycle does not complete, items must be resterilized prior to use.

2. Autoclave or Gas validation must be performed semiannually.
a. Documentation of semiannual validation must be available and accessible for review.

Additional Information/Guidance


History of Revisions

050-00 - new policy approved 10/18/13
050-01 - revised to clarify verification and validation, the requirement for initials to be included on the outside package of autoclaved items was removed, unused autoclaved items must be resterilized within one year; approved 11/18/16
050-02 - revised to clarify the definition for verification and include in the overview section that time and temperature depends upon the material sterilized; approved 11/15/19
050-03 - policy reviewed and approved 11/18/2022