



IACUC SOP:	SOP Surgical Sterilization Methods & Monitoring	
SOP#303.00	IACUC Approved: 7/17/2024	IO Approval: 7/29/2024

Guidelines:

The IACUC has provided a set of guidance documents (Policies, Guidelines, and Informational Sheets) for use when planning animal procedures at the Texas A&M-SA. An exception to this SOP must be described and justified in the Animal Protocol and approved during the normal review process.

Purpose

The purpose of this SOP is to provide guidance on commonly used methods for sterilization of surgical instruments and other materials for use in IACUC-approved Animal Protocols along with methods for monitoring the sterilization procedure during survival surgery or during other procedures.

Accepted Methods for Full Sterilization

- Autoclave (High pressure/temperature) is recommended for most surgical items.
- Chemical/Cold Sterilization is recommended for items that cannot be sterilized by other methods.

Autoclave Sterilization

- Autoclave utilizes steam at high heat and pressure which must penetrate the pack to attain sterilization.
 - Materials such as muslin cloth and crepe paper drape material allow steam to penetrate the pack.
 - Materials such as aluminum foil and wax paper should not be used due to the steam's inability to penetrate them.
- Exposure time in an autoclave will vary based on the type of autoclave.
 - For gravity displacement sterilizers, typically need exposure at 121°C (250°F) for at least 30 minutes.
 - For dynamic-air-removal sterilizers, typically need exposure at 132°C (270°F) for at least 4 minutes.
 - Bigger packs require more time to reach appropriate heat and pressure levels.
- Autoclaved pack should be stored in a dry, dust-free, well-ventilated area, preferably in a closed cabinet.
 - The length of storage time is indefinite if the pack is stored properly (cabinet, drawer) and does not get wet, torn open or have some other event that compromises its integrity and sterility.
- Monitoring
 - Autoclave must be monitored routinely for effectiveness of the sterilization procedure.



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- Shared laboratory autoclaves may be monitored by each lab or have a designated responsible individual(s)
 - Within each pack, place an integrator strip to indicate exposure to the sterilization process.
 - Packs should be sealed with autoclave tape.
- At least once a month, use a Type 5 integrating indicator to monitor the critical variables in the sterilization process.
 - Type 5 integrating indicators monitor all critical variables in the sterilization process and have stated values that meet or exceed performance requirements in the ISO 11138 series for biological indicators.
 - Alternatively, Type 5 integrating indicators may be used.
 - Examples of Type 5 Integrating Indicators:



- At least once a year, use a biological indicator to monitor the effectiveness of microbial killing
 - Biological indicators use resistant spores to monitor the lethality of the sterilization process
 - Requires either incubation or use of a reader to determine results
- Documentation
 - Integrator strip in packs
 - No documentation needed.
 - Monthly Type 5 integrator strip (if not used in every pack)
 - Keep a log near the autoclave or as part of the surgical records.
 - The log will be reviewed during semi-annual inspections.
 - Yearly biological indicator
 - The lab is responsible for keeping a log.
 - The log will be reviewed during semi-annual surgical site inspections.

Chemical/Cold Sterilization

- Examples of common commercial sterilants and their active ingredient(s):
 - NOTE: Refer to the manufacturer's instructions for how to appropriately prepare and use.
 - CIDEX® Activated Dialdehyde Solution: Glutaraldehyde
 - Active for up to 14 days once prepared
 - 10 hours of exposure required for sterilization at room temperature
 - Spor-Klenz®: Hydrogen peroxide and peroxyacetic acid
 - Concentrate Cold Sterilant
 - Dilute at 1% v/v with purified water
 - Use immediately and do not store



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- 11 hours of exposure required for sterilization at room temperature.
 - Ready To Use Cold Sterilant
 - May re-use for up to 14 days
 - 5.5 hours of exposure required for sterilization at room temperature.
 - Use of effective sterilant such as Sporidicin® or equivalent Sterilizing and Disinfecting Solution: glutaraldehyde, phenol, phenate
 - Active for 14 days once prepared.
 - 12 hours of exposure required for sterilization at room temperature.
- Discretion is required in using these agents to assure that they are used with appropriate safety precautions and that the items being sterilized are compatible with the sterilant
- Factors for effective and proper use of cold sterilization:
 - Chemicals must be classified as “sterilants”
 - Commonly used disinfectants such as alcohol, iodophors, quaternary ammonium and phenolic compounds **are not effective sterilants** and are not acceptable for use on items (e.g., catheters, instruments) intended to be sterile.
 - Physical properties of the items being sterilized must be smooth and impervious to moisture.
 - All surfaces, both interior and exterior, must be exposed to the sterilant.
 - Sterilant solution must be clean and fresh.
 - Date of preparation must be labeled on container.
 - Chemically sterilized instruments must be thoroughly rinsed both inside and out with sterile saline or sterile water prior to use to avoid tissue damage.
 - Instruments must be handled in an aseptic manner to maintain sterility (e.g. handle with sterile gloves and place on a sterile field)
- Standard Operating Procedures (SOP) approved by IACUC **MUST** be posted in the laboratory when using chemical sterilization methods and must contain the following information:
 - Agent used (i.e. active ingredient)
 - How sterilant is prepared
 - How long sterilant is active once prepared (expiration time)
 - Exposure time required for sterilization of instruments/supplies.
 - How the sterilant is removed prior to use in an aseptic technique
 - Required PPE
 - Engineering Controls
 - Waste procedures
- Consult with the BSO/veterinarian if there are any questions relating to the use of chemical/cold sterilant.

Dry Bead Sterilization

- Used to sterilize the tips of surgical instruments in between multiple surgeries.
- Instruments **MUST** be fully sterilized by another method between surgical sessions.
 - A surgical session includes those surgeries performed on the same day.



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- Sterilizer must be activated for a minimum of 20 minutes to reach the appropriate temperature before being used.
 - All biological debris (e.g. blood, tissue) must be removed before placing the instruments into the sterilizer.
 - Instruments must be inserted into the sterilizer for a minimum of 15 seconds before sterilization is attained.
 - Once the instruments are removed from the sterilizer, the tips will be VERY HOT
 - They must be allowed to cool before using them to avoid burning the animal.
 - Only the tips of the instruments are sterilized, and the handles are considered to be contaminated.
 - The instruments must be utilized in a fashion that the tips of the instruments remain sterile.
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<https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and>

<https://www.sterislifesciences.com/products/surface-disinfectants/sporicide-cleaners-and-sterilant/spor-klenz-concentrate-cold-sterilant>

<https://www.harvardapparatus.com/hot-bead-dry-sterilizers.html>

History:

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