IACUC Policy for the Use of Cold Sterilization for Surgical Equipment

Purpose

Investigators using heat sensitive instruments and equipment during surgical procedures must have a sterilization method that is effective, not toxic or harmful to the animals, and not destructive to the equipment being sterilized. This policy has been formulated to ensure adequate sterilization of surgical equipment and to prevent cross contamination between animals during batch surgeries.

Process

1. Cold sterilization solutions must be labeled with the date mixed and the expiration date.
2. Cold sterilization requires extended contact to be effective. Sterilization times vary between manufacturers. The following are the CDC recommended contact times for sterilization:

Disinfectant	Hydrogen Peroxide	glutaraldehyde	ortho-phthalaldehyde	peracetic acid and hydrogen peroxide
Sterilization claim*	6 hr @ 20°C	10 hr @ 20°C	none	3 hr @ 20°C
HLD claim*	30 min @20°C	20 -90 min @ 20°C	12 min @ 20°C	15 min @ 20°C
Reuse Life	21 days	14 - 28 days	14 – 28 days	14 days
Effective Concentration	7.5%	>2.0%	0.55%	7.35% / 0.23%
Processing	manual	manual	manual	manual
Organic material resistance	Yes	Yes	Yes	Yes
Product Names	Sporox II®	Cidex® Cetylcide-G® MetriCide28® Protectop®	RapidcideOPA28® MaxiCideOPA 28®	Spor-Klenz® Ygiene® Compliance Cold Sterile®

3. Follow all manufacturers' instructions for dilution and use. Disposal will follow UND hazardous waste procedures.
4. Cold sterilization solutions must be free of debris. Any solutions with debris or cloudy solution due to contaminants must be immediately discarded.
5. Instruments placed into sterilization solutions must be free of organic material including blood. All cold sterilization chemicals are ineffective in penetrating organic material.
6. Instruments for cold sterilization must be completely immersed in the solution.
7. Cold sterilization solutions are not recommended as the method of sterilization between animals during batch surgeries due to the long sterilization times.
8. Batch surgeries must utilize multiple surgical packs to allow adequate high-level (HLD) disinfection between surgeries.
9. Instruments from cold sterilization must be rinsed thoroughly with sterile saline prior to use.
10. Nitrile gloves are required when reaching into cold sterilization solutions.

*The indicated contact time is based only on the conditions to pass the AOAC Sporicidal Test as a sterilant and not on simulated use testing with devices. These solutions are commonly used as high-level disinfectants (HLD) when a shorter processing time is required. Generally, chemical liquid sterilants cannot be monitored using a biological indicator to verify sterility.

References

1. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 William A. Rutala, Ph.D., M.P.H, David J. Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC), https://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
2. FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm