

STERILISATION OF IMPLANTS

1 Policy statement

NACLAR Guiding Principles paragraph II.11.11.1 (page 37) states that, "PIs should be aware of the need for strict attention to aseptic technique when devices are surgically implanted." Contamination of prosthetic devices frequently requires their removal after antibiotic therapy has failed.

The Guide for the Care and Use of Laboratory Animals (page 119) recommends, "Specific sterilization methods should be selected on the basis of the physical characteristics of the materials to be sterilized (Callahan et al. 1995; Schofield 1994) and sterilization indicators should be used to validate that materials have been properly sterilized (Berg 1993). Autoclaving and plasma and gas sterilization are effective methods most commonly used to sterilize instruments and materials. Alternative methods, used primarily for rodent surgery, include liquid chemical sterilants and dry heat sterilization. Liquid chemical sterilants should be used with appropriate contact times and instruments should be rinsed with sterile water or saline before use. Bead or dry heat sterilizers are an effective and convenient means of rapidly sterilizing the working surfaces of surgical instruments but care should be taken to ensure that the instrument surfaces have cooled sufficiently before touching animal tissues to minimize the risk of burns. Alcohol is neither a sterilant nor a high-level disinfectant (Rutala 1990) but may be acceptable for some procedures if prolonged contact times are used (Huerkamp 2002)."

2 Definitions

Disinfectant	A substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi, and viruses (but not necessarily bacterial spores) on inanimate surfaces such as hard surfaces.
Institutional Animal Care and Use Committee (IACUC)	The Committee, constituted by an institution, responsible for the oversight and evaluation of all aspects of the institution's animal care and use programme.
Sterilant	A chemical agent that eliminates all forms of microbial life, including bacteria, bacterial spores, fungi, fungal spores, and viruses, from inanimate objects.
Sterilization	A validated process used to render a product free of all forms of viable microorganisms.

3 Scope

This policy applies to all animals' work covered under NUS Animal Care and Use Programme.

4 Guidelines

Investigators are expected to ensure that all materials used for implantation, must be sterilised, regardless of the contact time or tissue type, according to the manufacturer's recommendations for sterilisation.

4.1 Recommended sterilisation methods

- 4.1.1 **High-pressure/temperature steam sterilisation** for items that can withstand high temperature. Use of an autoclave and appropriate monitoring systems to assure sterility. Steam sterilisation is the optimal way to process an item for sterilisation; however, if an item may be damaged by heat, pressure, or moisture then an alternative method of sterilisation such as ETO may be used according to the manufacturer's recommendation.
- 4.1.2 **Dry Heat** e.g. hot glass bead steriliser (for items that can withstand high temperature). These units only sterilise the tip of instruments. Caution: instruments must be cooled before contacting tissue.
- 4.1.3 **Gas sterilisation with ethylene oxide (ETO)**, for items that cannot withstand high temperature. Use of an approved gas steriliser and appropriate monitoring systems to assure sterility and personnel safety. All materials sterilised by ethylene oxide require safe airing time.
- 4.1.4 **Cold chemical sterilisation** may be used effectively for many items (e.g., sodium hypochlorite, hydrogen peroxide, phenol, glutaraldehyde*). *Glutaraldehyde must not be used, except as necessary per the manufacturer's recommendation, because it is highly irritating and sensitizing.
- 4.1.5 **Ionising radiation sterilisation.** Gamma irradiation may be used for sterilisation. Ultraviolet (UV) light is not reliable and not recommended for sterilisation.

4.2 Handling of Fragile or Single-Use Surgical Devices

- 4.2.1 Fragile implants may be gas-sterilised or soaked in chemical sterilant and rinsed-off with sterile saline or sterile water before implanting.
- 4.2.2 Re-use of devices intended for single use is discouraged due to the difficulties of validating re-sterilisation procedures and inability to predict functionality after repeated sterilisation.
- 4.2.3 Discretion is required in using these agents to assure that they are used with appropriate safety precautions and that they are compatible with the items being sterilised. The use of sterilisation procedures other than those listed must be approved by the IACUC.

4.3 Guidelines for Cold Chemical Sterilisation

Effective and proper use of cold sterilisation is dependent on many factors including:

1. **The chemical agent to be used.** There are several acceptable commercial sterilants available. Only products classified as sterilants are to be used for sterilising implants for surgery and they must be used according to the manufacturer's recommendations for sterilisation.
2. **The physical properties of the items to be sterilised.** Materials must be relatively smooth, impervious to moisture, and be of a shape that permits all surfaces to be exposed to the sterilant. Materials tend to degrade when exposed to sterilants requiring that their integrity be assured prior to use.

3. **Exposure time.** All surfaces, both interior and exterior, must be exposed to the sterilant. Tubing must be completely filled and the materials to be sterilised must be clean and arranged in the sterilant to assure total immersion. The items being sterilised must be exposed to the sterilant for the prescribed period of time.
4. **Use of fresh solutions.** The sterilant solution must be clean and fresh. Most sterilants come in solutions consisting of two parts that when added together form what is referred to as an "activated" solution. The shelf life of activated solutions is indicated on the instructions for commercial products. The date of preparation of the sterilising solution must be noted on the container.
5. **Rinsing chemically sterilised items.** Implants, instruments and tubing (both inside and out) should be rinsed with **sterile saline** or **sterile water** prior to use to avoid tissue damage.

5. References

1. Callahan BM, Hutchinson KA, Armstrong AL, Keller LSF. 1995. A comparison of four methods for sterilizing surgical instruments for rodent surgery. *Contemp Top Lab Anim Sci* 34:57-60.
2. Schofield JC. 1994. Principles of aseptic technique. In: Bennett BT, Brown MJ, Schofield JC, eds. *Essentials for Animal Research: A Primer for Research Personnel*. Washington: National Agricultural Library. p 59-77.
3. Berg J. 1993. Sterilization. In: Slatter D, ed. *Textbook of Small Animal Surgery*, 2nd ed. Philadelphia: WB Saunders. p 124-129.
4. Rutala WA. 1990. APIC guideline for selection and use of disinfectants. *Am J Infect Contr* 18:99-117.
5. Huerkamp MJR. 2002. Alcohol as a disinfectant for aseptic surgery of rodents: Crossing the thin blue line? *Contemp Top Lab Anim Sci* 41:10-12.

Revision	Author	IACUC approval date
P217.01. Last reviewed.	Dr Lee Liying, Corinne	18 July 2018
P217.02. Reviewed to: <ol style="list-style-type: none">1. ensure policies are in compliance with the NAELAR Guidelines 2022 and the updated Animals and Birds (Care and Use of Animals for Scientific Purposes) Rules 2004; and2. up-to-date with current practices Changes made to update to: <ol style="list-style-type: none">1. NAELAR Guiding Principles paragraph II.11.11.1 (page 37); and2. The Guide for the Care and Use of Laboratory Animals (page 119); and3. include the references from The Guide updates.	Dr Chew Li Li IACUC	3 January 2023
P217.03. Revisions to: <ol style="list-style-type: none">1. update policy format.2. The policy title was changed from 'Guidelines on Sterilisation of Implants' to 'Sterilisation of Implants'.	Dr Chew Li Li Ms Keh Lee Hwei IACUC Designated Reviewers	17 November 2025