

Australian/New Zealand Standard™

**Reprocessing of reusable medical
devices in health service organizations**



AS/NZS 4187:2014

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-023, Processing of Medical and Surgical Instruments. It was approved on behalf of the Council of Standards Australia on 18 November 2014 and on behalf of the Council of Standards New Zealand on 26 November 2014. This Standard was published on 15 December 2014.

The following are represented on Committee HE-023:

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Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Day Surgery Nurses Association
Australian Dental Association
Australian Dental Industry Association
Australian Industry Group
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Australian/New Zealand Standard™

Reprocessing of reusable medical devices in health service organizations

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-023, Processing of Medical and Surgical Instruments, to supersede AS/NZS 4187:2003, Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.

This Standard incorporates Amendment No. 1 (July 2015). The changes required by the Amendment are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure or part thereof affected.

Prevention of health care associated infection in patients undergoing dental, medical or surgical procedures is an essential component of patient safety in the delivery of high quality health care. It avoids unnecessary pain and suffering for patients and lessens health care costs. Effective and safe reprocessing of reusable medical devices (RMDs) in health service organizations (HSOs) is a critical aspect in the prevention of health care associated infection.

The objective of this Standard is to ensure that HSOs correctly clean, disinfect and sterilize RMDs prior to and between patient uses in order to produce RMDs that are able to be used safely without risk of transmission of infectious agents.

There are significant differences in the structure, content and terminology of this edition of the Standard and that of the previous 2003 edition, as follows:

- (a) The structure and clause headings of this Standard mirror that of the International Organization for Standardization, Technical Committee 198 (ISO/TC 198), Sterilization of health care products, suite of Standards.
- (b) It is necessary to read this Standard in conjunction with relevant national and International Standards and guideline documents (see Clause 1.3, normative references).
- (c) This Standard does not reiterate all the technical requirements already identified in national or International Standards. For example, this Standard refers directly to ISO 17665-1, Sterilization of health care products—Moist heat, Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices, for the requirements concerning moist heat sterilization processes.
- (d) This Standard is not written as a procedural document. Therefore, it is necessary for HSOs to develop their own workplace procedures based on the requirements of this Standard.

Committee HE-023 recommends that HSOs implement the requirements of this Standard within 2 years of date of publication.

Statements expressed in mandatory terms in notes to tables are deemed to be requirements of this Standard.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the Appendix to which they apply. A 'normative' Appendix is an integral part of a Standard, whereas an 'informative' Appendix is only for information and guidance.

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FOREWORD

Reusable medical devices (RMDs) are used for diagnostic and/or treatment purposes for multiple patients and are intended by the manufacturer for reprocessing and reuse.

When an RMD is used for diagnostic or treatment purposes it can contact the patient's sterile tissues, mucous membranes or skin, or it might be used in a non-critical area around a patient without direct patient contact, e.g. a suction canister. As a result, there is potential for the RMD to become contaminated with microorganisms, blood, tissue and other biological material.

Correct, effective and safe reprocessing of RMDs is essential to protect patients and staff. Failure to correctly and effectively reprocess RMDs risks the transmission of infectious agents or an adverse reaction from residual cleaning, disinfecting or sterilizing agents.

Reprocessing of RMDs is a multistep process that includes cleaning, disinfection (if applicable), inspection and assembly, testing (if applicable), packaging and sterilization (if applicable) of used items to render them safe for reuse:

- (a) Manual or automated cleaning removes visible soil from RMDs. Thorough cleaning is an essential prerequisite prior to disinfection (thermal or chemical) or sterilization of RMDs as residual inorganic and organic soil on the surfaces of used items interferes with, or has the potential to interfere with, the effectiveness of these processes.
- (b) Disinfection (thermal or chemical) of RMDs kills many microorganisms, including human pathogens. Unlike sterilization, disinfection is not effective against high numbers of bacterial spores. Many factors affect the efficacy of a disinfecting process (presence of soil, nature and level of microbial contamination, RMD design, concentration of disinfectant, temperature, pH and exposure time and presence of biofilm).

Disinfectants differ significantly in their spectrum of antimicrobial activity and in their speed of action. Low-level instrument grade disinfectants kill vegetative bacteria, some fungi and some viruses. Intermediate-level instrument grade disinfectants kill vegetative bacteria, mycobacteria, viruses and most fungi but do not kill bacterial spores. High-level instrument grade disinfectants kill all microorganisms with the exception of high numbers of bacterial spores. Some disinfectants used as high-level instrument grade disinfectants are actually chemical sterilizing agents that kill high numbers of bacterial spores with prolonged exposure under controlled and defined conditions.

- (c) Sterilization destroys microorganisms on RMDs rendering them free from viable microorganisms. Moist heat sterilization, low temperature sterilization (e.g. hydrogen peroxide gas or plasma, liquid peracetic acid, low temperature steam formaldehyde and ethylene oxide) and dry heat sterilization are the principal processes used by HSOs to sterilize RMDs. Moist heat sterilization is the preferred process for sterilization of RMDs where the item to be reprocessed (including its packaging, if used) is able to withstand this process. Where an item cannot withstand a moist heat sterilizing process, a suitable, alternative sterilizing process will be necessary, e.g. a low temperature gas or plasma, or liquid chemical sterilizing process.

It is not necessary to sterilize all RMDs. The Spaulding Classification System provides a system to determine the level of reprocessing necessary for an RMD based on its intended use:

- (i) Critical RMDs require cleaning followed by sterilization.
- (ii) Semi-critical RMDs require cleaning followed by high-level disinfection at a minimum; however, sterilization of these items is strongly recommended.

- (iii) Non-critical RMDs require cleaning and this can be followed by low or intermediate level disinfection.

Critical and semi-critical RMDs are typically reprocessed in designated reprocessing environments in HSOs. However, non-critical RMDs, particularly non-invasive, non-critical RMDs are frequently reprocessed at the point of use.

Appropriate validation and control of cleaning, disinfecting, packaging and sterilizing processes reduces the risk of transmission of infectious agents associated with the use of RMDs. This requires a HSO to strive towards development of a state of the art reprocessing facility in which the requisite infrastructure and necessary resources are available to undertake effective and safe reprocessing activities, including, for example, the provision of water and steam of the specified quality. In this regard, the HSO needs to ensure that its reprocessing staff are educated and trained, that they adhere strictly to defined work practices and have demonstrated competency in reprocessing and associated activities.

Surgical techniques and diagnostic procedures are continually evolving. Developments in materials science and engineering, are resulting in an increasingly wide array of RMDs of varying design and complexity. These advances can pose significant challenges to the effective reprocessing of RMDs. The design of an RMD needs to ensure that the RMD is able to be effectively cleaned and disinfected, and sterilized. In this regard it is imperative that the design requirements for a RMD no longer only focus on clinical need and medical device functionality, but also on reuse considerations. Prior to purchasing an RMD, it is imperative that HSOs consider carefully the manufacturer's instructions for reprocessing of the RMD and evaluate their in-house capability to reprocess the RMD effectively and safely.

This Standard reflects the conscientious efforts of health care professionals representing national and regional health authorities, professional associations and industry associations in Australia and New Zealand, to develop minimum requirements for the effective and safe reprocessing of RMDs in HSOs.

The requirements of this Standard are applicable to all HSOs. It is necessary for individual HSOs to develop their own work place procedures based on the requirements of this Standard to ensure that their reprocessing activities result in a safe RMD that is able to be used for diagnostic or treatment purposes and that is not hazardous to either staff or to the environment.

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