AS/NZS 4187:2014
(Incorporating Amendment Nos 1 and 2)

AS/NZS 4187:2014

Australian/New Zealand Standard™

Reprocessing of reusable medical devices in health service organizations

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:

Australasian College for Infection Prevention and Control
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
Australian Institute of Packaging
Australian Nursing and Midwifery Federation
Department of Health, SA
Department of Human Services Victoria
Department of Health, WA
Federation Sterilizing Research and Advisory Council of Australia
Gastroenterological Nurses College of Australia
Institute of Hospital Engineering Australia
Medical Technology Association of Australia
New Zealand Nurses Organisation
New Zealand Sterile Services Association
NSW Ministry of Health
Queensland Health
Royal College of Pathologists of Australasia
Therapeutic Goods Administration

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at www.saiglobal.com or Standards New Zealand web site at www.standards.govt.nz and looking up the relevant Standard in the on-line catalogue.

For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of Standards Australia or the New Zealand Standards Executive at the address shown on the back cover.

This Standard was issued in draft form for comment as DR 100397.

AS/NZS 4187:2014
(Incorporating Amendment Nos 1 and 2)

Australian/New Zealand Standard™

Reprocessing of reusable medical devices in health service organizations

Originated in Australia as AS 4187—1994.
Previous and first joint edition AS/NZS 4187:2003.
Fourth edition 2014.
Reissued incorporating Amendment No. 1 (July 2015).
Reissued incorporating Amendment No. 2 (May 2019).

ISBN 978 1 74342 935 8

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) and Amendment No. 2 (May 2019). The changes required by the Amendments 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.

CONTENTS

Page

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.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard

Reprocessing of reusable medical devices in health service organizations

S E C T I O N 1 S C O P E A N D G E N E R A L

1.1 SCOPE

This Standard specifies the requirements and practices necessary for the effective and safe reprocessing, storage, handling and transportation of reusable medical devices (RMDs) in human health care.

The application of the principles of this Standard recognizes and acknowledges that there are similarities and differences between different types of HSOs (e.g. hospitals, and dental general and podiatry practices).

The similarities are the common need for quality systems, staff training, and compliance with reprocessing procedures. The major difference relates to the unique physical and organizational conditions in different types of HSO (e.g. reprocessing equipment and ability to physically segregate the reprocessing environment).

The principles of this Standard are also applicable to processing of single use medical devices supplied to HSOs by the manufacturer in a non-sterile state and which require sterilization in accordance with the medical device manufacturer's processing instructions prior to use.

This Standard is applicable wherever RMDs are reprocessed in HSOs, including the reprocessing of RMDs used in post-mortem examinations.

Infection prevention and control practices preclude the interchange of RMDs between post-mortem examinations and live patient health care. Infection prevention and control practices also preclude the interchange of RMDs between veterinary and human health care, including RMDs used in preclinical training on animal tissue.

The principles of this Standard may be applicable to the reprocessing of RMDs in veterinary practice.

1.2 EXCLUSIONS

This Standard does not include requirements for the following:

(a) The reprocessing of medical devices that are intended for single use only and that have been in contact with blood, tissue or body substances. Reprocessing of these medical devices is a manufacturing activity that is regulated by national regulatory authorities (e.g. in Australia, the Therapeutic Goods Administration).

(b) The reprocessing of RMDs potentially contaminated with Transmissible Spongiform Encephalopathies (TSEs) [e.g. Creutzfeldt Jakob Disease (CJD)]. The 'Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting' include specific recommendations in relation to the reprocessing of RMDs potentially contaminated with these agents.