SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Sterilisation: Definitive Cleaning of Reusable Medical Devices and Equipment
TYPE OF DOCUMENT	Procedure
DOCUMENT NUMBER	SESLHDPR/495
DATE OF PUBLICATION	August 2020
RISK RATING	Low
LEVEL OF EVIDENCE	National Safety Quality Health Service Standards: Standard 3 - Preventing and Controlling Healthcare Associated Infection Australian/New Zealand Standard AS/NZS 4187:2014
REVIEW DATE	October 2024
FORMER REFERENCE(S)	Nil
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director Clinical Governance and Medical Services
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KEY TERMS	Cleaning process definition, cleaning agent, cleaning methods, sterilisation, reusable medical devices, reusable medical equipment.
SUMMARY	To define a specification for the cleaning process to be applied to a defined Reusable Medical Device (RMD) without compromising the safety, quality and performance of that RMD.

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Sterilisation: Definitive Cleaning of Reusable Medical Devices and Equipment

SESLHDPR/495

1. POLICY STATEMENT

The essential prerequisites for effective disinfection and sterilisation are that a Reusable Medical Device (RMD) is clean and is able to withstand the process. If a RMD is not clean then the disinfecting and sterilising processes will be compromised.

Reprocessing instructions which are in accordance with ISO 17664 must be supplied by the manufacturer of the RMD.

2. BACKGROUND

The cleaning process for a RMD should ensure that all soil is removed prior to disinfection or sterilisation of that RMD. Disinfecting and sterilizing agents cannot penetrate, or become ineffective against, most soil, especially organic material. Inadequate cleaning may also cause a RMD to function incorrectly.

The cleaning process of a RMD should not cause an increase in the bioburden, and the RMD should also be free from cleaning agent residue at the completion of the process. Different cleaning processes can be required for different RMDs.

3. RESPONSIBILITIES

3.1 Employees will:

- Comply with the requirements of this procedure.

3.2 Line Managers will:

Nil

3.3 District Managers/ Service Managers will:

- Implement the requirements of this procedure to assure the quality and safety of reprocessed RMDs
- Be involved in the selection and evaluation process prior to the purchase of an RMD, to
  ensure compatibility with the defined cleaning processes available for use in the reprocessing facility.

3.4 Medical staff will:

- Comply with the requirements of this procedure.

4. PROCEDURE

4.1 Pre-Treatment

- Pre-treatment is to be done at the point of use, during and following procedure, to avoid the likelihood of adherent material to dry on the RMD, making removal of this

material more difficult.
- Pre-treatment can include damp wiping or rinsing with sterile water.

NOTE: When RMDs are used afterhours, RMDs should be pre-treated with, or soaked in, an enzymatic solution

4.2 Transportation

- Methods for transportation of used RMDs to the reprocessing facility, should protect the RMDs, personnel, and the environment from contamination and harm.
- RMDs should be transported in designated containers which are rigid, leak proof and an adequate size to contain the RMD safely, are able to be securely closed and able to be readily cleaned.

4.3 Cleaning

Definitive cleaning starts in the reprocessing facility.

4.3.1 Segregation

RMDs are segregated to the following cleaning pathways:
- Mechanical Cleaning
- Manual Cleaning

NOTE: RMDs are to be cleaned manually only where the RMD manufacturer's validated cleaning instructions require manual cleaning of the RMD.

4.3.2 Disassembly

RMDs will be disassembled to the point where all surfaces of the RMD can be successfully cleaned.

4.3.3 Mechanical Cleaning

- Loading techniques will ensure that all outer and inner surfaces of the RMDs are
- exposed to the cleaning process and protected from damage.
- RMDs with lumens will be pre-treated in an ultrasonic/irrigator or loaded onto load carriers which are designed to ensure an adequate flow of process fluids.

4.3.4 Manual Cleaning

- Dedicated and purpose specific cleaning equipment must be used.
- For each cleaning episode (one RMD and its accessories) fresh detergent solution is to be prepared.
- Cleaning technique ensures minimising the generation of particle splatter and creation of aerosols.
- RMDs are rinsed in warm running water at the completion of cleaning process.

4.3.5 Drying

- Drying cabinets should not exceed the temperature tolerances recommended by the manufacturer of the RMD.

- RMDs that cannot be dried mechanically should be dried manually and not left to dry in ambient air.

4.3.6 Cleaning efficacy

- In addition to visual inspection an objective means of assessing the performance of the cleaning process applied to an RMD shall be validated.
- Suitable industrially produced cleaning indicators may be used for routine monitoring of the efficacy of the cleaning process, these indicators can be applied to both mechanical and manual cleaning and must be recorded.

5. DOCUMENTATION

Specific HSO Procedures

6. AUDIT

- Reusable Medical Devices (RMD) - Mechanical cleaning of - Daily Audit
- Reusable Medical Devices (RMD) - Manual cleaning of - Daily Audit

7. REFERENCES

- AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service
- organisation
- ISO 15883: 2006 Washer Disinfectors - Part 1: General Requirements, terms and definitions and tests
- ISO 15883: 2006 Washer Disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc
- ISO 15883: 2006 Washer Disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
- ISO/TS 15883: 2005 Washer Disinfectors - Part 5: Test Soils and methods for demonstrating cleaning efficacy
- AS2773: Ultrasonic cleaners for health care facilities
- 2773.1 Benchtop
- 2773.2 Non-portable
- AS2774: 1985 Drying cabinets for respiratory apparatus
- AS2514: 1999 Drying cabinets for medical equipment

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
October 2015	1	SESLHD Sterilization Resource Group
June 2016	1	To Executive Sponsor for endorsement
July 2016	1	To Clinical and Quality Council for endorsement

July 2016	1	Approved by Clinical Quality Council
October 2019	2	SESLHD Sterilising Working Party (SSWP) conducted a minor review. Documentation updated to Specific HSO Procedures and references updated. Approved by Executive Sponsor. Formatted by Executive Services prior to publishing.
August 2020	3	Updated Executive Sponsor from Director Clinical Governance to Director Clinical Governance and Medical Services. Approved by Executive Sponsor. Published by Executive Services.