SESLHD PROCEDURE COVER SHEET

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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director of Clinical Governance and Medical Services
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KEY TERMS	Sterilisation process, sterility assurance level (SAL) parametric release, non-parametric release. Reusable Medical Devices (RMDs)
SUMMARY	To provide HSO personnel with evidence of the level of quality validation, monitoring of the process necessary to ensure patient safety.

1. POLICY STATEMENT

The sterilisation process is a pre validated procedure for obtaining, recording and interpreting the results required to establish that the process will consistently yield a product complying with pre-determined specifications.
The release of a processed load shall comply with one of the methods described on Table AS/NZS4187:Dec2014 – "Criteria for release of an *RMD from reprocessing".*

2. BACKGROUND

Bacterial spores are the most resistant of all living organisms because of their capacity to withstand external destructive agents. Although the physical or chemical process by which all pathogenic and non-pathogenic microorganisms, including spores, are destroyed is not absolute, supplies and equipment are considered sterile when necessary conditions have been met during a sterilisation process.

Reliable sterilisation depends on contact of the sterilising agent with all surfaces of the item to be sterilised. Selection of the agent to achieve sterility depends primarily upon the nature of the item to be sterilised. Time required to kill spores in the equipment available for the process then becomes critical.

Sterilisation process used to sterilise an RMD must meet the sterility assurance level (SAL) required, 10-6.

RESPONSIBILITIES

3.1 Employees will:

- Comply with the requirements of this procedure
- Report non-compliance to Sterilisation Services Manager

3.2 Line Managers will:

- Support compliance

3.3 District Managers/ Service Managers will:

- Implement the requirements of this procedure to assure the quality and safety of reprocessed RMD's.
- Be involved in the selection and evaluation process prior to the purchase of an RMD, to ensure compatibility with the defined sterilisation process is available for use in the reprocessing facility.
- Ensure performance requalification of sterilisers is conducted as per SESLHDPR/636 - Sterilisation: Validation of Sterilisers.

3.4 Medical staff will:

- Comply with the requirements of this procedure.

4. PROCEDURE

4.1 Pre-Sterilisation

Note: The essential prerequisites for effective disinfection and sterilisation are that an RMD is clean and is able to withstand the process. If an RMD is not clean, then the disinfection and sterilisation process will be compromised.

An RMD must be evaluated in conjunction with the manufacturer's instructions for use (IFU) prior to purchase to ensure the HSO has the capability to reprocess the RMD SESLHDPR/307 - Purchasing of Reusable Medical Devices (RMDs) and reprocessing equipment.

4.2 Selection of Sterilisation Process

The RMDs manufacturer's reprocessing instructions shall be used as a basis for selecting an appropriate method of sterilisation, including but not limited to:

- Moist heat
- Ethylene oxide sterilisation
- Low temperature sterilisation (peracetic acid, hydrogen peroxide and low temp steam formaldehyde).

4.3 Monitoring

- Data shall be recorded for each sterilisation process to demonstrate that the process specified has been delivered within the defined parameters and their tolerances.
- Routine monitoring and control of the sterilising equipment shall be performed in accordance with the requirements of table 8.2 AS4187 2014.
- Routine monitoring and control of the integrity of the RMDs sterile barrier system shall be performed after exposure to the sterilisation process.
- Records of routine monitoring and control shall be retained as per SESLHDPR/514 - Sterilisation: Records Management.

4.4 Release of RMD's

- A workplace instruction for RMD release from sterilisation shall be defined and specified by each HSO.
- Parametric release shall only be used if all parameters are specified controlled and directly monitored.

5. DOCUMENTATION

- Specific HSO Procedures

6. AUDIT

- Reusable Medical Devices (RMDs) – Packing and Sterilisation of- Audit

7. REFERENCES

- SESLHDPR/636 - Sterilisation: Validation Of Sterilisers
- SESLHDPR/307 - Purchasing of Reusable Medical Devices (RMDs) and reprocessing equipment
- SESLHDPR/514 - Sterilisation: Records Management
- AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisation and its normative references
- ISO11135 Sterilisation of health care products-Biological Indicators (series)
- ISO11140 Sterilisation of health care products-Chemical Indicators (series)
- ISO15882 Sterilisation of health care products-Chemical indicators-Guidance for selection, use and interpretation of results
- ISO17665 Sterilisation of health care products-Moist heat
- ISO17665-1 Part 1: Requirements for the development , validation and routine control of a sterilisation process for medical devices
- ISO25424 Sterilisation of health care products-Low temperature steam and formaldehayde-Requirements for development, validation and routine control of a sterilisation process for medical devices
- ISO14180 Sterilisers for Medical Purposes-Low Temperature Steam Formaldehayde Sterilisers –Requirements and Testing
- EN 285 Sterilisation-Steam Sterilisers-Large Sterilisers

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
April 2016	2	Review undertaken by SESLHD Sterilising Research Group. No changes
July 2016	2	Procedure renumbered by Executive Services
August 2016	2	Revised procedure approved by Executive Sponsor
February 2020	3	SESLHD Sterilising Working Party (SSWG) conducted a minor review to avoid duplication, add links to relevant SESLHD procedures and list all relevant standards.
May 2020	4	Approved by Executive Sponsor. Published by Executive Services.