SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Sterilisation: Purchasing of Reusable Medical Devices (RMDs) and reprocessing equipment
TYPE OF DOCUMENT	Procedure
DOCUMENT NUMBER	SESLHDPR/307
DATE OF PUBLICATION	April 2018
RISK RATING	Medium
LEVEL OF EVIDENCE	National Safety and Quality Health Service Standards: Standard 3 – Preventing and Controlling Healthcare Associated Infections
REVIEW DATE	April 2021
FORMER REFERENCE(S)	SESLHDPD/140
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KEY TERMS	Reusable Medical Devices (RMDs) Purchasing, Reprocessing Equipment
SUMMARY	This document was developed to ensure that reusable instrumentation that requires reprocessing is: • Supplied with manufacturer's Instructions for use (IFUs) • Evaluated for successful reprocessing • Procured following consultation between clinicians and Sterilisation Services.

Feedback about this document can be sent to SESLHD-ExecutiveServices@health.nsw.gov.au

Sterilisation: Purchasing of Reusable Medical Devices (RMDs) and reprocessing equipment

SESLHDPR/307

1. POLICY STATEMENT

To establish that the cleaning and sterilisation methods available in the healthcare facility are compatible with the RMD to be purchased and those on Loan.

Health Service Organisations (HSOs) shall ensure sufficient reprocessing equipment is available to meet the needs of the reprocessing facility.

2. BACKGROUND

Prior to purchasing of RMDs that require reprocessing, consultation shall take place between clinical staff and the Sterilisation Services Manager to establish that the RMD can successfully undergo the available / intended complete reprocessing steps. If all steps of reprocessing the device cannot be successfully completed, it shall not be re processed.

Prior to purchase of equipment required for reprocessing, reference shall be made to the relevant ISO Standards.

3. DEFINITIONS

Purchasing: To obtain or get
Reusable Medical Device (RMD): A medical device that is designated or intended by its manufacturer as suitable for reprocessing and reuse. It is not a medical device that is designated or intended by its manufacturer for single use only
Reprocessing equipment: Equipment that is used to ensure that a RMD is safe for its intended use
IFU: Instructions for use
HSO: Health Service Organisation

4. RESPONSIBILITIES

4.1 Employees will:

- Comply with the requirements of this procedure
- Report non-compliance with this procedure.

4.2 Line Managers will:

- Will inform equipment managers, purchasing officers and representatives of sponsors of the requirement of this process.

4.3 District Managers/Service Managers will:

- Implement the requirements of the procedure.

5. PROCEDURE

Sterilisation Services Manager shall be consulted prior to purchasing RMDs. Ensuring manufacturer's IFUs for reprocessing are considered. Establish that the device can be successfully processed by completing Clinical Product/Consumable Evaluation Form.

A risk assessment will be performed if required, and advice will be provided as to whether purchasing can proceed.

Representative of sponsors will provide reprocessing information (written documentation) in accordance to ISO 17664 (2004).

Advice and direction shall be given by the Sterilisation Mangers within the HSO when considering the purchase of equipment required for reprocessing RMDs.

6. DOCUMENTATION

Nil

7. AUDIT

- Risk assessment tool

8. REFERENCES

- AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisation and its normative references
- ISO Standards 17664(2004). Sterilisation of Medical Devices-Information to be provided by the manufacturer for the processing of re-sterilisable medical devices.

9. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
June 2013	1	Converted to Procedure by Scarlette Acevedo, District Policy Officer
October 2013	2	Revised by Jonathan Milligan, Manager Sterilising Services Reformatted by Scarlette Acevedo, District Policy Officer
November 2013	2	Approved by Prof. George Rubin, Director Clinical Governance
April 2018	3	SESLHD Sterilising Working Group (SSWG). Minor review approved by Kim Brookes, Director Clinical Governance.
April 2018	3	Processed by Executive Services prior to publishing