

# SESLHD PROCEDURE COVER SHEET



**Health**  
South Eastern Sydney  
Local Health District

<b>NAME OF DOCUMENT</b>	Sterilisation: Purchasing of Reusable Medical Devices (RMDs) and reprocessing equipment
<b>TYPE OF DOCUMENT</b>	Procedure
<b>DOCUMENT NUMBER</b>	SESLHDPR/307
<b>DATE OF PUBLICATION</b>	April 2021
<b>RISK RATING</b>	Low
<b>LEVEL OF EVIDENCE</b>	National Safety Quality Health Service Standards: Standard 3- Preventing and Controlling Healthcare Associated Infection Australian/New Zealand Standard AS/NZS 4187:2014
<b>REVIEW DATE</b>	April 2026
<b>FORMER REFERENCE(S)</b>	SESLHDPD/140
<b>EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR</b>	SESLHD Director Clinical Governance and Medical Services
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<b>FUNCTIONAL GROUP(S)</b>	Surgery, Perioperative and Anaesthetic
<b>KEY TERMS</b>	Reusable Medical Devices (RMDs) Purchasing, Reprocessing Equipment
<b>SUMMARY</b>	To ensure that RMDs that require reprocessing are: <ul style="list-style-type: none"><li>• Supplied with manufacturer's Instructions for use (IFUs)</li><li>• Validated for reprocessing by the manufacturer</li><li>• RMDs are procured following consultation between Sterilising Services Managers, Equipment Managers and Medical Staff.</li></ul>

## **COMPLIANCE WITH THIS DOCUMENT IS MANDATORY**

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# SESLHD PROCEDURE

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

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### 1. POLICY STATEMENT

To establish that the cleaning and sterilisation methods available in the reprocessing facility are compatible with the RMDs 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 the Sterilising Services Managers, Equipment Managers and Medical Staff to establish that the RMD can successfully undergo the available/intended complete reprocessing steps.

If all steps of reprocessing the RMD cannot be successfully completed, it shall not be reprocessed.

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

### 3. RESPONSIBILITIES

#### 3.1 Employees will:

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

#### 3.2 Line Managers will:

- Inform Equipment Managers, Purchasing Officers and Supplier Representatives of the requirement of this procedure.

#### 3.3 District Managers/Service Managers will:

- Implement the requirements of this procedure.

#### 3.4 Medical staff will:

- Comply with the requirements of this procedure.

### 4. PROCEDURE

#### 4.1 Sterilising Services Manager shall be consulted prior to purchasing RMDs ensuring manufacturer's IFUs for reprocessing are considered.

Establish that the RMDs can be successfully reprocessed by completing Clinical Product Evaluation Form.

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

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4.2 Supplier Representatives will provide reprocessing information (written documentation) in accordance to ISO 17664 (2004).

4.3 Advice and direction shall be given by the Sterilising Services Managers within the HSO when considering the purchase of equipment required for reprocessing RMDs.

### 5. DOCUMENTATION

- Clinical Product Evaluation Form

### 6. AUDIT

- Risk Assessment Form

### 7. REFERENCES

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

### 8. 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
April 2021	4	Minor review by SESLHD Sterilising Services Working Party (SSWP). Corrected wording of the positions. Approved by Executive Sponsor.