SESLHD PROCEDURE COVER SHEET

Health
South Eastern Sydney
Local Health District

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KEY TERMS	Release, Reprocessing, Reusable Medical Device (RMD)
SUMMARY	This procedure describes the criteria required for release of RMDs after reprocessing

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Sterilisation: Release of Reusable Medical Devices (RMD) after reprocessing

SESLHDPR/ 546

1. POLICY STATEMENT

The effectiveness of each individual phase of the overall reprocessing procedures shall be verified prior to a Reusable Medical Device (RMD) being released to the next phase of reprocessing.

2. BACKGROUND

A RMD shall not be released from reprocessing until all acceptance criteria for release of the RMD have been met.

2.1 Definitions

Reprocessing – all of the activities required to ensure that a used RMD is safe for its intended purpose

Reusable Medical Device (RMD) - a medical device that is designated or intended by its manufacturer as suitable for reprocessing and reuse.

Release – make available for the next phase

Sterile Barrier System (SBS) – minimum package that prevents ingress of microorganisms and allows aseptic presentation of product at the point of use

3. 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 Service Managers /Supervisor will:

- Implement the requirements of this procedure to assure the acceptance criteria for release of the RMD is met.

4. PROCEDURE

At a minimum, the criteria for release of a RMD from each phase of reprocessing shall comply with table 9.1

4.1 Criteria for Release of an RMD after cleaning

- RMD is visually clean and dry
- Cycle records comply with process specification.

4.2 Criteria for Release of an RMD after packing

- Sterile Barrier System (SBS) is suitable for the sterilising process
- SBS is of correct size for RMD to be sterilised
- SBS is intact
- Chemical indicator is present
- Seal is secure and intact.

4.3 Criteria for Release of a RMD after sterilisation

- Cycle records confirm achievement of process parameters
- External indicators show specified and consistent colour change
- SBS is intact
- There is no visible moisture
- Results of PCDs (when used) are correct
- Results of BIs (when used) are correct.

4.4 Criteria for Release of a RMD for storage and transport

- RMD is cold
- RMD is handled by staff trained in handling procedures.

5. DOCUMENTATION

- Electronic and/or hard copy documentation

6. AUDIT

- RMD - Manual Cleaning
- RMD - Mechanical Cleaning
- RMD - Packing and sterilisation

7. REFERENCES

- AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organization and its normative references

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
November 2016	1	SESLHD Sterilising Resource Group
November 2016	1	Endorsed by Executive Sponsor for Draft for Comment
December 2016	1	Approved by Clinical and Quality Council