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	Reusable Medical Devices (RMDs), Semi-critical RMDs, Critical RMDs, traceability/tracking
SUMMARY	This procedure describes the requirements that will enable the identification of a non-conforming product that has been used in the event that a recall s necessary.

Sterilisation: Traceability of Reprocessed Reusable Medical Devices (RMDs)

SESLHDPR/526

1. POLICY STATEMENT

The requirements for traceability of records related to the effective reprocessing of Reusable Medical Devices (RMDs) are maintained.

2. BACKGROUND

Provide a framework to support effective and efficient traceability and retrieval of all records and documents related to reprocessing RMDs.

2.1 Definitions

Traceability/tracking: the ability to trace the history, application or location of that which is under consideration

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

Semi-critical RMD: a reusable medical device that comes in contact with mucous membranes or non-intact skin

Critical RMD: a reusable medical device that comes in contact with the vascular system or sterile tissue and that must be sterile at the time of use.

3. RESPONSIBILITIES

3.1 Sterilising Health Service Managers will:

- Inform sterilising staff of the requirements of this procedure
- Act as a resource and be available for consultation in regards to tracking of equipment
- Ensure monitoring of the tracking process is documented
- Monitor staff work practices and ensure ongoing education is provided.

3.2 Employees will:

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

3.3 Line Managers will:

- Support compliance

4. PROCEDURE

Traceability systems shall require at a minimum, the identification of the following for each semi-critical and critical RMD:

- Type of RMD
- Unique identification of the RMD, eg, the serial number
- Date of reprocessing of the RMD and identification of the person responsible
- Identification of the person responsible for each stage of reprocessing of the RMD
- Identification of the equipment used to process the RMD.

- Other records, including but not limited to the following:
  - Results of any performance tests required to verify functional performances of the equipment prior to use eg, leak rate test, Bowie and Dick-type test
  - Results of chemical and biological monitoring undertaken for individual cycles or on a periodic basis
  - Type of the disinfectant/sterilant, batch number, expiry date
  - Cycle process record
  - Documented evidence of attainment of process parameters (NOTE: Process records can be paper based or electronic)
  - Identification of the person responsible for release of the RMD.

5. DOCUMENTATION

- Specific HSO Procedure

6. AUDIT

- Reusable Medical Devices (RMD) – Packing and Sterilisation of – Audit
- Reusable Medical Devices (RMD) – Mechanical Cleaning of - Audit
- Reusable Medical Devices (RMD) – Manual Cleaning of – Audit

7. REFERENCES

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

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
	1	SESLHD Sterilising Resource Group
September 2016	1	Endorsed for Draft for Comment
November 2016	1	Endorsed by SESLHD Clinical and Quality Council
February 2020	2	SESLHD Sterilising Working Party (SSWP) conducted a minor review to list and update relevant audits
May 2020	2	Approved by Executive Sponsor. Published by Executive Services.