SESLHD PROCEDURE COVER SHEET

Health
South Eastern Sydney
Local Health District

NAME OF DOCUMENT	Sterilisation: Reusable Medical Devices (RMDs) on Loan
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EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	SESLHD Director Clinical Governance and Medical Services
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KEY TERMS	Reusable Medical Devices (RMDs), Loan, Instructions for Use (IFU), Commercial Supplier, Individual Clinicians Health Service Organization (HSO)
SUMMARY	The objective of this procedure is to ensure that all RMDs on loan are provided to the HSOs with appropriate documentation and education, supplied in timely manner, and supplied in a manner that minimises the risk of manual handling and negative patient outcomes.

1. POLICY STATEMENT

This procedure outlines the requirements for management of (Reusable Medical Devices) RMDs supplied on loan by Commercial Suppliers, Other Health Service Organisations (HSOs) and Individual Clinicians.

2. BACKGROUND

RMDs are provided to HSOs for use in surgical procedures, on a case by case basis by Commercial Suppliers, other HSOs and Individual Clinicians.
The objective of this procedure is to ensure that all RMDs are/with:

- approved for use by TGA and are accompanied by evidence of approval;
- supplied with Manufacturer's Instructions for Use (IFU) compliant with ISO 17664:2017;
- prearranged and adequate education and in-servicing for the majority of staff
- packed and transported as per the Work Cover guide 'Design and handling of surgical instrument transport cases';
- supplied in timely manner to allow for adequate reprocessing.

RMDs provided on loan by other HSOs or Individual Clinicians shall undergo full reprocessing prior to use.

3. RESPONSIBILITIES

3.1 Perioperative Services Staff will:

comply with this procedure and report non-compliance.

3.2 Medical Staff will:

comply with this procedure.

3.3 Perioperative Services Managers will:

monitor compliance with this procedure.

4. PROCEDURE

Ordering of RMDs on Loan for each HSO within the SESLHD shall only be organised by a designated staff member with delegated authority to incur expenditure on behalf of the HSO.

4.1 Medical Staff shall provide the designated staff member with a full description of the RMDs required to be ordered on loan.

- designated staff member will notify Sterilising Services Department by providing clear and concise Booking Schedule;
- designated staff member will determine or consult with the Sterilising Services Manager if RMDs have been previously used by the HSO.

If the RMDs have been previously used by the HSO, the following shall occur:

- designated staff member will ensure the RMDs are ordered in a timely manner to ensure the RMDs can be provided to the HSO within the timeframe set by the HSO;
- the supplier of the RMDs shall ensure delivery within a HSOs set time frame to allow for adequate reprocessing;
- the supplier will provide at least two copies of detailed checklists, preferably with photos.

If the RMDs have not been used previously by the HSO, the following shall occur:

- designated staff member will consult with the Sterilising Services Manager to establish if the HSO can facilitate the reprocessing of the RMDs;
- supplier will provide Instructions for Use (IFUs) in accordance with ISO17664;
- supplier will provide a demo kit (minimum a week prior to the first use) for assessment of the RMDs and in-servicing of staff;
- supplier will deliver the RMDs on loan as per the Work Cover guide on health and safety standards.

4.2 Designated Sterilisation Technician will determine if the received RMDs on loan and accompanying documentation correspond with the booking schedule.

- designated Sterilisation Technician will assess if all requirements have been met;
- designated Sterilisation Technician will notify Sterilising Services Manager (within hours) or Operating Suite Nurse in Charge (after hours) of any noncompliance.

5. DOCUMENTATION

Check lists for RMDs supplied on loan, Booking Schedules, IFUs and HSO Procedures.

6. AUDIT

As per HSO Requirements.

7. REFERENCES

ASNZS 4187:2014 Reprocessing of reusable medical devices in health service Organisations.
ISO 17664:2017 Processing of health care products-Information to be provided by the medical device manufacturer for the processing of medical devices.
Work Cover 2011-Design and handling of surgical instrument transport cases-A guide on health and safety standards.

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
May 2004	0	Former SES Procedure CSP2004/003
May 2006	1	Document reviewed to meet requirements of merged AHS by Debbie Candsell, Perioperative Manager in consultation with SESIAHS Managers Perioperative Suites. Approved by Executive Management Committee for release 23 May 2006
Sept 2008	2	Renumbered from a Clinical Stream Procedure to a SESIH Procedure and minor formatting to cover sheet and header. No changes made to content.
February 2013	3	Updated policy references, additions to include use of RFID document (SESLHD Operating Suite Managers). Approved by Dr Greg Keogh Clinical Stream Director
August 2015	4	Reviewed and updated by Jonathan Milligan
September 2015	4	Endorsed by Executive Sponsor
September 2018	5	Reviewed to meet the requirements of the new ASNZS 2014. Reviewed by SESLHD Sterilizing Services Working Group (SSWG)
October 2018	5	Minor review. Processed by Executive Services prior to publication.