SESLHD PROCEDURE COVER SHEET

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KEY TERMS	Assembly, Packaging System, Reusable Medical Device (RMD)Information for Use (IFU), Inspection, Sterile Barrier System (SBS)
SUMMARY	This procedure outlines general requirements for inspection, assembly and packaging of reusable medical devices (RMDs) prior sterilisation.

Sterilisation: Inspection, Assembly and Packaging of Post Cleaned Reusable Medical Devices

SESLHDPR/306

1. POLICY STATEMENT

To ensure that RMDs intended for terminal sterilisation are inspected for cleanliness, functionality and completeness and the packaging system allows for sterilisation, provides physical protection, maintains sterility up to the point of use and allows for aseptic opening.

2. BACKGROUND

- The cleanliness of RMDs presented for terminal sterilisation is inspected and will not compromise the effectiveness of the sterilisation process.
- The purpose of the packaging and wrapping of RMDs for sterilisation is to provide an effective sterile barrier system to maintain sterility following processing, prior to use and to permit aseptic removal of the RMD.
- The design, intended sterilisation method, intended use, transport and storage of the RMD all influence the inspection, assembly/disassembly, packaging system and choice of materials. HSOs should develop processes to evaluate the performance of each sterile barrier system or packaging system before selection and implementation to ensure conditions for sterilisation, storage and handling can be met.

3. RESPONSIBILITIES

3.1 Employees will:

- Comply with the requirements of this procedure
- Report any non-compliance to the Sterilising Services Manager

3.2 Line Managers will:

- Nil

3.3 District Managers/ Service Managers will:

- Implement the requirements of this procedure to assure the quality and safety of reprocessed RMDs
- Be involved in the selection and evaluation process prior to the purchase of RMDs to ensure compatibility with the defined packaging and wrapping processes available for use in the reprocessing facility.

3.4 Medical staff will:

- Comply with this procedure

4. PROCEDURE

4.1 Inspection

- To ensure the RMDs and containment devices are visually clean and complete.

4.2 Assembly

- RMDs that are assembled into sets should be characterised by similar attributes (product families) such as mass, material, construction, shapes, lumens SBS, and should present similar challenge to the sterilising process. Multi part RMDs should be disassembled to ensure sterilant contact on all surfaces.
- Trays in which the RMDs are assembled and sterilized should be suitable for the intended sterilizing process and should permit penetration of the sterilizing agent to all parts of the RMDs.
- Hollowware should be:
    - Packaged so that all openings face the same direction
    - Separated to permit effective contact of the sterilising agent
    - Positioned to facilitate effective air removal, sterilisation and drying.

4.3 Packaging and Wrapping

- Packaging system shall provide physical protection and maintain integrity of the sterile barrier.
- Sterile barrier system (SBS) shall allow for sterilisation and be compatible with the sterilisation process.
- Materials shall comply with the requirement of ISO 11607-1.
- Supplier of preformed sterile systems should provide a statement of compliance to the applicable sections of ISO 11607-1.
- Sterile barrier systems shall be validated as per the requirements of ISO 11607-2.
- Maintenance of sterile barrier integrity may be used to demonstrate maintenance of sterility (ANSI/AAMI ST65:2000 – The loss of sterility is regarded as event related rather than time related).

5. DOCUMENTATION

- Specific HSO Procedures

6. AUDIT

Reusable Medical Devices (RMDs)-Packing and Sterilisation of - Daily Audit

7. REFERENCES

- AS/NZS 4187:2014 Reprocessing of reusable medical devices in health services organizations
- ISO 11607 Packing for terminally sterilised medical devices
  Part 1: Requirements for materials, sterile barrier systems and packing systems
  Part 2: Validation requirements for forming, sealing and assembly processes
- EN 868 Packing for terminally Sterilised Medical Devices
  Part 10: Adhesive Coated Nonwoven Materials of Polyolefines-Requirements and Test Methods

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
November 2013	2	Updates endorsed by Executive Sponsor
July 2016	3	Minor updates to procedure. Approved for two week Draft for Comment.
November 2016	3	Updates endorsed by Executive Sponsor.
November 2019	4	SESLHD Sterilising Working Party (SSWG) conducted a minor review. Documentation updated to Specific HSO Procedures. References updated and listed.
May 2020	4	Approved by Executive Sponsor. Published by Executive Services.