



**Australian Government**

**HLTSTE011 Inspect, assemble and package  
reusable medical devices**

# HLTSTE011 Inspect, assemble and package reusable medical devices

## Modification History

Release	Comments
1	This unit of competency was first released in HLT Health Release 11.0.

## Application

This unit describes the skills and knowledge required to inspect, assemble and package cleaned reusable medical devices according to manufacturer's instructions for use.

This unit applies to individuals working under general supervision and within established procedures in a range of health and non-health related facilities.

*The skills in this unit must be applied in accordance with Commonwealth and State/Territory legislation, Australian Standards and industry codes of practice.*

## Licensing/Regulatory Information

No licensing, legislative or certification requirements apply to this unit at the time of publication.

## Pre-requisite unit(s)

No pre-requisite units

## Competency field(s)

N/A

## Unit sector(s)

Sterile Medical Equipment

## Elements and Performance Criteria

Element	Performance criteria
<i>Elements define the essential outcomes</i>	<i>Performance criteria describe the performance required to demonstrate achievement of the element</i>
1. Prepare for inspection and packing	1.1 Select and wear appropriate attire and complete personal hygiene requirements according to organisational procedures

	<p>1.2 Clean area prior to processing reusable medical devices according to infection prevention and control guidelines</p> <p>1.3 Prepare and test auxiliary equipment for use and document results</p> <p>1.4 Retrieve clean reusable medical devices according to organisational procedures</p> <p>1.5 Minimise the risk of cross-contamination of cleaned reusable medical devices</p>
<p>2. Inspect reusable medical devices</p>	<p>2.1 Sort and separate reusable medical devices according to, specialties, product families, packaging and reprocessing requirements, according to manufacturer's instructions for use</p> <p>2.2 Visually inspect all reusable medical device surfaces for cleanliness and dryness</p> <p>2.3 Determine need for magnified viewer to inspect reusable medical devices</p> <p>2.4 Identify non-conforming reusable medical devices and return for reprocessing according to organisational procedures</p> <p>2.5 Inspect reusable medical devices for completeness and functionality according to manufacturer's instructions for use</p> <p>2.6 Complete insulation testing and document results according to manufacturer's instructions for use and organisational procedures</p> <p>2.7 Identify and report missing, faulty and damaged reusable medical devices according to organisation procedures</p>
<p>3. Prepare and assemble reusable medical devices</p>	<p>3.1 Select, inspect and prepare reusable medical device tray</p> <p>3.2 Open, unlock and reassemble hinged, ratcheted or multi-part reusable medical devices to confirm functionality and completeness</p> <p>3.3 Disassemble multi-part reusable medical devices to ensure sterilant contacts all surfaces</p> <p>3.4 Assemble reusable medical devices according to the reusable medical device tray checklist and organisational procedures</p> <p>3.5 Lubricate reusable medical devices according to manufacturer's instructions for use</p> <p>3.6 Prepare reusable hollow ware sets with all openings facing the same direction</p> <p>3.7 Protect delicate and sharp reusable medical devices according to organisational procedures</p> <p>3.8 Process chemical indicators according to organisational procedures</p>

4. Package reusable medical devices	<p>4.1 Select sterile barrier systems according to sterilisation method, organisational procedures and manufacturer's instructions for use</p> <p>4.2 Inspect sterile barrier systems for cleanliness and defects</p> <p>4.3 Prepare reusable medical device trays, and rigid containers according to manufacturer's instructions for use</p> <p>4.4 Operate heat-sealing equipment according to operating instructions</p> <p>4.5 Package and seal sterile barrier systems according to manufacturer's instructions for use and organisational procedures</p> <p>4.6 Label sterile barrier systems according to organisational traceability and storage procedures</p> <p>4.7 Prepare and package semi-critical disinfected reusable medical devices for storage and transfer to appropriate location</p> <p>4.8 Record quality assurance documentation using a tracking system</p> <p>4.9 Assemble, inspect and package reusable medical devices according to safe manual handling techniques</p>
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## Foundation skills

The foundation skills essential to performance of this unit, but not explicit in the performance criteria are listed here, along with a brief context statement.

Skills	Description
Learning skills to:	locate and apply complex technical information from organisational procedures, safety data sheets, manufacturer's instructions and Standards to familiar device configurations.
Reading skills to:	interpret organisational procedures, technical safety data sheets, manufacturer's instructions and familiar checklists.
Oral communication skills to:	report faults and/or non-conformance with equipment or process using industry terminology to supervisor.
Numeracy skills to:	complete insulation testing of reusable medical devices and follow diagrams to assemble and reassemble medical devices.

*Digital literacy outcomes are included in the Foundation Skills Companion Volume.*

## Range of conditions

N/A

# Assessment Requirements for HLTSTE011 Inspect, assemble and package reusable medical devices

## Performance Evidence

The candidate must show evidence of the ability to complete tasks outlined in elements and performance criteria of this unit, manage tasks and manage contingencies in the context of the job role. There must be evidence that the candidate has:

- followed established procedures, work processes and national standards for the inspection, assembly, packaging and labelling of 3 reusable medical devices on at least 3 separate occasions, 9 devices in total, ensuring the total evidence includes at least 1 of each of the following:
  - solid plain reusable medical devices
  - reusable medical devices requiring disassemble
  - reusable medical devices with textured surface
  - delicate reusable medical devices
  - manual and powered reusable medical devices
- operated and monitored equipment required for packaging on at least 3 separate occasions, ensuring the total evidence includes at least 1 of each of the following cannulated devices:
  - illuminated magnifier
  - cannulated, lumened reusable medical devices
  - blind ended instruments
  - insulation testing and inspection of integrity of electrosurgical devices
- completed quality assurance documentation for each of the 3 occasions, including recording and reporting any identified process and maintenance problems or variations
- addressed relevant work health and safety, infection prevention and control and manual handling requirements.

## Knowledge Evidence

The candidate must be able to demonstrate essential knowledge required to effectively complete tasks outlined in elements and performance criteria of this unit, manage tasks and manage contingencies in the context of the work role. This includes knowledge of:

- packaging in relation to client safety, and implications of negligence
- the requirements of AS5369, and its role in inspection, assembly and packaging reusable medical devices and other devices
- the role of regulatory requirements, safety data sheets (SDS) for sterile barrier systems
- different types of sterile barrier systems, including:

- single use
- rigid containers
- preformed sterile barrier systems
- single-use wraps
- pre-formed sterile barrier systems
- reusable sterile barrier systems
- product families and their relationship to reprocessing requirements
- use of reusable medical devices in different operative procedures
- testing and inspection requirements for reusable medical devices, including:
  - reusable medical device is clean, free from soil and dry prior to packaging
  - systems for identifying reusable medical devices and other devices
  - importance of inspection of insulation testing
  - report and remove damaged devices according to organisational procedures
- features of inspection, assembly, packaging and test equipment, including:
  - air guns
  - lighted magnification
  - automated lubrication device
  - heat sealer
  - drying cabinets
  - height adjustable workstations
  - insulation testing
  - labelling systems
  - manual and electronic tracking systems
  - patient specific implants
  - reusable medical device checklists
  - reporting processes
- packaging materials and wrapping techniques, including:
  - ensuring packaging material meets integrity standards
  - relationship of sterile barrier systems and wrapping material to sterilisation method used
  - sealing materials
  - single use and reusable sterile barrier systems
  - rigid reusable container systems
- classes of chemical indicators

- electronic or manual tracking, identification and traceability systems
- performance qualification for packaging
- features of quality assurance documentation
- safe work practices in the inspection and packaging work area, including:
  - manual task risk factors
  - infection prevention and control
  - personal hygiene, including facial hair

## Assessment Conditions

Skills must have been demonstrated in the workplace or in a simulated environment that reflects workplace conditions. The following conditions must be met for this unit:

- use of suitable facilities, equipment and resources, including:
  - AS5369
  - PPE
  - equipment manufacturer’s instructions for use
  - sterile barrier systems
  - insulation testing systems including different frequencies for testing various reusable medical devices
  - reusable medical devices
  - heat sealing equipment with different temperatures
  - sterile barrier systems
  - quality assurance documentation
  - electronic or manual tracking system
  - inspection, assembly and packaging procedures
- modelling industry operating conditions, including:
  - presence of situations requiring problem-solving

Assessors must satisfy the Standards for Registered Training Organisations (RTOs)/AQF mandatory competency requirements for assessors

## Mandatory Workplace Requirements

Assessment of performance evidence may be in a workplace setting or an environment that accurately represents a real workplace.

## Unit Mapping Information

Previous Code and Title	Equivalence	Comments
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HLTSTE002 Inspect and pack reusable medical devices	Equivalent	Updated terminology in unit application. Major changes to the elements and performance criteria. Major changes to performance evidence and knowledge evidence. Minor changes to assessment conditions.
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## Links

Companion volumes, including implementation guides, are found on the national training register - <https://training.gov.au/training/details/HLT>.