

General rules for reprocessing complex and difficult to clean devices - laryngoscopes



Health services have a responsibility to ensure Reusable Medical Devices (RMDs) are reprocessed to a safe level which eliminates or minimises infection risks to patients.

Procurement for RMDs must include a process that considers and evaluates the requirement for reprocessing. This includes liaising with sterilising departments, infection prevention and control and the end users. RMDs must be reprocessed in accordance with relevant Australian and international standards and the device's manufacturer's instructions (IFU - Instructions for Use). A local risk assessment must be undertaken to assess compliance with AS/NZS 4187:2014 Reprocessing Reusable Medical Devices in Health Service Organizations ⁽¹⁾.

Compliance with AS/NZS 4187:2014 is mandatory. Where the IFU is unclear, classification is open to interpretation or the IFU contradicts required standard:

1. Contact manufacturer to clarify and get clarification in writing
2. Report to Therapeutic Goods Administration (TGA)
3. Conduct risk assessment to either remove, replace device or develop procedures to adequately manage.

RMDs that come into contact with sterile body cavities or are used on the critical aseptic field during invasive procedures are considered critical medical devices and must be reprocessed to the highest level between uses, i.e. sterilisation or high level disinfection (HLD).

RMDs that come into contact with mucous membrane or non-intact skin are considered semi critical medical devices and must be reprocessed to the highest level between uses. i.e. sterilisation or HLD.

There is increasing evidence that laryngoscope handles not reprocessed properly display bacterial contamination. Cleaning and reprocessing of the handle is therefore an essential requirement before reuse.

Video laryngoscopes

Video laryngoscopes are an expanding technology originally designed to assist with difficult intubation. These devices are being used more frequently for routine intubation and there are a variety of designs that either incorporate the blade and handle as a single unit or that separates the blade from the handle.

Routine High level reprocessing of Video Laryngoscopes may degrade the device over time or may not be an option according to the manufacturer. Where contamination of the device occurs a risk assessment should be conducted and a higher level of reprocessing should occur.

- The video laryngoscopes may have a blade which is a pre-sterilised single use item which is applied over the imaging camera and light source OR imaging camera, light source and handle.
- During intubation blade advancement should not exceed beyond the length of the blade. By using the correct technique the camera and light source is unlikely to come into contact with the mucus membranes, reducing the risk of contamination to the imaging camera or light source. Where contamination of the camera and light source with body fluids does occur, the device should be cleaned and a higher level of disinfection or sterilisation (as per the IFU) should occur.

General rules for reprocessing complex and difficult to clean devices - laryngoscopes

- Parts of the device that are reusable such as handle, screen and cable are classified as a non-critical item require cleaning as soon as possible after use with a non-residual detergent solution. Disinfect with compatible low-level or intermediate-level instrument-grade disinfectant after cleaning. (This may be via dual purpose preparations).
- For specialised equipment which is difficult to clean and the application of detergent directly onto the device is not recommended by the manufacturer, a custom surface barrier should be used e.g. intraoral camera. Any custom surface barrier used on such equipment should be disposed of after each patient treatment and replaced with a new custom surface barrier (3)
- Reprocessing with alcohol is not recommended and will not comply with state or national standards (Refer to AS/NZS 4187 (1); Infection Prevention and Control Policy Directive (2); Australian Guidelines Infection Prevention and Control 2019 (3) for further information).

Cleaning processes should be monitored and compliance auditing should take place

Laryngoscopes

Device Part	Classification and Reprocessing Requirements
Reusable blades	Semi critical and requires HLD* or sterilisation* in between use
Disposable blades	Semi critical and disposed after each use
Reusable Handles	Non-critical and must be cleaned and low level disinfected* between use
Blades and Handles as a single unit	If reusable the unit is semi critical and must be HLD* or sterilised*. If single use, dispose after use

* IFU to be followed for compatible solutions/processes

General rules for reprocessing complex and difficult to clean devices - laryngoscopes

Video Laryngoscopes

Device Part	Classification and Reprocessing Requirements
Reusable blades	Semi critical and requires HLD* or sterilisation* in between use
Disposable blades	Semi critical and disposed after each use
Reusable Handles	Non-critical and must be cleaned and low level disinfected* between use
Blades and Handles as a single unit	If reusable the unit is semi critical and must be HLD* or sterilised*. If single use, dispose after use

* IFU to be followed for compatible solutions/processes

Summary

- Laryngoscope blades are categorised as semi-critical and must be reprocessed in accordance with the NSW Infection Control Policy, the Australian Infection Prevention and Control Guidelines, and AS/NZS 4187:2014.
- Non critical parts of the reusable device must be reprocessed as per manufacturers IFU. If gross contamination occurs during use, they should receive a high-level of disinfection or sterilisation.
- Monitoring of cleaning processes and auditing compliance should occur. Centralised processes should be considered to improve overall management.
- The information in this document may not be easily transferable to other devices.

References

1. Australian/New Zealand Standard. Reprocessing of reusable medical devices in health service organizations. Australia 2014.
2. NSW Health. Infection Prevention and Control Policy Directive. Sydney, 2017.
3. Australian guidelines for the prevention and control of infection in healthcare. National Health and Medical Research Council. 2019.