REPROCESSING REUSABLE MEDICAL DEVICES IN THE AGED CARE SETTING

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LEARNING OUTCOMES

At the completion of this presentation and with further reading, it is expected that participants will be able to:

- Explore the regulatory environment as it applies to the cleaning agents and disinfectants that are used to reprocess reusable medical devices
- Examine the Spaulding Classification and apply this correctly to the classification of reusable medical devices
- Describe the principles of effective cleaning and disinfection in the aged care settings

WHAT IS A MEDICAL DEVICE?

According to the Therapeutic Goods Administration (TGA):

"A medical device can be any instrument, product or software (including AI) that works to achieve a therapeutic purpose in a human being."

"Accessories" to medical devices are also considered medical devices if they are intended to be used with, or enable the use of a medical device as the manufacturer intended

- "any instrument, apparatus, appliance, software, implant, reagent, material, or other article (whether used alone or in combination) intended for human use to:
  - diagnose, prevent, monitor, predict, prognose, treat, or alleviate disease;
  - diagnose, monitor, treat, alleviate or compensate for an injury or disability;
  - control or support conception;
  - examine human specimens; investigate, replace, or modify the anatomy or a physiological or pathological process or state.
  - examine specimens derived from the human body for a specific medical purpose;
  - and does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

https://www.tga.gov.au/resources/guidance/understanding-medical-device-definitions-and-rules-system-or-procedure-packs

CLASSIFICATION OF MEDICAL DEVICES

- The TGA classifies medical devices based on
  - The intended use of the device
  - How invasive the device is
    - For example:
    - Is it placed on skin or is it inserted into the body?
    - Where on or in the body that the device is intended to be used?
    - How long will it be used for or will it remain in the body?

Risk level	Classification(s)	Examples
Low	Class I	• Surgical retractors • Tongue depressors
Low to Medium	Class I - supplied sterile Class I - with a measuring function Class IIa	• Sterile surgical gloves • Medicine cup with specific units of measurement • Dental drills; ultrasound machines; digital or infrared thermometers
Medium to High	Class IIb	• Surgical lasers • Diagnostic X-ray
High	Class III	• Prosthetic heart valves • Absorbable surgical sutures • Hip prostheses (for example, replacement of hip joint) • Pacemakers

www.tga.gov.au/products/medical-devices/medical-devices-overview

INVITRO DIAGNOSTIC MEDICAL DEVICES (IVD)

A medical device is an in vitro diagnostic medical device (IVD) if it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use

It must be intended to be used for the examination of specimens derived from the human body, for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures

IVD classification	Level of risk
Class 1	No public health risk or low personal risk
Class 2	Low public health risk or moderate personal risk
Class 3	Moderate public health risk or high personal risk
Class 4	High public health risk

Examples:

- blood glucose machines and test strips
- urinalysis test strips

TYPES OF MEDICAL DEVICES USED IN AGED CARE

Risk Level	Classification	Examples
Low	I	Stethoscope, bed pan urinal, glucose meter, ostomy pouches, examination gloves, reusable medical devices i.e. scissors, forceps
Low-Medium	Class I supplied sterile	Dressing packs, dressings, single use instruments
	Class I – with a measuring function	Medicine cup, oral syringe
	Class II	Uranalysis test strips (IVD)
	Class IIa	Bladder Scanner, Electronic vital signs monitors, ECG machine, intravenous and gastrostomy tubing, skin closure devices
Medium-High	Class IIb	Dressings for extensive ulcerated or decubitis ulcer type wounds, urinary catheters, IV cannula
High	Class III	Blood glucose test strips (IVD)

https://www.tga.gov.au/sites/default/files/2024-07/classification-medical-devices-not-ivds-20240702.pdf

What reusable medical devices do you use at your facility?

THE SPAULDING CLASSIFICATION

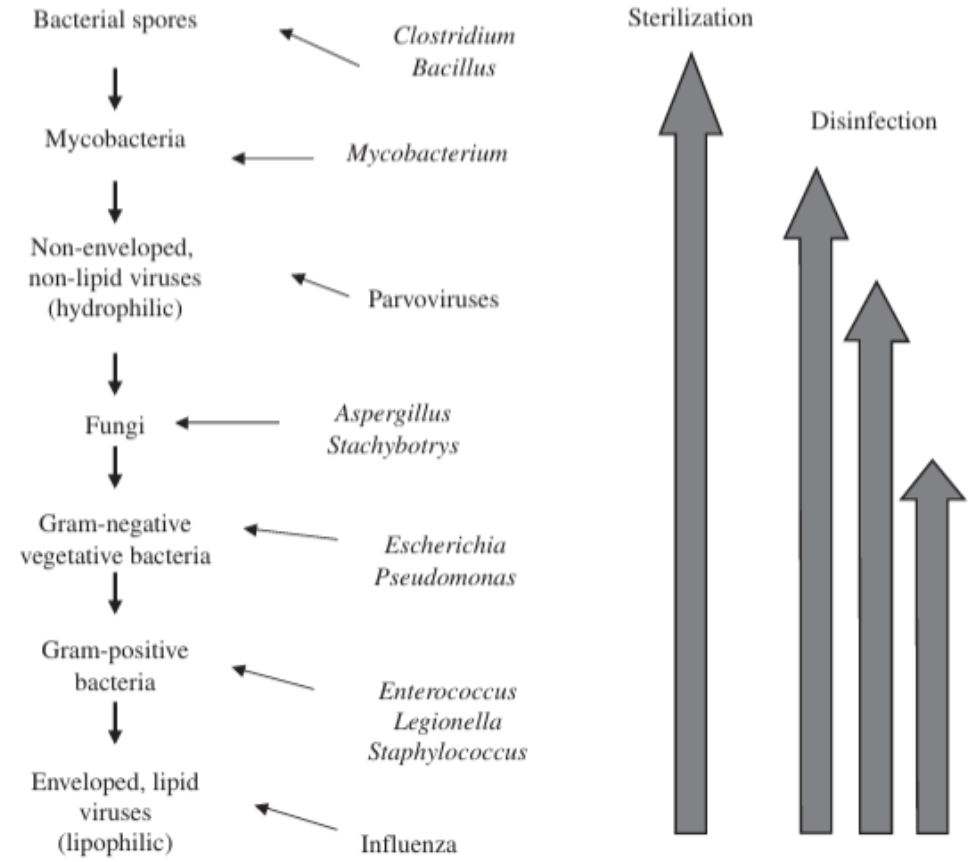


Figure 1. The Spaulding classification for device disinfection. (a) Based on Spaulding (1957). (b) As typically used today in healthcare facilities, with the decreasing level of resistance shown on the left, with examples of micro-organism types that are typical of each grouping and the equivalent levels of sterilization/disinfection.

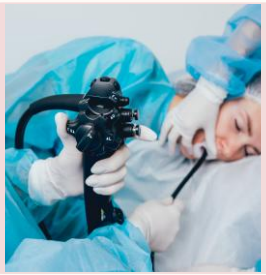
McDonnell & Burke 2011

- Dr Earle H. Spaulding was an American professor of medical microbiology at Temple University
- He developed a framework for classifying medical devices according to the degree of risk of transmission of infectious agents associated with their use
- Critical devices need to be sterile
- Semi-critical devices need to be high-level disinfected at a minimum
- Non-critical devices need to be cleaned and can also be low or intermediate level disinfected

THE SPAULDING CLASSIFICATION

Critical Medical Devices: Devices that enter sterile areas of the body

For example, devices that come into contact with, tissues or organs that are normally free from microorganisms, including contacting blood or the bloodstream



Semi-critical Medical Devices: Devices that come into contact with non-intact skin or mucous membranes

For example, devices that enter cavities such as the mouth, anus, vagina, urethra, or come into contact with wounds or breaks in the skin

Non-critical Medical Devices: Devices that come into contact with intact skin

SPAULDING CLASSIFICATION

Non-critical	Semi-critical	Critical
Stethoscope	Gastrostomy tubing	IV cannula
Bed pans and urinals	Oral syringe	Urinary catheters
Medicine cup	Ostomy pouches	Intravenous tubing
Uranalysis test strips (IVD)	Examination gloves	Skin closure devices
Electronic vital signs monitors and ECG machine	Nasogastric tubes	Reusable medical devices i.e. scissors, forceps
Bladder Scanner	Respiratory equipment	Lancets
Glucose meter & blood glucose test strips (IVD)		Dressing packs, dressings, single use instruments

WHAT ARE SOME REUSABLE MEDICAL DEVICES YOU USE IN AGED CARE?

Reusable Devices	Spaulding Classification	Reprocessing method
Bedpans and urinals	Non-critical	Cleaning +/- low or intermediate level disinfection
Bladder scanner	Non-critical	
ECG machines	Non-critical	
Stethoscope	Non-critical	
Vital signs monitors	Non-critical	
? ? ? ?	Semi-critical	Cleaning & high-level disinfection – sterilisation preferred
RMDs	Critical	Cleaning, disinfection and sterilisation

ACIPC RESOURCE

Reusable-Equipment-cleaning-toolbox-2024.pdf

Are there any reusable semi-critical medical devices that are used in your facility? If so, please list them.

CLEANING AGENTS

Cleaning agents used for *environmental* cleaning are not regulated by the TGA

- Unless the cleaning agent makes specific claims of activity against microorganisms
- In this case it is treated as a disinfectant product

Cleaning agents used to clean *medical devices* must be entered on the ARTG

- These are treated as ‘accessories’ to medical devices
- If the cleaning agent makes specific claims of activity against microorganisms, then it is regulated as a disinfectant product

What cleaning agents do you use to clean your non-critical medical devices?

LEVELS & TYPES OF DISINFECTION

Low level

- Kills most vegetative bacteria, fungi, and some viruses

Intermediate level

- Kills all of the above plus mycobacteria

High level

- Kills all microorganisms, including all vegetative bacteria, fungi, viruses, and mycobacteria, but not all bacterial spores

Instrument Grade Disinfectants

- Intended for use on medical devices
- Must be entered on the ARTG

Hospital Grade Disinfectants

- Intended for use on hard surfaces
- Can be 'with' or 'without' claims
- Products with claims need to be entered on the ARTG

TYPES OF DISINFECTION

Thermal

- Achieved by the application of hot water or moist heat
- Level of disinfection achieved is based on a mathematical calculation
- A_0 of 60 is equivalent to low level disinfection
  - 80^0C for 1 minute or 90^0C for 6 seconds
  - Usually used for bedpans and urinals
- A_0 of 600 is equivalent to intermediate level disinfection
  - 80^0C for 10 minutes or 90^0C for 1 minute

Chemical

- For maximum effectiveness of chemical disinfection, surfaces should be free from organic soils
- Some disinfectants are inactivated by organic materials, and this includes the cloths used to spread the disinfectant
- To achieve microbial kill, disinfectants must remain wet and in contact with the surfaces to be disinfected for the period of time specified by the manufacturer

What products are you using to achieve low or intermediate level chemical disinfection?

PAN SANITISERS

ISO15883-3 – for human waste containers

- Does not require the use of a detergent, although this is an option a customer can choose if desired
- Does require a display of the temperature achieved during the disinfection stage of the process cycle

WASHER-DISINFECTORS FOR NON-INVASIVE NON-CRITICAL MEDICAL DEVICES

- ISO15883 – 6
  - Has no formal requirement for detergent to be used, although cross references ISO15883-1 that does contain this requirement
  - These WDs can be used to clean and thermally disinfect equipment such as sponge bowls, emesis basins, wheelchairs, beds, walking frames etc
  - No requirement for validation or performance testing once installed but does require a visual display of process temperature achieved during the disinfections stage of the process cycle

HOW DO I REVIEW WHAT THE DENTIST / PODIATRIST IS DOING FOR THEIR RMDS?

Ask them!

- How are they transporting the sterile RMDs?
- Do they use the same containers for transporting clean / sterile items as they use to transport used / soiled RMDs back to their practice?

KEEP ASKING...

- Do they pre-clean the RMDs before transporting them back to their practice?
  - Is so what do they use and where are they doing this?
- Do they have a WD? If not how are their RMDs being cleaned at the practice?
- What type of steriliser do they use?
  - Does it have a Type B cycle?
  - Do they do a daily leak rate / vacuum test?
  - Do they do a daily air removal and steam penetration test?
  - Are the packages dry when they come out of the steriliser?
- How do they track the RMDs used on the patients back to their process records?

NOW IT IS YOUR TURN TO ASK!

Audience Q&A

THANK YOU

References

McDonnell, G. & Burke, P. *Disinfection: is it time to reconsider Spaulding?* *http://dx.doi.org/10.1016/j.jhin.2011.05.002*