

Spaulding Classification - Sterilization in Healthcare

(0:00 - 0:38)

Welcome to this introduction on the Spaulding Classification, an approach to disinfection and sterilisation of patient care items and equipment. The information in this presentation is adapted from the Guideline for Disinfection and Sterilisation in Healthcare Facilities published in 2008 by the Centres for Disease Control and Prevention and also the Processing, Reprocessing, Medical Devices in Healthcare Settings, Validation Methods, and Labelling, a draft guidance issued in May of 2011 by the Food and Drug Administration. Please refer to the latest CDC or FDA guideline for a definition of terms or for further questions.

(0:39 - 1:09)

Disinfection and sterilisation are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because sterilisation of all patient care items is not necessary, healthcare policies must identify, primarily on the basis of the items intended use, whether cleaning, disinfection, or sterilisation is indicated. More than 30 years ago, Dr. Earl Spaulding devised an approach to disinfection and sterilisation.

(1:09 - 1:45)

This classification scheme has been retained, refined, and successfully used by infection control professionals and organisations such as the FDA, EPA, and CDC. Spaulding believed the nature of disinfection could be understood readily if instruments and items for patient care were categorised as critical, semi-critical, and non-critical, according to the varying degree of risk or infection involved in the use of the items. There are too many types of sterilisation, disinfection, and cleaning to mention necessary for different types of devices, materials, and design.

(1:45 - 2:59)

Please refer to the CDC guidelines for more details. Critical Devices Critical items confer a high risk for infection if they are contaminated with any microorganism. Thus, objects that enter sterile tissue or the vascular system must be sterile because any microbial contamination could transmit disease.

This category includes surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities, just to name a few. Semi-critical Devices Semi-critical devices are devices that contain intact mucous membranes or non-intact skin. They do not ordinarily penetrate tissues or otherwise enter normally sterile areas of the body.

These devices should be reprocessed to be free from all microorganisms. However, intact mucosal surfaces are relatively resistant to small numbers of spores. Examples of semi-critical devices include endotracheal tubes, laryngoscope blades, and other respiratory equipment,

esophageal manometry probes, diaphragm fitting rings, etc.

(3:00 - 3:20)

At a minimum, certain semi-critical items require high-level disinfection using chemical disinfectants. Endoscopes are an example which contact intact mucosal surfaces and may be used with invasive devices such as biopsy forceps. Therefore, sterilisation may be preferable to high-level disinfection if feasible.

(3:24 - 3:46)

Non-critical Devices and Surfaces Non-critical items are those that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms. Examples of non-critical patient care items are bedpans, blood pressure cuffs, crutches, and computers.

(3:47 - 5:16)

In contrast to critical and some semi-critical items, most non-critical reusable items may be decontaminated where they are used and do not need to be transported to a central processing area. The CDC guideline mentions a 1991 study by Favreau and Bond which expanded this balding scheme by dividing the non-critical environmental surfaces into housekeeping services and medical equipment services, which may be something you might want to consider at your facility. Be aware that semi-critical and critical items may be used together and have different processing requirements.

Devices may also require disassembly. In addition, flexible endoscopes are particularly difficult to disinfect and easy to damage because of their intricate design and delicate materials. Meticulous cleaning must precede any sterilisation or high-level disinfection of these instruments.

Failure to perform good cleaning can result in sterilisation or disinfection failure and outbreaks of infection can occur. Both the manufacturer of the reusable medical device and user of the device have roles to play in ensuring the safe and effective reprocessing of medical devices. Provide anyone processing or handling equipment with proper standard operating procedures, training, competencies, materials or machines necessary to process, transport, and store equipment.

(5:18 - 5:26)

There are many factors that affect the efficacy of both disinfection and sterilisation. Refer to the CDC website for more information.