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Société Suisse de Stérilisation Hospitalière
Società Svizzera di Sterilizzazione Ospedaliera

HIGH LEVEL DISINFECTION, LIQUID STERILISATION WHAT IS BEHIND THE WORDS?

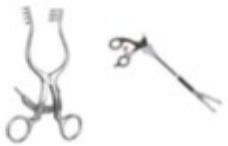
PINEAU Lionel

Eurofins Biotech Germande

SPAULDING CLASSIFICATION

To determine the level of decontamination required for a particular medical device, it is important first, to identify what is the risk associated with the use of this device.

The Spaulding classification

Patient Contact	Examples	Device Classification	Minimum Inactivation Level
Intact skin		Non-Critical	Cleaning and/or Low/Intermediate Level Disinfection
Mucous membranes or non-intact skin		Semi-Critical	High Level Disinfection ⚠
Sterile areas of the body, including blood contact		Critical	Sterilization

Decontamination and Reprocessing of Medical Devices for Health-care Facilities
World Health Organization [(a)]

The “Spaulding classification” should be applied to categorize a reused medical device (RMD) according to its intended use and the subsequent level of reprocessing required to render the RMD safe for reuse.

(a) http://apps.who.int/iris/bitstream/handle/10665/250232/9789241549851-eng.pdf;sequence=1. Last accessed 15th October 2021.

SPAULDING CLASSIFICATION

"The core principles of the Spaulding classification remains valid, however, changes have occurred over time. For example:

- Increased complexity of reusable medical device (microsurgery, endoscope, …).
- Prion, outbreak and patient susceptibility (e.g., immunocompromised patients)
- Regulators and international standard have increased the pressure on medical device manufacturers for improved, validated instructions for reprocessing (i.e. ISO 17664-1)
- **Choice of sterilization and disinfection methods has increased, is more difficult, and subject to local interpretations**."

https://wfhss-guidelines.com/reusable-medical-device/ Last accessed 15th October 2021

STERILIZATION

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Sterilization: the use of a physical or chemical procedure to destroy all microorganisms including large numbers of resistant bacterial spores.

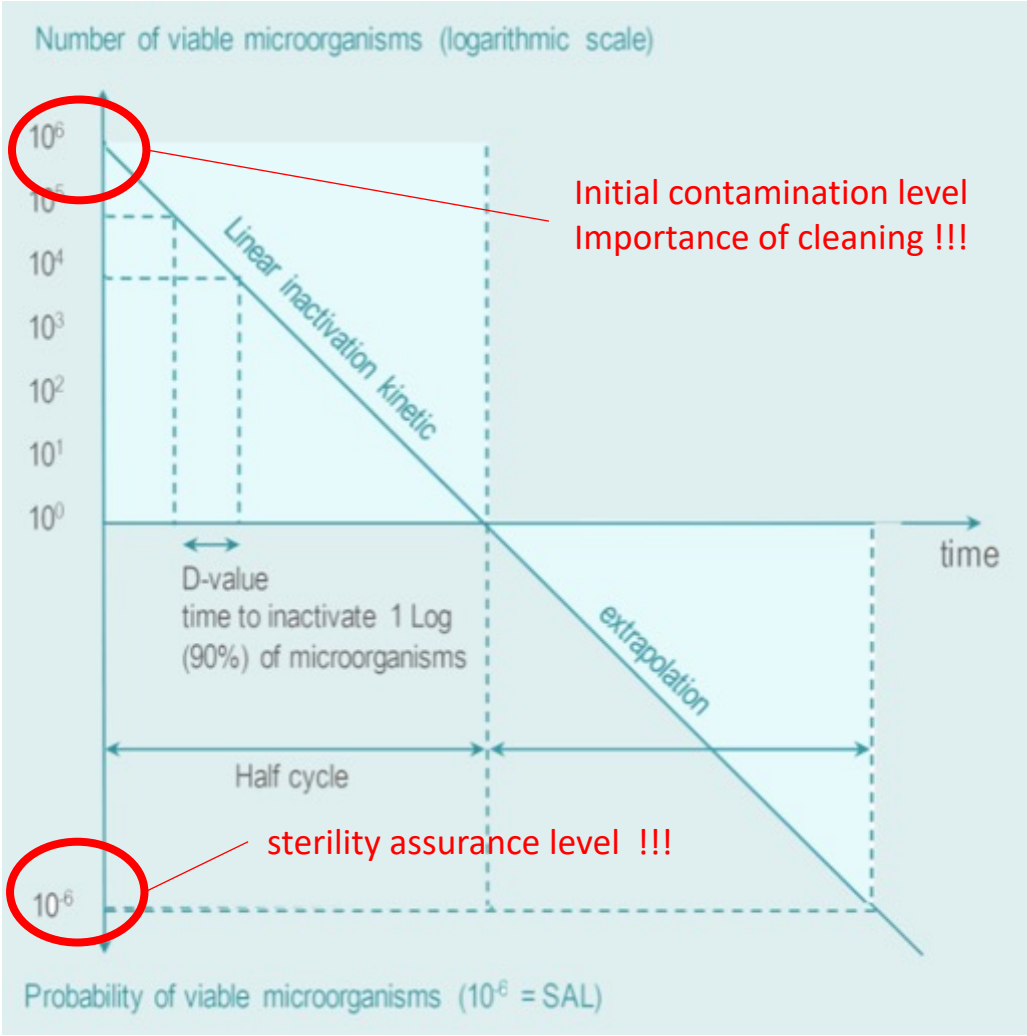
Sterile/sterility: state of being free from all living microorganisms. In practice, usually described as a probability function, (e.g., the probability of a surviving microorganism being 1 in 1,000,000).

ISO 11139:2018
Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards

Sterilization: process used to render product free from viable microorganisms

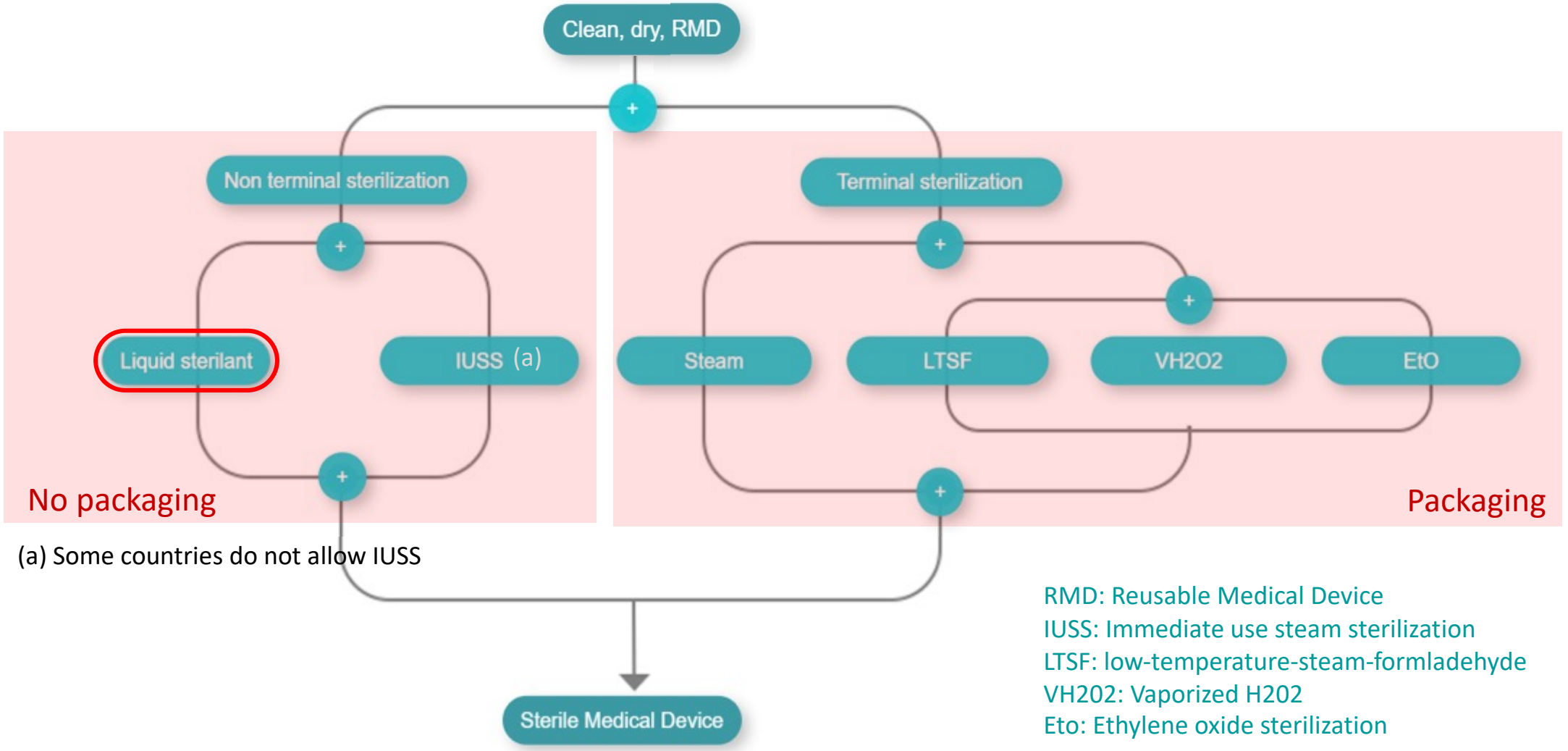
NOTE 1 to entry: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

Sterile: free from viable microorganisms



https://wfhss-guidelines.com/sterilization/ Last accessed 15th October 2021

STERILIZATION



(a) Some countries do not allow IUSS

RMD: Reusable Medical Device
IUSS: Immediate use steam sterilization
LTSF: low-temperature-steam-formladehyde
VH202: Vaporized H202
Eto: Ethylene oxide sterilization

https://wfhss-guidelines.com/sterilization/ Last accessed 15th October 2021

STERILANT

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Sterilant: a liquid chemical germicide that destroys all forms of microbiological life, including high numbers of resistant bacterial spores (1).

Several FDA-cleared liquid chemical sterilants include indications for sterilization of medical devices.

Active Ingredient(s)	Sterilant Contact Conditions	
Peracetic acid	3100-3400 ppm	2 hrs at 20ºC
	≥1820 mg/L	6 min at 46-55°C
Glutaraldehyde	3.5%	10 hrs at 25°C
	2.5%	7 hrs 40 min at 35°C
Hydrogen peroxide	7.5%	6 hrs at 20°C

No equivalent product in Europe

ISO **ISO 11139:2018 :** Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards.

Sterilant: chemical or combination of chemicals used to generate a sterilizing agent.

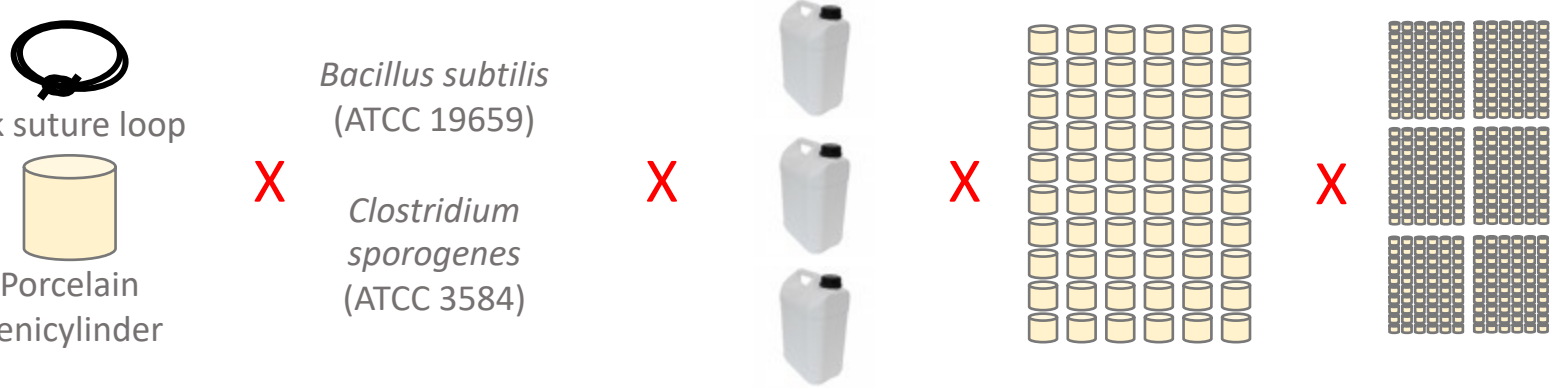
Note:In some cases, the sterilizing agent is generated by vaporizing the sterilant.

STERILANT


Guidance for Industry and FDA Reviewers

Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High Level Disinfectants

According to FDA (1), products with sterilant claims shall pass the Association of Official Analytical Chemists (AOAC) Sporicidal Test (AOAC 966.04).



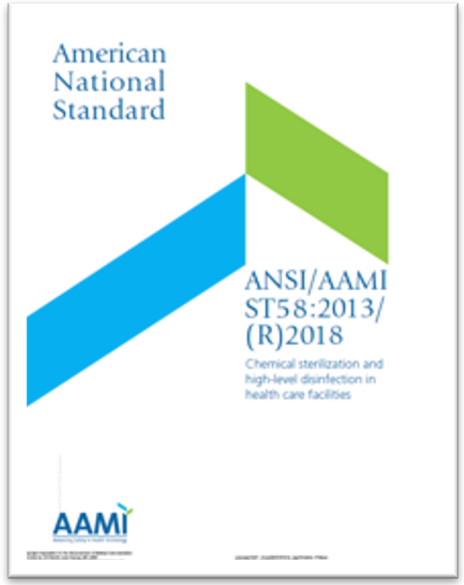
Passing citeria for sterilant : No growth from 720 tubes

2 carrier types × 2 test microorganisms × 3 product batches × 60 carriers/type = 720 carriers

Exposure of all RMD surfaces to a liquid sterilant for controlled time, temperature and concentration yields a SAL of $1.5\ 10^{-3}$.

(1) Guidance for Industry and FDA Reviewers Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High Level Disinfectants Document issued on: January 3, 2000

LIQUID STERILIZATION



ANSI/AAMI ST58:2013/(R)2018
Chemical sterilization and high-level disinfection in health care facilities

liquid chemical sterilant (LCS): Solution of a chemical that has been validated to provide microbial kill adequate to obtain FDA clearance for a sterilization label claim.

Chemical sterilants can be classified into two basic categories:

a. LCSs/HLDs in which the items to be processed are immersed manually or processed in an automated system under defined conditions
b. Gaseous chemical sterilants that are used in a sterilizer under defined cycle conditions

The microbial quality of the solution used to rinse items processed with LCSs/HLDs is an important aspect of the sterilization or high-level disinfection process.
If the device is not rinsed with sterile water, the sterility of the device will be compromised.

Medical devices processed using LCSs/HLDs should be either immediately used or stored in a manner that minimizes recontamination

LIQUID STERILIZATION

U.S. FOOD & DRUG ADMINISTRATION

https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/liquid-chemical-sterilization

Liquid Chemical Sterilization

Liquid chemical sterilization involves a two-part process:

- Devices are treated with a liquid chemical germicide (LCG).
- The processed devices are rinsed with water to remove the chemical residues.

There are several limitations with liquid chemical sterilization. Although the rinse water is treated to minimize any bioburden, it is not sterile.

Because the rinse water is not sterile, devices rinsed with this water cannot be assured to be sterile. Furthermore, devices cannot be wrapped or adequately contained during processing in a liquid chemical sterilant. This means that there is no way to maintain sterility once devices have been processed.

Recommendations

For the reasons stated above, FDA recommends that the use of liquid chemical sterilants be limited to reprocessing only critical devices that are heat-sensitive and incompatible with sterilization methods such as steam and gas/vapor/plasma low temperature processes.


CLINICAL—BILIARY

Randomized Comparison of 3 High-Level Disinfection and Sterilization Procedures for Duodenoscopes

Randomized Comparison of 3 High-Level Disinfection and Sterilization Procedures for Duodenoscopes (1)

- 3 months study
- 516 endoscopes
- Samples were collected from the elevator mechanism and working channel of each duodenoscope.

In a comparison of duodenoscopes reprocessed by sHLD, dHLD, or HLD/ETO, we found no significant differences between groups for MDRO or bacteria contamination.

Enhanced disinfection methods (dHLD or HLD/ETO) did not provide additional protection against contamination.

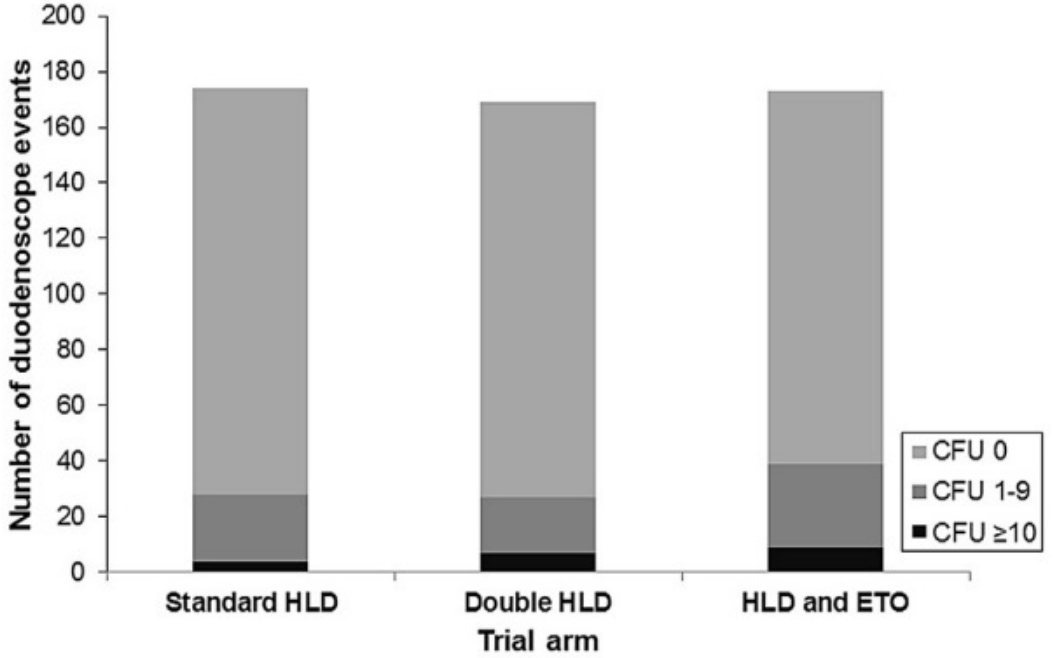


Figure 1. Frequency of no growth (0 CFU), low quantity of growth (1–9 CFU), and significant quantity of growth (≥10 CFU) in each of the trial arms. CFU, colony-forming units; ETO, ethylene oxide gas sterilization; HLD, high-level disinfection.

(1) Graham M. Snyder et all. Randomized Comparison of 3 High-Level Disinfection and Sterilization Procedures for Duodenoscopes. Gastroenterology 2017;153:1018–1025

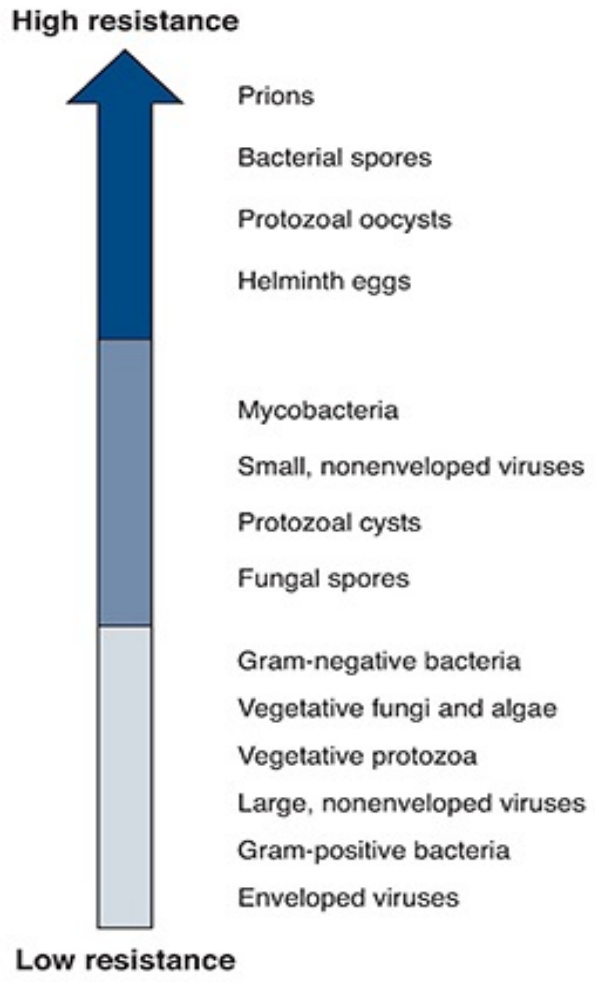
Does sterile reprocessing of thermolabile flexible endoscopes in endoscope washer-disinfectors increase the safety margin ? (1)

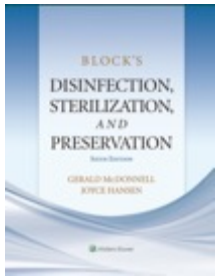
Reaching a higher safety margin by increasing one or more disinfection parameters (e.g. concentration, temperature, time) is possible but several issues need to be addressed before being able to claim that endoscopes are sterile after LCS in EWD:

- Make sur that the cleaning step was performed properly, (or demonstrate that cleaning is not necessary)
- Because the rinse water is not sterile, devices rinsed with this water cannot be assured to be sterile.,
- Ensure that all surfaces of the endoscope are submitted to the same disinfection efficacy level (i.e. contact surfaces between endoscope and connector),
- Devices cannot be wrapped or adequately contained during processing in a LCS (no way to maintain sterility once devices have been processed).

(1) Dr. Birgit Kampf* Prof. Dr. rer. nat. Heike Martiny, Dr. Lionel Pineau Does sterile reprocessing of thermolabile flexible endoscopes in endoscope washer-disinfectors increase the safety margin? Zentralsterilization 288 - Volume 28 - 5/2020

HIGH LEVEL DISINFECTANT





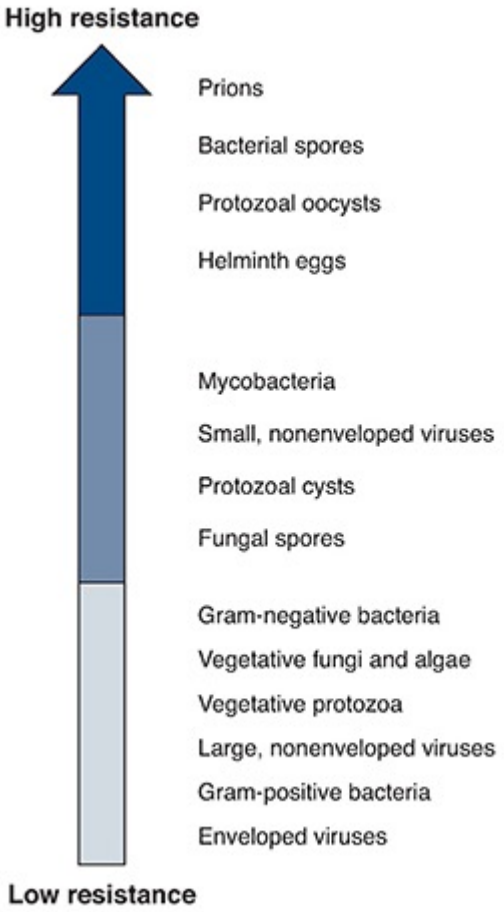
McDonnell, Gerald. ***Block's Disinfection, Sterilization, and Preservation****. Available from: Wolters Kluwer, (6th Edition). Wolters Kluwer Health, 2020*

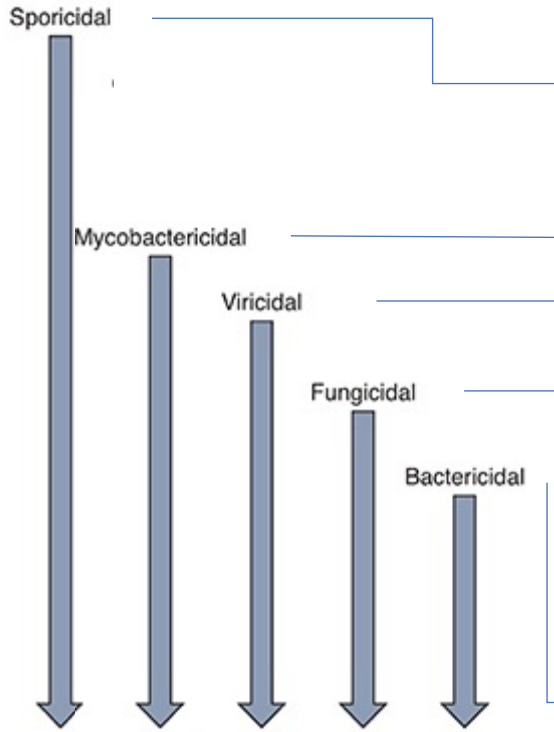
Hierarchy of the various types of micro-organisms and their resistance profiles to inactivation.

The resistance profiles can vary depending on the specific antimicrobial method under investigation, and this profile is given as a guide.

From a labeling (and therefore legal) point of view, the disinfectant may be further defined based on the ability to inactivate different groups of microorganisms using specific terms.

HIGH LEVEL DISINFECTANT





cen	FDA
EN 17126 (S – 4 $\log_{10}$)	AOAC 966.04 (C – 6 $\log_{10}$)
EN 14348 (S – 4 $\log_{10}$) EN 14563 (S – 4 $\log_{10}$)	AOAC 965.12 (C – 4 $\log_{10}$)
EN 14476 (S – 4 $\log_{10}$)	ASTM E1053.11 (C – 4 $\log_{10}$)
EN 13624 (S – 4 $\log_{10}$) EN 14562 (C – 4 $\log_{10}$)	AOAC 965.17 (C – 4 $\log_{10}$)
EN 13727 (S – 5 $\log_{10}$) EN 14561 (C – 5 $\log_{10}$)	AOAC 955.15 (C – 6 $\log_{10}$) AOAC 955.14 (C – 6 $\log_{10}$)

SPORICIDAL ACTIVITY

TGA instructions for disinfectant testing

A sterilant is a chemical agent, other than a gas, which is used to sterilise critical medical devices. A sterilant kills all microorganisms with the result that the sterility assurance level of a microbial survivor is ≤ 10 -6

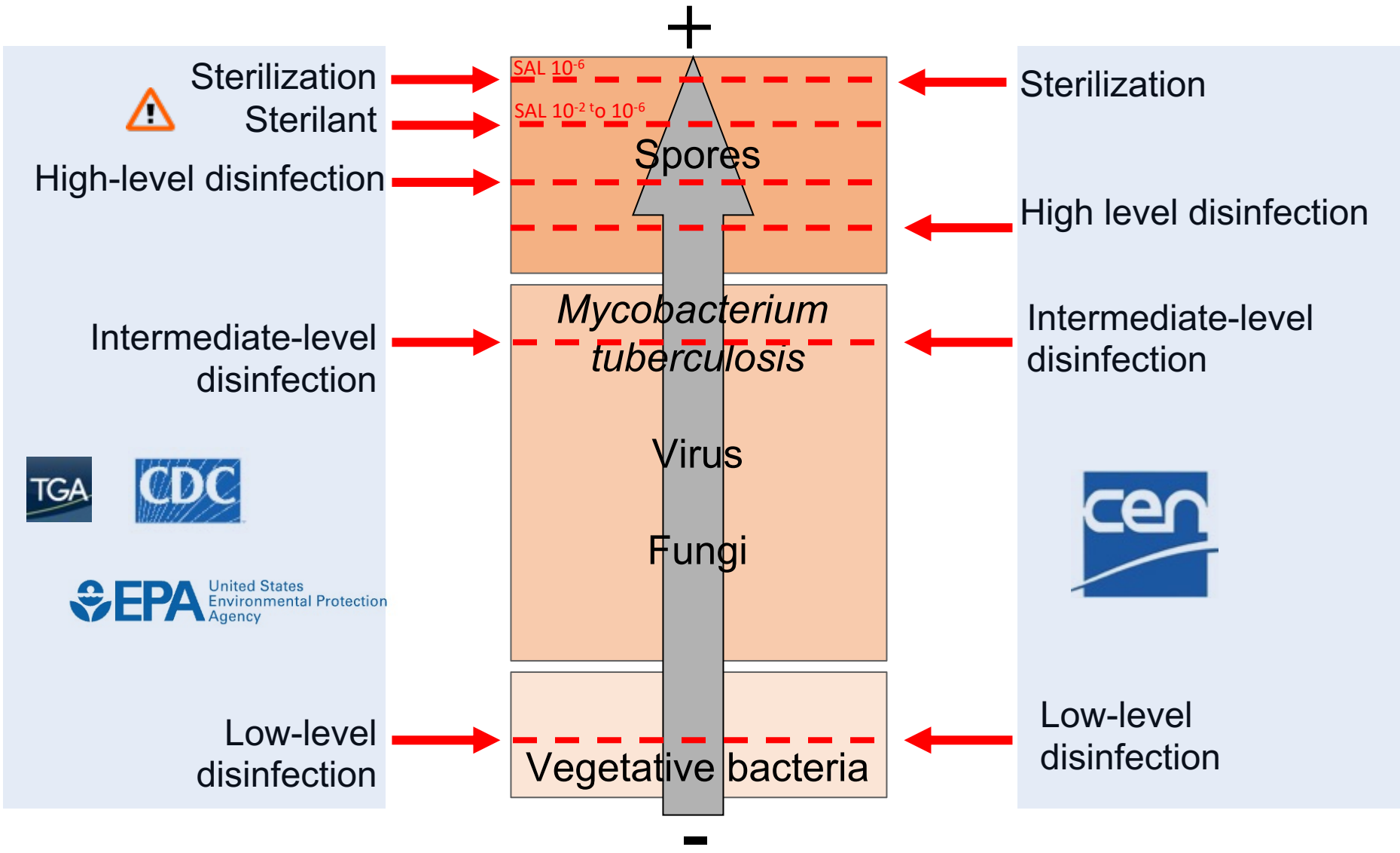
A high level disinfectant may be regarded as a subcategory of a sterilant, but exposure time is shorter than required for sterilisation. A high level disinfectant kills all microbial pathogens, except large numbers of bacterial endospores when used as recommended by the manufacturer, and is the minimum treatment recommended for the reprocessing of a semicritical medical device.

For a sporicidal claim, a 6-$\log_{10}$ reduction in spores is required.

- AOAC Sporicidal Test (AOAC 966.04), growth is allowed from two carriers or less.
- ASTM E2197, with acceptance criteria as for the AOAC Sporicidal Test.
- EN 1712625 modified to show a 6-log10 reduction in spores over the labelled exposure time

https://www.tga.gov.au/sites/default/files/disinfectants-evaluation-guidelines.pdf . Last accessed 15th October 2021

HLD, LIQUID STERILISATION, WHAT IS BEHIND THE WORDS?



MICROORGANISM SURVIVAL LEVELS VS CONTACT TIME

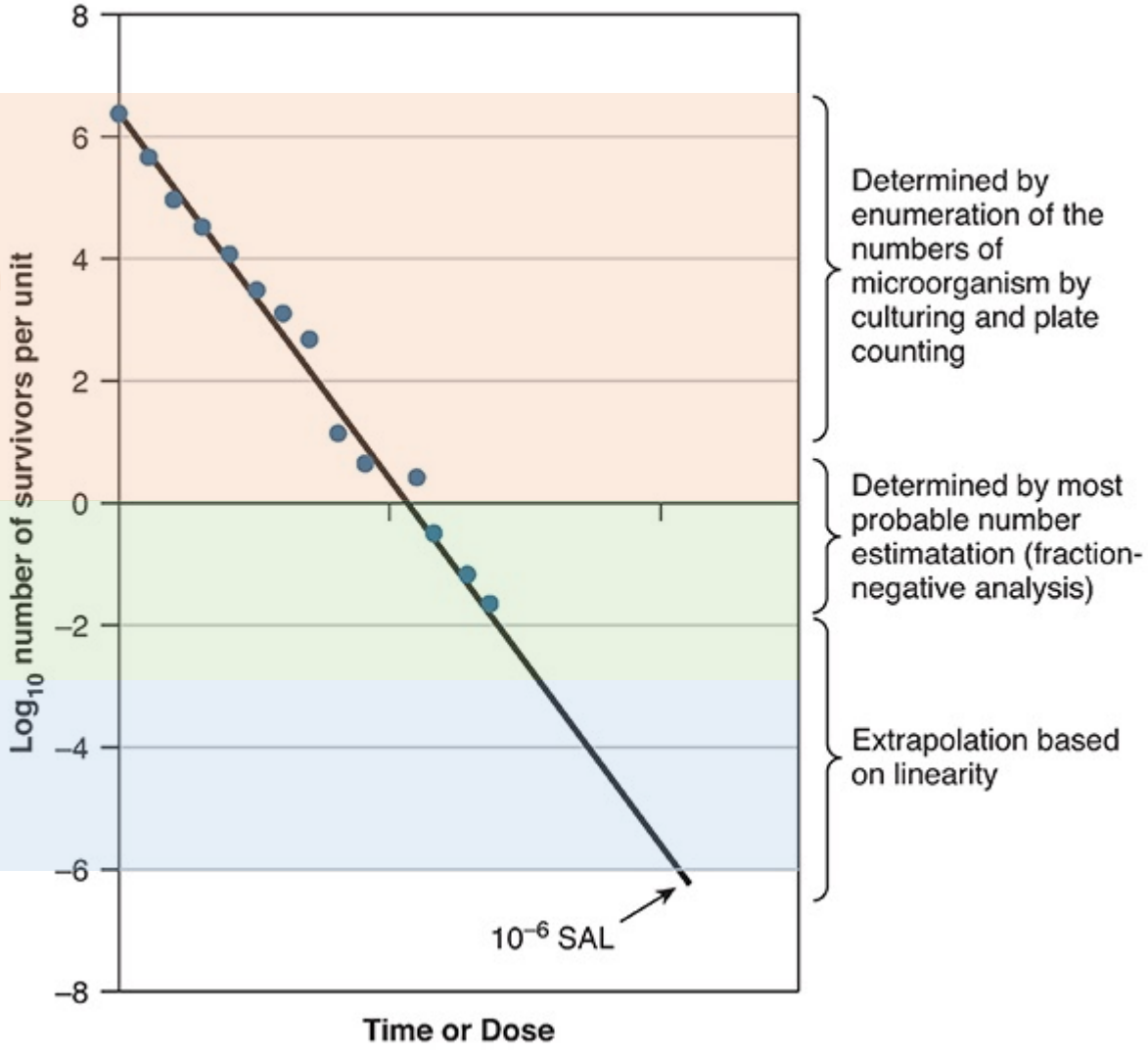
Low level disinfection

Intermediate level disinfection

High level disinfection

Sterilant/Liquid sterilization

Sterilization



McDonnell, Gerald. Block's Disinfection, Sterilization, and Preservation. Available from: Wolters Kluwer, (6th Edition). Wolters Kluwer Health, 2020.

REPROCESSING OF CRITICAL AND SEMI-CRITICAL DEVICES

Point of use processing — Eliminate gross soil, reduce microbial load and avoid drying of soils

↓

Cleaning — Reduce soil to a level now defined by ISO 15883-5, further reduce microbial load and ensure efficacy of sterilization and disinfection

↓

Terminal sterilization	Non Terminal sterilization	Liquid sterilant ?	HLD
Universal definition for healthcare facilities (overkill concept) Above 6 log of highly resistant spores Less than 10^{-6} risk of a surviving germ		**No universal definition**	
Protection until use by a sterile barrier system	No protection after reprocessing. Immediate use	Rinsing with sterile/treated water Immediate use	Rinsing with 0.2µm filtered water Storage cabinet
Ex.: Steam, H_2O_2, EO, LTSF ……	Ex: IUSS (not recommended by guidelines)	Ex: critical devices that are heat-sensitive	Ex: AER – 15883-4

High ⟵ Level of Sporicidal activity ⟶ Some

CONCLUSIONS

There are many chemicals and/or processes available to reprocess reusable medical devices in order to allow their safe reuse.

Everyone seems to agree on the definition of sterilization and on the importance of cleaning but for disinfection or liquid sterilant:

- The terms used to define the efficacy level required vary from one country/region to another,
- The methods used to evaluate these products/processes and validate the manufacturer's claims do not provide the same safety level.

Internationally harmonized practices and definitions are still needed to allow users to select the best technologies at the right time, place, and under the right controls and ensure the optimal use of these technologies.


THANK YOU
FOR YOUR ATTENTION