Decontamination of Reusable Invasive Medical Devices (RIMD)

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Clinical Nurse Manager 3 Central Decontamination Unit and Decontamination Lead

Presentation Contents

- The forefathers of decontamination
- Overview of decontamination Principles and guidelines
- Cleaning
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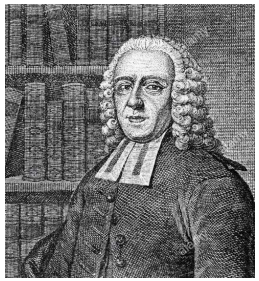
- Sterilisation
- Spaulding
- Log reduction
- EN Standards /HTM

The forefathers of decontamination

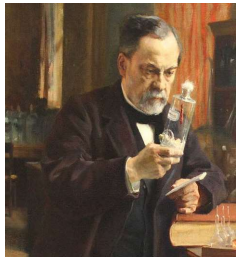
1683, Antonie van Leeuwenhoek, developed the microscope and the existence of microorganisms is proven.



1758 Dr. Johann Julius Walbaum formed a glove from the intestines of sheep and used it to deliver babies. This was the earliest known surgical glove.

Ignaz Semmelweis, a Hungarian obstetrician, in **1847** proved the value of hand washing and nail washing.

The forefathers of decontamination



1862, French chemist and microbiologist Louis Pasteur published his findings on how germs cause disease, which he later used to develop the pasteurization process.

Robert Koch and his associates in **1881** researched the disinfecting properties of steam and hot air. This marked the beginning of the science of disinfection and sterilization.

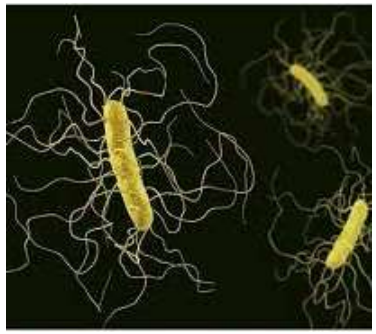
Nightingale was one of the first infection prevention and control advocates, through her promotion of **sterilisation, hand-washing** and cleanliness.

Earle H Spaulding (**1968**) proposed that a medical device should be disinfected or sterilized depending on how the device was used.

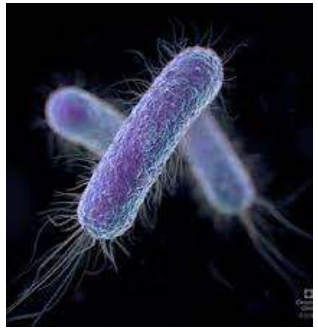
Decontamination – why?

We decontaminate to prevent cross contaminating our patients with life altering and potentially fatal diseases. We can prevent and control the risk of patients acquiring a nosocomial infections by considering how we decontaminate our equipment.

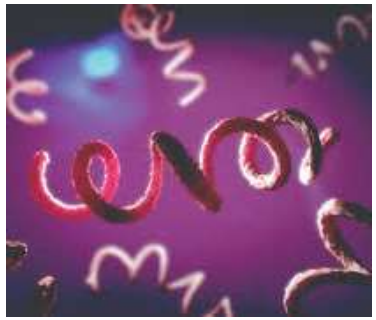
BACTERIA



C. Difficile



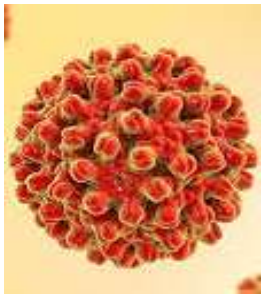
E. Coli



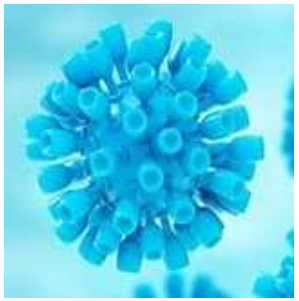
Syphilis

MRSA

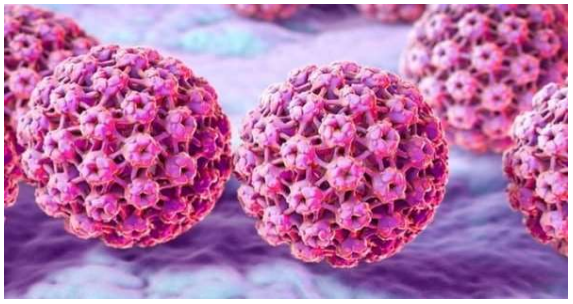
VIRUSES



Hepatitis B

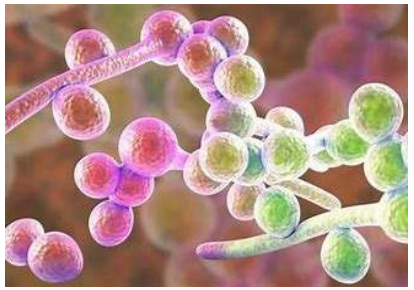


HIV



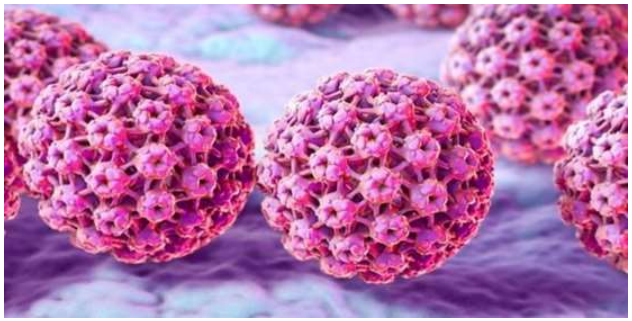
HPV

FUNGI

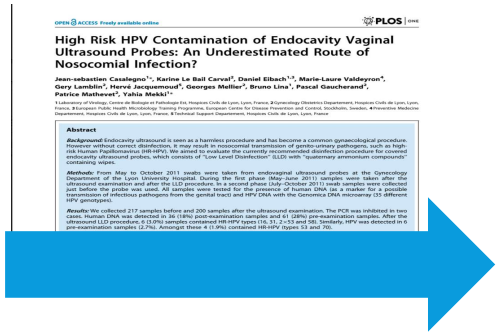


Candida auris

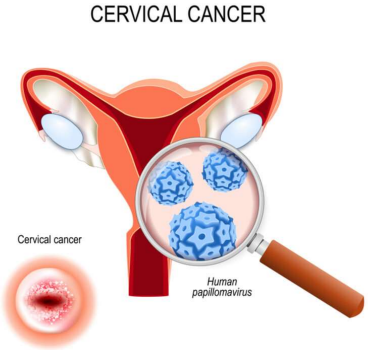
Bacteria, fungi, viruses, mycobacteria and spores that can cause life altering diseases

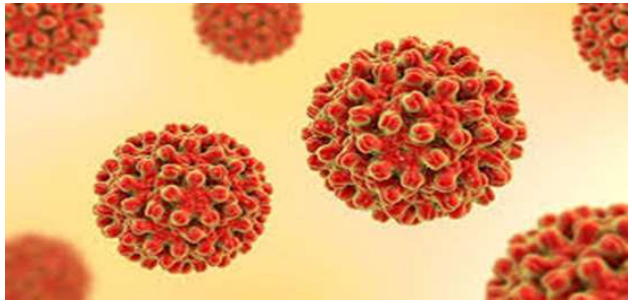


Human papilloma virus

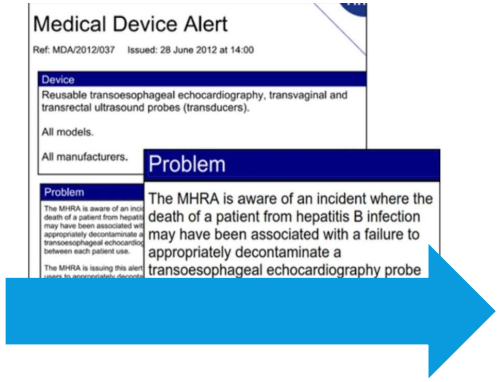


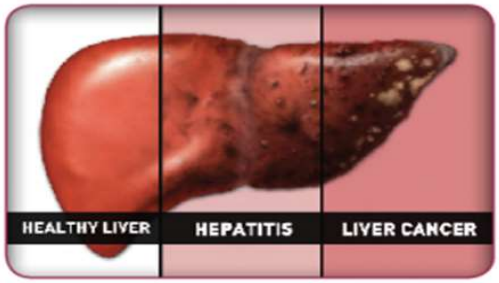
High Risk HPV Contamination of Endocavity Vaginal Ultrasound Probes: An Underestimated Route of Nosocomial Infection?





Hepatitis B

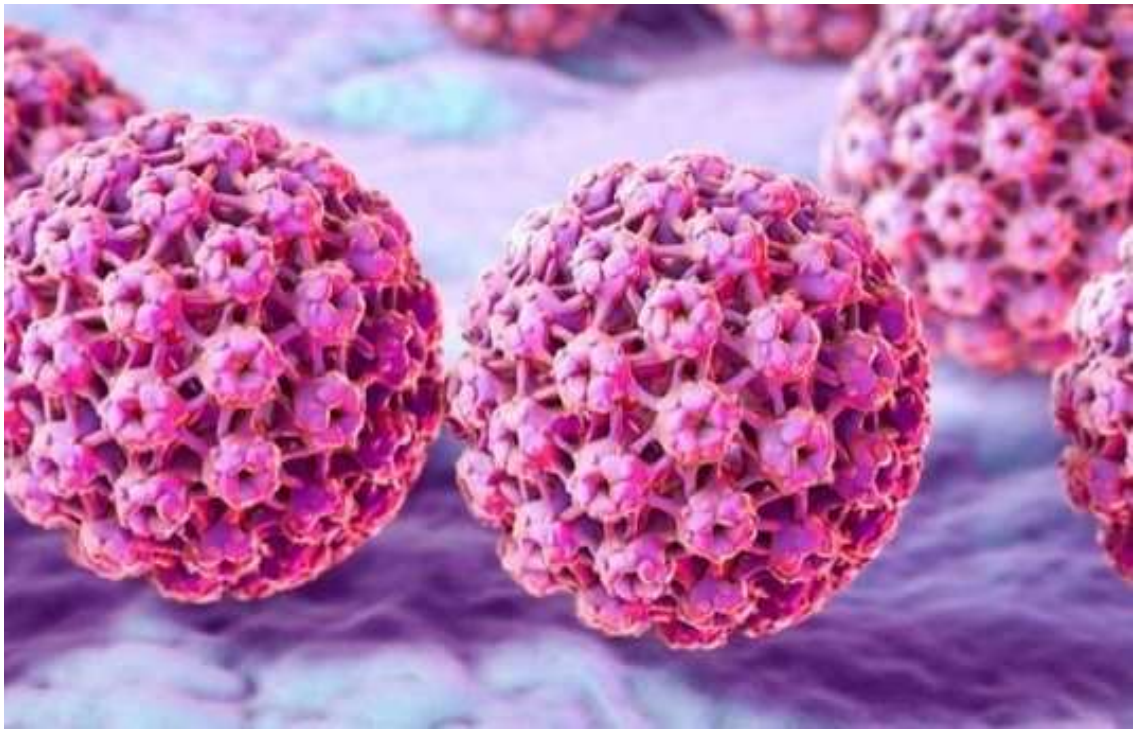




Healthcare associated infections

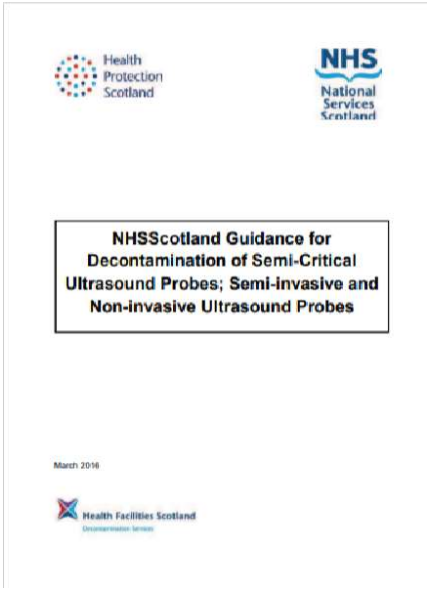
- Healthcare associated infections are the most frequent adverse event in healthcare delivery worldwide (World Health Organisation)

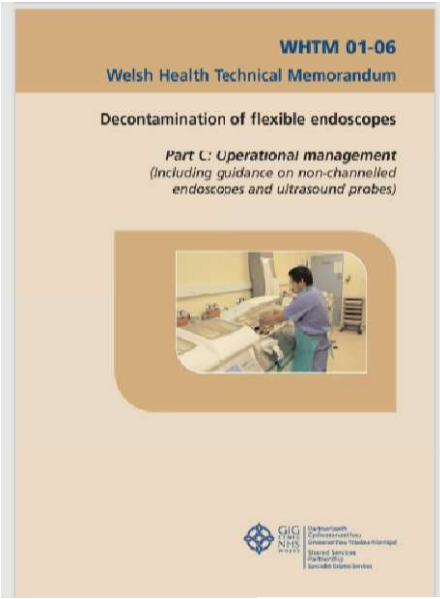
- Nosocomial infections can survive for months on inanimate objects (Kramer et al. 2006)

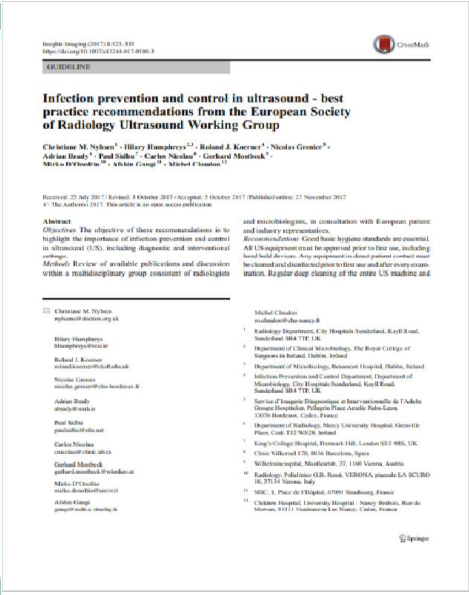


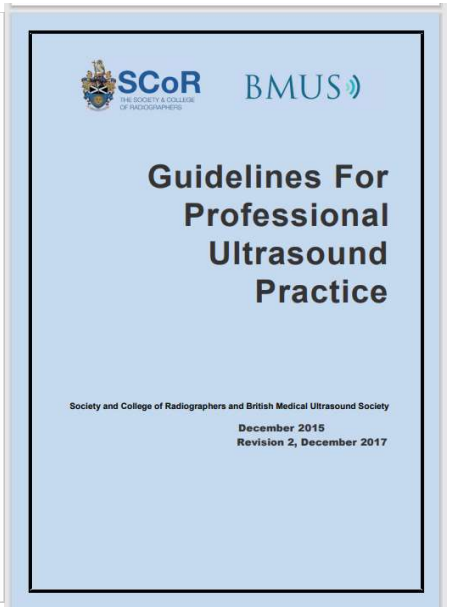
Human Papilloma Virus

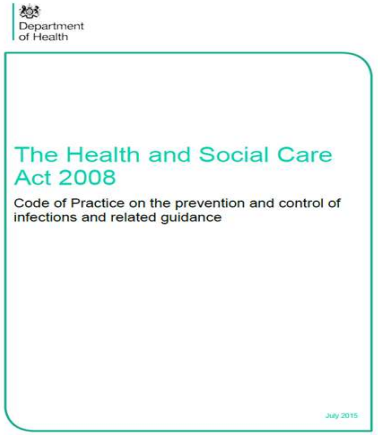
Guidance documents

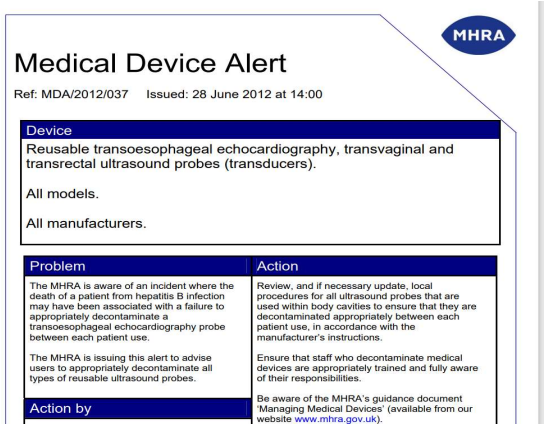




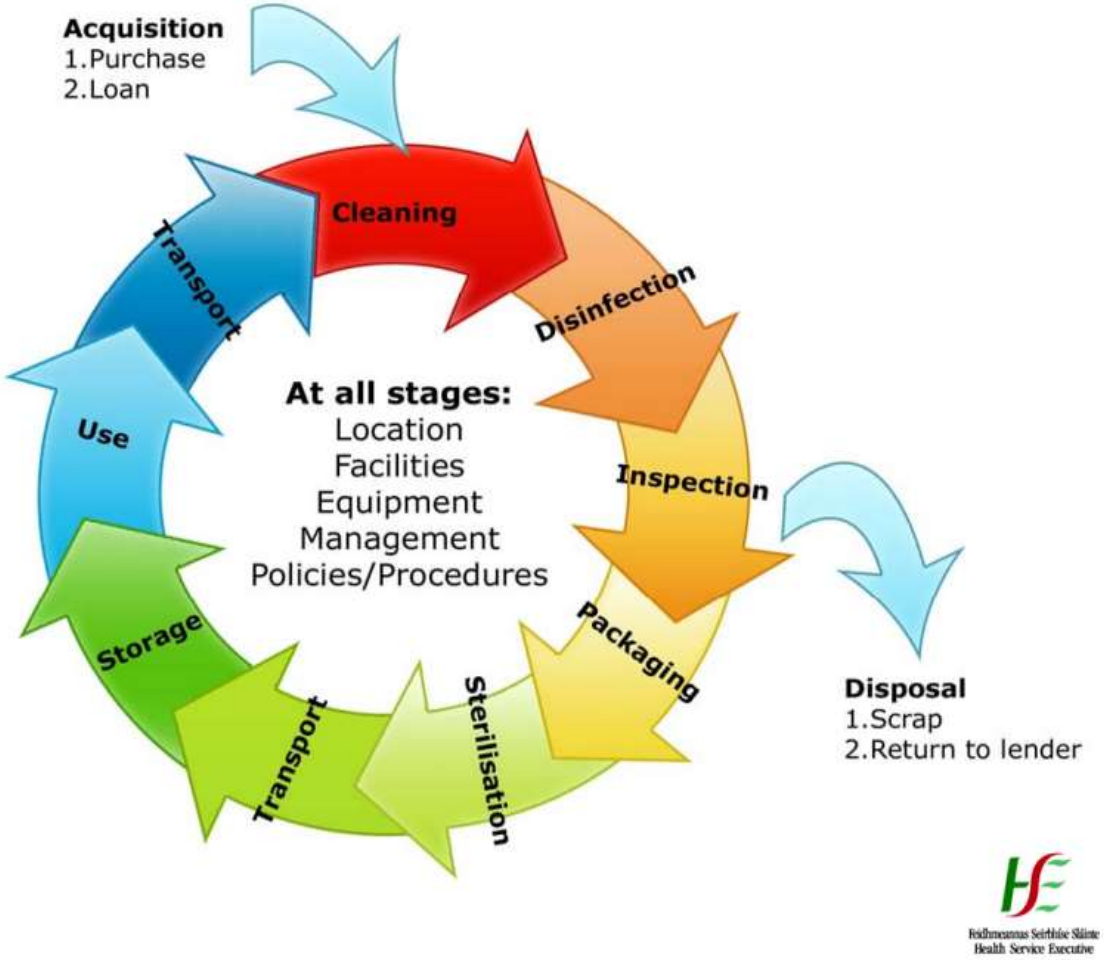








Decontamination lifecycle



Note: The lifecycle diagram used in this document is © Crown Copyright. Source—Department of Health, United Kingdom

Things to consider when choosing which decontamination process you should invest in

- What is the treatment the patient is undergoing - what level of decontamination is required (Spaulding Classification)
- What decontamination conditions is the medical device compatible with – will they tolerate heat / chemicals / pressure / moisture etc?
- How long does the decontamination cycle take – does it require a person to spend time physically undertaking the decontamination or can a person attend to other tasks while the device is being decontaminated?
- How is the process validated?
- Is the process quality assured and is the same quality repeatable - what are the variables – human error etc?
- Is there any risk to the person undertaking the decontamination – chemical risk etc, what PPE are required?
- Will there be training required and facilitated?
- Is the process cost effective?
- If purchasing a new medical device – is it compatible with your existing decontamination systems prior to purchase?

Guidelines: ensure probe compatibility with disinfection

- Probe damage from incompatible disinfection products may void probe warranties.
- Check disinfection products are compatible in probe instructions for use. Look out for disclaimers.
- Device damage can lead to infection risk:
  - Damaged seal between cable and body of surgical probe was a contributing source to contaminant reservoir that led to a Serratia marcescens outbreak.[5]

Werkgroup Infectie Preventie (Netherlands)
"Is the disinfectant suitable for disinfection of the intended medical tools? Important aspects are corrosion of materials, reaction materials from the medical device to the disinfectant and the adsorption of disinfectant residues. If necessary, consult with the manufacturer or supplier of the relevant medical device or the disinfectant is compatible with it."[1]

Hoge Gezondheidsraad/Conseil Supérieur de la Santé (Belgium)
"Check the compatibility with the DM to be disinfected (tests carried out by the manufacturer or by the manufacturer of the DM to be disinfected)".[3]

KRINKO/BfArM (Germany)
"Effects of the reprocessing procedure on material properties and technical-functional safety tend to be product-specific. They must therefore be verified on an individual basis, declared in the manufacturer's instructions for reprocessing, where appropriate indicating the tests or checks to be carried out after reprocessing, and must be taken into account by the operator in the standard operating procedures."[2]

Direzione Sanitaria AUSL Pescara
"When choosing a disinfectant to be used for patient care devices, the chemical compatibility of the object must also be taken into consideration, if subjected to repeated treatments."[4]

1. Werkgroep Infectie Preventie (2017). Reiniging, desinfectie en sterilisatie van medische hulpmiddelen voor hergebruik niet-kritisch, semi-kritisch of kritisch gebruik: 56. TRANSLATED FROM DUTCH
2. Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO), and Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM).
3. Hoge Gezondheidsraad/Conseil Supérieur de la Santé. 2019.. TRANSLATED FROM FRENCH
4. Direzione Sanitaria AUSL Pescara (2009). TRANSLATED FROM ITALIAN
5. Géry, et. al. J Hosp Infect. 2021 May;111:184-188. doi: 10.1016/j.jhin.2020.12.025. Epub 2021 Feb 12. PMID: 33582202.

Medical Device Directive 93/42/EEC

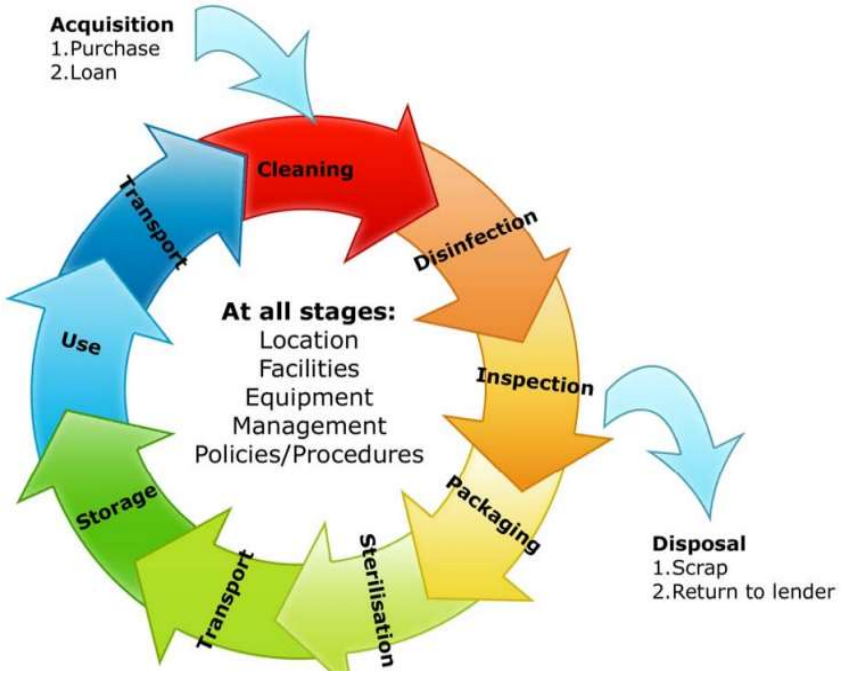
- In May 2021 the Medical Device Directive has been replaced with the new Medical Device Regulation.

- The MDR states that medical device manufacturers must provide details on how to decontaminate the device. The manufacturers must supply instructions for use and instructions on how to clean, disinfect and sterilise the device.

- Users need to ensure the disinfection product is designed for invasive devices and CE marked. The intended use of the disinfection product needs to match the clinical application of the device to be disinfected.

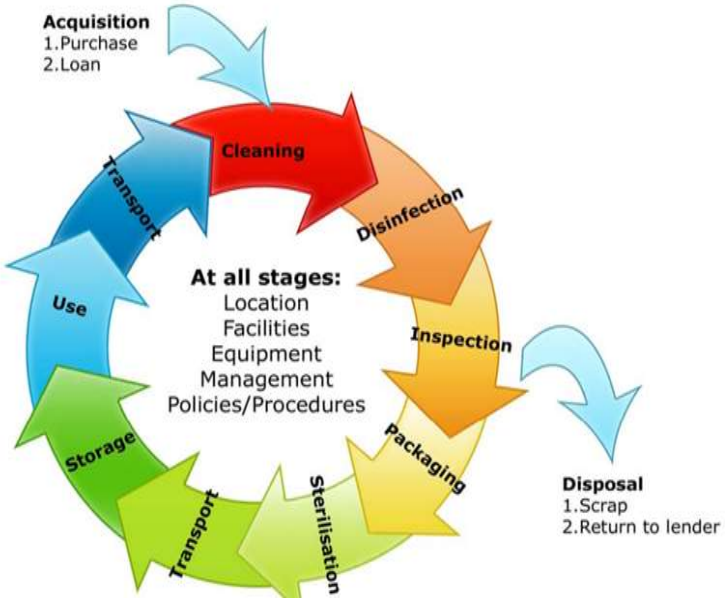
- Decontamination is the combination of processes - cleaning, disinfection and sterilisation. Each of these processes are used to help to remove or destroy contamination, including micro organisms. This renders the Reusable Invasive Medical Device safe for handling by staff and for use on our patients.

- Effective decontamination of RIMD is an essential component in the prevention of healthcare associated infection.



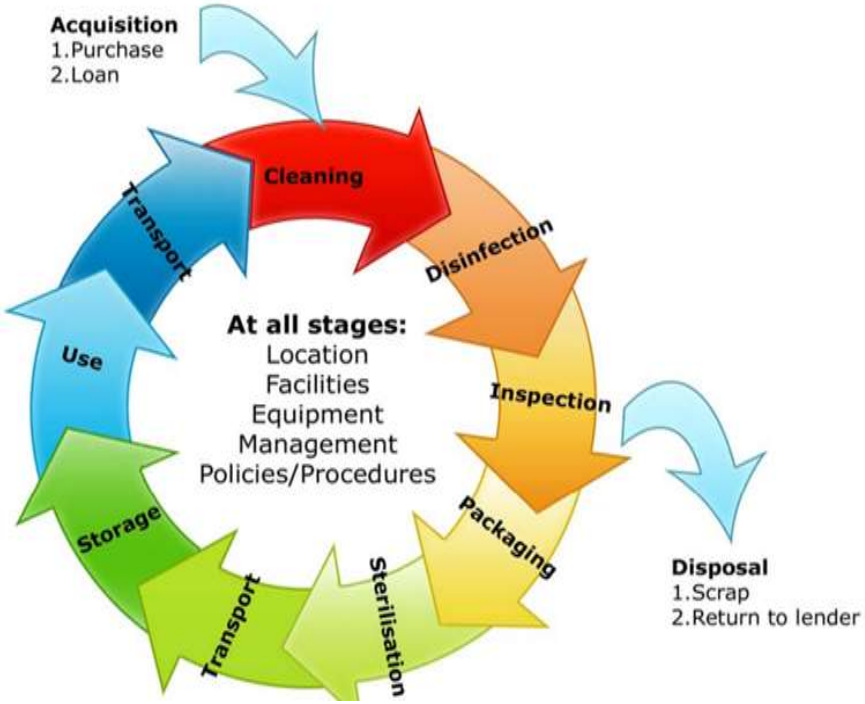
Cleaning

- Cleaning is the process that physically removes soiling including large numbers of microorganisms and the organic material on which they thrive.
- Cleaning should be done as soon as possible to avoid biofilm build up.
- Cleaning is essential and the most important step in reprocessing any medical device. Improper cleaning "will" render subsequent disinfection/sterilisation ineffective.
- Extra care and attention should be given to indentations or complex surfaces where matter can harbour and multiply.
- The RIMD IFU should always be consulted for cleaning instructions and lists of compatible products.
- Caution should be taken to prevent aerosol creation that could be ingested or contaminate otherwise clean surfaces.
- The cleaning method should be indicated for use on an RIMD, be effective, be compatible with the RIMD and be safe for the user.
- Ensure appropriate PPE is available for staff to undertake the cleaning process.
- Perform rinsing if required by the IFU of the cleaning product.
- At the conclusion of the cleaning process, the RIMD should be dried using lint-free cloths to prevent interference in subsequent steps.
- A good standard of cleaning is a prerequisite to effective disinfection and sterilisation.



Disinfection

- Disinfection describes a process that destroys many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial spores.
- Low Level Disinfection: Low-Level Disinfectants (LLD) are used to disinfect noncritical items that come into contact with skin.
  - This includes shared patient-care devices that staff would use on multiple patients through the course of any given work day, including hard surfaces like bed rails and equipment like blood pressure cuffs.
  - These usually come in the form of alcohol or detergent wipes.



High level disinfection (HLD)

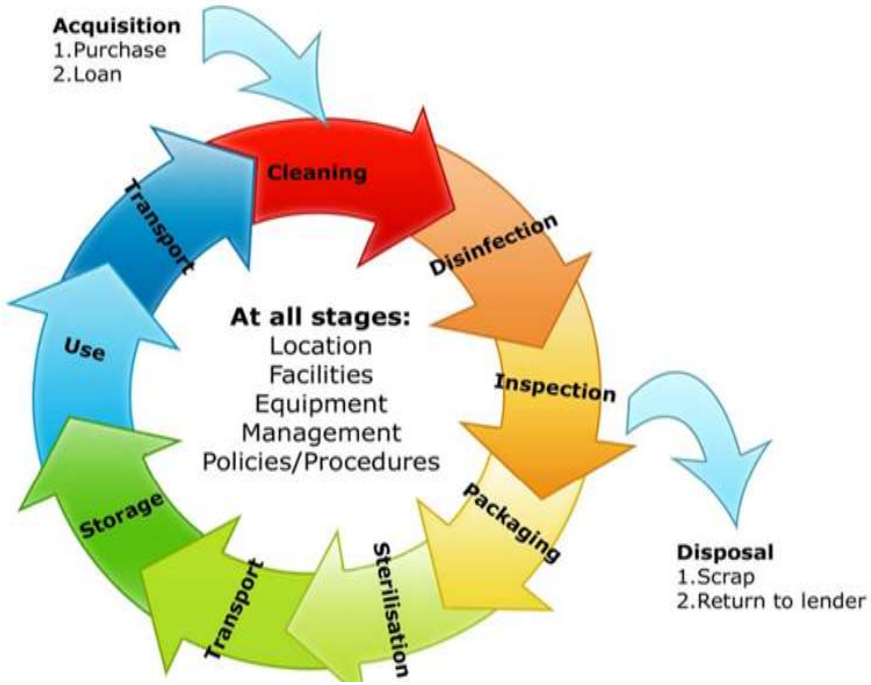
- High-Level Disinfectants (HLDs) are used in healthcare to kill microorganisms on medical devices such as endoscopes, ultrasonic probes, and cardiac catheters, in order to prevent the transmission of infectious diseases. HLDs are often formulated with aldehydes, peroxides, peracetic acid and Ultraviolet light.

- **High-level disinfection** traditionally is defined as **complete elimination of all microorganisms** in or on an instrument, **except for small numbers of bacterial spores.**

- In Europe, there is no regulatory definition of HLD and this claim is not controlled by regulators. So be careful that the High Level Disinfectant you choose is actually fully bactericidal, fungicidal, virucidal and mycobactericidal versus just a sporicidal wipe or virucidal spray.

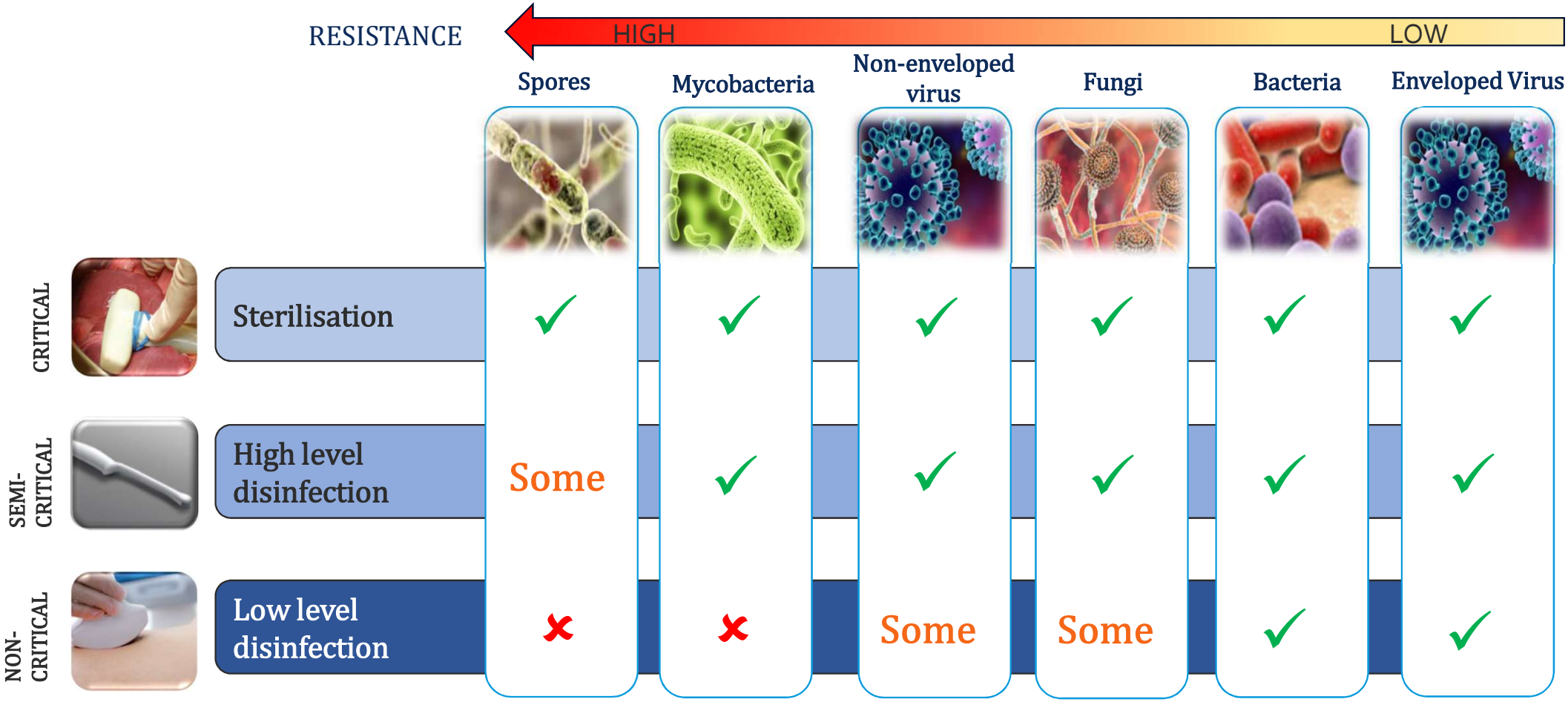
Sterilisation

- Sterilisation refers to a physical or chemical process that completely kills or destroys all forms of viable microorganisms from an object, including spores but excluding Prions.
- Sterility is an absolute condition - an item is either sterile or not sterile.
- When describing a sterilisation process, it is impossible to say that the chance of an organism surviving a process is zero.
- For medical equipment, it is acceptable to achieve a sterility assurance level of one in a million chances of a single organism surviving the process.
- This is called a Sterility Assurance Level (SAL) of 10^{-6}
- Methods of sterilisation include heat, chemical and radiation.
- Not all medical devices are suitable for undergoing sterilisation because of the delicate nature of the device for example some endoscopes and ultrasound probes cannot be exposed to high temperatures - they could end up like the next slide .....



Karren Staniforth
NUH Microbiologist (Decontamination)

Disinfection efficacy spectrum



Spaulding Classification

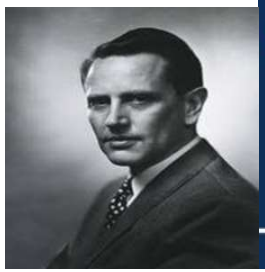
- Earle Spaulding of Temple University in 1968 published a paper on "Chemical disinfection of medical and surgical materials. Disinfection, sterilisation and preservation".

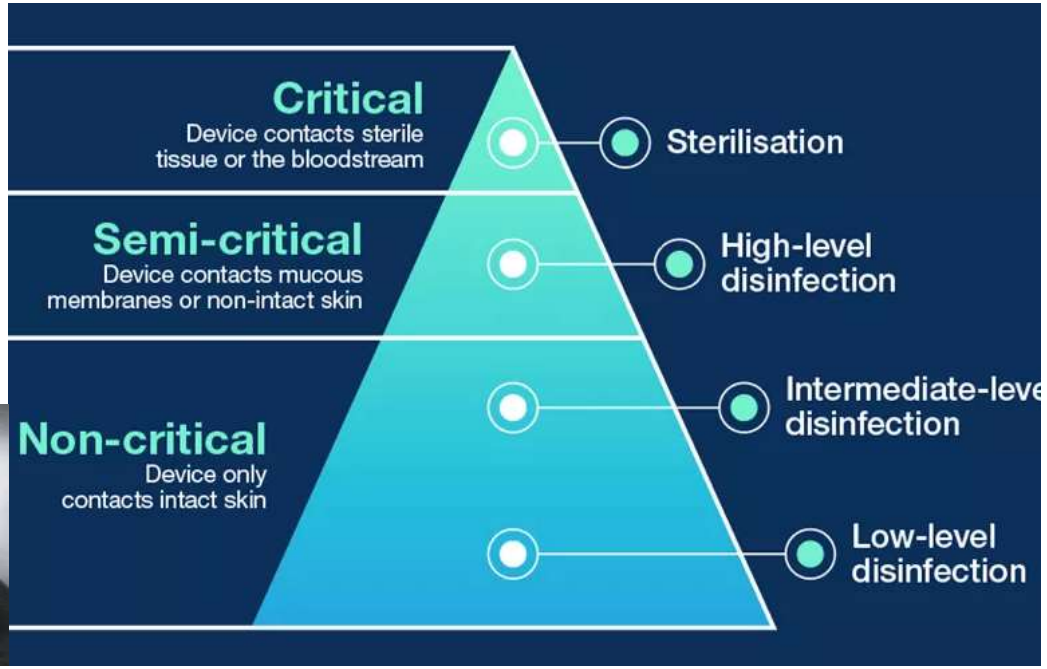
- He proposed a strategy for sterilization or disinfection of inanimate objects and surfaces based on the degree of risk involved in their use.

- Each RIMD should be classified according to the Spaulding criteria based on its intended use.

- Medical devices can be classified into three categories based on the patient tissues they contact and associated infection transmission risk.

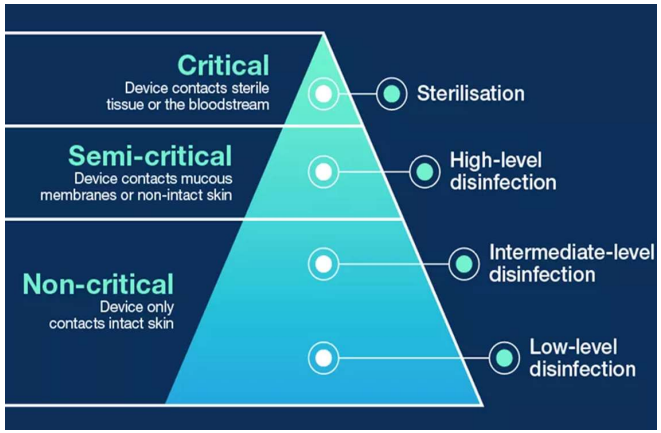
- The Spaulding Classification system dictates the level of disinfection/ sterilisation required for a reusable medical device.



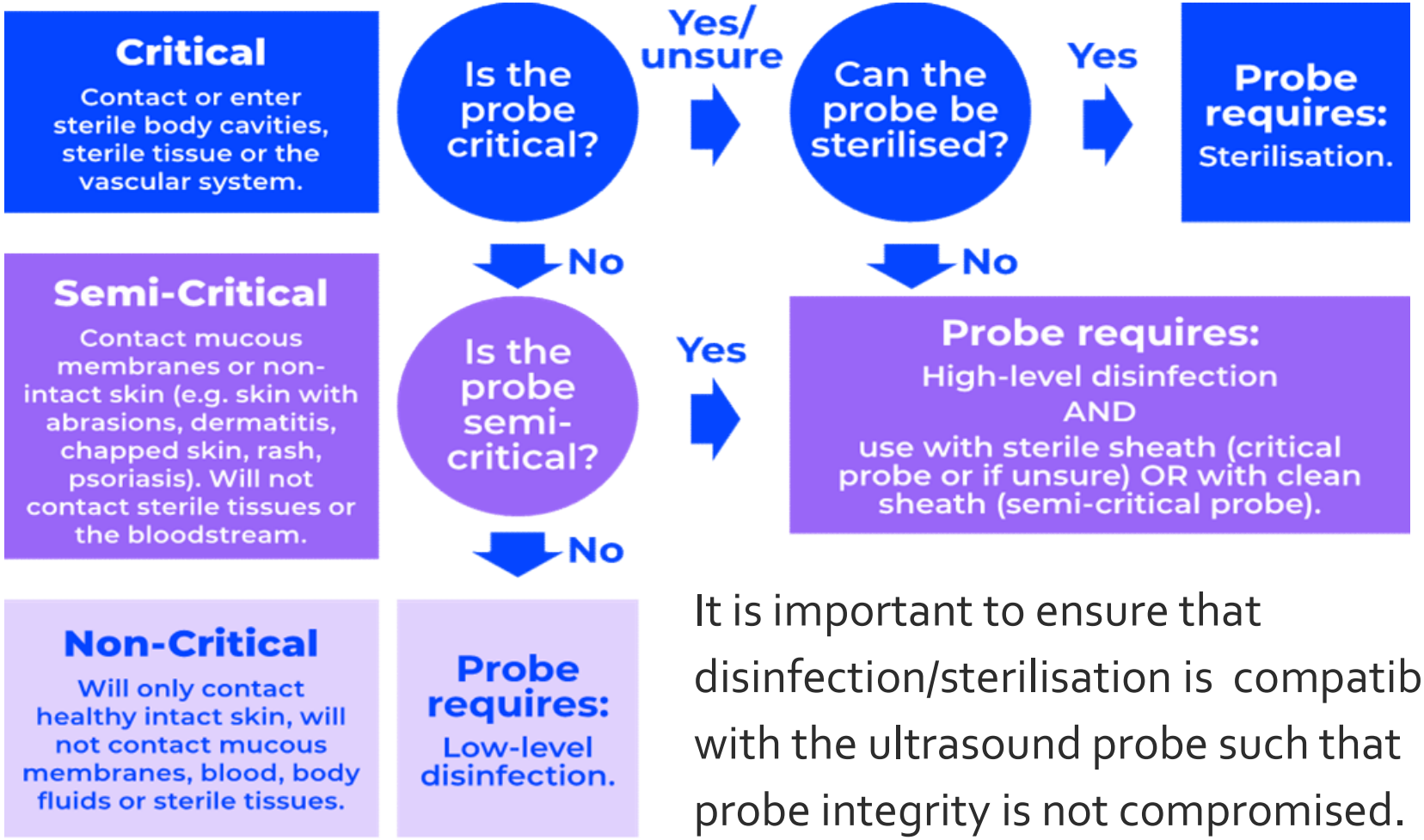


Decontaminating ultrasound probes

- **Non-Critical ultrasound probes**
  - Will only contact healthy intact skin, will not contact mucous membranes, the bloodstream or sterile tissues.
  - Require a minimum of low-level disinfection (LLD).
  - Example procedures where the ultrasound probe is non-critical include abdominal scans on healthy skin.
- **Semi-Critical ultrasound probes**
  - Contact mucous membranes or non-intact skin (e.g. skin with abrasions, dermatitis, chapped skin, rash, psoriasis). Semi-critical probes do not contact sterile tissues or the bloodstream.
  - Require a minimum of high-level disinfection (HLD) so that the device is free from all microorganisms except for a small number of bacterial spores.
  - Example procedures where the ultrasound probe is semi-critical include:
  - Endocavity ultrasound of healthy mucosa (e.g., transvaginal, transrectal, transoesophageal echocardiography scans)
  - Abdominal or other diagnostic scans on non-intact skin
  - Surface wound assessment (e.g. partly healed wound)
- **Critical ultrasound probes**
  - Contact or enter sterile body cavities, sterile tissue or the vascular system.
  - Confer high risk for infection transmission if they are contaminated with any microorganism.
  - Require sterilisation to be free from viable microorganisms, but if this is not possible use HLD in conjunction with a sterile sheath.
  - In general, critical ultrasound probes include those used in surgical procedures and some ultrasound guided interventions (e.g. percutaneous procedures where the probe can contact the puncture site). These invasive procedures require a sterile field and sterile instrumentation as they access sterile body sites.

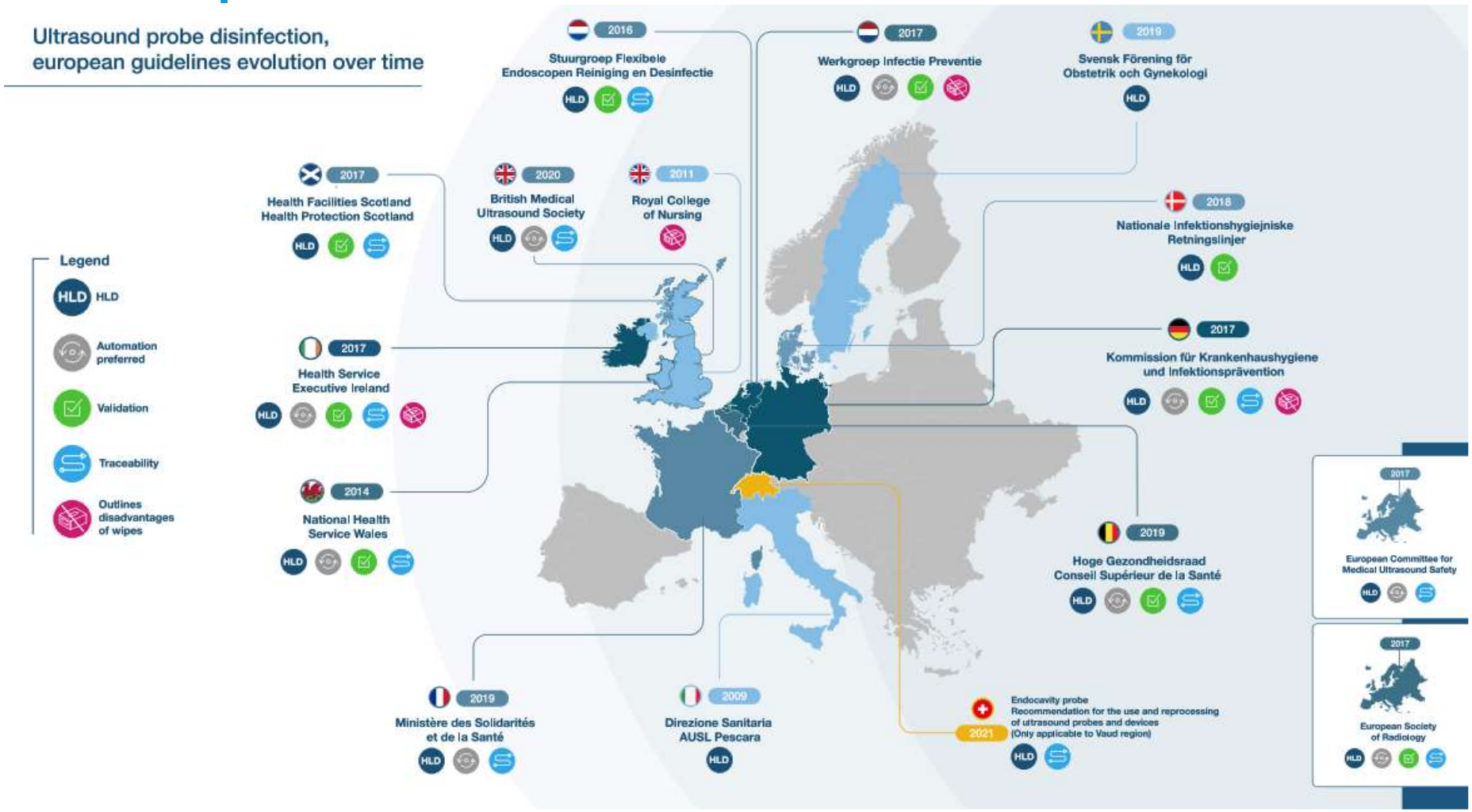


A flowchart decision tree to determine the level of reprocessing and sheath type is required before use of an ultrasound probe on a patient



It is important to ensure that disinfection/sterilisation is compatible with the ultrasound probe such that probe integrity is not compromised.

European consensus on the HLD requirement for semi-critical ultrasound probes



Rest of the world

Region	Issuing organisation	Name of guideline/standard	Year	HLD for TV probes
World	World Federation for Hospital Sterilisation Sciences	Guideline for Reusable Medical Devices.	2019	✓
	World Federation for Ultrasound in Medicine and Biology	Guidelines for Cleaning Transvaginal Ultrasound Transducers Between Patients.	2017	✓
United States	Centre for Disease Control and Prevention (CDC)	Guideline for Disinfection and Sterilization in Healthcare Facilities.	2019	✓
	Food and Drug Administration (FDA)	Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.	2019	✓
	American Institute of Ultrasound in Medicine	Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers Between Patients & Safe Handling and Use of Ultrasound Coupling Gel.	2018	✓
	Association of periOperative Registered Nurses	Guidelines for periOperative Practice.	2018	✓
	The Joint Commission	Comprehensive Accreditation Manual for Hospitals.	2016	✓
	American National Standards Institute (ANSI), Association for the Advancement of Medical Instrumentation (AAMI)	ST58:2013 Chemical sterilization and high-level disinfection in health care facilities.	2013	✓
Canada	CSA Group	CAN/CSA-Z314-18 Canadian medical device reprocessing.	2018	✓
	L'Institut national de santé publique du Québec	Retraitement des sondes d'échographie et des sondes pour compteur gamma intra-opératoire: 33.	2016	✓
Australia / New Zealand	Australasian College for Infection Prevention and Control/Australasian Society for Ultrasound in Medicine	Guidelines for Reprocessing Ultrasound Transducers.	2017	✓
	Australian Commission on Safety and Quality in Health Care	Reprocessing of reusable medical devices in health service organisations	2014	✓

EN 14885 Chemical disinfectants and antiseptics: application of European Standards for chemical disinfectants and antiseptics

- To make a claim that a product provides HLD, it must have proven bactericidal, fungicidal, mycobactericidal and virucidal efficacy

Quantitative suspension test for products

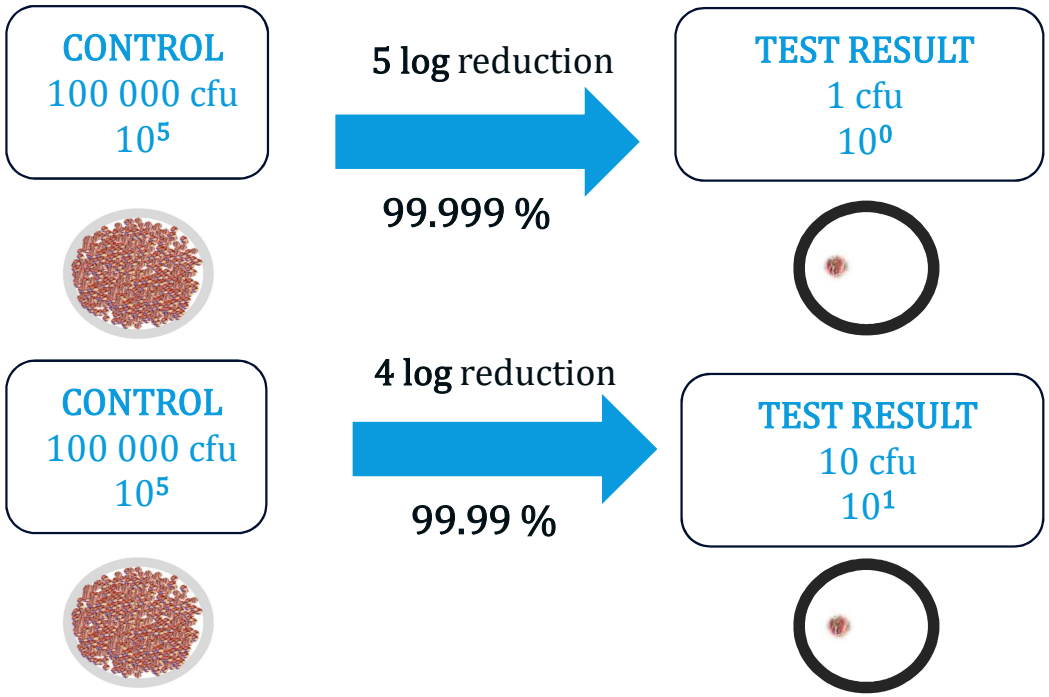
Quantitative carrier test for products

Claim	Testing required (EN standard)		Log reduction required
	Phase 2 Step 1 	Phase 2 Step 2 	
Bactericidal	EN 13727	EN 14561	5 log
Fungicidal (Yeasticidal)	EN 13624	EN 14562	4 log
Mycobactericidal (Tuberculocidal)	EN 14348	EN 14563	4 log
Virucidal	EN 14476	EN 17111	4 log

What is a log reduction?

- Log reduction is a measure of disinfectant efficacy, by quantifying how much a disinfectant reduces the concentration of a microbe

- E.g. If a control solution contains 100,000 (10^5) colony-forming units of bacteria and the test solution (with disinfectant added) contains 1 (10^0) cfu, this demonstrates a **5 log reduction**



Thank you for listening – any questions?