Decontamination and sterilization

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Abstract

Decontamination is the reduction or elimination of microorganisms from medical devices, surfaces and environment such that they cannot reach vulnerable sites to cause infection. With the increasing volume of surgical procedures and challenge of healthcare-associated infection the adoption of safe, appropriate decontamination processes across the healthcare environment is mandatory. It is vital that all healthcare providers be familiar with contemporary routines. The aim of this article is to outline current decontamination practices in the UK.

Keywords Decontamination; Sterilization; Surgical equipment

Introduction

Every year, hundreds of millions of people acquire healthcare-associated infections (HCAIs) globally. Sterilization and decontamination of medical instruments and devices play an important role in the prevention of avoidable HCAIs. Decontamination is a complex process or combination of processes that can encompass multiple facets of a healthcare organization. The principal aim is to remove or destroy micro-organisms or other contaminants from surgical equipment. This prevents them from reaching sufficient quantities in susceptible sites which otherwise could lead to micro-organism transmission to patients or healthcare workers resulting in infections or other harmful responses. In 2010 over four million surgical procedures and an estimated 400,000 endoscopies were performed in the UK with the numbers increasing annually. Reusable surgical instruments that have the potential to provide a route of transmission of micro-organisms between patients need to be properly decontaminated to remove this risk. For example, failure to properly disinfect or sterilize equipment may lead to person-to-person transmission via contaminated devices (e.g. *Mycobacterium tuberculosis* via contaminated bronchoscopes).[1] In addition, transmission of HCAI such as meticillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant, enterococcus (VRE) and *Clostridium difficile (C. difficile)* in surgical and immunocompromised patients can have major morbidity and mortality implications. More recently, the potential transmission of the causal agents of transmissible spongiform encephalopathies such as variant Creutzfeldt-Jakob Disease (vCJD)[2] has highlighted the need for diligent decontamination processes to prevent cross-infection.

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Transmission (person-to-person, fomit-to-person, etc) of such infections can be ameliorated by simple appropriate decontamination processes. Furthermore, any decontamination process should not cause harm to the patient (e.g. glutaraldehyde induced colitis) or staff (contact allergic dermatitis). While guidelines on various aspects of the decontamination process have been published by bodies as disparate as the National Health Service (NHS) in the UK, the Centre for Disease Control and Prevention (CDC) in US and the World Health Organization (WHO),[3–5] including a recently published WHO guideline specifically pertaining to decontamination of medical devices,[6] studies have shown that such evidence-based protocols are often not followed.[7]

It is imperative that surgeons have a thorough knowledge and understanding of the scientific principles and methods of decontamination utilized in contemporary healthcare settings. The decontamination cycle (Figure 1) illustrates the steps of decontamination, with each step as important as the last to ensure proper preparation of equipment prior to re-use. In this article we will further discuss the key aspects of decontamination including cleaning, disinfection and sterilization.

Decontamination

Decontamination is the process to reduce or eliminate microorganisms from medical devices, surfaces and environment such that they cannot reach vulnerable sites to cause infection.[8] This also serves to make instruments safe for staff to handle and re-use in patients. It consists of thorough cleaning alone or in combination with disinfection or sterilization. The level of decontamination should be such that there is no risk of infection when subsequently using the equipment.

The objectives of decontamination are threefold:

- to remove organic matter, e.g. body fluids, food and soil, which may contain or support the growth of pathogenic organisms
- to prevent the accumulation of dust which may contain pathogenic organisms
- removal of chemical hazards.

Almost four decades ago, Spaulding[9] devised a rationale regarding the approach to decontamination which is still utilized by infection control professionals today.

The choice of method depends on the:

- intended use of the equipment
- nature of the contamination
- time required for processing
- heat, pressure, moisture and chemical tolerance of the object
- availability of the processing equipment
- infection risk associated with the use of that equipment.

Spaulding classified medical equipment into three categories — namely, high risk (critical), intermediate (semi-critical), and minimal (non-critical) — according to the risk of infection involved in item (Table 1).

Successful decontamination prerequisites are encompassed by the decontamination cycle (see Figure 1). This includes:

- appropriate management control systems (i.e. a centralized decontamination site)
- dedicated decontamination facilities

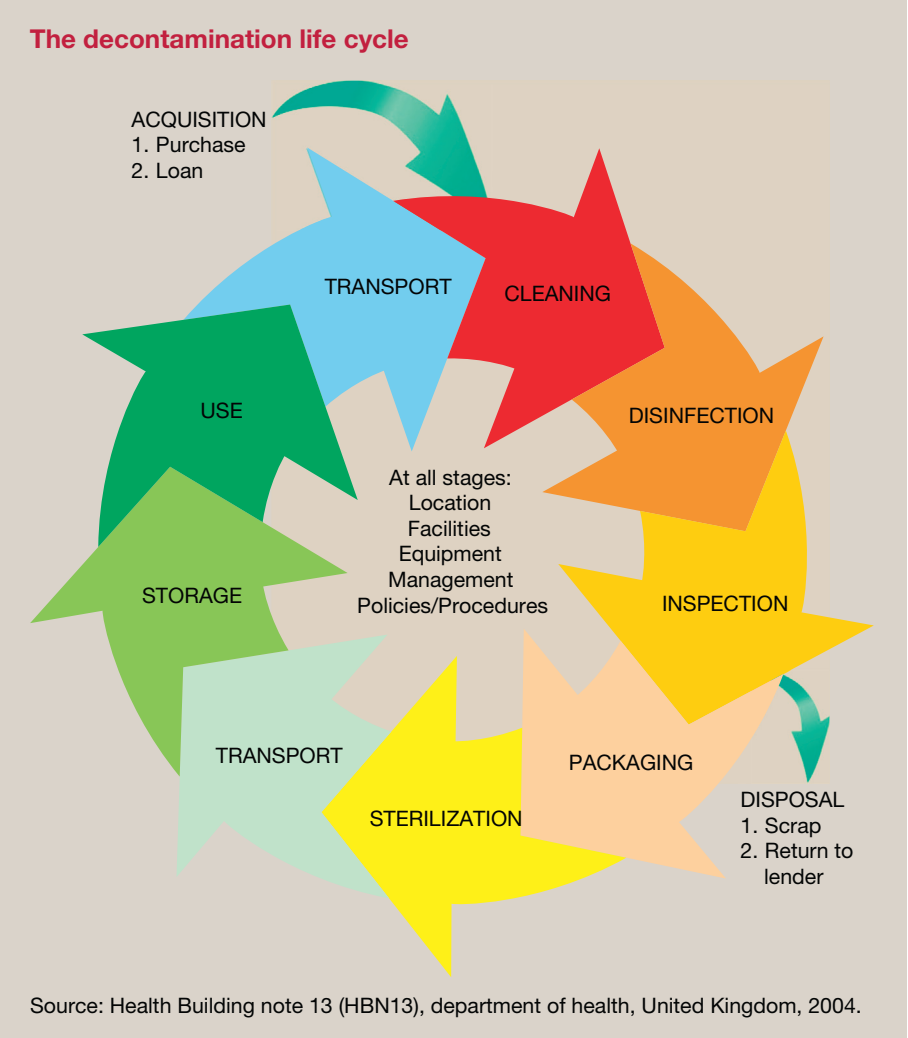

Figure 1

- equipment that is fit for its purpose (i.e. maintained, calibrated, monitored and validated)
- properly trained and supervized staff
- safe disposal of single-use items
- Monitoring and auditing of all decontamination practices.

Failure of any cycle element can compromize the entire process.

Cleaning

Cleaning is the physical removal of foreign material such as dirt, grease and organic matter (serum, blood, pus or faecal material). This reduces the number of micro-organisms present as well as the soil. It is the first and most important step in any decontamination process. There is no single cleaning agent that is able to remove all types of soil. Cleaning is usually performed using water with detergents or enzymatic products to remove the soil. It may be manual using friction (rubbing/scrubbing soiled area with a brush) and fluidics (fluids under pressure) or mechanical using ultrasonic cleaners or washer/disinfectors, which may serve to reduce staff contact handling and handling time. Good cleaning agents contain the following properties: saponification, emulsification, surfactation, dispersion, peptization, water softening, free rinsing and non-toxicity. Cleaning is essential for any device prior to disinfection and/or sterilization as organic material may inactivate chemical disinfectants and protect microorganisms from the decontamination process. The actual physical removal of microorganisms by scrubbing is often as important as the antimicrobial effect of the cleaning agent used. Manual and mechanical cleaning of endoscopes has been shown to achieve approximately a 4-log10 reduction in contaminating organisms.[10]

In accordance with The Association for the Advancement of Medical Instrumentation (AAMI) guidelines for manual cleaning of medical devices prior to disinfection or sterilization involves item disassembly, meticulous brushing in cold water (as it will remove most of the protein materials, e.g. blood, sputum, etc. coagulated by heat or disinfectants), rinsing with clean warm water and drying. Environmental cleaning of floors, surfaces, sinks and drains should be cleaned with water and detergent. Routine use of disinfectants is unnecessary. However, if a

Classification of infection risk from equipment or environment on the basis of infection risk and recommended level of decontamination

Risk of infection (item)	Level of decontamination	Tissue contact	Example	Minimal decontamination requirement
Minimal (non critical items)	Some microorganisms and spores	Intact skin but not mucous membranes. (Intact skin is an effective barrier to most microorganisms)	Blood-pressure cuffs, crutches, linens, patient furniture, and floors	Cleaning/low-level disinfection. Does not need transport to centralized decontamination site
Intermediate (semi critical items)	All microorganisms although small numbers of bacterial spores may be present	Mucous membranes or non-intact skin (intact mucous membranes, i.e. the gastrointestinal tract, are generally resistant to infection by common bacterial spores)	Anesthesia equipment, some endoscopes, laryngoscope blades, oesophageal manometry probes	High-level disinfection using chemical disinfectants
High (critical items)	All microorganisms or spores	Sterile tissue or vascular system	Surgical instruments, cardiac or urinary catheters and implants	Sterilization

Table 1

spillage or spore contamination is present (*C. difficile* exposure) general disinfection is sometimes recommended using 0.5–1% sodium hypochlorite (5000–10,000 ppm of Cl2) (household bleach) or a disinfectant with appropriate activity.

Disinfection

Disinfection is the process of killing or removing many or all pathogenic micro-organisms (except for bacterial spores and prions) from inanimate objects or skin, to a level that is not harmful to health and is safe to handle. An ideal disinfectant would have the following features: a high germicidal activity with rapid elimination of a wide variety of microorganisms including spores, it would be chemically stable, be effective in presence of organic compounds and be able to penetrate in to crevices. A few disinfectants, known as chemical sterilants, will kill bacterial spores with prolonged exposure times. These same disinfectants will kill all micro-organisms except large number of bacterial spores at similar concentrations but with shorter exposure times and are then known as high level disinfectants. Intermediate level disinfectants can be used against mycobacteria, vegetative bacteria along with most viruses and fungi but are not cidal against bacterial spores while low level disinfectants can kill most vegetative bacteria, some fungi and some viruses in a practical period of time.

Decontamination may involve the skin and mucous membranes of patients and healthcare workers in addition to medical devices and the environment. Thus disinfectants must limit trauma to normal tissues. Disinfection can be carried out by either thermal or chemical processes. As organic matter interferes with the antimicrobial efficiency of disinfectants and a greater microbial load increases disinfect time, scrupulous cleaning before disinfection is vital.

Chemical disinfection used on skin and mucous membranes of patients and staff alike include chlorhexidine, iodine and alcohol compounds at various concentrations. They can be used as preoperative skin preparations, surgical scrubs, hand washes and wound cleaning agents.

Iodine is commonly used in an alcohol solution as a preoperative and postoperative antiseptic. Its mechanism of action involves binding free sulfur amino acids and unsaturated fatty acids, which results in impaired protein synthesis. It is not recommended for minor wound infections as it slows wound healing and promotes excessive scarring. It can also stain tissues and fabrics, can cause dermatitis and is easily inactivated by blood, faeces or pus. Povidone-iodine compounds (an iodophor, complex of povidone, a water-soluble polymer, with tri-iodide anions I_3^-, containing about 10% of active iodine) are better tolerated, do not impair wound healing, and leave a deposit of active iodine, thereby creating the so-called 'remnant' effect. Iodine kills all principal pathogens and, given enough time, spores including *C. difficile*. Examples include 1% iodine in 70% alcohol, povidone–iodine antiseptic solution (e.g. Betadine™, Pevedine™), 7.5% povidone-iodine surgical scrub (e.g. Betadine™, Pevedine™).

Chlorhexidine is a chemical antiseptic, effective against Gram-positive and Gram-negative bacteria (although it is less effective with some Gram-negative bacteria) with both bactericidal and bacteriostatic mechanisms of action through membrane disruption. This agent has no effect on spores, tubercle bacilli and only limited effect on viruses. Chlorhexidine is available in various concentrations; 0.5% chlorhexidine in alcohol is generally used for preoperative skin preparation but it may be inactivated by pus, soaps or certain plastics. A Cochrane review found some evidence to suggest that 0.5% chlorhexidine in 70% alcohol reduced surgical site infections compared to standard betadine preoperative skin preparation; however, further trials are warranted to generate conclusive data.[11] Examples include 0.5% chlorhexidine in alcohol 0.05%, chlorhexidine aqueous solution

(Unisept™) and 4% chlorhexidine surgical scrub (Hydrex™, Hibiscrub™).

In the healthcare setting, 'alcohol' refers to two water-soluble chemical compounds — ethyl alcohol and isopropyl alcohol. These agents are rapid, effective, non-specific, antimicrobial agents. They are bacteriostatic and bactericidal (depending on the conditions and concentrations of use), have good fungicidal and tuberculocidal activity but poor activity against many viruses are not sporicidal. Their cidal activity drops sharply when diluted below 50% concentration with the optimum bactericidal concentration being 60–90% solutions in water (volume/volume).[12] Microbial death results from protein coagulation and denaturing of the membrane protein. Examples include alcohol wipes for skin cleaning before deep injection (impregnated with 70% isopropyl alcohol, e.g. Alcowipes™, Sterets™, Mediswaps™) and hand rubs with 70% ethanol or 60–70% isopropanol.

The exposure time for many high-level disinfectants varies from 10 to 45 minutes, at 20–25°C. Outbreaks of infection continue to occur when disinfectants, including iodophors, alcohol, and chlorhexidine are used inappropriately.

Thermal methods are generally preferred for medical devices as they are more reliable, leave no residues, are more easily controlled and non-toxic. For items such bedpans, urinals, linen and cutlery, this may be achieved using moist, saturated steam at 73°C for 15 minutes. Instruments that are sealed, oily, greasy or sensitive to heat are not suitable. Boiling water (for at least 10 minutes) may be used for non-invasive instruments in the community setting, but use should be minimized due to the risk of scalding. Washer disinfectors are automated machines that combine cleaning and heat disinfection followed by a drying stage.

Various chemical are used to disinfect medical items and environment not amenable to thermal disinfection.

Sodium hypochlorite is effective for dealing with blood spillage and the risk of transmission of viruses (e.g. viral hepatitis). It is a strong oxidizer and impairs bacterial oxidative reactions by releasing chlorine to damage bacterial cell walls. Bacteria are killed within 1 minute. Fungi and viruses are extremely susceptible, but tubercle bacilli are more resistant. The compound can be corrosive depending on concentration to metals, some plastics and fabrics, and needs to be thoroughly removed afterwards. It is also readily inactivated by organic matter. Sodium hypochlorite is used to disinfect baths, bedpans, cradles, furniture, mattress covers, lavatory seats, ophthalmic equipment and urinals.

Alcohol wipes are principally used for disinfection of telephones, thermometers, radiographic apparatus, trolley tops and stethoscopes. They have poor penetrative power and are ineffective against pus, blood clots or faeces.

A 2% glutaraldehyde solution rapidly (disinfection time of 10 minutes) destroys rapidly vegetative bacteria and viruses (including hepatitis B, HIV) but is only slowly effective against spores and mycobacterium. Glutaraldehyde acts by denaturing cell proteins. It is relatively inexpensive and has excellent compatibility with most materials. However, glutaraldehyde vapour can cause respiratory irritation, has a pungent odour, causes allergic contact dermatitis and also coagulates blood and fixes tissue to surfaces. Most devices (e.g. endoscopes) sensitive to heat are disinfected by immersion in 2% glutaraldehyde or an equivalent. Examples include (e.g. Cidex™, Totacide™, Asept™).

Sterilization

Sterilization is a process designed to eradicate all viable forms of microbial life, including viruses, bacterial spores and mycobacteria from the surface of an article or in a fluid to prevent disease transmission associated with use of that item. Prions are generally not susceptible to routine sterilization. Most medical and surgical devices are made of materials that are heat stable and can therefore undergo heat, primarily steam, sterilization. However, since the 1950s, there has been an increase in devices made from plastics that require low-temperature sterilization. The sterility assurance level (SAL) is the probability that a particular item is contaminated or unsterile following a sterilization process. A SAL of 10^{-6} is acceptable for instruments used in compromized tissue, i.e. tissues that have lost the integrity of natural body barriers including sterile body cavities and the vascular system. Successful sterilization is contingent on the three interdependent elements of the sterilization triad:

- intimate and adequate contact between the sterilant and all device surfaces (dismantle items and component parts)
- bio burden (soil) minimization (thorough cleaning)
- validated and appropriate sterilant and sterilizing equipment to achieve the correct temperature/sterilant combination.

Sterilization can only be performed on inanimate objects as it would cause severe damage to living tissue. The process must be monitored and audited using thermometers and biological indicators. The ability to kill mycobacterium strains and their associated spores are a good indicator of efficacy given the resistance of such microorganisms to disinfection/sterilization techniques.

Heat-tolerant items should be sterilized by steam in an autoclave which is the oldest, most widely used, economical, effective and reliable method. Air is evacuated and steam is introduced under pressure. The sterilizer chamber and all contents must be free of any air entrapment to ensure direct contact of the steam to all surfaces to be sterilized. Techniques to evacuate air include dynamic air removal process (pre-vacuum) and gravity displacement (steam is lighter than air and displaces it as the chamber fills with steam). The essential conditions for steam sterilization are temperature, saturated steam, time, pressure, nature of the item (porous/non-porous, etc.) and whether it is wrapped or not (Table 2). For example, recommended minimum sterilization times for wrapped instruments are prevacuum: 132°C 4-minutes exposure; 30 minutes drying time and gravity displacement: 121°C 30 minutes exposure; 45 minutes drying time. Flash sterilization is intended for emergency use when instrumentation is urgently needed and time does not allow for routine processing. Flash sterilized items are intended for immediate use. The process is monitored by thermometers, colourmetric chemical tapes,

Standard sterilization methods, indications, mechanisms and parameter

Method	Indications	Contraindications	Mechanism	Parameters	Advantages	Disadvantages
Steam (prevaccum or gravity displacement and flash)	Heat-tolerant devices	Heat- and moisture-sensitive items	Cellular protein coagulation and denaturation	Prevacuum: 132°C 4 min exposure; 30 min drying time Gravity displacement 121°C 30min exposure 45 min drying time at 880x10^{-5} kg/m2	Widely available, cost effective, rapid with the facility for 'flash' autoclaving	Limited materials only. Requires direct contact with instrument
Ethylene oxide (EO)	Heat- and moisture-sensitive medical devices (rubber, plastics, electrical equipment, lenses, sutures, single use Items prior to vacuum packing)	Porous items	EO directly binds and alkylates nucleic acids	Relative humidity: 50—75% Temperatures: 30—60 °C Exposure Time: approx. 2 h Aeration times/ temperatures: 8 h at 60°C 12 h at 30°C	Low and pressure temperature modality	Carcinogenic, mutagenic, flammable, expensive not widely available, risk to healthcare workers, limited availability and expensive
Hydrogen peroxide gas plasma	Heat- and moisture-sensitive medical devices	No activation required No disposal issues No odor or irritation issues Does not coagulate blood or fix tissues to surfaces Inactivates *Cryptosporidium* Published studies of use	Plasma cloud forms reactive oxygen species with oxidization of cellular proteins and nucleic acids	Temperatures 40—55°C Total cycle time: 28—75 min	Low and pressure temperature modality. Inexpensive, relatively non toxic	Concerns regarding compatibility with materials (brass, zinc, copper, and nickel/silver plating) and both cosmetic and functional damage Serious eye damage with contact
Liquid chemical sterilization (peracetic acid or glutaraldehyde)	Heat-sensitive devices that can be immersed (endoscopes, etc.)	Items that cannot be immersed	Cellular protein denaturation through reaction with cellular constituents	Total immersion. For disinfection: 12 min at room temp. For sterilization: Peracetic acid: 12 min at 50°C to 30°C. Glutaraldehyde: 10 h	Inexpensive, rapid and widely available	'Just-in-time use' no shelf life. Health risk to care workers Concerns regarding compatibility with certain materials and both cosmetic and functional damage Limited clinical use Potential for eye and skin damage
Dry heat	Anhydrous items (some reuseable needles and neurosurgical burrs)	Heat-sensitive items	Conduction from external to internal surfaces with oxidation	Temperature range: 30 min at 180°C to 6 hrs at 121°F ** (**exposure	Can be used with sharp instruments which could be damaged by moisture	Long sterilization process with great

(*continued on next page*)

Table 2 (*continued*)

Method	Indications	Contraindications	Mechanism	Parameters	Advantages	Disadvantages
			and coagulation of cellular proteins	times, do not include time to reach temp range)		variation in temperature and exposure times
Ozone	Heat- and moisture-sensitive medical devices	Lumen restrictions. Not cleared for flexible endoscopes, glass or plastic ampoules, liquids or implants	Oxidization of cellular proteins	Temperature range 30 —35°C for 4.5 hrs	Inexpensive, non-toxic and environmentally friendly. Rapid turnover	Low availability and item restriction

Table 2

Brownes tube and biological indicators like *Bacillus stearothermophilius* NCTC 10007 spores.

Heat-sensitive items are dealt with differently. Gamma ray irradiation generally from a cobalt-60 source at a 25 kGy dose are commercially utilized for single-use plastic items. Higher doses cause degradation of high-polymer compounds. *Bacillus pumilus* NCTC 8241 is the biological indicator of choice.

Ethylene oxide (EO) is a low-temperature process that is suitable for the sterilization of heat- and moisture-sensitive medical devices. It is, however, flammable, carcinogenic, highly penetrative, expensive and requires prolonged exposure and subsequent ventilation times to ensure no residual EO remains. Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) have developed permissible exposure limits and require continuous monitoring of the work area and personnel. The essential parameters for EO sterilization are gas concentration, humidity, temperature and time. Standard cycle parameters have been established to accommodate most circumstances because of the vast differences in the configuration, density, design and permeability of products routinely sterilized in the hospital setting (see Table 2).

Hydrogen peroxide gas plasma is a low-temperature sterilization alternative suitable for many heat- and moisture-sensitive medical devices. Gas plasma is devoid of the EO-associated occupational, environmental and patient safety concerns and is less expensive with significantly shorter total cycle times. A hydrogen peroxide plasma cloud in a vacuum chamber solution generates reactive species which react with microorganisms. Gas plasma is not compatible with highly porous absorbers, such as cellulose, and paper products and cannot be utilized to process liquids. Temperature range varies but is maintained between 40 and 55°C and total cycle time will range between 28 and 75 minutes (see Table 2).

Liquid chemical sterilization is utilized for heat-sensitive devices that can be completely immersed for a prescribed time period in germicidal solution to kill microorganisms.

Per acetic acid is used with a specially designed self-contained automated processor, commonly used for flexible endoscopes and components. Devices thus sterilized are intended for 'just-in-time use' and have no shelf life.

Glutaraldehyde can act as a liquid chemical sterilant when used according to the manufacturer's directions for sterilization. There are several disadvantages of using glutaraldehyde as a sterilant including toxic fumes, long exposure time, potential for contamination of sterile devices during rinsing and transfer to the area of use, and no method to biologically monitor the sterilization process. It can pose a risk to healthcare workers and patients, if they come in contact with tissue, skin, mucous membrane or eyes. Temperature and exposure times are variable but up to 12 hs for glutaraldehyde are standard (see Table 2).

Ozone sterilization is the newest low-temperature sterilization method suitable for many heat-sensitive and moisture-sensitive medical devices. It is a strong oxidizer and is generated using medical grade oxygen, water and electricity. It is inexpensive, non-toxic and environmentally friendly. ◆

Definitions

Antiseptics

Antimicrobial substances that are applied to living tissue/skin to reduce the possibility of infection.

Cleaning

The physical removal of dirt, grease and organic matter that reduces the number of micro-organisms present. It is an essential pre-requisite for any device prior to disinfection and/or sterilization.

Compromised tissue

Sterile tissues which have lost the integrity of natural body barriers including sterile body cavities and the vascular system.

Critical items

Enter sterile tissue or the vascular system and have a high risk of infection if contaminated.

Decontamination

The process of rendering an article safe to handle, by cleaning with or without disinfection or sterilization.

Disinfection

The process of killing or removing pathogenic micro-organisms, except for bacterial spores and prions from inanimate objects or skin, to a level which is not harmful to health.

High level disinfection

High level disinfection is a process which kills *Mycobacterium tuberculosis* and enteroviruses in addition to other vegetative bacteria, fungi and more sensitive viruses.

Noncritical items

Come in contact with intact skin but not mucous membranes and have a low risk of infection.

Prion

Proteinaceous infectious agent leading to Creutzfeldt-Jakob disease (CJD), variant CJD, kuru, Gerstmann-Straussler-Scheinker syndrome and fatal familial insomnia syndrome.

Semicritical items

Come in contact with mucous membranes or nonintact skin which is generally resistant to bacterial spores.

Sterilization

A process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to achieve an acceptable sterility assurance level (AAMI, 1996).

Sterility assurance level (SAL)

The probability that a particular item is contaminated or unsterile following a sterilization process. A SAL of 10^{-6} is acceptable for instruments used in compromized tissue.

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