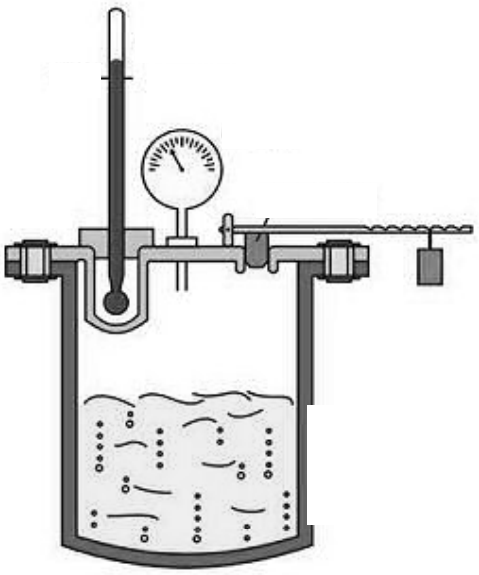
WFHSS ÖGSV

III

Fundamentals of Cleaning, Disinfection and Sterilization



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2009

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1 Terms

1.1 Cleaning

Cleaning means the removal of dirt or of any other unwanted material (blood, food residues, etc.). This removes visible contaminants.

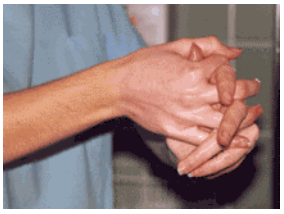


The **goal of cleaning** is to assure visible cleanliness

1.2 Disinfection

Disinfection kills the **disease-causing** bacteria. Bacterial spores (see Fundamentals of Microbiology) are not killed, however, in many cases disinfection suffices. **Disinfection** means that one can no longer contract infection from the disinfected objects (DIS-infection).





The **goal of disinfection** is to kill germs and reduce the number of germs such that the disinfected objects can no longer transmit infection.

1.3 Sterilization

Sterilization means the killing of **all** microorganisms, including bacterial spores.

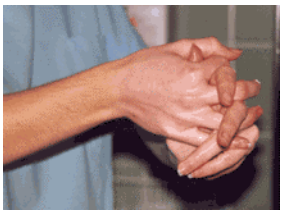
The goal of sterilization is to assure absolute absence of organisms. An object can be deemed to be sterile if the probability of a viable microorganism being present on an object is less than 1 : 1,000,000 (1 million). In other words, out of 1 million sterilized objects a viable microorganism may be present only on one single object. All instruments and objects that enter into in sterile body regions or come into contact with wounds must be sterile.

The **goal of sterilization** is to assure absolute absence of organisms.

2 Cleaning

Cleaning means the removal of dirt or of any other unwanted material (blood, food residues, etc.).This removes visible contaminants.

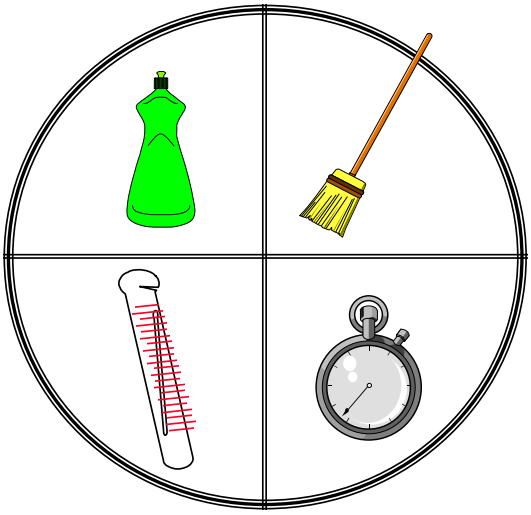




The goal of cleaning is to assure visible cleanliness.

Cleaning has – in addition to an aesthetic and psychological role – the task of mechanically removing bacteria and fungi or of depriving them of their source of nutrients. The number of germs (bioburden) can be considerably reduced (50 - 90 %) by cleaning thoroughly.

What factors are decisive for effective cleaning?



These are the **chemical action, mechanical action, time and temperature**: If one, for example, wants to use fewer chemicals, then one must clean for longer or use greater mechanical action, which means having to scrub harder.

Caution!!

Manufacturers who claim that perfect cleaning results can be achieved with minimal amounts of water in minimal time are, unfortunately, being mainly somewhat economical with the truth.

2.1 Detergents and methods of cleaning (summary)

The raw materials used in detergents (cleaning agents, cleaners) are:

Surfactants (tensides), acids, alkalis (lyes), water-soluble and water-insoluble solvents, auxiliary ingredients.

Surfactants are the most important of these raw materials.

Aqueous detergents (as well as other aqueous liquids) are either neutral, acidic or alkaline. The measurement unit used for this is known as the “pH”. Substances can be neutralized, acids with alkalis (lyes), and alkalis with acids.

Water is the starting point on the pH scale and it has a pH value of 7. Values of less than 7 indicate acids, and values above 7 alkalis. The smaller the pH value, the stronger will be the respective acid. The scale is divided such that for each value the acid strength increases by a factor of 10. An acid with pH 3 is ten times as strong as an acid with pH 4!

Approximate pH values of common substances and chemicals:

Hydrochloric acid 35%:	**pH = -0**	**Beer:**	**pH = 5**
Hydrochloric acid 3.5%:	**pH = 1**	**Surface of the skin:**	**pH = 5.5**
Hydrochloric acid 0.35%:	**pH = 1**	**Mineral water:**	**pH = 6**
Gastric acid:	**pH = 1**	**Pure water:**	**pH = 7**
Citric acid:	**pH = 2**	**Blood:**	**pH = 7.4**
Vinegar essence:	**pH = 2**	**Clean seawater:**	**pH = 8.3**
Vinegar:	**pH = 3**	**Intestinal juice:**	**pH = 8.3**
Coca Cola:	**pH = 3**	**Detergent solution:**	**pH = 10**
Wine:	**pH = 4**	**Sodium lye 3%:**	**pH = 14**
Sour milk:	**pH = 4.5**	**Sodium lye 30%:**	**pH = 15**

(note: there is no mistake in the table: there are indeed values that are smaller than 1 and others that are greater than 14)

Commercially available cleaning products can be classified as follows:

- Neutral detergents pH approx. 5 – 9
- Acidic detergents pH < 5
- Alkaline detergents pH > 9 (use concentration)
- Solvent detergents
- Detergents that cannot be clearly assigned to any particular class

Neutral detergents

- Principle ingredient: surfactants
- Neutral detergents are, in general, much weaker than alkaline detergents (lyes), therefore alkaline detergents should preferably be used to clean surgical instruments.

Acidic detergents:

- Remove lime and cement residues
- Acid types: acetic acid, citric acid, phosphoric acid,
- Toilet cleaners, with addition of surfactants: cleaners for sanitary fittings.

Alkaline detergents

- Remove incrustations in the kitchen as well as in industrial and hospital settings
- Alkali (= lye) e.g. caustic potash solution, soda (sodium carbonate), ammonia, etc.
- Concentrated as oven cleaners
- Alkaline detergents are stronger than neutral detergents.

Ultrasonic cleaning

A high-frequency sound wave is passed through the cleaning solution (water + detergent and/or disinfectant). This gives rise to alternating high and low pressure waves. These, in turn, trigger a process known as CAVITATION. Millions of microscopically small negative pressure bubbles are formed, only to immediately disintegrate. The energy thus released is several orders of magnitude greater than that generated by mechanical brushing. Cavitation also expedites the breakdown of soil particles and brings the solution into close contact with the surfaces of the items to be cleaned. Heat helps to promote the chemical interactions taking part in the detergent.

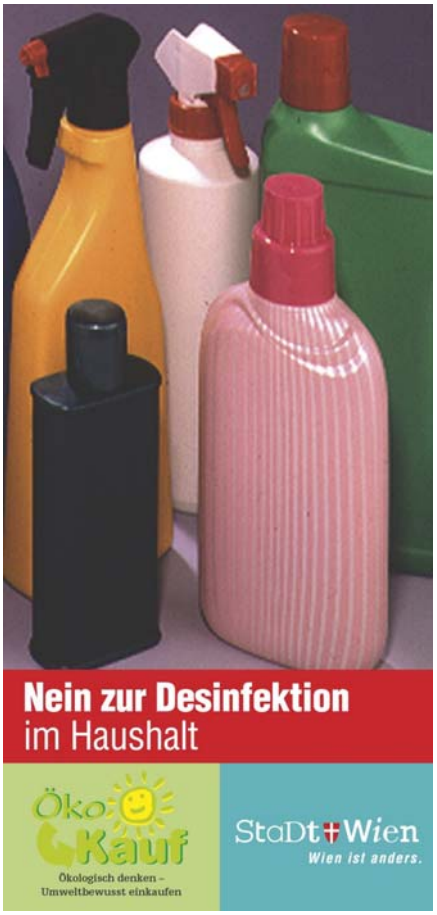
Tests (e.g. using aluminium foil) should be used to measure the energy in the ultrasonic baths.

3 Disinfection

Disinfection kills the **disease-causing** (pathogenic) bacteria. Bacterial spores (see Fundamentals of Microbiology) are not killed. However, in many cases disinfection suffices. **Disinfection** means that one can no longer contract infection from the disinfected objects (DIS-infection).

The **goal of disinfection** is to kill germs and reduce the number of germs such that the disinfected objects can no longer transmit infection.

"No to disinfection in the household"



In recent years, increasingly more antibacterial detergent and cleaning products have been placed on the market whose action far exceeds the hygiene measures needed in the household. In view of their toxic and allergenic effects in the household, they pose more a risk to human health than they offer protection. Furthermore, such substances pollute sewage treatment plants and, even at low concentrations, they are harmful to aquatic creatures such as crustaceans and fish. These agents also kill all bacteria, including those – and they are the majority – that are beneficial to humans in their daily lives.

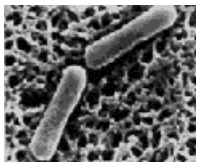
Therefore disinfection measures should be confined to the hospital and similar environments, and they are not at all needed in the average household. In the latter, cleaning and basic behavioural practices are enough to assure an adequate standard of hygiene

Disinfection is needed in the household only if the treating physician recommends it for special reasons.

Disinfection can be achieved with chemical (e.g. alcohol) or physical (e.g. temperature) methods, a combination of both such methods is known as a "chemothermal process"

3.1 Chemical disinfection

In chemical disinfection microorganisms are killed by certain chemicals. To that effect, several **chemical disinfectants** are available. To be deemed suitable for that purpose, they should meet the following requirements:



- have as broad a spectrum of action as possible, i.e. be able to kill several types of pathogens
- need only a short exposure time
- not be susceptible to any, or to only very few, loss of efficacy in the presence of proteins

- not have any, or only very little, unpleasant odour
- not cause any, or only very little, irritation to skin or mucous membranes
- have a high material compatibility profile

- be environmentally friendly
- be economical.

As one can easily imagine based on the above list, there is no ideal disinfectant. One must therefore carefully think about the purpose for which the disinfectant is to be used and what properties are important.

The following terms denote the **microbicidal (**germ-killing) action of a disinfectant:

- **bactericidal** = able to kill bacteria
- **bacteriostatic** = able to stop growth of bacteria
- **fungicidal** = able to kill fungi
- **fungistatic** = able to stop growth of fungi
- **virucidal*** = able to inactivate viruses (= destroy viruses)
- **sporicidal** = able to kill spores

* limited virucidal activity means that only certain viruses are inactivated

Spectrum of action:
bactericidal, fungicidal, virucidal

♦ **Info: Development of bacterial resistance to disinfectants**

Time and again one hears that disinfectants should be changed so that the microorganisms do not become accustomed to the disinfectant and thus develop resistance.

Scientific studies have shown that there is no need for such a change, provided that the disinfectant is being properly used. That is because microorganisms can become accustomed to a disinfectant only if the latter has been underdosed over a long period of time. By increasing just once the concentration of the disinfectant used, the seemingly resistant microbes can be killed again.

3.1.1 Expertise Lists

The microbicidal (germ-killing) properties of disinfectants are verified on the basis of special guidelines. Efficacy is confirmed by specialist associations

e.g.:

The Austrian Society for Hygiene, Microbiology and Preventive Medicine *(Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin - ÖGHMP*). www.oeghmp.at

Association for Applied Hygiene (*Verbund für angewandte Hygiene* - VAH, Germany)

The Expert´s Commission for Disinfectants certifies a disinfectant after it passes a test and places it on the **Expertise List**.

3.1.2 Active substances

There are several disinfectant substances. The most important substances, and their representatives, are listed in the table.

Often, combinations of different active substances are used in disinfectants so as to cover as broad a spectrum of action as possible.

♦ **Info: Aldehyde-free disinfectants**

Aldehydes, in particular formaldehyde, are irritant to skin and mucous membranes and can give rise to allergies. Furthermore, they have protein-fixing properties, i.e. proteins are denatured (changed) by them, causing them to adhere to surfaces. For that reason, they are used less and less often as disinfectants. Many manufacturers advertise their product as being "free of aldehydes", thus assuring the user that this product is completely free of aldehydes. Conversely, the declaration "free of formaldehyde" only means that the disinfectant is free of formaldehyde. Nonetheless, such a product generally contains aldehydes since there are many different types of aldehydes.

The "**spectrum of action"** indicates the group of microorganisms for which a particular disinfection process is effective.

Based on the disinfectants' efficacy profiles against pathogens, 4 different spectrums of action are distinguished:

A: able to kill vegetative* **bacteria,** including **mycobacteria** as well as **fungi,** including **fungal spores**
B: able to inactivate **viruses**
C: able to kill s**pores** of the bacterium causing **anthrax**
D: able to kill **spores** of the bacteria causing **gas gangrene a**nd **tetanus**

* Vegetative bacteria are able to multiply, i.e. they are not spores

Spectrum of action D can, accordingly, be assured only through sterilization.

3.1.3 Classes of active substances used in chemical disinfectants

Active substance	Spectrum of action	Fields of application	Pros	Cons
Aldehydes ▪ formaldehyde ▪ glutaraldehyde ▪ glyoxal	covers virtually the entire spectrum	▪ surfaces ▪ instruments	▪ biodegradable ▪ low use concentration	▪ unpleasant odour ▪ allergenic
Alcohols ▪ ethanol ▪ n-propanol ▪ isopropanol	▪ bactericidal ▪ fungicidal ▪ virucidal to an extent	▪ hands ▪ surfaces	▪ rapid onset of action ▪ biodegradable ▪ dries quickly ▪ generally good material compatibility	▪ risk of fire and explosion if used to disinfect large surfaces ▪ skin-degreasing effect
Quaternary ammonium compounds (QUATs)	depending on substance ▪ bactericidal ▪ fungicidal	▪ instruments ▪ hands	▪ sustained effect ▪ odourless	▪ adversely affected if used in combination with anionic surfactants (soap effects)
Halogens ▪ sodium hypochlorite ▪ povidone-iodine	covers virtually the entire spectrum	▪ instruments ▪ hands ▪ (mucous membranes)	▪ rapid onset of action	▪ poor biodegradability profile ▪ corrosive to metals ▪ irritant to mucous membranes
Per compounds ▪ hydrogen peroxide ▪ peracetic acid	covers virtually the entire spectrum	▪ instruments ▪ mucous membranes ▪ water	▪ rapid onset of action ▪ biodegradable	▪ unstable
Phenols and phenol derivatives	▪ bactericidal ▪ virucidal to an extent	▪ surfaces ▪ instruments	▪ few protein effects ▪ good cleaning performance	▪ poor biodegradability profile ▪ hazardous to health

3.1.4 Application of chemical disinfectant

Depending on the field of application, disinfectants are applied by **immersion** (e.g. for manual instrument disinfection in the case of medical devices that cannot be subjected to automated reprocessing), **wiping** (e.g. surfaces) or **rubbing** (e.g. hand disinfection). **Spray disinfection** is unreliable in terms of its efficacy, it has an adverse effect on staff and is comparatively more expensive than the wipe method, since only a fraction of the disinfectant agent actually lands on the surface. Hence, it should only be used – if indeed used at all – in situations where no other method (wipe or rub) can be used.

Depending on the respective product, the disinfectant will come as a ready-to-use solution or as a concentrate that must be mixed with water before use.

The following points must be borne in mind when handling disinfectants:

- To assure the right concentration of the use solution, the manufacturer's instructions must be observed. Measuring vessels or dosage systems must be used for dosing purposes. If too low a dose is used, the disinfectant will not work properly. If too much is used, the disinfectant action will not be any better, so this confers no advantage and simply damages the environment, is expensive, may damage materials and, not least, it is harmful to staff. A dosage table will make it easier to use disinfectants (see below).

- The disinfectants must be used only for the intended purpose. While that sounds logical, in practice this rule is not always followed.
- No detergents may be added (e.g. all-purpose cleaners) since this could detract from the disinfectant efficacy.
- For their own protection, staff must always wear protective gloves when handling disinfectants – except for hand disinfection.

- Staff must be trained

Dosage table:

Dilution	1 Litre	2 Litres	3 Litres	4 Litres	5 Litres
0.5 %	5 ml	10 ml	15 ml	20 ml	25 ml
1.0 %	10 ml	20 ml	30 ml	40 ml	50 ml
2.0 %	20 ml	40 ml	60 ml	80 ml	100 ml
3.0 %	30 ml	60 ml	90 ml	120 ml	150 ml
4.0 %	40 ml	80 ml	120 ml	160 ml	200 ml
5.0 %	50 ml	100 ml	150 ml	200 ml	250 ml
10.0 %	100 ml	200 ml	300 ml	400 ml	500 ml

How is the dose calculated?

For example, one wants to prepare 3 litres of a 0.5% solution

1 litre = 1000 ml

1000 ml 100%

10 ml.....1%

5 ml.....0.5%

Hence for **3** litres one needs 3 x 5 ml = 15 ml

Exercises:

5 litres of a 2% solution:

1000 ml.....%

.....ml.....1%

.....ml.....2%

Hence for 5 litres one needs

.... x .....ml = ... ml

4 litres of a 0.25% solution:

1000 ml.....%

.....ml.....1%

.....ml.....0.25%

Hence for 4 litres one needs

.... x .....ml = ... ml

Practical exercise on dosage accuracy:

Participants are given the task of preparing 4 litres of a 0.5 % solution. To that effect each participant is given a plastic beaker and asked to pour the requisite 20 ml (e.g. coloured water) from a bottle into the beaker, without using any dosing aid. Using a syringe, the water quantities obtained are measured and written on the blackboard.

The concentrations obtained are calculated and discussed.

3.1.5 Surface cleaning and disinfection

3.1.5.1 Contamination with microorganisms

The surfaces and objects in areas where medical device reprocessing is conducted may be contaminated by soiled instruments, the hands of personnel, dust or microorganisms. To reduce this contamination, both **selective** and **general disinfection measures** are needed. The surfaces of areas where medical device reprocessing is carried out must therefore be easy to clean and able to tolerate disinfectants.

A distinction is made between:

1. **Routine disinfection**
2. **Selective disinfection**
3. **Cleaning**

In principle, for surface disinfection the disinfectant must be applied to the surface and distributed (this is known as “scrub and wipe” disinfection). **Spray disinfection** on its own should only be used in exceptional cases and is recommended only for surfaces that do not lend themselves to **wipe disinfection**.

- It is important to wear **protective gloves** when handling disinfectants so as to avoid skin problems
- The solutions must be prepared with **cold water** (max. 25 °C) and dosed in accordance with the manufacturer’s instructions. Cold water is important to prevent formation of hazardous vapours.
- For routine disinfection **aldehyde-free disinfectant solutions** are generally adequate (tested by e.g. *ÖGHMP* or *VAH*) in the 4-hour concentration.

3.1.5.2 Routine disinfection

Work surfaces become increasingly dirtier and more contaminated in the course of the working day. To reduce the overall bioburden, **general routine disinfection** of all work and storage surfaces is conducted once daily, preferentially in the evening at the end of the working day.

For wiping use preferentially **disposable cloths** impregnated with the surface disinfectant. Drawers should be emptied and wiped at least once every three months. **Floor disinfection** appears to be needed only in the **unclean area** where medical devices are reprocessed.

3.1.5.3 Selective surface disinfection

This is understood to mean disinfection of surfaces in the presence of **visible contamination** (contamination with blood, saliva, etc.).

Coarse soils are removed with a **disposable cloth** impregnated with disinfectant and the cloth is then immediately disposed of.

This is followed by the actual disinfection of the surface, whereby a copious amount of the disinfectant is applied to the area concerned.

In the case of **selective disinfection** rapid onset of action is needed.

Alcohol is endowed with the most rapid onset of action, therefore an alcohol-based **quick disinfectant** is used for this purpose. To avoid the risk of fire or explosion, the use of such disinfectants must be confined to **small surfaces**. Hence they must never be used for disinfection of electrical equipment that has become hot (e.g. workplace lights). Moreover, one must ensure that the areas to be disinfected are compatible with alcohols since, otherwise, the disinfected materials could be damaged (e.g. Plexiglas).

3.1.5.4 Cleaning

Floors should be cleaned with environmentally friendly all-purpose cleaners at the end, or before the start, of the working day.

3.1.6 Cleaning and disinfection policies

A specific cleaning and disinfection policy must be formulated for each establishment, with each department having a separate one if necessary.

In doing so, the **scope** of tasks must be specified, **areas** with different requirements defined, and **methods** as well as **detergents** and **disinfectants** compatible with the respective materials and requirements specified. It must also be specified who is to conduct the various tasks and who is responsible for these. Provision must also be made for inspection.

3.1.6.1 Formulation of a disinfection policy

There is no need to replace disinfectant products on a routine basis.

While bacterial resistance to disinfectant substances can in theory develop (in particular if continually underdosed), this is of no significance in practice. Although the product is often changed, the active substance remains unchanged, i.e. the same active substance is used under a different name.

Accordingly, there must be a good reason to replace a product with which one has had good experiences.

Criteria for replacing a disinfectant could include:

* Not tolerated by personnel
* Material incompatibility
* Unpleasant odour
* Concern about environmental compatibility
* Price
* Delivery problems

Before opting for a particular product it is recommended that the product be tested out at the specific site of use, bearing in mind the aforementioned aspects.

The following procedures are recommended when setting out a disinfection policy:

⇒ Consultation with the management of the respective establishment
⇒ Consultation with the infection control team and the hospital's infection control director
⇒ Take an inventory of the currently used disinfection practices
⇒ Consultation with the staff to be entrusted with disinfection tasks (material compatibility, irritant effects, etc.)

⇒ Assemble all relevant documentation for prospective products (expert opinions, certificates of harmlessness, data safety sheets, etc.)
⇒ Consultation with the purchasing department (prices, delivery conditions, etc.)
⇒ Draw up the policy
⇒ Trial run (e.g. 3 months)
⇒ Record all feedback and make any amendments needed
⇒ Have policy adopted by the infection control (hygiene) commission

Assignment of responsibilities and competences appears to be of paramount importance to ensure compliance with the cleaning and disinfection policies.

3.1.6.2 Cleaning and disinfection policy for medical device central sterile supply departments (specimen)

Cleaning and disinfection policy: Medical device reprocessing (specimen)

Status:

Object	Product / process	Conc.	Exposure time	Frequency	Method	Preparations / Remarks
Hands	detergent		_	if contaminated	wash	liquid soap
	disinfectant	conc.	30 sec	see instructions	rub	alcohol-based product
Equipment (e.g. ultrasonic bath)	detergent		_	daily	wipe	
	disinfectant			daily	wipe	surface disinfectant
Floor on clean side	detergent		_	daily	wipe	
	disinfectant	conc.		selective	wipe	alcohol-based quick disinfectant
Floor on unclean side	detergent		_	daily	wipe	
	disinfectant			daily	wipe	surface disinfectant
Work surfaces on clean/unclean side	detergent		_	daily	wipe	
	disinfectant			daily	wipe	surface disinfectant
Washbasins	detergent		_	daily	wipe	
Cleaning cloths, mops	therm. disinfection	boiling programme		daily	washing machine	
Protective clothing	therm. disinfection	boiling programme		daily	washing machine	

3.2 Thermal disinfection

Thermal disinfection is disinfection by means of heat. This exploits the fact that normal bacteria are sensitive to heat, with most of them being inactivated at temperatures as from 60 °C and even the hepatitis B virus is rendered harmless at 90 °C (5 min).

3.2.1 Thermal disinfection of medical devices

In the washer-disinfectors (WDs) used to reprocess instruments and other medical devices (e.g. surgical drapes) pathogens are generally inactivated by means of heat.

3.2.1.1 The A_0 concept

Standard EN ISO 15883-1 Annex B uses the term A_0 as a measure for the killing of microorganisms in moist-heat processes (hot water). For such a disinfection process it can be expected that a temperature persisting over a particular period of time will have a predictable effect on microorganisms that have a specific level of resistance. If these values are observed, it can then be assumed that the process will guarantee the requisite reduction in the number of microorganisms. A precondition for this is, however, that the devices be thoroughly cleaned in advance.

3.2.1.2 A_0 values for thermal disinfection processes

Which A_0 value must be reached will depend on the species and number of microorganisms on the medical devices to be reprocessed as well as on the ensuing reprocessing steps (e.g. sterilization) and on the intended use.

The task of defining the A_0 values to be reached falls to the infection control team or the hospital's infection control director, with the following recommendations being given as a general guide:

The use of an A_0 value of 60 is viewed as a minimum for non-critical medical devices, i.e. medical devices that come into contact with only undamaged skin (e.g. bedpans).

An A_0 value of 600 is deemed to be adequate for semi-critical medical devices (MDs) provided that it can be assumed that they harbour only a low level of microbial contamination and that no heat-resistant pathogenic microorganisms are likely to be present.

For all critical medical devices that could be contaminated with heat-resistant microorganisms such as hepatitis B viruses and, as per their intended use, would come into contact with physiologically sterile body regions or blood, the Robert Koch Institute recommends thermal disinfection with an A_0 value of at least 3000.

For example, this can be achieved on exposure to hot water at 90 °C provided that the surfaces of the medical devices to be disinfected will withstand this temperature for at least 5 min.

Process temperature (°C)	Exposure time for A_0=3000 (e.g. I-WD, incl. hepatitis B)		Exposure time for A_0=600 (e.g. I-WD, excl. hepatitis B)		Exposure time for A_0=60 (e.g. bedpan WD)	
	sec	Min	Sec	min	sec	min
65	94,868	1,581.1	18,974	316.2	1,897	31.6
70	30,000	500.0	6,000	100.0	600	10.0
75	9,487	158.1	1,897	31.6	190	3.2
80	3,000	50.0	600	10.0	60	1.0
85	949	15.8	190	3.2	19	0.3
87	599	10.0	120	2.0	12	0.2
90	300	5.0	60	1.0	6	0.1
93	150	2.5	30	0.5	3	0.1
95	95	1.6	19	0.3	2	0.03

I-WD: Washer/disinfector for instruments

A_0 values for medical devices used for different applications

An automated thermal disinfection process comprises in principle five steps:

1. ***Preliminary rinse*** – in cold water without any additional substances so as to remove coarse soils
2. ***Cleaning*** – at a temperature of 40 – 60 °C cleaning is conducted with the dosed detergents
3. ***Intermediate rinse*** – the cleaning solution is removed by means of hot or cold water
4. ***Disinfection*** – thermal disinfection is conducted with demineralised water at a temperature between 80 and 93 °C. To destroy hepatitis B viruses, which are particularly heat resistant, a temperature of at least 90 °C is needed for 5 minutes or 85 °C for 16 (see A_0 concept)
5. ***Drying***

3.2.2 Procedure used in automated reprocessing

- Immediately after use (at the site of use) remove course organic soils with a cellulose cloth (e.g. tissue residues, pus, adherent materials such as e.g. bone cement)
- Contamination-proof transportation to the washer-disinfector
- Preparation of devices to be disinfected: dismantle into individual components, open jointed instruments
- Secure delicate instruments (e.g. probes) in racks or special supports
- Do not overload trays
- Pay attention to spray shadowing caused by bigger objects, e.g. kidney dishes!
- Lumen instruments: Appropriate loading trolleys with cleaning facility (internal cleaning)
- Inspect instruments for residues
- Clean and disinfect once again if necessary

Since the programme is automatically executed, there are far fewer risks of operator errors as can happen during chemical disinfection (incorrect dosage, too short a hold time, mistakes leading to recontamination). Hence thermal disinfection is the safest method of disinfection.

Thermal disinfection in washer-disinfectors must take precedence over chemical or chemothermal processes (Robert-Koch Institute).

3.3 Chemothermal disinfection processes

Some medical devices do not tolerate the high temperatures required for thermal disinfection (e.g. flexible endoscopes). These medical devices are reprocessed using automated chemothermal disinfection processes. This means that chemical disinfection is promoted and expedited by temperatures that are higher than the ambient temperature (up to a maximum of 60 °C). (Chemical reactions unfold more rapidly at high temperatures which is why infectious diseases give rise to fever, since at a higher body temperature the chemical reactions in our body will take place faster and the pathogens can be combated faster.)

4 Sterilization

Sterilization means the killing of **all** microorganisms, including bacterial spores.

The goal of sterilization is to assure absolute absence of organisms. An object can be deemed to be sterile if the probability of a viable microorganism being present on an object is less than 1 : 1,000.000 (1 million). In other words, out of 1 million sterilized objects a viable microorganism may be present only on one single object. All instruments and objects that enter into sterile body regions or come into contact with wounds must be sterile.

The **goal of sterilization** is to assure absolute absence of organisms.

4.1 Before sterilization

Before sterilization the following points must be noted:

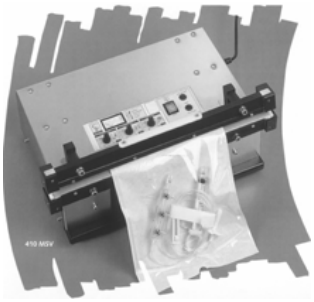
- Only clean medical devices may be sterilized. If there are still salt or protein residues on the surfaces, these could act as protective sheaths and impede killing of microorganisms.
- The devices to be sterilized must be dry. Moisture on medical devices can give rise to evaporation coldness that can adversely affect the sterilization results.
- The medical devices to be sterilized should as far as possible be dismantled into separate components (if this has been specified by the manufacturer) so that all parts are accessible to sterilization.

♦ **Info: Devices to be sterilized /sterile devices**

*The items to be sterilized are designated as "**devices to be sterilized"**, whereas those items have already been sterilized are known as "**sterile devices"**.*

4.1.1 Packaging

Medical devices that must be sterile when used on the patient must be sterilized in their packaging.



The packaging protects against moisture, dust and recontamination with microorganisms. It assures sterility from the time the medical devices are withdrawn from the sterilizer throughout the ensuing storage period until they are used.

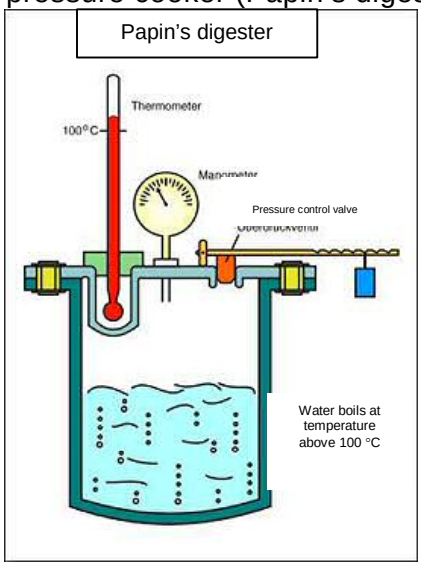
Conversely, unpackaged sterilized items forfeit their sterility when they are removed from the sterilizer and can then only be designated as being “of low microbial count”. This is adequate for use in certain areas (e.g. certain instruments in dentistry).

See Packaging Chapter!

4.2 Steam sterilization

Steam sterilization is the most reliable sterilization process and should take precedence over all other types of processes. The sterilization agent used here is **moist heat**. This leads to destruction of microorganisms, whereby the protein of the cell is destroyed.

The method of functioning used in a **steam sterilizer** can be compared with that of a pressure cooker (Papin’s digester).



Water is heated in an enclosed space and allowed to boil until the space is filled with **saturated steam**. Under normal atmospheric pressure, steam can never be hotter than 100 °C, since it escapes. However, inside the pressure cooker the steam cannot escape and it reaches a higher temperature. At the same time, the pressure inside the pressure cooker increases, giving rise to **pressurized steam**.

The saturated steam under pressure thus generated has a high heat content which, by condensing on the cooler sterile devices is transferred to these, thus killing the microorganisms present.

Superheated steam is generated when further energy is supplied to the saturated steam, but without water being supplied. **Superheated steam** is far less effective for sterilization than saturated steam since it cannot, or can only partially, condense.

♦ **Info: Saturated steam under pressure**

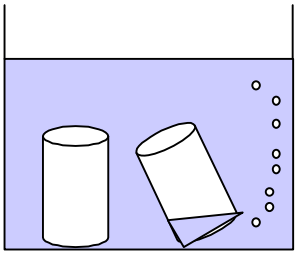
*Steam is called **saturated** if the steam contains the maximum amount of water possible. **Pressurized** steam (=steam under pressure) is generated if steam is heated to above 100 ° C in a sealed vessel.*

4.2.1 Steam as a sterilization agent (sterilant)

Water occurs in three states: in solid form as ice (below 0 °C), in liquid form as water and in gaseous form as steam (above approx. 100 °C). Steam (water vapour) is gaseous water and cannot be seen with the naked eye in the air. Only when the steam cools down e.g. in the air (condenses) can we see the droplets as a "steam cloud" (as e.g. right above a cooking vessel), but really this is, strictly speaking, not steam but rather fine water droplets (mist), i.e. the steam is restored to a liquid state on cooling down. The energy supplied to vaporize the water is released again and kills microorganisms.

It is particularly important here to ensure that there are no residual air pockets in the devices to be sterilized because, otherwise, the steam will not be able to condense at such sites. For the same reason the steam should, as far as possible, be free of any non-condensable gases (air).

Info: *Steam is a condensable gas, hence it is liquid under normal atmospheric pressure. Air is a non-condensable mixture of gases (nitrogen, oxygen, trace gases), i.e. it is gaseous under normal atmospheric circumstances.*



To ensure the presence of steam throughout the sterilizer and the devices to be sterilized, the air must first of all be removed because where there is air, there can be no steam, and vice versa. (Equally, where there is water, there can be no air, this is something we know from our daily working lives (see Fig.).

To remove the air from the sterilizer, the air is suctioned off with a vacuum pump. Negative pressure (vacuum) will then prevail within the sterilizer, i.e. this is a pressure level that is lower than normal atmospheric pressure. This means that the steam can now penetrate throughout the load. To remove as far as possible the entire air from the chamber and the devices to be sterilized, the air removal procedure is repeated several times in modern steam sterillizers. Once the entire chamber is finally filled with saturated steam, the pressure within the chamber is very high, for example on a door measuring 1 square meter a pressure of 10 tons is exerted at 121 °C , and of 20 tons at 134 °C. Hence during the sterilization time, the sterilizer operates under positive pressure, i.e. the pressure is much higher than normal atmospheric pressure.

Another example: the pressure exerted on a one square meter surface is similar to that generated if 5 elephants or 20 cows were standing on it.

Pressure is measured in bar (millibar) or Pascal.

What is the difference between a steam sterilizer and an autoclave?

Autoclave is rather an old-fashioned word for a steam sterilizer, but continues to be used in many places. It actually stands for the original type of steam sterilizer that did not contain a vacuum stage and is now only used in a laboratory setting and is not suitable for sterilization of medical devices. The term “autoclavable” can still be found in the reprocessing instructions of many manufacturers, meaning that something lends itself to steam sterilization.

4.2.2 Process

The operating time of a steam sterilizer comprises the following:

1. **Air removal phase**

   The chamber is evacuated repeatedly to remove as much air as possible from the sterilizer and the devices to be sterilized, this is followed by inflow of steam (= pulsed (fractionated) vacuum method). If there are any residual air pockets (e.g. in laundry) sterilization is not assured.

   The temperature of the devices to be sterilized lags behind that prevailing within the chamber. The interval from which the sterilization temperature is reached in the chamber until it is reached in the devices to be sterilized is called the **equilibration time** (is about a few seconds in pulsed vacuum method).

2. **Sterilization phase**

   During the sterilization time (= holding time, “killing time”) the microbes are killed.

3. **Drying phase**

   Drying after sterilization also constitutes an important process step. The moisture content of sterile medical devices must not exceed certain tolerance limits. Drying is promoted by once again evacuating the chamber, while at the same time the sterile devices cool down and then the pressure equalization follows .

Two programmes have become the gold standard in steam sterilization:

- Temperature: 121 °C / sterilization time: 15 minutes (pressure: 2.1 bar)
- Temperature: 134 ° C/ sterilization time: 3 minutes (pressure: 3.04 bar)

In most sterilizers the sterilization times are prolonged to increase the safety of the process (121 °C/ 20 min, 134 °C/ 5 min).

In most countries, a special programme is used for destabilization of prions (Creutzfeldt-Jakob disease):

- For example temperature: 134 °C / sterilization time: 18 minutes (pressure: 3.04 bar)

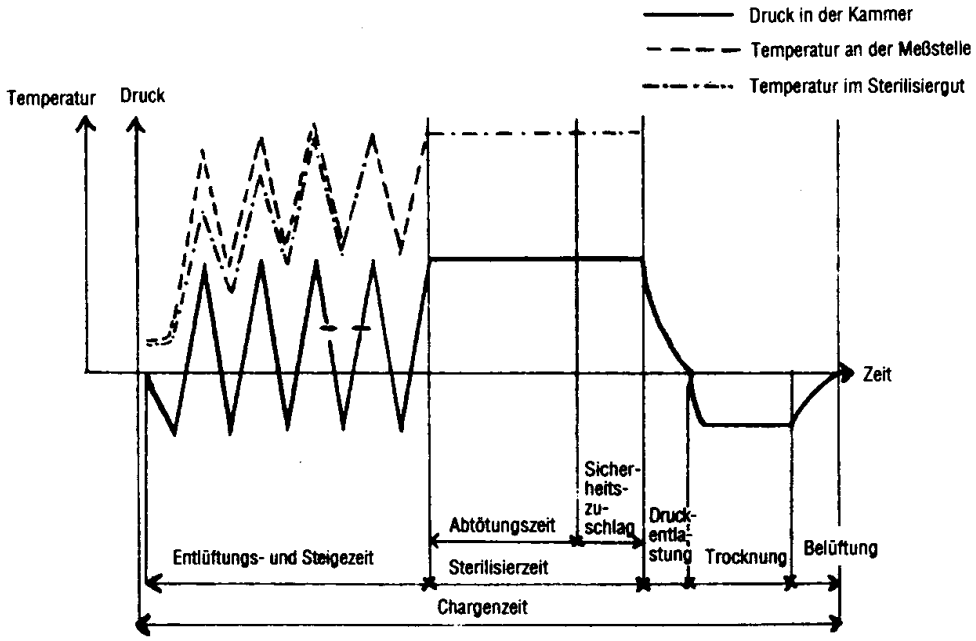


Fig.: Partial steps of the sterilization process (pulsed vacuum method)

Druck in der Kammer = pressure in the chamber

Temperatur an der Messstelle = temperature at measuring site

Temperatur im Sterilisiergut = temperature in devices to be sterilized

Temperatur = temperature

Druck = pressure

Entlüftungs- und Steigezeit = air removal and heating time

Abtötungszeit = killing time

Sterilisierzeit = sterilization time

Chargenzeit = batch time

Sicherheitszuschlag = safety margin

Druckentlastung = pressure release

Trocknung = drying

Zeit = time

Belüftung = aeration

4.2.3 Control of the sterilization process

To ensure impeccable functioning of the steam sterilizer, it must be properly cared for, maintained and inspected.

4.2.3.1 Vacuum test

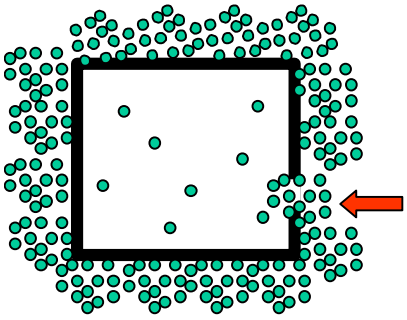
A vacuum (strictly speaking) means a space that contains absolutely no air.

A vacuum test is performed to check that the sterilizer is airtight.

Using the vacuum pump, a certain amount of air is removed. Then a check is carried out to verify whether this reduced pressure can be maintained. If there were to be a leak somewhere in the sterilizer, air would enter and the air pressure would rise again.

Why does air enter the sterilizer if there is a leak?

Air is a gas and gas particles always try to occupy the greatest space available. Hence during the vacuum test when there are only very few air particles present in the chamber, the air particles from outside would immediately occupy the new space as soon as a leak occurs.



For that reason the vacuum test is also called the leakage test or air-tightness test.

The vacuum test must be carried out at least once weekly.

Vacuum test: is my sterilizer airtight?

4.2.3.2 Bowie and Dick test

One of the most important daily checks performed for each steam sterilizer is the steam penetration test (Bowie and Dick test or BD test). The **Bowie and Dick test** is an air removal and steam penetration test. This test checks whether the air has been fully removed and the steam can penetrate the entire load. If the test is in order, the sterilizer can be released for operation on that day.

Bowie and Dick test: is my sterilizer functioning properly?

4.2.3.3 Treatment indicators

Treatment indicators show whether an item had been exposed to the sterilization process, but they do not provide any information on whether the sterilization process was properly executed. Hence the only insight gained is that the respective item had been exposed to the sterilization

process. However, that information can be very important, e.g. if one does not have a double door sterilizer, so as to avoid confusing sterilized with non-sterilized items.

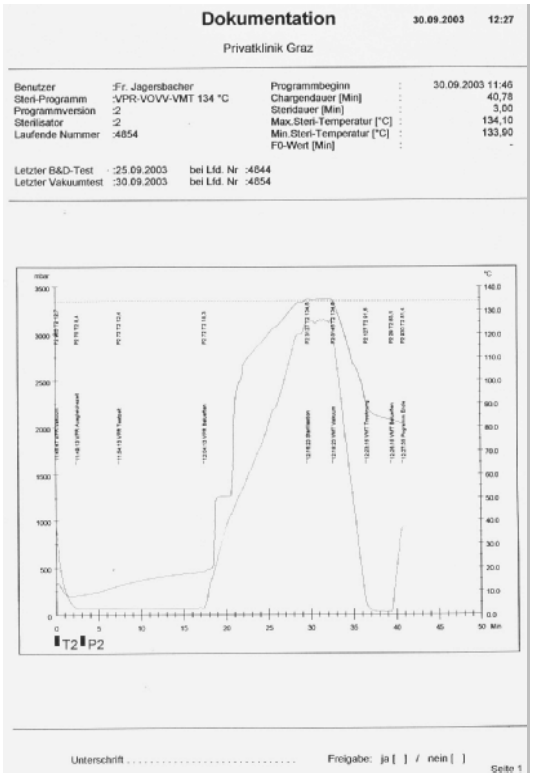
Treatment indicators: has the item been exposed to the sterilization process?

4.2.3.4 Batch control

Special chemical indicators can be used for batch control. These provide information on whether steam had been in the chamber and in the devices to be sterilized and whether the (prescribed) temperature and hold time had been observed. The helix model has proved very useful to that effect (see Fig.). Here the chemical indicator in inserted into a process challenge device (PCD) which is connected to a 1.5 m long Teflon tube. The sterilizer must now, first, remove the air from the tube and, second, drive the steam forward as far as the indicator.

Batch control: has the item successfully completed the sterilization process?

4.2.3.5 **Batch release**



If all the tests outlined above have been successfully passed, the sterilizer has not signalled any fault and the batch protocol (record kept of the temperature and pressure process parameters for the duration of the corresponding sterilization cycle) also meets the specifications, the batch can be released. Only staff who have received commensurate training are authorized to discharge this task.

4.2.4 Validation

In many countries there is a legal requirement that reprocessing procedures be validated.

Validation serves to furnish documented proof of the ongoing effectiveness of the sterilization process under the operating conditions prevailing at the installation site, using the sterile items encountered in routine operation in their respective packaging and with the reference loads used, i.e. it is able to produce sterile medical devices.

Accordingly, validation serves as a means of furnishing proof of quality, i.e. reprocessing must be conducted as per clearly defined guidelines and must continually produce equally good results (be reproducible). To prove that, comprehensive documentation and tests are needed.

The topic of validation will be described in detail in other documents

4.3 Other sterilization processes

4.3.1 Dry heat sterilization

There is, of course, not only moist heat (steam) but also **dry heat** (hot air). Air is less effective at storing and transferring energy than is water.

Take the example of the sauna: 90 °C hot air is no problem for sauna fans, but hot water of 90 °C, i.e. water that has almost reached boiling point, certainly is!

Since hot air is thus less effective than steam, higher temperatures and longer holding times are needed for dry heat sterilization.

In view of the lack of standardization (the operator can intervene in the process at any time; there are no defined equilibration times, loading mistakes, etc. and frequent damage to sterile devices during the sterilization process, **dry heat sterilization should in general be avoided** for sterilization of medical devices.

4.3.2 Sterilization with microbicidal gases (low-temperature processes)

Caution!!!

Not all low-temperature processes are permitted in all countries

Low-temperature sterilization processes are based on the microbicidal action of certain gases. In practice, the main gases used are ethylene oxide, formaldehyde and hydrogen peroxide (“plasma sterilization”).

Since low-temperature processes are not at all as effective as steam sterilization, the following conditions must be assured: the manufacturer’s instructions for reprocessing the respective medical device must specify a low-temperature process and **the device must not be amenable to steam sterilization (because** it is heat sensitive, i.e. it would not be able to withstand the high temperatures encountered during steam sterilization).

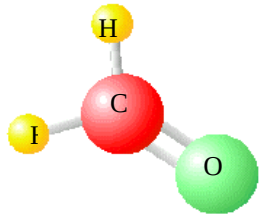
All medical devices that lend themselves to steam sterilization, should be sterilized with steam!!!

4.3.2.1 Sterilization with ethylene oxide (EO)

For sterilization with ethylene oxide the devices to be sterilized are exposed to gaseous ethylene oxide in a gastight, lockable chamber. In principle EO is very effective at sterilizing but suffers the drawback of being very toxic as well as the fact that sterile devices need a prolonged degassing time (desorption). All this is done in a fully automated ethylene oxide sterilizer. Only after complete degassing (due to a relatively long batch time) can the sterilizer be opened and the sterile devices safely removed.

Because of the hazardous nature of this gas, in Germany for example, there are special training courses (Certificate of Fumigation pursuant to the German Technical Regulation on Hazardous Substances - TRGS 513) which are mandatory for the operators of ethylene oxide sterilizers. If an EO sterilizer is being used, operators are strongly advised to attend such a course.

4.3.2.2 Sterilization with formaldehyde (FO)



Sterilization with formaldehyde has the advantage that the formaldehyde-steam mixture used is neither flammable nor explosive. Here, too, degassing takes place immediately after sterilization in the fully automated FO sterilizer. Once the sterilization cycle has been completed, there is no need for further deaeration and the sterile devices can be used immediately.

The disadvantage derives from the poor penetration into plastic materials and from certain drawbacks of the process when used for hollow items. Just as in EO, so here too must the manufacturer's reprocessing instructions be strictly observed. Training courses are being offered to operators, for example in Germany.

4.3.2.3 Hydrogen peroxide "plasma" sterilization

This process uses a high-frequency energy field where a gas (hydrogen peroxide) brought to a plasma state is used as the sterilization agent (sterilant). When hydrogen peroxide is used as a sterilant, the disintegration products remaining are water and oxygen.

4.4 Storage of sterile medical devices

The sterile devices must be protected against dust, light, extreme temperatures and mechanical stress. Hence it is recommended that they be stored at room temperature in dry and dustproof cabinets or drawers (protected storage). Such cabinets / drawers must be smooth and undamaged so that they can be regularly disinfected. Whereas containers can be placed one on top of the other, in the case of transparent sterilization packaging one must ensure that the packaging is not damaged, for example because of sharp instruments.

The first-in-first-out principle is of paramount importance for storage, with the older devices being used first.

The maximum storage period for packaged sterile devices will depend on the type of packaging and storage method used. Unprotected storage, such as on shelves, should be used only for devices intended for immediate use (up to a maximum period of 24 hours). Hence this form of storage should be avoided as far as possible. If the storage room is supplied with filtered air, the whole room is regarded as protected storage (just like a cabinet).

In the absence of country-specific guidelines, the following German standard could be observed.

Guide values for storage of packaged sterile medical devices (based on DIN 58953, Part 7-9)

<table>
<tr><th rowspan="2">Sterile supply packaging</th><th rowspan="2">Type of packaging</th><th colspan="2">Storage duration</th></tr>
<tr><th>Unprotected storage [1]</th><th>Protected storage [2]</th></tr>
<tr><td rowspan="2">Paper pouches as per ÖNORM EN 868-4 and transparent sterilization packaging as per ÖNORM EN 868-5 or packaging of a similar quality</td><td>Single- and double-wrapper sterile supply packaging</td><td>For devices intended for immediate use and should be avoided as storage packaging</td><td>6 months [3], but not after the expiry date [4]</td></tr>
<tr><td>Sterile supply storage packaging unopened or opened and resealed</td><td colspan="2">5 years or as per the expiry date given by the manufacturer</td></tr>
<tr><td>Sterilization containers as per ÖNORM EN 868- 1 or 8</td><td>Single- and double-wrapper sterile supply packaging</td><td colspan="2">6 months</td></tr>
</table>

[1] e.g. on shelves

[2] e.g. in cabinets or drawers

[3] Prolonging the storage duration in this type of packaging is not recommended for practical and economical reasons

[4] The hospital can use its own packaging systems as a substitute for sterile supply storage packaging. The labelling on the original packaging must be transferred in a suitable manner

Important instructions for handling by the user:

- The primary and secondary packaging may only be opened immediately before use
- Before opening sterile supply packaging, any dust on it must be removed
- Once sterile supply storage packaging has been opened, it must be closed again without delay. Under such circumstances, the storage duration specified above for sterile supply storage packaging applies

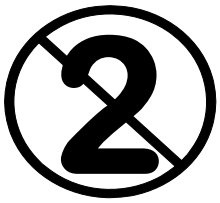
The storage periods listed here apply not only for medical devices sterilized by the respective institution itself but also for bought-in sterile single-use medical devices, i.e.

the expiry dates on the packaging applies only for as long as the device remains enclosed in the storage packaging.

4.5 Withdrawal of sterile medical devices

Before the sterile supply packaging is opened, it must be inspected. If one notices that it is moist, dusty, damaged or had been opened, such items will in general be deemed unsterile and must be reprocessed once again or discarded (single-use devices).

4.6 Sterilization of single-use devices



Such items will be marked “single use” This “single-use symbol” is a crossed-out “2“ (see Fig.). No provision has been made for reprocessing of single-use devices, and rightly so!

Either one can reprocess medical devices, and in such a case they should be marked accordingly, or this is not permitted. Of course, there are also those single-use devices that could really be reprocessed but are marked as „single use, to – as claimed by some sceptics – boost sales.

However, in such cases another supplier can generally be found who will label the device as “for reuse” and also provide the corresponding reprocessing instructions.

Reprocessing of single-use devices is strongly advised against because the liability is then shifted to the reprocessor, which means that if anything were to happen e.g. because of material fatigue, one bears complete liability and the manufacturer is absolved of any liability.

4.7 Flash sterilizers

The use of “flash sterilizers” have for a long time now no longer reflected the state of the art and certainly does not comply with the practices advocated in any of the relevant standards (no vacuum stage, no documentation, etc.). The argument sometimes put forward suggesting that they are definitely needed turns out in most cases to be untrue and generally shows a reluctance to give up habits to which one has become accustomed,

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Austrian Society for Sterile Supplies

Österreichische Gesellschaft für Sterilgutversorgung (www.oegsv.com)