

### **Washer-disinfectors – the best method for cleaning and disinfection**

Washer disinfectors have a double function: first a thorough cleaning process followed by heat disinfection where the water temperature is elevated almost to boiling point.

Another key feature of washer-disinfectors is the extremely high flow of water, in terms of both volume and pressure.

Washer-disinfectors are sophisticated medical devices. The relation between the increase in water temperature and process time is of great importance and must be well calibrated. There are a number of circumstances that the manufacturers have to take into account. These circumstances also call for regular process validation.

### **The force of massive water flow**

An important feature of washer-disinfectors is the extremely high flow of water, in terms of both volume and pressure. The massive flow of water spraying all items in the washer-disinfection process results in very effective physical (mechanical) cleaning. The washer-disinfection cycle should always start with cold water. The in-flowing water must be maintained at a temperature low enough to preclude the occurrence of protein coagulation. Temperatures higher than +45°C (+113°F) can cause protein coagulation during the flushing stage and cause cleaning problems in the further process.

In every thermal disinfection and sterilization cycle there is always an initial microbial activation phase before the temperature has become high enough to inactivate and kill the microbes. In a humid (wet) environment, germination of several species of endospores reaches its maximum in the temperature interval from +45°C (+113°F) to +52°C (+127°F). Slower changes in temperature parameters at specific temperature intervals in the washer-disinfection process will favor outgrowth (germination) of endospores. Bacteria are killed at much lower temperatures than the corresponding endospores. The washer-disinfector process is thus “indirectly sporicidal”, killing the endospores by first stimulating them to grow out in their vegetative bacterial stage.

The use of proper detergents is important in washer-disinfectors. They should have an anti-protein action at low temperatures and an anti-lipid action at higher temperatures. Most detergents intended for washer-disinfectors also have an enzymatic activity. The types of enzymes used normally have their highest activity at around +50°C (+122°F). The cleaning agents are often tailor-made so that different modes of action will appear at different temperatures. In the cleaning phase of the procedure, the articles are washed in water at temperatures up to +70°C (+158°F). Once the cleaning phase is completed and before the disinfection phase, residual chemicals (detergents) must be removed from all items. The residual level which can be tolerated will depend upon the nature of the chemical and the intended use of the product being cleaned. Elevated levels of chemical residuals on articles and goods can lead to adverse and, in the worst cases, toxic reactions and thus adversely affect treatment results.

In the final disinfection phase, the water temperature increases, providing thermal disinfection of the load. In the temperature range of +85°C (+185°F) to +95°C (+203°F), pathogenic microorganisms are inactivated or killed. Bacterial endospores survive these temperatures, but if the procedure has worked as intended, the endospores will be inactivated, tricked into germinating, and then killed (in its bacterial form) or simply washed away. In order to ensure inactivation of viruses, particularly heat-tolerant ones, it is now recommended that the water temperature during the disinfection phase should be just over +90°C (+194°F).

Even though there are international standards as well as European and other norms for washer-disinfectors, national regulations may differ. The disinfection capacity does not depend solely on the temperature; the contact time must also be considered. Lower disinfection temperatures require longer contact times (disinfection phase).

### **Common confusions – sterilization versus disinfection**

Sterilization is the use of a physical or chemical procedure to destroy all microbial life, including large numbers of highly resistant bacterial endospores.

Disinfection is generally a less lethal process than sterilization. It eliminates nearly all recognized pathogenic microorganisms but not all microbial forms (bacterial endospores) on inanimate objects.

### **Important definitions: cleaning, decontamination and disinfection**

Cleaning involves the removal of soil, organic substances and other residues from a surface or item. Cleaning in itself do not comprise any microbial killing action and should therefore not be confused with decontamination and disinfection.

Cleaning simply means that all visible soil is removed from an item, but this item may still be contaminated with harmful microorganisms.

However, if the cleaning procedure is carried out under certain conditions, e.g. in washer-disinfectors, the process may also include decontamination and disinfection.

Decontamination is a term used to describe a process capable of rendering an item (medical device, instrument, surface) safe to handle. Decontamination does not necessarily mean that the article in question is safe for patient use.

Decontamination involves cleaning, i.e. all harmful substances must be removed from the items. This does not necessarily mean that all microorganisms are killed; they might merely be reduced to a "non-hazardous" number. This means that the article is clean at this very moment but that it can become "recontaminated" if all the microorganisms are not inactivated through a disinfection process.

Disinfection is generally a process that inactivates (kills) nearly all recognized pathogenic microorganisms but not all microbial forms (bacterial endospores) on inanimate objects. Disinfectants are germicides intended to be used solely for destroying microorganisms on inanimate objects such as medical devices or environmental surfaces. The disinfection process only kills the microorganisms on items but does not necessarily mean that the items are clean.

### **Three levels of disinfection depending on the purpose of the procedure**

High-level disinfection is a procedure with a demonstrated level of activity against bacterial endospores. High-level disinfection does not necessarily destroy large numbers of highly resistant bacterial endospores, as is required of sterilization procedures.

High-level disinfection can be used to treat certain medical devices. The total absence of bacterial endospores cannot be ensured, but it has been shown that the numbers of spores on items subjected to such treatments are generally very low.

Intermediate-level disinfection refers to procedures that are not necessarily capable of killing bacterial endospores, but which do inactivate *Mycobacterium tuberculosis*. Mycobacteria are more resistant to disinfection than ordinary vegetative bacteria. Intermediate-level disinfection is also effective against fungi as well as naked and enveloped viruses.

Low-level disinfection cannot be relied on to destroy, within a practical period of time, bacterial endospores, mycobacteria, all fungi and naked viruses, but it inactivates vegetative bacteria, most fungi and enveloped viruses

### **Beware of endotoxins**

Disinfection and sterilization can be achieved by physical or chemical means, either by the removal of microorganisms from an item or by killing the microorganisms on site.

If microorganisms are simply killed on site, toxic products such as bacterial endotoxins and breakdown products will be left on the items.

Elimination of endotoxins continues to be a problem and standard methods of sterilization, such as autoclaving, have little effect on endotoxin levels.

### **Moist heat / water should always be number one choice**

Decontamination, cleaning and disinfection by thermal treatment is always preferable. The easiest method is in an automated washer-disinfector that cleans and disinfects in a single step.

### **Sterile goods in washer-disinfectors after completed cycle**

If handled (and especially if loaded) with goods as intended, and if maintained properly, the final results of washer-disinfectors will actually be sterilized goods.

The major difference between washer-disinfectors and sterilizers is that washer disinfectors remove bacterial endotoxins and breakdown products on items as well as chemical residuals.

The major disadvantage of washer-disinfectors is than even if the process results in sterilized products, the problem is how to get them out of the washer-disinfector in a dry and sterile condition and also how to maintain sterility.

**Sterilization adds wrapping possibilities for safe handling and storage**

What the subsequent sterilization process adds is the possibility of wrapping the products. Another very critical aspect is that sterilization substantially increases the safety margin.

Logistics, transport and storage makes it necessary to add a safe wrapping to washer-disinfected items and this can only be achieved in a sterilization process.

**Chemistry must never be an alternative to moist heat**

Chemical disinfectants as well as chemical sterilants can be useful in carefully selected situations. For instruments and similar articles, chemical disinfectants must never be an alternative to disinfection with moist heat in any situation where the latter is possible.

Chemicals can only be a complement – never an alternative – to sterilization procedures with moist heat – a sterile instrument should be sterile at the point of use. This requires a sterile wrapping for safe handling, transport and storage after the sterilization process, and sterile wrapping is impossible after immersion in a chemical agent. To be handled as sterile goods if chemistry has been the choice, chemical residuals must be removed and the object then wrapped and processed through a sterilizing cycle using moist heat.