ZENTRAL STERILISATION 6

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Which Sterilant is the Active Component in a Steam Sterilisation Process? Steam? No, it's water!

This provocative title is, to begin with, a hypothesis that must be proven. To that effect, the following 3 sterilants will be discussed.

1. Steam

It is well known that overheated steam, while it is in the gas phase at an unchanging temperature, is endowed with sterilisation properties that are only on a par with those of air. Likewise, the saturated steam that streams into a completely dry textile pack made of cellulose fibres, such as e.g. linen or cotton, generates an intrinsic heat due to hydroscopic condensation on the cellulose fibres on absorbing steam. It does not, however, moisten the fibres, hence inside these textile packs temperatures are measured that are higher than the saturated steam temperature. Therefore steam condensation cannot enter the inside region of the textile packs. Any standard biological indicators placed within the pack in accordance with EN 866-3 will not be killed at these sites on using standard steam sterilisation processes at 121 °C for 15 min. Of course, overheated steam can cool down, and condense when further cooled, on coming into contact with cold surfaces.

2. Condensing Saturated Steam

At saturated steam temperature, steam condenses on objects that are colder than the saturated steam temperature. In doing so, the steam transfers its condensation heat very quickly and effectively. Once the objects in question have reached the temperature of the saturated steam, no further condensation or heat transfer takes place. During the heat-up phase water condenses on the objects to be sterilised, whereas during the sterilisation phase no further steam consumption, and hence no condensation, takes place. Many authors claim that it is the condensing steam that acts as the sterilant without ever having provided proof of this. If one observes how biological indicators are inactivated in steam sterilisation processes, one sees that on illustrating a logarithmic plot of the surviving microbes against a linear plot of the time one gets a straight line. This means that during the condensation phase at the beginning of sterilisation there is no "kink"; rather, in this diagram we see linear inactivation, during which no further steam condensation takes place. This thus proves that condensing steam does not give rise to inactivation.

3. Water

Liquids can be sterilised in closed vessels without supplying steam. Here one can observe that the microbial kill kinetics evidenced in distilled water at an unchanging temperature is equal to the kill kinetics that would be manifest if the same microorganisms were killed in a steam sterilisation process under otherwise similar conditions. From this observation one can unequivocally conclude that it is only the water that can act as the sterilant.

Conclusions

The belief, which on occasion is still being propagated at specialist training courses, that wet sterilised articles are not sterile at the end of the sterilisation process is thus ill founded. This belief also runs counter to the fact that following sterilisation processes that do not include a drying cycle at the end, such as in flash sterilisers, the wet articles are likewise not sterile. Even today sterilisation processes that do not include drying are being used provided that the articles are immediately put to use. Wet articles at the end of the sterilisation process are thus sterile provided that the sterilisation process has been properly conducted. Hence wet articles can be released for immediate use without any reservation. But wet articles should not be stored because microbes can penetrate through wet soft packaging or growth conditions can be fostered within wet packaging, giving rise to a situation in which one sole surviving microbe would be enough to engage in multiple reproduction and thus recontaminate the respective article during storage.

To reliably sterilise all surfaces of an article, it is not only the requisite temperature effect that is important but additionally it must be ensured that all surfaces to be sterilised are covered with a, even if it is very thin, water condensate film. The articles may not be sterile at all sites where condensation on the surfaces to be sterilised is impeded, e.g.

(1) Sealed surfaces using elastic sealing materials.

(2) Lubricant or biofilms that prevent water from gaining access to the surface.

(3) Narrow gaps such as those found in the plugs of cocks which are lubricated and prevent condensation between the sealed surfaces.

(4) Non-condensable gases that accumulate in porous textile packs or hollow cavities, thus preventing steam condensation.

(5) Sealing materials such as rubber seals for sealing glass bottles or metal containers.

It is well known that microbial inactivation is a function of the carrier on, or in, which the microbes are to be found. For example, additives in the feedwater supplying steam generators affect the pH value of the water, as do the additives in fluids used for infusion solutions. Compared with distilled water at a pH value of 7, the

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sterilisation time needed for e.g. 1% saline must be increased by around 30% to kill the same number of microorganisms under otherwise similar conditions.

The porosity and material of surfaces, too, exert a strong influence on microbial inactivation. In our laboratories we have demonstrated that rubber plugs contaminated with *B. stearothermophilus*, at an unchanging temperature, will need around 50% longer sterilisation times than when killing the same microorganism under saturated steam conditions in water or on filter paper.

It is therefore paramount that care products can be mixed with water or contain water. They should not be allowed to prevent water condensation on the surfaces to be sterilised.

I would be delighted if this paper would lead to animated, and possibly controversial, discussion in this journal. ✦