The low temperature steam formaldehyde (LTSF) process is not a typical gas sterilization process but a modified steam sterilization process. Details of the sterilizer specifications are available in the standard EN 14180. This process is divided into the following consecutive steps:

(A) Conditioning phase
- air removal
- steam penetration
- condensation of steam to water on all surfaces to be sterilized

(B) Formaldehyde saturation
The condensate on the surfaces must be saturated with formaldehyde gas (gas: liquid concentration = 1:10.000 in equilibrium), therefore a long convection and/or diffusion phase is required until equilibrium is achieved

(C) Sterilization
Different sterilization times depending on the temperature and the formaldehyde concentration and on the load configuration are required

(D) Formaldehyde desorption
Elution of the formaldehyde with steam/water

(E) Drying
Cyclic aeration and deaeration under sterilization temperature conditions

(A) Conditioning phase

All processes have in common that they use a fractionated vacuum to carry out the conditioning phase (A) which assures air removal, steam penetration and condensation of water on all surfaces. Pressure differences in formaldehyde sterilization processes are quite low. The possible lower pressure value is depending on the quality of the pump and the cooling water temperature (approx. 3 – 7 kPa) and the upper pressure value is depending on the partial pressure of the water after reaching the working temperature (approx. 15 – 25 kPa). Therefore between 10 and 20 vacuum cycles are necessary to achieve an adequate air removal and steam penetration.

(B) Formaldehyde saturation

The formaldehyde saturation is performed quite differently in the sterilizers from various manufacturers and is described in the following 5 different procedures:

(1) Steam conditioning with subsequent injection of 30 – 40 % formaldehyde solution
This procedure uses a fractionated air removal and steam condensation to water. At the end of the fractionation, at the beginning of the plateau period a high percentage formaldehyde solution is injected in the sterilization chamber and evaporated.

Since the formaldehyde concentration in the gas phase is about 10.000 times lower than in the liquid phase, the saturation of the condensate with formaldehyde is time-consuming because of the low formaldehyde concentration in the gas phase. In tubes and hollow devices the formaldehyde is “absorbed” by the wet inner surfaces at the open tube ends so that it takes a long time until the formaldehyde gas gets into the inner areas of the hollow instruments and tubes.

(2) Steam fractionation with multiple formaldehyde injection to improve the process (1)

To improve the formaldehyde penetration of the process (1), into tubes instead of a one-time injection of concentrated formaldehyde solution before starting the plateau phase, concentrated formaldehyde is injected several times during the fractionation steps, with the advantage that the penetration of formaldehyde in tubes and hollow devices is improved but it is often still not sufficient.

(3) Evaporation of steam containing formaldehyde

To further improve the penetration of formaldehyde in hollow devices, instead of water about 2 - 3 % formaldehyde solution is used for steam generation with the advantage that in addition to air removal and steam penetration at the same time the formaldehyde penetration occurs during the 10 – 20 air removal cycles. Disadvantageous is, that the formaldehyde concentration depletes during the fractionation phase in the steam generator and the formaldehyde concentration in the active evaporating solution is continuously reduced during the plateau phase. The concentration reduction of formaldehyde is heavily dependent on the steam consumption of the load

(4) Injection evaporation of formaldehyde solutions

Also in this procedure the formaldehyde solution is used for fractionated air removal like in procedure (3). However, to avoid the concentration diminishing of the formaldehyde solution during the fractionation phase, the cold formaldehyde steam mixture is injected into the process using a separate evaporator. Therefore, the formaldehyde concentration of the formalin solution remains always constant during the whole process. This procedure assures a stable process which is not load-dependent.

(5) Sterilization with formaldehyde- and steam-saturated air

This procedure blows air through a concentrated formaldehyde solution. The air bubbling through the solution is almost saturated with steam and formaldehyde. With this air-steam-formaldehyde-mixture a fractionated vacuum process is carried out. However, it has become evident, that because of the low amounts of steam and formaldehyde only open surfaces are reached but not at all internal lumens which are blocked by air and therefore cannot be sterilized. This procedure is only suitable for solid instruments and has been stopped in the meantime from the manufacturer

because of the insufficient efficacy to sterilize hollow devices. Unfortunately this process is still used in some old sterilizers and shall be stopped.

The first four processes still on the market don't differ in air removal and in the desorption phase but only differ in the kind of formaldehyde saturation of the condensate on the surfaces.

Because of the different procedures the formaldehyde penetration – as described above – is heavily dependent on the process. For long, narrow volumes the processes (3) and (4) are most suitable. The efficacy of the process must be tested with a hollow load helix device with biological indicators described in EN 867-5 and used as a type test in EN 14180 for LTSF sterilizers. It is recommended to use a Process Challenge Device (PCD) which is adapted to the goods to be sterilized with suitable biological indicators to monitor the penetration characteristics of the process. For further information see our technical information TI 730-041 EN.

(C) Sterilization

The individual processes are working at different temperatures and times. Most of the processes assure that during the sterilization time the temperature within defined limitations and saturated steam conditions are kept. During the sterilization phase surfaces which are easy to reach are sterilized very well. As described above the difficulty is to penetrate formaldehyde into narrow lumens.

To check the penetration characteristics the LTSF sterilizer standard EN 14180 requires the test with the Helix-PCD "Hollow load" according to EN 867-5 as a type test. It is mentioned in the standard, that the PCD should be made of plastic. Recent tests showed that stainless steel PCDs, which are more stable, don't have any influence on the test result, since the LTSF sterilizers themselves are made of stainless steel. Therefore GKE offers all Helix- or Compact-PCD capsules for LTSF processes made of stainless steel.

(D) Formaldehyde desorption

In all procedures the sterilizing agent formaldehyde is safely removed from the load by several steam fractionation steps. The amount of fractionation steps is in accordance with the achievable pressure difference and the complexity of the load how difficult formaldehyde is removed from narrow lumens. Remaining amounts of formaldehyde can be detected easily after opening the sterilizer by smelling formaldehyde odour, since the human nose detects formaldehyde already in approx. 500 times lower concentration that ethylene oxide. Because of the detectability of extreme low concentrations by humans, users never expose themselves to toxic concentrations.

(E) Drying

By cyclic, fractionated aeration and deaeration drying can be achieved in all procedures. By comparing the weight of the goods before and after sterilization the degree of dryness can be determined easily.