

Steam sterilizers with class B cycle are necessary for the sterilization of hollow, porous and wrapped goods.

Steam sterilization with pre- and post-vacuum phases

In steam sterilizers with pre- and post-vacuum processes, the sterilization process comprises three main phases: pretreatment, sterilizing and post-treatment.

During pretreatment the air is expelled by a number of pulses of vacuum and the introduction of steam. The temperature increases successively, up to the degree at which sterilization is to take place.

In the pre-vacuum phases, each vacuum pulse brings the air pressure in the sterilizer chamber down below 300 mbar, the same air pressure as on the top of Mount Everest. Some steam sterilizers go as deep as 100 mbar in the pre-vacuum phases, which is the same air pressure as at 20,000 – 25,000 meters (65,000 – 82,000 feet) above sea-level, i.e. far above the maximum altitude of most aircraft.

Virtually all air must be evacuated during pretreatment (pre-vacuum phase) so that the saturated steam can affect the goods during the sterilizing phase. If present, trapped air pockets in the goods prevent steam penetration during sterilization of porous material such as textiles and hollow items. Solid instruments require only the surface of the instrument to be sterilized. Hollow instruments with cavities and/or tubules have both inner and outer surfaces and the inner surfaces are difficult to access with steam. It is also easy for air to remain entrapped in larger textiles.

The number of evacuation phases necessary is highly dependent on the degree of vacuum in relation to the number of vacuum pulses. A single vacuum pulse is insufficient and inadequate for wrapped/hollow/porous loads. Steam sterilization of hollow instruments and porous objects always requires at least three (3) pre-vacuum pulses. Steam sterilization of objects with long, narrow lumina, requires several pre-vacuum pulses to a defined, pre-set, vacuum level.

The actual sterilization period, called the holding time, starts when the temperature in all parts of the sterilizer chamber and its contents (the load) have reached the sterilization temperature. The temperature should then remain constant, within the specified temperature band ($134^{\circ}\text{C}\pm 2^{\circ}\text{C}$), throughout the sterilization phase (plateau/holding time).

The pressure / vacuum, in itself, has no lethal effect on the microorganisms. There are experiments where common bacteria have been able to keep alive under extreme pressures of up to 400 atm. The killing effect is due to the energy transferal when the saturated steam condenses on the items to be sterilized and thereby causes cleavage of intramolecular hydrogen bonds between proteins.

Steam sterilization – the safest and most reliable method

Steam sterilization is more effective than other forms of sterilization because brief exposure to steam destroys most resistant bacterial species and heat is rapidly achieved because of mass heat transfer as the steam condenses.

Steam sterilization requires exposure of each item to direct steam contact at the required temperature and pressure for the specific time. Well-designed steam sterilizers deliver steam to the bacterial sites throughout the load. The major problems during the process are air evacuation, superheating and load moisture.

Virtually all air must be evacuated during pre-treatment so that the saturated steam can come into contact with all surfaces of the goods during the sterilizing phase.

Dangerous and entrapped air-pockets

In the sterilizer, for energy to be released and to ensure that all items intended to be sterilized are accessible to the saturated steam, it is important that the air first be removed from the sterilizer chamber and from all parts of the goods intended to be sterilized.

Instruments and items located where there are pockets of air never come in contact with saturated steam and will therefore not be sterilized. The same goes for internal surfaces in hollow instruments, where air-pockets can easily be entrapped.

Steam sterilization with pre- and post-vacuum phases – safe and reliable

In steam sterilizers with pre- and post-vacuum processes, the sterilization process consists of three main phases: pre-treatment, sterilizing and post-treatment.

During pre-treatment, the air is expelled by pulses of vacuum and the introduction of steam. The temperature increases gradually, up to the degree at which sterilization is to take place.

Perfect steam within very narrow temperature range

The key prerequisite for saturated steam – and to achieve the relatively large release of energy – is that the water is at the boiling point, where a change of phase (saturated steam to water) can occur. The boiling point of a liquid is reached when the vaporization pressure of the liquid exceeds the surrounding air pressure. At normal air pressure (760 mm Hg – 1 atmospheric pressure at sea level), this occurs at +100°C. The boiling point varies according to air pressure and therefore under conditions of low or high pressure.

Superheated or supermoist steam will not work

The presence of supersaturated supermoist steam results in the failure of steam to penetrate the items in the chamber. Too much air can be compared to an attempt to force the air out of the leg of a pair of jeans: it is easy if the textile is dry, but if it is wet much more force is necessary to expel the air. The same phenomenon occurs with packages or porous items in supermoist steam.

Sterile does not mean clean and safe for use

The benefits of a sterilization process can easily be lost if goods are not wrapped. Logistics, transport and storage make it necessary to safely wrap high-level disinfected (washer-disinfected) items and this can only be achieved in a sterilization process for wrapped goods.

Sterility is defined as the total absence of any microorganisms capable of reproduction. There is confusion in the use of the term sterile; in the area of hygiene and infection control it often refers to a medical device being clean, safe and free of disease-causing microbes.

It is of great importance to fully understand that the term sterile means nothing less than *not being able to reproduce*.

The term sterility, in itself, has nothing to do with being clean, free of endotoxins, free of microbial residuals or being safe to use. In the internationally accepted definition, sterile items should have a sterility assurance level (SAL) of 10^{-6} . This definition of sterility as a probability function does not assume that one in a million products is allowed to be non-sterile but admits a finite mathematical, statistical probability that microorganisms may survive the sterilization process.

SAL calculations do not in any way define the amount of residual bioburden or the amount of endotoxins or other biological residuals. SAL only refers to the death rate of microbes.

Theoretical methods to prove sterility

There are no methods after the sterilization process to prove that the entire load is sterile without destroying the whole load. Therefore the quality assurance has to be based on so-called “process challenge devices” and theoretical, mathematical calculations on the probability of a specific process resulting in sterile goods.

Proper cleaning and decontamination – the number-one priority

For this reason it is important that the whole decontamination-disinfection and sterilization cycle is validated in accordance with a quality assurance program. This must include validation, qualification and process control of both the cleaning-disinfection procedure as well as the sterilization process. They cannot be seen as separate entities – if articles are not thoroughly clean, sterilization will fail.

Dangerous misunderstanding

There is a very common and dangerous misunderstanding that sterilization is the most important part in the hygiene and infection control cycle. *It cannot be emphasized enough that the most important part will always be cleaning!*

Sterilization procedures combined with wrapping are essential for safe handling, storage and transport, but sterilization can never be an alternative to cleaning. *Cleaning and subsequent disinfection (read: washer-disinfection) are always the most important procedures when reprocessing instruments and articles for sterile use.*

This is of course on condition that the washer-disinfection process is performed as intended and if proper maintenance and validation of the procedure are carried out.

Steam should be first choice.

Sterility may be achieved by various methods: heat, chemical and ionizing radiation. The simplest method is heat sterilization. There are two methods: dry heat sterilization, i.e. use of dry heat (usually a hot air oven or sterilizer), in which moist heat (steam) is used.

Dry heat is a slow process which requires high temperatures. The most definitive method of sterilization is incineration which will carbonize (char) all organic material. Heating instruments red-hot over an open fire is a well-known ancient method of sterilization, and in many situations still a useful method but unpractical for medical devices and also harmful. Incineration has its major use in the handling of hazardous biological waste.

Today, the quickest, safest and most efficient method is steam sterilization. Steam sterilization is also inexpensive and cost-effective.

Without wrapping, logistics are impossible

Regardless of the method, the result of sterilizing procedures depends, among other things, on the number of microorganisms and other biological material present on the article before inactivation and the resistance of some microorganisms to the sterilization process. The volume and composition of the bioburden on the articles to be sterilized determine the amount of energy required for sterilization. The physical properties of the materials to be sterilized are also of great importance: solid instruments, hollow items, porous loads, volume and weight of the load etc.

Gravity-displacement autoclaves – not for sterile articles

This is the simplest type of steam sterilizers. The standard method for air removal is based on steam being lighter than air; when steam is introduced in the autoclave chamber it forms a stratified layer across the top internal volume in the autoclave chamber. With increased volumes of steam introduced, the steam will press (force) the air towards the bottom of the autoclave chamber.

In the bottom of the autoclave chamber (at the floor), a valve opens and lets the air out when steam is forced into the chamber – downward displacement.

There are a number of important drawbacks with gravity-displacement autoclaves:

As the steam is introduced into the chamber, the air pushed downwards by the steam wave front can diffuse into the steam. Therefore the steam has to be constantly and rapidly renewed. Even if microscopic, the remaining air-pockets will prevent the steam from getting in contact with the items to be sterilized. And no contact means no condensation, no energy-release and consequently no sterilization in these areas. This is the major reason why such autoclave cycles can only be used for sterilization of solid and unwrapped articles.

Introducing steam with great speed into the chamber can cause other disadvantages. High-velocity steam carries with it microscopically small water particles – atomized particulate water droplets. This results in moist steam, which is not able to release as much energy as saturated steam.

An additional problem with high-velocity steam is that the introduction causes turbulence in the autoclave chamber, thereby increasing the mix of air into the steam.

Downward- (gravity-) displacement sterilizers are widely used. However, these are increasingly being superseded by steam sterilizers with pre- and post-vacuum processes. Preconditioning with several pre-vacuum phases is essential for sterilization of wrapped, hollow or porous items.

Flash steam sterilization – only in case of emergency

Flash steam sterilization is a process for steam sterilization of items for immediate use and should be used only in carefully selected clinical situations. Flash steam sterilization can be described as downward gravity displacement sterilization using a continuous flow of high-velocity steam throughout the sterilization phase.

Flash steam sterilization should be used only for solid, unwrapped items. Items must be transported immediately to the point of use so that sterility is maintained.

Dry-heat sterilization – oxidation of items

Dry heat can be used to sterilize items that might be damaged by moist heat. One advantage is the relatively low cost of equipment, but the disadvantages are the duration of the process and the high temperature. Diffusion and penetration of heat are slow because the heat transfer medium is poor, and there is a lack of available heat, particularly compared to steam. Long exposure times are required

because the killing rate by dry heat is slow, as is heat absorption. Killing by dry heat is an oxidation process and both the oxidation and the high temperatures required may damage the materials to be sterilized. Certain alloys can be softened by exposure to such high temperatures.

Since heating in a dry-heat sterilizer is slow, overloading of the dry-heat sterilizer can delay heat convection. This can be caused either by preventing circulation or by heat absorption in the goods. Consequently in an overloaded dry-heat sterilizer there is a risk for uneven heat distribution. A heavy load of instruments will then require an extremely long process time. Under such circumstances, organic material will tend to char and bake on the items to be sterilized.

For the sterilization of medical devices there has been almost no new development or improvement, and dry-heat sterilization is about the same as it has been for several decades.

Unsaturated chemical vapor sterilization

In several countries, unsaturated chemical vapor sterilization in worktop sterilizers is still common. ***Even though the procedure is based on the use of formaldehyde solution (formalin), unsaturated chemical vapor sterilization should not be confused with low-temperature sterilization.***

Unsaturated chemical vapor sterilization involves heating a chemical solution containing formaldehyde, ethanol, acetone, ketone, water and other alcohols in a closed chamber. Usually a solution of primarily ethanol with added water and a low percentage of formaldehyde (0.23%) is used. The temperature during the sterilization phase varies between different brands but is usually around +130°C (+270°F), but there are also programs with lower temperatures. The steam pressure during the holding time (sterilization phase) is 1 380 bar – 2 750 bar (20 – 40 psi).

Unsaturated chemical vapor sterilization of carbon steel instruments (e.g. dental burs) causes less corrosion than steam sterilization because of the low level of water present during the cycle. Instruments should be dry before sterilizing.

Although this procedure is less corrosive to sensitive instruments than steam sterilization, it has disadvantages. Formaldehyde has an extremely piercing smell even in low concentration.

After the process, all residuals of formaldehyde must be removed, which requires special separators and air-filters of exhausted vapor from the chamber.

Authorities should be consulted for hazardous waste disposal requirements for this sterilizing solution.

Unsaturated chemical vapor sterilization functions in accordance with the same principles as downward gravity displacement sterilization and should be used as such. There are reports of poor penetration of hollow items, e.g. rotary dental instruments (hand pieces, turbines).

A tremendous amount of lethal energy

In order to understand correctly the sterilization process it is important to understand how a steam sterilizer – sterilization with water vapor – functions. A basic prerequisite is a sterilizer chamber with so-called saturated steam. Heating one liter of water from room temperature to the boiling point requires approx 300kJ (kiloJoules).

When the water reaches the boiling point, all additional energy will be used to convert the liquid water to steam and only when all the water has been converted to steam can the additional energy be used to further raise the temperature. In this latter phase the temperature of the steam will increase. Converting one liter of boiling water to steam requires 2250 kJ.

If the saturated steam comes into contact with any object which is cooler than the boiling point, the steam will condense, releasing its intrinsic energy. A prerequisite for this great release of energy is that the water changes phase from saturated steam to liquid. It is this energy release that is used to sterilize the items in the steam sterilizer.

Extreme engineering

Tremendous forces affect the load during the sterilization phase. It takes 3 liters of water to sterilize a package comprising 7.5 kilograms of textile in a steam sterilizer with a 63-liter chamber volume, running a complete textile program. The energy released from the steam generated by the 3 liters of water when condensing on/in the load (changing phase from steam back to water) will be 3 x 2 250 kJ = 7 750 kJ. This is an enormous amount of energy, equivalent with the force needed to lift two jumbo jets 1 meter above the ground.

During the sterilization phase, the pressure within the chamber is increased up to slightly over 3000 bar, corresponding to a pressure on the back (inside) of the door of the sterilizer chamber in a small table-top sterilizer equivalent to 2 (two) metric tons. The size of the door is approximately 6 dm³ (75 sq. in.). In a larger hospital steam sterilizer (63-liter chamber volume), the corresponding pressure on the inside of the door will be 10 (ten) metric tons!

The sterilizer adds the wrapping

In the sterilization process, the microbial molecules will be destroyed (broken down to minor units) but the residuals will still be there. They can only be washed away! It cannot be stressed enough that the sterilization procedure adds the wrapping, and also gives a bigger safety margin!

“Visible steam” is not steam

When water boils, the saturated steam nearest the surface of the boiling water is invisible to the naked eye. The visible “foggy steam” at a distance of a few centimeters from the surface of the boiling water is actually not saturated steam. When steam can be discerned as fog it has already started to condense as it gets into contact with the cooler surrounding air. What can be seen is supersaturated or supermoist steam and it is the microscopically condensed liquid particles which make the “steam” visible. If you put your hand in this “visible steam” it will become warm and quickly moist from the condensation. However, if you put your hand into the invisible saturated steam, you will rapidly burn yourself due to the great release of energy from the saturated steam.

A cloud of condensed water (mist) coming out of the chamber of the sterilizer on opening the door after the completed sterilizing cycle, indicates that the steam intended for sterilization has been too wet.

This is usually due to overloading the sterilizer or trying to run the wrong load in the wrong program.

Residual moisture must be minimized

Residual moisture in the packaging material after sterilization acts as a potential pathway for microorganisms to penetrate the package. The most common fault is that the chamber has been packed too tightly or that the load is too heavy.

Post vacuum is an effective method for drying the load and removing remaining moisture.

Energy transfer is the basis for all types of sterilization. In steam sterilization, the death of the microbes is caused by very large amounts of energy in the form of heat attacking the microorganisms when steam condenses – turns from steam (the gas form of H₂O) into water (the liquid form).

Steam sterilization can be compared with the boiling of food. During boiling, carbohydrates and proteins break down, the food becomes softer – both more chewable and also easier for the human digestive system to absorb.

Without functional proteins and carbohydrates, a microbe cannot maintain its own metabolism and function during steam sterilization and will therefore die.

Gravity-displacement autoclaves are the simplest type of steam sterilizers. The standard method for air removal is based on steam being lighter than air. The whole sterilization process comprises three (3) phases: preheating of the load, holding time (i.e. when the actual sterilization takes place) and post-treatment to cool down the load and for removal of residual water.

Downward gravity-displacement sterilization always results in residual air in the autoclave chamber and should therefore only be used for solid, unwrapped items).

Items must be sterilized at the point of use for immediate re-use, so that sterility is maintained. Items must not be wrapped and must not be transported or stored.

In steam sterilizers with pre- and post-vacuum processes (i.e. B-cycle), the sterilization process consists of three main phases: pretreatment, sterilizing and post-treatment.

During pretreatment, the air is expelled by a number of pulses of vacuum and the introduction of steam. Virtually all air must be evacuated during pretreatment (pre-vacuum phase) so that the

saturated steam can affect the goods during the sterilizing phase. **If present, trapped air pockets in the goods prevent steam penetration during sterilization.**

A single vacuum pulse is inadequate for wrapped/hollow/porous loads. Steam sterilization requires at least three (3) pre-vacuum pulses.

If not dry, it is not sterile and safe!

In the post-treatment phase, either the steam or the revaporized condensed water is removed by vacuum to assure that the goods will dry rapidly. The boiling temperature (the temperature where water evaporates) can be elevated by increasing the pressure. This phenomenon also works the other way around; by lowering the pressure the boiling temperature will decrease. This is what is used in the post-vacuum phase of the sterilizing cycle.

Careful loading

Another factor which influences the result of the sterilizing procedure is the way in which the chamber is loaded.

The goods should not be tightly packed: the steam must be allowed to penetrate all parts of the goods.

Whether the residual water can be removed or not during the post-sterilization phase depends on several factors. If the condensate is collected where it is in contact with metal surfaces or absorbed in textile surrounding an instrument, practically all condensate will evaporate, resulting in a dry load.

Residual moisture must be minimized

Residual moisture in the packaging material after sterilization acts as a potential pathway for microorganisms to penetrate the package. The most common fault is that the chamber has been packed too tightly or that the load is too heavy.

If solidly packed instruments are to be sterilized, the total weight of the load must not increase by more than 0.2% after sterilizing, because of residual moisture in the load (packaging material). For sterilizing of textiles, the total weight of the load must not increase by more than 1% after sterilizing.

Post-vacuum is an effective method for drying the load and removing remaining moisture.

Steam sterilizers add the possibility of packaging the goods. Today's demands on sterile goods are that the goods are to be sterile the very moment they are to be used. This means they must be packaged in special, close-fitting packages that allow nothing to penetrate. This is why modern steam sterilizers must include pre- as well as post-vacuum treatment.

It is important to note that packaging material itself is a porous load (paper, textiles) and should be handled as such. All packaged/wrapped goods require sterilizing in steam-sterilizer processes with pre- and post-vacuum cycles.

Sterile wrapping (packaging) is also a prerequisite if sterile goods are to be transported and stored at different locations.

Endospores hiding in salt crystals

The result of a sterilization process is greatly influenced by the quality of the steam, and the water quality influences the quality of the steam produced. Certain standards are therefore required for the quality of the steam as well as the water being used. Solid particles such as welding parts, graphite, rust flakes, sand etc. must not be present. Nor can other liquids than the water itself or chemicals be present. The salt content should not exceed 1 mg/kg of steam.

Checking the so-called conductivity of the water gives a measurement of the salt (ion) content. The conductivity is the capability to transfer electricity which in turn is dependent on the amount of ions in the water. Higher levels of ions (salts) in the water will result in higher conductivity.

The result of all steps included in the reprocessing of instruments from usage through transport, decontamination, cleaning, disinfection, wrapping, sterilization, storage and delivery is greatly influenced by the handling itself.

Proper instrument handling directly influences the lifespan of the instruments and also to a great extent the quality as well as the final result of treatments carried out with these instruments.

To ensure proper and complete elimination of all biological materials prior to sterilization, it is crucial to control and handle the whole process of decontamination – cleaning and disinfection – correctly.

The cleaning of instruments and articles is the all-important issue in decontamination, disinfection and sterilizing. It is not only the microorganisms (i.e. bacteria, virus, fungi etc) that have to be removed during the cleaning process, but also organic substances. These substances consist of carbohydrates, fat and protein and if they are not removed from the instruments before sterilization, the sterilization process itself will prove inefficient.

What the steam sterilizer really adds is the possibility of packaging the goods. The demands on sterile goods are that they must be sterile the very moment they are to be used, and they must therefore be packaged in special, close-fitting packages that allow nothing to penetrate them. All packaged/wrapped goods require sterilizing in steam-sterilizer processes with pre- and post-vacuum cycles.

Residual moisture in the packaging material after sterilization acts as a potential pathway for microorganisms to penetrate the package. The most common fault is that the chamber has been packed too tightly or that the load is too heavy.

Steam sterilization requires:

- **evacuation of as much remaining air as possible from the sterilizer chamber;**
- **the sterilizer chamber to be filled with saturated water vapor;**
- **the correct pressure and temperature in the sterilizer chamber to achieve saturated water vapor;**
- **the sterilizer to be correctly packed, with the correct load of goods;**
- **instruments and articles being super-clean before sterilization.**

Healthcare providers must be able to rely on sterility

It is vital that sterilization procedures always promote the same level of safety and efficiency. Requirements include routine biological, mechanical and chemical monitoring to ensure that all parameters of sterilization are met before using the instruments on patients.

It is not feasible to check whether individual instruments or sets of instruments are sterile or not after sterilization. To do this, the wrapping would have to be opened and test samples taken from the sterilized goods – which would of course mean that any package checked would become unsterile and could not be used. For this reason, every single procedure in the reprocessing of sterile instruments has to be carefully monitored to make sure that the "production line" will render a sterile result.

There are a number of studies showing uncertainty about sterilizing equipment. To reliably provide sterile goods, it is necessary that the sterilizing equipment (the autoclave) is regularly checked and otherwise correctly operated.

The performance of a steam sterilizer shall be checked regularly with exact physical methods of measurement. The full procedure includes validation, commissioning and qualification of performance.

Validation of steam sterilizers to conform with standards

Qualification of performance requires determining on location that the steam sterilizer fulfils these basic criteria and that it functions with a load typical for the healthcare setting in question. As the qualification of performance applies to all steam sterilizers that produce sterile goods, the load used for qualification of performance must therefore be a typical sterilizing load. The reference load / loads should subsequently be used for repeated testing – details of the load and the location of each separate thermal sensor should therefore be documented and filed for future reference.

Performance qualification , measuring steam temperature and pressure

For performance qualification, a number of thermal sensors (thin wires) are placed in the sterilizer chamber and inserted into the packages, against the items to be sterilized. Each wire has a so-called thermal sensor at the tip, which measures the temperature inside the chamber and on the surface of the items selected as reference loads for the actual cycles, in order to determine that acceptable surface sterilization has been achieved. The thermal sensors, together with an extra pressure sensor, are connected to measuring equipment that registers temperature and pressure for each phase of the process. The registered measurements are then compared with the specifications in the relevant standard. The actual temperature measured on the goods and items in the load is compared with the theoretically calculated temperature which should apply at the measured chamber pressure.

It is important that the entire chamber and the packaged goods reach the vaporization temperature (boiling point) at a certain given pressure for a certain time for the processes to be tested. 134°C and 3.0 atm or 121°C and 2.0 atm.

In order to have as rapid a turnover of instruments as possible, the sterilizing time in the steam sterilizer should be minimal, at a minimal temperature at the relevant pressure. It is therefore important that the relationship between temperature, time and pressure is maintained, not only in the chamber but also in the packaged goods.

Process challenge devices for safer sterilization

Process monitoring should be carried out on every sterilizing process intended to produce sterile goods. This can be done using physical, chemical or biological indicators. Proper and complete monitoring of sterilization procedures should routinely include a combination of different process parameters. It is important to bear in mind that indicators do not actually prove that sterilization has been achieved, only that parameters have been attained.

Process challenge devices

- Physical, in the form of a printer or so-called pressure and temperature loggers.
- Chemical, in the form of integrated indicators, which give a color indication depending on pressure, saturation of steam and temperature.
- Biological, in the form of spore tests (*B. Stearothermophilus*). Although spore tests reveal whether the sterilization process in question can inactivate certain bacterial spores that are particularly resistant to heat, such tests provide no detailed information about the actual process. Furthermore, biological indicators are difficult to standardize and there may be variations in heat resistance between different batches. Biological indicators assess the sterilization process directly by using the most resistant microorganisms. *Bacillus* sp. spores used in biological indicators are more resistant and present in greater numbers than the common microbial contaminants found on patient care equipment. Inactivation of the biological indicator strongly implies that other potential pathogens in the load have also been killed. However, spore tests can, with the reservations described above, be a means of monitoring the function of steam sterilizers, but are not really adequate for full monitoring of the function of an sterilizer intended to produce sterile goods.

There are also specific test methods to monitor the functioning of sterilization cycles:

- The Bowie & Dick Type Test, which is used to verify conditions in the sterilizer chamber for sterilizing porous loads such as textiles.
- The Helix Test, which is used to verify conditions in steam sterilizers for sterilizing hollow instruments ("hollow loads").

When using biological indicators, they should be placed where sterilization is important to test, e.g. as in the left picture, inside the syringe. Biological indicators can either be sent to a microbiology laboratory or, even better, cultured directly on site.

Chemically integrated indicators can be tailored for specific sterilizing cycles. As process challenge devices they react to time, temperature and the quality of saturated steam. The test device can be placed in the type of load where sterility is essential. Readings can be made directly after the

sterilization process. Left within the wrapping, the process challenge device can also be monitored when the instrument set in question is about to be used. This gives possibilities for a double check.

The Bowie&Dick type test is a special application of a chemically integrated indicator that can be used as a process challenge device simulating a large porous load. Textiles, for example surgical draping, are important large porous loads.

The Helix test is a special application of a chemically integrated indicator that can be used as a process challenge device simulating a hollow load and hollow instruments.

It is not only instruments with long hollow lumens, such as dental handpieces, that are hollow. All instruments with hinges or parts held together by screws are considered hollow.

In all testing of sterilizers it is important to bear in mind that it is not the testing itself that is of importance but rather what answers are crucial to get from the different process challenge devices.

When the goods are released, the sterilizing personnel shall be able to assure, as far as possible, that goods are sterile. This is not possible after a single type of test, but only after numerous tests of several kinds, since they challenge the process for different types of loads.