MODE OF ACTION OF AN AESCULAP® STERILE CONTAINER IN STEAM STERILIZATION

DEFINITION OF A STERILE CONTAINER

All AESCULAP® sterile containers meet the requirements of DIN EN ISO 11607-1 for preformed sterile barrier systems (SBS). They are made from aluminum and are therefore reusable, dimensionally stable rigid packaging (in contrast to soft wraps or single-use pouch packaging). In this function, the sterile containers represent a microbial barrier which minimizes the risk of ingress of microbes and allows aseptic presentation of sterile surgical instruments / medical devices at the point of use in the operating theater (definition of sterile barrier system according to DIN EN ISO 11607-1). At the same time, AESCULAP® sterile containers are purposefully designed (see Figures 2 and 3) to protect this microbial barrier and, therefore, they also fulfill the function of protective packaging (DIN EN ISO 11607-1).

The microbial barrier is also provided during storage and transport and the sterility of the reusable surgical instruments / medical devices inside the container is maintained until their use or until the expiry date (assuming correct hygienic conditions). At the same time, sterile containers facilitate the sterilization of contained surgical instruments / medical devices and are exposed to high temperature and pressure differences during this process.

AESCULAP® Basis container

AESCULAP® PrimeLine® Pro container

AESCULAP® Vario container

AESCULAP Aicon® container

FIG. 1: IMAGES OF DIFFERENT AESCULAP® STERILE CONTAINERS

EXAMPLE STERILE CONTAINER STRUCTURE

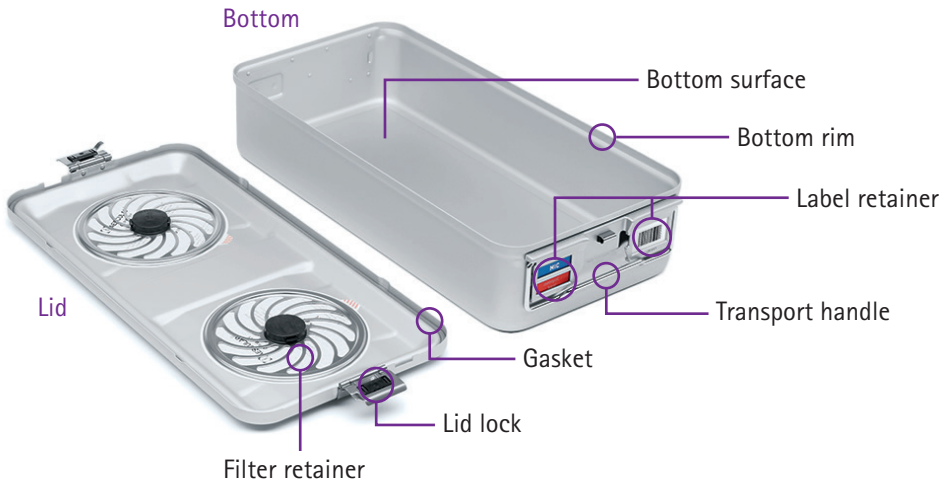


FIG. 2: EXAMPLE STRUCTURE OF AN AESCULAP® STERILE CONTAINER BASED ON THE BASIS MODEL

The lid has a gasket, a lid lock and a spring-loaded filter retainer, that is used to apply the filter to the perforation field. The bottom consists of the bottom surface, on which the basket with the instruments is positioned, the transport handle and a face plate for labeling the contents.

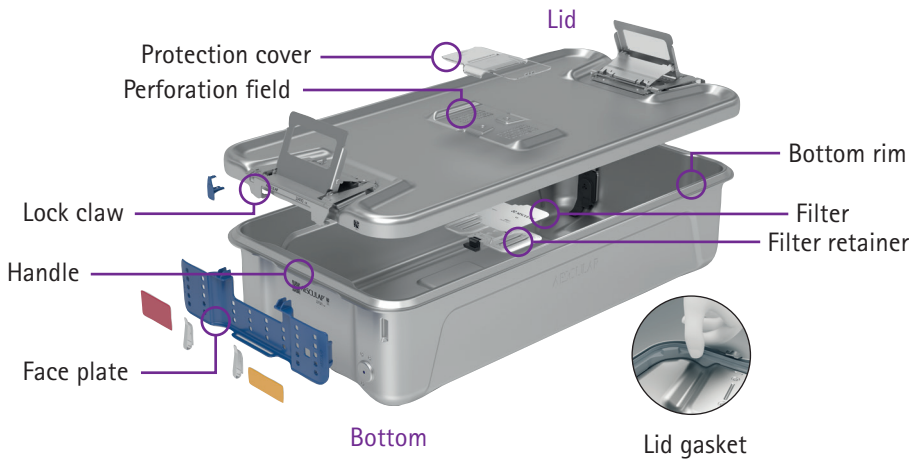


FIG. 3: EXAMPLE STRUCTURE OF AN AESCULAP® STERILE CONTAINER BASED ON THE AESCULAP Aicon® MODEL

The lid has a gasket, a lid lock with lock claw and a spring-loaded filter retainer, that is used to apply the filter to the perforation field. It can also be protected externally with a protective cover. The bottom consists of the bottom surface, on which the basket with the instruments is positioned and an ergonomic handle which also enables quiet transport. A colored face plate can be attached to label the contents.

STERILIZATION

As reusable surgical instruments and medical devices can become contaminated with blood and microbes to varying extents after every surgery, they represent a potential transmission route for microbes (1). To avoid potential transmission to other patients, surgical instruments are subjected to comprehensive reprocessing procedure (manual or mechanical cleaning, disinfection, care and maintenance, packaging and sterilization). Once the instruments / medical devices have been sorted into baskets according to the operation-specific packing list, they are packed in sterile containers and usually sterilized by steam sterilization. AESCULAP® sterile containers with perforated lid and closed bottom are suitable for steam sterilization in a sterilizer according to EN 285 in a fractionated vacuum process, validated according to DIN EN ISO 17665-1.

STEAM STERILIZATION WITH FRACTIONATED VACUUM

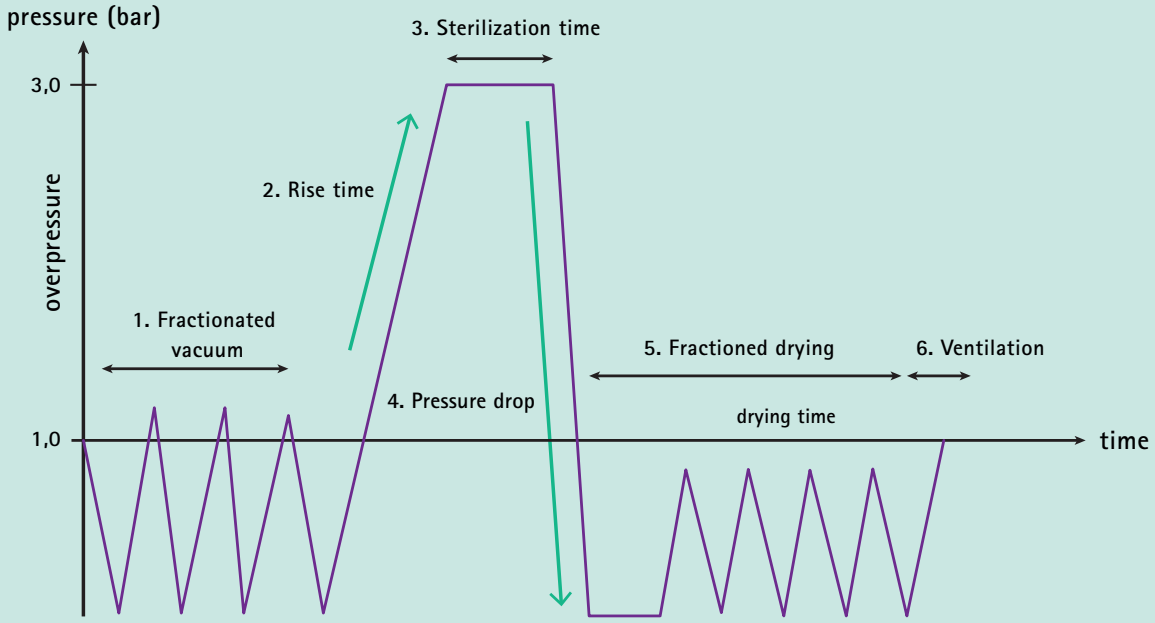


FIG. 4: EXEMPLARY PRESENTATION OF THE DIFFERENT PHASES OF STEAM STERILIZATION IN A FRACTIONATED VACUUM PROCESS
The different phases of steam sterilization are schematically shown in the above diagram: 1. Fractionated vacuum, 2. Rise time (temperature and pressure increase), 3. Sterilization time, 4. Pressure drop, 5. Fractioned drying, 6. Ventilation.

WHAT HAPPENS IN THE STERILE CONTAINER DURING STEAM STERILIZATION?

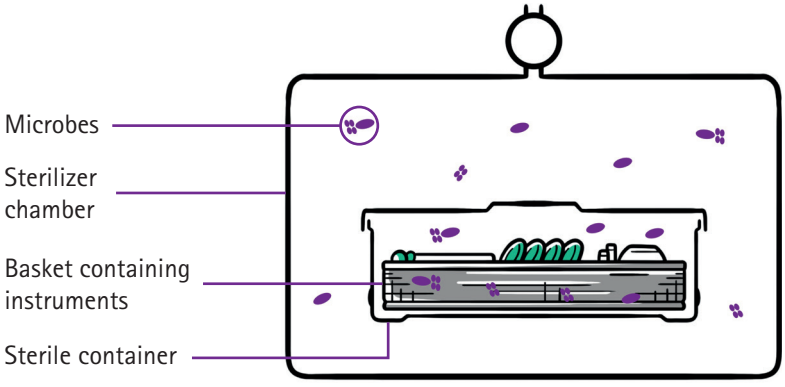
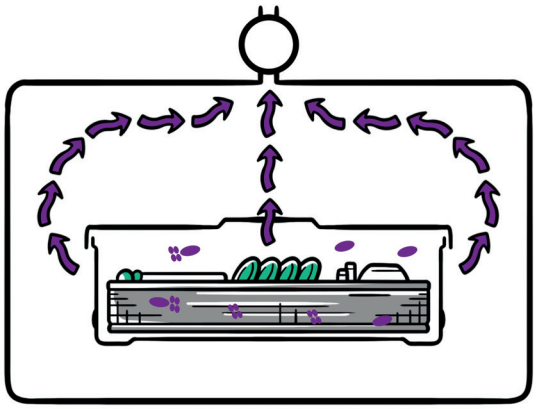


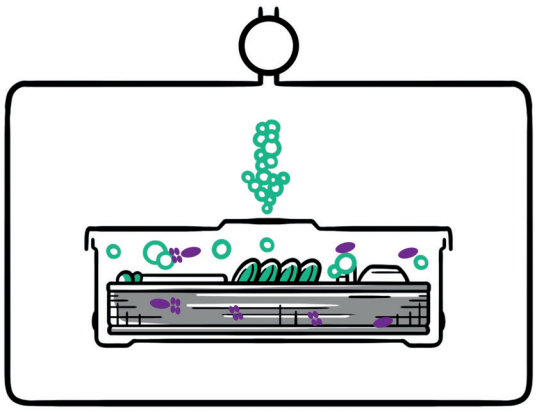
FIG. 5: EXEMPLARY IMAGE SHOWING THE INITIAL SITUATION BEFORE STERILIZATION
The image shows exemplary a sterile container containing a basket and surgical instruments inside a sterilizer chamber, surrounded by microbes such as bacteria.

1. FRACTIONATED VACUUM



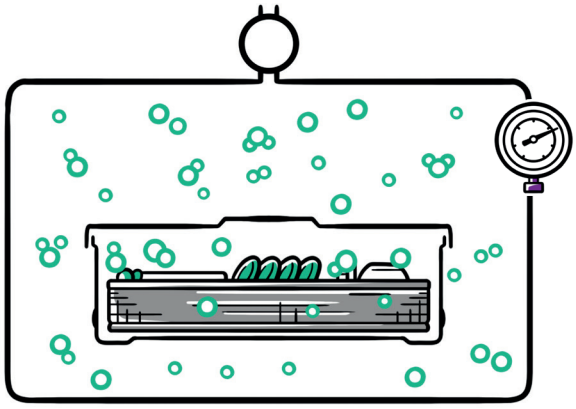
To enable uniform steam penetration within the sterilizer chamber and the load (e.g. sterile container), they must first be vented. For the venting a vacuum is generated. Thus, the air is sucked out through the perforation field in the lid through the filter. This is followed by a steam blast, to mix the existing residual air with steam. The mixture is then extracted again using a vacuum. This sequence (steam blast & subsequent vacuum) is repeated several times to completely remove the air from the sterilizer chamber and the sterile container. The reason for this is that air insulates. In other words, if there is still air (inert gases) in the chamber during the sterilization process, the instruments / medical devices might not reach the specified sterilization temperature.

2. RISE TIME (PRESSURE AND TEMPERATURE RISE)



During the rise time, the pressure rises to approximately 3 bar and the temperature to 134°C – 137°C and steam continues to enter the chamber. The pressure inside the sterilizer chamber is initially higher than that in the sterile container. This pressure difference is balanced by the filter perforation field as well as the filter retainer. For this purpose, the spring-loaded filter retainer lifts slightly from the lid so that hot steam reaches the inside of the sterile container more quickly and thus also onto the instruments / medical devices. The steam condenses on the items being sterilized and thus heats them.

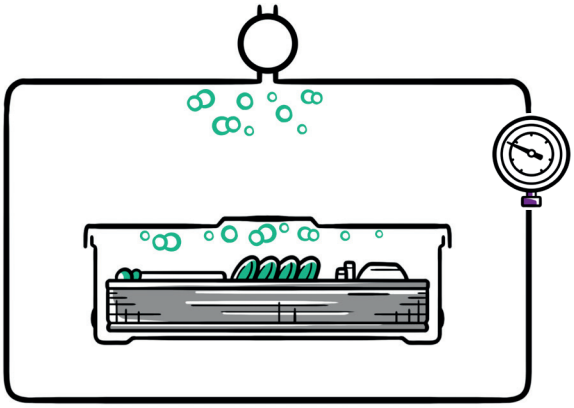
3. STERILIZATION TIME (PLATEAU TIME)



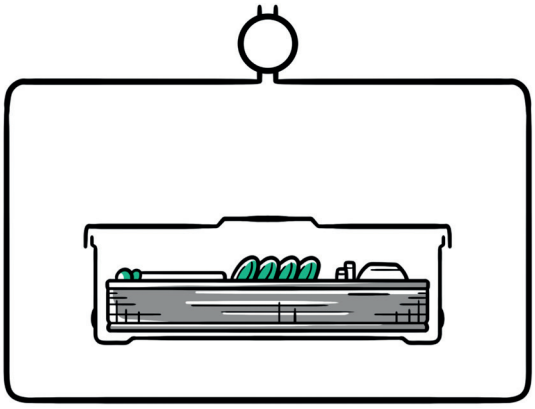
During the plateau time, the sterilization temperature (min. 134 °C, according to EN 285) is reached and maintained throughout the whole sterilizer chamber and the load (sterile container and the inside located surgical instruments / medical devices). Within this time, the proteins of the microbes (such as bacteria) denature due to the high temperature and are killed as a result.

4. PRESSURE DROP

After the sterilization time (plateau time), the pressure drops again. The decrease in pressure lowers the boiling point of the water, meaning that water that has already condensed turns back into steam.



5. FRACTIONATED DRYING AND 6. VENTILATION



In order to completely evaporate the condensate, fractional drying is used in addition to pressure reduction. The condensate produced during the sterilization phase has turned back into steam and now mixes with the incoming filtered air. This mixture is drawn out of the sterilizer chamber by pulsating pressure changes. The pulsating pressure changes create an exchange between the sterile container and the sterilizer chamber, allowing the steam / air mixture to escape from the sterile container through the filter. Lastly, the sterilizer chamber and the sterilized items are completely vented so that atmospheric pressure is reached again (2, 3).

STERILE CONTAINER AS A STERILE BARRIER

The sterile container is permanently exposed to microbes in the air during transport and storage. These microbes are often attached to particles (such as dust particles) and are found everywhere in the air as so called bioaerosols (4, 5). They can be found in the sterile supply store, on transport routes to the operating theater and even in the operating theater itself (6, 7). The aluminum housing of the sterile container is impermeable to germs. But the sterile packaging must be permeable to steam and air for their exchange. In the case of the AESCULAP® sterile containers, this is made possible by the filter system. The filter retains the microbes in the air (this is called "separating") and forms, together with the gasket and aluminum housing, the sterile barrier, protecting the sterile instruments inside the container. The filters (both single-use paper filters and reusable filters) enable this sterile barrier function due to their special structure (see document "Mode of action of filters used for sterile containers within steam sterilization", D-ST20144).

LITERATURE

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