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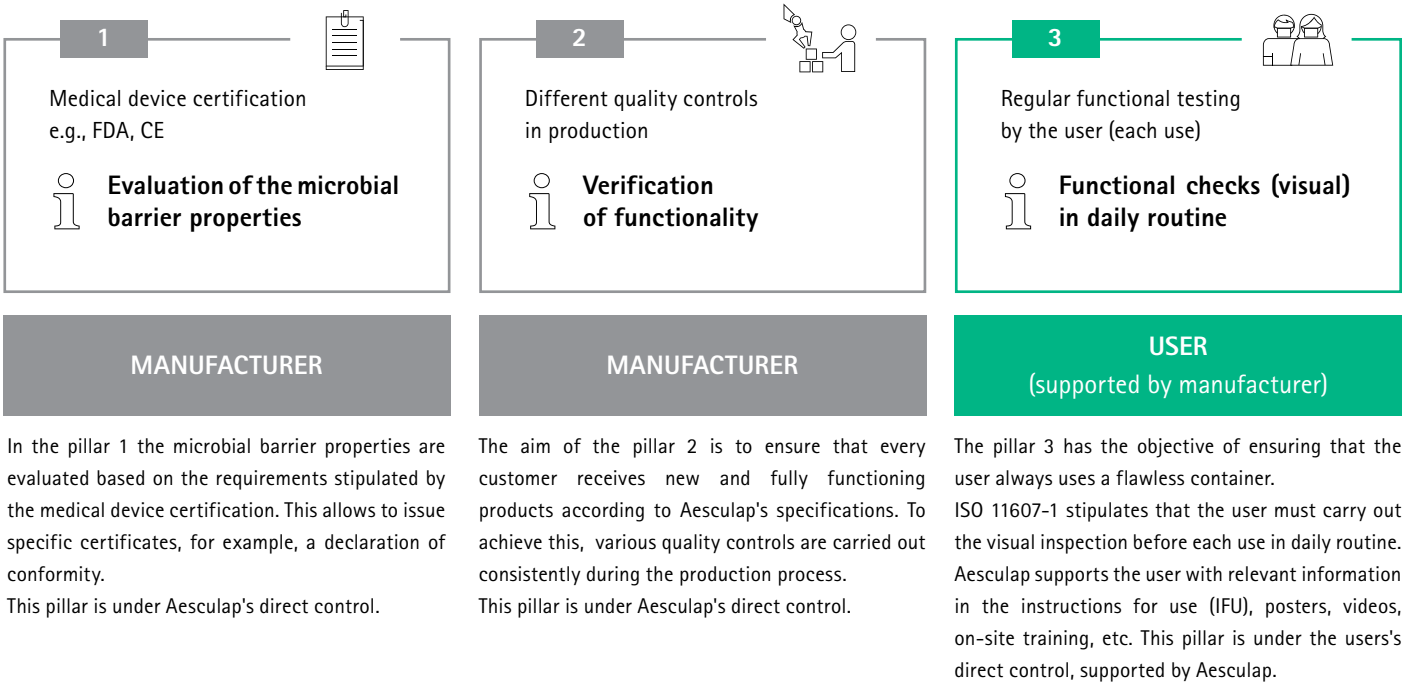
SHARING EXPERTISE

The 3 Pillars of Sterile Container Testing

AESCULAP® sterile containers belong to the preformed sterile barrier systems (SBS) according to ISO 11607-1. They are predominantly made from aluminum and are therefore a reusable, dimensionally stable rigid packaging system (in contrast to soft wraps or single-use pouch packaging). In this function, sterile containers function as a sterile barrier system (SBS), that minimizes the risk of ingress of microorganisms and allows aseptic presentation of sterile surgical instruments and medical devices at the point of use in the operating theater (definition of SBS according to ISO 11607-1).
To ensure the safe and reliable function of its sterile containers, Aesculap relies on a three-pillar approach of sterile container testing.

Objective: Safe and reliable function of sterile containers



In the pillar 1 the microbial barrier properties are evaluated based on the requirements stipulated by the medical device certification. This allows to issue specific certificates, for example, a declaration of conformity.
This pillar is under Aesculap's direct control.

The aim of the pillar 2 is to ensure that every customer receives new and fully functioning products according to Aesculap's specifications. To achieve this, various quality controls are carried out consistently during the production process.
This pillar is under Aesculap's direct control.

The pillar 3 has the objective of ensuring that the user always uses a flawless container.
ISO 11607-1 stipulates that the user must carry out the visual inspection before each use in daily routine. Aesculap supports the user with relevant information in the instructions for use (IFU), posters, videos, on-site training, etc. This pillar is under the users's direct control, supported by Aesculap.

Fig. 1: Three-pillar approach of sterile container testing.

Pillar 1: Medical device certification

In order to obtain certification as a medical device (e.g. FDA, CE), the pillar 1 of container testing is aimed at the regulatory authorities. Proof of function as a SBS is an important part of certification as a medical device for the authorities (regulatory requirements).
The microbial barrier properties of SBS are tested in validation tests using aerosol chamber tests according to ISO 11607-1. An aerosol chamber is usually used for this purpose, whose test setup is based on ASTM F1608. The sterilised SBS is placed in the aerosol chamber and bacterial or particulate aerosols (small droplets of liquid) are sprayed into the test chamber. Typically, an overkill concentration of bacteria ($1*10^7$ (colony forming units) CFU/ml) is used in this test scenario, which is much higher than the bacterial concentration measured for example in the outside air in Germany (max 800 CFU/m^3) (1) or measured in the hospital (max. 287 CFU/m^3) (2). By using agar plates or stainless steel coupons (as dummies for surgical instruments) the bacterial growth inside the SBS can be analyzed. At Aesculap, we have defined the acceptance criterion for passing the validation test and thus for the certificate as a medical device even more strictly than described in ISO 11607-1: no bacterial growth (0 CFU) inside the sterile container. Even when Aesculap sterile containers that had been subjected to accelerated ageing (in accordance with EN 868-8 and ISO 11607-1; 500 to 1,000 cleaning cycles and

1,000 sterilization cycles) were tested in an aerosol chamber, no penetration of microorganisms (0 CFU) could be detected.
These validation tests are typically carried out in accredited laboratories, because special equipment for microbiological testing is needed. Therefore, these tests are not suitable for daily testing in hospitals and central sterile supply departments (CSSD).

Pillar 2: Different quality controls in production

At Aesculap, we ensure that our containers are delivered to the customer in the condition in which they comply with the certification as a medical device. Therefore, the verification of functionality and production according to manufacturer's specifications (such as dimensions, closures, and other quality aspects) are constantly checked at relevant production steps. In addition, a final inspection of the sterile containers produced is carried out regularly during production in order to ensure that every user receives new, fully functioning products according to manufacturer's specifications. These quality tests often require expensive and bulky equipment, which is why they are not useful for the user in everyday hospital life.

Pillar 3: Visual inspection in daily routine by the user

In contrast to the rather complicated aerosol challenges (which are carried out in accredited laboratories), visual functional checks by the user are practicable in daily routine in each CSSD.
According to ISO 11607-1, medical devices should be visually inspected by the user prior to each use. In contrast to the rather complicated aerosol tests (which are carried out in accredited laboratories), visual functional tests of SBS by the user in daily routine are feasible. The instructions for use (IFU) describe how to perform this visual inspection.
Aesculap also supports the user with different trainings, posters and videos.
In addition to the visual inspection, further test methods that could also be labeled as being suitable for simple on-site testing in a CSSD were carried out in non-standard approaches. Various methods have emerged (partly also by the users) for testing SBS, such as the "water test" (3), the "smoke test" (4), "paper" or "dollar bill" test, the "pressure tests" and more. However, these tests do not show any cause-and-effect relationship with regard to the tightness or leakiness of the microbial barrier, i.e., a causal connection has not yet been scientifically proven. This also applies to the pressure test, for which no precise acceptance criteria have yet been defined.
Most test methods only check the tightness between the container lid and the container bottom, or the gasket itself, and do not take into account the entire system. This is only possible through visual inspection as of today. Another major disadvantage is that these tests are not equally applicable to all SBS (e.g. wrap or blister). It is important to have one test method which is applicable for all materials and all SBSs. This is still visual inspection as described in the ISO 11607-1 standard and which is a globally accepted common practice.

Aesculap internal comparative test results:

To test whether the visual inspection as daily routine is sufficient or not, Aesculap conducted internal tests (table 1). For this purpose, 17 container bottoms and 18 container lids of different ages were randomly selected from different hospitals & loaner services. These containers were visually checked by 6 individuals, who are familiar with sterile containers, but not specially trained. The containers were randomized.

Table 1: Aesculap internal comparative test results of visual inspection, smoke test and water test. (n.a. = not applicable)

17 bottoms in total

passed	visual inspection	smoke test	water test
yes	1	16	12
no*	16	1	5

18 lids in total

passed	visual inspection	smoke test	water test
yes	2	14	8
no*	16	3 (1x n.a.)	10

***no in visual inspection = need for repair**

After detailed visual inspection by these 6 users, Aesculap performed a smoke test (according to S. Law) (4) and a water test (according to AFNOR S95R) (3) in its own laboratory with the same containers. The results (table 1) show that 16 out of 17 container bottoms did not pass the visual inspection and should be removed from use and sent for repair (e.g., to Aesculap Technical Service (ATS)). The same container bottoms were subjected to the smoke test and the water test, with completely different results. 1 bottom did not pass the smoke test and 5 bottoms did not pass the water test. Concerning the container lids, it looks nearly the same; 16 out of 18 lids did not pass the visual inspection, while 3 of them did not pass the smoke test and 10 of them did not pass the water test.

These results show that visual inspection is still the most efficient test method for the entire SBS (sterile barrier system) in the daily hospital routine.

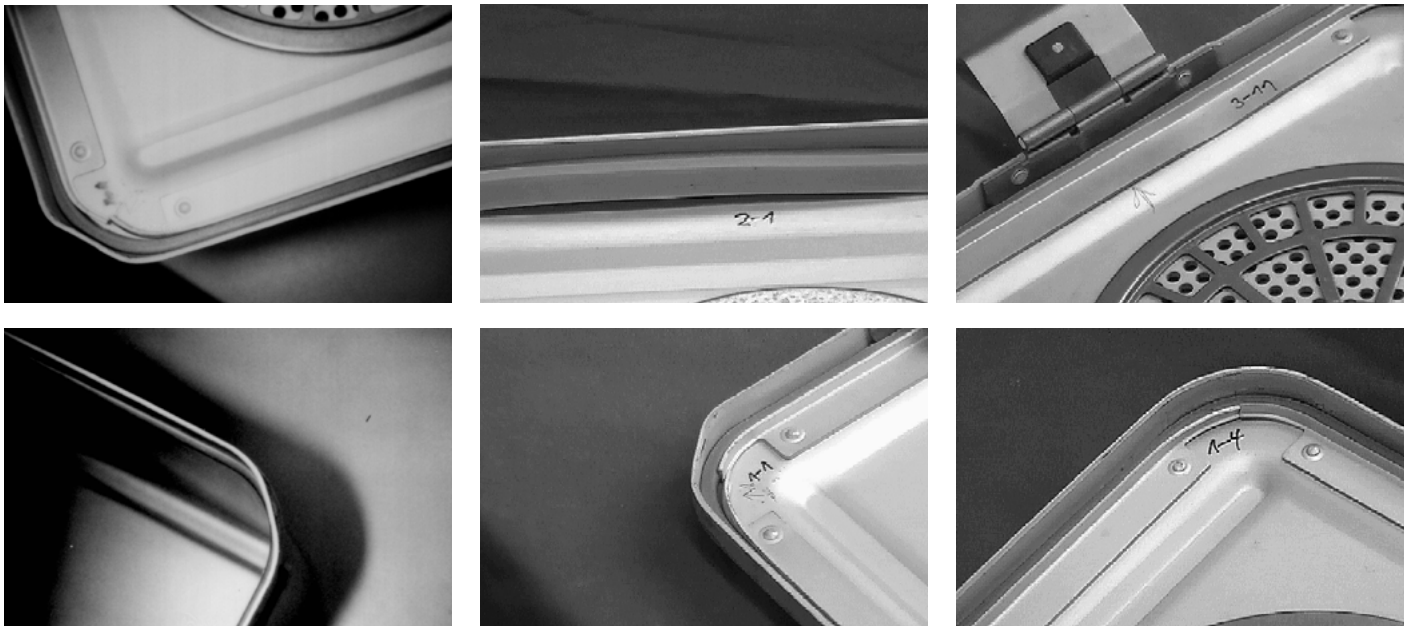


Fig. 2: Exemplary images of sterile containers with defects used in the study by Junghannß et al 1999 (5). These containers showed a kind of safety reserve, as they did not pass the visual inspection, but passed the aerosol chamber test.

In the study by Junghannß et al 1999 (5) the microbial integrity of approx. 10 year old, used and in the hospital deformed sterile containers was tested in the aerosol chamber. All of these containers failed the visual inspection, but passed the aerosol chamber test. This shows that there is a kind of safety reserve in visual inspection.

In addition, Dreikausen et al. 2023 (2) showed that sterile containers effectively fulfil their function as a sterile barrier system under real conditions in hospitals, regardless of how old they were and how bad they looked, as no bacterial growth (0 CFU) could be detected in sterilized and stored sterile containers.

Conclusion

- To ensure the safe function of our sterile containers Aesculap follows a three-pillar testing approach. This ensures high-quality testing in accordance with relevant standards and directives.
- Users can therefore rely on the proper functioning of the Aesculap sterile container system.
- Visual inspection is a safe & validatable test method for daily use in the CSSD.

Literature Cited

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