Visual routine control of sterilization containers

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The question of visual checks of sterilization containers is always a hot topic in the reprocessing of surgical instruments. Therefore, container systems with different lifetimes were randomly taken from a process to investigate their microbial integrity. During this process, the sterilization containers were strictly checked visually at each packing process. No growth of microorganisms could be observed during the tests. The results show that a visual inspection of the critical areas to evaluate the functionality of a sterilization container seems to be sufficient.

KEY WORDS
- visual control
- sterilization container
- lifetime

Problem

Again and again the question arises in practice how the functionality of container systems can be checked even after years of use. A variety of test methods have been discussed at conferences and in the literature, methods that are used to test especially the tightness and the maintenance of sterility. In most cases, these tests are limited to testing the tightness of the system and are difficult to apply and therefore of limited use in practice. The applicability is especially complicated when different types of container systems are used in a CSSD. An exclusively visual inspection of the components of a container system for assessing the functions is also questionable. Whether visual inspections are actually sufficient, or if more reliable test methods for container systems in the daily routine must be worked out, remains to be investigated.

Investigation concept

Because of this, we have tried a differentiated approach at the University Hospital Basel. For containers maintenance steps have to be indicated in accordance with EN 868-8: 2009. These maintenance steps are generally limited to visual inspections of critical areas or parts. In addition, manufacturers recommend to perform these checks before each reuse, i. e. during each packing process. For certain defects a repair or replacement of the affected parts is necessary.

To clarify the question of whether these suggested visual inspections are sufficient for guaranteeing the functionality, we have developed a random study.

A total of six containers of different ages were randomly taken from the CSSD process. The University Hospital of Basel is using two different generations of containers representing different stages of development. This made it easy for us to identify differently aged systems and we have taken containers which already had a real lifetime of 5 – 9 years.

These containers were then sent to the Institute of Microbiology and Hospital Hygiene at the University of Anhalt, Germany, with the aim to show the effectiveness of the sterility maintenance during a storage period of 4 weeks. This test is normally used by container manufacturers to simulate a storage period in a highly contaminated environment. This so called Aerosol test was developed by Prof. Junghannß et al. It seemed reasonable to us to use this already accepted and practically relevant test procedure for the investigation.

Process description of using the tested containers

Description of the reprocessing cycle

The University Hospital of Basel decided several years ago that containers are to be used for sterile packaging of instruments where possible. This decision was based on the simple and safe handling, the robustness of the material and not least on ecological reasons. However, other packaging materials such as pouches or nonwoven are also used for the packaging of individual instruments or bulky materials. Containers are used for the supply and disposal alike. They are reprocessed about 200 – 250 times per year.

Cleaning and Disinfection

The cleaning and disinfection of the container is carried out exclusively in a washer-disinfector. Generally we are using a multi chamber WD but in some cases single-chamber WDs are used as well.

A mildly alkaline solution with a pH value of about 10 is used. The A_0 value for the reprocessing of the containers is at least 600, but the settings of the process used are significantly higher.

Routine visual controls during packing

Since the containers used are equipped with a lifetime barrier system, the visual control is limited to a secure fit and the integrity of the barrier. The container itself is

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Fig. 1: Critical areas which should be tested during visual inspection

Fig. 2: Storage conditions of the sterilized items

visually inspected for defects, such as an uneven upper edge (rim) or other deformations. If the container is misused for stacking instrument trays, the top edge of the bottom can will show small notches after a period of time. A notch with appropriate depth may degrade the performance of the gasket. Even such containers were used for the testing procedure.

As for the container lids, the gasket and the closure requires special attention (Fig. 1). Especially the gasket which is set in a slight recess must be checked visually. But the surfaces must be inspected for very fine hairline cracks or other material changes as well. In total, the visual routine inspection shall include the following steps for each packaging process:

- secure fit of the microbial barrier
- gasket fits completely on the bottom
- closure mechanism is without defects and working smoothly
- no surface changes, or if so, evaluation of surface changes
- no cracks
- no deformation
- rim of the bottom part even and without any notches.

Sterilization

The containers are steam sterilized at 134 ° C and stacked together. Thereafter, parametric release of the sterilized material is performed.

Storage and transport

Figure 2 shows the storage after sterilization. The containers are stored in this way until they are used or transported to the operating theatre.

Laboratory testing

Test description

The test material comprises 6 containers, as described in Table 1. The containers were filled with an assortment of surgical instruments.

Experimental design

The fitness of the containers for sterilization and storage was tested. Accordingly, they were tested for integrity and functionality with regard to the intended use. Every container was fitted with 10 biological indicators in accordance with the standards EN 866-1, EN 866-3, EN ISO 11138-1 and EN ISO 11138-3, based on the organism *Geobacillus stearothermophilus*. The indicators used had a spore density of 1.8×10^6 CFU/biological indicator with a $D_{121°C}$ value of 2.3 ± 0.2 min.

The containers were filled with baskets containing general surgical instruments and each fitted with 10 biological indicators. Figures 3 and 4 show the loading of the baskets for each size. Figures 5 and 6 show the placement of the biological indicators in the containers.

The containers were then steam sterilized at 134 °C, 2 bar, for 5 minutes.

After the sterilization all containers were sprayed with *Bacillus subtilis* (10^9 cfu/ml) spore solution in an unventilated room. The room was also sprayed with this solution. The containers were stored in the

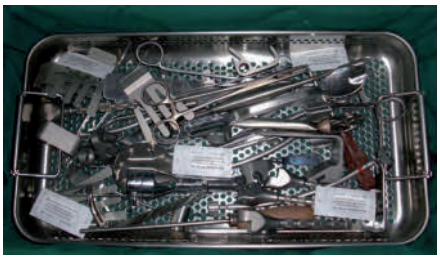

Fig. 3: Load in a 60 × 30 container

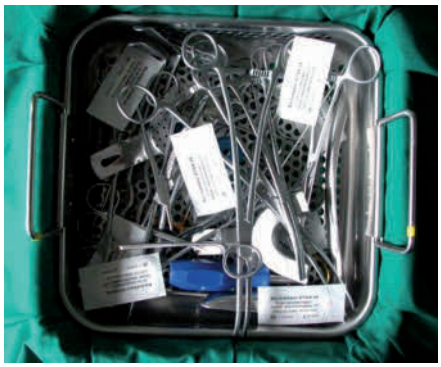

Fig. 4: Load in a 30 × 30 container

Table 1: Listing of the tested containers

Size of container	Type of loading	Age in real years	Age in real cycles	Description in test
60 × 30 × 16	Surgical instruments	5	ca. 1.000	01-06
60 × 30 × 16	Surgical instruments	5	ca. 1.000	02-06
60 × 30 × 16	Surgical instruments	8	> 1.600	03-06
30 × 30 × 16	Surgical instruments	5	ca. 1.000	04-06
30 × 30 × 16	Surgical instruments	>5	> 1.000	05-06
30 × 30 × 16	Surgical instruments	>5	> 1.000	06-06

Table 2: Test results after 4 weeks for each container

Description in test	Spore Strip No.										10 impression preparation samples										Positive growth control	
	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10	1	2 + 3
01-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	+	+
02-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	+	+
03-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	+	+
04-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	+	+
05-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	+	+
06-06	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	+	+
0 = no growth; + = heavy growth																						
Positive growth control: contact samples taken immediately before opening the container (1) and during the storage period (2 + 3)																						

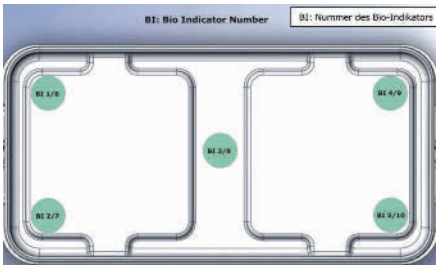

Fig. 5: Positioning of bio indicators (view from above)

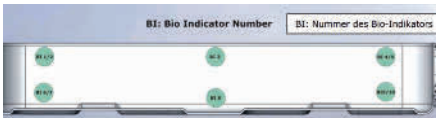

Fig. 6: Positioning of bio indicators (side view)

same room for four weeks. During this period the room was again sprayed with the *Bacillus subtilis* spore solution aerosol.

Evaluation and result

The containers were opened after four weeks and the biological indicators were removed under sterile conditions and incubated in a suspension for seven days at 55 °C ± 1 °C.

In addition, 10 contact samples per container were taken from the interior of the container (nutrient medium: casein tryptic soy peptone agar with disinhibitory agent). The samples were incubated for seven days at 36 °C ± 1 °C.

No growth of bacteria or fungi was observed on the samples.

Contact samples were taken twice during the storage period and immediately before opening the container outside the sterile barrier as a positive control for the presence of *Bacillus subtilis* and other bacteria and fungi. Indicators from the same production batch as the indicators used for the test were used as the positive control of the biological indicators. Growth was confirmed with all positive indicators

Table 2 shows the evaluation after 4 weeks for each container.

Conclusion

The positive result of the shortened shelf life test in a highly contaminated environment shows that the randomly selected containers with a usage period of 5 to 8 years are still an effective packaging system providing sterility integrity and that no bacteriological disturbances inside the containers occurred. As routine checks, only visual controls are applied during each packing process. This is an indication that the performed visual inspections of critical areas during each packing process may be sufficient to check the containers for their safe functionality. Therefore, it is all the more important to perform these visual inspections precisely and to send compromised containers for repair or to replace parts accordingly. According to the present study, additional tests of containers with respect to the functionality of the gaskets and the integrity of the container system appear to be unnecessary even after years of use. ■

References

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