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SHARING EXPERTISE

PRIME*Line*® PRO TEST RESULTS

AESCULAP® STERILE CONTAINER SYSTEM

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AESCULAP® STERILE CONTAINER SYSTEM

The right INSTRUMENTS

At the right TIME

In a sterile CONDITION

At the right PLACE OF USE

At a high level of PROFITABILITY

In a reliable PACKAGING SYSTEM

In 1971, Aesculap revolutionized the packaging world with the first sterile container and the systematic provision of sterile instruments.

Their durability, economic efficiency, the simple and comfortable use have made Aesculap Sterile Containers a permanent component in sterile services. Through the use of sterile containers, the entire circuit of provision and disposal of sterile goods can be standardized, controlled and documented.

Based on a uniform container bottom of aluminum, we offer various lid systems with the PRIME*Line*® PRO, BASIC and VARIO versions of our sterile containers.

PRIME*Line*® PRO lids consist of a reinforced aluminum and are equipped with filter technology suitable for 5000 sterilization cycles.

The PRIME*Line*® PRO underwent a comprehensive series of tests to ensure reliable function during the entire duration of use of the sterile container. On the following pages a selection of results of tests performed with the PRIME*Line*® PRO lid, among others, compliant to DIN, EN and ISO standards, can be found. All test results are on file at Aesculap AG.

Product information, catalogues and instructions for use can be ordered from your Aesculap partner.

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1. MANUAL AND MACHINE CLEANING VALIDATION

To examine the cleaning capability of the PRIME*Line*® PRO lid, both methods of manual and automatic cleaning validation were performed with the cleaning specifications in the instructions for use. The requirements of AAMI TIR 30[1] and the guidelines[2,3] of the DGKH (German Society for Hospital Hygiene), DGSV (the German Society of Sterile Services) and the AKI (Working Group on Instrument Preparation) were taken into consideration. The cleaning capacity was confirmed with proteins and hemoglobin detections.

Test description

The cleaning capacity of the PRIME*Line*® PRO lid was tested in manual and machine cleaning procedures with the specifications in the instructions for use. The validation was performed in an independent testing lab.

Test design

The PRIME*Line*® PRO lid was contaminated with test soil in various critical locations. The areas which are probably the most challenging for cleaning and for accumulation of contamination were taken into consideration during soiling.

After letting the test contamination dry, the PRIME*Line*® PRO lid was cleaned with an installed filter cover. A real use was then reconstructed with this worst case scenario. The PRIME*Line*® PRO lid was checked for hemoglobin and protein residues.

Test result

Despite severe contamination combined with dried on test soil the PRIME*Line*® PRO lid was clean after both methods of manual and machine cleaning. The successful cleaning was also confirmed with the installed filter cassette.

2. STERILIZATION

In accordance with EN 868-8[4] a full size container i.e. of one sterilization unit shall be designed and constructed to a total load capacity of 10 kg to be sterilized in accordance with EN 285[5].

	1/1 Sterile Container	3/4 Sterile Container	1/2 Sterile Container
Load weight with basket	10.0 kg	7.5 kg	5.0 kg

Testing was performed according to the specifications of standard EN 868-8[4], to evaluate:

- Does the sterile container achieve the desired temperature in every location of the sterilizer during sterilization?
- How much residual moisture can be detected for a PRIME*Line*® PRO lid, if used according to instructions for use?
- How is the function of the sterile container affected at high pressure gradients in accordance with EN 285?

2.1 REACHING TEMPERATURE DURING STERILIZATION

Test description

The sterilization behavior was checked with a test in compliance with EN 868-8[4], Annex F: Determination of sterilization performance. The measurement values of the thermal elements must fulfill the conditions for metal and textile loads described in the standard.

Test design

Container bottoms with PRIME*Line*® PRO lids were tested multiple times in various positions in the sterilizer. To record the temperature progression, thermal elements were placed in the middle of the load as well as between load and lid of the test container. Additional thermal elements were placed outside the container.

Positioning of thermal elements to evaluate the sterilization performance of PRIME*Line*® PRO and Basic container systems.

Test result

All test runs fulfilled the standard requirements.

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2.2 TESTING OF DRYING PROPERTIES FOR METAL AND TEXTILE LOADS

Test description

Drying was performed with metal and textile loads in accordance to EN 868-8[4], Annex G: Testing the dryness of the load, in pre-vacuum sterilization processes for all PRIME*Line*® PRO lid sizes.

Test design

The containers with PRIME*Line*® PRO lids and relevant metal and textile loads were sterilized. Residual moisture was evaluated directly after sterilization.

Test result

The weight gain was within the acceptance range of the standard.

Metal load for evaluating dryness.

2.3 EXAMINATION IN USE OF HIGH PRESSURE GRADIENTS

Test desciption

Compliant to EN 285[5] the sterilizer may not exceed average pressure change equalization rates of 10 bar/min within 3 seconds. This is the maximum possible rate of pressure change that occurs in the sterilization chamber. The plastic deformation of the PRIME*Line*® PRO lids, may not exceed 1mm at defined points.

Test design

Container bottoms with PRIME*Line*® PRO lids were exposed to a set pressure gradient: > 10 bar / min and then measured.

Test result

The test results show, that the requirements described above were fullfilled.

3. INTEGRATED GERM BARRIER SYSTEM (PTFE FILTER)

The integrated germ barrier system is a reusable PTFE filter and has the function to form a barrier to inhibit bacterial contamination and growth. The integrated germ barrier system allows steam and air to pass through.

In addition, the PTFE filter material has hydrophobic, dirt resistant and thermally stable features, and is resistant to cleaning chemicals. After 5000 sterilization cycles it is recommended to change the filter cassette.

After multiple uses, the PTFE material may have dark discoloration through influences of reprocessing, such as chemical detergents and residues in steam as well as residues of instrument care products.

The following aspects of the integrated germ barrier system were tested:

- Is the filter germ-proof after undergoing multiple reprocessing?
- Do the cleaning chemicals change the PTFE material and is it resistant to chemicals?
- Does the flow resistance of the filter material change after repeated reprocessing?

In all cases, the functionality of the integrated germ barrier system was intact, also with discoloration.

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3.1 INTEGRTED GERM BARRIER SYSTEM DRY AND MOIST

Test description

The germ-proof quality of the filter when moist was tested pursuant to DIN 58953-6[6] by an independent test lab.

Test design

The filters were put into a sterile container system and steam sterilized with a load. Then the filters were charged with a microbial suspension. In order to re-enact the worst case scenario, 3/4 sized container bottoms were used with the lowest ratio of filter surface to volume.

Test result

No germ growth was detected. The filters are sufficiently germ-proof.

3.2 CHEMICAL RESISTANCE OF INTEGRATED GERM BARRIER SYSTEM

Test description

The integrated germ barrier system - a filter cassette with a PTFE filter was checked for its chemical resistance.

Test design

For multiple hours, the PTFE filter cassette was exposed to a temperature of 96°C in various disinfection and neutralization agents for cleaning and disinfection devices. The concentration of the agent was twice as much as the value specified by the manufacturers information.

Test result

There were no determinable material changes detected. In some areas, discoloration was present resulting from deposits of the chemicals used by the reprocessing process.

3.3 FLOW RESISTANCE OF DISCOLORED INTEGRATED GERM BARRIER SYSTEM

Test description
The flow resistance (steam ingress) of an integrated germ barrier system displaying discoloration due to the impact of reprocessing was examined.

Test design
The flow resistance was tested and contrasted with unused filters and with filters subjected to an accelerated aging test.

Test result
No significant changes to the flow resistance were determined. Thus the functionality of the filter does not change.

Discolored filter disc due to the impact of repeated reprocessing.

4. GERM IMPENETRABILITY OF PRIME*Line*® PRO CONTAINERSYSTEMS

The germ impenetrability of the overall system was examined.

Test description
The sterile containers were tested in an independent lab for germ impenetrability.

Test design
The PRIME*Line*® PRO container system were sterilized and placed in a test chamber. Agar plates and metal specimens were located in the container system and in the test chamber.

The chamber was vaporised with a suspension enriched with bacteria. The sterile container was tested for germ growth.

Test results
With the performed test, it was demonstrated that a penetration of the microorganism into the sterile container was impeded.

The requirement in accordance to EN ISO 11067-1[7] is fullfilled.

The germ retention of the PRIME*Line*® PRO complies with the use requirements of the daily clinical routine.

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5. MECHANICAL TESTING WAS PERFORMED TO EVALUATE

Mechanical testing was performed to examine following points.

- Does the container deform when loaded containers with PRIME*Line*® PRO lids are stacked?
- Do the containers stack in a stable manner with the loads according to the standard, without slipping when a tensile force is applied?
- Is the stainless steel cover of the PRIME*Line*® PRO robust enough to withstand the demands of daily use?
- How does the filter cassette behave when turning the filter cassette in and out 10.000 times? (Following the instructions of use, the filter cassette should be exchanged if damaged or after completing 5000 reprocessing cycles)

5.1 MECHANICAL STACKING PRESSURE TESTING

Test description

According to EN 868-8[4], Annex D: Stacking test, a container with a PRIME*Line*® PRO lid must withstand a test load of 0.5 N / cm^2 (at least 100 N) when stacked. The plastic deformation may not be more than 1 mm.

Test design

The higher the container, the lower its side wall stability. Therefore the highest fullsize containers were used in this simulated stacking test.

Test result

There were no plastic deformations ≥ 1 mm after testing. All the lids tested with eight times the load were fully operational.

Mechanical stacking pressure testing with PRIME*Line*® PRO container system.

5.2 STACKING TENSILE TEST

Test description

According to EN 868-8[4], Annex E: Stacking device, a sterile container with test load of 10 kg must be stacked on a second fixed container. Conforming with the norm, the container must remain in position with a horizontal load. The test was conducted for all container sizes.

Test design

Tensile forces were used in the direction specified by the norm for all container sizes.

Test result

All container sizes fulfilled the requirements.

Performing a stacking tensile test with PRIME*Line*® PRO.

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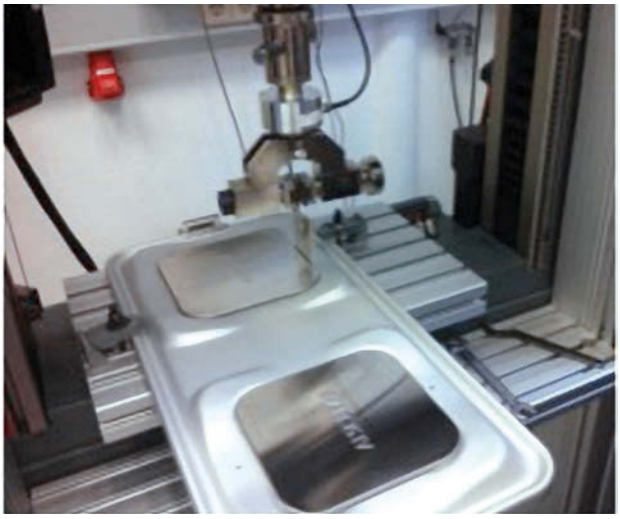
5.3 EXTRACTOR TESTING OF EXTERIOR STAINLESS STEEL COVER



Extractor Testing of the exterior stainless steel cover.

Components to fixate the stainless steel cover.

Test description

The stable fixation of the exterior stainless steel cover protecting the filter area of the PRIME*Line*® PRO was evaluated.

The background of the testing was a theoretical assumption of an unintended reflexive lifting of a loaded container, at the exterior cover by the user.

Test design

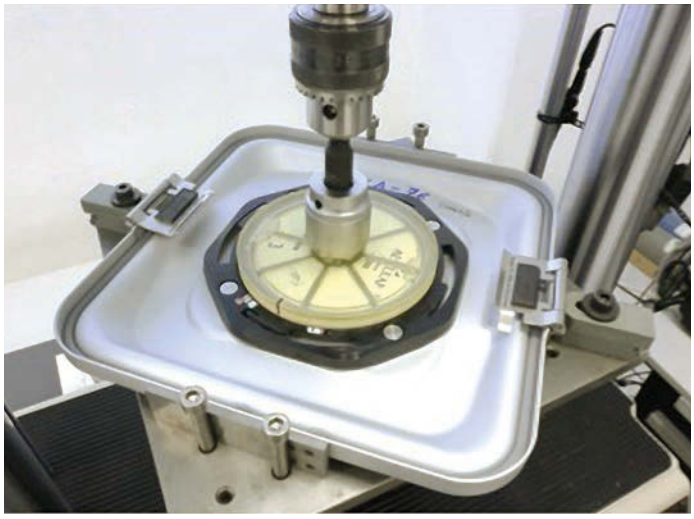
A worst case scenario was taken into consideration, while the stainless steel cover was introduced to reflexive tensile force by lifting the lid. The container lid was attached to the test table and exposed to a tensile force of 119 N with an extractor hook. The test was repeated from all sides of the stainless steel cover.

Test result

With the attachment of the exterior stainless steel cover, a sufficient and stable fixation on the aluminum lid is provided.

Even an unlikely load condition causing mechanical tensile forces, can not cause damage to the exterior cover or the fixation elements.

5.4 ASSEMBLY SIMULATION OF THE INTEGRATED GERM BARRIER SYSTEM



PRIME*Line*® PRO lid attached to the machine spindle for the repeated opening and closing.

Test description

The integrated germ barrier system is typically not removed after use.

A repeated opening and closing of the filter cassette of the integrated germ barrier system was tested for the PRIME*Line*® PRO lid. Overall, a filter cassette was subjected to 10.000 load cycles to test the impact of repeated assembling and disassembling.

Test design

The PRIME*Line*® PRO lid was positioned on a machine spindle to prevent rotation of the lid. The rotation of the opening and closing of the filter cassette was simulated with an adapter attached to the machine spindle.

Test result

Even after 10.000 load cyles, the mechanical properties and material of the filter cassette did not show any changes, which could restrict its function.

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6. EVENT-RELATED STORAGE TESTS FOR 30, 180 DAYS*

The test involved how the PRIME*Line*® PRO lids behave in combination with the Basic container bottoms. After sterilization of sterile containers the bacterial growth in an event related storage after 30 and 180 days were tested. The validations of the container systems showed no bacterial growth.

Test description

It was examined, if containers with the basic container bottom maintain sterility after 30 and 180 days of real time storage in an external laboratoy.

Test design

The cleaned container systems were loaded with maximum permissible weights of instruments and sterilized using the prevacuum method. Then the containers were stored in a simulated sterile storage unit.

Test result

The Aesculap sterile container with the PRIME*Line*® PRO lid displayed no bacterial growth after the tested storage durations of 30 and 180 days.

Storage of sterilized PRIME*Line*® PRO sterile containers.

7. BIOLOGICAL EVALUATION

The containers with PRIME*Line*® PRO lids are designed for sterilization including the subsequent storage period of medical products. Therefore a biological safety must be ensured.

Test description

The biological reliability conforming to EN ISO 10993-1[8] was evaluated.

Test design

Medical products were used as test specimens. Individual components of the sterile container and test specimens were cleaned and sterilized according to the instructions for use.

The test specimens were then checked for evidence of possible influence from the containers materials.

Test result

The test specimens did not show irregularities or deviation. The Aesculap sterile container is a multi-use sterile barrier system in which medical products are sterilized, stored and transported. To this end, the biological reliabilty and tolerance of the PRIME*Line*® PRO lid is proven for daily clinical use.

* 365 day storage study is currently being performed.

8. CITED STANDARDS

[1] AAMI TIR 30: 2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.

[2] Guidelines for validation of the manual cleaning and manual chemical disinfection of medical products. German Society for Hospital Hygiene (DGKH), the German Society of Sterile Services (DGSV) and the Working Group on Instrument Preparation (AKI) and Association for Applied Hygiene (VAH) (Status as of 2013).

[3] Guidelines for validation of the machine cleaning and thermal disinfection of medical products. German Society for Hospital Hygiene (DGKH), the German Society of Sterile Services (DGSV) and the Working Group on Instrument Preparation (AKI) (Status as of 2014).

[4] EN 868-8: 2009 Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 – Requirements and test methods).

[5] EN 285: 2016 Sterilization – steam sterilizers - large sterilizers.

[6] DIN 58953-6: 2010 Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized.

[7] EN ISO 11607-1: 2014 Packaging for terminally sterilized medical devices -Part 1: Requirements for materials, sterile barrier systems and packaging systems.

[8] EN ISO 10993-1: 2010 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system (ISO 10993-1: 2009).

AESCULAP® – a B. Braun brand

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