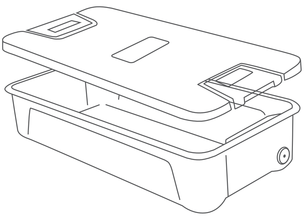
CONTAINERS: GUARDIANS OF STERILITY

SCIENTIFIC INFORMATION

B BRAUN SHARING EXPERTISE

Rigid sterile containers deliver surgical instruments in a sterile, functional condition to the right place at the right time. To achieve this, they have to be strong, stable, maintain sterility during storage and have a long shelf life – all whilst withstanding thousands of cycles of sterilization and usage. **The following tests demonstrate that the AESCULAP Aicon® Sterile Containers fulfill all these requirements.**



TESTS	RESULTS
STABILITY / ENDURANCE TESTING Container components (face plates, identification tags, filter holders, protection covers, enhanced drying system EDS, closing latches) were cleaned, sterilized **(zero, 250, 500 cycles)** and underwent thousands of cycles of **assembly + disassembly (2,000–10,000).**	All components fulfilled success criteria, **no** tearing, breaking or loss of function.
MECHANICAL LOAD TESTING **Stacking (without slipping or toppling over):** A load of up to **5,700 N or roughly 581.24 kg was applied for 10 min;** a tensile force of **50 N was applied in longitudinal, transversal and diagonal direction for 5 s** (according to DIN[1]). **Stability after pressure change with and without stacking:** Container was **loaded with 64 kg** and then underwent sterilization. **Stability of container grips:** A tensile machine using **4x** the maximum container load of **11.34 kg was lifted for 10 min.**	**No** slipping or sliding **No** optical transformation, measurements before and after loading differed **< 1mm** **No** deformations
STERILIZATION PERFORMANCE **Sterilization performance** Containers were loaded and placed in sterilizer[2]. Three different times were noted: **Equilibration time** Time until desired temperature is established within chamber. ISO norm: < 15 s with a chamber volume of < 800 l **Holding time** ISO norm: sterilization temperature of 134–137°C for ≥ 180 s **Plateau time** (holding time + equilibration time) ISO norm: 1–60 s: delta T ≤ 5 K; > 60 s: delta T ≤ 2 K **Sterilization validation after accelerated ageing** Sterilized, "aged" containers (**1,000 sterilization** cycles, **500 cleaning** cycles) were transferred to a test chamber, challenged with a test germ and incubated for **30 min**[3]. **Sterilization efficacy and thermal profile** Two containers were stacked in a steam cycle of **132°C for 3 min**. Instruments in the container were inoculated with spores in the most difficult to sterilize locations[4].	**Performance:** All normative criteria were met for all test samples[5]. **Validation:** No entrance of microorganisms was observed. **Sterilization efficacy and thermal profile:** All indicator test samples were negative for growth after incubating. Steady state thermal conditions were confirmed. Positive controls were performed.
SHELF LIFE The containers were fully loaded, sterilized and stored for **365 days**, followed by sterility testing in a microbiological culture medium[6].	**No** growth of microorganisms after sterilization, storage and incubation. Containers can maintain sterility after **365 days**.
STERILE UPPER EDGE **Upper edges of the container bottom** were sterilized and then inoculated with **bacterial spores** along the outer rim; test swabs were incubated for **7 days at 55–60°C**.	Aseptic presentation of internal contents was considered to be at a **safe distance from potential contamination** of the interior lip of the container and was determined to be at the **+2 mm** mark from the top rim of the container.
STERILE BARRIER INTEGRITY AFTER TRANSPORT AND VERTICAL MOVEMENT IN AN ELEVATOR Containers were sterilized, **transported** via a route with physical obstacles and changes in environmental conditions, taken up and down an **elevator (minimum 10 floors)** and then tested for sterility again[6].	Containers **maintained** whole package integrity and sterility after transportation and elevator transit.

Sources
(1) Packaging for terminally sterilized medical devices, Part 8: re-usable sterilization containers for steam sterilizers conforming to EN 285 – requirements and test methods; German version EN 868-8:200.
(2) DIN EN 868-8:2009-09, Packaging for terminally sterilized medical devices – Part 8: re-usable sterilization containers for steam sterilizers conforming to EN 285-Requirements and test methods.
(3) DIN EN ISO 11607-1:2017-10, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.
(4) Association for the Advancement of Medical Instrumentation (AAMI), International Organization for Standardization (ISO) Guidelines 4161:2009(R2014) Sterilization of Health Care Products.
(5) DIN EN 285-2016-05, Sterilization – Steam Sterilization – Large Sterilizers.
(6) Premarket Notification [501(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA; https://federalregister.gov/documents/2002/03/07/02-5489/medical-devices-draft-guidance-for-industry-and-fda-on-premarket-notification-submissions-for.