AESCULAP Aicon® STERILE CONTAINER SYSTEM TEST RESULTS

Scientific Information

SHELF LIFE

The tests investigated whether the AESCULAP Aicon® Container can effectively maintain the sterility of its contents for up to 365 days after sterilization.

TEST DESCRIPTION

Event-related real time shelf life testing is required by the FDA in order to demonstrate that sterility packaging systems are effective at maintaining the sterility of the internal contents following the proposed shelf life storage period (1). Three containers were processed in pre-vacuum steam cycles and then handled and stored. After 365 days, the containers were tested for shelf life sterility.

TEST DESIGN

The containers were fully loaded with instruments, stainless-steel coupons, biological indicators (BI) and chemical indicators, and then processed in a pre-vacuum steam cycle at 132°C with four minutes exposure. Handling and storing were in accordance with a typical Central Service Department in a hospital setting. After 365 days, the sterility was tested. This was done by first aseptically transferring the stainless-steel coupons and BIs to containers of microbiological culture medium, and then incubating them. As a negative control, one uninoculated tube from each lot of culture media was incubated with the test sample; as a positive control, one unprocessed *Geobacillus stearothermophilus* BI from the lot used in testing was transferred to a separate tube of culture media and incubated with the test samples. All test samples were incubated at 22-28°C for a minimum of 14 days.

TEST RESULT

All test samples demonstrated no growth following sterilization, storage period and incubation. This allows the conclusion that the Aesculap® containers are capable of maintaining the sterility of their contents after a maximum of 365 days of storage (as long as the sterile barrier is not compromised).

Sources:

1. Premarket Notification [501(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA;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

AESCULAP® – a B. Braun brand

Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 7461 95-26 00 | www.aesculap.com

D-ST19065 0120/PDF/2