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SHARING EXPERTISE

AESCULAP Aicon® STERILE CONTAINER SYSTEM TEST RESULTS

Scientific Information

DRYING WITH ENHANCED DRYING SYSTEM (EDS)

The determination of the proper drying time required for the AESCULAP Aicon® Series Rigid Container was conducted with and without the Enhanced Drying System (EDS). Complete dryness was confirmed by visual inspection for the presence of moisture and average pre- and post-sterilization total container weight difference.

TEST DESCRIPTION

The tested devices were AESCULAP Aicon® Rigid Container with (JJ111) and without (JJ110) the EDS. The acceptance criteria were: 1. No moisture visible, 2. Average pre- and post-sterilization weight difference of less than 0.2% (1). The validation was performed in an ISO 17025 accredited laboratory.

TEST DESIGN

JJ110 was loaded with stainless-steel bolts (2) until they met a weight (with lid) of 25 lbs. JJ111 was loaded with a total combined weight of 22 lbs. and in an additional test with 25 lbs. Container were seeded with two Crosstex/STEAMPlus™ Class 5 Integrators (3). Container samples were weighted and processed in a steam pre-vacuum cycle of 132°C (270°F) for 4 minutes exposure time. Systems were re-weighted after a cooling down of 5 minutes, pre- and post-sterilization weights were evaluated. After another 25 minutes the systems were visually inspected for the presence of moisture. 3 test cycles were carried out to show repeatability.

TEST RESULT

AESCULAP Aicon® Rigid Container with (JJ111) and without (JJ110) the EDS demonstrated an average pre- and post-sterilization weight difference of less than 0.2% (As required in DIN EN 868-8:2018); All integrators demonstrated steam penetration. The AESCULAP Aicon® JJ110 loaded with 25 lbs. is considered to be properly dried following the pre-vacuum steam sterilization cycle after 15 minutes. The AESCULAP Aicon® JJ111 with EDS loaded with 25 lbs. is considered to be properly dried following the pre-vacuum steam sterilization cycle after 9 minutes.

Sources:

1. ANSI /AAMI ST 77: 2013, Contaminated devices for reusable medical device sterilization.
2. EN 868-8:2018, Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods.
3. EN ISO 11140-1:2014, Sterilization of health care products - Chemical indicators.

AESCULAP® – a B. Braun brand

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