AESCULAP Aicon® STERILE CONTAINER SYSTEM TEST RESULTS

Scientific Information

MANUAL AND AUTOMATIC CLEANING VALIDATION

The evaluation of the cleaning success of reusable medical devices presented here are based on national and international standards and guidelines. The cleanability was confirmed with protein and hemoglobin detection; all applied acceptance criteria were fulfilled.

TEST DESCRIPTION

The tested devices were AESCULAP Aicon® container bottoms and lids. The acceptance criteria were: 1. No soil visible, 2. Amount of protein/cm^2 < 3.0 µg/cm^2, and 3. Amount of hemoglobin < 2.2 µg/cm^2. The references for these criteria were DIN ISO/TS, RKI, AAMI TIR30, DGKH, AKI and DGSV guidelines (1, 2, 3, 4, 5, 6). The validation was performed in an independent testing laboratory, which is accredited by the German Accreditation Agency DAkkS; both manual and machine cleaning procedures were investigated.

TEST DESIGN

The samples – container bottoms and lids – were contaminated with radioactively labeled test soil containing sheep blood, albumin and hydrochloride to identify, localize and quantify the contamination before and after the cleaning process (please note that EDS modules, perforation lids and faceplates can be left installed in the container during the cleaning process).The contamination was intentionally kept high and applied to typically hard-to-clean places, such as the closure mechanism and the filter retainer locked in place in the lid, to create a worst-case scenario. Subsequently, the samples were dried at ambient conditions for one hour and then cleaned manually and in a washer-disinfector according to manufacturer recommendations as noted in the IFU, after which the evaluation took place. The examples were visually checked using a gamma camera and extracted with SDS-solution to carry out a quantitative determination of the amount of protein and hemoglobin residues.

Please note: Sometimes, cleaning processes have to be extended dramatically because soiling in validation is performed in an excessive way (e.g. under filters, inside handling mechanics etc.). In these cases, we recommend to use a more realistic soiling as can be observed with used containers.

TEST RESULT

The cleaning performance of all container bottoms and lids tested fulfilled all three acceptance criteria described above, despite the high contamination in difficult to access locations such as under the closing latches.

Sources:

1. ISO/TS 15883-5:2006 (cleaning efficacy of washer-disinfectors)
2. Recommendation from the Commission on Hospital Hygiene and Infection Protection at the German Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (2012)
3. Association for the Advancement of Medical Instrumentation, compendium for cleaning reusable medical devices (2011)
4. German Society for Hospital Hygiene (2017)
5. AKI (Working Group Instrument Reprocessing) (2017)
6. DGSV (German Society for Sterile Supply) (2017)

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