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MEETING ABSTRACTS

IN VITRO CYTOTOXICITY EVALUATION OF SELECTED MATERIALS FOR WOUND DRESSING APPLICATION

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Every medical device that is in contact with human body must be subjected to series of biological tests during the risk assessment process. Cytotoxicity testing belongs to the group of endpoints for biological evaluation of medical devices and its whole process is defined in ISO 10993-5 "Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity". In a short time, it provides an initial information about toxicity, which serves as a good indicator of general toxic properties and thus it can reduce the number of *in vivo* models required for subsequent toxicity analyzes. There are different approaches to cytotoxicity testing, either direct contact toxicity evaluation or elution methods. In our study, we focused on the latter approach, namely on optimizing the preparation of the material extracts in accordance with recommendations from ISO 10993-12 "Biological evaluation of medical devices – Part 12: Sample preparation and reference materials". Based on the specific properties of tested materials, we selected volume of solvent used per surface area of test samples. Material samples were extracted in appropriate cell culture medium supplemented with serum. The materials were extracted at 37 °C for 24 hours with continuous circulation of sterile material immersed in the extraction medium in sealed tubes. In addition, we further extended the analyzes to dose ranging cytotoxicity evaluation to determine the level at which cytotoxicity no longer occurs.

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Keywords: medical devices; wound dressings; cytotoxicity