Solventum MedTech OEM
Product clinical data summary
Solventum™ Medical Component 9818, Flexfoam Closures
Effective: May 2017

The adhesive used on Medical Component 9818, as a part of a different construction, has been subjected to the following safety evaluations:

In Vitro Cytotoxicity
The test was to determine the potential for cytotoxicity based on the requirements of International Organization for Standardization (ISO 10993-5): Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity. Triplicate wells were dosed with a 1cm x 1cm of the test article. Triplicate wells were dosed with a 1 cm length of high density polyethylene as a negative control. Triplicate wells were dosed with a similar portion of latex as a positive control. Each was placed on an Agarose surface directly overlaying a sub-confluent mono layer of L-929 mouse fibroblast cells. After incubating at 37 degrees C in the presence of 5% CO_2 for 24 hours, the cultures were examined macroscopically and microscopically for any abnormal cell morphology and cell lysis.

The test article showed no evidence of causing any cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

MEM Elution
An additional in vitro study was conducted to evaluate for potential cytotoxic effects following the guidelines of International Organization for Standardization 10993-5: Biological Evaluation of Medical Devices, Part 5: Test for In Vitro Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium at 37 degrees C for 24 hours. The negative control, reagent control and positive control were similarly prepared. Triplicate monolayers of L-929 mouse fibroblast cells were dosed with each extract and incubated at 37 degrees C in the presence of 5% CO_2 for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration. The test article extract show no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Primary Skin Irritation
The test article was evaluated for primary skin irritation in accordance with guidelines of ISO 10993 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity. Two approximate 25mm x 25mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at 1, 24, 48, and 72 hours after removal of the single sample application. There was very slight to well defined erythema and no edema observed on the skin of the animals. The Primary Irritation Index for the test article was calculated to be 0.4. The response of the test article was categorized as negligible.

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