



Dear Valued Customer,

The biocompatibility of the radiopacifier ingredient used to formulate Foster's LoPro Clear™, radiopaque compounds was tested directly (not encapsulated in a polymer), by a third party testing service (NAMSA), under the guidelines of ISO 10993-5. A summary of the test and results are below:

"This *in vitro* study was conducted to evaluate potential cytotoxic effects following the guidelines of ISO-10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity. A single preparation of the test article was extracted in single strength Minimum Essential Medium (1X MEM) at 37° 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°C in the presence of 5% CO₂ for 48 hours. Following incubation, the monolayers were examined microscopically for abnormal cell morphology and cellular degeneration.

The test article extract showed evidence of causing slight cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity)."

In grading, a scale of 0 (none) to 4 (severe) is used to judge reactivity. The clear, radiopacifier rated a 1 (slight). A grade of 1 requires that "Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable. Actual results were 10% cells without intracytoplasmic granules and 10% lysis.

The test results are specific to the samples prepared. Any further extrapolation of the results would be the responsibility of the user of the clear, radiopaque compounds.

Respectfully submitted,

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