



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% CO<sub>2</sub> 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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