Dear Valued Customer,

The biocompatibility of the ingredients used to formulate Foster's ProPell™ lubricant packages were tested by third-party testing services, Toxikon and NAMSA. Testing was performed under ISO/IEC 17025, 2005 and ISO 13485:2003 conditions, respectively. A summary of the tests and results from the Toxikon and NAMSA studies are below:

Study	Class VI Test – USP	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Ratio	0.2 g/mL		
Extraction Conditions	70 ± 2 °C for 24 ± 2 hours		

REFERENCES: The studies were conducted based on the United States Pharmacopeia (USP) 39, National Formulary, General Chapter <88>, Biological Reactivity Tests, In Vivo.

GENERAL PROCEDURE: The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity through 72 hours post treatment. In addition, the test articles were implanted into the paravertebral muscles of rabbits for 7 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection.

RESULTS: None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema, or clinical toxicity. In both the Systemic and Intracutaneous Tests, the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

CONCLUSION: The test articles meet the requirements of the guidelines for the Biological Test for Plastics, Class VI – 70 °C.

The test results are specific to the samples prepared. Any further extrapolation of the results would be the responsibility of the user of the compound(s) containing the above-mentioned lubricant packages. It is the responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, with all applicable laws and regulations. Foster Corporation makes not representation, promise, or express or implied warranty concerning the suitability of Foster's products for use in any medical device.

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If you have any questions or require any additional information, please do not hesitate to contact the undersigned.

Respectfully Submitted,

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