

Biocompatibility and Cytotoxicity Statement (PTFE Natural®)

Issued: October 24, 2022

Products: All stainless steel and coated PTFE Natural® mandrels, fine wires and hypo-tubes

Applied Plastics LLC (AP) has performed the following subcontracted testing, with Nelson Labs (a Sotera Health company) in Salt Lake City, Utah.

- Cytotoxicity: MEM Elution L929 (non-implant) – ISO 10993-5
- Biocompatibility: USP Class VI – ISO 10993-1
 - Systemic Injection Test
 - Intracutaneous Injection Test
 - Intramuscular Implantation Test

All testing was performed in a GLP environment to ensure the testing was handled in a rigorous and structured manner.

Cytotoxicity Results (Nelson Labs Study No. 1537633-S01):

Test Article Results	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount
	#1	#2	#3	Avg		
Pass	0	0	0	0	6 cm ² /mL	30.0 cm ² / 5 mL

Biocompatibility Results (Nelson Labs Study No. 1537632-S01 / Labcorp Report: 22-01380-G1):

The USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG) extracts of the test articles, following Intracutaneous Injection in rabbits and Systemic Injection in mice, and the test article, following Implantation in rabbits, did not produce a biological response. Based on the criteria of the protocol and the USP guidelines for Class VI Plastics - 50 °C, the test article meets the requirements of the test.

Conclusion:

Biocompatibility has been confirmed acceptable based on prescribed Cytotoxicity and Class VI Testing Requirements. PTFE Natural® product testing received a zero-reactivity grade and do not produce a biological response evidenced by the above testing performed.

Edward Perry - Director of Quality and Regulatory

References:

- MEM Elution GLP Report, Study Number 1537633-S01, Nelson Labs, 19AUG2022
- Class VI Test – USP (GLP), Study Number 1537632-S01, Nelson Labs 10OCT2022

NOTE:

The information contained herein is for reference only and, to AP's knowledge, accurate as of the Issued date. As a custom manufacturer, we require our customers to specify their material and product requirements. As such, it is the customer's responsibility to inspect and/or test AP's products in order to assure their intended use and to meet their regulatory requirements. This statement shall not be considered a warranty of any kind.