

MEDICAL BIOCOMPATIBILITY TESTING – 900 Series

USP Biological Reactivity Tests, In Vivo, USP Plastic Class VI

Biocompatibility testing of medical devices is essential to ensuring the safety of patients who use the device. Such tests determine the interaction of the medical device and the tissues and physiological systems of the patient. These tests are only a part of the total assessment necessary for evaluating the safety of a device. In order to grant approval of a medical device, the FDA requires biocompatibility and other tests to be done on the actual part. FDA does not grant approval on components of a device. The table below lists the tests and results performed by independent testing organizations on behalf of Crysta-Lyn Chemical Company. **These results provide medical device manufacturers the confidence that the Clearweld® material will not be a barrier in obtaining FDA approval of their device.** Additional information relating to such testing can be provided upon request.

TEST	MATERIAL TESTED	RESULT
Cytotoxicity Study using the ISO Agarose Overlay Method	900 Series Powder	The test article extract showed no evidence of causing cell lysis or toxicity.
Cytotoxicity Study using the USP Elution Method	LD 940E spray coated on PC – pre laser exposure	The test article extract showed no evidence of causing cell lysis or toxicity.
USP Acute Systemic Toxicity Study in Mice	LD 940E extracted with: alcohol saline, polyethylene glycol, 0.9% sodium chloride	There was no mortality or evidence of systemic toxicity from the extracts injected.
USP Intracutaneous Study	LD 940E Extracted using alcohol saline, polyethylene glycol, 0.9% sodium chloride, sesame oil	There was no evidence of significant irritation from the extracts injected intracutaneously. Each test article extract met USP requirements.
USP Muscle Implantation Study	7 Day implant of LD 940E spray coated on PC, implantation using trocar method	The macroscopic reaction was not significant as compared to the negative control article. The implanted test article met USP requirements.



CLEARWELD®

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Clearweld samples coated on Covestro Makrolon 3108, supplied by Nekoosa CET Films