

MEDICAL BIOCOMPATIBILITY TESTING

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 Gentex Corporation. **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	CLEARWELD® MATERIAL TESTED	RESULT
Cytotoxicity	Raw IR absorber	Nontoxic ¹
	Coating applied to plastic — pre laser exposure	Nontoxic ²
	Coating applied to plastic — post laser exposure	Nontoxic ²
USP Systemic Toxicity	Coating applied to inert substrate — pre laser exposure	Meet the requirements of USP Class VI
	Coating applied to inert substrate — post laser exposure	Meet the requirements of USP Class VI
USP Intracutaneous Toxicity	Coating applied to inert substrate — pre laser exposure	Meet the requirements of USP Class VI
	Coating applied to inert substrate — post laser exposure	Meet the requirements of USP Class VI
USP Muscle Implantation	Coating applied to inert substrate — pre laser exposure	Meet the requirements of USP Class VI
	Coating applied to inert substrate — post laser exposure	Meet the requirements of USP Class VI
Extraction and Identification of Decomposition Products	Coating applied to inert substrate — post laser exposure; irradiated dye washed with methanol for extraction	No toxic byproducts were identified

¹Cytotoxicity study using the Agarose Overlay Method

²Cytotoxicity study using the MEM Elution Method



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