

TEST	TEST FACILITY	RESULTS/COMMENTS
Sensitization in the Guinea Pig	NAMSA	Extraction of Elast-Eon™ with sodium chloride and cotton seed oil showed no evidence of causing delayed sensitization.
In-Vitro Hemolysis (Modified ASTM – extraction method)	NAMSA	Extraction of Elast-Eon™ with sodium chloride. Extracts were evaluated via in-vitro red blood cell hemolysis. The results showed a nonhemolytic response
Acute intracutaneous activity study in the rabbit	NAMSA	No evidence of significant irritation from the extracts
C3a complement Activation Assay	NAMSA	The test article showed decreased activation compared to the control materials.
Cytotoxicity study using the ISO elution method	NAMSA	No evidence of cell lysis or toxicity.
Plasma recalcification time coagulation study	NAMSA	Satisfies ISO 10993 Part 4 requirements for interaction with blood
Plasma recalcification time coagulation study	University of New South Wales	Elast-Eon™ similar or better resistance to attack than Pellathane 55Dt.
Biostability in Juvenile Rats (Subcutaneous)	University of Liverpool	Elast-Eon™ similar or better resistance to attack than Pellathane 55 Dt.
Hydrodynamic function for a heart valve made from biostable polyurethane	University of Glasgow	No failures, degradation, biological attachments or calcification.
Direct Contact Cytotoxicity	University of Liverpool	No adverse reaction, cell growth
MTT Assay	University of Liverpool	Higher % metabolism compared with other “medical grade polyurethanes”
Subcutaneous implant in Juvenile Rats	University of Liverpool	No apparent evidence of calcification.
Coagulation – thrombin generation assay	Mitra-Flow	Elast-Eon™ has a low blood activation response.
Platelets – count + Gpiibiiia marker	Mitra-Flow	Elast-Eon™ has a low blood activation response.
Haematology – count +CD11b marker	Mitra-Flow	Elast-Eon™ has a low blood activation response.
Complement – complement convertase assay	Mitra-Flow	Elast-Eon™ has a low blood activation response.
In-Vitro Biostability	CoCl2/Peroxide Test Apparatus	Pass