

Elastron is fully dedicated to development, production, marketing and sales of thermoplastic elastomers (TPEs). The company was established in 1980 with initial production of SBS based Thermoplastic rubber compounds and significant technical developments resulted in adding SEBS and EPDM/PP based thermoplastic elastomers to the production range. **Elastron** devotes significant resources to technical developments of new products and applications to meet market and customer needs. **Elastron** markets its Medical Grade Compounds worldwide. A proven quality management system ensures a high level of quality for the products introduced on the market, from development through production, and to quality assurance. Our system is ISO 9001:2000 certified and is continually optimized. The right TPE formulation is the key for safe and successful medical product. When a standard formulation does not meet the needs of a unique application, **Elastron's** formulation development talents are available for custom solutions.

About Elastron

Elastron Medical TPE compounds



Some special features of Elastron Medical grade products are listed below:

- Latex free
- Nitrosamine free
- PVC free
- Phthalate free
- Non-toxic
- Biocompatible
- USP Class VI approved
- 100 % recyclable
- Excellent bonding to polyolefins
- Easy to colour

Special features



Production & Quality

Elastron medical TPEs are produced with advanced production equipment and with traceability and documentation. To achieve the maximum level of safety, we dedicated a special compounding line for medical compounds. Elastron medical compounds are produced under strict quality control systems.

Formulation Stability

Elastron guarantees that raw materials used in medical compound formulations are never changed. In case a formulation has to be changed for some reason Elastron will inform the customers in due time. In addition to formulation and raw material fixing, Elastron also stabilizes its production parameters to be sure that every batch has the same quality.

Sterilization performance

Many medical devices are sterilized prior to use, once or several times during their lifetime. Therefore it is important that the materials used retain their properties after numerous sterilizations. Products made from Elastron medical compounds can be sterilized with steam, ethylene oxide and gamma irradiation.

We offer two series of thermoplastic elastomer compounds for medical applications. **Elastron G** series and **Elastron V** series. In our product nomenclature G stands for SEBS based TPEs, V stands for EPDM/PP based TPVs and we combine these nomenclatures with P indicating pharma (medical) grade series of them. **Elastron V** medical TPE compounds combine the performance of vulcanized rubbers with the processing properties of thermoplastics, delivering sophisticated design opportunities through a wide and flexible range of products. **Elastron G** medical TPE compounds are based on Styrene-ethylene/butylene block copolymer and offers excellent material properties. **Elastron** medical TPE compounds are sterilizable with gamma, EtO and steam. Tested grades have passed **in vitro** cytotoxicity tests according to ISO 10993-5, USP <87> and **in vivo** biological reactivity test according to USP <88>. They will be a good material for PVC replacement. They are completely synthetic and latex free thereby minimizing allergy risks. Combining our medical knowledge and over 30 years of TPE experience we developed medical TPE compounds to obtain safe and high quality compounds for use in medical industry. **Elastron** medical compounds have already been used in medical applications. The increasing customer demand prompted us to intensify the development that we are expanding our range of TPEs to medical industry and we invested a dedicated production line for medical products to supply defect free, non-contaminated products.



About Elastron Medical

TPE compounds

Applications

Some applications of Elastron Medical compounds are listed below:

- Syringe plunger seals
- Infusion bottle closures
- Medical clean room clogs
- Artificial respiration hand pump
- Plastic infusion / transfusion bag injection ports
- Medical hoses



Regulatory compliance

Elastron medical compounds are tested according to USP <88> for their **in vivo** biocompatibility and ISO 10993-5, USP <87> for their **in vitro** cytotoxicity. All materials tested successfully passed the tests. Tested compounds all have USP Class VI approvals. Elastron medical compounds also meet requirements of European Pharmacopoeia monographs 3.2.8 Sterile single-use plastic syringes and 3.2.9 Rubber closures for containers for aqueous parenteral preparations for powders and for freeze-dried powders.



Biocompatibility Tests

The following lists the **in vivo** biocompatibility tests carried out for representative Elastron medical compounds by independent qualified laboratories. USP <88> "Biological Reactivity Tests, **in vivo**" Class VI procedures are performed:

USP Class VI contains the following main tests:

Systemic injection test- Acute systemic toxicity Tests:

The test material [extract] is tested for systemic toxic effects as a result of a single, acute exposure.

Intracutaneous Test:

Intracutaneous test is in vivo screening test to evaluate local responses of test materials or their extracts.

Implantation Test:

Implantation studies evaluate the local effects of test article that is surgically implanted into an animal tissue examining macroscopically.

Test results are listed below:

Systemic Injection Test:

No signs of toxicity.

Intracutaneous Injection Test:

No signs of erythema, edema or clinical toxicity.

Implantation Test:

No significant signs of hemorrhage, necrosis, discoloration, encapsulation or infection compared with the control sites.



Cytotoxicity Test IN VITRO

Following test were conducted on Elastron Medical Compounds for their cytotoxicity effect. The tests were done by independent qualified laboratories, following USP <87> "Biological Reactivity Tests, **in vitro**" and ISO 10993-5" Biological evaluation of medical devices, Tests for **in vitro** cytotoxicity. Cytotoxic effects did not occur in tested samples.



A Selection of

Elastron Medical Grades

Elastron Grades	Elastron Medical Grade	Colour	Hardness	Specific Gravity	Tensile Strength at Break	Elongation at Break	Test Resistance
	Unit		Shore A	g/cm ³	MPa	%	N/mm
	Test Method		ASTM D 2240	ASTM D 792	ASTM D 412	ASTM D 412	ASTM D 624
Elastron V TPV Grades	P.V101.A30.N	Natural	30	0,90	3,0	1000	15
	P.V101.A40.N	Natural	40	0,90	3,5	1000	18
	P.V101.A45.N	Natural	45	0,90	4,0	1200	20
	P.V101.A50.N	Natural	50	0,90	4,5	1000	24
	P.V101.A55.N	Natural	55	0,90	5,0	1000	28
	P.V101.A60.N	Natural	60	0,90	5,5	1000	29
	P.V101.A70.N	Natural	70	0,90	5,5	950	34
	P.V101.A80.N	Natural	80	0,90	8,0	900	50
P.V101.A90.N	Natural	90	0,90	12,0	850	75	

Elastron G SEBS Grades	P.G401.A30.N	Translucent	30	0,89	5,0	1000	18
	P.G401.A40.N	Translucent	40	0,89	6,0	1000	22
	P.G401.A45.N	Translucent	45	0,89	7,0	1200	25
	P.G401.A50.N	Translucent	50	0,89	7,5	1000	30
	P.G401.A55.N	Translucent	55	0,89	8,0	1000	34
	P.G401.A60.N	Translucent	60	0,89	8,5	1000	40
	P.G401.A70.N	Translucent	70	0,89	10,0	950	45
	P.G401.A80.N	Translucent	80	0,89	12,0	900	60
	P.G401.A90.N	Translucent	90	0,89	17,0	850	80

* Most Elastron medical products are delivered either naturally colored or black. In appropriate lot sizes, different colored compounds can be delivered.

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