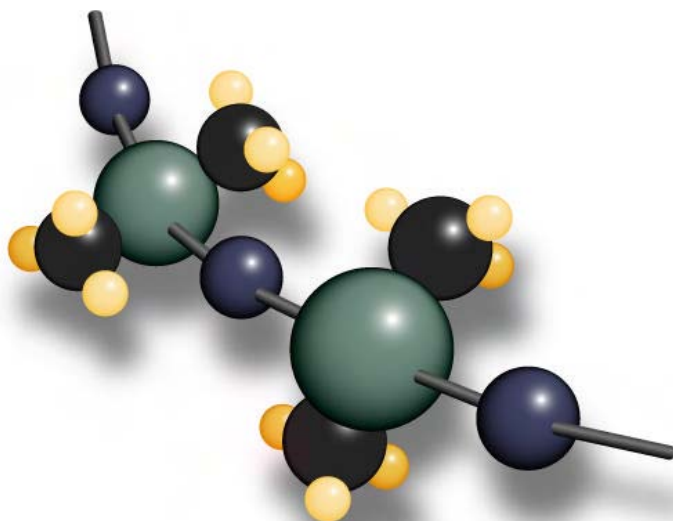


Polymer Systems Technology Limited

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Silicone for Healthcare Balloon Applications

Silicone elastomers possess unique properties making them an ideal material choice for balloon healthcare applications. Urological catheters, intra aortic angioplasty devices, and anchors for drug ports or feeding devices all commonly use silicone balloons. In addition to a proven history of being non-allergenic and biocompatible, silicone elastomers' physical properties contribute to a balloon's function and desired performance, including key properties such as modulus, tensile set, and recovery after inflation. The elastomers' filler content and related polymer interaction, crosslink density, and cure chemistry can all influence these key properties. NuSil monitors the tensile set properties of candidate materials in accordance with ASTM D412. This test method determines the recovery of original dimensions after a specimen of cured material has been elongated. Tensile set results for recommended high consistency rubbers are listed below when tested at 300% and 500% elongation. For more specific information on how this test is completed, please contact NuSil Technology directly.

	MED-4128	MED-4025
Typical Uncured Properties:		
Appearance	Translucent	Translucent
Worktime	-	2 h
Plasticity, Part A	65 mils	85 mils
Plasticity, Part B	-	85 mils
Typical Cured Properties:		
Cure	10 min @ 116°C catalyzed using 1.6PPH Percadox PD 50-S	10min @ 171°C 1:1 mix ratio
Post-Cure	2 hrs @ 200°C	-
Durometer, Type A	25	30
Tensile	1050 psi	1400 psi
Elongation	790%	900%
Stress @ 100%		
Strain	60 psi	65 psi
Stress @ 200%		
Strain	90psi	105 psi
Stress @ 300%		
Strain	135psi	175 psi
Tensile set @ 300%	3%	4%
Tensile set @ 500%	4%	6%
Tear	70 ppi	145 ppi
Rheometry @ 240°F:		
Maximum Torque	40 in·lbs	40 in·lbs
Scorch	0.50 min	1.15 min
T90	1.65 min	3.45 min

About NuSil Technology

NuSil Technology is a cutting edge global formulator and manufacturer of silicone compounds for the healthcare industries with 30 years of experience. Developing novel silicone systems, NuSil offers a complete line of customizable adhesives, elastomers, fluids, and gels. We meet the demands of new and innovative technologies by building on our experience and expanding our products and services to offer exclusive silicone solutions specifically designed for drug delivery and combination medical device products.

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For more information, please visit:
www.nusil.com

Regulatory Support

Customers interested in authorization to reference Master Access Files must contact NuSil Technology. In addition, these products are supported by the following biological testing:

MED-4025

TEST	TESTED PER USP	TESTED PER ISO 10993	TEST RESULTS
Cytotoxicity Test Using The ISO Elution Method In The L-929 Mouse Fibroblast Cell Line	Yes	Yes	A - Noncytotoxic B - Noncytotoxic C - Noncytotoxic
<i>In Vitro</i> Hemolysis Study (Extraction Method)	Yes	No	A - Nonhemolytic
USP Systemic Toxicity Study In The Mouse (Extracts)	Yes	Yes	A - Nontoxic
Acute Intracutaneous Reactivity Study In The Rabbit (Extracts)	Yes	Yes	A - Nonirritant
USP Muscle Implantation Study In The Rabbit With Histopathology (1 week)	Yes	No	A - Nonirritant
Ames Salmonella/Mammalian Microsome Mutagenicity Assay	Yes	No	A - Nonmutagenic
Rabbit Pyrogen Study -Material Mediated	Yes	Yes	A - Nonpyrogenic
Delayed Contact Sensitization Study (A Maximization Method) In The Guinea Pig (Saline Extract)	Yes	No	A - Nonsensitizer

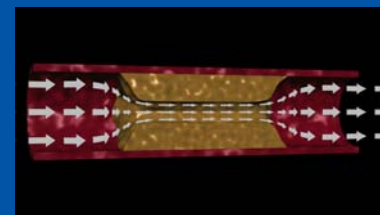
MED-4128

TEST	TESTED PER USP	TESTED PER ISO 10993	TEST RESULTS
Cytotoxicity Study Using The ISO Elution Method (1X MEM Extract)	Yes	Yes	Noncytotoxic
USP and ISO Systemic Toxicity Study Extract	Yes	Yes	Nontoxic
ISO Intracutaneous Study Extract	Yes	Yes	Nonirritant
ISO Muscle Implantation Study 1 Week	Yes	Yes	Nonirritant
ISO Maximization Sensitization Study	Yes	Yes	Nonsensitization

These are considered restricted materials and may be considered for use in short-term implant applications (29 days or less) or for external applications. It is the responsibility of the device manufacturer to determine the safety and efficacy of the device and the materials used in that device.

Additional Resources

To view more information and review white papers on NuSil's silicones for balloon applications, please visit our website www.nusil.com.



For more information, please visit:
www.nusil.com