

Resilient...

Excellent flex life enables superior performance in flexing medical devices

materials that belong to the body

BioSpan[®] segmented polyurethane

a DSM Product

BioSpan[®] segmented polyurethane (SPU) is a medical-grade polymer that offers superior mechanical characteristics, giving devices resistance to flex fatigue.

As one of the most elastomeric high-strength biomaterials available, BioSpan[®] SPU exhibits an impressive combination of properties including excellent flex life, low modulus, high strength and elongation, and proven biostability. It is used as the flexing, blood-contacting component in sac and diaphragm-type ventricular assist devices, artificial hearts, and in spinal implants. BioSpan[®] SPU is backed by a comprehensive FDA Master File.

Made to Last

- One of the most extensively tested and proven biomedical polymers on the market
- Able to withstand millions of flex cycles in properly designed devices
- Often chosen for cardiac assist devices that must survive over 40 million flex cycles per year

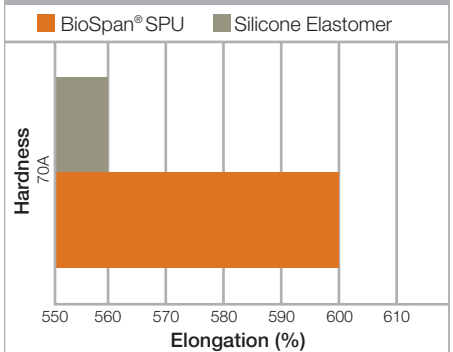
Versatile

- Adaptable for many applications
- Available in silicone-containing versions, which may improve biostability and thrombo-resistance in what is a very soft, rubbery polymer
- Solution-based and best suited for fabrication by casting, dipping, hand lay up and spraying

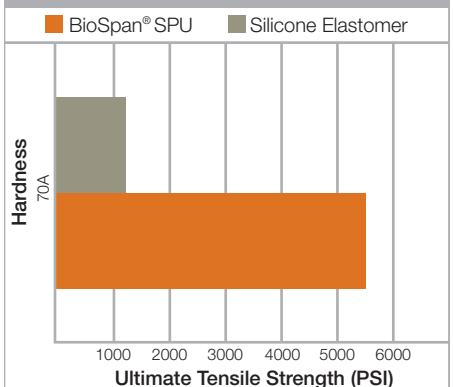
Unique Surface Modification Techniques

- Customizable with SME[®] technology, utilizing surface modifying end groups
- Enables the polymer to be equipped with different surface active end groups such as silicone, fluorocarbon and polyethylene oxide
- Eliminates the need for additional surface modification steps after the device component is fabricated

Great Combination of Elasticity and Strength



Outstanding Tensile Strength



Physical Properties

Typical Property (dry)	Testing Method	BioSpan® SPU
Initial Modulus (psi)	ASTM D1708	1750
Tensile Strength (psi)	ASTM D1708	5500
Ultimate Elongation (%)	ASTM D1708	600
Hardness	ASTM D2240	70A
Glass Transition Temperature (°C)	ASTM D3418	-65
Water Absorption (%)	ASTM D570	1.5
Weight Average Molecular Weight, Mw (Daltons)	ASTM D3593	180,000
Appearance	NA	Translucent
Solution Concentration by Weight (%)	NA	24

Note: Typical physical property values are not to be construed as sales specifications.

Representative Biological Test Results

Biological Test	Results
Primary Skin	Non-irritant
Primary Mucosal	Non-irritant
Kligman's Maximization-CSO extract	Weak allergic potential
Kligman's Maximization-NaCl extract	Weak allergic potential
USP Cytotoxicity (MEM Elution)	Non-cytotoxic
USP Acute Systemic	Non-toxic
Intracutaneous Injection	Non-toxic
Hemolysis	Non-hemolytic
Lee White Clotting	No effect on the clotting time of whole blood
USP Pyrogen	Non-pyrogenic
USP Muscle Implantation (14 days/rats)	Macroscopic-not significant tissue contact irritation Microscopic-Non-irritant
Ames Mutagenicity Assay	Non-mutagenic
Chromosome Aberration	Non-genotoxic
Balb/c-3T3 Cell Transformation	Does not induce morphological cell transformation in activated or non-activated test systems
Repeat Dose IV Study	Non-toxic
USP Muscle Implantation (120 days/rats)	Macroscopic-not significant tissue contact irritation Microscopic-slight irritant

Tests performed by and data on file at DSM PTG.

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