

Flexible...

The strength of polyurethanes with the added biocompatibility of silicone

materials that belong to the body

PurSil® thermoplastic silicone polyether-urethane

a DSM Product

PurSil® thermoplastic silicone-polyether-urethane (TSPU) is a novel copolymer that is strong, yet flexible with proven biocompatibility and biostability. Leveraging the benefits of both silicone elastomers and polyether urethanes, PurSil® TSPU has improved *in vitro* and *in vivo* stability. It has been used in medical device applications, including spinal implants and cardiac rhythm management. This polymer is backed by an established FDA Master File.

Flexible

- Comparable strength to traditional polyether urethanes (PEU) and added biostability from the silicone co-soft segment and silicone end groups
- Adaptable to various fabrication techniques to accommodate many different device shapes
- Capable of being extruded and injection or compression molded, as well as solvent bonded, dipped, coated and sprayed
- Available in aromatic and aliphatic versions

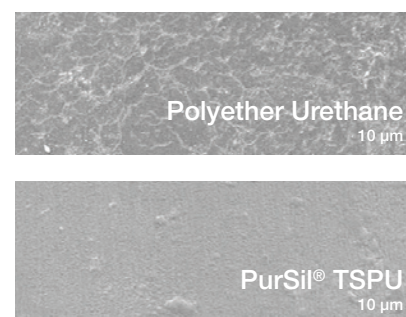
Biocompatible

- Outstanding hydrolytic stability compared to polyester urethanes
- Improved oxidative stability and thrombo-resistance over equivalent polyether urethanes without silicone
- Improved thrombo-resistance when used as a smooth blood-contacting surface
- Established FDA Master File

Unique Surface Modification Techniques

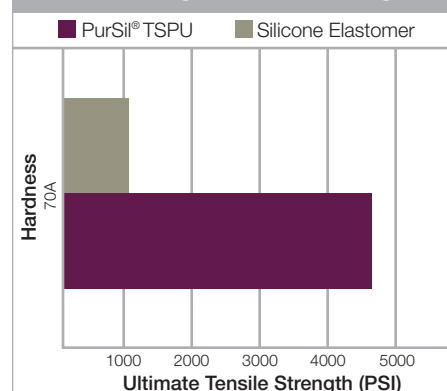
- Customizable through the incorporation of SME® technology utilizing surface modifying end groups
- Enables the polymer to be equipped with different end groups such as fluorocarbon and/or polyethylene oxide. Silicone end groups are standard.
- Eliminates the need for additional surface processing steps after the device component is fabricated

Improved Oxidative Stability



SEM surface image after **accelerated** exposure to harsh *in vitro* oxidative environment

Outstanding Tensile Strength



Physical Properties

Typical Property	Testing Method	PurSil® TSPU Silicone Content (%)		
		10	20	35
Color		Translucent, colorless to slightly yellow		
Hardness, Durometer	ASTM D2240	81A	80A	83A
Density, g/cm ³	ASTM D792	1.11	1.11	1.11
Ultimate Tensile Strength (psi)	ASTM D1708	5692	4669	3664
Ultimate Elongation (%)	ASTM D1708	571	565	492
Tensile Stress at				
psi at 50% elongation	ASTM D1708	NA	686	677
psi at 100% elongation		NA	897	916
psi at 300% elongation		NA	1846	1896
Tear Strength, Die 'C', pli	ASTM D624	350	390	330
Compression Set, %, 22 hrs @ 25°C	ASTM D395	23	28	29
Taber Abrasion, 1000g wt.	ASTM D1044			
Wear Index, mg/1000 cycles	H-18 wheel	25	26	85
Vicat Softening Temp.				
°C	ASTM D1525	82	73	67
°F		180	163	152
Coefficient of Linear Thermal Expansion				
x 10 ⁻⁶ /°C	ASTM E831	187.3	189	193.5
x 10 ⁻⁶ /°F	ASTM E1545	104.2	105	107.5
Approximate Melt Index, g/10 min at 224°C, 1200g	ASTM D1238	NA	30	32
Tg, °C	ASTM DSC	-68	-74	-86
Flexural Modulus, psi, 1% Secant Modulus	ASTM D790	5380	5550	6280
Flexural Stress, psi at 5% Deflection	ASTM D790	210	220	270
Dielectric Strength, (V/mil)	ASTM D149	340	350	420
Dielectric Constant, k', 60 hz	ASTM D150	7	6.7	5.8
Mold Shrinkage, %				
4.0" Disk	ASTM D955	1.2	1.1	1.1
Flame Bar		1.0-2.1	0.8-2.3	0.8-1.9
Optimum Extrusion Conditions				
°F		360-400	360-400	360-400
°C		182-204	182-204	182-204

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

Representative Biological Test Results

Biological test	Results	Biological test	Results
Cytotoxicity (1X MEM Elution)	Non-cytotoxic	<i>In Vitro</i> Hemolysis Study	Non-hemolytic
ISO Maximization Sensitization Study	No evidence of causing delayed dermal contact sensitization	Plasma Recalcification Time Coagulation	No significant effect on recalcification time
ISO Intracutaneous	No evidence of significant irritation from the extracts injected intracutaneously	ISO Rabbit Pyrogen	Non-pyrogenic
USP and ISO Systemic Toxicity	No mortality or evidence of significant systemic toxicity from the extract	Subchronic Intravenous Toxicity	No significant evidence of systemic toxicity
Genotoxicity: <i>in vitro</i> Chromosomal Aberration	Non-genotoxic	Mouse Bone Marrow Micronucleus	No evidence of cellular toxicity
Genotoxicity: Bacterial Reverse Mutation	Non-mutagenic		

Tests performed by and data on file at DSM PTG.

SEM images courtesy of Case Western University.

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