Technical Data Sheet





ChronoFlex AL[™]

| Aliphatic Polycarbonate-based Urethanes

Product Description

ChronoFlex AL is a family of Biodurable aliphatic polycarbonate-based thermoplastic urethanes designed to overcome surface degradation such as stress-induced micro fissures.

With a long history of reliable performance in both long- and short-term devices, this medical grade polymer has the versatility to be used across a broad range of applicational areas ranging from oncology and neurology to cardiovascular disease management.

These ether-free polyurethane elastomers are biostable and display a low modulus of elasticity, excellent solvent resistance and limited softening in-vivo and are adaptable to most standard manufacturing processes.

ChronoFlex AL products are available in harnesses ranging from 75 Shore A to 75 Shore D.

	Key Features	 Biodurable & Biocompatible USP Class VI Excellent Chemical Resistance Low Modulus of Elasticity Inherent Material Strength 	 Animal-Free Origin Certified Tailored To Meet Mechanical Specifications Reliable Performance in Long- And Short-Term Implantable Devices
	Forms	PelletSolution	
General	Processing Methods	 Extrusion Injection and Blow molding Dip Coating Solution casting Film formation Solvent coating methods 	
	Common Applications	CardiologySurgeryEndoscopicUrologyNephrologyNeurology	OrthopedicsDrug DeliveryDiabetes ManagementGastroenterologyEar/Nose/Throat

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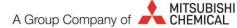
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FDA Master Files It is the responsibility of the user to establish safety with the FDA for their specific medical device.

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Technical Properties

	ChronoFlex AL™ (typical example ranges shown)*					
Characteristic Range	Durometer Range Available	75 Shore A – 75 Shore D			D2240	
	Specific Gravity	1.10 – 1.40			D792	
	Melt Flow	2-26 g/10 min I 205° C/ 3.26 kg			D1238	
	Durometer	75A – B20*	55D	75D	ASTM	
	Ultimate Tensile Strength (psi)	8000 - 10000	5000 - 10000	9000 - 12000		
	Tensile (psi)					
Mechanical	@ 50% elongation	450 – 650	1500 - 1800	5500 - 7500	D638	
	@ 100% elongation	650 – 850	1800 - 2200	6000 - 8000	D638	
	@ 200% elongation	1000 - 1450	2800 - 4200	-	D638	
	@ 300% elongation	1800 - 2400	4200 - 10000	-	D638	
	Ultimate Elongation (%)	400 - 600	200-400	100 - 300	D638	

^{*}Data provided herein is meant to show a general range for the ChronoFlex AL product lines; these properties can be tailored to meet specific values based on customer requirements.

Biocompatibility Testing	TEST	USP CLASS VI	ISO GUIDELINE
	MEM Elution		Meets ISO 10993-5 guidelines
	AGAR Overlay		Meets ISO 10993-5 guidelines
	Systemic Injection Test	Meets Class VI guidelines	Meets ISO 10993-11 guidelines
	Intracutaneous Injection Test	Meets Class VI guidelines	Meets ISO 10993-10 guidelines
	Intramuscular Implantation (macro)	Meets Class VI guidelines	
	Phthalate Free		Does not contain or in contact with DEHP
	Animal-Free Origin Certified		BSE/TSE free

Pre-Processing Recommendations:

ChronoFlex AL processing can be optimized by drying to a moisture content equal to or less than 0.05% by weight prior to melt processing.

Typically, the pellets must be dried for 3-4 hours with a dryer inlet air temperature of 180°F +/- 20°F. We recommend a machine-mounted desiccant-type hopper dryer, capable of reaching and maintaining a dew point of -40°F. If dry times are in excess of 8-10 hours, a hopper dryer temperature of 120-150°F is usually sufficient to achieve an optimal moisture content.

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