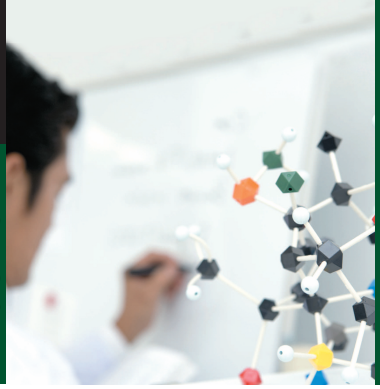
AROMATIC POLYCARBONATE-BASED URETHANES

ChronoFlex C®



AVAILABLE IN HARDNESSES RANGING FROM 75 Shore A to 75 Shore D

Strength you can rely on; Reliability you can trust.

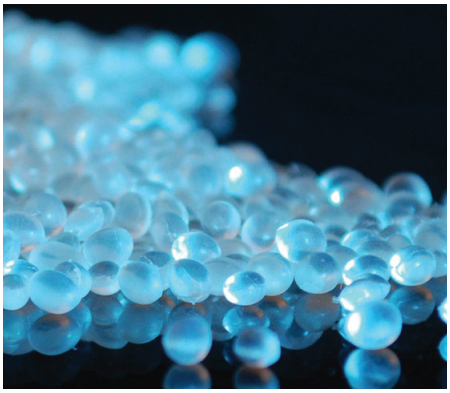
Description

ChronoFlex C is a family of biodurable aromatic polycarbonate-based thermoplastic urethanes designed to overcome surface degradation such as stress-induced microfissures.

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 orthopedics 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.

These products are adaptable to most standard manufacturing processes and are available in hardnesses ranging from 75 Shore A to 75 Shore D.



CHRONOFLEX C IN PELLET FORM

The ASB Advantage

AdvanSource Biomaterials synthesizes and manufactures medical grade materials offering the ability to tailor physical and mechanical characteristics to support and enhance your end product design.

These mechanical characteristic's, critical to the design and development of medical devices, can incorporate a wide range of physical and chemical properties while maintaining core characteristics such as biodurability and biocompatibility. In most materials, specialized characteristics such as the addition of colorant agents or antimicrobial properties (where applicable) can be added to the polymer to provide a homogenous material and limit secondary processing steps.

In addition, radiopaque agents may also be incorporated into the formula to provide additional product enhancements and may contain up to 40%, by weight, of a radiopaque agent thus allowing varied-scale visibility options.

With an expanding range of secondary operations including custom solution development, prototype coating capabilities, and project management services, ASB's expert team of chemists, scientists, engineers and industry professionals assist in every stage of customers' projects, from concept initiation through full-scale manufacture.

An ASB product

BIODURABLE

AVAILABLE IN ANTIMICROBIAL FORM

TAILORED TO MEET MECHANICAL SPECIFICATIONS

RELIABLE PERFORMANCE IN LONG AND SHORT TERM IMPLANTABLE DEVICES

AVAILABLE IN RADIOPAQUE FORM

AVAILABLE IN SOLUTION FORM

LIMITED IN-VIVO SOFTENING

ESC RESISTANT

EXCELLENT CHEMICAL RESISTANCE

LOW MODULUS OF ELASTICITY

INHERENT MATERIAL STRENGTH

USP CLASS VI

BIOCOMPATIBLE

ANIMAL-FREE ORIGIN CERTIFIED

AdvanSource biomaterials

Creating Technology. Enabling Success.

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ChronoFlex C®

An ASB product

TYPICAL MECHANICAL CHARACTERISTIC RANGES

ChronoFlex C

			ASTM Standard
Durometer Range Available	75 Shore A – 75 Shore D		D2240
Water Absorption	1.00%		D570
Melt Flow	2 – 26 g/10 min | 205° C/3.26 kg		D1238
MECHANICAL PROPERTY RANGES (EXAMPLE RANGES SHOWN)*			
Durometer	80A	75D	
Ultimate Tensile Strength (psi)	5500 – 8000	4500 – 6500	D638
Tensile (psi)			
@ 50% elongation	500 – 700	4200 – 5000	D638
@ 100% elongation	800 – 1000	4500 – 5200	D638
@ 200% elongation	1900 – 2100	4900 – 5800	
@ 300% elongation	5200 – 6000		D638
Ultimate Elongation (%)	300 – 500	200 – 350	D638

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

BIOCOMPATIBILITY TESTING

	USP CLASS VI TESTED:	ISO TESTED:
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	
Pyrogenicity		Meets ISO 10993-11 guidelines
Hemolysis		Non – Hemolytic
Phthalate Free		Does not contain or come in contact with DEHP
Animal-Free Origin Certified		BSE/TSE free

Pre-Processing Recommendations:

ChronoFlex C 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 180ºF +/- 20ºF. We recommend a machine-mounted desiccant-type hopper dryer, capable of reaching and maintaining a dew point of -40ºF. If dry times are in excess of 8-10 hours, a hopper dryer temperature of 120-150ºF is usually sufficient to achieve optimal moisture content.

FDA Master Files

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

AdvanSource biomaterials