

ChronoFlex AL™



AVAILABLE IN HARDNESSES RANGING FROM

75 Shore A to 75 Shore D

Exceptionally strong, safe and dependable.

Description

ChronoFlex AL is a family of biodurable aliphatic 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 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.

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



CHRONOFLEX AL IN PELLETT 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 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, specialized characteristics such as the addition of radiopaque or colorant agents and antimicrobial properties can be added in the formulation such to provide a homogenous material and limit secondary processing steps.

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

An ASB product

EUROPEAN COUNCIL DECISION -
1999/534/EC -COMPLIANT

EXCELLENT SOLVENT
RESISTANCE

BIODURABLE

LIMITED IN-VIVO SOFTENING

INHERENT MATERIAL STRENGTH

BIOCOMPATIBLE

RELIABLE PERFORMANCE IN
LONG AND SHORT TERM
IMPLANTABLE DEVICES

LOW MODULUS OF ELASTICITY

ESC RESISTANT

AdvanSource
biomaterials

Creating Technology. Enabling Success.

TYPICAL MECHANICAL CHARACTERISTIC RANGES

ChronoFlex AL 78A-B20*

PHYSICAL PROPERTIES

CF AL-78A-B20*

		ASTM Standard (ASB)
Durometer Range Available	75 Shore A – 75 Shore D	
Specific Gravity	1.34	D792
Melt Flow	2 – 26 g/10 min 205° C/3.26 kg	D1238
MECHANICAL PROPERTIES		
	Loaded w/ 20% Barium	
Durometer	80A 75A 55D	
Ultimate Tensile Strength (psi)	3300-7300 4500-8200 7450-10250	D638
Tensile (psi)		D638
@ 100% elongation	500-800 480 – 700 2500-3400	D638
Ultimate Elongation (%)	515-660 250-400	

*Mechanical characteristics can be synthesized to provide end-product specific mechanical properties.

BIOLOGICAL TEST RESULTS

CF AL-78A-B20

MEM Elution	Pass – Meets ISO 10993-5 guidelines
AGAR Overlay	Pass – Meets ISO 10993-5 guidelines
Pyrogenicity	Pass – Meets ISO 10993-11 guidelines
Hemolysis	Non - Hemolytic
Acute Systemic Toxicity	Pass – Meets ISO 10993-11 guidelines
Intracutaneous Toxicity	Pass – Meets ISO 10993-10 guidelines

Biological Durability

This product does not contain or come in contact with DEHP (Di(2-ethylhexyl) phthalate).

Independent laboratory results have shown ChronoFlex AL to be non-cytotoxic and meets the requirements of the MEM Elution and AGAR Overlay Testing as defined by ISO 10993-5 guidelines.

The ChronoFlex AL product family is compliant in accordance with the European Council Decision 1999/534/EC.

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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