

CryoProtect™ Bio-Containers

Storage Solutions for Cryogenic Applications

- Designed for storage, intermediate steps, final fill, and transport in bioprocessing applications
- Used in closed-system processing steps
- Extractables & Leachables (E&L) data available via validation package
- REACH / RoHS compliant

Benefits

- DEHP-free materials
- IPA-compatible
- Compatible with DMSO up to 20%
- Containers tested and validated to -196°C
- Double-Tyvek® cleanroom-compatible packaging
- Industry-standard label pocket design offers ease of use and label traceability



CPB-250

Standard Applications

- Intermediate and final frozen product storage
- Working cell banks
- Biomanufacturing

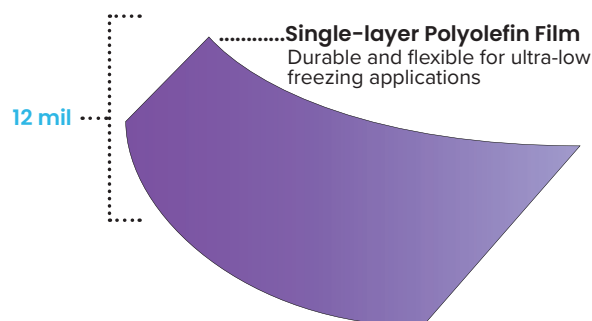
Custom Design Service

- Customize cryopreservation solutions from concept to prototype
- Compatible with Charter and industry-standard componentry

Ordering Information

Catalog #	Description	Case Qty
CPB-50	CryoProtect™ Bio-Container, 10-30 mL	40
CPB-250	CryoProtect™ Bio-Container, 30-70 mL	40
CPB-500	CryoProtect™ Bio-Container, 55-100 mL	40
CPB-750	CryoProtect™ Bio-Container, 80-190 mL	40

Freeze-Pak™ Film



Contact us today at www.chartermedical.com

Film Physical Test Data (pre-gamma irradiation)

Property	Test Protocol	Typical Value(s)
Tensile Strength at Break, MD/TD (psi)	ASTM D882	3,200/2,900
Elongation at Break, MD/TD (%)	ASTM D882	650/700
Modulus at 100% Elongation, MD/TD (psi)	ASTM D882	550/500
Tear Resistance, MD/TD (lbf/in.)	ASTM D1004	200/250
Low Temp. Brittleness (Masland) (°C)	ASTM D1790	Below -100
Glass Transition Temperature (T _g)	DSC	-48°C
Specific Gravity (g/cm ³)	ASTM D792	0.92
Particulates	USP <788>	Pass
Oxygen Transmission Rate (cm ³ /M ² /24 hrs @ 23°C, 0% RH)	ASTM D3985	2,200
Carbon Dioxide Transmission Rate (cm ³ /M ² /24 hrs @ 23°C, 0% RH)	ASTM F2476	9,000
Moisture Vapor Transmission (g/M ² /24 hrs @ 23°C)	ASTM F1249	3.9

Test performed on 0.014" film

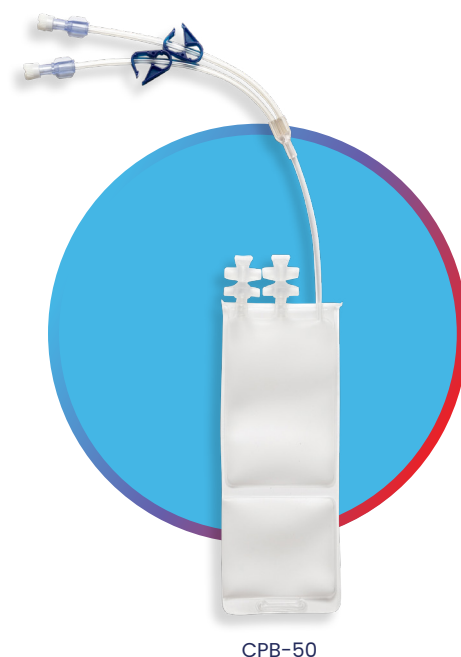
Final Container Biocompatibility Test Data (post-gamma irradiation)

Property	Test Protocol	Typical Value
USP Class VI	USP <88>	Pass
Cytotoxicity	USP <87> / ISO 10993-5	Pass
Hemolysis	ISO 10993-4	Pass

Drop Test Integrity

Test Description	Testing Criteria	Minimum Sample Size [1]	Testing Pass / Fail
Drop Testing (e.g., leaking)	Resistance to dropping post-thaw from a 1-meter height (ISO 15747:2018 Section 4.1.3)	29[1]	Pass

[1] Defines the sample size for each testing criterion. The sampling plan follows internal SOPs, ensuring a 95% confidence level and 90% reliability, as determined by the risk assessment plan.



CPB-50

Additional Cryogenic and Cold Transportation Studies

Test	Summary of Test	Purpose	Result	Customer Benefit
Long-term Cryogenic Study	Samples were frozen, stored at -192°C for 5 weeks, then tested for leaks and strength	Ensure reliable storage at -192°C with 20% DMSO	Pass	Proven to maintain strength and seal during extended cryogenic storage
Freeze-Thaw Cycling (3x)	Samples went through 3 freeze-thaw cycles, then tested for leaks, drops, and strength	Confirm durability after freezing and thawing	Pass	Reliable even after multiple freeze-thaw cycles, ideal for cryopreservation
Simulated Cold Transportation	Overfilled samples were transported under extreme cold and vibration, then tested	Ensure leak-proof transport under cryogenic conditions	Pass	Leak-proof during transport, supporting reliable cold chain logistics

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