

NxFlex™ F4000 Film

PRODUCT DESCRIPTION

NxFlex™ F4000 is a very strong, medical grade 8-layer composite film designed for bioprocess applications such as large 2-D Pillow Bags (50L and larger) and for 3-D BPC's. This film has been developed for clarity, high mechanical performance, puncture and tear resistance, and biocompatibility.

FILM CONSTRUCTION

The Inner solution contact layer is comprised of medical grade linear low density polyethylene (LLDPE) specially formulated to be non-leaching and chemically inert for the highest biocompatibility requirements. To this contact layer another layer of low density polyethylene (LDPE) is added.

To minimize gas diffusion, a layer of polyethylene vinyl alcohol copolymers (EVOH) is coextruded between two layers of medical grade polyethylene (PE) to provide excellent gas barrier properties.

An additional laminated layer of low density polyethylene (LDPE) is then added to the structure.

The Outer strength layer is formed from polyamide (Nylon) and is coextruded with polyethylene (PE) to create a bonding layer.

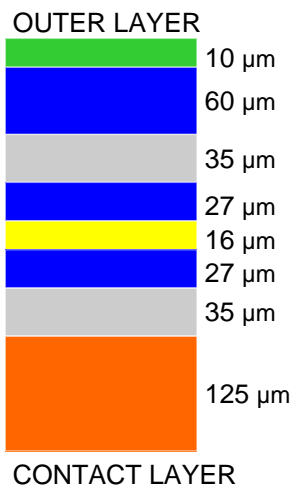
This 8-layer composite construction creates a clear and flexible film with very high mechanical strength, and good impact and tear resistance for large bioprocess containers.

VALIDATION

All NxFlex™ films undergo extensive physical and biocompatibility testing before release. We supply a Certificate of Conformance with each shipment to ensure adherence to specifications and for lot traceability.

ANIMAL DERIVED COMPONENT FREE

In the production of NxFlex™ films, no animal derived components or materials are used in the manufacturing process. The films are considered safe for use in food and bio-pharmaceutical applications.



Physical Data Characteristics		
PROPERTY	TEST PROTOCOL	AVERAGE VALUES
Film Gauge		335 µm
Tensile Strength (MD) (N/15mm)	ASTM D882	99.6 N/15mm
Tensile Strength (TD) (N/15mm)	ASTM D882	71.5 N/15mm
Ultimate Elongation (MD)(%)	ASTM D882	357%
Ultimate Elongation (TD)(%)	ASTM D882	444%
Oxygen Transmission Rate	ASTM D3985	3.46 cc/m ² /day/.01mpa
Moisture Vapor Transmission Rate	ASTM F1249	0.72 g/m ² /day
Solution Contact Material		LLDPE
Temperature Range		0°C to 60°C
Sterilizable Range		25kGy to 50kGy

Biocompatibility Data (Post Gamma Irradiation @ min. 25kGy)*		
PROPERTY	TEST PROTOCOL	AVERAGE VALUES
USP Class VI	USP 26 <88>	Pass
Cytotoxicity	USP 26 <87>	Pass
Non Volatile Residue	USP 26 <661>	<2 mg
Heavy Metals	USP 26 <661>	<1 ppm
Buffering Capacity	USP 26 <661>	<1 mL

* All biocompatibility testing performed by Toxikon Corporation, Bedford, MA.

