

NxFlex™ F2000 Film

PRODUCT DESCRIPTION

NxFlex™ F2000 is a clean medical grade laminated film designed for bioprocess applications especially cell culture bags on rocking platforms. This film has been developed for robust mechanical performance, puncture and tear resistance and excellent biocompatibility.

FILM CONSTRUCTION

The Inner solution contact layer is comprised of medical grade polyethylene (PE) specially formulated to be non-leaching and chemically inert for the highest biocompatibility requirements.

To minimize gas diffusion, a layer of polyethylene vinyl alcohol copolymers (EVOH) is sandwiched between the Inner and Outer layers to provide excellent gas barrier properties.

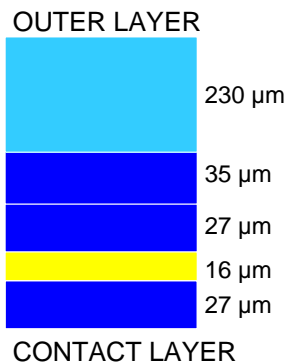
The Outer, non-contact layer is produced from an ethylene vinyl acetate/linear low density polyethylene (EVA/LLDPE) blend. This multi layer composite film is visually clear, flexible, and exhibits excellent puncture and tear resistance.

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	74.1 N/15mm
Tensile Strength (TD) (N/15mm)	ASTM D882	71.5 N/15mm
Ultimate Elongation (MD)(%)	ASTM D882	379%
Ultimate Elongation (TD)(%)	ASTM D882	484%
Oxygen Transmission Rate	ASTM D3985	0.5 cc/m ² /day
Solution Contact Material		PE
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.

