

NxFlex™ F1000 Film

PRODUCT DESCRIPTION

NxFlex™ F1000 is a clean medical grade multi-layer film designed for bioprocess applications such as 2-D hanging pillow bags for media storage and transport. The film has been developed for mechanical performance and biocompatibility.

FILM CONSTRUCTION

The Inner solution contact layer, is a custom formulated EVA/LLDPE copolymer designed with the purpose of minimizing extractables. An additional polyethylene (PE) layer is then added to this composite film.

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.

The Outer, non-contact layer is medical grade polyethylene (PE) created from the outer surface of the PE/EVOH coextrusion.

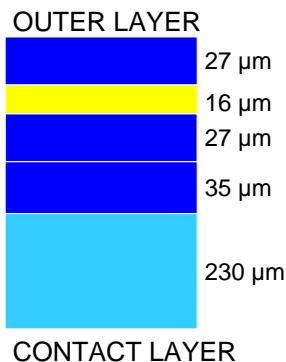
The combination of these specially selected film layers creates a visually clear and flexible multi-layer film that is also mechanically strong and puncture resistant.

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		EVA/LLDPE Blend
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.

