

# NxFlex™ F1000C1 Film

## PRODUCT DESCRIPTION

NxFlex F1000C1 is a medical grade multi-layer film specifically designed for high performance bioprocess applications, particularly cell culture bags on rocking platforms. This film is designated for use in high flexure applications that require exceptional toughness and maximum resistance to flex-cracking.

## FILM CONSTRUCTION

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

To minimize gas diffusion, a layer of polyethylene vinyl alcohol copolymers (EVOH) is coextruded between a PA (nylon) layer and a layer of medical grade polyethylene (PE) to provide enhanced gas barrier properties.

The Outer, non-contact strength layer is the polyamine (Nylon) surface that is coextruded with the EVOH and medical grade polyethylene (PE) layers.

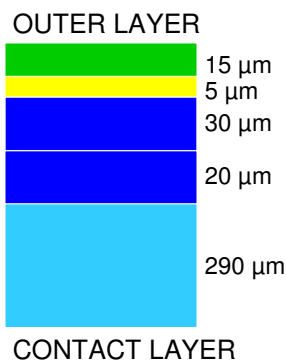
The combination of these specially selected film layers creates a visually clear and flexible multi-layer film that exhibits maximum flex-crack resistance.

## 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		360 µm
Tensile Strength (MD) (N/15mm)	ASTM D882	70 N/15mm
Tensile Strength (TD) (N/15mm)	ASTM D882	62 N/15mm
Ultimate Elongation (MD)(%)	ASTM D882	399%
Ultimate Elongation (TD)(%)	ASTM D882	484%
Oxygen Transmission Rate	ASTM D3985	2.17 cc/m <sup>2</sup> /day
Moisture Vapor Transmission Rate	ASTM F1249	2.32 g/m <sup>2</sup> /day
Solution Contact Material		EVA
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.



**RIM Bio, Inc.**

Single Use BioProcess Containers

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