

GE Healthcare

The many  
strengths of  
**one** *film*

**Fortem**<sup>™</sup>—a single-use platform  
film built for bioprocess



# The strength of *simplicity*

## One film for single-use bioprocessing.

Single-use technology has been transforming the modern biomanufacturing workflow. You can now find single-use bags at every stage of bioprocessing: bioreactor and mixing systems, harvest and collection, purification, and liquid and powder storage and transportation.

At GE, we're introducing one film for our entire portfolio of single-use systems. It's named Fortem after the Latin word for strong, and aptly so, since it is strong in many ways. It was born of customer collaboration, supplier partnership, and GE's bioprocessing expertise. It offers the simplicity of qualifying one film

across the full range of your single-use bioprocessing systems, saving you time, effort, and cost.

Unlike other platform films, Fortem is not a retrofitted solution. It has been designed from the ground up for bioprocess. To achieve this, we've partnered with Sealed Air Corporation, a manufacturer of primary films for pharmaceutical solutions. We've listened closely to your needs and applied our expertise and experience in **material science**, **application performance**, and **security of supply**, along with a deep commitment to **investment in the future**.

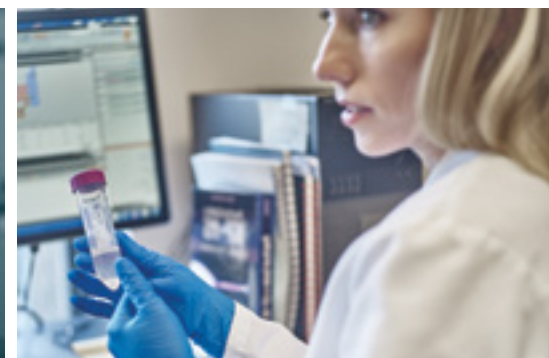
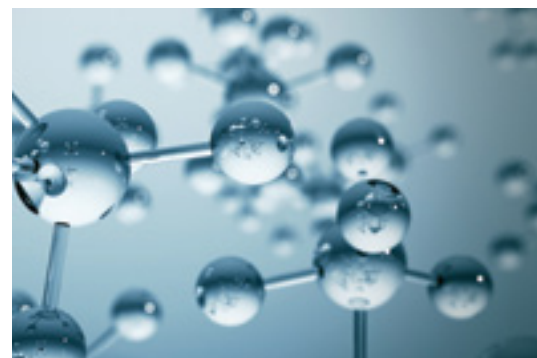


**one film**  
for your single-use bioprocess needs



# The strength of *knowledge*

MATERIAL SCIENCE



## There's nothing small about the slightest variation.

At GE, we've leveraged our partnership with Sealed Air to apply the full range of both companies' expertise in material science to defining and optimizing the critical quality attributes of a single-use platform bioprocess film.

Fortem is an exceptionally well characterized film, with specific analytical work done to identify and control degradative products. It has been developed in accordance with the latest industry guidance, in particular the BPOG extractables

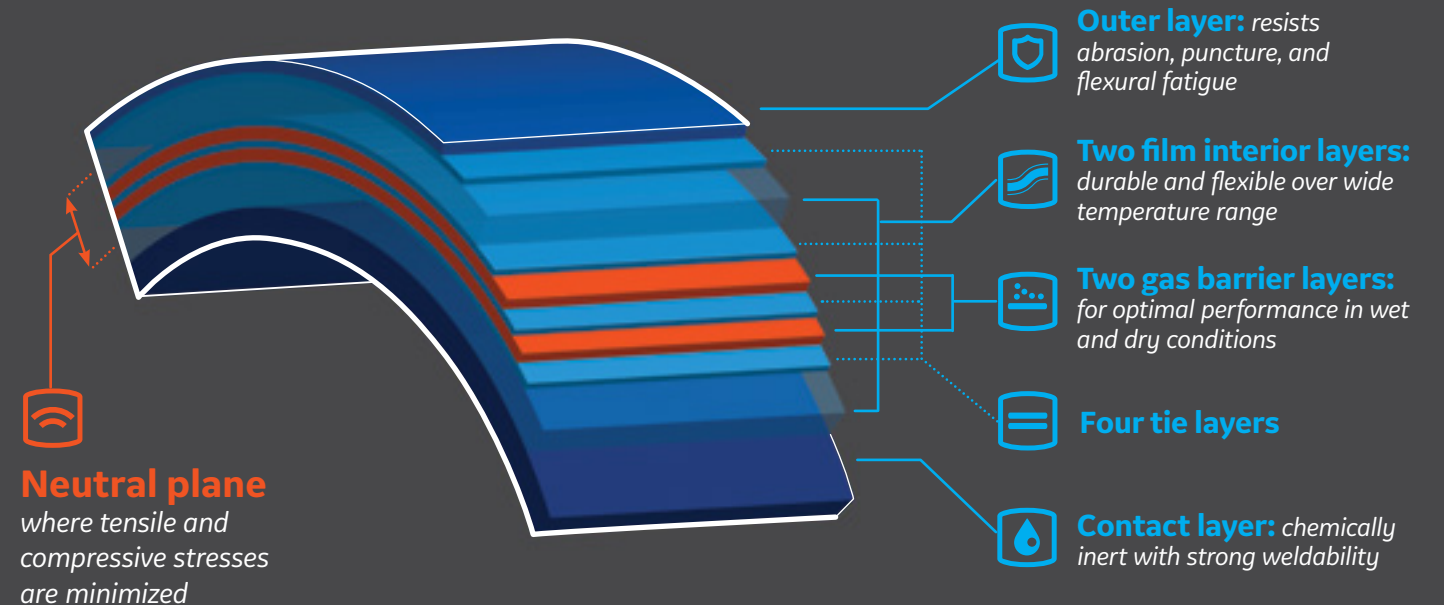
testing protocol. It has also been qualified extensively using new methodologies for film failure, including demanding tests for flexural fatigue, weldability, and abrasion resistance.

Fortem's architecture includes a polyamide outer layer that resists damage throughout the many rigors of bioprocessing conditions. It contains two internal gas barrier layers for maintaining pH stability during liquid storage and transportation, and provides

a controlled environment for cell culture applications. The contact layer is composed of an olefin resin blend with a low extractables profile and strong weldability characteristics.

The result is one film that is designed through bioprocess intelligence to deliver consistent performance from beginning to end.

## Ten-layer film architecture



Co-extruded film manufactured in Class 8 cleanroom. Supplied as double ply: contact layer exposed only to Class 5 air (Sealed Air Corp. film design patent).

# The strength of *flexibility*

APPLICATION PERFORMANCE



It stretches the entire length of your process train.

It's one thing to optimize a film for a single unit operation. It's quite another to optimize a film for your entire bioprocess workflow.

It requires a deep understanding of what happens to the film after it becomes a bag. In the case of Fortem, that bag comes in many shapes and sizes. If it's designed for a rocking system, like our WAVE Bioreactor™ bags, it must withstand repeated flexing. If it's designed for a stirred-tank system, like our

Xcellerex™ bioreactor and mixer bags, it must handle the prolonged agitation of large volumes of liquid. If it's a HyClone™ cell culture media and process liquids bag, it must sustain threats of puncture and abrasion during transport. And if it's a ReadyToProcess™ storage bag, it must provide long-term stability in a variety of conditions.

To design a single-use platform film that stretches across bioprocessing, the functional requirements of

every application must be balanced against one another, while weighing a host of considerations: choice of polymers, film thickness, flexural properties, degree of crystallinity, resistance to gas transmission, and many more.

Fortem addresses every one of these requirements, becoming the common denominator of a successful single-use bioprocessing platform.

## Application versatility

3D / stirred-tank bioreactor and mixer bags



2D / rocking bioreactor bags



variable sizes up to 2500 L



freeze / thaw / heat



cell culture / microbial



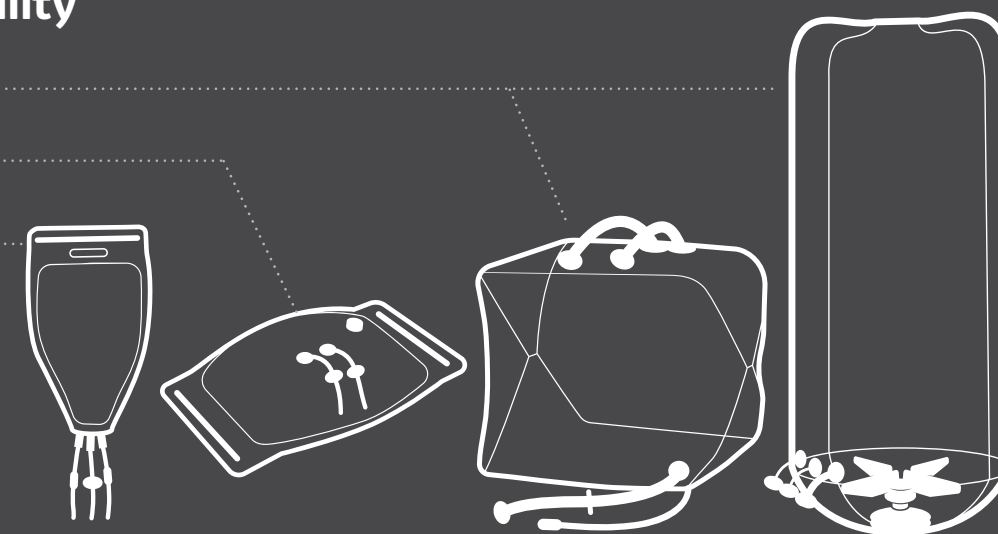
powder handling



bulk storage of liquids



liquid transportation



## Critical quality attributes

### Biocompatibility

No cell growth inhibition  
Regulatory compliance  
Low extractable profile

### Mechanical properties

Film strength  
Seal strength  
Film elongation  
Flex fatigue resistance  
Puncture / abrasion resistance

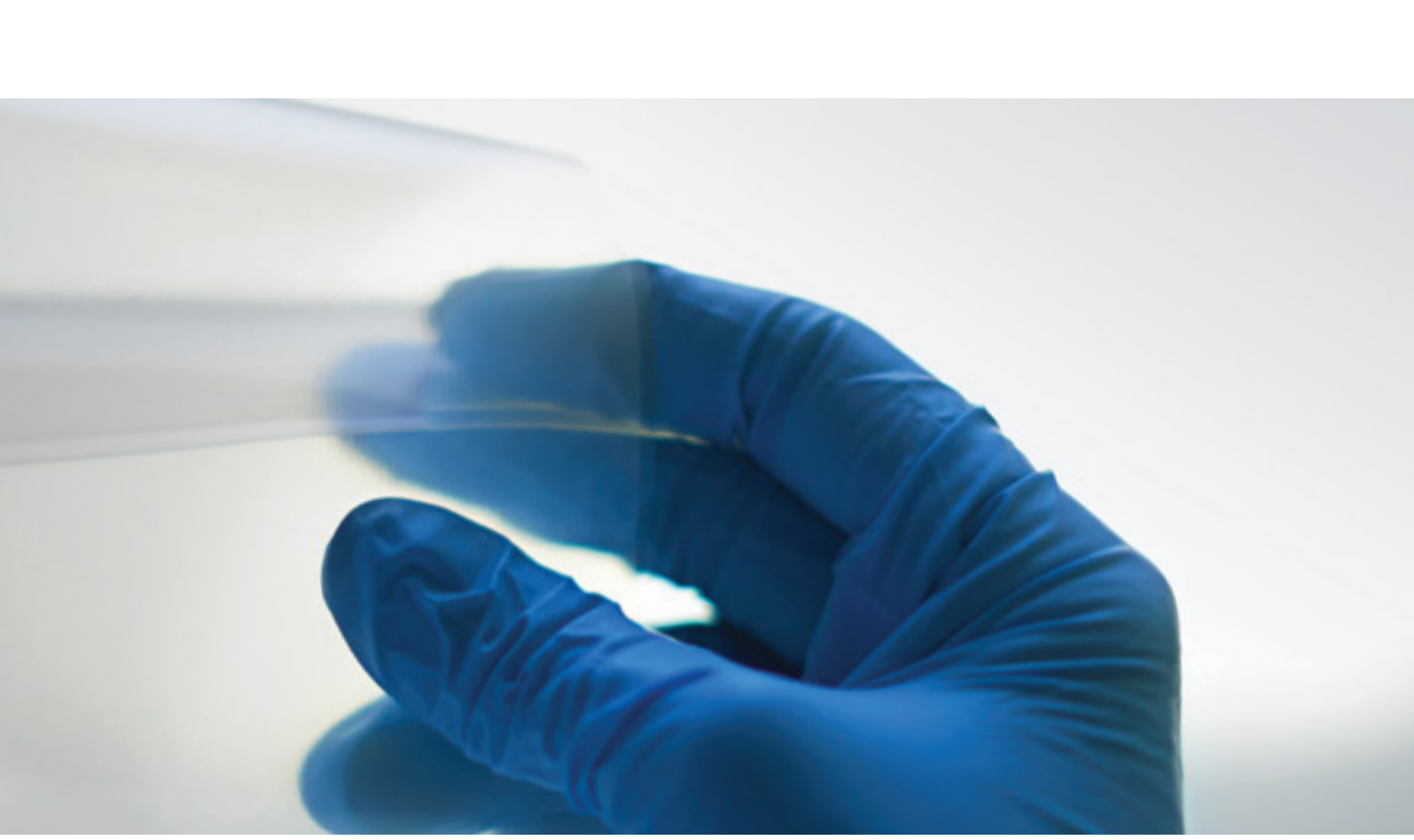
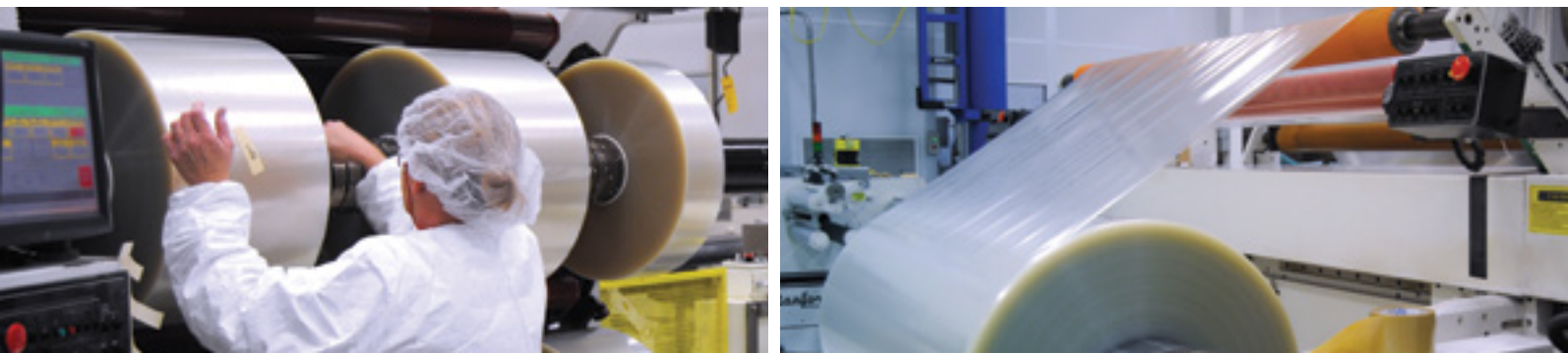
### Physical properties

Clarity / haze  
Heat stability  
Freeze / thaw stability  
O<sub>2</sub> and CO<sub>2</sub> barrier  
H<sub>2</sub>O barrier  
Gamma irradiation stability  
Suitable shelf-life  
Low chemical adsorption



# The strength of *transparency*

SECURITY OF SUPPLY



You can see deep into the supply chain behind it.

To ensure consistent performance, now and in the future, we've put in place an exceptionally robust security of supply framework for our new film.

We've outlined all of the film's critical quality attributes and process parameters, and we've implemented controls for transparency, quality, and business continuity around them. Central to it all is collaboration—between us, our partners at Sealed Air, and you, our customers.

We've established visibility throughout the supply chain, including change control programs that go back to the plastic resins and stabilizing agents. We're bringing that transparency to you, with an online portal that provides access to our database of change notifications, certificates of analysis, and validation guides.

Because quality is essential, we've implemented rigorous controls surrounding critical quality attributes and critical process

parameters by combining real-time monitoring and offline testing.

To protect you from unforeseen supply disruptions, we've developed a business continuity plan which is ISO22301 accredited. It includes robust site preventative and recovery plans, a ten-year strategic supply agreement, and strategic safety stocks in both raw materials and finished film.

Security of supply framework			
	Resins SUPPLY	Film PRODUCTION	Chamber MANUFACTURING
Supply	<p><b>Full risk assessment</b> including long term supply and quality agreements</p>	<p><b>ISO15378</b> <b>FDA 21CFR</b> aligned <b>Compliance</b> with USP, EP regulations, class 6</p>	<p><b>ISO 7 cleanroom</b> (ISO14644-1) <b>3x capacity expansion</b></p>
Quality	<p><b>Incoming inspection and analysis of all raw materials:</b> CQAs* include additives analysis, TBPP** analysis, melt flow, melt point, melt volume index, density, moisture content, relative viscosity</p>	<p><b>Real-time monitoring</b> of equipment parameters essential to the film extrusion process, including temperature, pressure, output rates, and CQAs, such as gauge monitoring and embedded gels</p>	<p><b>Incoming materials testing:</b> puncture, tensile, flex fatigue, seal strength, weldability, and abrasion <b>Finish assembly testing:</b> bag chamber leak, cell culture assay</p>
Continuity	<p><b>1-year</b> safety stock on materials <b>2-year</b> change notification</p>	<p><b>1-year</b> safety stock on finished film <b>Redundant</b> manufacturing line <b>Backup site</b> options</p>	<p><b>ISO22301</b> business continuity certificate</p>
Transparency	<p><b>Supply chain mapping</b> of resin suppliers <b>Disclosure of raw materials</b> down to CAS*** number</p>	<p><b>Batch traceability</b> under ISO15378, samples maintained for 8 years</p>	<p><b>Online support portal:</b> access to change notifications, certificates, validation guides</p>

\* Critical quality attributes    \*\* Tris(2,4-di-tert-butylphenyl)phosphite    \*\*\* Chemical Abstracts Service



The strength of  
**commitment**

INVESTMENT IN THE FUTURE

**Our commitment extends beyond the horizon.**

Our goal isn't just to make a better single-use film. It's to make single-use a better technology. To that end, we're implementing a total global investment across multiple centers of excellence that enhances our capabilities in single-use science, technology, and security of supply.



**Dedicated E&L lab, Uppsala, Sweden:** We've invested \$5.5 million in a dedicated laboratory and a further \$1.7 million to license a comprehensive compound library, augmenting our ability to identify and analyze potential extractables and to control their impact on bioprocessing.



**New research programs, Niskayuna, NY, USA:** We've funded additional material science programs at our global research center to support highly detailed characterization of film polymers and to develop new methodologies in film failure analysis.



**Enhanced manufacturing, Westborough, MA, USA:** We've invested \$7 million to expand our in-house manufacturing capabilities and quality control of single-use bags.



To order a free evaluation kit visit:

***[gelifesciences.com/Fortem](http://gelifesciences.com/Fortem)***

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