

Fortem — a single-use platform film built for bioprocess

The many strengths of one film



The strength of simplicity

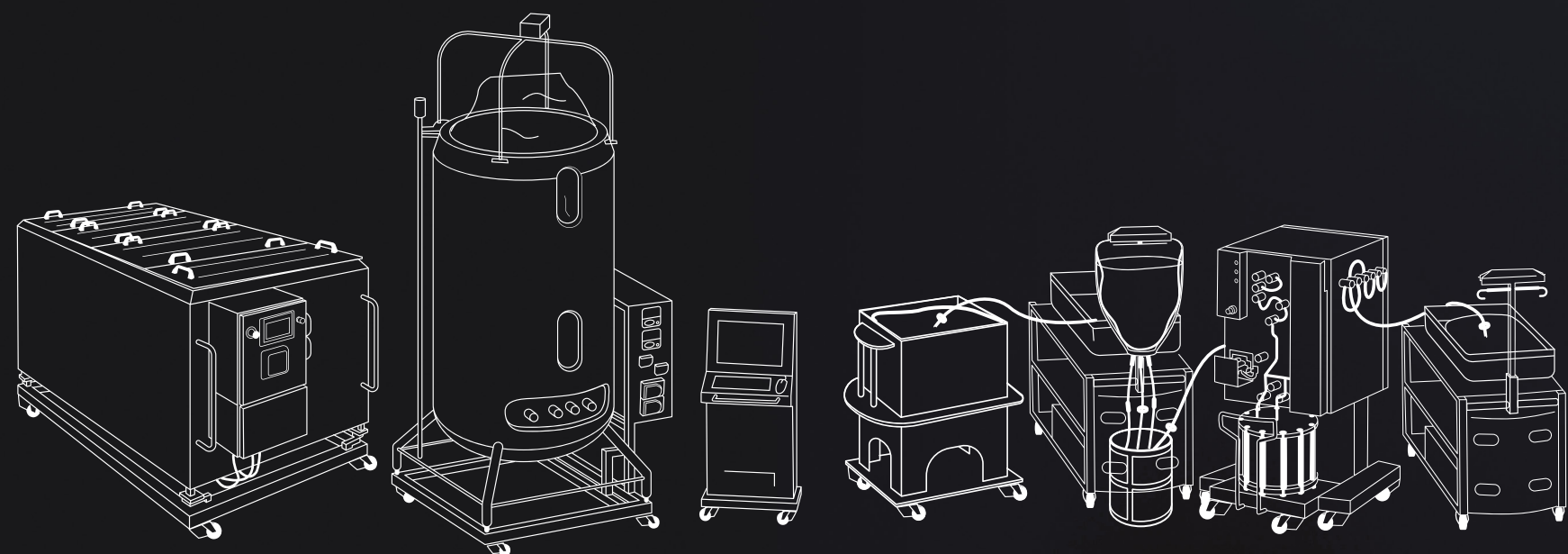
One film for single-use bioprocessing.

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 Cytiva, 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 Cytiva'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.



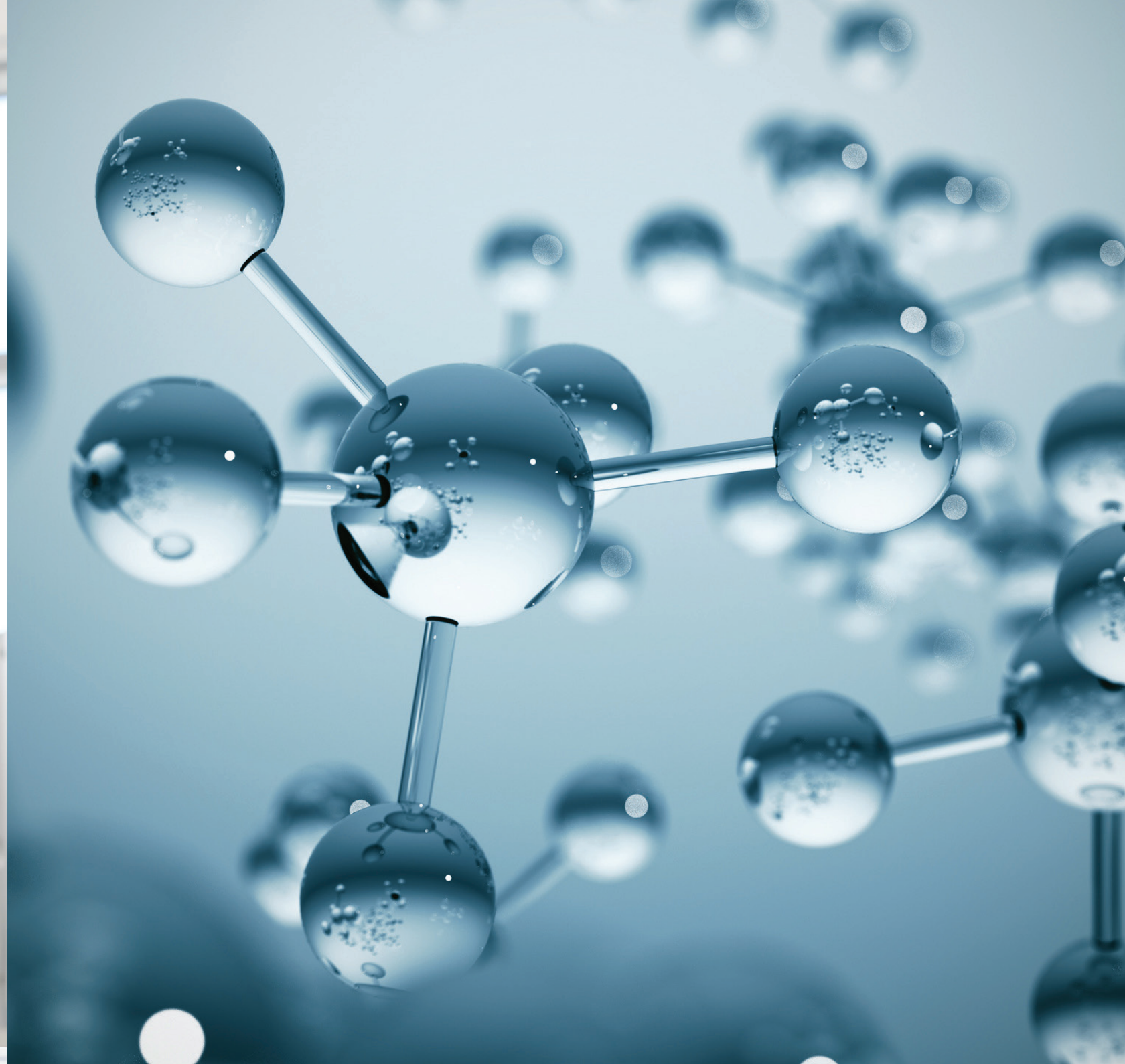
The strength of knowledge

Material science

There's nothing small about the slightest variation.

At Cytiva, 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.





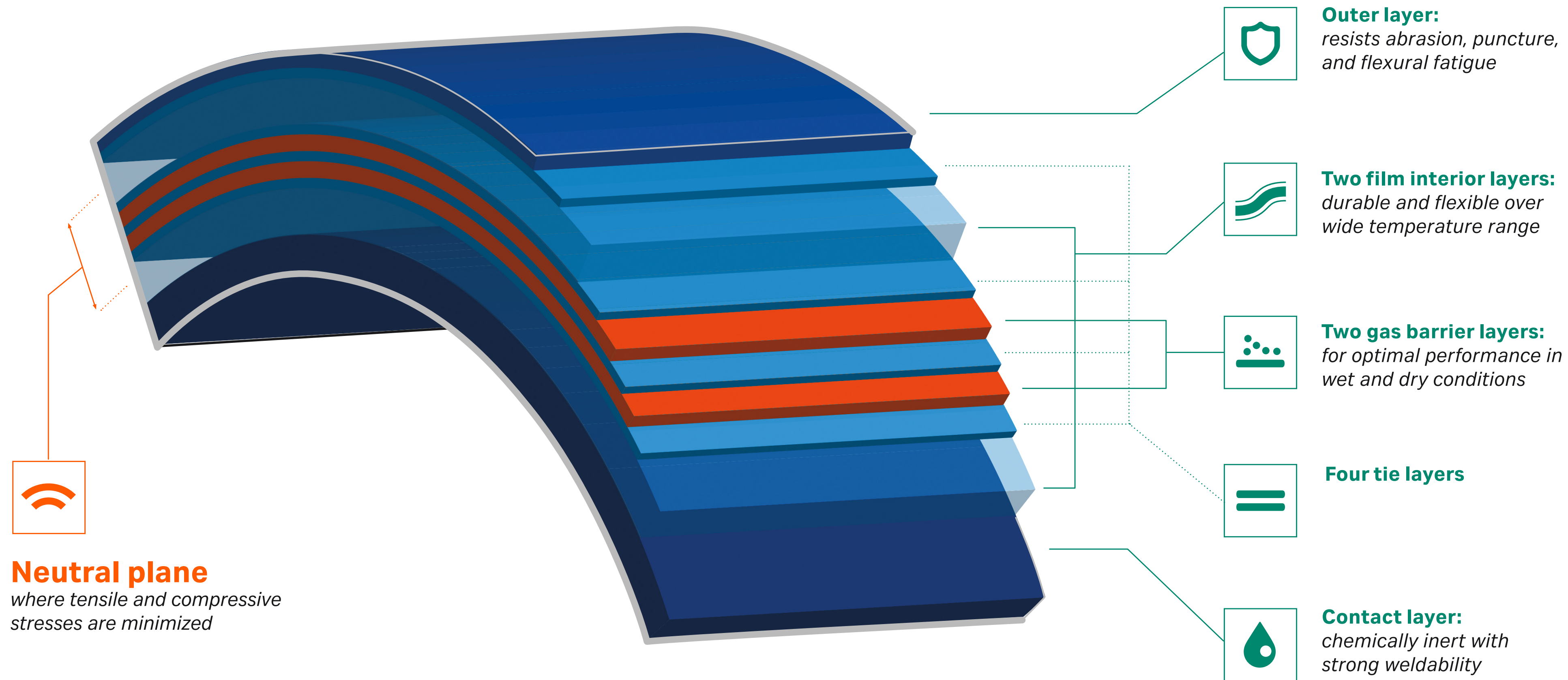
Fortem is an exceptionally well characterized film, with specific analytical work done to identify and control degradative products. It has been developed in accordance with the latest industry guidance, in particular the BPOG extractables testing protocol. It has also been qualified extensively using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



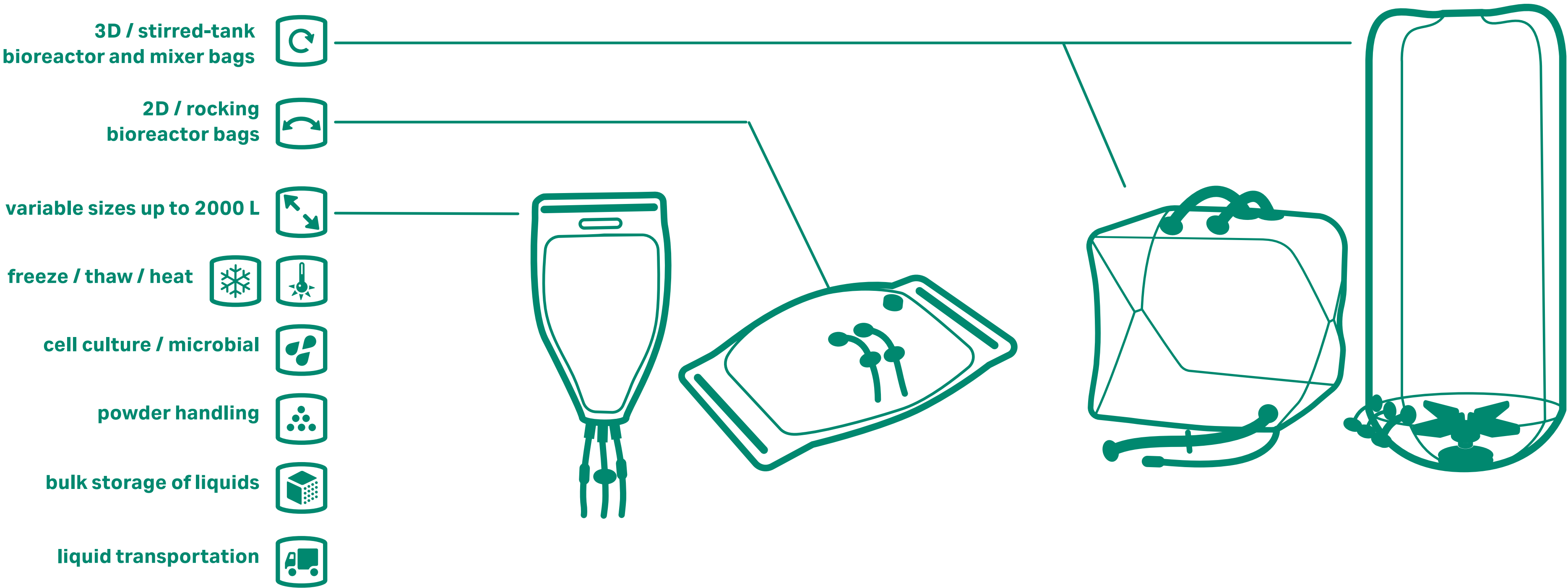
It requires a deep understanding of what happens to the film after it becomes a bag. In the case of Fortem, that bag comes in many shapes and sizes. If it's designed for a rocking system, like our WAVE Bioreactor™ bags, it must withstand repeated flexing. If it's designed for a stirred-tank system, like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



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
- O₂ and CO₂ barrier
- H₂O 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	Full risk assessment including long term supply and quality agreements	ISO15378 FDA 21CFR aligned Compliance with USP, EP regulations, class 6	ISO 7 cleanroom (ISO14644-1) 3× capacity expansion
Quality	Incoming inspection and analysis of all raw materials: CQAs* include additives analysis, TBPP† analysis, melt flow, melt point, melt volume index, density, moisture content, relative viscosity	Real-time monitoring of equipment parameters essential to the film extrusion process, including temperature, pressure, output rates, and CQAs, such as gauge monitoring and embedded gels	Incoming materials testing: puncture, tensile, flex fatigue, seal strength, weldability, and abrasion Finish assembly testing: bag chamber leak, cell culture assay
Continuity	1-year safety stock on materials 2-year change notification	1-year safety stock on finished film Redundant manufacturing line Backup site options	ISO22301 business continuity certificate
Transparency	Supply chain mapping of resin suppliers Disclosure of raw materials down to CAS‡ number	Batch traceability under ISO15378, samples maintained for 8 years	Online support portal: access to change notifications, certificates, validation guides

* 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.



To order a free evaluation kit visit: cytiva.com/Fortem



**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.



**Enhanced manufacturing,
Westborough, MA, USA:**

We've invested \$7 million to expand our in-house manufacturing capabilities and quality control of single-use bags.

cytiva.com/fortem

Cytiva and the Drop logo are trademarks of Global Life Sciences IP Holdco LLC or an affiliate. HyClone, WAVE Bioreactor, Xcellerex, and ReadyToProcess are trademarks of Global Life Sciences Solutions USA LLC or an affiliate doing business as Cytiva.

Fortem is a trademark of Sealed Air Corporation. All other third-party trademarks are the property of their respective owners.

© 2020 Cytiva

For local office contact information, visit cytiva.com/contact.

CY13189-17Nov20-BR

