



## Single-use BioProcess Containers

Standard and customized 2D and 3D  
fluid containment systems

# Single-use technologies

Whether you are looking for an economical catalog product or require a specific custom-designed and custom-built system, we offer proven solutions at every scale. With a wealth of experience, knowledge, and solid quality processes behind every Thermo Scientific™ product, we strive to assure you that your bioproduction process performs at its best.



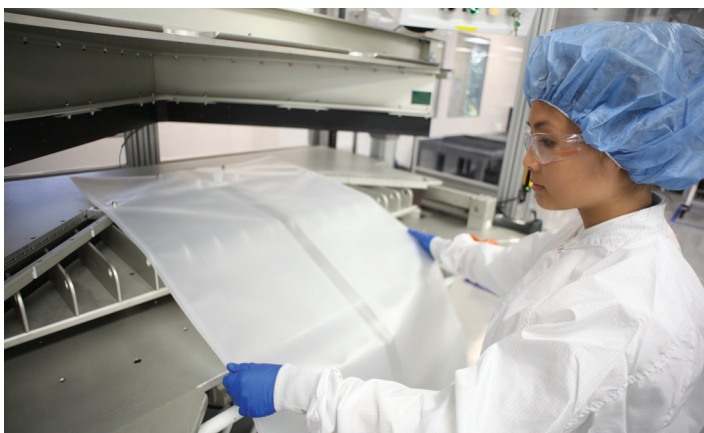
We take pride in offering one of the largest libraries and catalog components in the industry, allowing us to integrate connectors, tubing, and sensors to design a custom Thermo Scientific™ BioProcess Container (BPC) or a customized tubing assembly to fit your specific needs. Our services organization is here to assist you with drawings, implementation, and technical support to help ensure optimum production performance.

Our products and services are designed to enable proven performance through innovative and highly effective upstream or downstream applications. You can optimize production, improve process efficiency, add flexibility, and achieve fast-track product development and introduction to market by selecting product components and services from a single supplier.

## Quality control and assurance

To help ensure that BPC systems conform to the quality standards expected in the bioprocess industry, BPC systems are subject to rigorous quality control in compliance with current good manufacturing practices (cGMP) (21 CFR Part 820) and ISO 9001:2000 from the receipt of components to the release of final product.

Our production control processes help ensure complete lot traceability for each batch. The process control document becomes the stepwise manufacturing record that physically accompanies the lot through every step of the manufacturing process. At the end of the process, the production record is reviewed by the quality assurance team for completeness and correctness prior to the release of the lot and issuance of the certificate of analysis (CoA).



# What is a single-use BioProcess Container?

The heart of our single-use solutions is our BioProcess Containers (BPCs). BPCs are single-use, flexible container systems commonly used for critical liquid-handling applications in the biopharmaceutical industry.

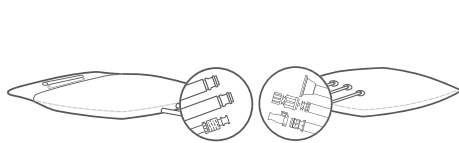
BPC systems are cost-effective alternatives to conventional stainless steel systems. They employ a novel design approach that is highly valued for its versatility and utility. BPC components are readily integrated into a variety of high-performance systems for all steps in the production of biologics.

## Key features

- All BPCs are produced in state-of-the-art cGMP facilities with common processes for manufacturing redundancy
- Production of chambers from 50 mL to 10,000 L capacity
- Automated lines for producing BPC chambers
- Strong engineering support to design and maintain products and processes
- BPCs are constructed of Thermo Scientific™ Aegis™ 5-14 film, a 5-layer film produced in a cGMP facility—the outer surface is a polyester copolymer with an EVOH barrier layer and a low-density polyethylene product contact layer

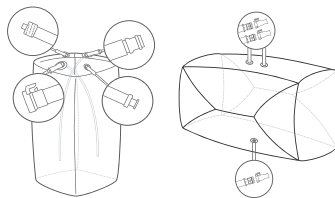
## Main types of BPC chambers

The 3 main types of BPCs are highlighted below, which are Thermo Scientific™ 2D Labtainer™ and 3D Productainer™ BPCs, and tank liners. Specialty BPCs are also available for specific applications and use in bioprocess equipment.



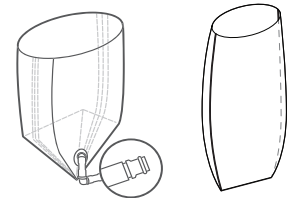
### 2D Labtainer BPC systems

This design is used for small, simple BPCs and is produced from two sheets of film that are heat-sealed around the perimeter to form a pillow-shaped chamber. The ports are heat-sealed into the end seal or onto one of the faces of the chamber.



### 3D Productainer BPC systems

This design is used for larger and more complicated BPCs. A square tube is formed by heat-sealing sheets of film together. Top- and bottom-porting options are available, and a greater range of size and complexity of chamber designs is possible.



### Tank liner BPC systems

This design is used with commercially available overhead mixers. Tank liners remove the need for tank cleaning and help reduce cycle times. Tank liners are optimized for use with Thermo Scientific™ drums and commonly used industry-standard cylindrical tanks.

## BPC manufacturing process

**Chamber manufacture**—the main components of a BPC chamber are the ports that enable tubing to be attached to the chamber. There are a number of different port designs depending on the type of chamber.

All BPC chambers and related components are produced in an ISO 7–certified cleanroom at our manufacturing facilities. Additional components are then attached to the BPC chamber to produce a complete BPC. BPC assembly is a manual process, which provides the required flexibility in BPC configuration. Thermo Scientific™ fluid transfer assemblies are also produced to complement BPC systems. Final assembly is done under the same controlled environment and to the same level of quality.

Each lot of BPCs is 100% visually inspected against product specifications, and packaged and sealed in two independent outer layers while still in the ISO 7–certified area. They are then placed in cardboard cartons labeled with product and lot identification.



## 2D Labtainer BPC systems

### Key features

- 2D Labtainer systems are 2-panel, pillow-style BPCs
- Labtainer BPC systems have 2–3 edge ports along one end with a handle on the opposing end
- 2-port Labtainer BPCs are available in sizes from 50 mL to 2,000 mL
- 3-port Labtainer BPCs are available in sizes from 2 to 50 L
- Line sets can be customized for easy integration with existing process operations and equipment
- Labtainers can be customized into multi-container manifold configurations
- Labtainers can be added as sample container adjuncts to 2D or 3D BPCs

### Applications

- Harvest from bioreactors or fermentors
- Feed into bioreactors or fermentors
- Sample collection from bioreactors or fermentors
- Buffer preparation and storage
- Culture media preparation and storage
- Process liquid preparation and storage
- Chromatography feed and fraction collection
- Harvest, storage, and transport of bulk drug product and bulk drug precursors



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# 3D Productainer BPC systems

## Key features

- Use this system to eliminate post-use cleaning steps required with reusable containers, and to reduce cross-contamination risks
- All 3D BPCs are constructed in an ISO 7–certified cleanroom under cGMP conditions
- All 3D BPCs are designed to fit the full range of support containers, both square and cylindrical, from 50 to 3,000 L

## Applications

- Hydration and filtration of process buffers, liquids, and culture media
- Chromatography feed and fraction collection
- Storage and transport of bulk drug product and bulk drug precursors
- Harvest from and feed into bioreactors and fermentors
- Dispensing, packaging, and storage of cell culture media, buffers, and process liquids

## Customize catalog BPC systems for optimized single-use technology

Choose from the industry's largest component library—with over 2,000 unique components that include:

- **Fittings**—straight, reducing, elbow, T-style, X-style, and cross-style
- **Connectors**—quick connectors and disconnectors, aseptic connectors and disconnectors, steam-to and steam-through connectors
- **Filters**—used for bioburden reduction; sterilization-grade filters and vent filters are available
- **Tubing**—thermoplastic elastomers, platinum-cured silicone
- **Sample ports**—septum-style and needle-free ports
- **Clamps**—sliders, pinch, and crimp bands



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## Tank liner BPC systems

### Key features

- Tank liners are designed for use with commercially available overhead mixers (not supplied)
- Removes the need for tank cleaning and helps reduce cycle times
- Chambers are constructed from Thermo Scientific™ TCX3-9 and ASI™ 26 films (and Aegis5-14 film for bottom-drain) with dimensions optimized for Thermo Scientific™ catalog drums and commonly used industry-standard cylindrical tanks
- Top entry for catalog products for maximum recovery using industry-standard cylindrical tanks in unit volumes of 50, 100, 200, 300, and 500 L
- Supplied gamma-irradiated to minimize bioburden

### Associated applications

- Hydration of powdered media and buffers
- Pooling of nonsterile solutions and fluids





# Powdertainer BPC system

Thermo Scientific™ Powdertainer™ BPCs are specifically designed for powder containment and discharge applications, and maintain a closed system for maximum recovery of powder while minimizing the risk of cross-contamination.

## Key features

- Designed for powder containment and powder hydration applications
- Employ a closed system to help minimize dust contaminant and cross-contamination risk
- Three-inch tri-clamp port designed for secure connection to, and easy integration with, hydration vessels
- Suspensor handle for support during discharge and neck clamp to retain powder prior to discharge
- Two models, including one with a washdown line to remove residual powder, enabling maximal recovery
- Three sizes for process flexibility: 1, 5, and 25 kg
- Constructed from CX3-9 film
- Stainless steel filling stand to facilitate the powder discharge process

## Applications

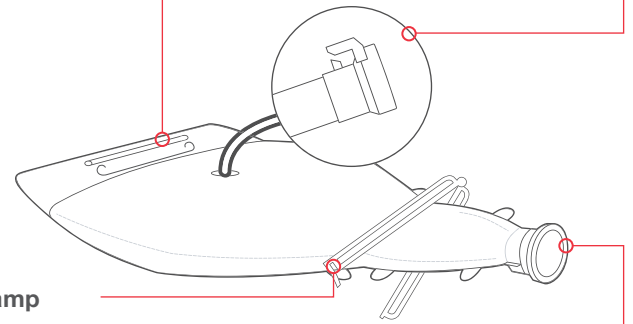
- Storage and delivery of Thermo Scientific™ powder culture media and buffers
- Storage and dispensing of preweighed chemicals or other process powders

### Handle

For support during emptying

### Tube with quick connector

For washdown to remove any powder residue



### Clamp

To retain powder prior to emptying

### Three-inch tri-clamp connector

For secure connection to formulation vessel



# Harvestainer Microcarrier Separation BPC system

The Thermo Scientific™ Harvestainer™ BPC system is a closed, single-use microcarrier separation system that helps to increase product yields compared to traditional methods, while reducing clean-in-place (CIP) and steam-in-place (SIP) requirements.

## Unique design features

The Harvestainer system enables separation of microcarrier beads and harvesting of the cell culture supernatant in a single-step, closed system.

The Harvestainer system is designed for both small- and large-scale applications. When 12 L or less of microcarrier beads are required to be separated, the 3 L or 12 L Harvestainer system is ideal. These systems are designed around our 2D pillow-style BPC in a preassembled tray, designed for secondary containment and optimal supernatant recovery.

The large-scale Harvestainer system features a dual-chamber system that comprises a 200 L 3D BPC with either one or two interior 25 L microbarrier 2D BPCs. These unique design features help enable the separation of cell culture supernatant from the microcarrier beads.



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# Three60 Single-Use Sampling System

The simple design behind the Thermo Scientific™ Three60™ Sampling System allows you to take a representative sample of your product with minimal effort. For a small-volume liquid transfer, use a CIP or SIP process to prepare your tank. The pre-irradiated BPCs and assemblies help ensure an integral fluid path while the quick-turn valve and pinch-and-cut disconnectors maintain liquid transfer and removal from BPCs.

The Three60 system is compatible with your vessel through a sanitary connector; no expensive hardware is needed. Each Three60 package contains a valve and four assemblies with pinch-and-cut disconnectors.

## Kit to tank

The Three60 system is pre-irradiated and assembled into a one-piece kit. Simply remove the device from the kit and apply to the vessel.

- **Quick-turn Three60 valve**—the face of the Three60 valve can be sterilized with the tank through traditional CIP/SIP processes. The valve has four assemblies. This helps keep the product and technician contamination-free.



- **Pinch-and-cut disconnectors**—the pinch-and-cut disconnectors allow the technician to quickly separate the sample and eliminate the need for tools or tube sealing.
- **Injection ports**—Luer lock injection site; extract through either the septum or twist-off Luer lock to pour.
- **Pre-irradiated BPC assemblies**—the Three60 system is provided with pre-irradiated BPC assemblies in sizes ranging from 50 mL to 2 L produced using the ASI 77 film.



# Services and support

Thermo Scientific™ Bioproduction services involve both field- and office-based teams. The office-based team is located in Logan, Utah, and includes technical support, BioProduction Xpress (BPX), quality, and services management teams. On a global scale, there are field application specialists (FASs) who are trained on hardware installation and servicing, and also offer other post-sales support such as training, consulting, and process optimization assistance.

## Key services

### • Field support

- Hardware installation—factory acceptance test (FAT) and site acceptance test (SAT)
- Training—single-use bioreactors, mixers, fermentors, outer support containers, and BPCs
- Validation service—installation qualification (IQ), operation qualification (OQ), and performance qualification (PQ)
- Warranty
- Service contracts

### • Technical support

- Phone support for sales, service, technical questions, and troubleshooting
- Interfaces with quality, product management, and R&D teams

### • BioProduction Xpress

- A full range of custom products and sizes on orders up to 4 units
- 2–5 week turnaround on most requests
- Full access to our standard component library
- Can also incorporate customer-supplied components to create final product
- Quickly confirm product fit, form, and function for your process
- Keeps you on schedule and within budget
- We collect your design requirements
- We generate a drawing and bill of materials
- Choose from a variety of products to meet your needs: 2D Labtainer BPCs, 2D Labtainer Pro BPCs, 2D Powdertainer BPCs, Harvestainer BPCs, 3D Productainer BPCs, manifolds, and tubing assemblies



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