

# BioProcess Containers

## What is a single-use BPC?

Thermo Scientific™ BioProcess Containers (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. BPCs are readily integrated into a variety of high-performance systems for all steps in the production of biologics. The three main types of BPCs are the Thermo Scientific™ 2D Labtainer™ BPC, 3D Productainer™ BPC, and tank liner BPC. Specialty BPCs are also available for specific applications and use in bioprocess equipment.

## Key features

- All BPCs are produced in state-of-the-art facilities with current good manufacturing practices (cGMPs) and 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

## BPC manufacturing process

- **Chamber manufacturing**—the main components of a BPC chamber are plastic film and ports that enable tubing to be attached to the chamber. There are a number of different port designs available depending on the type of chamber.
- **Final assembly**—additional components are attached to the BPC chamber to produce a complete BPC. This is done to either a standard or custom specification in an ISO 7 clean room in one of our four manufacturing facilities. 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.

- **Final inspection and packaging**—each lot of BPCs is 100% visually inspected against product specifications, and packaged and sealed in two independent outer dust cover polyethylene bags while still in the ISO 7–certified area. They are then placed in cardboard cartons labeled with product and lot identification.
- **Sterility assurance level**—BPCs are gamma irradiated in their outer packaging by external local contractors in the US and Europe at a dose of 25–40 kGy for BPCs produced in Logan, UT and Cramlington, UK and at a dose of 27.5–45 kGy for BPCs produced in Millersburg, PA and Matamoros, Mexico.

## BPC application solutions for different applications

Support operations	Applications	BPC solution
Media or buffer preparation	<ul style="list-style-type: none"> <li>• Powder delivery</li> <li>• Hydration in open-top vessel</li> <li>• Hydration in closed system</li> </ul>	<ul style="list-style-type: none"> <li>• Thermo Scientific Powdertainer BPC systems</li> <li>• Tank liners with outer support containers</li> <li>• Thermo Scientific Mixtainer BPCs</li> <li>• Thermo Scientific HyPerforma and impULSE Single-Use Mixers (S.U.M.s)</li> </ul>
Filtration	<ul style="list-style-type: none"> <li>• Filtration of media and buffers</li> </ul>	<ul style="list-style-type: none"> <li>• BPC assembly or manifold/transfer assembly, including a filter option</li> </ul>
Mixing	<ul style="list-style-type: none"> <li>• Mixing of media or buffers, protein solutions after chromatography, preparations, and final drug formulations</li> </ul>	<ul style="list-style-type: none"> <li>• HyPerforma and impULSE S.U.M.s</li> </ul>
Harvest	<ul style="list-style-type: none"> <li>• Collection and storage of harvest from a bioreactor or fermentor</li> </ul>	<ul style="list-style-type: none"> <li>• Catalog top- and bottom-drain BPCs from 50 L to 2,000 L with outer support containers</li> <li>• Custom BPCs with and without transfer assemblies</li> <li>• 3 L and 12 L small-volume solutions for separating microcarrier beads from cell culture supernatant</li> </ul>
Bulk storage	<ul style="list-style-type: none"> <li>• Storage of media, buffers, and intermediates</li> </ul>	<ul style="list-style-type: none"> <li>• Catalog BPCs from 50 mL to 3,000 L and outer support containers (custom BPCs also available)</li> </ul>
Waste collection	<ul style="list-style-type: none"> <li>• Non-aseptic collection of waste liquid</li> </ul>	<ul style="list-style-type: none"> <li>• Tank liners, standard BPCs, or custom BPCs</li> </ul>
Sampling	<ul style="list-style-type: none"> <li>• Collection of sample volumes from bioreactors, mixers, and storage containers</li> </ul>	<ul style="list-style-type: none"> <li>• Catalog BPCs from 50 mL to 50 L</li> <li>• Custom manifolds and transfer assemblies</li> <li>• Thermo Scientific Three60 Sampling System</li> </ul>
Shipping	<ul style="list-style-type: none"> <li>• Shipping of bulk liquids, buffers, process liquids, and intermediates between facilities</li> <li>• Bulk solutions or suspensions requiring mixing after shipping</li> </ul>	<ul style="list-style-type: none"> <li>• Top- and bottom-drain BPCs up to 3,000 L with shipping configurations up to 1,000 L</li> <li>• Mixtainer BPCs available in 50 L, 100 L, and 200 L</li> <li>• Thermo Scientific impULSE MDS (mixing, docking, and shipping) System</li> </ul>
Separation	<ul style="list-style-type: none"> <li>• Feeding and receiving liquid from the separation system</li> </ul>	<ul style="list-style-type: none"> <li>• Catalog top- and bottom-drain BPCs from 50 L to 2,000 L with outer support containers</li> <li>• Custom BPCs with and without transfer assemblies</li> </ul>
Purification	<ul style="list-style-type: none"> <li>• Feeding buffers to the purification system</li> <li>• Fraction collection and storage</li> </ul>	<ul style="list-style-type: none"> <li>• Catalog top- and bottom-drain BPCs from 50 L to 2,000 L with outer support containers</li> <li>• Catalog Labtainer systems from 50 mL to 50 L</li> <li>• Custom BPCs with and without transfer assemblies or manifolds</li> </ul>
Filling	<ul style="list-style-type: none"> <li>• Bulk reservoir for filling systems</li> </ul>	<ul style="list-style-type: none"> <li>• Catalog top- and bottom-drain BPCs from 50 L to 3,000 L with outer support containers</li> <li>• Transfer assemblies to transfer liquid from reservoir to filling system</li> </ul>

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