

CTS OpTmizer SFM family now in 5 L and 10 L BPCs

Designed to be versatile as you scale your manufacturing workflow

Introduction

Gibco™ OpTmizer™ One Serum-Free Medium (SFM); Gibco™ CTS™ OpTmizer™ T Cell Expansion SFM, no phenol red; and Gibco™ CTS™ OpTmizer™ Pro SFM are now available in 5 L and 10 L volumes in Thermo Scientific™ BioProcess Containers (BPCs) manufactured using Thermo Scientific™ Aegis™ 5-14 film with C-Flex™ and polyvinyl chloride (PVC) lines. These larger sizes can enable easier scale-up to larger bioreactors. A BPC with PVC tubing can help limit the number of open steps performed under an isolator or biosafety cabinet while the supplement, in addition to glutamine and cytokines, is added to the base medium. The arrangement also can enable a higher level of control and better risk management for media preparation and safety stocks.

Key features and benefits

- BPCs have weldable lines
- Reduces the number of open steps with your process
- Easy integration with closed, automated cell therapy equipment
- Used for autologous and allogeneic T cell processes through all stages of development and manufacturing

Applications

Transitioning to closed systems in cell therapy manufacturing helps reduce the risks of contamination and human error, and can increase manufacturing efficiencies, boosting the likelihood of clinical and commercial manufacturing success. To help you scale your closed process while maintaining flexibility throughout your manufacturing workflow, the BPCs are designed to be versatile, with the option of aseptic integration into your workflow through sterile welding or Luer-lock connections, or via a universal medical plastic coupling (MPC) quick connect.

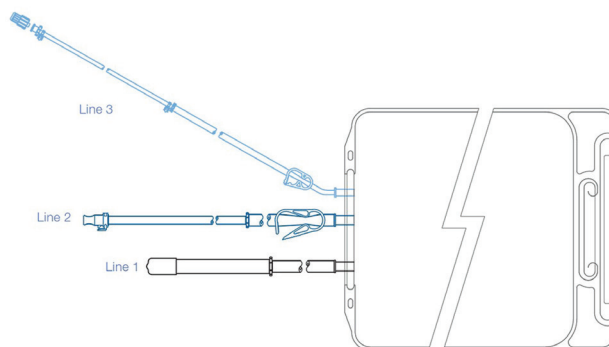


Figure 1. Lines of media BPCs. Lines 1 and 2: C-Flex tubings, and line 3: PVC tubing.

Design features

The BPC chamber is constructed from Aegis5-14 film, a five-layer, 14 mil cast film manufactured in a CGMP facility using no animal-derived components (Figures 1 and 2). The outer layer is a polyester elastomer coextruded with an ethyl vinyl alcohol (EVOH) barrier layer and a low-density polyethylene–product contact layer. This film has outstanding physical characteristics and low leachable and extractable profiles to support the purity, quality, and integrity of the product filled into the container.

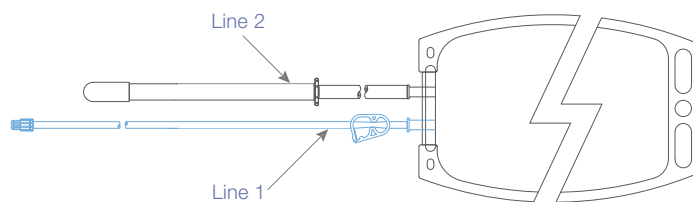


Figure 2. The basal medium supplement is available in 130 mL and 260 mL BPCs with two lines as pictured.

Table 1. Components of 5 L and 10 L BPCs that contain basal medium.

Parameter	Line 1	Line 2	Line 3	
Utility	Not intended for customer use—fill line used during product manufacture	Larger-diameter tubing to accommodate faster flow rate applications (e.g., media transfer)	Smaller-diameter tubing composed of two segments to give customer flexibility	
Connectors	Tubing is sealed	MPC quick connect	Septum port or female Luer-lock	
Tubing material	Ethyl vinyl acetate (EVA)	C-Flex line	Di(2-ethylhexyl) phthalate (DEHP)-free medical-grade PVC or C-Flex line	
Welding compatibility	Not intended for customer use	General sterile welding: 18 in. of C-Flex line	Sterile welding; Compatible with Gibco™ Xenon™, Rotea™, and DynaCollect™ consumables; 12 in. of PVC line	General sterile welding; 12 in. of C-Flex general sterile welding
Tubing dimensions	Not intended for customer use	1/4 in. inner diameter	3/32 in. inner diameter	1/8 in. inner diameter
		3/32 in. wall thickness	1/32 in. wall thickness	1/16 in. wall thickness

Table 2. Components of BPCs that contain basal medium supplements.

Parameter	Line 1	Line 2
Utility	Smaller-diameter tubing composed of two segments to give customer flexibility	Not intended for customer use—fill line used during product manufacture
Connectors	Septum port or female Luer-lock	Tubing is sealed
Tubing material	Medical-grade PVC, DEHP-free	EVA
Welding compatibility	Sterile welding; 24 in. of PVC	Not intended for customer use
Tubing dimensions	3/32 in. inner diameter	Not intended for customer use
	1/32 in. wall thickness	

These CTS OpTmizer formulations have the same trusted performance:

- Expansion of fresh or cryopreserved T cells
- Viability assessment of donor T cells
- Maintenance of CD4:CD8 ratio
- Maintenance of central memory T cell phenotype
- Detection of IFN- γ secretion by donor T cells

 Learn more at thermofisher.com/ctsmedia

