

3 L and 12 L Harvestainer BioProcess Container

Small-scale, self-contained single-use solution for harvesting and separating microcarrier cell culture

The Thermo Scientific™ Harvestainer™ BioProcess Container (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 and steam-in-place requirements and water for injection usage.

Using the Harvestainer BPC helps ensure full containment of the cell culture supernatant in a closed, single-use system for operator safety. Additionally, the sophisticated design of this BPC reduces holdup volumes to increase recovery efficiencies, giving more product with less effort. Simple post-use disposal reduces cleaning costs and process cycle times.

For smaller-scale applications, Thermo Fisher Scientific has developed the Harvestainer Microcarrier Separation System, an integrated microcarrier separation system designed for when 12 L or less of microcarrier beads require separation.

Key features and benefits

- In-line microcarrier separations
- Preassembled
- Scalability from 2D (3 L, 12 L) to 3D (25 L, 50 L) systems
- Secondary containment
- Operator safety with closed, single-use system
- High yield (cell recovery $\geq 85\%$)
- Reduces cycle time and the manual process of liquid decanting into separate microcarriers



Applications

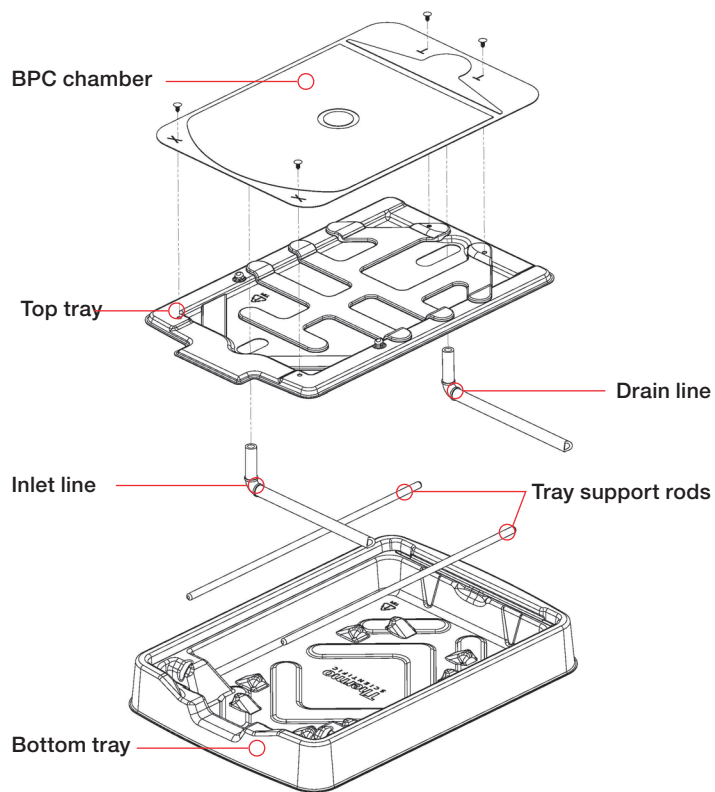
The Harvestainer system is designed to retain $\geq 90 \mu\text{m}$ microcarriers while allowing the supernatant to pass through to the next process stage. The Harvestainer system passes USP Class VI Biological Tests for Plastics.

Use the following calculation to determine the appropriately sized Harvestainer system: $\text{Number of grams of carriers} \times \text{swell factor of the carriers} = \text{total milliliters}/1,000 = \text{total liters}$

Design features

For small-scale applications, when 12 L or less of microcarrier beads require separation, the 3 L or 12 L Harvestainer system is ideal for in-line microcarrier separation. These systems consist of a preassembled 2D BPC and tray in a complete single-use unit, where the tray acts as the secondary containment device. The Harvestainer system consists of four parts:

- **Bioprocess Container (BPC)**—composed of three layers; the outer two layers are constructed of Thermo Scientific™ CX5-14 film with the inner layer constructed of the polyester mesh
- **Inlet and drain lines**—for easy system connection, these lines are made of weldable 3/8 x 5/8 in. C-Flex™ tubing with a 3/8 in. quick-connect body on the inlet line and a 3/8 in. quick-connect insert on the drain line
- **Support rods**—the Harvestainer system support rods are designed to angle the Harvestainer BPC for optimal drainage and improve recovery rates
- **Top support tray and bottom containment tray**—the support trays are made of polyethylene terephthalate (PETG) material. The top tray is designed to support the Harvestainer BPC while the bottom tray acts as a storage tray, bottom support, and secondary containment



12 L Harvestainer tray and BPC system

Table 1. 3 L and 12 L Harvestainer BPC specifications.

Description	3 L	12 L
Tray dimensions (H x W x D)	7.11 x 36.6 x 55.25 cm (2.8 x 15.2 x 21.75 in.)	7.59 x 57.09 x 81.28 cm (2.99 x 22.48 x 32.0 in.)
Chamber dimensions (H x W)	46.94 x 28.96 cm (18.5 x 11.4 in.)	70.36 x 50.04 cm (27.7 x 19.7 in.)
Chamber weight	0.11 kg (0.25 lbs)	0.25 kg (0.56 lbs)
Chamber surface area	2,303 cm ² (357 in ²)	5,909 cm ² (916 in ²)
Mesh surface area	1,000 cm ² (155 in ²)	2,710 cm ² (420 in ²)
Tray material thickness	0.18 cm (0.050 in.)	0.18 cm (0.050 in.)
Tray material type	PETG	
BPC inlet line	C-Flex tubing; ID x OD: 9.53 x 16.0 mm (3/8 x 5/8 in.) Polycarbonate quick connect 9.53 mm (3/8 in.) MPC body and MPC cap	
BPC drain line	C-Flex tubing; ID x OD: 9.53 x 16.0 mm (3/8 x 5/8 in.) Polycarbonate quick connect 9.53 mm (3/8 in.) MPC insert and MPC plug	

Physical and mechanical testing

This testing was designed to evaluate the Harvestainer product line that facilitates the separation of microcarriers and cells at the time of harvest. Testing was conducted to validate the functionality and performance of Harvestainer systems.

- Time and volume of filtration through mesh
- Mesh to retain microcarriers $\geq 90 \mu\text{m}$
- Cell yield in terms of percent recovery; specification to pass is a recovery of $\geq 85\%$
- Cell population viability before and after separation from beads; specification to pass is a viability loss of less than 3%
- Cell density and cell viability comparable in 2D and 3D systems
- Secondary containment
- Class VI testing data for all subcomponents

The validation report is available upon request.

Table 2. Physical and mechanical test results by BPC size.

Test	Results	
	3 L	12 L
Microcarrier bead retention	$\geq 90 \mu\text{m}$	$\geq 90 \mu\text{m}$
Flow rates	$\leq 2.5 \text{ L/min}$	$\leq 3.3 \text{ L/min}$
Shipping (ISTA 2A)	Pass	Pass
System integrity	Pass	Pass
Microcarrier bead capacity	3 L*	12 L*
Secondary containment	Yes	Yes
Cell yield	$\geq 85\%$	$\geq 85\%$
Cell viability	$> 97\%$	$> 97\%$
Sterility assurance level (25–40 kGy)	10^{-6}	10^{-6}
Maximum internal BPC pressure rating	0.5 psi	0.5 psi

* Use the following calculation to determine the appropriately sized Harvestainer system:
 Number of grams of carriers x swell factor of the carriers = total milliliters/1,000 = total liters

Ordering information

Product	Cat. No.
3 L Harvestainer system	SH31078.01
12 L Harvestainer system	SH31078.02

Find out more at thermofisher.com/harvestainer