

# Harvestainer BPC Microcarrier Separation Systems

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

Thermo Scientific™ Harvestainer™ BioProcess Containers (BPCs) are closed, single-use microcarrier separation systems that help increase product yields over traditional methods, while reducing clean-in-place and steam-in-place requirements and water-for-injection usage.

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

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

The Harvestainer BPCs are available with the Thermo Scientific™ BioTitan™ Retention Device. This universal tubing-retention solution was designed to provide the best method for retaining flexible tubing on a barbed fitting, and it helps eliminate the risk of leaks and failures at the tubing connection point.

## Applications

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



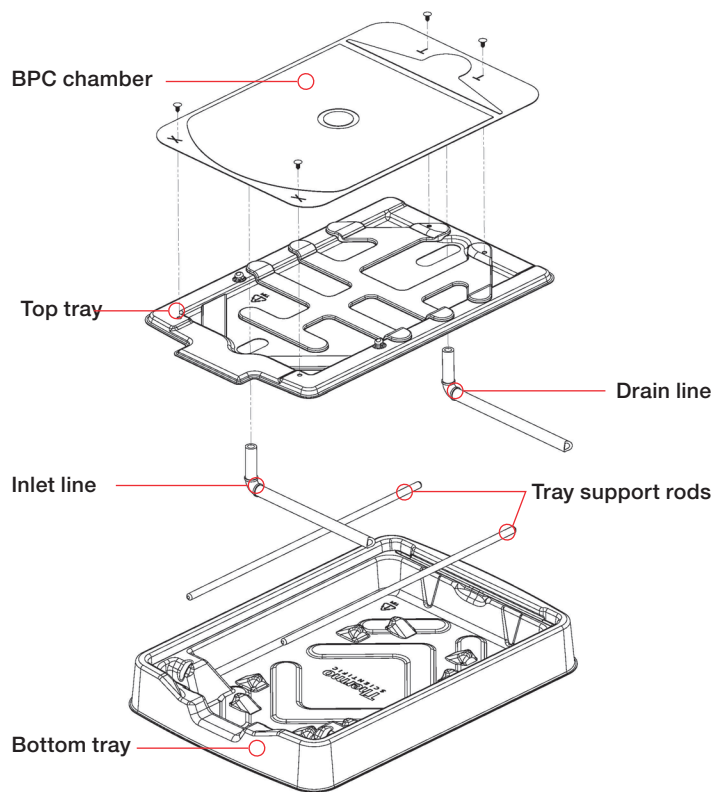
## Key features and benefits

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

## Design features

For small-scale applications, when <12 L of microcarrier beads require separation, the 3 L or 12 L Harvestainer system is ideal for in-line microcarrier separation. Each system consists 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 and the inner layer is constructed of 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 chamber for optimal drainage and improve recovery rates
- **Top support and bottom containment trays**—the support and containment trays are made of polyethylene terephthalate glycol (PETG) material. The top tray is designed to support the Harvestainer BPC chamber, while the bottom tray acts as a storage tray, bottom support, and secondary container



12 L Harvestainer tray and BPC system



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**Table 1. Harvestainer BPC specifications.**

Description	3 L	12 L
Tray dimensions (H x W x D)	7.11 x 36.61 x 55.25 cm (2.80 x 15.20 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 lb)	0.25 kg (0.56 lb)
Chamber surface area	2,303 cm <sup>2</sup> (357 in <sup>2</sup> )	5,909 cm <sup>2</sup> (916 in <sup>2</sup> )
Mesh surface area	1,000 cm <sup>2</sup> (155 in <sup>2</sup> )	2,710 cm <sup>2</sup> (420 in <sup>2</sup> )
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**

Testing was conducted to validate the functionality and performance of Harvestainer systems.

- Time and volume of filtration through mesh
- Ability of 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  $< 3\%$
- 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: Grams of carriers x swell factor of the carriers = total mL/1,000 = total L

**Ordering information**

Product	Cat. No.
3 L Harvestainer Microcarrier Separation System	SH31078.01
3 L Harvestainer Microcarrier Separation System with BioTitan Retention Device	SH31268.01
12 L Harvestainer Microcarrier Separation System	SH31078.02
12 L Harvestainer Microcarrier Separation System with BioTitan Retention Device	SH31268.02

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