

25 L and 50 L Harvestainer BioProcess Container

Large-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.

Key features and benefits

- In-line microcarrier separations
- 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

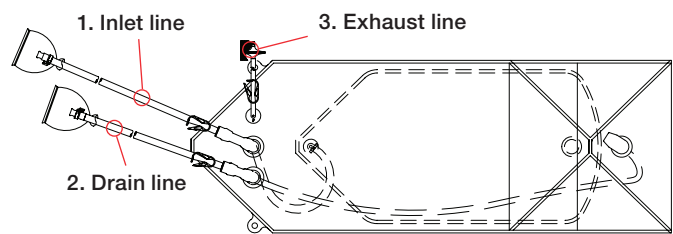
The Harvestainer system is designed to retain $\geq 90 \mu\text{m}$ microcarriers while allowing the supernatant to pass through to the next process stage. The Harvestainer system passes USP Class VI Biological Tests for Plastics.

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

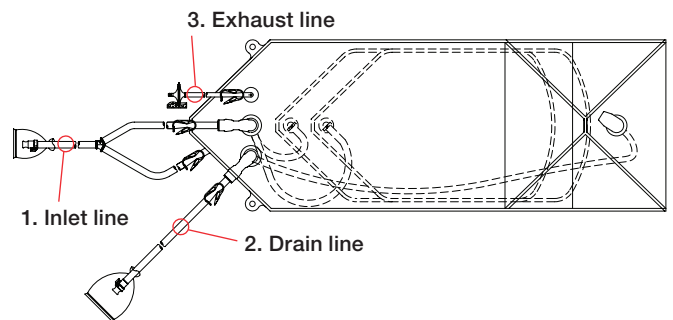
Design features

For large-scale applications, when greater than 12 L of microcarrier beads require separation, the 25 L or 50 L Harvestainer system is well-suited for in-process microcarrier separation workflows. This system consists of a 200 L 3D BPC with inner 25 L microbarrier 2D BPCs that fits into a conical bottom drum as the secondary containment device. The BPC features a dip tube design for better drainage and minimal manipulation.

- **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 polyester mesh
- **Microcarrier inlet line**—for easy system connection, the inlet line is made of weldable 1/2 x 5/8 in. C-Flex™ tubing with a 1/2 in. quick-connect insert on the inlet line
- **Drain line**—for easy system connection, the drain line is made of weldable 1/2 x 5/8 in. C-Flex tubing with a 1/2 in. quick-connect body; the dip tube drain line is connected to a dipwell and placed in a conical bottom drum to allow for optimal drainage and secondary containment with the top drain feature
- **Exhaust line**—exhaust line to be used for inflation of the Harvestainer BPC for setup and allow for air displacement during the separation process



25 L Harvestainer system (1 x 25 L microbarrier BPC)



50 L Harvestainer system (2 x 25 L microbarrier BPCs)

Table 1. 25 L and 50 L Harvestainer BPC specifications.

Description	25 L	50 L
Chamber dimensions (H x W x D)	137.16 x 48.26 x 48.26 cm (54 x 19 x 19 in.)	137.16 x 48.26 x 48.26 cm (54 x 19 x 19 in.)
Chamber weight	2.36 kg (5.2 lbs)	2.90 kg (6.4 lbs)
Chamber surface area	20,923 cm ² (3,243 in ²)	20,923 cm ² (3,243 in ²)
Mesh surface area	30,000 cm ² (465 in ²)	60,000 cm ² (930 in ²)
Line Descriptions	Lineset	End treatment
1 Inlet line	C-Flex tubing ID x OD: 12.7 x 16.0 mm (1/2 x 5/8 in.)	Polycarbonate quick connect 12.7 mm (1/2 in.) MPX insert Polycarbonate quick connect MPX cap
2 Drain line	C-Flex tubing ID x OD: 12.7 x 16.0 mm (1/2 x 5/8 in.)	Polycarbonate quick connect 12.7 mm (1/2 in.) MPX body Polycarbonate quick connect MPX plug
3 Exhaust line	C-Flex tubing ID x OD: 6.35 x 9.7 mm (1/4 x 3/8 in.)	Pall™ gas filter

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	
	25 L	50 L
Microcarrier bead retention	$\geq 90 \mu\text{m}$	$\geq 90 \mu\text{m}$
Flow rates	$\leq 6.7 \text{ L/min}$	$\leq 6.7 \text{ L/min}$
Shipping (ISTA 2A)	Pass	Pass
System integrity	Pass	Pass
Microcarrier bead capacity	25 L	50 L
Secondary containment	200 L	200 L
Cell yield	$\geq 85\%$	$\geq 85\%$
Cell viability	$> 97\%$	$> 97\%$
Sterility assurance level (25–40 kGy)	Pass	Pass
Maximum internal BPC pressure rating	0.5 psi	0.5 psi

Ordering information

Description	Cat. No.
25 L top-drain Harvestainer system with single 25 L microbarrier BPC	SH31071.01
50 L top-drain Harvestainer system with dual 25 L microbarrier BPCs	SH31071.02
Drum with offset conical insert	SV50517.07
Plastic drum dolly	SV50029.03

Find out more at thermofisher.com/harvestainer