DATA SHEET

Harvestainer BPC Microcarrier Separation Systems

Large-scale, self-contained, single-use solution for harvesting and separating microcarriers from cell culture media

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 the Harvestainer BPC helps ensure full containment of 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.

Key features and benefits

- In-line microcarrier separation from cell culture media
- Secondary containment
- User safety with closed, single-use system
- High yield (cell recovery ≥85%)
- Reduction of cycle time and the manual process of liquid decanting into separate microcarriers



Applications

The Harvestainer system is designed to retain ≥90 µm 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.



Design features

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

- 200 L 3D BioProcess Container (BPC)—composed of Thermo Scientific[™] CX5-14 film
- **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 dip well and placed in a conical bottom drum to allow for optimal drainage and secondary containment with the top drain feature
- Exhaust line—the exhaust line is used to inflate the Harvestainer BPC for setup and allow for air displacement during the separation process
- 25 L microbarrier 2-panel BPC—consists of one panel of CX5-14 film and an opposing panel of 51-micron, medical device—grade, polyester mesh

Table 1. Harvestainer BPC line specifications.

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 helps eliminate the risk of leaks and failures of the tubing connection point.



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



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

Line	Description	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.)	Hydrophobic vent filter



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Functional testing

These tests evaluated the Harvestainer system's microcarriers and cells at the time of harvest.

- Time and volume of filtration through mesh
- Ability of mesh to retain microcarriers of \ge 90 μ m
- Cell yield in terms of percent recovery; specification to pass is a recovery of ≥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. Functional test results by BPC size.

Test	Results	
	25 L	50 L
Microcarrier bead retention	≥90 µm	≥90 µm
Flow rates	≤6.7 L/min	≤6.7 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	≥85%	≥85%
Cell viability	>97%	>97%
Sterility assurance level (25–40 kGy)	Pass	Pass
Maximum internal BPC pressure rating	0.5 psi	0.5 psi

 * Use the following calculation to determine the appropriately sized Harvestainer system: Grams of carrier x swell factor of the carriers = total mL/1,000 = total L

Ordering information

Description	Cat. No.
25 L top-drain Harvestainer system with single 25 L microbarrier BPC	SH31071.01
25 L top-drain Harvestainer system with single 25 L microbarrier BPC with BioTitan Retention Device	SH31267.01
50 L top-drain Harvestainer system with dual 25 L microbarrier BPCs	SH31071.02
50 L top-drain Harvestainer system with dual 25 L microbarrier BPCs with BioTitan Retention Device	SH31267.02
Drum with offset conical insert	SV50517.07
Plastic drum dolly	SV50029.03

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