

3M Harvest RC Chromatographic Clarifier System

Single-stage chromatographic purification for recombinant protein therapeutic manufacturing

Thermo Fisher Scientific is an authorized distributor of the 3M™ Harvest RC Chromatographic Clarifier System. The system combined with the Thermo Scientific™ HyPerforma™ Single-Use Bioreactor options enables efficient, cost-effective harvesting for mammalian cell culture processes at any scale. The 3M Harvest RC system enables single-stage single-use chromatographic clarification. It is the next generation in harvest and clarification technology and is designed as an efficient option for harvesting and clarification of modern Chinese hamster ovary (CHO)-derived cell cultures.

Clarification using the 3M Harvest RC system provides many benefits including process compression, high product recovery, consistent clarified fluid quality, and process economics.

Benefits

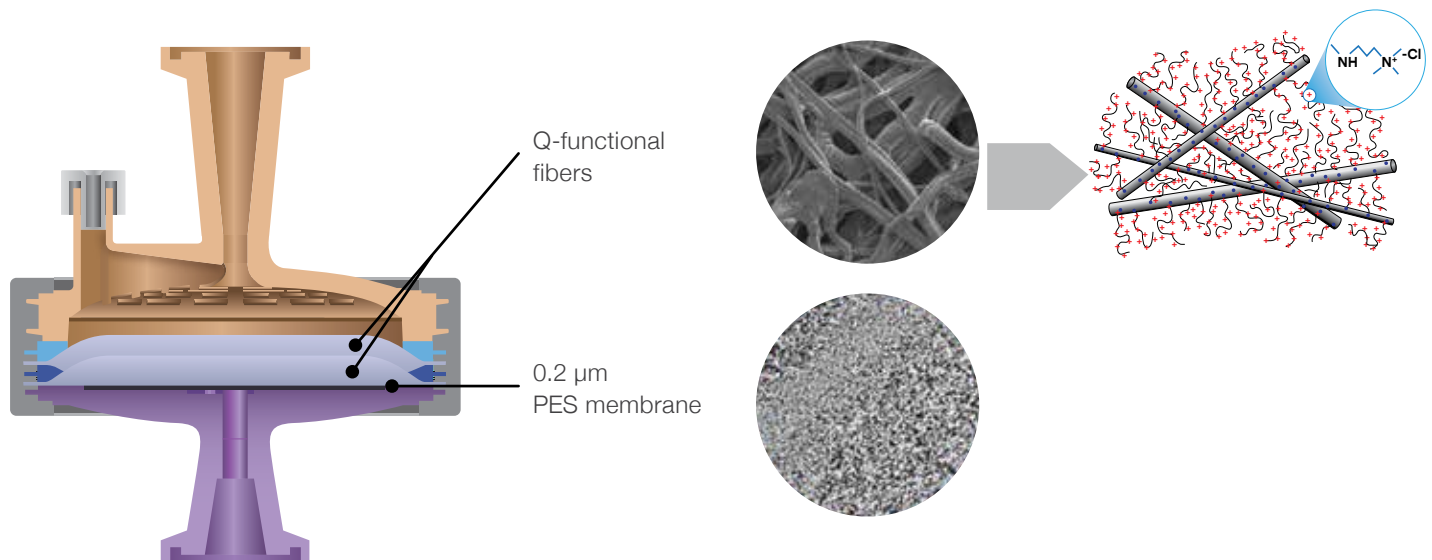
- Simplification of high-density cell culture fluid clarification unit operations
- Optimized for high packed cell volume (PCV) density CHO cell culture (5–8% PCV)
- Replacement of primary, secondary, and guard membrane clarification stages
- Typical product recovery of >95% (capsules)
- Synthetic chromatographic harvest media with chemically defined extractables
- Predictable scaling from discovery to manufacturing
- Lower total cost of manufacturing compared to centrifugation and depth filtration
- Lower consumption of buffer and water compared to depth filtration
- Capsules fit into a range of workflows, from laboratory to manufacturing scale
- Provides users of Thermo Scientific™ single-use equipment a seamless option to efficiently harvest cell culture
- Allows for a standardized harvest process at any scale

Single-step chromatographic clarification encapsulated solution

The innovative synthetic fibrous anion exchange (AEX) chromatographic clarification media enables a single-stage clarification process of low- to high-density CHO cell culture (>40 million cells per mL) with high product recovery and high fidelity of soluble and insoluble contaminant separation.

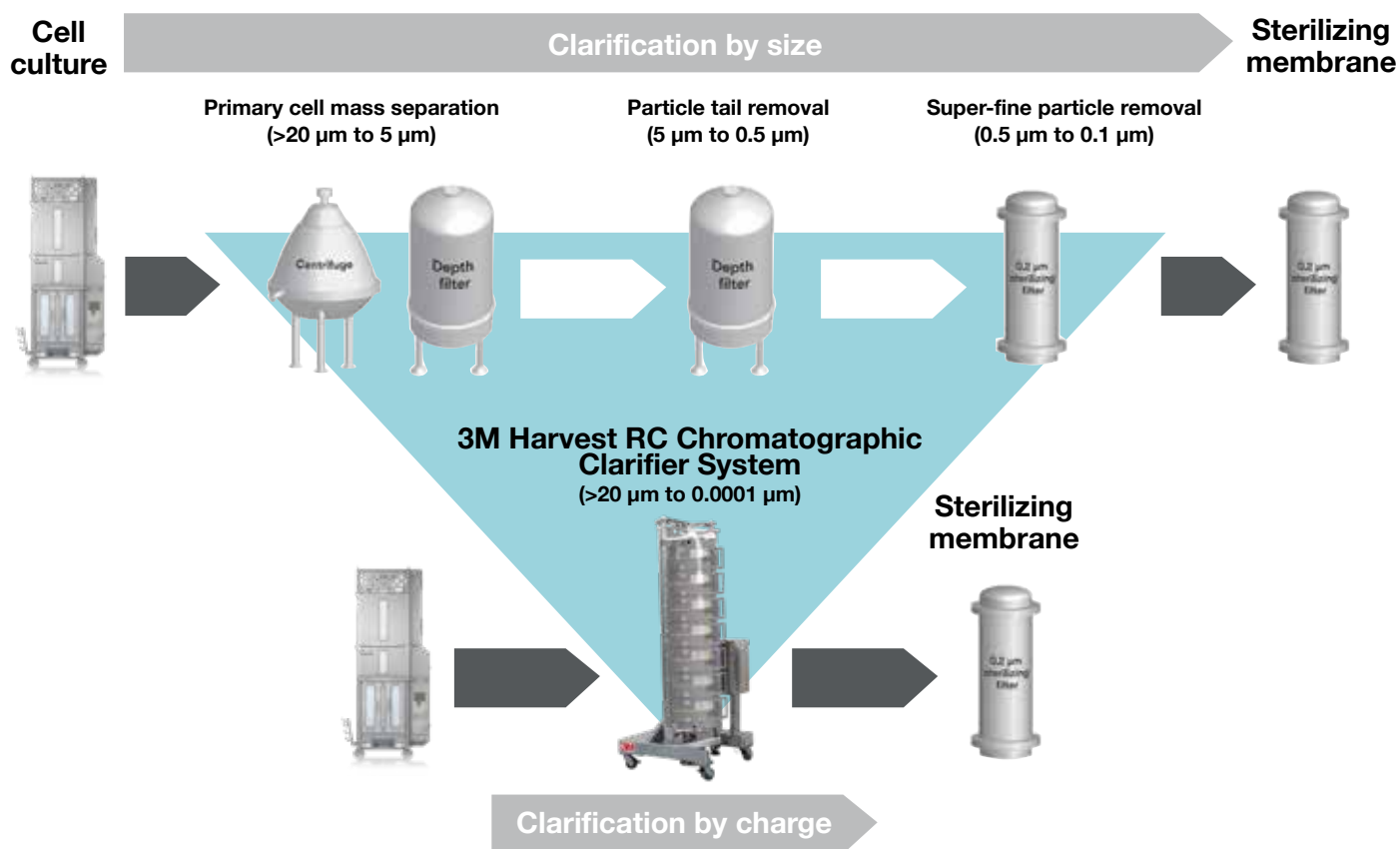
Downstream of the fibrous chromatographic clarification media is the 0.2 µm PES membrane that distributes the flow across the AEX media bed and enables protection of the downstream sterilizing-grade membrane filter. Also, the 0.2 µm PES membrane enables simple process endpoint measurement using pressure reading.

Expanding fibrous media platform



Simplify three stages into a single stage

The 3M Harvest RC system simplifies the harvest process by reducing three steps into one as compared to harvesting using centrifugation and depth filtration. This enables you to reduce time and risk.



Product specifications



Product name	BC4	BC25 Luer	BC25 Sanitary	BC340	BC1020	BC2300	BC16000
Cat. No.	SV30208.09	SV30208.10	SV30208.11	SV30208.12	SV30208.13	SV30208.14	SV30208.15
Dimensions (height x diameter)	5.9 x 4.3 cm (2.3 x 1.7 in.)	5.3 x 7.7 cm (2.1 x 3.0 in.)	8.6 x 7.7 cm (3.4 x 3.0 in.)	10.4 x 24.1 cm (4.1 x 9.5 in.)	15.2 x 24.1 cm (6.0 x 9.5 in.)	5.7 x 45.2 cm (2.2 x 17.8 in.)	20.3 x 45.2 cm (8.0 x 17.8 in.)
Dry weight	14.3 g	69.2 g	75.8 g	1.1 kg	1.6 kg	3.4 kg	9.8 kg
Media surface area	3.2 cm ²	3.2 cm ²	25 cm ²	340 cm ²	1,020 cm ²	2,300 cm ²	1.61 m ²
Cell culture volume range (5–8% PCV)*	20–32 mL	150–250 mL	150–250 mL	2–3.4 L	6–10 L	14–23 L	100–160 L
Weight wet post blow-down	17.2 g	81.2 g	88.1 g	1.2 kg	2.1 kg	4.4 kg	16.3 kg
Fill volume**	5.6 mL	27.6 mL	28.2 mL	0.66 L	1.7 L	3.3 L	16.3 L
Hold-up volume post blow-down†	3.0 mL	12.0 mL	12.3 mL	0.16 L	0.47 L	1.1 L	6.5 L
Capsule material	Polypropylene	Polypropylene, glass-filled polypropylene	Polypropylene, glass-filled polypropylene	Polysulfone, polypropylene, glass-filled polypropylene, thermoplastic elastomer, fluorocarbon	Polysulfone, polypropylene, glass-filled polypropylene, thermoplastic elastomer, fluorocarbon	Polycarbonate, polypropylene, glass-filled polypropylene, thermoplastic elastomer, silicone	Polycarbonate, polypropylene, glass-filled polypropylene, thermoplastic elastomer, silicone
Inlet/outlet connections	Luer lock	Luer lock	Sanitary	Sanitary	Sanitary	Sanitary	Sanitary
Maximum inlet pressure‡	3.4 bar	2.8 bar	2.8 bar	3.1 bar	3.1 bar	3.4 bar	3.4 bar
Maximum differential pressure	2.4 bar	2.4 bar	2.4 bar	2.4 bar	2.4 bar	2.4 bar	2.4 bar
Maximum temperature	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)
Required preconditioning flush volume††	8 mL	62.5 mL	62.5 mL	0.85 L	2.55 L	5.8 L	40.3 L
Recommended use flow rate	0.53 mL/min	4.2 mL/min	4.2 mL/min	57 mL/min	170 mL/min	0.38 L/min	2.68 L/min
Storage conditions	Controlled indoor temperatures: 0–30°C (32–86°F) in original sealed packaging						
Shelf life	Up to 2 years from the date of manufacture at 30°C						

* Cell culture volume range is the estimation for CHO cell culture fluid at 5–8% packed cell volume.

** Fill volume is defined as the volume of liquid that is required to fill the capsule.

† Post blow-down hold-up volume is defined as the volume of the residual liquid after air/gas blow-down.

‡ Do not use this product for continuous service with compressed gasses. The use of compressed gas is permissible for post-use integrity testing and blow-down purposes.

†† A preconditioning flush is required for the product to be compliant with USP Biological Reactivity Tests, including USP <87> and <88> Class VI. Refer to Installation and Operation Instructions for complete instructions on how to perform the preconditioning flush.

Product specifications, continued



Product name	WP6	CT15
Cat. No.	SV30208.07	SV30208.08
Dimensions (height x diameter)	12.8 x 8.5 x 8.8 cm (5.0 x 3.4 x 3.5 in.)	2.9 x 6.1 cm (1.2 x 2.4 in.)
Dry weight	Plate (with media): 100 g Collector plate: 110 g	10 g
Media surface area	3.2 cm**	3.2 cm**
Cell culture volume range (5–8% PCV)*	15 mL per well	15 mL
Fill volume**	15 mL per well	15 mL
Capsule material	Polycarbonate	Polycarbonate
Maximum temperature	40°C (104°F)	40°C (104°F)
Maximum relative centrifugal force	750 x g	750 x g
Recommended relative centrifugal force	400 x g	400 x g
Recommended spin time	10 min	10 min
Storage conditions	Controlled indoor temperatures: 0–30°C (32–86°F) in original sealed packaging	
Shelf life	Up to 2 years from the date of manufacture at 30°C	



Well plate



Conical tube

For more information, contact your Thermo Fisher Scientific Bioproduction Account Manager or visit us at thermofisher.com/3MHarvestRC



Authorized distributor
of 3M™ Harvest RC

 Learn more at thermofisher.com/3MHarvestRC

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Intended Use: 3M™ Harvest RC products are intended for use in biopharmaceutical processing applications of aqueous based pharmaceuticals (drugs) and vaccines in accordance with the product instructions and specifications, and cGMP requirements (for BC340, BC1020, BC2300 and BC16000) or GLP requirements (for CT15, WP6, BC4 and BC25), where applicable.

Since there are many factors that can affect a product's use, the customer and user remain responsible for determining whether the 3M product is suitable and appropriate for the user's specific application, including user conducting an appropriate risk assessment and evaluating the 3M product in user's application.

Product Selection and Use: Many factors beyond 3M's control and uniquely within user's knowledge and control can affect the use and performance of a 3M product in a particular application. As a result, customer is solely responsible for evaluating the product and determining whether it is appropriate and suitable for customer's application, including completing a risk assessment that considers the product leachable characteristics and its impact on drug safety, conducting a workplace hazard assessment and reviewing all applicable regulations and standards (e.g., OSHA, ANSI, etc.). Failure to properly evaluate, select, and use a 3M product and appropriate safety products, or to meet all applicable safety regulations, may result in injury, sickness, death, and/or harm to property.

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