Zeta PlusTM EXT Series Products Featuring Dual Zone ZB Filter Media

The media used in Zeta Plus™ EXT filter products *extends* depth filtration capacity and enhances the protection of downstream membranes thereby *extending* filter life. Zeta Plus EXT series is a family of advanced dual zone depth filters designed to provide optimal clarification of bioprocess, biological and pharmaceutical fluids. Zeta Plus EXT Series Products contain two distinct layers, or "zones," of filter media with the upstream zone more open than the downstream zone. This structure enhances the contaminant holding capacity of the filter media since larger particles are trapped in the upper zone of the filter media and smaller particles are trapped in the lower zone. This media structure helps reduce premature plugging and extends service life. The two filter zones can be independently selected and combined to optimize performance.

- Increased throughput with high turbidimetric efficiency
- Lower processing costs
- Smaller filter assemblies
- Consolidation of multiple filter stages
- Enhanced protection of downstream membrane filters

Applications

Zeta Plus EXT Series Filters with ZB Media are optimized for clarification of mammalian cell harvest fluids and for protection of downstream sterilizing grade membrane filters. Their strong positive charge provides enhanced reduction of negatively charged contaminants compared to a mechanical filtration mechanism alone. In solution cells, cellular debris, endotoxins, and nucleic acids (DNA, RNA) carry a negative charge. 3M's application of positive zeta potential to ZB filter media creates a filter matrix that enhances the capture of negatively charged contaminants for maximum filtration performance. The strong positive charge over a broad pH range makes these filters ideal for cell broth clarification and for protection of downstream membrane filters.

Regulatory Support

Zeta PlusTM EXT Series products with ZB Media are supported with a Regulatory Support File (3M literature 70-0203-0883-2) and Certificate of Quality to ease validation and regulatory submissions. The products are also documented in a Drug Master File (DMF) on record with the US Food and Drug Administration (FDA).



Applications

Clarification of mammalian cell culture process fluids (cell separation)

Protection of downstream processes including membrane filters and chromatography columns

Clarification of bacteria and yeast cell lysates

Endotoxin and nucleic acid reduction

Clarification of colloidal and haze forming contaminants



Zeta Plus[™] BC25 Capsule filters are ideal for laboratory evaluation and media selection



Cartridge Construction

Individual cells of Zeta Plus EXT Series with ZB Media are assembled together with polypropylene separators under predetermined compression and unitized by three, 316 stainless steel bands.* Each cell is constructed using thermoplastic elastomer or polypropylene molded edge seals and polypropylene separators for high performance. The standard gasket is composed of silicone, with other gasket materials available upon request. Filter cartridges are available in 8", 12", and 16" diameters, with surface area ranging from 0.16 m^2 (1.8 ft^2) to 2.8 m^2 (29.8 ft^2) per cartridge.

Capsule Construction

Zeta Plus EXT series products are available in autoclavable and single-use BC25 and Zeta Plus Encapsulated System capsules. With 25 cm² (3.9 in²) of filtration area, the BC filter capsule is ideal for laboratory feasibility and initial product sizing evaluations. The Zeta Plus Encapsulated System includes scale-up capsule filters with effective filtration areas at 170 cm² (0.18 ft²), 340 cm² (0.37 ft²), 1020 cm² (1.10 ft²); and large capsule filters with 0.23 m² (2.4 ft²), and 1.6 m² (17.1 ft²). They are ideal for both scale-up studies as well as large scale production. For more information on the Zeta Plus Encapsulated System, please refer to 3M literature 70-0202-3967-2.

Grade Selection

The Zeta Plus EXT Series Filters with ZB Media are available in six grades. Operating conditions and the fluid being filtered impact retention performance. 3M Purification recommends small-scale pilot runs to confirm grade selection prior to full scale-up. 3M Purification's Technical Services staff can assist in grade selection as well as perform onsite evaluations.

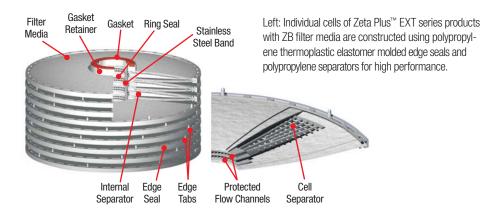


Table 2: Effective Surface Area

Cartridge Configuration	Surface Area		
BC25 Capsule	25 cm ² (3.9 in ²)		
E0170FSA Scale-up Capsule	170 cm ² (0.18 ft ²)		
E0340FSA Scale-up Capsule	340 cm ² (0.37 ft ²)		
E1020FSA Scale-up Capsule	1020 cm ² (1.10 ft ²)		
Z08 E05 (8 diameter cartridge plug-in, 5-cell)	0.16 m ² (1.8 ft ²)		
Z08 E06 (8 diameter cartridge D0E, 6-cell)	0.20 m ² (2.1 ft ²)		
Z08 E07 (8 diameter cartridge D0E, 7-cell)	0.23 m ² (2.4 ft ²)		
Z16 E01 (16 diameter cartridge, 1-cell)	0.23 m ² (2.4 ft ²)		
Z16 E02 (16 diameter cartridge, 2-cell)	0.46 m ² (5.0 ft ²)		
Z16 E08 (16 diameter cartridge, 8-cell)	1.8 m ² (19.8 ft ²)		
Z16 E12 (16 diameter cartridge, 12-cell)*	2.8 m ² (29.8 ft ²)		

^{*}Z16E12 (16" diameter cartridge, 12-cell) wet weight (29 kg [65 lb]) may require lifting assistance.

Table 3: Recommended Operating Parameters

Maximum Operating Pressure	BC25 Capsules	2.8 bar (40 psig) maximum inlet pressure, 2.4 bar (35 psid) maximum capsule pressure drop.				
	Scale-Up Capsules					
	Standard Zeta Plus™ Cartridges	2.4 bar (35 psid) maximum cartridge pressure drop.				
Maximum Operating Temperature	BC25 Capsules	40 °C (104 °F)				
	Scale-Up Capsules					
	Zeta Plus [™] Cartridges	82 °C (180 °F)				
Recommended Pre-use Rinse		54 L/m ² (1.33 gal/ft ²)				
Sterilization Parameters	BC25	Autoclave 30 min. at 121 °C (250 °F) (1 cycle).				
	Scale-Up Capsules	Autoclave 30 min @ 126 °C (259 °F)				
	Standard Zeta Plus™ Cartridges	Autoclave or <i>In situ</i> steam sterilize 30 minutes @ 126 °C (259 °F) (3 cycles)				

Sanitary Housings

3M Purification provides a wide array of standard and specially designed sanitary filter housings to accommodate Zeta PlusTM EXT series filter cartridges. All housings are designed to the requirements of the pharmaceutical and bioprocessing industries. The housings feature 316L polished surfaces and easy-to-clean components, along with accessories such as CIP spray-balls and the innovative Zeta Plus Lifting Device. Custom design skid systems incorporating Zeta Plus and membrane cartridge filter housings, together with process piping, flow control and complete validation documentation are also available.

Zeta Plus EXT series cartridges can be retrofitted into existing standard Zeta Plus housing offerings. For more information, please call your local 3M Purification Sales Representative or Distributor.

Figure 1: Nominal Retention Ratings

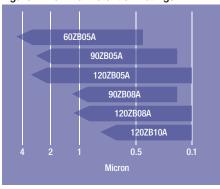
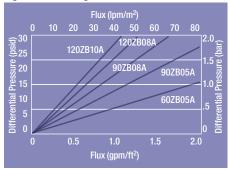
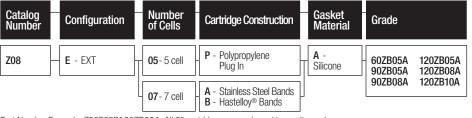


Figure 2: Cartridge Flow vs. Differential Pressure



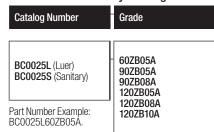
Zeta Plus[™] EXT Series Products Featuring Dual Zone ZB Filter Media Ordering Guide

8" Diameter Cartridges



Part Number Example: Z08E05PA60ZB05A. All 8" cartridges are packaged two units per box.

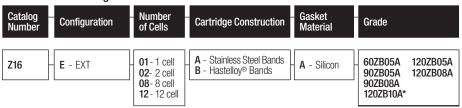
BC Series for Feasibility & Sizing Trials



12" Diameter Cartridges

Catalog Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade	
Z12 E - EXT Part Number Example: Z12E11AA60Z		A - Stainless Steel Bands B - Hastelloy® Bands artridges are packaged two uni	A - Silicone its per box.	60ZB05A 90ZB05A 90ZB08A	120ZB05A 120ZB08A 120ZB10A

16" Diameter Cartridges



Part Number Example: Z16E08AA120ZB08A. 8-cell cartridges are packaged one unit per box.

Important Notice

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3M

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^{*}Not available in 12 cell.