Zeta Plus™ EXT Series

Featuring Dual Zone SP Filter Media

The Zeta Plus™ EXT series media extends depth filtration capacity and protection of downstream membranes thereby extending filter life and lowering overall filtration costs. Zeta Plus EXT series is a family of advanced dual zone depth media designed to provide optimal clarification of bioprocess, biological and pharmaceutical fluids. Zeta Plus EXT series media consist of two distinct layers, or "zones" of filter media with the upstream zone more open than the down stream 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, reducing premature plugging and extending service life.

- Increased throughput with high turbidimetric efficiency
- Enhanced protection of downstream membrane filters
- A complete particle retention range from coarse to fine
- Open grade EXT filters are designed for primary clarification or to replace centrifuges and TFF systems
- Consolidation of multiple filter stages resulting in lower processing costs

Applications

Clarification of mammalian cell culture process fluids (cell separation)
Protection of downstream processes including membrane (0.2, 0.1 micron) filters and chromatography columns
Clarification of bacteria and yeast cell lysates
Endotoxin and nucleic acid reduction
Clarification of colloidal and haze forming contaminants

Applications

Zeta Plus EXT series with SP media are optimized for clarification of mammalian cell harvest fluids, clarification of high protein concentration feed streams and for optimal protection of downstream sterilizing grade membrane filters. Zeta Plus SP media are composed of inorganic filter aid, cellulose and a resin system that imparts a positive charge to the filter matrix.

Excellent Performance

Advances in mammalian cell line engineering, DNA transfer vector and cell culture media have increased protein yields in mammalian cell cultures by a factor of 10 over the last decade. This increase is due in part to the increased cell titers at harvest. Thus, the biopharmaceutical industry has encountered a new challenge to improve primary cell clarification while minimizing protein loss. Zeta Plus EXT series with SP media are designed to fulfill this need. Zeta Plus SP media are an advanced cellulose-based depth filtration media, designed to retain contaminants by both mechanical entrapment and electrokinetic adsorption. Zeta Plus filter media are composed of high surface area filter aids embedded in a cellulose fiber matrix. During the manufacturing process, molecules carrying a positive charge are chemically bonded to the filter matrix permanently forming an interconnected filtration structure with positively charged electrokinetic capture sites. The resulting porous depth filter is a tortuous network of charge enhanced flow channels capable of removing bacteria, particulate, cellular debris and submicronic contaminants.

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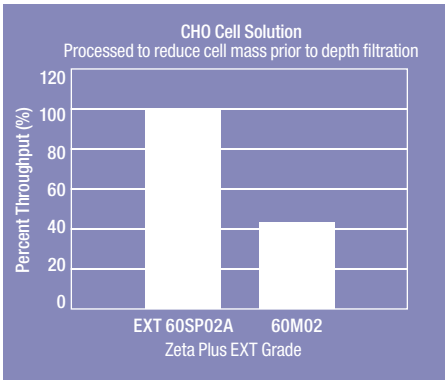
Figure 1: Zeta Plus™ EXT Series Performance



Zeta Plus BC25 & Scale-Up capsules are ideal for feasibility, sizing, small volume, and pilot scale trials.

Figure 2: Nominal Retention Ratings

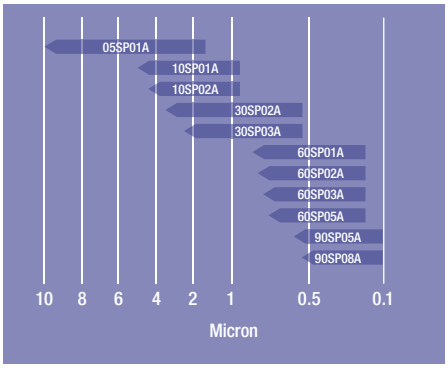


Figure 1 illustrates the superior Zeta Plus EXT series media performance using mammalian cell culture fluids. These media provide both superior throughput and turbidimetric efficiency, outperforming standard Zeta Plus media by a margin of 2:1 in throughput. To the end user, this superior performance translates into lower processing costs, smaller filter assemblies, and enhanced protection of downstream membrane filters.

Regulatory Support

Zeta Plus EXT series with SP media are manufactured in accordance with an ISO 9001:2008 Registered Quality Management system. All filter components success fully passed the USP <88> Class VI Biological Reactivity Tests. Each filter includes certificate of quality and, to ease validation and regulatory submission, a regulatory support file is available.

Cartridge Construction

Individual cells of SP 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 molded edge seals and polypropylene separators for high performance. Filter cartridges are available in 8" and 16" diameters, with surface area ranging from 0.16 m² (1.8 ft²) to 2.77 m² (29.8 ft²) per cartridge.

Capsule Construction

Zeta Plus EXT series is available in autoclavable and fully disposable BC25 and in Zeta Plus Encapsulated System capsules. With 25 cm² (3.9 in²) of filtration area, the ready-to-use BC filter capsule is ideal for feasibility and sizing trials. The Zeta Plus Encapsulated System includes capsule filters with effective filtration areas at 170 cm² (0.18 ft²), 340 cm² (0.37 ft²), 1020 cm² (1.10 ft²), 0.23 m² (2.4 ft²), and 1.6 m² (17.1 ft²). They are ideal for both the scale-up studies as well as large scale production.

Pilot Scale and Small Volume

For pilot scale and small volume trials, the Zeta Plus EXT series is available in 8" diameter cartridges or the Zeta Plus Scale-Up Capsules. Other units available are 1- and 2-cell 16" diameter cartridge and the 0.23 m² Zeta Plus Encapsulated filters. Small scale pilot runs are recommended to confirm grade selection prior to scale-up.

Grade Selection

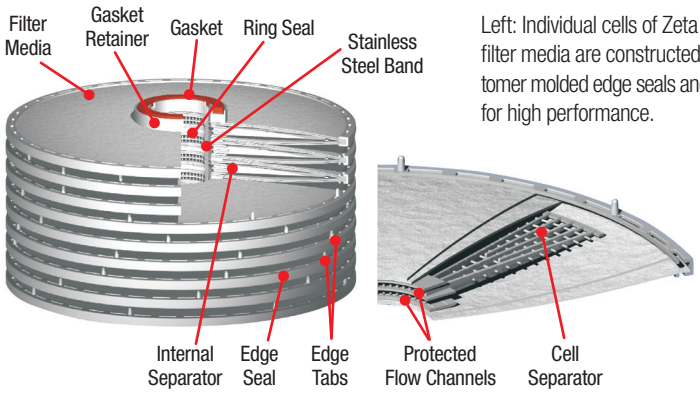
The Zeta Plus EXT series with SP filter media are available in 11 grades. Figure 2, on the facing page, is provided as a guide to proper grade selection based on nominal retention ratings and can be used in conjunction with the recommendations in Table 1 to determine the appropriate filter grade for your application. Operating conditions and the fluid being filtered impact retention performance. 3M recommends small scale pilot runs to confirm grade selection prior to scale-up. 3M's application engineering team can assist in grade selection as well as assist in on-site evaluations. Filter system optimization can also be conducted at our laboratory facilities.

Table 1: Application Recommendations

Application	Recommended Grades
Coarse (primary) clarification	05SP01A, 10SP01A, 10SP02A, 30SP02A, 30SP03A, 60SP01A
Fine Clarification	60SP05A, 90SP05A
Cell broth centrate and high protein concentration feed clarification	760SP02A, 60SP03A, 60SP05A, 90SP05A, 90SP08A
TFF, membrane protection	60SP03A, 60SP05A, 90SP08A
Endotoxin, nucleic acid reduction	90SP05A, 90SP08A

Table 1 is intended as a guide. Grade selection and performance should be confirmed with small-scale pilot trials.

*Except Z08E05, 8" plug-in style cartridge, which is unitized by a polypropylene post.



Left: Individual cells of Zeta Plus EXT series with SP filter media are constructed using thermoplastic elastomer molded edge seals and polypropylene separators for high performance.

Table 2: Effective Cartridge Surface Area

Cartridge Configuration	Surface Area
Z08 E05 (8 diameter cartridge plug-in, 5-cell)	0.16 m² (1.8 ft²)
Z08 E06 (8 diameter cartridge DOE, 6-cell)	0.20 m² (2.1 ft²)
Z08 E07 (8 diameter cartridge DOE, 7-cell)	0.23 m² (2.4 ft²)
Z16 E01 (16 diameter cartridge, 1-cell)	0.23 m² (2.4 ft²)
Z16 E02 (16 diameter cartridge, 2-cell)	0.46 m² (5.0 ft²)
Z16 E08 (16 diameter cartridge, 8-cell)	1.8 m² (19.8 ft²)
Z16 E12 (16 diameter cartridge, 12-cell)*	2.8 m² (29.8 ft²)

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

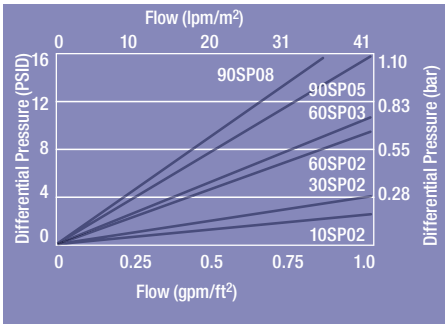
Table 3: Effective Capsule Surface Area

Cartridge Configuration	Surface Area
BC25 Capsule	25 cm² (3.9 in²)

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.
	Standard Zeta Plus Cartridges	2.4 bar (35 psid) maximum cartridge pressure drop.
Maximum Operating Temperature	**BC25 Capsules**	40°C (104°F)
	Zeta Plus Cartridges	82°C (180°F)
Minimum Required Preconditioning Flush		54 L/m² (1.33 gal/ft²) with water, or other suitable fluid, at a volumetric flow rate up to 1200 L/m²/hr
Sterilization Parameters	**BC25**	Autoclave 30 min. at 121°C (250°F) (1 cycle).
	Standard Zeta Plus Cartridges	Autoclave or *In situ* steam sterilize 30 minutes @ 126°C (259°F) (3 cycles)

Figure 3: Flow vs. Differential Pressure



Sanitary Housings

3M provides a wide array of standard and specialty designed sanitary filter housings to accommodate Zeta Plus filter cartridges. All housings are designed with the pharmaceutical and bioprocessing industries in mind and feature 316L polished surfaces and easy to clean components, along with accessories such as CIP spray balls. Custom design skid systems incorporating Zeta Plus and membrane cartridge filter housings, together with process piping, flow control and complete validation documentation (IQ, OQ), are also available.

Zeta Plus cartridges can be retrofitted into existing standard Zeta Plus housing offering. To accommodate both 1- and 2- cell 16" diameter EXT cartridges, 3M has specially designed two sanitary short dome housings that minimize working and hold up volumes. An ASME code certified housing is available as well as a lightweight band clamp version. Please call 3M for assistance.

Filter Flow Rates

Figure 3 displays initial flow rates obtained with 20°C clean water. Optimum flow rates vary by application, but, in general, the flow rate per unit area (flux) should not exceed 10 lpm/m² (0.25 gpm/ft²) of filter medium for best performance. Lower flux rates often result in longer service life, greater throughputs, and superior system economics.

Zeta Plus™ EXT Series Featuring Dual Zone SP Filter Media Ordering Guide

8" Diameter Cartridges

Catalog Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
Z08	**E** - EXT	**05**- 5 cell **06**- 6 cell **07**- 7 cell	**A** - Stainless Steel Bands **B** - Hastelloy® Bands **P** - Polypropylene Plug In	**A** - Silicone	**05SP01A** (5 & 6 cell) **10SP01A** (5 & 6 cell) **10SP02A** (5 & 6 cell) **30SP02A** (5 & 6 cell) **30SP03A** (5 & 6 cell) **60SP01A** (5 & 6 cell) **60SP02A** (5 & 6 cell) **60SP03A** (5 & 6 cell) **60SP05A** (5 & 7 cell) **90SP05A** (5 & 7 cell) **90SP08A** (5 & 7 cell)

Part Number Example: Z08E05PA60SP05A. All 8" cartridges are packaged two units per box.

16" Diameter Cartridges

Catalog Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
Z16	**E** - EXT	**01**- 1 cell **02**- 2 cell **08**- 8 cell	**A** - Stainless Steel Bands	**A** - Silicone	**05SP01A** **60SP02A** **10SP01A** **60SP03A** **10SP02A** **60SP05A** **30SP02A** **90SP05A** **30SP03A** **90SP08A** **60SP01A**

Part Number Example: Z16E08AA60SP05A. 1-cell and 2-cell cartridges are each packaged two units per box. 8-cell cartridges are packaged one unit per box.

BC Series for Feasibility & Sizing Trials

Catalog Number	Grade
BC0025L (Luer) **BC0025S** (Sanitary)	**05SP01A** **60SP02A** **10SP01A** **60SP03A** **10SP02A** **60SP05A** **30SP02A** **90SP05A** **30SP03A** **90SP08A** **60SP01A**

Part Number Example: BC0025S60SP05A.

Product Use

Identified uses: Manufacturing of pharmaceutical (drug) products, including active pharmaceutical ingredients and vaccines.

Prohibited uses: As a component in a medical device that is regulated by any agency, and/or globally exemplary agencies, including but not limited to: a) FDA, b) European Medical Device Directive (MDD), c) Japan Pharmaceuticals and Medical Devices Agency (PMDA); Applications involving permanent implantation into the body; Life-sustaining medical applications; Applications requiring FDA Food Contact compliance without use restrictions

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