

Zeta Plus™ EXT Series

Featuring Dual Zone ZA Filter Media

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

The new Zeta Plus EXT filter EXTends depth filtration capacity and EXTends 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 filters designed to provide optimal clarification of bioprocess, biological and pharmaceutical fluids. Zeta Plus EXT Series filters consist of 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, reducing premature plugging and extending service life. The two filter “zones” can be independently selected and combined to optimize performance.

Applications

Zeta Plus EXT filters with ZA media are optimized for clarification of mammalian cell harvest fluids and for optimal protection of downstream sterilizing grade membrane filters. In addition, their strong positive charge provides enhanced removal of negatively charged contaminants. In solution, cells and cellular debris, endotoxins and contaminating nucleic acids (DNA, RNA) carry a negative charge. CUNO’s patented* application of positive zeta potential to ZA 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.

Superior Performance

Zeta Plus EXT Series filters with ZA media offer unique advantages in contaminant removal because of their strong electrokinetic properties. In addition to the mechanical exclusion of particles by its depth loading feature, the filter medium adsorbs contaminants too small for removal by mechanical straining. Because most particles in suspension are negatively charged, virtually all contaminants can be removed with proper grade selection.



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 removal

Clarification of colloidal and haze forming contaminants



Zeta Plus BC25 & BCE03 filter capsules are ideal for feasibility, sizing, small volume, and pilot scale trials.

Figure 1: EXT ZA Throughput

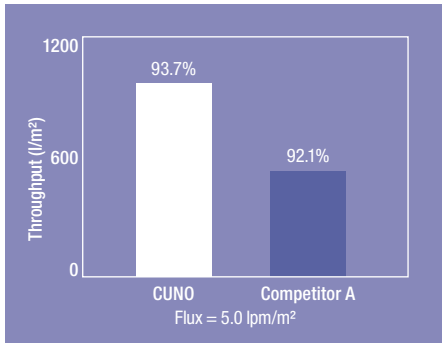
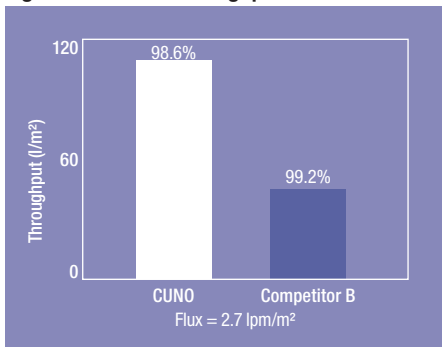


Figure 2: EXT ZA Throughput



% = Turbidimetric Efficiency

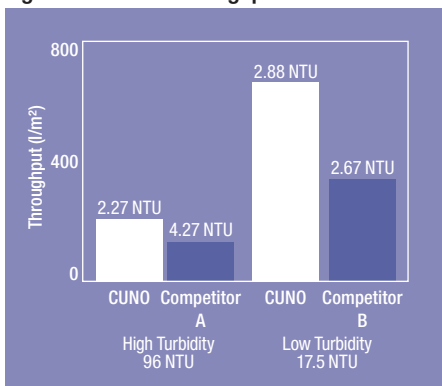
Turbidimetric Efficiency % =

$[(\text{Inlet Turbidity} - \text{Outlet Turbidity}) / \text{Inlet Turbidity}] * 100$
For example, the efficiency of the first bar shown on the graph:

Turbidimetric Efficiency = $[(37 - 2.34) / 37] * 100 = 93.7\%$

EXT filters with ZA media provide up to 2.5 times the throughput with better or equivalent turbidimetric efficiency.

Figure 3: EXT ZA Throughput



Even with the varying extremes of inlet turbidity, the EXT filter maintains superior throughput and effluent turbidity when compared to competitive product.

Figures 1 through 3 illustrate the superior Zeta Plus EXT filter performance, tested using mammalian cell culture fluids, when compared to competitive product. Zeta Plus EXT filters outperform competitive product in each scenario providing both superior throughput and turbidimetric efficiency. 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 filters with ZA media are documented in a Drug Master File (DMF) on record with the US Food and Drug Administration (FDA). Contact CUNO to request the file number. The product is also supported with a regulatory support file and certificate of quality in order to ease validation and regulatory submissions.

Cartridge Construction

Individual cells of Zeta Plus EXT featuring ZA media are assembled together with polypropylene separators under predetermined compression and unitized by three, 316 stainless steel bands.* Each cell is constructed using thermoplastic rubber molded edge seals and polypropylene separators for high performance. Filter cartridges are available in 8, 12, and 16-inch diameters, with surface area ranging from 1.8 ft² (0.16 m²) to 29.8 ft² (2.77 m²) per cartridge.

Feasibility and Sizing Trials

Zeta Plus EXT Series is available in autoclavable and fully disposable BC25 and BCE03 capsules. With 3.9 in² (25 cm²) and 1.1 ft² (0.1 m²) of filtration area, the ready to use BC filter capsule is ideal for feasibility and sizing trials.

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 BCE03 capsule. Other units available are 1- and 2-cell 16" diameter cartridges. Small scale pilot runs are recommended to confirm grade selection prior to scale-up.

Grade Selection

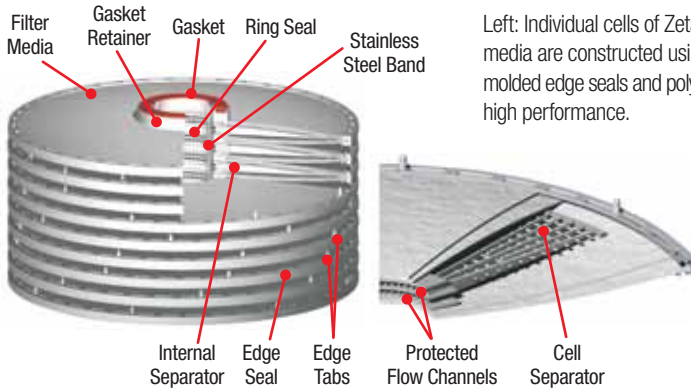
The Zeta Plus EXT Series with ZA filter media is available in six grades. Figure 4 provide a guide to proper grade selection based on nominal retention ratings and can be used in conjunction with the recommendations in Table 1 to determine the appropriate filter grade for your application. Operating conditions and the fluid being filtered impact retention performance. CUNO recommends small-scale pilot runs to confirm grade selection prior to scale-up. CUNO's Scientific Applications Support Services (SASS) staff can assist in grade selection as well as assist in on-site evaluations. Filter system optimization can also be conducted at CUNO's laboratory facilities.

Table 1: Application Recommendations

Application	Recommended Grades
Mammalian cell broth clarification	60ZA05A, 90ZA05A, 90ZA08A, 120ZA05A, 120ZA08A, 120ZA10A
Bacterial, insect, yeast cell/cell lysate clarification	60ZA05A, 90ZA05A, 120ZA05A, 120ZA08A
TFF, membrane protection	60ZA05A, 90ZA08A, 120ZA05A, 120ZA08A, 120ZA10A
Endotoxin, nucleic acid removal	90ZA05A, 90ZA08A, 120ZA05A, 120ZA08A, 120ZA10A
General clarification	60ZA05A, 90ZA05A, 120ZA05A, 120ZA08A

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 with ZA filter media are constructed using thermoplastic rubber molded edge seals and polypropylene separators for high performance.

Table 2: Effective Cartridge Surface Area

Cartridge Configuration	Surface Area
BC25 Capsule	3.9 in ² (25 cm ²)
BCE03 Capsule	1.1 ft ² (0.10 cm ²)
Z08 E05 (8" diameter cartridge plug-in, 5-cell)	1.8 ft ² (0.16 m ²)
Z08 E07 (8" diameter cartridge DOE, 7-cell)	2.5 ft ² (0.23 m ²)
Z12 E11 (12" diameter cartridge, 11-cell)	11.3 ft ² (1.00 m ²)
Z16 E01 (16" diameter cartridge, 1-cell)	2.5 ft ² (0.23 m ²)
Z16 E02 (16" diameter cartridge, 2-cell)	5.0 ft ² (0.46 m ²)
Z16 E08 (16" diameter cartridge, 8-cell)	19.8 ft ² (1.8 m ²)
Z16 E12 (16" diameter cartridge, 12-cell)*	29.8 ft ² (2.8 m ²)

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

Table 3: Recommended Operating Parameters

Maximum Operating Pressure	BC25 Capsules: 40 psig maximum inlet pressure, 35 psid maximum capsule pressure drop. BCE03 Capsules: 80 psig @ 25°C (40 psig @ 60°C) maximum inlet pressure, 35 psig maximum capsule pressure drop. Standard Zeta Plus Cartridges: 35 psid maximum cartridge pressure drop.
Maximum Operating Temperature	BC25 Capsules: 40°C BCE03 Capsules: 60°C Standard Zeta Plus Cartridges: 82°C
Recommended Pre-use Rinse	5.0 l/ft ² at 2 lpm/ft ² (53.8 l/m ² at 20 lpm/m ²)
Autoclave/Steam in Place Parameters	BC25: Autoclave 30 min. at 121°C (1 cycle). BCE03 Capsules: Autoclave 30 min. at 121°C (up to 3 cycles). Standard Zeta Plus Cartridges: <i>In-situ</i> steam 30 min. at 126°C (3 cycles).
Recommended Flow Rates*	BC25 Capsule: 3-30 ml/min. BCE03 Capsules: 0.025 - 0.25 gpm (0.1-1.0 lpm) Standard Zeta Plus Cartridges: 0.025 - 0.25 gpm/ft ² (1-10 lpm/m ²)

*Lower flow range recommended for maximum throughput.

Sanitary Housings

CUNO provides a wide array of standard and specially designed sanitary filter housings to accommodate Zeta Plus EXT Series 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 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 (IQ, OQ), are also available.

Zeta Plus EXT Series cartridges can be retrofitted into CUNO's existing standard Zeta Plus housing offering. To accommodate both 1- and 2-cell 16" diameter EXT cartridges, CUNO 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 light-weight band-clamp version. Please call CUNO or your local CUNO Distributor for assistance.

Figure 4: Nominal Retention Ratings

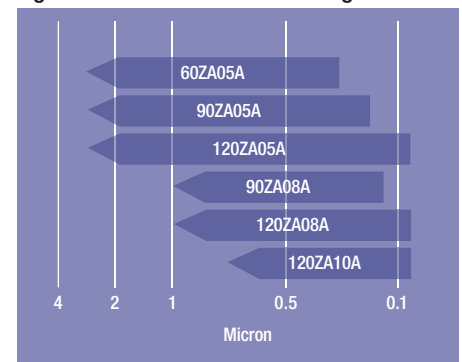
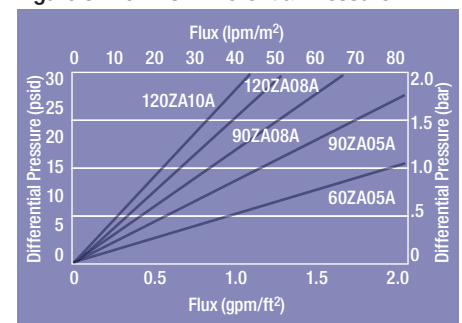


Figure 5: Flow vs. Differential Pressure



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

8" Diameter Cartridges

Catalog Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
Z08	E - EXT	05 - 5 cell	P - Polypropylene Plug In	A - Silicon	60ZA05A 120ZA05A 90ZA05A 120ZA08A 90ZA08A 120ZA10A
		07 - 7 cell	A - Stainless Steel Bands B - Hastelloy® Bands		

Part Number Example: Z08E05PA60ZA05A. All 8" cartridges are packaged two units per box.

12" Diameter Cartridges

Catalog Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
Z12	E - EXT	11 - 11 cell	A - Stainless Steel Bands B - Hastelloy® Bands	A - Silicon	60ZA05A 120ZA05A 90ZA05A 120ZA08A 90ZA08A 120ZA10A

Part Number Example: Z12E11AA60ZA05A. All 12" 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	A - Stainless Steel Bands B - Hastelloy® Bands	A - Silicon	60ZA05A 120ZA05A 90ZA05A 120ZA08A 90ZA08A 120ZA10A*
		02 - 2 cell			
		08 - 8 cell			
		12 - 12 cell			

Part Number Example: Z16E08AA120ZA08A. 1-cell and 2-cell cartridges are each packaged two units per box. 8-cell cartridges are packaged one unit per box.
*Not available in 12 cell.

BC Series for Feasibility & Sizing Trials

Catalog Number	Grade
BC0025L (Luer) BC0025S (Sanitary)	60ZA05A 90ZA05A 90ZA08A 120ZA05A 120ZA08A 120ZA10A

Part Number Example:
BC0025L60ZA05A.

BC Series for Pilot Scale & Small Volume

Catalog Number	Number of Cells	Packaging	Grade
BCE	03 - 3 cell	A - Single Filter B - 3 Filter Pack	60ZA05A 120ZA05A 90ZA05A 120ZA08A 90ZA08A 120ZA10A

Part Number Example:
BCE03A60ZA05A.

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Warranty

Seller warrants its equipment against defects in workmanship and material for a period of 12 months from date of shipment from the factory under normal use and service and otherwise when such equipment is used in accordance with instructions furnished by Seller and for purposes disclosed in writing at the time of purchase, if any. Any unauthorized alteration or modification of the equipment by Buyer will void this warranty. Seller's liability under this warranty shall be limited to the replacement or repair, F.O.B., point of manufacture, of any defective equipment or part which, having been returned to the factory, transportation charges prepaid, has been inspected and determined by Seller to be defective. THIS WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EITHER EXPRESSED OR IMPLIED, AS TO DESCRIPTION, QUALITY, MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE OR USE, OR ANY OTHER MATTER. Under no circumstances shall Seller be liable to Buyer or any third party for any loss of profits or other direct or indirect costs, expenses, losses or consequential damages arising out of or as a result of any defects in or failure of its products or any part or parts thereof or arising out of or as a result of parts or components incorporated in Seller's equipment but not supplied by the Seller.



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