

Zeta Plus® Maximizer® EXT Series Featuring ZA Filter Media



The new Zeta Plus® Maximizer® EXT filter EXTENDS depth filtration capacity and EXTENDS protection of downstream membranes thereby EXTENDING filter life and lowering overall filtration costs. Zeta Plus® Maximizer® EXT Series is a family of advanced dual zone depth filters designed to provide optimal clarification of bioprocess, biological and pharmaceutical fluids.

Maximizer® 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 optimise performance.

Advantages:

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

Applications Examples:

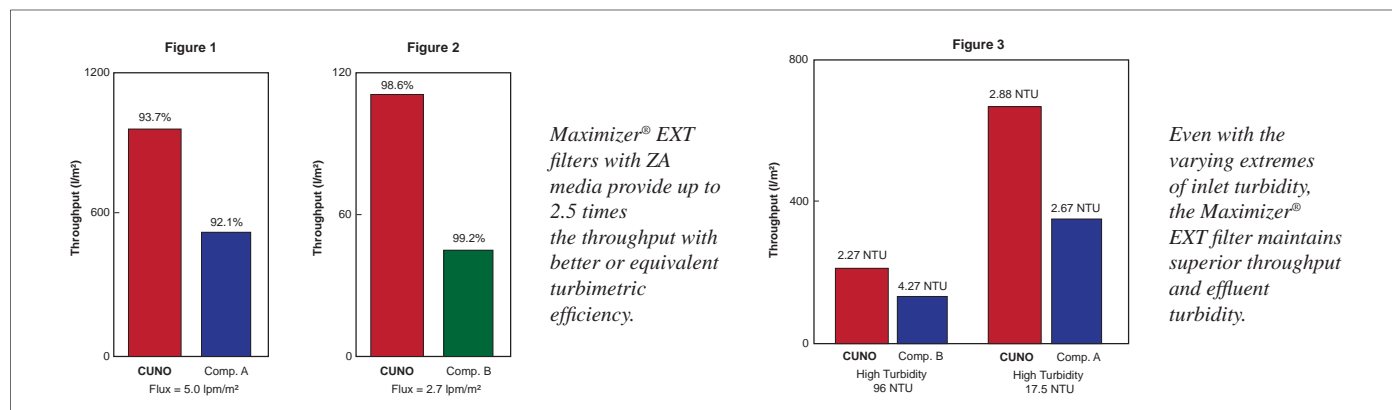
- Clarification of mammalian cell culture process fluids (cell separation)
- Protection of downstream processes including membrane (0.2, 0.1 µm) filters, TFF systems and chromatography columns.
- Clarification of bacteria and yeast cell lysates
- Endotoxin and nucleic acid removal
- Clarification of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

Applications

Maximizer® EXT filters with ZA media are optimised for clarification of mammalian cell harvest fluids and for optimal protection of downstream sterilising 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

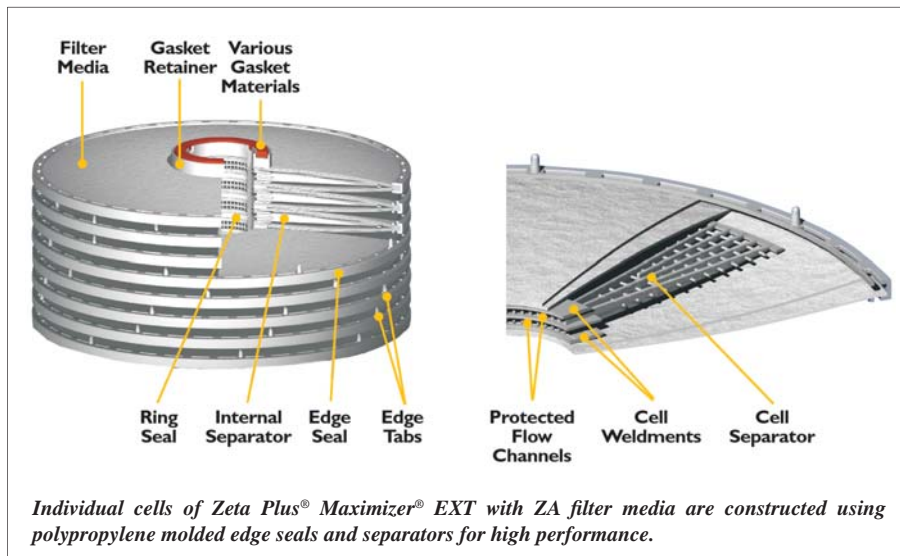
Maximizer® EXT Series filters with ZA media offer unique advantages in contaminant removal because of their strong electrokinetic properties. In addition to the mechanical exclusion of particles by its depth loading feature, the filter medium adsorbs contaminants too small for removal by mechanical straining. Because most particles in suspension are negatively charged, virtually all contaminants can be removed with proper grade selection. Figures 1 through 3 illustrate the superior Maximizer® EXT filter performance, tested using mammalian cell culture fluids, when compared to competitive product. Maximizer® EXT filters out perform 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.



* US Patent Numbers 4,981,591 ; 5,085,780 ; 5,085,784 and patents pending.

Regulatory Support

Zeta Plus® Maximizer® EXT filter 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 Maximizer® EXT ZA media are assembled together with polypropylene separators under predetermined compression and unitised by three, 316 stainless steel bands. Each cell is constructed using polypropylene molded edge seals and separators for high performance. Filter cartridges are available in 1-, 2-, and 8-cell 16-inch diameter, with surface area ranging from 0.23 m² to 1.84 m² per cartridge, 8" double open end (7 cells) and plug-in cartridges (5 cells) from 0.16 m² to 0.23 m² and 12" cartridges in 11 cells design providing 1 m² of effective filter area.

Feasibility and Sizing Trials

Zeta Plus® Maximizer® EXT Series is available in an autoclavable and fully disposable BioCap® 25 and BioCap® E03 capsules. With 25 cm² and 1000 cm² of filtration area, the ready to use BioCap® filter capsule is ideal for feasibility and sizing trials.

Pilot Scale and Small Volume

For pilot scale and small volume trials, the Maximizer® EXT Series is available in 1- and 2- cell 16" cartridge configurations. Other options are small 8" cartridges or the BioCap® E03 capsule. Small scale pilot runs are **recommended to confirm grade selection prior to scale up**.

Grade Selection

The Maximizer® EXT Series with ZA filter media is available in six grades. The chart 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.

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 optimisation can also be conducted at CUNO's laboratory facilities.

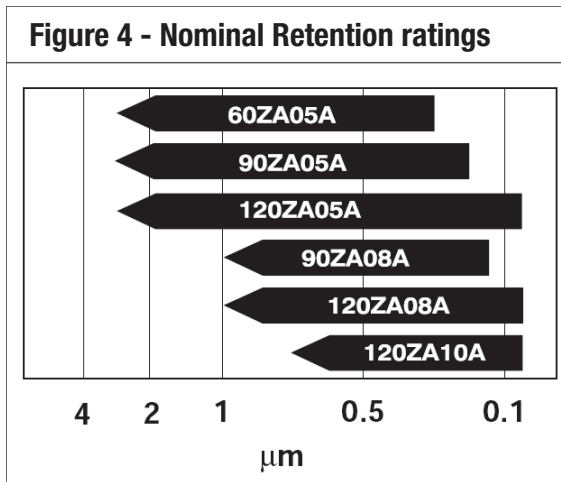
Sanitary Housings

CUNO provides a wide array of standard and specially designed sanitary filter housings to accommodate Zeta Plus® Maximizer® 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 ZetaGrip® cartridge 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® Maximizer® EXT cartridges can be retrofitted into CUNO's existing standard Zeta Plus® housing offering. To accommodate both 1- and 2- cell 16" diameter Maximizer® 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. The 8-cell cartridges can be retrofitted into CUNO's existing standard Zeta Plus® housing offering. Please call CUNO Department in 3M or your local CUNO Distributor for assistance.



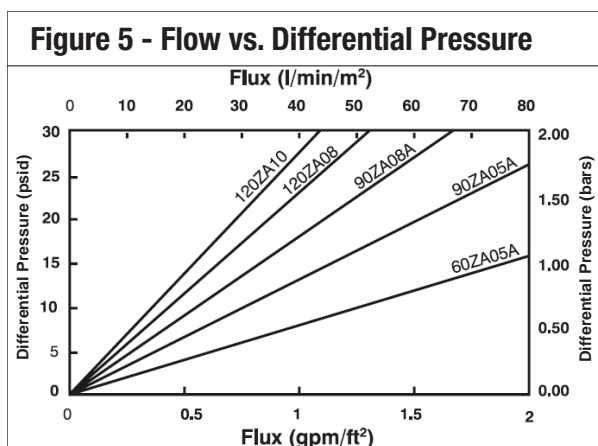
Zeta Plus® BioCap® 25 & BioCap® E03 filter capsules are ideal for feasibility, sizing, small volume, and pilot scale trials.



| 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 |

| Effective Cartridge Surface Area | |
|---|----------------------|
| BioCap® 25 Capsule | 25 cm ² |
| BioCap® E03 Capsule | 1000 cm ² |
| Z08 E05 (8" cartridge plug-in, 5 cells) | 0.16 m ² |
| Z08 E07 (8" cartridge DOE, 7 cells) | 0.23 m ² |
| Z12 E11 (12" cartridge, 11 cells) | 1.0 m ² |
| Z16 E01 (16" cartridge, 1 cell) | 0.23 m ² |
| Z16 E02 (16" cartridge, 2 cells) | 0.46 m ² |
| Z16 E08 (16" cartridge, 8 cells) | 1.84 m ² |
| Z16 E12 (16" cartridge, 12 cells)* | 2.77 m ² |
| Z16 E12 (16" diameter cartridge, 12 cells) wet weight (29 kg) may require lifting assistance. | |

| Recommended Operating Parameters | |
|--|--|
| Maximum Operating Pressure | BioCap® 25 Capsules : 2.75 bar maximum inlet pressure, 2.4 bar maximum capsule pressure drop |
| | BioCap® E03 Capsules : 5.5 bar at 25°C (2.75 bar at 60 °C) maximum inlet pressure, 2.4 bar maximum capsule pressure drop |
| | Standard Zeta Plus® cartridges : 2.4 bar maximum cartridge pressure drop |
| Maximum Operating Temperature | BioCap® 25 Capsules : 40 °C |
| | BioCap® E03 Capsules : 60 °C |
| | Standard Zeta Plus® cartridges : 82 °C |
| Recommended Pre-use Rinse | 54 l/m ² at 20 lpm/m ² |
| Autoclave / Steam in Place Parameters | BioCap® 25 Capsules : autoclave, 30 minutes at 121°C (1 cycle) |
| | BioCap® E03 Capsules : autoclave, 30 minutes at 121°C (up to 3 cycles) |
| | Standard Zeta Plus® cartridges : in-situ steam, 30 minutes at 126°C (3 cycles) |
| Recommended Flow Rates (lower flow range recommended for maximum throughput) | BioCap® 25 Capsules : 3 - 30 ml/min |
| | BioCap® E03 Capsules : 0.1 - 1.0 l/min |
| | Standard Zeta Plus® cartridges : 1 - 10 lpm/m ² |



Filter Flow Rate

Figure 5 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 of filter medium for best performance. Lower flux rates often result in longer service life, greater throughputs, and superior system economics.

8" Diameter Cartridges

| Catalog Number | Configuration | Number of Cells | Cartridge Construction | Gasket Material | Grade |
|----------------|---------------|-----------------|---|-----------------|---|
| Z 08 | E (Ext) | 05 - 5-cell | P = Polypropylene Plug-in | A - Silicone | 60ZA05A 90ZA05A 90ZA08A 120ZA05A 120ZA08A 120ZA10A |
| | | 07 - 7-cell | A = Stainless steel bands B = Hastelloy® bands | | |

12" Diameter Cartridges

| Catalog Number | Configuration | Number of Cells | Cartridge Construction | Gasket Material | Grade |
|----------------|---------------|-----------------|---|-----------------|---|
| Z 12 | E (Ext) | 11 - 11-cell | A = Stainless steel bands B = Hastelloy® bands | A - Silicone | 60ZA05A 90ZA05A 90ZA08A 120ZA05A 120ZA08A 120ZA10A |

16" Diameter Cartridges

| Catalog Number | Configuration | Number of Cells | Cartridge Construction | Gasket Material | Grade |
|----------------|---------------|---|---|-----------------|---|
| Z 16 | E (Ext) | 01 - 1-cell 02 - 2-cell 08 - 8-cell | A = Stainless steel bands B = Hastelloy® bands | A - Silicone | 60ZA05A 90ZA05A 90ZA08A 120ZA08A |

Ex. : Z16E08AA120ZA08AH - 16 characters

For 12" and 16" Maximizer® cartridges lifting handles can be added by adding the letter "H" at the back of the description.
1-cell and 2-cell cartridges are each packaged two units per box. 8-cell cartridges are packaged are unit per box.

BioCap® Series for Feasibility And Sizing Trials

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

Part Number Example : BC0025L60ZA05A

BioCap® Series for Pilot Scale and Small Volume

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

Part Number Example : BCE03A60ZA05A

* Hastelloy® is a registered trademark of Haynes International, Inc.

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