# LENNTECH

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# Zeta Plus™ EXT ZA S

Lenticular Depth Filter Cartridges

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

Zeta Plus EXT ZA 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.

#### **Applications**

Zeta Plus EXT ZA Series filters are optimised for clarification of mammalian cell harvest fluids and for optimal protection of downstream sterilsing 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. 3M Purification's 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.

#### **Grade Selection**

The Zeta Plus EXT ZA Series is available in six grades. Figure 4 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 Purification recommends small-scale pilot runs to confirm grade selection prior to scale-up. 3M Purification'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 3M Purification's laboratory facilities.



Picture 1: Zeta Plus Family

# **Applications**

Clarification of mammalian cell culture process fluids (cell separation)

Protection of downstream processes including membrane (0.2, 0.1  $\mu$ m) 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.

## **Features and Benefits**

Clarification of mammalian cell culture process fluids (cell separation)

Increased throughput with better turbidimetric efficiency

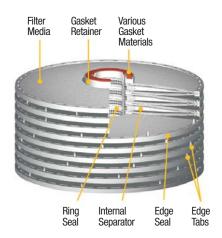
Lower processing costs

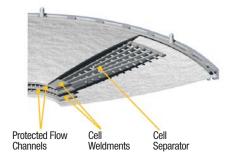
Smaller filter assemblies

Consolidation of multiple filter stages

Enhanced protection of downstream membrane filters







Picture 2: Zeta Plus Cartridge Construction



Zeta Plus production scale cartridge systems including 8", 12" and 16" diameter systems can meet the scale-up needs of a growing process

#### **Cartridge Construction**

Individual cells of Zeta Plus 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 EXT ZA Series is available in an autoclavable and fully disposable Zeta Plus BC25 and Zeta Plus BCE03 capsules. With 25 cm<sup>2</sup> and 1000 cm<sup>2</sup> of filtration area, the ready to use Zeta Plus BC filter capsule is ideal for feasibility and sizing trials.

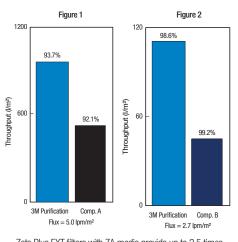
#### **Pilot Scale and Small Volume**

For pilot scale and small volume trials, the Zeta Plus EXT ZA Series is available in 1- and 2- cell 16" cartridge configurations. Other options are small 8" cartridges or the Zeta Plus BCE03 capsule. Small scale pilot runs are recommended to confirm grade selection prior to scale up.

#### **Superior Performance**

Zeta Plus EXT ZA Series filters 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 Zeta Plus EXT ZA filter performance, tested using mammalian cell culture fluids, when compared to competitive product. Zeta Plus EXT ZA filters out perform competitive product in each scenario providing both superior through put 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.

800



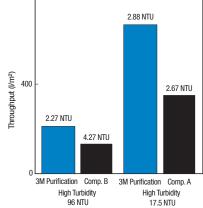


Figure 3

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

Even with the varying extremes of inlet turbidity, the Zeta Plus EXT filter maintains superior throughput and effluent turbidity.

#### **Regulatory Support**

Zeta Plus EXT ZA filter are documented in a Drug Master File (DMF) on record with the US Food and Drug administration (FDA). Contact 3M Purification 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.



#### **Surface Area**

Table 2: Effective Cartridge Surface Area				
Zeta Plus BC25 Capsule	25 cm <sup>2</sup>			
Zeta Plus BCE03 Capsule	1000 cm <sup>2</sup>			
Z08 E05 (8"cartridge plug-in, 5 cells)	0.16 m <sup>2</sup>			
Z08 E07 (8" cartridge D0E, 7 cells)	0.23 m <sup>2</sup>			
Z12 E11 (12" cartridge, 11 cells)	1.0 m <sup>2</sup>			
Z16 E01 (16" cartridge, 1 cell)	0.23 m <sup>2</sup>			
Z16 E02 (16" cartridge, 2 cells)	0.46 m <sup>2</sup>			
Z16 E08 (16" cartridge, 8 cells)	1.84 m²			
Z16 E12 (16" cartridge, 12 cells)*	2.77 m²			
Z16 E12 (16" diameter cartridge, 12 cells) wet weight (29 kg) may require lifting assistance.				

#### **Operating Parameters**

Table 3: Recommended Operating Parameters					
	Maximum Operating Pressure	Maximum Operating Temperature	Recommended Flush	Sterilization Parameters	
Standard and Special precoat Zeta Plus Cartridges	2.4 bar	82 °C	54 l/m² at 20 litre per min/m²	in-situ steam sterilisation for 30 minutes at 126 °C (3 cycles)	
	Inlet pressure: 2.75 bar Media pressure: 2.4 bar	40 °C	54 l/m² at 20 litre per min/m²	Autoclave for 30 minutes at 121 °C (1 cycle)	
Zeta Plus BCE03 Series Capsules	Inlet pressure: 5.5 bar at 25 °C 2.75 bar at 60 °C Media pressure: 2.4 bar	60 °C	54 l/m² at 20 litre per min/m²	Autoclave for 30 minutes at 121 °C (up to 3 cycles)	

#### **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 litre per min/m² of filter medium for best performance. Lower flux rates often result in longer service life, greater throughputs and superior system economics.

### **Sanitary Housings**

3M Purification provides a wide array of standard and specially designed sanitary filter housings to accommodate Zeta Plus EXT ZA 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 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 EXT ZA cartridges can be retrofitted into 3M Purification's existing standard Zeta Plus housing offering. To accommodate both 1- and 2- cell 16" diameter Zeta Plus EXT ZA cartridges, 3M Purification has specially designed two sanitary short dome housings that minimise 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 3M Purification's existing standard Zeta Plus housing offering. Please call your local 3M Purification representative or Distributor for assistance.

**Table 1: Application Recommendations** Recommended **Application** Grades Mammalian cell harvest 60ZA05A. clarification 90ZA05A, 90ZA08A, 120ZA05A, 120ZA08A, 120ZA10A 60ZA05A, Bacterial, insect, yeast cell/ cell lysate clarification 90ZA05A, 120ZA05A, 120ZA08A TFF, membrane protection 60ZA05A. 90ZA08A, 120ZA05A, 120ZA08A, 120ZA10A Endotoxin, nucleic acid 90ZA05A, removal 90ZA08A, 120ZA05A, 120ZA08A, 120ZA010A General clarification 60ZA05A. 90ZA05A. 120ZA05A, 120ZA08A

Figure 4: Nominal Retention ratings

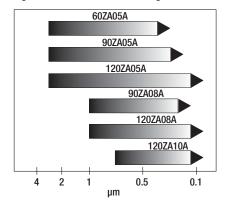
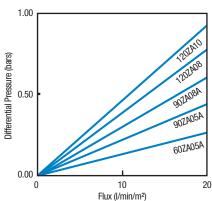


Figure 5: Flow vs. Differential Pressure





# Zeta Plus EXT ZA Series Ordering Guide

#### 8" Diameter Cartridges

	Catalogue Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
	<b>Z 08 E</b> (EXT)	<b>05</b> - 5-cell	<b>P</b> = Polypropylene Plug-in		60ZA05A 90ZA05A 90ZA08A	
		,	<b>07</b> - 7-cell	A = Stainless steel bands B = Hastelloy® bands	A - Silicone	120ZA05A 120ZA08A 120ZA10A

#### 12" Diameter Cartridges

Catalogue Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
Z 12	E (EXT)	<b>11</b> - 11-cell	A = Stainless steel bands B = Hastelloy® bands	A - Silicone	60ZA05A 90ZA05A 90ZA08A 120ZA05A 120ZA08A 120ZA10A

#### 16" Diameter Cartridges

Catalogue Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
Z 16	E (EXT)	01 - 1-cell 02 - 2-cell 08 - 8-cell	<ul><li>A = Stainless steel bands</li><li>B = Hastelloy® bands</li></ul>	A - Silicone	60ZA05A 90ZA05A 90ZA08A 120ZA08A

Ex.: Z16E08AA120ZA08AH - 16 characters

For 12" and 16" Zeta Plus® 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.

#### Zeta Plus BC Series for Feasibility And Sizing Trials

Catalogue Number	Grade
DC003EI	60ZA05A
BC0025L (Luer) BC0025S (Sanitary)	90ZA05A
	90ZA08A
	120ZA05A
	120ZA08A
	120ZA10A

Part Number Example: BC0025L60ZA05A

## Zeta Plus BC Series for Pilot Scale and Small Volume

Catalogue Number	Number of Cells	Packaging	Grade
BCE	<b>03</b> = 3-cell	A = Single Filter	60ZA05A 90ZA05A 90ZA08A 120ZA05A 120ZA08A 120ZA10A

Part Number Example: BCE03A60ZA05A

Important Notice
3M Purification MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Since a variety of factors can affect the use and performance of a 3M Purification product in a particular application, some of which are uniquely within the user's knowledge and control, user is responsible for determining whether or not the 3M Purification product is fit for a

Limited Warranty

3M Purification warrants it this product to be free from defects in material and workmanship during normal use for a period of one (1) year from the date of shipment from the factory. If the Product(s) is (are) defective within this warranty period, your exclusive remedy and 3M Purification's sold obligations shall be, at 3M Purification's option, to replace or repair the Product(s) or refund the original purchase price of the Product(s) This warranty does not apply to failures that result from abuse, misuse, alternation or damage not caused by 3M Purification or failure to properly follow installation and use instructions and use instructions.

Limitation of Liability: 3M Purification will not be liable for any loss or damage arising from the use of the Product(s), whether direct, indirect, special, incidental, or consequential, regardless of the legal theory asserted, including warranty, contract, negligence or strict liability. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

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Data may be subject to change without further notice.

Z08E05PA60ZA05A BC0025L60ZA05A BC0025L90ZA05A Z08E05PA90ZA05A Z08E05PA90ZA08A BC0025L90ZA08A Z08E05PA120ZA05A BC0025L120ZA05A Z08E05PA120ZA08A BC0025L120ZA08A Z08E05PA120ZA10A BC0025L120ZA10A Z08E07AA60ZA05A BC0025S60ZA05A BC0025S90ZA05A Z08E07AA90ZA05A Z08E07AA90ZA08A BC0025S90ZA08A Z08E07AA120ZA05A BC0025S120ZA05A Z08E07AA120ZA08A BC0025S120ZA08A Z08E07AA120ZA10A BC0025S120ZA10A Z08E07BA60ZA05A BCE03A60ZA05A Z08E07BA90ZA05A BCE03A90ZA05A Z08E07BA90ZA08A BCE03A90ZA08A Z08E07BA120ZA05A BCE03A120ZA05A Z08E07BA120ZA08A BCE03A120ZA08A

BCE03A120ZA10A

Z08E07BA120ZA10A Z12E11AA60ZA05A Z12E11AA90ZA05A

Z12E11AA90ZA08A

Z12L11AA30ZA00A

Z12E11AA120ZA05A

Z12E11AA120ZA08A

Z12E11AA120ZA10A

Z12E11BA60ZA05A

Z12E11BA90ZA05A

Z12E11BA90ZA08A

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