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Zeta Plus™ EXT SP Series

Lenticular Depth Filter Cartridges

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

Zeta Plus EXT SP 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.

Applications

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

Grade Selection

The Zeta Plus EXT SP Series is available in eleven grades. Figure 2 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.

Features and Benefits

Increased throughput with better 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



Picture 1: Zeta Plus Family

Applications

Clarification of mammalian cell culture process fluids (cell separation)

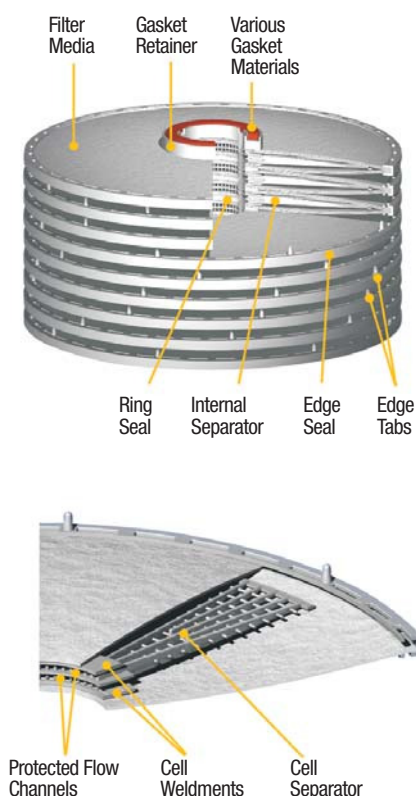
Protection of downstream processes including membrane (0.2, 0.1 µm) filters, TFF systems and chromatography columns.

Clarification of bacteria and yeast cell lysates

Endotoxin and nucleic acid removal

Clarification of colloidal and haze forming contaminants.

3M



Picture 2: Zeta Plus Cartridge Construction



Cartridge Construction

Individual cells of Zeta Plus EXT SP media are assembled together with polypropylene separators under predetermined compression and unitised by three, 316 stainless steel bands (except Z08E05, 8" plug-in style cartridge, which is utilised by a polypropylene post). Each cell is constructed using thermoplastic rubber molded edge seals and polypropylene separators for high performance. Filter cartridges are available in 8- and 16-inch diameters, with surface area ranging from 0.16 m² to 2.77 m² per cartridge.

Feasibility and Sizing Trials

Zeta Plus EXT SP Series is available in an autoclavable and fully disposable Zeta Plus BC25 and Zeta Plus BCE03 capsules. With 25 cm² and 1000 cm² 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 SP 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

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 in part is due to the increased cell titers at harvest. Thus, the biopharmaceutical industry has encountered a new challenge to improve primary cell clarification while minimising protein loss. Zeta Plus EXT SP Series filters are designed to fulfil this unmet need. Zeta Plus SP media is an advanced cellulose-based depth filtration media, designed to retain contaminants by both mechanical entrapment and electrokinetic adsorption. Zeta Plus filter media is composed of high surface area filter aids embedded in a cellulose fibre 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.

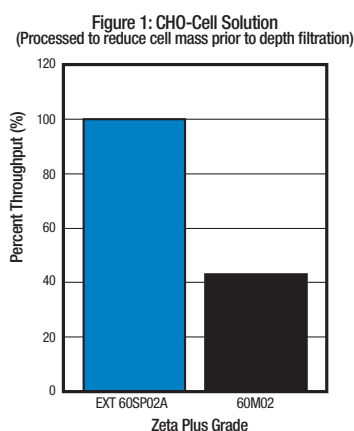


Figure 1 illustrates the superior Zeta Plus EXT filter performance using mammalian cell culture fluids. Zeta Plus EXT SP Series filters provide both superior throughput and turbidimetric efficiency, outperforming standard Zeta Plus EXT SP filters by a margin of 2:1 in throughput. To the end user, this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

Regulatory Support

Zeta Plus EXT SP Series filters are manufactured in accordance with an ISO Quality Management system. All materials of construction are 21 CFR listed and filter components successfully passed the USP Class VI Biological Reactivity test. Each filter includes a certificate of quality and, to ease validation and regulatory submission, a regulatory support file is available.

Surface Area

Table 2: Effective Cartridge Surface Area	
Zeta Plus BC25 Capsule	25 cm ²
Zeta Plus BCE03 Capsule	0.10 m ²
Z08 E05 (8" cartridge plug-in, 5 cells)	0.16 m ²
Z08 E06 (8" cartridge DOE, 6 cells)	0.20 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.	

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/m ² at 20 litre per min/m ²	<i>in-situ</i> steam sterilisation for 30 minutes at 126 °C (3 cycles)
Zeta Plus BC25 Capsules	Inlet pressure: 2.75 bar Media pressure: 2.4 bar	40 °C	54 l/m ² at 20 litre per min/m ²	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/m ² at 20 litre per min/m ²	Autoclave for 30 minutes at 121 °C (up to 3 cycles)

Filter Flow Rate

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 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 SP 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. 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 SP Series 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 SP Series 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

Application	Recommended Grades
Cell harvest clarification (no centrifugation)	05SP01A, 10SP01A, 10SP02A, 30SP02A, 30SP03A, 60SP01A
Fine Clarification	60SP05A, 90SP05A,
Cell harvest concentrate and high protein concentration feed clarification	60SP02A, 60SP03A, 60SP05A, 90SP05A, 90SP08A
TFF, membrane protection	60SP03A, 60SP05A, 90SP08A
Endotoxin, nucleic acid removal	90SP05A, 90SP08A

Figure 2: Nominal Retention ratings

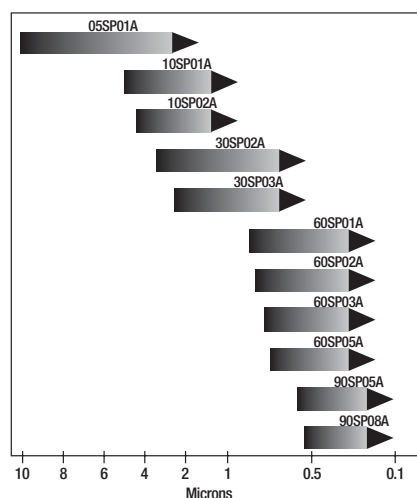
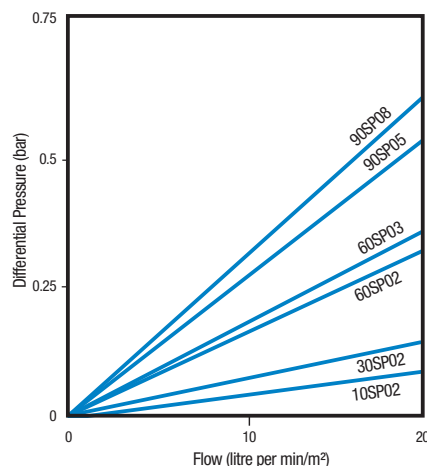


Figure 3: Flow vs. Differential Pressure



Zeta Plus EXT SP Series Ordering Guide

8" Diameter Cartridges

Catalogue Number	Configuration	Number of Cells	Cartridge Construction	Gasket Material	Grade
Z 08	E (EXT)	05 - 5-cell	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)
		06 - 6-cell 07 - 7-cell	A = Stainless steel bands		
Part Number Example. : Z08E05PA60SP05A			All 8" cartridges are packaged two units per box.		

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	A = Stainless steel bands	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. : Z16E08AA60SP05A			1-Cell and 2-Cell cartridges are each packaged two units per box. 8-Cell cartridges are packaged one unit per box.		

Zeta Plus BC Series for Feasibility And Sizing Trials

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

Part Number Example : BC0025S60SP05A

Zeta Plus BC Series for Pilot Scale and Small Volume

Catalogue Number	Number of Cells	Packaging	Grade
BCE	03 = 3-cell	A = Single Filter	05SP01A 10SP01A 10SP02A 30SP02A 30SP03A 60SP01A 60SP02A 60SP03A 60SP05A 90SP05A 90SP08A

Part Number Example : BCE03A60SP05A

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 particular purpose and suitable for user's method of application.

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 sole 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, alteration or damage not caused by 3M Purification or failure to properly follow installation 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.

This warranty gives you specific legal rights and you may have other rights which vary from state to state, or country to country.

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