

A collage of images related to biotechnology and pharmaceuticals. On the left, a white spherical filter capsule is shown with its cap removed. In the center, a rack of white microcentrifuge tubes is visible. On the right, a person wearing a blue lab coat and safety glasses is using a pipette to transfer liquid into a test tube. The background is a light blue gradient.

# Zeta Plus® BioCap™

Disposable Filter Capsules

for the **Biotechnology & Pharmaceutical** Industries



# Zeta Plus® BioCap™



**Totally Disposable Capsule Depth Filters for laboratory, process development, scale-up or small lot production.**

*The new Zeta Plus® BioCap™\* Series is a range of completely encapsulated disposable depth filter assemblies, designed for small volume biological, bioprocess and pharmaceutical filtration.*

*BioCap™ units are available in three sizes with a wide range of industry-leading Zeta Plus depth filter media to provide a high degree of application flexibility.*

## **Bioprocessing:**

- Clarification of cell culture process fluids (cell separation)
- Removal of contaminating host cell DNA
- Clarification of cell lysates
- Lipid removal upstream of chromatography columns (column guard)
- Prefiltration / protection of downstream processes including UF, sterile membrane filters and chromatography columns
- Prefiltration of fermentation feed streams
- Clarification of sera, reagents and buffers

## **Biologicals:**

- Clarification of plasma-derived biologicals (blood fractionation)
- Purification of serum and cell culture media feeds
- Clarification of toxoid broths for vaccine manufacturing
- Clarification and purification of allergenic extracts

## **Pharmaceutical:**

- Small volume parenteral (SVP) prefiltration
- Decolourisation of antibiotic solutions
- Reduction of bacterial endotoxins (pyrogens)
- Clarification of oral liquid pharmaceuticals

\* USA Patent

# BioCap™ Features & Benefits

<ul style="list-style-type: none"> <li>• Totally-Disposable</li> </ul>	<ul style="list-style-type: none"> <li>• No housings to purchase</li> <li>• Easy-to-use, quick set-up, and easy disposal</li> <li>• No housing cleaning protocols simplify validation processes</li> <li>• Eliminates potential for product cross-contamination</li> </ul>
<ul style="list-style-type: none"> <li>• Three capsule sizes available for Scale-up, process Development and Small Volume Filtration</li> </ul>	<ul style="list-style-type: none"> <li>• Flexibility for flow rate and batch volume requirements</li> <li>• Same Zeta Plus filter media used in larger diameter cartridges enables linear and predictable scaleup to manufacturing scale</li> </ul>
<ul style="list-style-type: none"> <li>• Self-Contained Filter Assemblies</li> </ul>	<ul style="list-style-type: none"> <li>• Minimises operator contact with process fluid to ensure operator safety</li> <li>• Minimal set-up time</li> </ul>
<ul style="list-style-type: none"> <li>• Zeta Plus Depth Filter Media</li> </ul>	<ul style="list-style-type: none"> <li>• Economical, efficient removal of negatively charged contaminants such as bacterial endotoxin, bacteria, DNA and particulates</li> <li>• FDA Drug Master Files (DMF) to assist manufacturers with regulatory submissions</li> </ul>
<ul style="list-style-type: none"> <li>• Sanitary Design</li> </ul>	<ul style="list-style-type: none"> <li>• Sanitary quick fit-up to plant process lines</li> <li>• Upstream vent and drain valves for easy process control</li> <li>• Designed for autoclave sterilization</li> <li>• Optional tripod support stand can be utilised for laboratory-bench operations</li> </ul>
<ul style="list-style-type: none"> <li>• Quality and Safe Operation</li> </ul>	<ul style="list-style-type: none"> <li>• 100% pressure tested before shipment to ensure pressure and temperature ratings</li> <li>• Broad chemical compatibility with pharmaceutical process fluids</li> <li>• Manufactured in an ISO-9002-registered world-class manufacturing facility for quality assurance and product consistency</li> <li>• No adhesives, surfactants or resins used in manufacturing process for very low filter extractables</li> <li>• Component part compliant with USP Class VI Biological Safety Tests for Plastics</li> </ul>



Zeta Plus® filter media are widely accepted as the depth filters that meet more criteria of excellence than any other of their type. Their widespread use is a reflection of their versatility and consistent filtration performance.

Hundreds of 3M CUNO Zeta Plus® process systems are in operation worldwide providing reliable and cost effective filtration at pharmaceutical, biotechnology, vaccine, veterinary, diagnostic and other process facilities.

With the Zeta Plus® BioCap™ Disposable Capsule Series, 3M CUNO now offers the widest range of depth filters for biological, bioprocess and pharmaceutical filtration.

# Zeta Plus® BioCap™

## *Unparalleled Filtration Performance and Safety in a Totally-Disposable Capsule Depth Filter.*



### **What is Zeta Plus® ?**

Zeta Plus® is a family of advanced cellulose-based patented 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 to a level which mechanical screening alone cannot achieve.

In solution, cells and cellular debris, endotoxin and contaminating DNA carry a negative charge. 3M CUNO's proprietary application of positive zeta potential to Zeta Plus filter media creates a filter matrix that enhances the capture of negatively charged contaminant for maximum filtration performance.

### **Zeta Plus® Generation 2 Filter Systems**

#### *The Most Complete Range of Depth Filtration Products Available*

Since its introduction over three decades ago, Zeta Plus® has been the industry standard in depth filtration for pharmaceutical and biologicals filtration. 3M CUNO has consistently raised depth filtration to higher levels of quality and performance with numerous technological breakthroughs such as low extractable media, large surface area 16-inch diameter Zeta Plus® cartridges and Clean-In-Place (CIP) systems.

Zeta Plus® Generation 2 products offer scalability from BioCap™ laboratory capsules (BioCap™ 25) to pilot-scale BioCap™ capsules (BioCap™ 1000 / 2000) to full manufacturing scale cartridge systems, to meet any flow or batch size requirement.

Zeta Plus® BioCap™ disposable depth filter capsules, continue 3M CUNO's tradition of technical innovations and new fluid clarification products to support and advance the pharmaceutical, biological and bioprocessing industries.



*The BioCap™ 25 capsule, smallest of the BioCap™ units, is ideal for laboratory and small volume filtration*

# Zeta Plus® Media Matrix for Pharmaceutical, Biological and Bioprocessing Applications

Zeta Plus® Formulation	Filter Media	Filter Aids	Pharmaceutical Grades	Primary Applications
<b>A Grade</b>	Cellulose & Glass Microfibres	None	01AP	<ul style="list-style-type: none"> <li>• Coarse prefiltration</li> <li>• Front end of blood plasma fractionation</li> </ul>
<b>C Grade</b>	Cellulose	Diatomaceous earth (D.E.), perlite	10CP, 30CP, 50CP, 60CP, 70CP	<ul style="list-style-type: none"> <li>• Blood plasma fractionation</li> <li>• Haze removal</li> <li>• Endotoxin reduction</li> </ul>
<b>S Grade</b>	Cellulose	Diatomaceous earth (D.E.), perlite	05SP, 10SP, 30SP, 50SP, 60SP, 90SP	<ul style="list-style-type: none"> <li>• Final sterile membrane protection</li> <li>• Buffer/solvent prefiltration</li> <li>• Chromatography column protection</li> <li>• Post-fermenter clarification/ Cell separation</li> <li>• Reduction of contaminating DNA</li> <li>• Endotoxin reduction</li> </ul>
<b>LA/CA/SA Low Aluminium Grades<sup>1</sup></b>	Cellulose	Pre-extracted (acid washed) Diatomaceous earth (D.E.)	30LA, 60LA, 90LA, 10CA, 30CA, 50CA, 60CA, 70CA, 30SA, 50SA, 60SA, 90SA	<ul style="list-style-type: none"> <li>• Blood plasma fractionation</li> <li>• Endotoxin reduction</li> <li>• Critical applications requiring ultra-low levels of extractables</li> <li>• Membrane protection</li> <li>• Post fermenter clarification/ Cell separation</li> <li>• Reduction of contaminating DNA</li> </ul>
<b>LP Grade</b>	Cellulose (optimised grade for low pyrogenic response)	Diatomaceous earth (D.E.), Perlite	30LP, 60LP, 90LP	<ul style="list-style-type: none"> <li>• Blood fractionation</li> <li>• Membrane protection</li> <li>• Endotoxin reduction</li> </ul>
<b>ZA Grade</b>	Cellulose	Pre-extracted (acid washed) Diatomaceous earth (D.E.)	30ZA, 60ZA, 90ZA	<ul style="list-style-type: none"> <li>• Endotoxin reduction in high purity pharmaceutical water systems</li> </ul>
<b>ZetaCarbon™</b>	Cellulose	Activated Carbon	R11SP, R12SP, R31SP, R32SP, R51SP, R52SP	<ul style="list-style-type: none"> <li>• Decolourisation of antibiotic solutions, chemical intermediates, large volume parenteral solution and blood plasma fractions</li> <li>• Endotoxin reduction</li> </ul>
<b>Delipid</b>	Cellulose	Precipitated silica, perlite	DEL 1	<ul style="list-style-type: none"> <li>• Lipid reduction from blood plasma fractions</li> <li>• Pre-chromatography column lipid reduction</li> </ul>

## NOTE :

<sup>1</sup> LA/CA/SA grades are specially developed media which are optimised for extremely low extractable levels (ultra-low aluminium ion extractables). LA is the low aluminium version of LP, CA is the low aluminium version of CP, and SA is the low aluminium version of SP. All LA/CA/SA media is manufactured and tested as pharmaceutical grade media.

# The Zeta Plus® Scale-up Progression

**BioCap™ disposable capsules are ideal for scale-up evaluation as process volumes move from the laboratory (bench-scale) to pilot plant scale to manufacturing scale operations.**

BioCap™ filtration performance is directly scaleable to production or cGMP manufacturing scale operations with Zeta Plus® 12-inch and 16-inch diameter cartridge systems, designed to fit 3M CUNO's range of sanitary design stainless steel cartridge housings. BioCap™ disposable capsules utilize the same Zeta Plus® filter media offered in 12 and 16-inch diameter filter cartridges enabling linear and predictable scale-up as batch volumes increase.

Filtration Unit	Filtration Area
Zeta Plus® BioCap™ 25 Disposable Capsule	25 cm <sup>2</sup>
Zeta Plus® BioCap™ 1000 Disposable Capsule	650 cm <sup>2</sup>
Zeta Plus® BioCap™ 2000 Disposable Capsule	1300 cm <sup>2</sup>
Zeta Plus® 8" diameter cartridge (fits 8ZP sanitary stainless housings)	0.065 to 2.60 m <sup>2</sup>
Zeta Plus® 12" diameter cartridge (fits 12ZP sanitary stainless housings)	0.7 to 6.0 m <sup>2</sup>
Zeta Plus® 16" diameter cartridge (fits 16ZP sanitary stainless housings)	0.23 to 15.6 m <sup>2</sup>

Note: Zeta Plus® 8, 12 and 16 inch cartridges can be stacked up to 4 cartridges per housing to obtain additional surface area in a single housing for manufacturing flexibility.

Numerous biotechnology companies worldwide have scale-up directly and predictably from small surface area Zeta Plus® benchtop development to successful large surface area Zeta Plus® filtration systems. Zeta Plus® cartridge systems are currently installed in cGMP cell culture manufacturing operations for cell separation at the 16.0 litre scale. Studies\* (request 3M CUNO literature LITTDCS1) have confirmed the ability to accurately predict the requirements for large scale Zeta Plus® filtration using small-scale Zeta Plus® data.

\* Singhvi, R., Schorr, C., Wang, D., et al., "Clarification of Animal Cell Culture Process Fluids Using Depth Microfiltration" BioPharm, Vol. 9, Num. 4, pp. 35 - 41, April 1996.

## Scientific Applications Support Services (SASS)

The cornerstone of 3M CUNO's philosophy is service to customers, not only in product quality and prompt delivery, but also in application support, validation and in the sharing of scientific information.



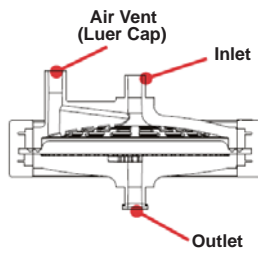
3M CUNO is ready to support your on-site testing needs. 3M CUNO's **Scientific Applications Support Services (SASS)** works closely with customers to solve difficult separations problems and to recommend the most efficient, economical filter systems. SASS specialists are skilled in performing scale-up evaluations with actual process fluids and relating test results to full manufacturing scale operations.

3M CUNO's SASS group is comprised of highly qualified scientists and engineers, supported by state-of-the-art laboratory facilities. SASS teams are located worldwide for prompt on-site response to your filtration needs.

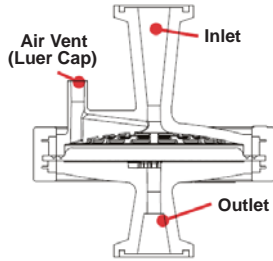


# Technical Specifications

## BioCap™ 25



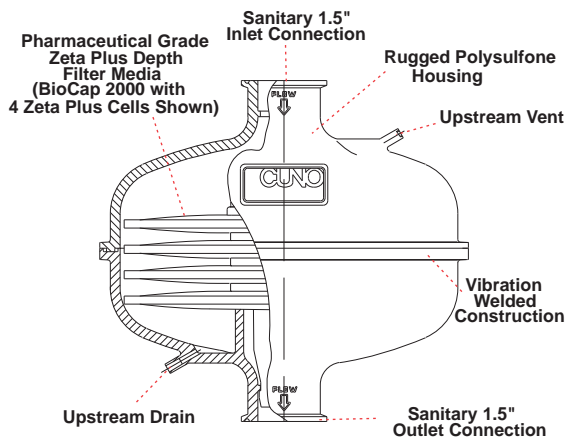
**Luer Style**



**Sanitary Style**

BioCap™ 25 Series Disposable Capsules	
Capsule Outer Shell	Polypropylene
Filter Media	See Ordering Guide
Effective Filter Area	25 cm <sup>2</sup>
Dimensions (approximate)	Diameter: 6.7 cm Height: 3.8 cm
Process Parameters	
Inlet/Outlet Connections	Female luer lock or 19 mm sanitary flange
Luer Cap/Adaptor Material	Polypropylene
Maximum Inlet Pressure	2,75 bar
Operating Temperature	38°C
Recommended Flow**	Maximum 115 ml min <sup>-1</sup>
Autoclave Sterilisation*	121°C for 1 cycle
Biological Safety	All materials of construction are in compliance with USP Class VI Biological Tests for Plastics

BioCap™ 1000 / 2000 Series Disposable Capsules	
Capsule Outer Shell	Polysulphone
Filter Media	See Ordering Guide
Internal Cartridge Support Components/Luer Caps	Polypropylene
Effective Filter Area	BioCap™ 1000 - 650 cm <sup>2</sup> BioCap™ 2000 - 1300 cm <sup>2</sup>
Dimensions (approximate)	Diameter 21.6 cm Height : 20.3 cm
Weight	BC 1000 : 1134 grams BC 2000 : 1327 grams
Process Parameters	
Inlet/Outlet Connections	38 mm Sanitary Flange Fittings
Vent / Drain connections	Female Luer Lock
Maximum Inlet Pressure	5.5 bar @ 25°C, 2.75 bar @ 60°C
Operating Temperature	60°C
Recommended Flow**	Maximum 42 l min <sup>-1</sup> m <sup>-2</sup> of media
Autoclave Sterilisation*	121°C for 30 minutes, up to 3 autoclave cycles
Biological Safety	All materials of construction are in compliance with USP Class VI Biological Tests for Plastics



## BioCap™ 1000/2000

\* BioCap™ assemblies are not designed for in situ steam sterilization.

\*\* Filter media used and fluid being processed dictate the ideal flow rate. Testing is recommended to determine optimum flow.

# BioCap™ Ordering Guide

## BioCap™ Series 25 Disposable Capsules

Cartridge Designation	Nominal Filter Area	Inlet/Outlet Options	Zeta Plus Media*
BC = BioCap™	0025 = 25 cm <sup>2</sup>	L = Luer Lock S = Sanitary Flange	01AP 10CP, 30CP, 50CP, 60CP, 70CP 05SP, 10SP, 30SP, 50SP, 60SP, 90SP 30LA, 60LA, 90LA, 10CA, 30CA, 50CA, 60CA 70CA, 30SA, 50SA, 60SA, 90SA 30LP, 60LP, 90LP 30ZA, 60ZA, 90ZA R11SP, R12SP, R31SP, R32SP, R51SP, R52SP, R53SP, R54SP... DEL 1

\* Non-exhaustive list, for more options refer to individual media brochures

## BioCap™ Series 1000/2000 Disposable Capsules

Cartridge Designation	Nominal Filter Area	Inlet/Outlet Options	Zeta Plus Media**
BC = BioCap™	1000 = 650 cm <sup>2</sup>  2000 = 1300 cm <sup>2</sup>	A = Single Pack B = 3 Pack <i>(3 identical per package)</i> C = 3 Pack <i>(1 capsule each of 10SP, 30SP, 90SP)</i>	01AP 10CP, 30CP, 50CP, 60CP, 70CP 05SP, 10SP, 30SP, 50SP, 60SP, 90SP 30LA, 60LA, 90LA, 10CA, 30CA, 50CA, 60CA 70CA, 30SA, 50SA, 60SA, 90SA 30LP, 60LP, 90LP 30ZA, 60ZA, 90ZA R11SP, R12SP, R31SP, R32SP, R51SP, R52SP, R53SP, R54SP... DEL 1

\* Non-exhaustive list, for more options refer to individual media brochures

\*\* Not Required for packaging option C



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