



Fluid Purification

Zeta Plus[®]

BioCap[™] Disposable Filter Capsules

For the Biotechnology and Pharmaceutical Industries

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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 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.

Applications include:

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
- Bioreduction and 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
- Decolorization of antibiotic solutions
- Reduction of bacterial endotoxins (pyrogens)
- Clarification of oral liquid pharmaceuticals

* Patent Pending

BioCap Features & Benefits

■ Totally-Disposable	■ No housings to purchase ■ Easy-to-use, quick set-up, and easy disposal ■ No housing cleaning protocols simplify validation processes ■ Eliminates potential for product cross-contamination
■ Three capsule sizes available for Scale-up, Process Development and Small Volume Filtration	■ Flexibility for flow rate and batch volume requirements ■ Same Zeta Plus filter media used in larger diameter cartridges enables linear and predictable scaleup to manufacturing scale
■ Self-Contained Filter Assemblies	■ Minimizes operator contact with process fluid to ensure operator safety ■ Minimal set-up time
■ Zeta Plus Depth Filter Media	■ Economical, efficient removal of negatively charged contaminants such as bacterial endotoxin, bacteria, DNA and particulates ■ FDA Drug Master Files (DMF) to assist manufacturers with regulatory submissions
■ Sanitary Design	■ Sanitary quick fit-up to plant process lines (BioCap 1000/2000) ■ Upstream vent and drain valves for easy process control ■ Designed for autoclave sterilization ■ Optional tripod support stand can be utilized for laboratory-bench operations
■ Quality and Safe Operation	■ 100% pressure tested before shipment to ensure pressure and temperature ratings ■ Broad chemical compatibility with pharmaceutical process fluids ■ Manufactured in an ISO-9002-registered world-class manufacturing facility for quality assurance and product consistency ■ No adhesives, surfactants or resins used in manufacturing process for very low filter extractables ■ Component parts compliant with USP Class VI Biological Safety Tests for Plastics

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 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, 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



BioCap 1000/2000 units are available with an accessory laboratory bench support stand.

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 fiber 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. Cuno's proprietary application of positive zeta potential to Zeta Plus filter media creates a filter matrix that enhances the capture of negatively charged contaminants for maximum filtration performance.

Zeta Plus Filter Systems

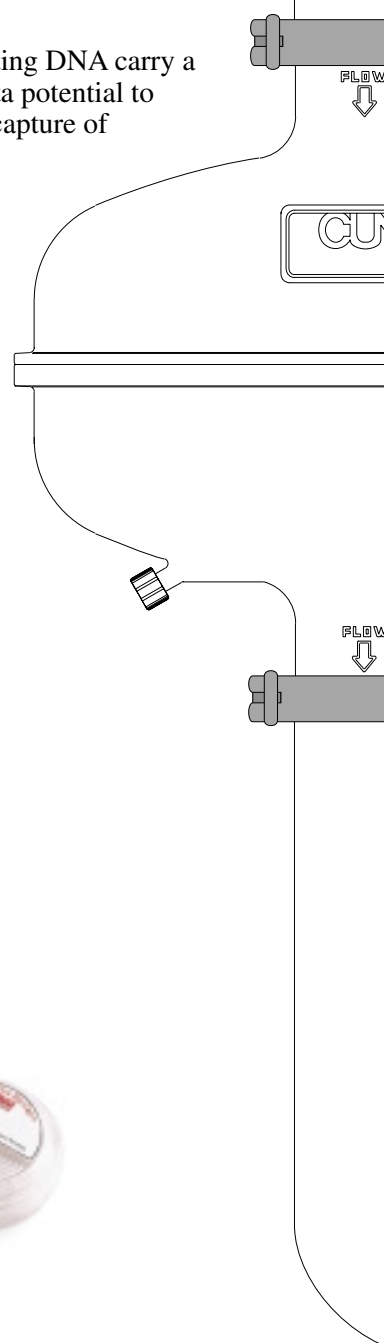
The Most Complete Range of Depth Filtration Products Available

Since its introduction over three decades ago, Zeta Plus has been the industry standard in depth filtration for pharmaceutical and biologicals filtration. 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 scaleability from BioCap laboratory capsules (BioCap 30) to pilot-scale BioCap capsules (BioCap 1000 / 2000) to full manufacturing scale cartridge systems, to meet any flow or batch size requirement. For more information on Zeta Plus production scale cartridge systems, request Cuno literature LITCZP21 and LITCATBP.

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

The BioCap 30 capsule, smallest of the BioCap units, is ideal for laboratory and small volume filtration.



Zeta Plus Media Selection Guide

Zeta Plus Media	Filter Media	Filter Aids Available	Available Grades	Primary Applications	Literature Ref#.
A	Cellulose	None	01AP	- Coarse prefiltration - Front end of blood plasma fractionation	LITZPA01
C	Cellulose	Diatomaceous earth (D.E.), perlite	10CP, 30CP, 50CP, 60CP, 70CP	- Blood plasma fractionation - Haze removal - Endotoxin reduction	LITZPC01
S	Cellulose	Diatomaceous earth (D.E.), perlite	05SP, 10SP, 30SP, 50SP, 60SP, 90SP	- Final sterile membrane protection - Buffer / solvent prefiltration - Chromatography column protection - Post-fermenter clarification/ cell separation - Reduction of contaminating DNA - Endotoxin reduction	LITZPS01
LA/CA/SA Low - Aluminum*	Cellulose	Pre-extracted (acid washed) Diatomaceous earth (D.E.),	30LA, 60LA, 90LA, 10CA, 30CA, 50CA, 60CA, 70CA, 30SA, 50SA, 60SA, 90SA	- Blood plasma fractionation - Endotoxin reduction - Critical applications requiring ultra-low levels of extractables - Membrane protection - Post fermenter clarification / cell separation - Reduction of contaminating DNA	LITZPLA2
LP	Cellulose (optimized grade for low pyrogenic response)	Diatomaceous earth (D.E.), perlite	30LP, 60LP, 90LP	- Blood Fractionation - Membrane protection - Endotoxin reduction	LITZPLP1
ZA	Cellulose	Pre-extracted (acid washed) Diatomaceous earth (D.E.)	30ZA, 60ZA, 90ZA	Endotoxin reduction in high purity pharmaceutical water systems	ZPZA1
Zetacarbon™	Cellulose	Activated Carbon	R11SP, R12SP, R31SP, R32SP, R51SP, R52SP	- Decolorization of antibiotic solutions, chemical intermediates, large volume parenteral solutions and blood plasma fractions - Endotoxin reduction	LITZPAC1
Delipid	Cellulose	Precipitated silica, perlite	DEL 1	- Lipid reduction from blood plasma fractions - Pre-chromatography column lipid reduction	ZP2020E

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

The BioCap 1000/2000 units can be used with a BioCap 30 Product Recovery Accessory Capsule enabling maximum product recovery.



Zeta Plus® BioCap™

The Zeta Plus Scaleup Progression

BioCap disposable capsules are ideal for scaleup 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 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 scaleup as batch volumes increase.

Filtration Unit	Filtration Area
New Zeta Plus BioCap 30 Disposable Capsule	4.2 in. ² (27 cm ²)
New Zeta Plus BioCap 1000 Disposable Capsule	0.9 ft ² (850 cm ²)
New Zeta Plus BioCap 2000 Disposable Capsule	1.8 ft ² (1700 cm ²)
Zeta Plus 8" diameter cartridge (fits 8ZP sanitary stainless housings)	3.5 ft ² to 14 ft ² (0.32 m ² to 1.3 m ²)
Zeta Plus 12" diameter cartridge (fits 12ZP sanitary stainless housings)	13.5 ft ² to 81.5 ft ² (1.25 m ² to 7.57 m ²)
Zeta Plus 16" diameter cartridge (fits 16ZP sanitary stainless housings)	37 ft ² to 148 ft ² (3.43 m ² to 13.75 m ²)

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 scaled-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 16,000 liter scale. Studies* (request Cuno literature LITDCS1) have confirmed the ability to accurately predict the requirements for large-scale Zeta Plus filtration using small-scale Zeta Plus data.



BioCap 30 and BioCap 1000/2000

BioCap 30 and BioCap 1000/2000 capsule units for laboratory scale, process development or small volume filtration

Zeta Plus Family of Cartridge Filter Systems

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

Scientific Applications Support Services (SASS)

The cornerstone of 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.

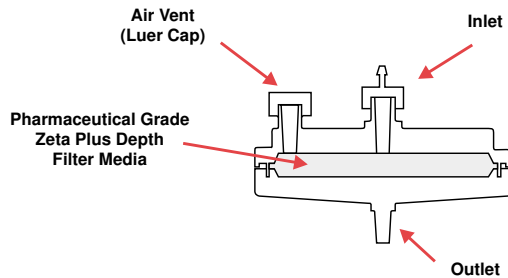
Cuno is ready to support your on-site testing needs. Cuno's Scientific Applications Support Services (SASS) works closely with customers to solve difficult separation problems and to recommend the most efficient, economical filter systems. SASS specialists are skilled in performing scale-up evaluations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



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.

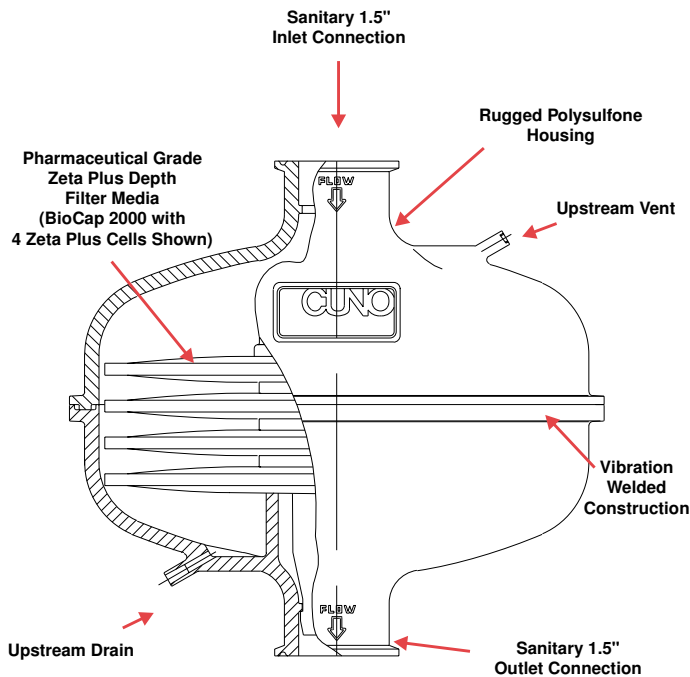
* Singhvi, R., Schorr, C., Wang, D., et al., "Clarification of Animal Cell Culture Process Fluids Using Depth Microfiltration", BioPharm, Vol. 9, Num. 4, pp. 35 - 41, April 1996.

Technical Specifications



BioCap 30

BioCap 30 Series Disposable Capsules	
Capsule Outer Shell:	Polycarbonate
Filter Media:	See Ordering Guide
Effective Filter Area:	4.2 in ² (27 cm ²)
Dimensions (approximate):	Diameter - 2.65 inches (6.73 cm)
	Height - 1.5 inches (3.81cm)
Weight:	0.10 lbs (45 grams)
Process Parameters	
Inlet / Outlet Connections:	Inlet-Female luer lock with hose barb, Outlet-Male luer slip
Luer Cap/Adaptor Material:	Polypropylene
Maximum Inlet Pressure:	50 psig (3.45 bar)
Operating Temperature:	104°F (40° C)
Recommended Flow**	Maximum 110 ml/min.
*Autoclave Sterilization:	250°F (121° C) for 30 minutes (1 cycle)
Biological Safety:	All materials of construction are in compliance with USP Class VI Biological Tests for Plastics



BioCap 1000/2000

BioCap 1000 / 2000 Series Disposable Capsules	
Capsule Outer Shell:	Polysulfone
Filter Media:	See Ordering Guide
Internal Cartridge Support Components/Luer Caps:	Polypropylene
Effective Filter Area:	BioCap 1000 - 0.9 ft ² (850 cm ²) BioCap 2000 - 1.8 ft ² (1700 cm ²)
Dimensions (approximate):	Diameter - 8.5 inches (21.6 cm)
	Height - 8.0 inches (20.3 cm)
Weight:	BC1000 - 2.5 lbs. (1134 grams) BC2000 - 2.9 lbs. (1327 grams)
Process Parameters:	
Maximum Inlet Pressure:	80 psig @ 77°F, 40 psig @ 140°F (5.5 bar @ 25°C, 2.76 bar @ 60°C)
Operating Temperature:	140°F (60°C)
Recommended Flow**	Maximum 1 gpm (3.78 lpm) per 1 ft ² (0.09 m ²) of media
*Autoclave Sterilization:	250°F (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
Inlet / Outlet Connections:	1.5 inch (38mm) Sanitary Flange Fittings
Vent / Drain Connections:	Female Luer Lock
*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	

Packaging Options

BioCap capsules are available in combination packs for process development scale-up to enable testing of different grades of Zeta Plus media with various retention ratings. Shown is the BioCap 30 Process Development Suitcase Pack that contains 32 BioCap 30 units (8 different Zeta Plus media types).



BioCap Ordering Guide

BioCap Series 30 Disposable Capsules

Cartridge Designation	Nominal Filter Area	Packaging Options	Zeta Plus Media*
BC - BioCap	0030 - 4.2 in. ² (27 cm ²)	A - Single Pack B - 10 Pack C - Combination 9 Pack (3 capsules each of 10 SP, 30SP, and 90SP) D - 32 Pack Process Development Suitcase (4 pieces each of 01AP, 05SP, 10SP, 30SA, 60SA, 90SA, 90ZA, Delipid) E - Product Recovery Accessory Capsule (provided with tubing and hose barb to mate with the BioCap 1000/2000)	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 DEL 1

* Not Required for packaging options C & D.

BioCap Series 1000/2000 Disposable Capsules

Cartridge Designation	Nominal Filter Area	Packaging Options	Zeta Plus Media*
BC - BioCap	1000 - 0.9 ft ² (850 cm ²) 2000 - 1.8 ft ² (1700 cm ²)	A - Single Pack B - 3 Pack (3 units with the same media) C - 3 Pack (1 capsule each of 10 SP, 30SP, and 90SP)	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 DEL 1

* Not Required for packaging option C.

BioCap Series 1000/2000 Disposable Capsule Benchtop Support Stand

Part Description	Part Number
Optional Benchtop Support Stand	74015-01

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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