

# LENNTECH

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## Zeta Plus™ DEL Series

Featuring DELI or DELP Media

Zeta Plus™ DEL Series is a family of depth filter media which incorporates lipid-specific adsorbents for selective removal of lipids, surfactants and biological hydrophobes from human blood plasma, serum-based products, recombinant proteins and other biological fluids. Two different DEL media types provide a range of lipid removal capacity and functionality: DELI and DELP.

### Applications

During protein purification processes, lipid contamination can cause an assortment of processing problems. Lipids can foul and plug expensive chromatography columns and membrane filters. Prior removal of lipids via depth filtration promotes column and membrane performance and extends useful life. Lipid contamination can also cause solution instability of intermediate and final protein products leading to a problematic lipoprotein haze. Zeta Plus DEL Series filter products can replace bulk silica operations which are labor-intensive, messy and difficult to prepare.

DEL filter media may be used to separate lipids within the following lipid classes: mono-, di-, and triglycerides, fatty acids, cholesterol, phospholipids, and lipoproteins. Enhanced removal of lipid contaminants from protein solutions is therefore highly desirable, leading to improved processing economies (extended column and membrane life), improved product purity, and enhanced final protein product stability (haze-free) for longer product shelf life.

### Features & Benefits

#### Two different media formulations available for varying degrees of lipid removal.

- Efficient removal of undesirable lipids, lipoprotein haze, and microbial and particulate contaminants.

#### Depth filter media with hydrophobe and lipid specific adsorbents.

- Provides effective protection and extended life for chromatography columns and reusable membranes.

#### Variety of cartridge sizes, disposable capsules and filter sheets.

- Highly scaleable.
- Flexible options for all flow and batch volume requirements.

#### Totally-enclosed, sanitary-design systems and cartridge housings.

- Easily cleanable, no external contamination, offers rapid assembly and take down.

#### Tested and optimized for pharmaceutical and biological service.

- Safe for critical pharmaceutical, bioprocessing and biological applications.
- Components meet USP Class VI Biological Safety Tests and requirements of CFR 21.



### Applications

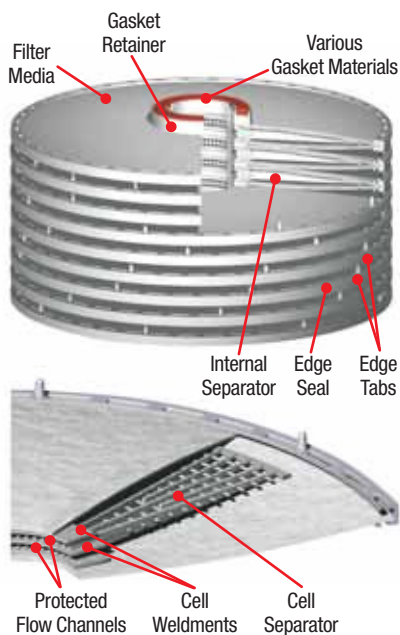
Lipid removal from human blood plasma proteins such as albumin, coagulation factors, fibrinogen, and immunoglobulins

Provide protection, enhanced performance and extended life for chromatographic columns and ultrafilters

Removal of residual lipids from serum, fermentation broths and cell culture fluids

Removal of detergents and surfactants from biologicals

Separation of hydrophobic bioprocess contaminants from aqueous solutions



All DEL filter media is available in totally-disposable BC filter capsules for lab-scale, process development or small-volume filtration. Shown are BC25 and BC1000/2000 capsule units with DEL filter media.

## DEL Disposable Capsules, DEL Filter Cartridges and DEL Filter Sheets... Configurations to Suit Every Need

DEL filter products are highly scaleable and can be used for applications ranging from milliliter laboratory volumes to production-scale cGMP manufacturing operations. Filter media is available in the following configurations:

**DEL filter Sheets:** DEL filter media is available in a range of filter sheet sizes to fit plate-and-frame filter presses (contact 3M Purification for specific sheet sizes and part numbers).

**BC Disposable DEL filter Capsules:** Zeta Plus DEL Series filters are available in three different sizes of BC disposable capsules for bench and pilot-scale filtration.

**DEL filter Cartridges and Sanitary Housings:** DEL filters are available in 8, 12, and 16-inch diameter, easy-to-use, disposable cartridges, providing effective filtration area from 0.7 ft<sup>2</sup> to 34.7 ft<sup>2</sup>. A range of sanitary design Zeta Plus filter housings is available for all sizes of DEL filter cartridges. For more information on Zeta Plus sanitary filter housings, request 3M Purification literature numbers 70-0201-8857-2 and 70-0201-8762-4.

## Zeta Plus Products: The Benchmark for Pharmaceutical & Biological Depth Filtration

Zeta Plus DEL Series filters are part of the Zeta Plus family of depth filtration products, which provide highly efficient, cost-effective clarification of turbid, difficult-to-filter biological fluids and pharmaceutical products. Zeta Plus cellulose-based depth filtration media is designed to retain contaminants by both size exclusion and adsorption. It is composed of high surface area filter aids embedded in a cellulose fiber matrix.

Zeta Plus DELI and DELP filter media incorporate added silica adsorbents, which are the active components for lipid removal. During the manufacturing process, molecules carrying a positive charge are chemically bonded to the matrix components, forming a permanent, interconnected, rigid filter sheet with positively-charged electrokinetic capture sites. The resulting porous depth filter structure is a tortuous network of adsorptive flow channels capable of retaining bacteria, endotoxin, cell debris and submicron contaminants to a level which mechanical screening alone cannot achieve. Zeta Plus depth filters provide high-efficiency submicron filtration, often surpassing the performance of pleated prefilters and competitive depth filters.

## Zeta Plus DEL Media Choices

Two different types of DEL filter media are available to suit varying application requirements. The chart below serves as a guideline for selecting the appropriate DEL media type:

Type	Lipid Removal Capacity	Optimized for Low Aluminum Extractable Levels	Optimized for Sensitive LAL* Test Procedures
DELI	Intermediate	No	No
DELP	High	Yes	Yes

\*Limulus Amoebocyte Lysate

### Recommended Operating Parameters

Nominal Porosity	0.5 to 0.8 micron
Maximum Operating Pressure	35 psid (2.4 bar)
Maximum Operating Temperature	180°F (82°C)
Recommended Rinse & Flow Rate (clean water or buffer)	5 l/ft at 0.5 gpm/ft, 50 l/m <sup>2</sup> at 20 l/m <sup>2</sup> /min
25°C Clean Water Flow Rate	0.09 gpm/ft <sup>2</sup> /psid (50 l/m <sup>2</sup> /min/bar)
In situ Steam Sterilization	121°C for 30 minutes-1 cycle

### Surface Area for Zeta Plus DELI and DELP Cartridges

Cartridge Configuration	Surface Area
BC25 Capsule	3.9 in <sup>2</sup> (25 cm <sup>2</sup> )
BC1000 Capsule	0.7 ft <sup>2</sup> (650 cm <sup>2</sup> )
BC2000 Capsule	1.4 ft <sup>2</sup> (1300 cm <sup>2</sup> )
45109 (8 diameter cartridge, 8-cell)	2.8 ft <sup>2</sup> (0.26 m <sup>2</sup> )
45167 (8 diameter cartridge, 7-cell, o-ring plug-in)	2.5 ft <sup>2</sup> (0.23 m <sup>2</sup> )
Z8FA2NPX (2-cell plug-in)	0.7 ft <sup>2</sup> (650 cm <sup>2</sup> )
Z8FA4NPX (4-cell plug-in)	1.4 ft <sup>2</sup> (1300 cm <sup>2</sup> )
45805 (12 diameter cartridge, 9-cell bodyfeed netted)	9.2 ft <sup>2</sup> (0.9 m <sup>2</sup> )
45211 (12 diameter cartridge, 15-cell netted)	15.4 ft <sup>2</sup> (1.4 m <sup>2</sup> )
45245 (12 diameter cartridge, 16-cell)	16.4 ft <sup>2</sup> (1.5 m <sup>2</sup> )
Z16P (16 diameter cartridge, 14-cell netted)	34.7 ft <sup>2</sup> (3.2 m <sup>2</sup> )

### Media Selection

3M Purification differentiates its DELI and DELP media offerings by varying the materials of construction used in their manufacture. Choice of silica type confers upon the media either a medium or a high capacity for lipids based upon the specific surface area (m<sup>2</sup>/gm) of the silica incorporated into the filter matrix. Choice of cellulose type affects the level of apparent endotoxin or Limulus Amoebocyte Lysate-Reactive Material (LAL-RM) extractables.

### LAL Reactive Material

Trace levels of cellulosic impurities (β-glucans) from several of the more useful types of cellulose interfere with some (but not all) FDA-approved LAL reagent systems designed to test for USP Bacterial Endotoxins. DELP media has been purposely formulated to alleviate this sort of interference.

### DELI and DELP Media Lipid Capacity Estimation Using Non-Ionic Surfactants

To demonstrate the ability of DELI and DELP media to remove biological hydrophobes such as lipids, lipoproteins, and detergents, two non-ionic surfactants (Tween 80 and Triton X-100) were chosen as models to characterize adsorptive binding capacities under dynamic flow-through conditions (Figures 1 and 2). Dynamic challenge conditions: media initially rinsed with 5 L/ft<sup>2</sup> water and then challenged with surfactant solution at 20°C. Methods of analysis: Isocratic RP-HPLC with UV-VIS detection.

Table 1: LAL Reactive Material (EU/ml)

% of 5 Liters/ft Rinse	DELI	DELP
EU/ml including LAL-RM		
33%	0.50	0.02
67%	0.25	0.01
100%	0.25	0.01

Figure 1: DELI & DELP Plus Media Tween® 80 Capacity

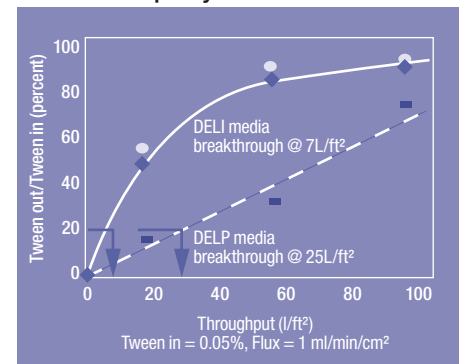
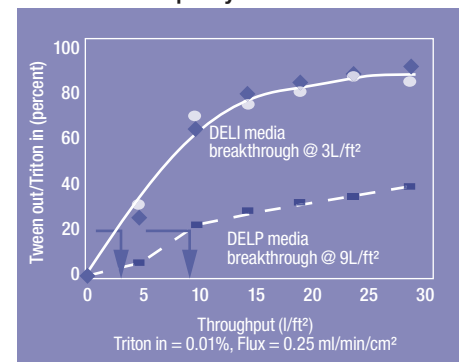


Figure 2: DELI & DELP Media Triton® X-100 Capacity



# Zeta Plus™ DEL Series Cartridge Ordering Guide

## 8" Cartridges

Catalog Number	Gasket	Delipid Formulation
45109 (8" 8-cell)	11 - Nitrile 13 - Fluorocarbon 14 - EPR 22 - Silicone	DELI DELP
45167 (8" 7-cell, O-ring plug-in)	01 - Nitrile 02 - EPR 03 - Fluorocarbon 04 - Silicone	
Z8FA2NP (2-cell plug-in) Z8FA4NP (4-cell plug-in)	A - Silicone B - Fluorocarbon C - EPR D - Nitrile	

## 16" Diameter Cartridges

Catalog Number	Gasket	Delipid Formulation
Z16P (16" 14-cell)	A - Silicone B - Fluorocarbon C - EPR D - Nitrile	DELI DELP

## 12" Diameter Cartridges

Catalog Number	Geometric Variation	Gasket	Delipid Formulation
45805 (12" 9-cell) 45211 (12" 15-cell) Netted Cartridges	01 - Standard polypropylene	A - Silicone B - Fluorocarbon C - EPR D - Nitrile	DELI DELP
45245 (12" 16-cell)	01 - Standard polypropylene	A - Silicone B - Fluorocarbon C - EPR D - Nitrile	DELP

## BC Capsules

Catalog Number	Delipid Formulation
BC0025L (Luer)	DELI DELP
BC0025S (Sanitary)	
BC1000A (single pack)	
BC1000B (3 pack)	
BC2000A (single pack)	
BC2000B (3 pack)	

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45109 11 DELI	Z16P A DELI
45109 13 DELI	Z16P B DELI
45109 14 DELI	Z16P C DELI
45109 22 DELI	Z16P D DELI
45109 11 DELP	Z16P A DELP
45109 13 DELP	Z16P B DELP
45109 14 DELP	Z16P C DELP
45109 22 DELP	Z16P D DELP
45167 01 DELI	BC0025L DELI
45167 02 DELI	BC0025S DELI
45167 03 DELI	BC1000A DELI
45167 04 DELI	BC1000B DELI
45167 01 DELP	BC2000A DELI
45167 02 DELP	BC2000B DELI
45167 03 DELP	BC0025L DELP
45167 04 DELP	BC0025S DELP
Z8FA2NP A DELI	BC1000A DELP
Z8FA2NP B DELI	BC1000B DELP
Z8FA2NP C DELI	BC2000A DELP
Z8FA2NP D DELI	BC2000B DELP
Z8FA2NP A DELP	45211 01 CDELI
Z8FA2NP B DELP	45211 01 DDELI
Z8FA2NP C DELP	45211 01 ADELP
Z8FA2NP D DELP	45211 01 BDELP
45805 01 ADELI	45211 01 CDELP
45805 01 BDELI	45211 01 DDELP
45805 01 CDELI	45245 01 ADELI
45805 01 DDELI	45245 01 BDELI
45805 01 ADELP	45245 01 CDELI
45805 01 BDELP	45245 01 DDELI
45805 01 CDELP	45245 01 ADELP
45805 01 DDELP	45245 01 BDELP
45211 01 ADELI	45245 01 CDELP
45211 01 BDELI	45245 01 DDELP