

Zeta Plus™ DELI and DELP Series Filter Media

Zeta Plus™ DELI and DELP series comprise a family of depth filter media which incorporates lipid-specific adsorbents for selective reduction of lipids, surfactants and biological hydrophobes from human blood plasma, serum-based products, recombinant proteins and other biological fluids. These media types provide a range of lipid reduction capacity and functionality.

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 reduction of lipids via depth filtration promotes column and membrane performance and extends their useful life. Lipid contamination can also cause solution instability of intermediate and final protein products leading to a problematic lipoprotein haze. Zeta Plus DELI and DELP series products can replace bulk silica operations which are labor-intensive, messy and difficult to prepare.

Zeta Plus DELI and DELP series filter media may be used to separate lipids within the following lipid classes: mono-, di-, and triglycerides, fatty acids, cholesterol, phospholipids, and lipoproteins.



Applications

Lipid reduction 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

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

Reduction of detergents and surfactants from biologicals

Separation of hydrophobic bioprocess contaminants from aqueous solutions

Features & Benefits

Two different media formulations available for varying degrees of lipid reduction.

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

Variety of cartridge sizes, disposable capsules and filter sheets.

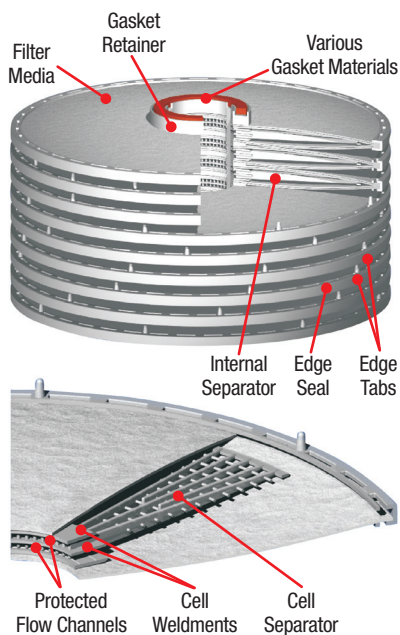
- Highly scaleable.
- Flexible options for all flow and batch volume requirements.

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.

- USP <88> Class VI Biological Reactivity Tests Compliant



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

Filters using Zeta Plus™ DELI and DELP series media are part of the Zeta Plus family of depth filtration products, which provide cost-effective clarification of turbid, difficult-to-filter biological fluids and pharmaceutical products. Zeta Plus cellulose-based depth filtration media are 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 reduction. 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 Delipid Media Choices

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

Type	Lipid Reduction Capacity	Optimized for Sensitive LAL* Test Procedures
DELI	Intermediate	No
DELP	High	Yes

* *Limulus* Amoebocyte Lysate



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

Media Selection

3M 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 (m²/g) 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 bacterial endotoxins. DELP media has been purposely formulated to alleviate this sort of interference.

Table 1: LAL Reactive Material (EU/ml)

Rinse Volume l/m ²	DELI	DELP
EU/ml including LAL-RM		
17.9	0.50	0.02
35.9	0.25	0.01
53.8	0.25	0.01

Table 2: Recommended Operating Parameters

Nominal Porosity	0.5 to 0.8 micron
Maximum Operating Pressure	2.4 bar (35 psid)
Maximum Operating Temperature	82°C (180°F)
Minimum Required Pre-conditioning Flush	54 L/m ² (1.3 gal/ft ²) with water, or other suitable fluid, at a volumetric flow rate up to 1200 L/m ² /hr
25°C Clean Water Flow Rate	50 l/m ² /min/bar (0.09 gpm/ft ² /psid)
In situ Steam Sterilization	121°C (250°F) for 30 minutes-1 cycle

Table 3: Surface Area for Zeta Plus™ DELI and DELP Cartridges and Capsules

Cartridge Configuration	Surface Area
BC25 Capsule	25 cm ² (3.9 in ²)
45109 (8 diameter cartridge, 8-cell)	0.26 m ² (2.8 ft ²)
45167 (8 diameter cartridge, 7-cell, o-ring plug-in)	0.23 m ² (2.4 ft ²)
Z8FA2NPX (2-cell plug-in)	650 cm ² (0.7 ft ²)
Z8FA4NPX (4-cell plug-in)	1300 cm ² (1.4 ft ²)
45805 (12 diameter cartridge, 9-cell bodyfeed netted)	0.9 m ² (9.2 ft ²)
45211 (12 diameter cartridge, 15-cell netted)	1.4 m ² (15.4 ft ²)
45245 (12 diameter cartridge, 16-cell)	1.5 m ² (16.4 ft ²)
Z16P (16 diameter cartridge, 14-cell netted)	3.2 m ² (34.7 ft ²)

Single-Use Capsules, Filter Cartridges & Sanitary Housings and Filter Sheets

Zeta Plus™ DELI and DELP series filter products are scaleable and can be used for applications ranging from milliliter laboratory volumes to production-scale cGMP manufacturing operations. Filter media are available in the following configurations:

Single-Use Capsule Filters: Zeta Plus DELI and DELP filter media are available in a laboratory scale disposable capsule for bench filtration: (BC25). The Zeta Plus Encapsulated System includes capsule filters with effective filtration areas at 170 cm² (0.18 ft²), 340 cm² (0.37 ft²), 0.23 m² (2.4 ft²), 1.6 m² (17.1 ft²)*, and 2.5 m² (27.0 ft²)*. They are ideal for both the scale-up studies as well as large scale production. For more information on the Zeta Plus Encapsulated System, please refer to 3M literature 70-0202-3967-2.

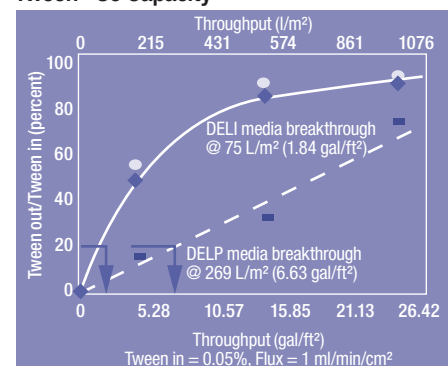
Filter Cartridges & Sanitary Housings: Filter cartridges are available in 8", 12", and 16" diameters, easy-to-use, disposable cartridges, providing effective filtration area from 0.06 m² to 3.2 m² (0.7 ft² to 34.7 ft²). A range of sanitary design Zeta Plus filter housings is available for all sizes of DELI and DELP series filter cartridges. For more information on Zeta Plus sanitary filter housings, request 3M literature numbers 70-0201-8857-2 and 70-0201-8762-4.

Filter Sheets: Zeta Plus DELI and DELP series filter media are available in a range of filter sheet sizes to fit plate-and-frame filter presses (contact 3M for specific sheet sizes and part numbers).

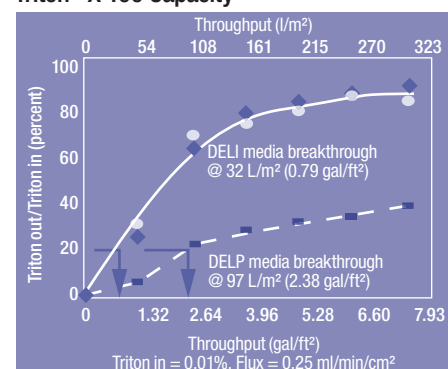
DELI and DELP Media Lipid Capacity Estimation Using Non-Ionic Surfactants

To demonstrate the ability of DELI and DELP media to reduce 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 54 L/m² (1.32 gal/ft²) water and then challenged with surfactant solution at 20°C. Methods of analysis: Isocratic RP-HPLC with UV-VIS detection.

Graph 4: DELI & DELP Plus Media Tween® 80 Capacity



Graph 5: DELI & DELP Media Triton® X-100 Capacity



* 1.6 m² double layer and 2.5 m² for single layer.

Zeta Plus™ DELI and DELP Series Product Ordering Guide

8" Cartridges

Catalog Number	Gasket	Media Formulation
45109 (8" 8-cell)	13 - Fluorocarbon 22 - Silicone	DELI DELP
45167 (8" 7-cell, O-ring plug-in)	03 - Fluorocarbon 04 - Silicone	
Z8FA2NP (2-cell plug-in) Z8FA4NP (4-cell plug-in)	A - Silicone B - Fluorocarbon	

12" Diameter Cartridges

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

16" Diameter Cartridges

Catalog Number	Gasket	Media Formulation
Z16P (16" 14-cell)	A - Silicone B - Fluorocarbon	DELI DELP

BC Capsules

Catalog Number	Media Formulation
BC0025L (Luer) BC0025S (Sanitary)	DELI DELP

Product Use

Identified uses: Manufacturing of pharmaceutical (drug) products, including active pharmaceutical ingredients and vaccines.

Prohibited uses: As a component in a medical device that is regulated by any agency, and/or globally exemplary agencies, including but not limited to: a) FDA, b) European Medical Device Directive (MDD), c) Japan Pharmaceuticals and Medical Devices Agency (PMDA); Applications involving permanent implantation into the body; Life-sustaining medical applications; Applications requiring FDA Food Contact compliance without use restrictions

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