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3M Separation and Purification Sciences

3M™ Zeta Plus™ Depth Filters

High performance, scalable,
single-use system

3M™ Zeta Plus™ Encapsulated System

The system of choice for single-use depth filtration

High performance filter media

The 3M™ Zeta Plus™ Encapsulated System utilises the high performing Zeta Plus depth filter series media, including the single and dual layer.

- ▶ Positive charge is capable of reducing negatively charged DNA, endotoxins and other host cell proteins
- ▶ The 3M™ Zeta Plus™ dual layer media enhances the contaminant holding capacity of the filter media. This allows for larger particles to be trapped in the upstream zone of the more open filter media and smaller particles to be trapped in the downstream zone, reducing premature plugging and helping extend service life of the media
- ▶ Can be used for post fermentation cell culture clarification or downstream impurity removal
- ▶ Can be employed independently or in conjunction with centrifugation or tangential flow filtration (TFF)

3M™ Zeta Plus™ Depth Filter quick start guide

Mammalian:

Application	Stage/product	
	First stage	Second stage
Post-Centrifuge operations	Centrifuge	60ZB05, 90ZB05, 90ZB08, 120ZB05, 120ZB08
Single stage operation	60SP02	-
Dual stage operation	05SP01, 10SP02, 30SP02	60ZB05, 90ZB05, 90ZB08, 120ZB05

Bacteria:

Application	Stage/product	
	First stage	Second stage
Lysate	30SP02	90SP08, 90ZB08
Cantrate (after lysis)	60ZB05, 90ZB05	90ZB08
Solubilisate	10SP02	60SP05, 60ZB05
Inclusion body refold	60ZB05	90ZB08
Renaturate	60ZB05	

Plasma:

Application	Stage/product	
	First stage	Second stage
Precipitate	05SP	60LA, 60SP
Supernatant	50LA, 60SP	90LA, 90SP
Redissolved precipitate	90LA, 90SP	
Polysorbate/lipid reduction	DELP, DELI, DELP08	

Media series

SP media	LA media	ZB media
Widest range	Cleanest	Highly charged
SP has the widest nominal pore size range relative to other 3M™ Zeta Plus™ media offerings, including a greater number of grades as well as grades with larger nominal pore sizes than LA or ZB media.	LA is the cleanest 3M™ Zeta Plus™ media family offered. 3M™ Zeta Plus™ LA series low aluminium (LA) filter media are designed to provide low levels of extractables, especially aluminium.	ZB media offers a higher charge level than SP or LA media, and offers single layer and dual layer grades with a smaller nominal pore size than either the SP media family or the LA media family.

Nominal retention rating guide

Pore size options: 3M™ Zeta Plus™ SP, LA and ZB Media

Media family				
Grades	SP	ZB	LA	Application
5	X			Primary
10	X			
30	X	X	X	
50			X	Secondary
60	X	X	X	
90	X	X	X	Centrate
120		X		

For reference only. Retention ratings may vary depending on application.

Features and benefits

Capsule/manifold design

Translucent plastic shell (standard capsules, polycarbonate shells)	▶ Easy detection of the liquid level inside, providing real time monitoring of the filtration process
Fully encapsulated shell around solid core	▶ Eliminates the need for a stainless steel housing and the cleaning step after filtration
Self guiding locking mechanism	▶ Fast and reliable capsule-to-capsule connectivity
Lenticular style capsule design	▶ Consistency between single-use and conventional depth filtration



Top manifold



Bottom manifold



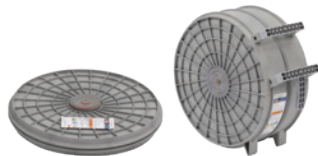
Small 0.23m² capsule (with double-layer or single-layer media)



Large capsule
 • 1.6m² with double-layer media
 • 2.5m² with single-layer media



3M™ Zeta Plus™ Capsules: encapsulated standard capsule with polycarbonate shells



3M™ Zeta Plus™ Capsules: encapsulated capsule with alkaline resistant* polyphenylene oxide/polystyrene

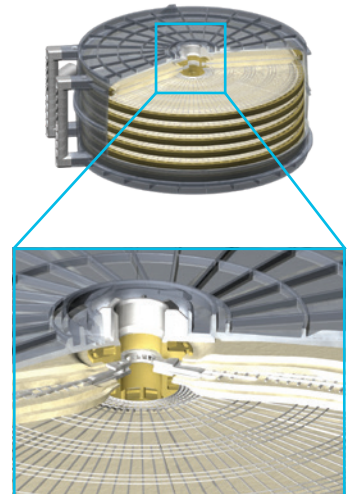


3M™ Zeta Plus™ Capsule Family

3M™ Zeta Plus™ Filter Media



Model# 16EZB



- ▶ Both single and dual layer Zeta Plus filter media are available
- ▶ Excellent performance in throughput and filtration efficiency with proper media selection and sizing
- ▶ The 3M™ Zeta Plus™ Encapsulated System is a single use depth filtration system
- ▶ The complete system is comprised of a holder, two manifolds and the desired number of capsules
- ▶ The polycarbonate capsules feature a translucent shell that allows for easy fluid level observation
- ▶ A self-guiding locking mechanism ensures fast and reliable capsule-to-capsule connection (see below)



* Based on testing with 1M NaOH and 5% NaClO (bleach).

3M™ Zeta Plus™ Encapsulated System

The system of choice for single-use depth filtration

Ergonomically designed large filter holders

Traditional depth filtration systems utilize lenticular style cartridge filters and a vertical filtration flow path to allow easy access to process liquids and efficient utilisation of filter media. However, stacking cartridges from bottom to top can be cumbersome, and dismantling the spent cartridges is often labour intensive.

Features and benefits

Ergonomically designed holder system

3M™ Encapsulated System Holder, Large (Model #16EZB): holder is pivoted between horizontal and vertical positions

- ▶ Enables loading and unloading at waist height
- ▶ Central inlets and outlets minimise fluid spills during post use handling
- ▶ Holder and capsule design allows the combination of multiple 3M Zeta Plus media types or even multiple 3M filtration products in a single holder

Vertical flow path

- ▶ Reduced footprint during operation



Recognising the need for a depth filtration system that is fast, easy and clean, 3M designed filter holders (Model# 16EZB) that can be pivoted between the horizontal position for loading and unloading the capsules and manifolds, and the vertical position for filtration. Allowing loading and unloading at waist height eliminates the need for operators to lift capsules above their heads and reduces the risk of fluid spills when handling spent capsules. The use of the vertical flow path allows for full media utilisation and a small system footprint during filtration.

3M™ Encapsulated System Holders, Small (Model# 16EZA)

The small holder is available for laboratory and pilot scale-up studies, in addition to low volume production filtration. The 1-high holder can accommodate from one to four 0.23m² capsules, or one 1.6m² (dual layer) or 2.5m² (single layer) capsule. A spacer is available as a spare part to allow for other configurations. The 3 high holder can accommodate up to three 1.6m² (dual layer) or 2.5m² (single layer) capsules. Either single stage or two-stage depth filtration can be performed within the same holder. Both 1-high and 3-high holders can be provided with an optional built-in torque limiter as an accessory that will signal the operator when the holder assembly is properly sealed – the torque limiter must be removed prior to autoclaving. All small holders have been designed to be fully autoclavable for applications where that may be required.

N.B. In some cases, we have to allow 3-high holders to be used in some combinations of capsules.

3M™ Encapsulated System Holders, Large (Model# 16EZB)

The large holder can accommodate up seven 1.6m² (dual layer) or 2.5m² (single layer) capsules. This holder is best suited for use in small to large production scale purification processes. However, this holder can also accommodate a single 1.6m² (dual layer) or 2.5m² (single layer) capsule should choose to use it for scale up studies.

Either single stage or two-stage depth filtration can be performed within the same holder.



Figure 1. 3M™ Zeta Plus™ Encapsulated System

Two stage operations

For two stage purification operations a second pair of manifolds is required between each stage of multistage operations. Manifold and capsule materials should always be the same.

Innovative capsule/manifold design

Two capsule configurations are available for use with the 3M™ Zeta Plus™ Encapsulated System.

- ▶ Single cell and multicell capsules are available
- ▶ Single cells have 0.23m² of filtration media
- ▶ Multicells have 1.6m² of dual layer media or 2.5m² of single layer media
- ▶ Alkaline resistant capsules available
- ▶ Dual stage filtration can be performed in the same holder by using an additional set of manifolds

*Based on testing with 1M NaOH and 5% NaClO (bleach).

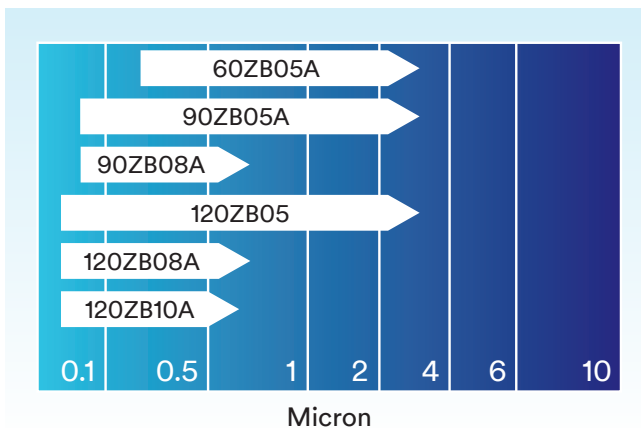


Figure 2a. Nominal retention ratings for 3M™ Zeta Plus™ ZB Series Dual Layer Grades

(For reference only. Retention ratings may vary depending on application.)

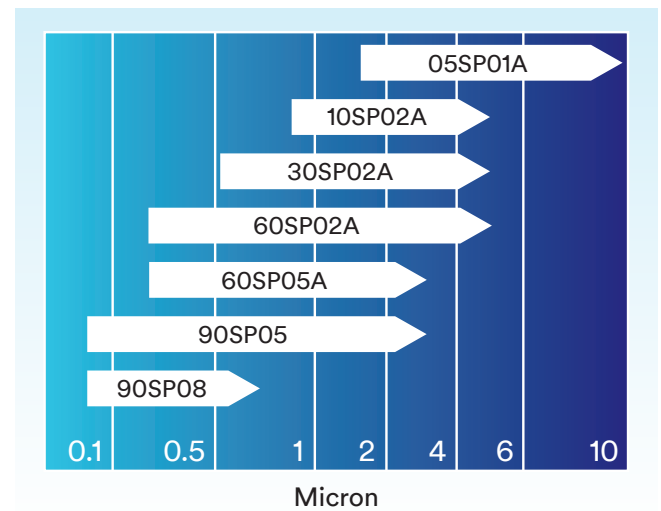


Figure 2b. Nominal retention ratings for 3M™ Zeta Plus™ SP Series Dual Layer Grades

(For reference only. Retention ratings may vary depending on application.)

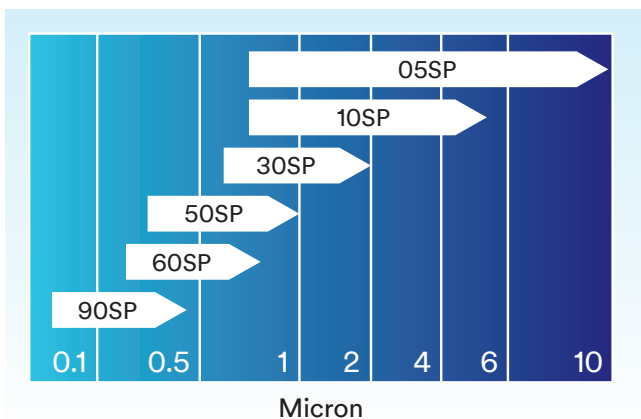


Figure 2c. Nominal retention ratings for 3M™ Zeta Plus™ SP Series Single Layer Grades

(For reference only. Retention ratings may vary depending on application.)

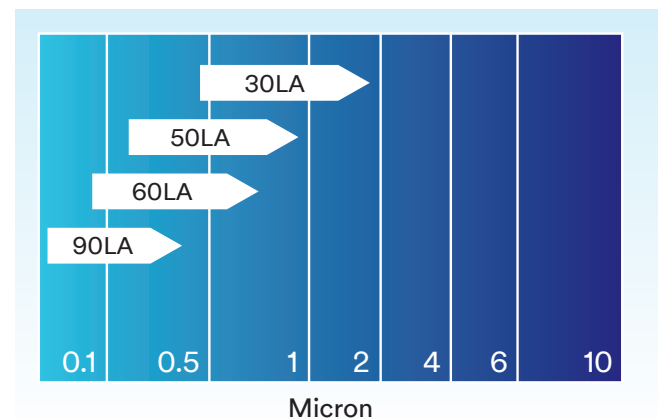
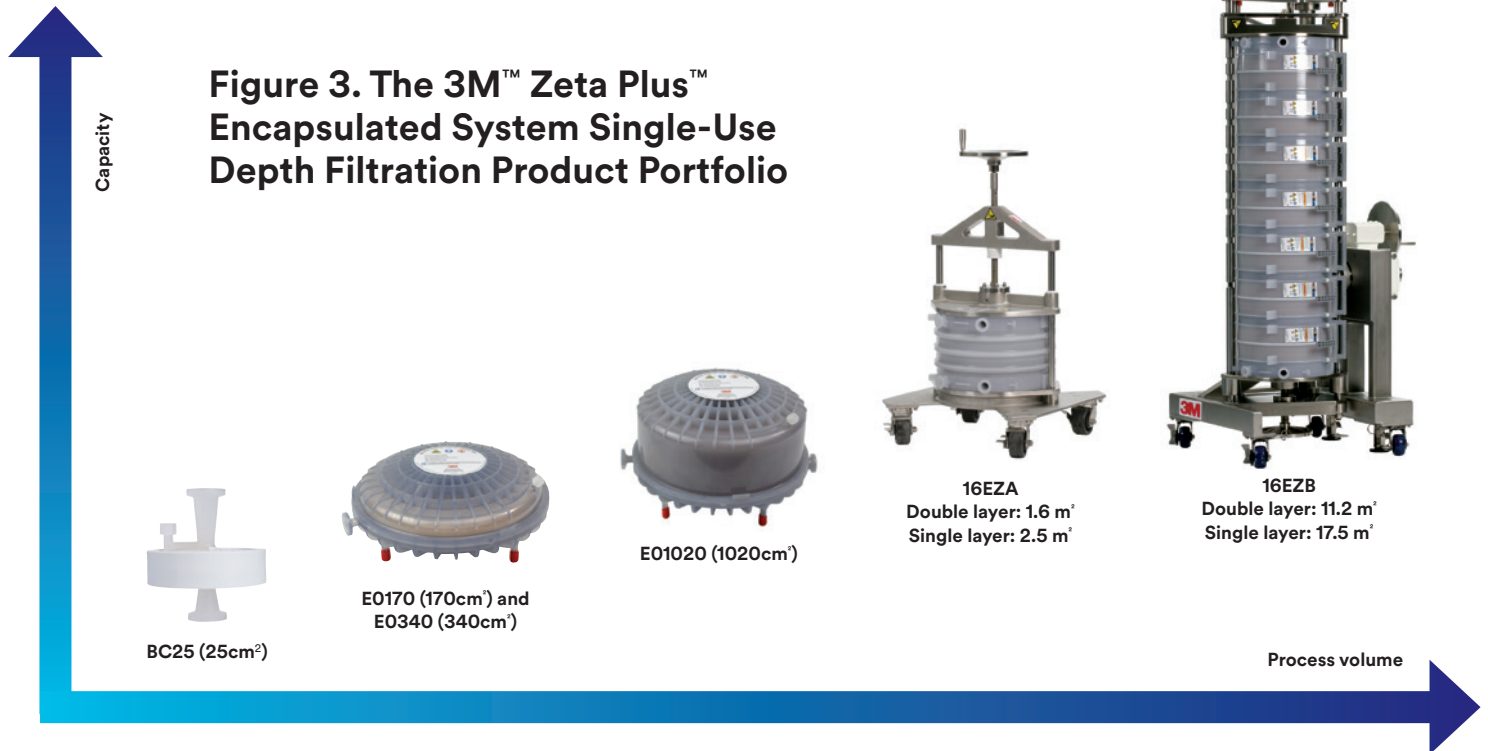


Figure 2d. Nominal retention ratings for 3M™ Zeta Plus™ LA Series Single Layer Grades

(For reference only. Retention ratings may vary depending on application.)

Scalability

The 3M™ Zeta Plus™ Encapsulated System retains the lenticular filter design and vertical flow path that are characteristics of traditional depth filtration systems. A full range of 3M™ Zeta Plus™ capsules is available from benchtop to production scale, which allows for lab scale, pilot testing and scale-up with the same filtration media.



Surface area and scaling factor

Device	Area (cm ²)	Scaling factor	Device	Area (cm ²)	Scaling factor
BC0025	25	N/A	E16-01	2300	2
E0170	170	7	E16-07	16000	7
E0340	340	2	E16-11	25000	11
E1020	1020	3			

Table 2a. 3M™ Zeta Plus™ Laboratory Capsules: filter specifications

	BC25, Luer		BC25, Sanitary	
Dimensions				
Single layer (height by diameter)	6.5cm × 7.6cm (2.6 inches × 3 inches)		7.9cm × 7.6cm (3.1 inches × 3 inches)	
Dual layer (height by diameter)	6.9cm × 7.6cm (2.7 inches × 3 inches)		8.3cm × 7.6cm (3.3 inches × 3 inches)	
Weight				
Dry – single layer	≈ 60g		≈ 64g	
Dry – dual layer	≈ 69g		≈ 75g	
Wet post blow-down – single layer	≈ 70g		≈ 75g	
Wet post blow-down – dual layer	≈ 86g		≈ 93g	
Materials of construction				
Shells	Polypropylene			
Ring seal (dual layer media)	Polypropylene			
Edge seal overmold	Glass fibre filled polypropylene			
Luer cap and luer-barb connector	Polypropylene			
Volume				
Capsule fill volume ¹ – single layer	≈ 17 mL			
Capsule fill volume ¹ – dual layer	≈ 25 mL			
Post blow-down hold-up volume ² – single layer	≈ 11 mL			
Post blow-down hold-up volume ² – dual layer	≈ 17 mL			
Miscellaneous				
Effective filtration area	25cm ²		25cm ²	
Connector	Luer		Can accommodate both ½" and ¾" Sanitary style	
Maximum differential pressure	2.4 bar		2.4 bar	
Recommended flow rate:	Flux (L/m ² /h)	50	100	150
	Flow rate (ml/min per device)	2	4	6

1 Volume of liquid required to fill capsule (experimentally measured).

2 Capsule post blow-down hold-up volume. Estimated volume of residual preconditioning flush liquid after air/gas blow-down, using water as the flush fluid and calculated by post-blow-down weight and flush fluid density. Actual amount depends upon exact blow-down conditions, media type in capsule, the number of capsules in the system, the process fluid, and loading level of the capsule.

Laboratory capsule filter schematics

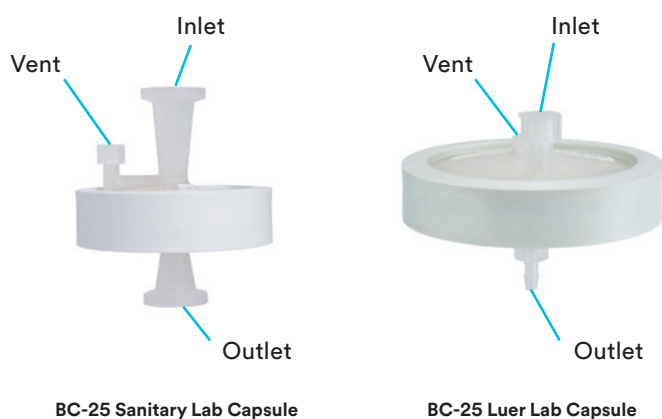


Table 2b. 3M™ Zeta Plus™ Scale-Up Capsules: filter specifications

		170cm ² Capsule			340cm ² Capsule			1020cm ² Capsule		
Dimensions										
Height × diameter		4.1" × 8.5" (10.3cm × 21.6cm)						6.0" × 8.5" (15.2cm × 21.6cm)		
Weight										
Dry – single layer		1.0kg (2.2lb)			1.0kg (2.2lb)			1.4kg (3.0lb)		
Dry – dual layer		1.0kg (2.2lb)			1.0kg (2.3lb)			1.6kg (3.5lbs)		
Wet post blow-down – single layer		1.1kg (2.4lb)			1.1kg (2.5lb)			1.8kg (4.0lb)		
Wet post blow-down – dual layer		1.2kg (2.6lb)			1.3kg (2.9lb)			2.4kg (5.2lb)		
Materials of construction										
Capsule shells		Polysulfone								
Separator, spacer, vent cap		Polypropylene								
O-ring		Fluorocarbon								
Endcap and edge seals		Thermoplastic elastomer								
Hold-up volume										
Capsule fill volume ¹	Single layer	≈ 0.67 L (≈ 1.5 gal)			≈ 0.69 L (≈ 1.5 gal)			≈ 1.7 L (≈ 3.7 gal)		
	Dual layer	≈ 0.63 L (≈ 1.4 gal)			≈ 0.65 L (≈ 1.4 gal)			≈ 1.6 L (≈ 3.5 gal)		
Post blow-down hold-up volume ²	Single layer	≈ 0.12 L (≈ 0.26 gal)			≈ 0.16 L (≈ 0.35 gal)			≈ 0.46 L (≈ 1.0 gal)		
	Dual layer	≈ 0.15 L (≈ 0.34 gal)			≈ 0.26 L (≈ 0.58 gal)			≈ 0.80 L (≈ 1.8 gal)		
Miscellaneous										
Effective filtration area		170cm ² (0.18ft ²)			340cm ² (0.37ft ²)			1020cm ² (1.10ft ²)		
Connector		1/2" Sanitary style								
Maximum differential pressure		2.4bar			2.4bar			2.4bar		
Recommended flow rate:	Flux (L/m ² /h)	50	100	150	50	100	150	50	100	150
	Flow rate (ml/min per device)	14	28	43	28	57	85	85	170	255

1 Volume of liquid required to fill capsule (experimentally measured).

2 Capsule post blow-down hold-up volume. Estimated volume of residual preconditioning flush liquid after air/gas blow-down, using water as the flush fluid and calculated by post-blow-down weight and flush fluid density. Actual amount depends upon exact blow-down conditions, media type in capsule, the number of capsules in the system, the process fluid, and loading level of the capsule.

IMPORTANT NOTICE: Always operate the filter system within the maximum differential pressure of 2.4 bar (35 psig).

Scale-up capsule filter schematics

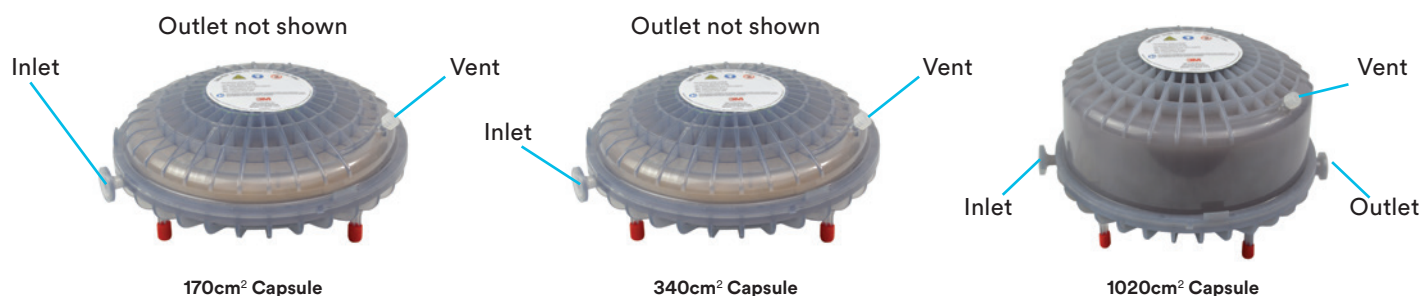


Table 2c. 3M™ Zeta Plus™ Production Capsules: filter specifications

	Configuration									
	Single cell capsule					Multi-cell capsule				
	Standard		Alkaline resistant ¹			Standard		Alkaline resistant ¹		
Dimensions (height × diameter)	5.7cm × 45.2cm (2.2" × 17.8")					20.3cm × 45.2cm (8.0" × 17.8")				
Weight										
Dry	3.3kg (7lbs)		3.4kg (8lbs)			10.0kg (22lbs)		10.7kg (24lbs)		
Wet (post blow-down)	4.4kg (10lbs)		4.8kg (11lbs)			19.3kg (43lbs)		19.7kg (43lbs)		
Materials of construction										
Filter media	Filter aids, cellulose, binding resin					Filter aids, cellulose, binding resin				
Outer shell	Polycarbonate		Polyphenylene oxide/polystyrene			Polycarbonate		Polyphenylene oxide/polystyrene		
O-rings	Silicone					Silicone				
Separators, spacers and connectors	Polypropylene					Polypropylene				
Edge seals	Thermoplastic elastomer					Thermoplastic elastomer				
Handles	N/A					Nylon				
Hold-up volume										
Capsule fill volume ²	Single layer	E16E01 & E16R01: ≈ 3.8 L (≈ 1.0 gal)				E16E11 & E16R11: ≈ 18.8 L (≈ 5.0 gal)				
	Dual layer	E16E01 & E16R01: ≈ 3.4 L (≈ 0.9 gal)				E16E07 & E16R07: ≈ 18.1 L (≈ 4.8 gal)				
Post blow-down hold-up volume ³	Single layer	E16E01 & E16R01: ≈ 0.7 L (≈ 0.2 gal)				E16E11 & E16R11: ≈ 7.5 L (≈ 2.0 gal)				
	Dual layer	E16E01 & E16R01: ≈ 1.3 L (≈ 0.4 gal)				E16E07 & E16R07: ≈ 9.0 L (≈ 2.4 gal)				
Maximum operating line pressure	3.4 bar (50 psig)					3.4 bar (50 psig)				
Maximum differential pressure	2.4 bar					2.4 bar				
Recommended flow rate:		E16E01 & E16R01			E16E07 & E16R07			E16E11 & E16R11		
	Flux (L/m ² /h)	50	100	150	50	100	150	50	100	150
	Flow rate (ml/min per device)	192	384	575	1333	2667	4000	2080	4166	6250
Effective filtration area	0.23 m ² (2.4ft ²)					Dual layer: 1.6 m ² (17.2ft ²) Single layer: 2.5 m ² (27.0ft ²)				

1 Based on testing with 1M NaOH and 5% NaClO (bleach).

2 Volume of liquid required to fill capsule (experimentally measured).

3 Capsule post blow-down hold-up volume. Estimated volume of residual preconditioning flush liquid after air/gas blow-down, using water as the flush fluid and calculated by post-blow-down weight and flush fluid density. Actual amount depends upon exact blow-down conditions, media type in capsule, the number of capsules in the system, the process fluid, and loading level of the capsule.

Single-use capsule filter schematic

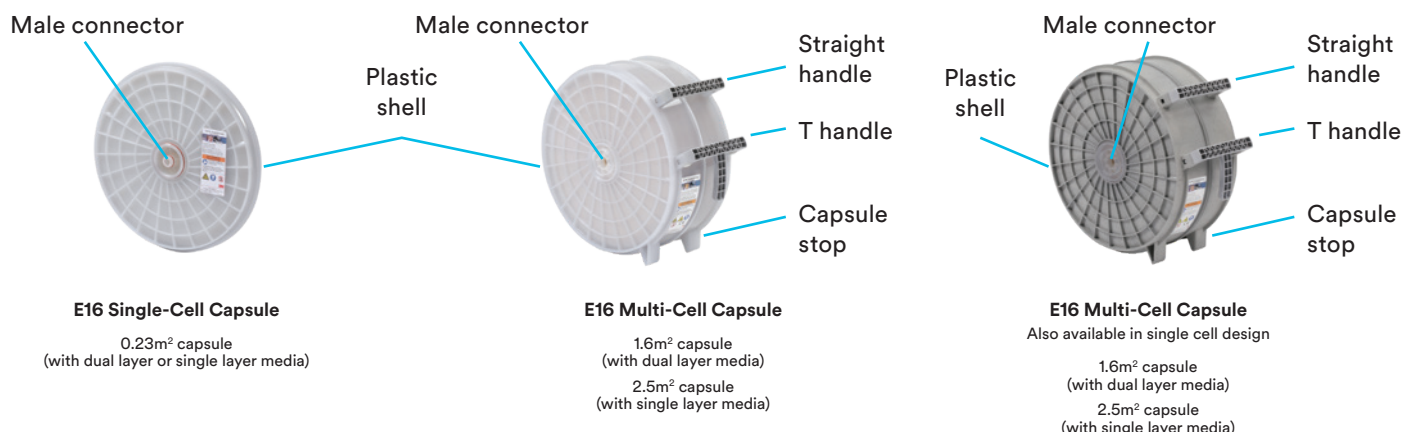
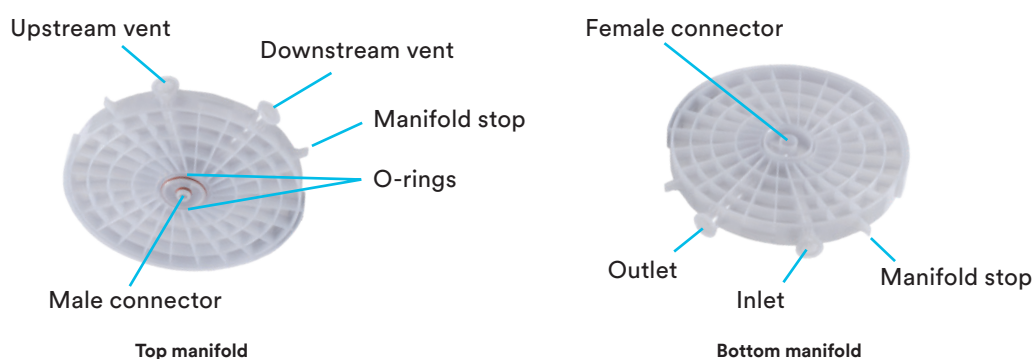


Table 2d. 3M™ Encapsulated System Manifold specifications

	Configuration	
	Standard	Alkaline resistant ¹
Dimensions (height × diameter)	5.2cm × 45.2cm (2.0" × 17.8")	
Connector	1.5" sanitary style	
Material	Polycarbonate	Polyphenylene oxide/polystyrene
Weight	4.4kg (9.6lbs)	4.7kg (10.4lbs)
Hold up volume per set	< 250 mL (<0.07 gal)	

Single-use manifold filter schematic



3M™ Zeta Plus™ Encapsulated System Spacer, 34859

	Configuration
Dimensions (height × diameter)	50 mm x 450.85 mm
Material	Polypropylene
Weight	8.1 Kg

Multi-use, no product contact

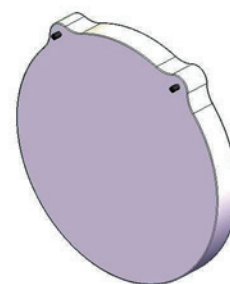


Table 3. 3M™ Encapsulated System Holder Capacity

Model	Single stage		Two stage	
	E16E01 Capsule	E16E07/E16E11 Capsule	E16E01 Capsule	E16E07/E16E11 Capsule
16EZA	4	1	2	N/A
16EZB	N/A	7	N/A	6

Table 3a. 3M™ Single Cell Capsule Capacities

Holder	Single cell capsules (E16E01, E16R01, BV800)	
	Single stage filtration (one set of manifolds)	Two stage filtration* (two sets of manifolds)
EZA, 1-high	up to 4	2
EZA, 3-high	up to 11	6 to 9 (<6 spacer is needed)

Table 3b. 3M™ Multi-Cell Capsule Capacities

Holder	Multi-Cell Capsules (E16E07, E16R07, E16E11, E16R11, BV5600)	
	Single stage filtration (one set of manifolds)	Dual stage filtration* (two sets of manifolds)
EZA, 1-high	1	N/A
EZA, 3-high	3	2
EZB	up to 7	2 to 6

* Number of 3M production capsules which will fit in a 3M holder along with two sets of 3M manifolds. For example, 2 single cell production capsules in the first stage followed by 1 single cell production capsule in the second stage meets the maximum of 3 single cell production capsules for Part Number 4552601.

Figure 9. Small Holder Family (Model# 16EZA) Dimensions

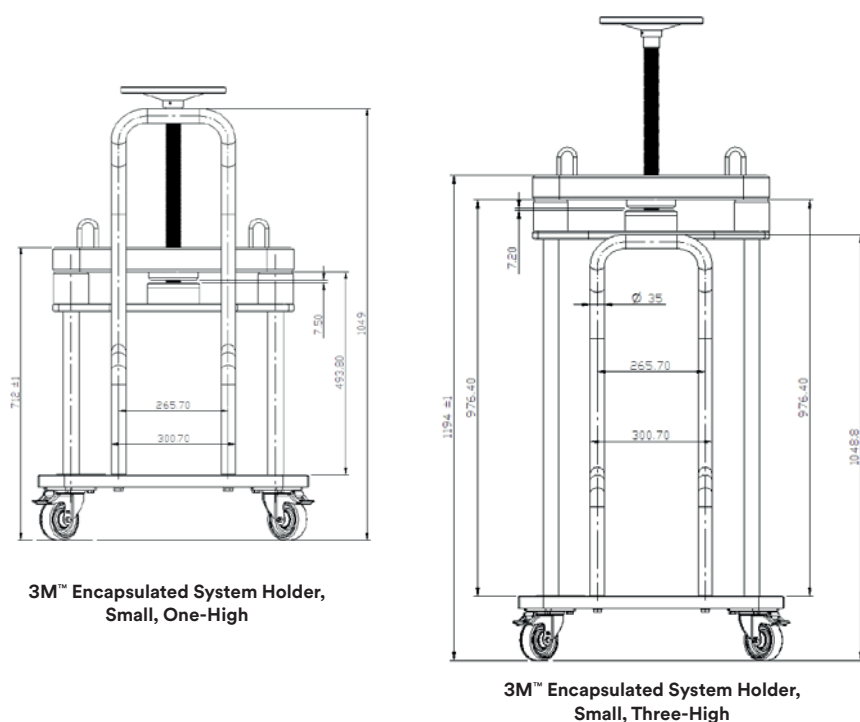
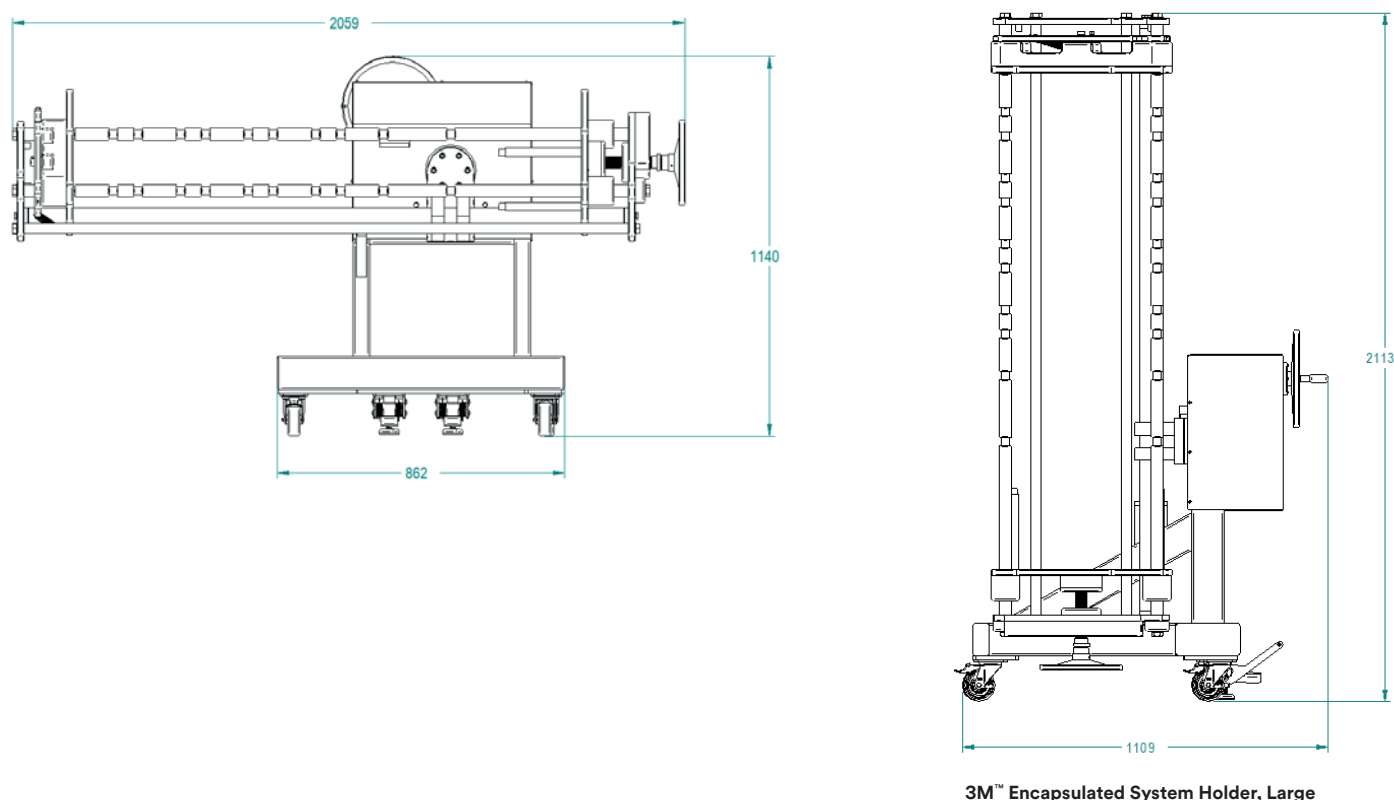


Table 4. 3M™ Encapsulated System Holder Specifications

	Holder model	
	Small holder (Model# 16EZA)	Large holder (Model# 16EZB)
Maximum operating pressure	3.46 bar	
Materials of construction		
Frame	304 stainless steel	304 stainless steel
End plates	304 stainless steel	304 stainless steel
Support rods	440 stainless steel	316 stainless steel
Stand	304 stainless steel	304 stainless steel
Hand wheels	300 series stainless steel	300 Series stainless steel
Gear box	N/A	Epoxy coated cast iron cover shrouded in 304 stainless steel
Locking bar	N/A	304 stainless steel
Casters	Stainless steel	Stainless steel
Wheels	Phenolic	Polyurethane
Material		
Standard	Mechanical polish finish (4552601)	Mechanical polish finish (6123502)
Special	Electropolish finish (4552602)	N/A

Figure 10. Large Holder (Model# 16EZB) Dimensions



Capsule ordering guide

Capsule product naming convention

E16 E 07 A 30 SP 02A

Diameter	Configuration	Number of cells	Gasket material	Lower layer	Media	Upper layer
16" Production	E – Standard R – Alkaline resistant	1, 7 or 11 Cells 1 or 11 = Single 1 or 7 = Dual	A-Silicone	05, 10, 30, 60, 90 are available for SP	SP, ZB, LA, DELI or DELP	01A, 02A, 03A, 05A, 08A indicate grade of second layer

Capsule filter ordering information – dual layer

Catalogue number	Configuration	Number of cells	Gasket material	Grade		
E16	E – Standard R – Alkaline resistant*	01 – 1 Cell 07 – 7 Cell	A-Silicone	05SP01A 10SP02A 30SP02A 30SP03A 60SP01A	60SP02A 60SP03A 60SP05A 90SP05A 90SP08A	60ZB05A 90ZB05A 90ZB08A 120ZB05A 120ZB08A 120ZB10A

Capsule filter ordering information – single layer

Catalogue number	Configuration	Number of cells	Gasket material	Grade		
E16	E – Standard R – Alkaline resistant*	01 – 1 Cell 11 – 11 Cell	A-Silicone	05SP 10SP 30SP 50SP 60SP 90SP	30LA 50LA 60LA 90LA	30ZB 60ZB 90ZB 120ZB DELI DELP

Ordering guide

Please consult your local sales team for the latest stock number.

BioCap 25 – dual layer

3M catalogue ID	EFAcm ²	Connector	Grade		
BC	0025	L (LUER) S (TC)	05SP01 10SP02A 30SP02A 30SP03A 60SP02A 60SP03A 60SP05A 90SP05A	90SP08A 60ZB05A 90ZB05A 90ZB08A 120ZB05A 120ZB08A 120ZB010A	60LA05A 90LA05A 90LA08A DELI08A DELP08A

BioCap 25 – single layer

3M catalogue ID	EFAcm ²	Material code	Grade		
BC	0025	L (LUER) S (TC)	05SP 10SP 30SP 50SP 60SP 90SP	30LA 50LA 60LA 90LA	30ZB 60ZB 90ZB 120ZB DELI DELP

Scale-up capsules – dual layer

3M catalogue ID	EFAcm ²	Material code	Grade		
E	0170 0340 1020	FSA	05SP01A 10SP02A 30SP02A 30SP03A 60SP02A 60SP03A 60SP05A 90SP05A 90SP08A	60LA05A 90LA05A 90LA08A 60ZB05A 90ZB05A 90ZB08A 120ZB05A 120ZB08A 120ZB10A	DELI08A DELP08A

Scale-up capsules – single layer

3M catalogue ID	EFAcm ²	Material code	Grade		
E	0170 0340 1020	FSA	05SP 10SP 30SP 50SP 60SP 90SP	30LA 50LA 60LA 90LA	30ZB 60ZB 90ZB 120ZB DELI DELP

* Based on testing with 1M NaOH and 5% NaClO (bleach). See Chemical Compatibility Guide (70-0202-2023-5/LITPHG03) for more information.



Intended Use: Single-use processing of aqueous based biological pharmaceuticals (drugs) and vaccines to remove biological contamination strictly following the product operating instructions and cGMP requirements, where applicable.

Prohibited Use: 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 Regulation (MDR), c) Japan Pharmaceuticals and Medical Devices Agency (PMDA); Applications involving permanent implantation into the body; Life-sustaining medical applications; Applications requiring FDA Food Contact or comparable compliance.

Product Selection and Use: Many factors beyond 3M's control and uniquely within user's knowledge and control can affect the use and performance of a 3M product in a particular application. As a result, end-user is solely responsible for evaluating the product and determining whether it is appropriate and suitable for end-user's application, including completing a risk assessment that considers the product leachable characteristics and its impact on drug and other safety conducting a workplace hazard assessment and reviewing all applicable regulations and standards (e.g., OSHA, ANSI, etc.). Failure to properly evaluate, select, and use a 3M product and appropriate safety products, or to meet all applicable safety regulations, may result in injury, sickness, death, and/or harm to property.

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