Millipore®
Expert Pharm/BioPharm
Products & CTDMO Services

Data Sheet

Millistak+® HC Pod depth filter system

High peformance modular depth filters for primary and secondary clarification operations in biopharmaceutical production

Millistak+® HC depth filter media is offered in a scalable, disposable format: the Pod filter system. Accommodating applications from lab to pilot to process-scale, the Pod format offers greater flexibility because of its modular and 100% disposable design.

The Millistak+® Pod system is ideal for a wide variety of primary and secondary clarification applications, including mammalian cell cultures, yeast and *E. coli* lysates post centrifuge, *E. coli* refolds, media, vaccines, plasma proteins and sera.

Millistak+® Pod filters are available in three distinct series of media grades in order to meet your specific application needs.

Millistak+® DE, CE and HC (high capacity) media deliver optimal performance through a gradient density matrix, as well as positive surface charge properties.

Benefits

- Low hold-up volume for greater product yield.
- Broad range of media types offered in single and multi-layer products.
- Millistak+® HC double layer media improves prefiltration and compresses clarification.
- Flexible, modular format offers scalability up to 20,000 L bioreactor volumes.
- Patented disposable design eliminates need for housing, CIP or cleaning validation.
- Self-contained Pod filters protect operators from exposure to biohazards.
- Robust construction is easy to use and set up.
- Smaller footprint facilitates use in tight spaces.
- 6 cm^2 and 20 cm^2 small surface area devices for screening and scalability studies for low feedstream volume requirements.
- Available in regionalized Optimized Packaging.

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Easy to Use

With the compact, modular design of our Millistak+® Pod system, you can increase productivity and shorten cycle times from bench to manufacturing scale.

Installation and setup of the Pod system is simple and straightforward. The unique design of the disposable adapters and disposable manifolds makes it easy to connect the Pod filters to the rest of the unit operations in the process. The self-contained and disposable system eliminates maintenance as well as cleaning validation requirements.

Configurations

- NanoPod NP6 filters (X0 grades) – 6 cm^2.
- Micro 20 filters (C0/D0/X0 grades) – 20 cm^2.
- µPod® filters (CE/DE, A0/A1/B1/F0 grades) – 23 cm^2.
- Lab-scale Pod filters – 0.027 m^2 and 0.054 m^2.
- Process-scale Pod filters:
  - Millistak+® DE and CE media – 0.11 m^2, 0.77 m^2 and 1.4 m^2.
  - Millistak+® HC media – 0.11 m^2, 0.55 m^2 and 1.1 m^2.
- Pilot-scale Pod holder – accommodates up to two process-scale Pod filters for configurations from 0.11 m^2 to 2.8 m^2, depending on media type. An optional accessory kit expands capacity to five process-scale Pod filters.
- Process-scale Pod holder – accepts from five to ten process-scale Pod filters per rack. Up to three racks can be stacked for process flexibility.
- Disposable adapter – connects Pod filters to process piping, creating a disposable flow path.
- Disposable diverter plate – enables two media grades to be processed on a single rack.

Millistak+® Depth Filter Media

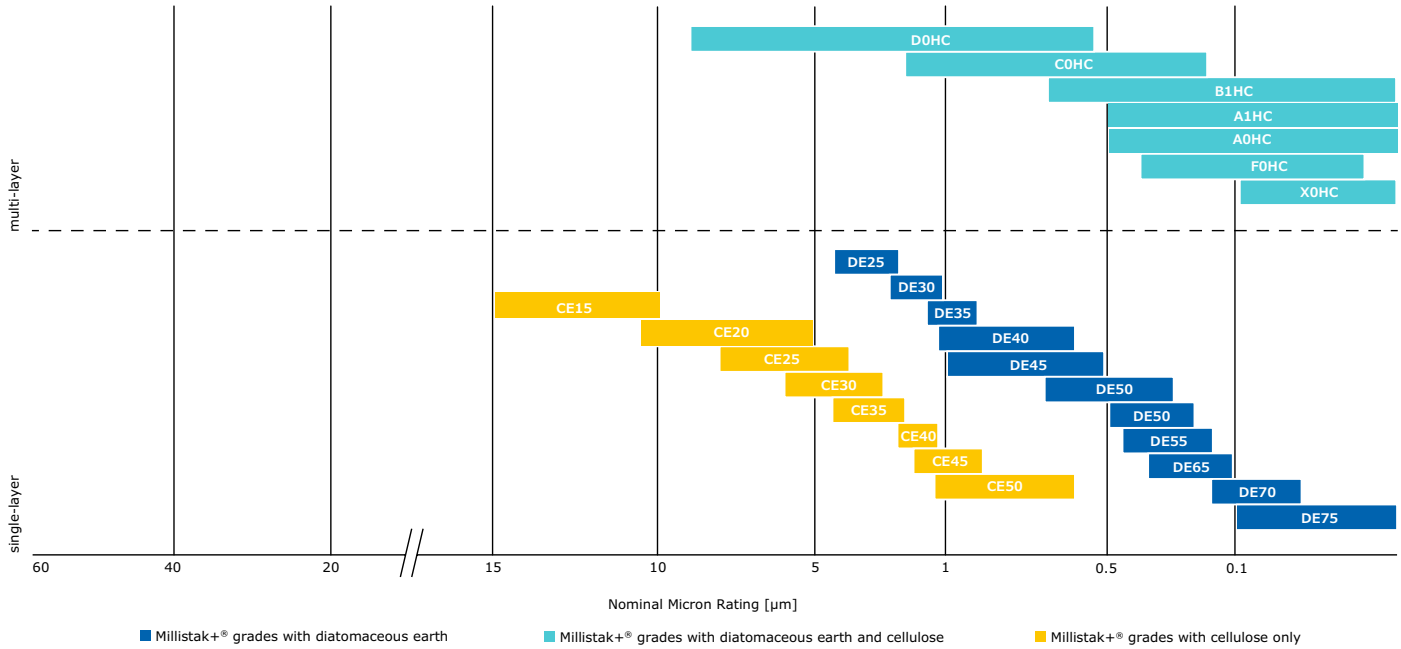
Millistak+® Pod filters incorporate multiple graded-density layers and adsorptive, positively charged filter media. Composed of select grade cellulose fiber and diatomaceous earth, the Millistak+® DE series not only improves the manufacturing process, but also increases contaminant holding. The Millistak+® CE series consists of single-layer media with cellulose fibers that are suitable for coarse filtration applications.

The Millistak+® HC series improves productivity by combining multiple media grades into one device, enabling compression of multiple filtration stages downstream of the bioreactor.

Millistak+® Pod Depth Filters are Supported by the Emprove® Program – The Smart Way to Master Compliance and Control

Complementing our product portfolio, the Emprove® Program provides convenient access to reliable technical and regulatory information in Emprove® Dossiers to support your risk assessment continuum. A subscription to our Emprove® Suite can help you stay current: In addition to accessing the Emprove® Dossiers, you can also receive notification updates to document changes, as well as generate metrics and reports.

For more information, please visit **https://sigmaaldrich.com/emprove**



Typical Extractables

	Millistak+® Single-Layer Pods (CE & DE Media)	Millistak+® HC Media (C0HC, D0HC, A1HC, A0HC, B1HC)	Millistak+® X0HC/F0HC Media
Conductivity	1.52–1.94 µS/cm post autoclave (1 cycle of 60 minutes at 123 °C) and pure water flush of 5 L/ft² (50 L/m²) of media surface area	3.64–10.5 µS/cm post autoclave (1 cycle of 60 minutes at 123 °C) and pure water flush of 10 L/ft² (100 L/m²) of media surface area	19.34–53.2 µS/cm (X0HC) and 21.4–42.7 µS/cm (F0HC) post autoclave (1 cycle of 60 minutes at 123 °C) and pure water flush of 10 L/ft² (100 L/m²) of media surface area
NVR Gravimetric Extractables	Not Tested	420–750 mg/ft² (process-scale) and 630–1251 mg/m² (lab-scale) per 24 hour static soak in pure water (type 1 DI water) post autoclave (1 cycle of 60 minutes at 123 °C) and pure water flush of 10 L/ft² (100 L/m²) of media surface area	Not Tested
TOC	910–1800 ppb post autoclave (1 cycle of 60 minutes at 123 °C) and pure water flush of 5 L/ft² (50 L/m²) of media surface area	720–4600 ppb post autoclave (1 cycle of 60 minutes at 123 °C) and pure water flush of 10 L/ft² (100 L/m²) of media surface area	1200–2800 ppb (X0HC) and 460–3200 ppb (F0HC) post autoclave (1 cycle of 60 minutes at 123 °C) and pure water flush of 10 L/ft² (100 L/m²) of media surface area
Metals	Per 24-hour static soak in 10 liters pure water post autoclave (1 cycle of 30 minutes at 123 °C) and pure water flush of 10 liters per ft² (100 L/m²) of surface area. Values based on worse case data from both process-scale and lab-scale pod devices.		

Nanopod NP6 filter:

HC (X0): 6 cm²

Micro 20:

HC (C0/D0/X0): 20 cm²

µPod® filter:

HC (A0/A1/B1/F0),
DE, CE: 23 cm²

Lab scale:

HC, DE, CE:
0.027–0.054 m²

Pilot scale:

HC: 0.11–5.5 m²
DE or CE: 0.11–7 m²

Process scale:

HC: 5.5–33 m²
DE or CE: 7–42 m²

Millistak+® Screening and Scaling devices specifications

	NanoPod NP6	Micro 20	µPod® Filter
Surface Area	6 cm^2	20 cm^2	23 cm^2
Media Grade	X0 media	C0, D0, X0 media	A0/A1/B1/F0, CE and DE media
Materials of Construction			
Filter Media	Cellulose fibers with inorganic filter aid (CE Media contains cellulose only)		
Filter Membrane	N/A	N/A	Mixed esters of cellulose (grades A1HC and B1HC only)
Pod Housings	Polypropylene		Glass-Filled Polypropylene
Inlet, Vent and Outlet Connections	Inlet: Female Luer-lock Outlet: Male Luer slip	Female Luer-lock	Female Luer-lock
Pod Dimensions			
Diameter	3.6 cm (1.4 in.)	6.4 cm (2.5 in.)	
Length			8.9 cm (3.5 in.)
Height			6.6 cm (2.6 in.)
Thickness	3.6 cm (1.4 in.)	4.3 cm (1.7 in.)	4.1 cm (1.6 in.)
Maximum Operating Pressure	30 psig (2.1 bar) at <40 °C	30 psig (2.1 bar) at <40 °C	50 psig (3.4 bar) at ≤40 °C
Maximum Differential Pressure			
Forward	30 psid (2.1 bar) at 25 °C		30 psid (2.1 bar) at 40 °C
Reverse	30 psid (2.1 bar) at 25 °C		15 psid (1.0 bar) at 40 °C
Sterilization	Integrity is maintained after 2 autoclave cycles of 60 minutes at 123 °C.		
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive Requirements cited in 21 CFR 177-182.		
Biological Reactivity	All component materials meet the criteria for Biological Reactivity Testing. These tests can be any or a combination of the following test methods: USP <88> Class VI (*in vivo*), USP <87> (*in vitro*), ISO 10993-5 (*in vitro*).		
Bacterial Endotoxin	An aqueous extraction contained less than 0.25 EU/mL as determined using the Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test or the gel-clot test as a secondary method (on filter media only), aligned with USP <85>, Ph. Eur. 2.6.14, and JP 4.01.		

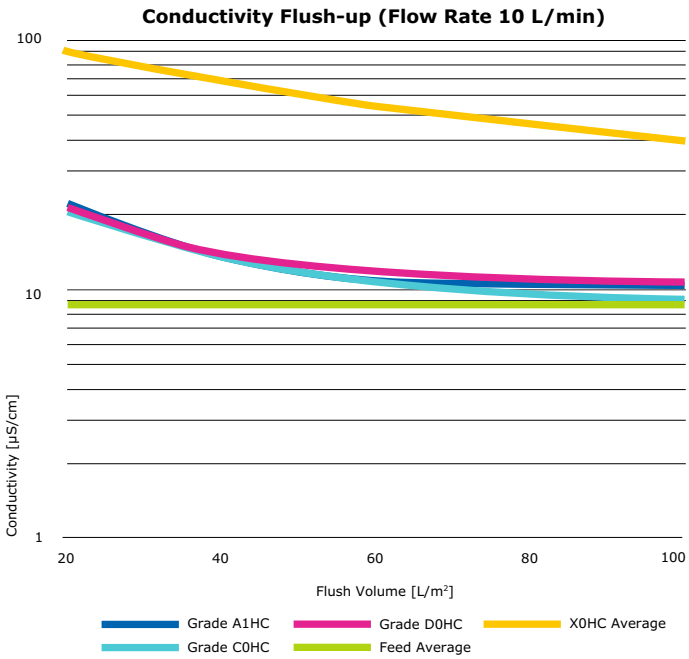
Millistak+® Lab devices and Process Scale Pod filters specifications

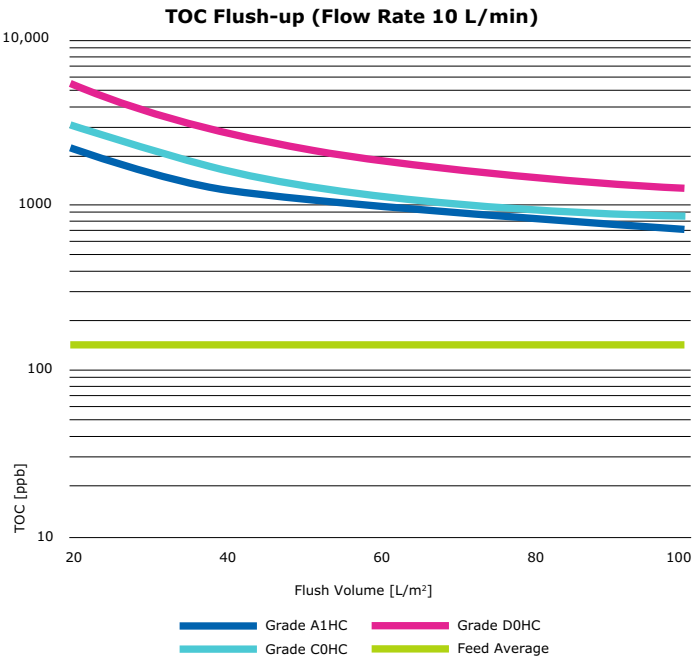
	Lab-scale Pod Filter		Multi-layer and Single-Layer Process-scale Pod Filter	Multi-layer Process-scale Pod Filter	Single-Layer Process-scale Pod Filter	Multi-layer Process-scale Pod Filter	Single-Layer Process-scale Pod Filter
Surface Area	0.027 m^2 (0.29 ft^2)	0.054 m^2 (0.58 ft^2)	0.11 m^2 (1.2 ft^2)	0.55 m^2 (5.9 ft^2)	0.77 m^2 (8.3 ft^2)	1.1 m^2 (11.8 ft^2)	1.4 m^2 (15.1 ft^2)
Media Grade	HC, CE and DE media	HC, CE and DE media	HC, CE and DE media	HC media	CE and DE media	HC media	CE and DE media
Materials of Construction							
Filter Media	Cellulose fibers with inorganic filter aid (CE Media contains cellulose only)						
Filter Membrane	Mixed esters of cellulose (grades A1HC and B1HC only)						
Pod Housings	Glass-Filled Polypropylene						
Adapters	Glass-Filled Polypropylene*						
Gaskets and Plugs	Thermo Plastic Elastomer (TPE)*						
Inlet, Vent and Outlet Connections	Hose Barb		Flat seal				
Pod Dimensions							
Length	8.5 in. (22 cm)		24.2 in. (62 cm)				
Height	5.3 in. (14 cm)		12.5 in. (32 cm)				
Thickness	2.9 in. (7.4 cm)	3.7 in. (9.4 cm)	1.2 in. (3.0 cm)	2.8 in. (7.1 cm)	3.1 in. (7.9 cm)	4.8 in. (12.2 cm)	5.0 in. (12.7 cm)
Maximum Operating Pressure	30 psig (2.1 bar) at 25 °C		50 psig (3.5 bar) at 25 °C; 15 psig (1.0 bar) at 80 °C				
Maximum Differential Pressure							
Forward	30 psid (2.1 bar) at 4 °C; 30 psid (2.1 bar) at 37 °C		30 psid (2.1 bar) at 25 °C; 15 psid (1.0 bar) at 80 °C				
Reverse	30 psid (2.1 bar) at 37 °C		30 psid (2.1 bar) at 25 °C				
Sterilization	Integrity is maintained after 2 autoclave cycles of 60 minutes at 123 °C		Integrity is maintained after 1 autoclave cycle of 60 minutes at 123 °C				
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive Requirements cited in 21 CFR 177-182.						
Biological Reactivity	All component materials meet the criteria for Biological Reactivity Testing. These tests can be any or a combination of the following test methods: USP <88> Class VI (*in vivo*), USP <87> (*in vitro*), ISO 10993-5 (*in vitro*).						
Bacterial Endotoxin	For Media Only: <0.25 EU/mL as determined by the Limulus Amoebocyte Lysate (LAL) test, aligned with USP <85>, Ph. Eur. 2.6.14 and JP 4.01.						
Pressure Equipment Directive 2014/68/EU	Devices and associated holders are designed and manufactured in accordance with the sound engineering practices (SEP) cited in Article 4(3) of 2014/68/EU.*						

* Process scale only

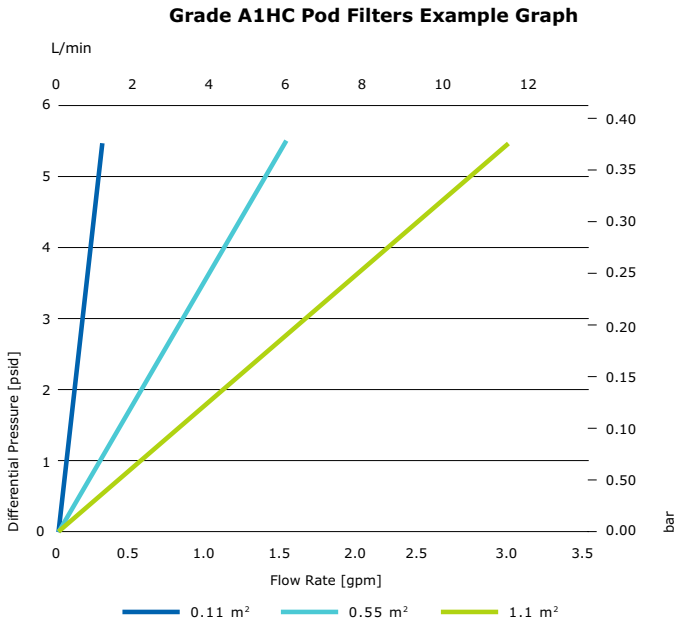
Select Millistak+® filtration media contain up to 30% pre-consumer fiber.

Conductivity/TOC





Water Permeability



Water Flow Rates

Millistak+® HC Filter Series		
Media Type/ Grade	**Water Flow Rate L/min/m² at 10 psid, 21 °C**	
D0HC	CE25	1425.8–2619.1
	DE40	454.6–835.1
C0HC	DE30	974.1–1789.3
	DE60	99.0–181.9
B1HC	DE50	212.2–389.8
	DE75	31.6–58.0
A0HC	DE60	99.0–181.9
	DE75	31.6–58.0
F0HC	DE60	99.0–181.9
	IM75	39.0–54.6
A1HC	DE60	99.0–181.9
	DE75	31.6–58.0
X0HC	IM75	39.0–54.6
	IM83	21.2–27.7

Millistak+® CE Filter Series	
Media Type/ Grade	**Water Flow Rate L/min/m² at 10 psid, 21 °C**
CE15	3054.9–5611.5
CE20	2082.6–3825.5
CE25	1425.8–2619.1
CE30	974.1–1789.3
CE35	665.5–1222.4
CE40	454.6–835.1
CE45	310.6–570.5
CE50	212.2–389.8

Millistak+® DE Filter Series	
Media Type/ Grade	**Water Flow Rate L/min/m² at 10 psid, 21 °C**
DE25	1425.8–2619.1
DE30	974.1–1789.3
DE35	665.5–1222.4
DE40	454.6–835.1
DE45	310.6–570.5
DE50	212.2–389.8
DE55	145.0–266.3
DE60	99.0–181.9
DE65	67.7–124.3
DE70	46.2–84.9
DE75	31.6–58.0

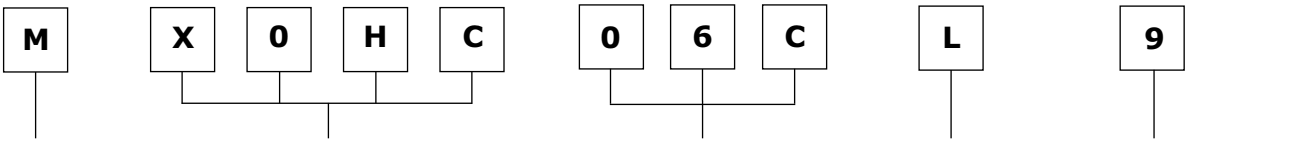
Choose the Right Media

Media Grade	Application	Characteristics	Media Construction
Single-layer CE	Primary (coarse) clarification	Cellulose fibers	CE15 to 50
Single-layer DE	Primary or secondary clarification	Cellulose fibers + inorganic filter aid	DE25 to 75
Double-layer D0HC	Primary clarification directly out of the bioreactor	A more open CE layer and DE media combination	CE25 + DE40
Double-layer C0HC	Perfusion bioreactor fluid	Two layers of a more open DE media	DE30 + DE60
Double-layer A0HC	Centrate clarification	Two layers of a tighter DE media	DE60 + DE75
Double-layer F0HC	Secondary clarification of pretreated harvest by acid precipitation or flocculation, *E. coli* and yeast	Two DE layers. Provides sterile filter protection without an RW01 membrane	DE60 + IM75
Double-layer X0HC	Secondary clarification of bioreactor harvests, primarily for cell cultures	Two DE layers. Provides sterile filter protection without an RW01 membrane	IM75 + IM83
Triple-layer A1HC	Post-TFF (Prostak™ system) clarification fluids and primary or secondary clarification	Tight media combination with an additional membrane layer to protect downstream membrane filters	DE60 + DE75 + RW01
Triple-layer B1HC	Post-centrifuge or settled permeate containing cellular particulate and primary or secondary clarification	A more open first layer with an additional membrane layer to protect downstream membrane filters	DE50 + DE75 + RW01

Note: For clarification of serum, plasma, vaccines, cell culture or other fluids, choice of media grade should be based on small-scale trials. Reference our Clarification Portfolio Guide (PB1241EN00) for additional information.

Ordering Information

Nanopod NP6



Millistak+® HC Filter

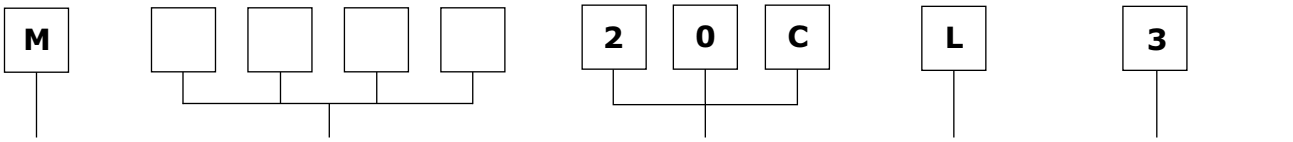
Media Type and Grade

Size
06C = 6 cm²

Connection
L = Luer Fitting

Package Quantity
9 = 9/pack

Micro 20



Millistak+® HC Filter

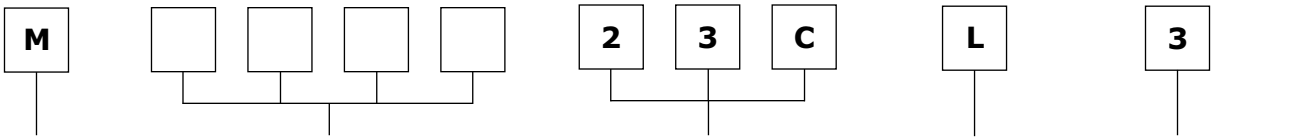
Media Type and Grade
C0HC
D0HC
X0HC

Size
20C = 20 cm²

Connection
L = Luer Fitting

Package Quantity
3 = 3/pack

µPod® Filter



Millistak+® Filter

Media Type and Grade

A1HC	CE15	CE45	DE45
B1HC	CE20	CE50	DE50
A0HC	CE25	DE25	DE55
F0HC	CE30	DE30	DE60
	CE35	DE35	DE65
	CE40	DE40	DE70
			DE75

Size
23C = 23 cm²

Connection
L = Luer Fitting

Package Quantity
3 = 3/pack

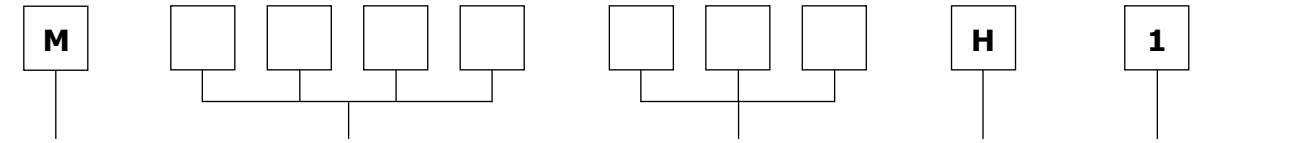
µPod® Filter Accessories

µPod® Tubing Kit Catalogue No. MTUBEKITL1

Gauge 0–60 psi and Connection Fittings Catalogue No. XXPXLGAGE

Ordering Information (continued)

Lab-scale Pod Filter



Millistak+® Filter

Media Type and Grade

A1HC	F0HC	CE30	CE50	DE40	DE60
B1HC	X0HC	CE35	DE25	DE45	DE65
A0HC	CE15	CE40	DE30	DE50	DE70
C0HC	CE20	CE45	DE35	DE55	DE75
D0HC	CE25				

Size

027 = 0.027 m^2
054 = 0.054 m^2

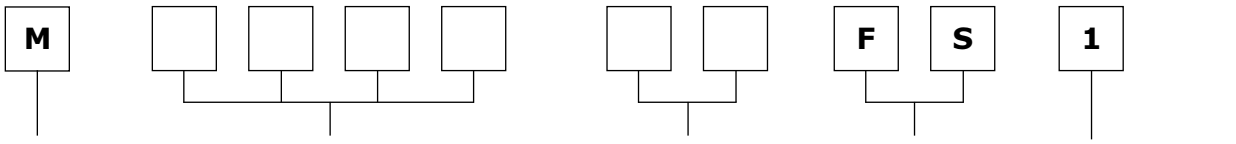
Connection

H = $^1/_4$ in. (6 mm) Hose Barb

Package Quantity

1 = 1/pack

Multi-layer Process-scale Pod Filter



Millistak+® Filter

Media Type and Grade

A1HC	C0HC	X0HC
B1HC	D0HC	F0HC
A0HC		

Size

01 = 0.11 m^2
05 = 0.55 m^2
10 = 1.1 m^2

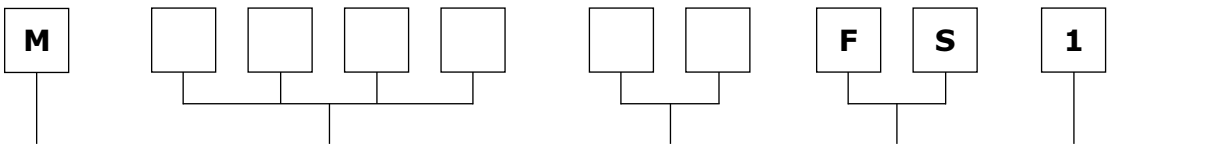
Connection

FS = Flat Seal

Package Quantity

1 = 1/pack

Single-Layer Process-scale Pod Filter



Millistak+® Filter

Media Type and Grade

CE15	CE35	DE25	DE45	DE65
CE20	CE40	DE30	DE50	DE70
CE25	CE45	DE35	DE55	DE75
CE30	CE50	DE40	DE60	

Size

01 = 0.11 m^2
07 = 0.77 m^2
13 = 1.4 m^2

Connection

FS = Flat Seal

Package Quantity

1 = 1/pack

Optimized Packaging

To improve sustainability of the packaging and shipping of filter products, optimized pack solutions for several grades of Millistak+® Process Scale Pod filters have been developed to optimize transport and receiving processes as well as to reduce waste.

Optimized packaging configurations include different quantities of pod filters distributed in 3 boxes on one regional standardized pallet size.

The key benefits are:

- 42% average reduction in corrugated packaging material per product.
- 29% decrease in the number of pallets further reducing energy use and emissions.
- 75% reduction in operator time to open and manage the product and packaging.

Optimized Packaging – North American format

Description	Item Description	Qty/Pk	Item Number
US Pallet format HDPE pallet 40 in. × 48 in. × 5.9 in.	Millistak+® HC Pod A0HC 1.1 m²	30	MA0HC10FS30
	Millistak+® HC Pod A1HC 1.1 m²	30	MA1HC10FS30
	Millistak+® HC Pod B1HC 1.1 m²	30	MB1HC10FS30
	Millistak+® HC Pod C0HC 1.1 m²	30	MC0HC10FS30
	Millistak+® HC Pod D0HC 1.1 m²	30	MD0HC10FS30
	Millistak+® HC Pod F0HC 1.1 m²	30	MF0HC10FS30
	Millistak+® HC Pod X0HC 1.1 m²	30	MX0HC10FS30

Optimized Packaging – European format

Description	Item Description	Qty/Pk	Item Number
Euro Pallet format EU Modified Heat treated (EU) Wooden CP2 1200 mm × 800 mm	Millistak+® HC Pod A0HC 1.1 m²	27	MA0HC10FS27EU
	Millistak+® HC Pod A1HC 1.1 m²	27	MA1HC10FS27EU
	Millistak+® HC Pod B1HC 1.1 m²	27	MB1HC10FS27EU
	Millistak+® HC Pod C0HC 1.1 m²	27	MC0HC10FS27EU
	Millistak+® HC Pod D0HC 1.1 m²	27	MD0HC10FS27EU
	Millistak+® HC Pod F0HC 1.1 m²	27	MF0HC10FS27EU
	Millistak+® HC Pod X0HC 1.1 m²	27	MX0HC10FS27EU

Optimized Packaging – APAC format

Description	Item Description	Qty/Pk	Item Number
Asian Pallet format HDPE Pallet 1100 mm × 1100 mm	Millistak+® HC Pod A1HC 1.1 m²	36	MA1HC10FS36AS
	Millistak+® HC Pod B1HC 1.1 m²	36	MB1HC10FS36AS
	Millistak+® HC Pod C0HC 1.1 m²	36	MC0HC10FS36AS
	Millistak+® HC Pod D0HC 1.1 m²	36	MD0HC10FS36AS
	Millistak+® HC Pod F0HC 1.1 m²	36	MF0HC10FS36AS
	Millistak+® HC Pod X0HC 1.1 m²	36	MX0HC10FS36AS

The PODs provided in bulk packaging will all be from one catalog item, all from one lot.
Millistak+® improved bulk packaging configuration was tested per the ISTA 3E and real-time ship testing. Devices were then visually inspected, and integrity tested according to the purchase specification. Testing was successful.

Catalog Numbering for Disposable Adapters

Connect Millistak+® Process-Scale Pods to process piping, creating a disposable flow path.

MP0DADAPT – disposable adapter kit with 3 through adapters and 3 blind adapters

MP0DADPTF – disposable adapter kit with 6 through adapters, required if using MP0DDIVERTR

Catalog Numbering for Disposable Diverter Plates

Enable more than one media grade on a single rack

MP0DDIVERTR – disposable diverter plates, 10/pk

Process-scale Pods require a pilot or process-scale Pod holder.
Lab-scale Pods and µPod® filters do not require a holder.

Please contact your local sales representative for more information.

For additional information, please visit **SigmaAldrich.com**
To place an order or receive technical assistance, please visit
SigmaAldrich.com/offices

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