Millipore®
Expert Pharm/BioPharm
Products & CTDMO Services

Data Sheet

Millistak+® HC Pro Depth Filtration System

Fully synthetic depth filters for clarification and downstream filtration applications

Millistak+® HC Pro filters are high capacity filters that contain synthetic depth filtration media. These disposable pod filters provide more consistent and cleaner clarification performance than current diatomaceous earth (DE) or cellulose (CE) filters. Multiple media grades are available for primary and secondary clarification as well as downstream filtration applications.

Features & Benefits

Synthetic materials of construction

- Reduced TOC extractables and a 50% reduction in the recommended pre-use flush volumes.
- No beta glucans to interfere with limulous amoebocyte lysate (LAL) testing for bacterial endotoxins.
- Lot-to-lot consistency for successful development and implementation of robust clarification processes.

Small Scale Devices

- 6 cm^2 and 20 cm^2 small area devices for screening and scalability studies reduce feedstream volume requirements.

Depth filter media formulation & design

- Provide as much as two times the filtration capacity with equivalent filter retention properties over commercial DE-based benchmarks.
- Improved HCP impurity clearance.

Disposable Pod device

- Flexible, modular format offers scalability up to 20,000 L bioreactor volume.
- Robust device format; easy to use and set up.

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.

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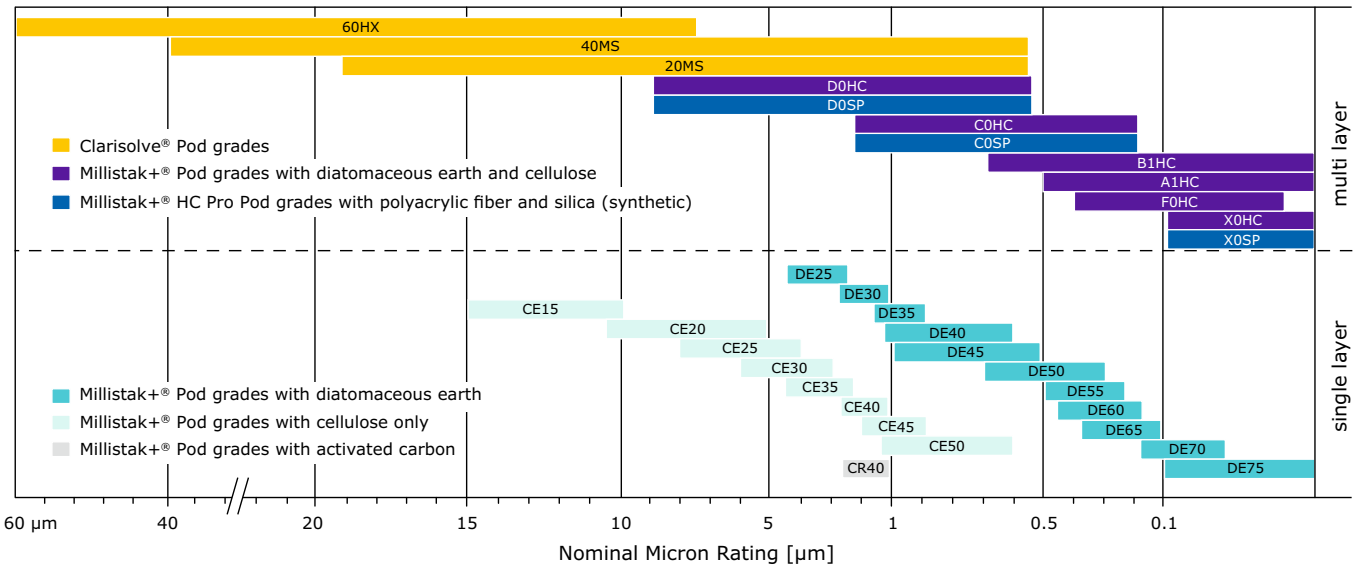
Millistak+® HC Pro Pod series

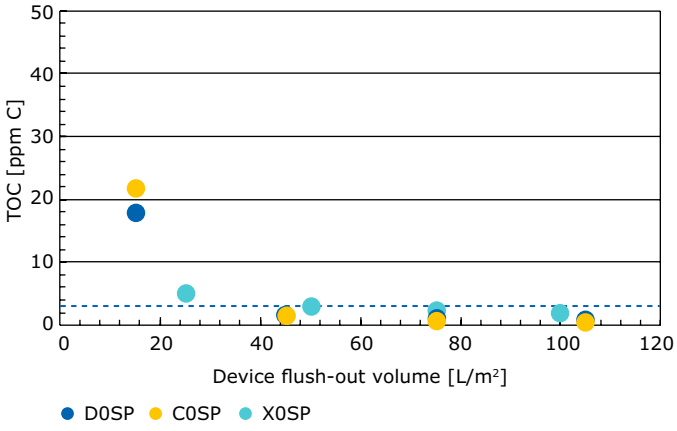
Millistak+® HC Pro synthetic depth filters are available in 3 media grades for primary and secondary clarification and downstream processing steps to protect chromatography columns.

Applications	Media Grade	Media Composition
Primary clarification (direct harvest)	**D0SP**	Four layer depth filter media which includes an upstream non-woven layer to improve filtration capacity.
Primary and secondary clarification (direct harvest, centrate)	**C0SP**	Four layer depth filter media configuration.
Secondary clarification (direct harvest and centrate), and downstream filtration	**X0SP**	Double layer depth filter media configuration.



Reduced Flushing Recommendations

The synthetic materials of construction used in Millistak+® HC Pro Pods are clean and exhibit consistent depth filtration performance with reduced TOC extractables. Pre-use flush volume recommendations are reduced by 50%.



Elimination of beta glucan interference with LAL assay

No extractable beta-glucans to interfere with LAL testing for bacterial endotoxins.

Format	Beta glucan LAL assay (pg/mL)[1]	
	Water	**Buffer**
X0HC[2]	<25.3	<80
X0SP	<LOQ	<LOQ

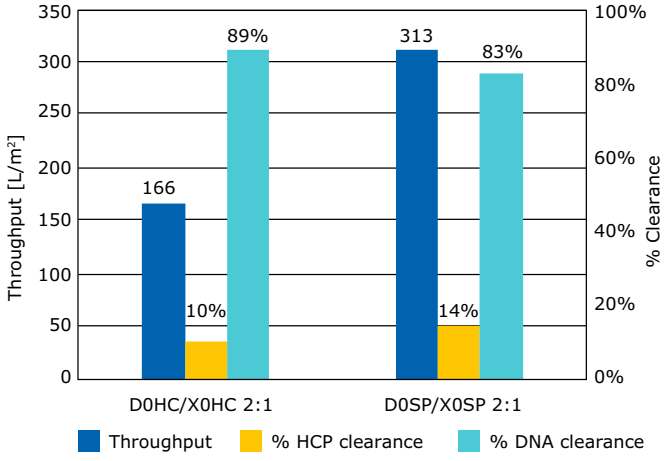
[1] Devices flushed with water/buffer, as indicated (600 LMH, 50 L/m² or 25 L/m² with buffer)

[2] X0HC is Millistak+® HC media (cellulose and diatomaceous earth based)

Enhanced Filtration Performance

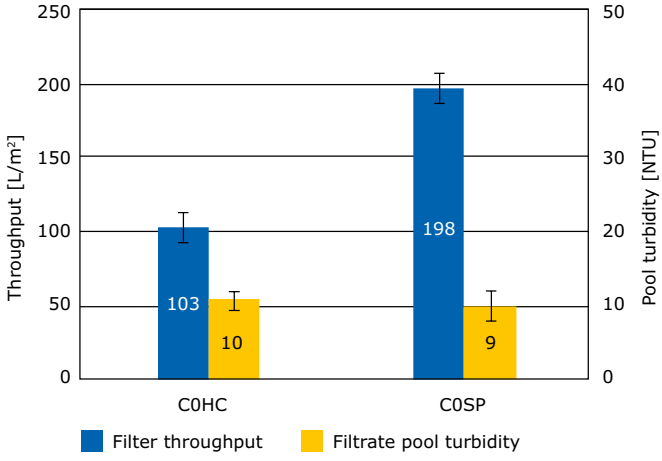
Millistak+® HC Pro synthetic depth filters provide as much as two times the filtration capacity with equivalent filter retention as compared to commercially available DE-based filter benchmarks.

Direct harvest filter capacity and impurity clearance



mAb02 feed properties: 12.4 × 10⁶ tc/mL (83% viability)

Average filtration capacity and filtrate pool turbidity



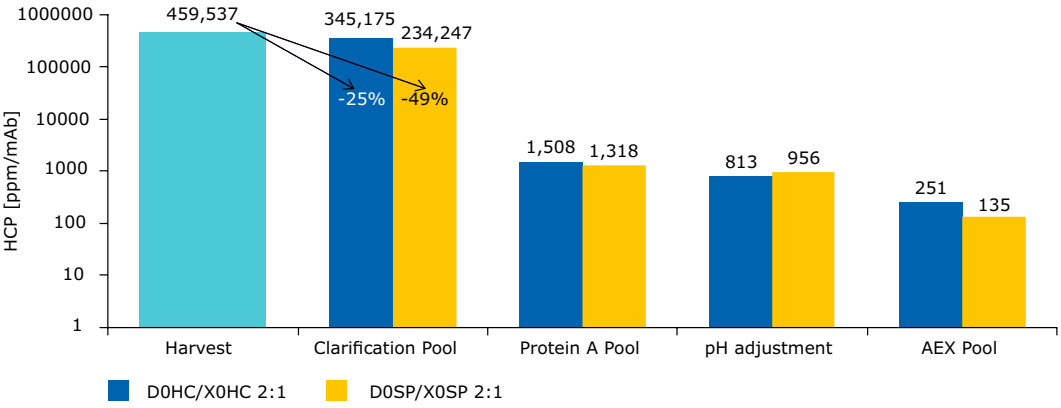
mAb05 feed properties: 9.7 × 10⁶ tc/mL (59% viability)

Impurity Clearance

Improved clearance of HCP during clarification may positively impact subsequent downstream process steps.

A slight increase in mAb product purity has been observed in both protein A bind/elute and anion exchange flow-through chromatography (AEX F/T) process steps.

Impact on impurity clearance in downstream process steps



Millistak+® HC Pro 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, regulatory and supply 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

Optimized Packaging

To improve sustainability of the packaging and shipping of filtration products, optimized pack solutions for several grades of Millistak+® HC Pro Process Scale Pod filters have been developed. These solutions improve productivity by optimizing transportation and receiving processes while reducing 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% reduction 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" × 48" × 5.9"	Millistak+® HC Pro Pod C0SP 0.77 m²	24	MC0SP07FS24
	Millistak+® HC Pro Pod D0SP 0.77 m²	24	MD0SP07FS24
	Millistak+® HC Pro Pod X0SP 1.1 m²	36	MX0SP10FS36

Optimized Packaging – APAC format

Description	Item Description	Qty/Pk	Item Number
Asian Pallet format HDPE Pallet 1100 × 1100 mm	Millistak+® HC Pro Pod C0SP 0.77 m²	24	MC0SP07FS24AS
	Millistak+® HC Pro Pod D0SP 0.77 m²	24	MD0SP07FS24AS
	Millistak+® HC Pro Pod X0SP 1.1 m²	36	MX0SP10FS36AS

The pods provided in optimized packging format will consist entirely of a single catalog item and will all come from the same lot.

Millistak+® optimized packaging configuration was tested per the ISTA 3E and real-time ship testing.

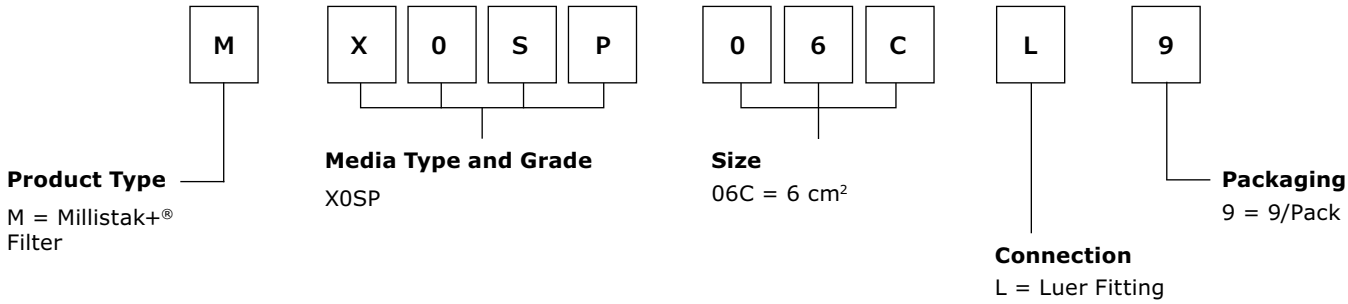
Devices were visually inspected, and integrity tested according to the purchase specification to confirm suitability of the packaging configuration.

Millistak+® HC Pro Lab Devices and Process Scale Pod Filter Specifications

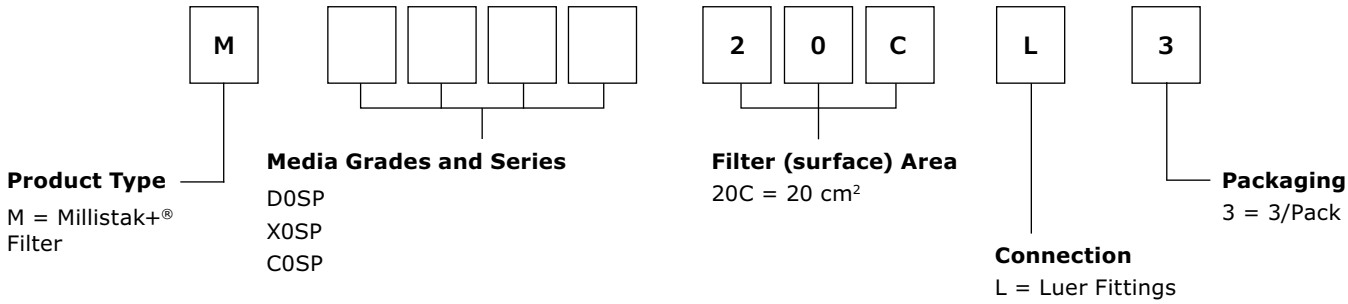
Media Grade	X0SP	X0SP / C0SP / D0SP								
Materials of Construction										
Depth Filter Media	Silica Filter Aid with Polyacrylic Fiber									
Filter Non-woven (D0SP grade only)	Polypropylene									
XOSP Media										
Housing Material	Polypropylene		Glass-Filled Polypropylene							
Inlet, Vent and Outlet Connections	Inlet: Female Luer-lock Outlet: Male Luer slip	Female Luer-lock	¼ in. (6 mm) Hosebarb		Flat seal					
Device Format (for all grades)	**Nanopod NP6**	**Micro 20**	**Lab-Scale Pod**		**Process-Scale Pod (D0SP and C0SP)**			**Process-Scale Pod (X0SP)**		
Surface Area	6 cm^2	20 cm^2	135 cm^2	270 cm^2	0.11 m^2	0.33 m^2	0.77 m^2	0.11 m^2	0.55 m^2	1.1 m^2
Pod (Device) Dimensions										
Length (cm)	-	-	21.84	21.84	61.47	61.47	61.47	61.47	61.47	61.47
Height (cm)	-	-	13.97	13.97	31.75	31.75	31.75	31.75	31.75	31.75
Diameter (cm)	3.6 cm	6.35	-	-	-	-	-	-	-	-
Thickness (cm)	3.6 cm	Single Packet: 4.19 Two Packet: 5.21	6.35	8.38	4.06	7.11	12.19	4.06	7.11	12.19
Maximum Operating Pressure	30 psig (2.1 bar) at <40 °C	30 psig (2.1 bar) at 25 °C	30 psig (2.1 bar) at ≤40 °C		50 psig (3.5 bar) at ≤80 °C					
Maximum Differential Pressure										
Forward	30 psid (2.1 bar) at 25 °C		30 psid (2.1 bar) at 40 °C		30 psid (2.1 bar) at 80 °C					
Reverse	30 psid (2.1 bar) at 25 °C				30 psid (2.1 bar) at 25 °C					
Operating Temperature Range	4 to 40 °C				4 to 80 °C					
Pre-use Sanitization	Integrity is maintained after 2 cycles of 60 minutes at 123 °C, however filtration performance may be impacted post autoclave. Recommended for post-use decontamination only.		Integrity is maintained after 1 autoclave cycle of 60 minutes at 123 °C. Filtration performance may be impacted post autoclave. Recommended for post-use decontamination only.							
Bacterial Endotoxin	An aqueous extraction contained less than 0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) clot test technique (on filter media only), according to USP <85>, Ph. Eur. 2.6.14, and JP 4.01.									
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*).									
Pressure Equipment Directive	Pressure Equipment Directive 2014/68/EU: Process-scale pod 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.									

Millistak+® HC Pro Screening and Scaling Devices:

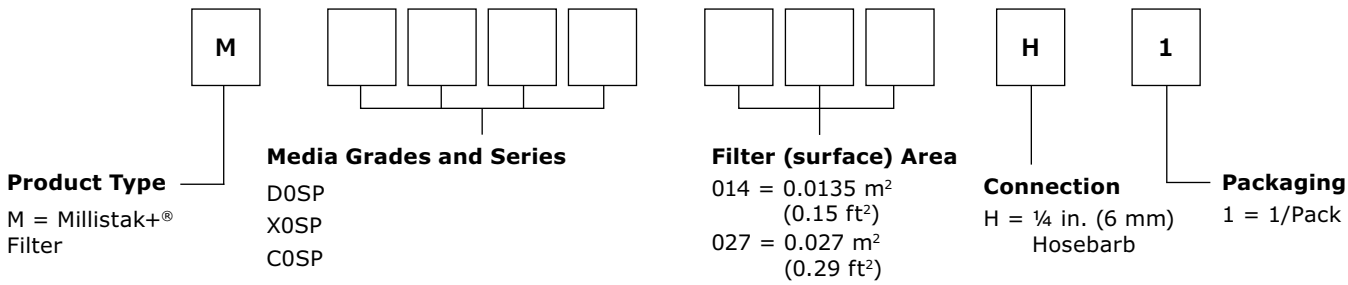
Nanopod NP6



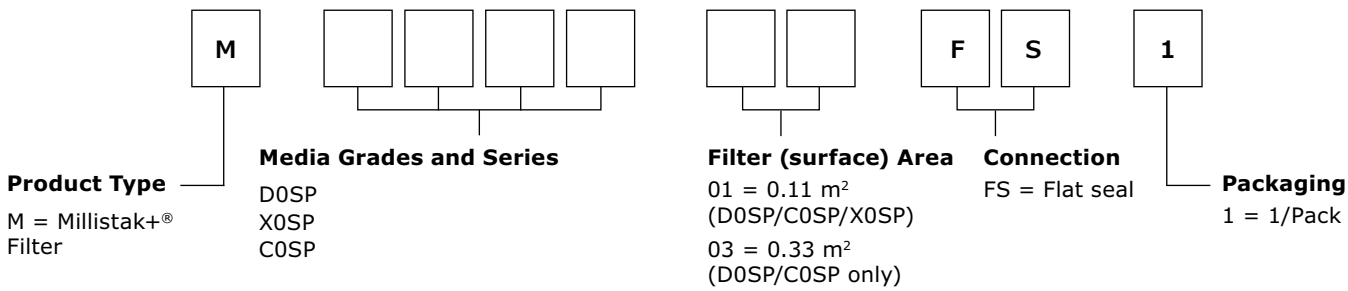
Micro 20



Millistak+® HC Pro Lab-Scale Pod:



Millistak+® HC Pro Process-Scale Pod:



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 Plate

Enable more than one media grade on a single rack
MP0DDIVERTR – disposable diverter plate, 10/pk

Read the clarification portfolio guide available at **SigmaAldrich.com** to learn more.

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

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