

Millistak+® HC Pro

Fully synthetic depth filters for clarification and downstream filtration applications.

Millistak+® HC Pro (high capacity synthetic media) is a family of synthetic depth filters providing a cleaner and more consistent depth filtration media over current diatomaceous earth (DE) and cellulose (CE) based filter offerings. 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

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

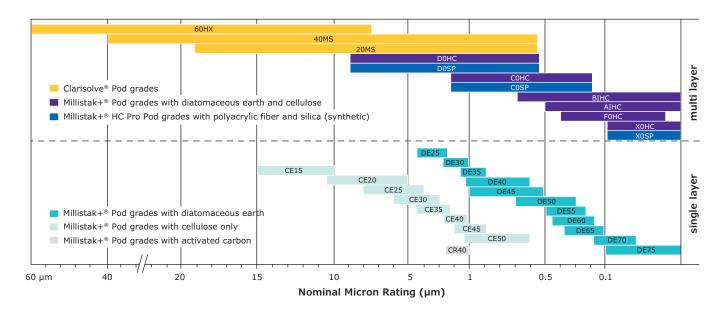
- Flexible, modular format offers scalability up to 20,000 liters
- Robust device format; easy to use and set up



Millistak+® HC Pro Pod series

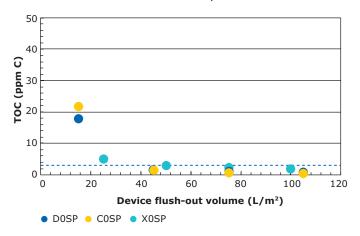
Millistak+® HC Pro synthetic depth filters are available in 3 media grades for primary and secondary clarification and downstream processing steps to protect chromatography columns.

Applications	Media Grade	Media Composition
Primary clarification (direct harvest)	DOSP	Four layer depth filter media composition which includes an upstream non-woven layer to improve filtration capacity.
Primary and secondary clarification (direct harvest, centrate)	COSP	Four layer depth filter media combination.
Secondary clarification (direct harvest and centrate), and downstream filtration	XOSP	Double layer depth filter media combination.



Reduced Flushing Recommendations

The synthetic materials of construction used in Millistak+® HC Pro Pods are clean and exhibit a 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 limulous amoebocyte lysate (LAL) testing for bacterial endotoxins.

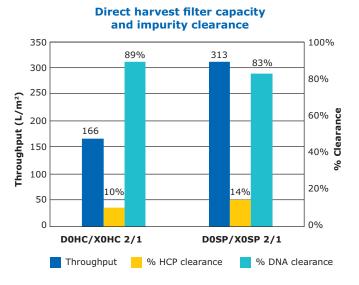
	Beta glucan LA	Beta glucan LAL assay (pg/mL) ¹					
Format	Water	Buffer					
X0HC ²	< 25.3	< 80					
X0SP	< LOQ	< LOQ					

 $^{^{1}}$ X0 devices flushed with water/buffer, as indicated (600 LMH, 50 L/m 2 or 25 L/m 2 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 of commercial DE-based benchmarks with equivalent filter retention properties.



Average filtration capacity and filtrate pool turbidity 250 50 200 40 Throughput (L/m²) 150 turbidity 198 100 20 Pool 50 10 10 0 n COSP C0HC

mAb02 feed properties: 12.4x10⁶ tc/mL (83% viability)

mAb05 feed properties: 9.7x106 tc/mL (59% viability)

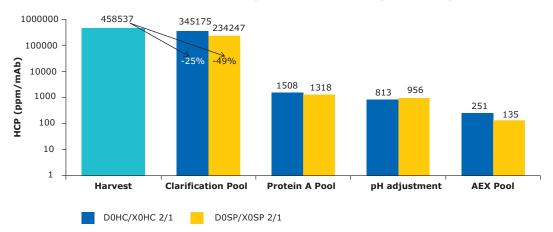
Filtrate pool turbidity

Filter throughput

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 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

Bulk Packaging

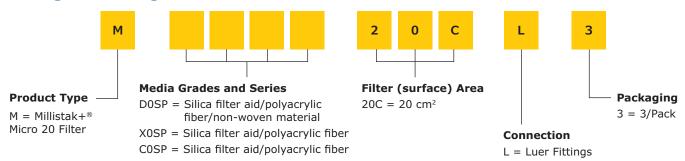
To improve sustainability of the packaging and shipping of filter products, we have developed a bulk pack solution for several grades of Millistak+® HC Pro Process-scale Pod filters with the aim to optimize transport and reception processes as well as to reduce waste. Bulk packaging configuration for COSP and DOSP includes 24 Pods in 3 boxes with 8 Pods per layer on 1 pallet. Bulk packaging configuration for XOSP includes 36 Pods in 3 boxes with 12 pods per layer on 1 pallet.

The key benefits are:

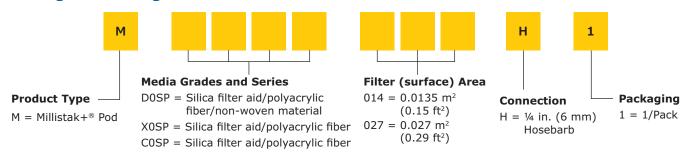
- 42% average reduction in corrugated packaging material per product
- 29% decrease in the number of pallets further reducing energy use and emissions
- 75% reduction in operator time to open and manage the product and packaging

Media Grade	DOSP / COSP / XOSP										
Materials of Construction Depth Filter Media Filter Non-woven (DOSP grade only)	Silica Filter Aid with Polyacrylic Fiber Polypropylene										
Pod Housings	Glass-Filled Polypropylene										
Micro 20 Filter Housing	Polypropylene										
Inlet, Vent and Outlet Connections	Female Luer	¼ in. (6 mm) Hosebarb									
Device Format (for all grades)	Micro 20	Lab-Scale Pod (LSP)		Process-Scale Pod (PSP) (D0SP and C0SP)		Process-Scale Pod (PSP) (X0SP)					
Surface Area	20 cm ²	135 cm²	270 cm ²	0.11 m²	0.33 m²	0.77 m²	0.11 m²	0.55 m²	1.1 m²		
Pod (Device) Dimensions Length Height Diameter Thickness	2.5 in. Single Packet: 1.65 in. Two Packet: 2.05 in.	8.6 in. 5.5 in. - 2.5 in.	8.6 in. 5.5 in. - 3.3 in.	24.2 in. 12.5 in. - 1.6 in.	24.2 in. 12.5 in. - 3.2 in.	24.2 in. 12.5 in. - 6.4 in.	24.2 in. 12.5 in. - 1.2 in.	24.2 in. 12.5 in. - 2.8 in.	24.2 in. 12.5 in. - 4.8 in.		
Maximum Operating Pressure	30 psig (2.1 bar) at 25°C	30 psid (at ≤40 °c		50 psid (3.5 bar) at ≤80 °C							
Maximum Differential Pressure Forward Reverse	30 psid (2.1 bar) at 25 °C 30 psid (2.1 bar) at 25 °C	30 psid (at 40 °C 30 psid (at 25 °C	,	30 psid (2.1 bar) at 80 °C (forward) 30 psid (2.1 bar) at 25 °C (reverse)							
Operating Temperature Range	4 to 40 °C			4 to 80 °C							
Pre-use Sanitization	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.										
Toxicity	All component materials meet the requirements of the current USP <88> biological reactivity test for class VI plastics.										
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.										

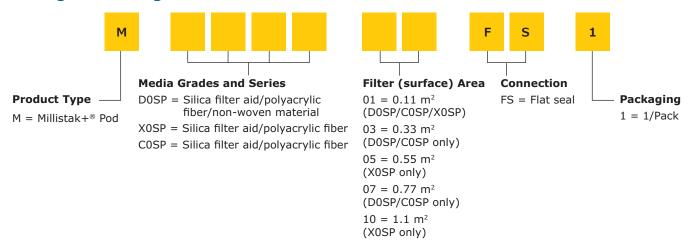
Catalog Numbering Matrix for Millistak+® HC Pro Micro 20 filter:



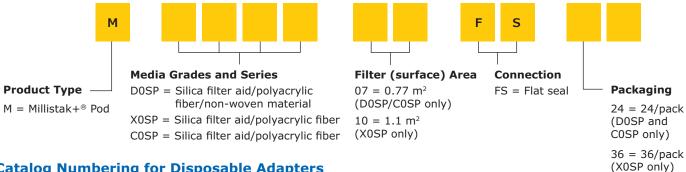
Catalog Numbering Matrix for Millistak+® HC Pro Lab-Scale Pod:



Catalog Numbering Matrix for Millistak+® HC Pro Process-Scale Pod:



Catalog Numbering Matrix for Millistak+® HC Pro Process-Scale Pod in Bulk Packaging Format:



Catalog Numbering for Disposable Adapters

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

MPODADAPT - disposable adapter kit with 3 through adapters and 3 blind adapters

MPODADPTF - disposable adapter kit with 6 through adapters, required if using MPODDIVERTR

Catalog Numbering for Disposable Diverter Plate

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

MilliporeSiama 400 Summit Drive Burlington, MA 01803

For additional information, please visit SigmaAldrich.com

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

