

# Millistak+<sup>®</sup> HC Pro Depth Filtration System

Fully synthetic depth filters for clarification and downstream filtration applications

Millistak+<sup>®</sup> 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 limulus 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<sup>2</sup> and 20 cm<sup>2</sup> small surface 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.

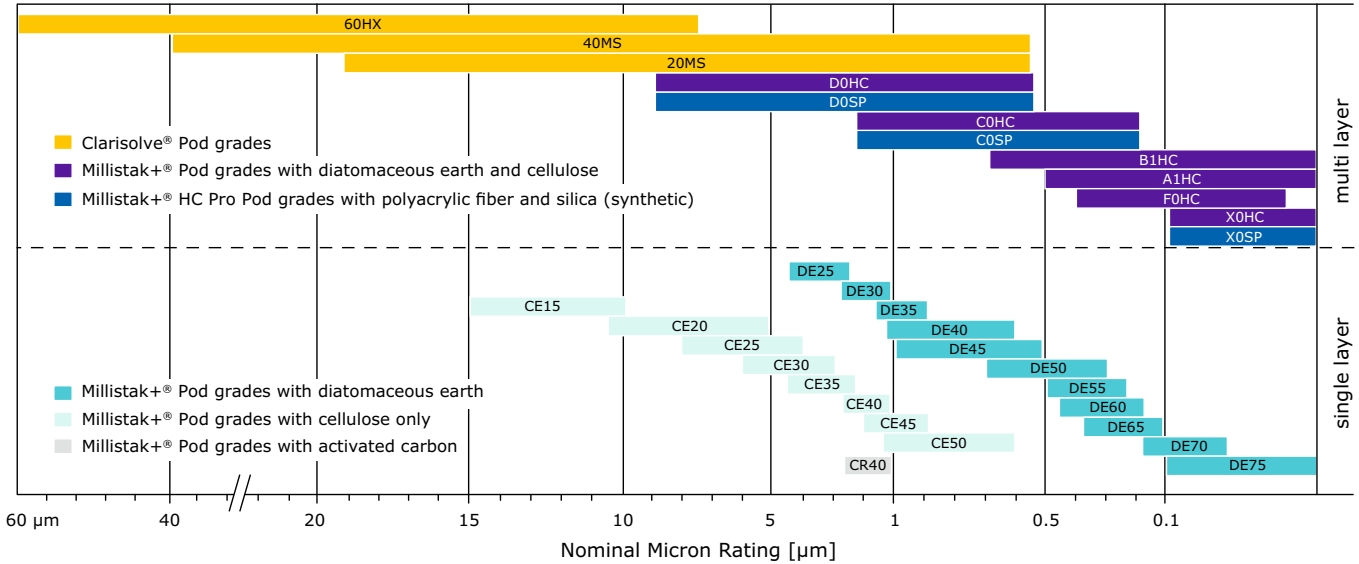
### Disposable Pod device

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

## Millistak+® HC Pro Pod series

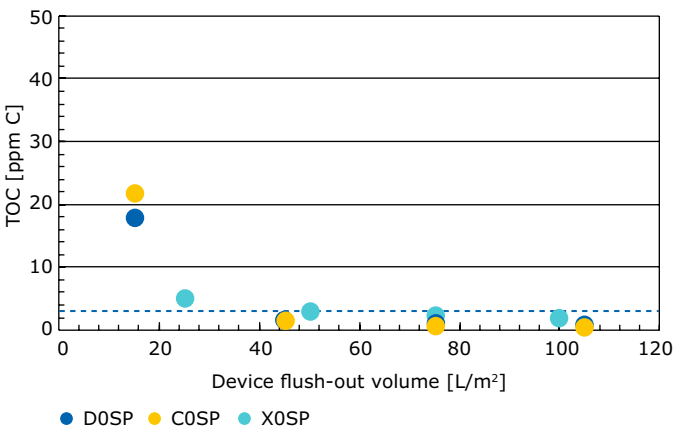
Millistak+® HC Pro synthetic depth filters are available in 3 media grades for primary and secondary clarification and downstream processing steps to protect chromatography columns.

Applications	Media Grade	Media Composition
Primary clarification (direct harvest)	D0SP	Four layer depth filter media composition which includes an upstream non-woven layer to improve filtration capacity.
Primary and secondary clarification (direct harvest, centrate)	C0SP	Four layer depth filter media combination.
Secondary clarification (direct harvest and centrate), and downstream filtration	X0SP	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 LAL testing for bacterial endotoxins.

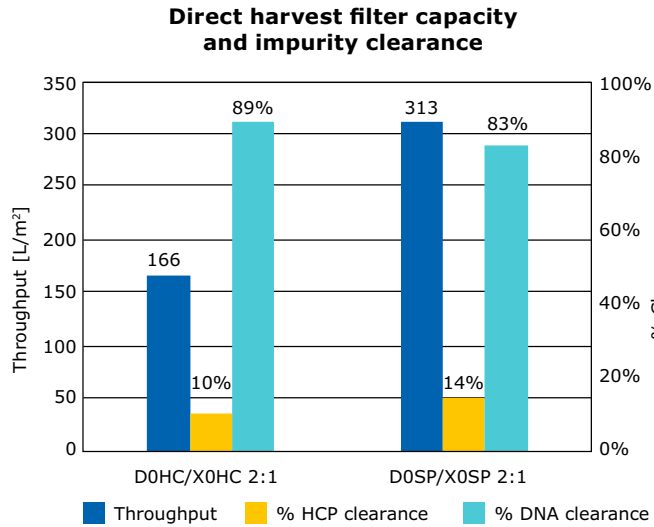
Format	Beta glucan LAL assay (pg/mL) <sup>1</sup>	
	Water	Buffer
X0HC <sup>2</sup>	<25.3	<80
X0SP	<LOQ	<LOQ

<sup>1</sup> Devices flushed with water/buffer, as indicated (600 LMH, 50 L/m<sup>2</sup> or 25 L/m<sup>2</sup> with buffer)

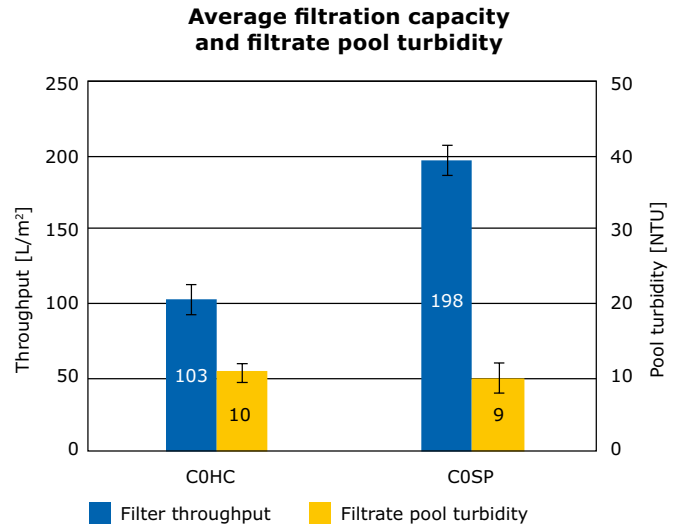
<sup>2</sup> X0HC is Millistak+® HC media (cellulose and diatomaceous earth based)

## 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.



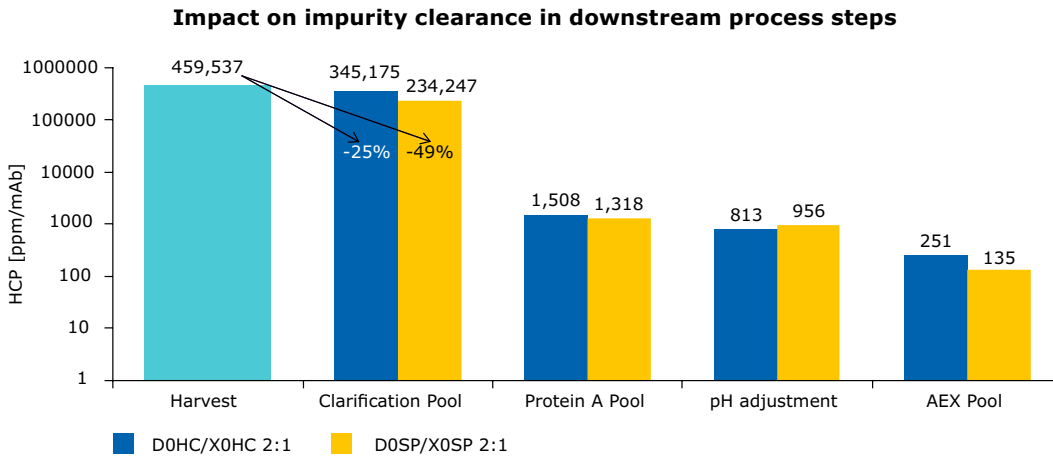
mAb02 feed properties:  $12.4 \times 10^6$  tc/mL (83% viability)



mAb05 feed properties:  $9.7 \times 10^6$  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.



## 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://sigmaldrich.com/emprove>

## Bulk Packaging

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

## Millistak+® HC Pro Lab devices and Process Scale Pod filters specifications

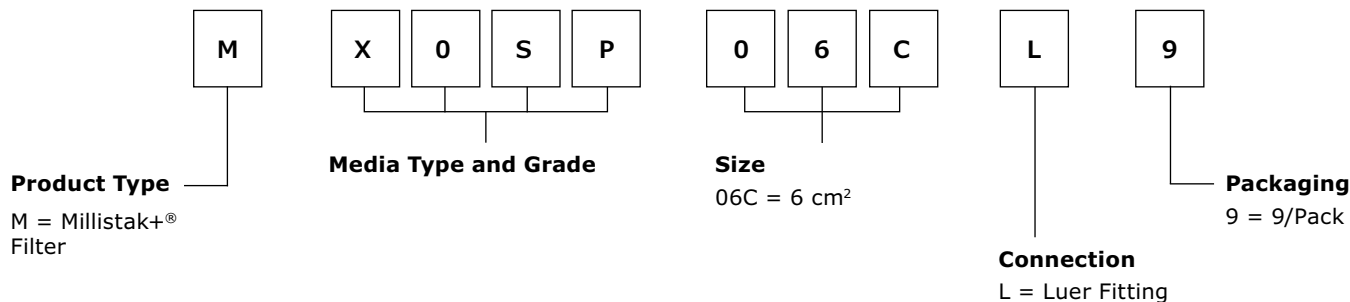
Media Grade	XOSP	DOSP / COSP / XOSP							
<b>Materials of Construction</b>	Silica Filter Aid with Polyacrylic Fiber Polypropylene								
Depth Filter Media Filter Non-woven (DOSP grade only)									
<b>Housing Material</b>	Polypropylene	Glass-Filled Polypropylene							
<b>Inlet, Vent and Outlet Connections</b>	Female Luer	¼ in. (6 mm) Hosebarb		Flat seal					
<b>Device Format (for all grades)</b>	<b>Micro 20</b>	<b>Lab-Scale Pod (LSP)</b>		<b>Process-Scale Pod (PSP) (DOSP and COSP)</b>			<b>Process-Scale Pod (PSP) (XOSP)</b>		
<b>Surface Area</b>	20 cm <sup>2</sup>	135 cm <sup>2</sup>	270 cm <sup>2</sup>	0.11 m <sup>2</sup>	0.33 m <sup>2</sup>	0.77 m <sup>2</sup>	0.11 m <sup>2</sup>	0.55 m <sup>2</sup>	1.1 m <sup>2</sup>
<b>Pod (Device) Dimensions</b>									
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)	6.35	-	-	-	-	-	-	-	-
Thickness (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
<b>Maximum Operating Pressure</b>	30 psig (2.1 bar) at 25 °C	30 psid (2.1 bar) at ≤40 °C		50 psid (3.5 bar) at ≤80 °C					
<b>Maximum Differential Pressure</b>				30 psid (2.1 bar) at 80 °C (forward)					
Forward	30 psid (2.1 bar) at 25 °C	30 psid (2.1 bar) at 40 °C		30 psid (2.1 bar) at 25 °C (reverse)					
Reverse	30 psid (2.1 bar) at 25 °C	30 psid (2.1 bar) at 25 °C							
<b>Operating Temperature Range</b>	4 to 40 °C			4 to 80 °C					
<b>Pre-use Sanitization</b>	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.						
<b>Bacterial Endotoxin</b>	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.								
<b>Biological Reactivity</b>	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 ( <i>in vivo</i> ), USP <87> ( <i>in vitro</i> ), ISO 10993-5 ( <i>in vitro</i> ).								
<b>Pressure Equipment Directive</b>	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.								

## Screening Devices

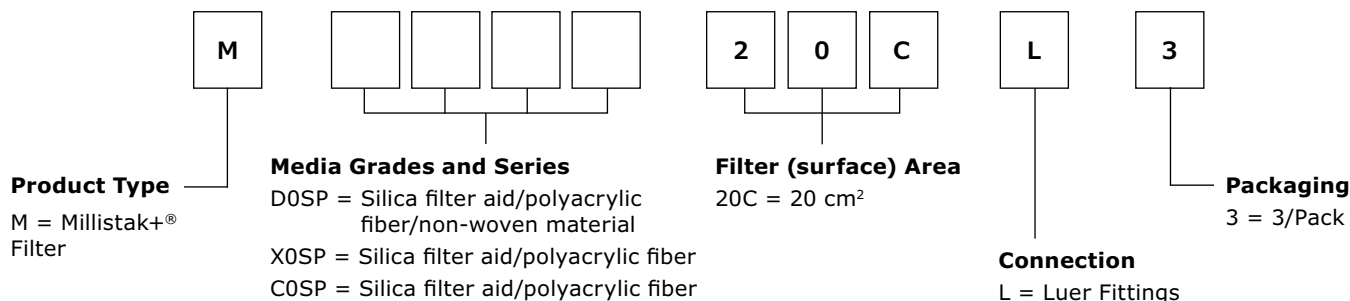
NanoPod NP6	
Surface Area	6 cm <sup>2</sup>
Media Grade	X0SP media
<b>Materials of Construction</b>	
Filter Media	Silica Filter Aid with Polyacrylic Fiber
Pod Housings	Polypropylene
Inlet, Vent and Outlet Connections	Inlet: Female Luer-lock Outlet: Male Luer slip
<b>Pod (Device) Dimensions</b>	
Diameter	3.6 cm
Thickness	3.6 cm
Maximum Operating Pressure	30 psig (2.1 bar) at <40 °C
<b>Maximum Differential Pressure</b>	
Forward	30 psid (2.1 bar) at 25 °C
Reverse	30 psid (2.1 bar) at 25 °C
Operating Temperature Range	4 to 40 °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.
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 ( <i>in vivo</i> ), USP <87> ( <i>in vitro</i> ), ISO 10993-5 ( <i>in vitro</i> ).

## Catalog Numbering Matrix for Millistak+® HC Pro Screening and Scaling Devices:

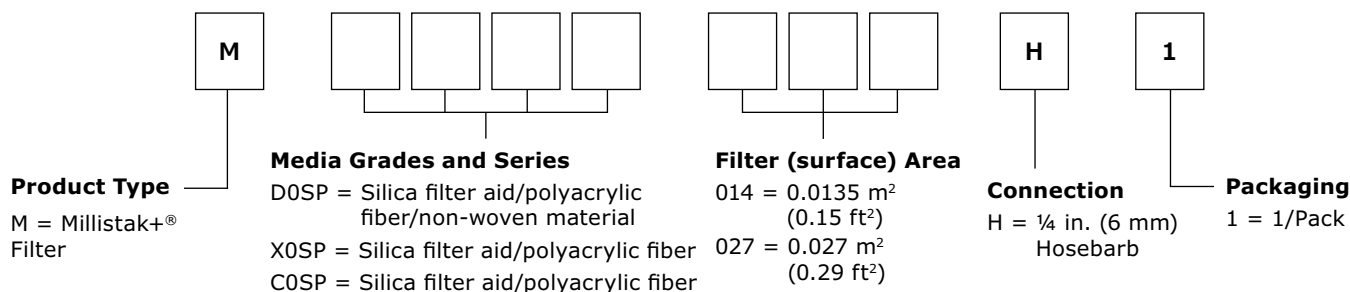
### Nanopod NP6



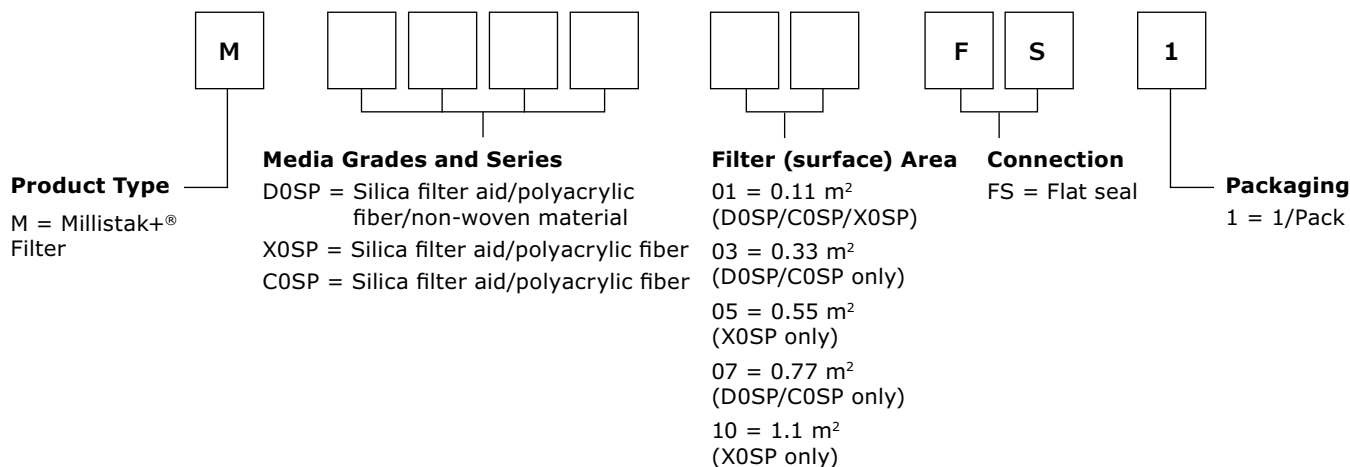
### Micro 20



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

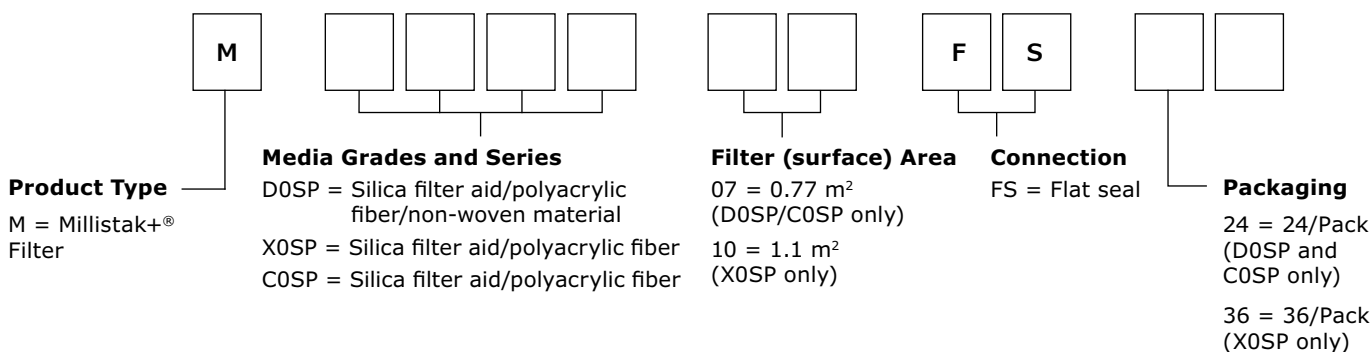


## Catalog Numbering Matrix for Millistak+® HC Pro Process-Scale Pod:

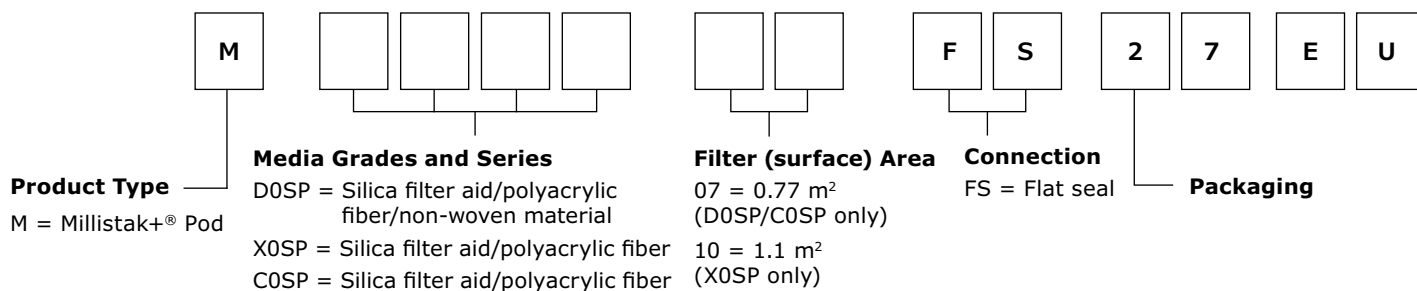


## Catalog Numbering Matrix for Millistak+® HC Pro Process-Scale Pod in Bulk Packaging Format:

### US Pallet format – HDPE black pallet – 40" x 48"



### Euro Pallet format – EU Modified Heat treated (EU) Wooden – CP2 1200 x 800 mm



## 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](https://www.sigmaaldrich.com) to learn more.

For additional information, please visit [SigmaAldrich.com](https://www.sigmaaldrich.com)  
To place an order or receive technical assistance, please visit [SigmaAldrich.com/offices](https://www.sigmaaldrich.com/offices)

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