



Biotech

USD2590c

Stax™ Disposable Depth Filter Systems

Providing High Performance Filtration



Filtration. Separation. Solution.SM

The Most Versatile Disposable Depth Filter Platform

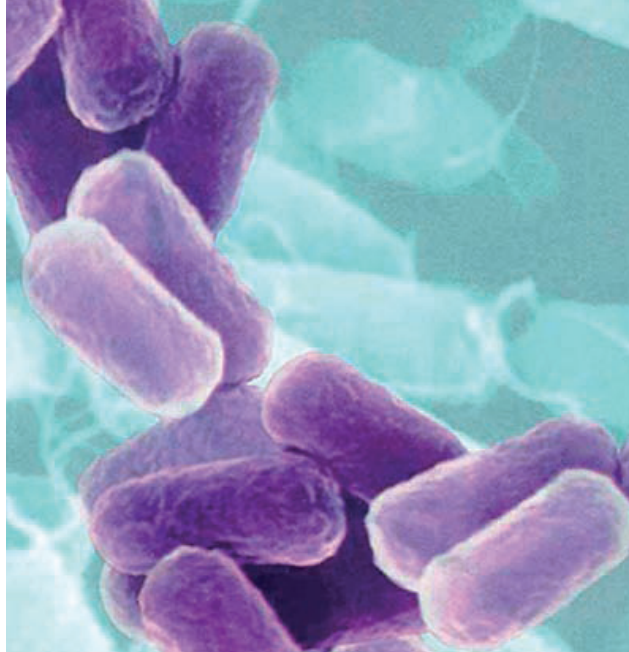


Stax capsules, utilizing Seitz® high performance depth filter media and the patented Supradisc™ II module design, are ideally suited for demanding prefiltration and clarification biopharmaceutical applications. This ready-to-use platform is an ideal tool to streamline your process filtration applications. Stax disposable depth filter capsules increase process efficiencies and address the needs for simplicity, safety, speed, and intuitive operation. Optimized with a small foot print design, the Stax platform makes for an easy to handle and operate process step

Scalable in size and performance to meet lab, pilot and process needs, Pall's Stax disposable capsules enable greater flexibility and ease of use than traditional depth filter technology. With three interchangeable capsule sizes ranging from 0.25 m² to 2.0 m² (2.70 ft² to 21.5 ft²). Stax capsules permit incremental increases in process fluid volume and filter area through the use of this modular design.

Simple, Intuitive Operation

Placed into one of three different sized chassis, Pall's single use Stax capsules eliminate the use of stainless steel housings which require costly cleaning and cleaning validation. Stax system chassis are designed for assembly and use by a single operator and provide a logically conceived disposable platform in which the operator can load, operate and unload in an ergonomically designed vertical orientation. The ability to operate with two different media grades in one chassis (serial filtration) further improves the flexibility and economy of operating the Stax platform. With simple, straight forward and familiar features, the Stax platform eliminates the risk of error or mishap and enables greater process success. Integrating Pall's Allegro™ platforms into a comprehensive single-use system will further maximize the overall benefits of implementing a single-use strategy and the Stax platform.



Complete Flexibility in Process Design

The Stax platform has been designed to accommodate nearly all processing options. Whether you want to process:

- ▶ Bottom up
- ▶ Top down
- ▶ Bottom in/bottom out
- ▶ In series

Simply using Pall's uniquely designed manifold kits provides complete flexibility in your process design. Appropriate for use in primary and secondary filtration steps, as well as post-precipitation clarification, in applications such as:

- ▶ Mammalian cell cultures
- ▶ Yeast
- ▶ E. coli lysates and refolds
- ▶ Vaccines
- ▶ Blood plasma proteins and serum
- ▶ Media

The Pall Stax capsules are available in a wide array of advanced pharmaceutical-grade Seitz depth filter media. Supported through comprehensive validation guides, Seitz depth filter media meets the highest pharmaceutical standards for:

- ▶ Quality
- ▶ Lot-to-lot consistency
- ▶ Manufacturing control
- ▶ Low extractable content
- ▶ Low endotoxin content

Features and Benefits of Stax Systems

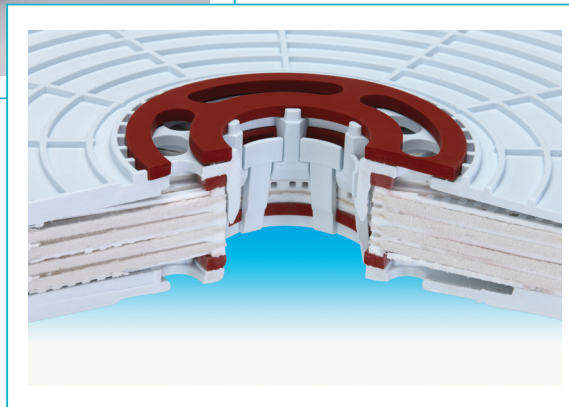
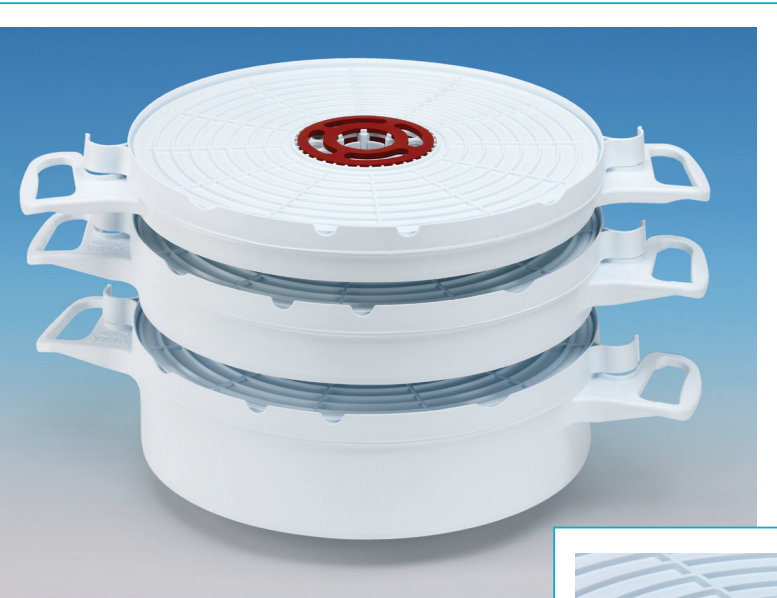
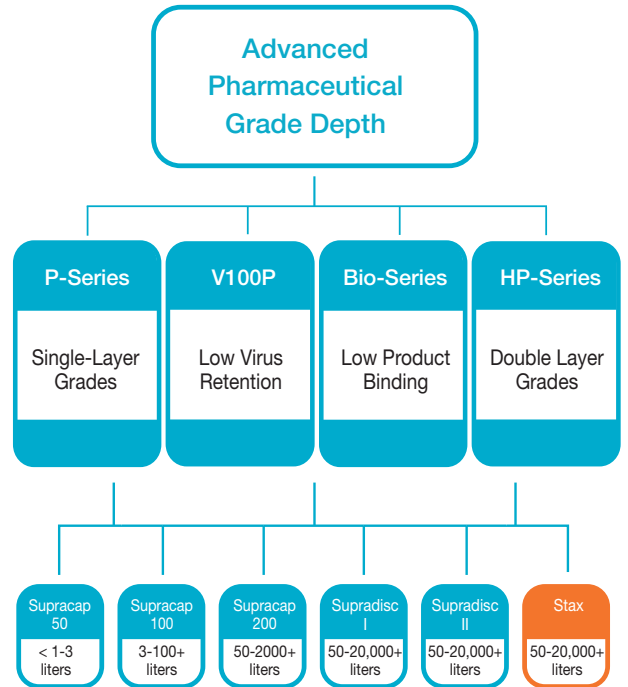
Features	Benefits
Low hold-up volume	Greater product recovery and lower post use rinse volume requirements than traditional modules and housings. Post use blow down in forward or reverse flow direction are possible.
Seamless linear scalability	Greater flexibility and assurance of process success from <1 L to 20,000+ L. Scalable through Pall's entire line of scale-up devices (Supracap™ 50 and Supracap 100 capsules) as well as traditional Supradisc I and Supradisc II modules. Provides assurance of meeting process design and requirements.
Minimized risk	The Stax capsules are based upon the outstanding design of Pall's Supradisc II modules, which provides benefits in process stability due to their high mechanical robustness.
No housings	Easier to use and manipulate while eliminating operator safety issues.
Completely disposable	Eliminates need for cleaning and cleaning validation.
Encapsulated design	Reduces operator exposure to potential biohazards.
Intuitive operation	Reduces operator training and increases time to acceptance.
Small footprint	Enables use in close proximity to other equipment and reduces cost to install.

Providing Linear and Seamless Scalability

Scalability

Enabling technologies such as the Pall Stax system must be supported with complementary products and devices that provide seamless linear scalability in filtration performance from bench to process. For this reason Pall has developed a complete line of scaled-down disposable capsules utilizing the same design principle, flow path, and filter media as the Stax capsules.

Scalability - Depth Filter Sheet Media Format



Top: Small, Medium and Large Stax Capsules
Right: Stax Capsule Cross Section



Scalability - Effective Filter Area

Supracap 50 capsules (<1 to 3 liters)

Capsule	22 cm ² (0.024 ft ²) of EFA*
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Supracap 100 capsules (3 to 100 + liters)

5 in. capsules	0.05 m ² (0.54 ft ²) SL ⁽¹⁾ EFA 0.025 m ² (0.27 ft ²) DL ⁽²⁾ EFA
10 in. capsules	0.1 m ² (1.08 ft ²) SL EFA 0.05 m ² (0.54 ft ²) DL EFA
20 in. capsules	0.2 m ² (2.15 ft ²) SL EFA 0.1 m ² (1.08 ft ²) DL EFA
30 in. capsules	0.3 m ² (3.23 ft ²) SL EFA 0.15 m ² (1.61 ft ²) DL EFA

Stax capsules (50 to 20,000 + liters)

Small capsules	0.5 m ² (5.38 ft ²) SL EFA 0.25 m ² (2.70 ft ²) DL EFA
Medium capsules	1.0 m ² (10.8 ft ²) SL EFA 0.5 m ² (5.38 ft ²) DL EFA
Large capsules	2.0 m ² (21.5 ft ²) SL EFA 1.0 m ² (10.8 ft ²) DL EFA

* EFA = Effective Filtration Area

⁽¹⁾ SL = Single layer Seitz depth filter media such as P-series and BIO-series

⁽²⁾ DL = Double layer Seitz depth filter media such as HP-series



Top: Supradisc II Module

Below Left: Supracap 100, Supracap 50 and Stax Capsules

Minimized Risk

Benefiting from Pall's Supradisc II mechanically robust module design, the Stax capsules provide stable filtration results batch to batch. Through the use of interlocking and welded dual drainage plates, this robust module design is able to provide the structural integrity necessary for:

- ▶ Unobstructed process flow
- ▶ Consistent filtration results
- ▶ Minimized risk to filter media ruptures due to reverse pressure
- ▶ Minimized risk of damage due to shipping and handling



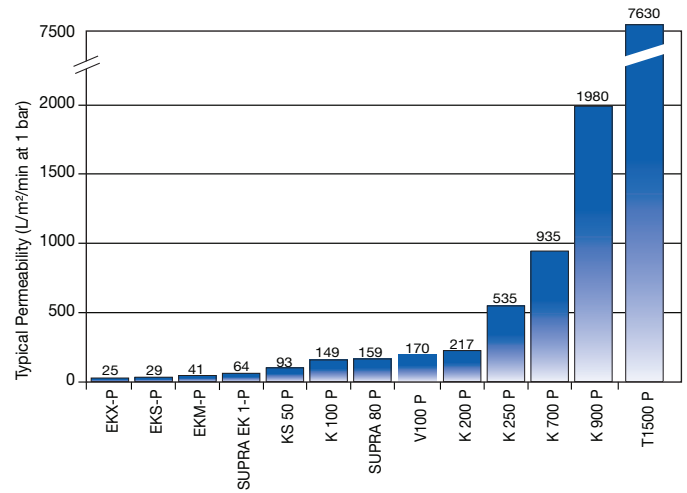
Seitz Depth Filter Media Available in Stax Capsules



P-series:

Seitz P-series depth filter sheets were specifically developed for the strict requirements in biotechnological and pharmaceutical industries. Manufactured with stringent in-process control methods assures consistent filtration quality, a very high purity of filter medium, and alignment with the requirements of the pharmaceutical industry. For further information, please reference Pall datasheet USD 2205 or validation guide USTR 2366.

Permeability - P-series



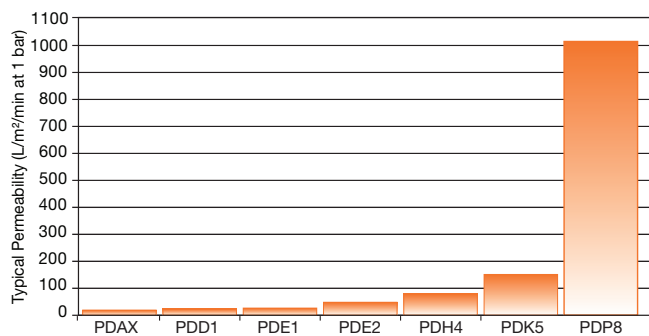
Top: Pilot Scale Chassis with Stax Capsules
Right: Seitz Depth Filter Sheet Media



HP-series:

Seitz HP-series depth filter sheets are comprised of two distinct layers of Seitz P-series depth filter sheets; a coarser layer upstream followed by a finer layer downstream. These performance-enhanced depth filter sheets have been designed for use in low viability, high solids containing applications. As small shifts in process conditions can cause dramatic differences in filtration requirements, the flexibility of combining any combination of P-series media in an HP format allows for improved process optimization. For further information, please reference Pall datasheet USD 2335 or validation guide USTR 2404.

Permeability - HP-series¹



¹ Test performed with water at 20 °C and a differential pressure of 1 bard (14 psid)

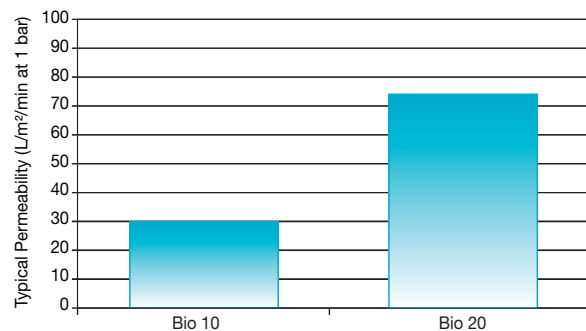
Bio-series:

Seitz Bio-series depth filter sheets are specially developed from highly purified natural and modified cellulose fibers and contain no inorganic materials such as diatomaceous earth (DE), perlite or glass fibers. The lack of these inorganic substances significantly reduces the levels of ash and heavy metal extractables. For further information please reference Pall datasheet USD 2201.

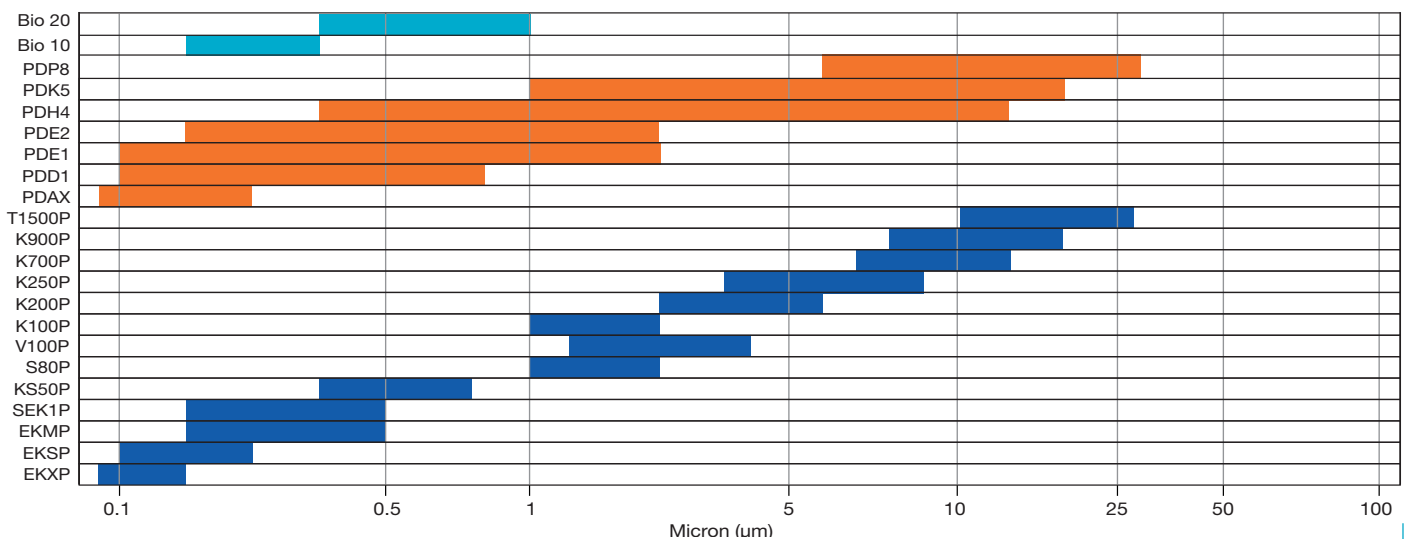
Stax CF Modules:

Containing Seitz P-series sheets, CF modules are configured with increased spacing to accommodate fluids with a high solids loading and are ideal for the retention of diatomaceous earth and activated carbon.

Permeability - Bio-series



Nominal Retention Rating of Seitz P-series, HP-series and Bio-series Depth Filter Sheet Media



Technical Information

Filter Area

Capsule Size	Effective Filter Area	
	Single Layer Media	Double Layer Media
Small	0.5 m ² (5.38 ft ²)	0.25 m ² (2.70 ft ²)
Medium	1.0 m ² (10.8 ft ²)	0.5 m ² (5.38 ft ²)
Large	2.0 m ² (21.5 ft ²)	1.0 m ² (10.8 ft ²)

Capsule Dimensions

Capsule Size	Capsule Footprint Size	
	Diameter	Height
Small	442 mm (17.4 in.)	58.5 mm (2.3 in.)
Medium	442 mm (17.4 in.)	80.8 mm (3.2 in.)
Large	442 mm (17.4 in.)	128.8 mm (5.1 in.)

Capsule Weight ⁽¹⁾

Capsule Size	Weight	
	Dry	Wet (Post blow down)
Small	442 mm (17.4 in.)	58.5 mm (2.3 in.)
Medium	442 mm (17.4 in.)	80.8 mm (3.2 in.)
Large	442 mm (17.4 in.)	128.8 mm (5.1 in.)

⁽¹⁾including internal module

Void Volume

Component	Void Volume ⁽¹⁾
Small Capsule	1.1 L
Medium Capsule	1.6 L
Large Capsule	2.6 L

⁽¹⁾Void volume is defined as the amount of liquid to fill the entire component with the cartridges installed in the capsules

Maximum Operating Pressure

3.5 bar (50 psi) at 25 °C

1.0 bar (14.3 psi) at 60 °C

Note: All pressure specifications are for capsules correctly installed into Pall Stax chassis

Maximum Differential Pressure

2.4 bar (35 psi) at 25 °C – forward direction

Maximum Operating Temperature

60 °C

Inlet and Outlet Dimensions (Distribution Manifold)

50.8 mm (2 in.) Tri-clamp or 38.1 mm (1.5 in.) Tri-clamp

Autoclave Capability/Limits

2 autoclave cycles: 60 minutes at 125 °C

Post Use Autoclave Sterilization

60 minutes at 121 °C (applies to entire Stax system - capsules and chassis together)

Sanitization

Hot water sanitization 80 °C at 1 bar (14.3 psi) for 60 minutes

Post use caustic treatment 1 M NaOH at 3.5 bar (50 psi) for 60 minutes at 25 °C

Traceability

Capsule part number laser engraved with the following:

Media batch number

Internal sales order number

Unique serial number

Bottom: 5-High Process Chassis without/with Capsules



Capsule Material of Construction

Capsule shell:	Glass filled polypropylene
Manifold assemblies:	Glass filled polypropylene
Internal module:	Polypropylene
Gasket:	Silicone
Depth filter media:	See specific filter media data sheet

For further information regarding extractables data and certifications for the capsules and manifolds please reference the Stax platform validation guide USTR 2528

Chassis Dimensions

Chassis Model	Footprint Size		
	Height	Length	Width
SXLSC02	1018 mm (40.0 in.)	516 mm (20.3 in.)	516 mm (20.3 in.)
SXLSC02W	1025 mm (40.4 in.)	552 mm (21.7 in.)	560 mm (22.0 in.)
SXPSC05P	1241 mm (48.9 in.)	610 mm (24.0 in.)	610 mm (24.0 in.)
SXPSC05W	1312 mm (51.6 in.)	1150 mm (45.3 in.)	800 mm (31.5 in.)
SXPSC10P	1864 mm (73.4 in.)	610 mm (24.0 in.)	610 mm (24.0 in.)
SXPSC10W	1935 mm (76.2 in.)	1150 mm (45.3 in.)	800 mm (31.5 in.)

Chassis Weights

Chassis Model	Weight
SXLSC02	75 kg
SXLSC02W	78 kg
SXPSC05P	190 kg
SXPSC05W	192 kg
SXPSC10P	238 kg
SXPSC10W	240 kg



Capacity – Maximum Number of Capsules

Chassis Model	Small Capsule	Medium Capsule	Large Capsule
SXLSC02*	4	3	2
SXPSC05*	10	7	5
SXPSC10*	22	16	10

- ▶ The table above indicates the total number of capsules in various sizes that each chassis size can accommodate.
- ▶ It is also possible to make combinations of different sized capsules to achieve the exact filtration area required to the nearest 0.25 m² DL (0.5 m² SL) (2.70 ft² DL (5.38 ft² SL))
- ▶ It is also possible to operate any of the three chassis with as few as (1) of the smallest capsules 0.25 m² DL (0.5 m² SL) (2.70 ft² DL (5.38 ft² SL))

Capacities – Filter Area

Chassis Model	Filtration Area
SXLSC02* (single layer media)	0.5 - 4 m ² (5.38 - 43.1 ft ²)
SXLSC02* (double layer media)	0.25 - 2 m ² (2.70 - 21.5 ft ²)
SXPSC05* (single layer media)	0.5 - 10 m ² (5.38 - 107.6 ft ²)
SXPSC05* (double layer media)	0.25 - 5 m ² (2.70 - 53.8 ft ²)
SXPSC10* (single layer media)	0.5 - 20 m ² (5.38 - 215.3 ft ²)
SXPSC10* (double layer media)	0.25 - 10 m ² (2.70 - 107.6 ft ²)

Chassis Materials of Construction

304/1.4301 Stainless Steel 1.2 µm / 64 µin Ra (typical) Electro-polish

Design Basis

- ▶ Conforms to Pressure Equipment Directive – Category 1 / Module A (SXLSC02 is Sound Engineering Practice)
- ▶ Outside scope of ASME VIII Div 1
- ▶ Complies with Universal Building Code (1997) – Zone 4 / Importance factor 1.25 (SXPSC**P ONLY)

* Placeholder for either a P or no letter (without casters) or a W (with casters)

** Placeholder for either 05 (indicating a 5 high process scale chassis) or 10 (indicating a 10 high process scale chassis)

Ordering Information

Stax Capsule Single Layer

Pall Part Number: SX

Code	Nominal Height
S	58 mm (2.3 in.) High
M	81 mm (3.2 in.) High
L	129 mm (5.1 in.) High

4

Code	Media Grade
PEXX	EKXP
PEKS	EKSP
PEKM	EKMP
PEK1	SEKP
P050	KS50P
P080	SUPRA 80P
P100	K100P
P200	K200P
P250	K250P
P700	K700P
P900	K900P
P1500	T1500P
B010	BIO10
B020	BIO20
V100	V100P

SP

Code	Number of Filter Cells
04	4
08	8
16	16

Example Part Number:
SXSPEKS404SP

Please note:

Code S is only available with code 04

Code M is only available with code 08

Code L is only available with 16

Stax Capsule Double Layer

Pall Part Number: SX

Code	Nominal Height
S	58 mm (2.3 in.) High
M	81 mm (3.2 in.) High
L	129 mm (5.1 in.) High

⁽¹⁾ other combinations of P-series media available

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Code	Media Grade ⁽¹⁾
PDAX	PDAX
PDD1	PDD1
PDE1	PDE1
PDE2	PDE2
PDH4	PDH4
PDK5	PDK5
PDP8	PDP8
PDK11	PDK11

SP

Code	Number of Filter Cells
02	2
04	4
08	8

Example Part Number:
SXL PDD1408SP

Stax CF Capsules

Pall Part Number: SX

Code	Nominal Height
L	129 mm (5.1 in.) High

4

Code	Media Grade ⁽¹⁾
PEKS	EKSP
PEKM	EKMP
PEK1	SEK1P
P050	KS50P
P080	SUPRA 80P
P100	K100P
P200	K200P
P250	K250P
P700	K700P
P900	K900P
D50P	SUPRAdur 50P

SP

Code	Number of Filter Cells	Filter Area (m ²)	Available Cake Volume (L)
02	2	0.5	13.2
04	4	1	9.9
06	6	1.5	6.8



Accessories



Top: Top Mount Pipe Support on 10 High Process Scale Chassis
 Left: Stax Manifold Kit, Part Number SXBBM400SP

Stax Chassis

Pall Part Number:

SX



Code	Description
LSC02	Pilot scale without casters
LSC02W	Pilot scale with casters
PSC05P	5-high process scale without casters
PSC05W	5-high process scale with casters
PSC10P	10-high process scale without casters
PSC10W	10-high process scale with casters

Example Part Number:

SXPSC05P

Stax Manifold Kits

Pall Part Number	Description
SXBBM400SP (1 1/2 in.)	Stax 1 1/2 in. manifold kit, bottom in bottom out
SXBBM400SP (2 in.)	Stax 2 in. manifold kit, bottom in bottom out
SXTBM400SP (1 1/2 in.)	Stax 1 1/2 in. manifold kit, bottom in top out
SXTBM400SP (2 in.)	Stax 2 in. manifold kit, bottom in top out
SXTBM400SP (2 in.)	Stax 2 in. manifold kit, bottom in top out

Stax Top Mount Pipe Support

Pall Part Number	Description
SXTMPS	Pipe support for bottom in, top out configuration

Provides support to flexible hose connected to distribution manifold during operation in:

- ▶ Bottom in top out configuration
- ▶ In series process configurations.



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