



Sartoclear P | Sartocell P
Depth filter sheets and
depth filter modules for
the biopharmaceutical
industry

Sartoclear P depth filter sheets and Sartocell P depth filter modules Ensuring quality in the biopharmaceutical industry



Modern biopharmaceutical processes use innovative products of Sartorius

Innovative biopharmaceutical production and engineering demands process technology of highest standards. The key technologies involved in the upstream- and downstream processing of biopharmaceutical applications are filtration and purification. Applying most suitable technologies in such applications for easier and more economical processing is the strategic approach of Sartorius.

One of the major challenges in filtration processes and technologies is the retention of high particle loads and colloidal contaminants.

With Sartoclear P depth filter sheets and Sartocell P depth filter modules Sartorius introduces products for enhanced clarification of biopharmaceutical media.

Sartoclear P and Sartocell P can be effective alternatives to standard filter cartridges, where economical process solutions cannot be achieved applying standard filtration technology.

Higher throughputs and effective removal of contaminants and colloids by Sartoclear P and Sartocell P allow the design of economic and reliable filtration systems for such biopharmaceutical applications.

Sartoclear P filter sheets

- Sartoclear P filter sheets were especially developed for use in the biopharmaceutical industry
- Sartoclear P filter sheets offer excellent clarification effect in conjunction with a high capacity for retaining particles and colloids
- Special production methods are applied during manufacture of Sartoclear P filter sheets to comply with the regulatory requirements of the USP
- Low in extractables and pyrogens
- Particles and colloids smaller than the nominal retention rating of the filter sheet are removed by adsorption due to the positive zeta potential
- Regardless of the application – clarification, fine filtration or bioburden reduction of pharmaceutical products – Sartorius filter sheets guarantee outstanding cost-effectiveness and ensure highest microbiological safety

Sartocell P filter modules

- Sartocell P filter modules are manufactured with the same filter materials as Sartoclear P filter sheets and combine all features and benefits of Sartoclear P with the benefits of a closed filtration system.
- The vertical-modular system reduces significantly the space requirements for process filtration compared to classic filtration systems.
- The modules provide a huge potential for savings thanks to their simple handling, quick assembly times and short cleaning intervals.
- The closed modular system ensures maximum product yield, particularly in the case of highly volatile media.
- Sartocell P filter modules guarantee absolute safety and protection against external contamination
- Highest safety for preventing droplet contamination
- Easy and hygienic process filtration.

Sartocell P filter modules are optionally supplied with a flat gasket adapter or a double O-ring adapter.

Sartoclear P filter sheets and Sartocell P filter modules enable you to perform your special filtration tasks

Sartoclear P filter sheets and Sartocell P filter modules are applied in biopharmaceutical processes along various applications such as:

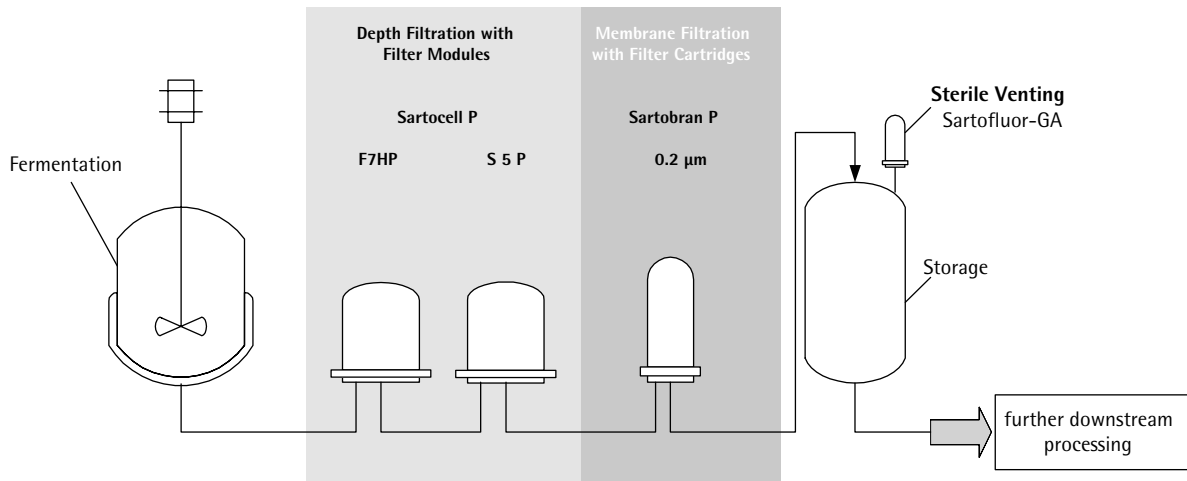
- Separating cells- or cell debris
- Removal of particles from bulk pharmaceuticals, such as infusion solutions and buffers
- Prefiltration of ophthalmic solutions
- Particle filtration of vaccines
- Downstream processing of protein solutions
- Removal of particles and lipids from serum and plasma solutions
- Separation of precipitants
- Chromatography column protection
- Reagent purification
- Particle removal from biopharmaceutical media
- Growth media purification

For these applications, filter sheets and filter modules with different retention ratings are available for particle filtration and clarification, fine filtration and reduction of bioburden.

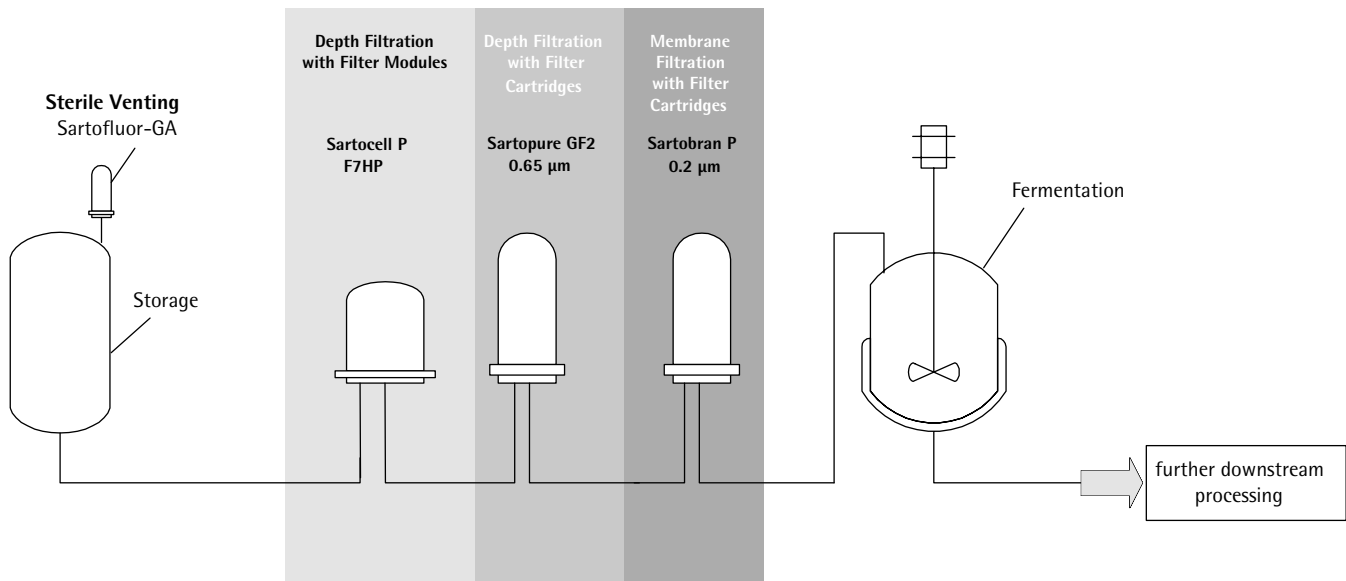
Sheet module type	Retention rating (nominal)	Application	Recommended flow rate [L/m ² h ⁻¹]
C3P	25 µm – 11 µm	Coarse clarification	500 – 1,000
C5HP	15 µm – 6 µm	Clarification	500 – 1,000
C8HP	7 µm – 4 µm	Clarification	400 – 800
F7HP	3 µm – 1 µm	Fine filtration	300 – 700
S5P	0.5 µm – 0.2 µm	Microbe-retentive filtration	< 200
S9P	0.2 µm – 0.1 µm	Microbe-retentive filtration	< 200

Application Examples

Downstream processing of fermentation broth

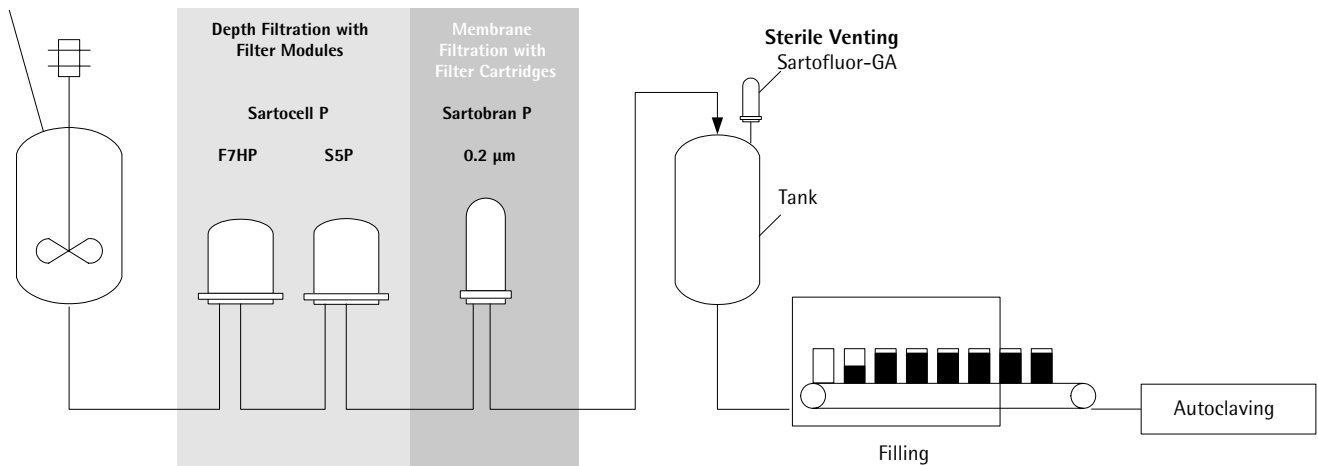


Filtration of Cell Culture Media



LVP-Production

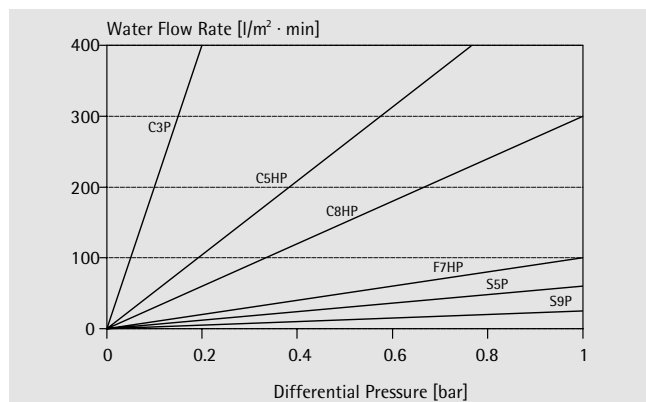
Compounding tank



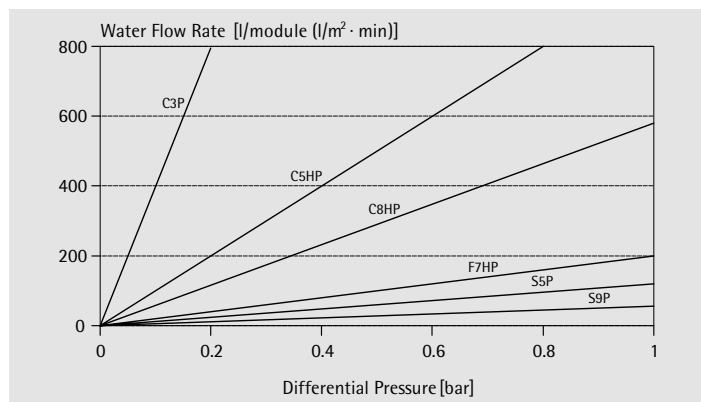
Specifications of Sartoclear P filter sheets

Type	Nominal retention rating [µm]	Water flow rate [l/min]	Thickness [mm]	Density [g/cm ³]	Ash content [%]	Unit weight [kg/m ²]	Wet tensile strength [N/50 mm]
C3P	25 - 11	1500-2100	3.2-3.4	0.23-0.31	<1.0	0.8-1.0	>50
C5HP	15 - 6	350-450	3.6-3.9	0.28-0.36	19.5-24	1.1-1.3	>50
C8HP	7 - 4	240-300	3.7-3.9	0.31-0.38	29.5-34.5	1.2-1.4	>50
F7HP	3 - 1	100-140	3.7-3.9	0.33-0.38	39.4-44.4	1.3-1.4	>50
S5P	0.5 - 0.2	46-56	3.7-3.9	0.34-0.40	42.5-47.5	1.3-1.5	>50
S9P	0.2 - 0.1	10-16	3.7-3.9	0.35-0.42	47.5-52.5	1.4-1.6	>50

Water Flow Rate Sheet



Module*



* 12" module, 16 cells

Chemical compatibility SartoclearP | Sartocell P

Substance	Concentration [%]	Compatibility at T= 20°C	Compatibility at T= 80°C
NaOH	1	■	■
	2	■	□
	3	■	--
	10	--	--
HCl	1	■	■
	3	■	■
	5	■	□
	10	■	--
HNO ₃	1	■	■
	3	■	■
	5	■	□
	10	■	--
H ₂ SO ₄	1	■	■
	5	■	□
	10	■	--
Acetic Acid	1	■	■
	5	■	■
	10	■	■
Citric Acid	1	■	■
	5	■	■
	10	■	■

■ = compatible
 □ = limited compatibility
 -- = not compatible

Bacteria retention rating

The following test organisms were used to determine the bacteria retention capability:

Brevundimonas diminuta, ATCC 19146
Serratia marcescens, ATCC 14756

Type	Test microbe	Bacteria challenge	Titer reduction	LRV
S5P	Serratia marcescens	$1.0 \times 10^8/\text{cm}^2$	2×10^7	>7
S9P	Brevundimonas diminuta	$1.0 \times 10^9/\text{cm}^2$	2×10^8	>8

Sanitization with hot water

Sartoclear P filter sheets and Sartocell P filter modules can withstand 20 sanitization cycles with WFI (Water for Injection) pumped in the direction of filtration for individual periods of 30 minutes at a temperature of 80° and a differential pressure of 1 bar.

In-line steam sterilization with saturated steam

Temperature	Sterilization cycles
121°C	3 cycles à 30 minutes
134°C	1 cycle à 20 minutes

Determination of oxidizable substances in accordance with USP

After autoclaving for 30 min at 121°C, the filter element is flushed with 50 liters of WFI water/m². The test is conducted in accordance with the current USP methods using potassium permanganate in WFI water.

Type oxidizable Substances in WFI-Water

C3P	fulfills current USP
C5HP	fulfills current USP
C8HP	fulfills current USP
F7HP	fulfills current USP
S5P	fulfills current USP
S9P	fulfills current USP

LAL Test (pyrogen release)

Determination of the pyrogens released from the filter element using the LAL (Limulus amoebocyte lysate) test.

The pyrogen release is determined after rinsing the filter element with 50 liters of WFI water /m².

The results of the LAL assay are stated in endotoxin units per milliliter (EU/ml).

Type Endotoxin release [EU/ml]

C3P	< 0.124
C5HP	< 0.124
C8HP	< 0.124
F7HP	< 0.124
S5P	< 0.124
S9P	< 0.124

Biocompatibility

Sartoclear P filter sheets and Sartocell P filter modules were supplied to an independent test institute for evaluation under the requirements of the current USP Class VI Plastics Tests, including tests as follows:

- Intracutaneous Test
- Systemic Injection Test
- Implantation Test (7 days)

All material used meet or exceed the requirements of the USP Class VI Plastics tests.

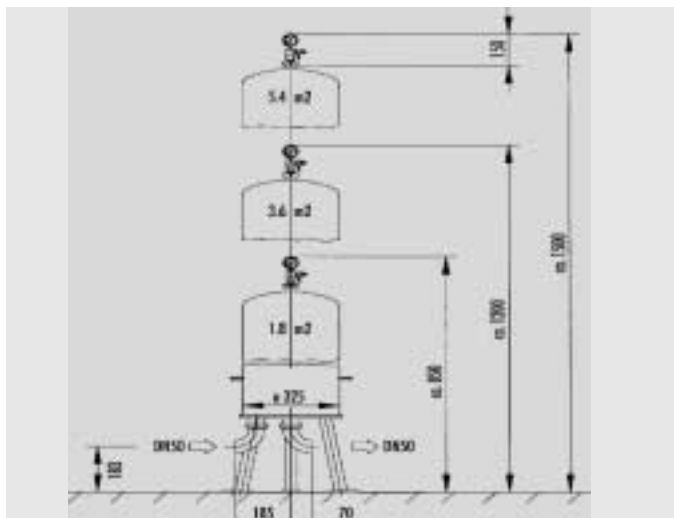
A certificate is available on request.

Modular housing design

The modular system of Sartocell P filter modules and filter housings fulfils all features of a modern filtration system:

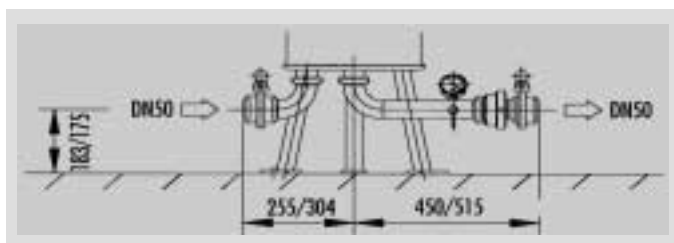
- Low investment costs
- Modular design
- Easy and quick handling
- Low dead volume
- High filtration security
- High flow rates

Depending upon your application, housings for 1–3 Sartocell P filter modules (12") are available. The filter module housings are alternatively available for the use of flat adapter or double O-ring adapter type modules.



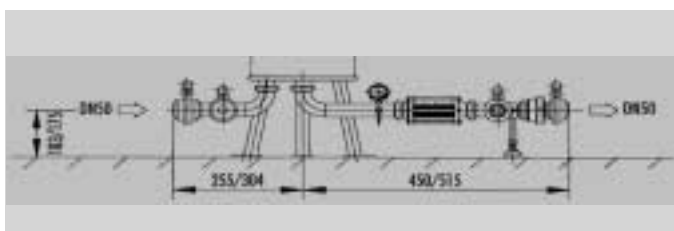
Standard housing:

- Air vent assembly
- Product inlet: Tub bend 90°
- Product outlet: Tub bend 90°



SET 1

- Air vent assembly
- Product inlet:
 - Butterfly valve
- Product outlet:
 - Pressure gauge
 - Sample valve
 - Non-return valve
 - Butterfly valve



SET 2

- Air vent assembly
- Product inlet:
 - Butterfly valve product
 - Butterfly valve water
- Product outlet:
 - Pressure gauge
 - Sample valve
 - Flow meter up to 30/60/90 hl/h
 - Butterfly valve product
 - Butterfly valve water

Gasket material

Standard: EPDM

Silicone, Viton on request

Please consider with the order:

If you would like to order the Sartocell P module housing in the configurations which are described as "SET 1" and "SET 2", please order the standard version together with the respective SET number. You will find the exact order code numbers in the overview at the end of the folder.

We at Sartorius offer more

You work with our experienced Sartorius filtration engineers, scientists and sales representatives who first gain a thorough understanding of your filtration needs before they recommend a specific filtration system for your production process. Only then do we offer a specific filtration system recommendation based on an understanding of your production process. More than 70 years of expertise in filtration technology and support of applications from laboratory bench scale to full manufacturing scale stand behind our recommendations.

Our subsidiaries, sales representatives, a qualified field service assistance, product and application specialists as well as our customer service organization are available worldwide to offer you intensive, competent and ongoing support. With our fully stocked, centrally controlled facilities all over the world, we are ready to respond to your product requirements at all times. We help you maintain productive and efficient use of your filtration products with a full range of global support services and filtration specialists.

Process validation

In order to validate the filtration products for your process, Sartorius offers a wide range of validation support services. Sartorius has assisted countless pharmaceutical manufacturers in validating their products and fulfilling the requirements for process validation relating to the use of filtration products. The use of these support services is growing as regulatory requirements change.

Applications and technical support

Whether you have a technical question regarding the specifications of our filter products or require assistance in filter selection, our Applications Department is available to assist you. We can perform filterability testing to properly select and optimize your filtration process, either in our laboratories or at your facility.

Training Seminars

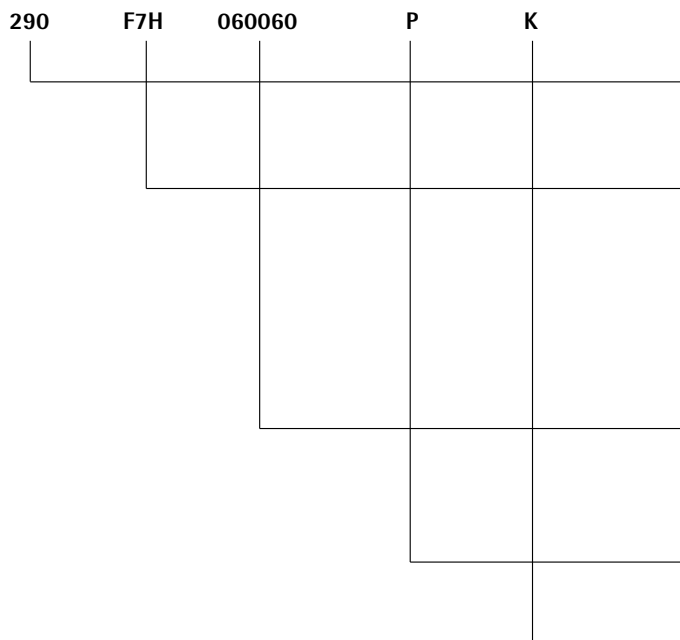
Sartorius offers a comprehensive training program for filter users. This seminar series can also be conducted at your site and covers topic including:

- General Filtration Technology
- Integrity Testing
- Crossflow Filtration and Technology
- Process Design
- Validation of Filtration processes

These are available at your site for the training and continued education of personnel in your facility. For more information or immediate assistance, contact your local Sartorius representative.



Ordering information for Sartoclear P | Sartocell P



Sartoclear Filter Sheets

Retention Rate

C3-	= 25 μm - 11 μm	(Type C3P)
C5H	= 15 μm - 6 μm	(Type C5HP)
C8H	= 7 μm - 4 μm	(Type C8HP)
F7H	= 3 μm - 1 μm	(Type F7HP)
S5-	= 0.5 μm - 0.2 μm	(Type S5P)
S9-	= 0.2 μm - 0.1 μm	(Type S9P)

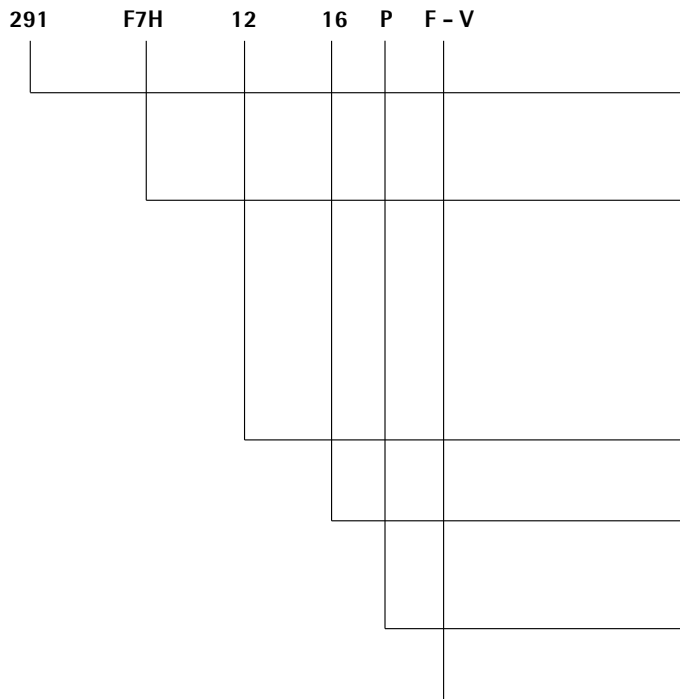
Dimensions (in cm)

040040	= 40 × 40 cm
060060	= 60 × 60 cm

P = Pharma Grade

Pack Size

K	= 50 Sheets/Package (60 × 60 cm)
N	= 100 Sheets/Package (40 × 40 cm)



Sartocell Filter Module

Retention Rate

C3-	= 25 μm - 11 μm	(Type C3P)
C5H	= 15 μm - 6 μm	(Type C5HP)
C8H	= 7 μm - 4 μm	(Type C8HP)
F7H	= 3 μm - 1 μm	(Type F7HP)
S5-	= 0.5 μm - 0.2 μm	(Type S5P)
S9-	= 0.2 μm - 0.1 μm	(Type S9P)

Module Diameter

12 = 12"

Cells

16	= 16 Cells (flat adapter)
17	= 17 Cells (double O-ring adapter)

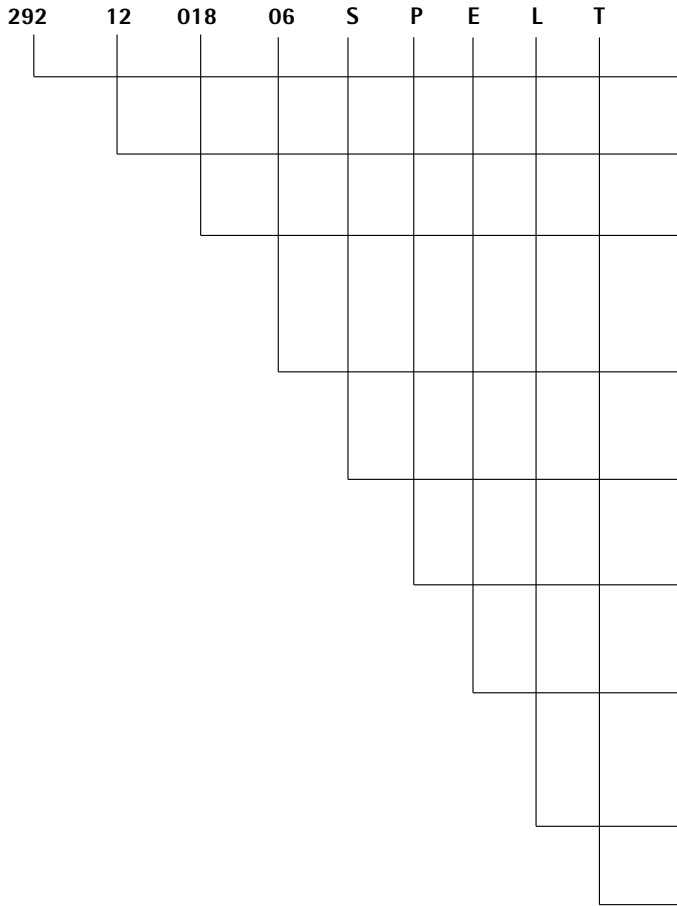
P = Pharma Grade

Module Adapter | Pack Size

S	= Double O-ring Adapter (1 Module/package)
F - V	= Flat Adapter (2 Modules/package)

Ordering information for Sartocell P Module Housing

Standard



Sartocell Module Housing
Standard

Module Diameter
12 = 12"

Filtration Area
018 = 1.8 m²
036 = 3.6 m²
054 = 5.4 m²

Max. Operation Pressure
06 = 6 bar | 87 psi
10 = 10 bar | 145 psi

Module Adapter
S = Double O-Ring Adapter
F = Flat Adapter

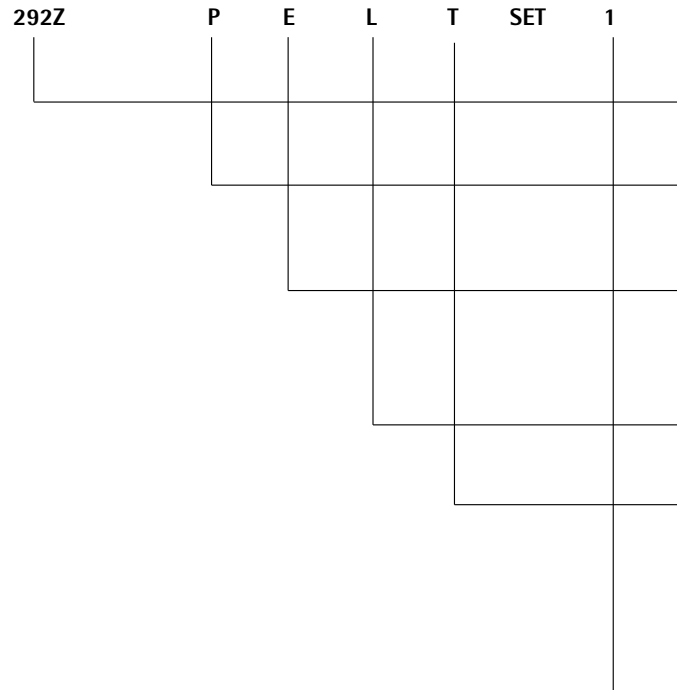
Connectors
F = Screw Pipe Connection DIN 11851
P = Triclamp

Gasket Material
E = EPDM (Standard)
S = Silicone
V = Viton

Housing Material
L = 1.4404 (AISI 316L)

Certificate
B = 3.1b Acceptance Test Certificate +
FDA Certificate for the gasket material
T = see B + TÜV Certificate

SET



Sartocell Module Housing
SET

Connectors
F = Screw Pipe Connection DIN 11851
P = Triclamp

Gasket Material
E = EPDM (Standard)
S = Silicone
V = Viton

Housing Material
L = 1.4404 (AISI 316L)

Certificate
B = 3.1b Acceptance Test Certificate +
FDA Certificate for the gasket material
T = see B + TÜV Certificate

SET
1 = SET 1
2 = SET 2

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