



Life Sciences



### **The Complete Filter System**

Now part of Pall, SeitzSchenk has consistently developed high performance depth filters for biopharmaceutical applications. The **SUPRAdisc** module design concept combines the advantages of conventional depth filter sheets with the positive features of enclosed filters.

### **SUPRAdisc Module Concept**

Each module consists of three major components:

- Filter cells
- Tubular center core
- Adapters

The individual filter cells have two filter sheets and a drainage plate which are edge sealed in an injection mold process. The drainage plate reduces the flow resistance, guarantees an excellent flow distribution over the filter sheet and enables a high filter cell stability.

Up to 21 cells can be stacked on a tubular core, compressed and joined to form a unit. This design results in a reliable sealing between the filter cells, even if the module is in a dry state, which eliminates the need for retightening after wetting.

#### SUPRAdisc Module - Filter Media

Depth filter sheets have been successfully used for over 25 years in a vast range of applications. Due to their excellent mechanical strength, these sheets can readily be incorporated into modules.

Almost all grades of depth filter available in **Pall** flat sheet format are also available in **SUPRAdisc** modules, so that the change from open sheet filter systems to closed systems is straightforward and requires a minimal amount of re-validation.

**SUPRAdisc** modules provide a system similar to membrane filter cartridges, with high efficiency and excellent filtration properties. In some applications, **SUPRAdisc** modules may provide a more economic alternative to cartridge filters.

### The Complete Filter System

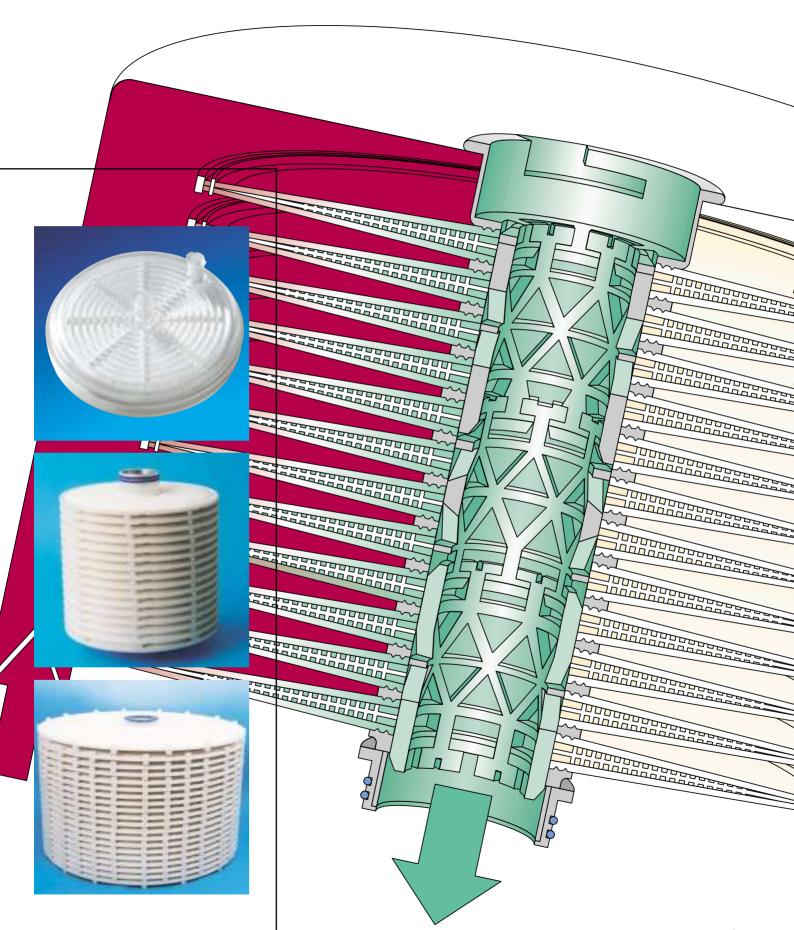
The **SUPRAdisc** module adapter has two O-rings and a bayonet lock, a concept successfully implemented by the biopharmaceutical industry for filter cartridges. Consequently, the **SUPRAdisc** modules can be installed quickly and easily into filter housings. A flat gasket adapter version is also available. For both adapter types, a module lifting device is available. In the flat gasket adapter version an integrated gripping groove permits the use of a module lifting device and in the double O-ring type the bayonet lock enables this capability.

### **SUPRAdisc Module Scale-up Information**

Product	Filter area in m <sup>2</sup>	Filter area in ft <sup>2</sup>	Typical filtered volume (L)
SUPRAcap EDF* 6-0 EDF* 6-3	0.002	0.022	0.5 – 5
EDF*14-0 EDF*14-3	0.012	0.13	1 – 10
EDF* 32-0 EDF* 32-5	0.075	0.81	3 – 20
SUPRAdisc 203	0.30	3.2	5 – 50
SUPRAdisc 205	0.50	5.3	5 – 300
SUPRAdisc 209	1.00	10.7	> 50
SUPRAdisc 216	1.80	19.3	> 50
SUPRAdisc 509	2.30	24.7	> 100
SUPRAdisc 516	4.00	43.0	> 100
SUPRAdisc 520	5.00	53.8	> 100

<sup>\*</sup> Filter holder

Top: SUPRAcap™ Capsule
Center and Bottom: SUPRAdisc Module



### **High Performance Filtration**

Due to their material composition and their structural design, depth filters can be compared with a maze-like, extremely fine three-dimensional sieve with a huge number of branched micro "channels".

Depth filters form a structure with a void volume of 70 - 85% of the total volume of the depth filter. This is indicative of the high dirt holding capacity. The void volume of a **Pall** depth filter can amount to almost 4 L/m<sup>2</sup> of filter area.

The passage of the liquid through the module channels is relatively slow so that the contact time with the filter medium is relatively long. Particles, microorganisms, colloids, viruses and pyrogens are trapped on this long passage through this fine maze with a synergistic effect between the three-dimensional mechanical screen and the adsorptive capabilities of the electrokinetic potential.

Table 1 indicates the factors which influence the retention rates of **Pall** depth filters.

In a special process developed originally by Pall, the relatively "coarse" cellulose fibers are processed to a specific fineness. In this way they are rendered suitable for the homogeneous incorporation of additives such as very fine mixtures of diatomaceous earth. Due to sophisticated manufacturing methods, a stable positive electrokinetic potential forms during aqueous product flow through the filter.

The special manufacturing process provides a highly permeable void volume with a characteristic, very high dirt holding capacity. As a result, the progressive differential pressure increase during filtration is slow, and the tendency for spontaneous blocking is practically eliminated. Careful selection of the raw materials, their specific upgrading, a well-balanced ratio between void volume and

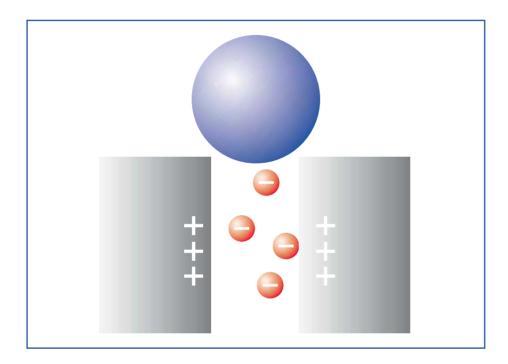
electrokinetic potential, the proportion of the ingredients, as well as reliable control of all process parameters, determine the desired properties of **Pall** depth filters and required to maximize performance.

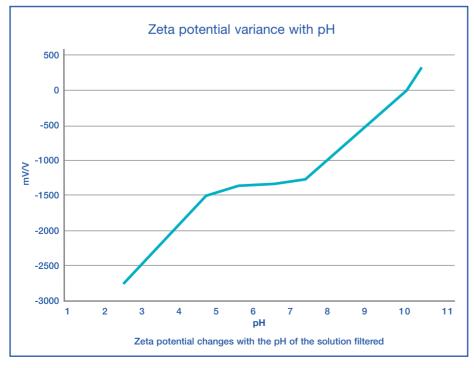
Fiber or particle release from the outlet side of the depth filters is prevented by special technologies.

Table 1

Mechanical Factors Product	Depth Filter	
Nature of the solids/particles	Void volume of the filter medium	
Number and size of the solids/particles	Structure of the "three-dimensional" screen	
Viscosity	Size of the internal surface area (dirt holding capacity)	
Chemical composition	Thickness of the filter medium	
	Composition and processing of media components	
Adsorptive Factors Product	Depth Filter	
Chemical composition	Structure of the "three-dimensional" screen	
Charge of the solids/particles	Number of the charge carriers	
Concentration of the solids/particles	Nature of the charge carriers	
рН	Magnitude of the charge carriers	
Polarity of the solids/particles		
Temperature		

### Factors with an Effect on the Retention Rates of Depth Filters





#### ZETA Potontial

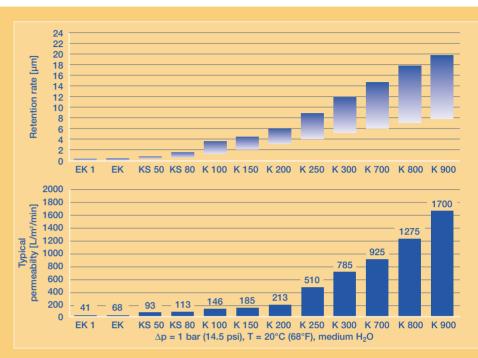
- Sieving
- Electrostatic interaction

Due to their electrokinetic adsorption potential, positively charged resins increase the retention of small particles, such as whole and crushed cells, cell lysate components, endotoxins, DNA and viruses which usually are negatively charged.

The filter matrix can assure retention rates down to 0.1 µm and thus enables an optimal prefiltration of biological products like no other depth filter for the protection of downstream process steps.

# SUPRAdisc Depth Filter Modules SD-Series





### **SD-Series**

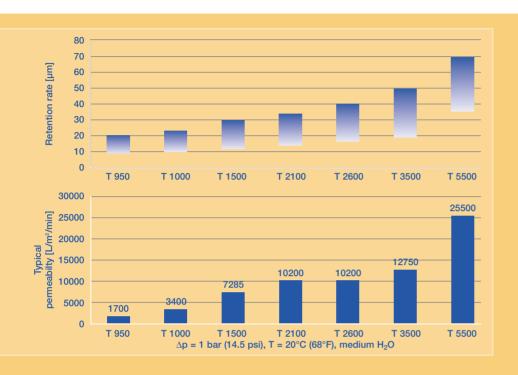
With 12 different retention rates the K series represents the standard depth filter media series of **Pall SUPRAdisc** modules.

The EK 1 and the EK are used for sterilizing filtration whereas the KS 50 and KS 80 are classified as micro-organism-reducing depth filters. They can produce a final filtrate with low organism counts. K 100 through to K 900 cover the entire range from fine filtration via clarifying filtration to coarse filtration.

In addition the K 100, K 250, K 800 and K 900 are also available in an ion reduced (IR) version. Application areas for these special depth filter sheets are ion sensitive products like protein solution, blood products and biologic products in general.

Application Areas	Medium	Application
Fine clarification (fine activated carbon),	EK 1	Aqueous cosmetics (clarifying/fine filtration) pharmaceuticals and biopharmaceuticals, plasma fractionation
vitamins, amino acids, enzymes, pharmaceutical	EK	Pharmaceuticals and biopharmaceuticals, (not susceptible to bacterial spoilage)
raw materials and	KS 50	Phytopharmaceuticals (clarifying filtration)
effective substances)	KS 80	Antibiotics (clarifying filtration), vaccines, infusion , solutions plant extracts (clarifying filtration), plasma fractionation
Clarifying filtration (retention of activated	K 100 (IR)	Cosmetics (clarifying filtration), protein solutions
carbon, catalyst retention from various solutions)	K 150	Pharmaceuticals and biopharmaceuticals (clarifying filtration), serum (pre-filtration)
	K 200	Vaccines (pre-filtration), phytopharmaceuticals (clarifying filtration)
	K 250 (IR)	Biological products
	K 300	Antibiotics (clarifying filtration), cosmetics (clarifying filtration), cell harvest
Retention of biomass Retention of gels from	K 700	Antibiotics (clarifying filtration), serum (pre-filtration), cell harvest
resins Fermenter harvest	K 800 (IR)	Vaccines (pre-filtration)
	K 900 (IR)	Infusion solutions (pre-filtration), cosmetics

# SUPRAdisc Depth Filter Modules T-Series





Application Areas	Medium	Application
Filtration of viscous oils	T 950	Catalyst removal
Filtration of highly	T 1000	Phytopharmaceuticals (prefiltration)
viscous fluids	T 1500	Cell harvest
Catalyst removal	T 2100	Cell harvest
API	T 2600	Pharmaceuticals and biopharmaceuticals
		(solid/liquid separation)
Coarse filtration	T 3500	Serum (pre-filtration)
API, biological products	T 5500	Coarse prefiltration

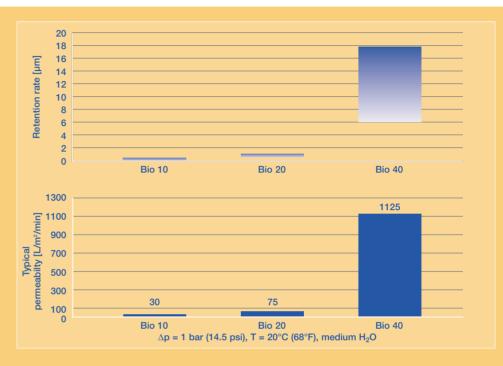
### **T-Series**

The T series of **Pall SUPRAdisc** modules includes filter media with 7 different degrees of permeability.

Grade T 950 is used for clarifying filtration. Due to its positive ZETA potential this depth filter possesses a high adsorption capacity. In contrast, grades T 1000 to T 5500 are designed for coarse filtration, and they have very low ZETA potential. They are characterized by an open structure and combine very high outputs with long filtration cycles due to their high dirt holding capacity. Grades T 1000 to T 5500 have proved successful in the filtration of viscous media, for the retention of gel particles and coarse dispersed substances at low differential pressures.

#### **Bio Series**





### **Bio Series**

The **Pall** Bio Series depth filter media were specially developed for the strict requirements in the biotechnological and pharmaceutical industry. For many years the reproducible manufacture and stringent control methods have guaranteed consistent high filtration quality as well as the highest purity of the filter medium.

BIO depth filter media are available in three different retention rates. Manufactured from highly purified natural and modified celluloses, these media are completely free from inorganic materials like kieselguhr, perlite or glass fibers. The distinguishing feature of the BIO depth filters is the reduced release of extractables.

BIO depth filters release reduced extractable metal ions, e.g. iron, aluminum or copper, than any other filter sheet. When filtering ion sensitive products such as parenteral solutions, therapeuticals, dialysis solutions or protein-based diagnostics, a considerably better filtrate quality is obtained when using BIO depth filters.

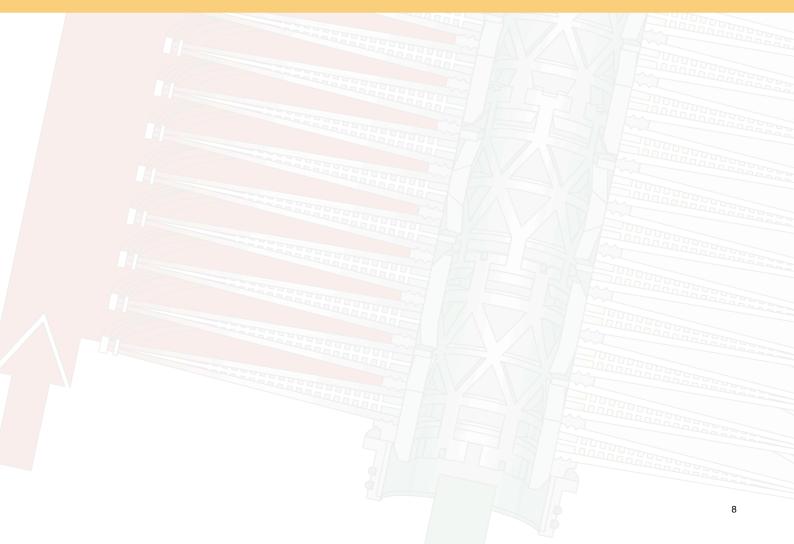
Application Areas	Medium	Application
High bioburden reduction	BIO 10	Cell harvest, clarifying filtration of fermenter broth (cell separation), clarifying filtration of TFF permeate, clarifying filtration of cell cultures, filtration of CHO cells, protection for chromatography columns and membrane processes, protection for sterile filter membranes, filtration of pharmaceuticals and biopharmaceuticals, filtration of therapeutical protein, vaccines, diagnostics and blood products, therapeutical DNA, filtration of nutrients
Bioburden reduction	BIO 20	Cell harvest, clarifying filtration of centrifugation supernatant, filtration of biopharmaceuticals, filtration of therapeutical protein, vaccines, diagnostics and blood products, plasma fractionation (fine filtration), filtration of nutrients, protection for chromatography columns and membrane processes, protection for sterile filter membranes.
Fine clarifying filtration	BIO 40	Fine filtration of pharmaceuticals and biopharmaceuticals plasma fractionation (fine filtration, protein separation), filtration of antibiotics, filtration of vaccines, separation of adsorbents, filter media, extraction residues.

The FDA (Food and Drug Administration) in the USA has registered SUPRAdisc modules under DMF (Drug Master File) No. 14325. SUPRAdisc modules' polypropylene components meet the requirements of Plastics Class VI of current USP.

The filter media meet the specifications set forth in the US Code of Federal Regulations Title 21, parts 177.2260 e, f, g, h, i, j, k, I, the materials for all polypropylene plastic components are listed in the US Code of Federal Regulations Title 21, part 177.1520. The Pall Quality Management System has been certified according to DIN EN ISO 9001 by TÜV Cert (Certification Office TÜV Rheinland, Sicherheit und Umweltschutz GmbH).

With regard to food law conformity the manufacture of depth filter sheets is also subject to ongoing analysis by the German ISEGA Forschungs- und Untersuchungsanstalt mbH, Aschaffenburg.





### **Technical and Ordering Information**

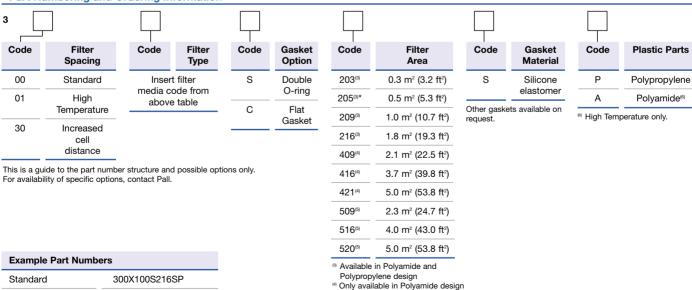
### **Filter Media Configurations**

Media Code	Depth Filter Type <sup>(1)</sup>	Weight per Typical Ash Area (g/m²) Content (%)		Extractable Ions Soluble in Acetic Acid (mg/m²) (Typical Values)		
				Ca	Fe	Al
B010	BIO 10	1400	< 1	< 0.5 ppm <sup>(2)</sup>	< 0.1 ppm <sup>(2)</sup>	< 0.05 ppm <sup>(2)</sup>
B020	BIO 20	1400	< 1	< 0.5 ppm <sup>(2)</sup>	< 0.1 ppm <sup>(2)</sup>	< 0.05 ppm <sup>(2)</sup>
B040	BIO 40	1200	< 1	< 0.5 ppm <sup>(2)</sup>	< 0.1 ppm <sup>(2)</sup>	< 0.05 ppm <sup>(2)</sup>
XEK1	EK 1	1400	51	1600	15	140
XEK0	EK	1350	46	1400	10	120
X050	KS 50	1350	46	1400	10	120
X080	KS 80	1350	46	1200	15	120
X100	K 100	1350	46	1400	15	120
X150	K 150	1350	46	1300	15	120
X200	K 200	1350	46	1200	15	110
X250	K 250	1300	46	1000	15	70
X300	K 300	1300	46	900	15	50
X700	K 700	1300	46	900	15	50
X900	K 900	1300	46	900	25	40
C100	K 100 IR	1400	51	200	20	75
C250	K 250 IR	1250	46	150	15	50
C800	K 800 IR	1250	46	120	10	30
C900	K 900 IR	1200	46	120	10	30
T950	T 950	850	40	600	13	25
T100	T 1000	950	35	570	15	30
T150	T 1500	850	33	500	12	25
T210	T 2100	700	15	350	11	20
T260	T 2600	700	< 1	300	1	5
T350	T 3500	880	15	450	15	30
T550	T 5500	750	< 1	300	1	5

<sup>(1)</sup> Other Depth Filter Types availiable on request.

### **Part Numbering and Ordering Information**

301X100S216SA



(5) Only available in Polyropylene design

\* Only available with Double O-ring.

High Temperature

Soluble after 50 L/m² flushing with WFI.

# SUPRAdisc Depth Filter Modules Technical Information

### Operating Characteristics(1)

Maximum Operating Temperature	80°C (176°F) in Polypropylene design 160°C (320°F) in Polyamide design
Maximum Operating Pressure	2.4 bard (35 psid)

With compatible fluids, which do not soften, swell or adversely affect the products or its material of construction.

### **Plastic Parts of Construction of SUPRAdisc Modules**

SUPRAdisc components	Polypropylene Polyamide (Only high temperature version)
O-rings	Silicone elastomer

### Sterilization

Steam In Place	125°C (257°F), for 30 minutes at 0.3 bard (43 psid) maximum
Nominal Dimensions	
SUPRAdisc Modules	
Nominal Total Length Double-O-ring	332 mm (13.1 in.)
Flat gasket	272 mm (10.7 in.)
Nominal Diameters	284 mm (12 in.) for ordering codes 203, 205, 209 and 216 in Polypropylene and Polyamide designs
	410 mm (16.1 in.) for ordering codes 409, 416 and 421 in Polyamide design
	413 mm (16.3 in.) for ordering codes 509, 516 and 520 in

Polypropylene design



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