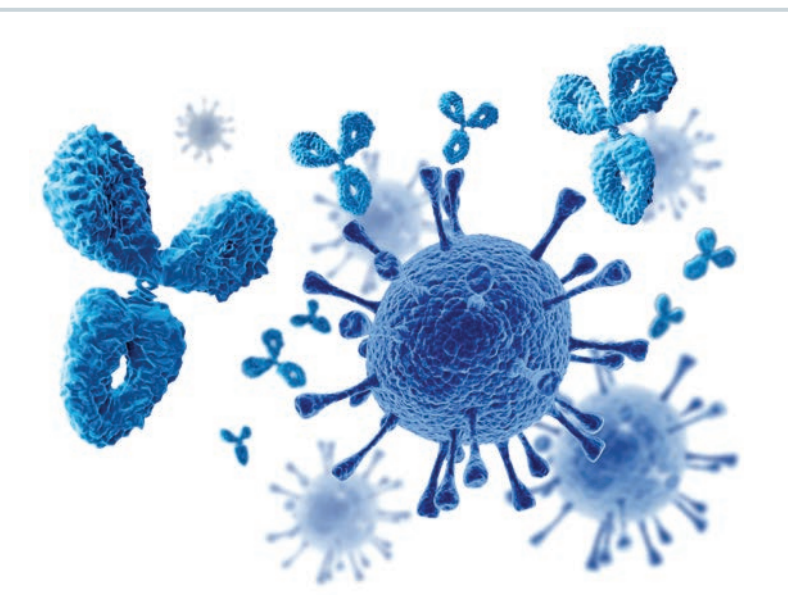




PLANOVA™ Filters

**VIRUS REMOVAL FOR
BIOTHERAPEUTIC
PRODUCTS**



Introducing Planova™ — Assurance Beyond Expectation

■ Asahi Kasei, World Leader

Planova™ filters are products of Asahi Kasei Medical Co., Ltd., one of the world's leading filter manufacturers and part of the Asahi Kasei Group, a global technology leader providing innovative, science-based solutions to a diverse range of markets.

■ World's First, Launched in 1989

Launched in 1989, Planova filters are the first filters developed specifically for removing viruses from biopharmaceutical drug products such as biopharmaceuticals and plasma derivatives.

■ Integrated Equipment Support

Complete filtration and test systems are made by Asahi Kasei Bioprocess.

■ Proven Worldwide

Planova filters have two decades of proven safety and reliability in the international biopharmaceutical industry.

To meet increasing demand, Asahi Kasei Medical Co., Ltd., continues to expand its Planova filter production capacity.

Product distribution and technical support are provided by Asahi Kasei Bioprocess America, Inc., N.V. Asahi Kasei Bioprocess Europe S.A., and Asahi Kasei Medical Co., Ltd.

■ Excellent Performance

Planova filters offer an excellent combination of high protein yield, validated virus safety, and scalability.

■ Robust Virus Removal

Virus removability is based on size exclusion and depth filtration mechanisms: viruses larger than the mean pore size become trapped. Planova filters are available in pore sizes to match the virus removal needs of particular product applications.

■ Advantage of Easy Scalability

The same format housing, combined with the scaled number of hollow fibers in each size filter, results in a reliable



scalability from development work on to large scale manufacturing.

■ Committed to Ongoing Research & Development

Asahi Kasei Medical's commitment to research and development continually enhances the Planova filter line. Research suggests that Planova filters can remove prions suspected of transmissible spongiform encephalopathies (TSE) such as Creutzfeldt-Jakob disease.^{1,2}

¹ *Scrapie Removal Using Planova™ Virus Removal Filters.* Tateishi, J., et al. *Biologicals* 29:17-25 (2001).

² *Current Strategies to Prevent Transmission of Prions by Human Plasma Derivatives.* Burnouf, T., et al. *Transfusion Clinique et Biologique* 13:320-328 (2006).



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Principles of Planova™ Filter Operation

■ Planova™ Virus Removal

Planova filters contain a bundle of straw-shaped hollow fibers.

When a protein solution with possible viral contamination is introduced into the inside of these hollow fibers, the solution penetrates the fiber wall, through a tortuous, three-dimensional network of interconnected void and capillary pores, to the outside.

The hollow fiber wall's dense pore structure is several tens of micrometers thick, resulting in high-capacity virus removal. Viruses are captured gradually and effectively, while proteins migrate outward with minimal adsorption or inactivation.

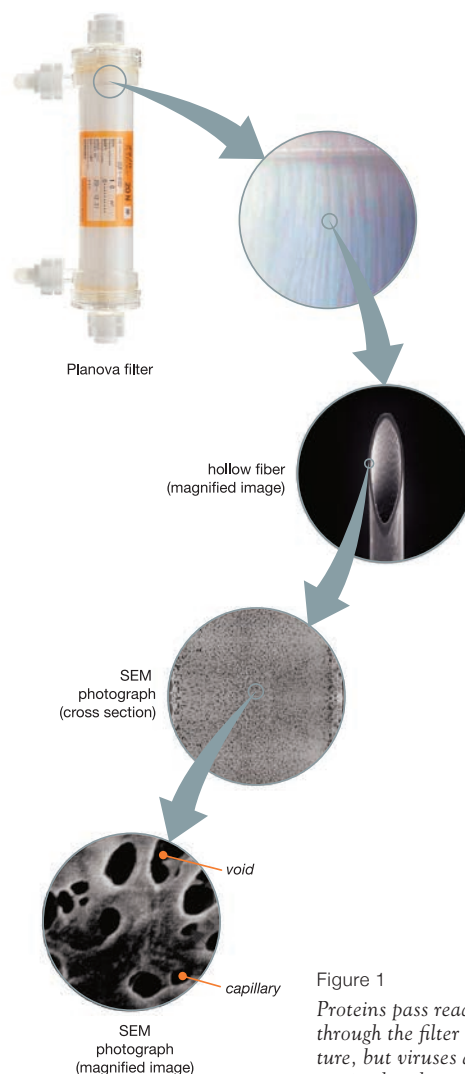
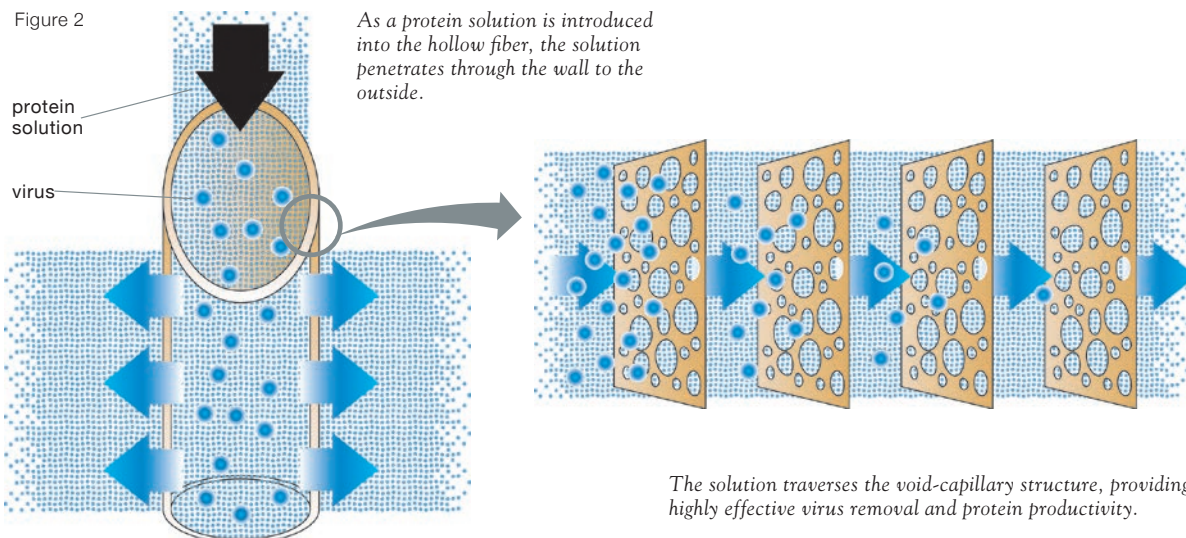


Figure 1
Proteins pass readily through the filter structure, but viruses are retained and removed from the purification stream.

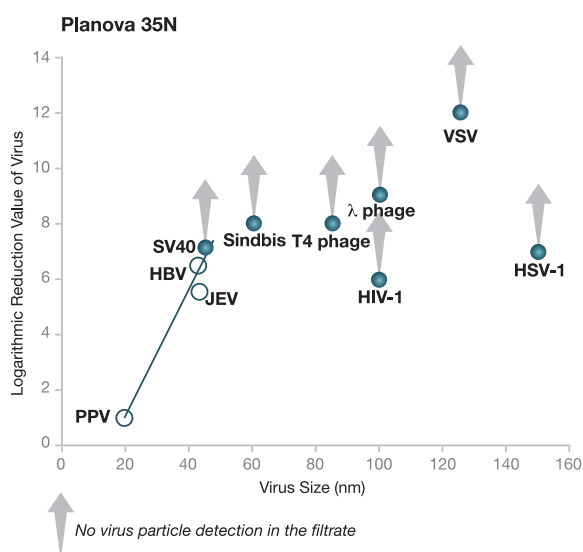
Figure 2



■ Size Exclusion

Planova's LRV (logarithmic reduction value) rises in proportion to the size of the virus, as shown in Figure 3. This shows that Planova virus removal works on the principle of size exclusion, relatively unaffected by physical or chemical effects, such as adsorption. Therefore, even unknown viruses can be excluded as long as the virus size meets the exclusion specification of the filter.

Figure 3



Planova filters operate on the principle of size exclusion, enabling removal of any virus that meets the specified size criteria. Note that the Planova 20N has an LRV of >4.0 for PPV. See "Sample Data on Virus Removal" on page 12.

■ Wide Range of Surface Areas with Excellent Scalability

The same format housing, combined with the scaled number of hollow fibers in each size filter, results in a reliable scalability from development work on to large scale manufacturing.

Planova 15N, 20N and 35N filters are

offered in 0.001 m², 0.01 m², 0.12 m², 0.3 m², 1.0 m² and 4.0 m² sizes. The 4.0 m² filter reduces the number of filters needed for a manufacturing cycle and shortens cumulative integrity test time.

The PVDF media Planova BioEX filter is offered in 0.0003 m², 0.001 m², 0.01 m², 0.1 m², 1.0 m² and 4.0 m² sizes.

Figure 4



All sizes of Planova filters have the same basic structure to simplify lab studies and allow rapid scale-up to process scale.



The Planova BioEX filter line includes 4.0 m², 1.0 m², 0.1 m², 0.01 m², 0.001 m² and 0.0003 m² sizes.

Planova™ BioEX Filters

■ PVDF Hollow Fiber Filter

Construction

The Planova™ BioEX filter membrane is made of hydrophilized polyvinylidene fluoride (PVDF), a robust material with a unique structure that permits high-flow-rate filtration of high-concentration protein solutions, while maintaining capacity for virus removal. This makes it highly suitable for large-volume production of biotherapeutic products.

Planova BioEX filters achieve high flow rates with reliable virus removal, thanks to a dense and homogeneous PVDF membrane produced by thermally induced phase separation. The PVDF membrane is made hydrophilic by graft polymerization.

Planova hollow fiber technology assures high quality consistency and provides outstanding scalability for biotherapeutic manufacturing.



PLANOVA™ **BioEX**



品番 Catalog No. EX1-0000

膜面積 Effective surface area 1.0 m²

製造番号 Production number E111111****

使用期限 Expiration date Jun. 01, 2099

紡糸シリーズ番号 Spinning series number ***

成型番号 Assembly number *****

高圧蒸気滅菌済 Sterilized via autoclave 旭化成メディカル株式会社 ASAHIKASEI MEDICAL CO., LTD.

■ **Effective for High-Pressure and High-Concentration Usage**

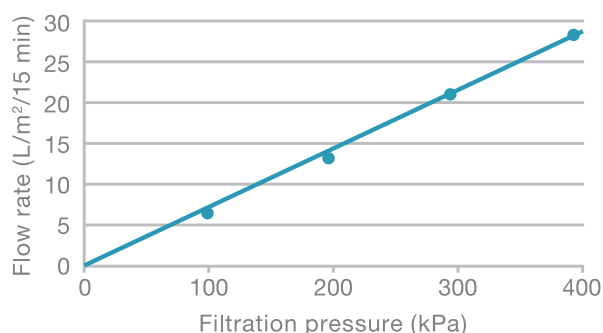
Research data supports the use of Planova BioEX filters for high-pressure, high-concentration filtrations.

Figure 5 shows the excellent correlation between filtration pressure and flow rate, which stays proportional even in the high pressure range.

Figure 6 shows that, with a 3% to 5% h-IgG solution, Planova BioEX maintains a high throughput of 6.5 kg/m²/3 hrs at filtration pressure of 294 kPa (42.6 psi).

Figure 5

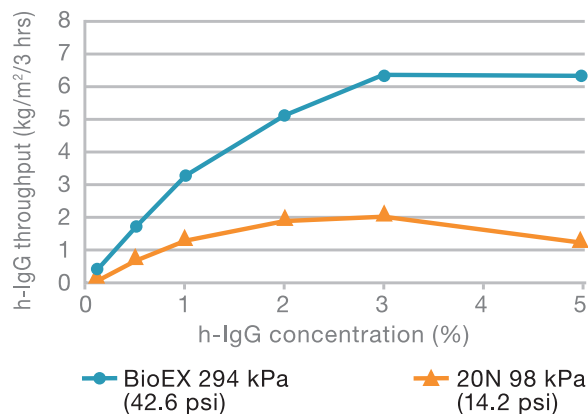
Correlation between flow rate of 3% h-IgG solution and filtration pressure



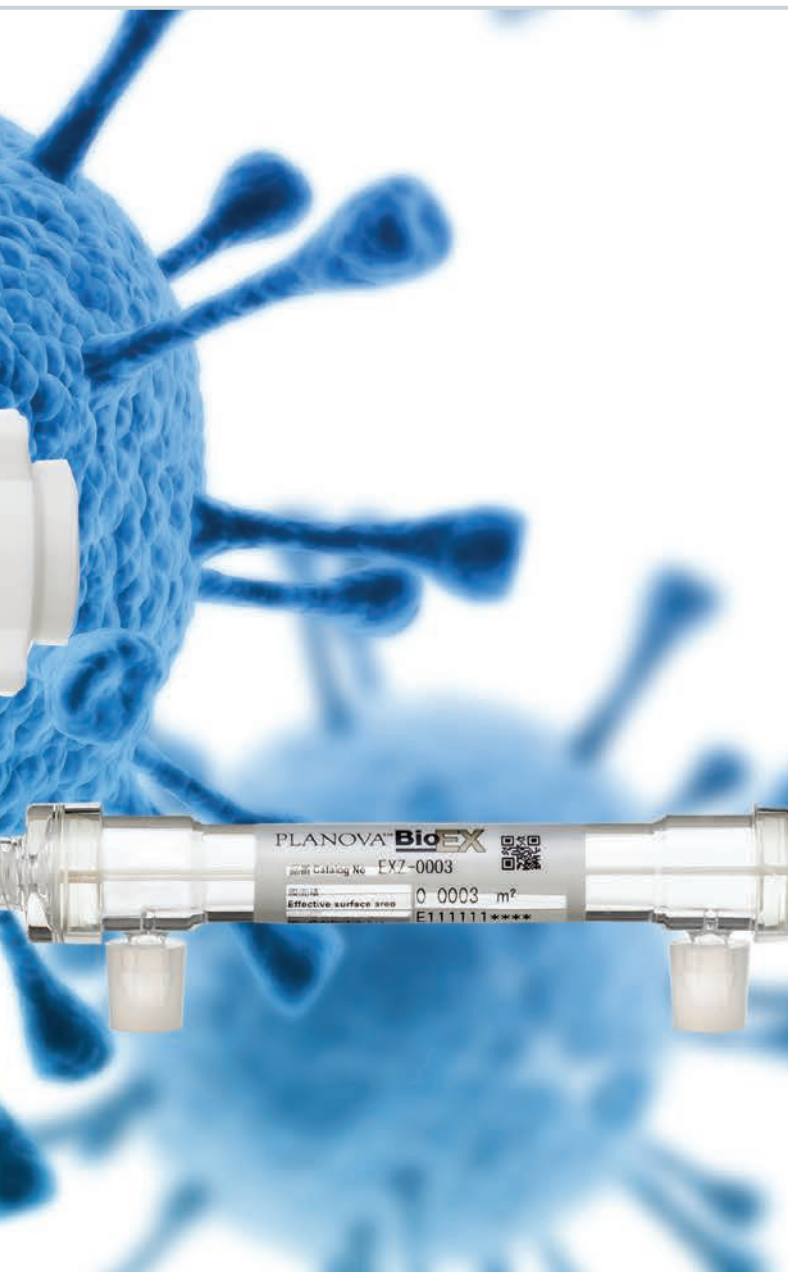
Flow rate is dependent on pressure. Higher pressure yields faster processing.

Figure 6

Relationship between h-IgG throughput and h-IgG concentration



Planova BioEX filters can withstand high-concentration solutions, thereby increasing the quantity of protein to be processed.



Planova™ BioEX Performance

■ High LRV for Parvoviruses and Larger Viruses

Planova™ BioEX filters are able to remove parvoviruses, which are among the smallest known viruses found in nature, achieving levels below the detection threshold. Planova BioEX filters are validated to deliver > 4.0 logs of removal for PPV.

For high productivity, this performance is sustained even for large-volume filtration of high-concentration solutions, as shown in Figure 7.

Extensive testing of Planova BioEX filters validates performance for large viruses as well. For example, BioEX achieves > 5.5 logs for A-MuLV, as also shown in Figure 7.

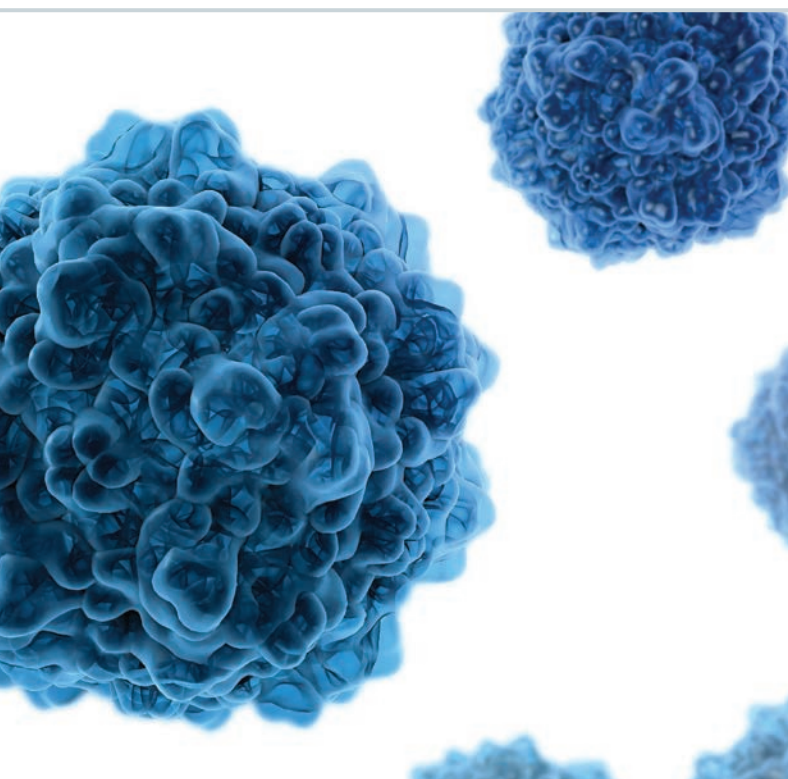
■ Laboratory-Scale and Process-Scale

In addition to the process-scale 4.0 m² and 1.0 m² Planova BioEX filter, the laboratory-scale 0.001 m² filter is offered for developing biological drug product manufacturing processes. Its smaller membrane surface area is convenient for scaled-down qualification or validation studies.

Additional Planova BioEX filter sizes, including 0.0003 m², 0.01 m² and 0.1 m², are available.

■ Standard Clamp Connections and SIP Capability

For easy integration into manufacturing processes, Planova BioEX 4.0 m², 1.0 m² and 0.1 m² filters are designed for standard sanitary connections.





Ferrule connection nozzle design enhances connection stability.

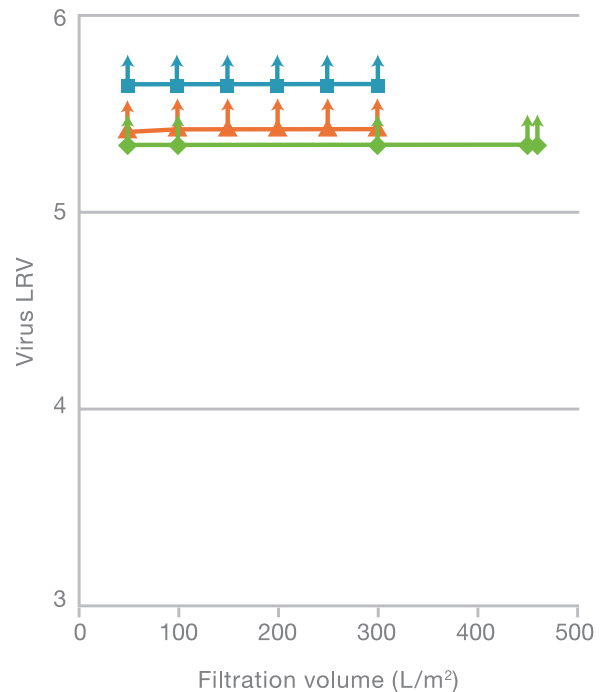
Membrane material and cartridge elements are constructed with the strength and integrity to withstand steam-in-place (SIP) operations.

Predictable Results

Planova BioEX filters provide predictable performance under a considerable range of conditions, in many cases without prefilters.

Figure 7

Removability of PPV, MVM and A-MuLV for Planova BioEX



↑ Not detected

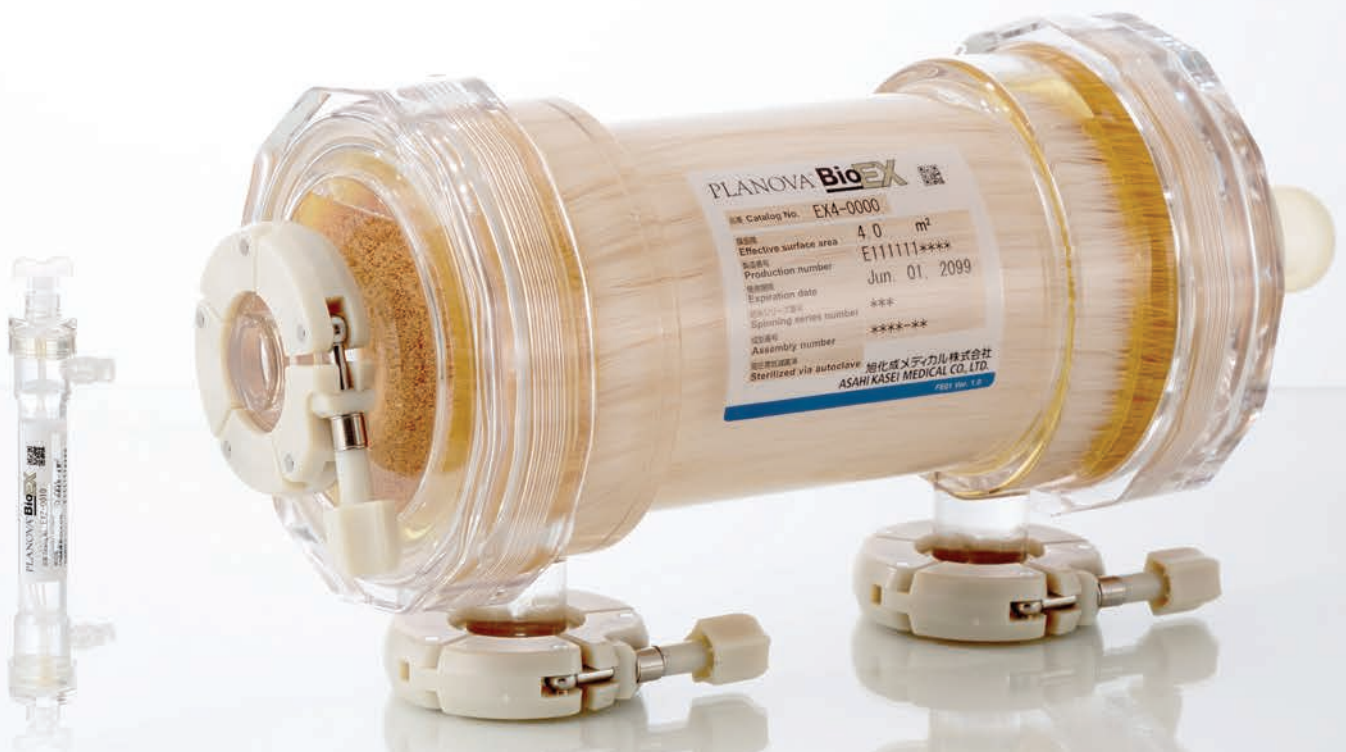
■ MVM

▲ A-MuLV

◆ PPV

3% h-IgG was spiked with 0.5% by volume of each virus solution.
Filtration Pressure: 294 kPa (42.6 psi)

Even for high-volume filtration of high-concentration solutions, Planova BioEX removes parvoviruses and larger viruses.

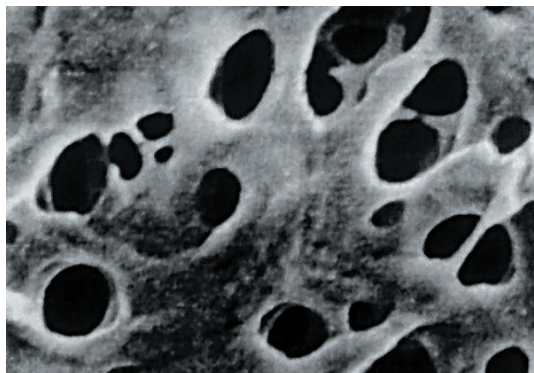


Planova™ 15N, 20N, 35N, 75N

■ Cuprammonium Regenerated Cellulose

The Planova™ 15N, 20N, 35N and 75N filters are made of cuprammonium-regenerated cellulose hollow fibers. They offer a choice of four mean pore sizes: 15 nm, 19 nm, 35 nm and 72 nm, respectively.

Planova filters work on the size exclusion principle and can be applied to a broad range of biologicals, including human



Highly effective virus removal of Planova filters is based on size-exclusion.

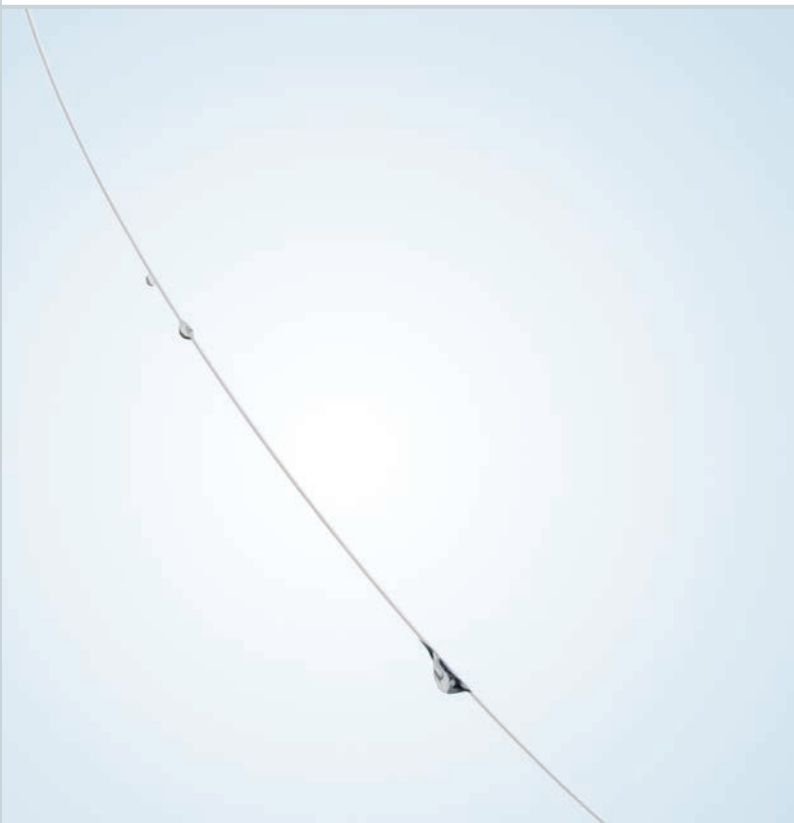
plasma-derived proteins and recombinant proteins, especially monoclonal antibodies.

■ Naturally Hydrophilic Material Maximizes Protein Recovery

Cellulose is the most hydrophilic filter material in use. This natural property of cellulose maximizes the yield of protein recovery by minimizing protein adsorption.



The Planova hollow fiber hydrophilic regenerated cellulose maximizes protein recovery.



In addition, cellulose maintains high output over long filtration times (Figure 8) and is minimally affected by detergent (Figure 9).

■ Drug Master Files

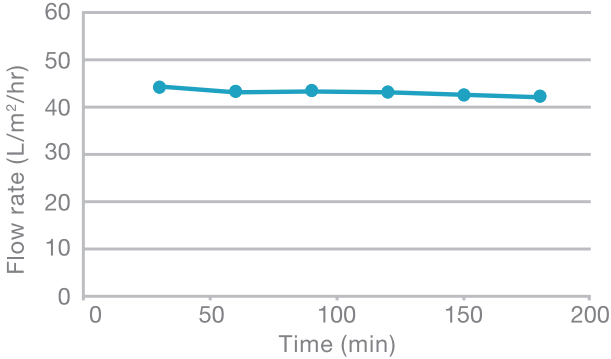
Filters in the Planova line are individually identified and supplied with a Certificate of Analysis. Drug Master Files are on file with the US FDA for Planova 15N, 20N, 35N and 75N filters.

■ Large-Pore Prefilter

The Planova 75N filter is designed to remove impurities or aggregated proteins prior to final virus filtration. It is available in 0.001 m², 0.01 m², 0.3 m² and 1.0 m² sizes.

Figure 8

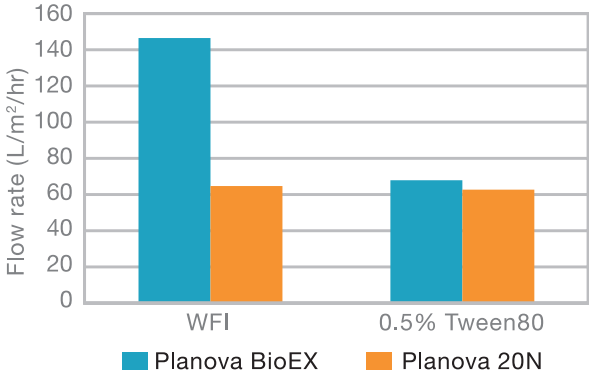
Flow rate vs. filtration time with Planova 20N



Filtration of 1% h-IgG solution. Planova 20N filters maintain high throughput over long filtration times.

Figure 9

Flow rate with Planova BioEX and Planova 20N



Detergent affects performance of Planova BioEX but has very little effect on Planova 20N.

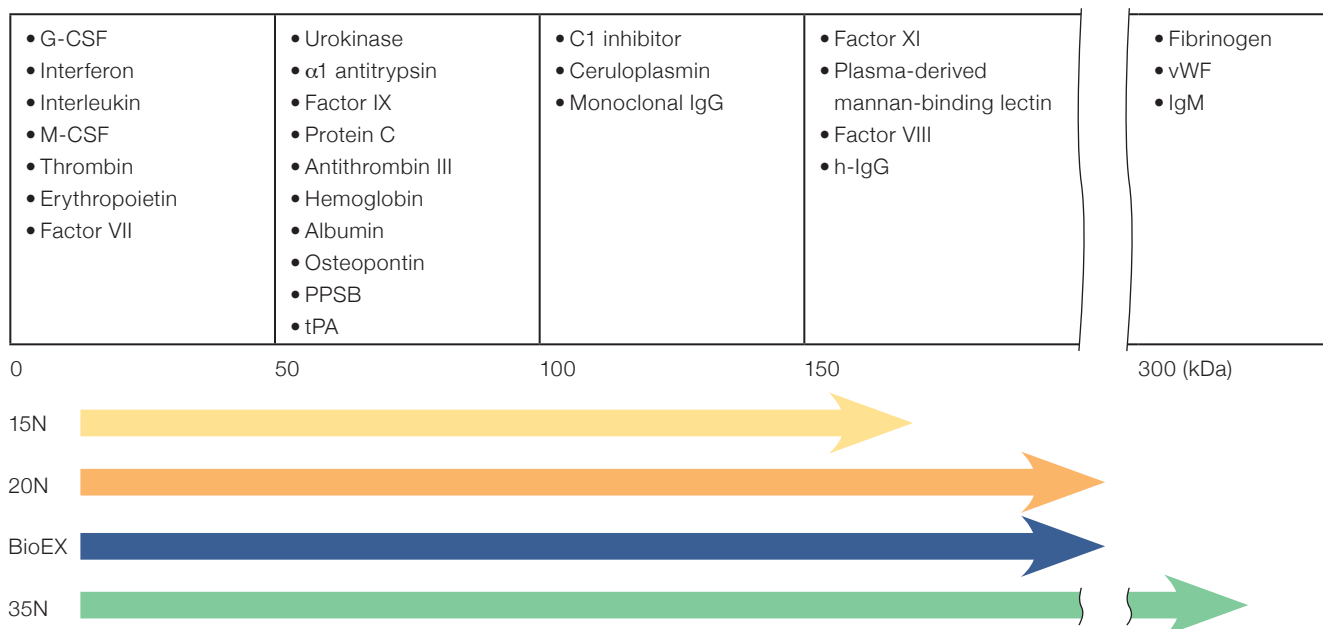


Reference

Sample Data on Virus Removal

Filter Type	Virus	Size (nm)	Genome	Physico-chemical resistance	LRV	Reference
15N	CPV	18-26	DNA	high	>4.5	Biologicals 35, pp.173-181 (2007)
15N	B19	18-26	DNA	high	>6.1	Vox Sang. 90, pp.21-32 (2006)
15N	PPV	18-24	DNA	high	>4.6	Vox Sang. 84, pp.54-64 (2003)
15N	EMCV	25-30	RNA	medium	>5.8	Vox Sang. 90, pp.21-32 (2006)
15N	Polio-1	25-30	RNA	medium	>7.8	Viral Blood Safety and Screening: Washington DC, Oct.17-18 (1994)
15N	HAV	27-32	RNA	high	>6.7	Biologicals 28, pp.129-136 (2000)
15N	BVDV	50-70	RNA	medium	>5.5	Biologicals 35, pp.173-181 (2007)
15N	HIV-1	80-120	RNA	low	>5.6	Biologicals 35, pp.173-181 (2007)
15N	XMuvLV	80-110	RNA	low	>6.4	Jpn J Apheresis 16, pp.160-164 (1997)
20N	B19	18-26	DNA	high	4.9	Vox Sang. 91, pp.119-125 (2006)
20N	MVM	18-24	DNA	high	6.9	Biotechnol Bioeng. 100, pp.488-496 (2008)
20N	PPV	18-24	DNA	high	>5.2	J Membr Sci. 278, pp.3-9 (2006)
20N	PPV	18-24	DNA	high	>5.1	Vox Sang. 91, pp.119-125 (2006)
20N	PPV	18-24	DNA	high	>4.2	Journal of the Society for Japanese Blood Programme 24, page 305 (2001) (in Japanese)
20N	EMCV	25-30	RNA	medium	>5.8	Vox Sang. 91, pp.119-125 (2006)
20N	EMCV	25-30	RNA	medium	4.8	Am J Ther. 15, pp.435-443 (2008)
20N	HAV	27-32	RNA	high	>3.4	Vox Sang. 91, pp.119-125 (2006)
20N	HIV-1	80-120	RNA	low	>4.7	Am J Ther. 15, pp.435-443 (2008)
20N	XMuvLV	80-110	RNA	low	>3.1	Biotechnol Prog. 25, pp.483-491 (2009)
20N	PRV	120-200	DNA	medium	>5.6	Am J Ther. 15, pp.435-443 (2008)
35N	B19	18-26	DNA	high	5(*)	Vox Sang. 86, pp.225-229 (2004) (*) from graph data
35N	PPV	18-24	DNA	high	<1.0	International Plasma Protein Congress (2003) 25-27 March (Brussels)
35N	SV40	40-50	DNA	high	>7.8	Vox Sang. 67, pp.132-138 (1994)
35N	BVDV	50-70	RNA	medium	>5.3	Vox Sang. 91, pp.119-125 (2006)
35N	Reo-3	60-80	RNA	medium	>6.1	Vox Sang. 67, pp.132-138 (1994)
35N	HIV	80-120	RNA	low	>7.3	Jpn J Apheresis 16, pp.160-164 (1997)
35N	HSV	150-200	DNA	low	>7.2	Jpn J Apheresis 16, pp.160-164 (1997)
BioEX	PPV	18-24	DNA	high	>5.3	Internal Study Report
BioEX	MVM	18-24	DNA	high	>4.8	Internal Study Report
BioEX	MVM	18-24	DNA	high	>6.1	Internal Study Report
BioEX	BVDV	50-70	RNA	medium	>6.2	Internal Study Report
BioEX	Reo-3	60-80	RNA	medium	>5.3	Internal Study Report
BioEX	A-MuLV	80-130	RNA	low	>5.2	Internal Study Report

Product Applications



Examples of Protein Recovery Rate

	Polyclonal IgG (30mg/ml)	Monoclonal IgG (20mg/ml)	Factor VIII (100IU/ml)
Planova 15N	<90%	>95%	20-80%
Planova 20N	>95%	>98%	>85%
Planova 35N	100%	100%	>95%
Planova BioEX	>95%	>98%	NT

NT: Not tested

Nomenclature

A-MuLV amphotropic murine leukemia virus
 B19 human parvovirus B19
 BVDV bovine viral diarrhea virus
 CPV canine parvovirus
 EMCV encephalomyocarditis virus
 G-CSF granulocyte-colony stimulating factor
 HAV hepatitis A virus
 h-IgG human immunoglobulin G
 HIV human immunodeficiency virus
 HIV-1 human immunodeficiency virus type-1
 HSV herpes simplex virus
 IgM immunoglobulin M

M-CSF macrophage-colony stimulating factor
 Monoclonal IgG monoclonal immunoglobulin G
 MVM minute virus of mice
 Polio-1 poliovirus type 1
 PPSB prothrombin complex
 PPV porcine parvovirus
 PRV pseudorabies virus
 Reo-3 reovirus type 3
 SV40 simian virus 40
 tPA tissue plasminogen activator
 vWF von Willebrand factor
 XMuLV xenotropic murine leukemia virus

Quality & Integrity Testing

■ Conformance with In-House Good Manufacturing Practice

Planova™ filters are assembled under strictly controlled conditions in a state-of-the-art plant conforming to in-house good manufacturing practice based on U.S. Food and Drug Administration cGMP.

■ Integrity Testing by Manufacturer

At the factory, each Planova filter is evaluated with two integrity tests.

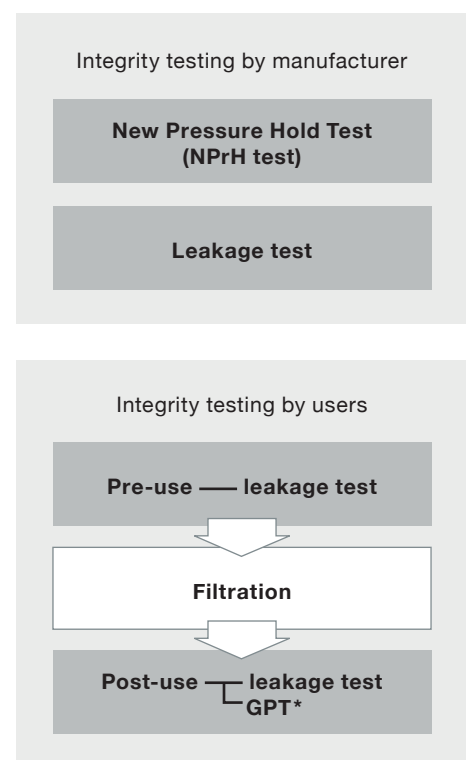
The New Pressure Hold (NPrH) Test, developed by Asahi Kasei Medical Co., Ltd., validates pore size distribution by nitrogen gas flow rate. The leakage test verifies the absence of larger fiber defects (pinholes).

■ Integrity Testing by Users

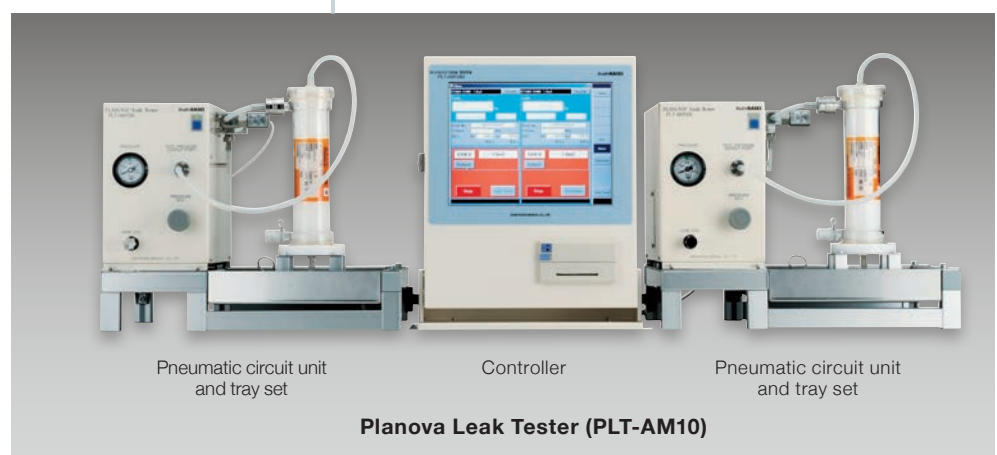
Users can perform the leakage test for large-defect testing and the high-precision Asahi Gold Particle Test (GPT) for pore size distribution testing. The leakage test is conducted before and after use to confirm that the Planova filter is free from pinholes or large defects. The unique GPT is performed after use to confirm that pore size distribution has not changed inappropriately during filtration. Combining these two tests maximizes the range of detectable filter defects to enhance the safety and reliability of virus removal processes.

Figure 10

Integrity Tests



**GPT is not necessary for Planova BioEX.*



One controller can control two pneumatic circuit units at the same time.

■ Leakage Test

The leakage test provides a reliable indication of filter membrane quality, both before and after filter use. It can be performed manually based on visual detection of pressurized air bubbling through the filter fibers. It can also be performed automatically for filters with surface areas of 4.0 m², 1.0 m², 0.3 m², 0.12 m² and 0.1 m² using the Planova Leak Tester (PLT-AM10), which measures air flow through the filter's hollow fibers. A touch panel display allows easy operation and read-out. Test results can also be printed out.

■ Asahi Gold Particle Test

The unique Asahi Gold Particle Test (GPT) is the most precise user-conducted

integrity test on the market. It serves to reconfirm filter quality (pore size distribution) after filtration. In the test, an Asahi Gold Particle (AGP) solution of colloidal gold particles is applied to the filter. The gold particles in the solution match the sizes of target viruses.

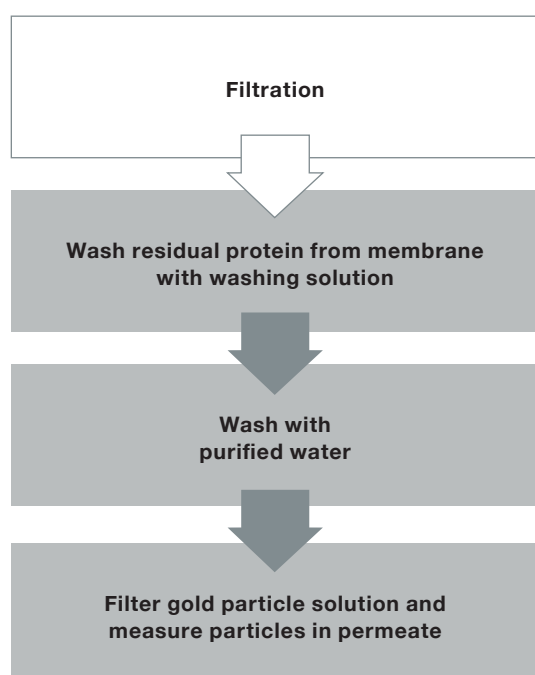
AGP solution kits are available to match specific Planova filters. The AGP-HA15, AGP-HA20 and AGP-HA35 are for Planova 15N, 20N and 35N filters.



AGP-HA series gold-particle solution for post-use integrity testing of Planova 15N, 20N and 35N filters.

Figure 11

Integrity Test with AGP Solution



Specifications & Suggested Operating Parameters

■ Planova 15N, 20N, 35N¹ & 75N^{2,3}

			Effective surface area (m²)					
			4.0	1.0	0.3	0.12	0.01	0.001
Component	Hollow fiber membrane		Cuprammonium regenerated cellulose					
	Housing and headers		Polycarbonate					
	Sealant		Polyurethane					
	O-rings		Silicone					
	Nozzle plugs		Silicone				–	
	Nozzle caps		–		Silicone			
	Ferrule caps		Polycarbonate		–			
	Balloon cap holders		Polycarbonate		–			
	Gaskets		Silicone		–			
	Balloon caps		Silicone				–	
	Nozzle stoppers		–	Silicone	–			
	Clamp bands		Polysulfone	–				
	Threaded clamps	Clamp bolts	–	Polypropylene	–			
		Clamp nuts	–	Polypropylene	–			
Pin bands			–		SUS304		–	

Membrane wetting agent	Filters are filled with purified water ⁴							
Sterilization method	Autoclaving							
Packaging	Packed individually in sterilization bags							
Suggested operating pressure	≤ 98 kPa							
Operating pH	3-9							
Endotoxin	Less than 0.25 EU/mL, confirmed in LAL testing							
Biological safety	Conformance with Japanese Pharmacopeia and USP standards for class VI plastics							

¹ Planova 35N filters can be used as effective prefilters prior to final virus filtration with 15N or 20N.

² Planova 75N filters are prefilters designed to remove impurities or aggregated proteins prior to final virus filtration and are not virus removal filters.

³ Planova 75N filters are only available in membrane surface areas of 1.0 m², 0.3 m², 0.01 m² and 0.001 m².

⁴ Purified water in 4.0 m² filters contains NaCl (≤0.1%).

■ Planova BioEX

			Effective surface area (m ²)						
			4.0	1.0	0.1	0.01	0.001	0.0003	
Component	Hollow fiber membrane		Hydrophilic modified polyvinylidene fluoride						
	Housing and headers		Polycarbonate						
	Locknut		Polycarbonate	–					
	Sealant		Polyurethane						
	O-rings		Silicone						
	Balloon caps		Silicone			–			
	Nozzle plugs		Silicone			–			
	Nozzle stoppers		–	Silicone		–			
	Gaskets		Silicone			–			
	Ferrule caps		Polycarbonate			–			
	Balloon cap holders		Polycarbonate			–			
	Clamp bands		Polysulfone	–					
	Threaded clamps	Clamp bolts	–	Polypropylene		–			
		Clamp nuts	–	Polypropylene		–			
	Luer lock plugs		–			Polypropylene			
Nozzle caps		–			Silicone				
Membrane wetting agent				Filters are filled with purified water					
Sterilization method				Autoclaving					
Packaging				Packed individually in sterilization bags					
Suggested operating pressure				≤ 343 kPa					
Operating pH				2-9					
Endotoxin				Less than 0.25 EU/mL, confirmed in LAL testing					
Biological safety				Conformance with Japanese Pharmacopeia and USP standards for class VI plastics					

Product Lineup & Catalog Numbers

Planova Filters	Effective Surface Area (m ²)	Catalog No.
-----------------	--	-------------

Planova 15N	4.0	15N4-000
	1.0	15F1-000
	0.3	15NZ-300
	0.12	15NZ-120
	0.01	15NZ-010
	0.001	15NZ-001

Planova 20N	4.0	20N4-000
	1.0	20F1-000
	0.3	20NZ-300
	0.12	20NZ-120
	0.01	20NZ-010
	0.001	20NZ-001

Planova 35N	4.0	35N4-000
	1.0	35F1-000
	0.3	35NZ-300
	0.12	35NZ-120
	0.01	35NZ-010
	0.001	35NZ-001

Planova 75N (Prefilter)	1.0	75F1-000
	0.3	75NZ-300
	0.01	75NZ-010
	0.001	75NZ-001

Planova BioEX	4.0	EX4-0000
	1.0	EX1-0000
	0.1	EXZ-1000
	0.01	EXZ-0100
	0.001	EXZ-0010
	0.0003	EXZ-0003

Asahi Integrity Test Kits	Size	Catalog No.
---------------------------	------	-------------

AGP-HA15	880 ml	AGP-HA15M
	110 ml	AGP-HA15S
AGP-HA20	880 ml	AGP-HA20M
	110 ml	AGP-HA20S
AGP-HA35	880 ml	AGP-HA35M
	110 ml	AGP-HA35S

Accessories	Application	Catalog No.
-------------	-------------	-------------

Module header (B)	0.3, 0.12 m ²	HEADER-B2
Module coupler	0.3, 0.12 m ²	COUPLER-01



Module Headers & Couplers

Planova Leak Tester	Application	Catalog No.
---------------------	-------------	-------------

Controller (for US)	4.0, 1.0, 0.3, 0.12, 0.1 m ²	PLT-AM10MU
Controller (for Europe)		PLT-AM10ME
Pneumatic Circuit Unit		PLT-AM10K0
Tray Set		PLT-AM10TS

Equipment

■ Bioprocess Equipment

Automated systems and filtration equipment and validated integrity test equipment are developed and made by Asahi Kasei Bioprocess to provide turnkey solutions for Planova™ virus filtration.

Asahi Kasei Bioprocess also offers these products and services for manufacturing process of biotherapeutic products.

- IBD™ inline buffer dilution skids.
Best in class buffer dilution accuracy using unique technology compensates for variability in the buffer concentrate — deliver precise and reproducible buffers to within 1 mS of setpoint or less.
- Bioprocess LC Systems.
- Process development, scale-up and tech transfer support.
- Equipment Validation services (IQ/OQ and GAMP-5).
- Service Contracts.

■ Viral Filtration Systems

Complete viral filtration systems are available to maximize the advantages of Planova filter technology.

Viral filtration systems can accommodate multiple Planova filters on one automated skid.



Viral filtration systems are built to order by Asahi Kasei Bioprocess.

■ Asahi Gold Particle Test System

The Asahi Gold Particle Test System (AGPTS) is an automated and validated system for conducting the Asahi Gold Particle Test (GPT), a post-use integrity test.

The system is easy to use and minimizes operator error in filter integrity testing. The

AGPTS also saves time and reduces costs associated with manual integrity tests.



The AGPTS can automate GPT procedure, a post-use integrity test for Planova filters, and supply validated data.

■ Custom Built with IQ/OQ Package

All products are custom built and designed on demand. It is fully validated with complete Installation and Operational Qualification (IQ/OQ) execution and documentation available for turnkey operation.

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