



FILTRODISC™ R2U

READY2USE DEPTH FILTRATION SYSTEM

Closed system – easy handling – no cleaning

Ready2Use depth filter modules make it possible to handle large filter areas in a simple manner. Filtration is carried out in an enclosed system (bag around the filter modules and DISCSTAR™ BIO SD housings). The installed depth filter sheets have a particle absorption capacity of up to 4 kg/m². Within the filtration process itself, the particles are slowed down in the filter sheet and finally held back due to their size or electrokinetic forces. These effects allow using the filter for a longer time than surface filters. All utilized materials are FDA-approved. The whole range of filter sheets can be installed in the modules.

Construction

The modules are made out of a support structure of polypropylene. The lenses from filter sheets, including drainage bodies, are fastened on them. In modules with fewer than 16 lenses (2–7 lenses), outside support bars can be applied for stabilization. The surrounded bag material is a double PE layer.

Material

Filter sheets:

- PURAFIX:
 - Cleaned and bleached cellulose
 - Natural filter aid (kieselgur, perlite)
 - Cationic wet strength agent
- SYNTHAFIX™:
 - Synthetics fibers

– Plastic modules:

- Polypropylene (standard module) USP Class VI

– Bag:

- Multilayer PE

– Tube:

- Pharma grade pressure stable

– Connectors:

All common types possible, for details please see information from the respective manufacturer.

Leachables & extractables

– Bag material:

Please refer to separate validation guide from the bag supplier. Available on request.

– Modules:

Please refer to validation guide FILTRODISC™ BIO SD. Available on request.

– Tubes:

Please refer to validation guide of the respective tube manufacturer.

– Connectors:

Please refer to validation guide of the respective connector manufacturer.

Validation guides for the bag material, modules and tubes can be requested from FILTROX.

Technical data for modules

	2" Mini Capsule	5" Capsule	12"K R2U	12"S R2U	12"D R2U	16" R2U
Number of filter lenses ¹	1	1	6	16	32	32
Max. filter area for sheet filtration [m ²]	0.002	0.0127	0.66	1.8	3.6	7.2
Size of inlet and outlet connection [DN]	4.5	6	10	10	15	20
Inner diameter of inlet and outlet [inch/mm]	1/4" / 6.4	3/8" / 9.5	1/2" / 12.7	1/2" / 12.7	3/4" / 19.5	1" / 25.4
Inner diameter of air vent [inch/mm]	Luer lock	Luer lock	3/8" / 9.5	3/8" / 9.5	3/8" / 9.5	3/8" / 25.4
Hold up volume of empty support system [l]			13.6	25	51	90
Max. hold up volume after filtration run [l] ²			9.9	16.4	33.0	53.7
Hold up volume after blow out [l] ³			5.5	5.8	5.8	10.3
Max. operating pressure at 25 °C [bar]	2.5	2.5	3.0	3.0	3.0	3.0
Max. operating pressure at 60 °C [bar]	2.0	2.0	3.0	3.0	3.0	3.0

¹ For 2" and 5" capsules: number of filter pads

² Hold up volume of empty support system

³ Volume of support system below lowest filter lens

Retention rates PURAFIX® CH P

Sheet type	Code	Retention rate [µm]	Water value* [l/m² min] Δ p = 1 bar	Filtration type
CH 6P	06	35–15	2800–3600	Coarse filtration
CH 9P	09	30–10	1500–2100	Coarse filtration
CH 15P	15	20–8.0	960–1240	Coarse filtration
CH 15ZP	15 Z	20–8.0	960–1240	Coarse filtration
CH 21HP	23	15–6.0	690–865	Clear filtration
CH 31HP	33	12–5.0	280–360	Clear filtration
CH 31HZP	33 Z	12–5.0	280–360	Clear filtration
CH 41HP	43	9.0–4.0	240–300	Clear filtration
CH 50P	53	6.0–3.0	200–240	Clear filtration
CH 71HP	73	3.0–1.5	170–210	Fine filtration
CH 81HZP	83 Z	3.0–1.5	170–210	Fine filtration
CH 101HP	103	1.5–0.6	98–121	Germ reducing filtration
CH ST 110P	113	0.8–0.5	68–80	Sterile filtration (germ removing filtration)
CH ST 130P	133	0.6–0.4	42–52	Sterile filtration (germ removing filtration)
CH ST 140P	143	0.4–0.2	26–34	Sterile filtration (germ removing filtration)
CH ST 145ZP	145 Z	0.3–0.1	19–29	Sterile filtration (germ removing filtration)
CH ST 150P	153	0.2–0.04	10–16	Sterile filtration (germ removing filtration)

Retention rates PURAFIX® CH PF P

Sheet type	Code	Retention rate [µm]	Water value* [l/m² min] Δ p = 1 bar	Filtration type
PF 9P	09 F	30–10		Coarse filtration
PF 50P	53 F	4–1.5		Clear filtration
PF 80P	83 F	2–0.8		Clear filtration
PF 120P	123 F	0.7–0.4		Sterile filtration (germ removing filtration)
PF 140P	143 F	0.4–0.2		Sterile filtration (germ removing filtration)

Retention rates SYNTHAFIX™ SY

Sheet type	Code	Retention rate [µm]	Water value* [l/m² min] Δ p = 1 bar	Filtration type
SY 30	33 S	12.0–5.0	421–758	Clear filtration
SY 50	53 S	6.0–3.0	225–393	Clear filtration
SY 100	103 S	1.5–0.6	140–253	Germ reducing filtration
SY 120	123 S	0.7–0.4	69–119	Sterile filtration (germ removing filtration)

Logarithmic bacterial retention value (LRV)

Type	Test microbe	Load	LRV
CH 103P / SY 103	Reduction of microbe quantities in the filtrate		
CH 113P	<i>Serratia marcescens</i>	1.0×10^7 / cm²	>5
SY 123	<i>Serratia marcescens</i>	1.0×10^7 / cm²	>6
CH 133P	<i>Serratia marcescens</i>	1.0×10^8 / cm²	>7
CH 143P	<i>Serratia marcescens</i>	1.0×10^7 / cm²	>8
CH 145ZP	<i>Serratia marcescens</i>	1.0×10^7 / cm²	>8
CH 153	<i>Brevundimonas diminuta</i>	1.0×10^7 / cm²	>8

Test microbes : *Serratia marcescens*: ATCC 14756 ; *Brevundimonas diminuta*: ATCC 19146

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CH 143P	<i>Serratia marcescens</i>	1.0×10^7 / cm²	>8
CH 145ZP	<i>Serratia marcescens</i>	1.0×10^7 / cm²	>8
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Extractable materials

FILTROX filter sheets fulfill the requirements in accordance with the LFGB (Lebensmittel-Bedarfsgegenstände und Futtermittelgesetzbuch = Food Contact Materials and Consumer Products and German Food and Feed Code) Recommendation XXXVI/I of the BfR (Bundesinstitut für Risikobewertung = Federal Risk Assessment Institute), as well as the testing criteria of the FDA (US Food and Drug Administration) CFR 21 § 177.2260. The filter sheets are manufac-

tured under controlled conditions in order to meet the highest demands on quality and purity (FDA Drug Master File: DMF # 16418). The utilized plastics polypropylene and polyamide correspond to the EU Directive 2002/72 and FDA 21CFR 177.1520 of the foods contact regulations. FILTRODISC™ CH P modules with polypropylene plastic fulfill the USP Biological Test classification VI.

PURAFIX® CH P module ion values

Ion	ppm	Ion	ppm
Ca	<1	Cu	<0.01
Mg	<0.5	Ni	<0.02
Pb	<0.06	Co	<0.025
Zn	<0.01	Fe	<0.05
Cd	<0.005	Al	<0.05

The description of the methods can be found in the filter sheet validation guide.

Pyrogen values

Endotoxin release:<0.125 EU/ml
MCPD and DCP in the wet
strength agent:in accordance with legal regulations
GMO: absent
Allergenic substances: absent

The description of the method can be found in the filter sheet validation guide.

Storage period and conditions

The filter modules must be stored in their original packaging in an odorless, dry and well vented area. We recommend using them within 36 months of the date of manufacture.

Disposal

Unused modules can be disposed of with household waste. Used modules must be disposed of in accordance with the type of contamination.

Operating conditions

Max. operating temperature:40 °C
Max. differential pressure:2.5 bar
Max. system pressure:3.0 bar
Recommended rinsing volume:50 l/m²
Recommended sterilization: gamma or x-ray radiation, upon request.

Quality assurance

FILTROX assures the best quality control according to international standards:

- ISO 9001:2008 (Quality management)
- ISO 14001:2004 (Environmental management)
- ISO 22000:2005 (Food safety incl. HACCP)
- FDA drug master file: DMF #16418
- FDA 21 CFR Compliance
- Kosher Certificate
- EN ISO 3834-2
- DGR 97/23/EG
- China Pressure Vessel Certification
- ASME Code Section VIII Division 1
- EU safety data sheets can be downloaded from the website.

External tests of lenticular modules and filter sheets were performed and certified according to

- USP plastic class VI (BSL, Munich).
- other CFR requirements by the NAMSA.

Order information

Part number	Media grade	Size	Code of module version only for 12" and 16"	Number of lenses only for 12" and 16"	Hose (inside diameter) only for 12" and 16"	Hose connector only for 12" and 16"	Sterilization
R2U	Media grade Code See at the respective retention rates list on page 2.	2" 5" 12" 16"	Code Version Number of lenses S Single 16 D Double 32 K Semi high 6		Inlet/Outlet-Vent Code Hose type Module type V 1/2"-3/8" Code S and K W 1/2"-3/8" Code D X 3/4"-3/8" Standard for 12" D Y 1"-3/8" Standard for 16" D	Code Irradiation H Not irradiated I Gamma or x-ray irradiated	
		Connector Code Connector type B Hose barb T TC only for 5" capsule				Code Connector type C CPC T TC N No connector	

Examples: R2U 113 2" T (FILTRODISC™ R2U with CH 113P sheet, 2" capsule, TC connector)
 R2U 09 12"K 2 VCI (FILTRODISC™ R2U with CH 09P sheet, 12" semi-high, 16 lenses,
 1/2"-3/8" hose, CPC connector, irradiated)
 R2U 53 12"D 10 XTH (FILTRODISC™ R2U with CH 53P sheets, 12" double, 32 lenses,
 3/4"-3/8" hose, TC connector, not irradiated)

CPC = Colder Products
 Company Connector
 TC = Tri-Clamp Connector