

PURAFIX®

MODULES FOR DEPTH FILTRATION

«Low Ion» or «Low Ion and Low Pyrogen»
For pharmaceutical and other high purity applications



Characteristics

Depth filter modules allow the user to handle large filter areas easily in a disposable assembly. Filtration is performed in a closed system. Depth filter sheets inside have a high particle load capacity of up to 4 kg per m². In the filtration process, dirt particles are slowed down and eventually retained by the tortuous path inside the filter sheet and by electrokinetical interactions («zeta potential»). Through this unique mechanism, a high capacity (long lifetime of filter until plugging) can be achieved. All materials are FDA approved.

Dimensions

Modules are available in the following versions:

	12"	16"
Diameter [mm]	300	400
Filter area/module [m ²]	1.8	3.6
Height (bayonet adapter) [mm]	330	330
Height (flat adapter) [mm]	272	272

Filter area for modules with 16 cells. Modules with reduced number of cells are available upon request.

Adapter types

The FILTRIX depth filter modules are available in all common adapter types:

- flat adapter (= DOE)
- bayonet adapter (= DOR = F)

Historically, the flat adapter is quite common.

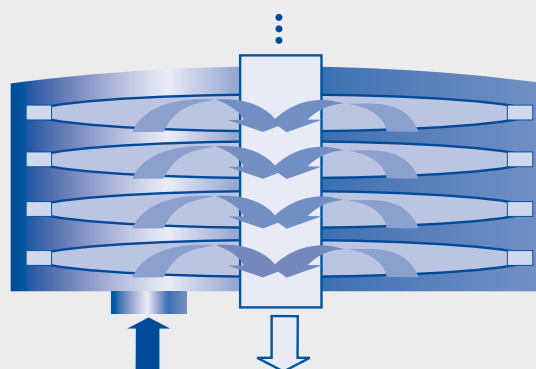
The bayonet adapter is a safer alternative and for sterile filtration the adapter of choice due to its double-o-ring sealing gaskets. The handling of that adapter type is, in addition, much easier.

Rigid construction

The module consists of a polypropylene backbone (rigid core) and depth filter sheets on drainage bodies.

Function principle

The module is placed in a special housing. Turbid liquid fills the space between the housing and the outside part of the module. The liquid flows through the sheets where dirt particles are retained. The clear liquid is drained through the inside of the drainage body and the rigid core to the outlet of the filter housing.



Applications

The filtration work is done by the depth filter sheets, which are available in a variety of porosities, from coarse, fine to germ reducing and -removing filtration («sterile filtration»). PURAFIX® modules are recommended for applications with high demands on purity (low concentration of extractable ions).

PURAFIX® «P» (=low pyrogen) modules are recommended, when in addition, a low concentration of extractable pyrogens is required.

Application examples:

- Pharmaceutical active ingredients
- Vaccines
- Injectables (absolute membrane as police filter required)

Retention rates of coarse and fine filtration sheets

The following nominal porosities (retention rates) are available:

Coarse / Fine filtration			Germ-reducing / Sterile filtering		
Type module	Retention rate [µm]	Flow rate [l/m ² min] Dp=1 bar	Type module	Retention rate [µm]	Flow rate [l/m ² min] Dp=1 bar
CH 03 (P)	20	2800 – 3600	CH 103 P	0.6	100 – 120
CH 09 (P)	10	1500 – 2100	CH 113 P	0.5	68 – 80
CH 23 (P)	6.0	560 – 700	CH 133 P	0.4	45 – 56
CH 33 (P)	5.0	280 – 360	CH 143 P	0.2	26 – 34
CH 43 (P)	4.0	240 – 300	CH 153 P	0.04	10 – 16
CH 73 (P)	1.5	170 – 210			

Pore size in depth filter sheets is measured indirectly by the flow rate. The correlation between pore size and flow rate is empirical. Nominal pore sizes in this list are only values for orientation. The real retention rate is depending on the nature of the dirt particles, solvent and other factors and must be tested as a part of the method development.

Operating conditions

Max. operating temperature:..... 82° C
 Max. differential pressure (module):..... 2.4 bar
 Recommended rinsing volume:..... 50 l/m²
 Recommended sterilization:..... hot water or chemical
 Note: For chemical sterilization with oxidizing agents do not exceed recommended contact time. Inline steam sterilization requires careful handling to avoid back pressure.

Logarithmic bacteria retention value (LRV)

Type	Test germ	Load	LRV
CH 103 (P)	Reducing the number of germs («Germ-Reducing»)		
CH 113 (P)	Serratia marcescens	1.0 X 10 ⁷ /cm ²	>6
CH 133 (P)	Serratia marcescens	1.0 X 10 ⁸ /cm ²	>7
CH 143 (P)	Serratia marcescens	1.0 X 10 ⁹ /cm ²	>8
CH 153 (P)	Brevundimonas diminuta	1.0 x 10 ⁹ /cm ²	>8
Test germs:	Serratia marcescens, ATCC 14756 Brevundimonas diminuta, ATCC 19146		

Pyrogen release (for PURAFIX® «P» series only)

Due to a special manufacturing process the Purafix P® series has a reduced specified endotoxin release < 0.125 EU/ml.

FILTRIX quality assurance

FILTRIX assures the best quality control according to international standards:

- ISO 9001 (Quality management)
- ISO 14001 (Environmental management)
- FDA drug master file: #16418

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

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

FILTRIX is using polyamidoamine as a wet strength agent in its filter sheets. The ISEGA Institute for food analysis in Aschaffenburg (Germany) performed a test for extractable MCPD and DCP. The FILTRIX filter sheets extracts were below the detection limit of the approved standard method for DCP and MCPD. The filter sheets are free of GMO and common allergens. The backbone material of the lenticular modules is polypropylene.

Extractables

Due to the special production conditions the PURAFIX® depth filter sheets have an extremely low release of extractables.

Ion	ppm	Ion	ppm
Ca	< 1	Cu	< 0.001
Mg	< 0.1	Ni	< 0.002
Pb	< 0.001	Co	< 0.0015
Zn	< 0.010	Fe	< 0.03
Cd	< 0.0001	Al	< 0.03

Chemical resistance (filter sheets)

Substance	Concentration [%]	Resistance	
		T = 20° C	T = 80° C
NaOH	1	r	r
	2	r	lr
HCl	5	r	lr
HNO ₃	5	r	lr
H ₂ SO ₄	10	r	lr
Acetic acid	Conc.	r	r
Citric acid	10	r	r
Peracetic acid	0.1	r	r
Butanol	80	r	r
Ethanol	80	r	r

r = resistant; lr = limited resistant

For the complete list please refer to our special documentation

Gasket material

Available material:

- Silicone (standard)
- EPDM
- Teflon® (encapsuled gaskets)

Material (filter sheets)

Purified and bleached cellulose, natural inorganic filter aid and polyamidoamine (< 3%).

Diatomaceous earth

Sheets with an ash content > 1 contain diatomaceous earth (DE/«Kieselguhr») or perlite as an inorganic filter aid. FILTRIX uses only natural kieselguhr with a cristobalite content < 1 % (detection limit).



REM picture of a depth filter sheet: round/disc-structures are DE particles, long structures represent cellulosic fibers

Your Filtrix dealer:

The information contained in this pamphlet is up-to-date at the time of release. However, each end user is requested to check the suitability of their product(s) with the types of filtration mentioned in this leaflet. Technical modifications are reserved.