Fluorodyne™ II

FILTERS

For bioburden, sterility, and mycoplasma control

Fluorodyne™ II filters feature a unique hydrophilic modified polyvinylidene fluoride (PVDF) membrane with low binding properties, broad chemical and temperature resistance, and high flow rates.

Fluorodyne II grade DBL filters

These 0.45 micron rated filters are predominantly used in pre-filtration applications or viscous fluid filtrations. Validated removal of *Serratia marcescens* (ATCC 14756) with a typical titer reduction (T_R) of > 10^6 ensures they are also suitable for bioburden control. A serial layer (0.65/0.45 micron) membrane construction allows for high throughputs and high flow rates compared with other 0.45 micron rated filters.

Fluorodyne II grade DFL filters

This validated 0.2 micron rated sterilizing grade filter retains *Brevundimonas diminuta* (ATCC 19146) at 10^7 CFU/cm^2 effective filter area (EFA) and permits very low extractables and adsorption. It is recommended for sterilizing filtration of pharmaceutical fluids including solutions with active ingredients, biologicals, biotech proteins, ophthalmics, and other dilute preservative solutions.

Fluorodyne II grade DJL filters

This 0.1 micron rated filter with serial layer (0.2/0.1 micron) membrane construction assures high flow rates compared with other 0.1 micron (and even some 0.2 micron) rated filters. Fluorodyne II grade DJL filters are validated for removal of *Acholeplasma laidlawii* mycoplasma (ATCC 28206) with a typical T_R > 10^{11} and retention of *B. diminuta* (ATCC 19146) at 10^7 CFU/cm^2 EFA. This allows for enhanced sterilization assurance as well as efficient mycoplasma control.

Fig 1. A range of filter cartridges, Novasip™ capsules, and Kleenpak™ capsules that contain the Fluorodyne II filter membrane.

Allegro™ systems: the single-use solution

Cross-contamination elimination, assured sterility, reduction of manufacturing time, costs, and greater flexibility are clear objectives for the biopharmaceutical industry. These factors, coupled with increasing titers in drug manufacturing, may demand a new approach.

Allegro single-use systems (SUS), featuring Kleenpak filter capsules, eliminate the need for cleaning and associated validation efforts, minimize major capital investments, increase flexibility, and provide high assurance of product safety.

We provide full support for our SUS including training and validation services to facilitate their use from upstream bioreactor to final formulation and filling.

With a comprehensive range of scalable products in the Fluorodyne II filter series and Allegro product platform, single-use systems incorporating Fluorodyne II filters can be used to process several milliliters up to large production-scale volumes.

The UpScale™ program

Save time, get results

Fluorodyne II filters are available in a wide range of scalable, encapsulated formats that allow for fast and easy scale-up, helping you rapidly deliver your products to the market.

Same materials [1]

From laboratory-scale filters to production-scale assemblies, all Fluorodyne II filter products incorporate the same membrane and identical materials of construction, eliminating the need to requalify filter units as processes are scaled up.

Quality

Every Fluorodyne II pleated filter is:

- Integrity-tested during manufacture
- Identified by lot and serial number for total traceability
- Supplied with a certificate of test confirming each filter:
  - meets USP biological reactivity test *in vivo*, for class VI 121°C plastics
  - meets cleanliness per USP particulates in injectables after flushing
  - is non-fiber-releasing
  - is non-pyrogenic per USP endotoxins (< 0.25 EU/mL)
  - meets total organic carbon (TOC) and water conductivity per USP purified water after flushing

[1] Except Novasip capsules. See material of construction tables for each product for further details.

Fig 2. Scientist in lab working with Allegro single-use systems.

Mini Kleenpak 20 capsules

Materials of construction	
Filter membrane	Hydrophilic modified PVDF
Housing, vent plug and support material	Polypropylene
Filling bell	Polycarbonate
Sealing technology	Thermal bonding without adhesives

Operating parameters [2]	
Maximum operating temperature and pressure	1.4 bar (20 psi) at 20°C

[2] In compatible fluids that do not soften, swell, or adversely affect the filter or its materials of construction

Sterilization [3]

Pre-sterilized, subject to a minimum of 25 kGy of gamma irradiation

[3] Pre-sterilized Mini Kleenpak capsules must not be re-sterilized. Mini Kleenpak capsules must not be sterilized *in situ* by passing steam under pressure

Typical hold up volume

< 2.5 mL

Nominal dimensions	
Capsule length	83 mm (3.3 in.)
Capsule diameter	67 mm (2.7 in.)

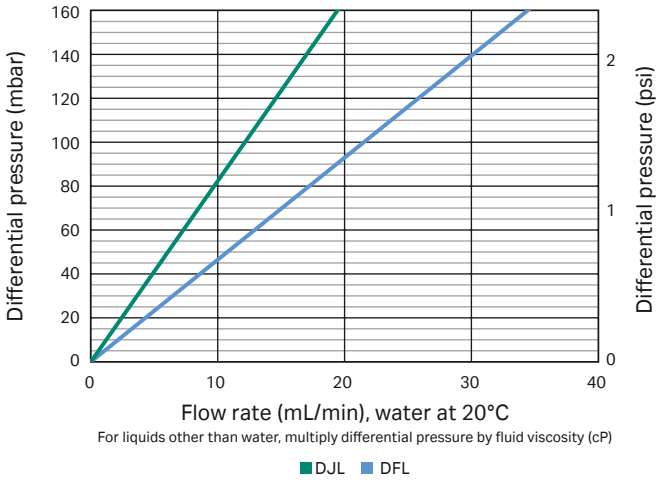

Fig 3. Typical liquid flow vs differential pressure.

Nominal EFA

20 cm^2 (3.1 $in.^2$)

Ordering information [4]

Product code: KM5 [ ] **P** [2] [S]

Code	Filter media
DFL	0.2 micron sterilizing grade
DJL	0.1 micron sterilizing grade and mycoplasma control

Inlet/outlet connection
¼ to ½ in. (6 to 13 mm) stepped hose barb with inner bore to accept female slip luer interior and outer diameter to accept filling bell outlet

Shipping format
Pre-sterilized using gamma irradiation

[4] 3 filters per box

Mini Kleenpak capsules

Materials of construction	
Filter membrane	Hydrophilic modified PVDF
Support/drainage	Polypropylene
Capsule shell	Polypropylene
Filling bell	Polycarbonate
Sealing technology	Thermal bonding without adhesives

Operating parameters [5]	
Maximum temperature	40°C
Maximum operating pressure	4.1 bar (60 psi) at 40°C
Maximum differential pressure (forward direction)	4.1 bar (60 psi) at 40°C

[5] In compatible fluids that do not soften, swell, or adversely affect the filter or its materials of construction

Sterilization [6]	
Autoclave (G option only)	3 × 60 minutes at 125°C
Gamma irradiation (G option only)	Maximum of 50 kGy

[6] Pre-sterilized Mini Kleenpak capsules must not be re-sterilized. Mini Kleenpak capsules must not be sterilized *in situ* by passing steam under pressure.

Typical extractables in water at 20°C [7]	
G option only	< 1 mg
S option only	< 5 mg

[7] Tested on capsules without pre-flushing

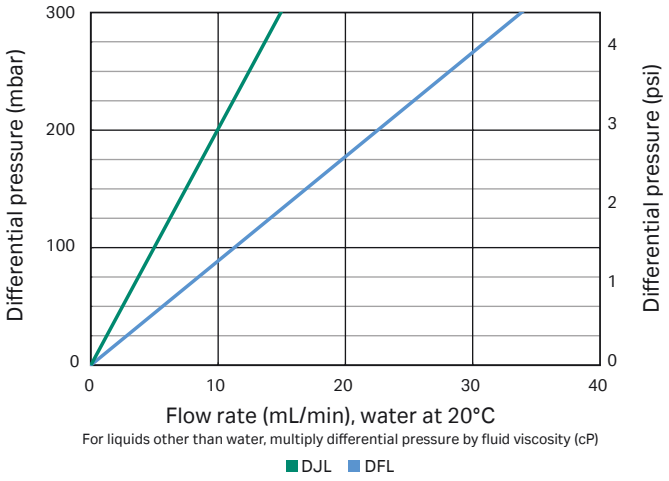

Fig 4. Typical liquid flow vs differential pressure.

Nominal dimensions	
Maximum diameter including valves	41 mm (1.6 in.)
Length – code 2	105 mm (4.1 in.)
Length – code 8	73 mm (2.9 in.)

Nominal EFA
200 cm^2 (0.22 ft^2)

Ordering information [8]

Product code: KA02 ☐ **P** ☐ ☐

Code	Filter media
DFL	0.2 micron sterilizing grade
DJL	0.1 micron sterilizing grade and mycoplasma control

Code	Inlet/outlet connection
2	¼ to ½ in. (6 to 13 mm) stepped hose barb
8	½ to ¾ in. (13 to 19 mm) sanitary flange

Code	Shipping format
G	Non-sterile gamma irradiatable/autoclavable
S [9]	Pre-sterilized using gamma irradiation

[8] 3 filters per box

[9] S option with code 2 connection is provided with filling bell on outlet. It is removable for in-line use.

Kleenpak capsules

Materials of construction

Filter membrane	Hydrophilic PVDF
Support/drainage	Polypropylene
End cap, core and cage	Polypropylene
Capsule shell	Polypropylene
Sealing technology	Thermal bonding without adhesives

Operating parameters [10]

Maximum temperature	40°C
Maximum operating pressure	5.2 bar (75 psi) at 20°C 4.0 bar (58 psi) at 40°C
Maximum differential pressure (forward direction)	4.0 bar (58 psi) at 40°C

[10] In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

Sterilization [11]

Autoclave (G and blank option only)	30 × 60 minutes at 135°C 10 × 60 minutes at 140°C
Gamma irradiation (G option only)	Maximum of 50 kGy

[11] Pre-sterilized Kleenpak capsules must not be re-sterilized. Kleenpak capsules must not be sterilized *in situ* by passing steam under pressure

Typical extractables in water at 20°C [12]

All styles	< 5 mg per capsule

[12] Tested on capsules without pre-flushing

Nominal EFA

KA1	400 cm^2 (0.4 ft^2)
KA2	800 cm^2 (0.9 ft^2)
KA3	1500 cm^2 (1.6 ft^2)
KA4	3300 cm^2 (3.6 ft^2)

Nominal dimensions

	KA1	KA2	KA3	KA4
Diameter incl. valves	94 mm (3.7 in.)	94 mm (3.7 in.)	105 mm (4.1 in.)	105 mm (4.1 in.)
Length - code 1	117 mm (4.6 in.)	157 mm (6.2 in.)	174 mm (6.8 in.)	287 mm (11.3 in.)
Length - code 2	158 mm (6.2 in.)	198 mm (7.8 in.)	–	–
Length - code 6	157 mm (6.2 in.)	197 mm (7.7 in.)	210 mm (8.3 in.)	327 mm (12.8 in.)
Length - code 12	137 mm (5.4 in.)	177 mm (7.0 in.)	–	–
Length - code 16	137 mm (5.4 in.)	177 mm (7.0 in.)	192 mm (7.6 in.)	305 mm (12.0 in.)

Ordering information [8]

Product code: KA [ ] [ ] **P** [ ] [ ]

Code
1
2
3
4

Code	Filter media
DBL	0.45 micron bioburden control
DFL	0.2 micron sterilizing grade
DJL	0.1 micron sterilizing grade and mycoplasma control

Code	Inlet/outlet connection
1	1 to 1½ in. (25 to 38 mm) sanitary flange
2	¼ to ½ in. (6 to 13 mm) stepped hose barb
6	½ in. (13 mm) single hose barb
16	1½ in. sanitary flange inlet and ½ in. (13 mm) single hose barb outlet

Code	Shipping format
G	Non-sterile gamma irradiatable/autoclavable
S [9]	Pre-sterilized using gamma irradiation
Blank [13]	Non-sterile autoclavable

[13] Only available with DBL and DFL filter media[

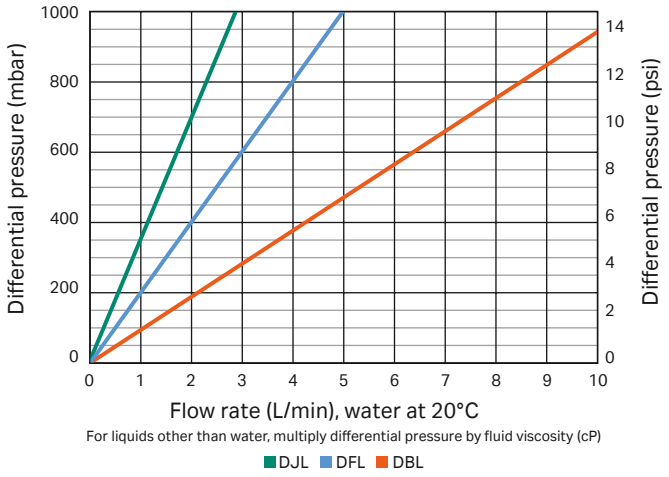

Fig 5. Typical liquid flow vs differential pressure (KA1).

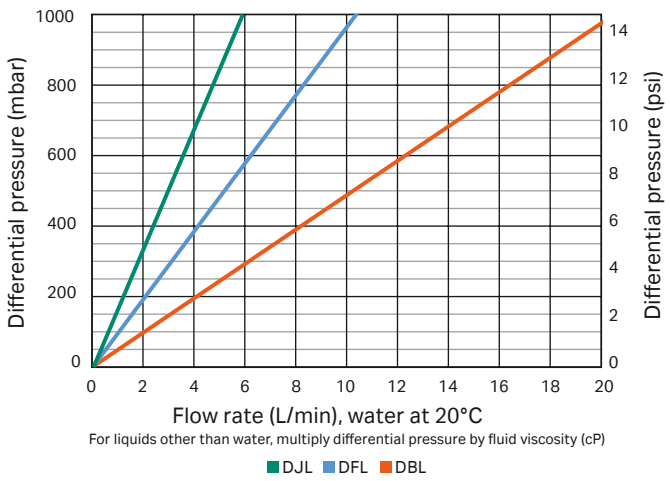

Fig 6. Typical liquid flow vs differential pressure (KA2).

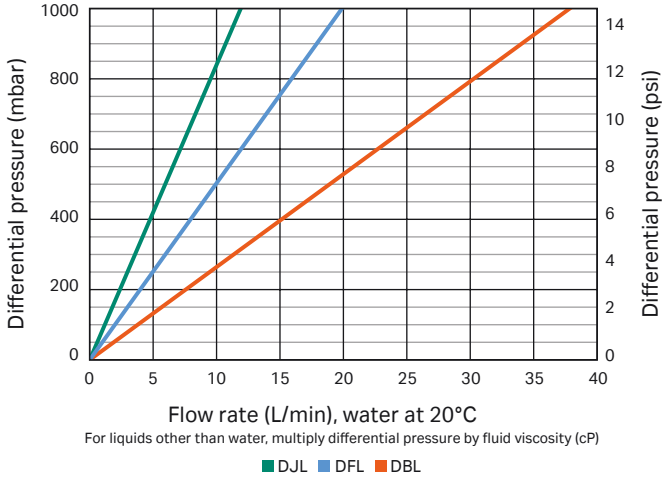

Fig 7. Typical liquid flow vs differential pressure (KA3).

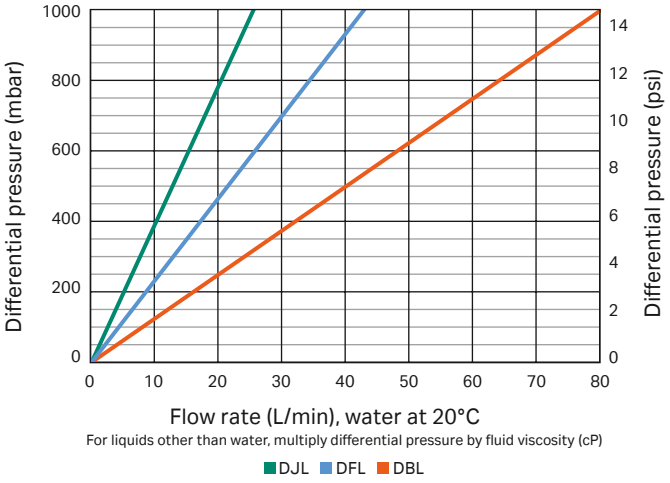

Fig 8. Typical liquid flow vs differential pressure (KA4).

Novasip capsules

Materials of construction

Filter membrane	Hydrophilic modified PVDF
Support/drainage	Polypropylene
End cap, core and cage	Polypropylene
Capsule shell	Polyetherimide
Sealing technology	Thermal bonding without adhesives
Housing head	Polyetherimide with TiO_2 whitener [14]

[14] TiO_2 is an insoluble inorganic mineral filler that does not contribute to organic extractables

Operating parameters [15]

Maximum temperature	60°C
Maximum operating pressure	6.5 bar (94 psi) at 40°C 2.0 bar (29 psi) at 60°C
Maximum differential pressure (forward direction)	5.3 bar (77 psi) at 40°C 4.1 bar (60 psi) at 60°C

[15] In compatible fluids that do not soften, swell, or adversely affect the filter or its materials of construction

Sterilization

Autoclave or *in situ* steam	30 × 60 minutes at 125°C 10 × 60 minutes at 140°C

Typical extractables in water at 20°C [16]

< 5 mg per capsule

[16] Tested on capsules without pre-flushing

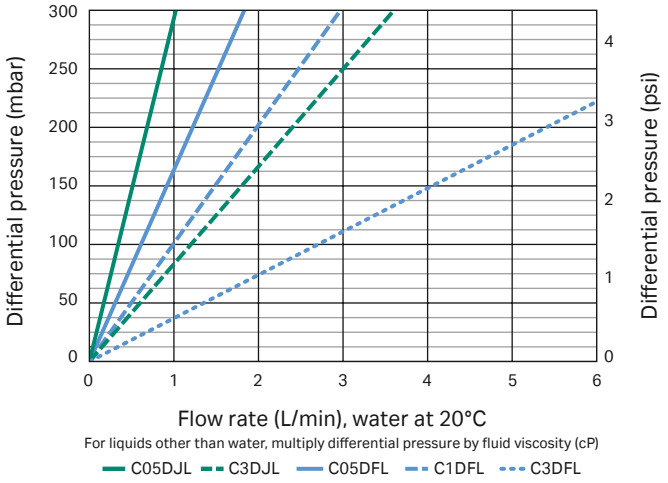

Fig 9. Typical liquid flow vs differential pressure.

Nominal dimensions

	CLM05	C05/C1/C3
Diameter incl. valves	123 mm (4.8 in.)	123 mm (4.8 in.)
Overall Length	84 mm (3.3 in.)	157 mm (6.2 in.)

Nominal EFA

C(LM)05	400 cm^2 (0.4 ft^2)
C(L)1	700 cm^2 (0.7 ft^2)
C(L)3	1500 cm^2 (1.6 ft^2)

Ordering information

Product code: C [ ] [ ] [ ] P **1** [ ]

Code	Holder volume
L	Special insert for low hold up volume
LM	Small bowl (only for size 05)
Blank	Standard capsule

Size
05
1
3

Code	Filter media
DFL	0.2 micron sterilizing grade
DJL [17]	0.1 micron sterilizing grade and mycoplasma control

Connection options
1 to 1½ in. (25 to 38 mm) sanitary flange

Code	Vent/drain
Blank	Vent: quick connect and disconnect coupling (compatible with Stäubli fitting). Drain: hose barb for ⅛ in. to ¼ in. (4 to 6 mm) internal diameter (ID) tube, with valve
A	Vent and drain: quick connect and disconnect coupling (Stäubli compatible) with valve
B	Vent and drain: ½ in. (13 mm) sanitary flange, no valve sanitary clamp

[17] DJL filter media is not available in Size 1

Junior filter cartridges: MCY and SBF style

Materials of construction	
Filter membrane	Hydrophilic modified PVDF
Support/drainage	Polypropylene
End cap, core and cage	Polypropylene
Sealing technology	Thermal bonding without adhesives
O-rings	Silicone elastomer

Operating parameters [18]	
Maximum temperature	80°C
Maximum differential pressure (forward direction)	5.3 bar (77 psi) at 40°C 3.4 bar (50 psi) at 80°C

[18] In compatible fluids that do not soften, swell, or adversely affect the filter or its materials of construction. DFL filter media may be used at 90°C. Contact us for further details.

Sterilization	
Autoclave or *in situ* steam	30 × 60 minutes at 125°C 10 × 60 minutes at 140°C [19]

[19] MCY style only

Typical extractables in water at 20°C [20]
< 5 mg per junior cartridge

[20] Tested on elements without pre-flushing

Nominal dimensions

	MCY1110	MCY2220	MCY4440	SBF
Length	32 mm (1.3 in.)	57 mm (2.2 in.)	106 mm (4.2 in.)	51 mm (2.0 in.)

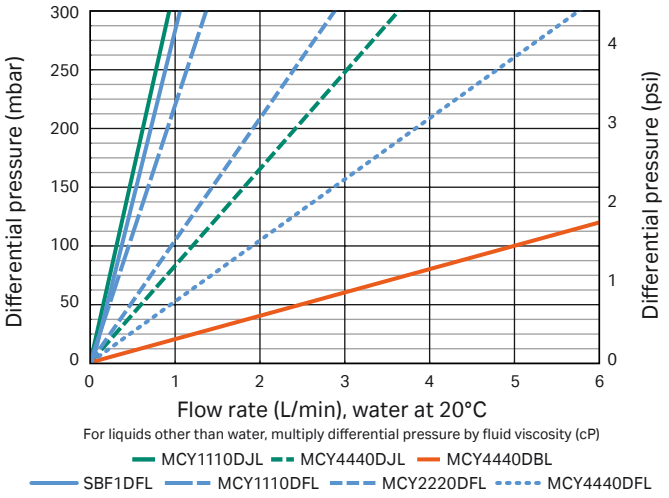

Fig 10. Typical liquid flow vs differential pressure.

Nominal EFA	
MCY1110	400 cm^2 (0.4 ft^2)
MCY2220	700 cm^2 (0.7 ft^2)
MCY4440	1500 cm^2 (1.6 ft^2)
SBF	400 cm^2 (0.4 ft^2)

Ordering information

Product code: [ ] [ ] P [H4]

Code	Style
MCY1110	Single open-ended with double external o-rings and locating lugs
MCY2220	Single open-ended with double external o-rings and locating lugs
MCY4440	Single open-ended with double external o-rings and locating lugs
SBF1 [21]	Single open-ended with double external o-rings

Code	Filter media
DBL [22]	0.45 micron bioburden control
DFL	0.20 micron sterilizing grade
DJL [23]	0.10 micron sterilizing grade and mycoplasma control

O-ring material
Silicone elastomer (standard)

[21] Only available with DFL filter media
[22] Only available in MCY4440 style
[23] Only available in MCY1110 and MCY4440 styles

Junior filter cartridges: Sealkleen™ filter style

Materials of construction	
Filter membrane	Hydrophilic modified PVDF
Support/drainage	Polypropylene
End cap, core and cage	Polypropylene
Sealing technology	Thermal bonding without adhesives

Operating parameters [24]	
Maximum temperature	80°C
Maximum differential pressure (forward direction)	5.3 bar (77 psi) at 50°C 3.4 bar (50 psi) at 80°C

[24] In compatible fluids that do not soften, swell, or adversely affect the filter or its materials of construction. DFL filter media may be used at 90°C. Contact us for further details.

Sterilization	
Autoclave or *in situ* steam	30 × 60 minutes at 125°C

Typical extractables in water at 20°C [25]
< 5 mg per Sealkleen cartridge

[25] Tested on elements without pre-flushing

Nominal dimensions		
	SLK7001	SLK7002
Overall length	66 mm (2.6 in.)	133 mm (5.2 in.)

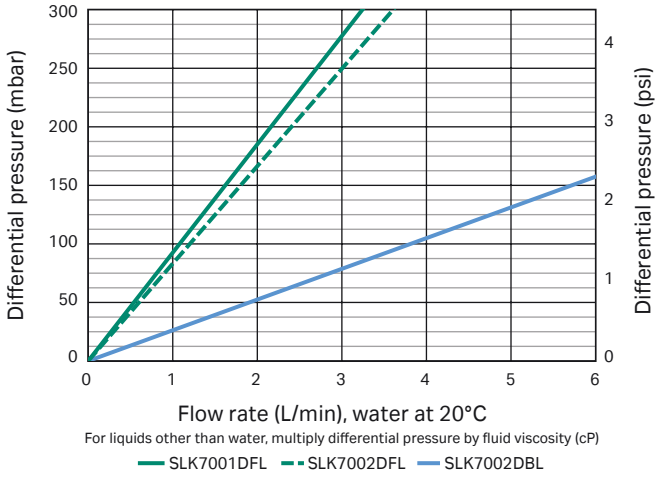

Fig 11. Typical liquid flow vs differential pressure.

Nominal EFA	
SLK7001	900 cm^2 (1.0 ft^2)
SLK7002	1900 cm^2 (2.0 ft^2)

Ordering information

Product code: SLK [ ] [ ] **P**

Code	Code	Filter media
7001 [26]	DBL	0.45 micron bioburden control
7002	DFL	0.20 micron sterilizing grade

[26] Only available with DFL filter media

High area filter cartridges

Materials of construction

Filter membrane	Hydrophilic PVDF
Support/drainage	Polypropylene
Core/end caps	Polypropylene
Cage (DFL and DJL filter media)	Polypropylene with TiO_2 whitener [27]
Cage (DBL filter media)	Polypropylene
O-rings	Silicone elastomer
Sealing technology	Thermal bonding without adhesives

[27] TiO_2 is an insoluble inorganic mineral filler that does not contribute to organic extractables

Operating Parameters[28]

Maximum temperature	80°C
Maximum differential pressure (forward direction)	5.3 bar (77 psi) at 50°C 3.4 bar (49 psi) at 80°C
Maximum differential pressure (reverse direction)	0.3 bar (4 psi)

[28] In compatible fluids that do not soften, swell, or adversely affect the filter or its materials of construction. DFL filter media may be used at 90°C. Contact us for further details.

Sterilization

Autoclave or *in situ* steam	30 × 60 minutes at 125°C 10 × 60 minutes at 140°C

Typical extractables in water at 20°C [29]

< 5 mg per 254 mm (10 in.) module

[29] Tested on capsules without pre-flushing

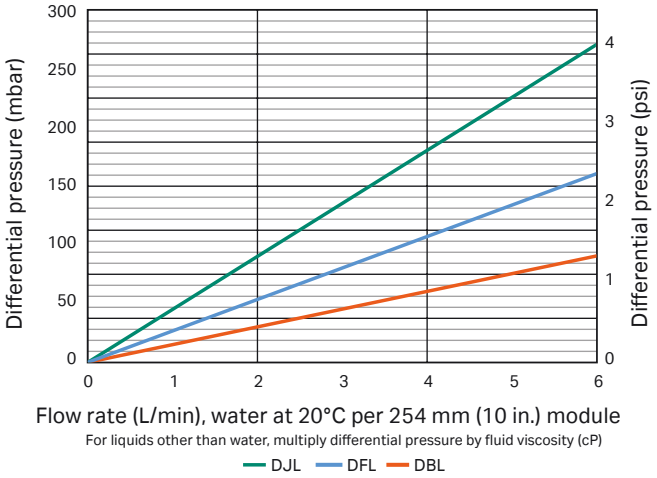

Fig 12. Typical liquid flow vs differential pressure.

Integrity test values (air test gas, water wet)

Max. allowable forward flow values for 254 mm (10 in.) module at 20°C	
DBL	13 mL/min at 1240 mbar (18 psi)
DFL	12 mL/min at 2760 mbar (40 psi)
DJL	29 mL/min at 4475 mbar (65 psi)

Contact us for multi-element integrity test values and recommended test procedures

Nominal EFA per 254 mm (10 in.) module

DBL	5500 cm^2 (5.9 ft^2)
DFL	5500 cm^2 (5.9 ft^2)
DJL	5500 cm^2 (5.9 ft^2)

Ordering information

Product code: AB [ ] [ ] [ ] **P** **H4**

Code	Nominal length
05	125 mm (5 in.)
1	254 mm (10 in.)
2	508 mm (20 in.)
3	762 mm (30 in.)

Code	Filter media
DBL	0.45 micron bioburden control
DFL	0.20 micron sterilizing grade
DJL	0.10 micron sterilizing grade and mycoplasma control

Code	Adapter style
7	Code 7 double o-ring bayonet lock and fin
2	Code 2 double o-ring bayonet lock, no fin (length code 05 only)

O-ring material
Silicone elastomer (other materials available on request)

High area Kleenpak Nova capsules

Materials of construction

Filter membrane	Hydrophilic modified PVDF
Support/drainage	Polypropylene
Core/end caps	Polypropylene
Cage (DFL and DJL filter media)	Polypropylene with TiO_2 whitener [30]
Cage (DBL filter media)	Polypropylene
O-rings	Silicone elastomer
Sealing technology	Thermal bonding without adhesives
Housing bowl	Polypropylene
Housing head	Polypropylene

[30] TiO_2 is an insoluble inorganic mineral filler that does not contribute to organic extractables

Operating Parameters [31]

Maximum temperature	40°C
Maximum operating pressure	3 bar (44 psi) at 40°C
Maximum differential pressure (forward direction)	3 bar (44 psi) at 40°C

[31] In compatible fluids that do not soften, swell, or adversely affect the filter or its materials of construction

Sterilization [32]

Autoclave (G option only)	30 × 60 minutes at 125°C
Gamma irradiation (G option only)	Maximum of 50 kGy

[32] Pre-sterilized Kleenpak Nova capsules must not be re-sterilized. Kleenpak Nova capsules must not be sterilized *in situ* by passing steam under pressure.

Typical extractables in water at 20°C [33]

G option	< 10 mg per 254 mm (10 in.) module
S option	< 20 mg per 254 mm (10 in.) module

[33] Tested on capsules without pre-flushing

Integrity test values (air test gas, water wet) [34]

Max. allowable forward flow values for 254 mm (10 in.) filter at 20°C	
DBL	13 mL/min at 1240 mbar (18 psi)
DFL	12 mL/min at 2760 mbar (40 psi)
DJL	29 mL/min at 4475 mbar (65 psi)

[34] Contact us for multi-element integrity test values and recommended test procedures

Nominal EFA per 254 mm (10 in.) module

DBL	5500 cm^2 (5.9 ft^2)
DFL	5500 cm^2 (5.9 ft^2)
DJL	5500 cm^2 (5.9 ft^2)

Nominal dimensions

In-line	NP5	NP6	NP7	NP8
Maximum diameter including valves	154 mm (6.1 in.)	154 mm (6.1 in.)	154 mm (6.1 in.)	154 mm (6.1in.)
Length with hose barb inlet/outlet	275 mm (10.8 in.)	397 mm (15.6 in.)	644 mm (25.4 in.)	895 mm (35.2 in.)
Length with sanitary inlet/outlet	213 mm (8.4 in.)	335 mm (13.2 in.)	584 mm (23.0 in.)	834 mm (32.8 in.)
T-style		NT6	NT7	NT8
Maximum diameter including valves	–	240 mm (9.5 in.)	240 mm (9.5 in.)	240 mm (9.5 in.)
Length	–	349 mm (13.7 in.)	598 mm (23.5 in.)	848 mm (33.4 in.)

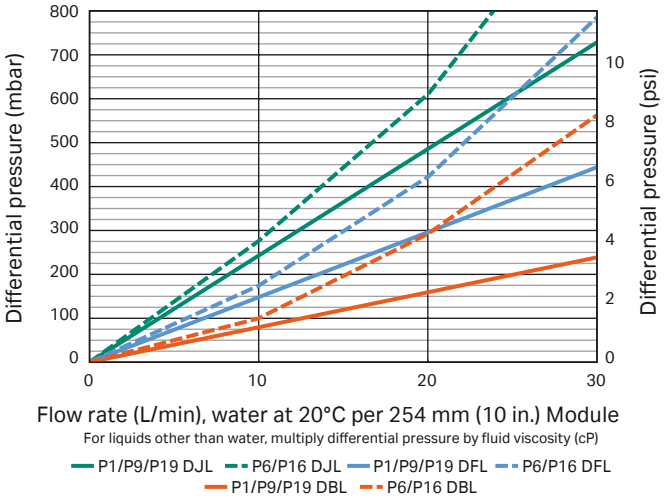

Fig 13. Typical liquid flow vs differential pressure for NP style in-line capsules.

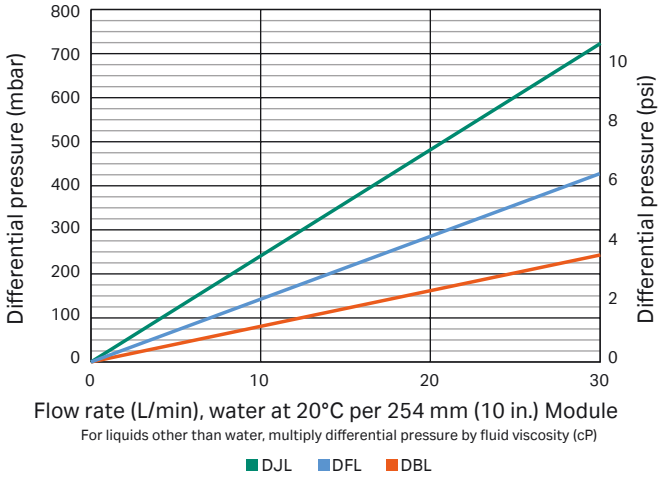

Fig 14. Typical liquid flow vs differential pressure for NT T-style capsules.

Ordering information

Product code: N [ ] [ ] [ ] **P** [ ] [ ] [ ]

Code	Style
P	In-line
T	T-style

Code	Filter size
5 [35]	127 mm (5 in.)
6	254 mm (10 in.)
7	508 mm (20 in.)
8	762 mm (30 in.)

Code	Filter size
DBL	0.45 micron bioburden control
DFL	0.20 micron sterilizing grade
DJL	0.10 micron sterilizing grade and mycoplasma control

Code	Shipping format
G	Non-sterile gamma irradiatable/ autoclavable
S	Pre-sterilized using gamma irradiation

Code	Connection options
1	1 to 1½ in. (25 to 38 mm) sanitary flange inlet and outlet
9	1 in. (25 mm) single barb hose barb inlet and outlet
19	1 to 1½ in. (25 to 38 mm) sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet
6 [36]	½ in. (13 mm) single barb hose barb inlet and outlet
16 [36]	1 to 1½ in. (25 to 38 mm) sanitary flange inlet and ½ in. (13 mm) single barb hose barb outlet
1H [37]	1 to 1½ in. (25 to 38 mm) sanitary flange inlet and outlet, with ½ in. sanitary port on inlet
1H9 [37]	1 to 1½ in. (25 to 38 mm) sanitary flange inlet and 1 in. (25 mm) single barb hose barb outlet with ½ in. sanitary port on inlet

Code	Vent/drain
Blank	Stäubli vent and stepped hose barb drain
A	Stäubli vent and drain

[35] Only available in in-line style and with DJL and DFL filter media only
[36] For in-line (code P) only
[37] For T-style (code T) only

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