

Polysep™ II Filters

Multiple filtration stages in a single compact device

Polysep™ II mixed media filters provide the high capacity of depth filters and the retention efficiency of a membrane in a single device. These versatile filters are ideal for removing particles from a broad range of challenging streams.

Benefits

- Combines the dirt-holding capacity of a depth filter with the retention efficiency of a membrane filter
- Protects downstream sterilizing filters enabling increased capacity, improving process economics
- Exceptional retention efficiency for critical prefiltration processes
- Perfect choice when high flow rate and high throughput are required
- Ideal for designing scalable solutions from benchtop to full-scale manufacturing

Available Pore Sizes

- 1.0/0.2/0.1 µm
- 1.0/0.2 µm
- 1.0/0.5 µm
- 1.0/1.2 µm
- 2.0/1.2 µm



Filter Formats

- OptiScale® 47 capsules
- Cartridge filters
- Opticap® XL capsule filters
- Opticap® XLT capsule filters

Formats for Every Process

OptiScale® Capsules

For Process Screening and Scaling

Our OptiScale® capsules are single-use, small-scale tools ideal for quickly evaluating performance of different prefilters with various process streams. OptiScale® 47 capsules are ideal for screening different filtration membranes.

Opticap® Capsules

For Pilot and Production-scale Processing

Our Opticap® XL and XLT filters are single-use capsules that eliminate the time and expense associated with assembling, cleaning, and validating stainless steel housings. Capsules are available in multiple filtration areas, are gamma or autoclave compatible and offer a range of inlet and outlet connections.

Cartridge Filters

For Pilot and Production-scale Processing

Our cartridge filters are designed for use in stainless steel housings and provide high throughput and minimal differential pressure. These cartridges are robust, strong, resilient and are designed to withstand multiple steam-in-place cycles. A full range of filtration areas and connection options are available for maximum flexibility.



Quality Management

Polysep™ II filters are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to an ISO 9001 Quality Systems Standard, and supported by a certificate of quality. The suitability for intended use of each Opticap® XL, Opticap® XLT capsule, and cartridge filter is supported by a validation document. For traceability and easy identification, each filter is marked with identifying characteristics.

OptiScale® Capsule Filter Specifications

Description	OptiScale® 47 Capsule Filters
Nominal Dimensions	
Maximum length	82 mm (3.24 in.) with flange inlet/hose barb outlet 74 mm (2.91 in.) with flange inlet/flange outlet 94 mm (3.70 in.) with hose barb inlet/hose barb outlet
Diameter	69 mm (2.75 in.)
Weight	69 g (2.4 oz)
Filtration Area (see legend below)	17.7 cm ²
Materials of Construction	
Filter media	Borosilicate glass microfiber and mixed esters of cellulose
Structural components	Polycarbonate
Vent cap	PVDF
Internal seal rings	Fluoroelastomers
Housing Vent	Adjustable vent with male luer and female Luer-Lok™ connections on inlet side of device.
Maximum Inlet Pressure	5.5 bar (80 psi) at 25 °C
Oxidizable Substances	Effluent is negative after a water flush of 100 mL per autoclaved capsule.
Sterilization	May be autoclaved for 3 cycles of 60 minutes at 121 °C.
Non-Fiber Releasing	Filter devices meet the non-fiber releasing claim, as defined in 21 CFR 210.3(b)(6) and will also support filter use for liquid filtration in the manufacture, processing or packing of injectable drug products, based on 21 CFR 211.72 cGMP for finished pharmaceuticals. Devices tested and meet requirements of USP <788> for large volume parenterals.
Component Material Toxicity	Component material meet the criteria for Biological Reactivity Testing. These tests can be any or a combination of the following test methods: USP <88> Class VI (<i>in vivo</i>), USP <87> (<i>in vitro</i>), ISO 10993-5 (<i>in vitro</i>).
Indirect Food Additive	All components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182 based on information provided by raw material suppliers.

Opticap® XL and XLT Capsule Filter Specifications

Description	Opticap® XL 2 Filters	Opticap® XL 4 Filters	Opticap® XL 5 Filters	Opticap® XL 10 Filters	Opticap® XLT 10 Filters	Opticap® XLT 20 Filters	Opticap® XLT 30 Filters
Nominal Dimensions							
Maximum length	14.2 cm (5.6 in.)	19.6 cm (7.7 in.)	21.6 cm (8.5 in.)	33.5 cm (13.2 in.)	37.6 cm (14.8 in.)	62.5 cm (24.6 in.)	87.1 cm (34.3 in.)
Body diameter	8.4 cm (3.3 in.)	8.4 cm (3.3 in.)	10.7 cm (4.2 in.)	10.7 cm (4.2 in.)	—	—	—
Vent to vent diameter	12.4 cm (4.9 in.)	12.4 cm (4.9 in.)	14.5 cm (5.7 in.)	14.5 cm (5.7 in.)	—	—	—
Fitting to Fitting							
Sanitary flange to sanitary flange:	—	—	—	—	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)	15.2 cm (6.0 in.)
Sanitary flange to hose barb:	—	—	—	—	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)	17.5 cm (6.9 in.)
Hose barb to hose barb:	—	—	—	—	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)	19.8 cm (7.8 in.)
Filtration Area (see legend below)							
W2, W3, W6, W9:	0.06 m ² (0.6 ft ²)	0.11 m ² (1.2 ft ²)	0.19 m ² (2.0 ft ²)	0.46 m ² (5.0 ft ²)	0.46 m ² (5.0 ft ²)	0.93 m ² (10.0 ft ²)	1.39 m ² (15.0 ft ²)
W1:	N/A	N/A	0.17 m ² (1.8 ft ²)	0.42 m ² (4.5 ft ²)	0.42 m ² (4.5 ft ²)	0.85 m ² (9.1 ft ²)	1.26 m ² (13.6 ft ²)
Materials of Construction							
Filter media:	Borosilicate glass microfiber and mixed esters of cellulose						
Structural components*:	Polypropylene						
Supports:	Polypropylene						
Vent cap:	Polypropylene						
Vent O-ring:	Silicone						
Vent/Drain:	¼ in. hose barb with double O-ring seal; Connects to 1/8 in. tubing						
Maximum Inlet Pressure	5.5 bar (80 psi) at 23 °C, 2.8 bar (40 psi) at 60 °C, 1.0 bar (15 psi) at 80 °C						
Maximum Differential Pressure							
Forward:	3.4 bar (50 psid) at 25 °C						
NVR Gravimetric Extractables	After autoclaving and a 24 hour soak in ASTM Type 1 reagent grade water at controlled room temperature:						
	≤ 45 mg after a 600 mL flush	≤ 85 mg after a 1.2 L flush	≤ 61 mg after a 5 L flush	≤ 145 mg after a 5 L flush	≤ 145 mg after a 5 L flush	≤ 290 mg after a 10 L flush	≤ 435 mg after a 15 L flush

*Cage, core, end caps, and capsule housing

Legend for Filter Media Layer(s) – Nominal pore size of media

W1 = 1.0/0.2/0.1 µm W3 = 1.0/0.2 µm W6 = 1.0/0.5 µm W2 = 1.0/1.2 µm W9 = 2.0/1.2 µm

Opticap® XL and XLT Capsule Filter Specifications (continued)

Description	Opticap® XL 2 Filters	Opticap® XL 4 Filters	Opticap® XL 5 Filters	Opticap® XL 10 Filters	Opticap® XLT 10 Filters	Opticap® XLT 20 Filters	Opticap® XLT 30 Filters
Oxidizable Substances	Meets the requirements of the USP Oxidizable Substances Test after a water flush of: ≤ 1000 mL ≤ 2000 mL ≤ 2000 mL ≤ 5000 mL ≤ 5000 mL ≤ 10000 mL ≤ 15000 mL						
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the <i>Limulus Amebocyte Lysate</i> (LAL) test, aligned with the test methods in USP <85>, EP 2.6.14 and JP 4.01.						
Sterilization	May be autoclaved for 3 cycles of 60 minutes at 121 °C. Cannot be steam sterilized in-line.						
Non-Fiber Releasing	Filter devices meet the non-fiber releasing claim, as defined in 21 CFR 210.3(b)(6) and will also support filter use for liquid filtration in the manufacture, processing or packing of injectable drug products, based on 21 CFR 211.72 cGMP for finished pharmaceuticals. Devices tested and meet requirements of USP <788> for large volume parenterals.						
Component Material Toxicity	Component material meet the criteria for Biological Reactivity Testing. These tests can be any or a combination of the following test methods: USP <88> Class VI (<i>in vivo</i>), USP <87> (<i>in vitro</i>), ISO 10993-5 (<i>in vitro</i>).						
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.						

Cartridge Filter Specifications

Description	4-inch Cartridge	per 10-inch Cartridge
Nominal Dimensions		
Outside diameter:	6.9 cm (2.7 in.)	6.9 cm (2.7 in.)
Filtration Area (see legend below)		
W2, W3, W6, W9:	0.19 m ² (2.0 ft ²)	0.46 m ² (5.0 ft ²)
W1:	0.17 m ² (1.8 ft ²)	0.42 m ² (4.5 ft ²)
Materials of Construction		
Filter media:	Borosilicate glass microfiber and mixed esters of cellulose	
Structural components*:	Rigid polypropylene	
Supports:	Spun bonded polypropylene	
O-rings:	Silicone	
Maximum Differential Pressure		
Forward:	3.4 bar (50 psid) at 25 °C	
NVR Gravimetric Extractables	After autoclaving and a 24 hour soak in ASTM® Type 1 reagent grade water at controlled room temperature, extractables level was ≤ 140 mg per 10-inch element after a 5000 mL flush.	
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the <i>Limulus Amebocyte Lysate</i> (LAL) Test, aligned with the test methods in USP <85>, EP 2.6.14 and JP 4.01.	
Oxidizable Substances	Cartridges meet the requirements of the USP Oxidizable Substances Test after a water flush of 5000 mL per 10-inch element.	
Sterilization	May be autoclaved for 10 cycles of 30 minutes at 121 °C, or steam sterilized for 10 cycles of 30 minutes at 121 °C, or hot water sanitized for 40 cycles of 30 minutes at 80 °C.	
Non-Fiber Releasing	Filter devices meet the non-fiber releasing claim, as defined in 21 CFR 210.3(b)(6) and will also support filter use for liquid filtration in the manufacture, processing or packing of injectable drug products, based on 21 CFR 211.72 cGMP for finished pharmaceuticals. Devices tested and meet requirements of USP <788> for large volume parenterals.	
Component Material Toxicity	Component material meet the criteria for Biological Reactivity Testing. These tests can be any or a combination of the following test methods: USP <88> Class VI (<i>in vivo</i>), USP <87> (<i>in vitro</i>), ISO 10993-5 (<i>in vitro</i>).	
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 based on information provided by raw material suppliers.	

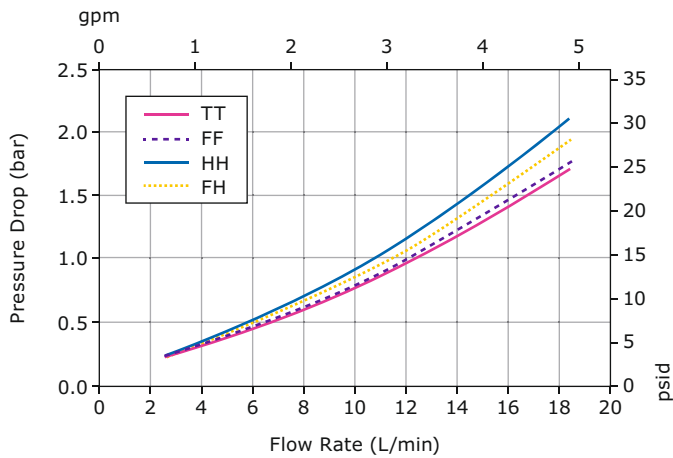
*Cage, core, end caps and capsule housing

Legend for Filter Media Layer(s) – Nominal pore size of media

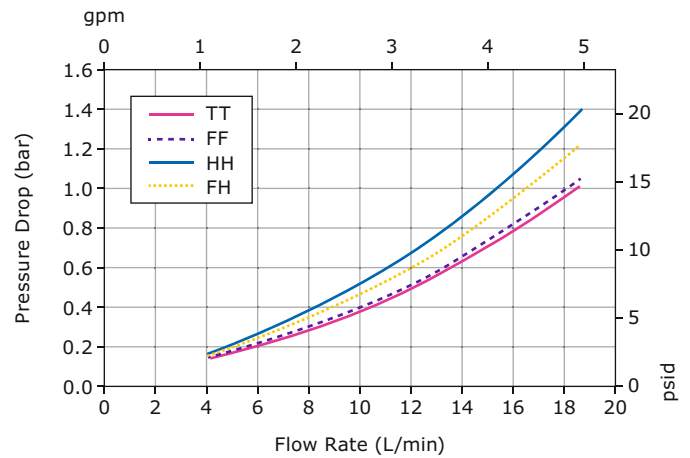
W1 = 1.0/0.2/0.1 µm W3 = 1.0/0.2 µm W6 = 1.0/0.5 µm W2 = 1.0/1.2 µm W9 = 2.0/1.2 µm

Typical Clean Water Flow Rates

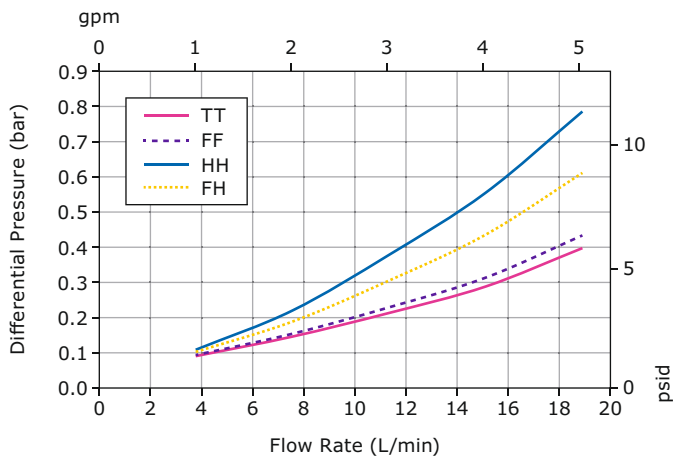
**Opticap® XL 2 Capsule with
Polysep™ II Media — 1.0/0.2 µm Nominal (W3)**



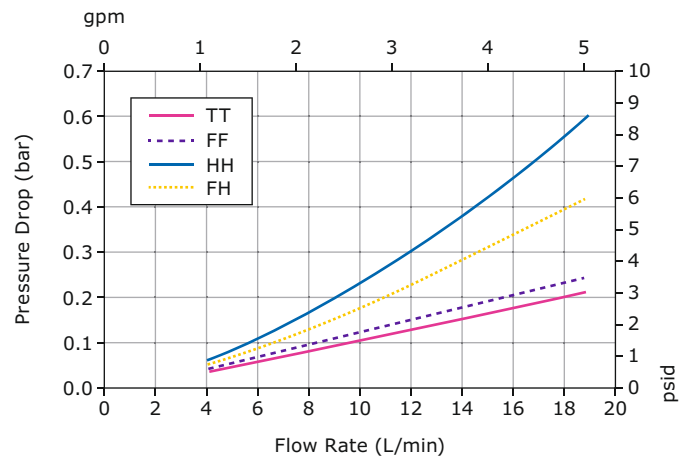
**Opticap® XL 2 Capsule with
Polysep™ II Media — 1.0/0.5 µm Nominal (W6)**



**Opticap® XL 2 Capsule with
Polysep™ II Media — 1.0/1.2 µm Nominal (W2)**



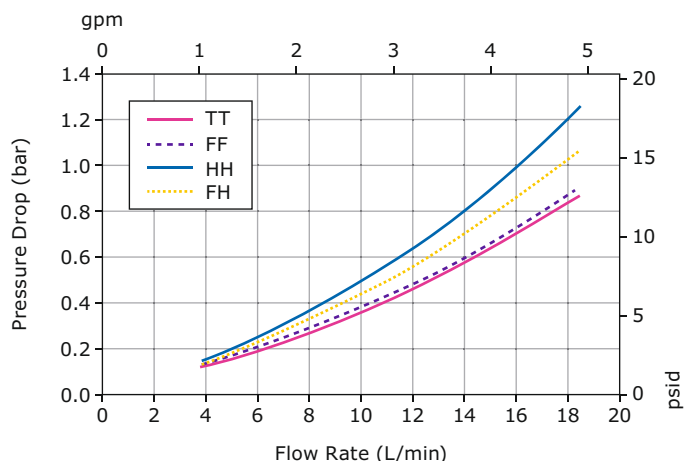
**Opticap® XL 2 Capsule with
Polysep™ II Media — 2.0/1.2 µm Nominal (W9)**



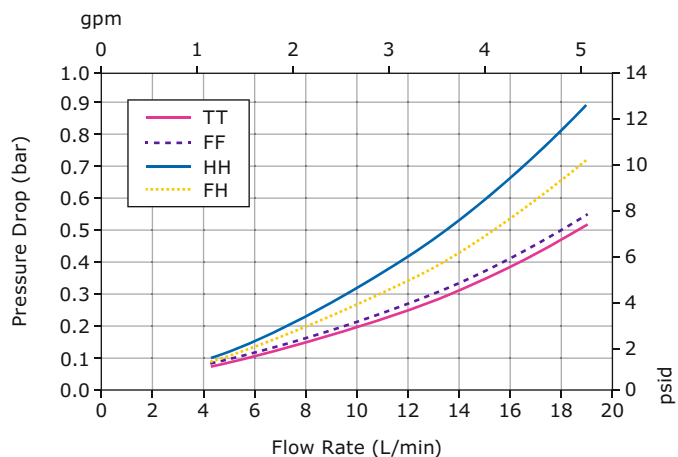
Opticap® XL Capsule Legends Refer to Connection Type

TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
 FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
 HH = 14 mm (⅝ in.) Hose Barb Inlet and Outlet
 FH = 19 mm (¾ in.) Sanitary Flange Inlet and
 14 mm (⅝ in.) Hose Barb Outlet

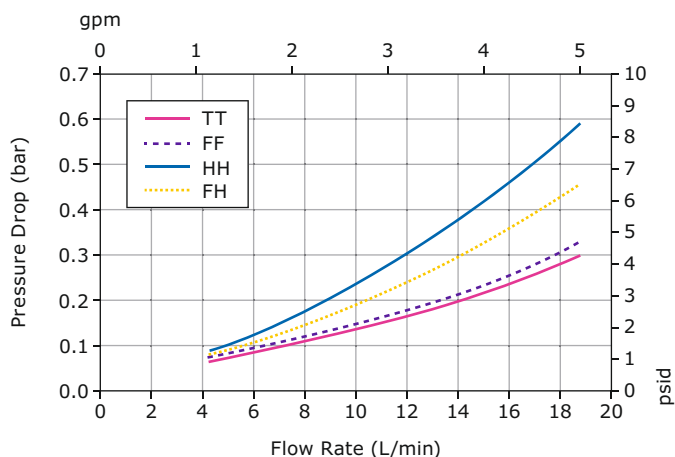
**Opticap® XL 4 Capsule with
Polysep™ II Media — 1.0/0.2 µm Nominal (W3)**



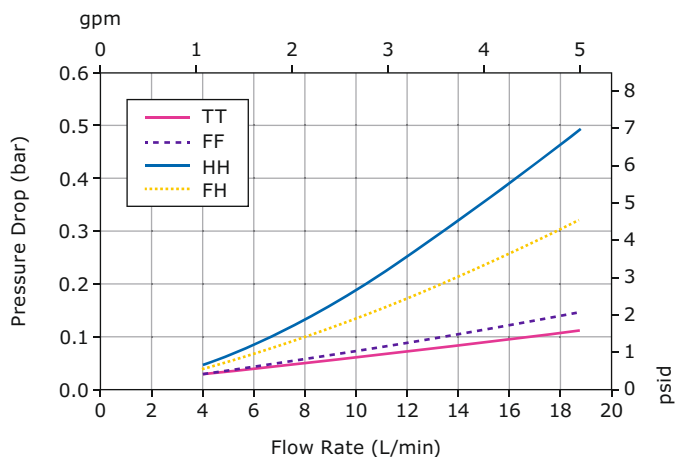
**Opticap® XL 4 Capsule with
Polysep™ II Media — 1.0/0.5 µm Nominal (W6)**



**Opticap® XL 4 Capsule with
Polysep™ II Media — 1.0/1.2 µm Nominal (W2)**



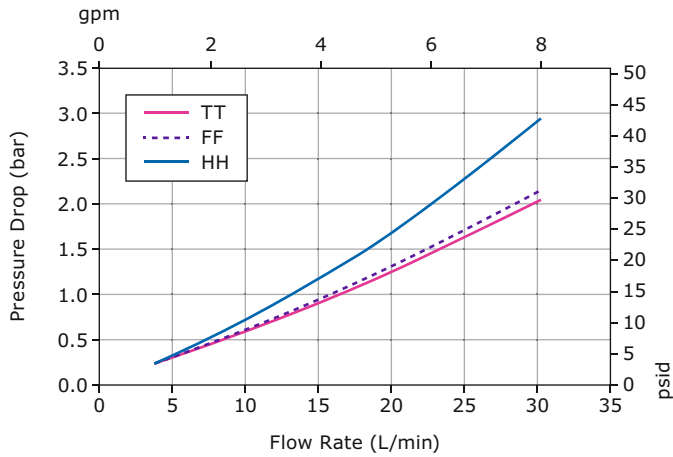
**Opticap® XL 4 Capsule with
Polysep™ II Media — 2.0/1.2 µm Nominal (W9)**



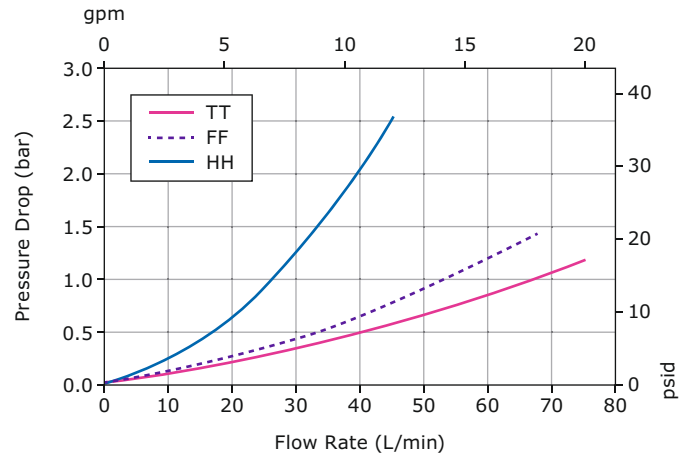
Opticap® XL Capsule Legends Refer to Connection Type

TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
 FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
 HH = 14 mm (½ in.) Hose Barb Inlet and Outlet
 FH = 19 mm (¾ in.) Sanitary Flange Inlet and
 14 mm (½ in.) Hose Barb Outlet

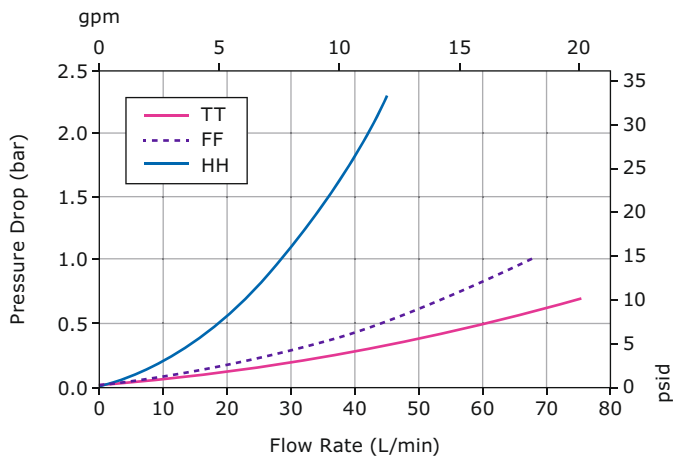
**Opticap® XL 5 Capsule with
Polysep™ II Media — 1.0/0.2/0.1 µm Nominal (W1)**



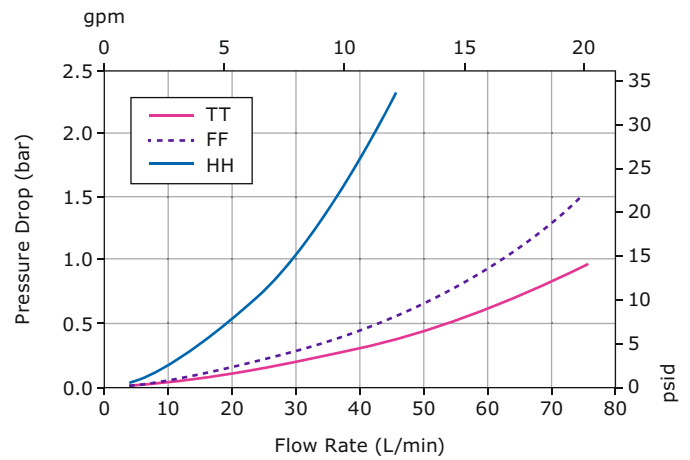
**Opticap® XL 5 Capsule with
Polysep™ II Media — 1.0/0.2 µm Nominal (W3)**



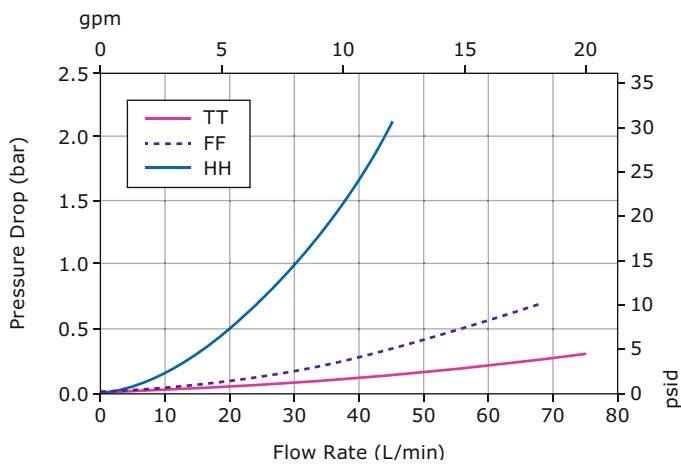
**Opticap® XL 5 Capsule with
Polysep™ II Media — 1.0/0.5 µm Nominal (W6)**



**Opticap® XL 5 Capsule with
Polysep™ II Media — 1.0/1.2 µm Nominal (W2)**



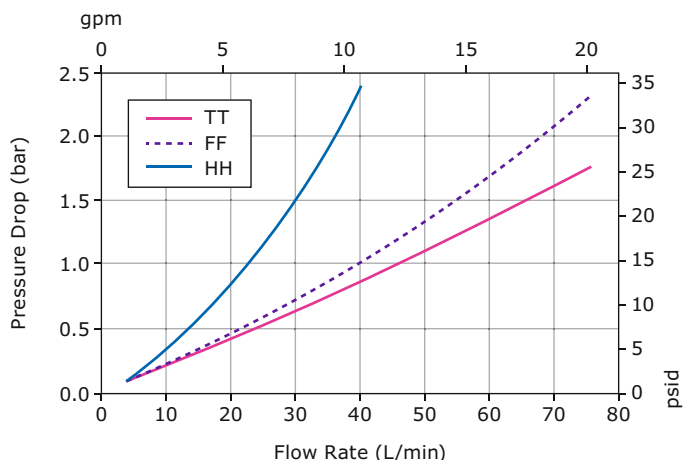
**Opticap® XL 5 Capsule with
Polysep™ II Media — 2.0/1.2 µm Nominal (W9)**



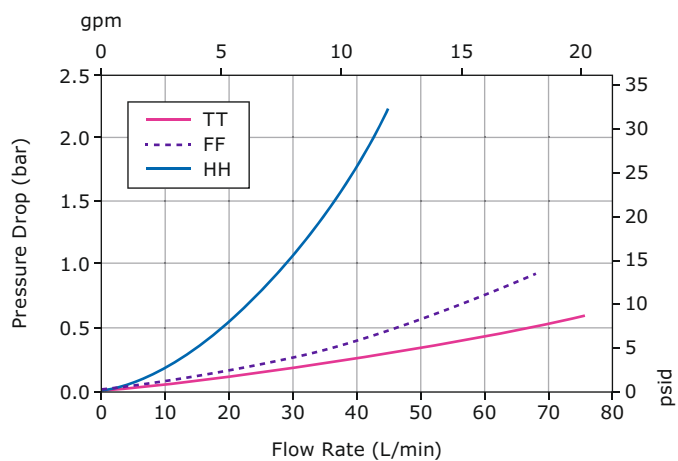
Opticap® XL Capsule Legends Refer to Connection Type

TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
 FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
 HH = 14 mm (½ in.) Hose Barb Inlet and Outlet

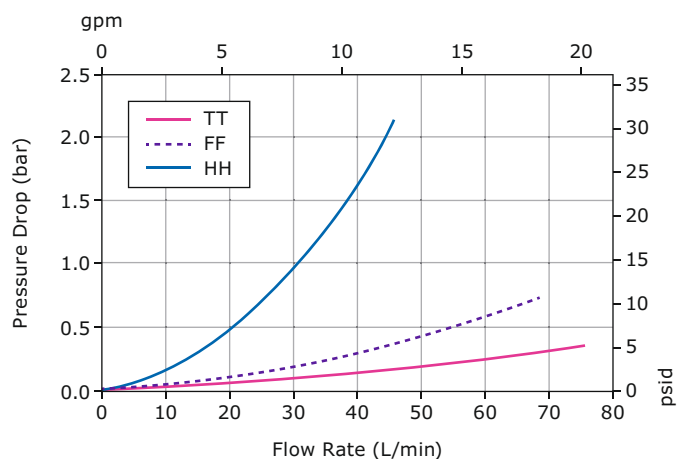
**Opticap® XL 10 Capsule with
Polysep™ II Media — 1.0/0.2/0.1 µm Nominal (W1)**



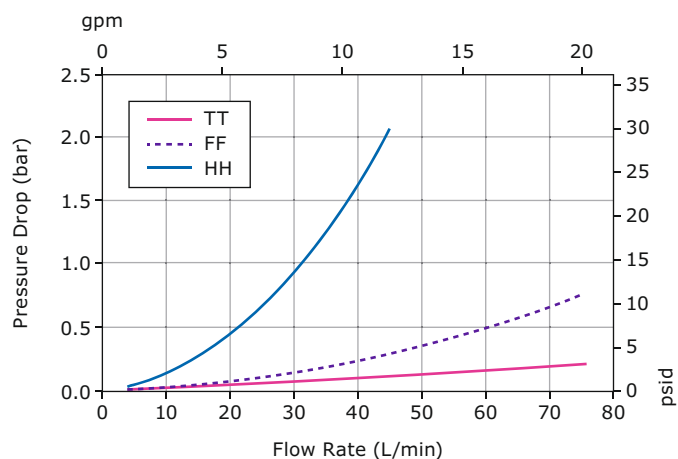
**Opticap® XL 10 Capsule with
Polysep™ II Media — 1.0/0.2 µm Nominal (W3)**



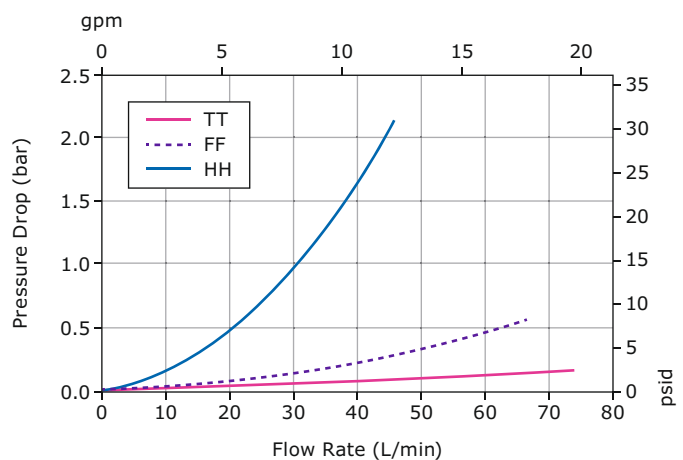
**Opticap® XL 10 Capsule with
Polysep™ II Media — 1.0/0.5 µm Nominal (W6)**



**Opticap® XL 10 Capsule with
Polysep™ II Media — 1.0/1.2 µm Nominal (W2)**



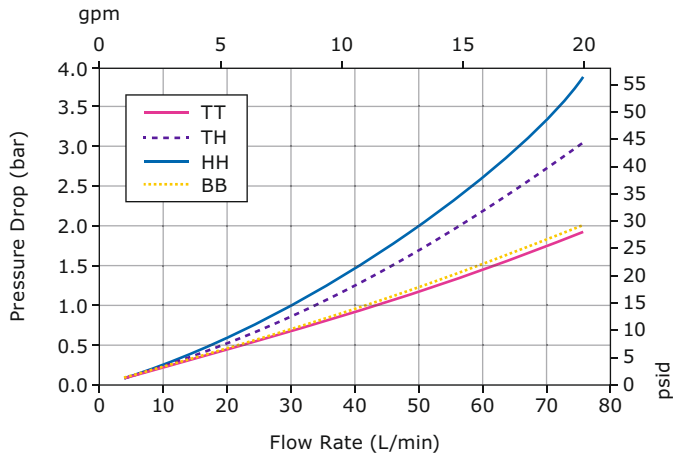
**Opticap® XL 10 Capsule with
Polysep™ II Media — 2.0/1.2 µm Nominal (W9)**



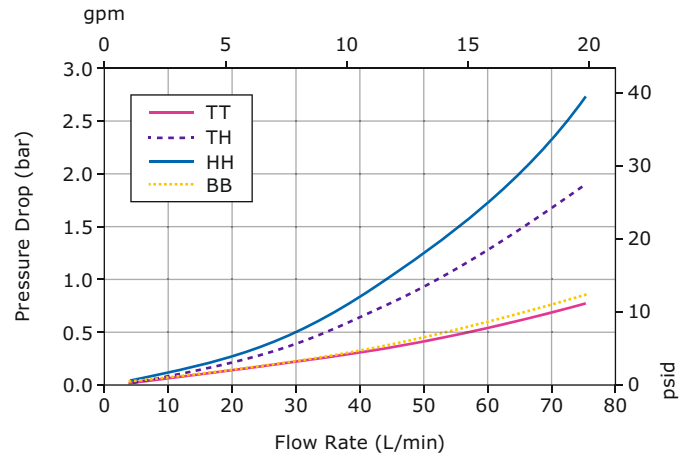
Opticap® XL Capsule Legends Refer to Connection Type

TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
 FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
 HH = 14 mm (½ in.) Hose Barb Inlet and Outlet

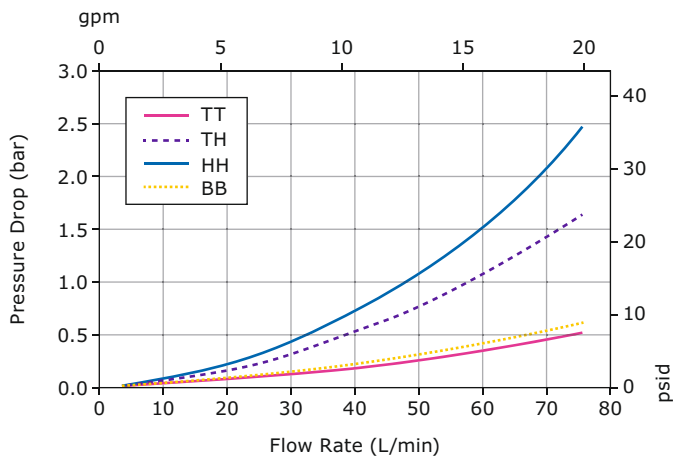
**Opticap® XLT 10 Capsule with
Polysep™ II Media — 1.0/0.2/0.1 µm Nominal (W1)**



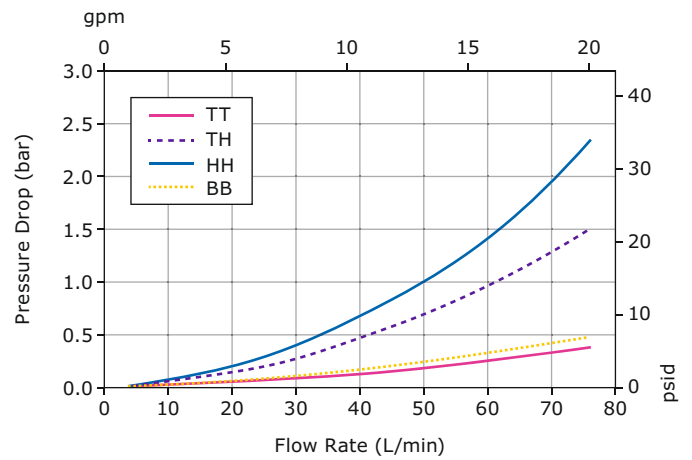
**Opticap® XLT 10 Capsule with
Polysep™ II Media — 1.0/0.2 µm Nominal (W3)**



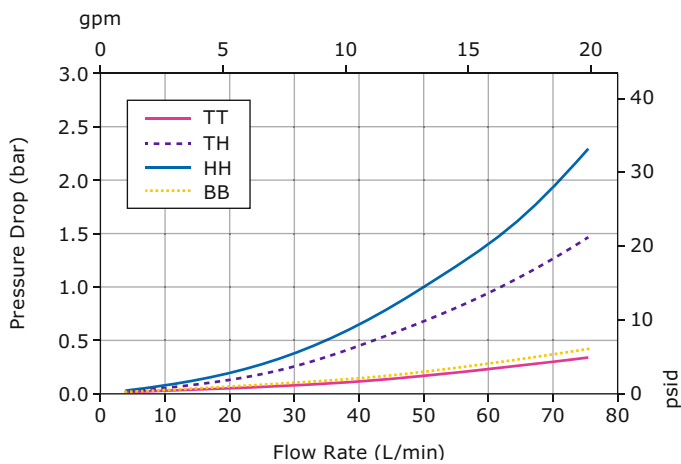
**Opticap® XLT 10 Capsule with
Polysep™ II Media — 1.0/0.5 µm Nominal (W6)**



**Opticap® XLT 10 Capsule with
Polysep™ II Media — 1.0/1.2 µm Nominal (W2)**



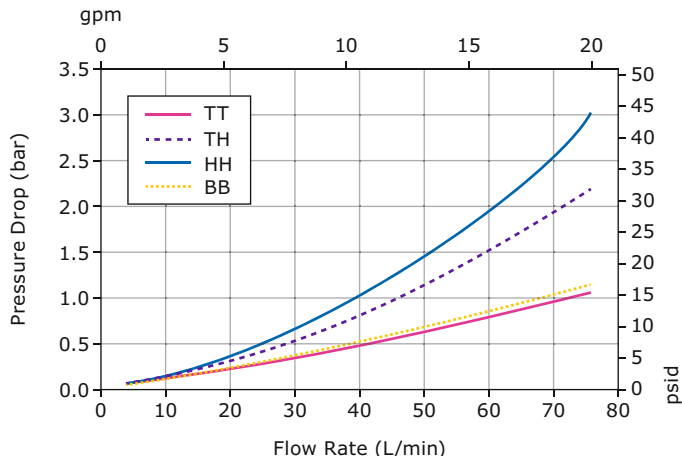
**Opticap® XLT 10 Capsule with
Polysep™ II Media — 2.0/1.2 µm Nominal (W9)**



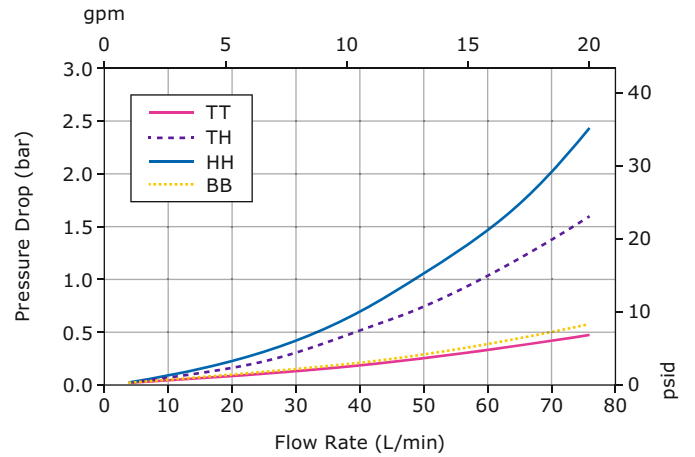
Opticap® XLT Capsule Legends Refer to Connection Type

- TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
- TH = 38 mm (1½ in.) Sanitary Flange Inlet and 16 mm (⅝ in.) Hose Barb Outlet
- HH = 16 mm (⅝ in.) Hose Barb Inlet and Outlet
- BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

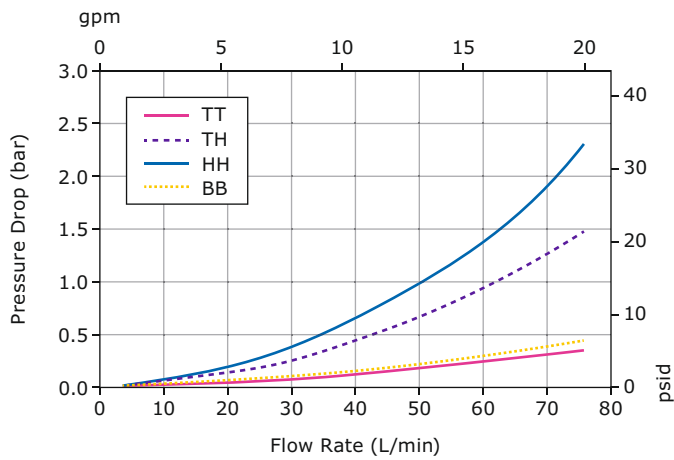
**Opticap® XLT 20 Capsule with
Polysep™ II Media — 1.0/0.2/0.1 µm Nominal (W1)**



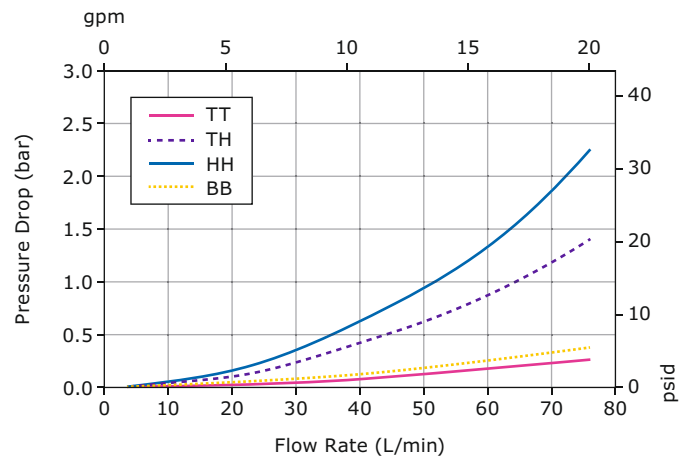
**Opticap® XLT 20 Capsule with
Polysep™ II Media — 1.0/0.2 µm Nominal (W3)**



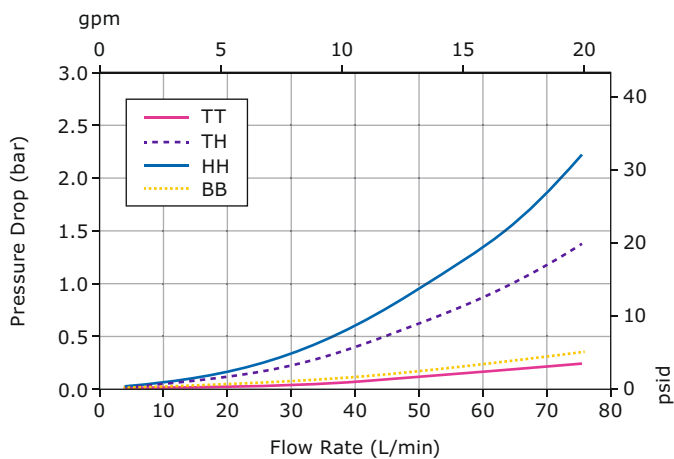
**Opticap® XLT 20 Capsule with
Polysep™ II Media — 1.0/0.5 µm Nominal (W6)**



**Opticap® XLT 20 Capsule with
Polysep™ II Media — 1.0/1.2 µm Nominal (W2)**



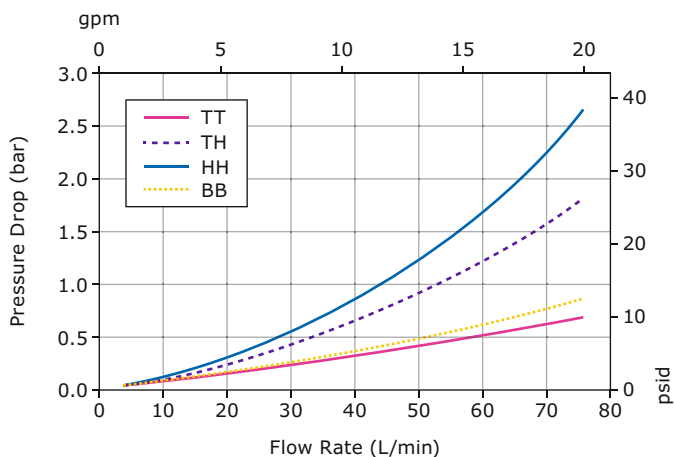
**Opticap® XLT 20 Capsule with
Polysep™ II Media — 2.0/1.2 µm Nominal (W9)**



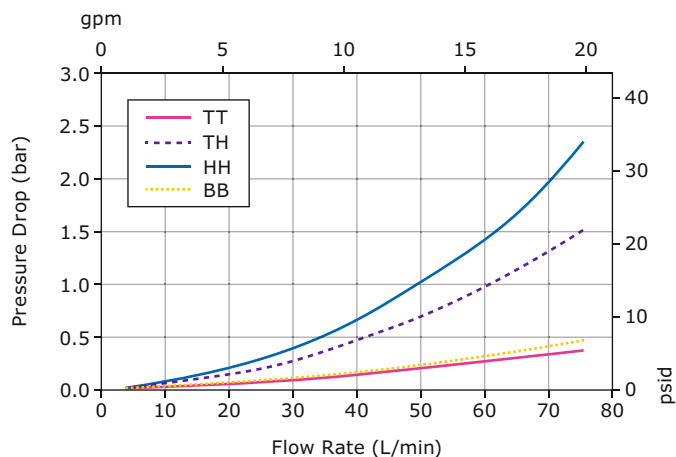
Opticap® XLT Capsule Legends Refer to Connection Type

- TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
- TH = 38 mm (1½ in.) Sanitary Flange Inlet and 16 mm (⅝ in.) Hose Barb Outlet
- HH = 16 mm (⅝ in.) Hose Barb Inlet and Outlet
- BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

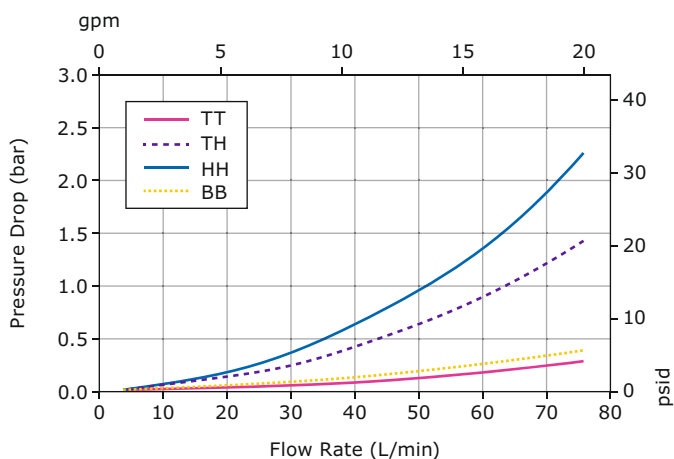
**Opticap® XLT 30 Capsule with
Polysep™ II Media — 1.0/0.2/0.1 µm Nominal (W1)**



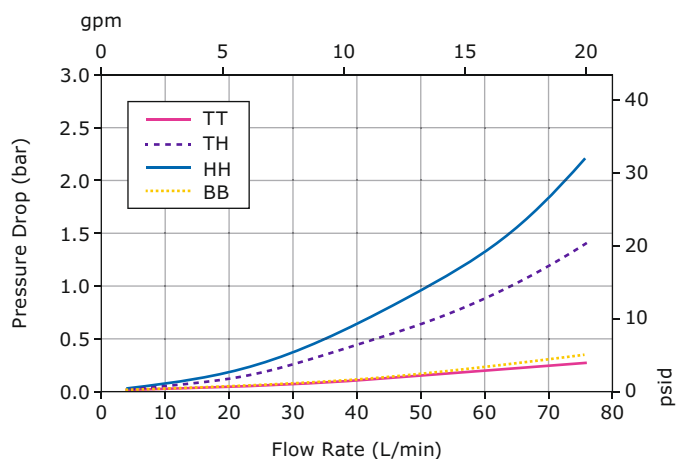
**Opticap® XLT 30 Capsule with
Polysep™ II Media — 1.0/0.2 µm Nominal (W3)**



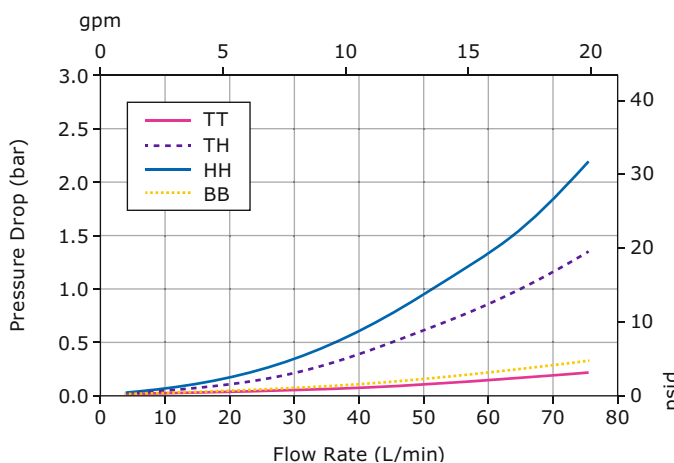
**Opticap® XLT 30 Capsule with
Polysep™ II Media — 1.0/0.5 µm Nominal (W6)**



**Opticap® XLT 30 Capsule with
Polysep™ II Media — 1.0/1.2 µm Nominal (W2)**



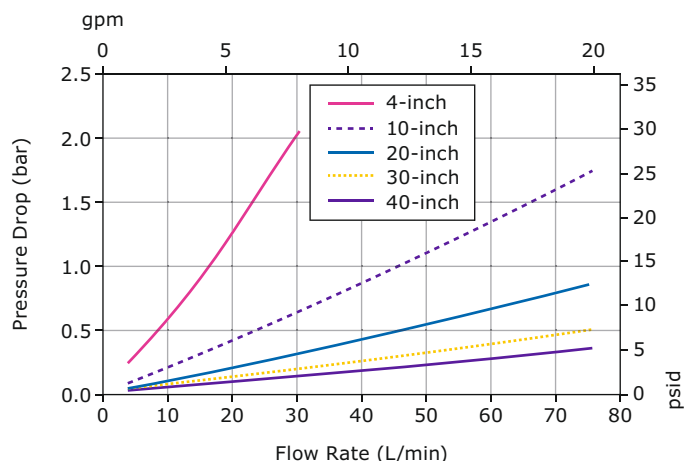
**Opticap® XLT 30 Capsule with
Polysep™ II Media — 2.0/1.2 µm Nominal (W9)**



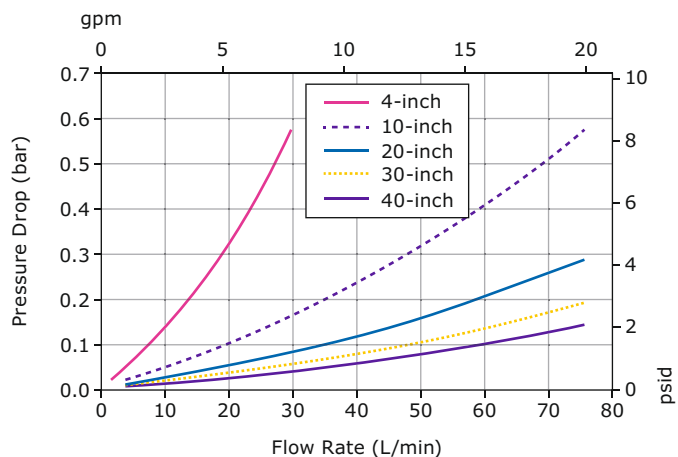
Opticap® XLT Capsule Legends Refer to Connection Type

TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
 TH = 38 mm (1½ in.) Sanitary Flange Inlet and 16 mm (5⁄8 in.) Hose Barb Outlet
 HH = 16 mm (5⁄8 in.) Hose Barb Inlet and Outlet
 BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

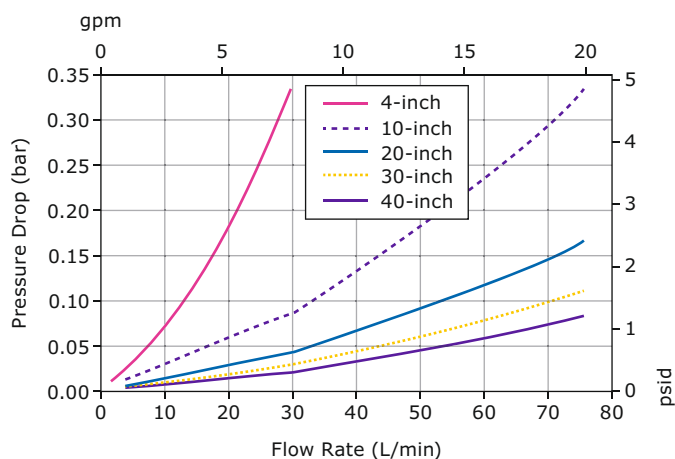
**Cartridges with
Polysep™ II Media — 1.0/0.2/0.1 µm Nominal (W1)**



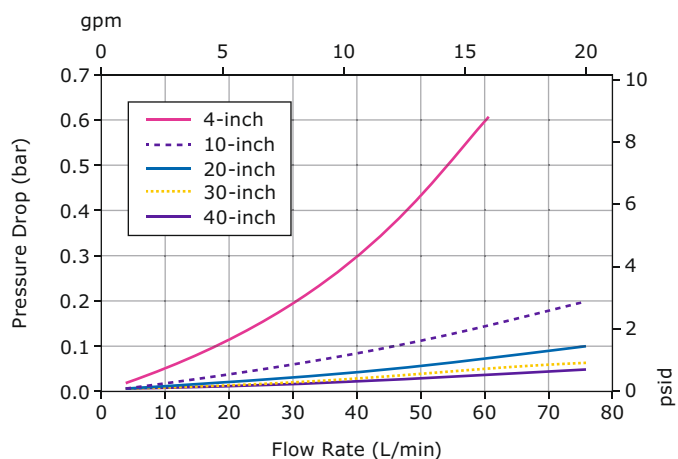
**Cartridges with
Polysep™ II Media — 1.0/0.2 µm Nominal (W3)**



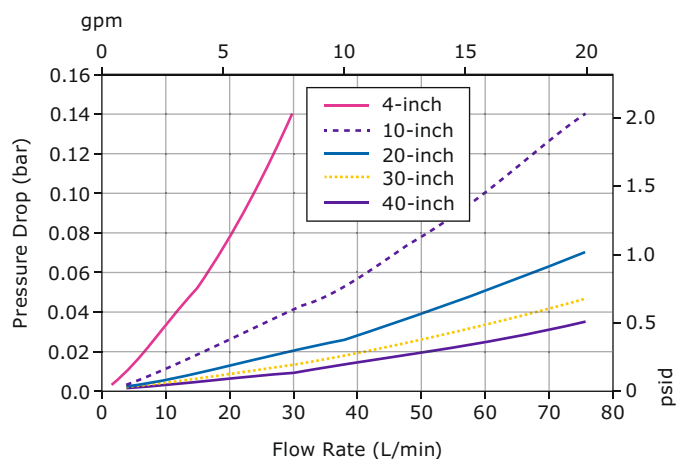
**Cartridges with
Polysep™ II Media — 1.0/0.5 µm Nominal (W6)**



**Cartridges with
Polysep™ II Media — 1.0/1.2 µm Nominal (W2)**

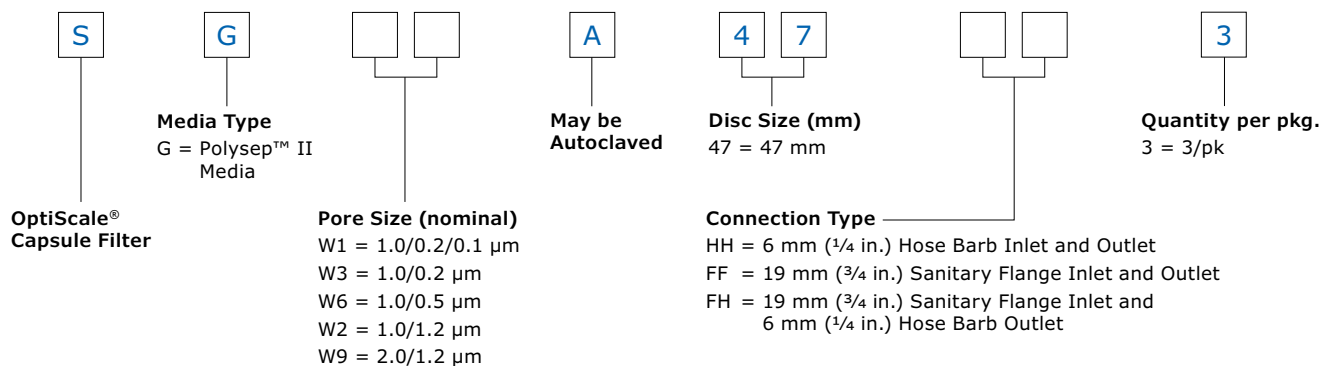


**Cartridges with
Polysep™ II Media — 2.0/1.2 µm Nominal (W9)**

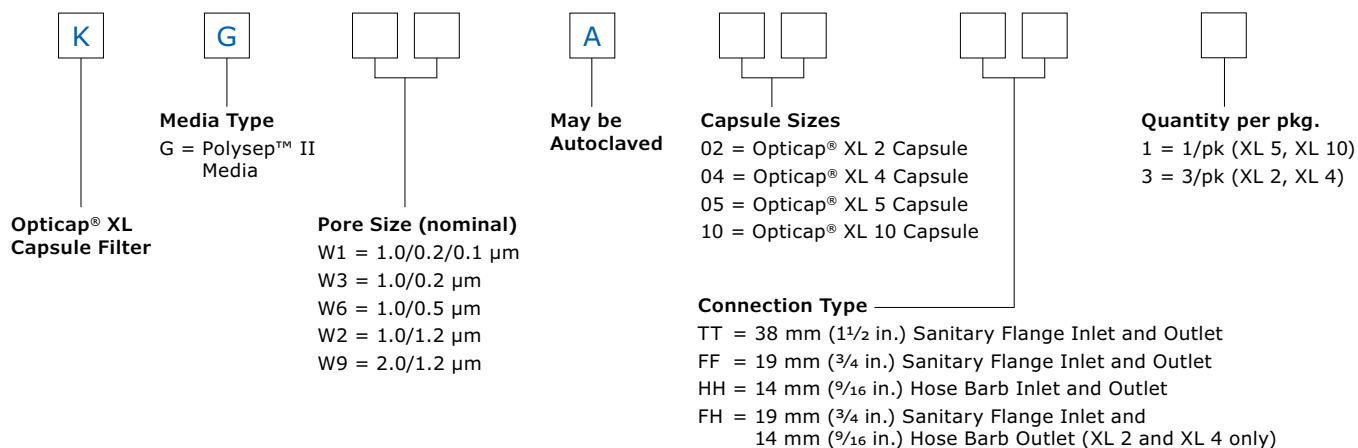


Ordering Information

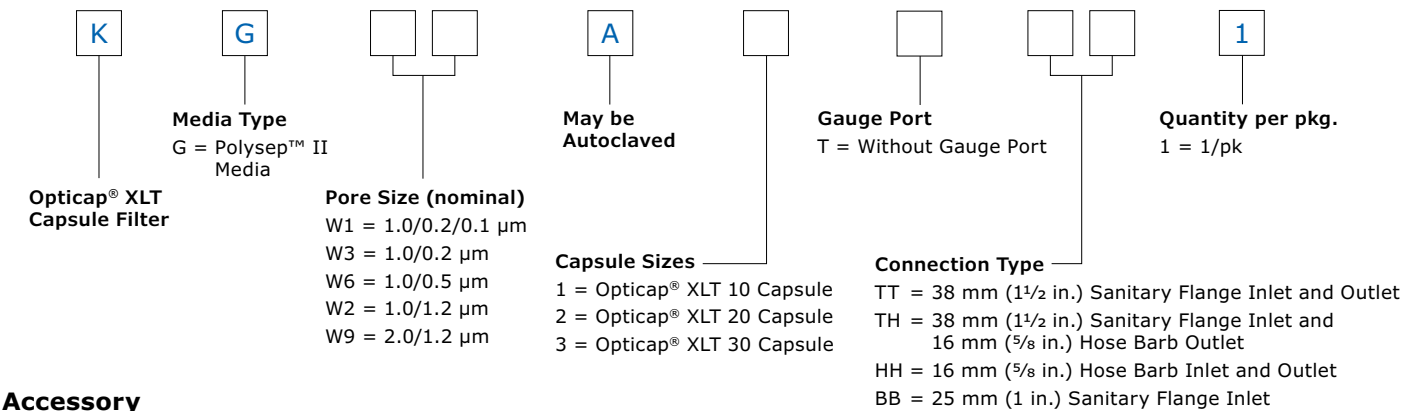
OptiScale® Capsule Filters



Opticap® XL Capsule Filters



Opticap® XLT Capsule Filters

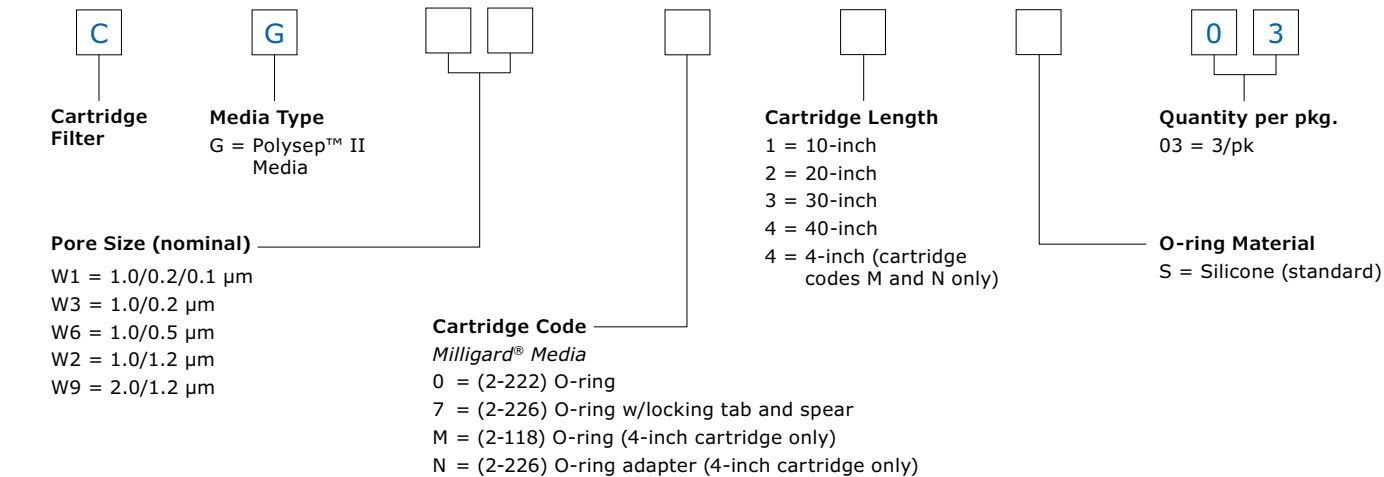


Accessory

Description	Qty/Pk	Cat. No.
Standard Opticap® XLT Capsule Filter Stand	1/pkg	XLTSTAND1

*Not all configurations available as standard product.

Cartridge Filters



Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt
Germany

