

Milligard® Filters

For protection of sterilizing-grade filters

Milligard® filters are designed for reliable particle removal from a broad range of fluid streams and are traditionally used before sterilizing grade filters. These filters are constructed of homogeneous polymers of cellulose esters on a polyester web, and provide high capacity and retention.

Milligard® filters are available in a range of pore sizes with both single and double layer configurations in three device formats. A special low protein binding (LPB) version is also available.

Benefits

- Effectively protect sterilizing-grade filters from premature plugging
- High capacity combined with high retention efficiency
- Validated to withstand multiple sterilization cycles
- The low protein binding version provides maximum protein recovery

Available Pore Sizes

Milligard® Filter

- 0.2 µm
- 0.5 µm
- 1.2 µm
- 0.5/0.2 µm
- 1.2/0.5 µm

Milligard® LPB Filter

- 0.2 µm
- 0.5 µm
- 1.2 µm
- 0.5/0.2 µm
- 1.2/0.5 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-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.



Opticap® XL Capsules



Opticap® XLT Capsules



Cartridge Filters

Quality Management

Milligard® 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	17.7 cm ²
Materials of Construction	
Filter media	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.
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.

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							
Single layer:	0.10 m ² (1.1 ft ²)	0.20 m ² (2.1 ft ²)	0.34 m ² (3.7 ft ²)	0.8 m ² (8.8 ft ²)	0.8 m ² (8.8 ft ²)	1.6 m ² (17.6 ft ²)	2.5 m ² (26.4 ft ²)
Double layer:	0.07 m ² (0.8 ft ²)	0.16 m ² (1.7 ft ²)	0.26 m ² (2.8 ft ²)	0.7 m ² (7.0 ft ²)	0.7 m ² (7.0 ft ²)	1.3 m ² (14.0 ft ²)	2.0 m ² (21.0 ft ²)
Materials of Construction							
Milligard® Media:	Mixed esters of cellulose				Mixed esters of cellulose		
Milligard® LPB Media:	Mixed esters of cellulose treated for low protein binding				—		
Supports:	Polyester				Polyester		
Structural Components*:	Polypropylene				Polypropylene		
Vent O-rings:	Silicone				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				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				Forward: 3.4 bar (50 psid) at 25 °C		

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
NVR Gravimetric Extractables	After autoclaving at 121 °C for 30 minutes and a 24 hour soak in ASTM® Type 1 reagent grade water at controlled room temperature:						
Milligard® Media:	≤ 15 mg	≤ 25 mg	≤ 25 mg	≤ 55 mg	≤ 55 mg	≤ 110 mg	≤ 165 mg
Milligard® LPB Media:							
0.2 µm	≤ 25 mg	≤ 45 mg	≤ 45 mg	≤ 105 mg	—	—	—
0.5 µm	≤ 25 mg	≤ 45 mg	≤ 45 mg	≤ 105 mg	—	—	—
1.2 µm	≤ 55 mg	≤ 105 mg	≤ 105 mg	≤ 255 mg	—	—	—
0.5/0.2 µm	≤ 60 mg	≤ 110 mg	≤ 145 mg	≤ 355 mg	—	—	—
1.2/0.5 µm	≤ 50 mg	≤ 90 mg	≤ 85 mg	≤ 205 mg	—	—	—
After a flush of:	1000 mL	2000 mL	2000 mL	5000 mL	—	—	—
Oxidizable Substances	Meets the requirements of the USP Oxidizable Substances Test after a water flush of:						
	1000 mL	1000 mL	2000 mL	5000 mL	5000 mL	10000 mL	15000 mL
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) bacterial endotoxins 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.						

*Cage, core, end caps, and capsule housing

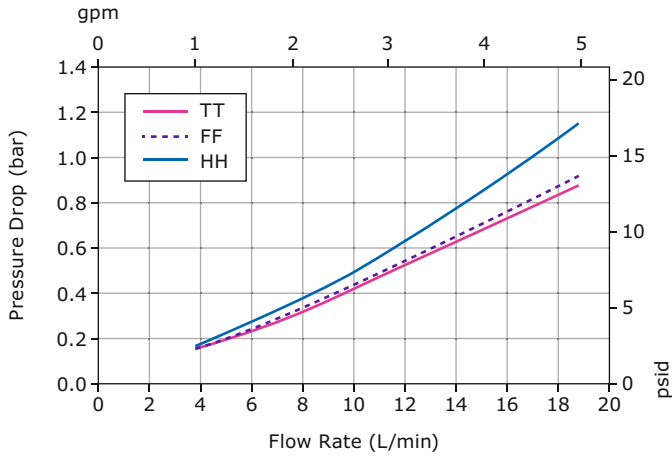
Cartridge Filter Specifications

Description	4-inch Cartridge	Per 10-inch Cartridge
Nominal Dimensions		
Outside diameter:	7.4 cm (2.9 in.)	7.4 cm (2.9 in.)
Filtration Area		
Single layer:	0.34 m ² (3.7 ft ²)	0.8 m ² (8.8 ft ²)
Double layer:	0.28 m ² (3.0 ft ²)	0.7 m ² (7.0 ft ²)
Materials of Construction		
Milligard® Media:	Mixed esters of cellulose	
Milligard® LPB Media:	Mixed esters of cellulose treated for low protein binding	
Supports:	Polyester	
Structural Components*:	Polypropylene	
Vent O-rings:	Silicone (unless otherwise specified)	
Maximum Differential Pressure		
Forward:	3.4 bar (50 psid) at 25 °C	
NVR Gravimetric Extractables	After autoclaving at 121 °C for 30 minutes and a 24 hour soak in ASTM Type 1 reagent grade water at controlled room temperature:	
Milligard® Media:	≤ 20 mg	≤ 50 mg
Milligard® LPB Media:		
0.2 µm	≤ 40 mg	≤ 100 mg
0.5 µm	≤ 40 mg	≤ 105 mg
1.2 µm	≤ 100 mg	≤ 250 mg
0.5/0.2 µm	≤ 80 mg	≤ 200 mg
1.2/0.5 µm	≤ 140 mg	≤ 350 mg
After a flush of:	2000 mL	5000 mL
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) bacterial endotoxins 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 for sterile water for injection after autoclaving at 121 °C for 30 minutes and a water flush of:	
	2 L per 4-inch cartridge	5 L per 10-inch cartridge
Sterilization	May be autoclaved for 10 cycles of 30 minutes at 121 °C. Cartridges may also be steam sterilized up to 10 times at 121 °C for 30 minutes, 5 psid maximum differential pressure.	
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.	

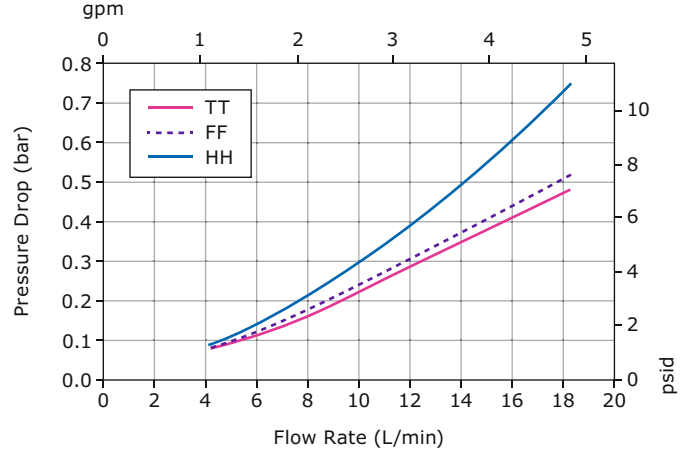
*Cage, core, end caps, and sleeve

Typical Clean Water Flow Rates

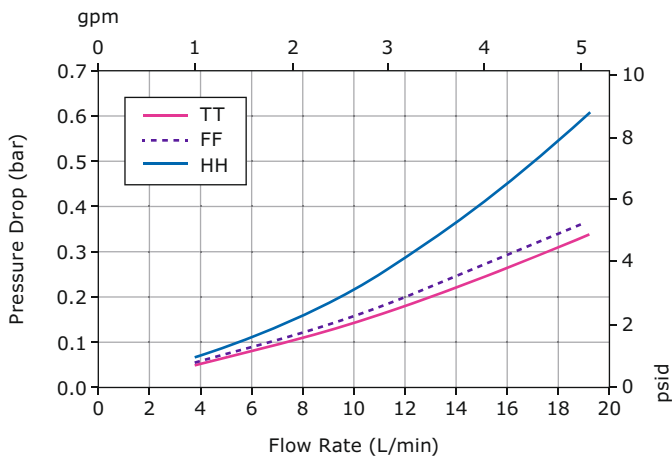
Opticap® XL 2 Capsule with Milligard® or Milligard® LPB Media – 0.2 µm Nominal (KW03 or KWL3)



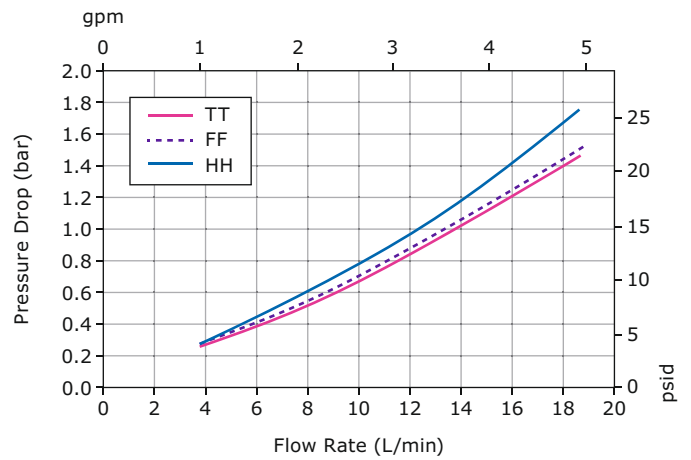
Opticap® XL 2 Capsule with Milligard® or Milligard® LPB Media – 0.5 µm Nominal (KW06 or KWL6)



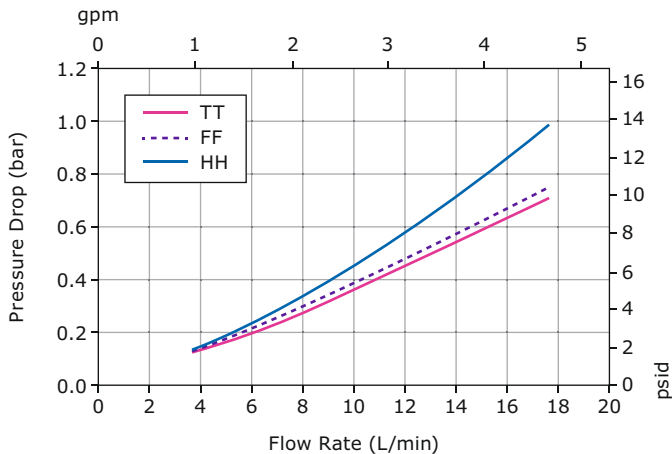
Opticap® XL 2 Capsule with Milligard® or Milligard® LPB Media – 1.2 µm Nominal (KW19 or KWL9)



Opticap® XL 2 Capsule with Milligard® or Milligard® LPB Media – 0.5/0.2 µm Nominal (KWSS or KWLS)



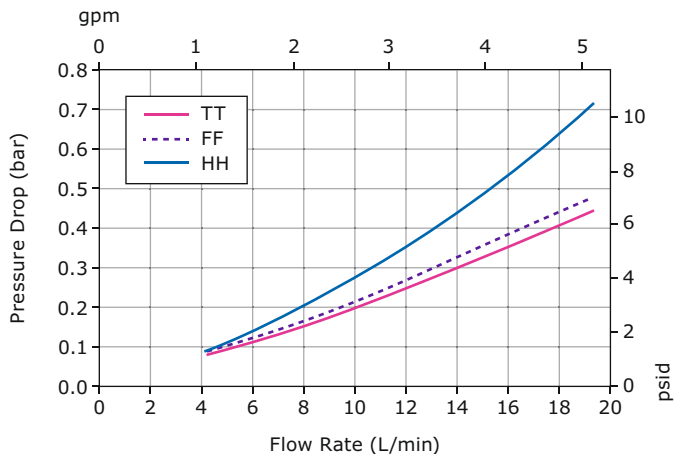
Opticap® XL 2 Capsule with Milligard® or Milligard® LPB Media – 1.2/0.5 µm Nominal (KWSC or KWLC)



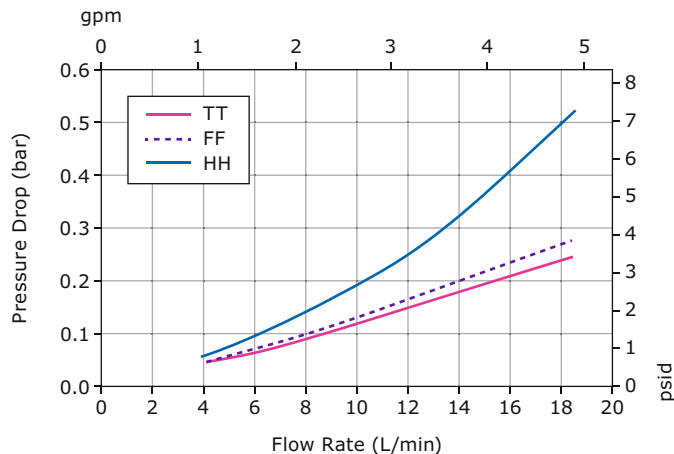
Opticap® XL Capsule Legends Refer to Connection Type

- TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
- FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
- HH = 14 mm (9/16 in.) Hose Barb Inlet and Outlet

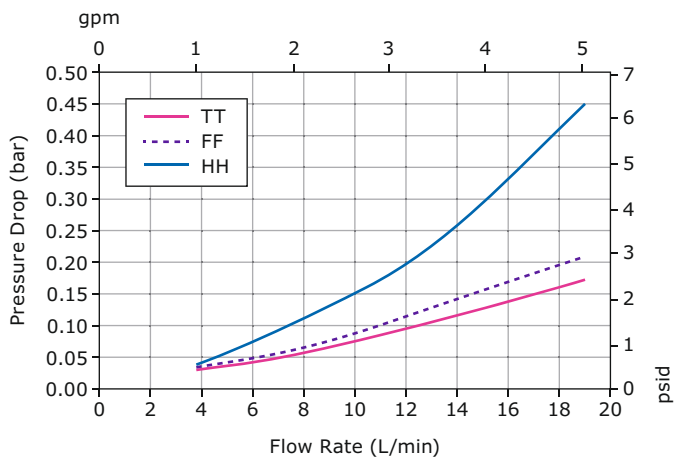
Opticap® XL 4 Capsule with Milligard® or Milligard® LPB Media – 0.2 µm Nominal (KW03 or KWL3)



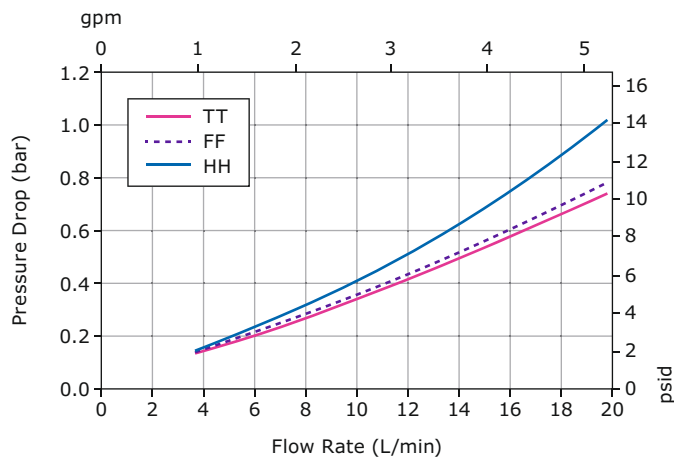
Opticap® XL 4 Capsule with Milligard® or Milligard® LPB Media – 0.5 µm Nominal (KW06 or KWL6)



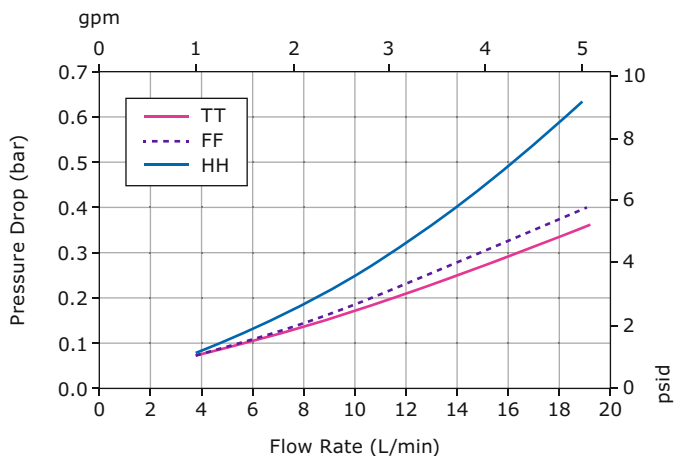
Opticap® XL 4 Capsule with Milligard® or Milligard® LPB Media – 1.2 µm Nominal (KW19 or KWL9)



Opticap® XL 4 Capsule with Milligard® or Milligard® LPB Media – 0.5/0.2 µm Nominal (KWSS or KWLS)



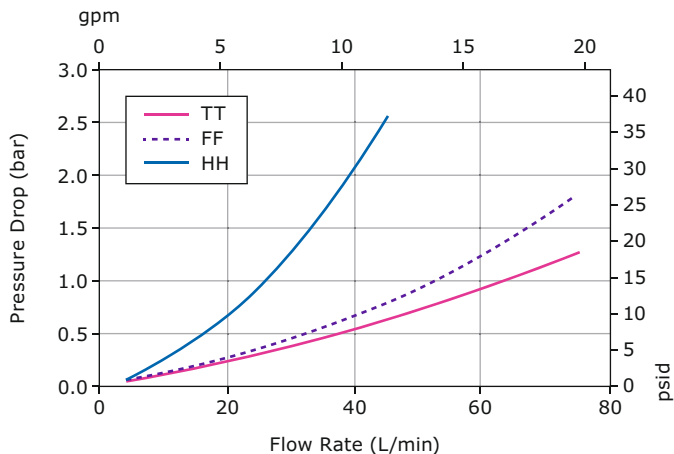
Opticap® XL 4 Capsule with Milligard® or Milligard® LPB Media – 1.2/0.5 µm Nominal (KWSC or KWLC)



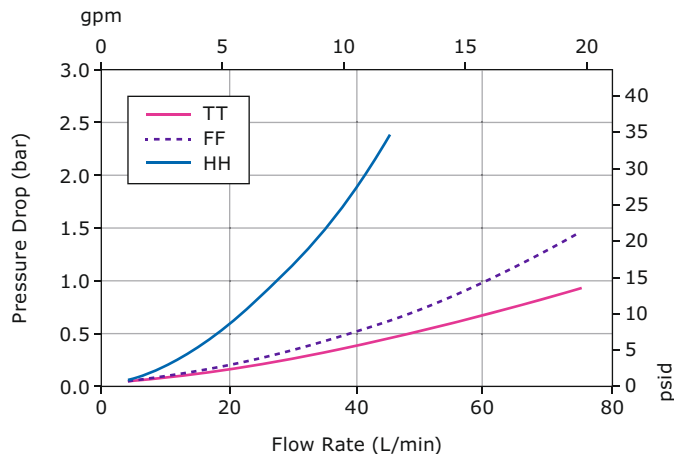
Opticap® XL Capsule Legends Refer to Connection Type

- TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
- FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
- HH = 14 mm (9/16 in.) Hose Barb Inlet and Outlet

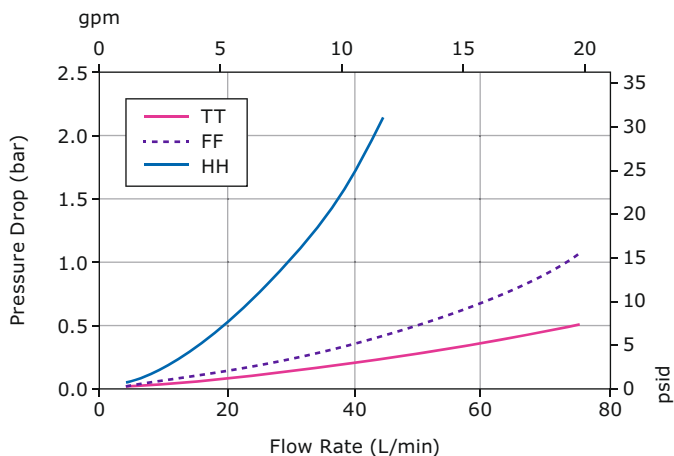
Opticap® XL 5 Capsule with Milligard® or Milligard® LPB Media – 0.2 µm Nominal (KW03 or KWL3)



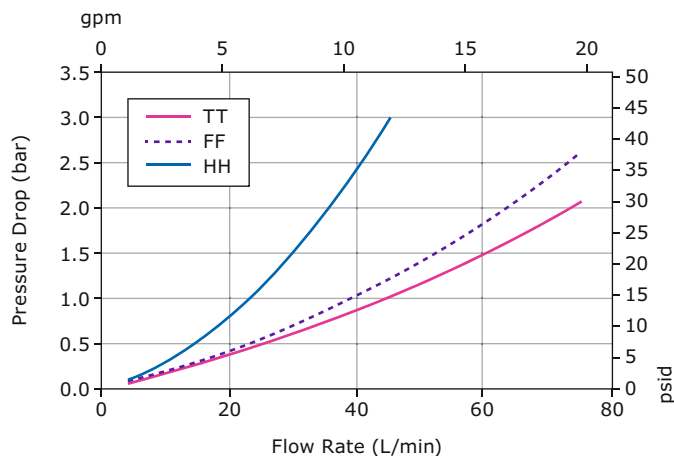
Opticap® XL 5 Capsule with Milligard® or Milligard® LPB Media – 0.5 µm Nominal (KW06 or KWL6)



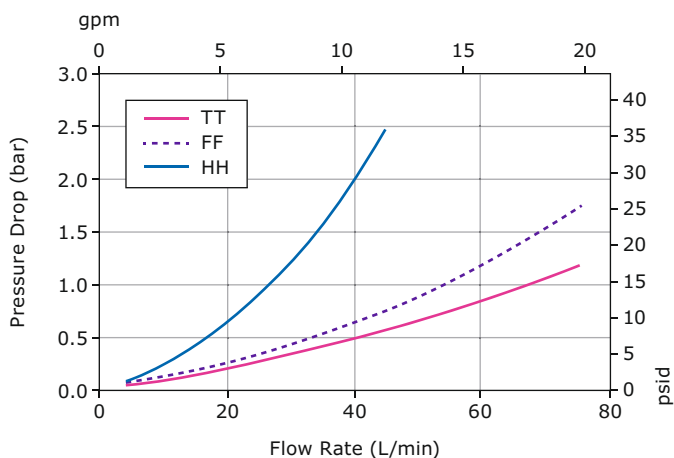
Opticap® XL 5 Capsule with Milligard® or Milligard® LPB Media – 1.2 µm Nominal (KW19 or KWL9)



Opticap® XL 5 Capsule with Milligard® or Milligard® LPB Media – 0.5/0.2 µm Nominal (KWSS or KWLS)



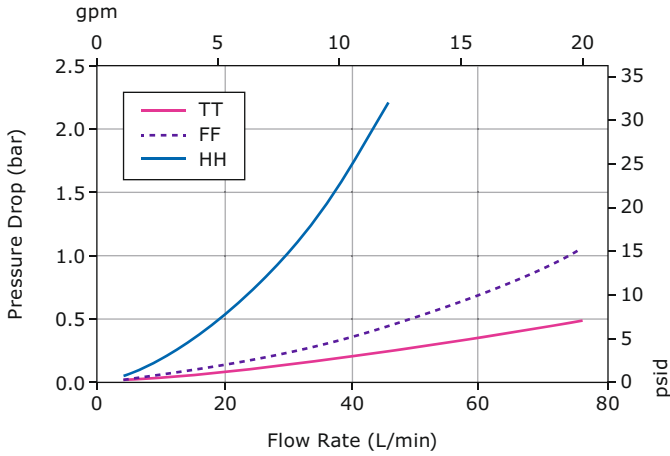
Opticap® XL 5 Capsule with Milligard® or Milligard® LPB Media – 1.2/0.5 µm Nominal (KWSC or KWLC)



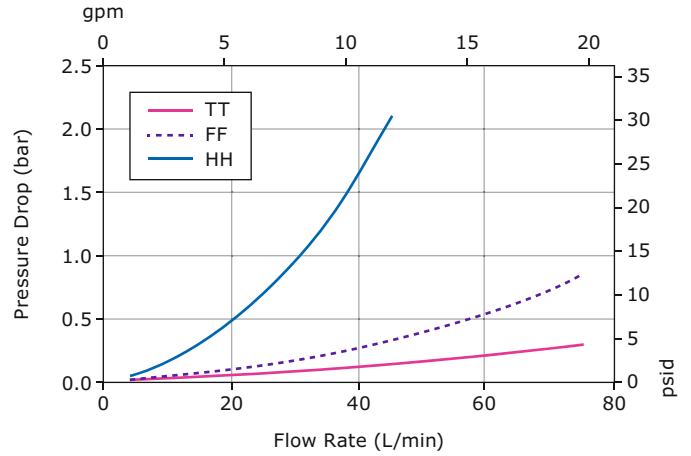
Opticap® XL Capsule Legends Refer to Connection Type

- TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
- FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
- HH = 14 mm (9/16 in.) Hose Barb Inlet and Outlet

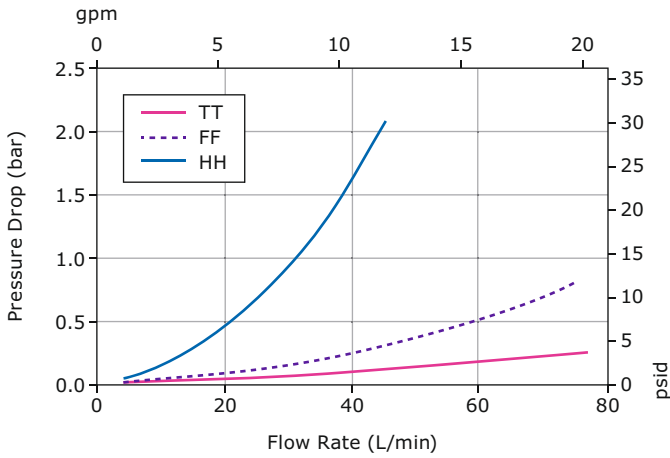
Opticap® XL 10 Capsule with Milligard® or Milligard® LPB Media – 0.2 µm Nominal (KW03 or KWL3)



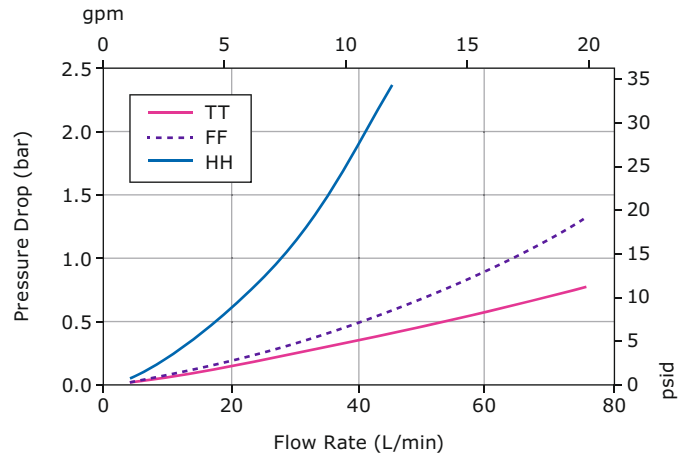
Opticap® XL 10 Capsule with Milligard® or Milligard® LPB Media – 0.5 µm Nominal (KW06 or KWL6)



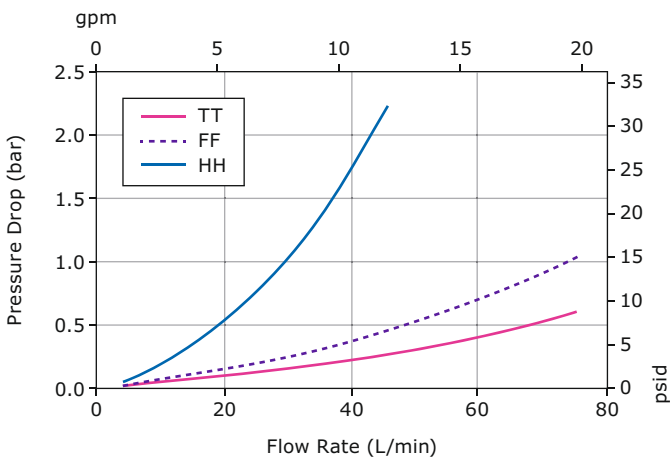
Opticap® XL 10 Capsule with Milligard® or Milligard® LPB Media – 1.2 µm Nominal (KW19 or KWL9)



Opticap® XL 10 Capsule with Milligard® or Milligard® LPB Media – 0.5/0.2 µm Nominal (KWSS or KWLS)

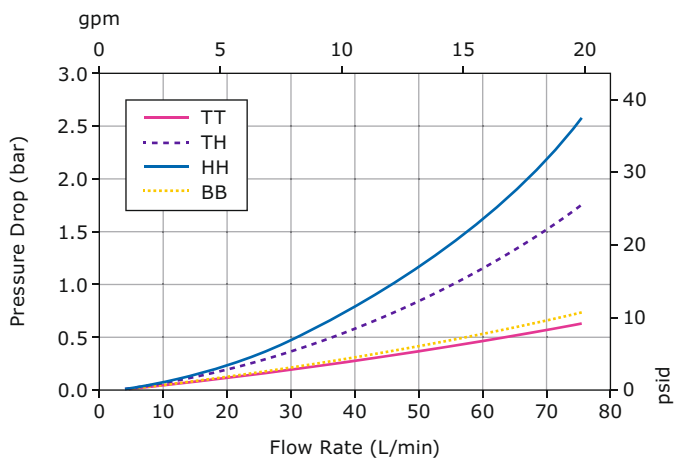


Opticap® XL 10 Capsule with Milligard® or Milligard® LPB Media – 1.2/0.5 µm Nominal (KWSC or KWLC)

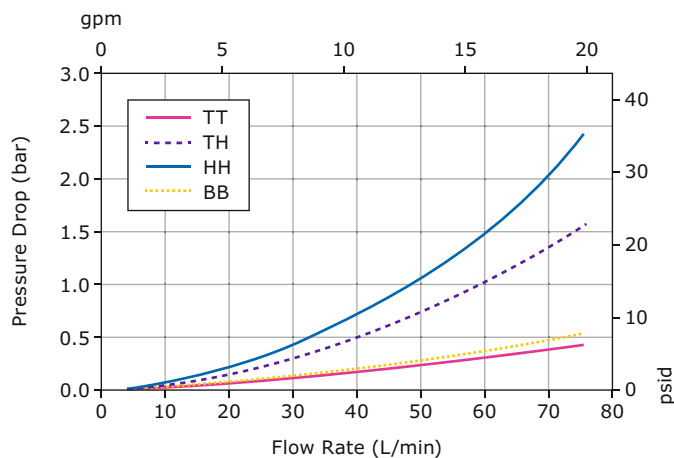


Opticap® XL Capsule Legends Refer to Connection Type
 TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
 FF = 19 mm (¾ in.) Sanitary Flange Inlet and Outlet
 HH = 14 mm (9/16 in.) Hose Barb Inlet and Outlet

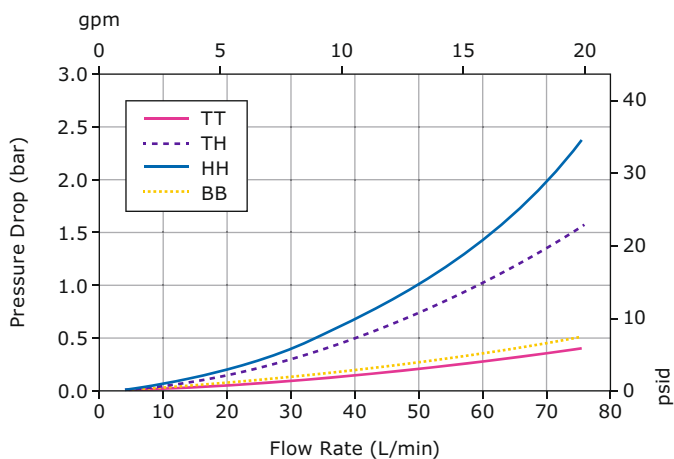
Opticap® XLT 10 Capsule with Milligard® Media – 0.2 µm Nominal (KW03)



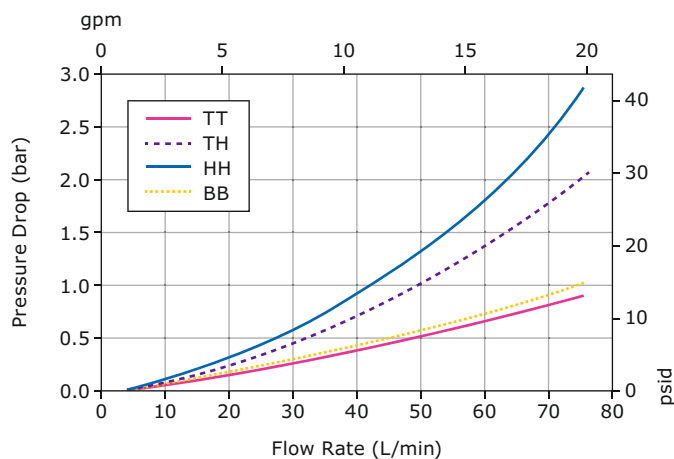
Opticap® XLT 10 Capsule with Milligard® Media – 0.5 µm Nominal (KW06)



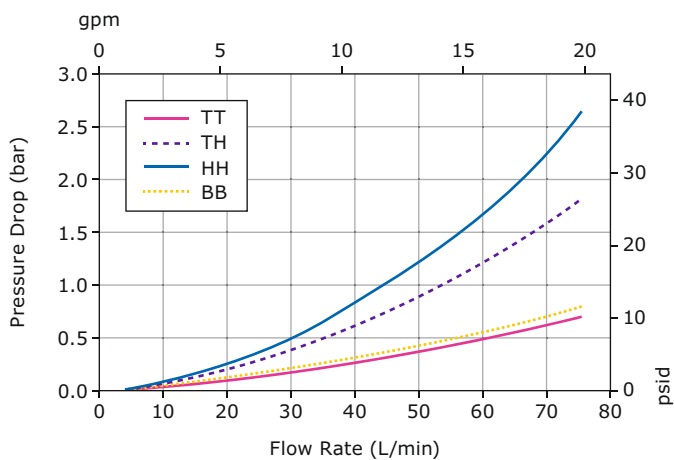
Opticap® XLT 10 Capsule with Milligard® Media – 1.2 µm Nominal (KW19)



Opticap® XLT 10 Capsule with Milligard® Media – 0.5/0.2 µm Nominal (KWSS)



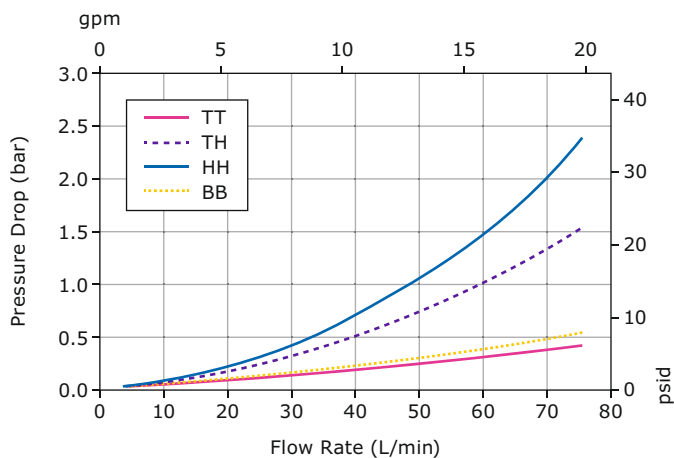
Opticap® XLT 10 Capsule with Milligard® Media – 1.2/0.5 µm Nominal (KWSC)



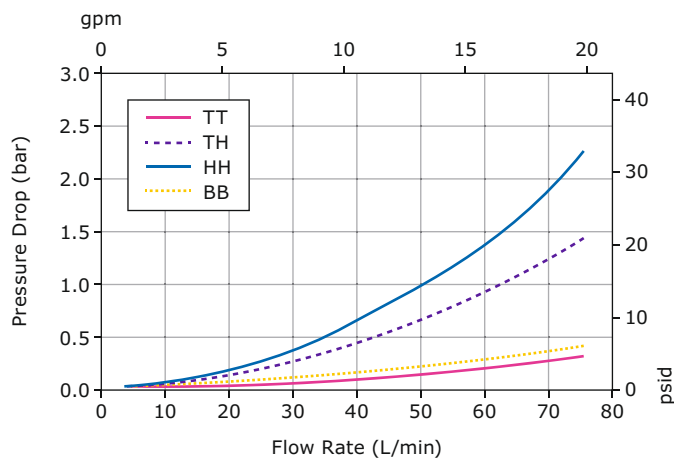
Opticap® XLT Legends Refer to Capsule Connection Type

- TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
- TH = 38 mm (1½ in.) Sanitary Flange Inlet and 14 mm (9/16 in.) Hose Barb Outlet
- HH = 16 mm (9/16 in.) Hose Barb Inlet and Outlet
- BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

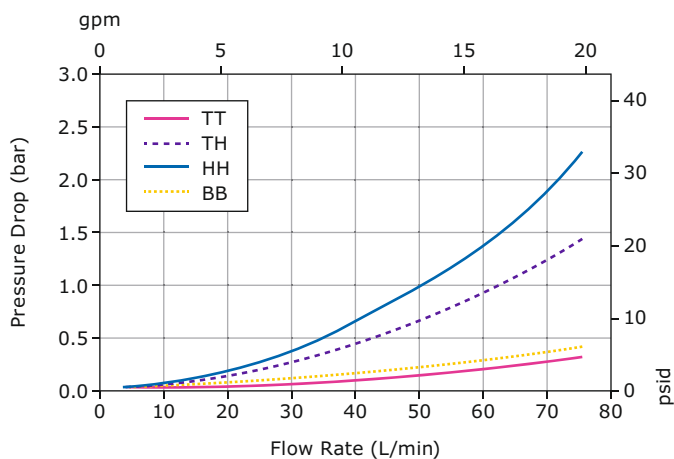
Opticap® XLT 20 Capsule with Milligard® Media – 0.2 µm Nominal (KW03)



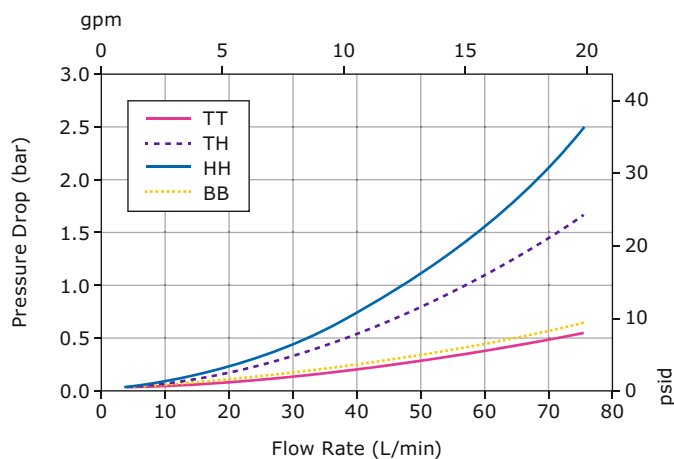
Opticap® XLT 20 Capsule with Milligard® Media – 0.5 µm Nominal (KW06)



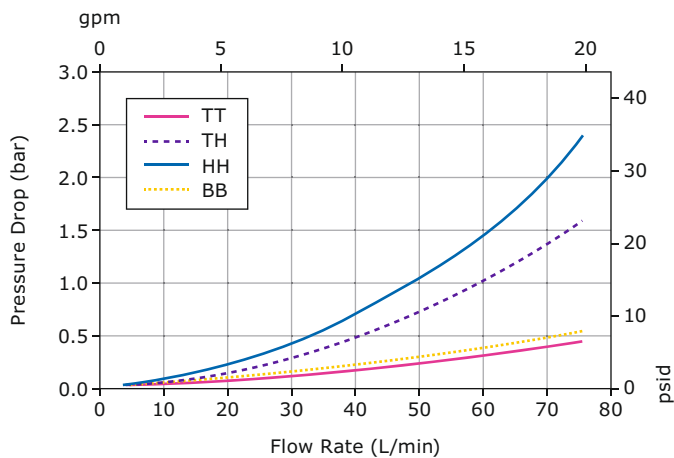
Opticap® XLT 20 Capsule with Milligard® Media – 1.2 µm Nominal (KW19)



Opticap® XLT 20 Capsule with Milligard® Media – 0.5/0.2 µm Nominal (KWSS)



Opticap® XLT 20 Capsule with Milligard® Media – 1.2/0.5 µm Nominal (KWSC)



Opticap® XLT Legends Refer to Capsule Connection Type

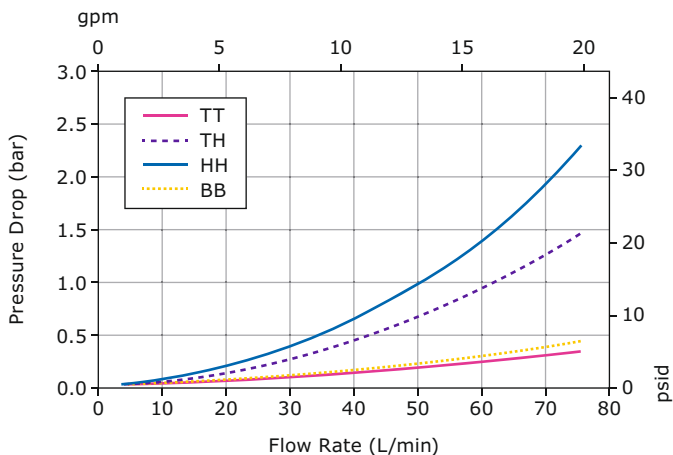
TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet

TH = 38 mm (1½ in.) Sanitary Flange Inlet and 14 mm (9/16 in.) Hose Barb Outlet

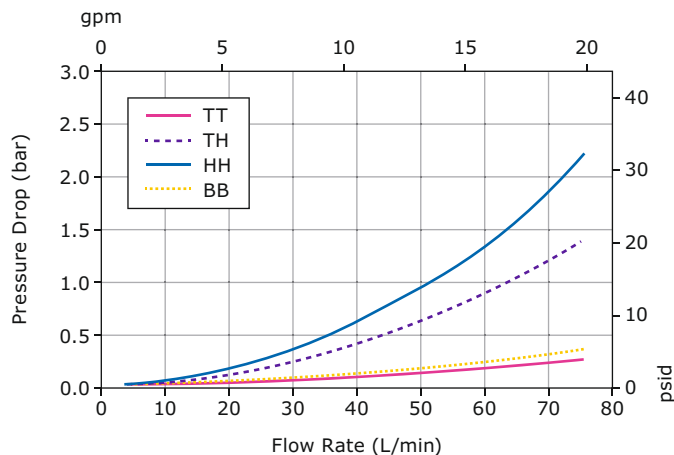
HH = 16 mm (9/16 in.) Hose Barb Inlet and Outlet

BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

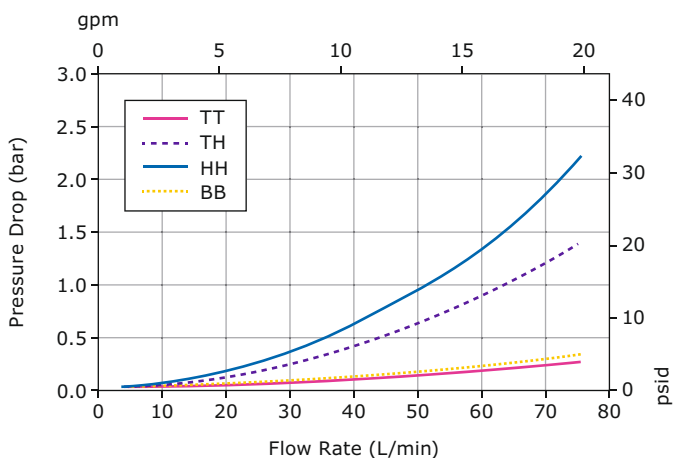
Opticap® XLT 30 Capsule with Milligard® Media – 0.2 µm Nominal (KW03)



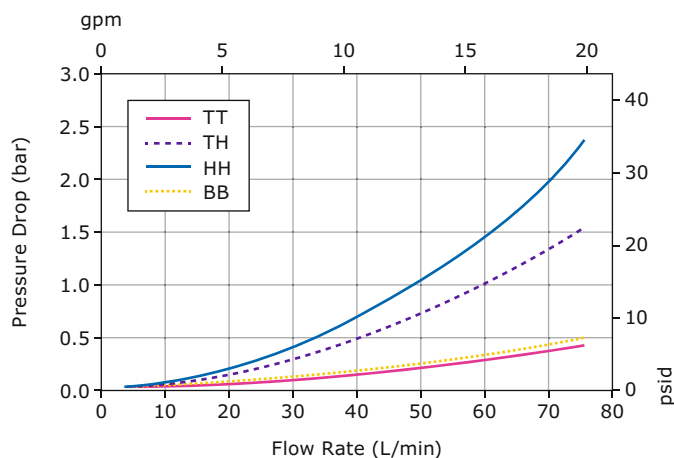
Opticap® XLT 30 Capsule with Milligard® Media – 0.5 µm Nominal (KW06)



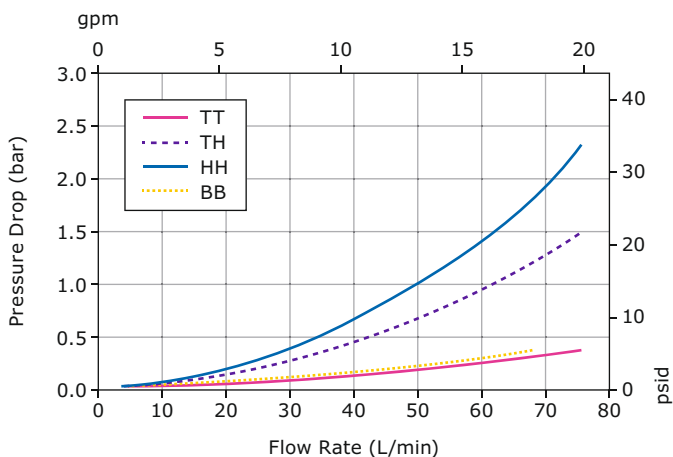
Opticap® XLT 30 Capsule with Milligard® Media – 1.2 µm Nominal (KW19)



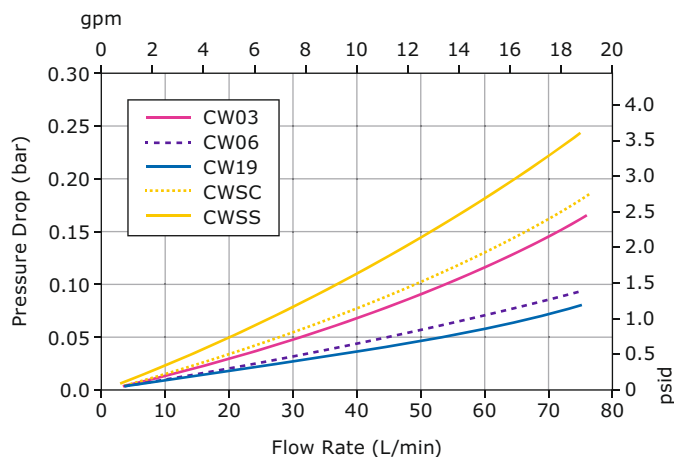
Opticap® XLT 30 Capsule with Milligard® Media – 0.5/0.2 µm Nominal (KWSS)



Opticap® XLT 30 Capsule with Milligard® Media – 1.2/0.5 µm Nominal (KWSC)



Cartridges with Milligard® or Milligard® LPB Media – 30-inch



Opticap® XLT Legends Refer to Connection Type

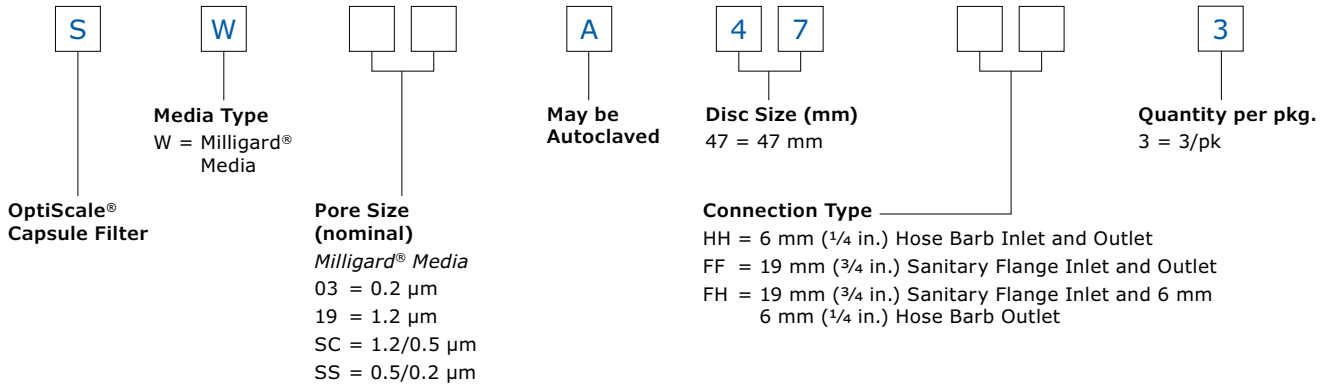
- TT = 38 mm (1½ in.) Sanitary Flange Inlet and Outlet
- TH = 38 mm (1½ in.) Sanitary Flange Inlet and 14 mm (9/16 in.) Hose Barb Outlet
- HH = 16 mm (9/16 in.) Hose Barb Inlet and Outlet
- BB = 25 mm (1 in.) Hose Barb Inlet and Outlet

Cartridge Legends Refer to Pore Size (nominal)

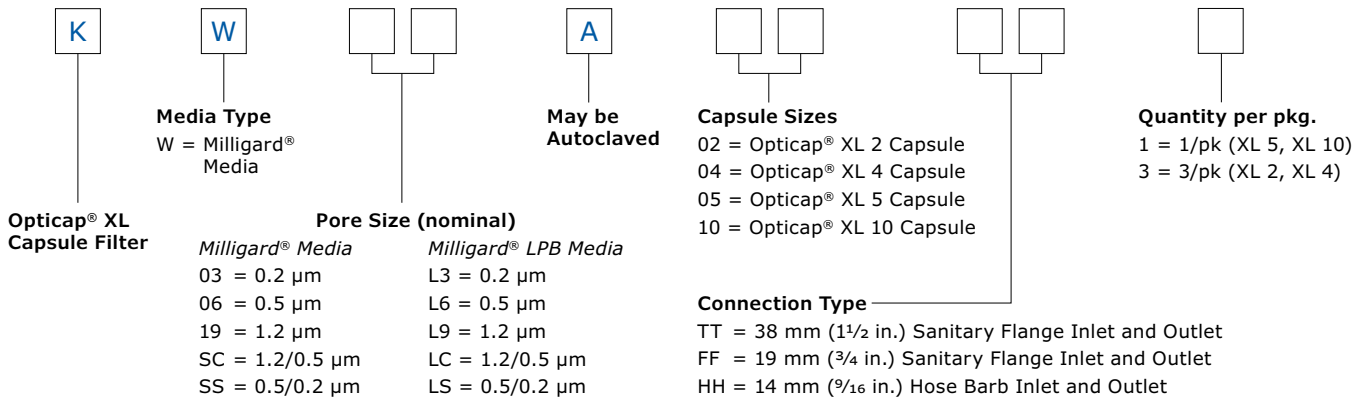
- Milligard® Media**
 - CW03 = 0.2 µm
 - CW06 = 0.5 µm
 - CW19 = 1.2 µm
 - CWSC = 1.2/0.5 µm
 - CWSS = 0.5/0.2 µm
- Flow curves for LPB Milligard® media will be similar to standard Milligard® media of comparable pore size.

Ordering Information

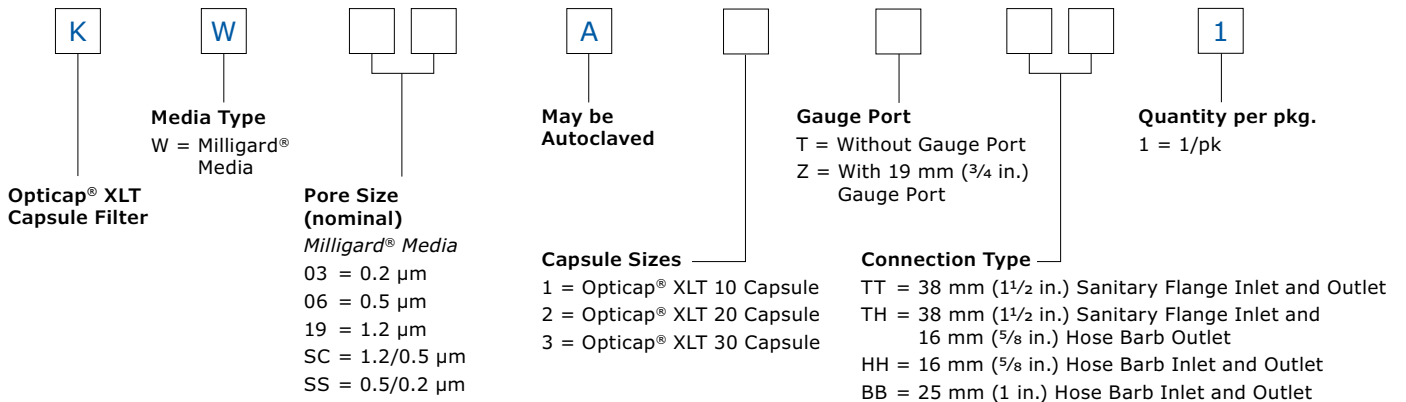
OptiScale® Capsule Filters



Opticap® XL Capsule Filters



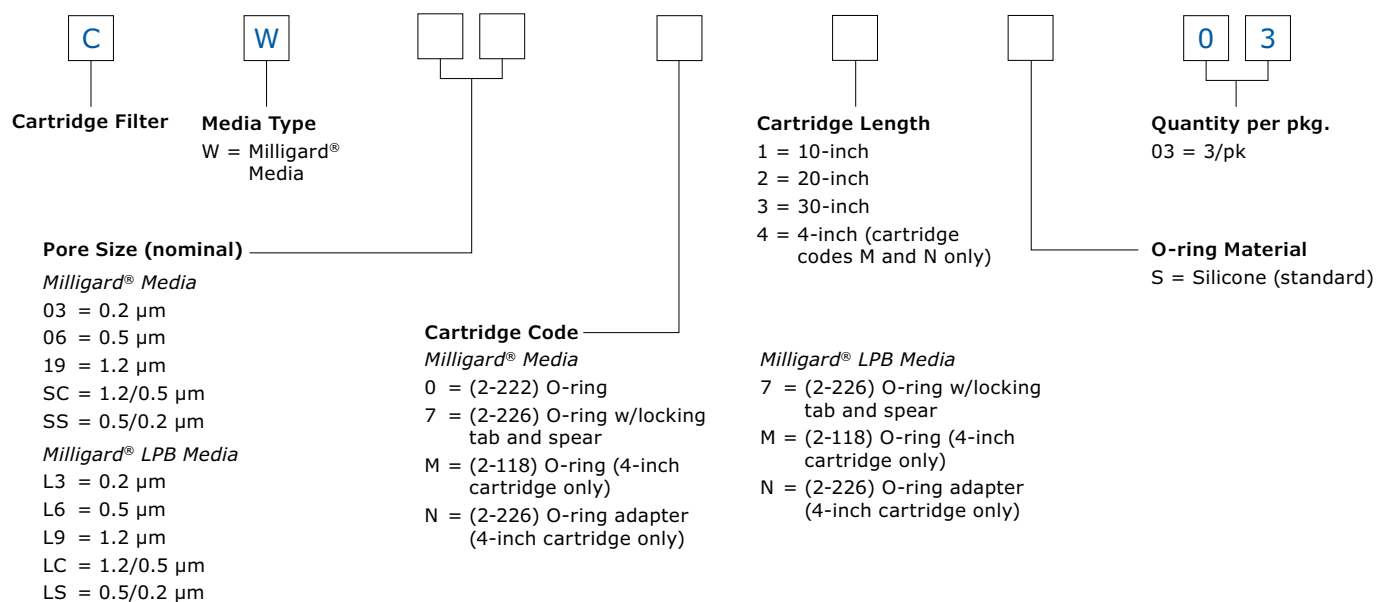
Opticap® XLT Capsule Filters



Accessory

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

Cartridge Filters



Learn more at sigmaaldrich.com/prefilters-bioburden-control

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

