SteriLUX® Filters

MEISSNER

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SteriLUX® Filters

SteriLUX® is a hydrophilic PVDF membrane filter with high flow rates, high throughputs, low protein binding properties and broad chemical compatibility. It is recommended for sterilizing filtration and bioburden reduction of pharmaceutical preparations, active ingredients, biopharmaceuticals, parenterals, vaccines, biologicals including dilute protein solutions, cell and tissue culture media, media additives, ophthalmic and other dilute preservative solutions, UPW, chemicals, alcohols and sanitizing agents.

Materials of Construction

The SteriLUX® filter is manufactured using high quality components made from nontoxic and biologically inert raw materials. All components of the SteriLUX® filter are FDA listed for food contact use in the Code of Federal Regulations (CFR), Title 21 as below:

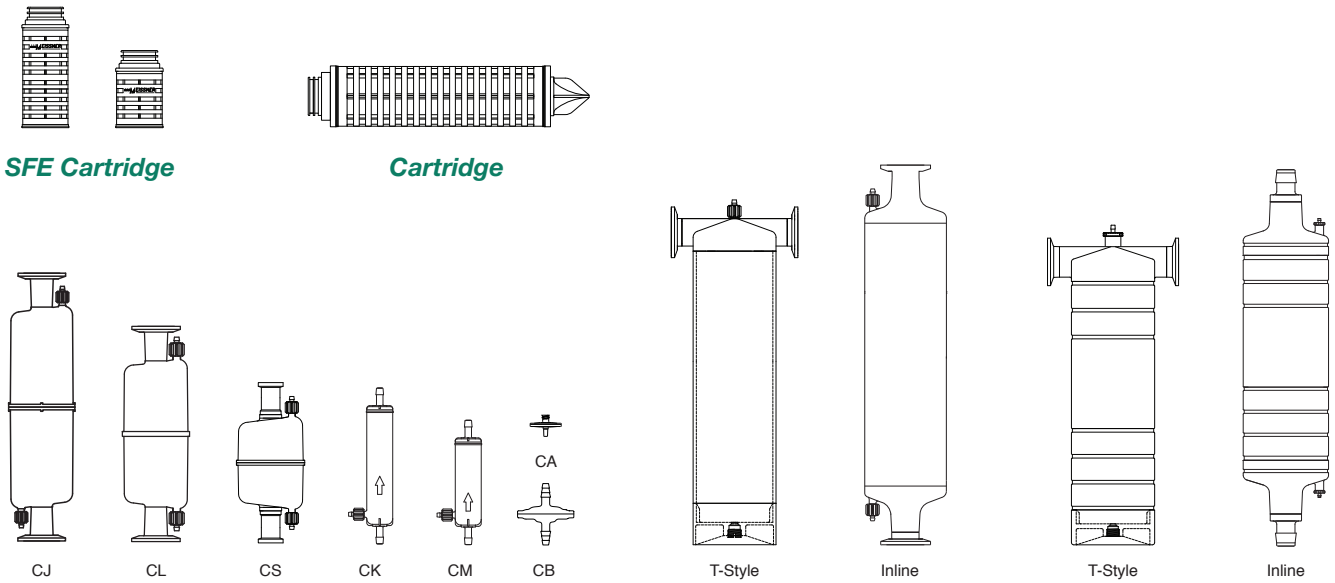
Components

Media:	Polyvinylidene fluoride (PVDF)	CFR Title 21, 177.2510
Upstream/Downstream support:	Polypropylene	CFR Title 21, 177.1520
Core/Outer guard:	Polypropylene	CFR Title 21, 177.1520
End caps/Adaptors:	Polypropylene	CFR Title 21, 177.1520
Capsule housing:	Polypropylene	CFR Title 21, 177.1520
O-rings:	Buna, EPR or silicone	CFR Title 21, 177.2600
	Teflon® over silicone or	CFR Title 21, 177.1550
	Teflon® over Viton®	
Sealing method:	Thermal bonding	

The SteriLUX® filter complies with European Commission Regulation No. 10/2011. The filter meets requirements as specified in the current USP Class VI plastics, pyrogen and cytotoxicity tests. No binders, adhesives, or surfactants are used in the construction of SteriLUX® filters. The filters are non-fiber-releasing as defined in 21 CFR 210.3(b)(6) and 211.72.

Configurations

SteriLUX® can be ordered in a variety of configurations from SFE filter cartridges through UltraCap® high capacity capsule filters.



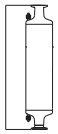
SFE Cartridge ***Cartridge*** ***Capsule*** ***UltraCap®*** ***UltraCap® H.D.***

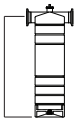
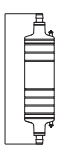
Dimensions

Cartridge	*Diameter*	*Length (nominal)*	*EFA***
	2.75" (7.0 cm	10" (25 cm)	7.9 ft² (0.73 m²)
		20" (50 cm)	15.8 ft² (1.47 m²)
		30" (75 cm)	23.7 ft² (2.20 m²)
		40" (100 cm)	31.6 ft² (2.94 m²)

SFE Cartridge	*Diameter*	*Length (nominal)*	*EFA***
	2.25" (5.7 cm)	2.5" (25 mm)	1.6 ft² (0.15 m²)
		5" (12.7 cm)	3.3 ft² (0.31 m²)

Capsule	*Diameter*	*Length (nominal)*	*EFA***
CA2	0.98" (25 mm)	1.18" (30 mm)	0.004 ft² (3.6 cm²)
CB2	1.97" (50 mm)	2.51" (64 mm)	0.02 ft² (19.6 cm²)
CK2	1.25" (3.2 cm)	6.25" (15.9 cm)	0.45 ft² (415 cm²)
CM2	1.25" (3.2 cm)	5.50" (14.0 cm)	0.36 ft² (335 cm²)
CL/CL2	2.75" (7.0 cm)	6.9" (17.5 cm)	3.3 ft² (0.31 m²)
CS/CS2	2.75" (7.0 cm)	4.5" (11.4 cm)	1.6 ft² (0.15 m²)
CJ2	2.75" (7.0 cm)	10.0" (25.4 cm)	5.2 ft² (0.48 m²)

UltraCap®	*Diameter*	*Length (nominal)*	*Capsule Dimension (overall)*	*EFA***
T-Style 	3.25" (8 cm)	10" (25 cm)	12.3" (31.2 cm)	7.9 ft² (0.73 m²)
		20" (50 cm)	22.3" (56.6 cm)	15.8 ft² (1.47 m²)
		30" (75 cm)	32.3" (82 cm)	23.7 ft² (2.20 m²)
Inline 	3.25" (8 cm)	10" (25 cm)	14.8" (37.6 cm)	7.9 ft² (0.73 m²)
		20" (50 cm)	24.9" (63.2 cm)	15.8 ft² (1.47 m²)
		30" (75 cm)	34.9" (88.6 cm)	23.7 ft² (2.20 m²)

UltraCap®H.D.	*Diameter*	*Length (nominal)*	*Capsule Dimension (overall)*	*EFA***
T-Style 	3.5" (9 cm)	10" (25 cm)	11.7" (29.7 cm)	7.9 ft² (0.73 m²)
		20" (50 cm)	21.1" (53.6 cm)	15.8 ft² (1.47 m²)
		30" (75 cm)	30.6" (77.7 cm)	23.7 ft² (2.20 m²)
		40" (100 cm)	40.0" (101.6 cm)	31.6 ft² (2.94 m²)
		50" (125 cm)	49.5" (125.7 cm)	39.5 ft2 (3.67 m²)
Inline 	3.5" (9 cm)	10" (25 cm)	17.3" (43.9 cm)	7.9 ft² (0.73 m²)
		20" (50 cm)	26.8" (68.1 cm)	15.8 ft² (1.47 m²)
		30" (75 cm)	36.2" (91.9 cm)	23.7 ft² (2.20 m²)
		40" (100 cm)	45.7" (116.1 cm)	31.6 ft² (2.94 m²)
		50" (125 cm)	55.2" (140.2 cm)	39.5 ft2 (3.67 m²)

**inlet/outlet fittings extend beyond stated diameter*

***EFA = Effective Filtration Area*

Operating Characteristics

Cartridges and SFE (Small Flow Elements)

Maximum Operating Temperatures and Pressures
80 psid @ 32 °F to 100 °F
(Δp 5.5 bar @ 0 °C to 38 °C)

60 psid @ 150 °F
(Δp 4.1 bar @ 66 °C)

30 psid @ 180 °F
(Δp 2.1 bar @ 82 °C)

Capsules - CA/CB Models

Maximum Operation Pressure & Liquids
80 psig @ 32 °F to 122 °F
(5.5 bar @ 0 °C to 38 °C)

Maximum Operating Temperature Rating
160 °F @ 35 psig
(71 °C @ 2.4 bar)

Capsules - CM/CK Models

Maximum Operation Pressure & Temperature, Liquids
100 psig @ 32 °F to 122 °F
(6.9 bar @ 0 °C to 50 °C)

Maximum Operating Pressure & Temperature, Gas
100 psig @ 32 °F to 122 °F
(6.9 bar @ 0 °C to 50 °C)

Capsules - CS/CL/CJ Models

Maximum Operating Pressure, Liquids
75 psig @ 32 °F to 100 °F
(5.2 bar @ 0 °C to 38 °C)

Maximum Operating Pressure, Gas
50 psig @ 32 °F to 100 °F
(3.4 bar @ 0 °C to 38 °C)

Maximum Operating Temperature Rating
160 °F @ 35 psig
(71 °C @ 2.4 bar)

UltraCap® Model

Maximum Operation Pressure & Temperature, Liquids
75 psig @ 32 °F to 100 °F
(5.2 bar @ 0 °C to 38 °C)

45 psig @ 140 °F
(3.1 bar @ 60 °C)

Maximum Operating Pressure & Temperature, Gas
50 psig @ 32 °F to 100 °F
(3.4 bar @ 0 °C to 38 °C)

30 psig @ 140 °F
(2.1 bar @ 60 °C)

UltraCap® H.D. Model

Maximum Operation Pressure & Temperature, Liquids
90 psig @ 32 °F to 100 °F
(6.2 bar @ 0 °C to 38 °C)

55 psig @ 140 °F
(3.8 bar @ 60 °C)

Maximum Operating Pressure & Temperature, Gas
60 psig @ 32 °F to 100 °F
(4.1 bar @ 0 °C to 38 °C)

35 psig @ 140 °F
(2.4 bar @ 60 °C)

Cartridge Installation Instructions

Meissner filters are available in a number of different adapter and O-ring configurations designed to fit modern filter housings. The filter should fit snugly in the housing. Improper installation can impair filtration efficiency.

1. Verify that the correct filter part number for the application has been chosen.
2. Keep the filter in its plastic bag to avoid contaminating the cartridge as long a possible. Cut open the bag at the O-ring end. While holding the bagged cartridge, lubricate the O-rings by dipping the O-rings into clean water or other suitable liquid compatible with the process fluid.
3. Line up the open end of the cartridge with the housing seat and install using a slight twisting motion while holding the bagged cartridge near the O-ring adapter. Verify that the O-rings are fully seated and not twisted. If the cartridge has locking tabs, rotate the tabs into place with a clockwise motion until engaged. Caution: always rotate cartridges while firmly grasping the O-ring end of the cartridge to prevent excessive torque damage to the filter.
4. Repeat with additional cartridges. Remove protective bags from the cartridges. If present, install cartridge retainer system (plate or spring). Reassemble housing.

Wetting Best Practices

Water & Product

The following is a guide for proper wetting of the membrane.

1. Attach and secure filter via tubing to source of wetting fluid.
    a. Users may use a pump to monitor flow rate or pressurized transfer to monitor pressure on the upstream.
2. Open any inlet vent valves to allow air to escape the housing/capsule and close the downstream valve.
3. Slowly fill the capsule/housing at the start to prevent turbulence (air entrapment); the capsule is oriented so the vent is on the highest position to allow air to escape.
4. Close the high point vent valve when all air is released (identified by fluid exiting vent valve).
5. Following closure of a vent valve, open downstream to allow flow.
6. Re-vent the housing after about a minute to allow any accumulated air to escape.
7. Typical filter wetting times are listed in the table below. Longer wetting times can be used to ensure complete wetting of the filter. Recirculated systems may be used for pre-use wetting.
8. Application of back pressure should be utilized to help ensure a uniform flow distribution through the entire length of the filter.
    a. Back pressure is not reverse pressure, it is a restriction placed on the outlet of the filter during forward flow by using a partially closed valve, smaller piping size, tubing clamp, or similar constriction.

Typical Filter Wetting Times

Configuration	Flow Rate L/min	Time
CM/CK Capsules	1	5-6 minutes
CS/CL Capsules, 2.5" and 5" SFE Cartridges	4	
CJ Capsules	8	4-10 minutes[1]
10" UltraCap®, UltraCap® H.D., Capsules & Cartridges[1]	15	

[1] For >10" filters, the wetting time should be multiplied by the number of 10" modules. It is advised to increase the flow rate if process conditions allow.

Configuration	Wetting guidance
CA/CB Capsules	Due to the size of the CA & CB capsules, very small volumes are required to wet the filter. If no vent is present, introduce fluid into the capsule with the outlet point upwards so that air may escape. For capsules without a vent, airlock can occur after the membrane has been wetted, if more fluid is introduced and air enters the capsule. Slowly add fluid to the filter capsule until no air bubbles are visible in effluent downstream. If the filter has a vent, slowly introduce fluid into the capsule until all air has escaped through the vent on the upstream side.

Isopropyl Alcohol

Isopropyl Alcohol (IPA) is a low surface tension fluid. As a result, membranes are more easily wetted when IPA is used. It is common practice to simply submerge the filter in a container with the IPA wetting product and allow it to sit. Following wetting, it is important to flush out any remaining product in the filter tubing, housing, or capsule filter prior to putting the filter into service. If available, a fume hood can be utilized to carry out the above steps, otherwise take normal precautions for solvents.

Configuration	Time
CA/CB Capsules	< 1 minute
CM/CK/CS/CL/CJ Capsules	3-5 minutes
2.5" and 5" SFE Cartridges	
10" UltraCap®, UltraCap® H.D., Capsules & Cartridges	10 minutes

Flushing Guidelines

Meissner recommends flushing the filter, prior to use or service, which can be used to wet the filter. This process is beneficial to filtrate quality and helps eliminate leachables by reducing extractables. Installation can generate contaminants in or on the filters. These contaminants are most evident during start-up but will dissipate after the initial few liters of fluid have passed through the filter. Without flushing prior to use, contaminants likely will be present downstream of the filter.

The following is a general guide for filter flushing. The flushing recommendations provided by Meissner are based on Rinse Up TOC data using DI water passed through a filter following sterilization. When passing DI water through the filter, the effluent's TOC was analyzed at intervals until the effluent's TOC value met the United States Pharmacopeia (USP) Requirement for purified water (< 0.5 ppm). Since the following is based on DI water as a flushing fluid, suitable flushing volumes may differ from process fluid to process fluid. We offer these recommendations as a general guideline, and users commonly devise their own flushing method based on the configuration or set-up of their process. Please contact Meissner for Rinse Up TOC data requests.

SteriLUX® Flushing Guidance[1]

Configuration	Suggested Minimum Flow Rate L/min	Typical Total Flush Volume, Liters[1]
CA Capsules	See Note 3	
CB Capsules	N/A	0.08
CM/CK Capsules	1	1
CS/2.5" Capsules, SFE Cartridges	4	2-4
CL/5.0" Capsules, SFE Cartridges	4	10-15
CJ Capsules	8	15-20
10" UltraCap®, UltraCap® H.D., Capsules & Cartridges[2]	15	20-30

[1] Flushing volumes vary based on sterilization method.

[2] For filters larger than 10", multiply the value by the number of 10" units in the cartridge/capsule.

[3] Due to the size of these capsules, please refer to wetting guidance.

Integrity Test: Manual Bubble Point of a Filter Housing System

(Consult Meissner for Pressure Hold Procedure)

Wetting

Please refer to wetting instructions on Page 7 under Wetting Best Practices.

Filter and Housings - Manual Bubble Point Test

The manual bubble point test relies on a wetted, microporous membrane filter, a housing or holder to contain the wetted filter, a calibrated pressure gauge, a regulated gas pressure source (usually compressed air or nitrogen), narrow diameter downstream tubing, and a beaker containing water in which the tubing is immersed. Pressure is increased gradually until a steady stream of bubbles is observed to come from the tubing. This pressure is referred to as the bubble point. The following highlights the basic steps required to perform a bubble point test on a filter.

Procedure (Figure 1)

1. Close all valves.
2. Open valves V_1 and V_3 fill the housing with water or appropriate wetting fluid. Close V_3 once fluid escapes. Open V_6 to wet the cartridge.
3. Close V_1 after the cartridge is wetted.
4. Open V_2 and apply regulated air pressure to the inlet side of the system.
5. If necessary, open V_4 to drain the downstream volume of water.
6. Close V_4.
7. Open V_5 and close V_6.
8. While observing for continuous bubbling from the bubble point tube, slowly increase the air pressure. When a rapid, steady stream of bubbles is observed, the bubble point pressure has been reached. (Do not confuse the diffusive flow for the bulk gas flow of the bubble point.) Record the pressure where this occurs and compare it to the SteriLUX® Bubble Point Specifications on Page 10.
9. A bubble point value lower than the specification is an indication of one of the following:
    - Fluid with different surface tension than the recommended test fluid
    - Integral filter but wrong pore size
    - High temperature
    - Incompletely wetted membrane
    - Non-integral membrane or seal

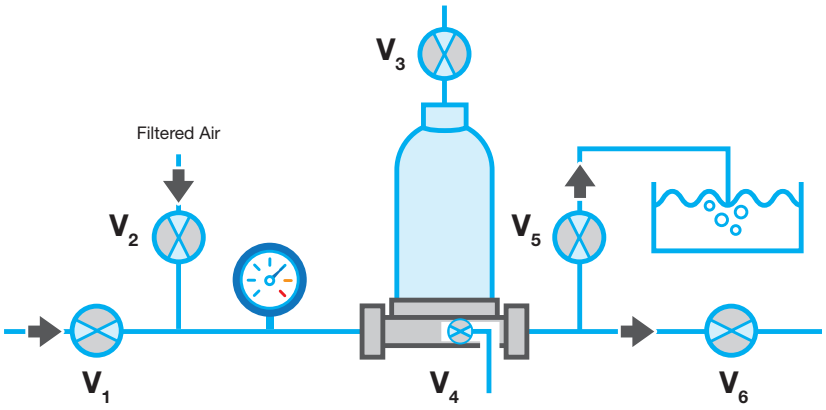


Figure 1

Integrity Test: Manual Bubble Point of a Capsule, UltraCap® & UltraCap® H.D.

1. Wet the filter capsule well. Drain the capsule housing.
2. Connect regulated compressed air and a calibrated gauge to the inlet and a narrow ID hose to the filter outlet and immerse the open hose end in a beaker of water. Alternatively, connect an automated integrity tester to the inlet and follow manufacturer's directions.
3. Apply air pressure to the filter to approximately 10 psi less than the minimum bubble point and observe the hose in the water beaker. The initial pleat pack compression will produce a large amount of bubbling that will decrease rapidly and be replaced by regularly spaced bubbles produced by air diffusing through the filter membrane.
4. Slowly increase the air pressure and observe the steady stream of bubbles in the water. The bubble point is the pressure at which a marked change in the rate of bubbling occurs, accompanied by an increase in sound volume. Record the pressure where this occurs and compare it to the SteriLUX® Bubble Point Specifications in the chart below.

Quality Awareness - All Integrity Test Methods

1. While increasing the air pressure, do not confuse the additional bubbles produced by a rapid increase in air pressure with the bubble point. Observe the bubbles when the air pressure has stabilized.
2. If the integrity test fails, rewet the filter with additional water and repeat the test. If the filter has been used to filter product, it may take several minutes of high volume flush to remove the product and return to the water integrity test value. It is not appropriate to recirculate the water in this case.
3. To troubleshoot membrane wetting challenges, the filter may be rewet with a low surface tension fluid such as 60% IPA and integrity tested in that fluid when applicable. Please see further guidance under Wetting Best Practices, Isopropyle Alcohol (Page 7), as well as Troubleshooting Guidance (Page 13) and Pre-Use/Post-Use FIT Considerations (Page 14).

SteriLUX® Bubble Point Specifications

Grade & Pore Size	DI Water	60% IPA PSI (bar)	70% IPA PSI (bar)
VTH0.1/VMH0.1	70 psi (4.83 bar)	26 psi (1.79 bar)	25 psi (1.72 bar)
VTH0.2/VMH0.2	50 psi (3.45 bar)	18 psi (1.24 bar)	17 psi (1.17 bar)
VTH0.4/VMH0.4	28 psi (1.93 bar)	10 psi (0.69 bar)	9 psi (0.62 bar)
VTH0.6/VMH0.6	14 psi (0.97 bar)	Contact Meissner	Contact Meissner
VPH0.1	50 psi (3.45 bar)	18 psi (1.24 bar)	17 psi (1.17 bar)
VPH0.2	28 psi (1.93 bar)	10 psi (0.69 bar)	Contact Meissner
VPH0.4	14 psi (0.97 bar)	Contact Meissner	Contact Meissner

Integrity Test: Manual Diffusive Flow Test (Filter Housing System)

The diffusion test may be performed on SteriLUX® filter cartridges and capsules. The filter is wetted, drained, and a constant air pressure is applied. Diffusional air flow through the membrane is measured.

The manual diffusive flow test relies on a wetted membrane filter of sterilizing grade, a housing or holder to contain the wetted filter, a calibrated pressure gauge, a regulated gas-pressure source (usually compressed air or nitrogen), downstream tubing, and an inverted, water-filled graduated cylinder suspended in a container of water. Test pressure is increased to the manufacturer's recommended test pressure, usually about 80% of the bubble point value for a given filter type. The following highlights the basic steps required to perform a diffusive flow test on a single cartridge filter.

***Procedure** (Figure 2)*

1. Close all valves.
2. Open V_1 and V_6. Thoroughly wet the filter with water, opening vent V_3 to allow trapped air to escape. The complete wetting of the filter is crucial to the accuracy of the test. An incompletely wet filter will fail. Close V_1 and V_3.
3. Open V_2 and apply the specified air pressure to the inlet side of the system. This will push the upstream volume of water through the filter.
4. If necessary, open V_4 to drain the downstream volume of water. Water remaining downstream of the filter may cause an inaccurate diffusion reading by interfering with the air flow in the outlet tube. Close V_4.
5. Open V_5 and close V_6.
6. Verify the test pressure and adjust as necessary.
7. Fill a graduated cylinder with water and place the outlet tube under the inverted opening. Record the volume of air diffused per minute. The recorded flow rate must not exceed the flow rate specified in the SteriLUX® Diffusive flow Specifications (Page12).

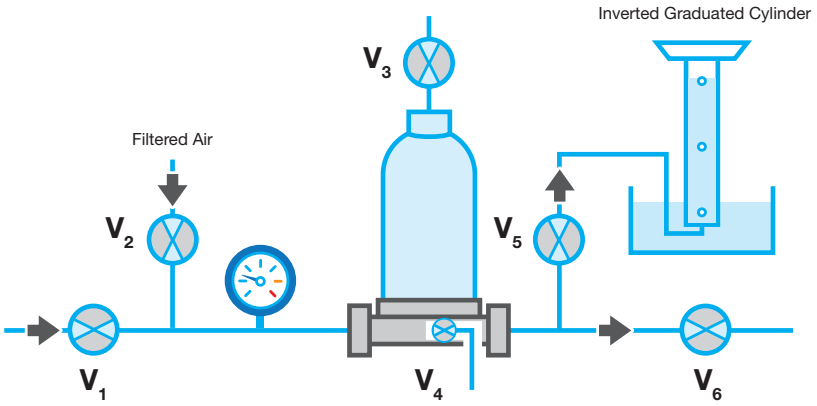


Figure 2

SteriLUX® Diffusive Flow Specifications

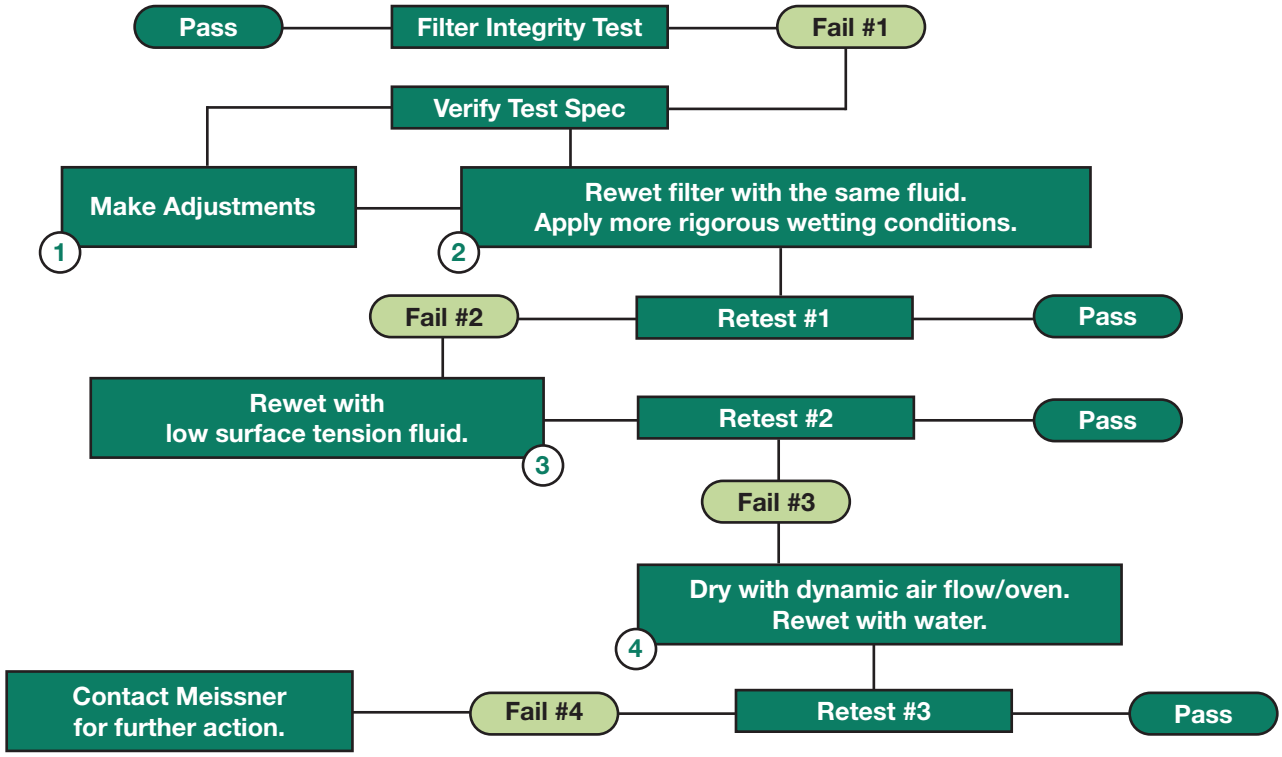
Grade	Nominal Filter Size	Air psi (bar)	Water mL/min
VTH0.1 VMH0.1	CA/CB/CM/CK Capsules	Meissner recommends using bubble point as a filter integrity testing method for these sizes.	
	CS/2.5" Capsules, SFE Cartridges	56 psi (3.86 bar)	4.0
	CL/5" Capsules SFE Cartridges		8.5
	CJ Capsules		13
	10" UltraCap®, UltraCap® H.D., Capsules & Cartridges[1]		20
VTH0.2 VMH0.2	CA/CB/CM/CK Capsules	Meissner recommends using bubble point as a filter integrity testing method for these sizes.	
	CS/2.5" Capsules, SFE Cartridges	40 psi (2.76 bar)	2.7
	CL/5" Capsules, SFE Cartridges		5.7
	CJ Capsules		8.8
	10" UltraCap®, UltraCap® H.D., Capsules & Cartridges[1]		13.5
VTH0.4 VMH0.4	CA/CB/CM/CK Capsules	Meissner recommends using bubble point as a filter integrity testing method for these sizes.	
	CS/2.5" Capsules, SFE Cartridges	22 psi (1.52 bar)	3.0
	CL/5" Capsules, SFE Cartridges		6.4
	CJ Capsules		9.8
	10" UltraCap®, UltraCap® H.D., Capsules & Cartridges[1]		15
VTH0.6 VMH0.6	CA/CB/CM/CK Capsules,	Meissner recommends using bubble point as a filter integrity testing method for these sizes.	
	CS/2.5"Capsules, SFE Cartridges	9 psi (0.62 bar)	2.0
	CL/5"Capsules, SFE Cartridges		4.2
	CJ Capsules		6.5
	10" UltraCap®, UltraCap® H.D., Capsules & Cartridges[1]		10
VPH0.1 VPH0.2 VPH0.4	All Sizes	Meissner recommends using bubble point as a filter integrity testing method for these sizes.	

[1] *For >10" filters, maintain the pressure and multiply the mL/min by the number of 10" units to get the diffusive flow specification.*

Filter Integrity Test Preparations

1. Verify filter P/N matches specification, SOP, and filter to be installed.
2. Visually inspect filter to ensure that it is not damaged. Note damages, if applicable.
3. Verify the wetting fluid required, as well as note any preparation needed to execute the test with the specified wetting fluid (additional flushing, tubing, housing flush, etc.).
4. Verify the specific test gas (air, nitrogen, etc.).
5. Verify the source pressure.
6. Verify that the filter assembly temperature is stable. Temperature changes can affect testing gas and distort diffusive flow values if not stable.
7. Verify testing set-up is without leaks. Leaks within the testing set up affect the FIT results by disturbing applied inlet pressure and by distorting the measured gas flow in the membrane.

Troubleshooting Guidance



1. Use the list on this page to verify testing specs. Make any adjustments needed and retest. If no adjustments are needed, rewet the filter in the same fluid and retest.

2. More rigorous wetting conditions can be enacted by increasing the flush time and volume, increasing pressure differential by increasing upstream pressure, or modifying downstream pressure. In addition to assisting with filter wetting, back pressure also facilitates the removal of air entrapped in the membrane pleats by further solubilizing the air (due to increase pressure in the system) and by compressing air bubbles to a size where they can freely pass through the membrane.

3. Rewet with a low surface tension fluid and retest.

4. Dry completely. For capsules, use with dynamic air flow or over drying at <50° C f for 12-24 hours. For cartridges, a drying oven can be used at 50° C for 8 hours. If the filter fails, contact Meissner for further action. If the filter passes, failure root cause is likely air lock. Air lock is the result of air being trapped between the downstream wetted membrane and the upstream wetted membrane and can be very difficult to remove with flushing alone.

Pre-Use/Post-Use FIT Considerations

Wetting Fluid	Pre-Use	Post-Use
Water	Ensure filter, any associated tubing, and housing are clean before wetting.	It is important to completely flush any remaining product from the filter, tubing, and housing prior to integrity testing. Any diluted product remaining can impact the FIT results.
60%/70% IPA	If using alcohol for a wetting fluid, the filter must be dried or flushed after FIT and before putting the filter into service.	It is important to completely flush any remaining product from the filter, tubing, and housing prior to integrity testing. Any product remaining can impact the FIT results.
Product	Flushing the filter (not just wetting) may be required and is recommended if using process product as a testing fluid.	The filter membrane should already be sufficiently wet, and no further action should need to be taken prior to conducting the filter integrity test. Note: If the FIT indicates failure and retesting is desired with other wetting fluids, ensure all product remaining in the filter is completely flushed as it can impact the FIT results of other wetting fluids used.

Autoclave Instructions

Meissner filters may be autoclaved repeatedly without loss of integrity.

Capsule, UltraCap® & UltraCap® H.D. Filters

The following outlines the steps recommended in the autoclave sterilization of Meissner filter capsules. Gamma irradiated filters should not be autoclaved before use due to increased extractables and brittleness after both sterilization methods are employed.

1. Loosely cover the capsule inlet and outlet with autoclave wrap. All capsule vents are on the upstream side of the filter and should be loosened or removed to facilitate steam penetration. Hose barb vent valves must be opened at least two full turns to prevent valve leakage post autoclaving.
2. The weight of clamps or fittings attached to the capsule must be supported to avoid damaging the adapters. Sanitary flanges may have clamps and gaskets loosely attached to the filter. If fittings must be attached to flanges, tri-clamps are preferable to bi-clamps and should be tightened after the assembly has cooled.
3. Autoclave the capsule at a minimum of 121°C for 60 minutes or 125°C for at least 45 minutes with the capsule in a horizontal position using a slow exhaust or liquid cycle. T-style UltraCap® capsules may be autoclaved horizontally or with the outlet oriented downward to facilitate the removal of condensate from the downstream side of the filter. As autoclave systems vary, sterilization cycles should be validated under actual system or autoclave loading conditions. Downstream attachments can significantly increase the time required to sterilize the filter core.
4. Allow the capsule to cool. Gently close vents finger tight. Excessive tightening of vent valves will damage the sealing surfaces. Integrity test if desired. Install filter into system aseptically.

Cartridge & SFE (Small Flow Elements)

The following outlines the steps required to autoclave a Meissner filter cartridge and housing assembly. A stainless steel reinforcement ring is required for filter configurations with 222 or 226 O-rings.

1. Install the filter into the housing. Loosely cover the inlet and outlet with autoclave wrap. Vent and drain valves should be fully open.
2. Autoclave the cartridge and housing assembly at a minimum of 121°C for 30 minutes with the filter outlets in an outlet down or horizontal position using a slow exhaust or liquid cycle. As autoclave systems vary, sterilization cycles should be validated under actual system or autoclave loading conditions. Assemblies attached to the outlet can increase the required sterilization times.
3. Allow the housing assembly to cool. Integrity test if desired.
4. Install the sterile filter assembly into the system using aseptic techniques.

Different autoclave temperature and time combinations may be used to sterilize the filters, but the combination should be validated to ensure that sterilization occurs under those conditions. Temperatures above 135°C are not recommended.

Inline Steam Sterilization Procedure

Steaming in place (SIP) is frequently used in critical applications where a sterile effluent is desired. To prevent damage to the filter cartridge's O-ring adapter, cartridges with 222 or 226 O-ring adapters must be reinforced with a stainless steel ring. Meissner filter cartridges with reinforced O-ring adapters are capable of repeated sterilization cycles without loss of integrity. The steps required to steam sterilize the SteriLUX® filter cartridge and system using saturated steam are outlined in the procedure below.

The steam should be free of rust and other particulates. The housing should be clean before the cartridge is installed. If you are steam sterilizing a wetted cartridge, upstream and downstream gauges must be provided to verify that the differential pressure across the membrane does not exceed 5 psi (0.3 bar). To assure sterilization, steam pressure in the assembly must not be allowed to fall below 15 psi (1 bar) or 121°C. Condensate should be drained from the system during sterilization. Figure 3 shows a typical piping schematic.

Caution: Capsules, UltraCap® and UltraCap® H.D. are not designed for inline steam sterilization!

***Procedure** (Figure 3)*

1. Close all valves.
2. Open valve V_4.
3. If cartridge is wet or there is a large volume tank downstream of the filter, open V_5.
   a. Slowly open V_2. This will connect both sides of the filter to steam pressure.
   b. Crack open V_7 to vent trapped air.
   c. Crack open V_6 allowing steam to flow through the system.
   d. Slowly close V_5 but do not allow the differential pressure across the cartridge to exceed 5 psi (0.3 bar).
   e. Leave drain V_8 cracked during sterilization to drain condensate.
4. If sterilizing a dry cartridge, slowly open V_2.
   a. Crack open V_7 to vent trapped air.
   b. Crack open V_6 to allow steam to flow through the system. Do not allow the differential pressure across the cartridge to exceed 5 psi (0.3 bar).
   c. Leave drain V_8 cracked during sterilization to drain condensate.
5. Steam sterilize for 30 to 60 minutes at 15 to 20 psig (1.0 to 1.4 bar), or as long as experience dictates.
6. When sterilization is complete, close V_2.
7. Open V_3 and introduce sterile air or nitrogen regulated to the same pressure as the steam.
8. Close V_8 once steam and condensate flow stops.
9. Allow the system to cool to room temperature. Do not allow the differential pressure across the cartridge to exceed 5 psi (0.3 bar). Then close V_3, V_7, and V_6. Keep the system under pressure until ready for use.
10. Crack vent V_7 and allow the system pressure to equalize. The filtration process may now be started or the filter can be wetted and integrity tested.

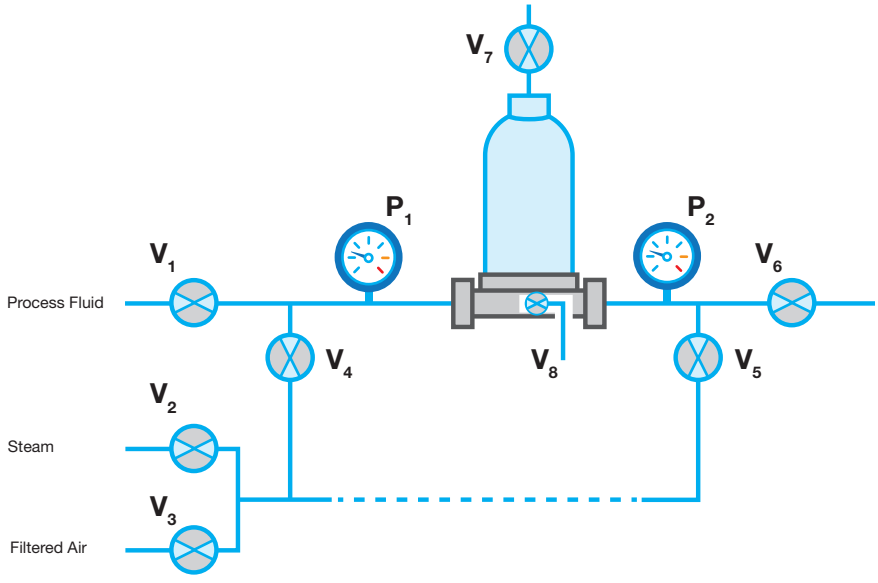


Figure 3

Storage & Shelf Life

Meissner Filtration Products, Inc. manufactures a complete line of filter products and One-Touch® single-use assemblies. Products are suitably bagged and boxed for shipping and may be stored in the original packaging in a clean, dry area between 0°C and 40 °C (32 °F and 100 °F). The following gives the minimum shelf life expectancies for SteriLUX® products.

Filters

The SteriLUX® filter has an expected shelf life greater than 5 years in the cartridge, small flow, non-irradiated large and small capsule lines and disc configurations. Filters may be used beyond their minimum expected shelf life if they were stored in their original packaging and are integrity tested prior to use and found to be within specification. Filter product age can be determined from the date on the original Certificate of Quality or Conformance.

Gamma irradiated filters, which include capsule, UltraCap®, and UltraCap® H.D. capsules have a shelf life of at least 2 years from the date of irradiation. Gamma irradiated capsules are distinguished with part numbers beginning with the letter “G”.

One-Touch® Products

The One-Touch® product line of single-use systems, including but not limited to biocontainers, tubing, and/or filter assemblies, has labeling that identifies the product specific expiration date. The standard shelf life of nonsterile and gamma irradiated One-Touch® products is 2 years from the date of manufacture. These standard time periods may be amended to reflect the various components included in a specific configuration, a change that will be indicated on the product label. Filters that are part of a One-Touch® single-use system begin with “C” and are irradiated once with the One-Touch® assembly.

SteriLUX® Membrane Grade Descriptions

VMH = This sterilizing grade filter is absolute, microbially rated and 100% integrity tested and flushed with DI water during manufacture. It is suited for critical applications when regulatory documentation requirements are minimal. A Certificate of Conformance is provided on a lot basis.

VTH = This absolute, microbially rated filter meets full traceability requirements for the pharmaceutical industry. It is 100% integrity tested and flushed with DI water during manufacture. Each VTH grade filter is shipped with a Certificate of Quality stating exact quality control criteria and test performance results. This is a validatable product to meet the stringent requirements of the pharmaceutical industry.

VLH = This filter is not 100% integrity tested or flushed with DI water during manufacture. It is offered as an economical prefilter or final filter when sterility assurance and validation are not required. A Certificate of Conformance is provided on a lot basis.

VPH = This is an absolute, particulate rated filter. It is 100% integrity tested and DI flushed during manufacture. A Certificate of Conformance is provided on a lot basis.

Application Documentation & Ratings Requirements

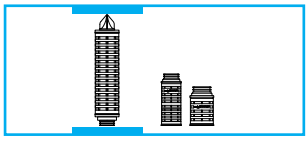
Filter Grade	Sterilizing Applications	Integrity Tested & Flushed	Certificate of Conformance per Lot	Certificate of Quality per Filter	cGMP Traceability Conformance	Bacterial Rating Requirements
VLH (all pore sizes)	No	No	Yes	No	No	P, BR
VPH (all pore sizes)	No	Yes	Yes	No	No	P, BR
VMH0.1	Yes	Yes	Yes	No	No	M, S, MR*
VMH0.2	Yes	Yes	Yes	No	No	M, S
VMH0.4	No	Yes	Yes	No	No	M
VMH0.6	No	Yes	Yes	No	No	M
VTH0.1	Yes	Yes	No	Yes	Yes	S, MR*
VTH0.2	Yes	Yes	No	Yes	Yes	M, S
VTH0.4	No	Yes	No	Yes	Yes	M
VTH0.6	No	Yes	No	Yes	Yes	M

Bacterial Rating Requirements Key

M: Microbially Rated
P: Particle Rated
MR: Mycoplasma Reduction
BR: Bioburden Reduction
S: Sterilizing Grade
AMR: Absolute Mycoplasma Retention

**SteriLUX® VTH0.1/VMH0.1 are rated for Mycoplasma Reduction, however, Absolute Mycoplasma Retention is achievable with 2 or more VTH0.1/VMH0.1 filters in a series."*

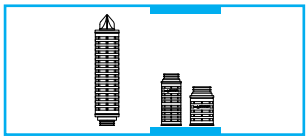
Cartridge Ordering Matrix



VMH	0.1	–	2	C6	R	S

Filter Grade	Absolute Rating (µm)	–	Cartridge Length	End Cap Configurations	Reinforcement Ring Option	Seal Material (O-ring or Gasket)
VMH	0.1, 0.2, 0.4, 0.6		1 = 10"	GS = DOE; flat gaskets (9.75", 19.5", 29.25", 39" length filters)	(Blank) = Standard - no reinforcement ring	**O-ring Seal** B = Buna E = EPR S = Silicone T = Teflon® over silicone V = Viton® X = Teflon® over Viton®
VTH	0.1, 0.2, 0.4, 0.6		2 = 20"	GL = DOE; flat gaskets (20", 30", 40" length filters)	R = Reinforcement ring - required only for the 222 and 226 adapter when autoclaving or steam sterilizing	**Gasket Seal** B = Buna E = EPR P = Polyethylene S = Silicone T = Teflon® V = Viton®
VLH	0.1, 0.2, 0.4, 0.6		3 = 30"	C1 = SOE; 222 nO-Ring®, button cap end		
VPH	0.1, 0.2,0.4		4 = 40"	C2 = SOE; 222 O-rings, button cap end		
				F1 = SOE; 222 nO-Ring®, fin end		
				F2 = SOE, 222 O-rings, fin end		
				C5 = SOE; 226 nO-Ring®, button cap end		
				C6 = SOE; 226 O-rings, button cap end		
				F5 = SOE; 226 nO-Ring®, fin end		
				F6 = SOE; 226 O-rings, fin end		
				DN = DOE; internal 120 O-rings		
				RN = SOE; internal 120 O-ring, recessed cap end		
				DA = DOE; internal 213 O-rings		
				RA = SOE; internal 213 O-ring, recessed cap end		

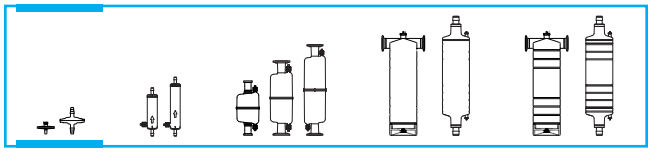
Small Flow Elements (SFE Filters) Ordering Matrix



L	VMH	0.1	–	5	6	R	S
L	☐	☐	–	☐	☐	☐	☐

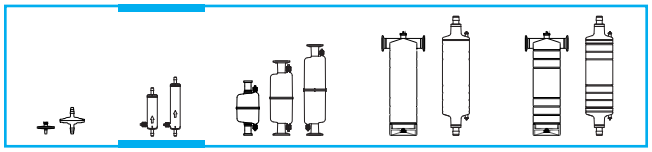
Model	Filter Grade	Absolute Rating (µm)	–	Length/Area	Adapter Selection	Reinforcement Ring Option	O-ring Material
L	VMH	0.1, 0.2, 04, 0.6		2 = 2.5"/1.6 ft² (0.15 m²)	P = Standard internal 116 O-ring	(Blank) = Standard - no reinforcement ring	B = Buna
	VTH	0.1, 0.2, 04, 0.6		5 = 5.0"/3.3 ft² (0.31 m²)	2 = 222 O-rings (for autoclave/SIP applications, select “R" under “Reinforcement Ring Option")	R = Reinforcement ring - required only for the 222 and 226 adapter when autoclaving or steam sterilizing	E = EPR
	VLH	0.1, 0.2, 04, 0.6			6 = 226 O-ring style locking adapter (for autoclave/SIP applications, select “R" under “Reinforcement Ring Option")		S = Silicone
	VPH	0.1, 0.2, 0.4			SK = Skirt-flange adapter (no reinforcement or O-ring options available)		T = Teflon® over Silicone
					L = 116 O-ring with Mini Lock		V = Viton®
							X = Teflon® over Viton®

Capsule (CA/CB) Ordering Matrix



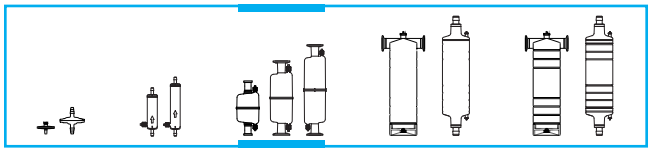
C	A	2	VMH	0.2	–	EF	0
Sterile Option	Effective Filtration Area	Material Code	Filter Grade	Retention Rating (µm)	–	Inlet/Outlet Connections	Vent/Drain Ports
C = Standard (non-sterile) G = Gamma Irradiated	A = 0.004 ft² 3.6 cm² B = 0.02 ft² 19.6 cm²	2= Animal component free polypropylene capsule shell material, optimized for gamma irradiation compatibility	VMH VTH	0.1, 0.2, 0.4, 0.6 0.1, 0.2, 0.4		**CA2 Capsule** EF = Female luer lock inlet; male luer slip outlet EG = Female luer lock inlet; 1/8" hose barb GG = 1/8" hose barb **CB2 Capsule** 33 = Stepped hose barb (1/4" - 3/8") 3B = Stepped barb (1/4" - 3/8") inlet; filling bell outlet 73 = 3/4" sanitary flange inlet; hose barb 3/8" outlet 77 = 3/4" sanitary flange inlet/outlet 7B = 3/4" sanitary flange inlet; filling bell outlet	**CA2 Capsule** 0 = No vent/drain port **CB2 Capsule** 0 = No vent/drain port 1 = One luer port with cap, inlet side

Capsule (CM/CK) Ordering Matrix



C	K	2	VMH	0.2	–	77	4
		2			–		
Sterile Option	**Effective Filtration Area**	**Material Code**	**Filter Grade**	**Absolute Rating (µm)**		**Inlet/Outlet Connections**	**Vent/Drain Ports**
C = Standard (non-sterile) G = Gamma irradiated	M = 0.36 ft² (335 cm²) K = 0.45 ft² (415 cm²)	2= Animal component free polypropylene capsule shell material, optimized for gamma irradiation compatibilityl	VMH VTH VLH VPH	0.1, 0.2, 0.4, 0.6 0.1, 0.2, 0.4, 0.6 0.1, 0.2, 0.4, 0.6 0.1, 0.2, 0.4		11 = 1/4" hose barb 1B = 1/4" hose barb with filling bell 22 = 3/8" hose barb 2B = 3/8" hose barb with filling bell 41 = 1/4" MNPT; 1/4" hose barb outlet 44 = 1/4" MNPT 71 = 3/4" sanitary flange inlet; 1/4" hose barb outlet 72 = 3/4" sanitary flange inlet; 3/8" hose barb outlet 77 = 3/4" sanitary flange	0 = No vent/drain port 1 = 1 luer port with cap, inlet side 2 = Standard - 2 luer ports with caps 4 = 2 sanitary valves with hose barb 5 = 1 sanitary valve with hose barb connection, inlet side 6 = 1 sanitary valve with hose barb, outlet side

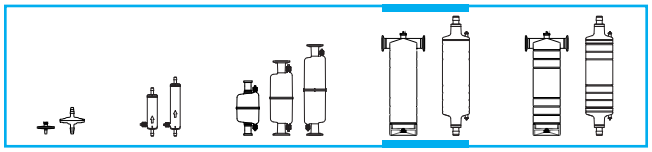
Capsule (CS/CL/CJ) Ordering Matrix



C	S	2	VMH	0.2	–	02	2

Sterile Option	Effective Filtration Area	Material Code	Filter Grade	Absolute Rating (µm)	–	Inlet/Outlet Connections	Vent/Drain Ports
C = Standard (non-sterile)	S = 1.6 ft² (0.15 m²)	(Blank) or 1= Polypropylene capsule shell material	VMH	0.1, 0.2, 0.4, 0.6		00 = 1" sanitary flange	0 = No vent/drain port
G = Gamma Irradiated	L = 3.3 ft² (0.31 m²	2 = Animal component free polypropylene capsule shell material, optimized for gamma irradiation compatibility	VTH	0.1, 0.2, 0.4, 0.6		02 = 1" sanitary flange inlet; 3/8" hose barb outlet	1 = 1 luer port with cap, outlet side
	J = 5.2 ft2 (0.48 m²)		VLH	0.1, 0.2, 0.4, 0.6		09 = 1" sanitary flange inlet; 1/2" hose barb outlet (flexible tubing)	2 = Standard - 2 luer ports with caps
			VPH	0.1, 0.2, 0.4		0C = 1" sanitary flange inlet; 1/2" hose barb outlet	4 = 2 sanitary valves with hose barb
						22 = 3/8" hose barb	5 = 1 sanitary valve with hose barb connection, outlet side
						2B = 3/8" hose barb with filling bell	6 = 1 sanitary valve with hose barb, inlet side
						CC = 1/2" hose barb	
						LL = 1" sanitary flange long neck	
						44 = 1/4" MNPT	
						55 = 3/8" FNPT	
						66 = 3/8" MNPT	
						72 = 3/4" sanitary flange inlet; 3/8" hose barb outlet	
						77 = 3/4" sanitary flange	
						88 = 3/4" hose barb	
						99 = 1/2" hose barb flexible tubing	

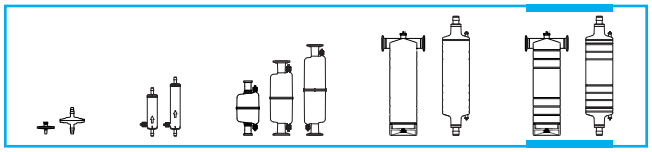
UltraCap® (T-Style & Inline) Ordering Matrix



CU	VMH	0.2	–	2	T	00	2

Sterile Option	Filter Grade	Absolute Rating (µm)	–	Cartridge Length	Body Style	Inlet/Outlet Connections	Vent/Drain Ports T-Style
CU = Standard (non-sterile) GU = Gamma Irradiated	VMH	0.1, 0.2, 0.4, 0.6		1 = 10"	T = T-style	00 = 1" sanitary flange	0 = No vent or drain
	VTH	0.1, 0.2, 0.4, 0.6		2 = 20"	N = Inline	77 = 3/4" sanitary flange	1 = No vent; 1/4" sanitary drain plug
	VLH	0.1, 0.2, 0.4, 0.6		3 = 30"		02 = 1" sanitary flange inlet; 3/8" hose barb outlet	2 = Sanitary vent; 1/4" sanitary drain plug
	VPH	0.1, 0.2, 0.4				0C = 1" sanitary flange inlet; 1/2" hose barb outlet	3 = Sanitary vent; 3/4" sanitary flange gauge port; 1/4" sanitary drain plug
						09 = 1" sanitary flange inlet; 9/16" hose barb outlet	4 = Sanitary vent; no drain
						08 = 1" sanitary flange inlet; 3/4" hose barb outlet	5 = Sanitary vent; 3/4" sanitary flange gauge port; no drain
						22 = 3/8" hose barb	6 = No vent or drain; 3/4" sanitary flange gauge port
						CC = 1/2" hose barb	**Vent/Drain Ports Inline**
						99 = 9/16" hose barb	
						88 = 3/4" hose barb	0 = No vent or drain
						AA = 1/2" Flaretek®	2 = Two sanitary vent/drain valves
						BB = 3/4" Flaretek®	4 = One sanitary vent or drain valve, outlet side

UltraCap® H.D. (T-Style & Inline) Ordering Matrix



CR	2	VMH	0.1	–	2	T	00	2
	2			–				
Sterile Option	Material Code	Filter Grade	Absolute Rating (µm)	–	Cartridge Length	Body Style	Inlet/Outlet Connections	Vent/Drain Ports T-Style

Sterile Option

CR = Standard (non-sterile)

GR = Gamma Irradiated

Material Code

2= Animal component free polypropylene capsule shell material, optimized for gamma irradiation compatibility

Filter Grade

VMH

VTH

VLH

VPH

Absolute Rating (µm)

VMH: 0.1, 0.2, 0.4, 0.6

VTH: 0.1, 0.2, 0.4, 0.6

VLH: 0.1, 0.2, 0.4, 0.6

VPH: 0.1, 0.2, 0.4

Cartridge Length

1 = 10"

2 = 20"

3 = 30"

4 = 40"

5 = 50"

Body Style

T = T-style

N = Inline

Inlet/Outlet Connections

00 = 1" sanitary flange

77 = 3/4" sanitary flange

02 = 1" sanitary flange inlet; 3/8" hose barb outlet

0C = 1" sanitary flange inlet; 1/2" hose barb outlet

09 = 1" sanitary flange inlet; 9/16" hose barb outlet

08 = 1" sanitary flange inlet; 3/4" hose barb outlet

0D = 1" sanitary flange inlet; 1" hose barb outlet

22 = 3/8" hosebarb

CC = 1/2" hose barb

99 = 9/16" hose barb

88 = 3/4" hose barb

DD = 1" hose barb

AA = 1/2" Flaretek®

BB = 3/4" Flaretek®

Vent/Drain Ports T-Style

0 = No vent or drain

1 = No vent; 1/4" sanitary drain plug

2 = Sanitary vent; 1/4" sanitary drain plug

3 = Sanitary vent; 3/4" sanitary flange gauge port; 1/4" sanitary drain plug

4 = Sanitary vent; no drain

5 = Sanitary vent; 3/4" sanitary flange gauge port; no drain

6 = No vent or drain; 3/4" sanitary flange gauge port

A = No vent; sanitary drain valve

B = Sanitary vent; sanitary drain valve

C = Sanitary vent; sanitary drain; 3/4" sanitary flange gauge port

Vent/Drain Ports Inline

0 = No vent or drain

2 = Two sanitary vent/drain valves

4 = One sanitary vent or drain valve, outlet side

K = Two SPD vent/drain valves at inlet and outlet

L = One SPD vent at outlet only

GD003-6.0-A