

Ultradyne® Filters



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Ultradyne® Filters

Ultradyne® is a hydrophobic PTFE membrane filter offering maximum chemical compatibility with minimal extractables in a wide range of fluids and applications. These filters provide reliable removal of particles and microorganisms from aggressive liquids, including strong acids, bases, and organic solvents. Ultradyne® is optimized for applications requiring complete removal of contaminant bacteria and viruses from air and gas streams, such as fermenter inlet air and exhaust, sterile process air, and sterile venting of tanks, lyophilizers, and autoclaves. The Ultradyne® filter provides sterility assurance, high flow rates and throughput under demanding conditions.

Materials of Construction

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

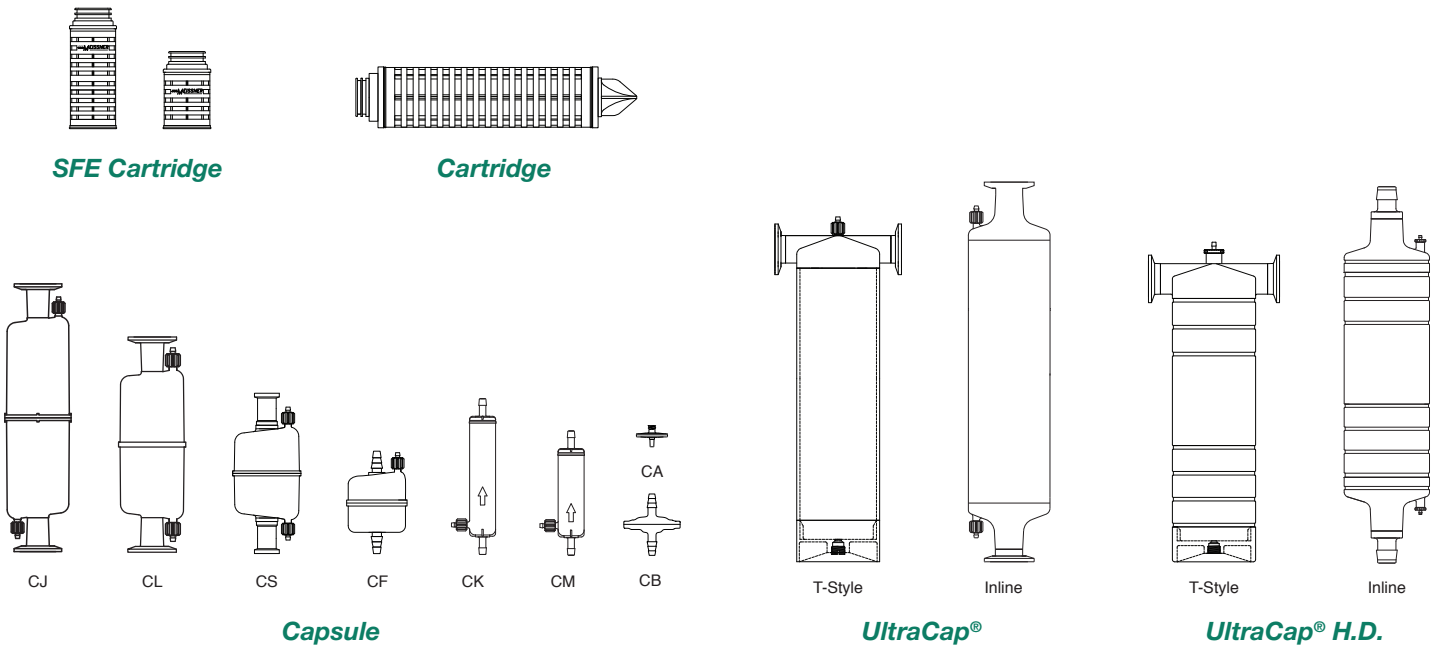
Components

Membrane:	PTFE	CFR Title 21, 177.1550
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 Ultradyne® filter complies with European Commission Regulation No. 10/2011. The filter meets requirements as specified in USP 43 Class VI plastics, pyrogen and cytotoxicity tests. No binders, adhesives or surfactants are used in the construction of Ultradyne® filters. The filters are non-fiber-releasing as defined in 21 CFR 210.3(b)(6) and 211.72. The following configurations are completely animal component free: CA, CB, CM, CK, and CJ.

Configurations

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

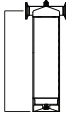


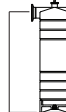
Dimensions

Cartridge	Diameter	Length (nominal)	EFA**
	2.75" (7.0 cm)	10" (25 cm)	6.0 ft ² (0.56 m ²)
		20" (50 cm)	12.0 ft ² (1.11 m ²)
		30" (75 cm)	18.0 ft ² (1.67 m ²)
		40" (100 cm)	24.0 ft ² (2.23 m ²)

SFE Cartridge	Diameter	Length (nominal)	EFA
	2.25" (5.7 cm)	2.5" (6.4 cm)	1.2 ft ² (0.11 m ²)
		5" (12.7 cm)	2.5 ft ² (0.23 m ²)

Capsule	Diameter	Length (nominal)	EFA
CA2	0.98" (25 mm)	1.18" (30 mm)	0.004 ft ² (3.6 cm ²)
CB2	1.97" (50 mm)	2.51" (64 mm)	0.02 ft ² (19.6 cm ²)
CM2	1.25" (2.9 cm)	5.50" (14.0 cm)	0.36 ft ² (335 cm ²)
CK2	1.25" (2.9 cm)	6.25" (15.9 cm)	0.45 ft ² (415 cm ²)
CF/CF2-B	2.25" (5.7 cm)	3.3" (8.3 cm)	0.50 ft ² (465 cm ²)
CS/CS2	2.75" (7.0 cm)	4.5" (11.4 cm)	1.2 ft ² (0.11 m ²)
CL/CL2	2.75" (7.0 cm)	6.9" (17.5 cm)	2.5 ft ² (0.23 m ²)
CJ/CJ2	2.75" (7.0 cm)	10.0" (25.4 cm)	5.3 ft ² (0.49 m ²)

UltraCap®	Diameter	Length (nominal)	Capsule Dimension (overall)	EFA
 T-Style*	3.25" (8 cm)	10" (25 cm)	12.3" (31.2 cm)	6.0 ft ² (0.56 m ²)
		20" (50 cm)	22.3" (56.6 cm)	12.0 ft ² (1.67 m ²)
		30" (75 cm)	32.3" (82 cm)	18.0 ft ² (2.20 m ²)
 Inline	3.25" (8 cm)	10" (25 cm)	14.8" (37.6 cm)	6.0 ft ² (0.56 m ²)
		20" (50 cm)	24.9" (63.2 cm)	12.0 ft ² (1.67 m ²)
		30" (75 cm)	34.9" (88.6 cm)	18.0 ft ² (2.20 m ²)

UltraCap® H.D.	Diameter	Length (nominal)	Capsule Dimension (overall)	EFA
 T-Style*	3.5" (9 cm)	10" (25 cm)	11.7" (29.7 cm)	6.0 ft ² (0.56 m ²)
		20" (50 cm)	21.1" (53.6 cm)	12.0 ft ² (1.67 m ²)
		30" (75 cm)	30.6" (77.7 cm)	18.0 ft ² (2.20 m ²)
		40" (100 cm)	40.0" (101.6 cm)	24.0 ft ² (2.23 m ²)
		50" (125 cm)	49.5" (125.7 cm)	30.0 ft ² (2.79 m ²)
 Inline	3.5" (9 cm)	10" (25 cm)	17.3" (43.9 cm)	6.0 ft ² (0.56 m ²)
		20" (50 cm)	26.8" (68.1 cm)	12.0 ft ² (1.67 m ²)
		30" (75 cm)	36.2" (91.9 cm)	18.0 ft ² (2.20 m ²)
		40" (100 cm)	45.7" (116.1 cm)	24.0 ft ² (2.23 m ²)
		50" (125 cm)	55.2" (140.2 cm)	30.0 ft ² (2.79 m ²)

* 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 - CF/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)

Maximum Operating Pressure & Temperature, Gas

50 psig @ 32 °F to 100 °F

(3.4 bar @ 0 °C to 38 °C)

45 psig @ 140 °F

(3.1 bar @ 60 °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)

Maximum Operating Pressure & Temperature, Gas

60 psig @ 32 °F to 100 °F

(4.1 bar @ 0 °C to 38 °C)

55 psig @ 140 °F

(3.8 bar @ 60 °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

Hydrophobic filters must be wet with a low surface tension fluid such as 60% isopropyl alcohol (60% IPA) before they can be integrity tested with the bubble point or diffusion test. The filter may be wet by flowing 60% IPA through the vented filter housing followed by soaking the filter in 60% IPA for 5 minutes.

To soak a filter cartridge, immerse the cartridge outlet end up in a cylinder of 60% IPA until the core completely fills with fluid. Note: remove Buna or silicone O-rings first to prevent O-ring swelling. Allow the cartridge to soak for approximately five minutes. Drain the cartridge but do not allow it to dry out. Reinstall the O-rings if necessary and install the filter into the housing.

Configuration/Product Model	Wetting guidance
CA/CB	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 upward so that air may escape. Slowly add fluid to the filter capsule until no air bubbles are visible. If the filter has a vent, slowly introduce fluid into the capsule until all air has escaped through the vent on the upstream side. Allow membrane to soak 5 minutes, then drain and promptly perform filter integrity test. For capsules without a vent, airlock can occur after the membrane has been wetted, if more fluid is introduced and air enters the capsule.

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. 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. In vent applications, directing the initial gas effluent to waste, if possible, will remove any residual particulate matter that may be present. Extractables and leachables are not an issue with vent applications as there is no fluid contact expected.

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 60% IPA 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 1-2 psi (0.1 bar) regulated air pressure to the inlet side of the system.
5. If necessary, open V_4 to drain the downstream volume of 60% IPA.
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 chart on Page 9.
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

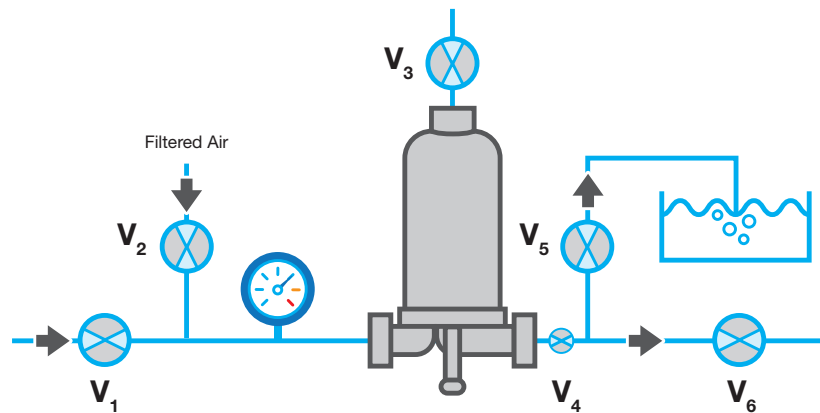


Figure 1

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 the 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 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 IPA 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 IPA integrity test value. It is not appropriate to recirculate the IPA in this case.

Ultradyne® Bubble Point Specifications

Grade & Pore Size	60% IPA PSI (bar)	70% IPA PSI (bar)
TA0.2/TT0.2	16 psi (1.1 bar)	16 psi (1.1 bar)
TM0.1	20 psi (1.4 bar)	19 psi (1.3 bar)
TM0.2	14 psi (1 bar)	14 psi (1 bar)
TM0.4	7 psi (0.5 bar)	7 psi (0.5 bar)
TM1.0	4 psi (0.3 bar)	4 psi (0.3 bar)

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

The diffusion test may be performed on Ultradyne 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. 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 60% IPA, 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 IPA through the filter.
4. If necessary, open V_4 to drain the downstream volume of IPA. IPA 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 for the filter per the charts on Pages 11-12.

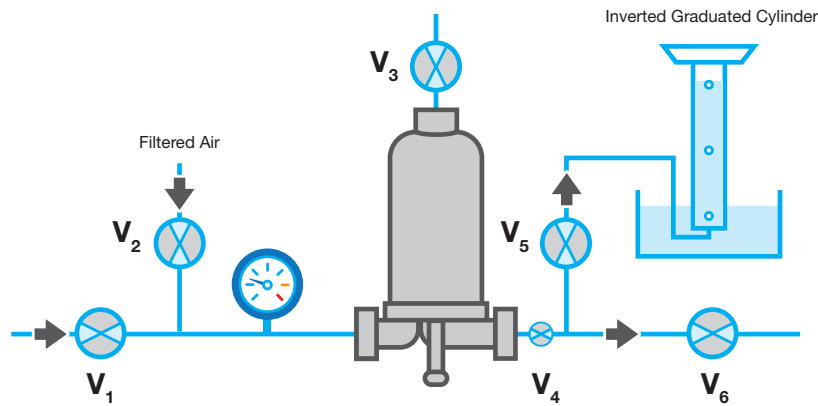


Figure 2

Ultradyne® Diffusive Flow Specifications¹

Grade	Nominal Filter Size	Test Pressure psi (bar)	Diffusive Flow (mL/min) 60% IPA/40% Air	Diffusive Flow (mL/min) 60% IPA/40% Nitrogen	Diffusive Flow (mL/min) 70% IPA/30% Air	Diffusive Flow (mL/min) 70% IPA/30% Nitrogen
TA0.2 TT0.2	CA, CB, CM, CK Capsules	Meissner recommends using bubble point as a filter integrity testing method for these sizes.				
	CF capsules	10 psi (0.69 bar)	Meissner recommends using bubble point as a filter integrity testing method for these sizes		1.6	1.3
	CS Capsules, 2.5" SFE Cartridge	10 psi (0.69 bar)	2.0	1.7	3.9	3.7
	CL Capsules, 5" SFE Cartridge	10 psi (0.69 bar)	4.2	3.6	8.1	6.5
	CJ Capsules	10 psi (0.69 bar)	8.8	7.7	17.2	13.7
	UltraCap®, UltraCap® H.D Capsules & Cartridges ¹	10 psi (0.69 bar)	10.0 mL/min per 10"	8.7 mL/min per 10"	19.5 mL/min per 10"	15.5 mL/min per 10"

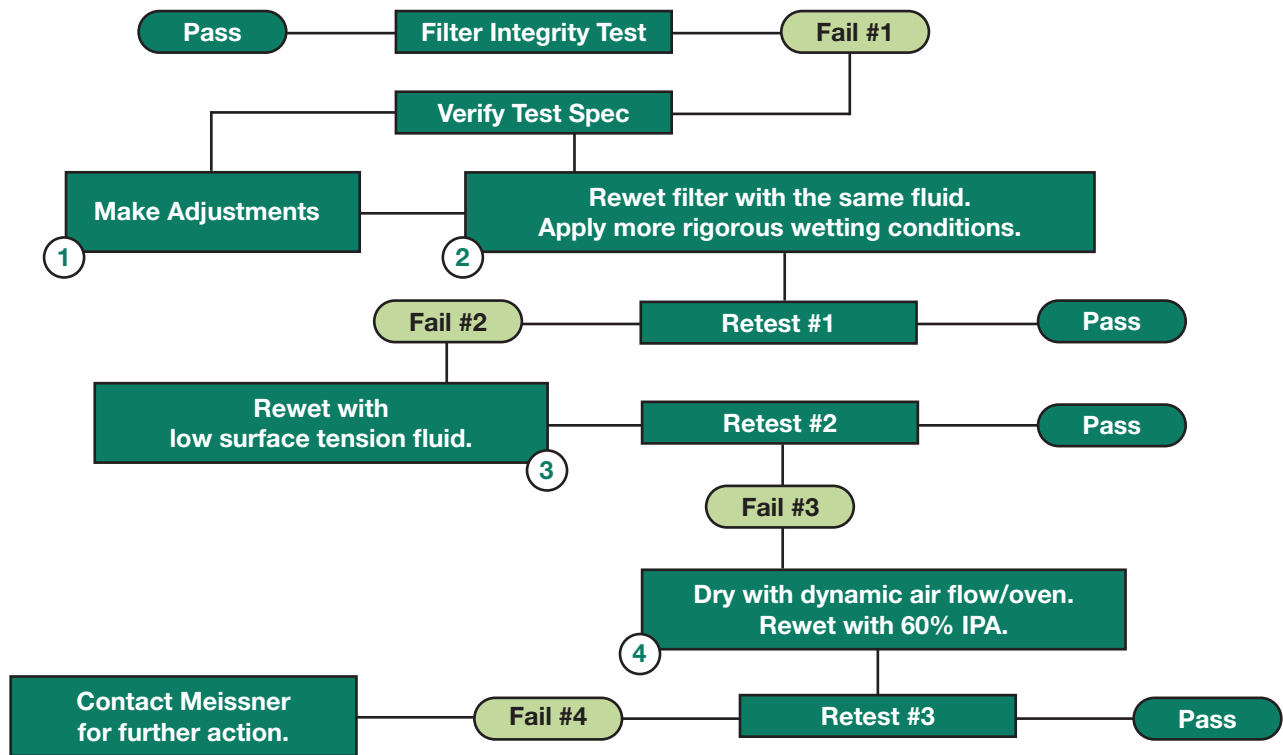
Grade	Nominal Filter Size	Test Pressure psi (bar)	Diffusive Flow (mL/min) 60% IPA/40% Air	Diffusive Flow (mL/min) 70% IPA/30 % Air or Nitrogen
TM0.1	CA, CB, CM, CK, CF Capsules	Meissner recommends using bubble point as a filter integrity testing method for these sizes.		
	CS Capsules, 2.5" SFE Cartridge	15 psi (1.03 bar)	3.0	Contact Meissner
	CL Capsules, 5" SFE Cartridge	15 psi (1.03 bar)	6.5	
	CJ Capsules	15 psi (1.03 bar)	13	
	UltraCap®, UltraCap® H.D Capsules & Cartridges ¹	15 psi (1.03 bar)	15 mL/min per 10"	
TM0.2	CA, CB, CM, CK, CF Capsules	Meissner recommends using bubble point as a filter integrity testing method for these sizes.		
	CS Capsules, 2.5" SFE Cartridge	9 psig (0.62 bar)	2.0	Contact Meissner
	CL Capsules, 5" SFE Cartridge	9 psig (0.62 bar)	4.2	
	CJ Capsules	9 psig (0.62 bar)	8.8	
	UltraCap®, UltraCap® H.D Capsules & Cartridges ¹	9 psig (0.62 bar)	10 mL/min per 10"	
TM0.4	CA, CB, CM, CK, CF, CS, CL, CJ Capsules	Meissner recommends using bubble point as a filter integrity testing method for these sizes.		
	UltraCap®, UltraCap® H.D Capsules & Cartridges ¹	4 psi (0.3 bar)	6 mL/min per 10"	Contact Meissner

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 part number matches specification, SOP, and filter to be installed.
2. Verify filter is visually integral and has not sustained damage. Note any 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, re-wet 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. If product residue is present on the filter post-use, soak overnight in IPA to try to remove it. Then re-wet with a low surface tension fluid and retest.
4. Dry with dynamic air flow or over drying at 50° C for 8 hours, let cool and retest with water. If the filter fails, contact Meissner for further action.

Pre-Use/Post-Use FIT Considerations

Wetting Fluid	Pre-Use	Post-Use
60%IPA/40% water 70% IPA/30% water	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.

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.

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 Ultradybe® 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. Upstream and downstream gauges should 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. A typical piping schematic is outlined in Figure 3.

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 if a large volume tank is 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.

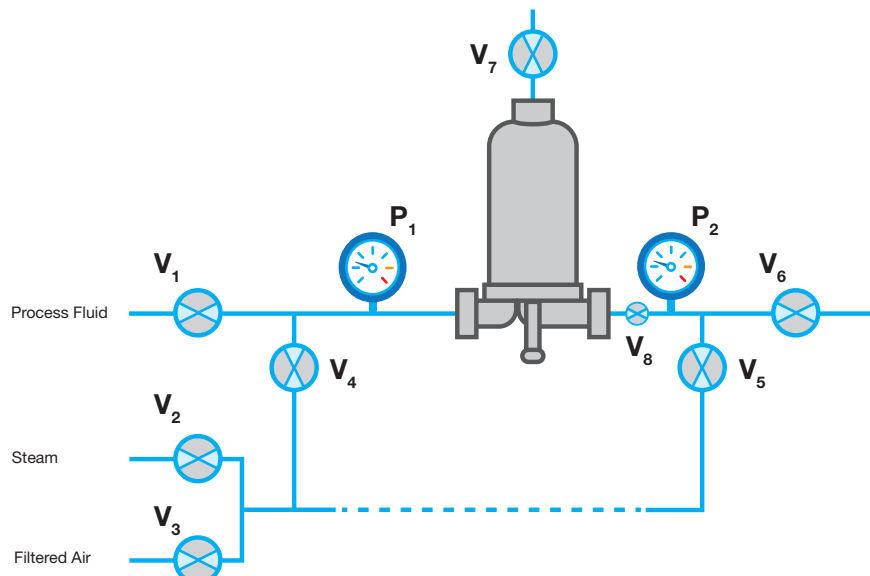


Figure 3

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 to 100 °F). The following gives the minimum shelf life expectancies for Ultradyne® products.

Filters

The Ultradyne® 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.

Ultradyne® Membrane Grade Descriptions

- TM =** This absolute, microbially liquid-rated filter is 100% integrity tested during manufacture. It is suited for high purity filtration of liquids, or for economical sterilization of air/gas when regulatory requirements are minimal. A Certificate of Conformance is available on a lot basis.
- TA =** This microbially liquid-rated sterilizing grade filter is absolute and 100% integrity tested during manufacture. (It qualifies as a microbially liquid-rated sterilizing grade filter per ASTM F838 liquid bacterial challenge.) It is suited for critical applications when regulatory documentation requirements are minimal. A Certificate of Conformance is available on a lot basis.
- TT =** This absolute, microbially liquid-rated, sterilizing grade filter meets full traceability requirements for the pharmaceutical industry. (It qualifies as a sterilizing grade filter per ASTM F838 liquid bacterial challenge.) It is 100% integrity tested during manufacture. Each TT 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.

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
TM	No	Yes	Yes	No	No	P, M
TA0.2	Yes	Yes	Yes	No	No	M, S
TT0.2	Yes	Yes	No	Yes	Yes	M, S

Bacterial Rating Requirements Key

M: Microbially Rated

P: Particle Rated

S: Sterilizing Grade

Cartridge Ordering Matrix



TM	0.2	—	2	C6	R	S
		—				
Filter Grade	Absolute Rating (µm)	—	Cartridge Length	End Cap Configurations	Reinforcement Ring Option	Seal Material (O-ring or Gasket)
TM	0.1, 0.2, 0.4, 1.0		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
TT	0.2		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	E = EPR S = Silicone
TA	0.2		3 = 30"	C1 = SOE; 222 nO-Ring [®] *, button cap end		T = Teflon [®] over silicone V = Viton [®]
			4 = 40"	C2 = SOE; 222 O-rings, button cap end		X = Teflon [®] over Viton [®]
				F1 = SOE; 222 nO-Ring [®] *, fin end		Gasket Seal B = Buna
				F2 = SOE; 222 O-rings, fin end		E = EPR
				C5 = SOE; 226 nO-Ring [®] *, button cap end		P = Polyethylene
				C6 = SOE; 226 O-rings, button cap end		S = Silicone
				F5 = SOE; 226 nO-Ring [®] *, fin end		T = Teflon [®]
				F6 = SOE; 226 O-rings, fin end		V = Viton [®]
				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		

¹ NO-Rings are not steam sterilizeable

Small Flow Elements (SFE Filters) Ordering Matrix



L	TM	0.2	–	5	6	R	S
L			–				
Model	Filter Grade	Absolute Rating (µm)	–	Length/Area	Adapter Selection	Reinforcement Ring Option	O-ring Material
L	TM	0.1, 0.2, 0.4, 1.0		2 = 2.5"/1.6 ft² (0.15 m²)	P = Standard internal 116 O-ring	Blank = Standard–no reinforcement ring	B = Buna
	TT	0.2		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
	TA	0.2			6 = 226 O-ring style locking adapter (for autoclave/ SIP applications, select "R" under "Reinforcement Ring Option")		S = Silicone
					SK = Skirt-flange adapter (no reinforcement or O-ring options available)		T = Teflon® over Silicone
					L = 116 O-ring with Mini Lock		V = Viton®
							T = Teflon® over Viton

Capsule (CA/CB) Ordering Matrix



C	A	2	TA	0.2	—	EF	0
		2			—		
Sterile Option	Effective Filtration Area	Material Code	Filter Grade	Retention Rating (µm)	—	Inlet/Outlet Connections	Vent/Drain Ports
C = Standard (non-sterile)	A = 3.6 cm ² B = 19.6 cm ²	2= Animal component free Polypropylene Capsule shell material	TA TT TM	0.2 0.2 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	CA2 Capsule 0 = No vent/drain port
						CB2 Capsule 33 = Stepped barb (1/4" - 3/8") B = Stepped barb (1/4" - 3/8") with filling bell 3 = 3/4" sanitary flange inlet & hose barb (1/4" - 3/8") outle 77 = 3/4" sanitary flange inlet/outlet 7B = 3/4" sanitary flange inlet & filling bell outlet	CB2 Capsule 0 = No vent/drain port 1 = One luer port with cap, inlet side

Capsule (CM/CK) Ordering Matrix



C	K	2	TM	0.2	—	77	4
		2			—		
Sterile Option	Filtration Area	Material Code	Filter Grade	Absolute Rating (µm)	—	Inlet/Outlet Connections	Vent/Drain Ports
C = Standard (non-sterile)	M = 0.36 ft² (335 cm²) K = 0.45 ft² (415 cm²)	2= Animal component free polypropylene capsule shell material	TM	0.1, 0.2, 0.4, 1.0	11 = 1/4" hose barb	0 = No vent/drain port	
			TT	0.2	1B = 1/4" hose barb with filling bell	1 = 1 luer port with cap, inlet side	
			TA	0.2	22 = 3/8" hose barb	2 = Standard - 2 luer ports with caps	
					2B = 3/8" hose barb with filling bell	4 = 2 sanitary valves with hose barb	
					41 = 1/4" MNPT; 1/4" hose barb out	5 = 1 sanitary valve with hose barb connection, inlet side	
					44 = 1/4" MNPT	6 = 1 sanitary valve with hose barb, outlet side	
					71 = 3/4" sanitary flange in; 1/4" hose barb out		
					72 = 3/4" sanitary flange in; 3/8" hose barb out		
					77 = 3/4" sanitary (TC) flange		

Capsule (CF) Ordering Matrix



CF	2	TM	0.2	—	33	B	1
				—		B	
Sterile Option	Material Code	Filter Grade	Absolute Rating (µm)	—	Inlet/Outlet Connections	Filtration Area (Nominal)	Vent/Drain Ports
CF = Standard (non-sterile)	(Blank) or 1 = Polypropylene capsule shell material	TM	0.1, 0.2, 0.4, 1.0		33 = Stepped barb (1/4" - 3/8")	B = 0.50 ft² (465 cm²)	0 = No vent/drain port
	2= Animal component free polypropylene capsule shell material, optimized for gamma irradiation compatibility	TT	0.2		3B = Stepped barb (1/4" - 3/8") with filling bell		1 = Standard 1 luer port with cap, outlet side
		TA	0.2		41 = 1/4" MNPT inlet; 1/4" hose barb outlet		2 = 2 luer ports with caps
					44 = 1/4" MNPT		4 = 2 sanitary valves with hose barbs
					73 = 3/4" sanitary flange in; stepped barb outlet		5 = 1 sanitary valve with hose barb, outlet side
					77 = 3/4" sanitary flange		6 = One sanitary valve with hose barb, inlet side

Capsule (CS/CL/CJ) Ordering Matrix



C	S	2	TM	0.2	—	02	2
					—		
Sterile Option	Filtration Area (Nominal)	Material Code ¹	Filter Grade	Absolute Rating (µm)	—	Inlet/Outlet Connections	Vent/Drain Ports
C = Standard (non-sterile)	S = 1.2 ft ² (0.11 m ²)	(Blank) or 1 = Polypropylene capsule shell material	TM	0.1, 0.2, 0.4, 1.0		00 = 1" sanitary flange	0 = No vent/drain port
	L = 2.5 ft ² (0.23 m ²)	2 = Animal component free polypropylene capsule shell material	TT	0.2		02 = 1" sanitary flange inlet; 3/8" hose barb outlet	1 = 1 luer port with cap, outlet side
	J = 5.3 ft ² (0.49 m ²)		TA	0.2		02 = 1" sanitary flange inlet; 3/8" hose barb outlet	2 = Standard - 2 luer ports with caps
						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	
						CC = 1/2" hose barb	6 = 1 sanitary valve with hose barb, inlet side
						44 = 1/4" MNPT	
						55 = 3/8" FNPT	
						66 = 3/8" MNPT	
						77 = 3/4" sanitary flange	
						88 = 3/4" hose barb	
						99 = 1/2" hose barb flexible tubing	

¹ CJ filters are only available with the ACF polypropylene capsule shell material.

UltraCap® (T-Style & Inline) Ordering Matrix Description



CU	TM	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)	TM	0.1, 0.2, 0.4, 1.0		1 = 10"	T = T-style	00 = 1" sanitary flange	0 = No vent or drain
	TT	0.2		2 = 20"	N = Inline	77 = 3/4" sanitary flange	1 = No vent; 1/4" sanitary drain plug
	TA	0.2		3 = 30"		02 = 1" sanitary flange inlet; 3/8" hose barb outlet	2 = Sanitary vent; 1/4" sanitary drain plug
						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 0 = No vent or drain 2 = 2 sanitary vent/drain valves 4 = 1 sanitary vent or drain valve, outlet side
						99 = 9/16" hose barb	
						88 = 3/4" hose barb	
						AA = 1/2" Flaretek®	
						BB = 3/4" Flaretek®	

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



CR	2	TM	0.2	-	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
CR = Standard (non-sterile)	2= Animal component free polypropylene capsule shell material	TM	0.1, 0.2, 0.4, 1.0		1 = 10"	T = T-style	00 = 1" sanitary flange	0 = No vent or drain
		TT	0.2		2 = 20"	N = Inline	77 = 3/4" sanitary flange	1 = No vent; 1/4" sanitary drain plug
		TA	0.2		3 = 30"		02 = 1" sanitary flange inlet; 3/8" hose barb outlet	2 = Sanitary vent; 1/4" sanitary drain plug
					4 = 40"		0C = 1" sanitary flange inlet; 1/2" hose barb outlet	3 = Sanitary vent; 3/4" sanitary flange gauge port; 1/4" sanitary drain plug
					5 = 50"		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
							0D = 1" sanitary flange inlet; 1" hose barb outlet	6 = No vent or drain; 3/4" sanitary flange gauge port
							22 = 3/8" hose barb	A = No vent; sanitary drain valve
							CC = 1/2" hose barb	B = Sanitary vent; sanitary drain valve
							99 = 9/16" hose barb	
							88 = 3/4" hose barb	C = Sanitary vent; sanitary drain; 3/4" sanitary flange gauge port
							DD = 1" hose barb	
								Vent/Drain Ports Inline
								0 = No vent or drain
								2 = 2 sanitary vent/drain valves
								4 = 1 sanitary vent or drain valve, outlet side
								K = SPD vent/drain valves inlet/outlet
								L = SPD vent/drain valves outlet only

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