



SPC Filters

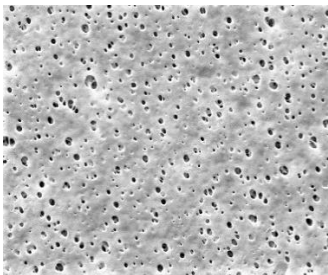
Positively Charged, Single Layer
PES Membrane



SPC cartridge and capsule filters consist of a single layer, positively charged Polyethersulfone (PES) membrane. Available in 0.03, 0.10, 0.22 and 0.45 μm , SPC filters are validated for absolute bacteria retention to provide reliable sterile filtration performance with a high flow rate.

The positive charge removes negatively charged biological contaminants such as endotoxin, virus and other cell fragments. Depending on level of contaminant and flow rate, SPC filters will typically exhibit > 3-log removal of endotoxin. This combination of functionality makes the SPC filter an excellent choice for pharmaceutical and biopharmaceutical applications.

Critical Process provides unrivaled delivery times, technical consulting before purchasing, and very competitively priced high-performance products. Our comprehensive testing & analysis and validation services support your team whenever they need it. Your process experts partnering with our filtration experts is how we deliver your company's solution right the first time.



SPC filters are recommended for sterilizing and endotoxin removal in:

- Process Water
- Water for Injection (WFI)

Sterilizing Filters

Endotoxin Removal



CARTRIDGES – Nominal Dimensions

Length: 5 to 40 in. (12.7 to 101.6 cm)

Outside Diameter: 2.75 in. (7.0 cm)



CAPSULES – Nominal Dimensions

Length: 2 to 30 in. (5.1 to 76.2 cm)

Outside Diameter: 3.50 in. (8.9 cm)

Maximum Operating Parameters

	CARTRIDGES	CAPSULES
Liquid Operational Pressure	N/A	80 psi at 68 °F (5.52 bard at 20 °C)
Gases Operational Pressure	N/A	60 psi at 68 °F (4.14 bar at 20 °C)
Operating Temperature (water)	180 °F at 30 psid (82 °C at 2.07 bard)	110 °F at 30 psid (43 °C at 2.07 bard)
Forward Differential Pressure	80 psid at 68 °F (5.52 bard at 20 °C) (Liquid and Gas)	Liquid - 80 psid at 68 °F (5.52 bard at 20 °C) Gas - 60 psi at 68 °F (4.14 bar at 20 °C)
Reverse Differential Pressure	50 psid at 68 °F (3.45 bard at 20 °C)	50 psid at 68 °F (3.45 bard at 20 °C)
Recommended Changeout Pressure	35 psid (2.41 bard)	35 psid (2.41 bard)

Sanitization & Sterilization

Filtered Hot Water*	90 °C (194 °F), 30 minutes, multiple cycles, max 3 psid forward flow	N/A
Inline Steam*	275 °F (135 °C), 30 min, 25+ cycles	N/A
Autoclave*	250 °F (121 °C), 30 min, 25+ cycles	250 °F (121 °C), 30 min, 25+ cycles
Chemical Sanitization	Performed using industry standard concentrations of hydrogen peroxide, peracetic acid, sodium hypochlorite and other selected chemicals.	

*Cartridge Filters – For all elevated temperature procedures above, a stainless-steel support ring is required.

Filtration Area (Nominal)

	CAPSULES	CARTRIDGES AND CAPSULES				CARTRIDGES
Length	2"	5"	10"	20"	30"	40"
	5.08cm	12.7cm	25.4cm	50.8cm	76.2cm	101.6cm
Area	1.2 ft ²	3.4 ft ²	7.3 ft ²	14.6 ft ²	21.9 ft ²	29.2 ft ²
	0.11m ²	0.32m ²	0.68m ²	1.36m ²	2.04m ²	2.72m ²

Integrity Testing

PORE SIZE	DIFFUSION TEST PRESSURE*		BUBBLE POINT MINIMUM*	
	PSIG	BARG	PSIG	BARG
μm				
0.03	60	4.14	**	**
0.10	48	3.30	**	**
0.22	35	2.41	50	3.5
0.45	20	1.37	25	1.7

DIFFUSION SPECIFICATIONS						
Length	2"	5"	10"	20"	30"	40"
mL/min	≤ 2.9	≤ 8.6	≤ 20	≤ 40	≤ 60	≤ 80

* For water wetted membrane

** Test pressure exceeds operational limits of capsule filters. Use the Diffusion Test method.

Construction Materials

Filtration Media	Positively Charged Single Layer Asymmetric Polyethersulfone (PES) Membrane (absolute rated)
Media Support	Polypropylene
End Caps, Center Core, Outer Support Cage, Capsule Housing	Polypropylene
Sealing Method	Thermal Bonding
O-Rings/Gaskets Cartridges only	Buna, Viton® (or FKM), EPDM, Silicone, FEP Encapsulated Silicone, FEP Encapsulated Viton (or FKM)

Validation

SPC filters are validated using test procedures that comply with ASTM F 838-15(ae1) protocols for the determination of bacterial retention in filters used for liquid filtration. The challenge level is a minimum of 10^7 organisms per cm^2 of filter media. CPF filters have > 7-log removal when challenged with the organisms listed below (0.03 μm , 0.10 μm and 0.22 μm meet the FDA definition of sterilizing grade filters).

0.03 μm : *Acholeplasma laidlawii*

0.10 μm : *Brevundimonas diminuta*

0.22 μm : *Brevundimonas diminuta*

0.45 μm : *Serratia marcescens*

Endotoxins

The levels of bacterial endotoxins in aqueous extracts from SPC filters are below current USP limits as specified for water for injection.

Extractables

SPC filters typically exhibit low levels of non-volatile residues.

TOC and Conductivity

SPC filters conform with TOC standards of USP <643> and the water conductivity standards of USP <645> after an appropriate flush with purified water.

Toxicity Compliance

Materials used to construct SPC filters are non-toxic and meet the requirements for the MEM Elution Cytotoxicity Test and the requirements for Biological Reactivity Tests in the current version of the United States Pharmacopeia (USP) for Class VI - 121 °C Plastics.

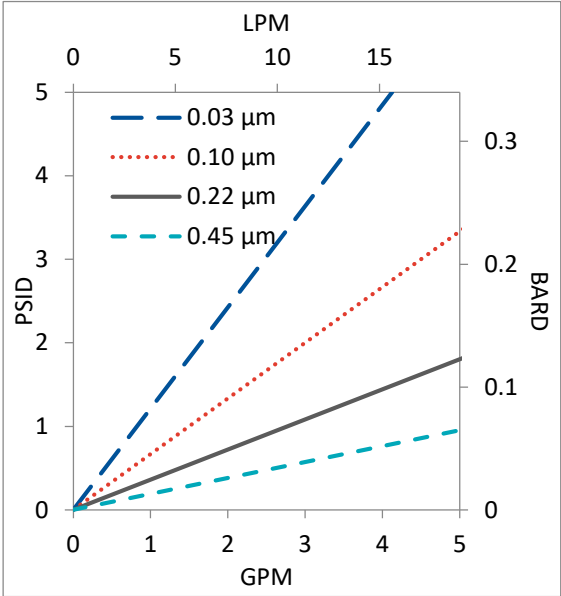
Non-Fiber Releasing

SPC filters comply with Title 21 CFR sections 210.3 (b)(6) and 211.72, for non-fiber releasing filters.

FDA Compliance

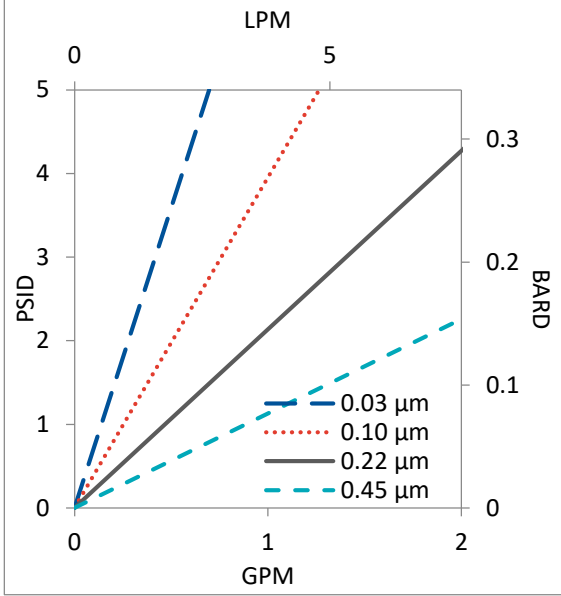
Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

Flow Rates for SPC Cartridges by Pore Size



Flow rates for Cartridge filters are per 10-inch length. The test fluid is water at ambient temperature.

Flow Rates for SPC Capsules by Pore Size



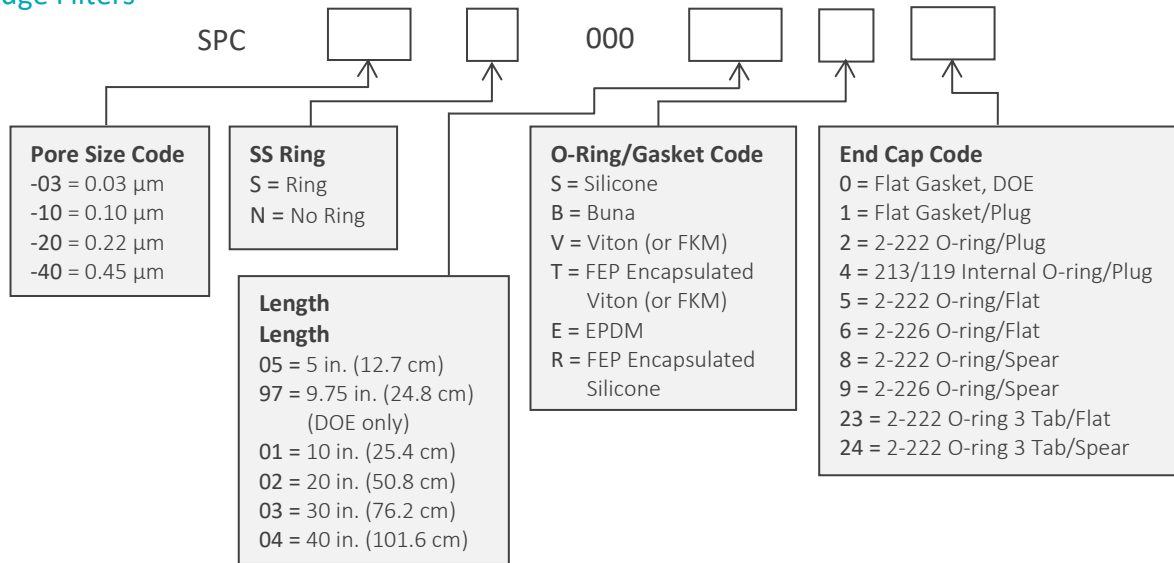
Flow rates for Capsule filters are tested using a 2" capsule filter with 1" sanitary inlet and outlet ports. The test fluid is water at ambient temperature. Flow rates for larger capsules will scale with filtration area. Rates will vary based on end configuration of the capsule.

SPC Filters Ordering Information

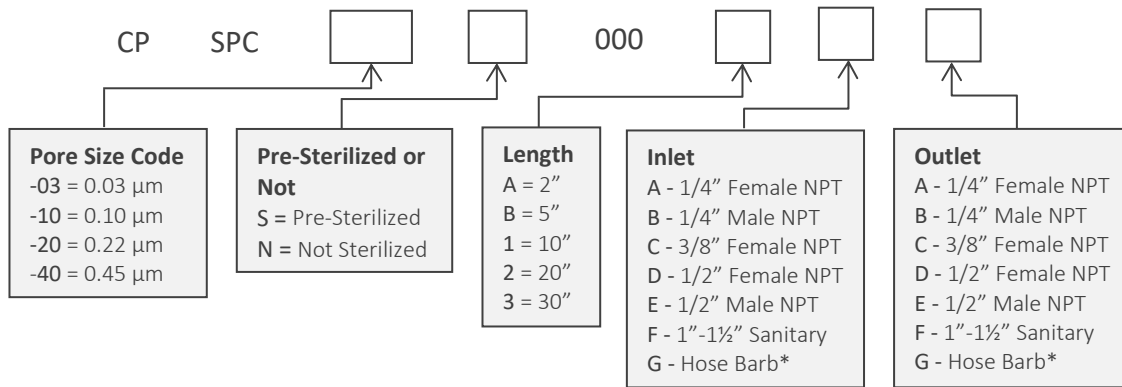
All Critical Process filters are configurable to meet customer specifications.
Fill in the corresponding codes in the boxes below to build your Part Number.

To consult with one of our technical team members, request a quote or place an order:
call (603) 880-4420 Ext. 106, or send an email to sales@criticalprocess.com

Cartridge Filters



Capsule Filters



*Fits hoses/tubes with inner diameter 11/32 to 9/16 inches

Housings

CPF offers Model CSH sanitary housings in Single-Round (Inline and T-Style) and Multi-Round (3, 6, 8, 12 and 21-round) configurations.



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