# 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 > 2-log removal of endotoxin.
This combination of functionality makes the SPC filter an excellent choice for pharmaceutical and biopharmaceutical applications.

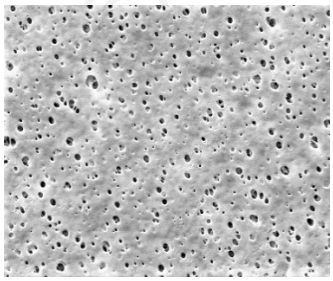
Critical Process provides unrivaled delivery times, technical consulting before purchasing, and very competitively priced high-performance products. Our comprehensive testing & analysis and validation services support your team whenever they need it. Your process experts partnering with our filtration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

## 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)



SPC filters are recommended for sterilizing and endotoxin removal in:

- Process Water
- Water for Injection (WFI)

## 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 $ft^2$ |
| | 0.11$m^2$ | 0.32$m^2$ | 0.68$m^2$ | 1.36$m^2$ | 2.04$m^2$ | 2.72$m^2$ |

## Integrity Testing

| PORE SIZE | DIFFUSION TEST PRESSURE* | | BUBBLE POINT MINIMUM* | |
|---|---|---|---|---|
| µm | PSIG | BARG | PSIG | BARG |
| 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 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 (0.03µm, 0.10µm and 0.22µm meet the FDA definition of sterilizing grade filters).

0.03µm: *Acholeplasma laidlawii*
0.10µm: *Brevundimonas diminuta*
0.22µm: *Brevundimonas diminuta*
0.45µm: *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.

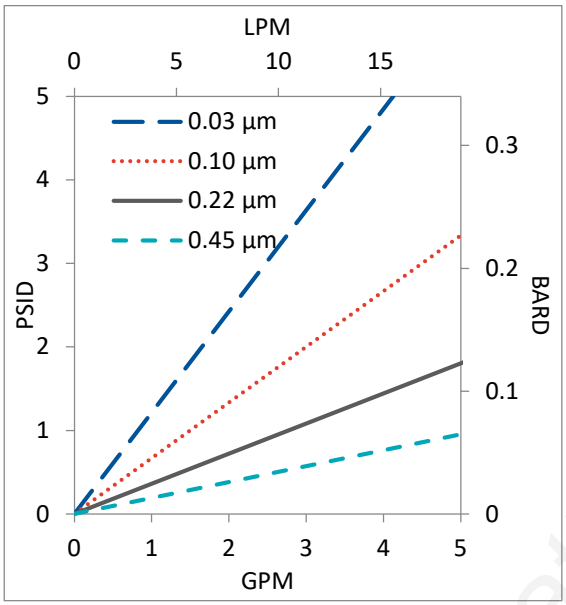
## Non-Fiber Releasing

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

## FDA Compliance

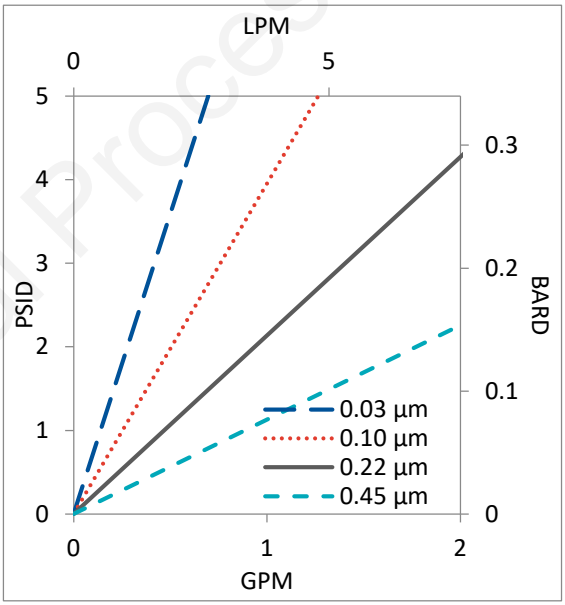
Materials meet the requirements listed by the FDA as appropriate for use in articles intended for repeated food contact as specified in Title 21 CFR sections 174.5, 177.1500, 177.1520, 177.1630, 177.2440, and 177.2600 as applicable.

## 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

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 or contact us here.

**Please note this product is not designed or approved for use in Hemodialysis applications**

## Cartridge Filters

SPC [ ] [ ] 000 [ ] [ ] [ ]

**Pore Size Code**
-03 = 0.03 µm
-10 = 0.10 µm
-20 = 0.22 µm
-40 = 0.45 µm

**SS Ring**
S = Ring
N = No Ring

**Length**
05 = 5 in. (12.7 cm)
97 = 9.75 in. (24.8 cm) (DOE only)
01 = 10 in. (25.4 cm)
02 = 20 in. (50.8 cm)
03 = 30 in. (76.2 cm)
04 = 40 in. (101.6 cm)

**O-Ring/Gasket Code**
S = Silicone
B = Buna
V = Viton (or FKM)
T = FEP Encapsulated Viton (or FKM)
E = EP
R = FEP Encapsulated Silicone

**End Cap Code**
0 = Flat Gasket, DOE
1 = Flat Gasket/Plug
2 = 2-222 O-ring/Plug
4 = 213/119 Internal O-ring/Plug
5 = 2-222 O-ring/Flat
6 = 2-226 O-ring/Flat
8 = 2-222 O-ring/Spear
9 = 2-226 O-ring/Spear
23 = 2-222 O-ring 3 Tab/Flat
24 = 2-222 O-ring 3 Tab/Spear

## Capsule Filters

CP SPC [ ] [ ] 000 [ ] [ ] [ ] - [ ] [ ]

**Pore Size Code**
-03 = 0.03 µm
-10 = 0.10 µm
-20 = 0.22 µm
-40 = 0.45 µm

**Pre-Sterilized or Not**
S = Pre-Sterilized
G = Gamma Stable
N = Not Sterilized

**Length**
A = 2”
B = 5”
1 = 10”
2 = 20”
3 = 30”

**Inlet**
A = 1/4” Female NPT
B = 1/4” Male NPT
C = 3/8” Female NPT
D = 1/2” Female NPT
E = 1/2” Male NPT
F = 1” Sanitary
G = Hose Barb*
H = 1 ½” Sanitary with side vent
I = ½” Single Stepped Barb with side vent
J = ¾” Single Step Barb with Side Vent
Y = 3/8” Compression (JACO©) (Top Luer lock vent only)
Z = 6mm Quick Disconnect (Top Luer lock vent only)

**Outlet**
A = 1/4” Female NPT
B = 1/4” Male NPT
C = 3/8” Female NPT
D = 1/2” Female NPT
E = 1/2” Male NPT
F = 1” Sanitary
G = Hose Barb*
H = 1 ½” Sanitary with side vent
I = ½” Single Stepped Barb with side vent
IB = ½” Single Stepped Barb with filling bell and side vent
J = ¾” Single Step Barb with Side Vent
Y = 3/8” Compression (JACO©) (Top Luer lock vent only)
Z = 6mm Quick Disconnect (Top Luer lock vent only)

**Side Vent Options**
1 = Luer Lock
2 = 1/8” Bleed Valve
3 = ¼” Bleed Valve

**O-Rings**
(Bleed Valves Only)
S = Silicone
E = EP
V = Viton
B = Buna
K = FFKM

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

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Data Sheet SPCDS Rev C