

Mini Capsule Filter (CM2/CK2 Model)

Description

Protec® is a borosilicate glass fiber prefilter that offers a high critical degree of retention and provides outstanding protection of more expensive downstream sterilizing filters. The filter is optimized for bioburden reduction as well as removal of colloidal contaminants, aggregated and non-product proteins, lipids, and other particles in a broad range of biopharmaceutical applications. It is ideal for prefiltration and clarification of biologicals, protein solutions, vaccines, fermentation broths, cell culture media, serum and plasma fractions. The Protec® filter protects final membrane filters in processing solutions with high particle loads and high bioburden.

Materials of Construction

All components of the Protec® filter capsule are FDA listed for food contact use in the Code of Federal Regulations (CFR), Title 21, as below:

Filtration Media:

RF (single layer):	Borosilicate glass microfiber	CFR Title 21, 177.2420
RM (double layer):	Borosilicate glass microfiber (outer layer)	CFR Title 21, 177.2420
	Polyvinylidene fluoride membrane (inner layer)	CFR Title 21, 177.2510
Upstream support:	Polypropylene	CFR Title 21, 177.1520
Downstream support:	Polypropylene	CFR Title 21, 177.1520
Outer guard:	Polypropylene	CFR Title 21, 177.1520
Core:	Polypropylene	CFR Title 21, 177.1520
End caps:	Polypropylene	CFR Title 21, 177.1520
Capsule housing:	Polypropylene	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

Retention Ratings (absolute)	RF: 0.5, 1.0 µm
	RM: 0.2, 0.3, 0.5 µm

Operating Characteristics

Operating temperature range:	32 °F to 100 °F (0 °C to 38 °C)
Maximum temperature rating:	160 °F @ 35 psig (71 °C @ 2.4 bar)
Maximum operating pressure:	100 psig @ 122 °F (6.9 bar @ 50 °C)
Maximum reverse pressure:	15 psig @ 100 °F (1.0 bar @ 38 °C)

Sterilization

Autoclave: 121 °C to 135 °C (15 to 30 psi, 1 to 2 bar), 30 to 60 minutes, ≥ 3 cycles.

Gamma irradiation: 25 to 40 kGy once. Do not autoclave irradiated capsules.

Capsules must not be in-line steam sterilized.

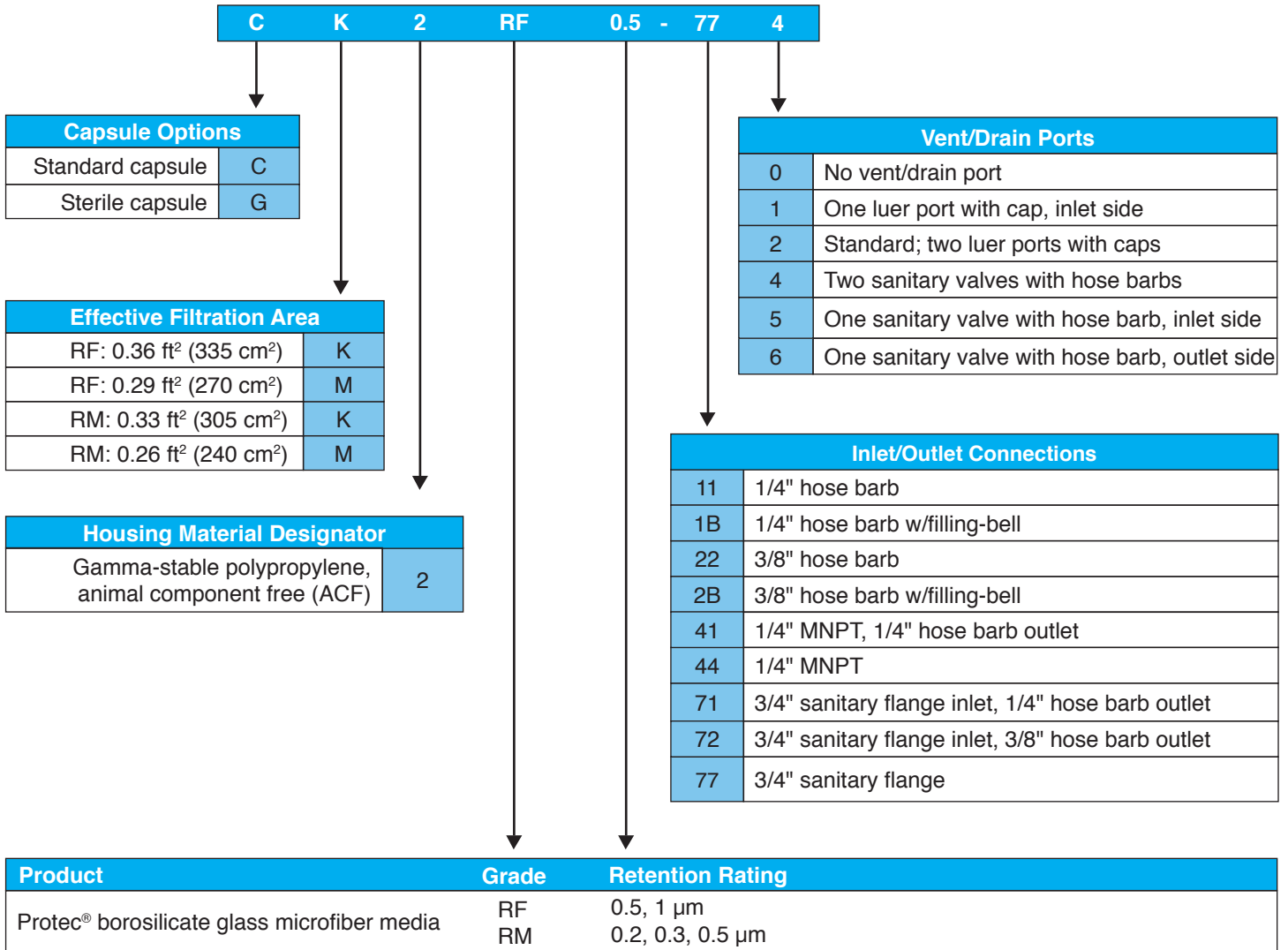
Biological Safety

Protec® filters meet the requirements as specified in the current USP <88> Class VI plastics and USP <87> cytotoxicity tests. No adhesives or surfactants are used in the construction of Protec® filters.

Quality Assurance

Protec® filters comply with the Food and Drug Administration Code of Federal Regulations, Title 21, Parts 210 and 211. Product is manufactured and packaged in a cleanroom facility that, through voluntary compliance, meets or exceeds FDA Good Manufacturing Practice Standards. To ensure product reliability, Meissner's Quality Assurance staff continually audits the manufacturing process for conformance to its Quality Management System. Each Protec® filter is clearly marked with filter type, lot number, and serial number.

Ordering Guide



Additional information about this filter product is available in the Protec[®] Green Docs document at www.meissner.com/green-docs.

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