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
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**

**Capsule Options**
- Standard capsule: C
- Sterile capsule: G

**Effective Filtration Area**
- RF: 0.36 ft² (335 cm²): K
- RF: 0.29 ft² (270 cm²): M
- RM: 0.33 ft² (305 cm²): K
- RM: 0.26 ft² (240 cm²): M

**Housing Material Designator**
Gamma-stable polypropylene, animal component free (ACF): 2

**Vent/Drain Ports**
- 0: No vent/drain port
- 1: One luer port with cap, inlet side
- 2: Standard; two luer ports with caps
- 4: Two sanitary valves with hose barbs
- 5: One sanitary valve with hose barb, inlet side
- 6: One sanitary valve with hose barb, outlet side

**Inlet/Outlet Connections**
- 11: 1/4" hose barb
- 1B: 1/4" hose barb w/filling-bell
- 22: 3/8" hose barb
- 2B: 3/8" hose barb w/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

**Product**
- **Protec® borosilicate glass microfiber media**
  - **Grade**
    - RF: 0.5, 1 µm
    - RM: 0.2, 0.3, 0.5 µm

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

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