Zebragard® Filters

MEISSNER

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Zebragard™

Zebragard™ is a dual hydrophilic and hydrophobic PVDF membrane barrier filter with high flow rates and rapid air flow recovery, optimized for the effective passage of both liquids and gases. Zebragard™ is designed to facilitate in-line pre-use, post sterilization integrity testing (PUPSIT) of single or redundant sterile process filter systems.

Materials of Construction

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

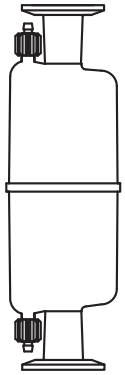
Components

Media:	Polyvinylidene fluoride (PVDF)	CFR Title 21, 177.2510
Upstream/downstream support:	Polypropylene (PP)	CFR Title 21, 177.1520
Core/outer guard:	Polypropylene (PP)	CFR Title 21, 177.1520
End caps/adapters:	Polypropylene (PP)	CFR Title 21, 177.1520
Capsule housing:	Polypropylene (PP)	CFR Title 21, 177.1520
Sealing method:	Thermal bonding	

The Zebragard™ filter complies with European Commission Regulation No. 10/2011. The filter meets requirements as specified in the current USP Class VI plastics, pyrogen, and cytotoxicity tests. No binders, adhesives or surfactants are used in the construction of Zebragard™ filters. The filters are non-fiber-releasing as defined in 21 CFR 210.3(b)(6) and 211.72.

Configuration

Zebragard™ can be ordered in a CL Capsule configuration.



CL Capsule

Dimensions

Capsule	*Diameter*	*Length (nominal)*	*EFA***
CL/CL2	2.75" (7.0 cm)	6.9" (17.5 cm)	3.3 ft^2 (0.31 m^2)

***EFA = Effective Filtration Area**

Operating Characteristics

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)

Integrity test: Manual Bubble Point if a Capsule

Wetting

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 though the vented filter housing or 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 5 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.

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. Then, immerse the open hose end in a beaker of water, or connect an automated integrity tester to the inlet and follow 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.

Zebragard™ Bubble Point Values Specifications – Room Temperature

Grade	60% IPA	70% IPA
VTZ 0.2	18 psi (1.24 bar)	17 psi (1.17 bar)

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 reference integrity test value. It is not appropriate to recirculate the wetting fluid in this case.
3. Integrity tests in IPA must be performed promptly to avoid drying the membrane out under pressure.

Autoclave Instructions

Capsule Filters

The following outlines the steps recommended in the autoclave sterilization of Meissner filter capsules. Gamma irradiated filters should not be autoclaved before use due to increased extractables and brittleness after both sterilization methods are employed.

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.

1. 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.
2. 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. 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.
3. 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.

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.

Storage and Shelf Life

Meissner 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 Zebragard™ products.

Filters

The Zebragard™ filter has an expected shelf life greater than 5 years in the non-irradiated capsule line configuration. 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. Gamma-irradiated filters have a shelf life of at least 2 years from the date of irradiation. Gamma-irradiated capsules are distinguished with part numbers beginning with the letter “G”.

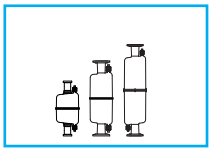
One-Touch® Products

The One-Touch® product line of single-use systems, including but not limited to biocontainers, tubing, and/or filter assemblies, has labeling that identifies the product specific expiration date. The standard shelf life of non-sterile and gamma irradiated One-Touch® products is 2 years from the date of manufacture. These standard time periods may be amended to reflect the various components included in a specific configuration, a change that will be indicated on the product label. Filters that are part of a One-Touch® single-use system begin with “C” and are irradiated once with the One-Touch® assembly.

Zebragard™ Membrane Grade Description

VTZ = This absolute, microbially rated, sterilizing grade filter meets full traceability requirements for the pharmaceutical industry. It is 100% integrity tested during manufacture. Each VTZ-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.

Capsule (CL)
Ordering Matrix



CL	2	VTZ	0.2	—	00	4
Capsule Option	Material Code	Filter Grade	Absolute Rating (µm)	—	Inlet/Outlet Connections	Vent/Drain Ports
CL = Standard (non-sterile) GL = Gamma irradiated	2 = Animal component free (ACF) polypropylene capsule shell material, optimized for gamma irradiation compatibility	VTZ	0.2		00 = 1" sanitary flange 22 = 3/8" hose barb 02 = 1" sanitary flange in; 3/8" hose barb out 77 = 3/4" sanitary flange 99 = 1/2" hose barb (flexible tubing) 09 = 1" sanitary flange in; 1/2" hose barb out 72 = 3/4" sanitary flange in; 3/8" hose barb out 88 = 3/8" hose barb LL = 1" sanitary flange, long neck	0 = No vent/drain ports 4 = Two sanitary valves with hose barb 5 = One sanitary valve with hose barb, outlet side 6 = One sanitary valve with hose barb, inlet side

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