

INSTALLATION

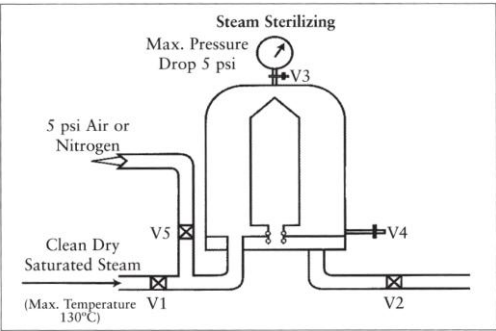
- 1. Remove the bagged filter from the filter cartridge box. Verify that the part number is correct and record the cartridge lot number if necessary.
- 2. Carefully open the filter cartridge bag. If the filter is a single open end style, cut the bag at the open end.
- 3. Do not completely remove the filter cartridge from the bag, but use the bag as a handling device to reduce the possibility of contamination.
- 4. Install the filter cartridge into the housing. If the cartridge has o-rings, the o-rings should be pre-wetted with a suitable fluid.
CAUTION: Do not over-tighten compression plate as this may damage filter and void warranty. If the cartridge will be steamed, the top plate must be left loose to allow for expansion of the cartridge.

SANITIZATION/ STERILIZATION

Graver Technologies ZTEC WB filters may be sterilized or sanitized by a variety of methods. Due to varying system designs and requirements, users should validate their procedure in order to demonstrate its efficacy.

In Line Steaming

- 1.) With the filters installed, close the downstream and gas valves on the housing (V2) and (V5) and open the vent (V3) and drain valve (V4).
 - 2.) Introduce clean, dry, saturated steam into the upstream side of the filter assembly by opening valve (V1). The maximum temperature of the steam must not exceed 275°F (135°C).
 - 3.) When steam issues from the vent and drain, slowly close the vent (V3) and the drain (V4) until they are only slightly open.
 - 4.) Slowly open the downstream valve (V2) to allow steam to pass through the filter. The differential pressure must not exceed 5 psi (0.34 bar) to avoid damage to the filter cartridge.
 - 5.) Continue the flow of steam for the prescribed length of time (typically at least 20 minutes after the filter assembly has reached the desired temperature).
 - 6.) Shut off the steam and close the vent (V3) and the drain (V4) and downstream valve (V2).
 - 7.) Allow the filter to cool while maintaining a positive pressure of gas at 5 psig (0.34 bar) on the upstream side by introducing regulated air or nitrogen.
- NOTE:** Due to the effects of temperature on o-rings, a new set of o-rings should be installed after every 5 steam cycles.



Hot Water Sanitization

- 1.) With the cartridges installed, fill the upstream side of the housing with cold water and ensure that all the air has been vented from the housing.
- 2.) Flow clean, hot water (maximum 180°F/82°C filtered to at least 1 micron nominal) through the filter with a maximum differential pressure of 5 psi (0.34 bar).

- 3.) Flow the hot water for at least 30 minutes or for a period of time in which sanitization efficacy has been documented.
- 4.) Stop the flow of hot water. Flow cold water through the filter at low differential pressures to cool the filter to operating temperature.

Autoclaving

Graver Technologies ZTEC WB filters are compatible with all autoclave cycles up to a temperature of 275°F (135°C).

Chemical Sterilization

Graver Technologies ZTEC WB filters may be sterilized/sanitized by many of the commonly used chemicals (Refer to Technical Brief TB-005). It is recommended that compatibility testing be conducted prior to using any specific chemical. For any chemical cleaning regimen, it is important to flush the filter completely to remove any chemical residue.

INTEGRITY TESTING

Graver Technologies ZTEC WB cartridges may be integrity tested by diffusion test or bubble point methods. In general, due to the large surface area, the diffusion test will yield more accurate results. In these circumstances, the bubble point test may show a “false failure” due to the rate of diffusion. If a bubble point test is performed and a failure is recorded, the results should be confirmed by diffusion testing. If the diffusion testing is satisfactory, then the filter can be considered integral.

Cartridge Wetting

With the cartridges installed, flow water through the filter system to thoroughly wet the filters and drive air out of the system. A general recommendation is as follows:

Membrane grade	Recommended Wetting/10” Filter
0.2 µm	10 GPM (37.8 lpm) for 20 min
0.45 µm	10 GPM (37.8 lpm) for 20 min
0.65 µm	10 GPM (37.8 lpm) for 20 min

To decrease the time required for wetting, install a pressure gauge (0-30 psi) on the upstream side (inlet side) and a valve on the downstream side (outlet side) of the housing. After initiating flow and purging the air, begin closing the valve until the upstream pressure gauge reads at least 18 PSID (1.24 bar). Continue flow for 5 minutes, then open the valve and begin integrity test. Refer to Technical Brief TB-017 for additional information.

Diffusion Testing

- 1.) Complete cartridge wetting procedure outlined above.
- 2.) With the filter completely wetted, close off water flow and apply 5 psid (0.34 bar) of compressed air to the upstream side of the filter. Allow any water in the housing to pass through the filter and drain on the downstream side of the housing.
- 3.) Slowly increase the pressure to the value shown in Table 1, “Diffusion Pressure” and allow the system to stabilize for two minutes. The pressure ramp should not exceed 10 psid (0.7 bar) per minute.
- 4.) Measure the diffusive air flow through the filter system and compare this value with the maximum values in Table 1 for the pore size being tested. If the diffusive flow is equal to or less than the published value, the system is integral. If the value exceeds the maximum, then:
 - a. Check the pressure gauges for accuracy
 - b. Re-wet the cartridge and repeat the diffusion test from Step1.

Bubble Point Testing

- 1.) Follow Steps 1 through 3 for Diffusion testing, stated above.
- 2.) Increase the pressure to the value shown in Table 1, "Bubble Point". The pressure ramp should not exceed 10 psid (0.7 bar) per minute.
- 3.) Observe the outlet and note the rate of bubbling. Note the pressure at which there is a marked increase in the rate of bubbling. This is the bubble point of the filter.
- 4.) If the pressure noted in Step 3 is equal to or above the bubble point value shown in Table 1, then the filter is integral. If the filter fails the test, verify the results by conducting Diffusion Testing

Integrity Test Parameters for ZTEC WB Filters

Pore Size	Diffusion Pressure	Max. Diffusion Flow / 10" Cartridge	Bubble Point (psig)
0.2	21 psig (1.72 bar)	≤ 35 cc/min	≥ 26 psig (2.07 bar)
0.45	16 psig (1.10 bar)	≤ 35 cc/min	≥ 20 psig (1.38 bar)
0.65	14 psig (0.97 bar)	≤ 35 cc/min	≥ 17 psig (1.17 bar)

Certification of Quality Assurance

Materials of Construction

Filtration Media: Polyethersulfone
Support layers: Polypropylene Microfiber
Structural Supports: Virgin Polypropylene

Operational Limits

Maximum Forward Differential:
80 psid (5.52 bar) @ 70°F (21°C)
40 psid (2.76 bar) @ 176°F (80°C)
Maximum Reverse Differential
40 psid (2.76 bar) @ 70°F (21°C)
Max. Sustained Operating Temp.: 176°F (80°C) @ 20 psid

USP Biosafety

ZTEC cartridges are non-toxic and meet the requirements of the current USP Plastic Class VI Testing.

Shelf Life

4 years from ship date providing filters are stored unopened in a dry and ambient environment. Ideal temperature is 25°C.

FDA

Materials comply with Title 21 of the Code of Federal Regulations, sections 174.5, 177.1520 and 177.2440 for food and beverage contact.

Integrity Testing

Where applicable, the universal assemblies utilized to construct the ZTEC cartridge are individually tested utilizing the forward flow test specified in this document.

Quality Assurance

The ZTEC filter cartridges are manufactured using Good Manufacturing Practices under a quality system that has been certified to meet ISO 9001 standards. Each ZTEC filter is assigned a lot code to ensure traceability of data and materials.



Graver Technologies

ZTEC™ PES Membrane Filter Series WB (Beverage) Grade

Operating Instruction, Test Procedures and Quality Certification

Graver Technologies
200 Lake Drive
Glasgow, DE 19702
302-731-1700
Fax: 302-369-0938

e-mail: info@gravertech.com
web site: www.gravertech.com

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