

# Whatman™ Polyvent (0.2µm PTFE)

## Product Information sheet

### Warning

For research use only.

Not recommended or intended for diagnosis of disease in humans or animals.

Do not use internally or externally in humans or animals.

The Polyvent family of integral vent filters provides a range of dedicated products for the venting of vessels. This family of filter products is constructed from a single standardized set of materials (polypropylene & PTFE), thus simplifying the task of approving materials. From Polyvent 4 to Polyvent 1000, the same materials for the housing and for the membrane are used throughout. By qualifying any one of the Polyvent products, the materials of the full family of Polyvent are tested.

The five Polyvent family members have been designed to provide the optimum sterilizing grade of hydrophobic vents ever manufactured. Venting is the reason for Polyvent, it is not an afterthought.

## Typical Applications for Polyvent

### VENTING of <sup>(1)</sup>

- Filling Vessels
- Mixing Vessels
- Holding Vessels
- Autoclave Vessels
- Fermentation Vessels
- Shipping Vessels
- Dispensing Vessels

<sup>(1)</sup> Sterile Venting

<sup>(2)</sup> Gases Pass, Liquids/Aerosols are Stopped

### ISOLATION of <sup>(2)</sup>

- Incubators
- Autoclaves
- Lyophilizers
- EtO Sterilizers
- Fermentors

## Especially Useful For

**Biotech:** Sterile vents & exhausts for growth environments.

**Pharmaceutical & Diagnostics:** Vents for liquid vessels.

**Food & Beverage:** Vents for holding, shipping and dispensing vessels.

Bulk tanks may store food products, biological products, or deionized water. Vent filters on these tanks allow only sterile, microfiltered air to replace the liquid drawn off for use.

Positive pressure may develop in some vessels as sterile gases are pumped into the vessel. Reaction gases must be safely vented off, without contaminating either the environment or the tank's contents.

A properly designed sterile vent filter allows pressure within a sealed vessel to equalize with external atmospheric pressure. In some applications, protection of the environment from contaminants in the

vessel is the objective; in other applications, the objective is to protect the contents of the vessel from external contamination.

- Integral
- Bi-Directional
- Sterile Vent Filters
- Pure Virgin Polypropylene Structure
- Broad Family of Devices Specifically for Venting
- Hydrophobic PTFE Membrane
- Autoclavable
- Identification and Lot Number (for GMP's) Permanently Bonded on each vent\*

\*Polyvent 4, due to size, does not have Lot or Serial No. on each vent

## The Polyvent Family of Vent Filters

Physical Size	Typical Effective Filter area	Connections	Typical Vessel Size
<p>Polyvent 4* 28 mm (1.1 inch) 23 mm (0.9 inch)</p>	4 cm <sup>2</sup>	Female Luer Lock Male Luer	 < 1 Liter
<p>Polyvent 16 53 mm (2.1 inch) 46 mm (1.8 inch)</p>	16 cm <sup>2</sup>	Stepped Hose Barbs ¼ to ¾ in. (6 mm to 10 mm)	 ≈ 5 Gal ≈ 19 Gal
<p>Polyvent 500 48 mm (1.9 inch) 66 mm (2.6 inch)</p>	500 cm <sup>2</sup>	Stepped Hose Barbs ¼ to ¾ in. (6 mm to 10 mm)	 Bulk Tank Vessels
<p>Polyvent 1000 96 mm (3.8 inch) 66 mm (2.9 inch)</p>	1000 cm <sup>2</sup>	Stepped Hose Barbs ¾ to ½ in. (10 mm to 13 mm)	 Tanks

## Operating Instructions: Venting

**Safety:** Considering the special factors of your application, consult the table of Technical Data to determine the correctness of use. Key safety concern is to not exceed the pressure, temperature, or chemical compatibility recommendations.

**PTFE membrane considerations:** PTFE membrane is hydrophobic and will not allow water (aqueous solutions) to pass without high pressures. These pressures are called the Water Breakthrough Test (WBT) values and change with the pore size of the membrane.

**Autoclavability:** At 121°C (132°C Max.) for 20 minutes. Multiple autoclave cycles may be possible, however, reuse is the responsibility of the operator, who should protect the device from cross contamination and detect loss of integrity by appropriate testing.

## Filtration Installations:

**Vents:** If exhaust gas is saturated with moisture, install vent filter in a vertical position to allow collected moisture to drain back into vessel rather than fill (and block) vent filter housing. Polyvents are Sterilizing vents, and therefore use a 0.2 µm membrane.



## Integrity Testing:

**Water Breakthrough Pressure (WBT):** The PTFE membrane is hydrophobic. This feature allows a simple yet practical test to be conducted with water to determine gross integrity of the filter device. This procedure is particularly helpful in testing "in situ" devices when used as vents. Use sterile water to fill **outlet side of filter**. The atmosphere **outlet connector** is indicated by the labeled side or the flow arrow. Apply 5.0 psi (0.3 bar) controlled pressure for 15 seconds. An integral membrane should hold water. This test is not designed to be definitive for pore size. A WBT cannot be performed following use of alcohol.

## Mode D'emploi: Aeration

**Securite:** En fonction des facteurs particuliers de votre application, consulter le tableau des **Caractéristiques techniques** afin de déterminer si l'utilisation est correcte. En matière de sécurité, la règle d'or est de ne pas excéder les recommandations relatives à la pression, à la température ou à la compatibilité chimique.

**Membrane PTFE:** La membrane PTFE est hydrophobe et elle ne permet pas le passage de l'eau (solutions aqueuses) sans hautes pressions. Ces pressions sont dénommées valeurs de Water Breakthrough Test (WBT: "test de percée de l'eau") et elles varient avec la taille du pore de la membrane.

**Autoclavabilité:** Autoclave: à 121°C (132°C Max.) pendant vingt minutes. Les cycles autoclaves multiples sont possibles, cependant, la responsabilité de l'utilisation incombe à l'opérateur qui devrait, en outre, protéger le dispositif contre la contamination croisée et détecter la perte d'étanchéité au moyen des tests appropriés.

## Installations de Filtration:

**Events:** Si le gaz d'échappement est saturé de moisissure, placer un filtre à événements verticalement afin de permettre à la moisissure recueillie de retourner dans le récipient plutôt que de remplir (et de bloquer) le corps de filtration des gaz. Les événements de stérilisation ont généralement une membrane de 0,2 µm.

## Test d'Étanchéité:

**Water Breakthrough Pressure (WBT):** La membrane PTFE est hydrophobe. Cette caractéristique permet d'effectuer un test simple mais pratique avec de l'eau afin de déterminer l'étanchéité globale du dispositif de filtration. Cette procédure est particulièrement utile pour tester les dispositifs "in situ" utilisés comme événements. Remplis **la sortie du dispositif** avec d'eau stérile. Le raccord ouvert à l'air est marqué avec l'étiquette ou la flèche. Appliquer une pression de 5.0 psi (0.3 bar) pendant 15 secondes. Une membrane intégrale devrait contenir d'eau. Ce test n'est pas conçu pour être décisif pour la taille des pores. Un WBT ne peut être effectué après alcool.

## Instrucciones de Utilización: Ventilación

**Seguridad:** Consulte el cuadro de Características Técnicas para cerciorarse de que las condiciones particulares de su aplicación corresponden a los valores del dispositivo. Es esencial respetar las recomendaciones sobre presión, temperatura y compatibilidad química.

**La Membrana PTFE:** La membrana PTFE es hidrófoba y no deja pasar agua (soluciones acuosas) a no ser que se ejerza una presión elevada. La presión de paso de agua (WBT) depende del tamaño de los poros de la membrana.

**Autoclavabilidad:** Autoclave; 121°C (132°C Max.) durante 20 minutos. Es posible esterilizar varias veces el filtro en autoclave. Ahora bien, el usuario asume los riesgos de la reutilización; debe proteger el dispositivo contra la contaminación cruzada y realizar las pruebas indicadas para cerciorarse de que el dispositivo está en perfecto estado.

## Instalación del Filtro:

**Ventilación:** Si los gases de descarga están saturados de humedad, monte el filtro de ventilación en posición vertical para que la humedad

recogida caiga al recipiente y evitar que se llene (y obstruya) el cuerpo del filtro. Se utilizan filtros de 0.2 µm para esterilización.

## Probar si esta en Perfecto Estado

**Presión de paso de agua (WBT):** La membrana PTFE es hidrófoba. Esta característica permite realizar con agua una prueba sencilla y muy apropiada para determinar si el filtro está en perfecto estado. Es interesante esta posibilidad especialmente para probar "in situ" sistemas que se utilizan para ventilación. Use agua esterilizada para llenar **la parte de salida del filtro**. El conector de atmósfera **la parte de salida** esta indicado en el lado de la etiqueta o la flecha de flujo. Ejercer una presión controlada de 5.0 psi (0.3 bar) durante 15 segundos. Una membrana en buen estado debe retener el agua. No se trata de una prueba absoluta para el tamaño de los poros. No se puede realizar la prueba WBT después de la de alcohol.

## Gebrauchsanleitung: Lüftung

**Sicherheit:** Unter Berücksichtigung der besonderen Gegebenheiten der jeweiligen Anwendung in der Tabelle im Abschnitt 'Technische Daten' nachsehen und anhand der dortigen Angaben überprüfen, ob die Filtereinheit richtig verwendet wird. Vor allem darauf achten, daß die angegebenen Werte für Druck, Temperatur oder chemische Verträglichkeit nicht überschritten werden.

**PTFE-membran:** Die PTFE-Membran ist hydrophob und läßt Wasser (Wässrige Lösung) nur bei Anwendung von hohen Drücken durch. Diese Drücke werden als Wasserdurchbruchtest (WBT)-Werte bezeichnet. Sie verändern sich mit der Porengröße der Membran.

**Autoklavierbarkeit:** Autoclav: 121°C (132°C Max.) für die Dauer von 20 Minuten. Mehrfachsterilisation ist möglich. Die Wiederverwendung erfolgt jedoch auf Verantwortung des Anwenders, der in diesem Fall den Filter vor Kreuzkontamination schützen und ihn auf Beeinträchtigung der Integrität durch geeignete Tests prüfen sollte.

## Filtrationsanlagen:

**BelüftungsfILTER:** Ist die Abluft mit Feuchtigkeit gesättigt, dann ist der BelüftungsfILTER in vertikaler Position anzubringen, damit die angesammelte Feuchtigkeit in den Behälter zurück-fließen kann und nicht das Filtergehäuse anfüllt (und blockiert). Für die Sterilbelüftung wird eine 0,2 µm-Membran verwendet.

## Überprüfung der Integrität

**Wasser-Durchbruchdruck (Water Breakthrough Pressure, WBT):** Die PTFE-Membran ist hydrophob. Diese Eigenschaft ermöglicht die Durchführung einer einfachen, aber praktischen Prüfung, bei der für die Feststellung der Gesamtintegrität der Filtereinheit Wasser verwendet wird. Dieses Verfahren eignet sich besonders gut für die Prüfung von Filtereinheiten "in situ", wenn sie als BelüftungsfILTER verwendet werden. Den **Filterauslaß** mit sterilem Wasser füllen. Der Anschluss der nach aussen offen bleibt, ist mit dem Etikett oder dem Richtungspfeil gekennzeichnet. Für die Dauer von 15 Sekunden einen Druck von 5.0 psi (0.3 bar) anwenden. Eine intakte Membran muß das Wasser halten. Die Prüfung hat keinen sicheren Aussage-wert in Bezug auf die Porengröße. Nach Alkoholbenutzung Alkohol kann kein WBT durchgeführt werden.

## Technical Data: Polyvent Filters for Sterile Venting

The Polyvent family of vent filter devices are designed and built with PTFE membrane and polypropylene housing. This compact design provides high effective filtration area in small size.

Polyvent's light weight is extremely important. When heavy filters are used, they can cause collapsed tubing, stopping the intake of air).

Manufactured in GMP controlled Clean Room facilities.

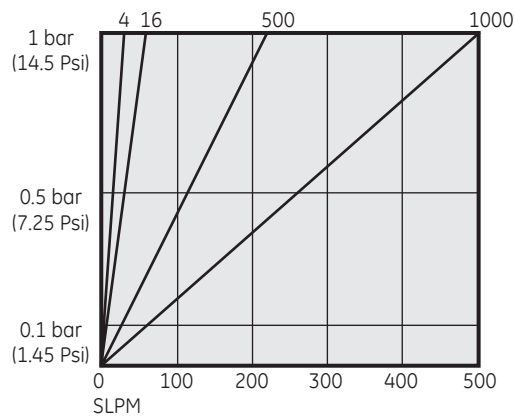
Catalog Number	PTFE Product	Membrane	Description		
			Housing	Connections <sup>1</sup>	Qty/Pk
6713-0425	Polyvent 4	0.2 µm	25 mm disc	ML/FLL 1/8"/3 mm ID Tube	50
6713-1650	Polyvent 16	0.2 µm	50 mm disc	SB 6 to 10 mm 1/4 to 3/8"	10
6713-1651	Polyvent 16	0.2 µm	50 mm disc	SB 6 to 10 mm 1/4 to 3/8"	100
6713-5036	Polyvent 500	0.2 µm	Capsule 36 (Vented)	SB 6 to 10 mm 1/4 to 3/8"	1
2103	Sterivent 36	0.2 µm	Capsule 36 (Vented)	SB 10 to 13 mm 3/8 to 1/2"	1
6713-1075	Polyvent 1000	0.2 µm	Capsule 75 (Vented)	SB 10 to 13 mm 3/8 to 1/2"	1
2107	Sterivent 150	0.2 µm	Capsule 150 (Vented)	SB 10 to 13 mm 3/8 to 1/2"	1
2108	Sterivent 150	0.2 µm	Capsule 150 (Vented)	1 1/2" Sanitary	1

**Maximum Pressure:** 2 bar (29 psi)  
**Housing:** Polypropylene  
**Filter Media:** PTFE 0.2 µm  
**Flow Direction:** Bi-directional.  
**Connectors:** For 3 mm to 13 mm (1/8 to 1/2 inches) ID tubing – See specific product.  
**Autoclavability:** Autoclave at 121°C (132°C Max) for 20 minutes. Multiple autoclave cycles are possible, however reuse is the responsibility of the operator, who should protect the device from cross contamination and detect loss of integrity by appropriate testing.  
**Integrity Testable:** WBT, Water Breakthrough - Test from **outlet side only** (Atmosphere connection is indicated by the label or the flow arrow.) - See instructions. I

However, it has been reported that no viable organisms have been found on the downstream side of hydrophobic membranes presented with a biological challenge at pressures below the WBT pressure (1, 2, 3 and 4)

1. *Medical Devices Bulletin*, March 1992, Vol. X, No. 3
2. Olsen, W.P.L. Vanden Houten, and J.E. Ellis, "Sterile Vent filter Function Test" *Journal of Parenteral Science and Technology*, March-April 1981, Vol.35, No. 2, pp. 35-36.
3. Port, F.K., and I.A. Bernstein, "Hepatitis Risk from Hemodialysis Pressure Monitors" *Proceedings of the Third Meeting of ISAO*, 1981, Supplement to Vol. 5, pp. 638-641.
4. Vincent, M.E., and J.C. Glorioso, "Evaluation of Vacuum/Suction Safety Devices in Preventing Transmission of Human Virus Pathogens" *American Clinical Laboratory*, January 1989.
5. Hinds, W.C., *Aerosol Technology*, A Wiley-Interscience Publication, 1982, p. 175.
6. *Ibid*, p. 185.

## Typical Air Flow Rates



## Polyvent Filters Retention and Hydrophobicity

Particle retention of membrane filters in air streams is more efficient than in liquid streams by a factor of 10 or more. (2, 6) Retention of particles in liquids is principally by mechanical entrapment while retention in air is by interception, inertial impaction, diffusion, gravitational setting, and electrostatic attraction. (5)

## Polyvent Filters (PTFE Membranes) are Rated 0.2 µm, in Liquid

Retention of aqueous solutions with particulates by hydrophobic microporous membranes is a function of their WBT value, rather than the pore size. (4)

Liquid water presented to the surface of a hydrophobic membrane at a pressure lower than the WBT pressure will be blocked by the membrane. Water in its vapor form may pass through a hydrophobic membrane as single molecules, which may condense again to form a liquid on the downstream side.

## Legal.

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