PTFE Single-Use Capsule Filters

MAIN FEATURES & BENEFITS

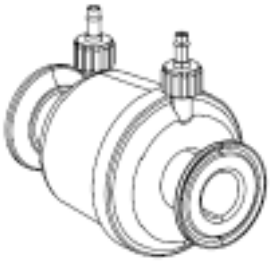
- Each element is 100% integrity tested.
- Compliance with EU and USA requirements for food contact use under Regulation (EC) No. 1935/2004 and FDA Colde of Federal Regulation (CFR) Title 21.
- Certificate of Quality (COQ) included in box with each element.
- Validation Guide available upon request.

PRODUCT DESCRIPTION

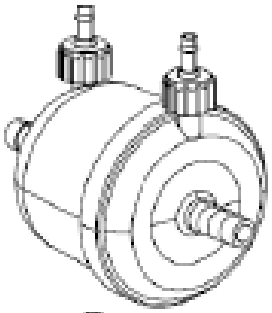
Donaldson PTFE Single-Use Capsule filters are ready to use cartridge filters sealed inside of a polypropylene housing. Each capsule is a sterilized (ETO), pleated, hydrophobic PTFE membrane filter for use with processed food and beverage applications.

		Actual Length	Connection	Part Number
2 Inch PTFE Single-Use Capsule Filter	0.22 Micron	124 mm (4.86 in)	1.5" Tri-Clamp	AG1341901
		130 mm (5.12 in)	1/2" Stepped Hose Barb	AG1342101
		128 mm (5.02 in)	1/4" Stepped Hose Barb	AG1342301
	0.45 Micron	124 mm (4.86 in)	1.5" Tri-Clamp	AG1342001
		130 mm (5.12 in)	1/2" Stepped Hose Barb	AG1342201
		128 mm (5.02 in)	1/4" Stepped Hose Barb	AG1342401
5 Inch PTFE Single-Use Capsule Filter	0.22 Micron	159 mm (6.24 in)	1.5" Tri-Clamp	AG1342501
		163 mm (6.40 in)	1/2" Stepped Hose Barb	AG1342701
		160 mm (6.30 in)	1/4" Stepped Hose Barb	AG1342901
	0.45 Micron	159 mm (6.24 in)	1.5" Tri-Clamp	AG1342601
		163 mm (6.40 in)	1/2" Stepped Hose Barb	AG1342801
		160 mm (6.30 in)	1/4" Stepped Hose Barb	AG1343001

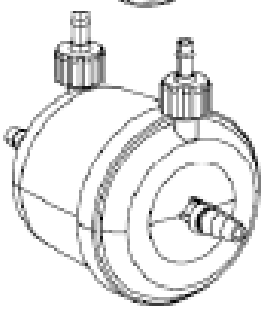
*All Air-Vent connections are a 1/4"Single Stepped Barb connection



1.5" Tri-Clamp Connection



1/2" Stepped Hose Barb Connection



1/4" Stepped Hose Barb Connection

MATERIAL COMPLIANCE

QUALITY TEST

All products have been inspected and released by Quality Assurance as having met the following requirements:

- All capsule filters are integrity tested to verify compliance with established quality and design specifications and to assure consistent and reliable performance.

- This capsule filter was staged, assembled, integrity tested, and packaged in an ISO 14644-1 Class 7 clean room facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality System Standard.

MATERIAL COMPLIANCE USA

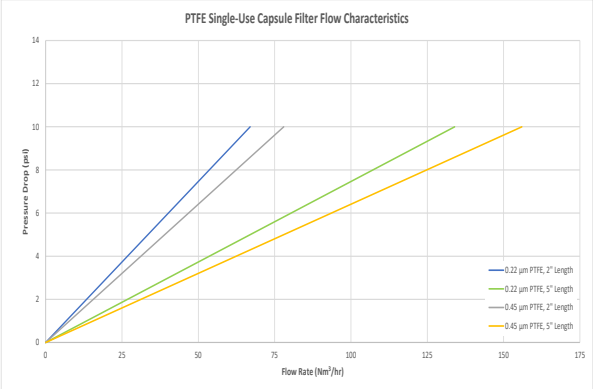
The PTFE Single-Use Capsule filters meet the US requirements for Food Contact Use in accordance with the Code of Federal Regulations (CFR) Title 21, and USP Class VI, <88> biological reactivity tests in vivo.

Filter Materials		CFR Title 21
Membrane	PTFE	§ 177.2440
Support Layer	Polypropylene	§ 177.1520
Molded Components	Polypropylene	§ 177.1520
O-Rings	Silicone	§ 177.2600

MATERIAL COMPLIANCE EU

The PTFE Single-Use Capsule filters meet the guideline for Food Contact Use as given in European Regulation (EC) Number 1935/2004.
All plastic components meet the requirements of (EU)No. 10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs.
Components manufactured per GMP requirements under EC 2023/2006.
This capsule filter has components that may contain tallow derived additives.
These tallow derived materials meet the requirements laid down in the Regulations (EC) No. 1069/2009, and (EU) No. 142/2011, and the „Note for Guidance“ EMA/410/01.

FLOW CHARACTERISTICS



OPERATING PARAMETERS/INTEGRITY TEST VALUES

Bubble Point Test		
Filter Grade	Minimum Bubble Points	
0.22 µm	> 1.4 bar (20 psi)*	
0.45 µm	> 0.8 bar (12 psi)*	
Water Intrusion Test Value		
Filter Grade	2 Inch	5 Inch
0.22 µm	≤ 0.3 mL/min @ 2 bar	≤ 0.5 mL/min @ 2 bar
0.45 µm	≤ 0.3 mL/min @ 1 bar	≤ 0.5 mL/min @ 1 bar
Max. Operating Conditions: 4 bar @ 25°C / 2 bar @ 80°C		
Autoclave 100 x 30 minute cycles at 121°C (250°F)		

*The values are based on a mixture of 70% IPA / 30% water as wetting fluid at 25°C.

Integrity test to be done by Bubble Point and Water Intrusion Test.

Bacterial Retention testing is correlated using the bubble point integrity test values.

- For information on test equipment or test services, please contact your Donaldson Sales Engineer and visit our website at www.donaldson.com!

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Donaldson Company, Inc.
Minneapolis, MN

Contact us

Important Notice: Many factors beyond the control of Donaldson can affect the use and performance of Donaldson products in a particular application, including the conditions under which the product is used. Since these factors are uniquely within the user's knowledge and control, it is essential the user evaluate the products to determine whether the product is fit for the particular purpose and suitable for the user's application. All products, specifications, availability and data are subject to change without notice, and may vary by region or country.

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