ROKI TECHNO

Surface (Membrane)

CERTAIN-PORE

ACTL Type

Major Applications

Tank vent (*Excluding WFI tank)

Sterilization of compressed air and various gases

Mixing air,
Positive pressure air, N_2 gas

*It is not recommended to use it under conditions where the temperature is always kept above 80℃ (176℉), such as in a WFI tank.

Quality standards

- Manufactured in ISO 9001 certified plant
- FDA 21 CFR compliant
- USP Class VI plastic biological safety testing compliant
- Certificate of quality is attached to the product
- 100% integrity test by diffusion test
- Traceability by lot number and serial number

Features

- Bacterial challenge test with *Brevundimonas diminuta* (ATCC 19146) in liquid and aerosol
- Hydrophobic PTFE membranes with low pressure drop and high airflow
- Use of highly durable materials that are less likely to be damaged by heat

Advantages

- High reliability for sterilization
- Creating a sterile environment for the manufacturing process
- High air supply efficiency
- Can be used repeatedly for high temperature in-line steam

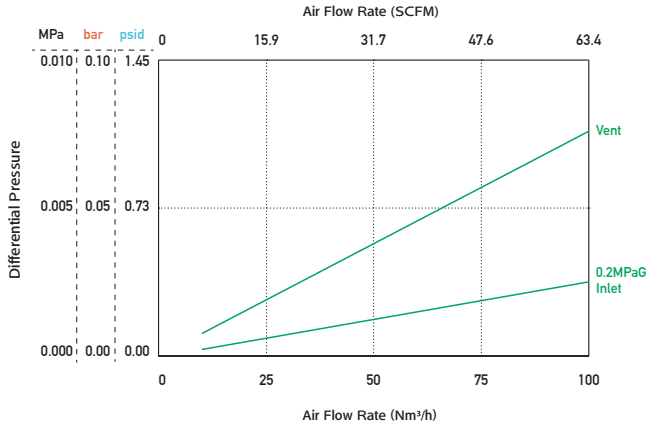
Specifications

Grades		002
Micron Ratings		0.2μm
E.F.A.		0.81m²/250mm
Materials	Media	Hydrophobic PTFE Membrane
	Core/Cage/Support	Polypropylene
End Cap		Polypropylene
Maximum ΔP		0.53MPa at 40℃ (76.9psi at 104°F)
Dimensions	Length	125／250／500／750 mm
	O.D.	70.0mm
	I.D.	29.5mm
Bubble Point		≧110kPa (60%IPA)
Diffusion		≦25ml/min (per 250mm, 60%IPA, 0.1MPa)
Water Intrusion		≦1.0ml/min (per 250mm, Pure Water, 263kPa)
Available sterilization methods		Inline steam, Autoclave
Inline steam sterilization		For Silicone O-rings : 142 ℃ (287.6°F) x 30 minutes x 200 cycles in positive pressure and 50 cycles in back pressure／ For FEP encapsulated silicone O-rings : 100℃ (212°F) x 60 minutes x 1cycles in back pressure*1

*If you need further information on specifcations (length, end cap type, etc.), please contact us.
*1 Do not use the filter once removed from the housing.

Differential Pressure vs Flow Rate

Fluid: Air / Cartridge Length: 250mm



*SCFM: Temperature 21.1℃ (70°F), Humidity: 0% RH, Standard pressure (101.3kPa)

Microbial removal performance

	Biological Indicator	LRV*
Liquid	*Brevundimonas diminuta* (ATCC19146)	>7
Aerosol	*Brevundimonas diminuta* (ATCC19146)	>7

*LRV represents Log Reduction Value (Refer to JIS K3835)
*Bacterial challenge level is more than 1×10^7CFU/cm².

Particle Removal Efficiency (Gas)

0.003 μm : >99.999%

* NaCl (>0.003 μm) CNC particle analysis.

Estimated continuous use period by operating temperature

60°C (140°F) dry hot air 12 months

Validation items

Items	Evaluation criteria
Bacteria Challenge (Liquid)	Retention capability of *Brevundimonas diminuta*(ATCC19146) in liquid challenge test at 10^7CFU/cm²
Bacteria Challenge (Aerosol)	Retention capability of *Brevundimonas diminuta*(ATCC19146) in aerosol challenge test at 10^7CFU/cm²
Durability for steam	Maintains integrity correlated with microbial capture performance under the conditions of 142 ℃ x 30 minutes x 200 cycles in positive pressure and 50 cycles in back pressure
Endotoxin (LAL)	Extraction volume with water is less than 0.25 EU/mL and complies with USP 〈85〉 requirements.
Evaporation residues	After autoclave sterilization, the evaporation residue after immersion in ultrapure water, ethanol, and IPA for 4 hours is less than 20 mg for each 250 mm cartridge

Items	Evaluation criteria
Potassium permanganate consumption	Meets the requirements of the USP Oxidizable Substance Test by flushing with at least 1,000 mL of ultrapure water after autoclaving
Fiber release	Meets the requirements of non fiber release which defined in 21 CFR210.3(b)(6)
Particle component flow out	Meets the requirements for particle contained in injection solution by the test method based on USP 〈788〉
Filter/component toxicity	USP 〈88〉 Biological Reactivity Tests For Class VI Plastics compliant
Cytotoxicity	Meets the requirements of the USP 〈87〉 Biological Reactivity Tests, In Vitro

*Please refer to the Validation Guide for detailed testing information.

Ordering Information

Length	Product Type	Micron Rating	O-Ring	End Cap Code	Packaging Code
5 0 0 L	-ACTL-	002	J	7	B
125 = 125mm 250 = 250mm 500 = 500mm 750 = 750mm		0.2 μm	J = Steam Resistant Silicone B = FEP Encapsulated Silicone	6 = 2-226 O-Ring 7 = 2-226 O-Ring + Fin	A = 1pc B = 6pcs C = 10pcs F = 25pcs

End Cap Code

Code 6

Code 7

*The contents of the catalog are subject to change without notice.
*The performance data listed in the catalog are Typical values obtained under specific conditions based on our tests.

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Manufacturing is based on our Quality Management Systems that meet ISO9001 standards.
Scope
Design, Development, manufacture, and sales of filter cartridges, housings and filtration equipment.

ISO 9001 JQA-QMA16323 JAB MS CM009

9th Issue
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