GORE® Microfiltration Media for Medical Devices
Series 101 for use in Infusion Systems



ENABLING MEDICAL DEVICE MANUFACTURERS TO DESIGN RELIABLE IV FILTERS

GORE® Microfiltration Media for Infusion Systems is engineered to enable efficient removal of gas bubbles from IV lines, while reliably retaining fluids and maintaining sterility. This unique combination of performance and versatility supports the rigorous demands of modern medical device manufacturing.

Key Features and Benefits

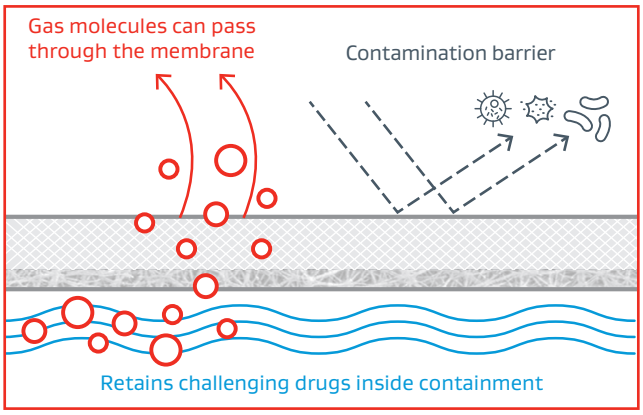
- Efficient, fast and reliable evacuation of gas bubbles from the infusion line while sustaining sterility
- Ability to retain low surface tension liquids within the enclosure and infusion line
- Robustness designed for common integration methods
- Proprietary microstructure enables fluid containment
- Consistent microstructure results in dependable performance and contributes to integration efficiency
- Can be suitable for irradiation sterilization*
- Biocompatibility to ISO 10993

Scope of Use

GORE Microfiltration Media for Medical Devices Series 101 is a key component for IV filter venting solutions used in gravity and pump infusion systems in hospital and home-care applications.

When the laminate is integrated correctly by the customer in an appropriate device design, GORE Microfiltration Media for Medical Devices Series 101 can be suitable for irradiation sterilization.*

Vent Functionality



GORE Microfiltration Media Performance[1]

Product	Reference pore size (µm)	Airflow[2] (l/h)	WEP[3] bar (psi)	Thickness[4] mm (mil)	BFE/ VFE[5] (LRV)
Series 101**	0.03	2.4	19.9 (288.63)	0.23 (9.1)	≥7

** "Sterilizing Grade" as described by PDA Tech Report 40 and tested per ASTM F838

1. Typical values measured over approximate two-year period.
2. Measured at 2.99 cm^2 and 1.2 kPa differential pressure with ATEQ measurement system.
3. Pressure point for instantaneous D.I. water intrusion.
4. Mechanical measurement equipment.
5. BFE/VFE performance is mechanical in nature. No antibacterial or antiviral coatings or agents are added. Contact Gore for test method details.

*Irradiation sterilization, whether gamma or electron beam or x-ray, is known to degrade PTFE mechanical properties (including but not limited to loss of tensile strength, physical and chemical changes, etc.). The extent of degradation depends mainly on the irradiation dose to which the ePTFE (expanded PTFE) membrane is exposed. The ultimate performance of the ePTFE laminate is dependent upon device design, integration/welding into the device or housing, sterilization conditions, and application needs. It is the responsibility of the medical device manufacturer to validate the device performance after the ePTFE laminate has been integrated into the device and after exposure to the desired sterilization process.

Together, improving life

Performance in Use

The following performance data is based on material conditioned with a gamma irradiation set point of 50 kGy.

Samples were welded onto polymeric discs with a circular unsupported area of 87 mm² (10.5 mm diameter).

Liquid Retention Performance After Gamma Irradiation

Liquid retention performance was tested and evaluated using gamma conditioned samples.

Liquid Entry Pressure testing was performed by exposing the samples to selected low-surface-tension fluid surrogates designed to replicate challenging application conditions. Tests were conducted under typical operating pressures to detect any signs of leakage.

Test Fluid	Surface Tension	Differential Pressure	Time at Pressure	Sample Size	Results
Distilled Water	~72 mN/m (~72 dynes/cm)	0.8 bar (12 psi)	120 hours	4	No leaks observed
Total Parental Nutrition (TPN) surrogate	~35 mN/m (~35 dynes/cm)	2.0 bar (29 psi)	0.5 hours	12	No leaks observed
Chemotherapy surrogate	~40 mN/m (~40 dynes/cm)	1.2 bar (18 psi)	3 hours	29	No leaks observed

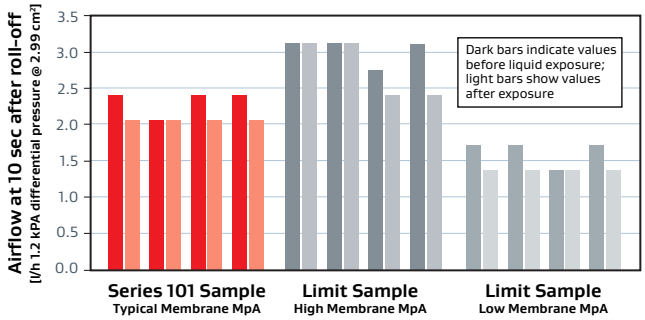
Series 101 passed 100% without any sign of leakage in active vent and weld area.

Airflow Recovery Performance after Gamma Irradiation

Airflow Recovery performance was tested and evaluated using gamma conditioned samples.

Airflow performance was tested pre and post exposure to low-surface-tension fluid surrogate representing Total Parenteral Nutrition with a free surface tension of ~35 mN/m. Fluid-to-material contact time lasting 30 sec.

Airflow Recovery Performance after Gamma Irradiation (irradiation set point: 50 kGy)



Three material lots, targeted at typical, high, and low membrane mass per area (MpA), were analyzed within ISO13485 compliant design verification.

Series 101 with typical MpA shows a minimum Airflow Recovery of 86 % and an average Airflow Recovery of 93 %.

Gore PharmBIO Products

Our technologies, capabilities, and competencies in materials science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers. The products in the Gore PharmBIO Products' portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

All technical information and advice given here is based on our previous experiences and/or test results. We give this information to the best of our knowledge, but assume no legal responsibility. Customers are asked to check the suitability and usability of our products in the specific applications, since the performance of the product can only be judged when all necessary operating data is available. Gore's terms and conditions of sales apply to the purchase and sale of the product.

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