

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 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

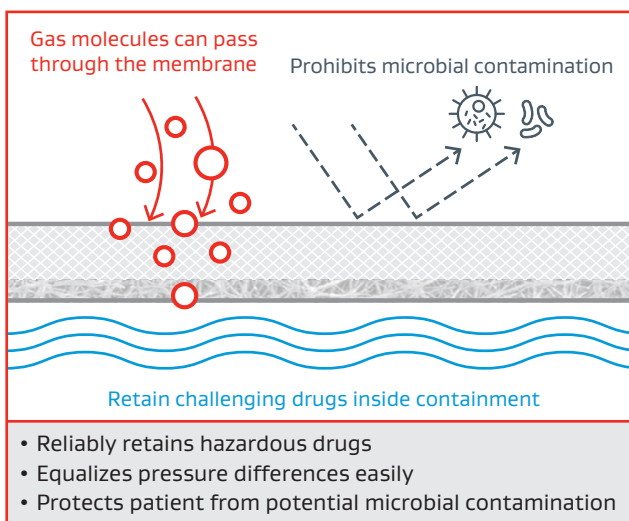
- Efficient, fast and reliable evacuation of gas bubbles from the infusion line while sustaining sterility
- Ability to retain low surface tension liquids within the enclosure and infusion line
- Robustness designed for common integration methods
- Proprietary microstructure enables fluid containment
- Consistent microstructure throughout rolls results in dependable performance and contributes to integration efficiency
- 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 Performance¹

Product	Airflow ² (l/h)	WEP ³ (bar)	Thickness ⁴ (mm)	BFE/VFE ⁵ (LRV)
Series 101	2.4	19.9	0.23	≥7

1. Typical values measured over approximate two-year period.

2. Measured at 2.99 cm² and 1.2 kPa differential pressure with ATEQ measurement system.

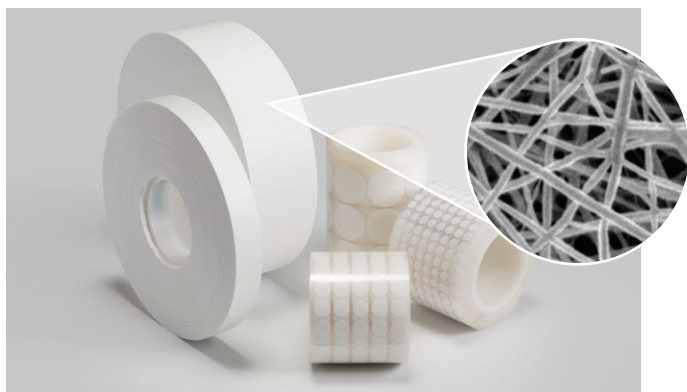
3. Pressure point for instantaneous D.I. water intrusion.

4. Mechanical measurement equipment.

5. 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.

Unique Membrane Structure



Series 101 features a bi-layer construction: a hydrophobic expanded polytetrafluoroethylene (ePTFE) membrane with a three-dimensional pore structure for optimal functionality, supported by a non-woven polyethylene terephthalate (PET) layer that enhances handling.

Ordering Information

Please contact Gore for ordering samples of GORE Microfiltration Media and for more information.

Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer 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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