

TRUSTED SOLUTIONS

for Medical Device Manufacturers



GORE® MICROFILTRATION MEDIA FOR MEDICAL DEVICES

Trusted to provide consistent performance, helping deliver reliable patient, personnel and equipment protection when it matters most.

- Best-in-class technical reliability
- Consistent product integration enabling high productivity
- Rigorous Quality Management System





GORE® Microfiltration Media for Medical Devices delivers superior performance to the medical industry in applications for non-implantable medical devices and is the material of choice when performance is critical.

Gore products enable rapid pressure equalization and degassing, while containing liquids and preventing contamination. Gore products with high-level, aerosolized microbial retention provide reliable protection for patients as well as health care personnel, environments and equipment.

Our diverse membrane portfolio is engineered to a broad range of retention and airflow characteristics to meet a variety of application needs.



UNIQUE CAPABILITIES OF GORE® MICROFILTRATION MEDIA

- *Aerosolized microbial and particulate retention with high airflow*
- *Liquid containment with high airflow*

Other Characteristics

- *Biocompatible*
- *Chemically inert*
- *Sterilizable*

PRODUCTIVITY AND EFFICIENCY

- *Consistent product performance and quality*
- *Enables ease of integration through ultrasonic welding and heat staking*
- *Compatible with common sterilization methods* such as ethylene oxide*

VERSATILITY AND CUSTOMIZATION

GORE Microfiltration Media can be engineered for specific applications:

- *Broad range of membrane performance*
- *Variety of non-woven support layers*
- *Roll goods in custom-slit widths*
- *Custom and complex die-cut parts*

*Irradiation sterilization methods such as gamma or e-beam is not recommended for PTFE because they may damage or degrade the mechanical and barrier properties of the product. Should a customer wish to use a GORE membrane in applications requiring radiation sterilization, please contact Gore.



FITNESS FOR USE

We are passionate about product performance and ensuring that the product does what we say it will do.

Gore is the supplier of choice where reliable, high performance is critical in applications such as: drug transfer and IV infusion systems, hemodialysis blood sets, point-of-care diagnostics, ostomy and urology devices, surgical suite equipment and hearing instruments.

We partner with customers to determine how we can apply our expertise in fluoropolymer science to deliver value-added solutions. Then, our products are rigorously tested to ensure they deliver reliable performance and suit your needs the first time and every time.

The GORE Microfiltration Media portfolio of products meets the applicable biological evaluation tests described in BS EN ISO 10993-4, -5, -6, -10, and -11, as relevant for medical devices.

MANAGING RISK

Gore products allow device manufacturers to keep pace with changing industry needs. As industry regulations become more stringent, Gore's understanding of these requirements and our robust design control practices can help you minimize risk. We maintain adherence to our disciplined quality system to ensure we meet rigorous standards for life sciences products.

- ISO 13485 and ISO 15378 certification
- Products manufactured under relevant cGMP
- Clean rooms maintained to ISO Class 8 requirements

Gore customers also value our expertise in providing high-quality, consistent products with a proven track record of being a low-risk, reliable supplier.



UP TO 99.9999999% RETENTION

Gore provides products in a range of aerosolized microbial retention capabilities. Depending on airflow needs:

- Bacterial Filtration Efficiency (BFE) ranges between LRV6 and LRV9
- Viral Filtration Efficiency (VFE) ranges between LRV3 and LRV9

$$LRV = \log_{10} \left(\frac{\text{Upstream Concentration}}{\text{Downstream Concentration}} \right)$$

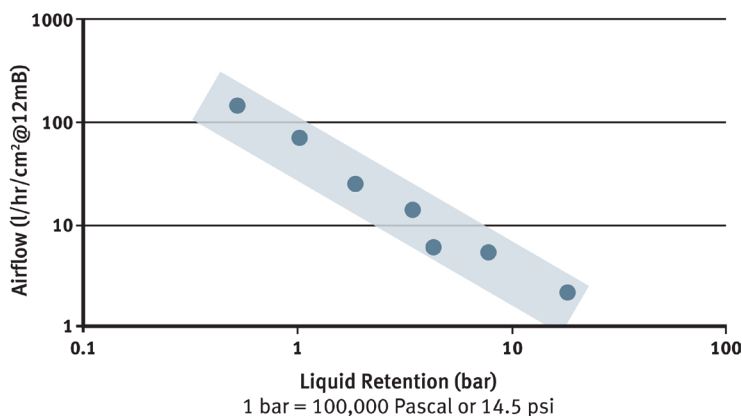
For more information, visit www.gore.com/medOEM



Helping you deliver performance and protection for patients, personnel and equipment.

Our products are engineered to meet a wide variety of application needs spanning a broad range of retention and airflow combinations.

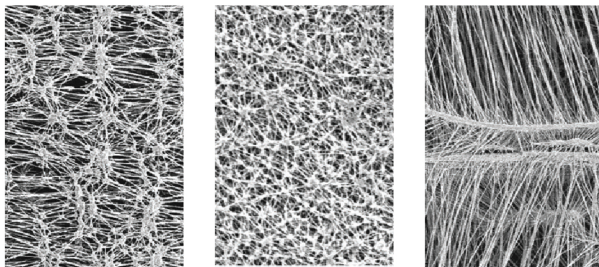
AIRFLOW VS. LIQUID RETENTION



UNPARALLELED EXPERTISE

Medical device designers and manufacturers have trusted Gore for more than 35 years to deliver expanded polytetrafluoroethylene (ePTFE) membrane solutions to vent and protect sensitive equipment.

Gore's unparalleled expertise in tailoring ePTFE delivers innovative materials that enable reliable device performance and protection of equipment, health care workers and patients.



Sample SEM Magnifications of ePTFE Structures Engineered for Specific Applications

Gore® Microfiltration Media for Surgical Suction

Effective protection of surgical suction vacuum systems for a safe operating room and hospital environment.

GORE™ Membranes provide equipment manufacturers with reliable system protection enabling safe and effective surgical procedures. Unlike other barrier materials, GORE Membrane is constructed of ePTFE to provide high aerosolized microbial and particle retention combined with high airflow and high liquid containment. Our unique solution enables use in both traditional and electro-surgical procedures.

Gore® Microfiltration Media for Drug Preparation

High airflow vent with liquid and solid retention properties for fast, safe operation of open and closed delivery systems.

GORE Membranes maintain the integrity of the system by preventing the ingress of contaminants into the system and containing the drug product, while providing pressure equalization to enable rapid drug transfer.

Gore PharmBIO Products

Our technologies, capabilities and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory and quality needs of medical device manufacturers, as well as pharmaceutical and bioprocessing customers.

The products in the Gore PharmBIO portfolio are tested and manufactured under our stringent quality system. These high-performance products provide creative solutions to our customers' design, manufacturing and performance-in-use needs.

Important Note:

GORE® Microfiltration Media products are strictly for use as vents or filters in non-implantable, external medical devices and pharmaceutical applications. They are not intended to be used as a component of an implantable medical device nor are they intended to be implanted in the body. Please inform us in advance if you intend to use Gore Microfiltration Media products in a medical device or pharmaceutical application.

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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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