GORE® Microfiltration Media
for Medical Devices, Series 602
for use in Ostomy Bags

ENSURING FUNCTIONALITY AND RELIABILITY OF OSTOMY BAGS

GORE Microfiltration Media for Ostomy Pouches mitigates vent leakage and pouch ballooning, even after fluid contact, with its high liquid entry pressure, high airflow, and oleophobic treatment. Manufacturers also benefit from enhanced production efficiency due to Gore's repeatable membrane performance and robust supply chain.

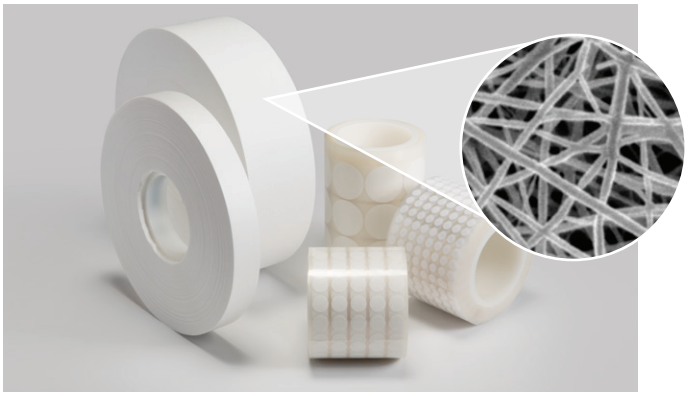
Key Features and Benefits

- High airflow mitigates pouch ballooning
- Proprietary microstructure enables fluid containment
- Durable oleophobic treatment enables prolonged use and greater patient activity
- Consistent microstructure throughout rolls results in dependable performance and contributes to integration efficiency
- Polyester support layer stabilizes material during processing, optimizing material usage

Regulatory Compliance

- GORE Microfiltration Media for Medical Devices are manufactured following the applicable material quality and regulatory requirements.
- Please contact Gore for current applicable compliance statements and quality control information

Unique Filter Membrane



This proprietary expanded polytetrafluoroethylene (ePTFE) membrane achieves airflow rates you would expect from a far larger membrane area.

Quality Statement

- GORE Microfiltration Media for Medical Devices are manufactured following the applicable material quality requirements, including relevant Good Manufacturing Processes as defined in the Gore PharmBIO quality system which is certified to ISO 13485.
- Each lot is quality-controlled in accordance with an agreed upon customer specification. Lot data can be provided on a Certificate of Analysis.
- Contact Gore for more information.

Together, improving life

Controlled Environment

- Assembly operations, final inspection, and packaging for GORE® Microfiltration Media are conducted in a cleanroom environment that employs a non-viable particulate monitoring program consistent with particle levels as defined for ISO 8 designation.

Ordering Information

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

GORE Microfiltration Media, Series 602, Performance

Product Performance

Airflow	• Nominal airflow of GORE Microfiltration Media: 273.6 l/h • Lots are tested for release using Gore's QATM 0217, which uses ATEQ measurement systems • Airflow is measured per 2.99 cm^2 at 1.2 kPa differential pressure
Water Entry Pressure	• Nominal water entry pressure (WEP): 8.6 psi • Lots are tested for release using Gore's QATM 0584, measuring the pressure point for instantaneous D.I. water intrusion
Laminate Thickness	• Nominal material thickness: 8.9 mils • Lots are tested for release using Gore's QATM 0201 using mechanical measurement equipment

Process & Integration Guidance

Process	GORE Microfiltration Media for Medical Devices are designed for manual, semi- and fully automated production. Please contact us for further support.
Integration	GORE Microfiltration Media for Medical Devices are designed for use with integration methods like ultrasonic and heat welding. Welding parameters are dependent on device design and integration technology. Please contact us for further support.

Material Characteristics	
Membrane material	Polytetrafluoroethylene (PTFE)
Membrane structure	Expanded PTFE with a three-dimensional pore structure
Membrane characteristic	Oleophobic
Support material	PET Nonwoven
Form	GORE® Microfiltration Media can be provided in different forms on 3-inch core rolls: • Rolled Goods in customized slit widths • Die Cut parts in customized designs Contact us for detailed custom part configuration information
Biocompatibility	Representative samples of the raw materials used to manufacture the Gore products listed above have been tested and met the applicable requirements of the following biological evaluation tests: • ISO 10993-4 Tests for complement activation assay, hemolysis and coagulation (PTT) • ISO 10993-5 Tests for in vitro cytotoxicity • ISO 10993-10 Tests for skin sensitization • ISO 10993-11 Tests for systemic toxicity • ISO 10993-23 Tests for skin irritation
Shelf Life	The shelf life of GORE Microfiltration Media for Medical Devices is one year when stored in the original packaging at the recommended storage conditions.*

*Storage Conditions: Product should be stored in the original packaging. It is also recommended to store at room temperature and out of direct sunlight

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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