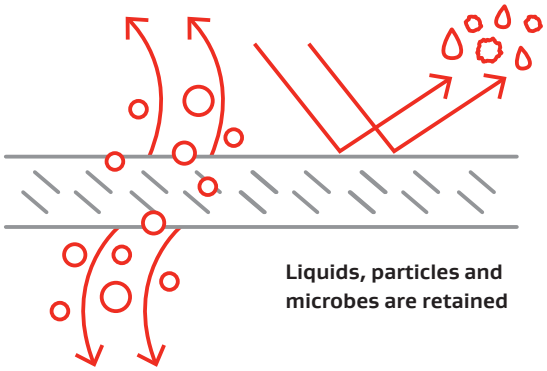
GORE® Microfiltration Media
for Negative Pressure
Wound Therapy

ENSURING PROPER FUNCTIONALITY AND LONGEVITY OF NEGATIVE PRESSURE WOUND THERAPY SYSTEMS

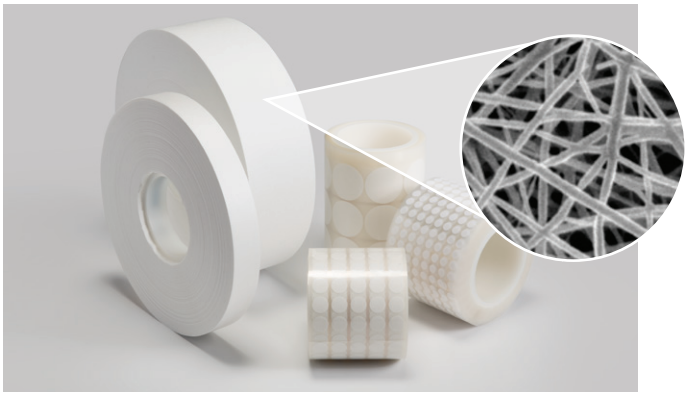
GORE® Microfiltration Media for Negative Wound Pressure Therapy (NPWT) act as a filter which help medical device manufacturers for NPWT to ensure proper functionality and longevity of the NPWT systems. Unlike other barrier materials GORE Microfiltration Media provide exudate containment and aerosol filtration as well as proper functioning of the equipment's control units.

NPWT Container Filter Functionality



- Wound exudate retention
- Microbial retention
- Vacuum control, pressure equalization, low pressure drop

Unique Filter Membrane



This proprietary expanded polytetrafluoroethylene (ePTFE) membrane delivers high bacterial and viral aerosol filtration efficiency, while achieving airflow rates you would expect from a far larger membrane area.

Key Features and Benefits

High airflow performance of GORE Microfiltration Media allows proper equipment function. GORE Microfiltration Media maximizes functionality of NPWT equipment control units and manages wound exudate retention.

- Low pressure drop and high airflow
- Aerosol Bacterial Filtration Efficiency (BFE) of 99.99999% (log 7 reduction)
- Viral Filtration Efficiency (VFE) of 99.99999% (log 7 reduction)
- Effective retention of wound exudate to protect equipment, personnel, and patients

Together, improving life

GORE® Microfiltration Media Performance*

Product Performance	
Airflow**	• The nominal airflow of GORE® Microfiltration Media for NPWT is 44.6 l/h (hydrophobic product) and 46.9 l/h (oleophobic product) • 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**	• The nominal water entry pressure (WEP) mean of GORE Microfiltration Media for NPWT is 185.9 kPa (hydrophobic products) and 163.3 kPa (oleophobic product) • Lots are tested for release using Gore's QATM 0584, measuring the pressure point for instantaneous D.I. water intrusion
Laminate Thickness**	• The nominal material thickness mean of GORE Microfiltration Media for NPWT is 0.23 mm • Lots are tested for release using Gore's QATM 0201 using mechanical measurement equipment
Bacterial Filtration Efficiency (BFE)	• GORE Microfiltration Media for NPWT was designed to provide a minimum individual Aerosol Bacterial Filtration Efficiency (BFE) of 99.99999 % or a Log Reduction Value of 7 • Gore's Quality Assurance Test 0807 measures Aerosol Filtration Efficiency • The aerosol microorganism retention results for BFE have been statistically correlated to Gore's Quality Assurance Test 0807 **Related BFE Customer Information** • Retention of aerosolized bacteria was measured using Brevundimonas diminuta as the model organism. A standard organism used for validating membrane filters, Brevundimonas diminuta (National Collection of Industrial, Food and Marine Bacteria (NCIMB) 11091, ATCC® 19146™) is a gram-negative bacteria between 0.4 and 1.0 micrometer in diameter. • BFE tests are conducted with a challenge load of >$1x10^8$ colony forming units (cfu) and ≥90% relative humidity to promote cellular viability
Viral Filtration Efficiency (VFE)	• GORE Microfiltration Media for Surgical Suction was designed to provide a minimum individual Aerosol Viral Filtration Efficiency (VFE) of 99.99999 or a Log Reduction Value of 7 • Gore's Quality Assurance Test 0807 measures Aerosol Filtration Efficiency • The aerosol microorganism retention results for VFE have been statistically correlated to Gore's Quality Assurance Test 0807 **Related VFE Customer Information** • Bacteriophage aerosol retention tests were conducted with MS-2 coliphage (National Collection of Industrial, Food and Marine Bacteria (NCIMB) 10108). This coliphage is an unenveloped, single-stranded RNA model virus, 23 nanometers (nm) in diameter with a molecular weight of 3.6 x 10^6 Daltons. • VFE tests are conducted with a challenge load of >$1x10^8$ plaque forming units (pfu) and ≥90% relative humidity to promote cellular viability

* The above data are based on two years of manufacturing lot data, representing 310 lots, and 99% of the manufactured product.

**Specified performance characteristics and consistency of the released material is ensured by Gore Quality Assurance Test Method (QATM) testing.

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

Product Performance (continued)

Biocompatibility	GORE® Microfiltration Media for NPWT was designed to meet the following Biocompatibility requirements • ISO 10993 – "Externally Communicating Devices; Blood Path Indirect; Prolonged Contact Duration (24 hours – 30 days)" Biocompatibility testing was performed by a certified laboratory and passed the requirements of: • 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 is one year when stored in the original packaging at the recommended storage conditions.***

Laminate Characteristic

Membrane material	Polytetrafluoroethylene (PTFE)
Membrane type	Expanded PTFE with a three-dimensional pore structure
Membrane characteristic	Hydrophobic or oleophobic properties
Backer 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

Intended Use

- GORE® Microfiltration Media for NPWT is a key component material for hydrophobic and oleophobic, antibacterial, antiviral aerosol filters to protect equipment and environment used in hospital and homecare NPWT applications

Performance in Use

- The nominal airflow of GORE Microfiltration Media for NPWT corresponds to an application airflow of 223 l/h/cm^2 at 125 mmHg (16.7 kPa, 2.6 psi) differential pressure
- The nominal water entry pressure of GORE Microfiltration Media for NPWT enables to withhold a typical wound exudate surrogate for over 30 minutes. A typical exudate exposure at a differential pressure of 300 mmHg (40.0 kPa, 5.8 psi) can be tolerated for over 1 min, which is the typical time for NPWT equipment to give an alarm.
- The consistent thickness (standard deviation of 0.018 mm) of GORE Microfiltration Media for NPWT enables an effective integration using standard integration methods like ultrasound and heat

Operating Conditions

- GORE Microfiltration Media for NPWT can be used applying application specific operating conditions used for NPWT equipment
- GORE Microfiltration Media for NPWT are designed to be compatible to typical integration methods, like ultrasonic and heat integration. Welding parameters are dependent on the device design, materials, and integration equipment.
- Contact Gore for integration support

Regulatory Compliance

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

Quality Statement

- GORE Microfiltration Media 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 produced lot is controlled according to an agreed upon customer specification and lot data can be provided on a Certificate of Analysis.
- For quality control information: contact GORE for more information

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 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.

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