GORE® Microfiltration Media
for Infusion Sets

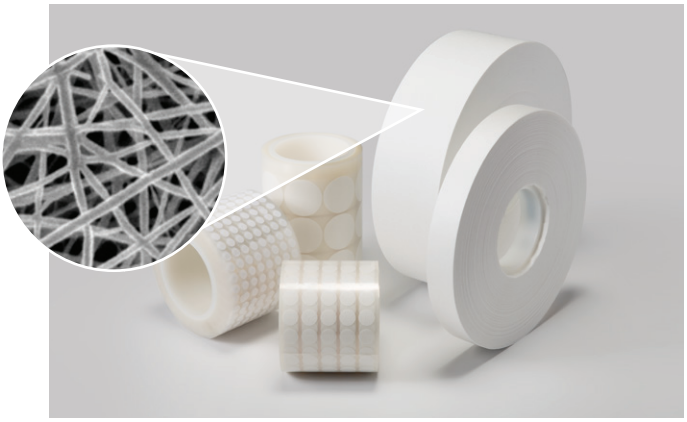
ENABLING MEDICAL DEVICE MANUFACTURERS TO DESIGN RELIABLE IV FILTERS

For more than 20 years GORE® Microfiltration Media for Infusion Sets have enabled medical device manufacturers to design IV filters with reliable micro-gas bubble evacuation while containing fluids and maintaining sterility.

Unlike other materials, GORE Microfiltration Media for Infusion Sets consistently deliver high performance without membrane surface modification and enable a stable integration process for high volume production.

Infusion Vent Functionality

- Reliable evacuation of gas bubbles from the infusion line
- Retain infusion liquid within the enclosure and infusion line
- Prevent microbial contamination of the fluid path



Key Features and Benefits

- Airflow of 3.9 l/h / 2.99 cm @ 12 mbar to allow proper equipment functionality
- Instantaneous Water Entry pressure of > 15 bar
- Aerosol Bacterial and Viral Filtration Efficiency of 99.99999% or a Log Reduction Value of 7
- Retains toxic drugs during typical infusion treatments
- High material consistency and uniformity enable high yield integration using ultrasonic or heat welding
- Inherently inert and meets cleanliness and biocompatibility requirements according to ISO 10993

Unique Filter Membrane

Gore unique three-dimensional expanded PTFE membrane structure is engineered to reliably meet the performance requirements while in contact with a wide variety of challenging drug liquids under various conditions.

Together, improving life

GORE® Microfiltration Media Performance

Product Performance	
Typical Airflow*	3.9 l/h/2.99 cm @ 12 mbar
Typical Water Entry Pressure*	> 15 bar
Typical Thickness*	0.20 mm
Bacterial Filtration Efficiency (BFE)	≥ 99.99999% or a Log Reduction Value of 7
Viral Filtration Efficiency (VFE)	≥ 99.99999% or a Log Reduction Value of 7

*based on two years lot data

Laminate Characteristic	
Membrane material	Polytetrafluoroethylene (PTFE)
Membrane structure	Expanded PTFE with a three-dimensional pore structure
Membrane reference pore size	0.03 µm
Membrane characteristic	Hydrophobic (no surface treatment)
Support material	Nonwoven PET
Biocompatibility	ISO 10993-4, -5, -10, -11, -23

Roll Characteristic	
Roll core inner diameter	77.6 mm. Standard 3 inch core
Roll width	Customized. Please contact Gore for support
Roll diameter	Customized. Please contact Gore for support
Roll length	Customized. Please contact Gore for support
Splice Colour	Red
Roll Shelf life	One year**

**In a clean climate-controlled room and the material remains in original packaging.

Integration Guidance

Processability	GORE® Microfiltration Media for Infusion Sets are designed to be suitable with typical manual, semi- and fully automated production steps. Specific considerations are required depending on used technology. Please contact Gore for support.
Integration	GORE Microfiltration Media for Infusion Sets are designed to be suitable for typical integration methods. Welding parameters are device design and integration technology depending. Please contact Gore for support. • Ultrasonic welding integration using a clean flat round welding area with a cavity inside. Avoid structured welding surface. • Heat welding integration using a clean flat welding horn with a cavity inside.

Details GORE Microfiltration Media Performance

Bacterial Filtration Efficiency (BFE)	GORE Microfiltration Media for Infusion Sets were designed to provide a minimum individual Aerosol Bacterial Filtration Efficiency (BFE) of 99.99999% or a Log Reduction Value of 7. Lots are tested for release using 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 µm in diameter. • BFE tests are conducted with a challenge load of $>1 \times 10^8$ colony forming units (cfu) and ≥90% relative humidity to promote cellular viability.
Viral Filtration Efficiency (VFE)	GORE Microfiltration Media for Infusion Sets was designed to provide a minimum individual Aerosol Viral Filtration Efficiency (BFE) of 99.99999% or a Log Reduction Value of 7. Lots are tested using 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 3.6×10^6 Daltons. • VFE tests are conducted with a challenge load of $>1 \times 10^8$ plaque forming units (pfu) and ≥90% relative humidity to promote cellular viability.
Biocompatibility	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 • 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

Material of Construction, Dimensions, Design

GORE® Microfiltration Media for Infusion Sets are constructed with an ePTFE membrane supported by a nonwoven PET layer.

Operating Conditions

GORE Microfiltration Media for Infusion Sets are engineered for a reliable IV-Filter operation of several hours at room temperatures using either gravity force or infusion pumps.

GORE Microfiltration Media for Infusion Sets are suited for use with ethylene oxide sterilization.

Intended Use

GORE Microfiltration Media for Infusion Sets is a key component for venting solutions in IV-Filters. It reliably enables the evacuation of micro gas bubbles while containing challenging liquids and helps maintain the sterility of the liquid path.

Point of use is possible in hospital and home-care application.

Regulatory Compliance

- GORE Microfiltration Media for Infusion Sets 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 agreed specification and lot data can be provided with 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 for Infusion Sets 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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