FILTERS AND MEMBRANES FROM BERGHOF FLUOROPLASTICS

Permeaflon®
Reliable Solutions for Medical & Life Science

BERGHOF

Permeaflon®

Reliable solutions for the Medical and Life Science sectors

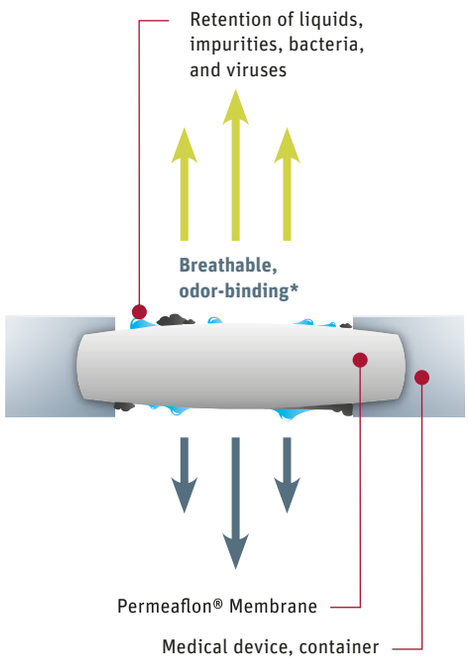
The term „Life Science“ highlights the immense social significance and diversity of this industry. It is dedicated to addressing the great challenges of our time – from medical research and the development of biotechnologies to environmental protection. As medical products and devices become increasingly intelligent and interconnected, they must also be safer and of the highest quality. To meet these high standards, companies in the medical field need reliable partners and innovative material solutions. Berghof Fluoroplastic Technology represents both.

Material & Production process

Permeaflon® from Berghof consists of pure, porous Polytetrafluoroethylene (PTFE), a material known for its outstanding properties. It is virtually resistant to all chemicals and media, which is particularly important in the medical field where cleanliness and purity are of utmost priority. Furthermore, Berghof's porous PTFE undergoes a sintering process where it is heated to over 300°C. This process provides the material with the highest temperature and robust pore structure, making it unrestrictedly usable, e.g. in autoclave processes.

Another special feature of Permeaflon® arises from its unique manufacturing process, the isostatic molding of the raw material. This step gives our filter media, which offer both surface and depth filtration functions, their homogeneous pore structure for consistent filtration efficiency. By using surface modifications or adding functional additives, the performance and functionality of our Permeaflon® can be further optimized. Thus, Berghof offers high-quality, durable and reliable products that meet today's requirements.

Permeaflon® Filters and Membranes



* Modified on its surface or enriched with additives, the functionality of Permeaflon® can be further optimized in terms of performance and durability, for example, through the use of odor-binding activated carbon.

Your specialist for high-quality solutions in the field of medical and pharmaceutical packaging

In the healthcare industry, innovative packaging solutions are crucial in protecting against infection. Our sterile barrier solutions made from porous PTFE play a key role in efforts to prevent infections and protect surgical and treatment areas from the entry of germ infestations. PTFE is often used as a filter solution in medical packaging, particularly for surgical instruments and equipment.

Due to its outstanding hydrophobic properties and chemical resistance, this material provides an effective sterile barrier against microorganisms and particles, maintaining the sterility of the packaging contents. Our commitment to quality, innovation and patient safety is reflected in every solution we provide.

Advantages

- → Pure PTFE, quality made in Germany
- → Filtration efficiency tested against bacteria and viruses (BFE[1] / VFE[2] according to ASTM F2101)
- → No leachable extractables, compliant with USP Class VI
- → Suitable for food contact (FDA-compliant)
- → Homogeneous pore distribution for consistent material properties
- → Breathable and water-repellent (superhydrophobic)
- → Can be modified with hydrophilic properties and optimized by functional additives
- → Temperature resistant from -200 to +260°C (autoclavable)
- → Almost universally resistant to chemicals
- → Sintered PTFE films do not require additional carrier material
- → Highest temperature and dimensional stability

Reusable sterilization filters for greater sustainability

In the packaging, transportation and storage of surgical and dental instruments, traditional container systems rely on single use disposable filters for steam sterilization. Reusable filters made from Permeaflon® offer a sustainable alternative. Made from medical-grade, sintered PTFE, they are temperature-resistant and fulfil two important functions in steam sterilization: they ensure continuous pressure equalization during repeated sterilization cycles and form a germ barrier for subsequent storage.

Permeaflon® permanent filters do not contain leachable, extractable substances and comply with USP Class VI requirements. Additionally, they provide greater convenience and cost savings compared to traditional disposable filters, as the need for replacement by the end customer is greatly reduced. Decide for improved efficiency and sustainability in sterilization with reusable filters made from medical-grade PTFE by Berghof.

Data on filtration efficiency

Membrane type	Filtration efficiency
	Bacterial (BFE)[1]
M10W	99,999%
M15W	99,99%
M60W	99,999%
M100WL	99,9999%
	Viral (VFE)[2]
M60W	99,999%
M100WL	99,99%

Berghof

Research shapes ideas,
experience shapes processes

Striving for new things, for innovations, for ever better products that secure decisive competitive advantages for our customers – this is the pioneering spirit for which Berghof Fluoroplastics has been valued by its partners for more than 50 years.

For us it is only logical: Companies that become complacent in their success will quickly lose their head start. Times change – but our clear focus as technology leader remains: Together with our partners and customers we work to continually utilize the great potential of our high-performance plastics to their fullest and to make it usable for evermore requirements.

A Wide Range of Applications

The requirements in the field of Medical & Life Science are often highly dynamic, making reliable medical materials and precise diagnostic solutions all the more important. Our Permeaflon® filters and membranes provide consistency and dependability for a variety of medical applications and they can be flexibly adapted to meet changing challenges, whether in terms of shape, porosity or composition. Berghof Permeaflon® impresses with excellent flow and filtration properties, including optimum air flow, high bacterial and viral filtration efficiency (ASTM F2101), as well as effective liquid barriers. From protecting medical devices in their sterile packaging, to ensuring pressure equalization in liquid containers and providing contamination-free diagnostics for indisputable results – in close collaboration with our customers, we tailor our materials to continuously enhance their applications.

Permeaflon®

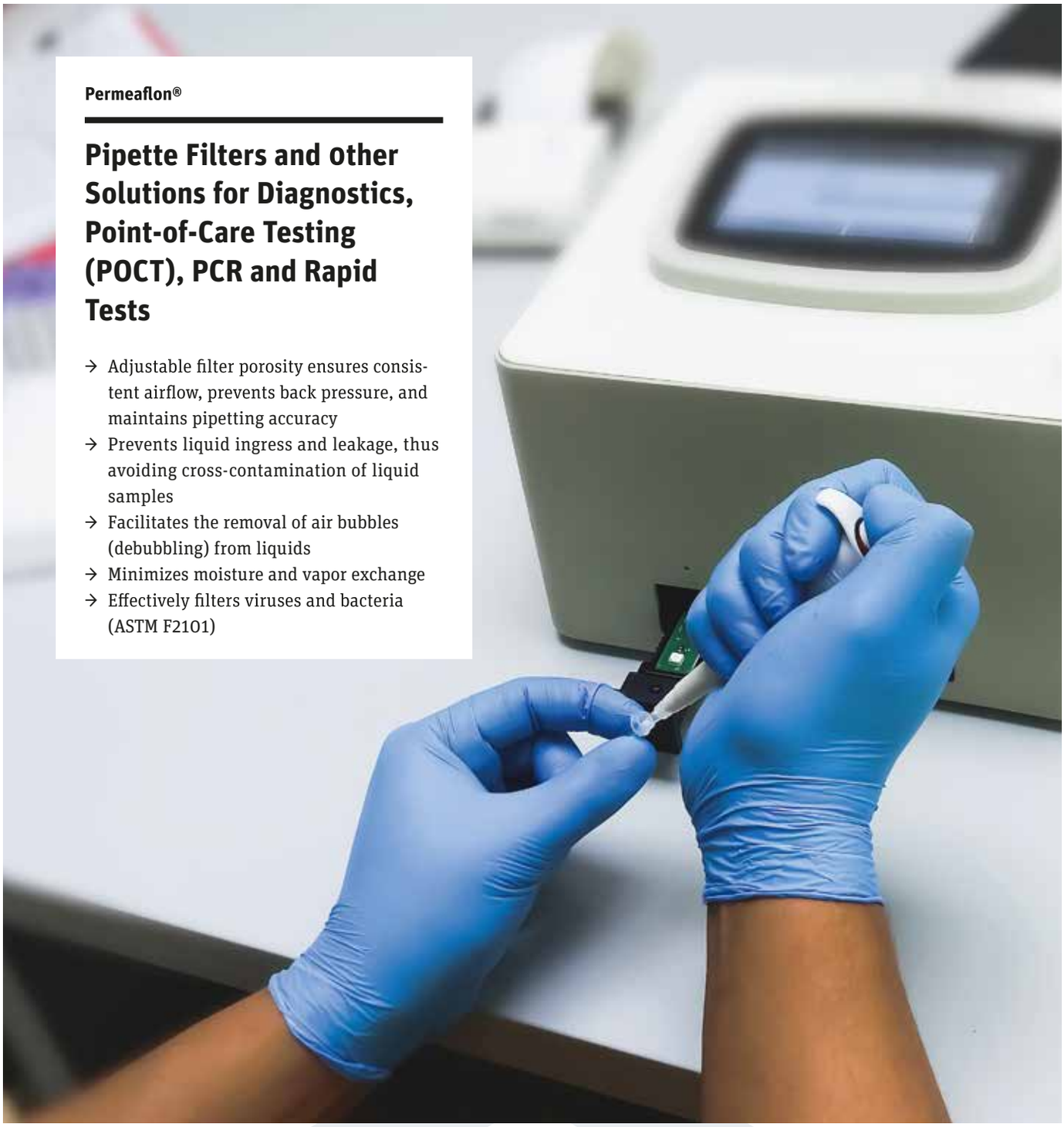
Permanent Filters for Sterilization Containers

- → Ensure continuous and rapid permeation
- → Steam permeable and water-repellent; unwanted liquids will drip off
- → Recontamination-proof; the filter acts as an effective barrier against bacteria and viruses (ASTM F2101)
- → High-temperature-resistant (DIN EN 285, DIN EN 13060, ANSI/AAMI ST79:2017/ R2022)
- → Reusable, making it more cost-effective and environmentally friendly compared to single-use filters
- → Universally resistant to almost all chemicals

Permeaflon®

Ventilation of Liquid Bags

- → Reliably regulates pressure equalization to prevent ballooning
- → Protects against the ingress of contaminants and liquid leakage
- → Compatible with common sterilization methods (steam or EtO gas sterilization)
- → Made from physiologically safe and chemically inert material
- → Universally resistant to almost all chemicals



Permeaflon®

Pipette Filters and other Solutions for Diagnostics, Point-of-Care Testing (POCT), PCR and Rapid Tests

- → Adjustable filter porosity ensures consistent airflow, prevents back pressure, and maintains pipetting accuracy
- → Prevents liquid ingress and leakage, thus avoiding cross-contamination of liquid samples
- → Facilitates the removal of air bubbles (debubbling) from liquids
- → Minimizes moisture and vapor exchange
- → Effectively filters viruses and bacteria (ASTM F2101)

Permeaflon®

Syringe Filters, Safety Catheters, IV and Spike Set Ventilations

- → Chemical resistance to aggressive substances such as solvents
- → No leachables or extractables
- → Leakage protection through liquid and aerosol barrier
- → Weldable, e.g. via ultrasonic welding, for high-purity component integration without adhesives and foreign materials

Permeaflon®

Ventilation of sterile Packaging

- → Continuous pressure equalization
- → Effective entry barrier against bacteria and viruses (ASTM F2101)
- → Protects contents from the ingress and egress of liquids
- → Robust and reliable in chemically aggressive environments
- → Weldable, e.g. via ultrasonic welding, for high-purity component integration without adhesives and foreign materials
- → Customizable, three-dimensional shapes according to customer specifications

Individual solutions

As a specialist in processing high-performance polymers, particularly PTFE, we contribute to developing innovative solutions for the Life Science sector. Our Permeaflon® permanent filters made from PTFE provide a reliable foundation for medical applications and meet the highest standards in terms of purity and durability. We always place special emphasis on the individual needs of our customers. Our products are available in various configurations (roll stock, cut-to-size sheets, die-cut parts, tubes, frits, diaphragms and other 3D geometries) and the technical properties of the material, such as pore size, airflow, and water entry pressure, can be tailored to your specific needs. This flexibility ensures that you receive a product that is perfectly suited to your requirements.

Starting from the initial inquiry, our experienced team of engineers and professionals support you through the entire development process. They assist you by providing material samples and work with you to develop a solution that fits your application. Discover the diverse application possibilities of Permeaflon® in the Life Science and medical technology fields and be convinced by our customized solutions. Contact us to learn more about our products and services.

„At Geister Medizintechnik we always act responsibly when it comes to raw materials. We strive to increase the sustainability of our products wherever possible. That is why we already use reusable sterilization filters from Berghof in a large number of SurgiBOX™ Sterilization Containers.“

Christian Geister, CTO

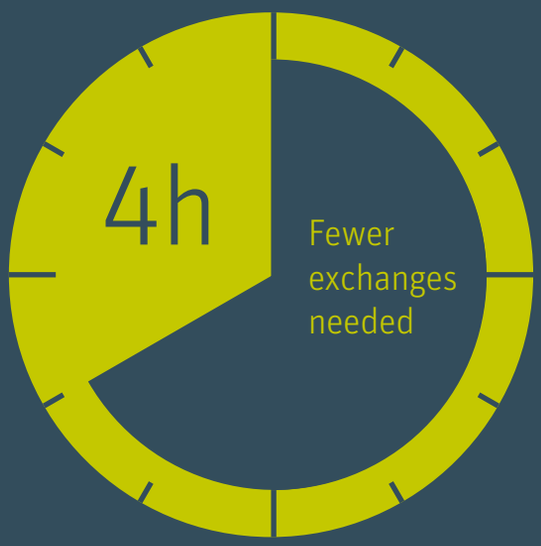
Permanent Sterilization Filter made from Permeaflon®

Advantages that will benefit your customers and the environment.

Cost & benefit of use

compared to conventional disposable filters:

Assumption:
Use of the Permeaflon® permanent filter for at least 1.200 cycles.



Assumption:
Use of the Permeaflon® permanent filter for at least 1.200 cycles and approximately 12 seconds per change of the disposable filter.

Technical datasheet

Physical and Technical Specifications	
Material	Permeaflon® - made from porous, virginal Polytetrafluoroethylene (PTFE) Symmetrically porous structure Hydrophobic on both sides Free of PFOA and PFOS Free of heavy metals Free of animal substances
Porosity	5 - 50%
Temperature resistance	-200 to +260 °C
Chemical resistance	Virtually universal
Physiological properties	Physiologically insignificant At temperatures of > 400 °C gaseous by-products from thermal decomposition, which are harmful to health must be reckoned with.
Transport and storage	Not classified as hazardous material according to transportation regulations, WGK (0). Product is lightly static-charged, avoid friction. May be stored indefinitely at room temperature.
Processing instructions	No predefined installation direction, as it is symmetrically porous. Can be welded to various plastics by thermal and ultrasonic means. Weldability should be tested in each instance.
Compliance	— Regulation 10/2011/EU on plastic materials and articles intended to come into contact with food (implemented in Germany through BedGgstV), supplemented by directives 2011/8/EU, 2007/19/EU, and 2002/72/EU. — Directive 2011/65/EU on restricting the use of certain hazardous substances in electrical and electronic equipment (RoHS2). — Directive 2003/11/EC on restrictions on the placing on the market and use of certain hazardous substances and preparations (Pentabromodiphenyl ether, Octabromodiphenyl ether) — Substances of Very High Concern (SVHC) (REACh). — Perfluorooctanesulfonates (PFOS) as identified in EU Directive 2006/122/EC (30th amendment to EU Directive 76/769/EEC) or Perfluorooctanoicacid (PFOA), its salts and related compounds as described in (EU) 2019/1021 (POP).
[1] BFE - Bacterial filtration efficiency	This Permeaflon® PTFE material exceeded the standard BFE value of 98%, all test method acceptance criteria were met. This standard BFE test procedure was modified from Nelson Laboratories, LLC (NL), in order to employ a more severe challenge than would be experienced in normal use. This method was adapted from ASTM F2101. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820. Complete testing data and information is available upon request.
[2] VFE - Viral filtration efficiency	With this Permeaflon® PTFE material all test method acceptance criteria were met. The VFE at an Increased Challenge Level test procedure was adapted from ASTM F2101. This standard VFE test procedure was modified from Nelson Laboratories, LLC (NL), in order to employ a more severe challenge than would be experienced in normal use. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820. Complete testing data and information is available upon request.

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