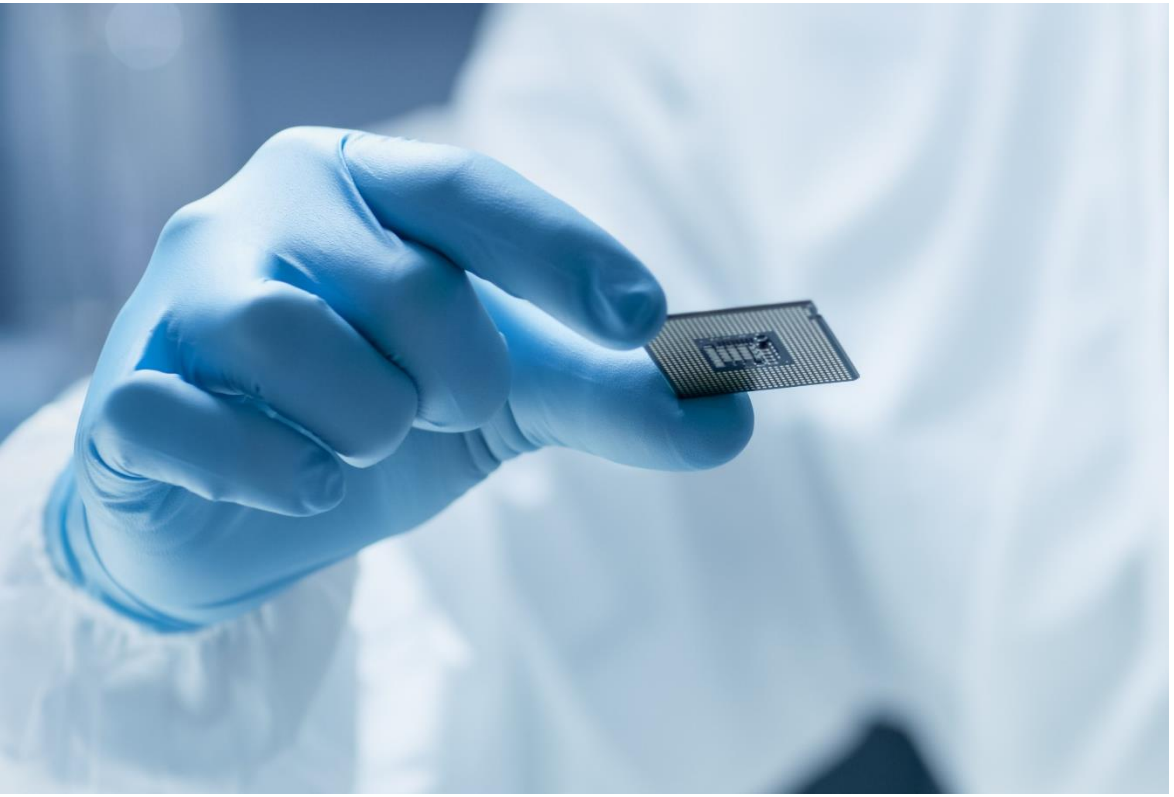
Leading the way in microfluidics in Point-of-care solutions

Diagnostics is a dynamic, growing industry that relies on faster and more accurate results to improve clinical outcomes, increase operational efficiencies, and reduce overall costs.

POREX Filtration Group



You are innovating

- To diagnose and detect nearer, faster, and cheaper
- To reduce manual handling steps and complexity
- To mitigate misdiagnosis

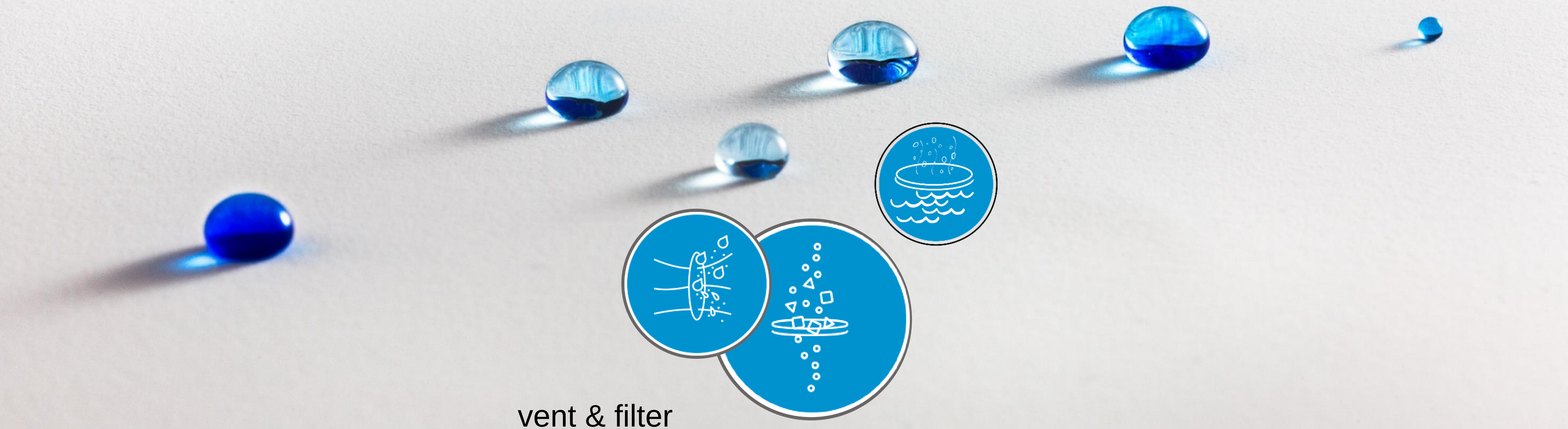
To ideally create

A device that is accurate, sensitive, rapid, and affordable to advance medical diagnosis[1]

1. Arshavsky-Graham S, Segal E. Lab-on-a-Chip Devices for Point-of-Care Medical Diagnostics. Adv Biochem Eng Biotechnol. 2020 May 21.

Micro functions make all the difference in microfluidics

Studies in microfluidics find that air vents accomplish a number of versatile functions than just air venting. Yet, as a standalone component, enables portability for the point-of-care device.



vent & filter

Allows air expression and pressurization; control of fluid delivery and metering; mitigate bubbling; eliminates sample evaporation; minimizes humidity; while acting as a bacterial and viral barrier to filter out contamination

Porex Virtek® hydrophobic PTFE vents make all the difference in microfluidics

Agenda

1. Support fluid flow and pressure equalization
2. Maintain a liquid tight, closed system barrier to minimize leakages and biohazards
3. Maintain sterility and minimize outside contaminants for sample integrity
4. A lower MVTR material to protect dried enzyme-based reagents from early reconstruction and minimize sample evaporation for test accuracy
5. A proven and effective mechanism for bubbling challenges

A Porex Virtek® Hydrophobic PTFE vent for fluid control

Keep fluid inside

Omni-directional pore structure with no front or back orientations, so membrane functions to **keep fluids in**, yet allows air to escape.

Air displacement

Air displacement supports **fluid movement**, which allows it to align and be accurately metered in volume in some designs[1].

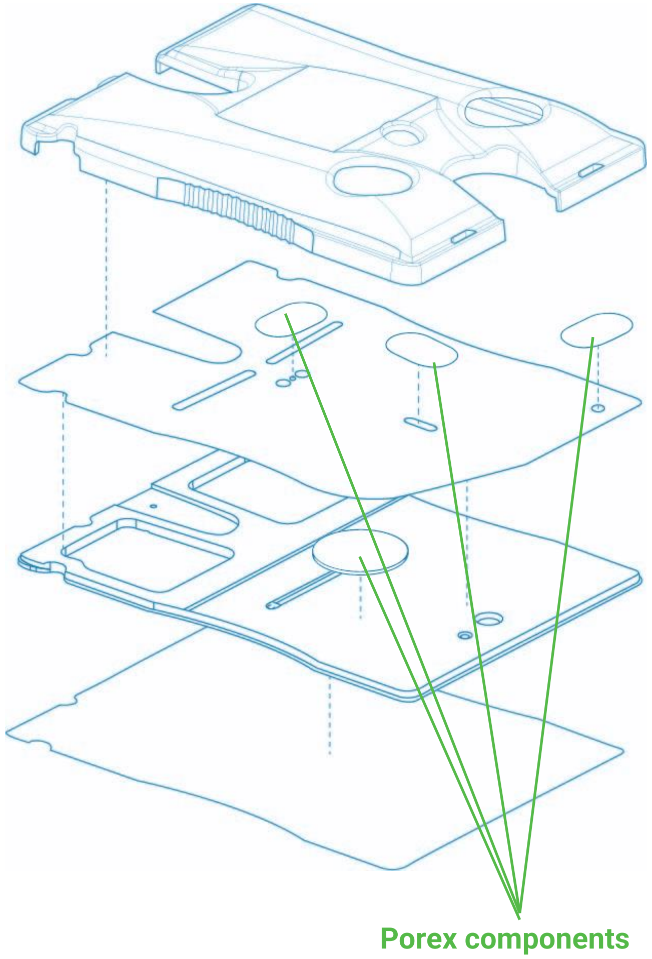
Pressure equalization

Proper air venting management, for **pressure equalization** during heating and cooling cycles.

1. A. Schneider, P. Pop and J. Madsen, "A novel metering component for volume management in flow-based microfluidic biochips," *2018 Symposium on Design, Test, Integration & Packaging of MEMS and MOEMS (DTIP)*, 2018, pp. 1-6,.

A Porex Virtek® Hydrophobic PTFE vent to maintain a closed system

- **Prevents leakage** and exposure of reagent amplicons where user handling errors may occur.
- Seals liquids inside, to **manage biological waste** after disposal to minimize spread of biohazards, especially with infectious disease testing.
- Surface **readily vents after** contact with liquid, unlike other porous membrane materials which can become blocked after fluid contact.
- Both sides **perform the same** unlike many cast or stretched membranes that have non-functional supporting layers.



Active venting maintains sensitivity by preventing contaminants entering the device, critical to sample integrity

Porex Virtek® PTFE has extremely high VFE & BFE (up to log 6) for high barrier protection from a durable vent with optimal airflow to meet (or exceed) FDA & EU guidelines.

A barrier against viral and bacterial particles[1]

Bacterial filtration efficiency (BFE)[2]:

- Determines the filtration efficiency by comparing bacterial counts to test article effluent counts.
- BFE greater than 99.99% filtration efficiency demonstrates the material is effective in blocking bacterial micro-organisms.

Viral filtration efficiency (VFE)[2] :

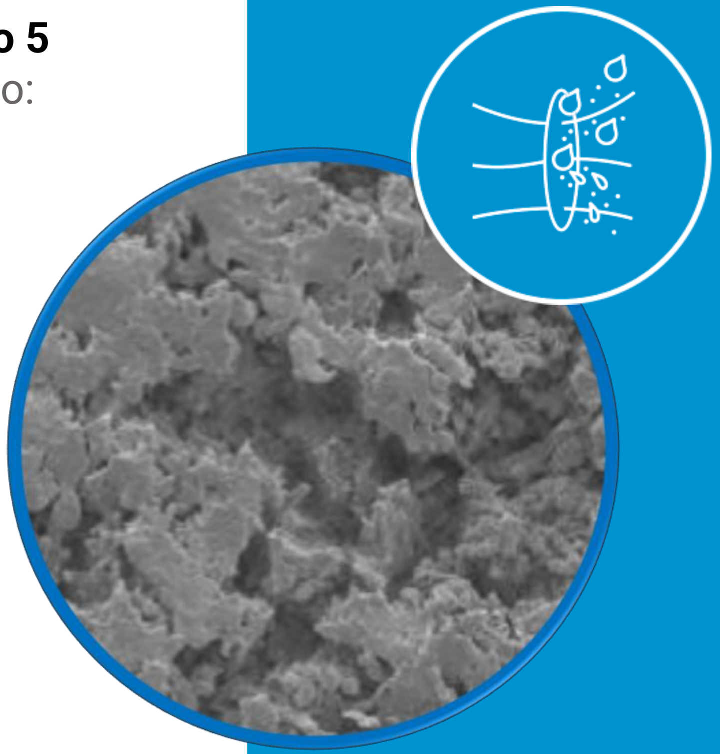
- VFE testing takes BFE a step further by measuring virus-containing aerosol particles of specific sizes to determine efficiency of filtration media in capturing those aerosols.
- VFE greater than 99.99% filtration efficiency demonstrates the material is effective in preventing infectious pathogens entering or exiting from test device.

1. Per IEST RP-CC007.2 2009 for airborne dry particle monitoring
2. Independent testing via outside laboratory

Up to 5 x lower MVTR than stretched porous membranes for a liquid-tight barrier that is critical to stability and sensitivity of test[1]

The **biggest roadblock** to commercialization and regulatory approval is accuracy, sensitivity, and specificity of the test[2]. Porex Virtek® PTFE vent membranes **have up to 5 times lower Moisture Vapor Transmission Rates** than stretched porous membranes to:

- Provide a **liquid tight barrier** to protect lyophilized reagents and minimize moisture and humidity exposure, avoiding early reconstruction.
- **Preserve liquid reagents** stored within a sterile, vapor-resistant reaction chamber, also critical to sensitivity of test.
- **Minimizes sample evaporation** during temperature cycling.
- Supportive to **storage and shelf life** of enzyme-based reagents.



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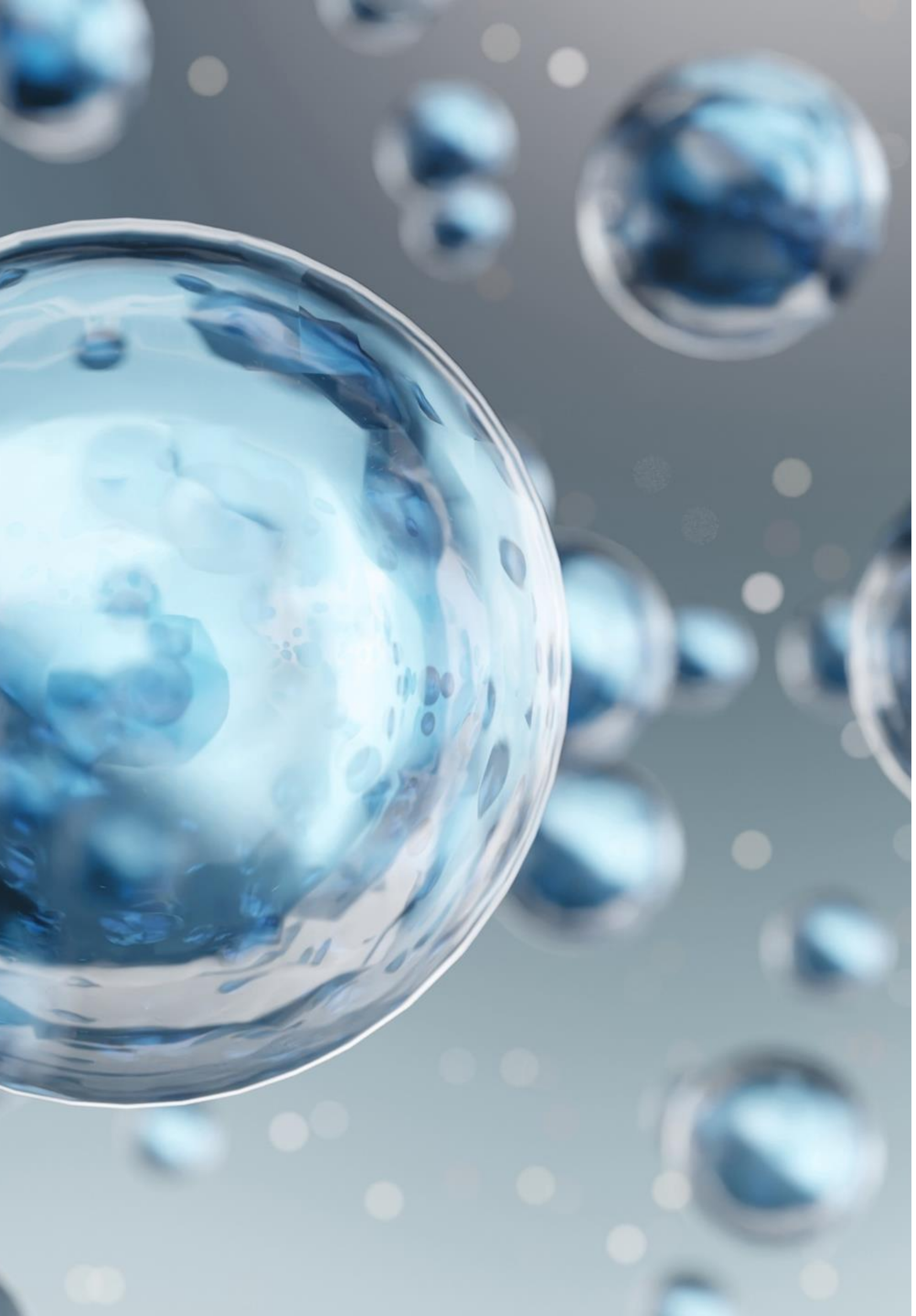
1. Date on file via third party independent group. Tested via ASTM E96-16 method in 23±2˚ C, 50±10%rH chamber conditions ; MVTR = Moisture vapor transmission rate
2. Sachdeva S, Davis RW and Saha AK (2021) Microfluidic Point-of-Care Testing: Commercial Landscape and Future Directions. *Front. Bioeng. Biotechnol.* 8:602659. doi: 10.3389/fbioe.2020.602659



Porex Virtek® PTFE as a passive "debubbling" mechanism to mitigate bubbles that become trapped

- The unique membrane surface structure promotes **microbubbles to burst** and exit.
- Allows **air pass through** of the vent to promote fluid movement and transport bubbles out of the system.
- Keeping sample liquids in, **minimizing sample evaporation** and expulsion of reagents.
- Yet **does not block** at contact with liquid, unlike some other porous membrane materials.

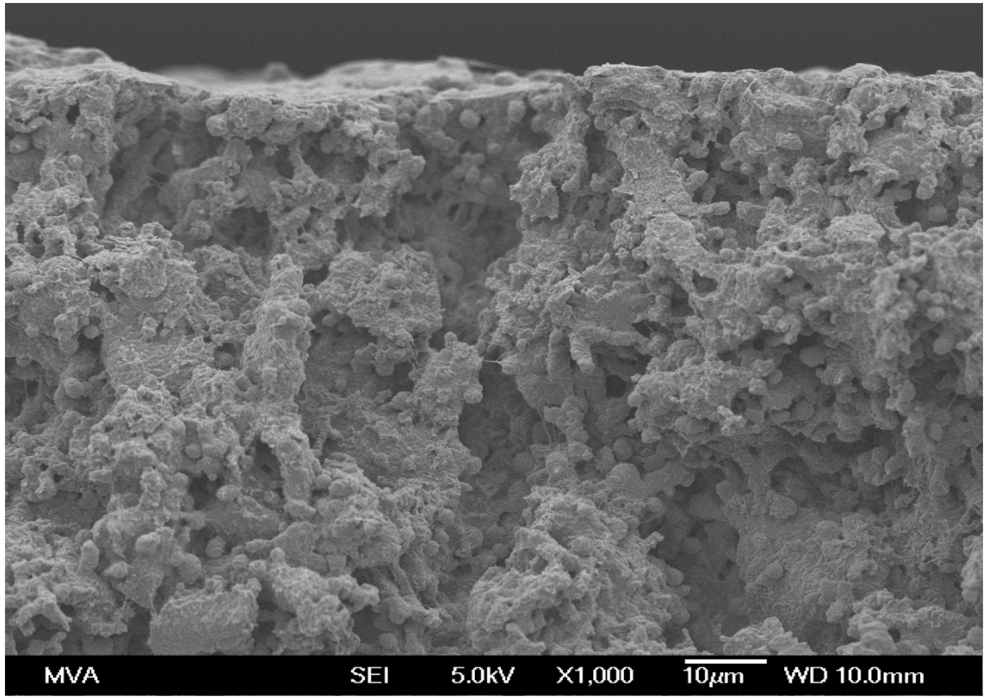
Micro functions that mitigate the challenge of bubbling in microfluidics

Bubbles occur due to	Creating issues such as
• Portability of device when tilting and shaking during transportation[1] • Oxidation of surface tension and irregularities when bringing liquid inside of microchannels[2] • During thermal cycling or changes in pressure conditions[3] • Commonly used chip plate materials like PDMS acrylic copolymer have relatively low gas removal which influences bubble formation[4]	• Difficult to remove micro-bubbles trapped within reaction chambers, metering channels, and optical systems, impacting quantitative measurements[5] • Increases in formation and size with changes in temperature and pressure conditions[6] • Distortion of fluid flow[7] • Causes damage to cells at liquid-gas interface[7] • Causes evaporation and expulsion of PCR reagents[8]

1. Combes RD, Balls M, Bhogal N. New technology for toxicity testing. Adv Exp Med Biol. 2012;745:v-xiii, xv, xvii passim.
2. Cheng, Hao-Bin & Lu, Yen-Wen. (2014). Applications of textured surfaces on bubble trapping and degassing for microfluidic devices. Microfluidics and Nanofluidics.
3. Prakash M, Gershenfeld N. Microfluidic bubble logic. Science. 2007 Feb 9;315(5813):832-5.
4. Sung JH, Shuler ML. Prevention of air bubble formation in a microfluidic perfusion cell culture system using a microscale bubble trap. Biomed Microdevices. 2009 Aug;11(4):731-8.
5. Podczerviensk, McDowell, Levine. Affect of Air Bubbles on Filling and Metering in a Microfluidic Device. NSTI-Nanotech 2012. Vol 2, 2012.
6. Liu, H. B., Gong, H. Q., Ramalingam, N., Jiang, Y., Dai, C. C., & Hui, K. M. (2007). Micro air bubble formation and its control during polymerase chain reaction (PCR) in polydimethylsiloxane (PDMS) microreactors. *Journal of Micromechanics and Microengineering*, *17*(10), 2055–2064.
7. Liu, C., Thompson, J. and Bau, H. (2011) "A membrane-based, high-efficiency, microfluidic debubbler", *Lab on a Chip*, 11(9), p. 1688.
8. Trung, N. B., Saito, M., Takabayashi, H., Viet, P. H., Tamiya, E., & Takamura, Y. (2010). Multi-chamber PCR chip with simple liquid introduction utilizing the gas permeability of polydimethylsiloxane. *Sensors and Actuators B: Chemical*, *149*(1), 284–290.

Porex Virtek® sintered PTFE
is compatible for microfluidic applications

- **Naturally hydrophobic**
  - 100% pure PTFE with no additives or treatments, that naturally resists water
  - No water drawn through membrane under typical vacuum and pressure conditions
- **Thermal stability**
  - Highly heat resistant up to 260° C
- **Chemical inertness**
  - Compatible with reagents that often contain alcohols, surfactants, proteins, and salts
- **Robust, pure and durable**
  - Requires no supporting layers or chemical treatments
  - Safe to handle without damaging
  - No assembly orientation required
  - High purity with virtually no leachable or extractables
- **Manufactured in class 100k cleanroom**
- **Raw material certified**
  - USP class VI (bio-compatibility)
  - Free of PFOA

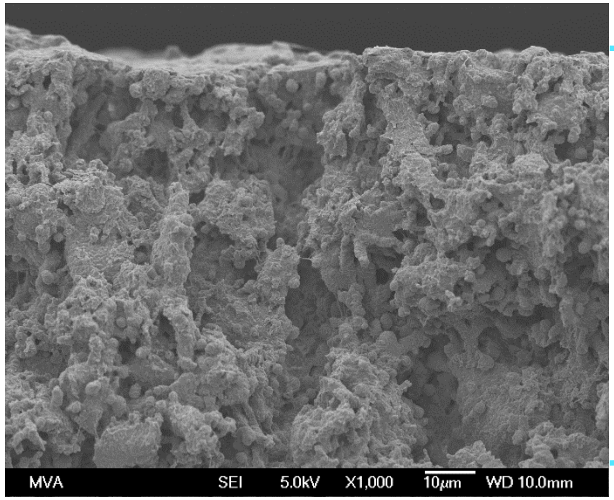


Cross section view

Free of PFOA
Compliant with (EC) 1907/2006 REACH / Regulation (EU) 2019/1021 POP

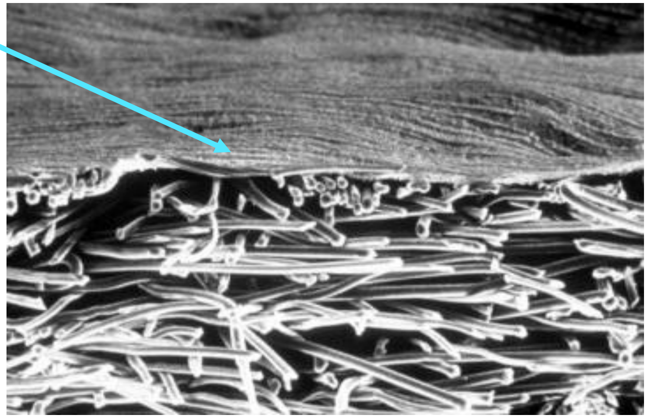
Microscopic comparison with other materials

Sintered PTFE Membrane



- Material has depth, is self supporting and will rebound under pressure
- Individual particles bonded to its neighbor for superior strength
- No additives or binders necessary
- Membrane is a depth filter and follows a torturous path
- Both sides identical and omnidirectional

Expanded / Stretched PTFE Membrane



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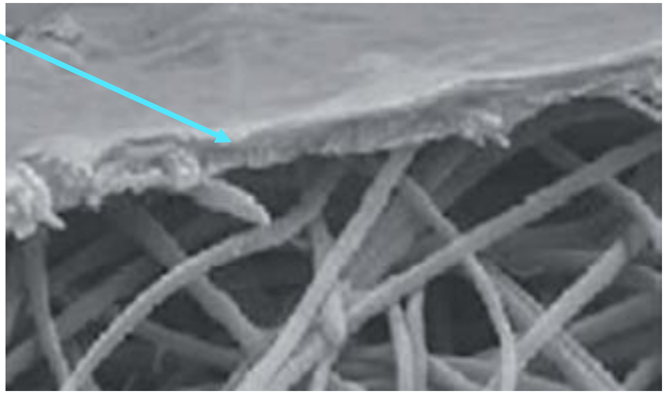
- Active membrane has minimal depth and is only a surface filter
- Bonding to substrate requires additional adhesives or lamination to tie layers together
- Service temperatures limited to substrate
- Both sides have different properties
- Membrane properties can be altered by applied pressure

Cast Membrane



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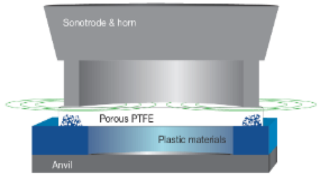
- Casting process often requires chemicals or other additives to create structure, leading to residuals and contamination issues
- Layers can delaminate
- Service temperatures and chemical resistance limited to substrate
- Membrane orientation is critical (different sides have different properties)
- Treatment often needed for hydrophobicity

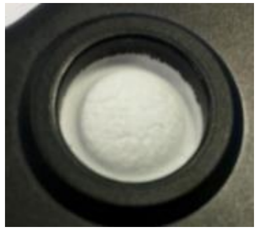
Common Assembly options for Porex Virtek PTFE

There is no standardization in design for microfluidic devices, so sourcing and fitting custom components can be tricky. Porex Virtek® PTFE vents make your process simpler by:

- Easily heat sealed, vibrationally welded or numerous other assembly options
- Has no right-side assembly orientation
- Is easy to handle and does not easily damage or changes with contact
- Enables quicker production and device finishing in high-speed assembly

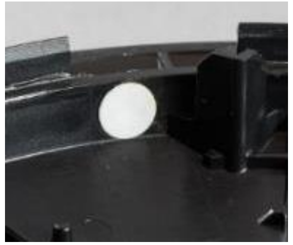


Thermal & Ultrasonic Welding

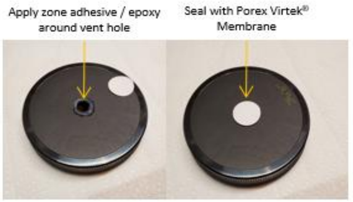


Overmolding

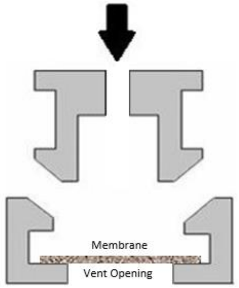
Press Fit



Pressure-sensitive adhesive (PSA)



Glue or Epoxy



Snap-fit or Clamping

Material Property Ranges:
physical properties

Material	Thickness mm nominal	Typical Airflow l/hr/cm² at 70 mbar	Dry Filtration Efficiency* >99.99%	BFE** % Nominal	VFE*** % Nominal	Typical WEP**** mBar	WIP
MD10	0.13	125 (min 70)	0.5 µm	>99.99	~	270 (min 175)	350
MD10L	0.3	85 (min 48)	0.5 µm	>99.99	~	270 (min 175)	350
MD15	0.18	70 (min 45)	0.4 µm	>99.99	~	380 (min 265)	450
MD20	0.25	34 (min 16)	0.1 µm	>99.9999	>99.999	520 (min 350)	600
MD22	0.1	15 (min 5)	0.2 µm	>99.99	~	750 (min 500)	900
MD25	0.19	5 (min 2)	0.1 µm	>99.9999	~	1000 (min 750)	950

Looking for Pore Size? Unlike typical surface filter membranes, depth filtration membranes like Porex Virtek retain particles smaller than its nominal pore size through pore-size gradients and tortuous path. Use dry filtration efficiency to better compare.

Oleophobic treated materials available to repel low surface energy fluids (oils, alcohols & surfactants)

** According to IEST RP-CC007.2 2009*
*** Bacterial Filtration Efficiency (BFE) data is based on a modified version of ASTM F2101*
**** Viral Filtration Efficiency (VFE), † Not tested but similar results to MD20 expected.*
***** WEP (Water Entry Pressure)*
Properties are typical and not meant for specifications. Selected options and adhesives may affect properties. Complete testing data and information is available upon request – all exceeded the standard BFE value of 98% RoHS, WEEE, REACH Compliant (PFOA Free)

Range of material options

- **Master roll:**
  - 330mm wide
  - Thickness from 0.1mm - 3.0mm
  - Roll length dependent on thickness (3m – 100m)

- **Converting options:**
  - **Slit Rolls**
    - 8mm minimum width (for most materials)
    - Provided on 76mm (3”) ID plastic cores
  - **Die-cutting**
    - Minimum 3mm diameter
    - Minimum 5mm diameter if with adhesive
    - Custom Shapes
    - Robotic Frit cutting for thicker membranes
  - **Adhesive Discs**
    - Numerous stock, standard and custom size/shapes available
  - **Lamination**
    - PP / PE scrim options available
    - Adhesive backing


TOGETHER, WE ARE MAKING
THE WORLD SAFER, HEALTHIER
AND MORE PRODUCTIVE.
Filtration Group®
Filtering The World