

Improving Life Science
Cleanroom Performance

“We Test **HEPA Filters** Because They Leak.”

—Dan Milholland
Expert in HEPA Filter Certification

Leaks have a dramatic effect on your business, on your bottom line. They are a challenge for every operation. The question is, how can you reduce them?



Loss From a Single Microglass Filter Leak:

Two hours of unplanned downtime:

\$250,000+ /hour

Documentation and meetings:

 **\$20,000**

Total Cost: **\$520,000+**

\$3K - \$20K Documentation costs associated with a single filter leak

Time to Address a Leak:



5-10 MINUTES
planned downtime
for an experienced
certification team to
scan a filter



2 LABOR HOURS
unplanned downtime
to remove, replace,
and retest a leaking
microglass HEPA filter

Hidden Cost of Microglass:

1% - 3%

microglass filters
discovered to have leaks
during each round of testing

100 microglass filters
x 3% leak rate:

Three Filters
\$20,000

PER FILTER
documentation & meetings
with a single leak

EQUALS

\$60,000

per round of
semi-annual leak testing

OR

\$120,000/yr
Total Annual Cost

**You need to understand the cost
of every leak you experience.**

Three Hidden Risks of Microglass HEPA Filters: It's Worth a Closer Look.

Some Leaks Are Harder to See Than Others. So Are the Risks They Can Cause.

HEPA leaks affect every step in the pharmaceutical process, from construction and production to federal compliance, unplanned downtime, and equipment failure. It's a major part of any company's reputation, financial bottom line, and, ultimately, patient safety.

Using HEPA filters with microglass media, even as a part of a Standard Operating Procedure, can lead to decreased production time, increased repair time, and increased energy consumption, not to mention FDA 483 Warning Letters and potentially disastrous recalls. Are you keeping your eye on the risks that are harder to see? And if not, have you considered the consequences?

Unscheduled Downtime:

Would It Surprise You if a Weaker Filter Also Increased Your Risk?

The pharmaceutical industry estimates that 77% of production downtime can be attributed to failures of equipment and environmental problems.* This downtime can be caused by HEPA filters failing. Traditional HEPA filters typically fail because of the poor mechanical strength of the media, a failure due to physical contact or degradation from caustic chemicals. The actions required when these failures occur include replacing the HEPA filter, certifying the installation, investigating potentially contaminated products, and generating a risk assessment report.

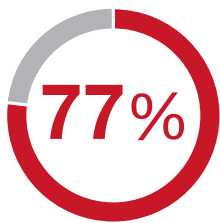
The poor durability and low tensile strength of microglass leads to media degradation when exposed to cleanroom chemicals. What's more, high pressure drops and media offgassing result in higher energy costs and lower air quality.

Fragile fiberglass media can lead to unplanned and costly situations, including the need for replacement filters, labor for installation, FDA 483's, and even recalls.

The costs and issues associated with using microglass may be viewed as a cost of doing business, but the ultimate risks are often unrecognized. It has been reported that 1% to 3% of microglass filters are discovered to have leaks during each round of testing. When leaks are found, just the documentation and meetings required in the investigation process alone are expensive, not to mention backup stock for filter replacement.

A company's reputation can also be damaged by these leaks. Publicly posted warning letters are brand killers for pharma, biotech, and medical device companies. And reputation damage from public fear will increase these concerns exponentially. Competitor leverage, loss of business, stockholder confidence—these are just some of the ways that leaks affect your bottom line.

*Pharmaceutical Manufacturing Magazine (2004)



77%
of production downtime
can be attributed to
failures of equipment and
environmental problems

FDA Testing Guidance

2x a year
Critical Areas
(ISO 5; Class A and B)

1x a year
Non-Critical
Areas
(ISO 7 and 8)

Excessive PAO Testing:

Twice the Testing Offers Twice the Reliability. Right?

Microglass may be PAO compatible, but it is also fragile. Very fragile. This fragility means that any interaction with this media entails a greater risk of damage—which CAN mean more testing, which WILL mean more risk of failure. That's a risk you just can't take.

HEPA filter testing has had a long and complex history. But the FDA requires this regular testing. It is an integral part of any cleanroom protocol. In fact, filters utilizing microglass require more testing than any other media. Microglass requires more testing because it is more fragile. It requires more testing because it can't be trusted to keep your cleanroom safe.

Obviously, it is critical that filter integrity is maintained throughout the entire manufacturing and testing process. Even though overcertification may seem like a solution, it is actually just another leak waiting to happen. Testing is a key part of any cleanroom validation, but every test includes specific risks.

Although additional testing may be appropriate when air quality is found to be unacceptable, testing less may mean testing smart. Over-testing may make you feel better about leaks in microglass filters, but it won't make the filters any better or stronger.

Overcertification

Overcertification in non-critical environments can cause significant problems for pharmaceutical production, such as additional costs for certification services, longer shutdown time, and greater exposure to damage, gel liquefaction, and leakage. However, while the FDA requires critical room leak testing twice a year, non-critical rooms only require the test once a year. But many companies still test twice a year due to the fragile nature of microglass and their well-founded concerns and fears associated with it.

Gel Degradation

Extra testing may help to find leaks, but there are inherent risks associated with these tests. One of the lesser-known risks is gel degradation. PAO can and does affect these gels. And the ensuing gel liquefaction can dramatically compromise cleanroom processes, in addition to damaging the filter itself and causing devastating cleanroom damage. Contamination and premature replacement, along with associated costs and concerns, not to mention lost production time, could cost millions of dollars. Testing only as required will improve the integrity of your filters, the performance of your cleanrooms, and your bottom line.

Financial Impact:

Do You Understand the Cost of Every Leak You Experience?

Maintaining filter integrity is a challenge for every cleanroom operation, and because of this, you need to understand the significant impact of inferior microglass media on your business.

The FDA has increased emphasis on enforcement and validation. While compliance may be expensive, it is nothing compared to the catastrophic expense of warnings, recalls, and unplanned downtime. What does that really mean? Is the continuous use of microglass worth the risk?

Three Hidden Risks of Microglass HEPA Filters (continued)

The status quo, a misplaced belief that this old media is sufficient, is a recipe for disaster. How could any faith remain in something that could properly be called “outdated”?

There is very little discussion in the pharma industry as a whole about what’s really going on here. Your competitors could also be listening to manufacturers about a product that will work “good enough” to keep them in business. The truth is, it may not. This provides a great opportunity for a competitive advantage, as well as protecting your reputation and improving your financial fundamentals.

Hidden Costs of Microglass HEPA Filters

We’re calling the costs of microglass use in cleanrooms “hidden,” but with every day that passes it becomes more and more apparent that the cost to individual companies and the pharma industry is staggering.

Let’s take a look at what it costs you EVERY TIME a microglass HEPA filter leaks. These are not theoretical numbers. These are the hard facts about this media and the price you’re paying for continuing with this outmoded technology.

Here is what you need to know:

The time it takes to address a filter leak:

Five to ten minutes planned time for an experienced team to scan a filter

At least **two labor hours** unplanned downtime to remove, replace, and retest a leaking filter

Loss from a single microglass HEPA filter leak:

\$250,000+ hr. (two hours of unplanned downtime)

\$20,000 (documentation and meetings)

\$520,000+ Total cost for a single microglass HEPA filter leak

\$3,000 to \$20,000 Documentation costs associated with a single filter leak

1% - 3% of microglass HEPA filters are discovered to have leaks during each round of testing.

100 filters x 3% leak rate:

3 filters x \$20,000 per filter (documentation and meetings with a single leak)

Cost: \$60,000 (per round of semi-annual leak testing)

OR

\$120,000/yr Total Annual Cost

It should be obvious at this point that a closer look at the use of microglass HEPA filters exposes the disturbing financial risks and extraordinary damage to reputations associated with its use. These expenses will continue to compound in future years. Microglass is unlikely to find a “fix” for its fragility. This fragility is inherent within the media itself. Add to that the fact that HEPA filters cannot be repaired inside critical areas and have to be replaced. Doesn’t it make sense to do it right the first time, for your company and for a public that depends on your end product?

Microglass HEPA Filtration: More That You Need to Know

Microglass HEPA filters pose an enormous risk to your process environment. The air filters used inside your HVAC system have a dramatic impact on the total cost of ownership, the labor resources required to support the systems, product quality, and most importantly, patient safety.

What's more, minimizing the hidden risks and costs associated with successfully operating pharmaceutical cleanrooms requires a continual review and updating of your Standard Operating Procedures, particularly the selection, installation, and maintenance of your filters.

There are other, better pharma-grade HEPA media options that are superior to microglass. These options will operate not only at a validated state with respect to installation and operation—but at an improved state. Before you choose your next HEPA filter, make sure you know what you're buying and what the actual cost in time, performance, and ownership will be.

There are choices in cleanroom filtration. Make certain you know what they are. Because the wrong decision could be a damaging one.

What to look for in HEPA Filters

This checklist will help you decide on the right HEPA filter for your cleanrooms.

Durability	<ul style="list-style-type: none">• Highest level of mechanical strength for resistance to damage and failure rate• Chemically inert to reduce media degradation in highly corrosive environments• Water resistance to extend the life of the filter
Performance	<ul style="list-style-type: none">• High PAO holding capacity for better performance and reliability• Low to zero offgassing of chemical components for higher quality clean air• Lowest available pressure drop to reduce energy consumption
Total Cost of Ownership	<ul style="list-style-type: none">• Clearly understand all of the operational risks associated with your filter selection• Invest in a technology that will give you the greatest impact with minimal effort• Choose a company that provides professional guidance to reduce spending, decrease risk, and save time

Acknowledgments:



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Hidden Dangers of HEPA Filter Leak Testing: The Risks are Hidden. The Consequences are Not.

History of Leak Testing

From the 1960s to mid-1980s, dioctylphthalate (DOP) was used in concentrations of 80 mg/m³ (µg/L) as an aerosol challenge for leak testing HEPA filters.¹ In the 1980s, the design of aerosol photometers progressed to incorporate solid state electronics, which helped these photometers become more sensitive instruments to identify filter leaks.

With the implementation of these more sensitive and stable units, the recommendation for DOP aerosol challenge concentrations was reduced to 10 mg DOP/m³ of air.²

The early 1990s brought a change to the challenge material, due to DOP being labeled as a potential carcinogen. Emery 3004 polyalphaolefin (PAO) was recognized as a non-hazardous replacement and has now become the industry standard.³

FDA regulations require regular testing, but how often testing procedures are utilized beyond those requirements depends on the quality of the filters and how they are used. HEPA filter integrity has to be maintained to ensure aseptic conditions. Leak testing should therefore be performed at installation to detect integrity breaches around the sealing gaskets, through the frames, or through various points on the filter media. Thereafter, leak tests should be performed at suitable time intervals for HEPA filters in the aseptic processing facility.

The FDA requires testing to be performed twice a year for aseptic processing rooms, although additional testing may be appropriate when air quality is found to be unacceptable. There can be other reasons for additional testing, such as facility renovations, or as part of an investigation into a media fill or drug product sterility failure. But extra testing due to the use of lower quality filters incurs the additional cost of more filters being certified, increasing time, money and potential damage.

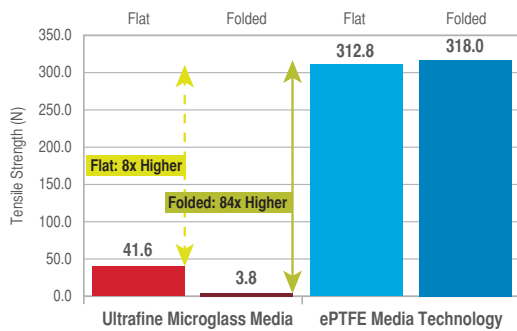
Overcertification In Non-Critical Environments

Excess certification can cause many problems for environments, some more obvious than others:

- Additional costs for certification services
- Consumes valuable time during shutdowns
- Increases exposure to damage
- Premature gel liquefaction and leakage
- Media degradation

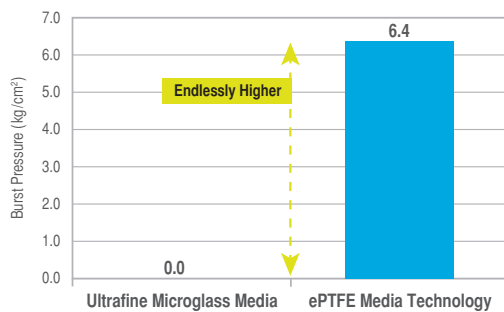
But there are steps that can be taken. While FDA Testing Guidance requires critical room leak testing twice a year, non-critical rooms require the testing only once a year. However, many companies still test twice a year, due to using fragile microglass media. There are risks associated with this, though.

Tensile Strength



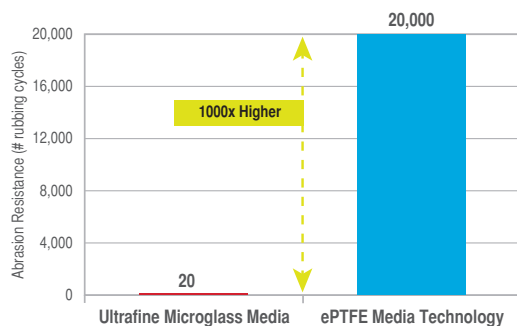
Results based on Test Standard DIN EN 29073-3.

Burst Pressure - Flat



Results based on Test Standard DIN EN 13938-2.

Abrasion Resistance - Flat



Results based on Test Standard DIN EN 12947-2.

Overexposure to PAO

One of these risks is Gel Degradation. It has been documented that PAOs can affect the stability of this gel. In fact, at least four Fortune 500 companies have recently reported problems with gel degradation, the liquefaction of the substance used to install and seal the filters. The integrity of the gel and the effectiveness of the filter seal are therefore compromised. Leaking issues caused by gel degradation are even more devastating than simple damage to the filter. When the gel itself becomes liquefied and drops to the floor of a cleanroom, the cleanroom is no longer sterile. This presents a major risk. Gel liquefaction also initiates an unplanned shutdown with enormous financial ramifications. These contamination failures bring about production losses and premature change-outs—and with them, potentially millions of dollars in damages and profits.

Reducing Your Risk

Effectively managing the risks and costs associated with successful operation requires utilizing HEPA filters with dramatically higher tensile strength that are highly resistant to chemical degradation, thereby eliminating premature leaking and failure. The only HEPA filter media with these properties is polytetrafluoroethylene (ePTFE). Utilizing ePTFE can increase time between testing, allowing for annual certification, which results in lower labor costs and reduces your risk to gel liquefaction contamination and early changeouts.

The strength of the HEPA filter material is critical to the success of a pharmaceutical environment. In fact, there is no more important component of a cleanroom. Depending on the carrier substrate, the strength of ePTFE filters is up to 100 times stronger than microglass. This creates a filtration media that does not fail under standard operating procedures, cleaning, installing, or testing, and provides a durability to mitigate almost all risks of contamination from airflow. The filter will not shed, tear, puncture, or sustain pleat tip separation.

The costs associated with failed media can be staggering:

- Complete loss of production for unspecified periods
- Costly FDA 483 citations, warning letters, and consent decrees
- Expensive follow up qualifications/validations
- Catastrophic recalls

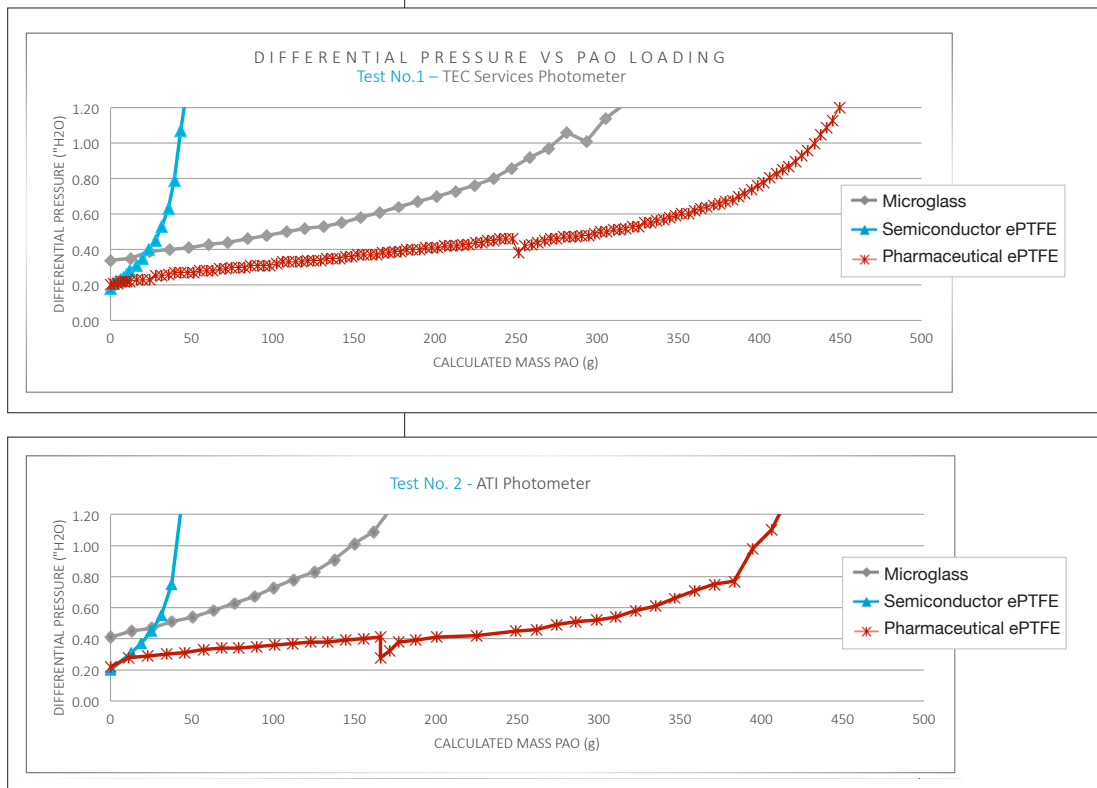
Hidden Dangers of HEPA Filter Leak Testing (continued)

ePTFE and Pharma

The benefits of ePTFE filters, including the significant reduction in energy cost, enhanced chemical tolerance, and increased durability, have long been known in critical semiconductor applications.⁴ However, until recently, this technology was not available for use in pharmaceutical environments.

But now there is an ePTFE media that is specifically designed to retain at least equivalent amounts of PAO aerosol with a pressure drop that is equivalent or lower than that of microglass. This new dual-layer ePTFE Technology allows for the in-depth capture of progressively smaller solid particles.

In fact, independent laboratory studies have shown that ePTFE filters possess a far superior PAO holding capacity over traditional microglass HEPA media, as seen in the results below.



Filter failures pose a significant cost to pharmaceutical manufacturers that produce product in a GxP critical environment. The ability to widely use ePTFE filters in pharmaceutical applications provides extraordinary benefits, as well as avoiding the setbacks that almost certainly will lead to disastrous repercussions in money, risk, and time.

You can't afford not to investigate ePTFE filters:

- Increase in cleanroom uptime
- Lower production loss and labor costs
- Increase in time between certifications
- Significant energy savings

Attention to these critical factors will lead to more than operational efficiency and risk mitigation—it will lead to a more viable commercial enterprise.

Challenges and Opportunities Concerning Testing: Looking Back and Planning Ahead

If business can learn anything from history, it is that the past is prologue. What we have seen before is likely to be seen again. And what we have seen is change.

Cleanroom testing has always been an integral, if expensive and sometimes dangerous, component of the pharmaceutical industry. It has also come with its own set of concerns, including DOP's cancer worries, and the more recent considerations of gel and media degradation. Decisions must be made to continually improve. In fact, the idea of using microglass HEPA filters as part of a standard operating procedure may very well become obsolete in the pharmaceutical industry in the near future.

Standard operating procedures and necessary change will always be, to a degree, in conflict. What was useful yesterday, even what is chosen as a solution today, will quickly become an obstacle on the road to progress and innovation. But vigilance and an openness to "what's next" will ensure the industry its best chance of continued growth and success.

References

1. Hale, Dean, "HEPA Filter Gel Seal Failure Study and Conclusions," 2006 CETA Presentation.
2. Mil Standard 286, 1956 Department of Defense Test Method Standard.
3. FDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing Current Good Manufacturing Practice, September 2004.
4. Galken, Ned, and Abhishek Saxena, "Air Filtration Applications for Membranes," AFS Web site.

Acknowledgements:



Rahul Bharadwaj is Senior Global Product Engineer at AAF Flanders. His areas of expertise involves filtration, separations, nanofibers, membranes and nonwovens. Bharadwaj is a member of the AFS scientific

committee, and is also a member of various other technical and research committees at ASHRAE (Vice Chair of US TAG 142 and Vice Chair Research TC2.4). Bharadwaj received his Doctorate in chemical engineering from the University of Akron, with a Master's in Business Administration from the Institute of Technology and Management, New Delhi. He can be contacted via email at rbharadwaj@aafintl.com.



Bill Kitch is Director of High Purity Products, West at AAF Flanders. He spent 10 years in a territory sales position focused on air filtration for the pharmaceutical market before moving to High Purity

Manager, responsible for AAF Flanders's Cleanroom Division. This project-driven market included air filtration, using both glass media and ePTFE media. Kitch then focused on the development of AAF Flanders' own media for use in high end filtration markets. He graduated from Ball State University with a BS in marketing, and is a member of ISPE and CETA. He can be contacted via email at bkitch@aafintl.com.



Mark Renn is Product Manager of High Purity products at AAF Flanders. He completed his undergraduate and graduate studies at the University of Louisville, where he was awarded a MS in Chemical

Engineering. Renn has spent 30 years focused on the design, application and testing of HEPA filters for multiple industries, including pharmaceutical, microelectronics and healthcare. Renn is a member of IEST and CETA. He can be contacted via email at mrenn@aafintl.com.

MEGAcel® II

with ePTFE Filtration Technology

MINI-PLEAT HEPA FILTER



Proven Reliability With Exceptional Performance

- MEGAcel II is designed to increase cleanroom uptime and reduce the risks associated with pharmaceutical manufacturing
- Pharmaceutical grade ePTFE Filtration Technology media is proven to be more durable than microglass, delivering superior performance
- Industry's first and only ePTFE media to be Polyalphaolefin (PAO) compatible, with a higher PAO holding capacity compared to microglass media
- Superior durability and tensile strength, 84 times the pleated strength of microglass
- Chemical-resistant capabilities reduce media degradation in highly corrosive environments
- Exceptional water resistance compared to ultrafine microglass
- Extremely low offgassing of chemical components, resulting in the highest quality clean air available
- Lowest pressure drop mini-pleat HEPA filter available, reducing energy consumption for significant savings
- MEGAcel II and ePTFE media are manufactured, tested, and packaged in ISO 7 clean facilities to ensure the highest purity, quality, and consistency

AAF Flanders ePTFE Filtration Technology— Today's Alternative to Fragile Microglass HEPA Filters

Designed specifically for the unique requirements and challenges of the pharmaceutical industry, the MEGAcel II mini-pleat HEPA filter has the proven durability, polyalphaolefin (PAO) compatibility, high particulate filtration efficiency, and the lowest pressure drop to meet the demands of pharmaceutical manufacturing. It is the best choice for the most demanding applications, saving both time and money, while reducing contamination risk and invasive unscheduled downtime. With the lowest Total Cost of Ownership of all mini-pleat HEPA filters, the MEGAcel II will help protect your environment, reduce your business risk, and optimize your clean air related spending.

MEGAcel® II Overview

- Patent pending, polymer-based, dual-density, expanded polytetrafluoroethylene membranes – ePTFE
- 99.99% minimum efficiency @ 0.3 µm
- Completely Polyalphaolefin (PAO) compatible
- Lowest pressure drop mini-pleat HEPA filter available
- 50mm pleated pack
- Anodized extruded aluminum or stainless steel frame
- Gel, gasket, or knife-edge seal available
- Thermoplastic hot-melt separators

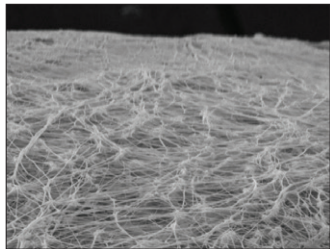
MEGAcel® II
with ePTFE Filtration Technology

Less Downtime. Less Worry. Less Risk.

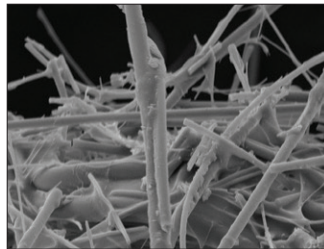
MEGAcel® II Filter

Industry-Leading Durability

Independent tests have shown that MEGAcel II HEPA filters with ePTFE Filtration Technology have superior mechanical strength over filters with traditional ultrafine microglass media.



Resilient ePTFE Filtration Technology media at fold tip @ 10,000x magnification.



Fractured ultrafine microglass media fibers at fold tip @ 10,000x magnification.

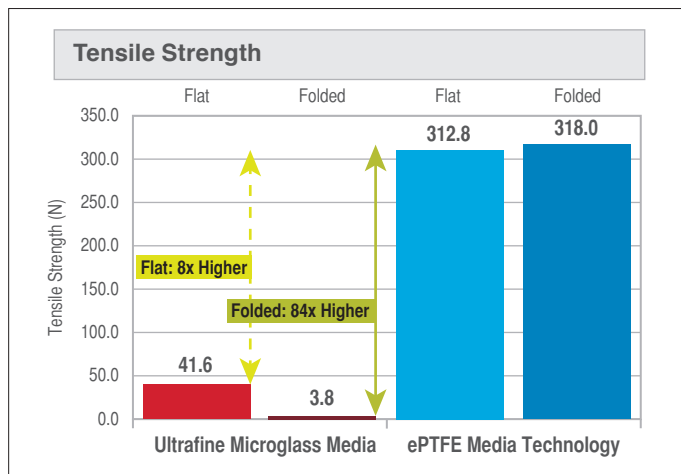
Superior mechanical strength is demonstrated by a high tensile strength, burst pressure, and abrasion resistance. ePTFE media retains its integrity with a high resistance to any potential damage, such as mishaps in handling or installation. This means that the risk of filter media failure is minimized and that fiber shedding, which could cause contamination when entering the airstream, is eliminated. As a result, there is a decreased risk of contaminants entering cleanroom environments. Protection of sterile products and cleanroom personnel is optimized. Improvement in quality risk management systems of critical applications ensures a consistent supply of quality products and a reduction of failure rates.

Reduce Operational Risk

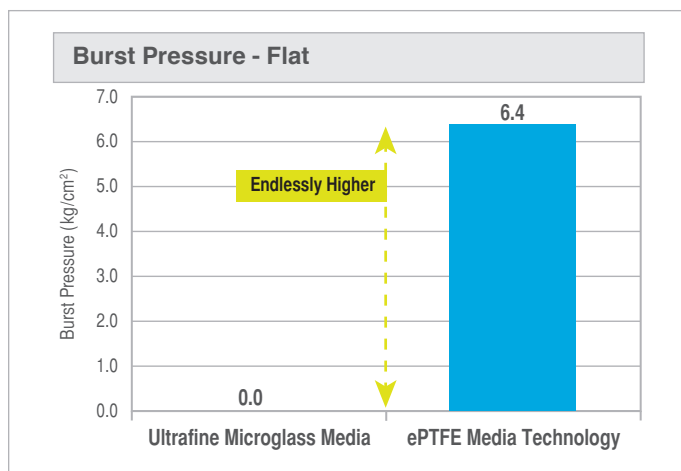
The pharmaceutical industry estimates that 77% of production downtime can be attributed to failures of equipment and environmental problems*. This downtime can be caused by HEPA filters failing. Traditional HEPA filters typically fail due to some form of contact combined with the poor mechanical strength of the filter. The actions required when these failures occur include repairing or replacing the HEPA filter, certifying the repair or new installation, investigating potentially contaminated product, and generation of a risk assessment report. Effectively managing the risks and costs associated with successful operation requires utilizing HEPA filters with dramatically higher tensile strength that are highly resistant to chemical degradation, thereby eliminating premature leaking and failure.

Increase Uptime

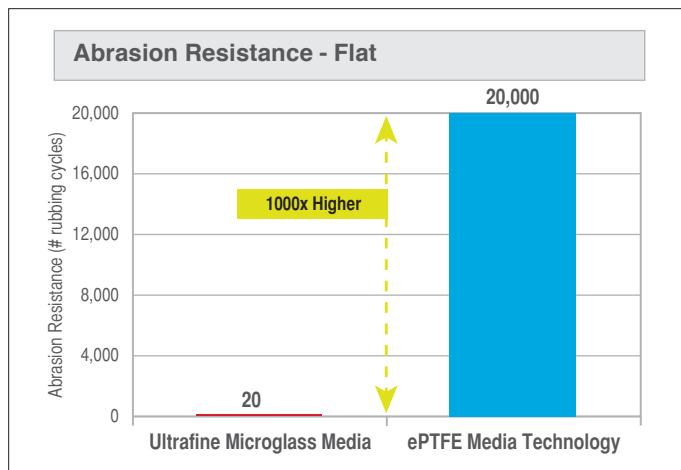
While FDA Testing Guidance requires critical room leak-testing certification twice a year, non-critical rooms require testing only once a year. With the extremely high tensile strength and durability of the ePTFE pleated filter media, 84 times stronger than microglass, ISO 7 and 8 areas could be tested annually. Increasing time between certifications results in less PAO exposure to the gel seal (gel degradation), lower labor costs, and increased production time.



Results based on Test Standard DIN EN 29073-3.



Results based on Test Standard DIN EN 13938-2.



Results based on Test Standard DIN EN 12947-2.

*Source: Pharmaceutical Manufacturing Magazine (2004).

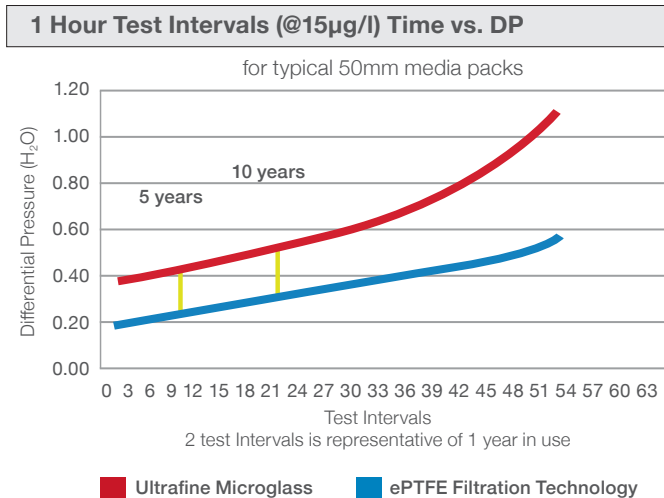
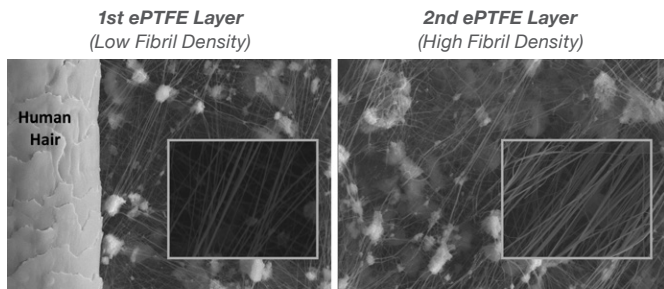
MEGAcel® II Filter

MEGAcel® II—First and Only PAO Compliant ePTFE Media HEPA Filter

The purpose of installed HEPA filter integrity testing, also called in-situ testing, is to confirm a flawless performance during normal operation. With AAF Flanders' new ePTFE Filtration Technology, MEGAcel II filters can now be scan tested with the industry standard photometer at standard aerosol concentrations, as well as the low aerosol concentration Discrete Particle Counter (DPC) method.

The MEGAcel II filter contains dual-layer ePTFE media specifically developed to retain equivalent amounts of PAO aerosol with the same or lower pressure drop increases as ultrafine microglass. The dual-layer ePTFE media allows for the in-depth capture of progressively smaller solid particles.

Independent laboratory studies have shown that MEGAcel II filters with ePTFE media have superior PAO holding capacity over traditional ultrafine microglass HEPA media, as seen in the results below.



Enhanced Chemical Tolerance

High Corrosion Resistance

ePTFE media is proven to be resistant in highly corrosive environments and will withstand attacks from common decontamination chemicals. Both components of the ePTFE media, the membrane and non-woven layers, are stable against exposure at the prescribed time and concentration for the above disinfectant agents.

Superior Water Resistance

Based on AAF Flanders' test lab results, ePTFE Media provides superior water resistance in comparison with ultrafine microglass media, reducing damage risk.

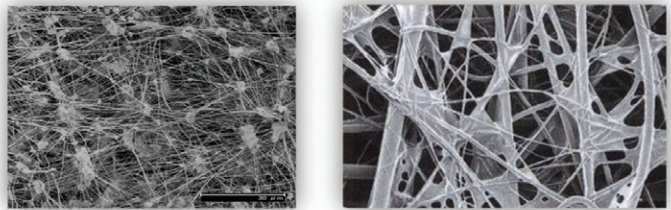
Negligible Offgassing

ePTFE media has extremely low offgassing of chemical components, resulting in the highest quality clean air available.

ePTFE Filtration Technology

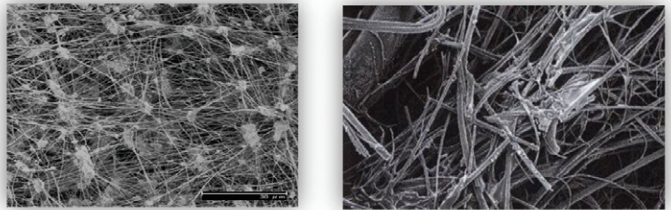
Ultrafine Microglass Media

BEFORE



AFTER

Damage after use of Hydrogen Peroxide (H₂O₂) for cleanroom sterilization.



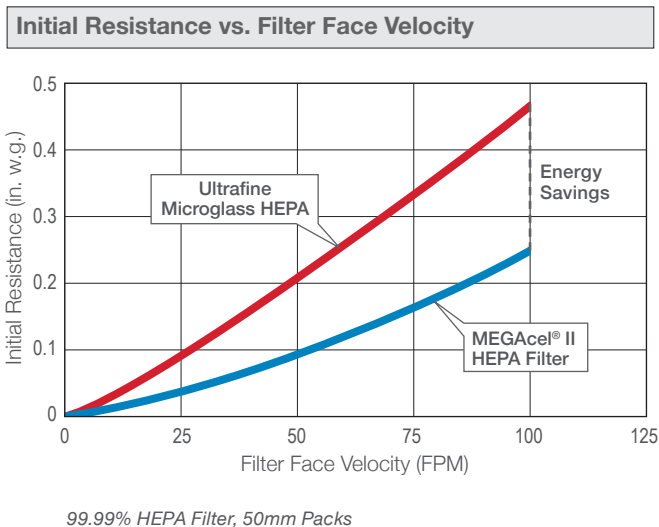
SEM photos at 5,000x magnification.

Lower Energy Consumption

Estimates show that up to 50% of a facility's energy consumption is used for heating, cooling, and air handling. With increasing utility prices and peak power billing plans, lowering energy consumption is a key initiative.

MEGAcel II filters with ePTFE media feature a lower pressure drop than traditional filters with ultrafine microglass media, up to 50% lower depending on the exact conditions. At the same time, the overall filtration efficiency for MEGAcel II filters has proven to be higher than for filters with ultrafine microglass media. The lower pressure drop and improved efficiency are achieved from an evenly distributed layer of fibers with very fine nanometer-scale diameters. Air molecules can efficiently pass through the fibers, and airborne particles can be captured more easily. **The result: air quality is optimized and energy costs are substantially reduced.**

Performance Data



Energy Savings Calculation

Average Pressure Drop

MEGAcel II Filter	0.25 in. w.g. (62 Pa)
Ultrafine Microglass HEPA	0.47 in. w.g. (117 Pa)

Airflow Rate 100 FPM – 0.5 m/sec

Annual Energy Consumption

ePTFE Media	285 kWh
Ultrafine Microglass HEPA	535 kWh
ΔSavings	250 kWh

Manufactured in ISO 7 Clean Facilities

Both the MEGAcel II HEPA filter and ePTFE Media are manufactured by AAF Flanders. By doing so, we can control the quality and consistency of the media. The media is produced in an ISO 7 cleanroom to ensure the purity and cleanliness of the product. The filter is then assembled, tested, and packaged in an ISO 7 clean manufacturing facility, resulting in unparalleled product performance and operational efficiency.



AAF Flanders ePTFE Filtration Technology produced in an ISO 7 cleanroom.

MEGAcel® is a registered trademark of AAF International in the U.S. and other countries.

Proven Expertise of AAF Flanders

AAF Flanders offers the most comprehensive air filtration portfolio in the industry, including particulate and gas-phase filters, to provide a customized clean air solution. Each product is carefully designed, manufactured, and tested in full compliance with all applicable standards to meet the most challenging demands with the lowest Total Cost of Ownership.

Contact your local AAF Flanders representative for a complete list of AAF Flanders Air Filtration Product Solutions.

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aafintl.com



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