

# MEGAcel® II

with ePTFE Filtration Technology

## MINI-PLEAT HEPA FILTERS



### 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

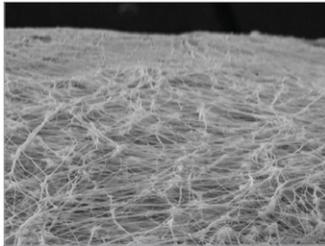
**MEGAcel® II**  
with ePTFE Filtration Technology

**Less Downtime. Less Worry. Less Risk.**

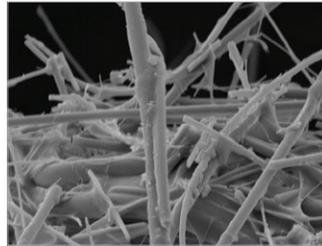
# MEGAcel® II Filters

## 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.

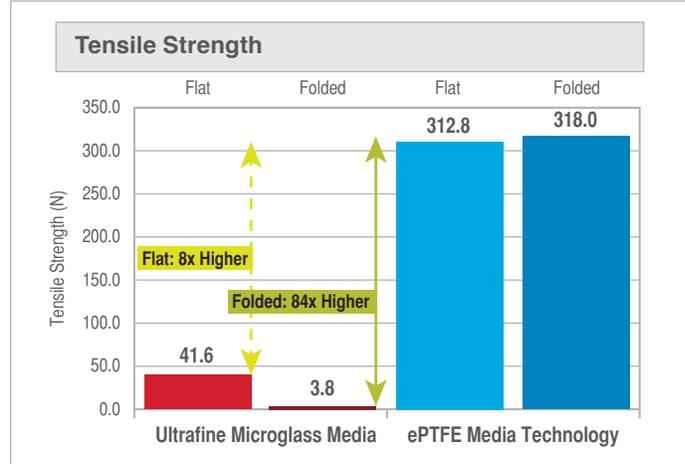
Superior mechanical strength is demonstrated by a high tensile strength, burst pressure, and abrasion resistance. ePTFE media retains its integrity with a high resistance to any potential damage, such as mishaps in handling or installation. This means that the risk of filter media failure is minimized 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

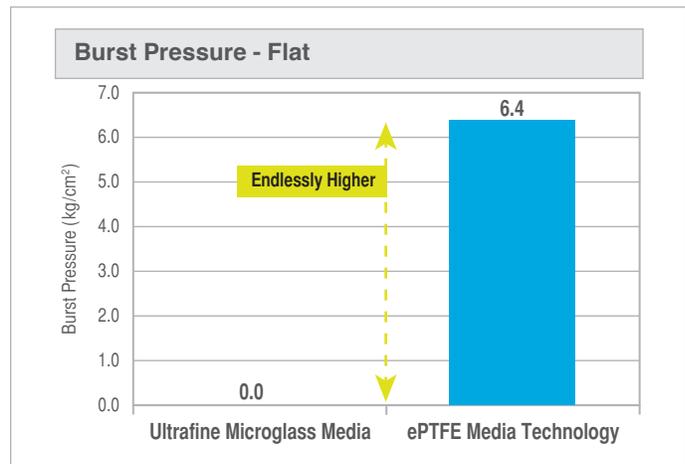
The pharmaceutical industry estimates that 77% of production downtime can be attributed to failures of equipment and environmental problems\*. This downtime can be caused by HEPA filters failing. Traditional HEPA filters typically fail due to some form of contact combined with the poor mechanical strength 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

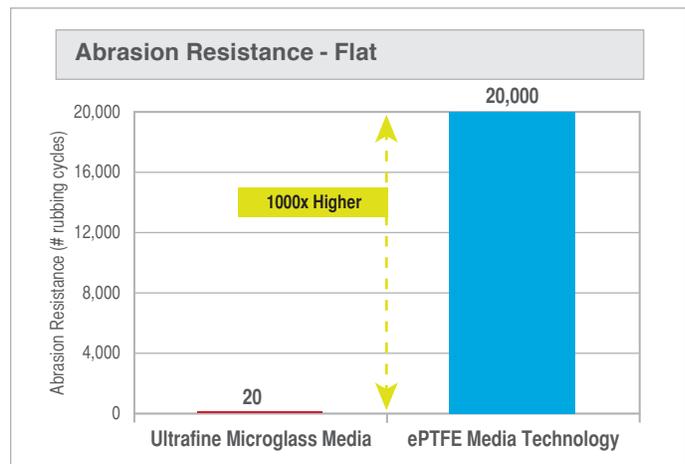
While FDA Testing Guidance requires critical room leak-testing certification twice a year, non-critical rooms require testing only once a year. With the extremely high tensile strength and durability of the ePTFE pleated filter media, 84 times stronger than microglass, ISO 7 and 8 areas can be tested 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.

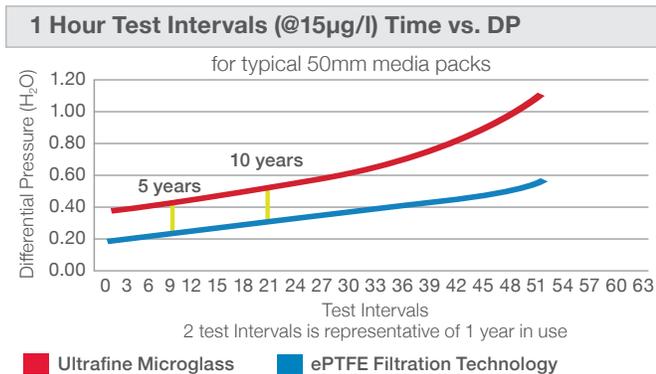
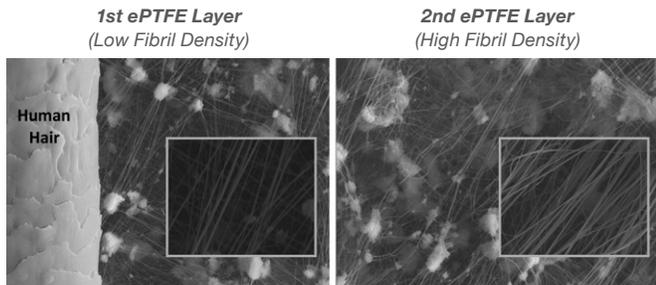
\*Source: Pharmaceutical Manufacturing Magazine (2004).

## MEGAcel® II—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.

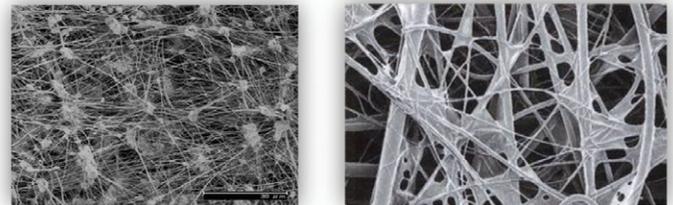
### Negligible Offgassing

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

## ePTFE Filtration Technology

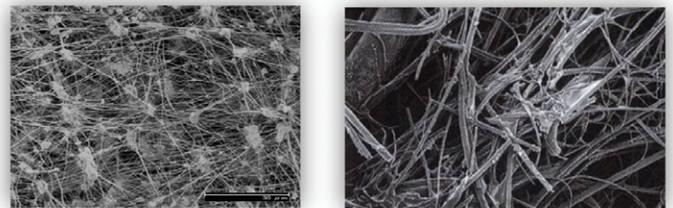
## Ultrafine Microglass Media

BEFORE



AFTER

Damage after use of Hydrogen Peroxide (H<sub>2</sub>O<sub>2</sub>) for cleanroom sterilization.



SEM photos at 5,000x magnification.

# MEGAcel® II Filters

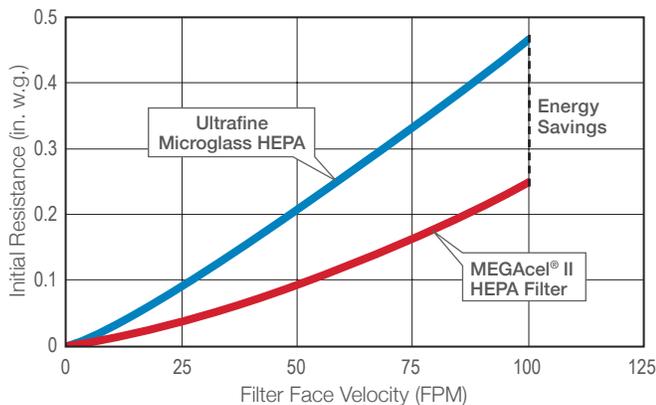
## Lower Energy Consumption

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

### Initial Resistance vs. Filter Face Velocity



99.99% HEPA Filter, 50mm Packs

## 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
$\Delta$ Savings	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.



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ISO Certified Firm

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