



# Filtros TETPOR® AIR

## Filtros de aire y gas de PTFE expandido

### Filtros de esterilización de aire TETPOR® AIR con un rendimiento de filtración de aire excepcional con los mayores niveles de bioseguridad en la industria de procesamiento

Los filtros TETPOR® AIR ofrecen soluciones de filtración a un precio asequible. La capa única de prefiltrado de polipropileno aumenta la vida útil en ambientes altamente contaminados.

Los cartuchos de filtro TETPOR® AIR usan una membrana de PTFE expandido hidrofóbica y de funcionalidad demostrada. Está validada con un grado de esterilización en líquido de acuerdo con ASTM F838-05. Esto asegura la eliminación de bacterias, virus y bacteriófagos aerotransportados.

### Regulaciones

Los materiales farmacéuticos se han manufacturado de acuerdo con cGMP, se han enjuagado con agua purificada y se han validado antes de su envío.

Los materiales farmacéuticos se ajustan a los requerimientos relevantes de:

- 21CFR Parte 177
- USP Plastics Class VI - 121°C y equivalentes ISO10993

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### Principales Beneficios

- Bioseguridad garantizada con filtración absolutamente validada
- Alta tasa de flujo con bajas caídas de presión
- Membrana de PTFE con alto volumen de huecos
- Se puede esterilizar con vapor a 142 °C (287,6 °F)
- Capa de prefiltrado única
- Vida útil larga

### Aplicaciones

- Filtración en ambientes altamente contaminados
- Eliminación de partículas biológicas aerotransportadas

Aplicaciones Técnicas Maquinsa, S.L. dispone de una zona de manipulación bajo norma ISO 9001/2015 y en la que se manipulan los materiales bajo las norma BPF (GMPs).

Bajo demanda podemos fabricar y manipular nuestros productos en sala blanca bajo norma. Nuestras plantas pueden ser auditadas a su requerimiento.

## Relacionados



Sensores Parker  
SciLog®



Sistemas de Laboratorio  
Automáticos



Carcasas para Filtros  
Parker



## TETPOR AIR Filters

- air / gas filters
- expanded PTFE

TETPOR AIR sterilization filter cartridges offer exceptional filtration performance while providing the highest levels of biosecurity throughout the process industry.

Operating at ambient temperature conditions, TETPOR AIR filter cartridges provide a cost-effective filtration solution. A unique polypropylene prefilter layer extends service life in heavily contaminated environments.

TETPOR AIR filter cartridges also utilize a well-proven, inherently hydrophobic expanded PTFE membrane validated as sterilizing grade in liquid in accordance with ASTM F838-05. This ensures the removal of all airborne bacteria, viruses and bacteriophage.

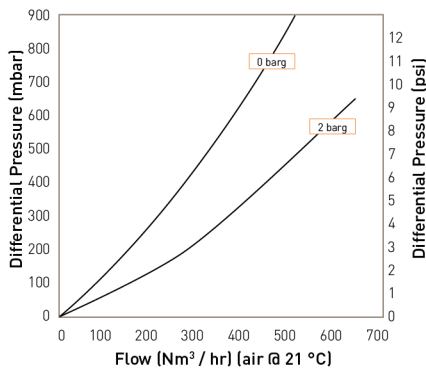
### Features and Benefits

- Assured biosecurity with absolute rated filtration
- High flow rates with low pressure drops
- High voids volume PTFE membrane
- Steam sterilizable to 142 °C (287.6 °F)
- Unique prefilter layer

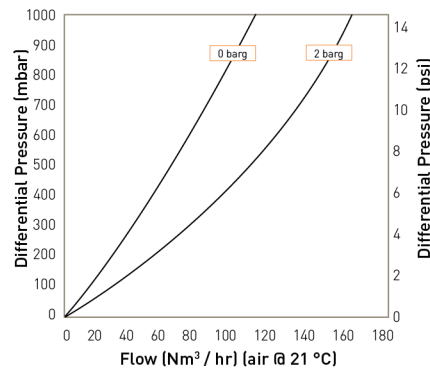


Note: TETPOR is a registered trademark of Parker Hannifin Corporation.

### Performance Characteristics



10" Size (250 mm) Cartridge



B Size (65 mm) Cartridge

## Specifications

### Materials of Construction

- Filtration Membrane: Expanded PTFE
- Upstream Support: Polypropylene
- Downstream Support: Polypropylene

#### Filter Cartridges

- Inner Support Core: Polypropylene
- Outer Protection Cage: Polypropylene
- End Caps: Polypropylene
- End Caps Insert: 316L Stainless Steel
- Standard o-rings/gaskets: Silicone

#### MURUS Disposable Filter Capsules

- Core: Polypropylene
- Sleeve: Polypropylene
- Standard o-rings: Viton
- Capsule Body: Polypropylene
- Capsules Vent Seals: Silicone

#### DEMICAP Filter Capsules

- Core: Polypropylene
- Sleeve: Polypropylene
- End Caps: Polypropylene
- Capsule Body: Polypropylene
- Capsules Vent Seals: Silicone
- Filling Bell: Polycarbonate

#### Syringe Filters

- Body: Polypropylene

### Recommended Operating Conditions

#### Filter Cartridges

Up to 60 °C (140 °F) continuous operating temperature and higher short-term temperatures during CIP to the following limits:

| Temperature |     | Max. Forward dP |       |
|-------------|-----|-----------------|-------|
| °C          | °F  | (bar)           | (psi) |
| 20          | 68  | 5.0             | 72.5  |
| 40          | 104 | 4.0             | 58.0  |
| 60          | 140 | 3.0             | 43.5  |
| 80          | 176 | 2.0             | 29.0  |
| 90          | 194 | 1.7             | 24.6  |

#### MURUS Disposable Filter Capsules

Up to 25 °C ( 77 °F) @ 5.5 barg (79.7 psig)

Up to 60 °C (140 °F) @ 2.8 barg (40.6 psig)

*Parker Hannifin certify that this product complies with the European Council Pressure Equipment Directive (PED) 97/23/EC Article 3, Paragraph 3 - Sound Engineering Practice (SEP). This product is intended for use with Group 1 & 2 Dangerous and Harmless Liquids and Group 2 Harmless Gases at the operating conditions stated in this document : In compliance with PED Article 3, Paragraph 3, SEP, this product does not bear the CE mark.*

#### DEMICAP Filter Capsules

Up to 40 °C (104 °F) at line pressures up to 5.0 barg (72 psig).

### Effective Filtration Area (EFA)

|                 |                       |                         |
|-----------------|-----------------------|-------------------------|
| 10" (250 mm):   | 0.77 m <sup>2</sup>   | (8.28 ft <sup>2</sup> ) |
| K Size:         | 0.36 m <sup>2</sup>   | (3.87 ft <sup>2</sup> ) |
| A Size:         | 0.25 m <sup>2</sup>   | (2.69 ft <sup>2</sup> ) |
| B Size:         | 0.12 m <sup>2</sup>   | (1.29 ft <sup>2</sup> ) |
| E Size:         | 0.06 m <sup>2</sup>   | (0.64 ft <sup>2</sup> ) |
| Syringe ø50 mm: | 14.50 cm <sup>2</sup> | (2.25 in <sup>2</sup> ) |

### Sterilization

|            | Autoclave |                   | Steam-in-Place |                   |
|------------|-----------|-------------------|----------------|-------------------|
|            | Cycles    | Temp              | Cycles         | Temp              |
|            |           |                   | (30 min.)      |                   |
| Cartridges | 120       | 142 °C (287.6 °F) | 120            | 142 °C (287.6 °F) |
| MURUS      | 5         | 130 °C (266 °F)   | -              | -                 |
| DEMICAP    | 100       | 135 °C (275 °F)   | -              | -                 |
| Syringe    | 1         | 130 °C (266 °F)   | -              | -                 |

For detailed operational procedures and advice on cleaning and sterilization, please contact the Technical Support Group through your usual Parker domnick hunter contact.

### Biological Safety

Materials conform to the relevant requirements of 21CFR Part 177 and current USP Plastics Class VI - 121 °C and ISO10993 equivalents.

## Performance Characteristics

### TOC / Conductivity

The filtrate quality from a 10" (250 mm) TETPOR AIR conforms to the requirements of current USP <643> (TOC) and USP <645> (conductivity).

### Endotoxins

Aqueous extracts from the 10" (250 mm) TETPOR AIR contain < 0.25 EU / ml when tested in accordance with the Limulus Amoebocyte Lysate test.

### Non-Volatile Extractables (NVE)

Total NVEs extracted in the first 5 litre flush of purified water for a 10" (250 mm) cartridge are <5 mg.

### Pharmaceutical Validation

A full validation guide is available upon request from Laboratory Services Group (LSG).

### Oxidizable Substances

TETPOR AIR filter cartridges meet current USP and EP quality standards for sterile purified water for oxidizable substances following a <1 litre water flush.

### Integrity Test Data

All filters are integrity testable to the following limits when wet with 60 / 40 : IPA /water and using air as the test gas.

| Cartridge | Test Pressure |        | Diffusional Flow | Water Intrusion Test Pressure |        | Water Intrusion | Water Flow    |
|-----------|---------------|--------|------------------|-------------------------------|--------|-----------------|---------------|
|           | (barg)        | (psig) |                  | (barg)                        | (psig) | (ml / 10 min)   | (µl / 10 min) |
| E         | 0.8           | 11.6   | 1.5              | 2.5                           | 36.3   | 1.3             | 371           |
| B         | 0.8           | 11.6   | 3.0              | 2.5                           | 36.3   | 2.6             | 742           |
| A         | 0.8           | 11.6   | 6.0              | 2.5                           | 36.3   | 5.3             | 1514          |
| K         | 0.8           | 11.6   | 8.3              | 2.5                           | 36.3   | 7.2             | 2060          |
| 10"       | 0.8           | 11.6   | 17.7             | 2.5                           | 36.3   | 15.3            | 4370          |

### Retention Characteristics

TETPOR AIR filter cartridges are validated by bacterial challenge testing with *Brevundimonas diminuta* to current ASTM F838-05 methodology (10<sup>7</sup> organisms / cm<sup>2</sup> EFA minimum) with typical in-house challenge levels being 10<sup>11</sup> organisms per 10" (250 mm) filter cartridge.