# Product information

# STERYKLEAR 0.1 micron

## 0.1 micron for MYCOPLASMA RETENTION

STERYKLEAR KSP and KSE filter elements adopt SE-TECH technology which allows to achieve better filtration results from the PES membranes; the design optimises the flow distribution between the filter media and the internal core to avoid restrictions and to exploit the full area of the cartridge to generate higher throughput and increase service life.
STERYKLEAR KSP and KSE are utilized as final sterilizing filters in pharmaceutical and biological process application. For critical applications is used PH-grade, which is preflushed with non-pyrogenic water and provided with certification of quality. Manufacturing is completed in a clean room and testing during the manufacturing process assures compliance with high quality standards.

### MATERIALS OF CONSTRUCTION

| | |
|---|---|
| **Filter media** | PES membrane |
| **Support KSP configuration** | polypropylene |
| **Support KSE configuration** | polyester |
| **Internal Core** | polypropylene |
| **External Cage** | polypropylene |
| **End caps/Adapters KSP** | polypropylene |
| **End caps/Adapters KSE** | polyester |

### FOOD-SAFETY AND FDA

STERYKLEAR KSP-KSE filter elements are made from materials listed for food contact use per Title 21 of CFR.

### BIO-SAFETY

Filter media and components pass USP Biological Reactivity and Chemical-Physical tests for CLASS VI plastics.
Specific for "PH" grade: the filter meets USP "Water for injection" requirements for particle release and the effluent is Non-Pyrogenic per USP Bacterial Endotoxins (< 0,25 EU/ml).

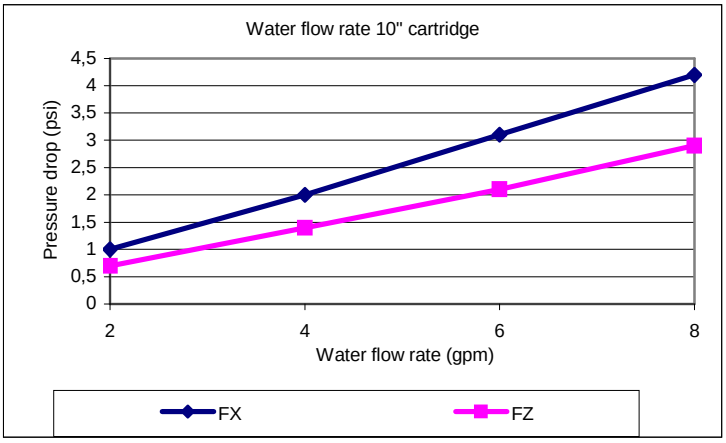
### QUALITY STANDARDS

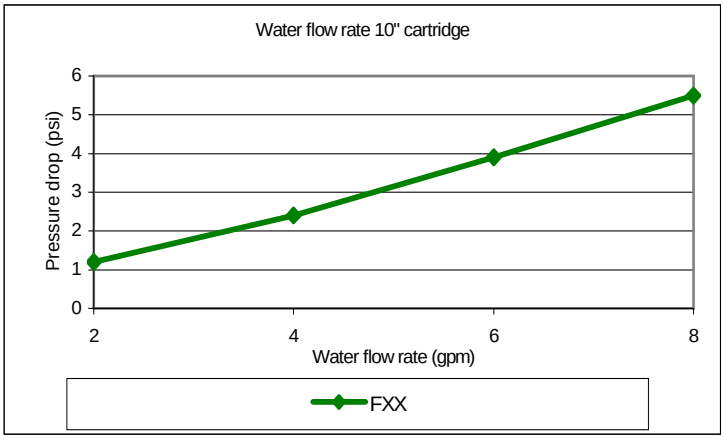
Produced under a certified ISO 9001 Quality System to guarantee traceability of manufacturing records and integrity testing results.

### OPERATING CONDITIONS

| | |
|---|---|
| **- max. continuous temperature** | 176°F (80 °C) |
| **- max. cumulative time of steam sterilization** | 13 hours at 257°F (125°C) with cycles of 30 minutes |
| **- sanitization with hot water** | 176°F (80 °C max) |
| **- sanitization with chemicals** | can be sanitized by standard chemical agents |
| **- max. differential pressure** | 73 psi at 77°F (5,0 bar at 25°C) |
| **- recommended change out differential pressure** | 29,0 psi at 77°F (2,0 bar at 25°C) |
| **- recommended rinse up volume** | 1 gallon/10" module (4 liters/10" cartridge) |

| CODE | ABSOLUTE FILTRATION RATING IN LIQUIDS | BACTERIAL RETENTION $>10^{10}$ CFU/10" CARTRIDGE* | ACCEPTABLE LIMIT FOR DIFFUSION FLOW TEST WITH WATER FOR 10" CARTRIDGE (ml/min) |
|---|---|---|---|
| FZ | 0,1 µm single membrane high flow rate | Brevundimonas diminuta | ≤ 40 @ 51 psi (or 3,5 bar) |
| FX | 0.1 µm single membrane | Acholeplasma laidlawii | ≤ 30 @ 51 psi (or 3,5 bar) |
| FXX | 0.1 µm double membrane | Acholeplasma laidlawii | ≤ 26 @ 51 psi (or 3,5 bar) |
| *as per ASTM F838-83 edition 1993 | | | |




## STERYKLEAR ORDERING INFORMATION

**KSE - 207 1 - FZ - PH - SB -** [ ]

| CODE | END CAPS MATERIAL |
|---|---|
| E | Polyester |
| P | Polyopropylene |

| END FITTING | CODE |
|---|---|
| SOE: open end with (2) O-Ring 2.226 and 2 bayonet locks. Blind end with fin. | 207 |

| CODE | NOMINAL LENGTH |
|---|---|
| 1 | 10″ |
| 2 | 20″ |

| ABSOLUTE FILTRATION RATING micron | CODE |
|---|---|
| 0.1 single membrane high flow rate | FZ |
| 0.1 single layer membrane | FX |
| 0.1 double layers membrane | FXX |

| CODE | PRODUCT GRADE |
|---|---|
| PH | Biological Grade; tested and preflushed with Non-pyrogenic water. Quality Certification, with serial number, in the box. |

| CODE | PACKING TYPE |
|---|---|
| SB | Single box |

| CODE | GASKETS | |
|---|---|---|
| No code | Standard | Silicone |

PI-002-KSP/KSE-UK-07-2

Data contained are informative and subject to change without notice.
User is responsible for determining whether the product is fit for particular purpose and suitable for User's method of application.

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