

Catalog Number: 431227

Product Description: Corning® syringe filter, Teflon™ (PTFE) membrane, 0.20 µM pore size, 50 mm diameter, individually packaged

Component Materials:

- Housing - Polypropylene, meets *USP, Class VI* requirements for plastic containers and closures.
- Membrane - Teflon™ (PTFE), 0.20 µM pore size, meets *USP, Class VI* requirements for plastic containers and closures.
Teflon is a registered trademark of E.I. DuPont DeNemours, Wilmington, Delaware

Product Dimensions:

- | | | | | | |
|---------------------------|---|----------------------|----------------|---|-----------------------|
| Diameter of unit | - | 2.52 in. (63.9 mm) | Length of unit | - | 2.72 in. (69 mm) |
| Diameter of membrane | - | 1.97 in. (50 mm) | Tolerances | - | +/- 0.05 in. (1.3 mm) |
| Effective filtration area | - | 20.0 cm ² | | | |

Sterilization:

This lot has been sterilized according to *Medical Devices - Validation and routine control of ethylene oxide sterilization* and released after successful sterility testing of Biological Indicators.
Sterility Assurance Level: SAL 10⁻⁵

HPLC Certified:

The product has been tested to ensure there are no extraneous peaks in the UV range.

Membrane Bubble Point:

The product has been tested according to an established procedure to determine the water bubble point of the product. The product meets the established criteria of >1.4 bar.

Housing Burst Pressure Test:

The product has been tested according to an established procedure to determine the housing burst pressure. The product meets the established criteria of >4 bar (approx. 58 psi).

Flow Rate Test:

The product has been tested according to an established procedure to determine the flow rate of air. The product meets the established criteria of >2 L/min/0.05 bar.

Bacterial Challenge:

The product has been tested and determined to be quantitatively retentive when challenged with a concentration of 10⁷ organisms per cm² using *Brevundimonas diminuta*.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

- | | |
|---------------------|--|
| Pressure Hold Test: | Forward pressurization of the unit to 0.8 bar. |
| Visual Attributes: | Visual examination of the product. |
| Packaging: | Inspection for seal and barrier integrity, accurate labeling, and correct product configuration. |

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date of manufacture; Next 2 digits - Year of manufacture; Last 3 digits - Run number for that year.

Revision Date:

01-24-19

Rev No: 2