

Supor™ AEF 0.2 µm Filter

Product Codes: AEF1E, AEF1NTE

Description

The Supor AEF Filter is an air eliminating filter with low protein binding 0.2 µm polyethersulphone membrane for up to 24 hours use with intravenous solutions.

Configuration

AEF1E: Supor AEF filter device with female Luer lock Inlet port with cap, 25 cm downstream microbore tubing with slide clamp, male Luer lock outlet port with cap (50 units per case).

AEF1NTE: Supor AEF filter device with female Luer lock inlet port with cap and male Luer lock outlet port with rotating luer locking collar and cap (50 units per case).

These products are CE marked under the Medical Device Regulation (EU) 2017/745.

Indications

It is indicated for up to 24 hours use, with any administration set, for the removal of inadvertent particulate debris, microbial contaminants and entrained air which may be found in solutions intended for intravenous use.

Contraindications

This device cannot be used to administer cellular blood products, suspensions, emulsions including microemulsion vitamin preparations, or medications that are not fully dissolved in the fluid being administered. The device should not be used to filter solutions that are known to be pyrogenic or contaminated with micro-organisms.

Precautions

FOLLOW INSTRUCTIONS FOR USE CAREFULLY

Materials of Construction

Refer to the Cytiva website (www.cytiva.com) for the Product Safety Data Information in the PSDI_AEF_Family Datasheet.



Performance

- 1. Filter Membrane:** The Supor membrane is inherently hydrophilic and chemically and biologically inert with no extractable wetting agents
- 2. Protein Binding/Drug Compatibility:** The Supor membrane has been tested with over 55 different drugs and demonstrated to have low protein binding and broad drug compatibility
- 3. Bacterial Removal:** ≥ 3 log reduction challenged with 1×10^7 CFU / cm² EFA (Effective Filtration Area) *Brevundimonas aeruginosa*
- 4. Maximum Recommended Working Pressure:** 200 kPa (2 bar, approx. 30 psi, 1500 mm Hg)
- 5. Flow rate with 0.9% saline at 1m gravity feed:**
AEF1E Approx. 8 to 9 mL/ min
AEF1NTE: Approx. 10 to 12 mL/min
Max. flow rate is dependant on factors such as variant used, viscosity of solution, other equipment in the IV line and particulate loading.
- 6. Can be used** with infusion pumps or under gravity, for continuous infusion or intermittent infusions.

Specifications

Filtration Media (hydrophilic Supor™ membrane)

Pore Size	0.2 µm
Effective Filtration Area	Approx. 4.5 cm ²

Air Elimination Membranes (hydrophobic PTFE)

Number	2
Effective Venting Area	Approx. 0.12 cm ² each

Tubing (AEF1E only)

Nominal dimensions	Microbore (0.9 mm ID/2.2 mm OD)
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Hold-up Volume

AEF1E	1.2 mL
AEF1NTE	1.0 mL

Filter Housing Dimensions (all approx.)

Length	5.6 cm (including ports)
Width	3.3 cm
Depth	1.0 cm

Device Weight

AEF1E	< 6.5 g
AEF1NTE	< 4.5 g

Natural rubber latex is **not** used as a material in the manufacturing of the product, its container, or its packaging.

Non-phthalate fluid pathway

Sterility

Sterile and non-pyrogenic fluid pathway. Sterilised by Gamma irradiation.

Shelf Life

5 years

Quality

- All materials in the fluid pathway meet relevant sections of ISO 10993 series of standards
- Conform to ISO 8536-11
- Male and female Luer connectors tested in accordance with ISO 80369-7
- Sterilised in accordance with ISO 11135
- Designed and manufactured using quality systems approved ISO 9001 and ISO 13485
- Manufacturing Environment: ISO 14644 Class 8

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