

Posidyne[®] NEO Filter

Product Codes (US): NEO96, NEO96NY

Description

The Posidyne NEO Filter is an air eliminating filter with positively charged 0.2 µm membrane for up to 96 hours use with solutions intended for intravenous administration.

Configuration

NEO96: Posidyne NEO filter device with 7 cm upstream ultramicrobore inlet tubing and female Luer lock inlet port with cap and with 7 cm downstream ultramicrobore tubing with slide clamp, male Luer lock outlet port with cap (50 units per case).

NEO96NY: Posidyne NEO filter device with 6 cm upstream ultramicrobore inlet tubing and female Luer lock inlet port with cap and with 12 cm downstream ultramicrobore tubing with slide clamp, needleless 'Y' access site, male Luer lock outlet port with cap (50 units per case).

Indications

It is indicated for up to 96 hours use, with any administration set, for the removal of inadvertent particulate debris, microbial contaminants and their associated endotoxins, entrained air which may be found in solutions intended for intravenous administration.

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.

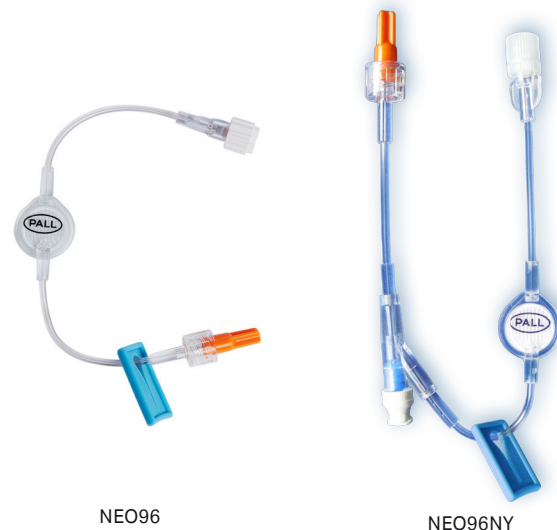
The device should not be used to filter solutions that are known to be pyrogenic or contaminated with micro-organisms.

Precautions

FOLLOW INSTRUCTIONS FOR USE CAREFULLY

Materials of Construction

Refer to the Cytiva website (www.cytiva.com) for the Product Data Information in the PSDI_NEO_Family Data Sheet.



NEO96

NEO96NY

Performance

- Bacterial Removal:** ≥ 3 log reduction challenged with 1×10^7 CFU / cm² EFA (Effective Filtration Area) *Brevundimonas aeruginosa*
- Endotoxin Removal:** < 0.1 EU/mL endotoxin detected downstream, challenged with 1×10^8 CFU *E.coli* over the device's 'in use' life of 96 hrs
- Maximum Recommended Working Pressure:** 200 kPa (2 bar, approx. 30 psi, 1500 mm Hg).
- Flow rate with 0.9% saline at 1 m gravity feed:**
NEO96: Approx. 1.8 to 2.4 mL / min
NEO96NY: Approx. 1.6 to 2.4 mL/min
Max. flow rate is dependent on factors such as variant used, viscosity of solution, other equipment in the IV line and particulate loading.
- Can be used** with infusion pumps or under gravity, for continuous infusion or intermittent infusions.

Specifications

Filtration Media (hydrophilic Posidyne® membrane)

Pore Size	0.2 µm
Effective Filtration Area	Approx. 1.65 cm ²

Air Elimination Membrane (hydrophobic PTFE)

Number	1
Effective Venting Area	0.12 cm ²

Tubing

Nominal dimensions	Ultra-microbore (0.5 mm ID/2.2 mm OD)
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Hold-up Volume

NEO96	0.5 mL
NEO96NY	0.6 mL
Y-site to Tubing Outlet Volume (NEO96NY)	0.2 mL

Filter Housing Dimensions (all approx.):

Length	3.8 cm (including ports)
Width	2.0 cm
Depth	0.8 cm

Device Weight

NEO96	< 4.0 g
NEO96NY	< 6.5 g

Not made with natural rubber latex

Non-phthalate fluid pathway

Sterility

Sterile and non-pyrogenic fluid pathway. Sterilized with Gamma irradiation for NEO96 and with ethylene oxide for NEO96NY

Shelf Life

NEO96	5 years
NEO96NY	3 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
- Sterilized 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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