

Posidyne[®] ELD Filter

Product Codes (US): ELD96LL, ELD96LYL, ELD96LYLS, ELD96NYS, ELD96NT

Description

The Posidyne ELD 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

ELD96LL: Posidyne ELD filter device with female Luer lock Inlet port with cap, 24 cm downstream microbore tubing with slide clamp, male Luer lock outlet port with cap (48 units per case).

ELD96LYL: Posidyne ELD filter device with female Luer lock Inlet port with cap, 24 cm downstream microbore tubing with slide clamp and 'Y' access site, male Luer lock outlet port with cap (48 units per case).

ELD96LYLS: Posidyne ELD filter device with female Luer lock Inlet port with cap, 24 cm downstream standard bore tubing with slide clamp and 'Y' access site, male Luer lock outlet port with cap (48 units per case).

ELD96NYS: Posidyne ELD filter device with female Luer lock Inlet port with cap, 24 cm downstream standard bore tubing with slide clamp and needleless 'Y' access site, male Luer lock outlet port with cap (48 units per case)

ELD96NT: Posidyne ELD filter device with female Luer lock inlet port with cap and male Luer lock outlet port with a rotating luer locking collar and cap (40 units per case).

These products are 510k cleared by FDA.

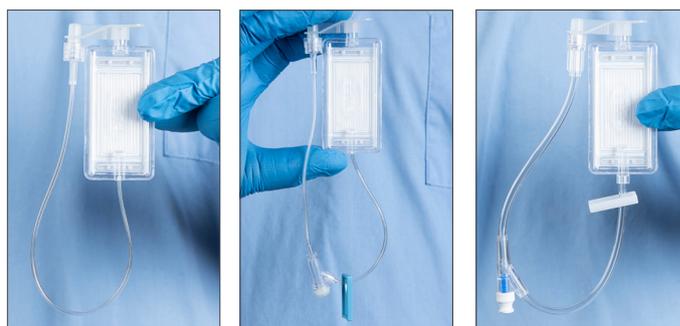
Indications

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 and entrained air which may be found in solutions intended for intravenous administration.

Contraindications

It is not designed, sold nor intended for use except as indicated. It 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.



ELD96LL

ELD96LYL

ELD96NYS

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_ELD_Family Data Sheet.

Performance

- 1. Bacterial Removal:**
≥ 3 log reduction challenged with 1×10^7 CFU / cm² EFA (Effective Filtration Area) *Brevundimonas aeruginosa*
- 2. 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
- 3. Maximum Recommended Working Pressure:** 200 kPa (2 bar, approx. 30 psi, 1500 mm Hg).
- 4. Flow rate with 0.9% saline at 1m gravity feed:**
Approx. 10 to 29 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.
- 5. 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. 11 cm ²

Air Elimination Membranes (hydrophobic PTFE)

Number	2
Effective Venting Area	Approx. 0.70 cm ² each

Tubing

Microbore 0.9 mm ID/2.0 mm OD (ELD96LL, ELD96LYL)
Standard bore 3 mm ID/ 4.1 mm OD (ELD96LYLS, ELD96NYS)

Hold-up Volume

ELD96LL, ELD96NT:	2.5 mL
ELD96LYL:	2.7 mL
ELD96LYLS, ELD96NYS:	4.3 mL
Y-site to Tubing Outlet Volume:	0.45 mL (ELD96LYL) 1.2 mL (ELD96LYLS) 1.0 mL (ELD96NYS)

Filter Housing Dimensions (all approx.):

Length	7.8 cm (including port) Except ELD96NT: 9.6 cm (including ports)
Width	3.6 cm
Depth	1.0 cm

Device Weight

ELD96LL	< 16 g
ELD96LYL	< 17 g
ELD96NT	< 14.5 g
ELD96LYLS	< 18.5 g
ELD96NYS	< 19 g

Not made with **Natural rubber latex**

Non-phthalate fluid pathway

Sterility

Sterile and non-pyrogenic fluid pathway. Sterilised by ethylene oxide.

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



ELD96LYLS



ELD96NT

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