

Pall Total Nutrient Admixture (TNA) Filter

Product Code (US)

TNA1

Description

This product is 510k cleared by FDA.

Indications

The Pall **Total Nutrient Admixture** TNA Filter is an air eliminating filter with 1.2 µm low protein binding membrane and non-phthalate fluid pathway.

It is indicated for the removal of inadvertent particulate debris and microorganisms (*Candida albicans*) from total nutrient admixtures and undiluted intravenous fat emulsions.

Designed for use with intravenous infusion pumps only.

Contraindications

This device is not designed, sold or intended for use excepted as indicated. The filter should not be used to filter cellular blood products or filter any preparation that is known to be pyrogenic or contaminated with micro-organisms.

Precautions

FOLLOW INSTRUCTIONS FOR USE CAREFULLY

Material of Construction (Fluid Pathway)

Filter Housing: Acrylic

Filter Media: Polyamide - hydrophilic

Air Elimination Membrane: Polytetrafluoroethylene (PTFE)/Polyester - hydrophobic

Tubing Extension: Non-phthalate (TOTM plasticised) polyvinyl chloride (PVC)

Male Luer Connector: Acrylonitrile-butadiene-styrene (ABS)

Not made with natural rubber latex

Performance

1. Contaminant Removal: For the removal of inadvertent particulate debris, entrained air and enlarged lipid droplets

2. Microbial Removal:

100 % removal of a total challenge of 6.0×10^8 CFU *Candida albicans*

100 % removal of a total challenge of 4.0×10^7 CFU *Malassezia furfur*

3. Protein binding: Contains a low protein binding filter membrane.

4. Recommended Change: 24 hours

5. Maximum Recommended Working Pressure:

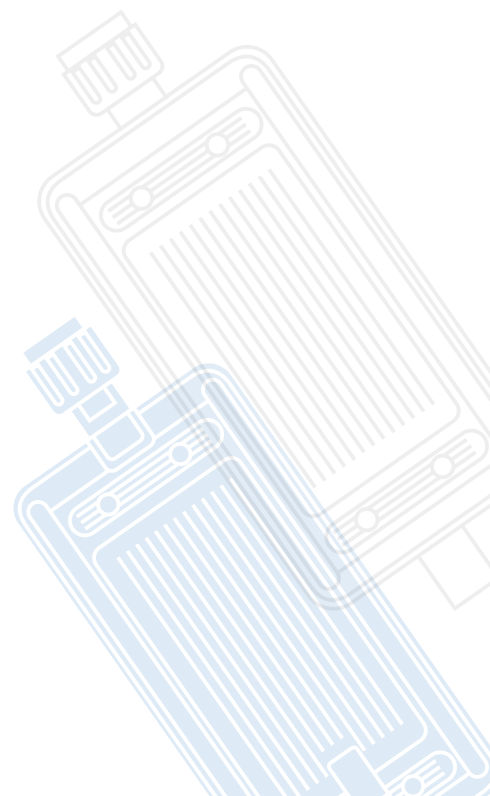
152 kPa (1.5 bar, approx. 22 psi, 1140 mmHg)

6. Maximum Recommended Flow Rate (with pump):

300 mL/hour for a typical lipid containing admixture

7. Infusion Pumps: When administering lipid containing preparations, an infusion pump must be used

8. Effect on Lipid Droplet Distribution: Does not adversely affect normal lipid droplet distribution



Pall TNA Filter Technical Data

Specifications

Filtration Media:

- **Pore Size:** 1.2 µm
- **Surface Area:** Approx. 11 cm²

Air Elimination Membranes:

- **Number:** 2
- **Surface Area:** Approx. 1.8 cm²

Tubing: Microbore (0.9 mm ID/2 mm OD),
24 cm length downstream of the filter

Hold-up Volume (including tubing): Approx. 2.3 mL

Connections: ISO male luer outlet and ISO female
luer inlet

Sterility: Sterile (Ethylene oxide) and non-pyrogenic
fluid pathway

Shelf Life: 5 years

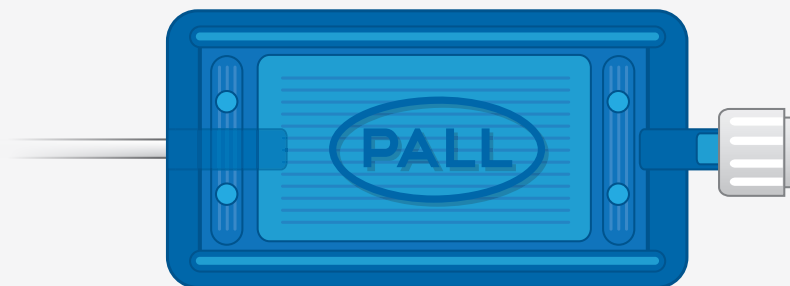
Packaging

40 Units Per Case

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 conform to ISO 594-2
- Sterilized in accordance with ISO 11135
- Designed and manufactured using quality systems approved ISO 9001 and ISO 13485

TNA Filter shown at approx. size



Filter Housing Dimensions
(approx.)

Length: 6.9 cm
Width: 3.6 cm
Depth: 0.7 cm



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