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Technical Report

Flow Rate Performance of the **PALL** *Lipipor* **TNA2E Filter in Gravity-Driven Parenteral Nutrition Infusions**

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Introduction

The **Pall** *Lipipor* TNA2E Filter is a self-priming, air-eliminating filter with a 1.2 µm low protein binding membrane and non-phthalate fluid pathway. It is indicated for the removal of inadvertent particulate debris, enlarged lipid droplets, fungal contaminants and entrained air that may be found in parenteral nutrition (PN) infusions containing lipid.

Gravity-driven infusions are used in the administration of parenteral nutrition when pumps are not required or are unavailable, whereas 1.2 µm filters intended for use with lipid-containing infusates have generally been used to deliver pumped infusions. Previous authors have already reported satisfactory performance of the **Pall** *Lipipor* TNA2E Filter in the delivery of an admixture typically delivered by gravity infusion[1]. This study was conducted to assess the gravity flow performance of the filter in the delivery of an admixture compounded to a different regimen that is widely delivered by pumped infusion

Method

Pall *Lipipor* TNA2E filters were tested with typical lipid-containing admixtures used in parenteral nutrition. Flexible containers of admixture were compounded by a commercial supplier to commonly used clinical regimens (Kabiven® and Kabi 11, Fresenius Kabi, Uppsalla, Sweden). Trace element and vitamin preparations (Additrace®, Vitlipid N® Adult and Solivito N®, Fresenius Kabi, Uppsalla, Sweden) were added to Kabi 11 admixture before use, according to the manufacturer's recommendations.

In the initial test, two control filters with 1.2 µm membranes indicated for pumped infusions were included and all tests were run in triplicate using Kabiven® admixture.

Each filter was attached to a typical gravity infusion system set to flow at 1 m head height and primed according to the Instructions for Use. The filter outlet was placed into a clean dry measuring cylinder and flow was initiated with the infusion set clamp completely open. The volume delivered was recorded every minute for ten minutes.
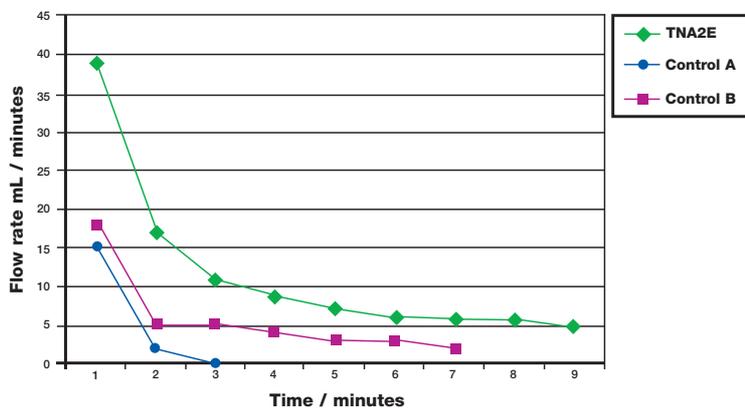
To assess the gravity flow performance of **Pall** *Lipipor* TNA2E Filters to deliver typical daily infusion regimens, filters from three different production lots were tested at two nominal infusion rates, to deliver typical daily volumes of Kabi 11 admixture.

Results

In unrestricted gravity flow conditions, the flow rate stabilised shortly after the start of the infusion in all filters tested (see Figure 1). The mean flow rate at T=3, T=7 and T=10 minutes was calculated for the replicate filter (see Table 1).

By T=3 minutes flow through control filter A had stopped. By T=7 minutes the flow through control filter B had declined to 2 mL/min. The test filters continued to deliver flow throughout the ten-minute test period. The mean flow rate over time through the test filters after the initial stabilisation period of three minutes was 5 mL/min

Figure 1: Unrestricted gravity flow rate of 1.2 µm filters for PN containing lipids.

Results

Table 1: Flow rate of the Pall *Lipipor* TNA2E Filter in unrestricted gravity flow infusion conditions.

	Mean flow rate (mL/min)		
T (min)	TNA2E	Control A	Control B
3	11	0	5
7	6		2
10	5		

Part two of the test assessed the TNA2E gravity flow performance over 24h. In these tests at pre-set nominal clinical flow rates, the **Pall** *Lipipor* TNA2E filters delivered a typical daily regimen of lipid-containing admixture under gravity flow conditions within a 24 hour period. (see Table 2).

Table 2. Gravity flow filtration of typical lipid-containing nutrient admixture with Pall *Lipipor* TNA2E Filters

	Volumes delivered during simulated daily gravity infusion	
Filter lot number	Nominal gravity flow rate, mL/min	Mean volume admixture delivered within 24 hours, mL
9576	2	2065
	2.5	3015
9577	2	2070
	2.5	2735
9578	2	2090
	2.5	2475

Discussion and Conclusion

The **Pall** *Lipipor* TNA2E Filter effectively delivered typical lipid-containing nutrient admixtures in gravity-driven infusions. This supports previous work in which the effective delivery of a different admixture, compounded with a different lipid emulsion, was demonstrated at flow rates of 1.3 to 2mL/min[1].

The use of filters for parenteral nutrition is recommended by several authorities and expert groups including the US Food and Drug Administration[2], the American Society for Parenteral and Enteral Nutrition[3] (ASPEN), and the British Pharmaceutical Nutrition Group[4] (BPNG); principally for the removal of inadvertent particulate material including precipitates. Filtration of admixtures has also been proposed for the removal of enlarged lipid droplets, which may become lodged within the lung microvasculature[5].

The **Pall** *Lipipor* TNA2E Filter is also designed to eliminate air, thus protecting against air embolism[6] and to retain fungal contaminants, such as *Candida* species, which can survive and replicate in lipid-containing preparations[7].

References

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