

<Customer Name>
<Postal Address>
<City>
<Country>

02 July 2021

Dear <Customer Name>,

URGENT FIELD SAFETY NOTICE

Commercial name of affected products:

Pall Nanodyne ELD™ Filter
Pall Lipipor TNA™ Filter

FSCA Identifier:

PNQ-CY21-010

Type of Action:

Voluntary Recall

Details on affected device:

Product Code	Lot Numbers
ELD96LLCE	21-674, 21-683
TNA1E	21-678, 21-716, 21-727

Description of the problem:

The Pall Nanodyne™ ELD Filter (product code ELD96LLCE) is an air eliminating filter with 0.2 µm Posidyne® membrane 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 and the reduction of nanosized particles which may be found in solutions intended for intravenous or subcutaneous administration.

The Pall Lipipor™ TNA Filter (product code TNA1E) is an air eliminating filter with 1.2 µm low protein binding membrane and non-phthalate fluid pathway. This device is indicated for the removal of inadvertent particulate debris, microbial contaminants and entrained air which may be found in intravenous preparations, and enlarged lipid droplets in the case of nutrient admixtures and lipid emulsions.

Pall have recently become aware of partially occluded male luer connectors as a result of a defect within moulded male luer connector components. This issue has been observed in one lot number of connectors which have subsequently been assembled into Pall Nanodyne™ ELD Filters and Pall Lipipor™ TNA Filters with the lot numbers identified in the table above. To date Pall have not received any reports of adverse events concerning this issue and an investigation is in progress to determine the root cause. This investigation will include identifying and implementing any appropriate corrective actions.

The observed defect appears to be on the internal fluid pathway, on the patient side of the filter. As such it has been determined that the use of Pall Nanodyne™ ELD Filters and Pall Lipipor™ TNA Filters from the affected lot numbers could potentially result in embolism if particles from the defect were to be released into the fluid pathway whilst the filter is in use.

It has therefore been decided to recall Pall Nanodyne™ ELD Filters (product code ELD96LLCE) and Pall Lipipor™ TNA Filters (product code TNA1E) with the lot numbers listed in the table above. It is advised that any such filters be removed from clinical use and replaced with filters from another lot number.

Advice on action to be taken by the user:

Please immediately identify and quarantine any Pall Nanodyne™ ELD Filters (product code ELD96LLCE) and Pall Lipipor™ TNA Filters (product code TNA1E) with the lot numbers identified in the table above. Quarantined units can be destroyed, or any unused filters returned to Pall.

Please complete the attached acknowledgement form and return it to <Name> by email <name>@pall.com. <Name> will arrange return of the quarantined units, if applicable, and will be in contact with you regarding credit for the affected product.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the devices within the scope of this Field Safety Notice have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

If you require any further information, please contact one of the following:

Primary Contact:

Andrew Norrish
QA/RA Manager
Pall Newquay
A Division of Pall Manufacturing UK
St Columb Major
Cornwall,
TR9 6TT, UK
Tel: +44 7929 766379
email: andrew_norrish@pall.com

Secondary Contact:

Nicky Wheatley
Regulatory Affairs Manager
Pall Medical
5 Harbourgate Business Park
Southampton Road
Portsmouth,
PO6 4BQ, UK
Tel: +44 7583 012377
email: nicky_wheatley@europe.pall.com

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Please accept our apologies for any inconvenience caused. Should you require any further assistance, please do not hesitate to contact us.

Yours sincerely,



ACKNOWLEDGEMENT OF FIELD SAFETY NOTICE CONCERNING:

PRODUCT NAME – Pall Nanodyne ELD™ Filter

PRODUCT CODE – ELD96LLCE

LOT NUMBERS – 21-674, 21-683

PRODUCT NAME – Pall Lipipor TNA™ Filter

PRODUCT CODE – TNA1E

LOT NUMBERS – 21-678, 21-716, 21-727

Please complete all sections below, sign and return this form to < Name> by email <name>@pall.com.

- I confirm that I have read and understood the attached Field Safety Notice.
- I have checked my inventory and quarantined all filters from the implicated lot numbers.

Please enter the relevant details in the following table:

Product code	Lot number	Number of unused filters returned to Pall	Number of filters destroyed
ELD96LLCE	21-674		
ELD96LLCE	21-683		
TNA1E	21-678		
TNA1E	21-716		
TNA1E	21-727		

- I have no filters from the implicated lot numbers.

Signature: _____

Name: _____

Title: _____

Hospital Name: _____

Hospital Address: _____
