

Pall International Sàrl

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Phone: +41 (0) 26 / 350 53-00

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

24 August 2020

Dear <Customer Name>,

URGENT FIELD SAFETY NOTICE

Commercial name of affected products:

Pall Breathing System Filter (For Ventilator Machine End and Medical Gas Equipment Applications)

FSCA Identifier:

PNQ-CY20-011

Type of Action:

Voluntary Recall

Details on affected device:

Product Code	Lot Number
BB50TES	20-1153

Description of the problem:

The Pall Breathing System Filter for machine end and medical gas equipment applications (product code BB50TES) is a highly efficient bi-directional bacterial/viral filter. The product is provided "Sterilised by Irradiation" as indicated by the product labelling.

Pall has recently identified that one lot number of Pall Breathing System Filters (product code BB50TES) has not been sterilised correctly as the product was not irradiated with the full, validated minimum sterilisation dose that is required to ensure the sterility status identified on the product labelling. The affected lot number is identified in the table above. An investigation to determine the root cause of this issue is in progress. This investigation will include identifying and implementing any appropriate corrective actions.

It has been determined that the use of Pall Breathing System Filters (product code BB50TES) from the affected lot presents a low probability of harm to a patient as Pall Breathing System Filters are available

as both sterile and non-sterile product variants, which in practice, are used in the same manner in gas filtration applications. Furthermore, sterile Pall Breathing System Filters (product code BB50TES) are not used in a controlled environment within the clinical setting and as such, are not considered sterile once the unit packaging for the device has been opened.

As the Pall Breathing System Filters (product code BB50TES) with the lot number identified in the table above have not been supplied in accordance with our specification for sterility, Pall has decided to recall the implicated product. It is advised that any such filters be removed from clinical use and replaced with filters from another lot.

Advice on action to be taken by the user:

Please immediately identify and quarantine Pall Breathing System Filters (product code BB50TES) with the lot number identified in the table above. Quarantined units can be destroyed or returned to Pall.

Please complete the attached acknowledgement form and return it to <Contact Name> by email <contact name>@pall.com. <Contact Name> will arrange return of the quarantined units, if applicable, and will be in contact with you regarding replacement of 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: +447929 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: +447583 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,



Sandra Racordon-Pape,
Director QARA

ACKNOWLEDGEMENT OF FIELD SAFETY NOTICE CONCERNING:

PRODUCT NAME: Pall Breathing System Filter (For Machine End and Medical Gas Equipment Applications)
PRODUCT CODE: BB50TES
LOT NUMBER: 20-1153

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

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

Please enter the relevant details in the following table:

Product code	Lot number	Number of unused filters returned to Pall	Number of unused filters destroyed
BB50TES	20-1153		

- I have no filters with the implicated lot number.

Signature: _____

Name: _____

Title: _____

Hospital Name: _____

Hospital Address: _____

