

“Customer Name”

“Postal Address”

“City”

“Country”

“Date”

Dear “Customer Name”,

URGENT FIELD SAFETY NOTICE

Commercial name of affected product:

Pall Ultipor™ 100 Breathing System Filter

FCSA Identifier:

1584-CY17-POR

Type of Action:

Voluntary Recall

Details on affected devices:

Product Code	Lot Number
BB100P	603902

Description of the problem:

The Pall Ultipor™ 100 Breathing System Filter, product code BB100P, is a highly efficient single use bacterial/viral filter and heat and moisture exchanger for patient end use.

Pall have recently received one report where a small number of units of product code BB100P from lot number 603902, were leaking between the endcap and the filter media housing. No permanent adverse effects on patients have been reported to Pall as a result of this occurrence.

An investigation has revealed that the leaking filters are the result of low penetration of the endcap when assembled with the filter media housing during the production of a small proportion of filters within lot number 603902. This was determined to be caused by a heater bank / thermocouple issue. We are currently in the process of implementing appropriate corrective actions for this issue.

It has been determined that filters within lot number 603902 may not perform in accordance with specifications. As a result there is the potential for inadequate patient ventilation and delivery of air way medication while these filters are in use. It has therefore been decided to recall from the market Pall Ultipor™ 100 Breathing System Filters, product code BB100P with lot number 603902 and it is advised that any such filters currently in use be removed and replaced with filters from another lot number.

Advice on action to be taken by the user:

Please immediately identify and quarantine any unused Pall Ultipor™ 100 Breathing System Filters, product code BB100P with lot number 603902.

Please complete the attached acknowledgement form and return to Patrick Warren by email (patrick_warren@europe.pall.com). Patrick Warren will arrange return of the quarantined units and appropriate credit.

For Pall Ultipor™ 100 Breathing System Filters, product code BB100P with lot number 603902 that are in use at the time of receipt of this Field Safety Notice:

- (a) Ensure that you are familiar with the events listed above.
- (b) Please remove from use and ensure the filter is disposed of.

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:

Mike Wise
Senior Quality Assurance Manager
Pall Newquay
A Division of Pall Manufacturing UK
St Columb Major
Cornwall
TR9 6TT
UK
Tel: +441637896204
mike_wise@europe.pall.com

Secondary Contact:

Nicky Wheatley
Regulatory Affairs Manager
Pall Medical
5 Harbourgate Business Park
Southampton Road
Portsmouth
PO6 4BQ
UK
Tel: +442392338481
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,



DRAFT

ACKNOWLEDGEMENT OF FIELD SAFETY NOTICE CONCERNING:

PRODUCT CODE – BB100P, LOT NUMBER – 603902

Please complete either (a) or (b) below, sign and return this form to Patrick Warren by email (patrick_warren@europe.pall.com).

(a) I will return the following which constitutes all of my current inventory of the implicated lot number:

Number of unopened (full) cases	Product code	Lot number
	BB100P	603902

Number of opened (partial) cases	Product code	Lot number
	BB100P	603902

I have removed from use and disposed of the following filters from the implicated lot number:

Number of BB100P filters in use	Product code	Lot number
	BB100P	603902

(b) I have no products from the implicated lot number:

I confirm that I have read the attached Field Safety Notice.

Signature: _____

Name: _____

Title: _____

Hospital Name: _____

Hospital Address: _____
