

URGENT FIELD SAFETY NOTICE***Recall of All Lots of Dk-line® (REF #: VRL100, 5mL, and VRL110, 7mL) and Okta-line® (REF #: VRL200, 5mL) Perfluorocarbon Liquids***

Tuesday, 06 October 2020

For the attention of Health Care Professional:

Bausch & Lomb, Inc. (1400 North Goodman Street, Rochester, NY 14609) is initiating a recall for all lots of the Dk-line® (REF #: VRL100, 5mL, and VRL110, 7mL) and Okta-line® (REF #: VRL200, 5mL) perfluorocarbon liquids in the European Union, European Economic Area, Switzerland and Turkey. Please immediately quarantine these products in your facility.

The Dk-line® and Okta-Line® perfluorocarbon liquids are surgical aids used in ophthalmic posterior segment surgery for retinal detachments/proliferative vitreoretinopathy, diabetic retinopathy, giant retinal tears, ocular trauma and for lifting of subluxated lenses and foreign bodies from the vitreous (see page 5 for additional product details).

This action is the result of an internal validation test that demonstrated that the packaging of the Dk-line® and Okta-line® perfluorocarbon liquids were not in compliance. As a result, we are not able to guarantee the sterility of these products.

While no related adverse events have been reported to date in association with this issue, sterile barrier failures may compromise the sterility of the packaged device which may result in contamination leading to microbial inflammation and/or infection requiring professional medical intervention. It is a known fact that, in the worst case, administration of a non-sterile product intended to be sterile may result in serious and potentially life-threatening infections and/or death.

We are committed to ensuring that all of our products meet the highest standards of quality and take matters such as this very seriously, which is why we are conducting this recall.

No other Bausch + Lomb products are affected by this action.

All appropriate regulatory bodies have been informed of this action. Additionally, all details regarding this recall are included in this document, therefore, no further information will be distributed.

QUARANTINE PRODUCT AND RETURN TO BAUSCH + LOMB

According to our records, your facility has received Dk-line® and Okta-line® perfluorocarbon liquids that are impacted by this recall. We urgently ask you to take the following steps in response:

1. Review your inventory and quarantine all Dk-line® (REF #: VRL100, 5mL, and VRL110, 7mL) and Okta-line® (REF #: VRL200, 5mL) perfluorocarbon liquids identified in your facility (see page 5 for additional product details, including examples of the product label for ease in identifying the product).

2. Complete the enclosed Acknowledgement Form (pages 3-4) and return it to Bausch + Lomb by email: UKSurgicalOps@bausch.com or fax: 020 8781 0001 **within 5 days** even if you do not have any Dk-line® and Okta-line® perfluorocarbon liquids in your facility.
3. Contact Bausch + Lomb at 020 8781 0000 to obtain a Return Material Authorization Number and arrange for pickup of the identified product.

For questions regarding this notice, please call Bausch + Lomb at: 020 8781 0000.

We confirm that the Healthcare Products Regulatory Authority has received a copy of this “Urgent Field Safety Notice.”

We greatly appreciate your understanding and prompt assistance and apologise for any inconvenience that this may cause.

Sincerely,



Ruben Angulo
Director, Quality
Bausch + Lomb

****IMPORTANT NOTE: This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred (as appropriate). Please transfer this notice to other organisations on which this action has an impact (as appropriate). Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.***

®/™ Dk-line and Okta-line are trademarks of Bausch & Lomb Incorporated or its affiliates.
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URGENT FIELD SAFETY NOTICE Acknowledgement Form

This is to acknowledge receipt of the above referenced recall notification dated Tuesday, 6th October 2020

Product Details:

Dk-line® (REF #: VRL100, 5mL, and VRL110, 7mL) and Okta-line® (REF #: VRL200, 5mL) perfluorocarbon liquids.

Please review and acknowledge (X) the following statement below:

We have reviewed the attached urgent field safety notice and acknowledge the alert.

Please review and acknowledge (X) one of the statements below that applies to your facility:

We do not have any of these products in our inventory.

We do have these products in our inventory. If checked, please fill out chart below.

Please insert the following information for the Dk-line® and Okta-line® perfluorocarbon liquids identified at your facility:

REF	Number	Quantity Received Since 2016 (Single Unit)	Quantity Unused in Stock
	Dk-Line® - VRL100, 5mL		
	Dk-Line® - VRL110, 7mL		
	Okta-line® - VRL200, 5mL		

I hereby certify that I have quarantined the Dk-line® and Okta-line® perfluorocarbon liquids identified in my facility to prevent use and will contact Bausch + Lomb to arrange collection of the products.

Date	Name (Print)
Bausch + Lomb Account Number	Signature
Facility Name	Telephone Number

Please complete, sign and return this form (pages 3-4) to:

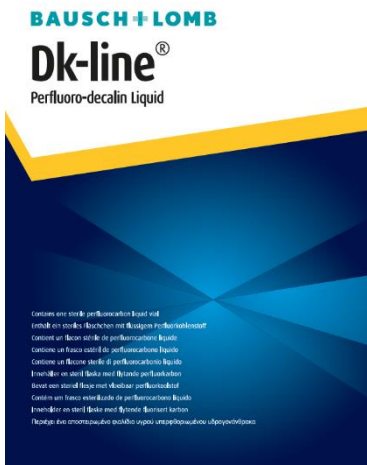


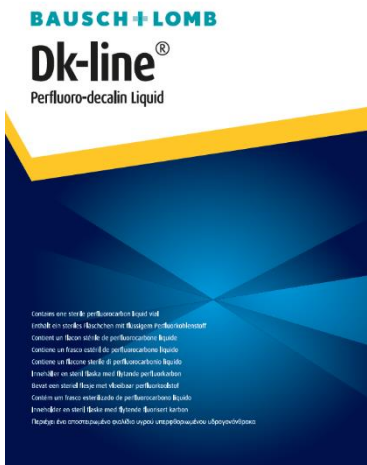


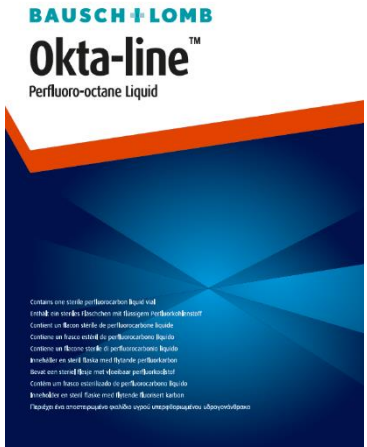

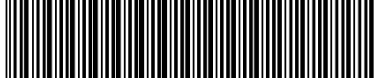
Email: UKSurgicalOps@bausch.com **or Fax:** 020 8781 0001

For questions regarding this notice, please call Bausch + Lomb at: 020 8781 0000.

Confidentiality Agreement: The information contained in this message is confidential information intended for the use of the address listed above. If you are neither the intended recipient nor the employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of the information is strictly prohibited. If you have received this in error, please immediately notify us by telephone to arrange for the return of the original document to us.

URGENT FIELD SAFETY NOTICE

Product Details

Product Package Image	Product Label Image
	<p>Dk-line[®] 5ml Vial REF VRL100</p> <p>LOT 12345  2011-12</p>  (01)07391899830537(17)111200(10)12345
	<p>Dk-line[®] 7ml Vial REF VRL110</p> <p>LOT 12345  2011-12</p>  (01)07391899830544(17)111200(10)12345
	<p>Okta-line[™] 5ml Vial REF VRL200</p> <p>LOT 12345  2011-12</p>  (01)07391899830551(17)111200(10)12345

REF Numbers	<ul style="list-style-type: none"> • Dk-line[®] perfluorocarbon liquids – REF #: VRL100, 5mL, and REF #: VRL110, 7mL • Okta-line[®] perfluorocarbon liquids – REF #: VRL200, 5mL
Dates of Manufacture	October 2016 – May 2020
Expiration Dates	September 2020 – April 2024
Packaging Configuration	One carton contains a single, sterile pouch with one vial, one syringe, one cannula, instructions for use and patient record labels. The glass vial, syringe and cannula are contained in individual pouches comprised of medical paper and foil. The glass vial is sealed with a metal cap.