FSN Ref: 22.1.5-NTEM-2 FSCA Ref: CAC-2020-011

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

6th October 2020

For the attention of Health Care Professionals,*

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 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 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: **kundenservice@bausch.com** or fax: **0848 228 725 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 **0848 228 725** 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: **0848 228 725.**

We confirm that Swissmedic has received a copy of this "Urgent Field Safety Notice."

We greatly appreciate your understanding and prompt assistance and apologize for any inconvenience 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 on 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.

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URGENT FIELD SAFETY NOTICE

Acknowledgement Form

This is to acknowledge receipt of the above referenced recall notification dated 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		

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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 pickup 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: kundenservice@bausch.com or Fax: 0848 228 725

For questions regarding this notice, please call Bausch + Lomb at: : **0848 228 724**.

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.

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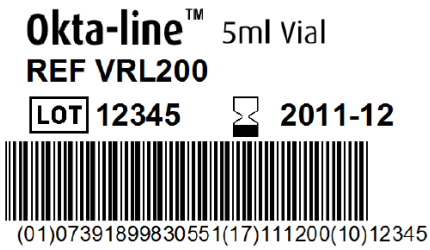
URGENT FIELD SAFETY NOTICE

Product Details

Product Package Image	Product Label Image
	
	
	

REF Numbers	• 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.