

Medical Device Recall

January 12, 2007

IMPORTANT – DEVICE PRODUCT RECALL

ATTENTION: EYE CARE PRACTITIONERS, DISTRIBUTORS, RETAILERS

O₂OPTIX™ (lotrafilcon B) Soft Contact Lenses

CIBA Vision Corporation is conducting a voluntary recall on select lots of spherical O₂OPTIX (lotrafilcon B) soft contact lenses in the United States and other countries. We are taking this voluntary action because we identified that some lenses in these lots may fall below our standard for ion permeability, a material characteristic that correlates with lens movement on the eye. Reduced ion permeability in O₂OPTIX (lotrafilcon B) lenses may lead to reduced lens movement, symptoms of discomfort and/or foreign body irritation.

The potential medical safety risk to consumers posed by lenses with reduced ion permeability includes discomfort, foreign body irritation and superficial localized corneal staining. The possibility of occurrence of these findings is moderate. As with any staining of the corneal tissue, the risk of corneal infection is somewhat increased, although the probability is remote.

This recall only affects the O₂OPTIX (lotrafilcon B) lenses identified below. No other CIBA Vision product is affected by this recall action. This voluntary action is being conducted in the United States with the knowledge of the U.S. Food and Drug Administration.

The affected O₂OPTIX (lotrafilcon B) lenses were distributed between September, 2006 and December, 2006. The lots affected in this recall are all lots numbers starting with 6644001 to 6721262 with expiration dates starting from 2011/09 to 2011/11, and lot numbers 6626127, 6636101, 6637017, 6637019, 6637103, 6640120, 6640124, 6642109, 6642119, and 6643080, all with expiration dating of 2011/08 (detailed in the attached table). We are asking that you locate and return these lenses from your stock in accordance with the attached instructions.

We recognize the inconvenience this causes you, your staff and your patients. However, this action reflects CIBA Vision's commitment to high quality standards and ensuring that our products fully meet your expectations. You will receive a separate communication regarding O₂OPTIX (lotrafilcon B) supply shortly. Please feel free to call our Customer Service Department at (800) 241-5999 or your CIBA Vision Sales Representative should you have any questions or concerns.

Sincerely,

William D. Schaeffer
Global Head of Quality
CIBA Vision Corporation

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O₂OPTIX™ (lotrafilcon B) Soft Contact Lenses

CLINICAL ASSESSMENT FOR THE EYE CARE PROFESSIONAL

Ion permeability is a measure of the ability of sodium ions to permeate through a contact lens material. It has been shown, along with other factors, to correlate with lens movement on the eye, which is an important fitting characteristic. The O₂OPTIX (lotrafilcon B) lenses with reduced ion permeability, subject to this recall, may cause reduced lens movement in some patients, possibly causing discomfort and/or foreign body irritation, usually within the first 1 to 4 hours of wearing the lens.

Superficial, localized corneal staining may be observed in symptomatic patients. The symptoms diminish quickly upon removal of the lenses. In addition, signs and symptoms usually resolve in 2-24 hours. If the same lens is replaced on the eye, the same symptoms will typically reoccur within a very short period.

The potential medical safety risk to consumers posed by lenses with reduced ion permeability includes discomfort and/or foreign body irritation and superficial localized corneal staining may be observed. As with any staining of the corneal tissue the risk of corneal infection is somewhat increased although the probability is remote (see summary table below).

	Medical Risk	Probability of Occurrence with Reduced IP lenses
Discomfort and/or Foreign Body Irritation	Negligible	Moderate
Superficial Localized Corneal Staining	Low	Moderate
Corneal Infection	Moderate	Remote

Foreign body irritation and corneal staining are expected non-serious events for routine contact lens usage and can occur for various reasons, such as dust or particulate matter, lens tears or other mechanical type effects. The foreign body irritation that may result from lenses with reduced ion permeability increases in intensity while the lens is worn, necessitating prompt lens removal. The Package Insert and Patient Instruction Booklet advise practitioners and wearers to remove the lens in cases of such irritation. Wearers are advised to seek professional eyecare evaluation if the symptoms persist.

No serious adverse events related to this issue have been reported on a global basis. We are presently aware of only seven (7) non-serious product complaints which are likely related to the use of O₂OPTIX (lotrafilcon B) lenses with reduced ion permeability.

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LENS LOTS SUBJECT TO RECALL

Please return the product from following affected lot numbers to CIBA Vision in accordance with the preceding Recall Notification Letter as soon as possible.

	Lot Numbers	Expiration Dates
All Lots Starting With:	6644001	2011/09
	Through	Through
<u>And Ending With:</u>	6721262	2011/11
<u>And Individual Lots:</u>	6626127	2011/08
	6636101	2011/08
	6637017	2011/08
	6637019	2011/08
	6637103	2011/08
	6640120	2011/08
	6640124	2011/08
	6642109	2011/08
	6642119	2011/08
	6643080	2011/08

**NO OTHER BRANDS OF CIBA Vision CONTACT LENSES
ARE IMPACTED BY THIS RECALL**

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O₂OPTIX™ (lotrafilcon B) Soft Contact Lenses

INSTRUCTIONS FOR PRODUCT RETURNS

Impacted O₂OPTIX (lotrafilcon B) lots should be returned to CIBA Vision at the following address:

CIBA Vision Corporation
c/o Stericycle Pharmaceutical Services
2670 Executive Drive, Ste A
Indianapolis, IN 46241
ATTN: O₂OPTIX Recall

Please follow these directions precisely to ensure proper return and tracking of the recall. Along with this letter, you should have received a package consisting of a Recall Tracking Form and a pre-paid air bill sticker.

1. To receive proper credit for your returned lenses, please complete the requested information on the “Recall Tracking Form” and return it along with the O₂OPTIX (lotrafilcon B) lenses (both trial and “for sale”) in a shipping container by attaching the pre-paid UPS air bill sticker. Credit will be issued upon receipt of your returned product. Please complete the Recall Tracking Form and return it within 30 days using the pre-paid air bill sticker, even if there is no affected product to return.
2. Use the prepaid air bill sticker only. This is to ensure there will be no charge to you. If you did not receive a pre-paid air bill sticker, contact CIBA Vision Customer Service Department at (800) 241-5999.
3. Please do not include non-recalled products, lots, kits, packs, or competitor's products with this shipment. Any non-recalled product or lots received in the prepaid UPS air bill will be destroyed with no credit issued.
4. Please do NOT use the "normal" CIBA Vision returns process for this product.

We have included below an example of the O₂OPTIX (lotrafilcon B) label to assist in identifying the lot number and expiration date information:

[Insert scan of both box and primary label with instruction arrows to identify lot number and expiration date codes.]

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RECALL TRACKING FORM

PLEASE COMPLETE THE TOP SECTION OF THIS FORM AND RETURN WITH PRODUCT TO CIBA VISION IMMEDIATELY

If you need additional information, please call CIBA Vision Customer Service at (800) 241-5999

Account Name: _____

Account No: _____ Telephone No: _____

YES

NO

I have recalled O₂OPTIX lenses (trial or "for sale") in stock and will return them to:

CIBA Vision Corporation
c/o Stericycle Pharmaceutical Services
2670 Executive Drive, Ste A
Indianapolis, IN 46241
ATTN: O₂OPTIX Recall

Contact Person (please print): _____

Signature / Date: _____

PRODUCT RETURN INFORMATION

PLEASE COMPLETE THIS SECTION IMMEDIATELY AND RETURN FULL PAGE WITH THE RECALLED LENSES

Recalled O ₂ OPTIX Soft Contact Lenses	Quantity Returned	Date Returned	Returned By
	_____	_____	_____

INSTRUCTIONS

- Please complete and return the Recall Tracking Form, even if there is no affected product to return.
- Please do not include non-recalled products, lots, kits, packs, or competitor's product with this shipment.
- Please do NOT use the "normal" CIBA Vision returns process. Please use the address above.

THIS SECTION TO BE COMPLETED BY CIBA VISION CORP.

Total O₂OPTIX Lenses Returned: _____ Product Returned Reconciles: Yes No N/A

Reviewed by: _____