

# MEDICAL DEVICE ALERT

Issued: 18 June 2007 at 14:00

Ref: MDA/2007/055

<input type="checkbox"/>	Immediate action
<input checked="" type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input type="checkbox"/>	Information request

<b>Device:</b> Contact lens solution: COMPLETE <sup>®</sup> MoisturePLUS <sup>™</sup> from Advanced Medical Optics (AMO).	▶ Page 2
<b>Problem:</b> Worldwide product recall. This product is associated with an increased incidence of <i>Acanthamoeba</i> keratitis.	▶ Page 2
<b>Action by:</b> Ophthalmologists, pharmacists, opticians, and optometrists who: <ul style="list-style-type: none"> <li>• supply contact lens solutions</li> <li>• manage individuals who wear soft contact lenses</li> <li>• see patients with keratitis who wear soft contact lenses.</li> </ul>	
<b>Action:</b> <ul style="list-style-type: none"> <li>• Do not supply COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> contact lens solution.</li> <li>• See detailed actions on page 2.</li> </ul>	▶ Page 2
<b>Distributed to:</b> NHS trusts in England Healthcare Commission (CHAI) Primary care trusts in England Health Protection Agency (HPA) <ul style="list-style-type: none"> <li>– Chief Executives*</li> <li>– Headquarters</li> <li>– Chief Executives*</li> <li>– Directors</li> </ul> <p style="text-align: right;">* via CE Bulletin</p>	▶ Page 2
<b>Contacts:</b> Details of manufacturer contacts and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for Healthcare Commission.	▶ Page 3
<b>Appendix:</b> Advanced Medical Optics suppliers letter (Appendix 1) and user letter (Appendix 2).	▶ Pages 5-6

### Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 26 June 2007

Deadline (action complete): 19 July 2007

This notice is also on our website: <http://www.mhra.gov.uk>

## Device:

COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> is a multi-purpose solution for soft contact lenses.

## Problem:

The product has been associated with an increased risk of *Acanthamoeba* keratitis infections following a study carried out by the U.S. Centre for Disease Control and Prevention (CDC)\*. In light of this the manufacturer has recalled this product and written to suppliers (see Appendix 1).

The MHRA has not received any reports of *Acanthamoeba* keratitis in the UK associated with the use of COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> contact lens solution.

\* Ref: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm56d526a1.htm>

## Action:

If you are a supplier of contact lens solutions:

- do not supply COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> contact lens solution
- consider giving customers a copy of AMO's user letter (see appendix 2).

If you manage individuals who use soft contact lenses, at their next appointment check if they use COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> contact lens solution. If so:

- advise the use of an alternative product
- advise discarding current lens storage container
- advise discarding current pair of soft contact lenses
- consider providing a copy of AMO's user letter (see appendix 2)
- report any adverse incidents related to this product to the MHRA.

## Distribution:

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

### Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Consultant microbiologists
- Eye casualty departments
- Hospital pharmacists
- Ophthalmologists
- Ophthalmology wards
- Supplies managers

### Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Private medical practitioners
- Treatment centres

### Health Protection Agency to:

Directors for onward distribution to:

- Consultants in communicable disease control
- Health protection nurses
- HPA laboratories

### Primary care trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Community hospitals
- Community pharmacists
- Directors of public health
- Dispensing opticians
- NHS pharmacists
- NHS walk-in centres
- Optometrists
- Pharmaceutical advisors
- Practice managers
- Practice nurses
- Prison healthcare managers
- Staff with responsibility for purchasing

**Contacts:**

Enquiries to the manufacturer should be addressed to:

Sangita Sagoo  
AMO United Kingdom Ltd.  
Jupiter House  
Mercury Park  
Wooburn Green  
High Wycombe  
HP10 0HH

Tel: 01628 551 604  
Fax: 01628 530 432

E-mail: [sangita.sagoo@amo-inc.com](mailto:sangita.sagoo@amo-inc.com)

Enquiries to the MHRA should quote reference number **2007/005/031/061/016** and be addressed to:

**Technical aspects:**

Ian Smith or Allan Hilderley  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7084 3306 / 3172  
Fax: 020 7084 3106

E-mail: [ian.smith@mhra.gsi.gov.uk](mailto:ian.smith@mhra.gsi.gov.uk)  
[allan.hilderley@mhra.gsi.gov.uk](mailto:allan.hilderley@mhra.gsi.gov.uk)

**Clinical aspects:**

Dr Susanne Ludgate  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7084 3123  
Fax: 020 7084 3111

E-mail: [susanne.ludgate@mhra.gsi.gov.uk](mailto:susanne.ludgate@mhra.gsi.gov.uk)

**Change of address or removal from address list for Healthcare Commission:**

Healthcare Commission  
Finsbury Tower  
103-105 Bunhill Row  
London  
EC1Y 8TG

Tel: 020 7448 0842

E-mail: [contacts@healthcarecommission.org.uk](mailto:contacts@healthcarecommission.org.uk)

## How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre  
Medicines and Healthcare products Regulatory Agency  
Market Towers, 1 Nine Elms Lane, London SW8 5NQ  
Telephone 020 7084 3080 or Fax 020 7084 3109  
or e-mail: [aic@mhra.gsi.gov.uk](mailto:aic@mhra.gsi.gov.uk)

(An answerphone service operates outside normal office hours)

**Medical Device Alerts are available in full text on the MHRA website:** <http://www.mhra.gov.uk>

Further information about **SABS** can be found at [www.info.doh.gov.uk/sar2/cmopatie.nsf](http://www.info.doh.gov.uk/sar2/cmopatie.nsf)

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**URGENT MEDICAL DEVICE RECALL NOTICE**  
**COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> CONTACT LENS CARE PRODUCTS**  
**Manufactured by AMO**

May 29, 2007

Dear XXXXXX,

We want to inform you that Advanced Medical Optics (AMO) is initiating a voluntary and immediate recall of its COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> contact lens solution. The recall results from an information received end of last week from the U.S. Centers of Disease Control and Prevention (CDC) regarding eye infections from *Acanthamoeba*, a naturally occurring water-borne organism which can contribute to serious corneal infections.

The CDC made data available to AMO on May 25 showing that it had interviewed 46 patients who had developed *Acanthamoeba* keratitis (AK) infections reported since January 2005. A total of 39 of these patients were soft contact lens wearers, 21 of whom reported using COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> products. The CDC estimates a risk of at least seven times greater for those who used COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> solution versus those who did not. This recall is being conducted on a voluntary basis, in cooperation with the respective regulators.

While AMO continues to work with the CDC and the U.S. Food and Drug Administration (FDA) to further assess the data, it is acting with an abundance of caution and has decided to remove AMO COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> from the market. There is no evidence to suggest that today's voluntary recall is related to a product contamination issue and this does not impact any of AMO's other contact lens products, including our hydrogen peroxide disinfecting solution. As user safety is paramount to AMO, the company is taking decisive action to stop shipments, recall product from the marketplace, and encourage consumers to discontinue the use of AMO COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> solution.

**Please examine your inventory immediately for recall product.**

1. With immediate effect please stop the sale of all AMO COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> products and remove all unsold goods from your shelves ready to be collected.
2. Please use the attached form to immediately audit your COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> stock.
3. This form needs to be faxed back to us on **01628 551643 within 48 hours**
4. Please make a copy of the completed fax back form and place with the returning stock, then call **0800 376 7950** to arrange return pick-up and credit.

If you have distributed the COMPLETE<sup>®</sup> MoisturePLUS<sup>™</sup> products to other retailers, you should immediately notify them of this recall. Upon request, AMO will provide a template letter for you to provide to these retailers.

While AMO believes the likelihood of users experiencing an adverse reaction is low, we have taken a conservative approach and are conducting the recall in the best interests of our customers.

We apologise for the inconvenience this has caused. AMO has built its reputation on consumer trust and the assurance that we provide products that meet the highest standards. Our first priority is protecting the ocular health of those who use our products and as such, we appreciate your assistance with this matter.

Please do not hesitate to contact us if with your questions on **0800 3767950** or contact your regular AMO representative.

## Appendix 2 to MDA/2007/055

**URGENT MEDICAL DEVICE RECALL NOTICE**  
**COMPLETE® MoisturePLUS™ CONTACT LENS CARE PRODUCTS**  
**Manufactured by AMO**  
May 29 2007

Advanced Medical Optics (AMO) has announced a voluntary and immediate recall of its COMPLETE® MoisturePLUS™ contact lens solution. The recall is being initiated because of concerns over eye infections from *Acanthamoeba*, a naturally occurring water-borne organism which can contribute to serious corneal infections.

There is no evidence to suggest that today's recall is related to a product contamination issue and this does not impact any of AMO's other contact lens care products, including our hydrogen peroxide disinfecting solutions.

The U.S. Centre for Disease Control and Prevention (CDC) made data available to AMO showing that it had interviewed 46 patients who had developed *Acanthamoeba* keratitis (AK) infections reported since January 2005. A total of 39 of these patients were soft contact lens wearers, 21 of whom reported using COMPLETE® MoisturePLUS™ products. The CDC estimates a risk of at least seven times greater for those who used COMPLETE® MoisturePLUS™ solution versus those who did not. This recall is being conducted on a voluntary basis, in cooperation with the respective regulators.

The incidence of AK infections has been estimated by the CDC at approximately one to two cases per million contact lens wearers. *Acanthamoeba* is an organism commonly found in water, soil, sewage systems, cooling towers, and heating/air-conditioning systems. AK infections are usually found among individuals who improperly store/handle/disinfect their lenses (e.g. use tap water to clean lenses, swim or shower while wearing lenses or come in contact with contaminated water, especially if the cornea has been damaged).

Our first priority is protecting lens wearers' vision and health. We remain fully committed to providing you with products that meet the highest standards for sterility, product effectiveness and customer safety. We are fully cooperating with the necessary regulatory authorities to meet these goals, and sincerely apologise for any inconvenience this action may have caused to you as a user of our products.

If you are a contact lens wearer and have any of these symptoms, you should consult your eye care professional: eye pain, eye redness, blurred vision, sensitivity to light, sensation of something in the eye, and excessive tearing. The symptoms, which can last several months, are not the same for everybody. Early in the infection, the symptoms of AK can be very similar to the symptoms of other more common eye infections but AK may eventually cause severe pain and possible vision loss with some people requiring a corneal transplant, if untreated.

If you use COMPLETE® MoisturePLUS™ contact lens solution products, please follow these steps

5. Check to ensure that the COMPLETE® product you have is a COMPLETE® MoisturePLUS™ contact lens solution product. This recall only pertains to COMPLETE® MoisturePLUS™ contact lens solution; all other COMPLETE® product is unaffected.
6. If you are using a COMPLETE® MoisturePLUS™ contact lens solution product please discontinue use immediately and call 0800 3767950 or visit [www.the-complete-experience.com](http://www.the-complete-experience.com)
7. If you have used a COMPLETE® MoisturePLUS™ contact lens solution product and are experiencing any problems with your eyes, consult your eye care professional immediately.
8. Please report any adverse reactions experienced with the use of this product by calling 01628551621

AMO has a 50 year heritage built on high safety and efficacy standards for our products. We are committed to protecting the trust Eyecare professionals and consumers place in our products and will take all necessary measures to ensure that our products remain safe and effective for daily disinfecting for all contact lenses.