



رقم المحفوظات: ٢٥٨١  
رقم الصادر: ١٣٨١٢٢٢٨٠  
بيروت، في: ١٥ شباط ٢٠١٣

جانب نقيب الاطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي

Contact lenses and shells, 1-Day Acuvue Moist brand contact

الجهاز المعنى بالمتابعة:

- Contact lenses and shells, 1-Day Acuvue Moist brand contact
- Trade Mark: Johnson & Johnson Vision Care
- Local Representative: Intermedic

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خطأ في التصنيع مما يؤثر على عمل الصنف المذكور أعلاه، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

د. وليد عمار  
مدير عام الصحة

# Johnson & Johnson Vision Care

PINEWOOD CAMPUS, NINE MILE RIDE  
WOKINGHAM, BERKSHIRE RG40 3EW  
TEL: 01344 864010  
FAX: 01344 864011

## URGENT FIELD SAFETY NOTICE

1-DAY ACUVUE® MOIST® (etafilcon A) Brand Contact Lenses.

ACUVUE® ADVANCE® (galyfilcon A) Brand Contact Lenses

Date: 9th January 2013

Action: Voluntary and limited recall of lots 2054890521, 2054895620 and B00DJPQ.

Dear Eye Care Professional:

The purpose of this communication is to inform you that Johnson & Johnson Vision Care, part of Johnson & Johnson Medical Ltd, is voluntarily recalling boxes from 2 lots of 1-DAY ACUVUE® MOIST® Brand Contact Lenses and 1 lot of ACUVUE® ADVANCE® Brand Contact Lenses with HYDRACLEAR®

This letter provides important information concerning this Field Action as our shipping records show that you are one of our customers that have received the affected lots. MHRA and our notified body, BSi, have been informed of this action. This voluntary action is only for those products with the affected lot numbers listed on the package (see below for more information). 1-DAY ACUVUE® MOIST® and ACUVUE® ADVANCE® contact lenses without the affected lot numbers can continue to be used, and no other products in the ACUVUE® family are affected. Please share this information with your staff so that we may work together to retrieve and replace all 1-DAY ACUVUE® MOIST® and ACUVUE® ADVANCE® product affected by this recall.

### Details of Field Action:

This action is being initiated as a precautionary measure following an internal quality review in which we discovered the potential for a limited number of contact lens packages to not have completely sealed. An incomplete seal may result in the loss of or leaking of the packaging solution in some individual contact lens units. Since an incomplete seal could possibly compromise contact lens sterility, an eye infection is a potential health risk associated with this occurrence. However, the chances of this occurring are remote. No adverse events have been reported to date. The cause has been identified and rectified.

Within the lots being recalled, it is estimated that about 0.25% (approximately 20 lenses) could potentially be affected. In some instances a user might open the individual contact lens package and see little or no solution inside the packaging and a lens that is dried out and unusable. In other situations, the incomplete seal and its effect on the package and the lens will not be noticeable to the user. However, regardless of the visible condition of the lens or the individual contact lens package, it is important to return all lenses in the affected lots in accordance with the instructions below. The company is initiating this voluntary recall as a precaution so that wearers will continue to experience the performance and quality they expect from ACUVUE® Brand Contact Lenses.

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## How to identify affected product:

The affected 1-DAY ACUVUE® MOIST® product distributed in the UK is 8.5 Base Curve, +2.25D and is from one of the two master lots listed below:

<u>Lot #</u>	<u>Power</u>	<u>Base Curve</u>	<u>Pack Size</u>
2054890521	+2.25D	8.5	30
2054895620	+2.25D	8.5	90 (contains 3x30 packs each with lot # 2054890620)

The affected ACUVUE® ADVANCE® product distributed in the UK is 8.3 Base Curve, -7.00D with lot number B00DJPQ

<u>Lot #</u>	<u>Power</u>	<u>Base Curve</u>	<u>Pack Size</u>
B00DJPQ	-7.00D	8.3	6

To identify affected product, check all the digits of the printed lot number reading from left to right on the outer package and on each individual contact lens container to see if it is from one of the affected lot numbers. ACUVUE® contact lenses without the affected lot numbers can continue to be used.

## Actions requested on your part:

- **Please contact your patients that may have received any of the affected lots and inform them not to use the product and promptly return to you for replacement.**
- Please read the "How to identify affected product" section carefully
- Check your practice/store inventory for affected product
- Pass this notice on to anyone in your practice that needs to be informed
- Please complete and return the "acknowledgement of receipt" form accompanying this letter
- Customer service will arrange for you the return and replacement of any affected product

In addition to your local sales representative, you may contact Johnson & Johnson Vision Care at **01932 733502** to answer any questions you might have.

We apologize for any inconvenience this causes you, your staff and your patients, and thank you for your understanding. Johnson & Johnson Vision Care remains committed to providing you with the highest quality products that fully meet the expectations of you and your patients.

Yours sincerely,



Michael Daniel. Head of Quality, Europe, Middle East and Africa