**JOHNSON & JOHNSON VISION CARE (A DIVISION OF JOHNSON & JOHNSON (M) SDN. BHD.) ANNOUNCES VOLUNTARY RECALL OF CERTAIN *1•DAY* ACUVUE® TRUEYE™ BRAND CONTACT LENSES (NARAFILCON A) IN MALAYSIA**

Malaysia, August 20, 2010

Johnson & Johnson Vision Care (a division of Johnson & Johnson (M) Sdn. Bhd.) is voluntarily recalling a limited number of boxes from select lots of *1•DAY* ACUVUE® TruEye™ Brand Contact Lenses (narafilcon A) manufactured in Ireland and distributed in Malaysia. Ministry Of Health Malaysia has been informed of this action.

Johnson & Johnson Vision Care (a division of Johnson & Johnson (M) Sdn. Bhd.) is initiating this voluntary recall because it has received outside of Malaysia a limited number of customer complaints associated with these affected lots of narafilcon A contact lenses. Some of the reported complaints described unusual stinging or pain upon insertion with narafilcon A contact lenses and some were also associated with ocular redness. Long-term health consequences arising from this situation are unlikely.

Upon investigation, the company determined that an isolated issue in one portion of the lens rinsing process on a particular manufacturing line affected a limited number of lots. The investigation has determined that no other lots of this product and no other ACUVUE® Brand Contact Lenses products are affected by this manufacturing issue.

In addition to the voluntary recall of affected products released to the market, the company has suspended shipment of the affected lots still in its control and, following a comprehensive quality assessment, has implemented corrective actions to ensure that products meet the company's standards.

The company advises consumers to check the lot number on the product's outside packaging to see if it is from one of the affected lot numbers and, if so, to immediately discontinue use and contact the company so arrangements can be made to return the affected product. Johnson & Johnson Vision Care (a division of Johnson & Johnson (M) Sdn. Bhd.) will provide replacement contact lenses to consumers who have any of the products with the affected lot numbers. All ACUVUE® Brand Contact lenses without the affected lot numbers can continue to be used.

For additional information, including the lot numbers of affected products and the process for returning affected product and receiving replacement contact lenses, consumers should visit the Johnson & Johnson Vision Care (a division of Johnson & Johnson (M) Sdn. Bhd.) website at www.acuvue.com.my or call +603-7955-7269 (Weekdays: 9am - 6pm, Weekends: 10am – 4pm) or email us at inquiry@rantaupr.com.my .

For additional information, contact Rantau PR Sdn. Bhd. at:
Julia Nicholas, +6012-3288 117, julia@rantaupr.com.my
Adeline Phun, +6012-711 0075, adeline@rantaupr.com.my
Joanne Goh, +6012-3266 362, joanne@rantaupr.com.my

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**How to know if your *1•DAY* ACUVUE® TruEye™ Brand Contact Lenses (narafilcon A) are from one of the affected lots?**

The affected products have the following characteristics:

- Brand: *1•DAY* ACUVUE® TruEye™ Brand Contact Lenses (narafilcon A)
- Parameters: Base curve (BC) 9.0, Diameter (DIA) 14.2, Diopter (D) among the following: -1.00, -2.50, -2.75, -3.50, -3.75, -4.00
- Lot number: The Lot number is the 10 digit number shown in parenthesis on the outer package containing 30 blisters and on each blister.

Example:


The affected lot numbers are as follows:

| Lot Number | Product Description |
|---|---|
| 4922370104 | *1•DAY* ACUVUE® TruEye™ -1.00 D |
| 4922380103 | *1•DAY* ACUVUE® TruEye™ -1.00 D |
| 4922920103 | *1•DAY* ACUVUE® TruEye™ -2.50 D |
| 4922890701 | *1•DAY* ACUVUE® TruEye™ -2.75 D |
| 4922510107 | *1•DAY* ACUVUE® TruEye™ -2.75 D |
| 4922870109 | *1•DAY* ACUVUE® TruEye™ -2.75 D |
| 4922830400 | *1•DAY* ACUVUE® TruEye™ -3.50 D |
| 4922800809 | *1•DAY* ACUVUE® TruEye™ -3.75 D |
| 4922810907 | *1•DAY* ACUVUE® TruEye™ -3.75 D |
| 4922811508 | *1•DAY* ACUVUE® TruEye™ -3.75 D |
| 4922811607 | *1•DAY* ACUVUE® TruEye™ -3.75 D |
| 4922520401 | *1•DAY* ACUVUE® TruEye™ -4.00 D |
| 4922540106 | 1•DAY ACUVUE® TruEye™ -4.00 D |

Johnson&Johnson Vision Care

Unit 11.01, Level 11, Uptown 2, 2 Jalan SS21/37,Damansara Uptown, 47400 Petaling Jaya, Malaysia.
Tel: (603) 7710 0068 Fax: (603) 7710 5058

**DATE: August 19, 2010**

## Voluntary Recall Summary

1. Product name: 1-Day Acuvue TruEye

2. Lots boundary, quantity for recall and shipping timeframe

Lot number affected: AS IMPORTED INTO MALAYSIA

The affected product is BC 9.0 and one of the following master lots listed below. The master Lot is 6 digit number from the left shown on the outer package containing 30 blisters and on each blister.

| SKU | SKU | Master Lot No. | Shipped volume |
|---|---|---|---|
| Base Curve | Power | | Packs |
| BC 9.0 | -1.00 | 492237, 492238, 492239, 492248 (4 lots total) | 74 |
| BC 9.0 | -2.50 | 492292 (1 lot total) | 89 |
| BC 9.0 | -2.75 | 492249, 492250, 492251, 492266, 492286, 492287, 492288, 492289, 492290 (9 lots total) | 253 |
| BC 9.0 | -3.50 | 492282, 492283 (2 lots total) | 94 |
| BC 9.0 | -3.75 | 492279, 492280, 492281 (3 lots total) | 274 |
| BC 9.0 | -4.00 | 492252, 492253, 492254 (3 lots total) | 91 |
| | | Total | 875 |

Shipping timeframe : Mar 12th, 2010 ~ Jun 16th, 2010

3. Reason for recall

A limited number of complaints regarding "unusual stinging or pain upon inserting lens" were reported from patients using the product from the affected lots. Based on the investigation on the lens from the complaints, it was found that a processing agent was not properly extracted from the lens. Following detailed root cause investigation, it was found that there was an isolated issue in one portion of the lens rinsing process during a certain timeframe on a particular line. A voluntary recall for the affected lots was determined to be an appropriate field correction. Further investigation shows this issue is isolated to the lots listed above.

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4. Concerning Health risk

The most common reported potential health risks include, for example, stinging, ocular pain, redness, tearing, blurred vision, and possibly irritation. Other reported health risks include loss of the corneal epithelium and a local allergic reaction manifested by itching or periorbital swelling. Persistent corneal epithelial defects, while not reported, are a potential health consequence. Long-term health consequences arising from this situation are unlikely.

Yours sincerely,

Johnson & Johnson Vision Care

NG WENG LEONG
Professional & Regulatory Affairs Manager

Tel: 03-7710 0068 ext 217