

November 23, 2009

**Urgent: Field Safety Notice**  
Affecting 2 Lots of  
OneTouch® Ultra® Test Strips

Dear Valued Customer:

At LifeScan we hold our products to the highest standards of quality; constantly working to ensure they provide glucose results you can rely on. For that reason, we're also committed to communicating with you when we learn of product that may not meet our expected standards.

**The Issue: Very Small Number of Damaged Test Strip Vials**

We have recently determined that two lots of 100-count OneTouch® Ultra® Test Strips may contain a very small number of damaged test strip containers (also called "vials").

The defect in the bottom of the vial (Figure 1) does not penetrate the inner portion of the vial which contains the test strips. Due to the fact that the test strips are not exposed, performance of the test strips is not impacted when vials are stored and used as instructed.



Figure 1

Only 100-count OneTouch Ultra Test Strips with lot numbers **#2960566** or **#2960878** are included in this notice.

**Do Not Return Any OneTouch Ultra Test Strips To LifeScan**

We estimate that less than 25 damaged vials are among all the test strips in the two lots that have been identified as having this issue in the U.S. In addition, damaged vials can only be identified by opening the carton and inspecting the vial inside.

Due to the extremely low incidence of damaged vials (approx. 12 vials per lot), and the inability to identify them without opening each carton, we request that you **do not return** any OneTouch Ultra Test Strips from the affected lots unless further notified by LifeScan to do so.

Please continue to sell and distribute any inventory you may have of 100-count OneTouch Ultra Test Strips from lots **#2960566** and **#2960878**. Credit will not be given for unauthorized returns.

While it is important that distributors and pharmacists are aware of this issue, we believe patients are in the best position to identify the extremely small number of

damaged vials through their normal receipt and inspection of the product before use.

### **How LifeScan Is Addressing This Issue**

We take this issue very seriously and are conducting a broad-based notification program to alert patients, healthcare professionals, pharmacists and distributors. The U.S. Food & Drug Administration is aware of this issue and the steps we are taking to address it.

We apologize for any inconvenience this may cause. If you have any questions about OneTouch Ultra Test Strips, please call our Customer Solutions group at **800 600-7226**. Thank you for your continued support of LifeScan.

Sincerely,

LifeScan Customer Service