



February 24, 2010

**Urgent Medical Device Recall**  
8 Lots of OneTouch® SureStep® 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 your members can rely on. For that reason, we're also committed to communicating with you when we learn of product that does not meet our customers' expectations.

**We are immediately recalling 8 lots of OneTouch® SureStep® Test Strips because they may provide falsely low test results when the blood glucose is greater than 400 mg/dL.**

**Please Help Us Reach Your Members With This Important Information**

Please share this information with your members that use OneTouch SureStep Systems. To assist you, enclosed is a notification template to use in communicating with your members.

1. We are recalling the following 8 lots of OneTouch SureStep Test Strips.

Recalled Lot	Size	Description	Recalled Lot	Size	Description
# 2969251	100-ct	OneTouch SureStep	# 2969795	50-ct	OneTouch SureStep
# 2969798	100-ct	OneTouch SureStep	# 2982566	50-ct	OneTouch SureStep
# 2982369	100-ct	OneTouch SureStep	# 2969481	50-ct	Medicare/Mail Order
# 2983467	100-ct	OneTouch SureStep	# 2998193	50-ct	Medicare/Mail Order

*Lot #'s are located on the outer carton and test strip vial.*

If patients need help checking their test strips, or if they have test strips from the lots listed above, they should immediately call LifeScan Customer Service at **800 574-6139** between 5:00 a.m. to 7:00 pm Pacific Time, seven days a week or visit [www.SureStep.com](http://www.SureStep.com). Replacement product will be shipped to them immediately at no charge.

2. While patients wait for their replacement product to arrive, it is important that they continue to test their blood glucose. If they have access to a meter that does not use OneTouch SureStep Test Strips, they should use this other meter to test until replacement product from LifeScan arrives. If an alternate meter is not available, they may continue to test using the recalled OneTouch SureStep Test Strips. However, if they obtain results above 400 mg/dL, they should contact their healthcare professional for further instructions because their glucose may be significantly higher.

No injuries associated with these recalled test strips have been reported. However, if patients use the falsely low test results to determine their insulin dose, they may give themselves too little insulin, which could result in poor blood glucose control. Patients with high blood glucose may or may not have certain symptoms including increased thirst, frequent urination, headaches, difficulty with concentration, blurred vision and fatigue (weak, tired feeling). High blood glucose must be identified and treated promptly to avoid serious complications, such as coma and death.

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Our first priority is to provide the highest quality products so that your members can test with confidence. We are conducting a broad-based communications program to alert patients, healthcare professionals, pharmacists and distributors. As part of this program, we are sending notices to our registered OneTouch SureStep System users as well as an alert to retail pharmacies in the U.S.

If you have any questions about this issue, please contact your LifeScan Strategic Account Manager. We apologize for any inconvenience this issue may cause and thank you for your continued support.

Sincerely,

LifeScan Customer Service

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