



MEMORANDUM

To: Clinic Manager

From: Sean Strong, QI Director
Lisle Mukai, QI Coordinator

Subject: **FDA Recall: LifeScan OneTouch SureStep Test Strips**

Date: March 1, 2010

FDA RECALL:
LifeScan OneTouch® SureStep® Test Strips

The Network is required to distribute information regarding recalls that potentially affect ESRD facilities and/or patients. The following recall was posted on February 26, 2010.

LifeScan, Inc. is conducting a voluntary recall in the United States of eight lots of OneTouch® SureStep® Test Strips, used by people with diabetes to measure their blood glucose levels at home. The test strips are being recalled because they may provide falsely low glucose results when the glucose level is higher than 400 mg/dL.

The eight lots of consumer OneTouch SureStep Test Strips being recalled are:

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

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

Patients with test strips from the recalled lots are asked to call LifeScan at (800)574 - 6139 between 5:00 am and 7:00 pm Pacific Time, seven days a week or visit **www.surestep.com** to request replacement product. Replacement product will be shipped immediately and provided free of charge.

For more information regarding this recall please see the attached KCER Notice and/or log on to the FDA website at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm202254.htm>

Please share this information as applicable within your organizations/practices.
Thank you for your time and attention to this important patient safety issue.

Cc: Steven Preston, Project Officer, CMS RO X

Mission Statement

To provide leadership and assistance to renal dialysis and transplant facilities in a manner that supports continuous improvement in patient care, outcomes, safety and satisfaction.

Recall: OneTouch SureStep Test Strips (LifeScan)



LifeScan and FDA notified healthcare professionals of a voluntary recall of eight lots of OneTouch SureStep Test Strips, used by people with diabetes to measure their blood glucose levels at home. The test strips are being recalled because they may provide falsely low glucose results when the glucose level is higher than 400 mg/dL.

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. High blood glucose must be recognized and treated promptly to avoid serious complications, such as coma and death.

The eight lots of consumer OneTouch SureStep Test Strips being recalled are identified in the firm's press release. Lot numbers are located on the outer carton and test strip vial. LifeScan estimates approximately fourteen thousand packages (50- and 100-count) of consumer OneTouch SureStep Test Strips were distributed nationwide between August 1, 2009 and January 28, 2010.

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

Read the complete MedWatch 2010 Safety summary, including a link to the firm's press release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm202254.htm>