



**Indiana State  
Department of Health**  
*An Equal Opportunity Employer*

**Michael R. Pence**  
Governor

**William C. VanNess II, MD**  
State Health Commissioner

**DATE:** January 15, 2014

**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer

**FROM:** *A. Scott Gilliam*  
A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program

**SUBJECT:** Tandem Diabetes Care®, Inc. [Drug]

**AFFECTED PRODUCT:** Specific lots of insulin cartridges that are used with the t:slim® Insulin Pump.

**SUMMARY:** Unclassified Recall; The affected cartridges may be at risk for leaking. A cartridge leak could potentially result in the device delivering too much or too little insulin, which can lead to a serious adverse event.

Customers who received affected cartridges are being contacted by the Company or its authorized distributors and asked to call Tandem Technical Support to receive replacement cartridges at no charge.

**SUGGESTED**

**ACTION:** For consumer inquiry only. Tandem Customer Support is available 24 hours a day, 7 days a week at 1-877-801-6901.

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**Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.



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To promote and provide  
essential public health services.

**Tandem Diabetes Care Initiates Voluntary Recall for Specific Lots of Insulin Cartridges Used with t:slim Insulin Pump**

*Company Is Providing Replacement Cartridges to Its Customers at No Additional Charge*

**Contact:**

Consumer:  
(877) 801-6901

Media:  
Steve Sabicer  
(714) 907-6264  
Email: [ssabicer@thesabicergroup.com](mailto:ssabicer@thesabicergroup.com)

**FOR IMMEDIATE RELEASE - SAN DIEGO** - January 10, 2014 - Tandem Diabetes Care®, Inc. (NASDAQ: TNDM) today announced that it is initiating a voluntary recall of specific lots of insulin cartridges that are used with the t:slim® Insulin Pump. The affected cartridges may be at risk for leaking. The cause of the recall was identified during Tandem's internal product testing, and has not been associated with any complaints or adverse events reported by customers. However, a cartridge leak could potentially result in the device delivering too much or too little insulin, which can lead to a serious adverse event.

"The safety of our customers is our top priority, and we are committed to quickly addressing issues if they arise," said Kim Blickenstaff, President and CEO of Tandem Diabetes Care. "The potential for a cartridge leak was identified during in-house product testing, and the cause has been identified. Modifications to our cartridge manufacturing process have been implemented to prevent this issue from occurring in the future."

Customers should discontinue using cartridges labeled with the below lot numbers, which were shipped on or after December 17, 2013. The affected lots represent approximately 4,746 boxes of cartridges (10 cartridges per box).

Affected Lot Numbers				
M001963	M001980	M002027	M002083	M002119
M001964	M001987	M002028	M002096	M002120
M001973	M001988	M002029	M002097	
M001974	M001990	M002030	M002099	
M001979	M001991	M002082	M002100	

All other cartridge lots and the t:slim Insulin Pump are not affected by this recall. Customers who received affected cartridges are being contacted by the Company or its authorized distributors and asked to call Tandem Technical Support to receive replacement cartridges at no charge. Tandem expects to have sufficient quantities of cartridges to replace affected lots in a timely manner. Tandem Customer Support is available 24 hours a day, 7 days a week at 1-877-801-6901.

### **About Tandem Diabetes Care, Inc.**

Tandem Diabetes Care, Inc. is a medical device company with an innovative, user-centric and integrated approach to the design, development and commercialization of products for people with insulin-dependent diabetes. The Company manufactures and sells the t:slim Insulin Pump, the slimmest and smallest durable insulin pump currently on the market, and the first and only with a high resolution, color touch screen. Tandem is based in San Diego, Calif.

### **Forward Looking Statement**

This press release includes forward-looking statements concerning Tandem's voluntary recall of specific lots of cartridges that are used with the t:slim® Insulin Pump, the scope of the recall, the cause of the potential cartridge leak, the implementation of remedial actions that are intended to prevent this issue from occurring in the future, and Tandem's ability to replace affected cartridges on a timely basis. Tandem's actual results may differ materially from those indicated in these forward looking statements due to risks and uncertainties, including: future actions of the FDA or any other regulatory body or governmental authority; Tandem's ability to modify its cartridge manufacturing process in order to prevent this issue from occurring in the future; Tandem's reliance on distributors to facilitate the product recall; the potential that Tandem may subsequently discover additional lots of cartridges subject to this recall; the possibility that this recall could subject Tandem to claims or proceedings which may adversely impact its business and financial condition; and other risks identified in Tandem's Registration Statement on Form S-1. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Tandem undertakes no obligation to update any forward-looking statement in this press release.

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