



Tandem Diabetes Care Expands Voluntary Recall for Select Lots of Insulin Cartridges Used with t:slim Insulin Pump

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

SAN DIEGO, Jan. 20, 2014 /PRNewswire/ -- Tandem Diabetes Care®, Inc. (NASDAQ: TNDM), or Tandem, today announced that it is expanding 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. This 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. For that reason, even after our previous announcement Tandem's team continued to perform further testing. Based on this work we recognized that additional cartridge lots could also be at risk for leaking and so we are expanding the scope of this recall," said Kim Blickenstaff, President and CEO of Tandem. "We are confident that we have identified all of the affected cartridge lots that may have been shipped to customers or distributors and that we have implemented appropriate corrective actions to prevent this from happening in the future."

Customers should discontinue using cartridges labeled with any of the lot numbers listed below. The affected lots shipped to customers or distributors represent an aggregate of approximately 13,000 boxes of cartridges (10 cartridges per box). The affected lots announced on January 10, 2014 were shipped from December 17, 2013 to January 10, 2014. The affected lots announced on January 20, 2014 were shipped prior to October 16, 2013.

Affected Lot Numbers

Announced January 20, 2014		Announced January 10, 2014		
M000857	M001414	M001454	M001963	M002028
M000869	M001415	M001455	M001964	M002029
M001344	M001416	M001456	M001973	M002030
M001345	M001417	M001457	M001974	M002082
M001346	M001420	M001458	M001979	M002083
M001347	M001421	M001459	M001980	M002096
M001389	M001422	M001460	M001987	M002097
M001390	M001423	M001528	M001988	M002099
M001391	M001451	M001529	M001990	M002100
M001392	M001452	M001530	M001991	M002119
M001393	M001453	M001532	M002027	M002120

All other cartridge lots shipped to customers or distributors and the t:slim Insulin Pump are not affected by this recall. The Company, or its authorized distributors, is asking customers who received affected cartridges 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.

The Company has determined that under certain conditions a specific piece of equipment used in the cartridge test process caused the affected cartridges to be at risk for leaking. Tandem has already implemented modifications to the cartridge manufacturing test process to prevent this issue from occurring in the future, and the Company's manufacturing facility is able to support ongoing customer demand.

The Company is working with its customers and distributors to replace cartridges subject to the recall. Based on the periods during which the affected lots were shipped, the Company believes a significant number of the affected cartridges have already been used and therefore will not be exchanged. In addition to the expenses associated with replacing affected cartridges, the Company may also incur additional logistical shipping fees and other recall coordination costs. Tandem is also in the process of evaluating additional cartridges still in the Company's internal inventory to determine whether they will be usable, and may incur expenses with those that are unusable.

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 and the Company's belief that it has identified all of the affected cartridge lots that may have been shipped to customers or distributors, the cause of the potential cartridge leak, the implementation of remedial actions that are intended to prevent this issue from occurring in the future, Tandem's ability to replace affected cartridges on a timely basis, the Company's ability to continue to manufacture cartridges without significant disruption in order to meet ongoing customer demand, Tandem's estimate of the portion of affected cartridges that will be replaced and estimated expenses and charges that Tandem may incur as a result of the recall, or from the write off of internal inventory. 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 the actual replacement rate for affected cartridges may be higher or lower than estimated; the potential that the company may incur additional expenses that it does not anticipate at this time; the inherent difficulty of predicting the total financial impact associated with the 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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