Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: December 2, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Insulet Corporation – RECALL [Medical Device]

AFFECTED PRODUCT: **OmniPod (Pod) Insulin Management System**

SUMMARY: **Unclassified Recall; This Notification is due to a slight increase in the reported cases in which the Pod's needle mechanism failed to deploy or there was a delay in the deployment of the needle mechanism.**

OmniPods from the affected lots listed below were distributed to customers in September 2015:

Distribution	Catalog Number	Description	Lot Number
United States	POD-ZXP420	OmniPod®, Insulin Management System	L41880 L41881 L41892 L41895 L41897 L41898 L41899 L41900 L41901 L41902 L41903 L41904 L41905 L41906 L41907

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions may contact Insulet Customer Care via telephone at 1-855-407-3729 at any time.**

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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.

Insulet Corporation Issues Field Safety Notification of OmniPod Insulin Management System
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For Immediate Release

December 1, 2015

Contact

Consumers

Insulet Customer Care
1-855-407-3729
Firm Press Release

On November 2, 2015, Insulet Corporation (Insulet or the Company) initiated a lot-specific voluntary Field Safety Notification (Notification) for 15 lots of the OmniPod (Pod) which were distributed in the U.S. and three lots which were distributed internationally.

Insulet has notified its distributors and customers by email, FedEx, and phone calls beginning on November 2, 2015, as well as all applicable regulatory agencies, including U.S. Food and Drug Administration (FDA). Consumers with questions may contact Insulet Customer Care via telephone at 1-855-407-3729 at any time.

This Notification is due to a slight increase in the reported cases in which the Pod's needle mechanism failed to deploy or there was a delay in the deployment of the needle mechanism. The reported incidence of this product issue in the affected lots is approximately 1%-2%. Once this issue was recognized, the Company corrected the manufacturing process and implemented additional inspection steps.

This Notification does not affect the OmniPod Personal Diabetes Manager (PDM).

In the event a needle mechanism fails to deploy, the needle will not be inserted and insulin delivery will not begin. The interruption of insulin delivery may cause elevated blood glucose (hyperglycemia), which, if left untreated, can result in diabetic ketoacidosis (DKA). If a patient has activated a Pod and experiences unexpected elevated blood glucose levels, a healthcare professional should be consulted.

The affected Pod lots have resulted in 66 Medical Device Reports, of which three required medical intervention. **No serious injuries or deaths have been reported in patients using OmniPod devices from the affected lots.**

Consumers who have Pods from the affected lots should ensure the needle mechanism has deployed properly, and may contact Insulet Customer Care via telephone at 1-855-407-3729 at any time.

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Distribution	Catalog Number	Description	Lot Number
United States	POD-ZXP420	OmniPod®, Insulin Management System	L41880 L41881 L41892 L41895 L41897 L41898 L41899 L41900 L41901 L41902 L41903 L41904

Distribution	Catalog Number	Description	Lot Number
			L41905 L41906 L41907
International	14810	OmniPod®, Insulin Management System	L41908 L41910 F41935

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm.
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-332-0178.

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