Insulet Corporation
November 2, 2015

URGENT: Field Safety Notification
OmniPod® Insulin Management System
Certain OmniPod Lots Specified Below

Dear Valued Insulet Customer,

Insulet Corporation, the manufacturer of the OmniPod Insulin Delivery System, is committed to keeping you and your healthcare professionals up-to-date in the event there are any issues that arise related to our products.

As part of our product quality monitoring process, we have identified that 15 lots of OmniPod which were distributed in the U.S. had 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 we recognized this, we corrected the manufacturing process and implemented additional inspection steps.

No serious injuries or deaths have been reported in patients using OmniPod devices from the affected lots.

How do I know if I have affected product?

This Field Safety Notification affects only the Pods and does not affect the OmniPod Personal Diabetes Manager (PDM). The slight increase was identified in the following lots of Pods:

U.S. Lot Numbers		
L41880	L41898	L41903
L41881	L41899	L41904
L41892	L41900	L41905
L41895	L41901	L41906
L41897	L41902	L41907

The lot number is located on the Pod tray lid label, the side of the Pod and on the end of the box of Pods.

What is the risk?

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 you believe you have successfully activated your Pod and you experience unexpected elevated blood glucose levels, please consult your healthcare professional.

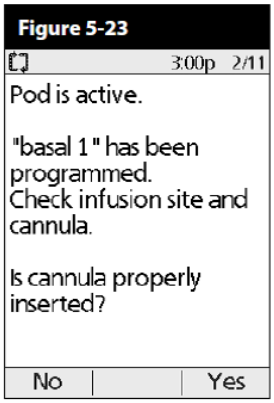
Upon activation, how do I know if the needle mechanism deployed?

After you press the Start button on the PDM, you should hear a few soft clicks and then a louder click from the Pod indicating that the needle mechanism has deployed. If you do not hear this within a few seconds after pressing Start, the Pod has failed to deploy.

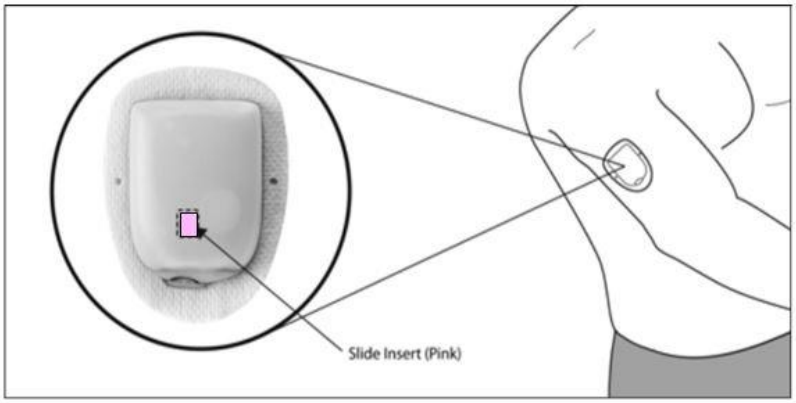
You should also feel the insertion of the needle mechanism deployment. The PDM will indicate that the Pod is active and prompt you to check to ensure the cannula is properly inserted (Figure 5-23 below). For more information, please see the User Guide.

You should always check the infusion site after insertion to ensure that the cannula was properly inserted.

Figure 5-23



When you see the pink slide insert in this position, it means that the cannula is inserted (See figure below).



The PDM will automatically remind you to check your blood glucose 1.5 hours after each Pod change. If the cannula is not properly inserted, hyperglycemia may result.

If you experience unexpected elevated blood glucose levels, change your Pod and contact your healthcare provider.You may also call Customer Care at 1-855-407-3729 if you have any questions regarding this Field Safety Notification.

This voluntary action is being taken by Insulet Corporation with the knowledge of the U.S. Food and Drug Administration (FDA). 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 or by regular mail or by fax.

We appreciate how you depend on us and sincerely regret any inconvenience this may cause you. We are focused on delivering the highest level of product quality and your complete satisfaction is our top priority.

Sincerely,

Michael Spears
Vice President, Quality, Regulatory & Clinical Affairs
Insulet Corporation