Medical Devices

Medtronic MiniMed Paradigm Insulin Infusion

Recall Class: Class I

Date Recall Initiated: June 7, 2013

Products: Medtronic MiniMed Paradigm Insulin Infusion Sets

Models: MMT-317, MMT-318, MMT-324, MMT-325, MMT-312S, MMT-312L, MMT-386, MMT-387, MMT-394, MMT-396, MMT-397, MMT-398, MMT-399, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384, MMT-368, MMT-862, MMT-864, MMT-866, MMT-874, MMT-876, MMT-884, MMT-886, MMT-921, MMT-923, MMT-925, MMT-941, MMT-943, MMT-945, MMT-961, MMT-963, MMT-965, & MMT-975 Paradigm Infusion sets.

These affected products were manufactured from October, 2001 through June, 2013 and distributed from December, 2001 through June, 2013.

Use: The Paradigm infusion sets are intended for use with Paradigm insulin infusion pumps. Infusion sets are used by patients with diabetes mellitus who require administered insulin to maintain acceptable blood glucose levels.

Recalling Firm:
Medtronic MiniMed
18000 Devonshire St
Northridge, California 91325-1219

Manufacturer:
Unomedical A/S
Aaholmvej 2, Osted
Roskilde, Denmark

Flextronics International USA Inc.
677 Gibraltar Ct.
Milpitas, California 95035-7700

Reason for Recall: Medtronic is taking this action for the Medtronic MiniMed Paradigm Insulin Infusion Sets because of a potential safety issue that can occur if insulin or other fluids come in contact with the inside of the tubing connector. If this occurs it can temporarily block the vents that allow the pump to properly prime. This can result in too much or too little insulin being delivered resulting in hypoglycemia or hyperglycemia which can be severe and lead to serious illness.

Public Contact: For questions about this recall contact Medtronic's 24 hour Helpline at 1-888-204-7616

FDA District: Los Angeles District Office

FDA Comments:

Patients: If you notice anything unusual during the infusion set prime process such as the insulin continuing to drip from the tip of the infusion set cannula when priming has been completed, this may indicate that the connector vents are not working properly. If this occurs, **do not insert the infusion set** and **immediately call** the HelpLine at 1-888- 204-7616, for assistance.

Physicians: No action is required beyond the recommendations provided in the Urgent Medical Device Safety Notification letter.

On June 7, 2013, Medtronic sent an urgent medical device safety notification to healthcare professionals to inform them of the potential for over or under delivery of insulin if insulin or other fluids contact the inside of Medtronic Paradigm Tubing Connectors. This issue applies to all

Medtronic infusion sets designed for use with Medtronic Paradigm family infusion pumps. On June 10, 2013 Medtronic sent an urgent medical device safety notification to all Paradigm Insulin pump users and distributors to inform them of this issue. Paradigm Insulin Pump users, distributors, and healthcare professionals are all instructed to contact Medtronic's 24 hour helpline at 1-888 204-7616.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by FAX.

Additional Link for Medtronic's safety actions and reference information:

- Firm Safety Information

Page Last Updated: 07/16/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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