



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

VIA FEDERAL EXPRESS

JUL 15 2009

Christopher O'Connell
President, Medtronic Diabetes
Medtronic Diabetes
18000 Devonshire Street.
Northridge, California 91325-1219

Dear Mr. O'Connell:

This is in reference to your firm's recall of Paradigm QUICK-SET® Infusion Sets models MMT-396, MMT-397, MMT-398 and MMT-399 with lot numbers beginning with "8" (8xxxxxx).

The Food and Drug Administration (FDA) has reviewed the information obtained from your firm concerning this matter. We have concluded that the defect with this product, a vent that may be clogged with silicone oil during manufacturing, by its use or exposure to, has a reasonable probability to cause serious adverse health consequences, including death. We are, therefore, classifying your voluntary action as a Class I recall.

The seriousness of this recall requires Level A (100 percent) effectiveness checks. Your firm should verify that every consignee has been notified of the recall and that appropriate action has been taken. The FDA's policy concerning recalls is located in Title 21, Code of Federal Regulation, Part 7.

Your recall has been assigned recall number Z-1705-2009. Information regarding your recall will be published in the weekly FDA Enforcement Report.

Our Los Angeles District Office will remain in close contact with your firm regarding this recall until the matter is resolved.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Center for Devices and
Radiological Health

**Class I Recall
Action Memo Model
OC**

Date:

From: Tim Ulatowski, Director, Office of Compliance, WO66-3408
Center for Devices and Radiological Health

Subject: Approval Requested for Class I Recall –**ACTION MEMO**
Paradigm Quick-set Infusion Sets

To: Director, Center for Devices and Radiological Health
Attn: Daniel G. Schultz, M.D., WO66-5442

Recalling Firm: Medtronic MiniMed
18000 Devonshire St
Northridge, California 91325
United States

ISSUE Clogged Vents

Medtronic MiniMed has initiated a voluntary recall of the Paradigm QUICK-SET® Infusion Sets. This infusion set is a thin plastic tube used to deliver insulin from an insulin pump to the patient, and is typically replaced by the patient every three days. The firm reported that approximately 2% of the 28 million sets manufactured since December 2007, may have the vent clogged with silicone oil. If the vent becomes clogged, the pump will not work properly, and could result in over-infusion or under-infusion of insulin. The firm has determined that use of the defective device may result in patients experiencing severe hypoglycemia and/or hyperglycemia and may result in serious injury or death.

INTENDED USE

This product is intended for use in combination with Paradigm reservoirs (models MMT- 326 or MMT-332) and Paradigm external insulin infusion pumps to deliver insulin (subcutaneously) to patients who require exogenous insulin to maintain glycemic control.

Paradigm Quick-set infusion sets include a thin tube (cannula) that extends either 6mm or 9mm beyond the base of the distal end of the set. The cannula is inserted into the subcutaneous tissue using a preinstalled insertion needle. This needle is removed after insertion of the set. The cannula is oriented perpendicular to the adhesive base at the distal end of the set and therefore the Paradigm Quick-set is referred to as a 90 degree set.

Patients may temporarily disconnect the infusion set by removing the plastic hub of the set from the base. The set is reconnected to the infusion site by reversing this procedure.

Individual sets are intended for use for a maximum of three days, after which they are discarded. The sets are supplied sterile and are intended for single use only.

Paradigm Quick-set infusion sets may be inserted manually or by using the Quick-serter insertion device. The Quick-serter (model MMT-395) is a small, spring operated insertion device

that is intended for use to insert either Quick-set, Paradigm Quick-set or Paradigm Quick-set Plus infusion sets quickly and relatively painlessly into the subcutaneous tissue (typically in the abdominal area).

During use, the plunger of the Quick-serter is pulled back to compress the spring and lock the mechanism in the ready position. The distal portion of the infusion set is installed into the Quick-serter and two buttons are pressed simultaneously to release the mechanism and propel the insertion needle and cannulae through the skin.

BACKGROUND

The firm has received a total of 13 reports of incidents in which the device has malfunctioned, including 0 deaths. Of the 13 complaints provided by the firm, two patients experienced low blood sugars (46, 63) consistent with over-infusion of insulin, and three patients experienced elevated blood sugar levels (465, 432, 220) consistent with under-infusion of insulin. The firm reported that approximately 2% of the 28 million sets manufactured since December 2007, may have the vent clogged with silicone oil.

FDA became aware of this problem through the firm's submission of a corrections and removal report to the Los Angeles District Office on June 29, 2009.

Medtronic MiniMed informed FDA that they are recalling approximately 28 million Paradigm Quick-set Infusion Sets due to a vent that may be clogged with silicone oil during manufacturing. When the vent becomes clogged, the insulin pump may not work properly, and could result in an over-infusion or under-infusion of insulin which may result in serious injury or death. The device is used by diabetic patients requiring insulin therapy.

The firm's investigation determined that the vent may be clogged with silicone oil.

The firm has distributed 28 million units in the United States and Canada, which are subject to the recall. The firm estimates that approximately 3 million sets are currently in distribution. Also affected are 7256 sets in international distribution. This device was manufactured from December 2007 to June 2009. The recall includes models MMT-396, MMT-397, MMT-398 and MMT-399 with lot numbers beginning with "8" (8xxxxxx).

The firm is notifying customers, healthcare practitioners, and distributors of the recall by mail and a press release. The firm instructs customers to "Stop using your "Lot 8" Quick-set infusion sets right away" and to contact the firm to obtain replacement product.

The firm's timeline for distribution of the recall materials is as follows:

- Monday July 6, 2009: distribute notifications to healthcare professional and distributors via UPS overnight letter.
- Tuesday July 7, 2009: mail notifications to inactive customers, distribute notifications and replacement sets to active customers (batch 1).
- Wednesday July 8, 2009: distribute notifications and replacement sets to active customers (batch 2).
- Thursday July 9, 2009: distribute notifications and replacement sets to active customers (batch 3).
- Friday July 10, 2009: issue press release.

The firm defines an “active customer” as one that has purchased product since January 1, 2009. An “inactive customer” is one who has not purchased product since January 1, 2009.

The firm has a controlled distribution plan in place to avoid a shortage. This plan entails shipping single boxes of 10 sets (approximately 1 month supply) at a time to customers instead of immediately filling large orders. These actions will not cause a device shortage.

See a copy of the firm’s notification letters and press release attached to this memo.

FDA is drafting a directed inspectional assignment for Medtronic and their Danish manufacturer Unomedical A/S. This recall will appear in the weekly FDA Enforcement Report and be posted on the Med Watch internet site.

DISTRIBUTION

There are a total of 28 million units in distribution worldwide with 28 million of those units in distribution nationwide and 7256 sets in international distribution. The firm estimates that 3 million of the 28 million sets distributed sets remain unused. The primary users of this device are patients. This product was distributed from December 2007 to June 2009. The devices under recall includes models MMT-396, MMT-397, MMT-398 and MMT-399 with lot numbers beginning with “8” (8xxxxxx).

HEALTH HAZARD EVALUATION

A Health Hazard Evaluation (HHE) was conducted on July 8, 2009. The conclusions of the HHE are:

- The risk of serious adverse health consequences or death for the overall population as well as the population at greatest risk is considered to be Reasonable Probability.
- The population at greatest risk represents a significant portion of the total population using the device.
- Patients are at greatest risk when they receive a sudden bolus of insulin as this may result in a rapid onset of serious adverse health consequences.
- Patients experiencing an under delivery of insulin may have a slower onset time of serious adverse health consequences.
- In addition, patients may not have rapid access to healthcare, and the health consequences may not be rapidly reversible.
- Both under and over delivery may lead to serious adverse health consequences or death.

See a copy of the HHE attached.

On March 2, 2004, Medtronic MiniMed had a Class I recall for their Medtronic MiniMed Paradigm Quick-set Plus Infusion Sets. Models MMT-359S6; MMT-359S9; MMT359L6; & MMT-359L9.

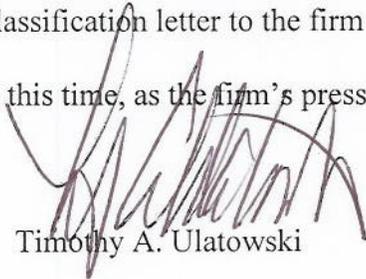
There were complaints of bent cannulas, occlusions, leaking at the insertion site, and accidental dislodging of the infusion set while removing the insertion device. Additionally there were reports of adhesive failure, which causes the device to detach from the skin. These problems resulted in the interruption of insulin flow to the patients.

The important issues were that insulin flow to the diabetic is interrupted and since it is not a pump malfunction, there will be no corresponding alarm to alert the diabetic that they are no longer receiving insulin.

RECOMMENDATION

We recommend that the action taken by Medtronic MiniMed be classified as a Class I recall. The recall recommendation and CDRH's Classification letter to the firm are attached.

An FDA press statement is not warranted at this time, as the firm's press release appears to have properly notified the public.



Timothy A. Ulatowski

CENTER DIRECTOR'S DECISION:

Approved _____ Disapproved _____ Date _____

Attachments

- TAB A – Recall Classification Letter to Firm
- TAB B – District Recall Recommendation
- TAB C – CDRH's HHE Form
- TAB D – Firm's Recall/Notification Letter
- TAB E – Recalled product labels/labeling
- TAB F – Recalling firm's press release
- TAB G – Recalling firm's HHE (if submitted)



Center for Devices and Radiological Health

Health Hazard Evaluation X

Health Risk Assessment

RES #: 52521 ORACLE #: RECALL # (s):

Date: July 8, 2009 Safety Officer: Jason A. Brookbank

I. Product Data

Panel Code: 80	Device Name: QUICK-SET® INFUSION SETS
Product Code: FPA	
Model: MMT-396 MMT-397 MMT-398 MMT-399	Lot/Serial Numbers: All lots beginning with "8"

Marketing Status (Include 510(K) or PMA Number, Specify if Exempt From 510(K) : 510(k) K011071

Total Number of Devices In Distribution: The firm has distributed 28 Million units in the United States and Canada which are subject to the recall. The firm estimates that approximately 3 million sets are currently in distribution.

U.S.: 28 Million Foreign: 7256

Number of Devices Subject to Recall or Review: 28 Million

U.S.: 28 Million Foreign: 7256

Manufacturer / Recalling Firm, Address:	
Manufacturer	Recalling Firm
Unomedical a/s Aaholmvej 1-3, Osted DK-4320 Lejre Denmark	Medtronic MiniMed 18000 Devonshire St Northridge, California 91325 United States

Product Description (Include Intended Use from labeling or known off-label uses):

The Paradigm Quick-set infusion sets are intended for use in combination with Paradigm reservoirs (models MMT- 326 or MMT-332) and Paradigm external insulin infusion pumps to deliver insulin (subcutaneously) to patients who require exogenous insulin to maintain glycemic control.

Paradigm Quick-set infusion sets include a thin tube (cannula) that extends either 6mm or 9mm beyond the base of the distal end of the set. The cannula is inserted into the subcutaneous tissue using a preinstalled insertion needle. This needle is removed after insertion of the set. The cannula is oriented perpendicular to the adhesive base at the distal end of the set and therefore the Paradigm Quick-set is referred to as a 90 degree set.

Patients may temporarily disconnect the infusion set by removing the plastic hub of the set from the base. The set is reconnected to the infusion site by reversing this procedure.

Individual sets are intended for use for a maximum of three days, after which they are discarded. The sets are supplied sterile and are intended for single use only.

Paradigm Quick-set infusion sets may be inserted manually or by using the Quick-serter insertion device. The Quick-serter (model MMT-395) is a small, spring operated insertion device that is intended for use to insert either Quick-set, Paradigm Quick-set or Paradigm Quick-set Plus infusion sets quickly and relatively painlessly into the subcutaneous tissue (typically in the abdominal area).

During use, the plunger of the Quick-serter is pulled back to compress the spring and lock the mechanism in the ready position. The distal portion of the infusion set is installed into the Quick-serter and two buttons are pressed simultaneously to release the mechanism and propel the insertion needle and cannulae through the skin.

TAB-C
FDA's
HHE

Center for Devices and Radiological Health

Health Hazard Evaluation X

Health Risk Assessment

RES #: 52521 ORACLE #: _____ RECALL # (s): _____

Date: July 8, 2009 Safety Officer: Jason A. Brookbank

II. Problem Definition and Analysis

Reason for Recall or Risk Assessment

- **Description of the Defect, Malfunction or Error in Use of the Device:**
Paradigm Quick-set Infusion Sets failures are apparently due to a vent that may be clogged with silicone oil during manufacturing. When the vent becomes clogged, the insulin pump may not work properly, and could result in an over-infusion or under-infusion of insulin.
- **Root Cause of the Problem (If Known):**
Vent that may be clogged with silicone oil during manufacturing.
- **Factors that May Contribute to Product Risk (i.e. Device Design, Manufacturing Problems or User Error):**
Manufacturing problems
- **If Device Failure Occurs is it Easily Recognized by User?**
No, the pump displays will not indicate if an over-infusion or under-infusion of insulin occurs. The display will not accurately display the amount of insulin delivered if over-infusion or under-infusion of insulin occurs.

Manufacturer's CAPA Investigation (If Available):

- **Summary:**
Paradigm Quick-set Infusion Sets failures are apparently due to a vent that may be clogged with silicone oil during manufacturing. When the vent becomes clogged, the insulin pump may not work properly, and could result in an over-infusion or under-infusion of insulin.
- **Date of Analysis:**
- **Firm's Estimate of Number of Devices that will Develop the Defect and/or Fail :**
 - **How Many Devices from the Affected Lots Are Expected to Have or Develop the Defect?**
2% of all sets are expected to have this problem. This equals 560,000 sets.
 - **How Many Devices with the Defect are Likely to Exhibit the Failure over the Lifetime of the Device?**
 - **Of Those Devices that Fail, How Many are Likely to Cause Injury if Used?**
 - **Any Comments on How these Estimates were Reached:**
The firm tested (b) samples from 8 retained lots and determined that 2% of the sets tested had vents that were clogged with silicone oil.

Center for Devices and Radiological Health
Health Hazard Evaluation X Health Risk Assessment

RES #: 52521 ORACLE #: _____ RECALL # (s): _____
Date: July 8, 2009 Safety Officer: Jason A. Brookbank

- **Firm's Conclusion About Health Risk. (Attach a Copy of Firm's HHEs or HHAs):** "In summary, our analysis suggests that there is a risk of serious injury or death in the unlikely event that a Paradigm Quick-set infusion set with clogged p-cap vents is being used at the time a sudden decrease in ambient pressure is experienced.

"Testing performed using (b) (4) infusion sets with clogged vents and (b) (4) model (b) (4) infusion pumps demonstrated that the amount of insulin delivered into a vial when the ambient pressure was decreased to (b) (4) Torr (pressure equivalent to (b) (4) above sea level) ranged from a minimum of one unit to a maximum of (b) (4) units."

▪ **Any FDA Comments:** The firm has not determined the minimum pressure differential required to generate this problem.

Adverse Events, Complaints and Problems or Incidents that may be Related to the Device Defect:

Number of Complaints 13 Malfunction Reports _____

Injuries Reported U.S. _____ International _____
Deaths Reported U.S. _____ International _____

Sources: The recalling firm provided a list of complaints.

Manufacturer _____ Inspection _____ MDR's _____

Explanation:

FDA and the firm have concerns about underreporting of events due to the fact that this failure triggers no alarms and the pump display will not show actual delivery when this event occurs.

Describe the Complaints and Injuries Reported to Date:

Of the 13 complaints provided by the firm, two patients experienced low blood sugars (46, 63) consistent with overinfusion of insulin, and three patients experienced elevated blood sugar levels (465, 432, 220) consistent with underinfusion of insulin. None of these patients appear to have suffered serious injury or death.

Center for Devices and Radiological Health

Health Hazard Evaluation X

Health Risk Assessment

RES #: 52521 ORACLE #: _____ RECALL # (s): _____

Date: July 8, 2009 Safety Officer: Jason A. Brookbank

III. Health Risks

TO BE COMPLETED BY MEDICAL OFFICER OR COMMITTEE

THE FOLLOWING ASSESSMENT IS BASED ON CURRENTLY AVAILABLE INFORMATION. CONCLUSIONS MAY CHANGE IF ADDITIONAL INFORMATION BECOMES AVAILABLE IN THE FUTURE.

Immediate and Long Range Health Consequences:

- A. Describe the Immediate and Long Range Health Consequences (Injuries or Illnesses) That May Result from Use of or Exposure to the Defective Device. (Include Known Off Label Uses)**
 Over-delivery: If there is a decrease in pressure, there is a risk of hypoglycemia that may result in serious injury or death.
 Under-delivery: If there is an increase or no change in pressure, there is a risk of hyperglycemia that may result in serious injury or death.
- B. Describe Any Factors That May Mitigate the Risk:** This is a silent failure, and is unlikely to be mitigated in a timely fashion.
- C. What Segment of the Population is Most at Risk? (e.g. Infants, Elderly, Pregnant Women, Critically Ill Patients, Immunocompromised, etc.)** Pregnant women, young children, patients with a low body mass, brittle diabetics, patients who undergo changes in altitude/barometric pressure.
- D. Does the Health Consequence Have Significant Public Health Impact Beyond Users (e.g. Spread of Serious Infection to Others)?** Yes, vehicle and machinery operators may experience hyperglycemia or hypoglycemia, which may result in unsafe operation which could potentially injure others.

Assess the Hazards Associated with Use of the Defective Product

Check All that Might Occur:

Population at Greatest Risk	Overall Population Using Device	
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Life-threatening (death has or could occur)
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Results in permanent impairment of body function or permanent damage to a body structure.
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Necessitates medical or surgical intervention.
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Temporary or reversible (without medical intervention).
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Limited (transient, minor impairment or complaints).
<input type="checkbox"/>	<input type="checkbox"/>	No adverse health consequences.

Center for Devices and Radiological Health

Health Hazard Evaluation X

Health Risk Assessment

RES #: 52521 **ORACLE #:** _____ **RECALL # (s):** _____

Date: July 8, 2009 **Safety Officer:** Jason A. Brookbank

Explanation: The severity of the injury may vary depending on the insulin dose delivered, rate of delivery, and the patients' access to healthcare facilities. Patients may not have immediate access to medical care, for example a patient on a flight.

Center for Devices and Radiological Health

Health Hazard Evaluation X

Health Risk Assessment

RES #: 52521 ORACLE #: _____ RECALL # (s): _____

Date: July 8, 2009 Safety Officer: Jason A. Brookbank

IV. PROBABILITY
 TO BE COMPLETED BY MEDICAL OFFICER OR COMMITTEE
 Assess the Probability that Use of, or Exposure to, Product under Recall will Cause

A. Serious Adverse Health Consequences or Death

	Overall Population Using Device	Population at Greatest Risk
Reasonable Probability	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Remote Probability	<input type="checkbox"/>	<input type="checkbox"/>
Not Likely	<input type="checkbox"/>	<input type="checkbox"/>

Explanation / Comments: The risk of serious adverse health consequences or death for the overall population as well as the population at greatest risk is considered to be Reasonable Probability. The population at greatest risk represents a significant portion of the total population using the device.
 Patients are at greatest risk when they receive a sudden bolus of insulin as this may result in a rapid onset of serious adverse health consequences.
 Patients experiencing an under delivery of insulin may have a slower onset time of serious adverse health consequences. In addition, patients may not have rapid access to healthcare, and the health consequences may not be rapidly reversible.
 Both under deliver and over delivery may lead to serious adverse health consequences or death.

B. Temporary or Medically Reversible Adverse Health Consequences

	Overall Population Using Device	Population at Greatest Risk
May Cause	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Not Likely to Cause	<input type="checkbox"/>	<input type="checkbox"/>

Explanation / Comments: