Patient Safety Alert

Veterans Health Administration Warning System
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May 19, 2004

Item: Class I Recall of Medtronic MiniMed Paradigm® Quick-set® Plus Infusion Sets.

Specific Incident: Medtronic MiniMed issued a Class I recall on the Paradigm® Quick-set® Plus Infusion Sets Model MMT-359S6, MMT-359S9, MMT-359L6 and MMT-359L9. Problems with the infusion sets can interrupt insulin flow resulting in serious injury.

Actions:

1. If you still have any of the above mentioned product in inventory, immediately stop distributing them to your patients.
2. Please complete the enclosed Distributor Response Form indicating how you will proceed with this mandatory notification and return it by fax as soon as possible to the manufacturer.
3. Please also complete the enclosed Exchange Request Form so that arrangements can be made to return all affected product to the manufacturer for disposal and send you the replacement products of your choice.

Additional Information: See **www.minimed.com/QSP** for FAQs and customer letters.

Source: Medtronic MiniMed and FDA.

Contact: Cathy Haley at Medtronic MiniMed: (818) 576 5594.

OR

Bryanne Patail at National Center for Patient Safety (NCPS) phone: (734) 930-5890.

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.

Medtronic Recalls Quick-Set® Plus Infusion Sets

Contact:
Bob Hanvik (Media)
(763) 505-2635
Rachael Scherer (Investors)
(763) 505-2694
FOR IMMEDIATE RELEASE -- Northridge, CA -- May 18, 2004 **--** Medtronic, Inc. today announced that its Diabetes division began notifying diabetic patients, healthcare professionals and distributors that it is conducting a nationwide recall of Quick-set ® Plus infusion sets because of problems that can interrupt insulin flow to diabetics who use them. These problems have resulted in a number of serious injuries, including some hospitalizations.

The company is asking patients to contact its 24-Hour Help Line at (800) MINIMED (1-800-646-4633) to exchange any unused Quick-set Plus infusion sets for replacement sets available currently from Medtronic. In the event that it is necessary to continue use of the Quick-set Plus while replacement sets are in transit, Medtronic is recommending that patients monitor their blood glucose levels frequently and be prepared to treat any elevated glucose levels that may occur with injections. Patients are also being instructed to contact their healthcare professional in the event of excessively high or low glucose levels or with any questions about their care. Information regarding the exchange of Quick-set Plus infusion sets is available at www.minimed.com/QSP.

This recall applies to all Paradigm Quick-Set Plus models (MMT-359S6, MMT-359S9, MMT-359L6 and MMT-359L9) and lot numbers. **This action affects only the Quick-set Plus infusion set; no other Medtronic devices or infusion sets are involved in this recall.**

This notification is a follow-up to a voluntary action undertaken by the company in March 2004 in response to an increased number of complaints related to the use of the Quick-set Plus infusion set, which delivers insulin from an infusion pump to a patient's body. The complaints involved problems with bending of the infusion set's cannula or unintentional disconnection of the set at the insertion site. At that time, customers were provided with a Quick-set Plus tips guide and offered replacement infusion sets upon request. The company also discontinued selling the Quick-set Plus infusion sets in conjunction with this initial notification.
The U.S. Food and Drug Administration (FDA) has classified this voluntary action as a Class I recall. The FDA defines a Class I recall as a situation in which there is a reasonable probability that the use of the product will cause serious adverse health consequences or death.

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325-1219
www.minimed.com

Important Recall Information:
Paradigm® Quick-set® Plus Infusion Sets

Dear Medtronic MiniMed Distributor,

This letter is provided to inform you that Medtronic MiniMed is recalling all Paradigm Quick-set Plus infusion sets. The U.S. Food and Drug Administration has classified this voluntary field action as a Class 1 recall, and therefore all patients who have been sent Quick-set Plus infusion sets must be notified.

If you still have any Quick-set Plus infusion sets in inventory, please immediately stop distributing them to your customers. Please note: **This recall only affects Paradigm Quick-set Plus infusion sets.** Other infusion sets distributed by Medtronic MiniMed (Sof-set®, Silhouette® and Quick-set) are not affected.

Enclosed is a copy of the customer letter we are sending to people who have purchased Quick-set Plus from us. We are requesting that you either send the enclosed letter to your Quick-set Plus customers or provide a customer mailing list so we can notify them on your behalf.

Please complete the enclosed **Distributor Response Form** indicating how you will proceed with this mandatory notification, and return it by fax as soon as possible. Please also complete the enclosed **Exchange Request form** so that we can arrange to return all Quick-set Plus inventory that you have to us for disposal and send you the replacement product of your choice.

If your customers contact us directly, we will exchange their unused Quick-set Plus infusion sets at no charge.

Thank you in advance for your speedy response to this letter. We sincerely appreciate your cooperation. Moreover, we apologize in advance for this inconvenience. We will stand by to assist your organization in any way we can.

As a company dedicated to improving lives, we have committed all our resources to resolving this situation as quickly as possible. Moreover, we are putting additional quality control procedures in place to prevent similar situations from occurring in the future.

Sincerely,

Jeffery A. McCaulley
Vice President and General Manager
Medtronic MiniMed

When Life Depends on Medical Technology

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Distributor Response Form
For Quick-Set® Plus Infusion Set Recall

Company Name _____

Contact Person _____

Address1 _____

Address2 _____

City _____ State _____ Zip _____

Telephone _____

Fax _____

E-mail _____

Do you have any Quick-set Plus infusion sets in inventory that need to be returned for exchange?
If yes, please complete the attached Product Exchange form.
_____ Yes _____ No

Please indicate how you will ensure your Quick-set Plus customers are informed of this important Recall information:

_____ We will mail all of our Quick-set Plus customers the recall letter within seven (7) business days. (Note: Medtronic MiniMed will provide copies of the letter for your mailing upon request.)

_____ We will provide a mailing list (in Excel) of our Quick-set Plus customers to Medtronic MiniMed within seven (7) business days and request that Medtronic MiniMed conduct the mailing directly.

Please sign below to confirm that you have received this information and understand that all customers must be notified as soon as reasonably possible.

Print Name _____

Signature _____

Title _____

Date _____

Please fax this completed form to 1-888-268-0200.

For questions, please contact Cathy Haley at 1-800-MINIMED, ext. 5594 (direct: 818-576-5594) or via e-mail at cathy.haley@medtronic.com. We appreciate your speedy response and apologize for the inconvenience this may cause. Please do not hesitate to call if you have any questions, or if we can assist you in any way.

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Medtronic
MINIMED

Product Exchange Request

Distributor Name:_____

Account Number: _____

Contact: _____ Phone: _____

Shipping address: _____

City:_____State: _____Zip Code _____

Please list quantity by part and lot number:

MMT-359S6	Qty	Lot Number
	_____	_____
	_____	_____
	_____	_____

MMT-359S9	Qty	Lot Number
	_____	_____
	_____	_____
	_____	_____

MMT-359L6	Qty	Lot Number
	_____	_____
	_____	_____
	_____	_____

MMT-359L9	Qty	Lot Number
	_____	_____
	_____	_____
	_____	_____

Please fax this completed form to 1-888-268-0200. After receipt of form, the Product Returns department will contact you with a return number and further instructions.

We appreciate your speedy response and apologize for the inconvenience this may cause. Please do not hesitate to call if you have any questions, or if we can assist you in any way. For questions, please contact Cathy Haley at 1-800-MINIMED, ext. 5594 (direct: 818-576-5594) or via e-mail at cathy.haley@medtronic.com.

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