Urgent Field Safety Notification

January 17, 2017

Dear Valued Medtronic Customer:

This letter is to inform you that we've recorded a higher than expected number of reported complaints related to kinked cannulas and elevated blood glucose levels among those using the MiniMed® Pro-set® infusion set.

What You Should Do

To minimize your risk of experiencing kinked cannulas while using the MiniMed Pro-set infusion sets you have remaining, please remember to:

- Review the online learning instruction: http://www.medtronicdiabetes.com/infusion-set-support
- Consider using the MiniMed® Quick-serter® insertion device
- Follow the instructions for use provided with the product
- Continue monitoring your blood sugar levels frequently

If you would prefer to switch to another Medtronic infusion set of your choice, or return any unused MiniMed Pro-set infusion sets, we will be happy to replace them for free. To replace them:

A. Use the online form at http://www.medtronicdiabetes.com/notice5 (fastest method)
   OR
B. Call us at 866-222-7304

This notification applies to all MiniMed Pro-set infusion set models, as shown below:

Model	Description	Connector
MMT-280	MiniMed Pro-set – 6 mm, 24 in	MiniMed
MMT-281	MiniMed Pro-set – 6mm, 42 in	
MMT-290	MiniMed Pro-set – 6 mm, 24 in	Luer Lock
MMT-291	MiniMed Pro-set – 6mm, 42 in	

As always, please call the Medtronic 24-hour helpline at 866-222-7304 with any product concerns. You can also report a concern to the FDA's MedWatch Adverse Event Reporting program:

A. Online at: http://www.fda.gov/safety/medwatch/howtoreport/default.htm
B. Report by telephone: 1.800.FDA.1088
C. Fax report: 1.800.FDA.0178

Medtronic considers patient safety and customer satisfaction our primary priorities. You are receiving this letter because our records indicate you have received MiniMed Pro-set infusion sets. We appreciate your time and attention in reading this important notification.

Sincerely,

James Dabbs
Vice President, Quality Assurance
Medtronic Diabetes

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