Medtronic plc
18000 Devonshire St.
Northridge, CA 91325
www.medtronicdiabetes.com

Urgent: Field Safety Notification

June 11, 2015

Dear Valued Medtronic Customer,

Medtronic is committed to keeping you and your healthcare professional informed of issues and solutions related to our products and services.

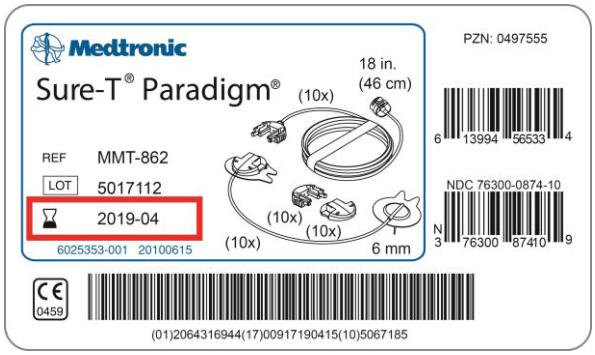
As part of Medtronic's product quality monitoring process, we identified that certain MiniMed® Sure-T® infusion sets* had a slight increase of reported cases where the steel needle broke during use. In a small number of these reported cases, the needle break led to hospitalization for the management of glucose levels and/or treatment for removal of the needle. Since then, an improvement in the needle manufacturing was implemented, which has reduced the number of reported cases of needle breaks.

If a needle break occurs, insulin delivery is interrupted and the pump will not alarm to notify you. The interruption of insulin delivery can cause hyperglycemia, which, if left untreated, can result in diabetic ketoacidosis (DKA). If you experience a needle break while the infusion set is inserted, consult your healthcare professional.

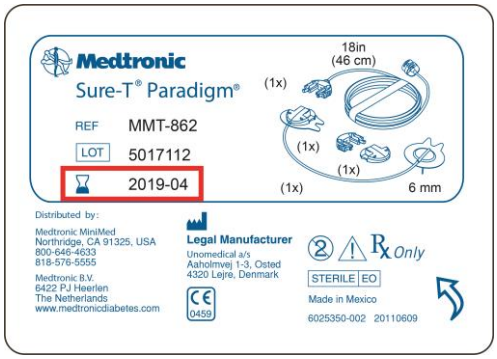
How do I know if I have affected product (that does not contain the manufacturing improvement)?

Affected MiniMed Sure-T infusion sets are those with an expiration date on or before April 2019. The expiration date is located next to the hourglass symbol ⌛ on the box and pouch labels. The date format is year followed by month, ex. YYYY-MM.

BOX LABEL



POUCH LABEL



Affected product expires on or before April 2019 (2019-04)

If you have affected product and would like it replaced free of charge:

A. Use the online form at http://www.medtronicdiabetes.com/notice1 (fastest method)
OR
B. Call us at 1.866.222.7304

*This field notification involves models MMT-862, MMT-862T, MMT-863, MMT-864, MMT-864T, MMT-865, MMT-866, MMT-866T, MMT-873, MMT-874, MMT-874T, MMT-875, MMT-876, MMT-876T, MMT-883, MMT-884, MMT-885, MMT-886, and MMT-886T infusion sets.

If you decide to use affected product, carefully review the instructions for use included with the product, as well as the following:

Prior to use:

- Carefully remove the needle guard before inserting the infusion set. The needle guard should be removed without the use of any twisting or bending of the needle guard.
- Do not use the infusion set if the needle is bent or has been damaged.
- Do not bend the needle prior to insertion.
- Consult your healthcare provider for the proper insertion site.

During use:

- As always, it is essential to monitor your blood sugar levels frequently using your blood glucose meter.

After use:

- Carefully remove the infusion set after use to avoid twisting or bending on the needle.
- Please ensure the needle is present on the used infusion set before discarding it.
- Please contact your healthcare provider if you suspect that a needle has broken off and remained under the skin.
- Continue to monitor your blood sugar.

As always, please call the Medtronic 24-Hour HelpLine at 1.866.222.7304 with any product concerns. It is through the careful monitoring of customer reports that we are able to identify issues and implement solutions.

You can 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 is committed to delivering high quality products and services. We appreciate your time and attention to this important notification.

Sincerely,

Jim Dabbs
Vice President, Quality Assurance
Medtronic Diabetes