Medtronic Australasia Pty Ltd
97 Waterloo Road
North Ryde
NSW 2113

Urgent Recall for Product Correction

(No actual Product is being Recalled from the Market)

Medtronic MiniMed® Sure-T® infusion sets*

***Model Numbers:** **MMT-860, MMT-862, MMT-863, MMT-864, MMT-865, MMT-866, MMT-870, MMT-873, MMT-874, MMT-875, MMT-876, MMT-883, MMT-884, MMT-885, MMT-886**

ARTG # 119216

June 23, 2015

Dear Customer,

Medtronic after consultation with the TGA (TGA Ref# RC-2015-RN-00506-1), is initiating a voluntary Recall for Product Correction for the above mentioned devices.

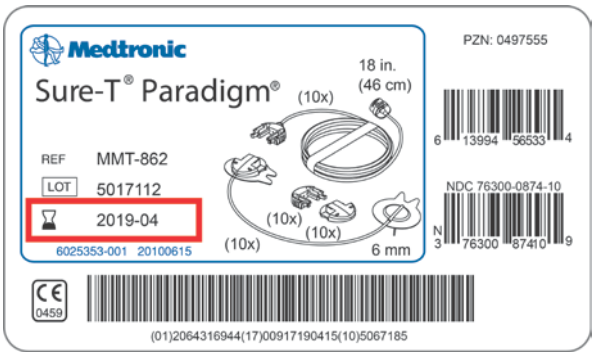
As part of Medtronic's product quality monitoring process, we identified that certain MiniMed® Sure-T® infusion sets* had a slight increase of reported cases where the steel needle broke during use. In a small number of these reported cases, the needle break led to hospitalization for the management 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). There is also a possibility of local infection necessitating administration of antibiotics if the needle remains in the body. If you experience a needle break while the infusion set is inserted, consult your healthcare professional.

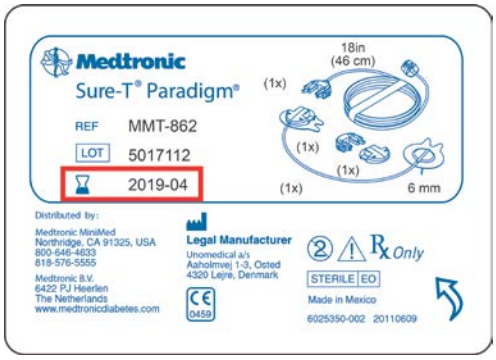
How do I know if I have affected product (that does not contain the manufacturing improvement)?

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)

There are two actions available for consumers:

Action 1:-
If you have affected product and would like it replaced free of charge:

A. Call us at 1800 777 808, option 1

Action 2:-
If you decide to use affected product, carefully review the instructions for use included with the product, as well as the following specific additional instructions:

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.

To assist us to ensure that you have received this notification, please complete the attached form and send it back to us either using the return envelope / fax or the email address referenced on the form.

As always, please call the Medtronic HelpLine at 1800 777 808, option 1 with any product concerns. Medtronic is committed to delivering high quality products and services. We appreciate your time and attention to this important notification.

Sincerely,

John Farquhar
Vice President
Medtronic Minimed Asia-Pacific

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TGA Reference Number: RC-2015-RN-00506-1

To assist us in this Recall for Product Correction please complete and sign this Acknowledgment Form, and return to Medtronic Australasia by post, fax, or e-mail.

Medtronic is requesting your support to return this form, as it is a regulatory requirement to document confirmation.

Fax completed forms to 02 9888 1283

or email: rs.anzdibimportantinfo@medtronic.com

or return using the enclosed Reply-paid envelope

DECLARATION:

I have read and understand the Medtronic notification concerning the Medtronic Minimed™ Sure T Insulin Infusion Sets.

Name (Please print): _____

Signature: _____Date: _____

City: _____