

URGENT SAFETY NOTIFICATION

November 5, 2014

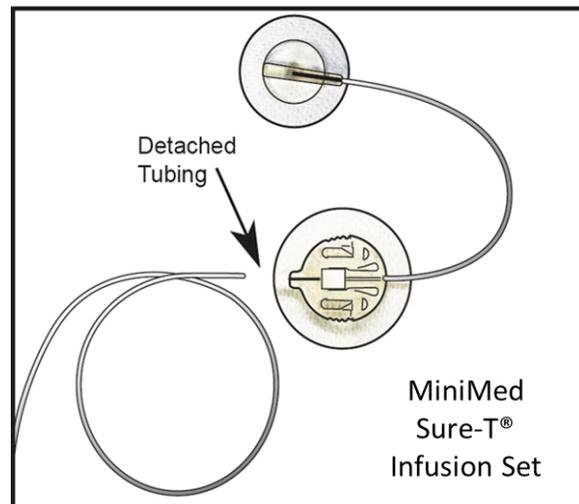
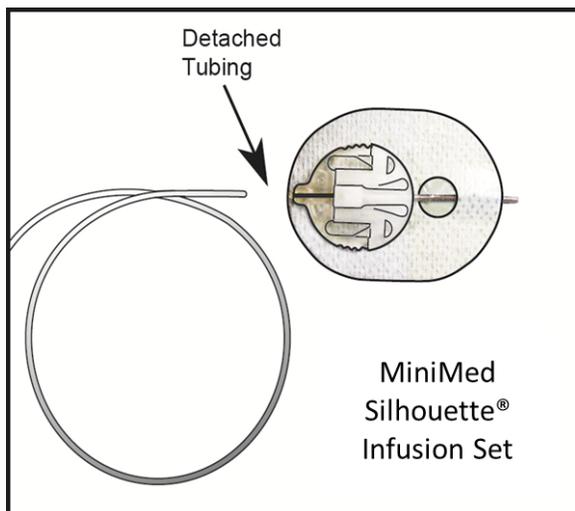
Dear Medtronic Customer:

Medtronic is committed to keeping you and your healthcare professional informed of issues and solutions concerning our products and services. The purpose of this letter is to inform you of a potential safety issue regarding the MiniMed Silhouette® and MiniMed Sure-T® infusion sets*.

As a part of our global quality monitoring process, we identified an increase in reports of the tubing becoming detached at the connect/disconnect location on the MiniMed Silhouette and MiniMed Sure-T infusion sets (please see images below). While the number of these reports remains low, you are being notified of this potential issue because your safety is our top priority.

If tubing detachment 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). DKA is a serious condition that can cause a severe impact to health, including death. Symptoms of DKA may include nausea, vomiting, shortness of breath and excess thirst/urination. Seek medical attention immediately if you are experiencing any of these symptoms.

Example of Tubing Detachment



What action do I need to take?

You do not need to return your product. You can continue to use your infusion sets while following the directions below.

1. When changing your infusion set, closely follow the instructions for use included in the product box. Check the tubing at the site connector location identified in the drawings above to make sure it is not loose.
2. As always, it is essential to monitor your blood sugar levels frequently using your blood glucose meter. Proactively check your tubing connections occasionally to ensure tubing is secure. It is especially important to check your blood sugar and tubing connections at bedtime to confirm insulin delivery is occurring.

3. If you experience a high blood sugar, check your tubing connections and infusion site closely to ensure your tubing is secure.

If you discover the tubing is detached:

1. Do not attempt to reattach the tubing. Replace the infusion set immediately.
2. Treat any high blood sugar based on guidelines provided by your healthcare professional.
3. Call the Medtronic HelpLine at 1-800-646-4633 to report the issue. We will give you instructions on how to return the affected infusion set to us.

We have identified a solution and are working to incorporate improvements pending regulatory approval. Healthcare Professionals have been notified. In the meantime, you will still be able to order these infusion sets. If you would like to try another type of MiniMed infusion set instead, please call our Consumer Care Team at 1-800-284-4416.

Managing marketed health product-related adverse incidents depends on healthcare professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse incidents are generally presumed to underestimate the risks associated with health products. Any incident of serious or unexpected adverse incidents involving medical devices manufactured and/or distributed by Medtronic should be reported to Medtronic, and/or to Health Canada at the following addresses:

Medtronic of Canada, Ltd.

99 Hereford St.
Brampton, Ontario L6Y 0R3
Medtronic Diabetes Product Support Line
Tel: 1-800-646-4633

Health Products and Food Branch Inspectorate

HEALTH CANADA
Address Locator: 2003D
Ottawa, Ontario K1A 0K9
Tel: The Inspectorate Hotline: 1-800-267-9675

The Medical Devices Problem Report Form and Guidelines can be found on the Health Canada web site.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/md-mm_form-eng.php

http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2011-devices-materiaux/index-eng.php

We appreciate your time and attention to this important notification.

Sincerely,

Laura Cameron
Director
Medtronic Diabetes, Canada

*This field notification involves models

MMT-368600, MMT-377600, MMT-378600, MMT-381600, MMT-383600, MMT-384600, MMT-373, MMT-371, MMT-862, MMT-864, MMT-874 infusion sets.