

## URGENT: MEDICAL DEVICE CORRECTION

November 5, 2014

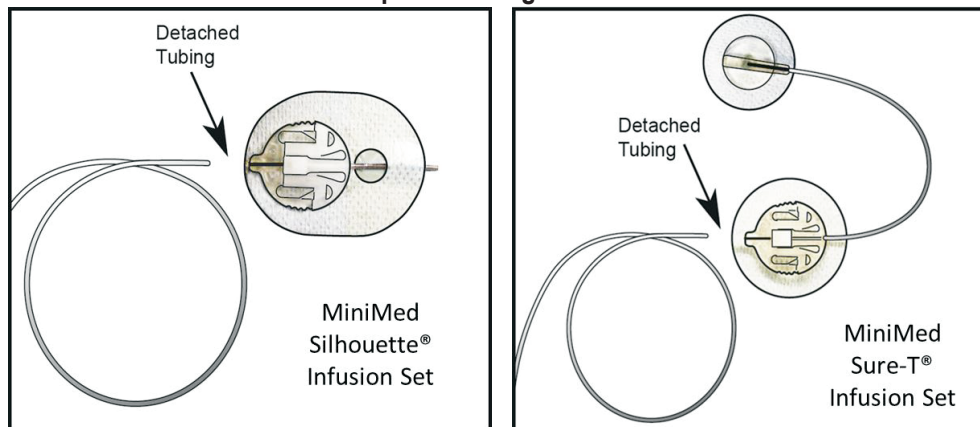
Dear Valued Medtronic Customer:

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\*, which our records indicate you have purchased.

As 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 can continue to use your infusion sets by following the advice below:**

1. When changing your infusion set, closely follow the instructions for use included in the product box. Check the tubing at the connect/disconnect 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 throughout the day 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 24-Hour HelpLine at 866.222.7304 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 within the coming weeks. In the meantime, you will still be able to order these infusion sets. If you would like to try another type of infusion set instead, we can exchange your infusion sets with the MiniMed Quick-set® or MiniMed Mio®. To learn more about these infusion sets or to find additional information about this notification, please call us or visit [www.medtronicdiabetes.com/tubingdetachment](http://www.medtronicdiabetes.com/tubingdetachment).

You can always report a concern to the FDA's MedWatch Adverse Event Reporting program:

Online at: <http://www.fda.gov/safety/medwatch/howtoreport/default.htm>

Report by telephone: 1.800.FDA.1088

Fax report: 1.800.FDA.0178

We appreciate your time and attention to this important notification.

Sincerely,



Jim Dabbs

Vice President, Quality Assurance

Medtronic Diabetes