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Urgent: Field Safety Notification

June 10, 2015

Dear Healthcare Professional,

Enclosed is a letter we are sending to **MiniMed® Sure-T®** infusion set patients to inform them of a field safety notification for certain MiniMed Sure-T infusion sets.

The affected 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 during the infusion set wear, the primary clinical risk is the interruption of insulin delivery and the pump will not alarm to notify your patient. If a patient is concerned a broken needle may be in their body, they are instructed to consult their healthcare professional to discuss options. There is evidence[1] that suggests infusion set steel cannulas left in the body result in minimal tissue damage or needle migration. Therefore, leaving the steel cannula alone may be the preferred option versus attempting surgical removal.

Actions Medtronic is taking:

1. All MiniMed Sure-T patients are being informed of this field safety notification.
2. Patients who received affected product are able to replace unopened boxes, free of charge, with product that contains the manufacturing improvement.

If you have any questions or concerns about this letter, please contact the Office at (Karin Lim at +65 6506 4869).

Reporting of Adverse Event:
Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions to your local Medtronic Office (Karin Lim at +65 6506 4869). Alternatively, healthcare professionals may report the adverse events to the Vigilance Branch, Health Products Regulatory Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae online. Events that are reported to Medtronic will be investigated and subsequently reported to HSA.

* This field notification involves models MMT-862, MMT-864, MMT-866, MMT-874, MMT-876, MMT-884, MMT-886 infusion sets.

1 Biester, T., Gough, H., Gharabil, R., Testoni, V., Bilstrom, T., Kordonouri, O., Danne, T. Steel Needle Infusion Set Breakage: A Cause for Concern? *ISPAD Poster* P224, 2014

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We appreciate your time and attention to this important notification.

Sincerely,

Manish Kapoor
Business Manager
Medtronic Diabetes ASEAN

ATTACHED:
Patient Notification Letter