



Medtronic of Canada Ltd.
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IMPORTANT MEDICAL DEVICE INFORMATION

April 2, 2009

RE: Paradigm® Silhouette® Infusion Set Instructions

Dear Silhouette User:

Recently, we have become aware of a typographical error in the Instructions For Use (IFU) included with your recent shipment of Silhouette infusion sets. Only the following catalog numbers are affected by this error:

MMT-377600 MMT-378600 MMT-381600 MMT-382600

The IFU instructs patients to fill the empty space in the cannula with a fixed prime volume of 0.3 units of U-100 insulin. **The correct fixed prime volume is 0.7 units.** Please note that there is nothing wrong with your products. You should continue to use the products in your possession with the correct 0.7 units fixed prime volume.

We are voluntarily notifying Health Canada regarding this issue, and informing all affected customers.

In light of this error, we are enclosing a replacement IFU with the corrected information. Please,

- 1) Discard the incorrect IFU(s) that came with your products
- 2) Replace with the enclosed corrected IFU
- 3) Complete and return the enclosed Customer Contact Record in the enclosed postage paid reply envelope

Please contact our Canadian Customer Services at 1-800-284-4416, if you have any questions.

We apologize for any inconvenience this may have caused, and thank you for your continued support.

Sincerely,

Medtronic Diabetes