

Urgent Field Safety Notice

Potential for Over or Under Delivery of Insulin if Insulin or Other Fluids Contact the Inside of Medtronic Paradigm ~~Infusion Set Connector~~ Tubing connectors

June xx, 2013

Medtronic Reference: FA577

Dear Healthcare Professional:

The purpose of this letter is to notify you that Medtronic Diabetes has become aware of a potential safety issue that can occur if insulin or other fluids come in contact with the inside of the connector on Medtronic Paradigm infusion sets. This letter also provides information on how to prevent this from occurring.

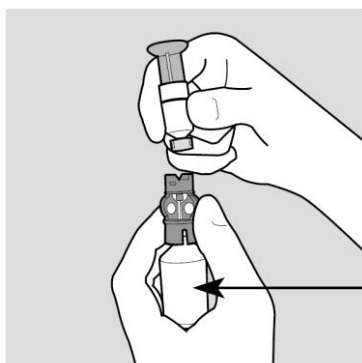
Medtronic is informing directly patients for which we have contact details. **Because Medtronic does not have your patients' records on file, we kindly ask you to inform Paradigm pump users using the enclosed letter.**

Exposure of the inside of the ~~infusion set connector~~ tubing connector to fluid is most likely to occur if insulin is spilled on the top of insulin reservoir when the reservoir is removed from the transfer guard after filling the reservoir from a vial of insulin. If this occurs, the insulin can temporarily block the vents in the connector that allow the pump to properly prime. If these vents are blocked, this can potentially result in too much or too little insulin being delivered, which may cause hypoglycemia or hyperglycemia, which, in extreme cases, may cause loss of consciousness or death.

The information in this letter applies to all Medtronic infusion sets designed for use with Medtronic Paradigm family infusion pumps. The specific model numbers affected are listed at the end of this letter. Please note that the potential for temporary blocking of the infusion set vents can be avoided by not applying liquid to make contact with the inside of the ~~infusion set connector~~ tubing connector and following the recommended reservoir filling procedure with careful attention to the information provided below.

Below are the recommendations to patients to prevent fluid from blocking the connector vents:

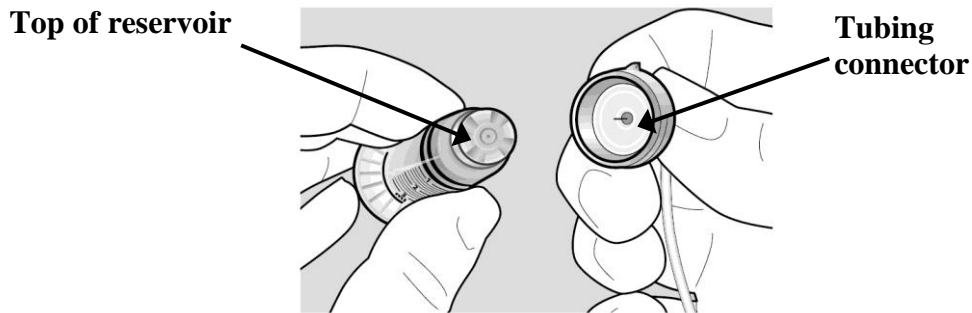
1. After filling the reservoir, make sure the vial of insulin is held upright when removing the reservoir from the blue transfer guard. This prevents insulin from accidentally getting on the top of the reservoir, which could transfer liquid into the tubing connector.



**Vial
upright**

Hold insulin vial upright when removing reservoir.

2. If any liquid (such as insulin, isopropyl alcohol, or water) gets on the top of the reservoir or inside the tubing connector, start over with a new reservoir and infusion set.



Make sure these are dry when connecting.

How to recognize that the infusion set vents may be blocked

If you notice anything unusual during the infusion set prime process such as the insulin continuing to drip from the infusion set cannula when the manual prime has been completed, this may indicate that the connector vents are not working properly. If this occurs, do not insert the infusion set and call the HelpLine immediately for additional assistance.

In addition to providing this communication to current users of Medtronic Paradigm insulin pumps, we are also updating the instructions for use to include this information on how to avoid temporary blocking of the infusion set vent membranes due to exposure to fluid.

The Competent Authority of your country has been notified of this action.

This notice needs to be passed on all those who need to be aware within your organization.

We deeply apologize for any disruption this may cause your practice. Please know, patient safety is our top priority. Feel free to contact us <insert contact details> if you have any questions or concerns. We appreciate your time and attention to this important notification, and thank you for continuing to put your trust in Medtronic.

Sincerely,

Country Manager or BU Country Manager

Medtronic Diabetes

Enclosure: - Letter: Dear Paradigm Insulin Pump User

This field notification involves models MMT-317, MMT-318, MMT-324, MMT-325, MMT-312S, MMT-312L, MMT-386, MMT-387, MMT-394, MMT-396, MMT-397, MMT-398, MMT-399, MMT-377, MMT-378, MMT-381, MMT-382, MMT-383, MMT-384, MMT-368, MMT-862, MMT-864, MMT-866, MMT-874, MMT-876, MMT-884, MMT-886, MMT-921, MMT-923, MMT-925, MMT-941, MMT-943, MMT-945, MMT-961, MMT-963, MMT-965, & MMT-975 Paradigm infusion sets.