

URGENT PRODUCT RECALL

ACCU-CHEK™ Ultraflex infusion sets: Potential for full or partial separation at the luer lock-tubing connection

This recall applies to all ACCU-CHEK Ultraflex infusion sets.

Issue

In the course of normal daily use, ACCU-CHEK Ultraflex Infusion Sets can bend at the luer lock-tubing connection. This bending can lead to full or partial separation at the luer lock-tubing connection. In the event that a full or partial separation occurs, it is possible that insulin could leak from the infusion set tubing causing an interruption of insulin delivery, which can and has contributed to hyperglycemia.

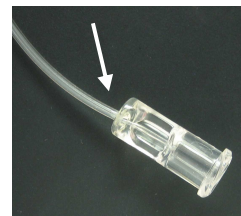
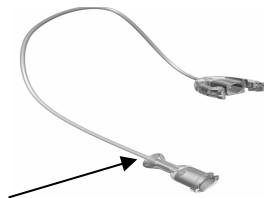
We are taking this action because we have recently received an increase in complaints regarding fully or partially separated luer lock-tubing connections with ACCU-CHEK Ultraflex infusion sets. We are conducting an ongoing investigation into these issues and will update you as new information becomes available.

Warning

You must check your infusion set at the luer lock-tubing connection during use at least every 3 hours and before bedtime. A full or partial separation may result in leakage, causing interruption of insulin delivery and elevated blood glucose levels.

If you notice a full or partial separation, change your infusion set immediately and check your blood glucose to ensure that your blood glucose level is within an acceptable range as defined by your healthcare team.

ACCU-CHEK Ultraflex Infusion Set



Illustrations above depict the ACCU-CHEK Ultraflex luer lock-tubing connection.

Actions Required

- You may continue to use your ACCU-CHEK Ultraflex infusion sets. If you decide to discontinue using your ACCU-CHEK Ultraflex infusion sets, or if you have a fully or partially separated tubing or leaking infusion set, retain your infusion set and call Disetronic Medical Systems Pump Support at 1-800-688-4578 for replacement with ACCU-CHEK Ultraflex. The potential for separation of the luer lock-tubing connection still exists with the replacement ACCU-CHEK Ultraflex infusion set.
 - In the course of normal daily use, infusion sets can be subjected to a variety of stresses, including bending at the luer lock-tubing connection, which can lead to full or partial separation at the luer lock-tubing connection. Customers also have the option of replacing their ACCU-CHEK Ultraflex infusion sets with ACCU-CHEK Tender, or ACCU-CHEK Rapid-D infusion sets. Your healthcare provider or our Pump Support specialists can help you determine which infusion set might be right for you. You can view these products on our website at www.disetronic.com/...If you do experience product problems, we will send you a pre-paid mailer to send the affected infusion set back to Disetronic for analysis.
 - You must periodically check your infusion set at the luer lock-tubing connection. We recommend you check your infusion set at least every 3 hours and before you go to bed. This is a safe practice for all infusion sets.
 - Follow your instructions for use to check glucose levels 1-3 hours after changing the infusion set. Continue to check glucose levels throughout the day as instructed by your Healthcare Professional. *If your blood glucose level is not within an acceptable range (as defined by your healthcare team) before going to bed, please follow the medical advice given to you by your Healthcare Professional.*
 - If you experience an interruption of insulin causing hyperglycemia, take appropriate medical intervention according to your healthcare team's instructions.
 - File this Urgent Product Recall for future reference.
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Additional Information

An interruption of insulin delivery for this or any other reason can lead to hyperglycemia. The symptoms of hyperglycemia are:

- Nausea/Vomiting
- Blurred Vision
- Excessive Thirst or Hunger
- Frequent Urination
- Fatigue/Tiredness/Sleepiness
- Headache
- Fruity acetone breath
- Abdominal Pain

If you experience these symptoms please check your blood glucose to ensure that your blood glucose level is within an acceptable range as defined by your healthcare team and follow the medical advice given to you by your Healthcare Professional or contact your physician.

Questions

This Urgent Product Recall is being made with the knowledge of Health Canada. If you have experienced a problem with any of these infusion sets, please call 1-800-267-9675. If you have further questions about the information contained in this Urgent Product Recall, please contact Pump Support at 1-800-688-4578, 24 hours a day, 365 days a year.
