

Urgent Field Safety Notice

For attention of: **Healthcare Professionals**

Manufacturer's reference: SB_RDC_2022_07

SRN number: **DE-MF-xxx**

Location, Date

Important information related to the Accu-Chek® Insight Flex cannula – Lot No. 1375604

Dear Healthcare Professional **[please personalise]**,


At Roche Diabetes Care, we strive for the highest quality of our products and services and are committed to keeping you timely informed as soon as there is a potential issue of which you should be made aware. This is why we would like to inform you today about an issue related to one production lot of the Accu-Chek Insight Flex cannula Lot No. 1375604.

Description of situation and rationale giving rise to this corrective measure

As part of our ongoing quality monitoring and market surveillance processes, we have identified that insulin leakage can occur in a low number of cases with Accu-Chek Insight Flex cannulas out of Lot No. 1375604. The leakage has been found to materialize at the cannula head. As such insulin leakage might not be immediately detectable when using the Accu-Chek Insight system, this could potentially lead to an under-delivery of insulin. The possible consequences could range from no clinical impact to adverse health events including severe hyperglycemia or DKA.

Details on affected devices

The following product is affected:

Product Description	
Accu-Chek Insight Flex cannula (8mm)	
Product Material Numbers	
Lot No. 1375604 REF No. 06541810001	

Actions taken by Roche Diabetes Care

Roche Diabetes Care has conducted an in-depth evaluation of the issue and implemented the appropriate quality management measures by means of a 100% material inspection to ensure that all products



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distributed to customers do not show this failure. In addition, Roche Diabetes Care recalls the quantities of the affected lot which have been distributed to the market.

Actions to be taken by healthcare professionals:

Please check your inventory for Accu-Chek Insight Flex supply out of Lot No. 1375604. In case you have affected material in stock, please contact our Roche Diabetes Care Customer Care line at xxx-xxx-xxx (workdays from xx a.m.- xx p.m.) to receive instructions on how to send back affected materials and obtain replacements free of charge.

Please ask your patients using the Accu-Chek Insight system to check the Accu-Chek Insight Flex supply they have stored at home if this belongs to Lot No. 1375604. If this is the case, please ask them to

- discontinue using cannulas from the affected lot immediately and
- contact our Roche Diabetes Care Customer Care line at xxx-xxx-xxx (workdays from xx a.m.- xx p.m.) to receive instructions on how to send back affected materials and obtain replacements free of charge
- please make sure to follow the steps described in the instructions for use of the Accu-Chek Insight Flex cannulas, whenever changing the cannula.

Please be assured that all other lots offered for Accu-Chek Insight Flex as well as all other Accu-Chek cannulas are not affected by this issue. These are fine and safe to use.

Communication of this Field Safety Notice

Your national competent authority, distributors, retailers, and users of the Accu-Chek Insight system have been informed about this field action.

We sincerely apologise for any inconvenience this may cause and hope for your understanding and cooperation. Please call our Roche Diabetes Care Customer Care line at xx-xxxxx-xxxxx (workdays from xx a.m.- xx p.m.), if you need any additional advice or have any further questions or concerns. We appreciate your time and attention to this important notification.

Yours sincerely,

Roche Diabetes Care