

Urgent Field Safety Notice

For attention of: **Distributors**

Manufacturer's reference: SB_RDC_2022_09

SRN number: DE-MF-000006276

Location, Date

Important information related to Accu-Chek Solo cannula assembly & pump holder

Dear Distributor [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 on any update to our offering. This is why we would like to notify you today of a voluntary recall that we are initiating to promote access to the new and design-improved version of the Accu-Chek Solo cannula assembly & pump holder for people with diabetes using the Accu-Chek Solo micropump system.

Description of situation and rationale giving rise to this corrective measure

As part of our ongoing quality monitoring, we have identified that insulin leakage has occurred in a low number of cases with the Accu-Chek Solo cannula assembly & pump holder. As such insulin leakage might not be noticed immediately when using the Accu-Chek Solo 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 diabetic ketoacidosis (DKA).

Details on affected devices:

Product Description	REF Number	Device Identifier	LOT Number
Accu-Chek Solo cannula assembly & pump holder (9 mm; 10+3)	07858833001	04015630881659	Cannula lot numbers 847468303 and lower
Accu-Chek Solo cannula assembly & pump holder (6 mm; 10+3)	07858841001	04015630881642	
Accu-Chek Solo supply kit (9 mm)	07858817001	04015630881666	
Accu-Chek Solo supply kit (6 mm)	07858825001	04015630881673	

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Actions taken by Roche Diabetes Care

Roche Diabetes Care has conducted an in-depth evaluation of the issue and implemented the appropriate product improvement measures. We have enforced a number of changes to the Accu-Chek Solo cannula production which is leading to a more seamless user experience and shows a more robust product performance compared to previous versions. To expedite access for users to this new and design-improved version of the Accu-Chek Solo cannula assembly & pump holder, we are now initiating a voluntary recall aiming at timely replacing the remaining product quantities in the market.

Actions to be taken by distributors:

Please check your inventory for Accu-Chek Solo cannulas or Accu-Chek Solo supply kits with Lot Number 847468303 and lower. The relevant Lot Number can be found on the single cannula assembly & pump holder blister (see picture). 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 customers using the Accu-Chek Solo system to check the Accu-Chek Solo cannulas or Accu-Chek Solo supply kits they have stored at home if these show Lot Number 847468303 and lower. The relevant Lot Number is shown on the single cannula assembly & pump holder blister. In this case, please ask them to

- discontinue using cannulas included in this voluntary recall 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 be assured that all other Accu-Chek Solo cannula assembly & pump holder lots are not affected by this issue. These are fine and safe to use.

Communication of this Field Safety Notice

Your national competent authority, healthcare professionals, and users of the Accu-Chek Solo 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**

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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