

Urgent Field Safety Notice

For attention of: **Retailer/Distributor**

Manufacturer's reference: SB_RDC_2024_05

SRN number: DE-MF-000006276

Location, Date

Important information related to the Accu-Chek® Spirit 3.15 ml cartridge system: Potential of insulin leakage

Dear Retailer/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 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 a manufacturing issue for the Accu-Chek Spirit 3.15 ml cartridge systems which can potentially lead to insulin leakage.

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 with the Accu-Chek Spirit 3.15 ml cartridge system due to a manufacturing issue at a third party supplier. The leakage can occur at the luer connection, where the cartridge connects to an infusion set. As such, insulin leakage might not be immediately detectable when using the Accu-Chek Spirit 3.15 ml cartridge system. This could lead to an under-delivery of insulin. The potential consequences could range from no clinical impact to adverse health events, including severe hyperglycemia or diabetic ketoacidosis (DKA).

Details on affected devices

The following product is affected:

Product Description	Product REF Number	Product Device Identifier (UDI / GTIN)	Product Date of Manufacture
Accu-Chek Spirit 3.15 ml cartridge system 5 pcs	04949935001	04015630882755	Manufactured  between 2024-03-01 and 2024-10-31
Accu-Chek Spirit 3.15 ml cartridge system 25 pcs	05206073001	04015630882908	

Urgent Field Safety Notice

For attention of: **Retailer/Distributor**

Manufacturer's reference: SB_RDC_2024_05

SRN number: DE-MF-000006276



Actions taken by Roche Diabetes Care

Roche Diabetes Care has conducted an in-depth evaluation of the issue with the third party supplier and the third party supplier is implementing the appropriate corrective measures by means of technical enhancements to the manufacturing process of the Accu-Chek Spirit 3.15 ml cartridge system to eliminate this potential cause of leakage. Until the implementation is completed, shipment of potentially impacted material has been voluntarily paused. Once Accu-Chek Spirit 3.15 ml cartridge systems with the expected quality are available again, Roche Diabetes Care will subsequently replace all affected supplies in the home and professional inventory.

Actions to be taken by retailers/distributors

Please check the Accu-Chek Spirit 3.15 ml cartridge supply you have on stock if it was manufactured between March 01, 2024 and October 31, 2024. If this is the case, we would like to ask you to

- discontinue distributing Accu-Chek Spirit 3.15 ml cartridge systems from the affected manufacturing timeframe immediately and retain them until further instructions are received and
- make your customers using the Accu-Chek Spirit 3.15 ml cartridge system aware of this field action and provide them the Urgent Field Safety Notice version for patients with diabetes or healthcare professionals
- in case of any further questions or when in need of additional support you can contact our Roche Diabetes Care Customer Care line **at xxx-xxx-xxx (workdays from xx a.m.- xx p.m.)**

Urgent Field Safety Notice

For attention of: **Retailer/Distributor**

Manufacturer's reference: SB_RDC_2024_05

SRN number: DE-MF-000006276

Availability of replacement Accu-Chek Spirit 3.15 ml cartridge systems is planned for the end of January 2025. Further information will be provided once the cartridges are available.

We would also like to use this opportunity to re-emphasize the following important information from the pump user manual:

- *“Successful insulin pump therapy requires you to check your blood glucose levels frequently. It is therefore recommended that you use an Accu-Chek blood glucose meter as often as directed by your doctor or healthcare team (at least 4 times a day).”*
- *“Your pump cannot detect infusion set leakage. You should inspect all parts of your infusion set regularly during the day and before you go to sleep. If there seems to be any loss of insulin and all parts are correctly tightened, look for and immediately replace a leaking component. Check your blood glucose level immediately, as insulin delivery has been interrupted. Take appropriate action according to your doctor's or healthcare team's instructions.”*

Communication of this Field Safety Notice

Your national competent authority, healthcare professionals and users have been informed about this field action.

We sincerely apologize for any inconvenience this may have caused 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



Urgent Field Safety Notice

Please complete and return by e-mail / fax / post

Manufacturer's reference: SB_RDC_2024_05

SRN number: DE-MF-000006276

Acknowledgement Form

Please submit this acknowledgement form to Roche Diabetes Care:

via e-mail:

Local RDC e-mail address

or via fax:

Local RDC fax number

or postal address:

Local RDC postal address

☐

I confirm to have received, read and understood the information in this Field Safety Notice of dd.mmm.yyyy for the mentioned medical devices and intend to perform the requested actions.

Form completed and returned by:

Name (CAPITAL LETTERS):	
Position/Title of Person completing this Form:	
Company Name:	



Urgent Field Safety Notice

Please complete and return by e-mail / fax / post

Manufacturer's reference: SB_RDC_2024_05

SRN number: DE-MF-000006276

Phone Number:	
E-mail:	
Address:	
Date (dd-mmm-yyyy):	

Signature