

Urgent Medical Device Recall

For attention of: **Accu-Chek Spirit 3.15 ml cartridge Users**

Manufacturer's reference: SB_RDC_2024_05/ **RC-2024-RN-01064-1**

ARTG: 215786

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

Dear Accu-Chek Spirit 3.15 ml cartridge customer,

Roche Diabetes Care, would like to inform you about a manufacturing problem 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 problem 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 25 pcs	05206073001	04015630882908	Manufactured  between 2024-03-01 and 2024-10-31



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Actions taken by Roche Diabetes Care

Roche Diabetes Care has conducted an in-depth evaluation of the problem 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 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 people with diabetes

Please check the Accu-Chek Spirit 3.15 ml cartridge supply you have stored at home 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 using Accu-Chek Spirit 3.15 ml cartridge systems from the affected manufacturing timeframe immediately and
- consult with your doctor or healthcare team to switch to an alternative therapy method, e.g. multiple daily injections (MDI), until Accu-Chek Spirit 3.15 ml cartridge systems are available again and
- in case of any further questions or when in need of additional support you can contact our Roche Diabetes Care Customer Care line at 1800 251 816 (Mon-Fri from 9a.m.- 5p.m.)

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 Medical Device Recall

Your national competent authority, distributors, retailers, and healthcare professionals 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 **1800 251 816 (Mon-Fri from 9a.m.-**



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5p.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

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Customer acknowledgement form

Please complete this form *even if you do not have any affected stock.*

URGENT MEDICAL DEVICE RECALL

Title: Accu-Chek Spirit 3.15 ml cartridge Issue: Leaky luer connection

TGA Recall Reference Number: RC-2024-RN-01064-1

Product	Material No.	Device Identifier
Accu-Chek Spirit 3.15 ml cartridge system 25 pcs	05206073001	04015630882908
ARTG number:	215786	
TGA Reference:	RC-2024-RN-01064-1	
Sponsor Reference:	SBN_RDC_2024_05	

On behalf of this organisation I acknowledge receipt of the Urgent Medical Device Recall notice date [insert date of notice] relating to the above product.

FROM:

Organisation	
Position	
Name	
Email or fax no.	
Telephone no.	
Date	
Signature	

Affected Stock [Recall and Product Defect Correction only]

If you have **no affected** stock, tick this box:

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If you have affected stock, please complete the stock details table below.

Product	Batch/Lot/Date	Quantity of stock received	Quantity of unused stock subject to recall (currently in quarantine)
Total affected product			
Other Relevant Details:			

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

No

Yes I/we will forward all the recall information to the suppliers/distributors/customers

OR

Yes (please supply names and contact information of the organisations)

Return completed forms by email to:

Name	Deepti Rao
Position	Regulatory Affairs and Quality Associate
Organisation	Roche Diabetes Care Australia Pty Limited
Address	2 Julius Avenue, North Ryde NSW 2113, Australia
Email	australia.qra@roche.com



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Subject of email	URGENT MEDICAL DEVICE RECALL; Accu-Chek Spirit 3.15 ml cartridge Issue: Leaky luer connection
Telephone no.	+61 2 9860 2222