SARSTEDT AG & Co. KG | Sarstedtstraße 1| 51588 Nümbrecht

Sample Business Name
Mr/Mrs
Sample Name
Sample Address Line 1
Sample Address Line 2
Sample Country

06/12/2024

Urgent Safety Information

Trade name:	**REF:**	**BATCH:**
Universal blood culture adapter	14.1209	4074321 4074322 4074521
LongNeck blood culture adapter	14.1207	4074421
Measure/action:	Safety advice	

Sender:	SARSTEDT AG & CO.KG Sarstedtstr. 1 51588 Nümbrecht, Germany
Recipient:	Users
Affected medical device:	REF: 14.1209 BATCH: 4074321, 4074322, 4074521 REF: 14.1207 BATCH: 4074421

Factual circumstances:

Due to a production-related error, leaks may occur in very rare cases in the above-mentioned batches of blood culture adapters 14.1209 and 14.1207. The leak is due to an incorrectly fitted membrane. It is then possible that air will be drawn when filling a blood culture bottle, which is counterproductive in the cultivation of anaerobic pathogens and can lead to false negative results. If air is drawn in, this is clearly detectable in the blood culture bottle due to the formation of bubbles and slight to moderate underfilling. If this is the case, discard the affected anaerobic blood culture bottle and do not use it for pathogen identification. Continue blood collection using a new adapter and fill a new anaerobic blood culture bottle.

Corrective action:

Before using the blood culture adapters from the above-mentioned batch, please ensure that the membrane disc fits snugly and does not bulge (see Figure 1). When filling the blood culture bottles, ensure that bubbles do not form in the sample and avoid underfilling. If you identify any blood culture adapters with misaligned membranes, please separate these and contact SARSTEDT Customer Service. If you notice bubble formation or underfilling in anaerobic blood culture bottles, discard the filled bottle and repeat the sample collection using a new adapter. Contact SARSTEDT customer service.

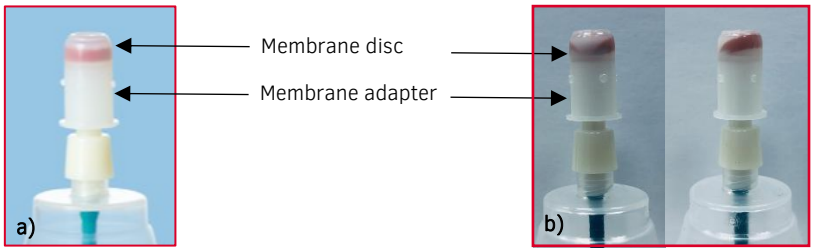

Figure 1: a) Good part: Membrane disc seated correctly in the membrane adapter, b) Defect characteristic: Membrane disc does not fit precisely and is bulging slightly.

Please complete and return the attached reply form within the next 20 days to produktrueckruf@sarstedt.com with the subject reference: *"Urgent safety information for blood culture adapter / customer number"*
Please retain this information until the action has been completed.

Forwarding the safety information:

Please ensure that all affected users of these named products and other parties to be informed are made aware of this urgent safety information. If you have supplied these products to third parties, please forward a copy of this information or inform the contact person named below.

The German Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

SARSTEDT AG & Co. KG | Registered office: 51588 Nümbrecht | Sarstedtstraße 1 | Court of Registration: Siegburg District Court | HRA 4094
General Partner: SARSTEDT Verwaltungs AG | Registered Office of the Partner: 51588 Nümbrecht | Court of Registration: Siegburg District Court HRB 7848 | Management Board: Timo Schretzmair (Chairperson), Rainer Schuster | Supervisory Board: Jürgen Sarstedt (Chairperson), Doris Sarstedt (Deputy Chairperson) | Phone: +49 2293 305 0 | Email: info@sarstedt.com | Web: www.sarstedt.com

Point of contact:

Should you require any further information or assistance in this matter, please contact the following persons:

For customer-specific questions: Your local contact person

For product-specific questions: Your local contact person

SARSTEDT always endeavours to supply high-quality, safe and effective products. In accordance with our corporate philosophy as a responsible distributor of medical devices, we believe it is our duty to take this action. SARSTEDT regrets any inconvenience this matter has caused you.
Should you have any further questions, you can contact your sales representative or customer service representative at any time.

Kind regards,

SARSTEDT AG & Co. KG

[redacted]

Head of Quality Management PRRC acc. to IVDR Art. 15 Head of Sales Management

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CUSTOMER RESPONSE

Thank you in advance for supporting SARSTEDT AG&Co.KG in fulfilling the legally prescribed duties of disclosure. ***Please complete this form and return it to us preferably by email to:*** *produktrueckruf@sarstedt.com*

To: SARSTEDT AG&Co.KG

With this reply, we confirm receipt of the following letter regarding the

Urgent safety information

Leak in blood culture adapter 14.1209 and 14.1207 of 06/12/2024

We also confirm that the corrective action in the aforementioned letter has been read, understood and implemented or will be implemented.

Customer name:	
Address:	
Postcode, city:	
Customer number	

Notes:

Place, Date *Signature*

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