SARSTEDT Ltd | Optimus Way | Optimus Point | Leicester | LE3 8JR

16/12/2024

Urgent Field Safety Notice

Blood Culture Adapter

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

Sender:

Sarstedt Ltd
Optimus Point
Optimus Way
Leicester
LE3 8JR

Recipient:

NHS Supply Chain
Normanton
Maidstone

Affected medical device:

REF: 14.1209
BATCH: 4074321

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.

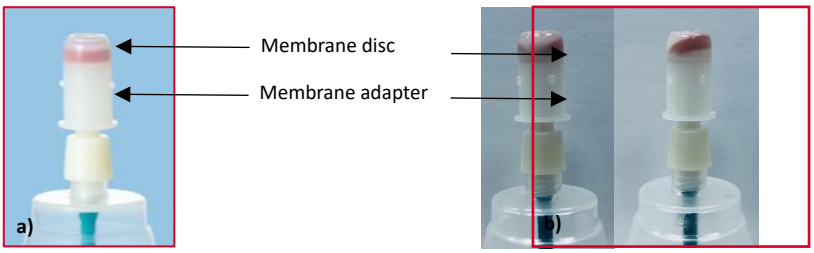

Figure 1: a) Good part: Membrane disc seated correctly in the membrane adapter, b) Defect characteristic: Membrane disc does not fit precisely and is bulging slightly.

Please complete and return the attached reply form within the next 20 days to regulatory.gb@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 National Competent Authority has received a copy of this Field Safety Notice.

Point of contact:

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

For customer-specific questions: orders.gb@sarstedt.com

For product-specific questions: info.gb@sarstedt.com

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 Account Manager or Customer Support representative at any time.

Kind regards,

SARSTEDT Ltd

CUSTOMER RESPONSE

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

To: SARSTEDT Ltd

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

Urgent Field Safety Notice

Leak in blood culture adapter 14.1209 and 14.1207 of 16/12/2024

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*