

Urgent Field Safety Notice

Rociale Healthcare Limited

RML228-023 – Bowl 6000ml Blue double wrapped

RML114-003 – XL Quiver Sterile

Date: 11/06/2024

FSN 2024-06

Details of affected devices:

The following batches of Rociale RML228-023 – Bowl 6000ml Blue double wrapped and RML114-003 – XL Quiver Sterile are affected by this Field Safety Notice.

RML228-023

W544624
W544160
W544046
W543327

RML114-003

W545003 W543902
W544502 W543487
W544082 W543205
W543990 W543096

Description of the problem:

These batches have been packed in a sterile barrier system which has not been fully validated. There is a risk, therefore, that the products within the sterile barrier system will not be sterile.

Action to be taken by the user:

Customers are to discard the product or request a return. If the customer would like their stock of these packs to be replaced, Rociale kindly requests that customers log this issue on the Rociale customer complaint portal here: [Report a Problem - Rociale AcuteCare](#), after which the customer services team will organise the uplift and replacement of any remaining stock of these devices.

We are advised by our clinical team that if the product has been used and there has been no adverse patient effect, there is nothing else that can be done. If the user has any concerns, they should monitor patients that the products has been used on for up to 10 days after the procedure.

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation, or to any organisation where the potentially affected products may have been transferred (if appropriate).

Please transfer this notice to other organisations on which this action has an impact, if appropriate.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action, if appropriate.

Contact reference team:

If you have any queries regarding this Field Safety Notice, please contact:

Rociale Healthcare Limited
Regulatory Team
Ty Mynydd
Cwm Cynon Business Park (North)
Mountain Ash
Rhondda Cynon Taff
CF45 4ER

Email: regulatory@rocialehealthcare.com

Tel: 01443 471300