URGENT FIELD SAFETY NOTICE

Reference **FSN 2023-02**

Type of action **Product Recall**

Date **22nd September 2023**

This Notice is to inform you of a product recall involving procedure packs containing all lots of the following product:

Product Name:	Vinyl Examination Gloves – Medium
Rocialle Ref	RFEB16-1040
Lot Number	All
Expiry date	Various

Details of the Affected Packs:

Product Code	Product Name	Lot Number
RML101-007*	Woundcare 6 - National Opt II (Yellow) Latex Free	ALL
RML101-008	Pack Woundcare Plus 8 With Latex Free Gloves	ALL
RML101-180	Aseptic Soft Pack - Medium Gloves	ALL

***Please Note:** **RML101-007-REVB is NOT affected by this FSN**

Description of the defect

This FSN has been issued because of the potential for the gloves included in the procedure packs detailed above not to function correctly. Since the manufacture of these packs, Rocialle has been informed by the glove manufacturer that the Force at Break test, as specified in EN 455-2 clause 5.2 is not being met for gloves sterilised by electron beam. The specification for this test is that the gloves have a minimum Force at Break of $\geq$3.6N whereas recent test results obtained by the manufacturer range from 2.49 to 3.14N, with an average result of 2.86N.

Clinical Risk Statement:

In most cases, the identified issue will lead to a degree of user dissatisfaction due to glove breakage. However, Rocialle can report that they have received NO customer complaints or feedback as a result of glove breakage.

Although unlikely to lead to user or patient injury consistent with a serious adverse event, the fault presents a minor risk to the patient and user.

If the affected product has already been safely used, then no further product-related action is required.

Please be aware that your Competent Authority is being notified of this Field Safety Corrective Action. As part of this action, we require that you follow the instructions below and notify Rocialle of your compliance with this Field Safety Corrective Action.

Actions to be taken by the user:

As appropriate:

- Identify and quarantine the affected device(s).
- ***Do not use or further distribute any of the product codes listed above for affected device packs.***
- You will have been contacted by the Rocialle customer services team. Please contact them to inform them what product codes/ lots you have and what quantities. Customer services will advise on returning products.
- Recommended patient follow up: None at this time.
- ***Please respond with the requested information within 48 hours of reading this notice.***

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 devices 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 persons:

Regulatory Affairs	Annette Callaghan
Telephone:	+44 (0) 1443 471 340
Email	annette.callaghan@rociallehealthcare.com
Customer Services:	Lisa Poole
Telephone	+44 (0) 1443 471 349
Email	lisa.poole@rociallehealthcare.com
Address:	Rocialle Healthcare Limited, Ty Mynydd, Cwm Cynon Business Park (North), Mountain Ash, Rhondda Cynon Taff, UK, CF45 4ER