

FIELD SAFETY NOTICE

Urgent Field Safety Corrective Action Required

This letter is to inform you of a product recall involving the following procedure packs:

Product Name:	Suture Pack – Imperial College
Rociale Identifier	RML102-909

Details of the Affected Device Packs:

Pack Code	Pack Name	Batch Number	Case Quantity
RML102-909	Suture Pack – Imperial College	W479426	21
RML102-909	Suture Pack – Imperial College	W476419	25
RML102-909	Suture Pack – Imperial College	W473305	20
RML102-909	Suture Pack – Imperial College	W471104	25
RML102-909	Suture Pack – Imperial College	W469096	17

Reference	2020-001
Type of action:	Product Recall

Date of this Notice: 1st June 2020

Description of the defect

This FSCA has been issued because of the potential for the contents of the packs detailed above to be non-sterile, thereby potentially causing injury to the patient. On analysis of process data, it was found that incorrect packing cases had been used that may result in an under-dose of radiation being achieved for packs in certain positions in the cases. The process has failed to meet the minimum sterilisation dose required by our procedures.

Clinical Risk Statement:

In most cases, the identified issues (non-sterile components) may be associated with a risk of injury to the patient. Although unlikely to lead to user or patient injury consistent with a serious adverse event, the fault presents a risk to use of the product. 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 Rociale 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 code/batch number combinations listed above for affected device packs.***

- Please contact the Rociale Customer Services department to inform them which lots of RML102-909 you have remaining in stock 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)

Rociale contact personnel:

Customer Services:

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Email

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