A Sysmex Group Company

URGENT FIELD SAFETY NOTICE

Date: 22 May 2023
FSCA identifier: VC/2023/003
Type of action: Device destruction

DEVICE INFORMATION	
NAME(S):	RET Breakapart Probe
CATALOGUE NUMBER(S):	LPS 045-S / LPS 045
UDI(S):	N/A
LOT NUMBER(S):	080135, 081732, 080168, 082962, 082885, 083731
PRODUCT EXPIRY DATE(S):	080135, 080168, 082962: 2024-02-15 081732: 2024-02-01 082885, 083731: 2024-08-25
MANUFACTURER NAME AND SINGLE REGISTRATION NUMBER (SRN)	GB-MF-000016893

Dear [Customer/Distributor Name],
The purpose of this letter is to advise you that Cytocell Ltd is issuing a Field Safety Corrective Action (FSCA) on product LPS 045 and LPS 045-S RET Breakapart Probe, Lots 080135, 081732, 080168, 082962, 082885 and 083731 (Probe lots 220420-013, 220420-014 and 220906-010). Our records show that you have received one or more units of the affected devices.

Technical details:
This FSCA has been initiated due to a complaint investigation establishing that, during manufacture of this probe, the individual components have been labelled with incorrect colours. As a consequence, the red and green colours are opposite to those specified in the product labelling. The RET proximal probe has been labelled in red rather than green, and the RET distal probe has been labelled in green rather than in red. This means that the signal pattern in an unbalanced translocation will be opposite to what the user would expect. The expected signal pattern in a normal specimen and in an abnormal specimen with a balanced translocation are not affected.

Cytocell have identified a risk that an incorrect result may be reported out due to this issue in an unbalanced translocation. FISH tests would be used as an adjunct to other diagnostic laboratory tests, and therapeutic action would not be initiated on the basis of the FISH result alone, Cytocell have identified the risk of adverse health consequences as 'remote'.

Recommended actions for distributors and end users:
Immediately examine your inventory and quarantine all product subject to recall. Cytocell requests that you destroy the remaining inventory. We also suggest that

laboratories undertake a review of the results obtained with the affected devices and check that no results were misinterpreted due to the incorrect labelling of the DNA.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

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

Please follow up on this notice and resulting action for an appropriate period to ensure required actions have been carried out.

We wish to sincerely apologise for any inconvenience caused as a result of this Urgent Field Safety Notice. If you have any questions or comments arising from this Urgent Field Safety Notice, please contact us at on +44(0) 1223 294048 or email us at vigilance@ogt.com.

Yours sincerely,

[redacted]

Executive Vice President of Regulatory, Medical, and Quality Affairs
Cytocell Ltd.

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DECLARATION FORM

Commercial name of the affected product: RET Breakapart Probe
FSCA identifier: VC/2023/003
Type of action: Device destruction

Email: vigilance@ogt.com **or Fax to:** +44 (0) 1223 294986

Customer Information

Organisation: [Customer/Distributor Name]

Address: [Customer/Distributor Address]

Contact person: [Customer/Distributor Contact Name]

Our records show that you have received the following quantities of affected devices. Please complete the table below, sign the declaration and return to Cytocell as soon as possible.

Affected Product Reconcilliation Table (from distributors)					
Product / Description		LPS 045			
UDI	Lot	Quantity Received	Quantity Used (by end users)	Quantity destroyed	Quantity of replacements required
N/A					
Product / Description		LPS 045-S			
UDI	Lot	Quantity Received	Quantity Used (by end users)	Quantity destroyed	Quantity of replacements required
N/A					

Declaration

I hereby confirm that we have read and understood the Urgent Field Safety Notice on LPS 045/LPS 045-S RET Breakapart Probe and we have communicated this to all our end users of the above stated device. We confirm that all actions have been carried out and evidence of completion can be provided as requested.

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As declared by (name):

Job Title:

Signature and date:

Please sign this form and return the completed document (by FAX or as a scanned PDF) to the address provided above within tw

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CytoCell