GE Healthcare

Field Safety Notice

8 May 2019

Dear Valued Customer
(cc Chairman Medical Board and relevant Head of Department)

Subject: CS-430.1 Sepax Kit Sterility indicator issue

We have detected six units of Sepax Kit, batch CS43011808A01 (delivered only to China) with purple EO indicator (instead of green when indicators have been in contact with EO). Please see the attached original letter attached.

The above batch is not supplied in Singapore, however the device model has obtained marketing authorisation in Singapore (Device Registration No:DE0007156) , hence this notice is issued as a precautionary measure. If you have detected similar situation on other models, please inform us.

If you need any further information or support concerning this issue, please contact us.

Yours sincerely,

Name: Nora
Position: RA officer

Attached: GEHC Ref# Eysins 01

URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
Biosafe SA,
Route du Petit-Eysins 1
1262 Eysins, Switzerland

April 10th, 2019

GEHC Ref# Eysins 01

To: China Bright Group CO., LTD
Bank of China Tower
1, Garden road, 48th floor
Hong Kong

RE: CS-430.1 Sepax Kit Sterility indicator issue

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

Six units of Sepax Kit, batch CS43011808A01 have been detected with purple EO indicator (instead of green when indicators have been in contact with EO). Potentially an unknown quantity of cord blood units processed with this batch may not be sterile. The identified issue is potentially impacting the sterility of the product. There have been no injuries reported as a result of this issue.

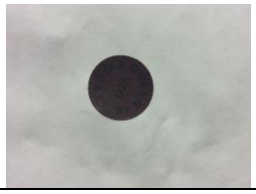
Safety Instructions

Therefore, we recommend the following actions:

1. Identify the end users of the batch, and relative quantity delivered.
2. Quarantine the remaining stock (if applicable) and check conformity of the stock as per below instructions.
3. Contact the end user to request them to check conformity of their stock and evaluate any risk to already used product (if applicable).
4. Please fill and return the feedback form in the appendix 1.
5. If you identify non-conform product, contact us for the return of the goods, so we can further investigate the root cause.

<u>Instructions to identify product that may not have been sterilized</u>: Check the colour of the sterility indicator on each single kit. The indicator is located on the Tyvek cover of the primary package.

Acceptance criteria:

Indicator is green: conform	Indicator is dark purple: non-conform
	

We also recommend the following actions:

- Evaluate potential contamination risk according to your own process, and/or
- Perform a sterility test on the reduced cord blood unit for all units of this batch as part of your quality controls (sample segment might be used here), and/or
- Inform the cord blood unit receiver (transplant center/physician) of the potential contamination.
- Ensure revising your standard operating procedure to include the above recommendations.

Affected Product Details

Product Name	Article/Catalogue No.	Lot/batch/Serial No
Sepax Kit CS-430.1	10017	CS43011808A01

NMPA Licence number: 20173407131

Product Correction

GE Healthcare will correct all affected products at no cost to you. A GE Healthcare representative will contact you to arrange for the correction.

Contact Information

If you have any questions or concerns regarding this notification, please contact your local GEHC representative:
Carray Tang, [redacted] +86 21 38774568

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

[redacted]

James W. Dennison
Vice President - Quality Assurance
GE Healthcare

[redacted]

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

Appendix 1: Feedback form

Company name: _____

Stock level:

Quantity of product delivered from the impacted batch (CS43011808A01): _____ box(es)
Quantity in stock: _____ box(es)
Quantity already used: _____ box(es)

Check results:

How many units are conform: _____ units
How many are non-conform: _____ units

If units are non-conform, please report below the serial number (SN):

Please send back this form to your contact by 26th April 2019:
Carray Tang, [redacted], +86 21 38774568

Date:
Name and sign: