Formulaire de notice d'information de sécurité (Field Safety Notice)

Field Safety Notice

Commercial name of the affected product:
- RegenET (Ref. R-ET-3 x 10, Batch 020)
- RegenET (Ref. R-ET-3 x 10, Batch 022)

FSCA-identifier 2022-12-02-A2

Type of action *Quarantine and destruction of products*

Please note that this action only applies to specific product codes and does not affect all product codes and LOTs of Regen Lab products.

Date: 25th January 2023

Attention to: *QA Responsible, Warehouse Manager, Physicians, Hospitals, Clinics, Pharmacists and Health professionals who received the concerned products.*
This notice should be forwarded to all those who need to be aware of it within your organization and to maintain the awareness over the appropriate defined period.

Details on affected devices:
Are concerned by this quarantine and destruction specific product codes of class IIa devices:

Product Code	Batch Number	Expiration Date
R-ET-3 x 10	020	2024-06-03
R-ET-3 x 10	022	2024-07-18

Description of the problem:
R-ET tubes consist in glass tubes for aspiration and/or centrifugation and/or preparation and/or transfer of biological tissue. They can be used to prepare L-PRF (leukocyte- and platelet-rich fibrin), which is a biological product obtained by coagulation of blood under certain centrifugation conditions. We observed on several tubes of the batches concerned, after centrifugation, that the resulting solid clot was not formed, or delayed. Separation of the blood components is proper but only a liquid phase is obtained.

The absence of clot prevents the use of the biological product. However, (1) there is no safety risk in handling for the user as only the performance of the biological product is impacted. (2) R-ET tubes are not life-sustaining devices, so the absence of treatment will not lead to severe consequences for the patient.

Product Identification Procedure
For this safety measure, the only way to identify affected products is by comparing product code and batch number to the products listed in the above table.
See Annex 1 for example of package labeling that highlights the location of the product code and batch number on the device label which is located on the primary packaging. The product code (reference number) is preceded by the word "REF" and the batch number is preceded by word "LOT".

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Advise on action to be taken by the distributor/user:
Our traceability shows that you have taken delivery of affected product. Please follow the steps below according to whether you are a distributor or an end-user in order to quarantine and destroy the identified product *:*

Actions to be taken by the distributor or logistics entity	Actions to be taken by the end-user
1. *Please **immediately stop distributing, quarantine, and destroy** all affected products.* 2. *Please complete and return the "Quarantine and Destruction Response Form for Distributors" (pages 3 and 4) **no later than 2 weeks after reception of this notification,** to Mr. Jean-Baptiste Pignier (jpignier@regenlab.com) and Mr. Baptiste Laroche (blaroche@regenlab.com).* 3. ***Inform and send the FSN to end-users immediately after reception of this notification.** They must fill and return to you the "Quarantine and Destruction Response Form for End-Users" (pages 5 and 6).* *You must then return to Regen Lab the end-user FSN form **immediately after reception** to Mr. Jean-Baptiste Pignier (jpignier@regenlab.com) and Mr. Baptiste Laroche (blaroche@regenlab.com).* 4. *Your Sales Representative from Regen Lab will advise on suitable replacement stock.*	1. *Please **immediately stop using all affected products, quarantine, and destroy them**.* 2. *Please fill and return to your distributor (or logistics entity) the "Quarantine and Destruction Response Form for End-Users" (pages 5 and 6) **no later than 2 weeks after reception of this notification**.* 3. *Destroyed products will be progressively replaced by Regen Lab.* 4. *Your Sales Representative from Regen Lab or Distributor will advise on suitable replacement stock.*

Thank you for your business and continued support. We sincerely apologize for any disruption this situation may cause to your organization.

If you have any questions about these actions, please do not hesitate to contact:

- **For Sales and Logistic queries**
  - Mr. Alain Lecompte, alecompte@regenlab.com
- **For queries related to quarantine**
  - Mr. Baptiste Laroche, QA/RA Manager, blaroche@regenlab.com
  - Mr. Jean-Baptiste Pignier, PMS Manager, jpignier@regenlab.com

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The undersigned confirm that this notice has been notified to the appropriate Regulatory Agencies.

	QA/RA Manager	PMS Manager
Full name and signature	DocuSigned by: Baptiste Laroche Nom du signataire : Baptiste Laroche Motif de la signature : J'approuve ce document Heure de signature : 25 janvier 2023 | 3:56:34 PM CET D3A7483D2A9C487380E76CEA650879F9	DocuSigned by: Signer Name: Jean-Baptiste Pignier Signing Reason: I approve this document Signing Time: 25 January 2023 | 3:54:10 PM CET 6EF3C675236445C5B416379567360C11

Formulaire de notice d'information de sécurité (Field Safety Notice)

QUARANTINE AND DESTRUCTION RESPONSE FORM for DISTRIBUTORS

FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN by Email

Distributor Name	
Distributor Address	

Please indicate the quantity of the affected products distributed to your facility:

Product Code / REF No.	LOT N°	Quantity Delivered (pieces)
R-ET-3 x 10	020	
R-ET-3 x 10	022	

Please answer each of the following.

Have You Distributed the Product Further? ☐ NO ☐ YES

*If YES, have you notified down to your customer? ☐ NO ☐ YES

*If NO, explain why :

☐ We have NO affected products

☐ We have the following affected products

Record quantity for each LOT to be quarantined (for partially used kits, indicate the number of non-used tubes):

Product Code / REF N°	LOT N°	Units on hand	Units quarantined

Record quantity (kit) for each LOT to be destroyed (for partially used kits, indicate the number of non-used tubes):

Product Code / REF N°	LOT N°	Quantity destroyed

Specify your method of destruction:
Date of destruction:
Destruction done by:

Name	
Job title	
Signature	
Witness (if applicable)	

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FORM completed and returned by:

Name	
Job title	
Date	
Signature	

Regen Lab SA disclaims all responsibility for the use of the lots concerned upon reception of this notification.

Is the QUARANTINE AND DESTRUCTION RESPONSE FORM for DISTRIBUTORS returned to Regen Lab ?

☐ YES ☐ NO

Is the QUARANTINE AND DESTRUCTION RESPONSE FORM for END-USERS returned to Regen Lab ?

☐ YES ☐ NO

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QUARANTINE AND DESTRUCTION RESPONSE FORM for END-USERS

FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN by Email to your Distributor

End-User Name	
End-User Address	

The following product codes have been distributed to you:

Product Code	Lot Number	Expiration Date

Please answer each of the following.

☐ We have NO affected products in stock
☐ We have the following affected products

Record quantity for each LOT to be quarantined (for partially used kits, indicate the number of non-used tubes):

Product Code / REF N°	LOT N°	Units on hand	Units quarantined

Record quantity (kit) for each LOT to be destroyed (for partially used kits, indicate the number of non-used tubes):

Product Code / REF N°	LOT N°	Quantity destroyed

Specify your method of destruction:
Date of destruction:
Destruction done by:

Name	
Job title	
Signature	
Witness (if applicable)	

Formulaire de notice d'information de sécurité (Field Safety Notice)

FORM completed and returned by:

Name	
Job title	
Date	
Signature	

Regen Lab SA disclaims all responsibility for the use of the lots concerned upon reception of this notification.

Is the FORM returned to Distributor ?
☐ YES ☐ NO

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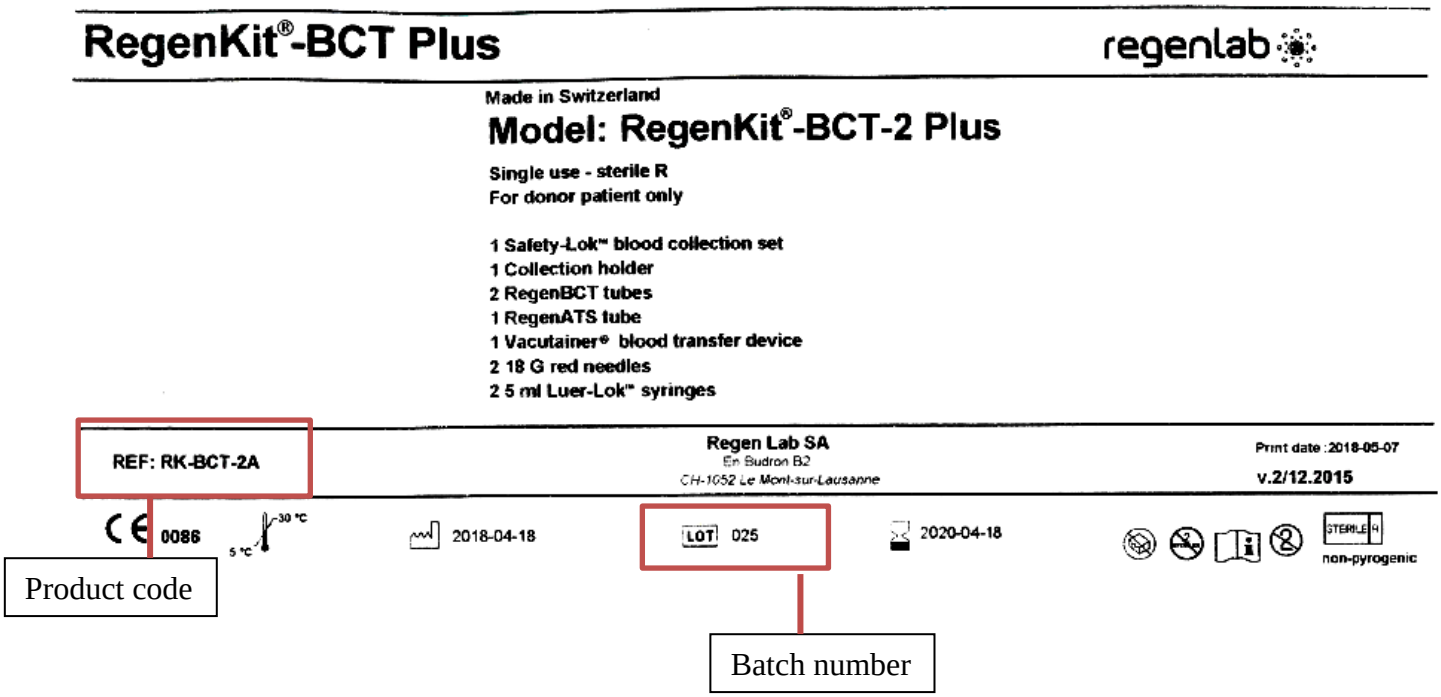
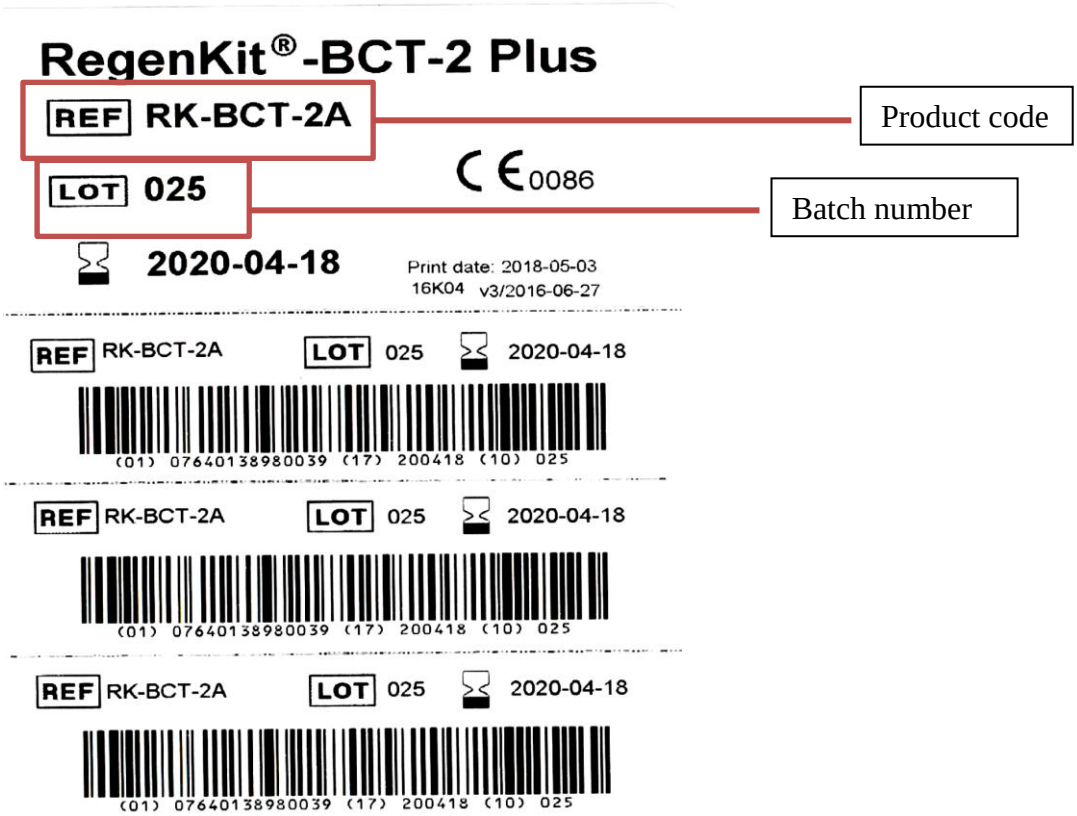
Annex 1: Examples of Product Labelling

Labeling printed on Tyvek



Label on the folding box



- **End of Form -**

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Document history

Version	Modification(s)	Auteur	Date
03	Section 4 : Adding of SOP and FORM specific to certain regions and of deadlines for notification of incidents	GP	16.10.2015
04	Update with Veeva format Complete review of document following CC-2019-03-18-A (revue bisanuelle des documents)	JBP	07.01.2021

- **End of document -**