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

Field Safety Notice

This FSN follows the one released in August 2022 for quarantine

Commercial name of the affected products:

Family	Device Name	Reference
A-CP Kits Family	A-CP-Kit-3	A-CP-3
	A-CP-Kit-3	A-CP-3 USA
	A-CP-Kit-3 (20ml)	A-CP-3-20
RegenKit-BCT Family	RegenACR-C Plus	R-ACR C/BA
	RegenACR-C Extra	R-ACR C2/B
	RegenKit-BCT-1	RK-BCT-1
	RegenKit-BCT-1	RK-BCT-1 USA
	RegenKit-BCT-2 Plus	RK-BCT-2A
	RegenKit-BCT-3	RK-BCT-3
	RegenKit-BCT-3	RK-BCT-3 USA
	RegenKit-BCT-T	RK-BCT-T

FSCA-identifier FSCA-2022-05-16-A

Type of action *Destruction of product following previous quarantine*

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: September 29th 2022

Attention to: *QA Responsibles, Warehouse Managers, Physicians, Hospitals, Clinics, Pharmacists and Healthcare 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.

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Details on affected devices:
Are concerned by this destruction request, the class IIb devices with these specific product codes and lot numbers below:

Product Code	Lot Number
A-CP-3	059
A-CP-3 USA	031 032 033 034 036 037 038 039 040 041 042 043 044 048 050 051 053 054 055
A-CP-3-20	047
R-ACR C/BA	141 142
R-ACR C2/B	138 139
RK-BCT-1	086 087
RK-BCT-1 USA	085
RK-BCT-2A	030
RK-BCT-3	301 302 303 305 306 307 308 309 310 311
RK-BCT-3 USA	300 304
RK-BCT-T	015

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Description of the problem:

At the beginning of May 2022, French customers have reported several cases of patient's inflammatory reaction after Platelet-Rich Plasma (PRP) injection characterized by pain and/or joint effusion. Transient inflammatory reaction is identified as expected undesirable side-effects of the PRP injection as mentioned in our risk analysis and clinical report evaluation. These cases have only been reported following an intra-articular injection into the knee, and have generally resolved spontaneously, or have required medical treatment in several case. The analysis of the synovial fluid did not reveal any infection.

The medical follow-up of the patients stops when the inflammatory reaction due to the injection of PRP disappears, there is no need for additional follow-up. No particular follow-up is necessary for patients without inflammatory reaction following an injection of PRP.

From systematic literature searches conducted to identify all published data pertaining to RegenKits, it was found that side effects associated with the use of PRP for a large variety of medical use were minor and were of short duration. These reactions were of mild to moderate severity, localized to the treated area, transient, resolved spontaneously, or required the intake of medical treatment. Globally, when risks of use of PRP and other plasma-derived products prepared with RegenKits are compared to other conventional treatments according to the medical use, the use of RegenPRP is still associated with a lower risk profile.

The incriminated lots of tubes have been investigated. Some particles in the sodium citrate solution, with an irregular appearance of the separator gel and the presence of a white layer on the surface of the gel have been observed. Note: The separator gel is used for the blood separation, it makes a physical barrier between the red blood cells and the Platelet Rich Plasma. Only the plasma is reinjected to the patient, the gel is not.

An investigation on the concerned tubes was carried out on this potential degradation of the gel. After an internal investigation led with manufacturing documentation and reference samples, this issue seems to be due to a combination of factors during manufacturing. .
If one of these factors is absent, the visual defect does not appear, suggesting this combination to be the contributory cause of the visual defect on the separator gel, and, consequently, to the patient's inflammatory reaction. The first reported customer complaints involve RK-BCT-3, batch number 302, manufactured in January 2022. Before January 2022, this combination was not used for BCT references.

The internal and external tests performed confirmed the root cause of the anomaly, i.e. a faulty combination of factors during manufacturing.
We also confirm that the impacted lots should not be used in order to avoid potential new inflammatory reactions after injection of PRP.

Regen Lab is therefore requesting the destruction of previously quarantined products (see table above). Discarded products will be progressively replaced.
Since July 2022, the defective combination has been removed and increased vigilance has been deployed to guarantee the conformity, safety and performance of the products distributed.

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Product Identification Procedure:
For a destruction, the only way to identify affected products is by comparing product code and batch number to the destruction product list (see table above).
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".

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 discard the affected product:

Actions to be taken by the distributor	Action to be taken by the end-user
1. *Please **maintain the distribution stop** and discard all affected products previously quarantined*	1. *Please **maintain the stop use** and discard all affected products previously quarantined*
2. *Please complete and return the "Certificate of destruction" (page 6) **no later than 2 weeks after reception of this notification**, t* [redacted]	2. *Please fill and return the "Certificate of destruction" (page 6) **no later than 2 weeks after reception of this notification,** to your distributor and to Regen Lab SA:* - [redacted]
3. *Inform and send this new FSN to end-users **no later than 2 weeks after reception of this notification.** They must fill and return to you the "Certificate of destruction". You must then return to Regen Lab the "Certificate of destruction" **immediately after reception.*** [redacted]	3. *Discarded products will be progressively replaced by Regen Lab SA*
4. *Your Regional contact will advise on suitable replacement stock.*	4. *Your Regional contact 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.

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

- **For Sales and Logistic queries**
  - [redacted]
- **For queries related to batch quarantine**
  - [redacted]
  - [redacted]

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Fax +41 21 864 0110

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

	QA/RA Manager	PMS Manager
Full name and signature	[redacted] 17 octobre 2022 DocuSigned by: [redacted] Nom du signataire : [redacted] Motif de la signature : J'approuve ce document Heure de signature : 17 octobre 2022 | 12:06:28 PM CEST D3A7483D2A9C467380E76CEA650879F9	[redacted] 17 octobre 2022 DocuSigned by: [redacted] Nom du signataire [redacted] Motif de la signature : J'ai examiné ce document Heure de signature : 17 octobre 2022 | 12:19:29 PM CEST 6EF3C675236445C5B416379567360C11

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CERTIFICATE OF DESTRUCTION

FIELD SAFETY NOTICE

PLEASE COMPLETE AND RETURN by e-mail

Name of the facility	
Address	

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

Product Code / REF No.	LOT number	Quantity discarded

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

Name	
Job title	
Signature	
Witness (if applicable)	

CERTIFICATION 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 the Certificate of Destruction.

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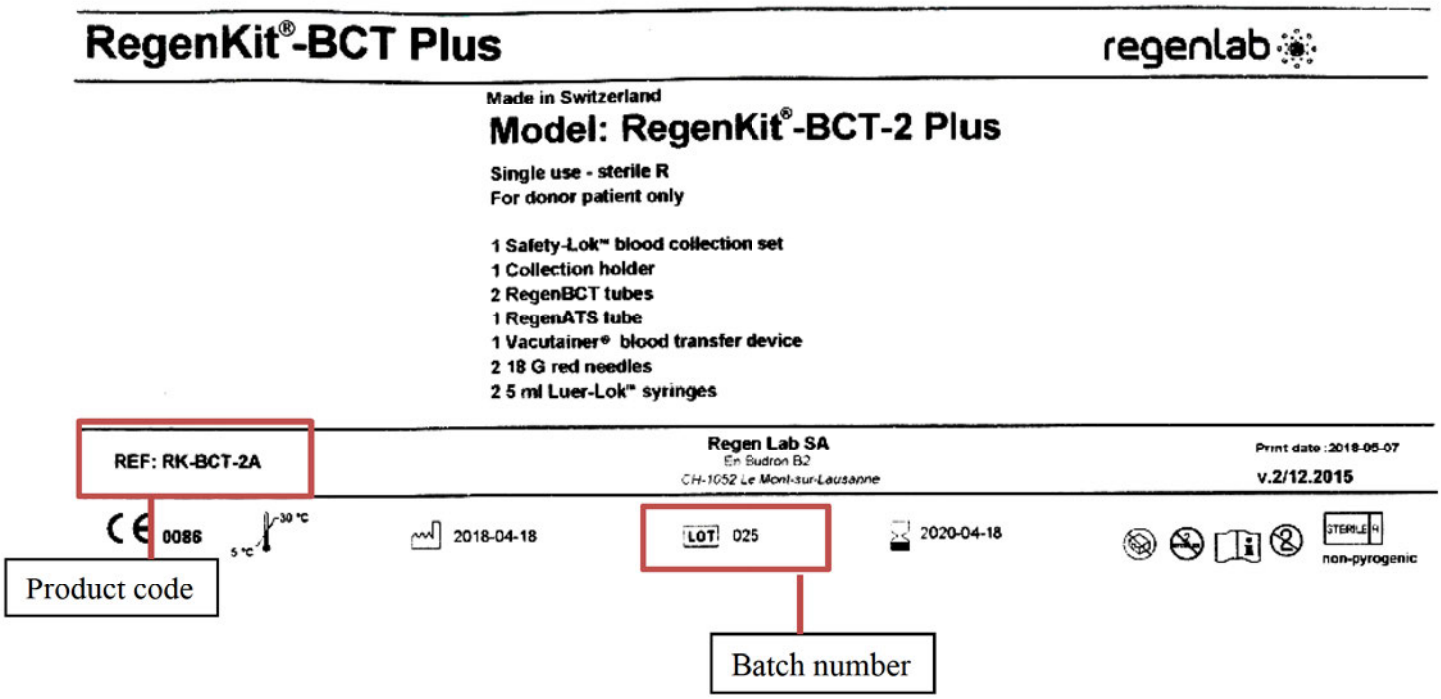
Annex 1: Examples of Product Labelling

Labeling printed on Tyvek



Label on the folding box