

Field Safety Notice

Commercial name of the affected product: Cellular Matrix BCT-HA-1 and 3T,
Cellular Matrix A-CP-HA-1 and 3T
ArthroVisc40-1
SkinVisc40-1

FSCA-identifier 2018-03-22-A-FSCA

Type of action *Product Recall*

Please note that this action only applies to specific product codes and does not affect all product codes and LOTs of Cellular Matrix BCT-HA, Cellular Matrix A-CP-HA, ArthroVisc40, SkinVisc40.

Date: 10.07.2018

Attention to: *QA Responsible, Warehouse Manager, Physicians, Hospitals, Clinics and Pharmacists 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 recall specific product codes of class III devices (tubes/syringes prefilled with hyaluronic acid):

Product Code	Lot Number	Expiration Date
BCT-HA-1	001	31.07.2019
	002	30.11.2019
BCT-HA-3T	001	31.07.2019
	002	14.11.2019
	003	30.11.2019
A-CP-HA-1	001	28.08.2019
A-CP-HA-3T	001	12.09.2019
	002	18.01.2020
	003	13.02.2020
SKV-HA40-1	014	29.08.2019
ARV-HA40-1	025	23.08.2019
	026	14.09.2019
	027	30.09.2019
	028	30.09.2019
	029	30.09.2019
	031	23.01.2020
	032	15.02.2020

Description of the problem:

Regen Lab SA, with Swissmedic consultation, has voluntarily initiated a recall for specific product codes listed above to correct a regulatory discrepancy. Patient and user safety is not affected. This action is being performed by Regen Lab SA with the full knowledge of the national regulatory authorities.

The product codes included in the recall were newly created after removal of a layer of protective packaging. However, these product codes were distributed without being covered by the existing design certificate.

Safety of the new packaging system is guaranteed and all Essential Requirements (MDD 93/42/EEC) are fulfilled. Indeed, this layer of packaging does not interfere with the sterility of the device and does not impact the safety of patients or users. The new protective packaging still ensures protection, safety and performance of the device.

Although safety and performance requirements are fulfilled, this procedure recall is performed only to fulfill administrative regulatory requirements and to stay compliant with existing CE certificates.

The recall is conducted at end-user level.

No supplementary actions will be undertaken on treated patient (as safety and performance of the device is guaranteed).

Product Identification Procedure:

The only way to identify affected products is by comparing product code to the recalled product list (see table above).

See Annex 1 for example of package labeling that highlights the location of the product code on the device label which is located on the primary packaging. The product code (reference number) is preceded by the word “REF”.

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 return the identified product to Regen Lab:

Actions to be taken by the distributor	Action to be taken by the end-user
<ol style="list-style-type: none"> 1. Please immediately stop distributing and quarantine all affected products. 2. Inform and send the FSN to end-users no later than August 15, 2018. They must fill and return to you the “Recall Response Form for End-Users” (page 5). 3. Please complete and return the “Recall Response Form for Distributors” (page 4) to all the following persons Eiman Atiek (eatiek@regenlab.com) Genta Plasari (gplasari@regenlab.com) Daphné Van Diermen (ddiermen@regenlab.com) 4. Please return the “Recall Response Form for End-Users” (page 5) to all Regen Lab persons listed above. 5. All affected products must be returned to Regen Lab no later than September 15, 2018 to the following address Regen Lab SA, En Budron B2, 1052 Le Mont-sur-Lausanne, Switzerland 6. Your Regional contact will advise on suitable replacement stock. 	<ol style="list-style-type: none"> 1. Please immediately stop using all affected products. 2. Please fill and return to your distributor the “Recall Response Form for End-Users” (page 5). 3. Please return all the unused affected products to your distributor no later than August 30, 2018. 4. Returned products will be replaced by Regen Lab SA. 5. 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 your organization.

If you have any questions about this action please do not hesitate to contact:

For Sales and Logistic queries Mr. Alain Lecompte, +41218640139, alecompte@regenlab.com

For regulatory queries

Mrs. Daphné Van Diermen, Resp. Pharm., Technical Director, or
Mrs. Genta Plasari, PhD, QA Responsible

REGEN LAB SA
En Budron B2,
CH-1052 Le Mont-sur-Lausanne,
Switzerland
Tel. +41 21 864 0111
Fax +41 21 864 0110
e-mail : gplasari@regenlab.com, ddiermen@regenlab.com

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Signatures

Daphné Van Diermen
Resp. Pharm., Technical Director



Genta Plasari
PhD, QA Responsible



RECALL RESPONSE FORM for DISTRIBUTORS
FIELD SAFETY NOTICE
PLEASE COMPLETE AND RETURN by Email

Distributor Name	
Distributor Address	

The following product codes have been distributed to your facility:

Product Code / REF No.	LOT N°	Quantity Delivered (pieces)

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 YES, have you recall the product from your customer? NO YES

*If NO explain why not:

- We have NO affected products
- We have the Following affected products

Record quantity (pieces) for each LOT to be returned to Regen Lab:

Product Code / REF No.	LOT N°	Units on hand	Units returned

- The RECALL RESPONSE FORM for DISTRIBUTORS returned to Regen Lab
- The RECALL RESPONSE FORM for END-USERS returned to Regen Lab

FORM Completed and Returned From:

Name
Date
Signature

RECALL RESPONSE FORM for END-USERS
FIELD SAFETY NOTICE
PLEASE COMPLETE AND RETURN by Email to your Distributor

End-User Name	
Address	

The following product codes have been distributed to you:

Product Code	Lot Number	Expiration Date	Product Code	Lot Number	Expiration Date
BCT-HA-1	001	31.07.2019	SKV-HA40-1	014	29.08.2019
	002	30.11.2019		025	23.08.2019
BCT-HA-3T	001	31.07.2019	ARV-HA40-1	026	14.09.2019
	002	14.11.2019		027	30.09.2019
	003	30.11.2019		028	30.09.2019
A-CP-HA-1	001	28.08.2019		029	30.09.2019
A-CP-HA-3T	001	12.09.2019		031	23.01.2020
	002	18.01.2020		032	15.02.2020
	003	13.02.2020			

Please answer each of the following.

- We have NO affected products in stock
- We have the Following affected products

Record quantity (pieces) for each LOT to be returned to Regen Lab via the Distributor:

Product Code / REF No.	LOT N°	Units on hand	Units returned

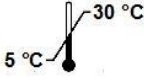
- FORM returned to the distributor

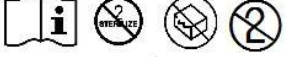
FORM Completed and Returned From:



Name
Date
Signature

Annex 1: Examples of Product Labeling

Labeling printed on Tyvek

REGEN LAB SA
Switzerland

 V1/2017-09-06





STERILE
 non-pyrogenic

CE 0086
REF A-CP-HA-3T
LOT 


Product code



Label on the folding box



Intended use: EN Device used to prepare intra-articular injections for symptomatic treatment of articular pain and mobility improvement. Device used to prepare intra-dermal injection for hydration of dehydrated and wrinkled skin tissues



REF BCT-HA-1
LOT    CE 0086

 (01) 07640138980534 (17) 160525 (10) 123 v1/2017-09-06



Product code

Cellular Matrix / A-CP-HA Kit

Product code **REF** A-CP-HA-3T
LOT 002
 2020-01-18

 CE 0086
 Print date 2018-01-23
 17F15 v1/2017-09-06

REF A-CP-HA-3T **LOT** 002  2020-01-18

 (01)07640138980947(17)200118(10)002

REF A-CP-HA-3T **LOT** 002  2020-01-18

 (01)07640138980947(17)200118(10)002

REF A-CP-HA-3T **LOT** 002  2020-01-18

 (01)07640138980947(17)200118(10)002