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# 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.**

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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** |
|---|---|
| 1. *Please **immediately stop distributing** and quarantine all affected products.*<br><br>2. *Inform and send the FSN to end-users **no later than August 15, 2018**.*<br>*They must fill and return to you the “Recall Response Form for End-Users” (page 5).*<br><br>3. *Please complete and return the “Recall Response Form for Distributors” (page 4) to all the following persons*<br>*Eiman Atiek (eatiek@regenlab.com)*<br>*Genta Plasari (gplasari@regenlab.com)*<br>*Daphné Van Diermen (ddiermen@regenlab.com)*<br><br>4. *Please return the “Recall Response Form for End-Users” (page 5) to all Regen Lab persons listed above.*<br><br>5. *All affected products must be returned to Regen Lab **no later than September 15, 2018** to the following address*<br>*Regen Lab SA, En Budron B2,*<br>*1052 Le Mont-sur-Lausanne, Switzerland*<br><br>6. *Your Regional contact will advise on suitable replacement stock.* | 1. *Please **immediately stop using** all affected products.*<br><br>2. *Please fill and return to your distributor the “Recall Response Form for End-Users” (page 5).*<br><br>3. *Please **return** all the unused affected products to your distributor **no later than August 30, 2018**.*<br><br>4. *Returned products will be replaced by Regen Lab SA.*<br><br>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

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Switzerland
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**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 |
|---|---|---|
| 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 |
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| Product Code | Lot Number | Expiration Date |
|---|---|---|
| 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 |

**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 |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

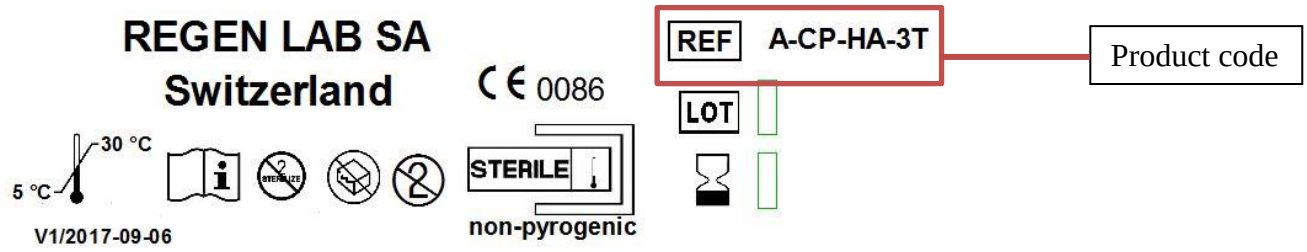
□ FORM returned to the distributor

FORM Completed and Returned From:

Name
Date
Signature

Annex 1: Examples of Product Labeling

## Labeling printed on Tyvek




## Label on the folding box