Rev 1: September 2018
FSN Ref: 02/2021 FSCA Ref: 01/2021

Date: 07.05.2021

Urgent Field Safety Notice / Urgent Field Safety Notice

Esteemed customer,

As manufacturers of the medical devices listed in this document, we hereby notify you of the issue of a Field Safety Corrective Action relating to the products described (Annex 1 – List of the Impacted batches).

Explanation of the problem

Adria Srl is a manufacturer of class IIa and IIb medical devices.
The devices are marketed in sterile form, after having undergone an ethylene oxide sterilization process performed by the company Steril Milano Srl.
We have received communication from the sterilization company concerning the non-respect of the process parameters of the sterilization cycles.

This problem has affected many European companies.

Therefore, Adria conducted a thorough investigation on the products for sterility tests and ETO residue, with positive feedback results on all the involved products.

As a precaution, we decide to recall the devices (listed in Annex 1) remaining in stock at our distributor's warehouse.
Regarding hospitals and health care centers, the immediate quarantine and segregation of the devices listed in Annex 1 is required.
In Annex no. 1 you can find the list of the affected batches.

Clinical impact

The use of non-sterile devices may lead to an increased risk of patient infection.
We would like to specify that Adria Srl has never been notified of adverse events or damage to patients potentially attributable to the problem covered by this report.
There are no specific follow-up actions for patients, where the product has already been used.

All batches of the concerned devices are listed in Annex 1 "List of Impacted batches"

Actions required to distributors and economic operators

1. Immediately suspend deliveries, identify and quarantine all the devices in your possession which are listed in Annex no. 1 "List of Impacted batches".
2. Share this Field Safety Notice within your organization with all interested parties. If you have distributed the products covered by this FSN to third parties, identify these subjects and forward this letter to them immediately, communicating to each hospital the detailed list of the goods subject to this action that have been supplied by you, using the template of the Annex no. 2 "Letter of the Distributor to Hospitals" – Table A1 (making sure to fill in Table A1 with the detail of the article codes and the lots destined for that hospital).

3.Fill in and sign the attached Annex no. 3 "Acknowledgment of the distributor" specifying the quantity of the quarantined goods, including their lot number, their code and inform Adria Srl by sending an email to qa@adriamedical.com and export@adriamedical.com as soon as possible / within 10 days of receipt of this letter.
4.Adria Srl will contact you to organize the collection of the goods. Adria Srl will replace the goods as soon as possible.

Actions required of hospitals and healthcare facilities

1. Identify and immediately stop using the concerned products.
Place in quarantine all items listed in Table A1 that are still present at your facilities.

2.Fill in and sign the attached Annex no. 4 “Acknowledgement of hospitals and health facilities” specifying the quantity of the goods placed in quarantine, including their lot number, their code and inform your dealer and Adria Srl by sending an email to qa@adriamedical.com and export@adriamedical.com as soon as possible and in any case within 10 days of receipt of this letter.

3. Wait for information from Adria Srl for the actions regarding the concerned devices.

Corrective Actions in place

Adria Srl has validated a new supplier for the sterilization process.

Contacts

For further information regarding this FSN please contact Adria Srl at +39 347 2441014 or by email at the address qa@adriamedical.com or export@adriamedical.com and your distributor.

We confirm that the relevant competent authorities have been notified of the actions described herein.
We would like to mean that the safety of our devices is a primary objective for us, in issuing this FSN Adria we wanted to maintain a prudent and collaborative approach, we trust to manage the planned actions in the best possible way.

We apologize for any inconvenience this situation may cause. We are available for any clarification.

ADRIA srl
Società Unipersonale
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40017 S. GIOVANNI IN PERSICETO (BO) - Italy
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E-mail: adria@adriamedical.com - www.adriamedical.com
Partita IVA. 02042571204

Yours faithfully

Maria Vittoria Avaltroni
QA / RA Manager
Adria Srl

Product Code	Lot n.	Device type
495041123	AD0653/20	Cement Injection Cannula kit
495041123	ZV0874	Cement Injection Cannula kit

Annex 2 - letter from distributors to hospitals

San Giovanni in Persiceto, 07/05/2021

This letter contains important information that requires your immediate attention.

Dear Customer,

We, Adria Srl, are undertaking this Field Safety Corrective Action in relation to the lots listed in attachment 1 of this letter.

Explanation of the problem

Adria Srl is a manufacturer of class IIa and IIb medical devices.
The devices are marketed in sterile form, after having undergone an ethylene oxide sterilization process performed by the company Steril Milano Srl
Adria Srl received communication from the sterilizer about the falsification of the process parameters of the sterilization cycles.
So, we conducted a thorough investigation accompanied by sterility tests and residue eto, with positive feedback on the tested products.
As a precaution, we decide to recall the devices (listed in Annex 1) in stock at our distributors. With regard to hospitals and health services, the immediate quarantine and segregation of the same devices listed in Annex 1 present in the structure is required.
In attachment 1 you can find the extract of the affected lots.

Clinical impact

The use of non-sterile devices may lead to an increased risk of patient infection.
We would like to specify that Adria Srl has never been notified of adverse events or damage to patients potentially attributable to the problem covered by this report.
There are no specific follow-up actions for patients, where the product has already been used.

Actions required of hospitals and health facilities

1. Immediately discontinue use, identify and quarantine all items listed in Table A1 (list of products supplied), that are still present at your facility, that are new, unused, and still in their original packaging.

2.Fill in and sign the attached letter of Attachment 4 "Acknowledgment letter of Hospitals and Health facilities" specifying the quantity of the goods placed in quarantine, including their lot number, their code and inform your distributor and Adria Srl by sending an email to the following address: qa@adriamedical.com and export@adriamedical.com as soon as possible and in any case within 10 days of receipt of this letter.

3. Wait for information from your distributor and Adria Srl for the handling of the goods in question.

Corrective actions in place

Adria Srl is completing the qualification of a new OE sterilization service provider.

Contacts

For further information regarding this FSN please contact your distributor and Adria Srl at +39 347 2441014 or by email at the address qa@adriamedical.com or export@adriamedical.com

Adria Srl confirms that the relevant competent authorities have been notified of the actions described herein. Adria Srl would like to mean that the safety of its devices is a primary objective, and by issuing this FSN, Adria Srl wanted to maintain a prudent and collaborative approach, in order to manage the planned actions in the best possible way.

We apologize for any inconvenience this situation may cause and stay at your disposal for any clarification.

In faith

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Table A1 - list of goods delivered to your facility

Code	Lot number	Quantity delivered

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Headquarters: via Modena 46, 40017 San Giovanni in Persiceto (BO) - Italy
Warehouse and logistics: via San Francesco d'Assisi 15, 46020 Pegognaga (MN) - Italy
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