Rev 1: September 2018

FSN Ref: 02/2021 FSCA Ref: 02/2021

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 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 all the involved 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 Annex no. 1 you can find the list 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.

All batches of potentially non-sterile devices supplied to your company 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 items 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.

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Actions required of hospitals and health facilities

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

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 the distributor and Adria Srl for the handling of the involved goods.

Corrective Actions in place

Adria Srl is completing the qualification of 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.

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Yours faithfully

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Adria Srl