Rev 1: September 2018
FSN Ref: 01/2021 - finale FSCA Ref: 01/2021 - finale

Date: 15/07/2021

Urgent Field Safety Notice

Dear Customer,

Following the previous safety warnings sent, we hereby inform you of the issue of the final Field Safety Corrective Action related to the products described (Annex 1).

Explanation of the problem

Adria S.r.l. is a manufacturer of class IIa, IIb medical devices.
The devices are marketed in sterile form, after being subjected to sterilization by ethylene oxide by Steril Milano S.r.l.
ethylene oxide sterilization process performed by the company Steril Milano S.r.l.
We have received communication from the same sterilizer about the falsification of the parameters of process parameters of the sterilization cycles.
After conducting a thorough investigation accompanied by sterility tests and ethylene residue, and after initiating the recall and sending the previous safety notices to quarantine the goods and get information about the stocks, we inform you that we are proceeding with the destruction of the reported products.
We therefore ask you to proceed as reported below for the devices (listed in Annex 1) in stock at our distributors. As far as hospitals and health services are concerned, we request instead
the immediate return to the reference distributors or to Adria S.r.l. of the devices listed in Annex 1 previously quarantined.
In Annex 1 you can find the extract of the impacted lots.

Clinical Impact

The use of non-sterile devices may involve an increased risk of patient infection.
We would like to specify that Adria S.r.l. has never been notified of any adverse events or damage to patients potentially attributable to the problem object of this report.
There are no specific follow-up actions for patients on whom the product has already been used.

All batches of potentially non-sterile devices, supplied to your company, are listed in Attachment 1 "List Impacted batches".

Actions required to distributors and traders

1 - Return to Adria S.r.l. all products quarantined and withdrawn from hospitals/healthcare facilities, which fall within the lots reported in Annex 1 "List of Impacted batches",
OR
2 - Directly send the quarantined products withdrawn from hospitals/clinics, which are among the batches indicated in attachment 1 "List of Impacted batches", to the destruction/maceration.
3 - Notify Adria S.r.l. of the destruction by providing written confirmation by e-mail to qa@adriamedical.com indicating lot and number of pieces.
4 - Adria S.r.l. will replace the goods as soon as possible.

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Actions required to hospitals and health care facilities

Send the quarantined products to your reference distributor or to Adria S.r.l. who will arrange for their destruction/maceration.

Corrective Actions

We are proceeding with the destruction of the reported devices.
The new supplier of the sterilization service has been approved by our Notified Body, so we can resume production and the products will be replaced as soon as possible.

Contacts

For further information about this FSN please contact Adria S.r.l. at the number +39 3472441014 or by e-mail at qa@adriamedical.com or export@adriamedical.com or your distributor.
We confirm that the relevant authorities have been informed of the actions described herein.
We would like to signify that the safety of our devices is a primary objective for us, in issuing
this FSN we wanted to maintain a prudent and cooperative approach, we trust that we will handle the actions in the best possible way.
Thank you for the cooperation and we are available for any clarification.

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Yours faithfully

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Adria S.r.l.