

**Field Safety Notice  
Recall letter**



Diffuplast S.r.L.  
Via Piave 48,  
21057 Olgiate Olona (VA),  
Itália

Rev. 0 - 24/02/2021

To the attention of (*distributor name*),  
Diffuplast has been informed by its EO sterilization supplier that, after an internal review, the sterilization data received by Diffuplast differs from the original raw data.

The involved batches are:

Product name	Code	Batch	Quantity
<i>(Listed with distributors naming)</i>			

Based on the analysis of the original raw data, we can provide the following information: only the preconditioning cycle was affected, while the sterilization cycle and degassing cycle have been performed correctly, all the biological indicators have been processed correctly and all of them are sterile (no growth of the test organism). No information is yet available to assess whether the data recorded during routine processing meets the specifications of the sterilization process since a discrepancy in the data was found.

While waiting for the investigation to be completed, as a precaution, please stop the distribution of the involved products until further notice and perform the recall of the involved batches from end users.

To implement this recall, please perform the following actions:

1. Examine Your inventory and quarantine the affected products.
2. Discontinue the use and distribution of batch numbers listed above.
3. Inform Diffuplast of the quantity of affected medical devices in Your stock.
4. If the number of medical devices in Your stock differs from the original batch quantity, please request Your customers to return the affected devices and report to Diffuplast in which countries the devices have been distributed so that a FSN for end users can be issued.
5. If the number of medical devices in Your stock matches with the original batch quantity, please quarantine devices until the investigation is complete.

Diffuplast has sent an FSCA report to the relevant National Competent Authorities.

Your assistance is sincerely appreciated. Diffuplast apologizes for any inconvenience that this recall may cause to You and Your staff.

If You any question, please do not hesitate to contact us at number +390331640646 or write to [info@diffuplast.it](mailto:info@diffuplast.it).

