

Field Safety Notice Recall letter



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

23 March 2021

Dear [REDACTED]

Diffuplast has been informed by its EO sterilization supplier that, after an internal review, the sterilization certificates received by Diffuplast differs from the original raw data.

Based on the analysis of the original raw data the sterilization cycle could be compromised even if all the biological indicators have been processed correctly and all of them are sterile (no growth of the test organism). Diffuplast is intentionally conducting a recall from the market of the following medical devices:

Product name	Code	Batch	Quantity
Exacta Mix	E1402OD	M002FB	12.000 pcs
Exacta Mix	E1302OLPF	M002CB	7.200 pcs

Diffuplast has not identified any reports of adverse events to date that could be associated to this field safety corrective action. No specific patient follow-up activities are required if the product has already been used.

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 according to Distributor Reply Form.
4. In case You have already distributed some of the affected products, please identify Your customers and notify them of this product recall.
5. Please provide an acknowledgement form to Your customers to complete and return to You to track the numbers of devices in stock or used.
6. Please request Your customers to return the affected devices and quarantine them.
7. If the bags were already filled with parenteral solution and the sterility test is confirmed by compounding centres or hospital pharmacists on the involved batches, no recall is necessary.
8. This recall should be carried out to the final customer level if sterility test by compounding centres or hospital pharmacists is not confirmed.

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.

Giuseppe Vignati
Diffuplast S.r.l.

Distributor Reply Form

Please read in conjunction with FSN recall letter of 23 March 2021. Please return this form to info@diffuplast.it no later than 30 April 2021.

Distributor details:

Company name: _____

Contact name: _____

Email: _____

☐ I confirm the receipt, the reading and understanding of the FSN

☐ I have checked my stock and quarantine the inventory

Code	Batch	Quantity
E1402OD	M002FB	
E1302OLPF	M002CB	

☐ I have informed the identified customers of this FSN

Customer name	Address

☐ I confirm that the following affected units have been used, destroyed or returned

Customer name	Code	Batch	Quantity	Used, destroyed or returned

Signature and date: _____