

**Field Safety Notice for  
Parenteral nutrition bag  
Trade mark: Exacta Mix  
Recall letter**



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

June 05th, 2019

Dear Baxter SA,

Based on routine post-market surveillance Diffuplast S.r.l has become aware of an issue with some batches of Exacta Mix products. Diffuplast has identified that there is a possibility that the products detail in this FSN may have microleakages.

The defect in the products should be visible to the healthcare professional and trained user, however, if the user missed the defect, an infection could be caused. Diffuplast is not aware of any reports of patient harm.

The purpose of this letter is to advise you that Diffuplast is voluntary recalling the following medical devices which were distributed after March 2019.

<b>Description</b>	<b>Code</b>	<b>Batch</b>
Parenteral nutrition bag 2000ml	E1420OD	I034FE
Parenteral nutrition bag 3000ml	E1430OD	I034FF
Parenteral nutrition bag 2000ml	E1420OD5	I038NE
Parenteral nutrition bag 2000ml	E1420OD	I038FE
Parenteral nutrition bag 3000ml	E1430OD	I043FF

To implement this recall, please take the following actions:

1. Examine your inventory and quarantine the products affected by the recall.
2. Discontinue the use and distribution of the identified batch numbers.
3. In case You have already distributed some of the affected products, please identify Your customers and notify them of this product recall. Please provide an acknowledgement form to Your customers to complete and return to You to track the numbers of devices to be discarded and credited.
4. Maintain awareness of this FSN until all stock of the affected batches has been destroyed.
5. A credit note will be issued covering the cost of the recalled products.
6. This recall should be carried out to the final customer level.

Diffuplast confirms that a FSCA has been communicated to the relevant National Competent Authorities.

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

If You have any questions, please don't hesitate to contact us at number +39.0331.640646 or write at [info@diffuplast.it](mailto:info@diffuplast.it).

Yours faithfully,

*Giuseppe Vignati*  
*Diffuplast S.r.l*