

RECALL NOTIFICATION

30/07/2024

Attention: Distributors and users of the enteral syringe 1 ml NUTRIFIT

Dear Customer,

The purpose of this communication is to inform you of a product Field Safety Corrective Action (FSCA) initiated by PENTAFERTE ITALIA s.r.l.: a recall concerning 3 lots of the enteral syringes 1 ml NUTRIFIT.

Details on affected devices

The medical devices affected by this recall are stated in the following table:

Product description:	Enteral syringe 1 ml NUTRIFIT
REF:	1015.018
Involved LOTs:	26A05, 26D01, 26D02

Description of the problem

In some syringes 1 ml NUTRIFIT of the above-mentioned lots, the wall of the barrel, produced with cavity no. 5 of the mould, has a very small hole at the zero line, due to a problem of incomplete filling of the cavity by the polypropylene with which the semi-finished product is moulded. Obviously, the pierced barrel impairs the proper functioning of the syringe during both withdrawal and liquid administration.

How to identify affected products

The LOT number of the products is printed on the labels of each packaging level.

Actions to be taken by distributors and users:

- All distributors and users of the affected products shall read and take into consideration all instructions and information provided in this communication.
- A 100% physical inventory should immediately be performed to identify and remove affected product(s) from commercial distribution.
- If the distributor has further distributed affected product(s) to other persons or facilities, promptly forward a copy of this communication and *Reply Form* hereby attached to those recipients.
- Fully complete the attached *Reply Form* and return it to the following email addresses:

rosa.digioia@numantec.eu; rita.romagnoli@numantec.eu

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Product returns

We will contact you on receipt of the fully completed and signed the *Reply Form*, regarding the arrangement of product return and replacement.

We apologize for the inconvenience we cause you and will do our best to replace the non-compliant product as soon as possible.

Thank you for your cooperation

Best regards

