Urgent Field Safety Notice

Surefuser™ +
FSCA 2016/10/24
Type of action : Return of a Medical Device to the supplier

Date: 24/10/2016

Attention: Customer details

Details on affected devices:

Size	*Model Number*	*Lot Number*	*Quantity*	*Surefuser model*
250 ml	SFS-5-25P-EJ	15K28P	60	SurefuserPlus 250 ml 2D

Description of the problem:
Nipro has been informed about leakages between the infusion line and the filter (balloon side). After first investigations, it was found that this was due to a temporary low level of solvent used in the production process. This has been resolved and the manufacturer has been able to determine that the affected products have been limited to the above mentioned model number and lot number.
Additional investigations are still ongoing.

Advise on action to be taken by the user:
Please put the goods from these lot numbers in quarantine and do not further distribute or use them.
Our Quality department will contact you very soon with instructions on how to proceed with the goods.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Contact reference person:

Vanessa Windscheid / Ann Vankrunkelsven
Nipro Europe NV
Weihoek 3H
1930 Zaventem
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The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

[redacted]

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