

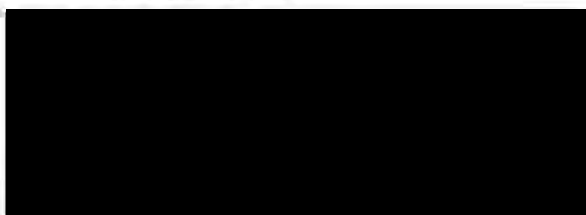
Urgent Field Safety Notice

Surefuser™ +

FSCA 2016/04/20

Type of action : Return of a Medical Device to the supplier

Date: 20/04/2016



Details on affected devices:

| <i>Size</i> | <i>Model Number</i> | <i>Lot Number</i> | <i>Quantity</i> | <i>Medac-Material Number</i> | <i>Surefuser model</i> |
|-------------|---------------------|-------------------|-----------------|------------------------------|------------------------|
| 100ml | SFS-1002DP | 15J05P | 6750 | 85910-2D | SurefuserPlus 100ml 2D |
| 250ml | SFS-5-25P | 15J16P | 1770 | 85920-2D | SurefuserPlus 250ml 2D |

Description of the problem:

Nipro has been informed about leakages between the infusion line and the filter. The investigation on the exact root cause of these issues is still in process.

Advise on action to be taken by the user:

Please put the goods from these lot numbers separately 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:

Ann Vankrunkelsven
Nipro Europe NV
Weihoek 3H
1930 Zaventem
Belgium



The undersign confirms that this notice has been notified the appropriate Regulatory Agency.



Ann Vankrunkelsven
Nipro Europe NV
Weihoek 3H
1930 Zaventem
Belgium

