

5 May 2016

URGENT FIELD SAFETY NOTICE – PRODUCT RECALL

Silo Bags for the treatment of gastroschisis (all serial numbers)

Attention: All Distributors, Nursing, Medical, and Technical staff using this product.

Reason for the Recall Notice

It has been identified that the manufacturing process for this product resulted in the risk of non-organic foreign particles (contamination) in the product. The root cause of this issue has been resolved for future manufacture. There have been no reports of adverse incidents relating to the use of the product to date, however there is a possibility that the current product contains foreign particles. Those particles could present a health risk to patients. All batches of the product currently distributed are therefore being recalled as a precautionary measure.

Details of Device

All SB03, SB04, SB05, SB06, SB35 and SB45 silo bags, all lot numbers.



Action to be taken

If you hold any of these silo bags, please remove them from use and contact Medicina to arrange the return/collection of these products.

Contact

Michelle Prescott

Unit 2, Rivington View Business Park

Station Road, Blackrod, Bolton, BL6 5BN

Email: michelle@medicina.co.uk

Tel: + 44 (0) 1204 695050

Fax: + 44 (0) 1204 697755

Medicina confirms that this FSN has been notified to the appropriate Regulatory Agency.

ACKNOWLEDGEMENT FORM

Recall Notice 5 May 2016

SB03, SB04, SB05, SB06, SB35 and SB45 silo bags for the treatment of gastroschisis

Please complete this form and return it to:

Michelle Prescott, Quality Assurance Administrator **FAX: 01204 697755**

Alternatively, this can be sent to us by **EMAIL: michelle@medicina.co.uk**

We hereby certify that we have received, read, and distributed this Product Recall Notice to anyone it may concern within our organisation.

Organisation _____

Account number (if known) _____

Department _____

Please tick the appropriate box:

- We have the following stock
- | | |
|--------------------------|------------|
| Code/Serial: _____/_____ | QTY: _____ |
| Code/Serial: _____/_____ | QTY: _____ |
| Code/Serial: _____/_____ | QTY: _____ |
| Code/Serial: _____/_____ | QTY: _____ |

(Please attach an additional sheet if required)

We are currently checking the quantity of the product

We have no stock to be returned of this product

The above product(s) were supplied to us directly by: _____

Signed _____

Print Name _____

Job Title _____

Contact number/email _____

Date _____