

27th October 2014

URGENT FIELD SAFETY NOTICE – PRODUCT RECALL

Medicina Gastrostomy Button (BXX/YY)

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

Reason for the Recall Notice

The safety and performance of these devices have not been properly evaluated and so the CE marking of the device is not valid. We therefore advise that the product is recalled from the market.

Details of Device

Medicina Gastrostomy Button BXX/YY where XX is the size of the button in French gauge and YY is the length of the button in centimetres.



All Batch/lot numbers and sizes of the Medicina Low Profile Gastrostomy Button to be are to be recalled.

Action to be taken

If any you hold any stock of Medicina Gastrostomy Buttons we advise that the following actions are taken:

1. Contact Medicina using the details below and either return to Medicina or Medicina will make arrangements for collection.

Contact

Carol Cole
Quality Assurance
Unit 2
Rivington View Business Park
Station Road
Blackrod
Bolton
BL6 5BN
Email: carol@medicina.co.uk

Tel: +44 (0) 1204 695050
Fax: +44 (0) 1204 697755

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

FAX BACK FORM
Recall Notice – October 2014
BXX/YY Medicina Gastrostomy Buttons

Please fax back to: Carol Cole, Quality Assurance, and **Fax:** +44 (0) 1204 697755

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

Hospital/Depot:

Name:

Department:

Function:

Date:

Print name.

Signature: