[redacted]

URGENT FIELD SAFETY NOTICE

Device Name: Access Port Needle 10-Pack, 20 G x 51mm (2 in.)
FSN Ref and Date: FSN/B-20302-10/18MARCH2011
Type of Action: Product recall of Product Code: B-20302-10
Scope: Lot Number: 9L01N

Date

Dear Health Care Provider:

This letter provides important information on a recall of the Access Port Needle 10-Pack products in Lot 9L01N. Our records indicate that you have received a shipment of Lot 9L01N.

Product description:
20 gauge, 51mm (2 in.) length non-coring deflected tip (Huber) needle, used with the LAP-BAND™ System for band adjustment. Only Product Code B-20302-10 with Lot Number 9L01N is affected.

Description of the issue:
Allergan has determined that a small number of Access Port Needle pouches from one specific lot may have small gaps in a pouch seal. Consequently the product may no longer be sterile. No customer complaints or reports of infection regarding the Lot 9L01N product have been received to date.

Clinical implications and recommendation:
The gap in the pouch seal could result in a loss of sterility of the product and potential contamination of the needles. Theoretically, this could result in infection, including port-site infection, contamination of the fluid in the LAP-BAND™ System, or infection due to a needle-stick injury to the patient or medical personnel. If infection were to occur, it should be treated as clinically required.

Action requested:
Please review your inventory of the Access Port Needle, Product Code B-20302-10, immediately to see if you have any remaining inventory of Lot Number 9L01N. Please remove any Lot Number 9L01N from your inventory, ensure that product within this lot will not be used for patient care, and contact Allergan Medical Product Support at productsupport_eame@allergan.com or +44 (0)1628 494456 for return and immediate replacement.

If any infection has occurred in a patient treated using needles from this lot, please report this promptly to Allergan Medical Product Support at productsupport_eame@allergan.com or +44 (0)1628 494456 and indicate that a needle from this lot was used.

We apologize for any inconvenience this incident may have caused you and appreciate your assistance in completing the requested information. If you have questions regarding this recall, please contact Allergan Medical Product Support at the number cited above.

Sincerely,

[redacted]
Director, Global Product Support, EAME Regulatory Affairs
Allergan Medical

Attachments:
FSN Physician Acknowledgement Form