



Medtronic

Urgent Field Safety Notice - Medtronic on behalf of Argon Medical

KYPHON® 11 Gauge Bone Access Needle (Model A02A)

Lot Number 11088329

Recall

June, 2015

Dear Risk/Materials Manager,

This letter is to inform you that you have received product associated with a voluntary recall being conducted by Argon Medical. The scope of this recall includes one lot of KYPHON® 11 Gauge Bone Access Needles (Model# A02A Lot number 11088329) which are used to obtain percutaneous access to bone. Argon Medical announced the voluntary recall [copy attached], advising Medtronic as follows:

“Argon Medical received a customer report of a potential defect in the forming of the primary package of the blister that may compromise the sterility of the product inside the tray. Argon Medical has evaluated all in-house inventories, and the expected defect rate is extremely small. As a precautionary measure, Argon Medical is conducting a voluntary recall to notify customers of the potential of this packaging defect.”

Neither Argon Medical nor Medtronic has received any reports of patient harm or infection attributed to this issue; however, invasive medical procedures conducted using non-sterile products could result in an infection for the patient.

Your Sales Representative will contact you to facilitate the return of any impacted products you may have in your possession. Please disseminate this information to additional personnel within your facility as appropriate.

Instructions to Customers:

- 1.) Please locate and remove the product (Model# A02A Lot 11088329) from normal storage locations. Do not use this product.
- 2.) Return any unused affected inventory to Medtronic.

If you have any questions or concerns, please do not hesitate to contact your Medtronic Sales Representative at <XXXXX>.

We sincerely apologize for this inconvenience, but this action is necessary to assure that our high standard of quality is maintained.

Sincerely,