



Urgent–Product Recall Notice

30th Jun 2015

Dear Hospital Administrator,

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 has conducted an internal evaluation of all in-house inventories, and the expected rate of this defect is extremely small. As a precautionary measure however, Argon is conducting a voluntary recall to notify our customers of the potential packaging defect of the following devices.

DBMNI1601 BMHN130LLVX DBMNJ1104TL DBMNI1501 DBMNJ0804TL

Invasive medical procedures conducted using non-sterile products could result in an infection for the patient. **To date, there have been no reports of patient harm or infection attributed to this issue.** Argon has identified the cause in the manufacturing process, and corrective actions and inspections have been implemented to prevent this from happening again in the future.



Please examine your inventory immediately to determine if you have any of the devices cited above. If so, discontinue use of the devices specified.

The package will not deteriorate over time; if there are no holes in the current package/inventory then the product integrity has not been compromised and it is not necessary to return any product to Argon. However we do ask that you kindly complete Attachment A and return the enclosed response immediately in the enclosed, postage paid envelope even if you do not have the device(s) identified in your possession.

If you determine that any of your inventory shows the package defect described above, please discontinue use of these devices and promptly return the affected products and the completed Attachment A to your distributor at the address provided below. Please contact your distributor for instructions on how to return the affected products free of charge. You can contact the Sales Representatives by calling **Mark Cathedral** or by email at **mark@singmed.com.sg**.

**Singmed Healthcare Systems
10 Ubi Crescent #05-18
Ubi Techpark (Lobby B)
Singapore 408564**

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Tel: (65) 6547 4916

Fax: (65) 6547 4925

Email: singmed@singmed.com.sg

Replacement units will be provided by Argon Medical Devices. Your distributor will make arrangements for replacements.

Argon Medical is coordinating this recall action with the Health Sciences Authority-Singapore. Your assistance in accounting for the affected devices in your possession is greatly appreciated.

Argon Medical is committed to providing our customers with high-quality, effective medical devices. We take this commitment seriously and understand that on rare occasion, actions such as this may be necessary to uphold that commitment. Thank you for choosing to do business with Argon Medical and we apologize for any inconvenience this action may cause you.

Sincerely,

Beckie Ellis,
Vice President, Regulatory Affairs/Quality Assurance
Argon Medical Devices, Inc.

Attachment A – Argon Recall Bone Biopsy Blister Pack, RMA#15697, Product Recall Report

Urgent—Product Recall Notice

Attachment A:
Argon Recall: Bone Biopsy Blister Pack
Argon Medical Devices, Inc.
1445 Flat Creek Road,
Athens, TX 75751 USA

RMA# 15697
Product Recall Report
Argon Medical Devices

- We do not have any of the stock listed below on hand.
- We have recalled devices, Argon Bone Marrow Biopsy Needles with below listed lot numbers on hand and are returning the below indicated.

Part Number	Lot Number	# of units shipped to your facility	# Currently on hand at your facility	# to be returned to Singmed Helathcare Systems
DBMNJ1104TL	11088596			

Signature

Name

Title

Date

*(Affix mailing label here)
This will allow you to match easily in
case a different individual signs the return
letter.)*