



## Urgent—Field Safety Notice

22 June 2015

Dear Physician, Clinician, Hospital Administrator, or Distributor

Argon Medical is conducting a field safety corrective action of specific lots of the T-Lok™ Bone Marrow Biopsy products listed below.

**Affected Model Numbers:**

**DBMNI1501  
DBMNJ1104TL**

**DBMNI1601  
A02A**

**DBMNJ0804TL**

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 recall to notify our customers of the potential of this packaging defect.

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.



Our distribution records indicated that some of the potentially affected products were shipped to your facility. Please examine your inventory to determine if you have any of the devices specified on the Affected Product List in Attachment A at your facility.

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. Please return the completed Attachment using the postage-paid envelope provided.

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 Argon Medical at the address provided below. Please contact Argon Medical Customer Service for instructions on how to return the affected products free of charge. You can contact one of our Customer Service Representatives by calling +41 (0)21 560 57 31 or by email at [customer.service@argonmedical.com](mailto:customer.service@argonmedical.com).

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RMA# xxxx  
Argon Medical Devices, Inc.  
DSV Solutions N.V.  
Eddastraat 21  
BE-9041 Gent

Argon Medical will proactively ship you replacement products once we receive your returned product and a completed inventory assessment from Attachment A.

Argon Medical confirms that this notice has been notified to the appropriate Regulatory Agency. Your assistance in accounting for the affected devices in your possession is greatly appreciated. If you have any questions about this letter or the recall action it describes please contact Customer Service at +33 2 99 68 94 95 or at [info-europe@argonmedical.com](mailto:info-europe@argonmedical.com)

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

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ATTACHMENT A  
Argon Recall: Bone Biopsy Blister Pack  
Argon Medical Devices, Inc.  
DSV Solutions N.V.  
Eddastraat 21  
BE-9041 Gent

RMA# xxxx  
Product Recall Report

**Argon Staff to prepare personalized listing based on shipment history**

Part Number	Lot Number	# of units shipped to your facility	# Currently on hand at your facility	# Inspected and holes found	# To be returned to Argon

\_\_\_\_\_  
Signature of Individual Completing Inventory

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Facility Name

\_\_\_\_\_  
Contact Phone Number for Questions

\_\_\_\_\_  
Date Completed

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