
Urgent Field Safety Notice

2017-05-24

RE: URGENT MEDICAL DEVICE RECALL FIELD SAFETY NOTICE (FSN)

Date: 24 May 2017

Attention: Product Safety Officer

Details on affected devices:

ARGON ARTERIAL ACCESS NEEDLE

Lot Number	***Model Number***	***Description***
11161099	*195318*	*7cm x 18G AMC/4*
11160990	*195352*	*7cm x 18G AMC/4*

Description of the problem:

Argon Medical has received a complaint from one of our distributors of a potential packaging defect. The product is sealed in a pouch and the defect if present shows as a potential void or unsealed edge of the pouch. Argon has conducted an internal investigation and has determined that the risk is limited to any products packaged on December 15, 2016. Argon has examined all in-house inventories, and the expected rate of this defect is small. This type of defect is visible with the naked eye. The product literature warns the user to not use this product if the packaging is opened or damaged.

As a precautionary measure however, Argon is conducting a FSCA to notify our customers of the potential of this packaging defect. Theoretically, there is a risk that if product from an unsealed pouch is used that the product might have become contaminated post sterilization and if used during an invasive medical procedure, such an occurrence 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.

Advise on action to be taken by the user:

The package will not deteriorate over time; if there are no gaps or voids in the current package/inventory then the product integrity has not been compromised and it is not necessary to return any product to Argon. Even so, Argon asks that the distributor or user facility kindly complete the status survey below and return it to Argon so that we may complete our FSCA activity.

Part Number	Shipping Date	Lot Number	# of units Shipped to you (boxes of 10)	# Currently on hand at your facility	Number Inspected and holes found	Number to be Returned to Argon

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. Products may be returned using **FEDEX number 281807340**.

RGA#23697

Argon Medical Devices, Inc.

1445 Flat Creek Road,

Athens, TX USA 75751

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for the next 60 days to ensure effectiveness of the corrective action.

Contact reference person:

Beckie Ellis,
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Email: beckie.ellis@argonmedical.com
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The undersign confirms that this notice has been notified the appropriate Regulatory Agency

Sincerely yours,

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