Urgent—Field Safety Notice

Urgent Field Safety Notice

DEVICE: Double Male Luer Lock Adapter, Septishield II 80 cm, Stopcock 1-Way Clear with Male Luer Lock, 4-WAY Stopcock with Male Luer Lock
FSCA: 2018-10-22-1, 2018-10-22-2, 2018-10-22-3
RECALL- Return to Argon Medical Devices, Inc.

Date: 23 October 2018

Attention: MEDICA EUROPE/MAXXIM EUROPE
ATT: MEDICA EUROPE
WAALKADE 12,
5347 KS OSS, NETHERLANDS

Argon Medical has identified an internal manufacturing issue on the formation of the sterile seal on some of our pouched product. Because of damage to a packaging die there is a possibility that the seal formed on the edge of the pouch may be incomplete for some product, which could result in a loss of sterility to the affected product. Argon is recalling all product packaged with that die to prevent the inadvertent use of a potentially non-sterile device. In addition to our communications to the field we will be communicating this issue to the US FDA and other Competent Authorities, as well as our Notified Body.

Our records indicate that we have shipped the following affected units to your organization.

Argon Part Number	Shipping Date to your facility	Lot Number	Number of units Shipped to your facility (boxes of 25)
497302	09/20/18 and 10/04/18	11228251	2 boxes of 25 units
041216000A	09/20/18	11226187	3 boxes of 25 units
041210002A	09/20/18	11226656	4 boxes of 25 units
040184000A	10/04/18	11231393	5 boxes of 25 units

The inventory sheet at the end of this letter helps us know what product is still in your possession. We request that you complete this form and return it as quickly as possible to our attention. This will allow us to begin staging replacement product to you and minimize interruption to service. All affected

product should be returned to our Argon Athens facility using RGA#24932, attention Arbee Cummings. The mailing address is listed below:

RGA# 24932
Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens, TX 75751 USA

Argon Medical will ship replacement devices once we receive your returned product. 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 me at Beckie.Ellis@argonmedical.com. You may also contact Ms. Arbee Cummings (Arbee.Cummings@argonmedical.com) or Ms. Kimberli Scott at Kimberli.Scott@argonmedical.com.

Argon is committed to providing our customers with high-quality, effective medical devices. We take this commitment seriously and understand that on rare occasion, corrective actions such as this recall 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.

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

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Sincerely,

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

Cc: Kimberli Scott, Quality and Compliance Manager

- *Please proceed to next page to respond to inventory on hand –*

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Argon Recall: Product Packaging – Potential Non-Sterile Product

Argon Medical Devices, Inc.
1445 Flat Creek Road,
Athens, TX 75751 USA
Attn: Ms. Arbee Cummings, Quality Specialist
Arbee.Cummings@argonmedical.com

RGA# 24932

Product Recall Report

Customer Address: **MEDICA EUROPE/MAXXIM EUROPE**
ATT: MEDICA EUROPE
WAALKADE 12,
5347 KS OSS, NETHERLANDS

Argon Part Number	Shipping Date to your facility	Lot Number	# of units Shipped to your facility (boxes of 25)	# Currently on hand at your facility	Number to be Returned to Argon
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040184000A	10/04/18	11231393	5 boxes of 25 units		

_____ _____
Signature of Individual Completing Inventory Printed Name

_____ _____
Title Date Signed by Facility Representative

Contact Phone Number:_____ Proposed Date to Return to Argon: _____