Urgent Field Safety Notice
BioPince™, BioPinceUltra™ and TruCore™ II Automatic Biopsy Instruments

04-Jul-2024

To: NAME
ADDRESS
CITY, STATE, ZIP

For the Attention of: Physician, Clinician, or Hospital Administrator,

Argon Medical Devices is conducting a Field Safety Corrective Action of specific lots of the following devices:

1. Information of Affected Devices		
Device Type – GMDN 22726 End-Cut biopsy gun handpiece / needle		
Commercial Name(s): BioPince™, BioPinceUltra™ and TruCore™ II Automatic Biopsy Instruments		
UDI-DI		
Primary Clinical purpose of device: Biopsy instruments intended to be used for harvesting multiple core specimens from soft tissue for clinical diagnosis.		
Device Model / Catalog Number(s): 360-1080-01, 360-1080-02, 360-1080-03, 360-1580-01, 360-1580-02, 360-1580-03, 360-2080-01, 360-2080-02, 360-2080-03, 370-1080-01, 370-1080-02, 370-1080-03, 370-1580-01, 370-1580-02, 370-1580-03, 763114100x, 763116100X, 763116160X, 763118100X, 763118200X, 763120100X, 763120160X, 763418200X, 763418250X, 763114200X		
Affected lot numbers: 11563436 11568010 11568790 11569552 11572560 11562475 11562476 11563678 11566932 11567139 11568361 11569013 11569844 11571094 11572044 11572886 11562477 11564861 11567888 11568554 11569845 11570075 11563438	11563439 11562478 11563440 11563682 11565238 11566882 11570132 11570814 11573339 11563442 11566173 11566883 11568153 11570288 11570813 11563564 11566036 11567992 11570142 11570863 11562964 11563922 11564189 11563443	11566936 11567889 11564795 11562608 11562748 11564843 11566037 11567890 11571101 11571360 11564844 11566690 11571100 11573030 11564366 11562114 11566038 11569846 11571824 11569414 11571104

Associated devices: N/A

2. Reasons for Field Safety Corrective Action (FSCA)

Description of product problem: Argon has received complaints of holes in the sterile barrier of the tray packaging for some products.

Hazard Giving Risk to the FSCA: Non-sterile product exposes patients to the possibility of the introduction of micro-organisms into the access site, leading to an infectious process, bacteremia, or sepsis. There is no risk to user, only the patient.

Probability of problem arising: It is estimated 0.29% of products subject to this recall may have the hole present.

Predicted Risk to patients / users: Evaluation through the HHE indicates the anticipated risk at less than .1% of patients exposed would encounter direct harm.

Background: Argon became aware of the issue through a product complaint. Investigation was immediately initiated. The root cause of the occurrence was determined to be associated with a manufacturing process. A corrective action has been initiated.

3. Type of Action to Mitigate the Risk

Action to be taken by the User:

☒ Identify Device ☒ Quarantine Device ☒ Return Device

The response form at the end of this notification helps us know what affected products are still in your possession. We request that you complete this form and return it to us as quickly as possible. Please return the product at Argon's expense to the mailing address below. Please be sure to clearly mark the return shipment with the returned good authorization number (RGA#) 28370.

RGA# 28370
Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens, TX 75751 USA
Attn: Arbee Cummings

Complete this action by: As quickly as possible, no later than **11-July-2024**

Is Customer Reply Required: Yes – using the response form and the instructions attached.

Action Being Taken by the Manufacturer: Argon is removing affected lots and has initiated a corrective action.

Is the FSN required to be communicated to patient / lay user? No, it is not required.

4. General Information

FSN Type: New

Further advice or information already expected in follow-up FSN? No

Manufacturer Information:
Argon Medical Devices Inc.

1445 Flat Creek Road
Athens, TX 75751
USA
www.argonmedical.com

The Competent (Regulatory) Authority of your country has been informed about this communication to customers.

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. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Our company is committed to provide 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. We apologize for any inconvenience this action creates for you or for your organization.

Sincerely,

Scott Bishop, MS
Vice President, Regulatory Affairs
Argon Medical Devices, Inc.

Cc: Jorge Garcia, Manager Quality & Compliance

Please proceed to next page to respond to inventory on hand

BioPince™, BioPince Ultra, and Tru-Core II Automatic Biopsy Instruments
Product Recall Response Form
RGA# 28370

Customer Address: NAME
ADDRESS
CITY, STATE, ZIP

I read and understand the instructions provided in the recall letter. I checked my stock and quarantined the items listed below.

Argon Part Number	Shipping Date to your facility	Lot Number	# of units Shipped to your facility	# Currently on hand at your facility	Number to be Returned to Argon
#	##/##/####	#	#		

Any adverse events associated with recalled product? ☐ Yes ☐ No

If yes, please explain: _____

_____

_____ _____
Signature of Person Completing Form | Printed Name of Person Completing Form

_____ _____
Title of Person Completing Form | Date Signed

_____ _____
Phone Number | Email Address

Proposed Product Return Date: _____

Please return the complete form to:
Attn: Arbee Cummings
Argon Medical Devices, Inc.
1445 Flat Creek Road,
Athens, TX 75751 USA
Arbee.cummings@argonmedical.com