

# Urgent Field Safety Notice BioPince<sup>™</sup>, BioPinceUltra<sup>™</sup> and TruCore<sup>™</sup> 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:

Commercial Name(s): BioPince™, BioPinceUltra™ and TruCore™ II A   UDI-DI   Primary Clinical purpose of device: Biopsy instruments intended to core specimens from soft tissue for clinical diagnosis.   Device Model / Catalog Number(s): 360-1080-01, 360-1080-02, 360-1580-03, 360-2080-01, 360-2080-02, 360-2080-03   370-1080-03, 370-1580-01, 370-1580-02, 370-1580-03, 763114100   763118100X, 763118200X, 763120100X, 763120160X, 763418200   Affected lot numbers:   11562085 11564330   11562114 11564330   11562475 11564366   11562476 11567889   11562477 11564366   11562478 11567890   11562478 11564843   11562815 11565238   11562478 11565618   11562481 11568361   11562483 11568454   11562436 11565618   11562438 11566036   11563436 11565619   11563436 11566036   11563438 11566036   11563430 11569844   11563440 11566038 11569846   11563443	1. Information of Affected Devices							
UDI-DI   Primary Clinical purpose of device: Biopsy instruments intended to core specimens from soft tissue for clinical diagnosis.   Device Model / Catalog Number(s): 360-1080-01, 360-1080-02, 360 1580-03, 360-2080-01, 360-2080-02, 360-2080-03   370-1080-03, 370-1580-01, 370-1580-02, 370-1580-03, 763114100   763118100X, 763118200X, 763120100X, 763120160X, 763418200X   Affected lot numbers:   11562085 11564330   11562114 11564331   11562475 11564366   11562476 11564366   11562477 11564795   11562478 11567899   1156268 1156789   11562478 11564843   11562478 11564861   11562478 11564861   11562478 11564861   11562478 11564861   11562478 11564861   11562478 11565618   11562478 11565618   11562478 11565618   11562436 11565618   11562436 11565618   11563436 11566037   11563438 11566036   11563	Device Type – GMDN 22726 End-Cut biopsy gun handpiece / needle							
Arimany Clinical purpose of device: Biopsy instruments intended to core specimens from soft tissue for clinical diagnosis.   Device Model / Catalog Number(s): 360-1080-01, 360-1080-02, 360-1580-03, 360-2080-01, 360-2080-02, 360-2080-03   370-1080-03, 370-1580-01, 370-1580-02, 370-1580-03, 763114100   763118100X, 763118200X, 763120160X, 763120160X, 763418200   Affected lot numbers:   11562085 11564330   11562114 11564331   11562475 11564366   11562476 11564594   11562477 11564795   11562478 11567992   11562608 11564843   11562478 11564861   11562608 11567992   11562478 11564843   11562478 11564861   11562478 1156518   11562478 11565618   11562815 11565619   11563436 11569013   11563438 1156037   11563439 1156037   11563430 11569846   11563443 1156037   11563443 11566173   11563673 11566213	Commercial Name(s): BioPince™, BioPinceUltra™ and TruCore™ II Automatic Biopsy Instruments							
Accore specimens from soft tissue for clinical diagnosis.   Device Model / Catalog Number(s): 360-1080-01, 360-1080-02, 360-1580-03, 360-2080-01, 360-2080-02, 360-2080-03   370-1080-03, 370-1580-01, 370-1580-02, 370-1580-03, 763114100   763118100X, 763118200X, 763120100X, 763120160X, 763418200   Affected lot numbers:   11562085 11564330   11562114 11564331   11562475 11564366   11562476 11564594   11562477 11564795   11562608 11564843   11562478 11564843   11562608 11564843   11562608 11564861   11562608 11564844   11562608 11564861   11562748 11565618   11562815 11565618   11562964 11565618   11563436 1156913   11563438 11566036   11563439 11566037   11563440 11566038   11563443 11566166   11563443 11566173   11563673 11566690   11563673 11566890	UDI-DI							
Device Model / Catalog Number(s): 360-1080-01, 360-1080-02, 3601580-02, 360-1580-03, 360-2080-01, 360-2080-02, 360-2080-03370-1080-03, 370-1580-01, 370-1580-02, 370-1580-03, 76311410763118100X, 763118200X, 763120100X, 763120160X, 763418200Affected lot numbers:1156208511564330115621141156433111562475115643661156247611564594115624771156479511562478115648431156247811564844115626081156788911562478115648611156260811564861115626081156486111562748115656181156281511565238115624761156561811563436115656191156343611566036115634381156603611563440115660361156344311566173115636731156621311563678115668821156367811566882	Primary Clinical purpose of device: Biopsy instruments intended to be used for harvesting multiple							
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### 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 🖾 Re

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

Argon Medical Devices, Inc 3

# 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

Argon Medical Devices, Inc 4

# BioPince<sup>™</sup>, 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?  $\Box$  Yes  $\Box$  No

If yes, please explain:

Signature of Person Completing Form

Title of Person Completing Form

Phone Number

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 <u>Arbee.cummings@argonmedical.com</u>

1445 Flat Creek Road, | Athens, TX 75751 www.argonmedical.com Printed Name of Person Completing Form

Date Signed

Email Address