



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

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](http://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.

***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:

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\_\_\_\_\_  
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](mailto:Arbee.cummings@argonmedical.com)