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

04-Jul-2024

To: «Cust_Name»
«Address_Line_1»
«Address_Line_2»
«Address_Line_3»
«City», «Postal_Code»
«Country»

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 00886333004379, 00886333224005, 00886333224012, 00886333004355, 00886333224029, 00886333224036, 00886333004348, 00886333224043, 00886333224050, 00886333004386, 00886333224067, 00886333224074, 00886333004362, 00886333224081, 00886333224098, 00886333006649, 00886333006625, 00886333006618, 00886333006601, 00886333006588, 00886333006656, 00886333006564, 00886333006571, 00886333006809, 00886333006816

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:

11562085	11564330	11567139	11570814
11562114	11564331	11567888	11570863
11562475	11564366	11567889	11571058
11562476	11564594	11567890	11571061
11562477	11564795	11567992	11571063
11562478	11564843	11568010	11571065
11562608	11564844	11568153	11571094
11562748	11564861	11568361	11571100
11562815	11565238	11568554	11571101
11562964	11565618	11568790	11571104
11563436	11565619	11569013	11571360
11563438	11566036	11569414	11571824
11563439	11566037	11569552	11572044
11563440	11566038	11569844	11572175
11563442	11566106	11569845	11572456
11563443	11566173	11569846	11572560

11563564	11566213	11570075	11572868
11563673	11566690	11570132	11572886
11563678	11566882	11570142	11573030
11563682	11566883	11570288	11573300
11563922	11566932	11570356	11573339
11564189	11566936	11570813	

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 UK Ltd
Eastgate Business Centre, Eastern Avenue,
Burton on Trent, DE13 0AT, UK
Attn: Mark Thurley

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: «Cust_Name»
«Address_Line_1»
«Address_Line_2»
«Address_Line_3»
«City», «Postal_Code»
«Country»

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
«Item_Number»	«Date»	«LotSerial»	«EACH»		

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 by email to:
Attn: Mark Thurley
Argon Medical Devices UK Ltd
Eastgate Business Centre, Eastern Avenue,
Burton on Trent, DE13 0AT, UK
uksales@argonmedical.com