# Urgent—Field Safety Notice

## Urgent Field Safety Notice

**DEVICE: SuperCore Semi-Automatic Biopsy Instrument**
**FSCA: 1625425-09/30/2021-001-R**
**RECALL- Return to Argon Medical Devices, Inc.**

Date: October 4, 2021

**Re:** RECALL - **SuperCore Semi-Automatic Biopsy Instrument**

Dear Physician, Clinician, or Hospital Administrator,

Argon Medical Devices has received complaints that the SuperCore™ Semi-automatic Biopsy Instrument is coming apart during shipping or prior to use. Because it occurs prior to use, there is very little risk of harm to the patient. If the device becomes disassembled, it cannot be used.

Argon has conducted an internal investigation and tracked the affected parts to a narrow time frame resulting from a specific manufacturing event. The plastic housing and plunger can be separated more easily than normal for the lots manufactured during this time frame.

To ensure continued customer satisfaction, Argon Medical Devices has decided to issue a Field Safety Corrective Action of the affected lots because of the high rate of reports of unintentional disassembly of these devices. The appropriate authorities have been notified.

The recall is of certain lot numbers and catalog numbers of the SuperCore products listed below:

| Item Number | Lot Numbers |
|---|---|
| 701114090 | 11364350 |
| | 11365643 |
| | 11368388 |
| | 11371872 |
| | 11374998 |
| 701114150 | 11368389 |
| 701116090 | 11362716 |
| | 11363320 |
| | 11365935 |
| | 11377634 |
| 701118090 | 11362759 |
| | 11363229 |
| | 11364420 |
| | 11367439 |

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

| | |
|---|---|
| | 11370106 |
| | 11372917 |
| | 11376074 |
| 701118150 | 11370107 |
| | 11375663 |
| | 11377819 |
| 701118200 | 11372225 |
| | 11374410 |
| | 11377431 |
| 701120090 | 11374411 |
| 701120150 | 11367440 |
| | 11376374 |
| 701120200 | 11366253 |
| 701214090 | 11369916 |
| 701214150 | 11377967 |
| | 11382843 |
| 701216090 | 11364421 |
| | 11367443 |
| | 11374684 |
| | 11379724 |
| 701216150 | 11382845 |
| 701218090 | 11361701 |
| | 11364247 |
| | 11367445 |
| | 11372366 |
| | 11374807 |
| 701218150 | 11371404 |
| | 11373084 |
| | 11377636 |
| 701218200 | 11377432 |
| | 11382998 |
| 701220090 | 11367446 |
| | 11370574 |
| | 11375664 |
| 701220150 | 11368750 |
| | 11371876 |
| | 11372228 |
| 701220200 | 11362655 |
| | 11363516 |
| | 11372322 |
| | 11378295 |

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All customers who were shipped affected lots are being advised to return all unused product to our Argon Athens, Texas, facility **using RGA#26683, attention Andrea Wieczor**. The mailing address is listed below:

**RGA# 26683**
**Argon Medical Devices, Inc.**
**1445 Flat Creek Road**
**Athens, TX 75751 USA**
**Att: Andrea Wieczor**

Argon Medical will ship replacement devices upon receipt of returned product. If you have any questions about this letter or the FSCA it describes please contact me at Brian.Rogers@argonmedical.com. You may also contact Arbee Cummings at Arbee.Cummings@argonmedical.com or Andrea Wieczor at Andrea.Wieczor@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 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.

Sincerely,

Brian Rogers
Director, Post-Market Experience
Argon Medical Devices, Inc.

Cc: Andrea Wieczor, Quality and Compliance Manager

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## Acknowledgement Form

**Argon Recall: SuperCore Disassembly**
Argon Medical Devices, Inc.
1445 Flat Creek Road,
Athens, TX 75751 USA
Attn: Arbee Cummings

## RGA# 26683
**Product Recall Report**

**Customer Address:** _____
_____
_____

| Argon Part Number | Shipping Date to your facility | Lot Number | # of units Shipped to your facility (boxes of 10) | # Currently on hand at your facility | Number to be Returned to Argon |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

_____ _____
Signature of Individual Completing Inventory Printed Name

_____ _____
Title Date Signed by Facility Representative

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