Urgent—Field Safety Notice

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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

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	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: _____