



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: November 2, 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 specific change to the manufacturing process. All lots manufactured after that change was made are being recalled. 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 for certain lot numbers and catalog numbers of the SuperCore products listed below. The reason that this FSN is being resent is because some additional lots have been added to the scope of the recall. The new lots are identified below with “No” under “Included in Original FSN Scope?”

Item Number	Lot Number	Included in Original FSN Scope?
701114090	11364350	Yes
	11365643	Yes
	11368388	Yes
	11371872	Yes
	11374998	Yes
	11376772	No
	11378864	No
	11382837	No
701114150	11368389	Yes
701116090	11362716	Yes
	11363320	Yes

Urgent—Field Safety Notice

	11377634	Yes
	11388461	No
701118060	11361702	No
	11365788	No
	11371012	No
	11374235	No
	11376598	No
	11379722	No
	11382768	No
	11383890	No
701118090	11362759	Yes
	11363229	Yes
	11367439	Yes
	11370106	Yes
	11372917	Yes
	11376074	Yes
	11377430	No
	11378217	No
	11383193	No
	11383785	No
	11384243	No
701118150	11370107	Yes
	11375663	Yes
701118200	11372225	Yes
	11377431	Yes
	11384193	No
	11388505	No
701120090	11374411	Yes
	11383280	No
701120150	11366252	No
	11367440	Yes
	11376374	Yes
701120200	11366253	Yes
701214090	11369916	Yes
	11378293	No
	11383587	No
701214150	11377967	Yes
701216090	11367443	Yes
	11374684	Yes
701216150	11388550	No
701218090	11361701	Yes

Urgent—Field Safety Notice

	11364247	Yes
	11367445	Yes
	11374807	Yes
	11378687	No
	11383784	No
701218150	11371404	Yes
	11373084	Yes
	11377636	Yes
	11387833	No
701218200	11366315	No
	11372227	No
	11377432	Yes
701220090	11375664	Yes
	11381572	No
701220150	11372228	Yes
	11376375	No
	11377429	No
	11380104	No
	11384717	No
701220200	11362655	Yes
	11363516	Yes
	11378295	Yes
	11380103	No

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

RG# 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,

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

Urgent—Field Safety Notice



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

Cc: Andrea Wieczor, Quality and Compliance Manager

Urgent—Field Safety Notice

Acknowledgement Form

Argon Recall: SuperCore Disassembly

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

RG# 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: _____