



Urgent—Field Safety Notice

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DEVICE: TLAB Transjugular Liver Biopsy System

FSCA: 2020-12-10-1

RECALL- Return to Argon Medical Devices, Inc.

Date: December 10, 2020

Re: **RECALL - TLAB Transjugular Liver Biopsy System**

Dear Physician, Clinician, or Hospital Administrator,

Argon Medical received complaints from our customers regarding the TLAB Transjugular Liver Biopsy System for a potential defect of the 7F Introducer Sheath, where the distal tip can potentially separate during use if the tip is flexed or experiences lateral bending stresses. Argon has conducted an internal investigation and has determined that an error in the production process resulted in a small number of devices that could potentially have this defect. Actions have already been identified and implemented to improve the process.

As a precautionary measure, Argon is conducting a recall to notify our customers of the potential separation of the 7F Introducer Sheath distal tip that is included in certain TLAB kits. In addition to our communications to the field, we will also be communicating this issue to the US FDA and other Competent Authorities, as well as to our Notified Body.

Argon has identified the cause in the manufacturing process, and corrective actions and inspections have been implemented to prevent this from happening again in the future.

The recall is of certain lot numbers of six specific catalog numbers of the TLAB product listed below:

Item Number	Lot Number
TL-18C	1394204
	1424962
	1464709
	1473181
	1477229
	1481735
	1495182
TL-18N	1419198
	1467762
	1473975
	1502312

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TL-18S	1419196
	1460291
	1469844
	1502325
TL-19	1428364
	1451428
	1486448
TL-19N	1439836
	1451430
	1486441
TL-19S	1439835
	1451429
	1486445

All customers who were shipped affected lots are being advised to return all unused product to our Argon (Athens, TX) facility using RGA#26124, attention Arbee Cummings. The mailing address is listed below:

RGA# 26124
Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens, TX 75751 USA

Argon Medical will ship replacement devices once upon receipt of returned product. If you have any questions about this letter or the FSCA it describes please contact me at beckie.ellis@argonmedical.com. You may also contact Mr. Brian Rogers at brian.rogers@argonmedical.com or Ms. 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.

Sincerely,

xxx
Argon Medical Devices, Inc.

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Acknowledgement Form

Argon FSCN: Potential Sheath Distal Tip Separation Defect

Argon Medical Devices, Inc.

1445 Flat Creek Road,

Athens, TX 75751 USA

Attn: Ms. Arbee Cummings, Quality Specialist

Arbee.Cummings@argonmedical.com

RG# 26124

Product Recall Report

Customer Address: _____

Argon Part Number	Shipping Date to your facility	Lot Number	# of units Shipped to your facility (boxes of ____)	# 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: _____