# Urgent—Field Safety Notice

## Urgent Field Safety Notice

**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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www.argonmedical.com

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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,

Beckie Ellis
Vice President, Regulatory Affairs/Quality Assurance
Argon Medical Devices, Inc.

Cc: Andrea Wieczor, Quality and Compliance Manager and Brian Rogers, Director of Post-Market Experience

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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

## RGA# 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: _____