TERUMO MEDICAL CANADA INC.
TERUMO MÉDICALE CANADA INC.

URGENT PRODUCT RECALL NOTICE

Date: December 14, 2020

To: Sir / Madam

Re: RECALL - TLAB TRANSJUGULAR LIVER BIOPSY SYSTEM

Dear Physician, Clinician, or Hospital Administrator,

Argon Medical Devices, Inc. ("Argon") has received complaints from 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 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 all customers of the potential separation of the 7F Introducer Sheath distal tip that is included in certain TLAB kits.

The voluntary recall of the affected TLAB kits is listed below. Our distribution records indicate that these devices were shipped to your facility by Terumo Medical Canada Inc.

In addition to our communications to the field, we will be communicating this issue to Health Canada.

Our records indicate that we have shipped the following affected devices to your organization.

Argon Part Number	Shipping Date to your facility	Lot Number	Number of units Shipped to your facility

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The Acknowledgement and Receipt Form at the end of this letter helps us know what device is still in your possession. We request that you complete this form and return it as quickly as possible to our attention. This will allow us to begin staging replacement device(s) to you and minimize interruption to service. **It is requested that this form still be completed and returned even if there are none of these devices currently in your possession.**

If you have device(s) to return, please reach out to Terumo Medical Canada Inc. ("TMCI") Customer Service Team via email (TerumoCanadaCustomer.Admin@terumomedical.com) or phone 833.883.7866 to request an RMA# for your return. All affected devices should be returned to TMCI facility using Recall reference: **TLAB Recall 2020**, attention Atchadev Bhangroop. The mailing address is listed below:

TLAB Recall 2020
TERUMO MEDICAL CANADA INC.
10911 KEELE STREET UNITS 2-4
VAUGHAN ON, L6A 5A6

TMCI will provide credit for your devices once we receive your returned device(s) at the address above. Your assistance in accounting for the affected devices in your possession is greatly appreciated. If you have any questions about this letter or the recall action it describes please contact Atchadev Bhangroop at atchadev.bhangroop@terumomedical.com.

TMCI 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 recall may be necessary to uphold that commitment. Thank you for choosing to do business with TMCI and we apologize for any inconvenience this action may cause you.

Sincerely,

Kimberly Feitl
Director, Quality Systems & Compliance
Terumo Medical Corporation

- *Please proceed to next page to respond to inventory on hand –*

MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form (Response is Required)

TLAB Recall 2020: TLAB TRANSJUGULAR LIVER BIOPSY SYSTEM
TERUMO MEDICAL CANADA INC. (TMCI)
10911 KEELE STREET UNITS 2-4
VAUGHAN ON, L6A 5A6

Attn: Mr. Atchadev Bhangroop (atchadev.bhangroop@terumomedical.com)

I have read and understand the recall instructions provided in the letter. ☐ Yes ☐ No

Have you experienced any adverse events associated with recalled product? ☐ Yes ☐ No

If yes, please explain:

Argon Part Number	Shipping Date to your facility	Lot Number	# of units Shipped to your facility	# Currently on hand at your facility	Number to be Returned to TMCI

If you have questions or need assistance, please reach out to Terumo Medical Canada Inc. Customer Service Team via email (TerumoCanadaCustomer.Admin@terumomedical.com) or phone 833.883.7866.

Signature of Individual Completing Inventory

Printed Name

Title

Date Signed by Facility Representative

Contact Phone Number:

Proposed Date to Return to TMCI: