TERUMO MEDICAL CANADA INC.
TERUMO MÉDICALE CANADA INC.

URGENT PRODUCT RECALL NOTICE

Date: December 3, 2019

To: Sir / Madam
Hôpital Maisonneuve-Rosement
5415 Boulevard Assumption
Montreal (Quebec)
H1T 2M4

Re: RECALL - BIOPINCE™ AUTOMATIC FULL CORE BIOPSY INSTRUMENT

Dear Physician, Clinician, or Hospital Administrator,

Argon Medical Devices has received a complaint from customers regarding incorrect labelling information on one lot of BioPince. The complaint alleges that the box label is correct for the 16ga x 15cm; however, the tray label is incorrect (18ga x 15cm). An internal investigation determined the root cause to be a data entry error into the Labeling software. Argon has examined all in-house inventories, and the issue identified traces back only to this lot.

This type of labeling error can be seen with the naked eye and users should double-check the tray label before using the product. Users can recognize the color code on the product to distinguish between 16ga versus 18ga.

As a precautionary measure, Argon is conducting a recall to notify our customers of this labeling error. Theoretically, there is a risk that if product is used with the wrong product dimension, those units could contribute to heightened risk associated with the procedure.

To date, there have been no reports of patient harm attributed to this issue. 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 voluntary recall is of one specific lot of the BioPince product 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 units to your organization.

Argon Part Number	Shipping Date to your facility	Lot Number	Number of units Shipped to your facility
370-1580-01	10/29/2019	11277175	5

URGENT PRODUCT RECALL NOTICE

The inventory sheet at the end of this letter helps us know what product 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 product to you and minimize interruption to service. All affected product should be returned to Terumo Medical Canada Inc. (TMCI) facility using RGA#52681, attention Atchadev Bhangroop. The mailing address is listed below:

RGA# 52681
TERUMO MEDICAL CANADA INC.
10911 KEELE STREET UNITS 2-4
VAUGHAN ON, L6A 5A6

TMCI will ship your replacement devices once we receive your returned product. 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 me 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 –*

Argon Recall: Product Packaging – Labeling Error

TERUMO MEDICAL CANADA INC. (TMCI)
10911 KEELE STREET UNITS 2-4
VAUGHAN ON, L6A 5A6

Attn: Mr. Atchadev Bhangroop, Quality Engineer

Atchadev.bhangroop@terumomedical.com

RGA# 52681

Product Recall Report

Customer Address:
Hôpital Maisonneuve-Rosement
5415 Assumption Blvd,
Montreal (Quebec)
H1T 2M4

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 Argon (TMCI)
370-1580-01	10/29/2019	11277175	5		

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 Argon TMCI: _____