Terumo Medical Canada Inc.
10911 Keele Street. Unit 2-4
Vaughan, Ontario
L6A 5A6

URGENT PRODUCT RECALL NOTICE

Date: October 07, 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.

Argon has conducted an internal investigation and tracked the affected parts to a narrow time frame resulting from a specific manufacturing event. 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 voluntary recall of the affected lots because of the high rate of reports of unintentional disassembly of these devices.

Our records indicate that we may have shipped the following affected units to your organization:

Argon Part Number	Lot Number	Number of units Shipped to your facility(boxes of 10)
701118090	11362759	130
701114090	11364350	120
701120200	11366253	160
701216090	11364421	130
701218090	11364247	250
701118090	11364420	1,500
701116090	11362716	60
701214090	11369916	110
701114090	11365643	60
701218090	11372366	150
701118090	11370106	230
701118150	11370107	160
701120150	11367440	150

701218090	11374807	110
701120150	11376374	290
701220200	11378295	40
701220200	11372322	20
701118090	11376074	360
701218150	11373084	90
701116090	11363320	300
701118150	11375663	120
701114090	11374998	60
701114150	11368389	20
701216090	11379724	30
701218200	11377432	60
701116090	11365935	100
701120090	11374411	220
701218150	11377636	50
701220090	11370574	50

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: SuperCore™ Semi-automatic Biopsy Instrument Recall 2021, Attention: Cristina Lorusso

The mailing address is listed below:

SuperCore™ Semi-automatic Biopsy Instrument Recall 2021
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:
Cristina Lorusso at cristina.lorusso@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)

SuperCore™ Semi-automatic Biopsy Instrument Recall 2021

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

Attention: Cristina Lorusso cristina.lorusso@terumomedical.com

Customer Address:

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 (individual completing inventory):	**Printed Name:**
Title:	**Date Signed by Facility Representative:**
Contact Phone Number:	**Proposed Date to Return to TMCI:**