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

URGENT PRODUCT RECALL NOTICE

Date: November 04, 2021

Re: RECALL - **SuperCoreTM Semi-automatic Biopsy Instrument** -Additional Lots

Dear Physician, Clinician, or Hospital Administrator,

Argon Medical Devices has received complaints that the SuperCoreTM 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 **additional** units to your organization:

Argon Part Number	Shipping Date	Lot Number
701214090	8/9/2021 & 8/18/2021	11378293
701214090	8/18/2021	11376598
701218200	8/25/2021	11372227
701220150	9/3/2021	11377429
701118060	9/3/2021 & 9/17/2021	11379722
701114090	9/14/2021	11376772
701118090	9/14/2021 & 9/17/2021	11377430
701218090	9/14/2021	11378687
701220150	9/14/2021 & 9/17/2021	11380104
701120150	9/17/2021,9/28/2021, 10/5/2021 & 10/6/2021	11377820

701118090	9/17/2021, 9/28/2021 & 9/30/2021	11378217
701118090	9/17/2021 & 9/30/2021	11383785
701218150	9/28/2021	11377636
701120090	9/28/2021 & 10/6/2021	11378865
701118060	9/30/2021	11383890
701220150	9/30/2021	11384717
701114090	10/5/2021	11382837
701220090	10/6/2021	11381572
701220200	10/6/2021	11382884
701118090	10/8/2021	11383193
701218150	10/8/2021	11383195
701116090	10/8/2021	11388461
701118060	7/15/2021	11371012
701118060	6/10/2021	11361702
701120150	6/25/2021	11366252

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

The mailing address is listed below:

SuperCoreTM 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)

SuperCoreTM 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:**