ATTENTION: RISK MANAGER/MATERIALS MANAGER

URGENT MEDICAL DEVICE RECALL NOTIFICATION

BARD® MAX-CORE® Disposable Core Biopsy Instrument

September 28, 2017

Dear Valued Customer,

cc: Chairman Medical Board and relevant Head of Departments

This letter is to inform you of a voluntary product recall initiated by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of C.R. Bard, Inc. Specific product code / lot number combinations of BARD® MAX-CORE® Disposable Core Biopsy Instruments are affected as outlined in Attachment 3. Our records show that your facility has purchased one or more of the affected product code / lot number combinations.

All other product code / lot number combinations not listed in Attachment 3 can continue to be used by your facility as they are safe to use and are not affected by this product recall.

Reason for Recall:

BPV has identified that the product code / lot number combinations listed in Attachment 3 may be at risk of having issues related to proper functioning of the device. This includes difficulty with priming and firing, failure to obtain tissue sample, and in some instances self-activating after priming.

Clinical Risk Statement:

In most cases, the identified issues (failure to prime, failure to fire, failure to obtain a sample) will lead to a varying degree of user dissatisfaction or may be associated with a prolonged procedure or minor tissue injury. Although unlikely to lead to user or patient injury consistent with a serious adverse event, the unpredictable nature of self-activation presents some risk to use of the product.

There is no residual risk to users or patients that used the product previously without incident.

Required Actions:

Please find attached instructions detailing the steps we are requesting you take regarding this product. The local regulatory authority has been made aware of this action and as such records of completion are subject to verification by the Authority. **BPV must document your compliance with this action.**

Please complete and return the attached Customer Acknowledgement Form as soon as possible to acknowledge your reading and understanding of this notice.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action. If there is any assistance that you require regarding this action please do not hesitate to contact your Bard representative.

Sincerely,

[redacted]

Mary Kennell
Director of Regulatory Affairs & Quality, ANZ and RoA
Bard Australia Pty Ltd

Attachment 1 – Instructions for Completing the Required Actions
Attachment 2 – Recall and Effectiveness Check Form
Attachment 3 – List of Affected Product Code / Lot Number Combinations

BARD | PERIPHERAL VASCULAR

Attachment 1
INSTRUCTIONS FOR COMPLETING REQUIRED ACTIONS

1. Our records show that your facility has purchased product codes affected by this voluntary recall. Do not use or further distribute any affected product.

2. Please check all inventory locations within your institution for affected product code / lot number combinations listed in the recall notice. If you have further distributed any of the product code / lot numbers, please immediately contact that location, advise them of the recall, forward these instructions and have them return the affected product to BPV.

3. Please remove any identified product from your shelves.

4. If you have used the affected product, complete and return the attached ***Recall and Effectiveness Check Form*** indicating no product will be returned.

Once the product affected by this recall has been removed from your inventory:

5. Fill out the ***Recall and Effectiveness Check Form*****.** Be sure to state the quantities and lot numbers of each recalled product that you intend to return. It is extremely important that we receive this information as soon as possible.

6. Email the completed ***Recall and Effectiveness Check Form*** to Complaints.Singapore@crbard.com, fax it to +65 6337 3588 or hand it to your Bard Sales Representative.

7. All recalled products should be returned to the following shipping address or handed to your Bard Sales Representative. The shipping address is:

   Bard Singapore Pte. Ltd.
   1 Harbourfront Avenue #04-11 to #04-13
   Keppel Bay Tower
   Singapore 098632
   Singapore

   Please mark the outside package as “RECALLED PRODUCT”.

8. Please report any new and/or previously unreported adverse events associated with this recall by emailing Complaints.Singapore@crbard.com.

BARD | PERIPHERAL VASCULAR

Attachment 2
RECALL AND EFFECTIVENESS CHECK FORM

BARD® MAX-CORE® Disposable Core Biopsy Instrument

Please complete this form and either email to Complaints.Singapore@crbard.com, fax it to +65 6337 3588 or hand it to your Bard Sales Representative.

Please PRINT your contact information and fill form out completely:

Name of facility:

Account #:

Address:

City: State: Zip:

Name:_____ Title:_____

Phone:_____ Date:_____

1. Do you currently possess any of the affected lots of product? (*Please check both consignment and purchased inventory for possible locations of this affected product.*)

   Yes_____ No_____

2. If you have affected product, do you intend to return the affected product?

   Yes_____ If YES, Total # of Pieces to be returned: _____

Product Code	Lot Number	Qty to be Returned

No_____If NO, please provide reason for not returning. [ ] Used [ ] Destroyed [ ] Other

BARD | PERIPHERAL VASCULAR

Attachment 3 – List of Affected Product Code / Lot Number Combinations
BARD® MAX-CORE® Disposable Core Biopsy Instrument

Product Code	Lot Number
MC1410	REBN2123
	REBP1199
	REBP1419
	REBP1807
	REBQ0084
	REBQ0343
	REBQ1012
	REBQ1904
	REBR0468
MC1616	REBP0019
	REBP1420
	REBP1809
MC1816	REBN0342
	REBP0869
MC1820	REBP1266
	REBP1267
	REBP1421
	REBP1422
	REBP1810
	REBQ0087
	REBQ0088
	REBQ0347
	REBQ0811
	REBQ1014
	REBQ1898
	REBQ1978
	REBQ2296
	REBR0474
MC1825	REBP0158