C. R. Bard GmbH
Wachhausstrasse 6
76227 Karlsruhe
Germany

[Contact Name]

[Department/Title]
[Hospital Name]
[Address Line 1]
[Town/City]
[Postal Code]
[Country]

[Date]

Reference: FA2015-15

URGENT FIELD SAFETY NOTICE

Bard® Max-Core® Disposable Core Biopsy Instrument

Dear [Contact Name]

This letter is to inform you of a Field Safety Corrective Action (recall) initiated by Bard Peripheral Vascular (BPV), a wholly owned subsidiary of C.R. Bard, Inc.

Reason for Field Safety Notice:

BPV has confirmed that certain lots of Bard® Max-Core® Disposable Core Biopsy Instruments, as listed below in Table 1, may be at risk of having self-activation related issues. BPV became aware of this through an increase in reported complaints for these related issues. The harm associated with these related issues during use may compromise the outcome of biopsy procedures.

Product Code	Lot Number
MC1820	REYA2017
MC1820	REYC2853

Table 1: List of affected product codes

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 Table 1 can continue to be used by your facility as they are safe to use and are not affected by this product recall.

If you have already used the affected devices listed in Table 1, no further product related action is required.

Please be aware that your Competent Authority is being notified of this Field Safety Corrective Action. As part of this action, we require that you follow the instructions below and notify Bard of your compliance with this Field Safety Corrective Action.

Required actions for you and your Healthcare Facility:

1. **Do not use or further distribute any Bard® Max-Core® Disposable Core Biopsy Instruments with the product codes listed in Table 1.**
2. Check all inventory locations within your institution for Bard® Max-Core® Disposable Core Biopsy Instruments with the product code / lot numbers listed in Table 1.
3. Pass this Field Safety Notice to all those who need to be aware of it within your organisation and to any organisation where the potentially affected devices have been transferred.
4. If you have further distributed any of the product code / lot number listed in Table 1, please immediately contact that location, advise them of the recall and have them return the affected product to Bard (address listed below).
5. Please remove any identified product from your shelves.
6. If you have products to return please contact your local Bard representative. Please mark the outside package as "RECALLED PRODUCT" and include the Reference Number FA2015-15.

Once the product affected by this recall has been removed from your inventory;
Please complete the attached Reply Effectiveness Check Form and fax to +49 (0) 721 9445-230.
Alternatively this can be emailed to [redacted]@crbard.com

Note: It is extremely important that we receive this information. If you cannot fax or email the form please telephone your local Bard Customer Service Representative and report the required information verbally.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action. Should you have any questions or require assistance in this matter, please contact your local sales specialist or local Bard Customer Service Representative on +49 (0) 721 9445-124.

Yours faithfully.
For and on behalf of C. R. Bard, Inc.

[redacted]

RA/QA Specialist Germany, Austria, Switzerland
Wachhausstrasse 6, 76227 Karlsruhe, Germany
Tel: +49 (0)721 9445-[redacted]
Fax: +49 (0)721 9445-[redacted]

REFERENCE: FA2015-15 **RGA # FA2015-15**

REPLY EFFECTIVENESS CHECK FORM

Bard® Max-Core® Disposable Core Biopsy Instruments

It is important that the Product Code / Lot Number combination of the Bard® Max-Core® Disposable Core Biopsy Instruments listed in the Table below be immediately removed from your inventory and isolated from use.

Product Code	Lot Number
MC1820	REYA2017
MC1820	REYC2853

Please complete this form and fax to +49 (0) 721 9445-230.
Alternatively this can be emailed to [redacted]@crbard.com

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 the answer to question 1 is YES, please list Product Codes, Lot Numbers and Quantity being returned by completing the table below:

Customer Name	Customer PO#	Actual Ship Date	Item Code	Lot#	Quantity Ordered	Quantity to Return	ACTUAL QTY RETURNED (BARD ONLY)
[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	
[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	[Pre-populated field]	

Please PRINT Your Contact Information and fill form out completely	
Name	
Title	
Name of Account / Hospital	[Pre-populated field]
Contact Phone Number	
Date	

Please return completed form and any affected product to:

[redacted]
RA/QA Specialist Germany, Austria, Switzerland
C. R. Bard GmbH, Wachhausstrasse 6, 76227 Karlsruhe, Germany
Tel: +49 (0)721 9445-[redacted] Fax: +49 (0) 721 9445-[redacted]
E-Mail: [redacted]@crbard.com