

Bard Limited
Forest House, Tilgate Forest Business Park
Brighton Road, Crawley
West Sussex, RH11 9BP
England, UK.

[Contact Name]

[Department/Title]

[Hospital Name]

[Address Line 1]

[Town/City]

[Postal Code]

[Country]

[Date]

Reference: FA2015-51

URGENT FIELD SAFETY NOTICE

BARD ENCOR® PROBES

End Item Code	Description
ECP017GV	Biopsy Probe – 7g Vertical
ECP0110GV	Biopsy Probe – 10g Vertical
ECP0112GV	Biopsy Probe – 12g Vertical

Refer to Attachment 1 for affected lots

Dear **[Contact Name]**

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

Reason for Field Safety Notice

Bard has confirmed that the product code / lot number combinations listed in Attachment 1 may be at risk of having an incorrect sample trap assembly. A portion of the affected lots may contain units with incorrect sample trap assemblies affixed to the probe inside the product tray. **The labelling on the outer product carton and inside packaging tray is correct.** Specifically, the issue is that the incorrect sample trap assembly contains a shorter vacuum tubing and no clear tray cover.

To date, we have received two (2) complaints from customers that have received this product; neither resulted in an adverse event to patient or loss of functionality of the device. We believe these to be isolated events; however, out of an abundance of caution, we are notifying all customers who have received EnCor® Probes.

The images shown in Figures 1 and 2 illustrate the incorrect and correct sample trap assembly. Figure 1a illustrates the incorrect sample trap with incorrect tubing and figure 1b illustrates the correct sample trap with the correct tubing. Figure 2a illustrates the incorrect sample trap without a tray cover and Figure 2b illustrates the correct sample trap with a tray cover.



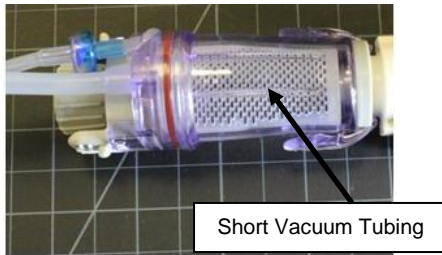


Figure 1a: Incorrect Tubing Length

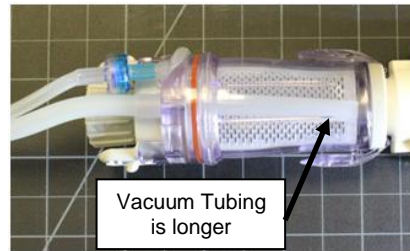


Figure 1b: Correct Tubing Length

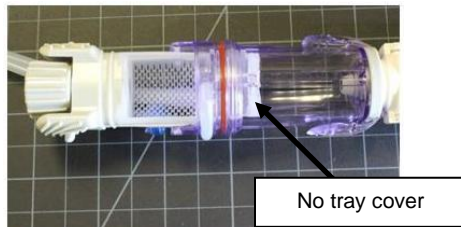


Figure 2a: No Tray Cover



Figure 2b: Correct Tray Cover

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 Notice. Bard is not requiring that you return affected product.

Clinical Risk Statement

The potential harm associated with attempting to use this device may result in the sample trap assembly being filled with fluid during use and when removing the sample collection tray (basket), the sample(s) may fall out of the collection tray because of the lack of a cover. This might lead to a varying degree of user dissatisfaction rather than actual harm to the patient. The user would still be able to sample the lesion as intended.

Required Actions for your Facility

Our records show that you received affected product as listed in the attached Reply Effectiveness Check Form. Therefore we require you and/or your Healthcare Facility to take the following actions:

1. Pass this Field Safety Notice to all personnel involved with the use of Bard Encor® Probes.
2. Ensure the contents of this Field Safety Notice are understood by the associated personnel.
3. If you have further distributed this product, please identify that organisation and notify them at once of this notification. You may include a copy of this letter in your notification.
4. Please complete the attached Reply Effectiveness Check Form and return to Bard either by fax to +44(0)1293 606775 or by email to customer.services@crbard.com

Note: Although Bard is not requiring that you return affected product, it is extremely important that we receive your completed Reply Effectiveness Check Form as soon as possible.

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 +44(0)1293 529 555

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

QA & Customer Care Representative

Attachment 1: List of Affected Product Code / Lot Number Combinations

Product Code	Lot Number
ECP017GV	VT14B0082
ECP017GV	VT14F0195
ECP017GV	VT14N0516
ECP017GV	VT15A0044
ECP017GV	VT15B0077
ECP017GV	VT15B0081
ECP017GV	VT15H0371
ECP017GV	VT15L0477
ECP0110GV	VT14C0086
ECP0110GV	VT14C0093
ECP0110GV	VT14E0128
ECP0110GV	VT14E0150
ECP0110GV	VT14E0151
ECP0110GV	VT14F0190
ECP0110GV	VT14F0191
ECP0110GV	VT14G0222

Product Code	Lot Number
ECP0110GV	VT14G0223
ECP0110GV	VT14G0229
ECP0110GV	VT14G0230
ECP0110GV	VT14K0326
ECP0110GV	VT14K0327
ECP0110GV	VT14L0386
ECP0110GV	VT14L0387
ECP0110GV	VT14M0445
ECP0110GV	VT14M0485
ECP0110GV	VT15A0004
ECP0110GV	VT15B0073
ECP0110GV	VT15B0074
ECP0110GV	VT15C0105
ECP0110GV	VT15C0106
ECP0110GV	VT15D0180
ECP0110GV	VT15F0266

Product Code	Lot Number
ECP0110GV	VT15G0321
ECP0110GV	VT15G0345
ECP0110GV	VT15H0408
ECP0110GV	VT15H0409
ECP0110GV	VT15K0439
ECP0110GV	VT15K0440
ECP0110GV	VT15L0482
ECP0110GV	VT15L0483
ECP0110GV	VT15M0571
ECP0110GV	VT15M0572
ECP0112GV	VT14C0087
ECP0112GV	VT14L0390
ECP0112GV	VT15M0574
ECP0112GV	VT15E0244



REFERENCE: FA2015-51

REPLY EFFECTIVENESS CHECK FORM

BARD ENCOR® PROBES

By completing the below information you confirm that the Field Safety Corrective Action Reference Number FA2015-51 has been received by your Healthcare Facility or Organisation and that it has been read and understood.

Our records show that you have received the following units affected by the bounding of this communication.

Customer Name	Customer PO#	Actual Ship Date	Item Code	Lot#	Quantity Ordered

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 to:

Donna Ayling

Quality Assurance & Customer Service Representative

Phone + 44 (0) 1293 606775

Fax + 44 (0) 1293 552428

Bard Ltd, Forest House, Tilgate Forest Business Park, Brighton Road, Crawley, West Sussex, RH11 9BP

