



April 13, 2016

ATTENTION: MATERIALS MANAGEMENT/STORE RECEIVING

MEDICAL DEVICE NOTIFICATION

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 Customer,

This letter is to provide information to you about the EnCor® probe manufactured by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of C.R. Bard, Inc. Specific product code / lot number combinations of Bard EnCor® Probe are affected as outlined in Attachment 1. 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 1 can continue to be used by your facility as they are safe to use and are not affected by this notification.

Reason for Notification:

Bard Peripheral Vascular (BPV) has confirmed that the product code / lot number combination listed above 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 labeling 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 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.

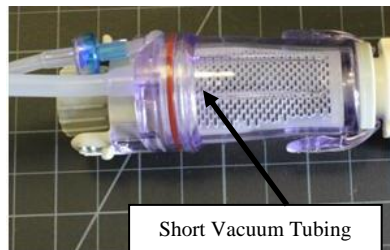


Figure 1a: Incorrect Tubing Length

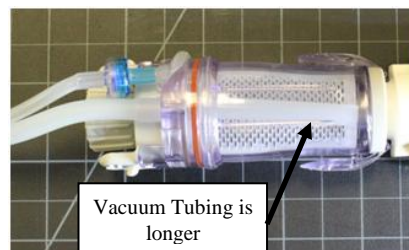


Figure 1b: Correct Tubing Length



Figure 2a illustrates the incorrect sample trap without a tray cover and Figure 2b illustrates the correct sample trap with a tray cover.

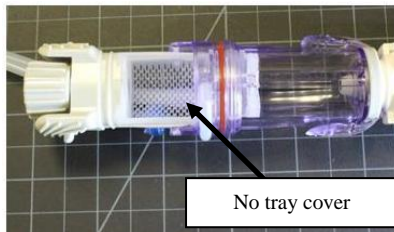


Figure 2a: No Tray Cover



Figure 2b: Correct Tray Cover

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.

Instructions to Customer:

The issue does not impact the product use. **No action is required on your part.** If the unit does not meet your needs we will provide you with a replacement unit.

Please complete and return the attached Customer Acknowledgement Form within (5) five business days to acknowledge your reading and understanding of this notice.

We sincerely regret any inconvenience this may cause to you or your facility. If you have any questions please do not hesitate to contact your Bard representative.

Sincerely,

[Redacted signature]

Mary Kennell
Director of Regulatory Affairs & Quality, Australia, New Zealand and South East Asia

Attachment 1 – List of Affected Product Code / Lot Combinations

Bard Singapore Pte Ltd

No 1 Coleman Street #06-07

The Adelphi

Singapore 179803

Tel: (65) 6580 5988

Fax: (65) 6337 3588

Co Reg No. 199901639R

**Attachment 1: List of Affected Product Codes**

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

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CUSTOMER ACKNOWLEDGEMENT FORM

MEDICAL DEVICE NOTIFICATION

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ECP0112GV	Biopsy Probe – 12g Vertical

PLEASE SCAN BACK TO: Complaints.Singapore@crbard.com

Please fill out and return this customer acknowledgement form confirming receipt of this notification as soon as possible and either hand it to your Bard Sales Representative, scan a copy to Complaints.Singapore@crbard.com or fax it to 6337 3588.

I have read and understood the attached medical device notification.

Signature: _____

Date: _____

Print Contact Name:		Company Stamp:	
Name of Facility:			
Contact Phone:		Fax:	