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

25 August 2016

ATTENTION: MATERIALS MANAGEMENT/STORE RECEIVING

MEDICAL DEVICE NOTIFICATION

End Item Code	Description
ENCFINSERT10G	EnCor® Needle Guide Insert (GE/Siemens/Fisher/Giotto) 10G

Dear Customer,

This letter is to provide information to you about an accessory to the EnCor® product family, manufactured by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of C. R. Bard, Inc. Specific lot numbers of the ENCFINSERT10G are affected as outlined in Attachment 1. Our records show that your facility has purchased one or more of the affected lot numbers.

All other lot numbers not listed in Attachment 1 can continue to be used by your facility are not affected by this notification.

Reason for Notification:

Bard Peripheral Vascular has confirmed that the lot numbers listed in Attachment 1 may be at risk of having an incorrect EnCor Accessory Needle Guide Insert. Specifically, a smaller diameter (12G) insert may be contained within the larger (10G) package. To date we have received 6 complaints from customers that have received the smaller product in error; none have resulted in an adverse event to the patient or loss of functionality of the EnCor® Probe. We believe these to be isolated events; however out of an abundance of caution, we are notifying all customers who have received the ENCFINSERT10G device lots listed in Attachment 1.

Clinical Risk Statement:

The potential harm associated with attempting to use a (12G) needle guide with a (10G) probe is that the (10G) cannula would not fit through the (12G) insert at the time of preparation for the procedure. During preparation for stereotactic use, the user is instructed to manually slide the needle guide insert onto the EnCor® Probe Cannula/Cutter. Therefore, if the needle guide insert is designed for a smaller gauge cannula (12G), the (10G) cannula, which is larger, will not, under any circumstance, fit through the (12G) needle guide insert. This essentially, renders the device unusable and the user will have to replace the incorrect needle guide with one that is of the correct (10G) size.

In the event the user was going to use the EnCor® Breast Biopsy Probe manually under ultrasound guidance, the needle guide insert would not interfere in any way as it is not used.

Instructions to Customer:

No action is required on your part. If the unit does not meet your needs we will provide you with a replacement unit.

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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]

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

Attachment 1 – List of Affected Lot Numbers

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Attachment 1: List of Affected Lot Numbers

End Item Code	Lot/Serial
ENCFINSERT10G	VT14G0257
	VT14H0288
	VT14K0360
	VT14K0381
	VT14M0477
	VT15B0099
	VT15C0131
	VT15D0185
	VT15E0219
	VT15F0282
	VT15G0362
	VT15H0387
	VT15K0449
	VT15L0501
	VT15L0502
	VT15L0503
	VT15N0655
	VT16B0123
	VT16B0135
	VT16C0184

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CUSTOMER ACKNOWLEDGEMENT FORM

MEDICAL DEVICE NOTIFICATION

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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:**	