

Bard Singapore Pte Ltd  
1 Harbourfront Avenue, #04-11/13  
Keppel Bay Tower, Singapore 098632  
Tel: (65) 6250 5988  
Fax: (65) 6337 3588  
GST Reg No. 19-9901639-R



ATTENTION: RISK MANAGER/MATERIALS MANAGER

**URGENT MEDICAL DEVICE RECALL NOTIFICATION**

**GHIATAS® Beaded Breast Localization Wire**

Product Code	Lot Number
47920	REBW0024

18 September 2018

Dear Valued Customer,

This letter is to inform you of a voluntary product recall issued by Bard Peripheral Vascular, Inc. (BPV), a wholly owned subsidiary of Becton, Dickinson and Company. One product code / lot number of GHIATAS® Beaded Breast Localization Wires is affected as outlined in the table above. Our records show that your facility has purchased one or more units from the affected lot.

All other product code / lot number combinations not listed above 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 listed in the table above may be at risk of incorrectly containing a 5cm length introducer needle instead of a 9cm length introducer needle.

**Clinical Risk Statement:**

The introducer needle mix-up (5cm instead of 9cm) is unlikely to lead to an immediate or long-term health consequence, as it is very likely that the user would notice that the needle is nearly half of the desired length and request another before proceeding with the procedure. If however, the unsuspecting user inserted the 5cm needle, only to realize that it was not long enough to reach the lesion, the user would have to withdraw the needle and reinsert another longer needle under imaging guidance.

**Required Actions:**

Please find attached instructions detailing the steps we are requesting you take regarding this product. **BPV must document your compliance with this action.**

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,

Melvin Tay  
Business Director, SEA  
BD Interventional

Attachment 1 – Instructions for Completing Required Actions  
Attachment 2 – Recall and Effectiveness Check Form

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### 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 Bard.
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.

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#### **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.
6. Email the completed ***Recall and Effectiveness Check Form*** to [Complaints.Singapore@crbard.com](mailto:Complaints.Singapore@crbard.com) or fax it to Bard Singapore at **+65 6337 3588**. If you cannot email or FAX the form, please call your Bard representative or distributor.
7. Please report any new and/or previously unreported adverse events associated with this recall to us by emailing [Complaints.Singapore@crbard.com](mailto:Complaints.Singapore@crbard.com).
8. You will be contacted regarding product return once we receive the ***Recall and Effectiveness Check Form*** from you.

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Attachment 2

**RECALL AND EFFECTIVENESS CHECK FORM**

**GHIATAS® Beaded Breast Localization Wire**

Please complete this form and email to [Complaints.Singapore@crbard.com](mailto:Complaints.Singapore@crbard.com) or fax to +65 6337 3588.  
Contact your local distributor or Bard representative regarding product return.

**Please PRINT your contact information and fill form out completely:**

Name of facility: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Name of Contact Person: \_\_\_\_\_ 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 ☐ No

If YES, Total # of Pieces to be returned: \_\_\_\_\_

<u>Product Code</u>	<u>Lot Number</u>	<u>Qty to be Returned</u>
47920	REBW0024	

No \_\_\_\_\_ If NO, please provide reason for not returning.

☐ Used

☐ Destroyed

☐ Other: \_\_\_\_\_

Please email the completed form to [Complaints.Singapore@crbard.com](mailto:Complaints.Singapore@crbard.com) or FAX completed form to:

**Fax: +65 6337 3588**

Attn: Merryn Ang  
Regulatory Affairs and Quality Assurance  
Bard Singapore Pte Ltd