**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: FA2013-12**

# URGENT FIELD SAFETY NOTICE
# VOLUNTARY RECALL

## Bard® ULTRACLIP® DUAL TRIGGER TISSUE MARKER

Dear [Contact Name]

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

**Reason for Recall:**

Bard Peripheral Vascular (BPV) has confirmed that some devices from product code / lot number combinations in Table 1 may have the metal tissue marker separated from the needle prior to use.

**Only specific product code / lot number combinations of Bard® UltraClip® Dual Trigger Tissue Markers are affected as outlined in Table 1. Our records show that your facility has purchased one or more of the affected product code / lot number combinations listed in Table 1.**

**All other product code / lot number combinations that are 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, then no additional action is required. No special follow-up treatment or clinical care is recommended for patients who have already undergone treatment with the devices affected by this Field Safety Notice.**

**Table 1: Affected Product Code and Lot Numbers**

| Product Code | Lot Number |
|---|---|
| 864017D | HUWI1522 |
| 864017D | HUWI1941 |
| 864017D | HUWI1942 |
| 864017D | HUWI1943 |
| 864017D | HUWJ1851 |
| 864017D | HUWJ1852 |
| 864017D | HUWK0350 |
| 864017DL | HUWJ1610 |

Individuals most at risk include patients who undergo a breast biopsy requiring placement of a Bard® UltraClip® Dual Trigger Tissue Marker at the biopsy site. The potential hazard associated with a loose Bard® UltraClip® Dual Trigger Tissue Marker includes the potential for an incremental risk, ranging from dissatisfaction to failure to deploy the marker at the desired location, either during placement visualisation (ultrasound) or after post placement mammography. This issue may result in an incremental risk of minor tissue injury leading to potential prolongation of the procedure and/or the need for additional local anaesthesia.

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 affected product**.
2. Our records show that your facility has purchased the product code and lot number affected by this voluntary recall.
3. We ask that you check all inventory locations within your institution for Bard® UltraClip® Dual Trigger Tissue Marker with the product code / lot number listed in Table 1.
4. Please pass this Field Safety Notice to all those who need to be aware of it within your organization and to any organization where the potentially affected devices have been transferred.
5. 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).
6. Please remove any identified product from your shelves. *If you do not have any product listed in Table 1 or have used the inventory, no further action is required.*
7. If you have products to return please contact your local Bard representative. Please mark the outside package as "RECALLED PRODUCT" and include the RGA number

Once the product affected by this recall has been removed from your inventory:

**Please complete the attached Reply Effectiveness Check Form and fax to +34 9320 58656. Alternatively this can be emailed to** CRW-FA201312@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 [Tel #]

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

[Signature]

Enclosures: Reply Effectiveness Check Form

**REFERENCE: FA2013-12** **RGA #** _____

# REPLY EFFECTIVENESS CHECK FORM

## Bard® UltraClip® Dual Trigger Tissue Marker

### Catalogue numbers: 864017D and 864017DL

It is important that the Product Code / Lot Number combination of the Bard® UltraClip® Dual Trigger Tissue Marker listed in Table 1 be immediately removed from your inventory and isolated from use.

**Please complete this form and fax to +34 9320 58656.**
**Alternatively this can be emailed to** CRW-FA201312@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] | |

3. If you have affected product, do you intend to return the affected product?

   Yes ☐ No ☐

   If YES, Total # of Pieces: _____
   If NO, please explain why below:

| 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:**
[Local Contact Name]
[Local Contact Title]
[Bard® XYZ (Insert IBC Name / Address / Country]
[Tel. (Local Tel #)] [Fax. (Local Fax #)]
[Email. (name@crbard.com)]