



[Contact Name]

[Department/Title]

[Hospital Name]

[Address Line 1]

[Town/City]

[Postal Code]

[Country]

[Date]

Reference: FA2014-18

URGENT FIELD SAFETY NOTICE

DuaLok Breast Localisation Wire – Exposed Wire

Dear [Contact Name]

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

Reason for Field Safety Notice:

BPV received four (4) complaints where Bard® DuaLok Breast Lesion Localisation Wires had damaged packaging and the wires protruded from the packaging.

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 product recall.

If you have already used the affected devices listed in Attachment 1, it is advisable to closely monitor the patients and the medical management should be at the discretion of the treating physician.

Please be aware that your Competent Authority is being notified of this Field Safety Corrective Action. Our records show that your facility has purchased product affected by this recall therefore, 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 Bard® DuaLok Breast Lesion Localisation Wires with the product codes listed in Attachment 1.**
2. Check all inventory locations within your institution for DuaLok Breast Lesion Localisation Wire with the product code / lot number listed in Attachment 1.
3. Pass this Field Safety Notice to all those who need to be aware of it within your organisation and to any organisation where the potentially affected devices have been transferred.

4. If you have further distributed any of the product code / lot number listed in Attachment 1, please immediately contact that location, advise them of the recall and have them return the affected product to Bard (address listed below).
5. Please remove any identified product from your shelves.
6. 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;

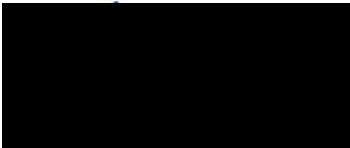
Please complete the attached Reply Effectiveness Check Form and fax to +49 (0)721 9445-230. Alternatively this can be emailed to [REDACTED]@crbard.com.

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 +49 (0) 721 9445-124.

Yours faithfully.

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



RA/QA Specialist Germany, Austria, Switzerland
Wachhausstrasse 6, 76227 Karlsruhe, Germany
Tel: +49 (0)721 9445-[REDACTED]

Attachment – 1 List of Affected Product Codes

20g X 3.7cm

Item #	Lot #
LW0037	REXH0625
LW0037	REXJ0285
LW0037	REXK0279
LW0037	REXD1346
LW0037	REXE1663
LW0037	REXH0210
LW0037	REXJ1662
LW0037	REXL1233
LW0037	REXC0151
LW0037	REXC1597
LW0037	REXJ0487
LW0037	REXK2010
LW0037	REYB1500
LW0037	REYC1644
LW0037	REYE2175
LW0037	REYG0975

20g X 5.7cm

Item #	Lot #	Item #	Lot #
LW0057	REXH1110	LW0057	REXF0126
LW0057	REVJ0284	LW0057	REXF2249
LW0057	REVJ1392	LW0057	REXG2346
LW0057	REVK0821	LW0057	REXH0014
LW0057	REWA0386	LW0057	REXH1180
LW0057	REWB0291	LW0057	REXJ0280
LW0057	REWB1686	LW0057	REXJ0560
LW0057	REWC0831	LW0057	REXJ2036
LW0057	REWD1328	LW0057	REXK0397
LW0057	REWE1476	LW0057	REXK0676
LW0057	REWF1566	LW0057	REXL0506
LW0057	REWG1788	LW0057	REYA0345
LW0057	REWG1807	LW0057	REYA1244
LW0057	REWJ1663	LW0057	REYA2521
LW0057	REWJ1664	LW0057	REYB1364
LW0057	REWK1459	LW0057	REYC0520
LW0057	REWL1432	LW0057	REYD1314
LW0057	REXB0180	LW0057	REYE2170
LW0057	REXC0152	LW0057	REYF0719
LW0057	REXC1592	LW0057	REYF1846

20g X 7.7cm

Item #	Lot #
LW0077	REVJ0287
LW0077	REVJ1391
LW0077	REVK0280
LW0077	REVL0641
LW0077	REWA1600
LW0077	REWB0099
LW0077	REWB1751
LW0077	REWC0848
LW0077	REWC1485
LW0077	REWD1230
LW0077	REWD1426
LW0077	REWE1052
LW0077	REWE1479
LW0077	REWF0904
LW0077	REWG1776
LW0077	REWH0282
LW0077	REWI0065

Item #	Lot #
LW0077	REWI1706
LW0077	REWJ1174
LW0077	REWJ1679
LW0077	REWK1425
LW0077	REWL0885
LW0077	REWL1436
LW0077	REXA1813
LW0077	REXC0751
LW0077	REXC1113
LW0077	REXD1361
LW0077	REXD1362
LW0077	REXE1361
LW0077	REXF0129
LW0077	REXG0098
LW0077	REXG0602
LW0077	REXG1586
LW0077	REXG2360

Item #	Lot #
LW0077	REXH1476
LW0077	REXH1519
LW0077	REXI1623
LW0077	REXI1846
LW0077	REXJ2030
LW0077	REXK0937
LW0077	REYA0199
LW0077	REYA0346
LW0077	REYA2522
LW0077	REYB1366
LW0077	REYC0486
LW0077	REYC0648
LW0077	REYC2209
LW0077	REYD1387
LW0077	REYE2137
LW0077	REYF1017
LW0077	REYG1057

20g X 10.7cm

Item #	Lot #
LW0107	REXH1111
LW0107	REXJ0282
LW0107	REVK0267
LW0107	REVK0284
LW0107	REVK0817
LW0107	REVL0570
LW0107	REWA0735
LW0107	REWB0295
LW0107	REWB1683
LW0107	REWC0818
LW0107	REWD1248
LW0107	REWD1471
LW0107	REWE1080
LW0107	REWE1483
LW0107	REWE1678
LW0107	REWF0895
LW0107	REWF1677
LW0107	REWG0934
LW0107	REWH0182
LW0107	REWH0231
LW0107	REWI0053
LW0107	REWI0097
LW0107	REWI0997

Item #	Lot #
LW0107	REWI1586
LW0107	REWI1746
LW0107	REWJ1560
LW0107	REWK0101
LW0107	REWK1426
LW0107	REWL1438
LW0107	REXA1919
LW0107	REXB0181
LW0107	REXB1602
LW0107	REXC0153
LW0107	REXC0990
LW0107	REXC1593
LW0107	REXD1822
LW0107	REXE1360
LW0107	REXE1822
LW0107	REXF1309
LW0107	REXF2250
LW0107	REXG1585
LW0107	REXG2347
LW0107	REXH2398
LW0107	REXH2399
LW0107	REXI1196
LW0107	REXI1807

Item #	Lot #
LW0107	REXJ0484
LW0107	REXJ1985
LW0107	REXJ2326
LW0107	REXK1320
LW0107	REXK2000
LW0107	REXL0556
LW0107	REXL0794
LW0107	REYA2523
LW0107	REYB0456
LW0107	REYB0950
LW0107	REYB2182
LW0107	REYC0484
LW0107	REYC1490
LW0107	REYC2848
LW0107	REYD1711
LW0107	REYE0543
LW0107	REYE1146
LW0107	REYE2177
LW0107	REYF0183
LW0107	REYG0968
LW0107	REYG1607

20g X 13.7cm

Item #	Lot #	Item #	Lot #
LW0137	REXH0330	LW0137	REXD1069
LW0137	REVJ0283	LW0137	REXG0099
LW0137	REVK0266	LW0137	REXG2348
LW0137	REVK0841	LW0137	REXH1956
LW0137	REWB1757	LW0137	REXI1193
LW0137	REWC1479	LW0137	REXJ0486
LW0137	REWD1331	LW0137	REXJ2029
LW0137	REWE1452	LW0137	REXK0402
LW0137	REWF1572	LW0137	REXK1345
LW0137	REWG1621	LW0137	REXL0507
LW0137	REWI0521	LW0137	REYA1245
LW0137	REWI1707	LW0137	REYB0486
LW0137	REWJ1672	LW0137	REYC1961
LW0137	REWK1449	LW0137	REYE1382
LW0137	REXB0182	LW0137	REYF0642
LW0137	REXB1527	LW0137	REYG1464
LW0137	REXC0154		

REPLY EFFECTIVENESS CHECK FORM

DuaLok Breast Localization Wire – Exposed Wire

It is important that the Product Code / Lot Number combination of the DuaLok Breast Localization Wire listed in Attachment 1 be immediately removed from your inventory and isolated from use.

**Please complete this form and fax to +49 (0) 721 9445-230.
Alternatively this can be emailed to [REDACTED]@crbard.com.**

<p>1. Do you currently possess any of the affected lots of product? (<i>Please check both consignment and purchased inventory for possible locations of this affected product.</i>)</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
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<p>2. If the answer to question 1 is YES, please list Product Codes, Lot Numbers and Quantity being returned by completing the table below:</p>

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]	

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:

[REDACTED]
 RA/QA Specialist Germany, Austria, Switzerland
 C. R. Bard GmbH, Wachhausstrasse 6, 76227 Karlsruhe, Germany
 Tel: +49 (0)721 9445-[REDACTED] Fax: +49 (0) 721 9445-230
 E-Mail: [REDACTED]r@crbard.com