

C. R. Bard GmbH
Wachhausstrasse 6
76227 Karlsruhe
Deutschland



[Contact Name]

[Address]

[Date]

Reference: FA2014-08

URGENT FIELD SAFETY NOTICE

Bard® Ventralight™ ST Mesh with Echo PS™ Positioning System and the Bard® Composix™ L/P Mesh with Echo PS™ Positioning System

Dear [Contact Name]

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

Reason for Recall:

Davol Inc. has confirmed that some devices from specific lots of product in Table 1 may have a weak pouch seal for the included, separately packaged, sterile inflation assembly and inflation adapter.

Individuals most at risk include patients who undergo surgical treatments for soft tissue deficiencies, such as for repair of hernias. The potential hazard associated with a package having a defective chevron seal is loss of sterility.

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.

Our records show that your facility has purchased the product codes and lot numbers below. All other Davol, Inc. product codes and lot numbers 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.

Table 1: Affected Product Codes and Lot Numbers

Product Code	Description	Lot Number
0144113	Composix™ LP with Echo PS™ 10"x13"	HUXH0294
		HUXL0314
0144610	Composix™ LP with Echo PS™ 6"x10"	HUXK1536
0144680	Composix™ LP with Echo PS™ 6"x8"	HUXK0073
		HUXK1537
0144790	Composix™ LP with Echo PS™ 7"x9"	HUXK1539
0144810	Composix™ LP with Echo PS™ 8"x10"	HUXK1540
5955113	Ventralight™ ST w/Echo PS™ 10"x13"	HUXK0900
		HUXK0901
		HUXL1148
5955124	Ventralight™ ST w/Echo PS™ 12"x14"	HUYA1057
5955450	Ventralight™ ST w/Echo PS™ 4.5" Circle	HUXH0535
		HUXH0696
		HUXK0747
5955460	Ventralight™ ST w/Echo PS™ 4"x6"	HUXH0695
5955600	Ventralight™ ST w/Echo PS™ 6" Circle	HUXH0694
		HUXL1149
		HUXL1150
		HUYA1005
5955610	Ventralight™ ST w/Echo PS™ 6"x10"	HUXK0744
		HUXL1004
5955680	Ventralight™ ST w/Echo PS™ 6"x8"	HUXH0688
		HUXK0743
		HUXL0803
		HUXL0804
5955790	Ventralight™ ST w/Echo PS™ 7"x9"	HUXK0899
5955800	Ventralight™ ST w/Echo PS™ 8" Circle	HUXK0058
5955810	Ventralight™ ST w/Echo PS™ 8"x10"	HUXH0691
		HUXL0336
		HUXL0495
		HUXL0660
		HUXL1006
		HUXL1007
		HUXL1147

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® Ventralight™ ST Mesh with Echo PS™ Positioning System and Bard® Composix™ L/P Mesh with Echo PS™ Positioning System with the product code and 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 +49 (0) 721 9445-100. Alternatively this can be emailed to miriam.miller@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 9445-223

Enclosures: Reply Effectiveness Check Form

REPLY EFFECTIVENESS CHECK FORM**Bard® Ventralight™ ST Mesh with Echo PS™ Positioning System and
Bard® Composix™ L/P Mesh with Echo PS™ Positioning System**

Product Code	Description	Lot Number
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		HUXL0336
		HUXL0495
		HUXL0660
		HUXL1006
		HUXL1007
		HUXL1147

It is important that the Product Code / Lot Number combination of the Bard® Ventralight™ ST Mesh with Echo PS™ Positioning System and Bard® Composix™ L/P Mesh with Echo PS™ Positioning System listed above be immediately removed from your inventory and isolated from use.

**Please complete this form and fax to +49 (0) 721 9445-100.
Alternatively this can be emailed to miriam.miller@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:
 Miriam Miller
 RA/QA Specialist Deutschland, Österreich, Schweiz
 C. R. Bard GmbH, Wachhausstrasse 6, 76227 Karlsruhe, Deutschland
 Tel: +49 (0)721 9445-223 Fax: +49 (0) 721 9445 100
 E-Mail: miriam.miller@crbard.com