

URGENT: MEDICAL DEVICE RECALL



August 20, 2012

BARD EUROPE
ATTN: MARK O'DWYER, QUALITY ASSOCIATE
FOREST HOUSE, TILGATE FOREST BUSINESS PARK
BRIGHTON ROAD, CRAWLEY
WEST SUSSEX RH119BP
ENGLAND, UNITED KINGDOM

Dear Valued Customer:

Applied Medical is conducting a voluntary recall on specific lot numbers of its Vascular Catheters. This is due to a potential for packaging particulate matter to reside on the product. Further distribution or use of any affected product should cease immediately.

The model numbers affected include: CB0XXXXX, CE0XXXST and CE0XXX. A complete list of the affected model numbers and lot numbers is located on [Page 2](#).

Our records indicate that you have received one or more of the affected lots. Please perform the following actions:

- Check your inventory for recalled product (Complete recall list is on [Page 2](#))
- Complete the attached [Recall Notification Confirmation Form \(Page 3\)](#)
- Return the confirmation form to Applied Medical by emailing to recall60476587@appliedmedical.com or faxing to (949) 713-8832
- Return affected product and a copy of the confirmation form to Applied Medical (Product Return Instructions are on [Page 4](#))

We apologize for any inconvenience this action may cause. Your immediate attention is appreciated.

For product return questions, please contact Chris Stolrow, Sales Operations Administrator, at (949) 713-8652 or by e-mail at cstolrow@appliedmedical.com.

For regulatory questions, please contact me, Susan Fehrenbacher, at (949) 713-8041 or by e-mail at sfehrenbacher@appliedmedical.com.

Sincerely,

Susan Fehrenbacher
Vice President, Regulatory Affairs
Applied Medical

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List of Models and Lot Numbers Being Recalled

Our shipping records indicate YOU HAVE RECEIVED one or more of the following lots of affected Vascular Catheters. Please complete the attached confirmation form and return any product listed below that you have in your facility.

Model Numbers	Lot Numbers
CB052308, SYNTEL BILIARY 5F-23CM CATH	1164350
CB054008, SYNTEL BILIARY 5F-40CM CATH	1164305
CB062313, SYNTEL BILIARY 6F-23CM CATH	1164306
CE0260ST, L2F-60CM PREM SYNTEL CATH	1164307, 1168569
CE0280ST, L2F-80CM PREM SYNTEL CATH	1164351
CE0340ST, 3F-40cm (PREM) SYNTEL CATHETER	1164348
CE0380ST, 3F-80CM PREM SYNTEL CATH	1164308, 1164337, 1166033, 1166281, 1166032, 1169029
CE0440ST, 4F-40CM PREM SYNTEL CATH	1164336, 1168610
CE0480ST, 4F-80CM PREM SYNTEL CATH	1164302, 1164303, 1164335, 1164304, 1166283, 1166284, 1166468, 1168605
CE0580ST, 5F-80CM PREM SYNTEL CATH	1164345, 1164346, 1168613
CE0680ST, 6F-80cm (PREM) SYNTEL CATHETER	1164330, 1166470
CE0780ST, 7F-80CM PREM SYNTEL CATH	1164354
CE0340, 3F-40cm, SYNTEL RT-EMB	1166904
CE0380, 3F-80cm, SYNTEL RT-EMB	1164344
CE0440, 4F-40cm, SYNTEL RT-EMB	1164347, 1168609
CE0480, 4F-80cm, SYNTEL RT-EMB	1164343
CE0580, 5F-80CM PREM SYNTEL CATH	1164349
CE0680, 6F-80cm, SYNTEL RT-EMB	1164353
CE0780, 7F-80cm SYNTEL RT-EMB	1169926

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Recall Notification CONFIRMATION FORM

PLEASE COMPLETE THIS FORM AND E-MAIL OR FAX TO:

E-mail: recall60476587@appliedmedical.com

Fax: 949-713- 8832

Attention: Regulatory Affairs

Customer/Hospital Name: BARD EUROPE

Applied Medical "Sold To" Account Number: 1004628

Applied Medical "Ship To" Account Number: 2000179

Information on the individual completing this form (please print):

Name: _____ Title: _____

Date: _____ Telephone: _____ Fax: _____

Address for which you are responding: _____

If no products are being returned, please check here:

(If no products are returning, it is assumed that all products were previously used and are no longer available.)

Information for Units Being Returned:

Model Number	Lot Number	Number of Units Being Returned

Please select credit or replacement: Credit Replacement

If you are requesting replacement product, please include the following information:

No charge P.O. #: _____

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Product Return Instructions

Please return the recalled Vascular Catheters immediately to the following address:

**Applied Medical
ATTN: RGA# 60476587
9401 Toledo Way
Irvine, CA 92618**

Please write RGA# 60476587 on the outside of the package.

Please include a copy of the filled out Recall Notification Confirmation Form along with your returned product.

Product may be returned using Federal Express Account# 119124913.

If you have questions about the Recall Notification Confirmation Form (Page 3) or how to return the product, please contact:

Chris Stolrow
Sales Operations Administrator
Phone: (949) 713-8662
Email: cstolrow@appliedmedical.com

If you have any regulatory questions, please contact:

Susan Fehrenbacher
Vice President, Regulatory Affairs
Phone: (949) 713-8041
Email: sfehrenbacher@appliedmedical.com