[redacted]

BARD

Fax 00968-248 13472

C. R. Bard GmbH - Wachhausstrasse 6 - D - 76227 Karlsruhe

[redacted]

URGENT FIELD SAFETY NOTICE

Product Code: 5583705 – Guidewire 70 cm x 1 mm (0.038")
Type of Field Safety Action - PRODUCT RECALL

August 30, 2007

Dear Valued Customer,

This letter is to inform you of a voluntary recall initiated by Bard Access Systems, Inc. (BAS), a wholly owned subsidiary of C.R. Bard, Inc.

Please Note: **Only one product code with specific lot numbers is affected. No other products are included in this recall. Please refer to the *Affected Products List* provided below. Our records show that your facility has purchased some of these affected products.**

All other lots/codes, containing this wire, are beyond their expiration date. In accordance with accepted medical practice, they should have been discarded and not used.

Product Code – 5583705.

Lot Numbers

22FMA202	22FO6086	REPK0058	RERC0052
22IM0531	22GO6026	REPK0729	RERD0719
22KM0573	22HO6101	REPL0298	
22DN2914	22IO6111	REQB0030	
22FN5232	22KO6124	REQB0224	
22GN5835	22CP6268	REQD0200	
22GN5878	22EP6831	REQF0429	
22HN6574	REPG0035	REQF0736	
22BO6078	REPG0643	REQJ0282	
22BO6183	REPH0954	REQK0875	

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Reason for Recall: BAS have confirmed complaints that the guidewire packaged in the kits in the above product may be incorrectly loaded in the Trigger Guidewire Dispenser. This results in the stiff tip of the guidewire extending out of the Dispenser first. Instead, the flexible tip should be extending out of the Dispenser first. **Do not use or further distribute any affected product.**

There have been no injuries reported in association with this situation. However, the stiff tip of the guidewire should not be introduced into a vessel as the leading portion of the guidewire. This may lead to inadvertent vessel wall perforation by the guidewire and subsequent over-the-wire devices.

Our records indicate that product affected by this recall has been shipped to your facility.

It is important that the product numbers and lot numbers as listed on the Attachment of the enclosed Urgent Reply Form are immediately removed from your inventory and isolated from use.

Please return all devices affected by this recall to the following address:

C. R. Bard GmbH
[redacted]
RGA#: 08-07
Wachhausstr. 6
76227 Karlsruhe
Germany

There is no need to explant the catheter due to this action, since only the guidewire used for implant is affected.

Please be informed that we will inform your Ministry of Health accordingly.

BARD

Please confirm the receipt of this letter by fax ++49-721-9445-212.

BAS apologises for any inconvenience caused by this action. If you have any questions regarding this matter please call our Customer Service Export.

Yours sincerely
C.R. Bard GmbH

[redacted]
[redacted]
General Manager
Area Vice President

[redacted]
[redacted]
Regulatory Affairs

C. R. BARD GmbH, Wachhausstr. 6, 76227 Karlsruhe / Germany
Phone.: ++49 721-9445-367; Fax: ++49 721-9445-212

[redacted]

Telefax Reply to ++49-721-9445-212
RGA-# 08-07

Product Code: 5583705 – Guidewire 70 cm x 1 mm (0.038")

Item Number	Lot-Number	Delivery Date	Amount of units sent	Amount of units used up	Amount of returned units
5583705	22EP6831	24.10.2006	1		

Please fill in the grew colored fields.

Contact person For questions:	
Direct Telephone No.:	
Date / Stamp and Signature:	

RA

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