C. R. Bard GmbH
Wachhausstrasse 6
76227 Karlsruhe
Deutschland

[redacted]

Reference: FA2014-21

URGENT FIELD SAFETY NOTICE
Bard® Dimension® Stone Basket
Catalog Number 042316
Lot Number BMXJM031

Dear [redacted]

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

Reason for Field Safety Notice:

This Field Safety Corrective Action involves **Bard® Dimension® Stone Basket Catalog Number 042316, Lot Number BMXJM031** and has been identified due to the product (labelled as sterile) being non-sterile. A copy of the product label can be found attached to this notice for ease in identifying the product.

Stone Baskets are used to retrieve kidney stones during endourology procedures. Using this specific lot (**BMXJM031**) of stone baskets puts patients at an increased risk for infection. Symptoms of an infection could include fever, pain and burning sensation upon voiding.

If you have used the affected product, monitor your patients for symptoms and signs of localized and/or systemic infection.

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 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® Dimension® Stone Basket Catalog Number 042316, Lot Number BMXJM031.**
2. Check all inventory locations within your institution for the affected batch of **Bard® Dimension® Stone Basket** with the product code / lot number listed above.
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 above, 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 +49 721 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 +49 721 9445 124.

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

[redacted]

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

Attachment 1: Copy of Bard® Dimension® Stone Basket Label