

Bard Singapore Pte Ltd

1 Harbourfront Avenue, #04-11/13
Keppel Bay Tower, Singapore 098632
Tel: (65) 6250 5988
Fax: (65) 6337 3588
GST Reg No. 19-9901639-R



URGENT: Medical Device Product Notification

17 May 2018

Dear Valued Customer,

This letter is to inform you of a voluntary Medical Device Product notification initiated by C. R. Bard, Inc. a wholly owned subsidiary of Becton Dickinson. The current labeling for the ARCTIC SUN® 5000 Temperature Management System instructs the use of distilled water or sterile water to be used when filling the device. However, only sterile water is recommended, and all product labeling is being updated accordingly.

Reason for Notification:

C. R. Bard, Inc. is updating the ARCTIC SUN® 5000 Temperature Management System product labeling, in all referenced locations, to specify only sterile water is to be used when filling the device.

Clinical Risk Statement:

There are no health issues identified with the use of distilled water.

Action required:

- Examine your inventory and identify any product subject to this communication.
- Product return is not required. If you have any questions, please contact us at Complaints.Singapore@crbard.com
- If you may have further distributed or transferred this product, please identify the respective organizations, and notify them at once of this product communication. Your notification to these organizations may be enhanced by including a copy of this medical device communication letter.

We appreciate your assistance and apologize for any inconvenience this may cause.

Sincerely,

Melvin Tay
Business Director
BD Interventional, SEA

cc: Chairman Medical Board and relevant Head of Departments

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ATTACHMENT 1:

Acknowledgement Receipt Form

ARCTIC SUN® 5000 Temperature Management System

Please complete this form by as soon as possible and email a scanned copy to Complaints.Singapore@crbard.com or return to a Bard Representative

- 1. By signing below, you are acknowledging receipt and understanding of the attached letter.**

I, _____ have read and understand the instructions provided in this letter.
Print Name

Signature

Date

- 2. Please PRINT CLEARLY your Complete Contact Information:**

Name: _____ Title: _____

Phone: _____ Email: _____

Facility Name: _____

Address _____

- 3. Email a scanned copy to Complaints.Singapore@crbard.com.**