**Bard Limited**
Forest House, Tilgate Forest Business Park
Brighton Road, Crawley
West Sussex, RH11 9BP
England, UK.

**[Contact Name]**

[Department/Title]
[Hospital Name]
[Address Line 1]
[Town/City]
[Postal Code]
[Country]

[Date]

**Reference: FA2016-27**

# URGENT FIELD SAFETY NOTICE

## Medivance, Inc. ARCTICSUN® ARCTICGEL™ Neonatal Pad

Dear [Contact Name]

This letter is to inform you of a Field Safety Corrective Action initiated by Medivance (Bard), a wholly owned subsidiary of C.R. Bard, Inc. involving the **ARCTICGEL™ Neonatal Pads**. The ARCTICGEL™ Neonatal Pads are used with the Arctic Sun Temperature Management System.

Specific product code / lot number combinations of the **ARCTICGEL™ Neonatal Pads** are affected as outlined below in the table below.

| Product Code | Product Description | Lot Numbers |
|---|---|---|
| 318-02 | ArcticSun® ArcticGel™ Neonatal Pad (Single pack) | NGZKY606 |
| 318-02-02 | Arctic Sun® ArcticGel™ Neonatal Pad (Two pack) | NGAP2009 |

**Table1: Affected product code / lot number combinations**

### Reason for Field Safety Notice

Bard has confirmed that the product code / lot number combinations listed in Table 1 contain an incorrect version of the Instructions for Use (IFU). The IFU accompanying the listed lots only contains the English and Japanese translations. It does not contain all of the required languages for use in various geographies. Also, the related Images and these Directions were removed from the IFU:

1. The pad is designed to fit into an incubator 60 cm x 35 cm (23.6 in x 13.8 in) and provide whole body cooling for patients (1.8 - 4.5 kg; 4.0 - 9.9 lb).
2. One Neonatal ArcticGel™ Pad should be placed in the incubator. The rate of temperature change and potentially the final achievable temperature is affected by pad surface area coverage, placement, patient size, and water temperature range. Place pad in the incubator, route the pad lines through the access ports at the end of the bed.

The finished medical device product from these lots conforms to the product specification and functions as intended. Bard became aware of this event through an internal inspection and there have been no reported complaints to date associated with this issue. This communication is to provide you with the correct multilingual version of the IFU. Only the lots listed in Table 1 above are affected and

our records show that your facility has purchased at least one of the two product code / lot number combinations.

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 Notice. **Bard is not requiring that you return affected product**.

**Clinical Risk Statement**

The potential hazard associated with the translations missing from the IFU is that a User may not be able to apply an ArcticGel Pad and so the Arctic Sun Temperature Management System is not available for use. There have been no changes to the product's indications for use, contraindications or warnings. If the affected device has already been safely used, then no further product or patient related action is required.

**Required Actions for your Facility**

**Our records show that you received affected product as listed in Table 1. Therefore we require you and/or your Healthcare Facility to take the following actions:**

1. Examine your inventory and identify any product subject to this communication. A sample of the product pouch labelling for the product has been enclosed (Attachment 1) to assist in product code and lot number identification.
2. Should you have any remaining product, remove the original IFU and substitue a copy of the enclosed IFU (PK7640432 08/2015) with each product.
3. If you have further distributed this product, please identify the respective organisations and notify them at once of this product communication. Your notification to these organisations may be enhanced by including a copy of this product communication letter and accompanying enclosures.
4. Please complete the attached Reply Effectiveness Check Form and return to Bard either by fax to 01293 552428 or by email to customer.services@crbard.com.
   **Note**: Although Bard is not requiring that you return affected product, it is extremely important that we receive your completed Reply Effectiveness Check Form as soon as possible.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologise 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.

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

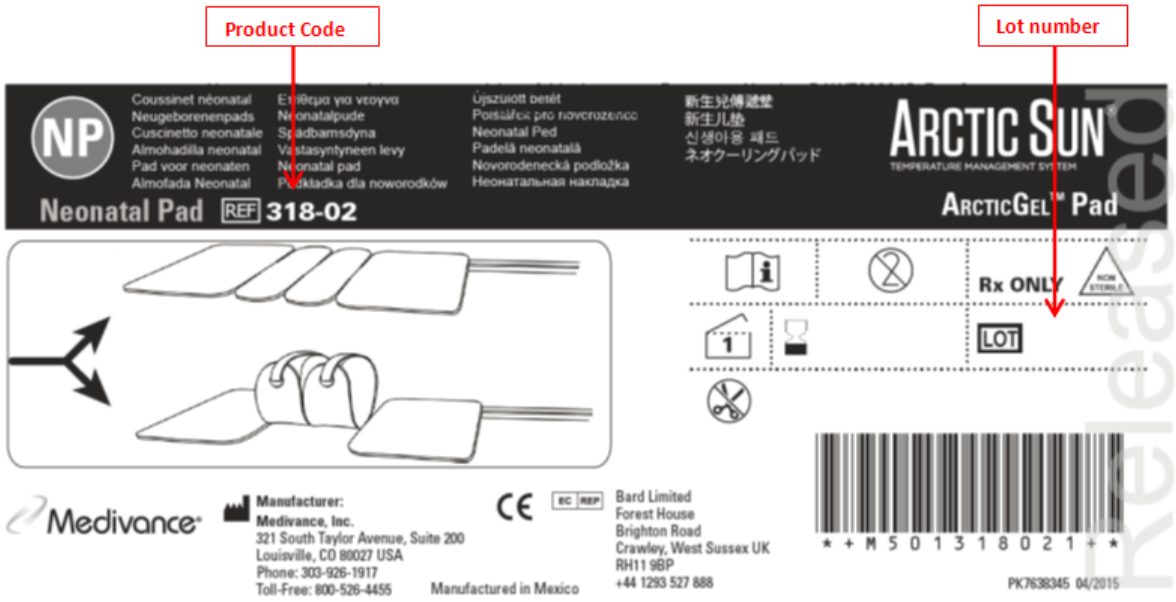
[Signature]

Enclosures (3):

1. Attachment 1: Sample Product Labelling
2. Reply Effectiveness Check Form
3. Multilingual IFU (PK7640432 08/2015)

## Attachment 1: Sample Product Labelling

Identifying Product Code and Lot numbers for your Medivance, Inc. ARCTIC SUN® ARCTICGEL™ Neonatal Pad



**REFERENCE: FA2016-27**

# REPLY EFFECTIVENESS CHECK FORM

## Medivance, Inc. ARCTICSUN® ARCTICGEL™ Neonatal Pad

By completing the below information you confirm that the Field Safety Corrective Action Reference Number FA2016-27 has been received by your Healthcare Facility or Organisation and that it has been read and understood.

You also acknowledge that you have received a copy of the multilingual IFU (PK7640432 08/2015) to accompany all product from the affected lots listed in Table 1.

Our records show that you have received the following units affected by the bounding of this communication.

| Customer Name | Customer PO# | Actual Ship Date | Item Code | Lot# | Quantity Ordered |
|---|---|---|---|---|---|
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| Please PRINT Your Contact Information and fill form out completely | |
|---|---|
| Name | |
| Title | |
| Name of Account / Hospital | [Pre-populated field] |
| Contact Phone Number | |
| Date | |
| Signature | |

**Please return completed form to:**
customer.services@crbard.com
[Local Contact Name]
[Local Contact Title]
[Bard® XYZ (Insert IBC Name / Address / Country]
[Tel: (Local Tel #)] [Fax: (Local Fax #)]
[Email: (name@crbard.com)