

October 21, 2011

URGENT - MEDICAL DEVICE CORRECTION

Alcohol non-sterile prep pads (B339) manufactured by Professional Disposables International (PDI)

Dear Hospital Administrator/Biomedical Manager/Office Manager:

Details on affected devices:

Alcohol prep pads (B339) manufactured by Professional Disposables International (PDI)

Description of the problem:

This letter is to inform you of a potential hazard associated with the use of PDI alcohol prep pads. These non-sterile alcohol prep pads are included in Spacelabs Healthcare hook-up kits and may have the presence of a bacterium, *Bacillus cereus*, which could lead to life-threatening infections.

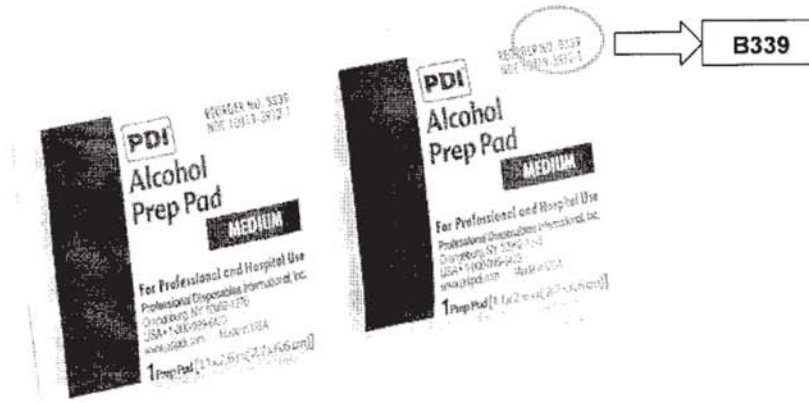
Advise on action to be taken by user:

We at Spacelabs Healthcare recognize and share your concern for patient safety. Please stop using these alcohol prep pads immediately and dispose of them per your hospital or clinic protocol. The following are the Spacelabs Healthcare products and kits that carry these PDI alcohol prep pads:

SLHC Product	Kit Part Number	Description
Aria	23189-010	Kit, Basic hookup, AA
CardioCall	23189-020	Kit, Hookup, CardioCall
Aria	23189-106	Kit, Aria Hookup
Aria	23189-110	Kit, Aria Hookup
Flashcorder	23189-111	Kit, Flashcorder Hookup
Aria	23189-113	Holter Hookup Kit 7 electrode
LifeCard 12	23189-114	Kit, Hookup, LC12, Multilingual
Aria	23189-115	Kit, Basic Hookup, AAA
LifeCard	23189-116	Kit, Holter Hookup, LifeCard
483	23189-117	Kit, Holter Hookup 483
Aria	23189-153	Holter Hookup Kit, 7 electrode
Aria VLC	23189-207	Kit, Aria Hookup, VLC
EVO	50-0048	4 electrode hookup kit without pouch

EVO	50-0049	4 electrode hookup kit with pouch
EVO	SK10456	Sample Kit, Disposables

For ease of identification, the following is a picture of the alcohol prep pads stated above.



The customer letter from PDI is attached for your information.

Contact reference person:

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Roger Moldon, EMEA Quality Manager
 Spacelabs Healthcare Ltd.
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 Hertford SG13 7NW, UK
 Tel: +44 (0)1992 507730
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 e-mail: roger.moldon@spacelabs.com

The local contact information is:

If you have any questions about this corrective action program, please contact Spacelabs Healthcare at 1-800-522-7025 and select 2 for Technical Support.



OUR PASSION IS PREVENTION™

September 16, 2011

PROFESSIONAL SERVICES

URGENT: VOLUNTARY PRODUCT RECALL
PDI NON STERILE ALCOHOL PREP PADS

PDI is voluntarily recalling the following non sterile alcohol prep pads due to the potential presence of low levels of a microorganism, *Bacillus cereus*. This recall is for all lots of the below items within product expiry.

Item #	Product Description	Packing	NDC
B33901	PDI Alcohol Prep Pads non sterile - Medium	10/200's	10819-3912-1
B33905	PDI Alcohol Prep Pads non sterile - Medium	15/200's	10819-3912-1
B33973	PDI Alcohol Prep Pads non sterile - Medium	3000	10819-3912-1
B68870	PDI Alcohol Prep Pads non sterile - Medium	12/100's	10819-3912-3
C29600	PDI Alcohol Prep Pads non sterile - Large	10/100's	10819-3912-2

Please examine your inventory immediately to determine if you have any of the affected products. If you are unsure, please visit www.pdivoluntaryrecall.com. Please remove any affected product from your inventory immediately and return product to your distributor.

Please return the enclosed response form immediately providing the requested information via fax to 1-800-933-6423 or e-mail to productsupport@pdipdi.com. If you have questions, please contact [redacted] at [redacted] or productsupport@pdipdi.com.

This recall is being made with the knowledge of the US Food and Drug Administration.

We appreciate your assistance in this matter.

[redacted]
President and CEO

Two Nice-Pak Park, Orangeburg, New York 10962-1376 • Phone: 1.800.999.6423 • Fax: 1.845.398.5347 • www.pdipdi.com • ISO 9001:2008 Certified

PDI Alcohol Prep Pads
Field Corrective Action Plan