

CUSTOMER FREQUENTLY ASKED QUESTIONS (FAQs)

Voluntary Product Recall of PDI's Non-Sterile Alcohol Prep Pads

September 19, 2011

PDI has decided to voluntarily recall its non-sterile alcohol prep pads as a precaution to emerging concerns posed by the FDA regarding the presence of certain microorganisms in non-sterile alcohol prep pads. PDI has been actively working with the FDA to determine whether recalling these product codes was the best action. This past week, PDI decided to do so as a precaution.

The products identified in the recall met United States Pharmacopeia (USP) standards prior to shipping. Again, this recall is precautionary and voluntary.

To ensure we continue to provide safe and efficacious products that meet and exceed FDA requirements, PDI has updated our product specifications to ensure the absence of these microorganisms in its non-sterile alcohol prep pads. In addition, PDI has always and will continue to conduct pre-shipping testing of all non-sterile alcohol prep pads products manufactured under cGMPs (Good Manufacturing Practices), and only ship those products that met our high quality standards.

All of us at PDI -- who invented the category of alcohol prep pads -- are deeply committed to continuing to provide safe and efficacious products. PDI has and will continue to work with FDA to ensure our products meet or exceed FDA requirements.

1. What products are you recalling?

Effective immediately, PDI is initiating a voluntary product recall of PDI non-sterile alcohol prep pads - This recall is for lots of the below mentioned products still within product expiration date.

Item #	Product Description	Packing
B33901	PDI Alcohol Prep Pads non sterile - Med	10/200's
B33905	PDI Alcohol Prep Pads non sterile - Med	15/200's
B33973	PDI Alcohol Prep Pads non sterile - Med	3000
B68870	PDI Alcohol Prep Pads non sterile - Med	12/100's
C29600	PDI Alcohol Prep Pads non sterile - Lge	10/100's

2. Where do I return product?

To receive credit, all products must be returned to your Distributor. For additional information please visit www.pdivoluntaryrecall.com or email productsupport@pdipdi.com.

3. Does PDI have an alternate product I can order?

Yes, please see the following items for your consideration.

PDI Item No.	Description	Packing (Cases)
B60301	PDI Alcohol Prep Pads Sterile – Medium	10/200's
B60307	PDI Alcohol Prep Pads Sterile – Medium	20/200's
C69900	PDI Alcohol Prep Pads Sterile – Large	10/100's
B10800	PDI Chlorascrub (3.15% Chlorhexidine, 70% Isopropyl Alcohol) Swab	10/100's

4. You haven't been shipping this product for awhile, was it due to this issue? Why has it taken so long to initiate the recall?

Yes, we proactively identified the issue and have been working collaboratively with the FDA to understand their emerging concerns regarding *B. cereus* in non-sterile alcohol prep pads.

5. Will this product affect any kits?

Yes, PDI has new information that some manufacturers have provided this product as a component into medical kits.

6. How do I identify a product number? Where is the product number found? How do I know if my current supply of PDI's non-sterile alcohol prep pads is affected by this voluntary product recall? How do I get more information?

The number can be found on the front of each individual packette as well as on the carton. You can also check to see if your product is affected by going to the Affected Products section of www.pdivoluntaryrecall.com and typing your lot number in the provided area. Once that is entered, please click the Check button.

Affected Products

Please type the Lot Number located on your product packaging in the box below to check if it's affected.

Lot Number:

After the Check button is clicked it will display whether your product is affected and give you direction on how to proceed.

Affected Products

Please type the Lot Number located on your product packaging in the box below to check if it's affected.

Lot Number:

Your product is affected.

You can send the affected product (Lot Number 0918845) back to your authorized distributor. If you are an authorized distributor please contact PDI support for more information.

ITEM NUMBER - CARTON



ITEM NUMBER – INDIVIDUAL PACKETTE (lot number and expiry printed on back of this package)



To determine whether your current supply is affected by this voluntary product recall, visit www.pdivoluntaryrecall.com or contact customer support productsupport@pdipi.com or 800-444-6725.

7. What does potential presence of *B. Cereus* mean?

There are recovery levels of microorganisms allowed under standards set by the United States Pharmacopeia (USP) for non-sterile alcohol prep pads, specifically less than 100 colony forming units, referred to as

CFUs. In this case, the recovery of *B.Cereus*, an organism commonly found in the environment, was recovered at non countable low levels. While PDI products met requirements at the time of release, the company decided to conduct the voluntarily recall for non-sterile alcohol prep pads due the agency's change in position regarding recovery of any level of *B.cereus*.

8. How was the organism detected? When?

The organism recovery was at extremely low levels and was only detectable through an enrichment method. Testing of the organism in question is not a requirement of current United States Pharmacopeia (USP) standards for topical non-sterile products. However, PDI initiated testing as soon as they learned of FDA's concerns. Specifications were updated at the same time and only product meeting these new specifications was released.

9. Are there new FDA guidelines? What are they?

No, none of the regulations have been updated, including the United States Pharmacopeia (USP) standards. However, PDI has instituted the new requirements as a precautionary measure.

10. How will PDI prevent similar future product recalls?

PDI manufactures its products under strict cGMPs (current Good Manufacturing Practices), validated test methods, employ rigorous quality systems and are fully compliant with United States Pharmacopeia (USP) standards and are routinely tested prior to shipping. PDI has updated its specifications for non-sterile alcohol prep pads to eliminate the pathogen in question.

11. What about your sterile alcohol prep pads; were they affected?

No, this is a voluntary recall of only our non-sterile alcohol prep pads as a precaution to emerging concerns posed by the FDA regarding the presence of certain microorganisms only in this product.