

State of California—Health and Human Services Agency

California Department of Public Health



March 22, 2011

AFL 11-28

TO: All Facilities

Director and State Public Health Officer

SUBJECT: H & P Industries, Inc., the Manufacturer of Povidine/Povidone-Iodine Prep Pads: Recall Due to

Potential Microbial Contamination

The California Department of Public Health is requesting action based on an urgent message from the FDA. The FDA has requested "you immediately remove all Povidine-Iodine Prep Pads from your inventory due to a voluntary recall by H & P Industries, Inc., a manufacturer of over-the-counter products. The FDA notified healthcare professionals and patients of the recall involving all lots of Povidine-Iodine Prep Pads manufactured by H&P Industries, Inc. but sold as private labels at the consumer level. This recall has been initiated due to concerns about potential contamination of the products with the pathogenic bacterium Elizabethkingia meningoseptica . This recall involves those products marked as STERILE as well as non-sterile products. Use of contaminated Povidine-Iodine Prep Pads could lead to life-threatening infections, especially in at-risk populations including neonates, immune suppressed patients, and surgical patients. Elizabethkingia meningoseptica infections are resistant to most common antibiotics and

treatment options are limited.

BACKGROUND: Povidine-Iodine Prep Pads are used to disinfect prior to medical invasive intervention. They were distributed nationwide to retail pharmacies and are packaged in individual packets and sold in retail pharmacies in a box of 100 packets. The affected Povidine-Iodine Prep Pads can be identified under several different distributors' names, including Amerinet, Cardinal Health, Versapro/Medical Specialties, Novation/VHA, Triad, Triad Plus, North Safety and Total Resources. Please see the FDA web site www.fda.gov for more information.

RECOMMENDATION: If a consumer has any of these Povidine-Iodine Prep Pads in their possession listing Amerinet, Cardinal Health, Versapro/Medical Specialties, Novation/VHA, Triad, Triad Plus, North Safety and Total Resources or H&P Industries, Inc. as the manufacturer, they should not use the product and should return it to the place it was purchased for a full refund. Customers with questions should call Triad Group Customer Service at 1-262-538-2900, ext 2680.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the preaddressed form or submit by fax to 1-800 FDA-0178.

Thank you for your prompt attention.

Sincerely,

Original Signed by Pamela Dickfoss

Pamela Dickfoss Acting Deputy Director

Attachment: Povidine-Iodine Prep Pad Recall from H&P Industries, Inc.

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Department Website (cdph.ca.gov)



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