AVOX Systems Inc.



AIRCRAFT SYSTEMS

Date: June 13, 2011

To: All Aircraft Operators, Airframe OEMs, Distributors, Zodiac Services Locations,

that may be in possession of suspect Applicator, Antiseptic AVOX P/N 70135-00

From: AVOX Systems Inc.

Subject: Recall Notification Povidine Prep Pads, (Applicator, Antiseptic, AVOX P/N 70135-00)

AVOX Systems was recently notified by the Food and Drug Administration (FDA) and our supplier (*H*&P Industries Inc.) of a recall for Povidine Prep Pads, (Applicator, Antiseptic AVOX P/N 70135-00).

This recall has been initiated due to concerns expressed by the FDA regarding the potential contamination of these products with an objectionable organism, *Elizabethkingia meningoseptica*. H&P Industries Inc. internal investigation also concluded a raw material component as the potential source of this contamination.

Use of contaminated Povidine Prep Pads, (Applicator, Antiseptic, AVOX P/N 70135-00) could lead to life threatening infections, especially in at risk populations, including neonates, immune suppressed patients, and surgical patients. Treatment options are limited for *Elizabethkingia meningoseptica infections*. To date we have not received any reports of adverse events.

This recall extends to all lots of PVP -Iodine Prep Pads (Applicator, Antiseptic AVOX P/N 70135-00) remaining within their labeled expiration dating (three years), including all lot numbers beginning with the digits 8, 9, 0 or 1. PVP -Iodine Prep Pads packages (AVOX P/N 70135-00) identified with and expiration dates between March - 2011 and April 2014 are affected.

The above mention item may have been delivered to your facility in two forms:

- a) Delivered as a detailed component of a First Aid Kit 1st (see Appendix I)
- b) Delivered as a detailed component Applicator, Antiseptic AVOX P/N 70135-00 (see Appendix II)

Please immediately examine your inventory and quarantine product subject to the recall.

To secure replacements go to http://www.avoxsys.com/website.

Complete the form located under heading "Customer Support"

Titled: Recall - PVP - Iodine Prep Pads. (AVOX PN # 70135-00)

Please email your completed form to: Carol Messina – AVOX Customer Service Representative E-mail: carol.messina@zodiacaerospace.com

AVOX apologizes for all inconveniences caused by this situation and pledges its full resources towards a quick resolution.

Sincerely,

Deborah Rindfuss Ellis Director of Quality Assurance 716-686-1562 Deborah.Ellis@zodiacaerospace.com





Appendix I

First Aid Kit PN#	Qty of PVP- Iodine Prep Pads AVOX P/N 70135-00 per Kit	Range of Expiration Dates Effected
70001-00	2 boxes containing (10 each)	
70002-00	4 boxes containing (10 each)	
70003-00	6 boxes containing (10 each)	
70004-00	6 boxes containing (10 each)	March -2011
74050-00	2 boxes containing (10 each)	and April 2014
74051-00	4 boxes containing (10 each)	and April 2014
74052-00	6 boxes containing (10 each)	\neg /
74052-01	2 boxes containing (10 each)	\Box /
73777-01	2 boxes containing (10 each)	

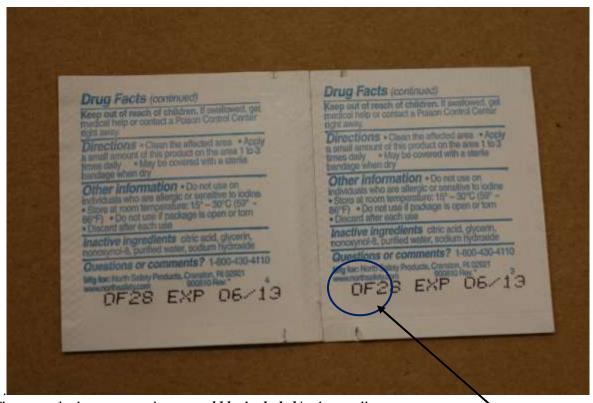




Oxygen Systems



Appendix II



The example that appears above <u>would be included</u> in the recall.

Individual PVP -Iodine Prep Pads identified with lot numbers beginning with the digits 8, 9, 0 or 1 are affected.

