

Health Update:

Plak-Vac Oral Care System

Health Update November 10, 2011

FROM: MARGARET T. DONNELLY DIRECTOR

SUBJECT: Plak-Vac Oral Care System

November 10, 2011

This document will be updated as new information becomes available. The current version can always be viewed at http://www.health.mo.gov

The Missouri Department of Health & Senior Services (DHSS) is now using 4 types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

On October 21, 2011, the Missouri Department of Health and Senior Services (DHSS) issued a Health Alert (http://health.mo.gov/emergencies/ert/alertsadvisories/pdf/HA-BCepacia.pdf) advising health care facilities to temporarily suspend the use of Plak-Vac Oral Care System due to contamination with Burkholderia cepacia. The distributor of this product issued a product recall on October 25, 2011, and notified its customers by letter on October 27, 2011. This Health Update provides additional information on the recall.

This recall affects only the lot numbers shown below. The distributor and manufacturer of the Plak-Vac Oral Care System have been working with the U.S. Food and Drug Administration (FDA) to assure that all remaining product is acceptable for patient use.

Recalled Lots: Lot numbers are located at the lower left hand corner of the main kit label, or on the lower right hand corner of the box label (see pages 2 and 3 for examples taken from the distributor's recall letter). These kits contain cetylpyridinium chloride (CPC) mouthwash packets that are marked with Lot Number 13068. Please contact your distributor if you still have any of these lots in your facility.

- Kit # Lot #
2329 0390016-090711
2329 0390963-101111
2358 092711
2358 0390016-090711
2358 0390077-090811
2330A 082611
2330A 090611
2330A 091211
2330A 091411
2330A 091611
2330A 092611
2330A 092911
2336 389839
2381 101011
2460 092211

The distributor's recall letter is available at: http://trademarkmedical.com/docs/Plak-Vac Oral Care Kit Recall Notification Web Site Posting.pdf.

Questions should be directed to DHSS' Section for Environmental Public Health at 573-751-6141.

Office of the Director
912 Wildwood
P.O. Box 570
Jefferson City, MO 65102
Telephone: (800) 392-0272
Fax: (573) 751-6041
Web site: http://www.health.mo.gov

Example Kit Label

Plak-Vac[®]

Oral Care System

Example Label q4 Oral Care Kit

Kit Contents:

- 2 - 0.34 oz. Pack Mint Mouthwash (1.5% Hydrogen Peroxide)
- 2 - 0.5 oz. Pack Mint CPC Mouthwash (.05% Cetylpyridinium Chloride)
- 6 - 2 gm. Tube Mouth Moisturizer
- 1 - 0.6 oz. Tube Fluoride Mint Toothpaste
- 6 - Foam Applicator Swabs
- 4 - Suction Swabs
- 1 - Yankauer Suction Instrument
- 1 - Sani-Stor Yankauer Storage Holder
- 1 - Plak-Vac Storage Holder
- 1 - Tubing Clamp
- 1 - "Y" Connector
- 1 - Plak-Vac Suction Toothbrush

Order No. 23XX
Lot No. XXXX11 Contents are Non-Sterile
Exp Date:

Manufactured for:
Trademark Medical
St. Louis, MO 63011
800-325-9044

Lot Number

Order No. 23XX
Lot No. XXXX11

Contents are Non-Sterile
Exp Date:

Manufactured for:
Trademark Medical
St. Louis, MO 63011
800-325-9044

Example Mouthwash Packet



Example Box Label

