MEDICAL DEVICE REPORTING — FDA MEDICINE MANUFACTURERS

User Facility Reporting

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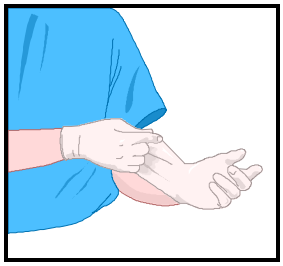
NEW LABELING FOR NATURAL RUBBER LATEX

By Vesna J. Tomazic–Jezic, Ph.D.



Surgical and examination natural rubber latex (NRL) gloves that contain reduced levels of residual chemical additives have been on the market for several years. These gloves, labeled "hypoallergenic," are less likely to cause contact dermatitis in frequent users. However, because of the high prevalence of allergy to NRL proteins (not just chemical additives), this label became misleading and frequently misinterpreted. Because the label "hypoallergenic" pertained only to the glove's chemical content, gloves with this label are capable of causing serious reactions in individuals allergic to NRL proteins. The Food and Drug Administration (FDA), therefore, issued a regulation prohibiting the label "hypoallergenic." The regulation was issued in September of 1997 and went into effect on September 30, 1998 (21 Code of Federal Regulations 801.437).

To assure that glove users would still be protected from chemical sensitization, FDA developed new guidance for manufacturers. The guidance gives recommendations for labeling gloves containing reduced levels of sensitizing chemicals. It also describes the type of testing and data needed to support the claims. The newly issued guidance, entitled *Premarket Notification [510(k)] Submission for Testing for Skin Sensitization To Chemicals In Natural Rubber Products*, offers two claims that would indicate various levels of safety to glove users. (See below for Internet address.)

The first claim, identified as "Low Dermatitis Potential," is for gloves tested by manufacturers and proved less likely to sensitize users. The guidance contains a detailed description of the testing recommended to manufacturers to support this particular claim.

In the same document, FDA also identifies a second claim for "Low Thiuram, and/or Carbamate, and/or Thiazole." This claim is for gloves tested by manufacturers and proved not to cause skin reaction in users already sensitized to these chemicals. This claim must be supported with additional testing pertaining to each of the specific chemicals. Gloves with this claim are suitable for use by individuals who are already sensitized to the particular chemical(s) specifically identified in the label.

With continued glove use, users with chemical sensitivity usually develop severe and persisting skin lesions. Because of the increased need for proper protection from blood-borne pathogens (such as AIDS and hepatitis), lesions can threaten the user's career. Users are frequently forced to completely avoid the use of NRL gloves. Availability of gloves with one of these two claims will be of great benefit, both for preventing sensitization of frequent users and for allowing those who are already sensitized to safely continue their professional activities.

A complete text of the guidance document is available from the FDA home page: http://www.fda.gov/cdrh/ode/944.pdf or from the CDRH Facts-on-Demand system at 1-800-899-0381 or 301-837-0111. Specify number 944 when prompted for the document shelf number.❄

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In This Issue:

MEDICAL DEVICE YEAR 2000 UPDATE

By Thomas B. Shope, Jr., Ph.D.

Many medical devices contain computer chips and software that incorporate two digits to represent the year. This use of two digits is expected to present a problem for those devices that remain unmodified when the year 2000 (Y2K) arrives. Performance of devices may be affected in unexpected and unpredictable ways when the date changes from December 31, 1999 to January 1, 2000.

Although there is the potential for all devices containing computer chips and software to be affected, many manufacturers of medical devices have anticipated this problem and have taken steps to originally design or modify their devices not to be affected January 1, 2000. The Food and Drug Administration (FDA) believes that only a few types of devices are likely to present a significant or substantial risk to patients as a result of a date-related failure due to Y2K or other results of using only two digits to represent the year.

FDA does not know of any implanted device whose function will or can be affected by the transition to Y2K or by the use of two digits to represent the year. A few of these types of devices have external accessories or controls that are date dependent. Most have been identified and solutions or replacements (upgrades) are available. FDA anticipates no reason to contemplate removal of an implanted device for Y2K-related reasons.

Types of Devices That Might Be Affected

Because of their intended functions and use of date-related information, FDA knows of a limited number of devices that need to be identified and corrected or accommodated. Based on current information, the following device types have the greatest potential for presenting a risk to patients if a date problem is not corrected.

- Radiation Treatment Planning Systems

Several older versions of these systems are known to be Y2K non-compliant. Manufacturers have identified these systems and have notified users that the systems should be discontinued or the systems modified, usually with a software version upgrade.

- Hemodialysis Delivery Systems and Therapeutic Apheresis Systems

Hemodialysis delivery systems are software-controlled devices that regulate blood and/or plasma flow in an extracorporeal circuit. Therapeutic apheresis systems are software-controlled centrifuge and column type systems. Neither type of device specifically uses a date to start or stop flow or to automatically control treatment. However, FDA believes that most of these devices have a clock function to assist the operator in recording and managing treatment data. If the date/time function is not Y2K compliant, it might affect device function.

- Alpha-fetoprotein Kits for Neural Tube Defects

Some products use computer calculation of the multiple of the median value for patients at the same gestational week. The patient's test value is divided into the median, and that number is then used to assess the risk of an affected pregnancy. This could give an incorrect calculation, if there is a problem associated with recording the last period or gestational time.

- Chemistry Analyzers for Clinical Use

These automated analysis devices are used for performing a variety of clinical tests. Problems that could result from date errors include: (1) misreading or not reporting expected age-related values or reference ranges; and (2) on-board stored quality control (QC) data being lost or rejected due to dating change. The risk associated with these devices results from the inability to get a timely clinical test result in an emergency situation.

- Blood Establishment Computer Software

This software performs a variety of functions including critical tasks such as donor deferral. A number of systems have been reported as Y2K non-compliant. Manufacturers are continuing assessments and developing upgrades.

- Image-generating Medical Devices

Various types of image-generating medical devices, including communication, storage, and display work-stations and systems that need to store, track, and recall images in a given chronological order, might present problems.

Failure of the system to accurately maintain date information associated with each image could lead to or contribute to incorrect diagnosis or mismanagement of therapy. These problems could also arise with systems producing the images in devices such as x-ray systems, computed tomography systems, magnetic resonance imaging systems, and diagnostic ultrasound systems.

Federal Y2K Biomedical Equipment Clearinghouse Web Site

FDA recently announced the planned expansion of product information at its Year 2000 (Y2K) web site. This was prompted by feedback to FDA from users who wanted one central, comprehensive source of information on both compliant and non-compliant Y2K medical devices. The site, now formally designated as the Federal Y2K Biomedical Equipment Clearinghouse, is intended to provide comprehensive and up-to-date information on the Y2K status of biomedical equipment. (The new area is for products that do not have problems.) The Federal Y2K Biomedical Equipment Clearinghouse is located at:

www.fda.gov/cdrh/yr2000/year2000.html

FDA plans to expand the Y2K Biomedical Clearinghouse site in two basic areas:

- Year Y2K Non-Compliant Products

FDA has asked manufacturers to provide more detailed identification of non-compliant products, as well as more detailed descriptions of how products will operate as a result of their uncorrected date problem.

- Year Y2K Compliant Products

FDA has asked manufacturers to submit lists of their specific product models that are Y2K compliant. FDA requested that this compliance information be furnished to the Federal Y2K Biomedical Equipment Clearinghouse, even if the manufacturer maintains this information at another web site. Having the information at one site is more convenient for users.

Reporting Problems to FDA

FDA also warned hospitals, emergency medical services, and healthcare practitioners that the kind of date-related computer problems expected to occur on January 1, 2000 could affect some medical devices one year earlier (January 1, 1999) or at other times during 1999 as programs that anticipate dates beyond January 1, 2000 are used. As with any device-related serious injury or death in your facility, report deaths to FDA and the manufacturer and injuries to the manufacturer only. Use the mandatory MedWatch (FDA's reporting program) reporting form 3500A. If the manufacturer is not known, report to FDA.

Users may voluntarily report to MedWatch any Y2K-type problems that did not result in injury or death but caused unexpected performance not anticipated in information from the manufacturer. Report these events by telephone to 1-800-FDA-1088, by FAX to 1-800-FDA-0178, or by mail (using form 3500) to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857-9787.

The Health Care Financing Administration (HCFA), in conjunction with the nonprofit RX2000 Solution Institute, is presenting seminars in various cities to provide Y2K strategies for Medicare and Medicaid providers. These seminars are especially directed to rural healthcare facilities. Information about the benefits of the conference, agenda, locations, dates, and registration can be found at:

www.rx2000.org/data/conferences/RSCMMP/present.asp

You can also call HCFA's toll free Y2K hotline, 1-800-958-4232, Monday through Friday, 8:00 a.m. to 8:00 p.m. (EST). ❄

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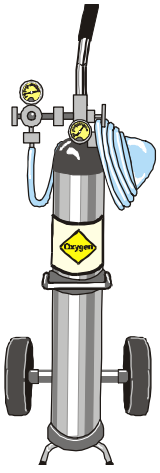
EXPLOSIONS AND FIRES IN ALUMINUM OXYGEN REGULATORS



In February 1999, the Food and Drug Administration (FDA) and the National Institute for Occupational Safety and Health (NIOSH) jointly issued a Public Health Advisory about hazards associated with oxygen regulators made of aluminum. The full text of the advisory is available on the Internet at:

www.fda.gov/cdrh/safety.html.

The Problem

Over the past 5 years, FDA has received 16 reports of burning or exploding aluminum regulators used with oxygen cylinders. These incidents caused severe burns to 11 healthcare workers and patients. Many of the incidents occurred during emergency medical use or during routine equipment checkout. It is believed that aluminum in the regulators was a major factor in both the ignition and severity of the fires, although there were likely other contributing factors. Most of the reports received by FDA were for the Model L270 series of aluminum regulators manufactured by Life Support Products Inc. and Allied Healthcare Products Inc. (Earlier models were known as "270" regulators.)

Allied Healthcare Products makes about 60 percent of the oxygen regulators for emergency use. The manufacturer plans to discontinue distributing all regulators containing aluminum and to manufacture only brass regulators. In order to avoid potential product shortages, Allied is instituting an interim measure to replace internal high-pressure aluminum components with brass components in all models manufactured.

Because aluminum is lighter in weight than steel, it is also used in oxygen cylinders. FDA and NIOSH believe that aluminum cylinders can be used safely with brass regulators, but that the combination of both oxygen regulators and cylinders made from aluminum poses an increased fire hazard. Contamination of the oxygen supply with particulate matter can also increase the risk of fire.

Background

Most oxygen regulators are made of brass or aluminum. Aluminum and its alloys are more likely to ignite than brass. In standard tests, aluminum can burn vigorously at pressures as low as 25 pounds per square inch (psi), while brass will not burn at pressures below 10,000 psi. Although there have been instances of fires in brass oxygen regulators, they are rare. Brass oxygen regulators have a long history of safe use and are believed to be safer than aluminum oxygen regulators for use with high pressure compressed oxygen. FDA has no reports of fire or explosion with aluminum oxygen regulators used in low pressure systems (e.g., piped distribution to wall mounted supply taps at <50 psi).

Recommendations

FDA is working with manufacturers to improve the safety of oxygen regulators and to restrict the use of aluminum exposed to high-pressure oxygen in regulators. In the meantime, FDA and NIOSH advise that the following precautions be taken.

- If using high pressure oxygen regulators that contain any aluminum exposed to high-pressure oxygen, replace them with regulators made of brass. Consult with the manufacturer, if you do not know what material was used in your regulators.

- If non-aluminum oxygen regulators are not available, follow the precautions described below to minimize the risk of fires until brass replacement regulators become available.

Safe Practices for Handling and Operating Oxygen Equipment

Oxygen used in the medical profession can be very hazardous. Although oxygen does not burn, it does support combustion. A material that will not burn in air may burn in high pressure pure oxygen, such as the metal in oxygen regulators or cylinders.

Comprehensive guidelines and training on the safe handling of oxygen are available from several sources listed below. Following are some general guidelines for minimizing the chance of fire.

FDA is working with manufacturers to improve the safety of oxygen regulators….

Storage, Maintenance and Handling

- Do not allow smoking near oxygen.

- Store oxygen in clean, dry locations away from direct sunlight.

- Do not allow post valves, regulators, gauges, and fittings to come into contact with oils, greases, organic lubricants, rubber, or any other combustible substance.

- Make sure that any cleaning, repair, or transfilling of oxygen equipment is performed by qualified, properly trained staff.

- Do not work on oxygen equipment with ordinary tools. Designate special tools and clean, store, and label them for "Use With Oxygen Equipment Only."

- Make sure that any components added to the regulator (e.g., gauge guards) are installed so that they do not block the regulator vent holes.

- Use plugs, caps, and plastic bags to protect "off duty" equipment from dust and dirt.

- Minimize particulate migration from the cylinder by installing a standoff tube (bayonette) at the inlet of the post valve.

Use

- Make sure that all staff members using oxygen equipment are adequately trained in its operation and in oxygen safety and have knowledge of the manufacturer's instructions for using the equipment.

- Visually inspect the post valve gasket and regulator inlet prior to installation. If not visually clean, they should not be used.

- Momentarily open and close ("crack") the post valve to blow out debris prior to installing a regulator.

- Make sure that the regulator is set with the flow knob in the off position before attaching it to the cylinder.

- Position equipment so that the valve is pointed away from the user and other persons.

- Open the cylinder valve slowly and completely to minimize the heat produced and to achieve the desired flow conditions within the equipment.

- Do not look at the regulator pressure gauge until the cylinder valve is fully opened.

Getting More Information

If you have questions about aluminum oxygen regulators or the Public Health Advisory, contact the Issues Management Staff, Office of Surveillance and Biometrics (HFZ-510), by mail at 1350 Piccard Drive, Rockville, MD, 20850; by FAX at (301) 594-2968; or by e-mail at ssm@cdrh.fda.gov or aag@cdrh.fda.gov. Future FDA Public Health Advisories, Safety Alerts, and other FDA postmarket safety notifications can be obtained by list server subscription via e-mail. To subscribe, send an e-mail request to fdalists@archie.fda.gov. In the text of the message, type **subscribe dev-alert**.❄

AVOIDING STICKS FROM SHARP CONTAINERS*

by Audrey Morrison, R.N., B.S.N.

While placing a lid onto a container for disposal of sharps, a housekeeper received a needle-stick injury. The housekeeper reported that he had used extra force to push the lid down, because the container was overfilled.

Another housekeeper stuck her finger while removing a full sharps container from a wall bracket. A needle protruded from the front wall of the container which was filled beyond the recommended fill line. The container had several 60-cc syringes as well as plastic bags and disposable gloves.

What went wrong?

When used properly, sharps containers can prevent needle-stick injuries. When used improperly, they can create a serious hazard. In the examples above, several things went wrong:

- Containers were filled beyond recommended levels.
- The user forced the lid onto an overfilled container.
- Large (60-cc) syringes were placed in a container not intended to handle them.
- Materials other than sharps were placed into the container, preventing needles from falling to the bottom.

What precautions can you take?

- Read cautionary statements on sharps containers.
- Do not exceed the recommended fill line or use containers identified for disposal.
- Avoid forcing sharp instruments into containers.
- Drop syringes into container as directed by the label.
- Use the containers for sharps only.
- Before handling filled containers, check carefully for protruding sharps.
- Replace containers when they are full.
- Make education regarding needle safety and sharps containers available to all workers at risk for needle-stick injury. ❄

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*This article has been adapted from the October issue of *Nursing '98.*

GLASS CAPILLARY TUBES POSE RISKS

In February 1999, three government agencies jointly issued a safety advisory about potential risks posed by breakage of glass capillary tubes. Accidental breakage of glass capillary tubes used to collect blood may cause injury and/or infection from bloodborne pathogens, including human immunodeficiency virus (HIV) and hepatitis B and C viruses.

The Food and Drug Administration (FDA), the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), and the Occupational Safety and Health Administration (OSHA) issued the warning to healthcare workers. They also made recommendations to minimize these risks.

Background

Glass capillary tubes are used for the collection of blood in a variety of healthcare settings, including hospitals, ambulatory care facilities, physicians' offices, blood donation facilities, and blood testing centers. Accidental breakage of these slender, fragile tubes has been reported when the tubes are inserted into putty to be sealed and during centrifugation.[1] Breakage of the tubes during putty insertion may result in a penetrating wound and blood inoculation to the user. One such injury resulted in the transmission of human immunodeficiency virus (HIV) to a physician, who has since died of acquired immunodeficiency syndrome (AIDS).[2] Glass capillary tubes can break during centrifugation and cause blood to splatter, potentially exposing personnel to bloodborne pathogens. The broken glass fragments can injure the user, resulting in a percutaneous exposure to blood.

At one acute-care facility in 1992, the injury rate associated with glass capillary tubes was 2.6 per 100,000 tubes.[3] Approximately 108 million glass capillary tubes are sold each year in the United States, suggesting that approximately 2,800 injuries may occur nationwide, if a similar injury rate occurs at other healthcare facilities.[3] Two systems for surveillance of injuries to hospital-based healthcare workers have reported injuries from glass capillary tubes, some of which caused blood exposure and resulted in the need for antiretroviral post-exposure prophylactic therapy.[4]

Recommendations

To reduce the risk of injury from breakage of capillary tubes, FDA, NIOSH, and OSHA recommend using blood collection devices less likely to break, such as:

- capillary tubes that are not made of glass;[5]
- glass capillary tubes wrapped in puncture-resistant film;
- products that use a method of sealing that does not require manually pushing one end of the tube into putty to form a plug; or
- products that allow the blood hematocrit to be measured without centrifugation.

Although FDA, NIOSH, and OSHA cannot recommend specific products, blood-collection devices with these characteristics are currently available. Their use may reduce the risk of injury and blood exposure.

Reporting and Recordkeeping

The Safe Medical Devices Act (SMDA) of 1990 requires hospitals and other user facilities to report deaths, serious illnesses, and injuries associated with the use of medical devices, including glass capillary tubes. Readers should follow the procedures established by their own facilities for such mandatory reporting of adverse events. Practitioners who become aware of any medical device-related adverse event or product problem/ malfunction should report to their designated contact person for medical device reporting.

Even if a medical device-related incident or product quality problem is not required to be reported under the SMDA, health professionals are encouraged to report any medical device-related concerns to the FDA's voluntary MedWatch reporting program. Submit reports to MedWatch by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; via the MedWatch website at www.fda.gov/medwatch; or by mail to MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, MD 20857-9787.

Occupational illnesses and injuries sustained from glass capillary tubes may be recordable under OSHA's record-keeping requirements (see 29 CFR Part 1904: Recording and Reporting Occupational Injuries and Illnesses). Additionally, post-exposure follow-up for employees may be indicated [see OSHA's Instruction CPL 2-2.44C (March 6, 1992): Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens Standard, 29 CFR 1910.1030].

Getting More Information

If you have questions about the safety advisory on glass capillary tubes, contact:

•FDA: Office of Surveillance and Biometrics, FAX at (301) 594-2968 (Attn: Carol L. Herman, Public Health Analyst, by e-mail at czh@cdrh.fda.gov);
•CDC: National Institute for Occupational Safety and Health, at 1 (800) 35-NIOSH (1-800-356-4674); or
•OSHA: Directorate of Technical Support, Office of Occupational Health Nursing, at (202) 693-2120 (attn: Elise Handelman).

Copies of the safety advisory and additional relevant information can be found on the following WebPages:

http://www.fda.gov/cdrh/safety.html
http://www.cdc.gov/niosh/homepage.html
http://www.osha-slc.gov/SLTC/needlestick/index.html

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AAMI AND FDA TO HOLD CONFERENCE ON REUSE OF SINGLE-USE DEVICES

The Association for the Advancement of Medical Instrumentation (AAMI) and the Food and Drug Administration (FDA) are jointly sponsoring a conference on the reuse of single-use devices when multiple patients are involved. The conference will be held May 5-6, 1999, in Arlington, Virginia.

The conference will provide a forum for professionals from healthcare institutions, government, and the medical device industry to discuss current practice and recent scientific findings regarding reuse of single-use devices. A series of panel presentations will address the patient's perspective and the ethics of reuse, the economics of reuse, and the views of healthcare professionals, manufacturers and reprocessors. Findings from the conference will be used to determine if additional regulatory controls, voluntary consensus standards, or other guidance are needed to ensure patient safety.

AAMI and FDA are collaborating with various organizations including the American Society of Healthcare Central Service Professionals, Association of Disposable Device Manufacturers, Association of Medical Device Reprocessors, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, ECRI, Health Industry Manufacturers Association, International Association of Healthcare Central Service Material Management, and the Medical Device Manufacturers Association.

To register for the conference, contact AAMI's customer service department at 1-800-332-2264. For additional information, including the preliminary conference program, visit AAMI's website at www.aami.org.

FREE MEDWATCH SOFTWARE

Computer software for electronic reporting is now available free through the MedWatch Program. The address is:

www.fda.gov/medwatch

The software allows healthcare professionals, user facilities, manufacturers, and distributors to easily complete and print copies of both the MedWatch Voluntary Form 3500 and the Mandatory Form 3500A. The software can be used to file all types of adverse events and product problems involving FDA-regulated products, including medical devices, drugs, biologics, and special nutritional products.

BILIBLANKET PHOTOTHERAPY LIGHT SAFETY TIPS*

by Eileen K. Woo, R.N., B.S.N.

A 6-day old, 34-week gestation infant was being treated with a biliblanket phototherapy light for hyperbilirubinemia. When the nurse removed the biliblanket from the infant, she noticed a scratch and some blood on the infant's knee.

What went wrong?

Investigation of the infant's scratch revealed that the disposable cover had been cut crosswise in half, exposing the infant to a small amount of dried adhesive where the cable was connected to the pad. The dried adhesive caused the scratch, but fortunately the injury was minor.

The biliblanket, used to treat jaundice, consists of a fiber-optic pad and a portable illuminator that deliver therapeutic light to the infant. The pad should be covered completely with a disposable cover and placed underneath or wrapped around the infant. Any alteration of the cover, such as cutting it in half, may contribute to an adverse event.

What precautions can you take?

Follow these tips to ensure that you use the biliblanket safely:

- Inspect the biliblanket phototherapy system to ensure that the fiber-optic pad is smooth and free from flaws. Determine that the cable and illuminator work properly.
- Check that the disposable cover completely protects the fiber-optic pad, including the area where the cable is connected to the pad. Do **not** cut or alter the cover.
- Secure the disposable cover around the pad cable with self-adhesive tabs.
- Expose as much of the infant's skin as possible to the illuminating side of the fiber-optic pad.
- Remove everything except the disposable cover from between the infant's skin and the light pad. The infant may wear a diaper, clothing, or a blanket *over* the pad.
- Shield the infant's eyes from direct exposure to the light with an opaque eye mask.❄

Eileen Woo, R.N., B.S.N., is a nurse consultant in CDRH's Office of Surveillance and Biometrics.

*This article has been adapted from the August issue of *Nursing '98*.

User Facility Reporting Bulletin

FDA produces the *User Facility Reporting Bulletin* quarterly to assist hospitals, nursing homes and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Administration Modernization Act of 1997.

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