FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING

# USER Facility Reporting

Issue No. 21 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Fall 1997

## CORNSTARCH AS A GLOVE DONNING POWDER

*by Vesna J. Tomazic-Jezic, Ph.D.*

Manufacturers of latex gloves are now using cornstarch to help users slip on gloves more easily. Previously, talc was used as a donning powder, but it can cause post-operative complications such as adhesions and granulomas. For this reason, the Food and Drug Administration (FDA) recommends that talc no longer be used.

Eliminating talc significantly reduces the risk of granuloma formation, but cornstarch has also been implicated in other complications. Some of these problems have been documented in the clinical literature. For example, cornstarch is a highly absorbent powder that reduces the skin's natural moisture and oils; this can cause dryness and cracking of the user's hands. This drying and cracking can allow infectious agents, chemicals, and even cornstarch particles themselves to penetrate the skin.

Cornstarch also has a propensity to bind the proteins that are present on natural rubber latex gloves. These proteins are known to cause latex allergy. When the cornstarch and proteins are aerosolized and inhaled, the results can be severe respiratory reactions in latex allergic individuals. The chance of **non-allergic** users becoming allergic may increase after direct contact of latex proteins with mucous membranes. In an environment where glove use is

*(Continued on page 2)*

## FDA ISSUES FINAL RULE ON NATURAL RUBBER DEVICE LABELING

On September 30, 1997, the Food & Drug Administration (FDA) issued a final rule (*Federal Register*, Vol. 62, page 51021) requiring cautionary statements in the labeling of all medical devices that contain natural rubber likely to come in contact with humans. This rule also affects device packaging that contains natural rubber. Highlights of the rule are:

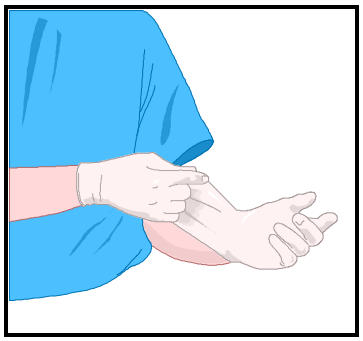
- Labeling of medical devices containing natural rubber latex that is likely to come in contact with humans must state in bold print: **"Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."**

- Labeling of medical devices that contain dry natural rubber likely to come in contact with humans must state in bold print: **"This Product Contains Dry Natural Rubber."**

- Packaging that contains natural rubber latex likely to come in contact with humans must state in bold print on the device labeling: **"Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."** *(Continued on page 2)*

### In This Issue:

## CORNSTARCH AS A GLOVE DONNING POWDER - *(from page 1)*



great, the amount of aerosolized allergens may be high enough to affect not only glove users, but also other individuals in the area who are not using gloves. Allergenic powder may remain on clothing and equipment, even when powdered gloves are not in use.

Patients can also be affected in other ways. Cornstarch can enter a patient's tissues during surgical and post-surgical procedures. Powder could be on the inside and the outside of the gloves. Each time a healthcare worker dons or removes gloves, the powder becomes airborne and stays in the environment for some time. If cornstarch enters the surgical site, it can cause an acute inflammatory process that later may become chronic and result in tissue adhesions. Because adhesions of the peritoneal tissues after surgery have been observed in clinical practice, the role of glove powder in this process remains a concern.

It is important to note that the level of an airborne allergen depends not only on the amount of powder, but also on the amount of protein on the gloves. **Cornstarch, without latex proteins, does not cause allergic reactions**. Therefore, the problems caused by airborne latex allergens can be decreased by reducing the amount of powder in the air and the amount of allergen contained in the natural rubber latex gloves. Manufacturers are already developing latex gloves with reduced levels of protein and reduced amounts of powder as well as powder-free gloves. Several of these products are now on the market.

Some manufacturing processes that make the gloves powder-free also lower the total protein allergen on the finished latex product. Based on preliminary observations, the use of powder-free gloves appears to reduce both the level of airborne allergen and the amount of allergen remaining on the finished latex glove. But, the new technologies for production of powder-free gloves may affect other glove properties, such as barrier effectiveness and shelf life.

Since the primary concern with glove powder is its role as an allergen carrier, both the amount of powder and the amount of protein on finished latex devices are important. For these reasons, latex sensitive healthcare workers should consider using the reduced-protein, reduced-powder, or powder-free latex gloves now available.

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*Vesna J. Tomazic-Jezic, Ph.D., is an immunologist in CDRH's Office of Science and Technology.*

## FDA Issues Final Rule On Natural Rubber Device Labeling - *(from page 1)*

- Packaging that contains dry natural rubber likely to come in contact with humans must state in bold print: **"The Packaging of This Product Contains Dry Natural Rubber."**

- Labeling of medical devices that contain natural rubber likely to come in contact with humans shall not contain the term **"hypoallergenic."**

This final rule is effective on **September 30, 1998**. If manufacturers reorder labeling stock before the effective date, FDA encourages them to add the required labeling and/or to remove the hypoallergenic claim at that time.

A copy of the final rule can be obtained from either CDRH's Facts-on-Demand system or the World Wide Web at http://www.fda.gov/cdrh/fr/fr0930bf.html. For Facts-on-Demand, dial 800-899-0381 or 301-827-0111 from a touch tone phone and follow the prompts:

1. Press "1" for DSMA Facts.
2. Press "2" to order a document.
3. Press 454# for the document.

For more information on this rule, call the Division of Small Manufacturers Assistance, 301-443-6597 or 800-638-2041 and ask for Andrew Lowery on extension 116 or Arthur Yellin on extension 146. You may also send your comments or questions by FAX to 301-443-8818.

Dr. Melvin Stratmeyer of the Office of Science and Technology is also available to discuss this regulation. He can be contacted at 301-443-7209.

## FDA ANSWERS LATEX GLOVE QUESTIONS

### Q. Does FDA agree with the recommendations in the NIOSH Alert published June 23, 1997?

**A.** FDA agrees that latex allergy is a significant problem for some healthcare workers and that switching to reduced-protein gloves, reduced-powder gloves, or powder-free gloves to minimize exposure to latex protein may help to minimize the chance of developing an allergy. But, we are concerned that if all medical facilities were to switch immediately, a shortage of reduced-protein gloves and powder-free gloves would occur. If this results in some healthcare workers not using gloves, it could endanger them and their patients. Another concern is that manufacturing processes for reduction of powder and protein may compromise barrier properties and shelf life of gloves. From a public health standpoint, this could be a more serious problem than the potential for latex allergy.


The most prudent course of action would be to immediately provide non-latex gloves to all latex-sensitive healthcare workers and then to phase in the use of reduced-protein gloves, reduced-powder gloves, and powder-free gloves by those healthcare workers who are not sensitive to latex as supplies become available.

### Q. How many reports of allergic reactions has FDA received and how many were of deaths?

**A.** Since 1974, FDA has received over 1700 reports of allergic reactions to latex. Seventeen deaths have been reported. However, since adverse reactions are often under-reported to FDA, it is possible that there are many more adverse reactions and deaths. Other sources of data suggest a frequency of latex allergy among healthcare workers greater than would be indicated in the FDA reports. The records do not differentiate between powdered and powder-free gloves.

### Q. Are powder-free gloves as good as powdered gloves?

**A.** All latex gloves currently marketed (powdered and powder-free) are required to meet the same performance specifications, but the shelf life for powder-free gloves may be shorter than for powdered gloves. Although there are no special requirements or limitations on the use of powder-free gloves, some non-allergic healthcare workers may prefer to continue to use the powdered type.

### Q. Why is FDA continuing to allow the marketing of latex gloves?

**A.** The basic criterion FDA uses in allowing the marketing of latex gloves is their effectiveness in creating a barrier against the transmission of infectious agents. Although FDA is concerned about latex allergies, the agency recognizes that many of the materials used in medical products can cause allergic reactions in some people. FDA believes healthcare workers and medical facilities are responsible for protecting sensitive individuals by choosing non-allergenic products where appropriate. In the case of latex allergies, there are several types of non-latex gloves on the market, as well as several brands of reduced-protein gloves and powder-free gloves.

### Q. Will using petroleum-based skin care products affect latex gloves?

**A.** Any skin care product or lubricant containing petroleum oils (petrolatum, mineral oil, etc.) can degrade latex. In the case of gloves, this could cause tearing and premature failure. Thus, when handling infectious agents, it is especially important to avoid the use of skin care products containing petroleum oils.

## INFUSION PUMP MISHAP: OUTSIDE THE CHANNEL*

*By Christine Parmentier, R.N.*

A patient with chest pain had an order for I.V. nitroglycerin. The infusion was initiated at 12 ml per hour. After loading the administration set into the pump, the nurse programmed the pump to deliver the solution as ordered. The pump display indicated that the medication was being delivered correctly, and no pump alarms sounded.

When the nurse next checked, she discovered that the patient was still having pain. After consulting with the physician, she gradually increased the infusion rate to 40 ml per hour, but the patient continued to have chest pain and hypertension. Even though the display indicated that the pump was working correctly, the nurse suspected a problem with the infusion when she noticed that no drops were forming in the drip chamber. When she opened the pump door, she found tubing lying outside the tubing channel. Because the tubing was not in contact with the pumping fingers, the pump was not delivering any solution.

### What went wrong?

Linear peristaltic pumps, which use a synchronized squeezing motion to propel fluid through the tubing, are sometimes used with standard I.V. administration sets. According to reports, the tubing has been found outside the tubing channel, occasionally collapsed or kinked. How the tubing became displaced is not clear. Perhaps there was a little slack in the tubing when it was loaded. If so, then the pumping fingers could have pushed the tubing away from the tubing channel, so that the pumping fingers could no longer squeeze the tubing and push the contents through the tube. The result is inadequate or no delivery.

> If you have a problem with a medical device,…FDA wants to hear about it.

Because a pump display indicates that the pump is performing correctly, the problem may go unnoticed and patients can be harmed.

### What precautions should you take?

To prevent this problem, take these steps when loading this type of infusion pump with a standard I.V. administration set:

- Make sure that you have loaded the I.V. tubing within the tubing channel and aligned the tubing properly with the pumping fingers.
- Before you close the pump door, verify that you have not left any excess tubing in the channel.
- Check the drip chamber to confirm that the solution is dripping. If the pump display indicates that the solution is infusing but you do not see drops forming, reload the tubing and check the drip chamber again.

### Reporting to FDA

If you have a problem with a medical device, such as the one described above, the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) wants to hear about it. CDRH maintains a data base of adverse device event reports, including malfunctions, injuries, and deaths. As the primary user of a medical device, you are in a unique position to report a device that is not performing properly.

Although you need to support the adverse event reporting policy of your healthcare facility, you can also submit a voluntary report through the MedWatch program whenever a medical device fails to work as expected. Your report of difficulty using a specific device can alert the FDA to widespread problems. To file a report, call 1-800-FDA-1088 or FAX to 1-800-FDA-0178.

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*Christine Parmentier, R.N., is a Nurse Consultant in CDRH's Office of Science and Biometrics.*

**This article was adapted from the April issue of Nursing 97.*

### FEEDBACK ON MDR REPORTING

In response to requests for feedback on MDR reporting, we have included five articles originally written by FDA staff for *Nursing 97.*

## HEATING DEVICES: HOW TO AVOID BURNS*

*By Joan Ferlo Todd, R.N., B.S.N.*

A patient with arthritis suffered a second-degree burn to the hip after receiving treatment for pain with a heating pad. The heating pad had been set at low and left on for less than 20 minutes. The patient had been lying on top of the pad. Later testing showed that the pad was working properly and met the manufacturer's specifications.

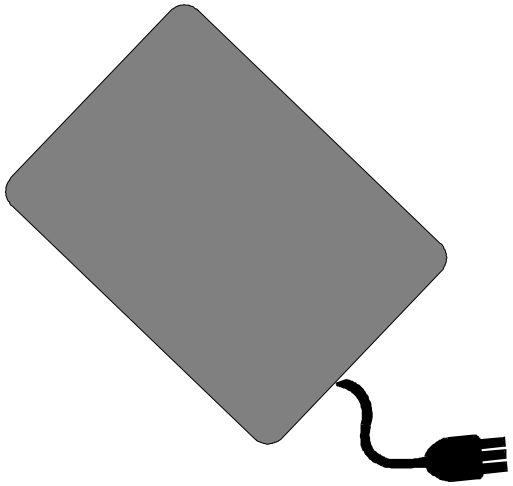
### What went wrong?

Although generally safe, therapeutic heating devices (such as heating pads, microwavable hot packs, and hot-water bottles) can cause burns. Most burns result from improper use or use with inappropriate patients such as infants or elderly patients. The severity of the burn is influenced by factors such as heat intensity, length of application, and the patient's age, medical history, and ability to sense pain.

### What precautions should you take?

Follow these do's and don'ts to keep your patient safe when using heating devices:

- DO inspect the device before each use to ensure that it is in proper condition.
- DO read directions and contraindications for use.
- DO use a protective cover.
- DO place the pad or pack on top of – **not under** – the patient.
- DO assess skin integrity frequently and adjust the therapy according to the patient's skin tolerance – **no longer than15 to 20 minutes.**



- DO NOT use the device on someone who is sleeping or unconscious, an infant, or a patient with altered mental status or decreased skin sensation (such as people with diabetes or compromised skin circulation).
- DO NOT use pins to fasten the device in place.
- DO NOT use with ointments or salve preparations containing heat-producing ingredients.
- DO NOT use electrical heating devices in an oxygen-enriched environment or near oxygen-emitting equipment.

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*Joan Ferlo Todd, R.N., B.S.N., is a Nurse Analyst in CDRH's Office of Science and Biometrics.*

**This article was adapted from the October issue of Nursing 97.*

### SCHEDULE FOR BULLETIN TO BE RELEASED

This is the first issue of the *User Facility Reporting Bulletin* to be sent to readers by FAX. For those readers who prefer the Internet, the *Bulletin* will be posted quarterly on CDRH's Website (http://www.fda.gov/cdrh/fusenews.html) by

**January 15 April 15 July 15 October 15**

## DISPOSABLE DEVICES: TIME FOR A CHANGE*

*By Christine Parmentier, R.N., and Caroline Webb, R.N., C.C.R.N., B.S.N.*

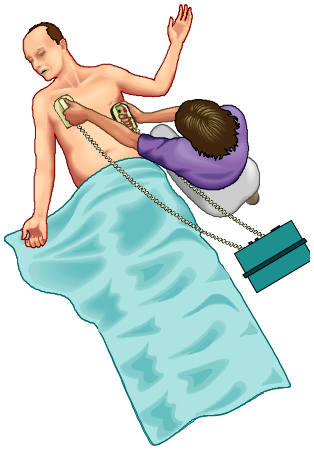
When a patient in the Emergency Department (ED) suffered cardiac arrest, a nurse new to the ED attempted to defibrillate him. After placing gel pads on his chest, she put the defibrillator paddles on the gel pads and tried to deliver the current. Instead of delivering a shock to the patient as intended, the current caused an arc between the paddles. In addition to creating a potential hazard to the patient and healthcare staff, the incident delayed efforts to resuscitate the patient, further jeopardizing his condition.

### What went wrong?

An investigation revealed that the expiration date on the gel pads had passed. The gel on the pads may have dried out – acting as a barrier to the current instead of conducting it.

### What precautions can you take?

This example illustrates why you should not use medical devices after the labeled expiration date. Most disposable devices, such as electrocardiographic pads, I.V. catheters and glucose test strips, degrade over time and no longer function properly. FDA is reviewing the need for expiration dates on many medical devices that currently do not carry them.



Make sure you always

- learn which devices have expiration dates on the label;
- check the expiration date before using the device;
- remove outdated devices and any devices that may have damaged packaging;
- check for discoloration or other changes in the material;
- store medical devices as the labeling recommends, at the correct temperature, and in a manner that will not damage the packaging;
- schedule routine checks for outdated devices; and
- rotate hospital stock frequently according to your facility's policies.

*Christine Parmentier, R.N., and Caroline Webb, R.N., C.C.R.N., B.S.N., are Nurse Consultants in CDRH's Office of Science and Biometrics.*

**This article was adapted from the July issue of Nursing 97.*

## HOSPITAL BED SIDE RAILS: PREVENTING ENTRAPMENT*

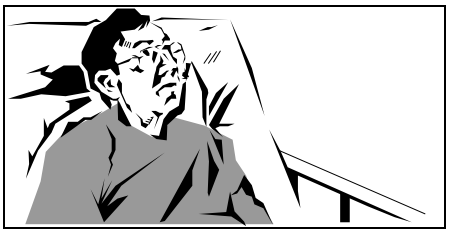
*By Joan Ferlo Todd, R.N., B.S.N.*

A 68-year-old man with left-side paralysis caused by a stroke was hospitalized for onset of seizures. When the nurse checked him at 11:00 p.m., he was resting quietly in bed. Twenty minutes later, she found the patient with his head caught in the middle section of the raised right upper side rail. He had no pulse and was unresponsive. Resuscitation attempts failed and the patient died.

### What went wrong?

Side rails pose a threat to any patient who has altered mental status or is restless because of illness or medication. Since 1985, FDA has received more than 146 reports of deaths and injuries resulting from hospital bed side rail entrapment. *(continued on page 7)*

## Hospital Side Bed Rails: Preventing Entrapment - *(from page 6)*



### What precautions should you take?

Here are some ways you can increase your patient's safety:

- Inspect hospital bed frames, side rails, and mattresses for potential entrapment areas.
- If bed side rails and mattresses are purchased separately from the bed frame, make sure they are compatible in size and have no gaps in which a patient could become entangled. Verify that the side rails have been installed according to the manufacturer's instructions.
- Develop a patient risk profile for patients at risk for entrapment (for example, those with low body weight or altered mental status).
- Use additional safety measures such as side rail protective barriers for high-risk patients.
- Minimize reasons that a patient might try to get out of bed; offer a bedpan at regular intervals or, if appropriate, help the patient out of bed to the bathroom or to a chair.

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*Joan Ferlo Todd, R.N., B.S.N., is a Nurse Analyst, in CDRH's Office of Science and Biometrics.*

**This article was adapted from the May issue of Nursing 97.*

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## INCORRECT RESTRAINT USE: DEADLY PROTECTION*

*By Audrey Morrison, R.N., B.S.N.*

A confused and restless elderly female patient wearing a restraint was found asphyxiated. The waist restraint was wrapped tightly around her chest.

### What went wrong?

- The patient was not an appropriate candidate for restraint use.
- The patient was not properly monitored.
- The wrong-size restraint was used.

### What precautions should you take?

- Understand why restraints are needed.
- Explore restraint-free alternatives.
- Use the correct size of restraint and apply it according to the manufacturer's instructions.
- Follow your facility's written policy on restraint use.
- Tie restraints only to the bedsprings or frame–never elsewhere.
- Supervise the patient closely.

Between 1987 and 1996, manufacturers of protective restraints reported 131 deaths to FDA. However, the future looks hopeful. Restraint use is on the decline as more healthcare providers elect to use restraint-free alternatives and become better educated about the proper use of restraints. Also, FDA has provided additional labeling recommendations to guide the design and manufacture of these devices. With continued education and vigilance, this danger to public health should continue to decline.

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*Audrey Morrison, R.N., B.S.N., is a nurse consultant in the Division of Postmarket Surveillance in CDRH's Office of Surveillance and Biometrics.*

**This article was adapted from the June issue of Nursing 97.*

*Important information from FDA about Medical Device Reporting*

## LATEX EDUCATIONAL TELECONFERENCE

In Spring 1998, FDA and other federal agencies and professional organizations will hold an educational teleconference on latex used in medical products.

**Watch the *Bulletin* for an announcement!**

**User Facility Reporting**
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The *User Facility Reporting Bulletin* is an FDA publication 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 and the Medical Device Amendments of 1992.



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