MEDICAL DEVICE REPORTING

User Facility Reporting

Issue No. 40 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Fall 2002

MONITORING TEMPORARY PACEMAKER CONNECTIONS*

By Diane Dwyer, RN, BSN

A patient with myocardial infarction and bifascicular block was admitted to the ICU. A physician inserted a temporary invasive cardiac pacing catheter. However, because the catheter pin design was incompatible with the pacer adapter, the staff members could not connect it to the pulse generator. Instead, they connected the patient to a transcutaneous pacemaker. The patient was transferred to another facility and died shortly after arrival.

What went wrong?

A temporary invasive cardiac pacing system produces an electrical pulse to stimulate the heart. Because pacing systems and pacing catheters vary, assembled temporary systems may contain equipment from one or more manufacturers. The U.S. market currently offers two different types of cardiac pacing connectors. Without the proper connection to the pulse generator, the device will not pace properly. In the above case, the incompatible equipment used to assemble the system created a faulty connection.

What precautions can you take?

To prevent delays in pacing therapy, careful planning and selection of compatible connectors is needed.

- Take an inventory of your facility's temporary pacing equipment and identify the types of connector design.
- Make sure that all pacing components are compatible and fit properly. Remove and replace any incompatible components.
- Ask the manufacturer of your pacing system if it requires adapters. If so, obtain the correct ones.
- Report all pacing connection problems to your supervisor and the manufacturer.
- Share with colleagues the FDA's Public Health Advisory "Unsafe Electrode Lead Wires and Patient Cables Used with Medical Devices." You can get a copy at http://www.fda.gov/cdrh/safety.html by scrolling down and clicking on 12-28-93.

If a death, serious injury or device malfunction occurs, notify the person in your facility responsible for reporting adverse events to the either the manufacturer or the Food and Drug Administration or both. You may voluntarily report a medical device problem:

- by calling FDA's MedWatch reporting system at 1-800-FDA-1088;
- by FAX: 1-800-FDA-0178); or
- on-line at http://www.fda.gov/medwatch.

Diane Dwyer is a nurse-consultant in the Center's Office of Surveillance and Biometrics.

*Adapted from an article by the author in Nursing 2002: 32(9), 76.

In This Issue:

SELECTING A THIRD-PARTY REPROCESSOR FOR SINGLE-USE DEVICES

When selecting a third-party reprocessor of single-use devices (SUDs), FDA suggests you talk with other hospitals to determine their experiences with third-party reprocessors and arrange to visit the reprocessor's facilities. In addition, you might consider asking a potential reprocessor the following questions:

- When did FDA last inspect your facility? What were the results of that inspection?
- Do you have documentation that your company has premarket clearance or approval for each type of SUD that it reprocesses?
- How do you monitor the manufacturing processes and what records do you maintain in order to comply with FDA's Quality System Regulation?
- What aspects of your overall process have been validated, for example, cleaning, packaging, sterilization?
- Has your company set limits on the number of times a SUD can be reprocessed? If yes, how did you determine the number of times a SUD can be reprocessed? What procedures do you have in place to ensure that a SUD is not reprocessed beyond the set number of times?

To obtain the 483 inspection report from a reprocessor's most recent FDA inspection, contact FDA's Freedom of Information Staff by fax at 301-443-1719 or 301-443-1726. Also, you can obtain information about a reprocessor's inspection history at http://www.fda.gov/cdrh/foicdrh.html.

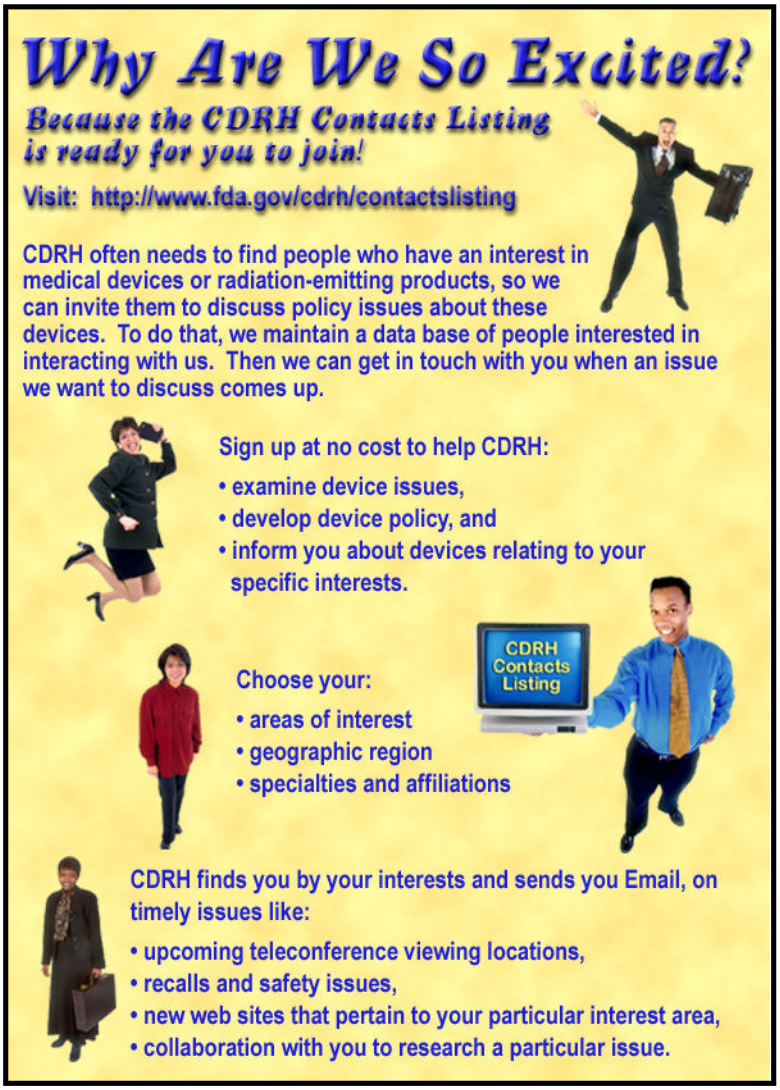
REUSE CD ROM AVAILABLE

The Center for Devices and Radiological Health developed a CD ROM entitled: **"An Overview of the Regulatory Requirements for Reprocessing of Single-Use Devices by Hospitals."** While supplies last, a free copy of the CD-ROM is available by request at http://www.fda.gov/cdrh/Reuse/reuse-messages.html.

The two-disc set covers the regulatory requirements that a hospital must meet if it reprocesses single-use devices (SUDs). Topics include:

- Introduction about reprocessing SUDs
- Registration and Listing
- Premarket Review
- Labeling
- Corrections and Removals
- Medical Device Tracking
- Problems with Reprocessing
- Medical Device Reporting
- Quality System Regulation
- Useful Information

To see the PowerPoint presentations from the CD ROM, visit the Reuse Web Page at: http://www.fda.gov/cdrh/reuse/reuse-documents.html#10.



HAZARDS IN PATIENT-CONTROLLED ANALGESIA

Editor's note: The following excerpt is from the August 2002 broadcast of FDA Patient Safety News. For additional information about the televised series and to read scripts from previous broadcasts, visit http://www.fda.gov/cdrh/psn/.

This time we want to talk about three recent articles by the Institute of Safe Medication Practices (SMP), warning of the potential danger of misusing patient-controlled analgesia, or PCA.

The articles point out that when the patient is truly controlling the administration of the analgesic drug, there's a built-in safeguard, because when the drug dose exceeds the amount needed for analgesia, the patient becomes sedated, and then he or she can no longer push the button to administer more of the drug.

The problem occurs when other people push the button, bypassing this built-in safeguard. That can happen when well-meaning family members push the button, and sometimes even when staff members do so. As the ISMP puts it, "PCA means patient controlled analgesia. It does not mean family-controlled, visitor-controlled or clinician-controlled."

One of the articles cites the case of a 72-year old women who received morphine through PCA after surgery, and who died of an overdose. Despite the patient's inability to verbalize pain, and the fact that she remained obtunded after surgery, nurses pushed the PCA button and delivered frequent doses of morphine for 48 hours. The patient suffered a cardiorespiratory arrest and seizure, and died several months later without having regained consciousness.

ISMP points out that in this case, nurses did not recognize the signs of morphine toxicity, and they continued to administer the drug despite serious hypotension and very shallow respiration.

The ISMP articles don't say that nurses should never push the patient's PCA button. They say that nurse-controlled analgesia may be appropriate in critical care settings, but only with guidelines for selecting patients, along with tools to assess the level of pain and sedation.

Here are the ISMP recommendations:

- First, establish selection criteria for patient controlled analgesia. Note that some patients are not suitable for PCA because of their level of consciousness, their psychological state, or their intellectual capacity.
- Also, establish selection criteria for nurse-controlled analgesia. Decide in advance on risk factors that would call for increased monitoring, such as age and concomitant medications.
- Develop protocols and standardized order sets for infusion devices, drugs, dosing, and lockout periods.
- Carefully monitor patients. Opiates can suppress respiration, heart rate and blood pressure, so patients must be observed and monitored. Pay particular attention to the first 24 hours, since the effects of opiates on intellectual functioning can be unpredictable. Also be sure to monitor and observe the patient at night, since nocturnal hypoxia can be a serious side effect.
- Double check the patient's ID and the dose setting before starting to use PCA, and also before each pump refill. In other words, you should require two clinicians to perform this check independently.
- Educate patients and families about the proper use of PCA. Warn family members about the danger of pressing the button for the patient. Explain that this should only be done when the patient has clearly expressed a need for the medication and requires physical assistance to press the button.
- Finally, educate the staff about the proper use of PCA. Encourage them to think about the cumulative dose the patient could receive if the maximum dose were given, and ensure that they fully understand the hazards of using analgesics.

Additional Information: ISMP Medication Safety Alert - More on avoiding opiate toxicity with PCA by proxy: http://www.ismp.org/MSAarticles/PCA.htm.

ELECTRONIC NOTIFICATION FOR THE *USER FACILITY REPORTING BULLETIN* IS NOW AVAILABLE

If you would like to be notified electronically (via e-mail) when a new issue of the *User Facility Reporting Bulletin* is released, you can sign-up for our List Service at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCDRHNew/listman.cfm

FDA Patient Safety News

FDA Patient Safety News Home | View Webcasts | Search Broadcasts | Report a Device Problem to FDA | Send Comments to FDA | View Future Broadcasts / Order Videotape

FDA Patient Safety News is a televised series for health care personnel, carried on satellite broadcast networks aimed at hospitals and other medical facilities across the country. Each edition features information on new medical devices, on FDA safety notifications and product recalls, and on ways to protect patients when using medical devices.

This site (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/psn/index.cfm) contains the text for each broadcast, plus links for more information on each story. You can also search the Patient Safety News Headlines. It also has instructions for purchasing videotapes of previous broadcasts and sending comments to FDA about the broadcast.

Topics from September 2002 Broadcast...

- Annals of Internal Medicine Wrong-Patient Case Study
- Expanded Use for Defibrillators
- Cochlear Implants and Meningitis
- Recall of Cryolife Human Tissue Allografts

Public Health Notification: Human Tissue Processed by Cryolife, Inc.

(You are encouraged to copy and distribute this information)

August 21, 2002

This provides information about recent actions taken by the Food and Drug Administration (FDA) against Cryolife, Inc. ("Cryolife") of Kennesaw, Georgia. FDA has ordered Cryolife, a human tissue-processing firm, to recall all distributed human allograft tissues, except allograft heart valves, that have been processed by Cryolife since October 3, 2001. This FDA recall order was issued after FDA discovered regulatory violations related to the processing of human tissue by Cryolife, documented fungal and bacterial contamination of Cryolife tissues, and found that Cryolife had not fully implemented adequate corrective actions.

Allograft heart valves processed and supplied by Cryolife have not been included in the FDA recall order. This is because these devices are essential for the correction of congenital cardiac lesions in neonate and pediatric patients and no satisfactory alternative device exists. Under these circumstances, the benefit of these devices outweighs the risk associated with the current manufacturing deficiencies.

Even though FDA has not included allograft heart valves in the FDA recall order for the reason stated above, FDA still has serious concerns regarding the processing and handling of allograft heart valves by Cryolife because patients who receive these devices may be at increased risk for infection. Accordingly, FDA recommends that you consider the following information when determining the appropriate treatment for your patients who have either already received any allograft tissues, including allograft heart valves, processed by Cryolife on or after October 3, 2001, or who have not yet received, but may need to receive an allograft heart valve.

Background

FDA has ordered Cryolife to recall distributed human tissue, other than allograft heart valves, processed since October 3, 2001. Under the order, the firm also must withhold from the market all allograft tissue, other than allograft heart valves, processed since October 3, 2001. This Web Notification is alerting you of FDA's action and is also advising you of certain steps to consider when deciding whether to use Cryolife allograft heart valves. FDA has taken these actions because it has determined that Cryolife cannot ensure that the human tissue it processes for implantation is free from fungal and bacterial contaminants.

PUBLIC HEALTH WEB NOTIFICATION - *Continued*

Tissue from a donor processed by Cryolife on and after October 3, 2001, has been associated with the November 7, 2001, death of a patient who received a soft tissue implant during reconstructive knee surgery. Additionally, in March 2002, FDA learned that a patient who received a Cryolife allograft heart valve implanted in 2001 developed a fever within two months of the surgery. Cultures of the valve grew Candida Tropicalis and Candida Albicans. FDA learned of a second event that occurred in March 2002 of a patient who also received a Cryolife valve who suffered a cerebrovascular accident and had positive blood cultures for Staphylococcus Epidermidis.

Current federal regulations for human tissue, like that subject to FDA's recall order, require firms to prepare, validate, and follow written procedures for tissue processing to prevent infectious disease contamination or cross-contamination. Current federal regulations applicable to allograft heart valves also help ensure that appropriate procedures are validated and followed.

During inspections of Cryolife from March 25 through April 12, 2002, FDA found numerous, significant violations of FDA regulations. FDA issued a Warning Letter to Cryolife on June 17, 2002, after determining, among other things, that the firm did not adequately validate its processing and testing methods and did not adequately implement procedures recommended by the Centers for Disease Control and Prevention (CDC), or adequately implement any other appropriate procedures, to ensure that tissue processed by the firm is not contaminated.

After determining that Cryolife failed to take adequate corrective measures to address possible infectious disease contamination of tissue, and after reviewing information provided by the firm in response to FDA's warnings, FDA issued the present order for retention, recall and/or destruction of allograft tissues other than allograft heart valves, and is issuing this Web Notification to physicians regarding FDA's recommendations for both allograft heart valves and other allograft tissues. FDA's concerns described in the order relate specifically to bacterial and fungal contamination of soft tissues, such as cartilage and tendons.

If a bacterial or fungal infection were to occur following tissue implantation, the signs and symptoms usually appear within days to weeks after implantation. Therefore, it is unlikely that patients who have not recently received a tissue implant are likely to be at future risk. However, concerned patients are encouraged to contact their physicians.

FDA Recommendations

A. Allograft tissues (except allograft heart valves) that are subject to the FDA Order for Retention, Recall, and/or Destruction:

If you are a physician who is caring for a patient who was recently implanted with Cryolife processed tissue, FDA recommends that you:

- Carefully monitor the patient for both fungal and bacterial infections

If you are a surgeon who is considering using Cryolife processed tissue, FDA recommends that you:

- Quarantine all tissue subject to the recall order. Follow the instructions for disposal when received from Cryolife
- Consider using processed allografts from alternative manufacturers/processors

B. Cryolife allograft heart valves:

If you are a physician who is caring for a patient who was recently implanted with a Cryolife allograft heart valve, FDA recommends that you:

- Carefully monitor the patient for both fungal and bacterial infections
- Report all adverse reactions to both FDA and Cryolife
- Inform your patient of FDA’s concerns with Cryolife allograft heart valves and discuss the potentially higher risk for infection

If you are a surgeon who is considering implanting a Cryolife allograft heart valve, FDA recommends that you:

- Consider the information provided in this notification in your evaluation of therapeutic options for potential heart valve recipients
- Consider using processed allografts from alternative manufacturers/processors
- Inform the prospective patient of FDA’s concerns with Cryolife allograft heart valves and discuss the potentially higher risk for infection

PUBLIC HEALTH WEB NOTIFICATION - *Continued*

Reporting Adverse Events to FDA

FDA has different adverse event reporting requirements for allograft heart valves and allograft tissues:

FDA regulates allograft heart valves as medical devices while it regulates other allograft products as tissues. Because FDA considers Cryolife allograft heart valves to be medical devices, hospitals and other user facilities are subject to the mandatory reporting requirements for reporting deaths or serious injuries associated with these devices (see 21 Code of Federal Regulations part 803 for details on reporting certain deaths and serious injuries). On the other hand, because FDA considers the other allograft products subject to the recall order to be tissues, hospitals and other user facilities are not subject to mandatory reporting requirements for these products.

Reports of Deaths or Serious Injuries associated with allograft heart valves:

If you become aware of an adverse event that reasonably suggests that a Cryolife allograft heart valve has or may have caused or contributed to a death or serious injury, you should follow the procedures established by your facility for mandatory reporting.

Reports of any other adverse events or information about contaminated allograft tissues:

While it is not mandatory to report such events to FDA, if you have reason to believe that you have received contaminated tissue from Cryolife, please be aware that MedWatch, the FDA's voluntary reporting program, is open to receiving such reports. MedWatch reports are accepted four ways: online at http://www.accessdata.fda.gov/scripts/medwatch; by telephone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; or by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857.

Getting More Information

If you have questions regarding the soft tissue products distributed by Cryolife, please use the Voice Information System – Direct access to a Consumer Safety Officer or Public Affairs Specialist (800-835-4709; 301-827-1800). You also may contact FDA by emailing your questions about biological products to OCTMA@CBER.FDA.GOV.

If you have questions regarding allograft heart valves, please contact the Consumer Staff, Center for Devices and Radiological Health, at 301-827-3990 (Press 5 to speak with a staff member).

All of the FDA medical device postmarket safety notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html. Postmarket safety notifications can also be obtained through email on the day they are released by subscribing to our list server. You may subscribe at http://list.nih.gov/archives/dev-alert.html. You may also subscribe by sending an email to listserv@list.nih.gov. In the body of the text, type "SUBSCRIBE DEV-ALERT firstname lastname".

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. The *Bulletin's* contents may be freely reproduced. Comments should be sent to the Editor.

Editor: Nancy Lowe • Assistant Editor: Mary Ann Wollerton • Associate Editor: Edie Seligson

Department of Health and Human Services • Public Health Service • Food and Drug Administration
Center for Devices and Radiological Health, HFZ-230 • Rockville, MD 20857 • FAX: 301-594-0067
e-mail: nsl@cdrh.fda.gov