MEDICAL DEVICE REPORTING
User Facility Reporting

Issue No. 32 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Fall 2000

SERIOUS INJURIES FROM MICROWAVE THERMOTHERAPY USED FOR BENIGN PROSTATIC HYPERPLASIA

by Laura Alonge

The Food and Drug Administration (FDA) issued a Public Health Notification on October 11, 2000 concerning the potential for serious thermal injury and related complications associated with the use of microwave energy to treat benign prostatic hyperplasia (BPH). The Notification also provides information that can help avoid these complications. Although the use of microwave thermotherapy for the treatment of BPH has been demonstrated to be safe and effective (over 25,000 procedures have been performed), FDA is concerned about unexpected procedure-related complications, some of which were not listed in the original labeling.

Currently marketed devices include the Prostatron (Edap Technomed, Inc.) and the Targis System (Urologix, Inc.). Dornier Medical Systems, Inc. has received approval to market its UroWave System but is not yet marketing it. FDA is working with the manufacturers to ensure that labeling and training programs address these complications.

Nature of the Problem

Since 1996, FDA has received reports of 16 thermal injuries related to microwave thermotherapy systems. Of these, 10 resulted in fistula formation and 6 resulted in clinically significant tissue damage to the penis or urethra. These injuries may not be apparent at the time of treatment and may take hours or days to develop. The original labeling for these devices did not list fistula formation as a prcedure-related complication. The reported injuries required colostomies, partial amputation of the penis, and/or other therapeutic interventions. FDA has identified several factors that may have contributed to the injuries:

- incorrect placement or undetected migration of either the treatment catheter or the rectal temperature sensors;
- failure of the physician to remain with the patient throughout the entire treatment duration;
- failure to pause treatment when the patient communicated serious pain;
- oversedation of the patient which compromises ability to communicate pain;
- treatment of patients who have undergone prior radiation therapy to the pelvic area;
- treatment of patients whose prostate sizes are outside the ranges specified in the labeling; and
- leakage from the balloons used to retain either the urethral catheter or the rectal temperature sensor in the correct anatomical position.

Background

Microwave thermotherapy systems are intended to heat the prostate, resulting in the necrosis of periurethral prostatic tissue and providing relief of urinary symptoms in patients with obstructive BPH. These devices heat the prostate to therapeutic levels using microwave energy delivered by an antenna contained within a specially designed urethral catheter. The catheter is designed so that when the balloon is seated at the neck of the bladder, the active portion of the antenna is positioned within the prostate. To prevent overheating, the systems circulate cooling fluid through the urethral catheter to protect the urethral tissue from excessive heat. The systems automatically vary microwave energy output during treatment, based on information supplied by temperature sensors placed posterior to the prostate within the rectum. Treatment may last from 30 to 60 minutes.

Because the catheter and/or the rectal temperature sesors can migrate during treatment, the following requirements can help ensure that this does not *(Cont. on page 5)*

In This Issue:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857
September 28, 2000

REPROCESSING OF
SINGLE-USE DEVICES

To: Risk Management
Hospital Administration
Central Supply
Infection Control Departments
Safety Office
Operating Room
Medical Department
Nursing Department
(Please make copies for relevant departments.)

This is to advise you that on August 14, 2000, the U.S. Food and Drug Administration (FDA) released its final guidance on the practice of reprocessing and reusing medical devices that are intended to be used only once. In the enclosed guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," FDA states that hospitals and third parties that reprocess single-use devices (SUDs) will be regulated in the same way as original equipment manufacturers. This means that hospitals reprocessing SUDs are subject to the requirements of the Food, Drug, and Cosmetic Act, including:

- registration and listing;
- good manufacturing practice (GMP) under the Quality System (QS) regulation;
- submission of adverse-event reports under the Medical Device Reporting (MDR) regulation;
- medical device labeling;
- medical device tracking;
- corrections and removals; and
- premarket notification and approval.

The goal of the SUD reuse policy is to protect the health of the public by ensuring that the practice of reprocessing and reusing SUDs is based on good science and that the regulatory requirements are equitable to all parties (i.e., third-party and hospital reprocessors and original device manufacturers).

The major points of the reuse policy for hospital reprocessors are:

- FDA intends to enforce premarket submission requirements by:
  - February 14, 2001, for all class III devices;
  - August 14, 2001, for all non-exempt class II devices; and
  - February 14, 2002, for all non-exempt class I devices.

  These enforcement priorities are based on a device's classification (i.e., class I, class II, or class III) as listed in the Code of Federal Regulations (CFR).

- FDA intends to enforce the non-premarket requirements (i.e., registration and listing, the QS regulation, medical device reporting, labeling, tracking, and corrections and removals) by August 14, 2001. FDA will use the one-year period to educate hospitals about their regulatory obligations if they reprocess SUDs.

  The Agency encourages hospitals to pay particular attention at this time to the regulatory requirements for Good Manufacturing Practices (www.fda.gov/cdrh/dsma/cgmphome.html). Any hospital that intends to continue reusing and reprocessing SUDs will need to understand these requirements, which include process validation, corrective and preventive action, quality system inspection, and controls used for packaging, labeling, storage, installation, and servicing of all reprocessed SUDs.

- FDA has developed a list of known reprocessed SUDs that range from technically simple to complex devices. (See Appendix A of the guidance document.) Although many SUDs are exempt from some of the regulatory requirements, all reprocessed SUDs are still subject to the GMP requirements of the QS regulation.

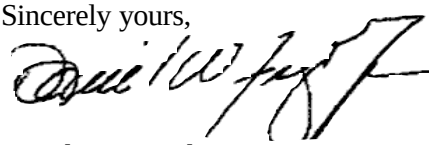
- The SUD enforcement priorities do not apply to:

  - permanently implantable pacemakers;
  - "open-but-unused" single-use devices;
  - health care facilities that are not hospitals; and
  - hemodialyzers. The reuse of hemodialyzers is addressed in "Guidance for Hemodialyzer Reuse Labeling" (October 6, 1995) and is available at www.fda.gov/cdrh/ode/dilreuse.pdf.

Nothing in the guidance document precludes FDA from taking immediate action against any device that is causing harm.

Please read the enclosed guidance document. It is important that you become familiar with it in order to understand your hospital's responsibilities. Hopefully, this information will assist you as you evaluate your SUD reprocessing program with the goal of promoting and enhancing patient safety. To further assist you, we have attached the names of several sources that have listings of medical device consultants. If you have any questions or need additional information, contact us at our e-mail address reuse@cdrh.fda.gov or at FAX number 301-443-8818.

Sincerely yours,



David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and Radiological Health

Attachment: Sources of Medical Device Consultants
Enclosure: SUD Enforcement Priorities Guidance (http://www.fda.gov/cdrh/reuse/1168.html)

Attachment

SOURCES OF
MEDICAL DEVICE CONSULTANTS

The following sources provide lists of medical device consultants who can provide assistance with meeting the regulatory requirements [such as 510(k) and PMA] of the FD&C Act.

Food and Drug Law Institute (FDLI)
1000 Vermont Avenue, NW, Suite 200
Washington, DC 20005
http://www.fdli.org

Canon Communications
http://www.devicelink.com/consult

Regulatory Affairs Professional Society (RAPS)
11300 Rockville Pike, Suite 1000
Rockville, MD 20852
http://www.raps.org/memb/yellow.cfm

Periodically, check our Reuse Homepage at http://www.fda.gov/cdrh/reuse/index.shtml for additions to the above sources and other important information.

REUSE MEETING SCHEDULE

November 30, 2000
Association for Healthcare Risk Management (http://www.ashrm.org/)
Mt. Sinai, New York
Scheduled FDA Speaker: Lily Ng

December 4, 2000
FDA Circulatory Support Advisory Panel
Gaithersburg, Maryland
Scheduled FDA Speaker: Barbara Zimmerman

December 15, 2000
West Virginia Hospital Association (http://www.wvha.com/)
Charleston, West Virginia
Scheduled FDA Speaker: Barbara Zimmerman

Remember to periodically check for upcoming events (http://www.fda.gov/cdrh/reuse/reuse-events.shtml) on the CDRH Reuse Homepage. Speaker slides from past events are also available.

MICROWAVE THERMOTHERAPY - *From page 1*

occcur and deliver either undetected excessive heating of surrounding tissues or therapeutic heating levels to areas of the body that are not intended to receive treatment. Because the correct placement of both components is critical for safe and effective treatment, the labeling for these devices instructs the treating physician to:

- verify that the urethral catheter(and rectal temperature sensor probe, if applicable) has a working retention balloon prior to placement; and
- verify the proper position of both the urethral catheter and the rectal temperature sensors prior to and at specified time intervals consistent with the manufacturer's recommendation for treatment.

The labeling also instructs the treating physician to:

- monitor the equipment during treatment;
- monitor the patient during treatment; and
- manually reduce or pause the microwave power if the patient experiences excessive pain or if extreme heating is observed.

Recommendations

Patient Selection

A patient for microwave thermotherapy for BPH should:

- meet the device's indications, including the criteria for eligible prostate size indicated for the specific system being used;
- have had no prior radiation therapy to the pelvic area, because these patients are at increased risk of fitula formation; and
- be chosen from specific patient populations for which safety and effectiveness of this therapy are known. This therapy is not recommended for patients with prostate cancer.

Patient Information

It is important to ensure that the patient understands the risks and benefits listed in the labeling of the specific device. He should also understand the following:

- duration of the procedure;
- level of pain or discomfort that should be considered normal;
- importance of telling the physician of any unusual pain during treatment;
- operation of any emergency stop button; and
- the need to remain as still as possible during treatment.

Physician's Role

The physician must:

- continually supervise the procedure throughout the entire treatment period;
- verify that the retention balloons of the urethral catheter and rectal temperature sensor probe are free of leaks;
- confirm the placement of the urethral catheter and rectal temperature sensor using acceptable methods (e.g., direct visualization, ultrasound imaging);
- constantly remember that either patient movement or component breakage may cause migration of a properly placed urethral catheter or rectal temperature sensor;
- be careful not to over sedate the patient, since his perception of pain is an important safety mechanism to ensure that the heating of the tissue is not excessive;
- never use general or spinal anesthesia;
- closely monitor the patient and the equipment throughout the entire treatment; and
- manually pause treatment if the patient complains of excessive pain or anything unusual occurs.

REPORTING ADVERSE EVENTS TO FDA

The Safe Medical Devices Act of 1990 (SMDA) requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. Healthcare providers who are employed by facilities subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. All other providers may submit their reports to MedWatch, FDA's voluntary reporting program. The reports can be submitted by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, Maryland 20857, or online at www.accessdata.fda.gov/scripts/medwatch.

Laura Alonge is a biologist in CDRH's Office of Surveillance and Biometrics.

GETTING MORE INFORMATION

If you have questions regarding either the microwave thermotherapy or the circumcism clamp article, please contact the Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland 20850, by fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 301-594-0650 and your call will be returned as soon as possible.

FDA's postmarket safety notifications for medical devices are available on the Internet at http://www.fda.gov/cdrh/safety.html. Postmarket Safety Notifications can also be obtained through e-mail on the day that they are released by subscribing to FDA's list server. To subscribe, send an e-mail message to fdalists@archie.fda.gov. In the body of the text, type "subscribe dev-alert."

POTENTIAL FOR INJURY FROM CIRCUMCISION CLAMPS

by Sherry Purvis-Wynn, R..N., B.S.N., M.A.

The Food and Drug Administration (FDA) sent a letter on August 29, 2000 to healthcare professionals to alert them about the potential for injury from two commonly used circumcision clamps, the Gomco®/gomco-type and Mogen®/mogen-type clamps. Both are widely used during circumcision to remove the foreskin while protecting the glans penis.

Although circumcision is generally a safe procedure, FDA is concerned that some serious device-related complications have occurred. FDA has received 105 reports of injuries involving circumcision clamps between July 1996 and January 2000[1]. Injuries included laceration, hemorrhage, accidental penile amputation, and urethral damage.

Nature of the Problem

Gomco® and Gomco-type Clamps

The primary reasons for Gomco® and gomco-type clamps breaking, slipping, falling off during use, tearing penile tissue, or failing to make a tight seal are:

- reassembling by users with parts from different manufacturers; or
- having bent parts or mismatched components.

Although Gomco® and gomco-type clamps may appear to have interchangeable parts, these parts may not always be safely interchanged, because they may vary slightly in dimensions.

Mogen® and Mogen-type Clamps

The primary reasons for Mogen® and mogen-type clamps leading to patient injuries are:

- the jaw gap dimensions are greater than those in the manufacturer's specifications; or
- the use of clamps inappropriately sized for patients.

In such cases, the clamp may allow too much tissue to be drawn through the opening of the device resulting in the removal of an excessive amount of foreskin and, in some cases, a portion of the glans penis.

Recommendations

FDA is making the following recommendations to help avoid these complications.

General:

Before performing a circumcision procedure, examine the clamp to determine that all parts are available, undamaged, and within the manufacturer's specification.

For Gomco® and Gomco-type clamps

- Either contact the device manufacturer to obtain replacement parts or discard the clamp if (1) you are unsure that a clamp component is part of the original clamp, or (2) the clamp has:
  - stripped threads,
  - a warped or bent base plate,
  - a bent arm,
  - twisted forks, or
  - a scored or nicked bell.[2]
- When requesting a replacement part, obtain the assurance of the manufacturer or supplier that the part ordered is compatible with the other components of your device. Do not substitute parts from different clamp manufacturers.
- Be sure to reassemble a clamp with only its own parts. Do not mix parts from different clamps, even from the same manufacturer, unless the manufacturer has assured you that the parts are interchangeable.
- If marking clamp parts to assure that they are correctly reassembled, ask the manufacturer to recommend the best way to mark them. Some marking methods may weaken the device or compromise your ability to sterilize it.

For Mogen® and Mogen-type clamps

- Ensure that the clamp being used is appropriate for the patient size. Some manufacturers have two sizes of clamps: adult and infant.
- Periodically measure the gap between the device's clamping jaws to ensure that it is within the manufacturer's specification.[3] Using a device with an inappropriate jaw gap could allow the tip of the penis to be drawn through the clamp with the foreskin and be inadvertently severed or injured.

Bibliography

1. FDA MedWatch Reports, July 1992 through January 2000.
2. IPM Procedure: Circumcision Clamps, Health Devices 2000 January; 29(1): 22-3.
3. Hazard: Routine inspection needed for scissors-type circumcision clamps, Health Devices 1999 Mar; 28(3): 115-6.
4. Hazard: Incompatibility of different brands of Gomco-Type circumcision clamps. Health Devices 1997 Feb; 26(2): 76-7.
5. Hazard: Amputations with use of adult-size scissors-type circumcision clamps on infants. Health Devices 1995 Jul; 4(7): 286-7.
6. Hazard: Damaged Allied Healthcare Products Gomco circumcision clamp. Health Devices 1993 Mar; 22(3): 154-5.

Sherry Purvis-Wynn, R.N., B.S.N., M.A., is a nurse consultant in the Center for Devices and Radiological Health's Office of Surveillance and Biometrics.

Reprocessing Single-Use Devices in Hospitals: A Primer on FDA Requirements

An FDA Interactive Satellite Teleconference

Wednesday, December 13, 2000
Test: 12:30 - 1:00 p.m. EST
Program: 1:00 - 3:00 p.m. EST
Satellite Coordinates: C-Band GE-2, Trans 3 Vertical, Channel 3, Downlink Freq. 3760 MHz, Audio 6.2/6.8
http://www.fda.gov/cdrh/reuse/index.shtml

Why This Program is Important to Watch

Many hospitals currently reprocess and reuse medical devices that are labeled or intended by the device manufacturer for one time use. Hospitals may also contract third-party companies to reprocess their single-use devices (SUDs).

This satellite teleconference on the reuse of SUDs will help hospitals that reprocess SUDs understand how changes in FDA's enforcement of its regulatory requirements will affect them. The program will provide an overview of FDA's recently issued final guidance on the practice of reprocessing SUDs, including the timing for FDA's phased-in enforcement of regulatory requirements.

The impact of FDA's Quality System (QS) requirements on health care facilities' procedures will be a major focus for the broadcast, with an emphasis on how these requirements help to ensure the safety of reprocessed SUDs.

A variety of formats will be used, including taped illustrations of device reprocessing, interviews with health professionals and industry, and panel discussions with FDA personnel. Viewers will have the opportunity to question the panelists live via telephone, fax, and e-mail.

Panelists

- David W. Feigal, Jr., MD, MPH, Director, CDRH
- Linda S. Kahan, J.D., Office of Center Director, CDRH
- Larry Kessler, ScD, Office of Surveillance and Biometrics, CDRH
- Larry Spears, Office of Compliance, CDRH
- Cap Uldriks, Office of Compliance, CDRH
- Kimberly Trautman, Office of Compliance, CDRH
- Barbara Zimmerman, Office of Device Evaluation, CDRH
- Sharon Ellerbe, Office of Compliance, CDRH
- Moderated by Anita Rayner, Office of Surveillance and Biometrics, CDRH

You may e-mail your question to the panelists prior to the teleconference to: reuse@cdrh.fda.gov.

What You Need to Watch the Teleconference

To watch this teleconference, you will need a steerable analog satellite dish capable of receiving a C-Band transmission. This is a free program; it will not be scrambled.

Watching the Live Broadcast

1. This program will be carried live on the GE TiP-TV Satellite Network. Many radiology departments have GE-TiP TV. To find out if your facility is a subscriber, call toll free at 1-877-438-4788.

2. This program will be carried live on the Health and Sciences Television Network (HSTN) and the Joint Commission Satellite Network (JCSN). To find out if your facility is a subscriber, call toll free at 1-800-942-4786.

3. Some health care facilities have their own satellite dishes. If your facility has a satellite dish, ask your teleconference coordinator to make this program available (to "down-link").

4. Some Veterans Administration hospitals will be carrying this program live. Most of these facilities will open their sites for others to watch the program. Check with your local VA hospital.

5. There are many down-link sites that charge a moderate fee. Here are some places to go for information and help: Universities, libraries, vocational schools, community colleges, public schools, video rental, sales or production businesses, and cable companies (ask if they can down-link the program for you and send it to your meeting site via the local cable.)

6. If the above services are unavailable, please e-mail reuse@cdrh.fda.gov for help in locating a site to view this program.

For additional information about FDA's CDRH Division of Communications programming and programs, see: http://www.fda.gov/cdrh/ohip/dcm/PROGRAM_CALENDAR/program_calendar.htm

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
Asst. Editor: Mary Ann Wollerton
Design: 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