FDA Public Health Notification:
Serious Injuries from Microwave Thermotherapy for Benign Prostatic Hyperplasia

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October 11, 2000

Dear Colleague:

This is to notify you of the potential for serious thermal injury and related complications associated with the use of microwave energy to treat benign prostatic hyperplasia (BPH), and to provide 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, and more than 25,000 procedures have been performed, we are concerned about some unexpected procedure-related complications that have occurred since the marketing of these devices.

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

Nature of the Problem

Since 1996, we have 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. (Note that the original labeling for these devices did not list fistula formation as a procedure-related complication.) The reported injuries have required colostomies, partial amputation of the penis, and/or other therapeutic interventions.

We have identified several factors that may have contributed to the injuries noted:

- 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 is communicating serious pain;
- Oversedation of the patient, which compromises his 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;

Recommendations

1. When considering a patient for microwave thermotherapy for BPH, ensure that he meets the device's indications, including the criteria for eligible prostate size indicated for the specific system being used. Additionally, it is important to verify that the patient has not had prior radiation therapy to the pelvic area, as these patients are at increased risk of rectal fistula formation. Furthermore, the labeling of each device lists specific patient populations for which safety and effectiveness of this therapy are unknown (e.g., those with prostate cancer).

2. When discussing the procedure with the patient, it is important to ensure that he understands the risks and benefits listed in the labeling of the specific device. He should also understand the duration of the procedure, the level of pain or discomfort that should be considered normal, the importance of

telling the physician of any unusual pain during treatment, how to operate any emergency stop button, and the need to remain as still as possible during treatment.

3. Carefully follow the instructions for use provided with these microwave systems. Note that they require the physician to continually supervise the procedure throughout the entire treatment period. The physician must (1) verify that the retention balloons of the urethral catheter and rectal temperature sensor probe are free of leaks, and (2) confirm the placement of the urethral catheter and rectal temperature sensor using acceptable methods (e.g., direct visualization, ultrasound imaging) both prior to treatment and other specified times consistent with the manufacturer's recommendations. Either patient movement or component breakage may cause migration of a properly placed urethral catheter or rectal temperature sensor.

4. Be careful not to oversedate the patient. As patient perception of pain is an important safety mechanism to ensure that the heating of the tissue is not excessive, general or spinal anesthesia should not be used.

5. 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.

Background

Microwave thermotherapy systems are intended to heat the prostate, resulting in the necrosis of periurethral prostatic tissue, to provide 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 and 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 sensors can migrate during treatment, and because the correct placement of both of these components is critical for safe and effective treatment, the labeling for all these devices instructs the treating physician to: (1) verify that the urethral catheter (and rectal temperature sensor probe, if applicable) has a working retention balloon prior to placement, and (2) 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. These requirements are intended to help ensure that catheter or rectal temperature sensor migration does not occur in a manner which would cause undetected excessive heating of surrounding tissues or the delivery of therapeutic heating levels to areas of the body that are not intended to receive treatment. The labeling for microwave thermotherapy devices also instructs the treating physician to monitor the equipment and patient during treatment, and manually reduce or pause the microwave power if the patient experiences excessive pain or extreme heating is observed.

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. FDA is interested in additional data on adverse events involving the use of microwave thermotherapy systems. When submitting a report, please identify the treatment protocol and catheter type, if known. Healthcare providers that are employed by facilities that are 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.

Getting More Information

If you have questions regarding this letter, please contact the Issues Management Staff, 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. Additionally, a voice mail message may be left at 301-594-0650, and your call will be returned as soon as possible.

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 e-mail on the day they are released by subscribing to our list server. To subscribe, go to: http://list.nih.gov/cgi-bin/wa?SUBED1=dev-alert&A=1.

Sincerely yours,

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