From the FDA

Heart pump approved

An implantable cardiac device has been approved by the US Food and Drug Administration. Heartmate, developed by Thermo Cardiosystem, Inc, (Woburn, Mass) is intended for use in patients who are awaiting heart transplants. Implanted in the abdominal cavity, the air-driven pump operates the left ventricle of the heart. The device pumps the blood into the main artery. An external console, plugged into an electrical outlet and mounted on a cart, serves as the power source. A battery powerpack also provides enough energy for 30 minutes at a time.

In clinical trials, 65% of patients with the device implanted survived at least 60 days with the device in place compared with only 30% of control subjects. The device has already been approved for use in Europe and is expected to be available there in 1995.

Warning of radiation-induced skin injuries

Physicians performing fluoroscopically guided invasive procedures should be aware of the potential for serious radiation-induced skin damage. Except for mild signs and symptoms (transient erythema), radiation effects of skin damage are not immediately apparent. They may not manifest until weeks after the patient undergoes the procedure. *Any* signs and symptoms, regardless of severity, should be recorded in the patient's records, so as to estimate the absorbed dose of radiation to the skin.

The radiation dose required to induce skin damage varies; however, the typical threshold at which skin absorbs radiation is measured at: 3 Gy (300 rad) for temporary epilation; approximately 6 Gy (600 rad) for main erythema, and 15 to 20 Gy (1500 to 2000 rad) for moist desquamation, dermal necrosis, and secondary ulceration.

The absorbed dose rate in the skin from the direct beam of a fluoroscopic x-ray system typically measures between 0.02 Gy/min and 0.05 Gy/min (2 to 5 rad/min). The absorption rate and dosage may be higher, depending on the mode in which the equipment is operated and the patient's size. *Even typical dose rates can result in skin injury after less than 1 hour of fluoroscopy.*

Facilities that perform fluoroscopy procedures should follow these guidelines:

- Establish standard operating procedures and clinical protocols for each specific procedure performed, keeping in mind the potential for radiation injury. Protocols should consider limits on fluorscopy-exposure time, using the minimum dosage to achieve the desired clinical results and avoid cumulative doses that would induce unacceptable adverse effects.
- Know radiation dose rates for the specific fluoroscopic systems and each mode of operation.
- Enlist a qualified medical physicist to assist in implementing the aforementioned guidelines.

Practitioners who become aware of any medical device-related adverse event or product problem or malfunction should report these findings as required under the Safe Medical Devices Act of 1990 or directly to MedWatch, the FDA's voluntary reporting program. MedWatch can be contacted by telephone [(800)-FDA-1088], telefax [800-FDA-0178], modem [800-FDA-7737], or by mail: MedWatch, HF-2, Food and Drug Administration, 5600 Fishers Ln, Rockville, MD 20857.

From the PHS

New mammography guidelines issued

The Agency for Health Care Policy and Research has issued new clinical practice guidelines for mammography. The intent is to improve the quality of mammography and, with it , reduce the number of deaths from breast cancer. These guidelines are meant to enhance the effectiveness of the Mammography Quality Standards Act, which went into effect October 1, 1994.

The guidelines include:

- using high-quality, modern, dedicated x-ray equipment with film processors dedicated specifically for mammorgraphy film;
- having only properly certified and trained personnel (radiologic technologists, interpreting physicians and medical physicists) supply mammography services; and
- maintaining an effective, ongoing quality control program at each facility that includes annual evaluation by a qualified medical physicist and more frequent quality control tests at specified intervals by a qualified radiologic technologist.

Mammography facilites are strongly urged to give the patient her test results in writing within 10 days of the procedure.

Free copies of *High-Quality Mammography—Information for Referring Providers: Quick Reference Guide for Clinicians* and *Things to Know About Quality Mammograms: A Woman's Guide* are available from te AHCPR Publications Clearinghouse at (800) 358-9295, PO Box 8547, Silver Spring, MD 20907, or by telefax at (301) 594-2800. ♦