

Devices That Keep the Heart Beating

Heat devices such as pacemakers and defibrillators have extended and improved the lives of millions of people worldwide.

February is American Heart Month

FDA approvals and oversight have made scientific and technological breakthroughs accessible, greatly expanding the number of people who can benefit from these devices.

FDA's Center for Devices and Radiological Health (CDRH) is responsible for ensuring the safety and effectiveness of all medical devices, including heart devices, sold in the United States.

Recent Actions and Approvals

Recent FDA actions and approvals related to heart devices include

- Approval of the first compact heart assist device. In April 2008, FDA approved the first device to support the weakened heart of a small-sized adult man or woman who is at risk of dying while awaiting a heart transplant. Previous models of these surgically implanted mechanical pumps were too large to be placed in the upper abdomen of some people.
- Comprehensive review of drug coated stents to address concerns about their safety. FDA has concluded that these stents are safe and effective when used within their labeled indication.



Photo: FDA/Michael Ermarth

Automated external defibrillators (AEDs) are portable devices that help restore normal heart rhythm to patients in cardiac arrest.

- Approval of the first totally implanted permanent artificial heart for humanitarian uses. The device is for patients with advanced heart failure involving both of the organ's pumping chambers, who are not eligible for a heart transplant, and who are unlikely to live more than a month without intervention.
- Approval of pacemakers that reduce severe heart failure symptoms by resynchronizing the pumping action of both heart chambers.
- Approval of new monitoring devices that allow implantable cardioverter defibrillators (ICDs) to transmit basic information about the patient and the device to physicians between office visits.

Types of Heart Devices

Through its "Heart Health Online" Web page at www.fda.gov/hearthealth/index.html, FDA offers consumers extensive information about a variety of heart devices.

These devices include


- **Automated External Defibrillators (AEDs):** Portable and automatic, these devices help restore normal heart rhythm to patients in cardiac arrest. They analyze heart rhythm and can help rescuers determine whether a shock is needed to restore a normal heartbeat.
- **Cardiac Ablation Catheters:** Long, thin flexible tubes that are threaded into or onto the heart, cardiac ablation catheters treat abnormally rapid heartbeats that cannot be controlled with lifestyle changes or medications. They work by modifying small areas of heart tissue that are causing abnormal heart rhythms.
- **Cardiac Angioplasty Devices:** These are long, thin, flexible tubes that are threaded into a heart blood vessel to open narrowed or blocked

areas. They improve blood flow to the heart, reduce chest pain, and treat heart attacks.

- **Cardiac Pacemakers:** Small and battery-powered, pacemakers are implanted permanently into the body. Used when the heart beats too slowly or has other abnormal rhythms, they monitor the organ's electrical impulses and, when needed, deliver electrical stimuli to make it contract in a more normal tempo.
- **Implantable Cardioverter Defibrillators (ICDs):** These monitor heart rhythms and deliver shocks if dangerous rhythms are detected. Many record the heart's electrical patterns whenever an abnormal heartbeat occurs, allowing doctors to review the patterns. New monitoring devices allow ICDs to transmit basic information to physicians.
- **Prosthetic (Artificial) Heart Valves:** Used for replacing diseased or dysfunctional heart valves, these are available in two forms. Mechanical valves are made of man-made materials and can usually last a lifetime. Biological valves are made from tissue taken from animals or human cadavers.
- **Stents:** Small, lattice-shaped, metal tubes that are inserted permanently into an artery, stents help improve blood flow. Some contain drugs that reduce the chance that arteries will become blocked again.
- **Ventricular Assist Devices (VADs):** Mechanical pumps that help weak hearts pump blood adequately, VADs were originally intended for short-term use until donor hearts became available. Some are now used for long-term therapy in patients with severe heart failure who are not candidates for heart transplants.

Reporting Problems

If you're having problems with your heart device, or any other medical device, contact MedWatch, FDA's program for reporting serious reactions, product quality problems and product use errors regarding medical products. MedWatch can be found at www.fda.gov/medwatch/report/consumer/consumer.htm

Consumers can also call FDA's toll-free information line, 1-888-INFO-FDA (1-888-463-6332) for information about medical products. 

For More Information

FDA Approves First Compact Heart Assist Device
www.fda.gov/bbs/topics/NEWS/2008/NEW01820.html

Heart Health Online (FDA)
www.fda.gov/hearthealth/index.html

Recently Approved Devices
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/MDA/mda-list.cfm?list=1

Home Healthcare Medical Devices—A Checklist
www.fda.gov/cdrh/CDRHHHC/brochure-checklist.html