MATURITY HEALTH MATTERS

FDA Health News for Older Adults and Their Caregivers

Issue 1 **Inaugural Issue 2005**

Welcome to the first issue of the Food and Drug Administration's (FDA) ***Maturity Health Matters*****. This online newsletter about FDA regulated products is for older adults, their families and their caregivers.** ***Maturity Health Matters*** **will focus on FDA regulated products that are helping people live longer, more productive lives. It will be published three times a year.**

In this first issue, you will find valuable health information on medical devices used to diagnose and treat heart disease and diabetes. Heart disease remains the leading cause of death in the United States; diabetes is the sixth cause of death. Future issues will feature information on FDA regulated medical products and health news.

This newsletter is for you because ***Maturity Health Matters*****!**

Diabetes and Heart Disease Are Linked

Diabetes is a leading cause of heart disease and strokes. The Centers for Disease Control and Prevention (CDC) announced in its 2003 preliminary mortality data that heart disease caused nearly 700,000 deaths; these deaths represented 28% of all deaths in the United States.

This issue of *Maturity Health Matters* contains articles on medical devices that can help you with diabetes and heart disease: blood glucose monitors and other related diabetes devices, automatic external defibrillators (AEDs), pacemakers, and implantable cardioverter defibrillators (ICDs).

Because there is a strong connection between heart disease and diabetes, careful control of your blood sugar levels can lessen the extent of or prevent heart disease. Control of your blood sugar can also help prevent strokes, blindness, kidney failure, poor circulation and other problems.

Medical Devices Are Key to Diabetes Management

If you have diabetes, you can protect yourself by regularly measuring and monitoring the level of sugar (glucose) in your blood with a self-testing, blood glucose monitor. Monitoring will allow you to determine if your blood sugar level is in the proper range. Based on your blood sugar level, you may need to adjust your diet or medication.

People with diabetes use other medical devices. For example, many blood glucose monitors call for small blades called lancing devices to pierce the skin to draw a blood sample for glucose testing. There are many types of lancets. Two types are automatic lancing devices and laser skin perforators.

(See article on lancing device, page 3)

In This Issue

Diabetes and Heart Disease - *Continued from page 1*

Patients May Need Heart Devices to Survive

- If you experience an unexpected and serious irregular heart beat, you may need an AED to shock your heart into a regular rhythm. AEDs are portable life-saving devices used by many rescuers.
- If your heart beats too slowly or has an abnormal rate, you may need a pacemaker. This is a small, implanted battery-powered device that monitors the electrical impulses of the heart and delivers electrical stimuli to keep the heart beating at a more normal rate.
- If you have trouble with your heart, your doctor may advise you to have an ICD. An ICD is a device that continuously monitors your heart to detect an abnormal heart rhythm. When an abnormal heart rhythm is detected, the ICD delivers a therapeutic shock to the heart to restore a normal heart rhythm.

Blood Glucose Meter Can Help Protect the Health of Someone with Diabetes

Diabetes is a leading cause of heart disease and strokes, adult blindness, kidney failure, and circulation problems that may lead to limb amputation. If you have diabetes, you can protect yourself by regularly measuring and monitoring the level of sugar (glucose) in your blood with a self-testing, portable medical device called a **blood glucose meter (glucometer)**.

A blood glucose meter is a small, portable machine used to check your blood glucose levels. Each meter has test strips designed especially for it to test your blood samples. The blood is usually drawn from a prick of your fingertip. Because each meter is different, read and follow the manufacturer's instructions carefully. Your doctor will prescribe a testing schedule.

Some newer meters can use blood from other areas of the body besides the fingers, reducing your discomfort. This alternate site testing must be done carefully and only in certain circumstances. It is important to discuss testing with your doctor and to follow the manufacturer's instructions to get accurate results.

The glucose meter test allows you to carefully monitor your blood glucose levels to assure that they are within the target range advised by your doctor. You can then respond quickly either too high (hyperglycemia) or too low (hypoglycemia) blood sugar levels with appropriate changes in your diet, medicine, and physical activities. Blood glucose levels go up after eating but should return to the normal range 1 or 2 hours later. Talk with your doctor about what your blood glucose targets should be before and after meals and ask when you should perform the checks. You should record your daily meter readings and discuss them with your doctor.

- **Normal** values range from 60 to 140 milligrams per deciliter (mg/dl), but can vary depending on your physical activity, meals, and insulin needs.
- **Abnormal** values can be either too low or too high. Levels that are too low may mean you are in a state of hypoglycemia and may need to increase their glucose level by eating food. You may also need to alter your next insulin dose and possibly future insulin doses as well. If levels are too high, you may be hyperglycemic and may need additional insulin.

High results, particularly in a person not yet known to have diabetes, may also indicate a need to obtain a further test called fasting blood glucose or a glucose tolerance test.

It may be hard to reach your target range all of the time. But the closer you get to your goal, the more you will reduce your risk of diabetes-related problems, such as heart disease. Take every possible precaution and you will feel better. You should always follow your doctor's recommendations.

More FDA Information

Visit FDA's diabetes Web site at http://www.fda.gov/diabetes for a wide-range of information including recent news, women and diabetes, new products, patients and their advocates, *FDA Consumer* magazine articles, and other government and non-government Web sites.

RECENTLY APPROVED DEVICES

The link below gives you more information about FDA's Recently Approved Devices featured in this newsletter. Select "List by Category of Device" and scroll through to:

- automated external defibrillators
- glucose monitoring
- implantable cardioverter defibrillators
- pacemakers

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/MDA/mda-list.cfm?list=1

Which Lancing Device Will You Choose and How Will You Dispose of It?

Lancing devices (lancets) are fine, sharp-pointed blades or needles used to pierce the skin to draw a sample of blood for glucose testing. There are many types of lancets and some have protective caps. Lancets are sometimes referred to as "sharps."

Automatic Lancing Devices

Most automatic lancing devices consist of a hand-held tube with a spring-loaded lancing device. To pierce the skin, you hold the device against your skin and press a button to release the lancet. Most lancing devices come with different lancet covers to allow different amounts of skin penetration. Before the next use, you must clean and reset your lancing device.

Laser Skin Perforators

Laser skin perforators pierce (perforate) the skin, much like lancing devices. These devices produce a single pulse of laser energy that makes a small hole in your fingertip. These devices can be used at home by both adults and children. Clinical testing shows that trained patients can use perforators as accurately as lancets. Laser skin perforators are available by prescription only.

Lancet Disposal

FDA recommends that you use a sharps disposal container for your used lancets. The following information about sharps disposal containers is based on the Occupational Safety and Health Administration (OSHA) requirements.

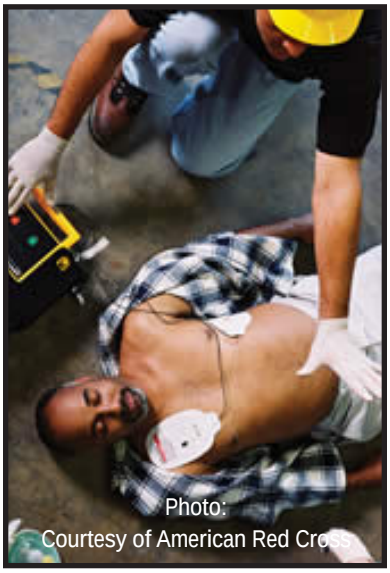
The container must be:

- closable
- upright and stable during use
- puncture resistant
- leak proof at sides and bottom
- properly labeled with the biohazard symbol and legend or color coded

According to the American Diabetes Association, an easy way to get rid of used lancets is to put them in a heavy-duty plastic or metal container with a tight-fitting lid (such as an empty laundry detergent bottle). When the container is full, you dispose of it according to your local government waste-disposal rules.

The label on the container should clearly inform the user that the container holds sharps waste. The phrase "Infectious Sharps Waste" or a similar warning must be clearly visible on the container label.

For more information about disposing of medical sharps, visit http://www.epa.gov/epaoswer/other/medical/sharps.htm.



Portable Defibrillator Gives Your Heart a Shock

An **automated external defibrillator** (AED) is a portable, automatic device used by rescuers and others to restore normal heart rhythm in a patient who has a sudden, life-threatening heart rhythm, or cardiac arrest. These rhythms include ventricular fibrillation and ventricular tachycardia. Ventricular fibrillation is the most common cause of death in adults in the United States.

Though different from cardiac arrest, heart attacks may set the stage for cardiac arrest by depriving the heart of blood supply or scarring the heart muscle moments or years before the actual arrest. If ventricular fibrillation occurs, electrical signals in the lower heart chambers (the ventricles) are uncoordinated and useless. As a result, very little blood is pumped from the heart to the lungs or to the rest of the body. Ventricular tachycardia is a regular, coordinated rhythm but similarly dangerous because the heart beats too fast to pump effectively. If these rhythms are not treated, cardiac arrest and death may occur.

An AED consists of a small computer connected to insulated wires (leads) and adhesive skin electrode pads. The electrodes collect information about the rhythm of the beating heart. The computer monitors the rhythm to determine if a therapeutic shock could benefit the patient. If so, a shock is delivered back through the electrode pads to the patient. All this happens within seconds.

A rescuer who encounters someone who appears to be in ventricular fibrillation should remove the clothing from the patient's chest and place the AED electrode pads directly on the skin. The AED automatically analyzes the patient's heart rhythm and advises the rescuer whether a therapeutic shock would help. When the rescuer pushes a button on the AED, the device delivers an electric shock through the patient's chest wall into the heart. This is called defibrillation.

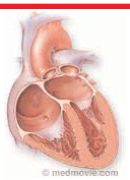
When a shock is effective, all activity of the heart stops for just a moment, giving the heart a chance to restart normal electrical activity. Repeated shocks or more energy may be necessary to effectively defibrillate.

An AED will not deliver a shock unless it is needed. Sometimes the AED will tell the rescuer to perform cardiopulmonary resuscitation (CPR) instead. When the rescuer follows the instructions given by the AED, there is a better chance the outcome will be successful.

You can find AEDs in public places, such as airports and some office buildings. Doctors sometimes recommend home AEDs for patients with heart conditions. Currently, you can buy one model of an AED without a prescription. If you decide to purchase an AED, you should discuss its proper use with your healthcare provider.

Risks from the Procedure

The AED instructs the rescuer to avoid touching the patient during therapeutic shock delivery. This prevents the rescuer from receiving an electrical shock. Risks to the patient include skin burns from the electrode pads and abnormal heart rhythms. Although blood clots or impaired thinking may be caused by the ventricular fibrillation or ventricular tachycardia, they are not caused by using the AED.



FDA's Heart Health Online

This Web site provides valuable information about the heart, including how it works, risk factors for heart disease, and tips for heart-healthy lifestyles. It also has information on FDA-approved tests and treatments for heart disease.

http://www.fda.gov/hearthealth

Implanted Pacemaker Makes Your Heart Beat More Normally

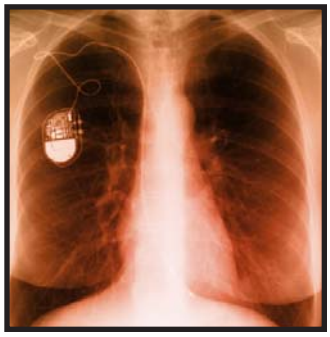
A **pacemaker** is a small, battery-powered device implanted permanently in the body. It monitors the electrical impulses of the heart and, when necessary, delivers small electrical impulses to stimulate the heart to beat at a more normal rate. Pacemakers are designed to sense if the heart is beating too slowly and automatically stimulate the heart to beat faster. The pacemaker restores a normal heart rate so the heart can pump more effectively. This can reduce or stop symptoms of abnormally slow heart beating, such as dizziness, confusion, fatigue, or fainting.

A pacemaker consists of a battery, electrical circuitry (pulse generator), and leads. The battery can power the pacemaker for eight or more years. The electrical circuitry is the component that checks the heart rate and provides electrical stimulation to keep the heart beating at a more normal pace. The leads are insulated wires that send information from the heart to the implanted pacemaker and back. They send unnoticeable stimulations from the pulse generator to the surfaces of the heart.

The pulse generator of a pacemaker is implanted in a "pocket" made surgically under the skin, usually in the upper chest area. However, due to anatomical restrictions, this part of the system may be placed in the abdomen.

There are several types of pacemakers especially made to meet specific needs. Some examples are single-chamber pacemakers, dual-chamber pacemakers, and cardiac resynchronization therapy (CRT) pacemakers. Many newer pacemakers have a feature called rate-response that constantly adjusts the heart rate setting to match your level of physical activity.

Your doctor will review your needs to select the pacemaker that is best for you.



Risks from the Procedure

Some risks from the pacemaker surgery include:

- bleeding
- swelling
- bruising under the skin
- blood clot formation
- infection
- blood vessel damage

Note: You may need additional surgery to correct any pacemaker lead movement that occurs infrequently but can affect your pacemaker's effectiveness. Most patients need eventual minor surgery to replace the pulse generator of the pacemaker after its battery wears out. Fortunately with current technology, batteries deplete in a very predictable fashion that is easy to monitor over time during regularly scheduled office visits.

Pacemakers should not be implanted in people who

- cannot tolerate the surgical procedure.
- are sensitive or allergic to the exposed parts of the device

Your doctor will tell you more about the risks of the surgical procedure.

See page 8 for general information on recalls and specific information on a July 2005 recall of a pacemaker.

What Are the Differences Between a Heart Attack, Cardiac Arrest, Cardiopulmonary Arrest, Heart Failure, and a Sudden Cardiac Arrest?

- A **heart attack** occurs when damage is done to the heart muscle due to an inadequate supply of oxygen-rich blood to the heart (when a blood clot or other blockage interrupts the flow of blood).
- **Cardiac arrest** occurs when the heart stops beating suddenly and is unable to pump blood to the vital organs.
- **Cardiopulmonary arrest** occurs when both breathing and effective heart functions stop.
- **Heart failure** occurs when the heart cannot pump an adequate amount of blood to the body tissues.
- **Sudden cardiac death** occurs within minutes or hours after a cardiac arrest.

Electromagnetic Interference (EMI)

EMI is a naturally occurring phenomenon when the electromagnetic field of one device disrupts, slows, or degrades the electromagnetic field of another device by coming very close to it. Until the interference is removed, some types of EMI may cause medical devices such as pacemakers or implantable cardioverter defibrillators (ICDs) to:

- stop delivering therapy
- work incorrectly
- enter an incorrect response

Pacemaker and ICD patients can find examples of strong magnetic field sources in homes, hospitals, airports, and public buildings. Here are some locations where you may experience EMI:

Homes - Cellular phones and stereo speakers may cause problems. Ask your doctor to help you identify other magnetic forces in your home so you can avoid them.

Medical Offices - Some medical equipment can damage your pacemaker or ICD. Before beginning any testing or treatment, tell your doctor or dentist that you have an implanted device. For example, Magnetic Resonance Imaging (MRI) and electro-surgery in hospitals can cause major problems.

Airport/Building Security and Anti-Theft (Stores and Libraries) Systems - Some security devices may temporarily stop your pacemaker or ICD from working properly or give you cardiac symptoms. A general rule is don't lean on the security system and pass through quickly. **The anti-theft industry's slogan is "Don't linger. Don't lean."**

Construction Sites - Welding equipment and electric generators may affect your device.

Chain of Survival

In 1990, the American Heart Association introduced a series of four critical steps for the treatment of sudden cardiac arrest called the **Chain of Survival**. The American Heart Association, the American Red Cross, and others are strong advocates of these four steps:

Step 1: Early access to care (Call 911 or another emergency number);

Step 2: Early Cardiopulmonary Resuscitation (CPR);

Step 3: Early defibrillation; and

Step 4: Early use of advanced cardiac life support as needed.

Implantable Defibrillator Can Shock Your Heart into Normal Rhythm

An **implantable cardioverter defibrillator** (ICD) is a device that is implanted under the skin of the chest to continuously monitor the heart's rhythm and continuously protect the patient from cardiac arrest. Its leads are insulated wires that are typically threaded through the blood vessels to connect the pulse generator to the surface of the heart. When the ICD senses a life-threatening rapid heart rhythm such as ventricular tachycardia or ventricular fibrillation, it delivers special pacing or one or more electric shocks to restore the rhythm of the heart.

Cardioversion is a synchronized shock that is most appropriate for stopping organized rapid ventricular rhythm abnormalities. Defibrillation is an unsynchronized shock, used when disorganized rhythm (ventricular fibrillation) occurs. Painless rapid pacing may sometimes allow the device to restore normal rhythm without a shock. In these three ways (cardioversion, fibrillation, and rapid pacing), ICDs stop cardiac arrest if it begins.

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ICD *- Continued from page 6*

Although pacemakers can correct only abnormally slow heart rates, ICDs have the ability to treat patients with abnormal heart rhythms. This is because newer ICDs also include basic pacemaker functions. ICDs are used to prevent repeat occurrences of cardiac arrest and to prevent first episodes of cardiac arrest in patients who are at risk. This risk may result from a previous heart attack or unexplained heart muscle weakness.

The ICD pulse generator is a small box that contains the battery and an electrical circuitry system. This is what senses, analyzes, and records the heart's electrical patterns. Doctors will review records of these functions during your regular check-ups and during assessment of previous episodes of ICD treatment. As noted, the ICD can be programmed to sense and treat abnormal heart rhythms, using sophisticated rapid pacing, precisely timed shocks called cardioversion or unsynchronized shocks called defibrillation.

Risks from the Procedure

Risks of implanting an ICD may include infection, bleeding, and bruising. Rare complications include stroke, heart attack, blood clots, and puncture of a major blood vessel, lung, or the heart muscle. When a complication occurs, the ICD may have to be surgically removed. Your doctor will discuss any additional risks associated with ICDs and arrange scheduled check-up visits. These check-ups give your doctor an opportunity to adjust ICD treatment to match your updated heart condition, check the battery, and detect any device related problems.

ICDs are not intended for use in patients whose heart rhythm condition is reversible, temporary, or who cannot tolerate the device.

See page 8 for general information on recalls and on a specific information on a June 2005 recall of ICDs.

FDA Needs Your Help: Report Adverse Reactions to FDA's MedWatch Program

The FDA MedWatch program is designed to identify serious reactions and problems with medical devices and other medical products. These other products include medicines (prescriptions and over the counter), blood products, and special nutritional products (dietary supplements, infant formulas, and medical foods). FDA designed this program to ensure that new safety information is quickly communicated to medical professionals. One of the program's aims is to monitor medical products once they are used in clinical practice.

A reaction is considered serious if a medical product caused or is suspected of having caused at least one of the following:

- death
- life-threatening situation
- admission to a hospital
- longer-than-expected hospital stay
- permanent disability
- a birth defect
- medical care to prevent permanent damage

If you or a family member have experienced or witnessed a serious adverse reaction or other problem with any FDA regulated product, call MedWatch at 1-800-FDA-1088 (1-800-332-1088) to request a one-page reporting form. Your return postage will be paid. Forms and instructions can also be downloaded from http://www.fda.gov/medwatch/.

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MedWatch *- Continued from page 7*

FDA encourages consumers to take the form to their health professional (doctor, dentist, pharmacist, or nurse) to complete. The health professional can voluntarily provide more detailed clinical information, such as laboratory results, that can help FDA evaluate the report.

However, if you prefer, you can complete the form yourself and mail it to the FDA address on the form or FAX it to 1-800-FDA-0178 (1-800-332-0178). You are encouraged to file a report if your health professional chooses not to.

You will receive an acknowledgement from FDA after we receive your report. You will be personally contacted only if we need additional information.

For information about a medical product, please call the FDA's toll-free information line at 1-888-INFO-FDA (1-888-463-6332). Follow the directions to select the medical product you are interested in.

Don't Miss Future Issues

If you have found this newsletter by "surfing the net," add http://www.cdrh.fda.gov/maturityhealthmatters.html to your favorites. At the site you can subscribe to the newsletter and receive email notification when new issues are published.

While you are online, why not check our website http://www.fda.gov/cdrh/consumer where you will find many topics of interest especially for consumers.

Medical Device Recalls

A recall is an action taken to address a problem with a medical device that violates FDA regulations, is defective, or could be a risk to health. FDA classifies its recalls into Class I, II, and III. Class I is the most serious recall. The classification depends on the level of risk to the patient. For more information on recalls you can go to: http://www.fda.gov/cdrh/recalls

FDA Announces Recalls of Certain Guidant ICDs & Pacemakers

For this inaugural issue, we bring several Class I recalls to your attention. Visit the sites listed below for more information:

Class I Recall of Certain Guidant Corporation Implantable Cardioverter Defibrillators

- FDA's July 1, 2005 updated *FDA News*: http://www.fda.gov/bbs/topics/NEWS/2005/NEW01198.html
- FDA's *Advice to Patients*: http://www.fda.gov/cdrh/medicaldevicesafety/atp/071405-guidant.html
- Update of July 14, 2005 FDA *Preliminary Public Health Notification*: http://www.fda.gov/cdrh/safety/101305-guidant.html

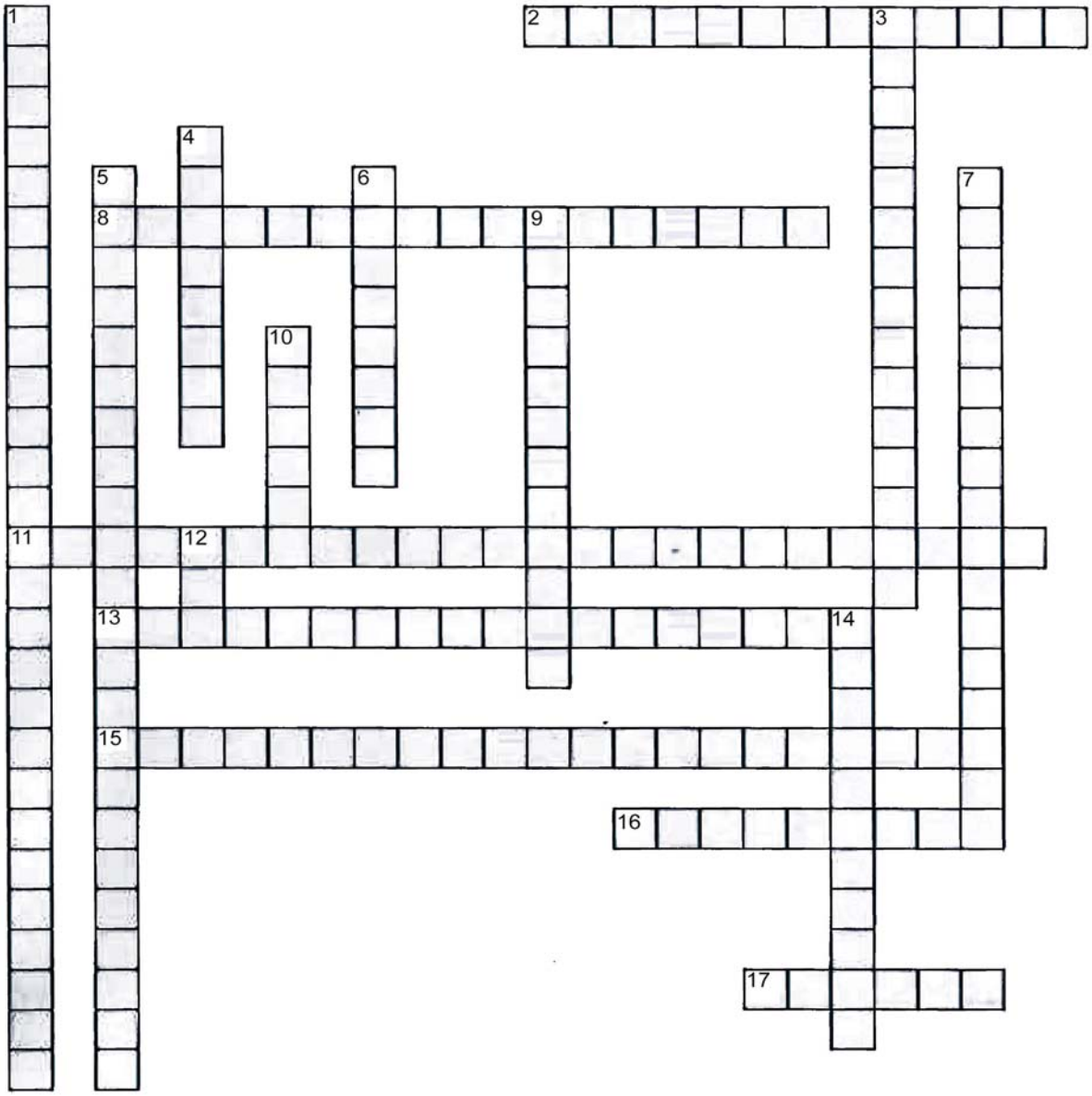
Class I Recall of Certain Guidant Corporation Pacemakers

- *FDA News*, July 22, 2005 press release: http://www.fda.gov/bbs/topics/NEWS/2005/NEW01210.html

Guidant's website on their Implantable Cardioverter Defibrillator and Pacemaker Models

- To get specific information, it will help if you know your model number. http://www.guidant.com/webapp/emarketing/lookup.jsp

Maturity Health Matters - Crossword



ACROSS

2 High blood sugar levels.
8 FDA's website for valuable heart information (three words).
11 An implanted device that senses a life-threatening rapid heart rhythm and delivers a special pacing or electric shock(s) to restore the heart's rhythm (two words).
13 Occurs within minutes or hours after cardiac arrest (three words).
15 Occurs when both breathing and effective heart functions stop (two words).
16 Implanted, small, battery-powered device that stimulates the heart to beat at a more normal rate.
17 When a product goes off the market because of a perceived risk, or even death, to patients.

DOWN

1 Occurs when the electromagnetic field of one device disrupts, slows, or degrades the field of another device by coming very close (two words).
3 American Heart Association's four critical steps for treating cardiac arrest (three words).
4 Disease recognized by the level of sugar in the blood.
5 Closable, stable, puncture and leak resistant container for needles (three words).
6 FDA's program to report adverse reactions and problems with our regulated products.
7 Small, portable machine to check blood glucose levels (three words).
9 Low blood sugar levels.
10 Device to pierce the skin to get a blood sample.
12 Portable automatic device to restore normal heart rhythm.
14 Damage to the heart muscle due to an inadequate supply of oxygen-rich blood to the heart (two words).

Maturity Health Matters

Maturity Health Matters is an FDA publication for older adults and their caregivers. We will provide our readers with current information on FDA-regulated medical products. This publication can be reproduced. If you have comments about our publication, please send them to the Editors.

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Crossword Answers

ACROSS
2 Hyperglycemic
8 Heart Health Online
11 Implantable defibrillator
13 Sudden Cardiac Death
15 Electromagnetic interference
16 Pacemaker
17 Recall

DOWN
1 Cardiopulmonary Arrest
3 Chain of Survival
4 Diabetes
5 Sharps Disposal Container
6 MedWatch
7 Blood Glucose Meter
9 Hypoglycemic
10 Lancet
12 AED
14 Heart Attack