

Helping people with cardiac devices live full, active lives



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WELCOME TO LIFEBEAT 2010

In the tradition of providing an informative newsletter, we have a great surprise for you online.

In June 2010, LifeBeat Online changes from a newsletter archive of great information for device patients and their families to an extraordinary set of resources and tools for people living with heart disease.

As part of our commitment to helping heart patients live full and active lives, we have created a website that can help patients from the moment they learn of their heart disease to their implant and life with device therapy. Check out these topics:

- Explore heart disease animation and compare a healthy heart to those with known heart conditions.
- Learn about cardiac procedures, what is involved, how to prepare, and what to expect.
- Listen and see how other heart patients live with therapy.
- Subscribe to our free e-newsletter, created for patients with cardiac devices.

Our new website features more information that is easy to find. Patient-specific guides can be printed. A searchable directory helps you find information about your heart, your device and support services to help answer your questions.

We would like to hear from you. Join us online and send us your feedback as we continue to improve this site.

MEET THESE PATIENTS ONLINE



Waylen "Bud" Lilly
heart failure patient

"When I found how that I had had a silent heart attack and one of the major arteries was about half dead, it was really a shock and took quite a lot of adjustment for me to accept that."



Michael Sorrell
sudden cardiac arrest survivor

"People talk about being in service or being a servant leader to others, but they often take it for granted that they will get those opportunities. If my life had ended back in September when this happened, I would have left an incomplete book. I want at the end of my time to leave the best, most complete book that I can."



Dave Paterson
pacemaker patient

"With my first pacemaker, sweeping the floor or walking I would get tired very quickly. When I went on to get my second pacemaker, I didn't expect it to be any different. Was I surprised! I hadn't felt this good in a long time. I don't know what I can't do."

www.lifebeatonline.com
www.bostonscientific.com/heartpatient



Dark chocolate is “healthiest” when it is raw or bittersweet and dairy free.

Dark Chocolate

When *free radicals* start fighting *flavonoids* acting as *antioxidants*, you are either playing a new computer game or eating dark chocolate!

- *Free radicals* are unstable particles in the blood that can damage cells in the body. Damaged cells are less resistant to disease. A body with too many free radicals has an increased risk of high cholesterol and coronary artery disease.¹
- *Antioxidants* help the body's cells resist damage caused by free radicals.

- *Flavonoids* are found in many vegetables and fruits, especially ones with dark colors, wine, and chocolate. They are powerful antioxidants that protect the body from toxins and repair damaged cells. When we eat foods rich in flavonoids, we benefit from the antioxidant properties of flavonoids.¹

Cornell University food scientists found that cocoa powder has nearly twice the antioxidants of red wine and up to three times what is found in green tea.²

True or False:

Eating dark chocolate can help reduce the risk of heart disease.

True. Research studies over the last 40 years suggest that the flavonoids in chocolate play a part in reducing heart disease.²

Most research that showed the benefits of dark chocolate used raw, unprocessed cocoa powder. More than 10 percent of the weight of cocoa powder is flavonoid.

However, not all chocolate has the same flavonoid levels.

- Bittersweet chocolate contains 70% cocoa mass. The rest is cocoa butter and sweeteners.¹
- Semi-sweet chocolate contains 60% cocoa mass. The rest is cocoa butter and sweeteners.¹
- Dutch chocolate is processed with alkaline salt to reduce the natural bitterness of cocoa. This process destroys some of the flavonoids in the cocoa.
- Milk chocolate has cocoa powder with milk and sugar

products added. Milk products can block the antioxidants of the cocoa and reduce their benefits by more than half.

- White chocolate is not chocolate at all. It is made from milk, sugar, and cocoa butter. It is not classified as chocolate by the FDA.

Dark chocolate is “healthiest” when it is raw or bittersweet and dairy free. Watch out for the extra ingredients, like caramel, marshmallow, and refined sugars. These add fat and calories with no heart healthy benefits. For now, enjoy a normal piece of chocolate, a one-ounce serving, a few times per week. Have a half cup of hot cocoa and relax while letting the antioxidants do their job. And, don't forget to eat other flavonoid-rich foods like apples, red wine, tea, onions, and cranberries as your health-care provider recommends.

1. Cleveland Clinic. Healthy Benefits of Chocolate Revealed. my.clevelandclinic.org. Accessed 031010.

2. Ding EL, et al. Chocolate and Prevention of Cardiovascular Disease: A Systematic Review. *Nutrition and Metabolism*. 2006;3:2.

LIVING IN A WORLD OF ELECTROMAGNETIC INTERFERENCE

Airport Security in the New Decade

It is not unusual for implanted device patients to fly to their vacation or business destinations. However, it can be confusing going through security at different airports.

LifeBeat Online understands that the key to dealing confidently with this part of your journey is knowing what to expect and how to prepare.

As with every medical question, **get specific advice from your own doctor** about travel.

Information from the Transportation Security Administration (TSA)

Did you know? 48,000 Transportation Security Officers serve on TSA's frontline in 457 U.S. airports. They use their training and experience to effectively and efficiently screen approximately 2 million people a day.

As an airport passenger, you must pass through a checkpoint to access your departure gate. Security Officers will screen you and your carry-on baggage. You should find this screening process familiar, although enhanced security measures are in place since January 2010 [see below].

Some airports have signs posted that warn patients with implanted devices about the security systems used. *Lifebeat* asked the TSA about the signs.

TSA replied: "Signs are just one way the Transportation Security Administration communicates with the traveling public. Some signs are required by law; others explain specific procedures required by law. TSA recognizes that signs will never answer every question. Our website, www.tsa.gov, provides additional information, including everything you need to know before you fly."

TSA Tips for Traveling Device Patients

1. Present your Medical Device ID card at the first security station. This card identifies you as a pacemaker or defibrillator patient.
2. After showing your card, follow the security staff's directions. Depending on the airport, the staff may do one of the following:
 - Tell you to continue through the security archway. This will not harm your device or change the programmed settings. However, it may set off an alarm.
 - Use a hand-held security wand. If a wand must be used, inform the Security Officer that you have an implanted device. Tell the Security Officer that the search must be done quickly and to not hold the wand over your device.
 - Do a hand-pat search. If you request a hand-pat search, you can request a private area, out of view of the general public.


Can the security checkpoint arch hurt my Boston Scientific device?

No. The device is well protected from the magnetic field of the security arch in airports and stores. These will not harm the components inside the device.

Some sources about airports and security claim that the security arch can hurt the device. They may not know about the technology used in today's devices. Boston Scientific pacemakers and defibrillators are safe from the security arch's potential magnetic field.

What should I do if the security archway alarm goes off?

Tell the security staff that you have an implanted cardiac device. Then show them your Medical Device ID card. The staff may want to check you with a hand-held security wand or do a hand-pat search.

Medical Device ID 

Implanted Cardiac Rhythm Management Patient
Contact physician for medical questions or emergency

DEVICE MAY TRIGGER METAL DETECTION SYSTEMS

Boston Scientific Patient Services
1.866.484.3268 (USA) • 1.651.582.4000
Outside the United States:
001.651.582.4000

Boston Scientific websites
www.bostonscientific.com
www.lifebeatonline.com

If your name, mailing address, or physician changes, please call Medical Records:
1.866.484.3268, 7 AM-7 PM Central Time, Monday-Friday CRM8-1371-0709

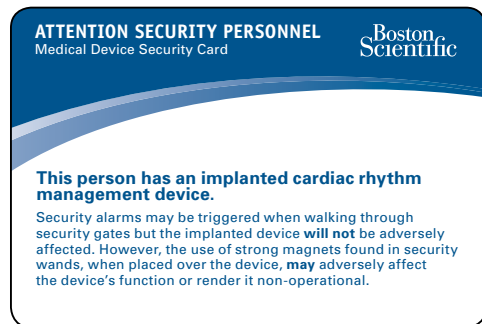
Remember: Security Officers will need to resolve all alarms associated with metal implants. Most alarms can be resolved during a pat-down. Clothing will not need to be removed or lifted as part of the inspection process.

How will a hand-held security wand affect my cardiac device?

Airport security wands could temporarily affect your device. If a wand is held over the device for an extended period of time it could make the device function differently than how it is programmed. If used, the wand should be passed quickly over any implanted device.

Should I show my ID and just ask for a hand search?

Your experience may help you decide the best time to request a hand-pat search. Some patients request a hand search when they present their ID card. This can save time.



When you show your Medical Device ID card, you may get a reaction from some security personnel. They are trained that it may be dangerous for a patient with a medical device to go through the security arch. They may refuse your walk through the arch. The staff may suggest a hand-held security wand or do a hand-pat search.

If you are an international traveler:

Boston Scientific can provide a security card that you can carry when traveling. The security card has the same message in many languages.

- It explains that the implanted device can trigger alarms at security checkpoints.
- It also explains that strong magnets can affect the function of the device.

This can be helpful information for the security personnel you meet.

New TSA Guidelines for 2010

Passengers do not need to do anything differently, but they may notice additional security measures at the airport.

TSA requires that every passenger flying **into the U.S.** from anywhere in the world who (a) holds a passport issued by a country of interest, or (b) is traveling from or through nations or other countries of interest will be required to go through enhanced screening. A traveler will see increase use of enhanced screening technologies—more random checks, more often—on U.S. bound international flights.

More information about the security changes can be found at www.tsa.gov.

You can take certain steps to travel safely with a heart device—don't feel that your device limits you. Knowing the issues ahead of time can help you manage them in the best way.

Remember, wherever you go, enjoy yourself!

LEARN MORE

Travel with Your Device is a resource to help you find facilities around the world that treat individuals with Boston Scientific devices. It is available online at www.lifebeatonline.com in the Daily Living section.

Sources of Electromagnetic Interference (EMI) offers guidelines to help you identify types of equipment and tools that are safe to use near cardiac devices, as well as the types to avoid. It is available online at www.lifebeatonline.com in the Daily Living section.

LATITUDE IN YOUR LIFE

Digital Phone Service



VoIP— Voice over Internet Protocol

If you have an implanted Boston Scientific ICD or CRT-D device, your healthcare provider may prescribe the LATITUDE® Patient Management system to monitor your device. The LATITUDE Communicator is used to send your device information to a secure website that only your healthcare team can view. It requires a standard, analog telephone line.

Some homes built today may not include an analog phone line. In addition, your cable company may offer a package of services for the television, Internet, and phone service. This may result in a new “digital phone service” for your house that runs over the Internet. This type of phone service is called voice-over-internet-protocol, or “VoIP.”

What is VoIP?

VoIP—Voice over Internet Protocol—is a type of phone service that uses an Internet connection to send and receive your phone calls. This service does not use standard analog phone lines.

When you sign up for VoIP, you may be given a phone adapter. The adapter allows you to continue using your regular telephone.

In the industry, “VoIP” is often advertised as “digital phone service.”

What are common providers of VoIP?

Cable companies like Comcast, Time Warner, and Cox Communications are the most common VoIP providers. Vonage is another VoIP provider that offers customers a phone adapter that plugs directly into an existing Internet connection.

Standard phone companies are also changing their phone services into “digital.” Companies like AT&T, Qwest, and Verizon are installing fiber-optic phone connections. Fiber optics can be run into the neighborhood or all the way to the home. Once the phone service is changed to “digital,” it operates the same as a VoIP service.



Will the Communicator work over VoIP?

The LATITUDE Communicator uses an analog phone jack to connect to the Latitude network. The Communicator may work over VoIP if an analog phone jack is available. Some VoIP providers support analog devices very well. Other companies do not support analog devices at all, or work intermittently.

If you have any questions when trying to setup the LATITUDE Communicator with a VoIP connection, please call Boston Scientific Patient Services for assistance at 1-866-484-3268.

WHERE DOES THE DATA GO?

What is a Clinical Study? Part 2

A clinical study, or trial, is a scientific study that can involve people. You may hear that a new study was published. You may hear that a product was shown to help patients based on clinical research.

In this article, we shall look what happens to the results of a clinical study. In future issues, we will look at how clinical information leads to more options for patients with heart disease. We will also talk to patients that have been part of a clinical study.

A clinical study tries to answer a question about a certain disease or health issue. Many treatments used today are the result of past clinical research.

How long does a clinical study last?

Most clinical studies follow patients for a set amount of time. This timeframe varies depending on the data that is needed. Information is often collected over years. The trial ends when the researchers have the information they need from the last patient enrolled. Sometimes the study is stopped early if the therapy affected one group of patients in a significant way when compared to another group of patients.

The first ICD was implanted in 1980 as part of a clinical study. Five years later, in 1985, the FDA approved ICD therapy as safe for patients.¹

Not all ICD trials last five years. The MADIT II² trial enrolled more than 1200 patients and followed them for an average of 20 months each. After two years, the trial was stopped early when the group of patients that received the therapy had better survival from sudden death than the patients without the therapy.

What happens when a clinical study is over?

After a study is completed, the information is analyzed by the researchers. Researchers may work for a university (i.e., University of Rochester), a company (i.e., Boston Scientific), or a government agency (i.e., National Institute of Health).

The results are usually reported in the medical literature or presented at medical meetings. This lets them be shared with other health-care providers and scientists. If the clinical results are particularly

important, they may be featured in news media and discussed at scientific meetings and by patient advocacy groups.

The study may be required to be submitted to regulatory agencies, such as the FDA. The data could be on a new drug, a new device, or a therapy for a new type of patient. The FDA would then review data presented and use the information along with other information presented by the manufacturer, to decide if the new therapy has been proven safe and effective.



The first ICD was implanted in 1980 as part of a clinical study. Five years later, in 1985, the FDA approved ICD therapy as safe for patients.¹

1. Mirowski M, Reid PR, Mower MM, et al. Termination of malignant ventricular arrhythmias with an implanted automatic defibrillator in human beings. *N Engl J Med.* Aug 7 1980;303(6):322-4.

2. Moss, A, et al. Prophylactic Implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction: Multi-center Automatic Defibrillator Implantation Trial (MADIT II). *N Engl J Med.* 2002;346:877-83.

WHO USES THE INFORMATION FROM A CLINICAL STUDY?

The following are four organizations that help bring clinical research about heart devices to use in a specific patient population.

- **The Food and Drug Administration (FDA)**

The FDA reviews clinical data presented by a drug or medical device manufacturer. They use this data, along with other information presented by the manufacturer, to help determine if the therapy, device or drug is safe and effective based on the strength of the clinical results.

- **AHA/ACC Practice Guidelines**

The American Heart Association (AHA) and the American College of Cardiology (ACC) publish guidelines for treatment of heart patients. These guidelines are for healthcare providers to help in the diagnosis, management, and prevention of specific diseases or conditions in patients. These organizations use clinical study data to help develop the language used in the guidelines.

- **Heart Rhythm Society**

The Heart Rhythm Society (HRS) provides information about heart rhythm problems to heart professionals and patients. HRS is involved in clinical guidelines that improve patient care. HRS also stays up-to-date on the latest in clinical practice and research, and advocates for fair reimbursement.

- **Centers for Medicaid and Medicare Services (CMS)**

Medicare reimburses hospitals and healthcare providers for medical treatments used with certain types of patients. The type of patient treated is often determined by clinical evidence and the AHA/ACC practice guidelines.

For more information on clinical studies or find out about a specific study, go to www.clinicaltrials.gov or the National Library of Medicine's PubMed® database: <http://www.ncbi.nlm.nih.gov/PubMed>.

In the News

30 Years

JOIN OUR 30TH ANNIVERSARY PARTY

This year marks the 30th anniversary of the first human implant of a defibrillator device. On February 4, 1980, doctors at Johns Hopkins University Hospital in Baltimore placed an experimental device in a woman who had survived two sudden cardiac arrests. The implant was a success and a new type of medical therapy broke into the light.

Boston Scientific (then known as CPI) released the first, FDA approved implantable cardioverter defibrillator (ICD) in 1985. The company continued to advance the capabilities of the ICD to meet the needs of more than 600,000 ICD patients.



If you would like to tell us about your life with ICD therapy – in text or video - send an email to lifebest.online@bsci.com or contact us on www.lifebestonline.com.



Delivering what's next.™

Cardiac Rhythm Management

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Patients and Families:

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