Boston Scientific
Advancing science for life™

LIFEBEAT

A patient education resource from Boston Scientific

2014 Summer

Contents

Contents

You Asked. We Answered

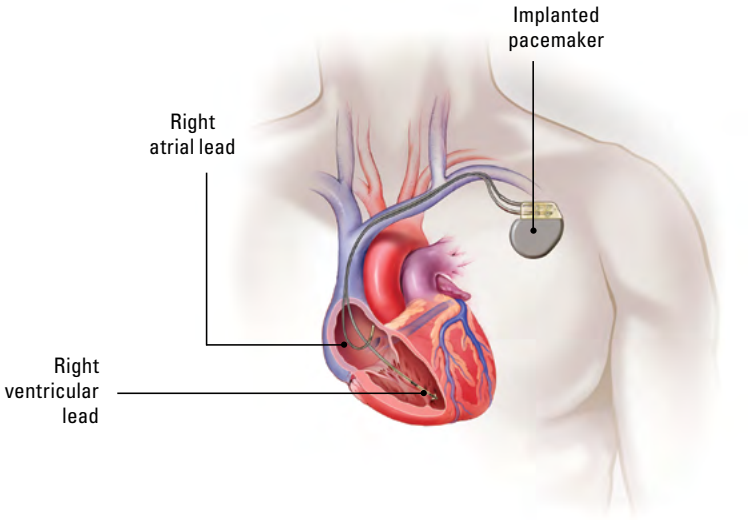
Helpful information about EMI and your implanted cardiac device, Part II

Myths and Facts about Cardiac Devices

Do you feel informed about your heart device? Check and see if you can tell myth from fact. LifeBeat compiled a few more statements to test your knowledge about cardiac devices.

1. Myth or Fact? I can't have sexual relations anymore because my elevated heart rate will make my device deliver a shock.

Myth. When you have sexual relations, your heart rate increase is similar to what would happen during exercise. Your doctor can program your ICD system settings so that you can comfortably engage in a broad range of physical activities.

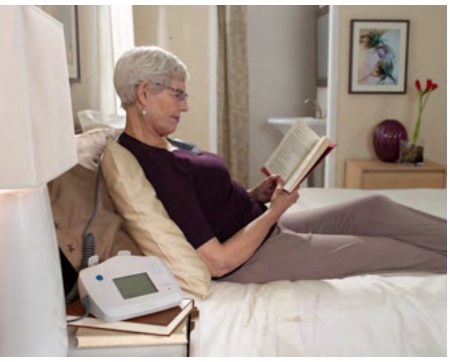


2. Myth or Fact? A pacemaker will keep my heart rate from being irregular.

Myth. A pacemaker does not prevent an irregular heartbeat. Instead, it detects when the heartbeat is too slow or has not adjusted to your activity level. It then sends electrical signals to increase the heart rate to an appropriate level. If an irregular heart rate is found by the pacemaker, features in the device may help your heart beat in a normal rhythm.

3. Myth or Fact? I must wear a MedicAlert® bracelet if I have an implanted device.

Myth. It is your choice whether to wear a MedicAlert® bracelet. However, if you are often by yourself, it can be a good idea. The bracelet allows doctors to easily identify that you have a pacemaker or defibrillator. What you should always carry with you is your Medical Device Identification Card. You will receive this card shortly after your operation. The card lets healthcare professionals know that you have a device and tells doctors the exact model of your pacemaker or defibrillator. Also be sure to let all your healthcare providers know that you have an implanted device.



4. Myth or Fact? If I'm touching someone and my ICD delivers a shock, that person will be shocked too.

Myth. If you receive a shock while touching someone, the energy from the ICD may pass from your skin to the other person. They may feel a tingle or a buzz, but not a shock.

5. Myth or Fact? If I have an implanted device, I should refrain from exercise like running and biking.

Myth. If your general health permits, having an implanted device should not prevent you from running or biking. In fact, maintaining a moderate exercise program will help keep you healthy. Talk to your heart doctor about creating an exercise plan that's right for you.

6. Myth or Fact? I don't have to wait at home for my LATITUDE® Communicator. It will find me when I get home.

FACT: The LATITUDE Communicator is smart enough to know to look for you. It will keep looking if it doesn't find you. You can go about your daily life as though it's just another fun little gadget in your house.

CRM Tech

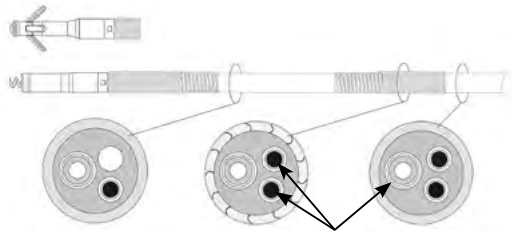
How do we build a reliable lead?

It has been more than 30 years since the implantable defibrillator was first crafted by Michel Mirowski. In that time, both the pulse generator and the lead system have evolved to become smaller and more pacemaker-like.

Implantable cardioverter defibrillator (ICD) leads are built to withstand hundreds of millions of heart beats, bending and contorting the lead body with each beat. All the while, they wait for a lethal rhythm to appear so the system can take center stage with life-saving therapy.

Let's take a look at how that therapy gets to the heart – through the ICD lead.

An ICD lead and cross sections of the lead body.



PTFE-coated conductors

Tri-lumen lead design

- Each wire (conductor) has its own container in the lead body
- A sleeve over the lead body is made of silicone and helps make the lead body resistant to surface abrasion
- PTFE (Teflon®) coating on both pacing wires and the shocking coil wire allows them to move more easily inside the lead body with each heartbeat

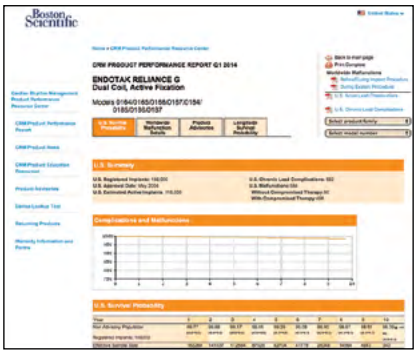
The Reliance® G ICD Lead

Coated conductions

The GORE™ material (expanded Polytetrafluoroethylene - ePTFE) over the shocking coils allows fluid to pass through, but not blood cells or heart tissue. This means that electrical signals – shock therapy – can pass through the GORE covering into the blood stream and flow to the heart muscle.

GORE ePTFE material on the shocking coils prevents tissue in-growth, leading to greater success should the lead ever need to be replaced.[1]

1. Effectiveness of ICD lead coil treatments in facilitating ease of extraction. *Heart Rhythm.* 2010;7(7):890-897.



Long term lead performance

How well leads perform over time is important for your safety and overall ICD system performance.

For example, the RELIANCE G lead has reported 98.5% survival probability at 10 years.

To see the Boston Scientific leads for your system, go to this link. You may need your medical ID card to find the specific information for your leads.

Important Safety Information

Indications
ICD leads provide pacing and rate-sensing and deliver cardioversion and defibrillation shocks for ICD systems.

Contraindications
Use of ICD leads are contraindicated in: patients who have a unipolar pacemaker, patients with a hypersensitivity to a single dose of approximately 1.0 mg of dexamethasone sodium phosphate and/or 1.0 mg of dexamethasone acetate, patients with mechanical tricuspid heart valves.

Warnings
Do not attempt to use the lead system with any device other than a commercially available ICD with which it has been tested and demonstrated safe and effective. Potential adverse consequences include, but are not limited to, undersensing of cardiac activity and failure to deliver necessary therapy. The safety and efficacy of the tip electrode placement above midseptum has not been clinically established (extendable retractable helix leads). Lead fracture, dislodgment, abrasion and/or incomplete connection can cause a periodic or continual loss of rate-sensing, possibly resulting in inappropriate delivery of a PG shock or inadequate delivery of conversion energy. The lead is not designed to tolerate excessive flexing, bending or tension. This could cause structural weakness, conductor discontinuity and/or lead dislodgment. Failure to obtain appropriate electrode position may result in higher defibrillation thresholds or may render lead unable to defibrillate a patient whose tachyarrhythmia(s) might otherwise be convertible by an ICD system. In order to deliver defibrillation therapy, the single-coil lead must be implanted with a separate defibrillation electrode. Boston Scientific CRM recommends using the single-coil lead with a pectorally implanted device that uses the metallic housing as a defibrillation electrode. When connecting the lead to ECD cables and/or the ICD PG it is very important that proper connections are made. Damage to the heart could result if a highvoltage defibrillating pulse were to be delivered through the pace/sense tip electrode. Use of any component of the lead system to assist in the delivery of external-source rescue shocks could cause extensive tissue damage. Do not kink, twist, or braid the lead terminals as doing so could cause lead insulation abrasion damage.

Precautions
Refer to the lead product labeling for cautions specific to handling, implanting and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage, and/or harm to the patient. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone sodium phosphate/acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the Physician's Desk Reference. Tricuspid valvular disease may be exacerbated by the presence of a lead. Use medical judgment when deciding to place a lead in a patient with triscuspid valvular disease. The lead and its accessories are intended only for one-time use. Do not reuse.

Potential Adverse Events
Potential adverse events from implantation of the ICD lead system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy

(shocks/pacing/sensing), infection, procedure related, and component failure. In rare cases severe complications or device failures can occur.
Rev L.

Top call to Patient Services

QUESTION: Will the Communicator dial 911 in an emergency?

ANSWER: No. The LATITUDE® system is not intended to assist with medical emergencies. If you are not feeling well, call your health care provider or dial 911.

Top Posts on our Facebook Page*

Date	Post	People
2/18/14	Do you take your heart seriously? Each day, your heart pumps about 1,900 gallons (7,200 liters) of blood…How do you take care of your heart?	1057
1/20/14	Get to know your customer day	998
1/29/14	Join the AHA and Boston Scientific at the Hearts of Fashion event at the Mall of America., MN.	911
1/6/14	See our important safety information	763
12/12/13	EMI Week: How can a magnet affect my device?	762
12/19/13	The Subcutaneous ICD System is a new type of implantable defibrillator available today.	730
12/13/13	EMI Week: What's that sound?	711
12/22/13	Laughing lowers levels of stress hormones and strengthens the immune system. now a good joke?	687
12/29/13	By the time you turn 70, your heart will have beat nearly 3 billion times.	633
12/07/13	Being happy doesn't mean everything is perfect. It means you decided to see beyond imperfections. Frank A Clark	626
1/28/13	Check here for a picture of your device, how long it lasts, and how it works.	595

*As of February 18, 2014.

Join us on Facebook www.facebook.com/GuardsMyHeart

Preparing for a replacement device

Implanted device batteries typically last 5, 8 or even 10 years. Long before the battery is ready to expire, the battery status screen will show your health care provider that it is time to replace your device with a new one.

The battery status gauge will show how much battery is left at each follow-up, and may even report what that means in years and months. If you have an implantable defibrillator, it can also be programmed to beep when replacement time is reached. This is a periodic series of beeps that may sound like an alarm clock coming from your device.

Your doctor will schedule the replacement procedure when the device battery is low. You may get a device sooner if your condition changes. Device replacement is a surgical procedure. It is done in a sterile environment and requires you to be in a hospital setting. Here are a few questions you may want to ask your healthcare provider as you prepare for your device replacement.

Procedure

- What is the replacement procedure like?
- Will I have any discomfort afterwards?
- What are the risks of the procedure?
- Do I need to stay overnight?

Medications

- Do I need to alter my medication schedule?

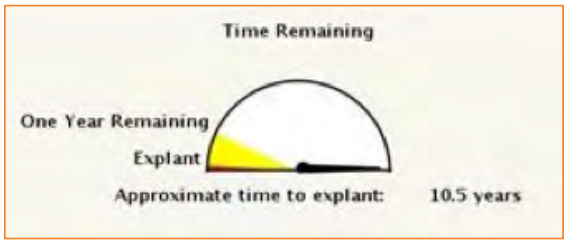
Device

- Will I get the same type of device?
- Will the device be from the same manufacturer?
- Will I need any new leads or adapters?

Follow-up

- Will my new device be monitored from home?
- How soon can I return to my regular activities?

We covered how this graph is made in our last issue, Fall 2013.



To learn more, click here

Why don't pacemakers and ICD's use rechargeable batteries?

The technology for recharging batteries has been around for several decades. So why don't medical device companies build rechargeable pacemakers?

You may be surprised to learn that the original implantable pacemakers from 1958 had rechargeable nickel-cadmium (NiCad) batteries. These pacemakers were recharged by holding a coil up against the skin, near the pacemaker, for several hours. Patients may even had a vest to wear that held the coil in pace. This procedure had to be repeated every few days.

Rechargeable pacemakers ultimately failed for two reasons.

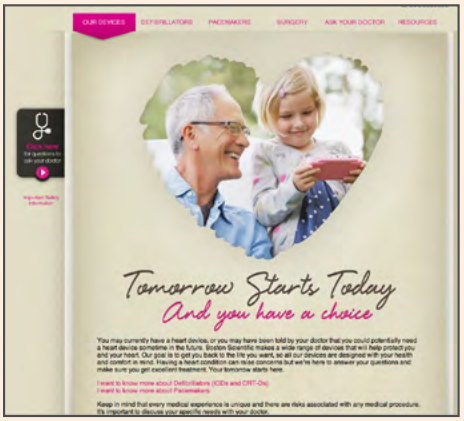
- Even though they were rechargeable, NiCad batteries have a relatively short service life, so these pacemakers still needed to be replaced often.
- With human nature being what it is, patients often failed to recharge their pacemakers according the demanding schedule that was imposed upon them.

Other types of batteries were developed. Mercury-zinc batteries could keep a pacemaker going for up to two years. In 1972, lithium-iodine batteries could power a pacemaker far longer – 5 to 10 years. Lithium Iodine batteries are still used in most cardiac pacemakers today.

Tomorrow Starts Today

If you wonder how devices compare, you can learn about the size, thinness, battery life and leads, and hear patients talk about the choices they made. *Click here to learn more.*

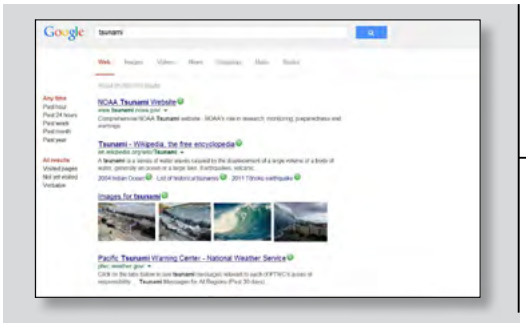
Find more information about devices available today.



Source: Fogoros RN. My Battery Is Low - So Why Does My Whole Pacemaker Need To Be Replaced? 05.01.2014, www.about.com

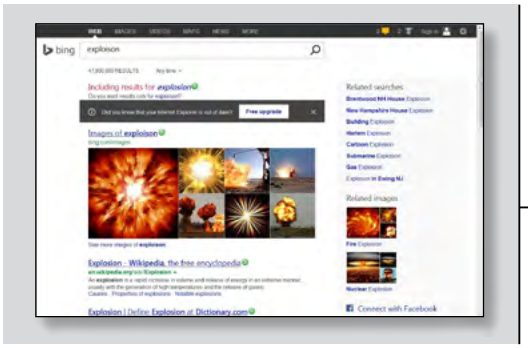
Search Tips and Tricks

In addition to providing easy access to LifeBeat Online, search engines such as Google™, Yahoo!®, and Bing® have features to help you to find exactly what you are looking for. What do your search for?



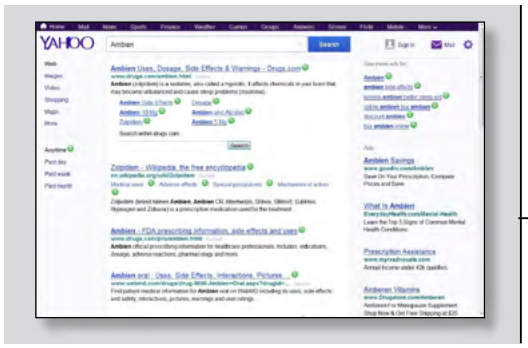
1. Geological Events:
Information about major events with or without the location

Tsunami



2. Spell Checker:
Let the search engine suggest the correct spelling

expolison



3. Medication:
Find generic and brand name prescription drugs

Ambien

Are You Heart Smart?

The more you know about your heart and physical health, the better you can care for it.

Fill in the blank with the most appropriate comparison:

What is the best kind of crossword puzzle you can do for your brain?

A. Whatever's available in the bathroom

B. One you can finish

C. One you can't finish

D. I don't know.

Show Answer

Heart Patient News

Snapshot of recent research on cardiovascular disease and its treatments

Please direct your questions about this information to your healthcare provider. Boston Scientific cannot tell you about the trial or relate it to your individual condition.

Blame the Moon for Bad Sleep

Study participants felt as though their sleep was poorer when the moon was full, and they showed reduced levels of melatonin, a hormone known to help control sleep and wake cycles.

Find more information at WebMD

- The brain patterns of 33 volunteers in two age groups were monitored while sleeping.
- At the time of the full moon, brain activity related to deep sleep dropped by 30%. People also took five minutes longer to fall asleep, and they slept for 20 minutes less time overall.

Cajochen C, Altanay-Ekici S, Munch M, Frey S, Knoblauch V, et al. Evidence that the Lunar Cycle Influences Human Sleep. *Current Biology.* 2013;23:1485-1488.

Happy Hearts: Good Attitude Helps Heart to Heal

Ischemic heart disease patients who had positive attitudes were more likely to exercise and were less likely to die from any cause at 5-year follow-up, researchers found.

Find more information at MedPage Today

- High positive attitude was associated with a significantly reduced risk of all-cause mortality and an increase chance of exercising among 607 Danish ischemic heart disease patients.
- Patients who exercised had a 42% lower risk of all-cause mortality at five years and were 50% more likely to participate in an exercise program than those with lower levels of positive affect.

Hoogwegt MT, Versteeg H, Hansen TB, et al. "Exercise mediates the association between positive affect and 5-year mortality in patients with ischemic heart disease." *Circ Cardiovasc Qual Outcomes.* 2013;6.

Mummies and the Tale of the Clogged Arteries

In the Horus study, an international group of researchers performing whole-body CT scans on mummies found atherosclerosis present and not uncommon across a very wide span of human history in geographically disparate groups of human populations, including hunter-gatherers.

Find more information at MedPage Today

- Results reported from CT scans of 137 mummies up to 4,000 years old from four ancient populations of Egyptians, Peruvians, Ancestral Puebloans of the U.S. Southwest, and Unangans from the Aleutian Islands (present-day Alaska).
- Scans revealed high rates of calcification, suggesting that the development of atherosclerosis in humans predates the influences of modern lifestyles.

Thompson RC, Allam AH, Lombardi GP, Wann L, Sutherland M, et al "Atherosclerosis across 4,000 years of human history: The Horus study of four ancient populations." Lancet 2013;381 (9873):1211-1222.

ANSWER

C. By constantly challenging your mental self, you increase the growth of brain cell dendrites and brain functioning.

Back to Heart Smart

Source: RealAge® "What's your actual age?", www.realage.com

Important Information to Discuss with Your Doctor

Be sure to talk with your healthcare provider so that you thoroughly understand all of the risks and benefits associated with the medications, procedures and tests involved in the implantation of a stent. Results may vary from patient to patient. This information is not meant to replace advice from your doctor. Be sure to talk to your doctor about these risks and possible side effects.

Implantable Cardioverter Defibrillators

An implantable cardioverter defibrillator is designed to monitor and treat heart rhythm problems, greatly reducing the risks associated with them. These devices are sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnet fields. With all medical procedures there are risks associated. In regard to an implanted ICD, the risks include but are not limited to inappropriate shock, lead moves out of place, loss of stimulation capability, allergic reaction, fluid underneath the skin, and infection. In rare cases device failure or death can occur. Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of this system. To obtain a copy of the device Patient Handbook for more detailed device safety information, go to www.bostonscientitic.com, or you can request a copy by calling 1/866-484-3268 or writing to Boston Scientific, 4100 Hamline Ave N., St. Paul, MN, 55112.
(Rev. J)

Pacemakers

A pacemaker system is designed to monitor and treat your heart rhythm problems, greatly reducing the risks associated with them. These devices are sensitive to strong electromagnetic interference (EMI) and can be affected by certain sources of electric or magnet fields. With all medical procedures there are risks associated. In regard to an implanted pacemaker, the risks include but are not limited to inappropriate heart rate response to exercise, lead moves out of place, loss of stimulation capability, allergic reaction, fluid underneath the skin, and infection. In rare cases device failure or death can occur. Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of this system. To obtain a copy of the device Patient Handbook for more detailed device safety information, go to www.bostonscientitic.com, or you can request a copy by calling 1/866-484-3268 or writing to Boston Scientific, 4100 Hamline Ave N., St. Paul, MN, 55112.
(Rev. J)

Device Quality and Reliability

It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. Refer to Boston Scientific's CRM product performance report on www.bostonscientific.com for more information about device performance, including the types and rates of malfunctions that these devices have experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products. Also, it is important that you talk with your doctor about the risks and benefits associated with the implantation of a device.
(Rev. J)

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1.866.484.3268

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Contents